INTERNATIONAL STANDARD

ISO 8835-3

Second edition
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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

Reference number
ISO 8835-3:2007(E)

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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).

8.3 Outlet of receiving systems

If the receiving system can be detached by the operator from the disposal system, the connector at the outlet of the receiving system shall be either

— a type 1L connector for receiving systems intended to be connected to a low-flow disposal system

or

— a type 1H connector for receiving systems intended to be connected to a high-flow disposal system.

1L and 1H connectors shall comply with ISO 9170-2.

NOTE 1 The use of differing connectors is intended to prevent connection to an inappropriate disposal system (see ISO 7396-2 and ISO 9170-2).

NOTE 2 Alternative designs of AGSS terminal units and mating probes with equivalent levels of risk control meeting regional or national conditions can be used.

8.4 Visual indicator

A visual indicator shall be provided to indicate that the AGSS is working within the design extract flow rates stated by the manufacturer.

NOTE The visual indicators complying with the above can be quantitative information (e.g. flow or pressure values) or qualitative devices (e.g. reservoir bags filling and discharging or go/no-go indicators).

8.5 Particle filter

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 [see 11 f)].

8.6 Receiving hoses

Hoses used in the receiving system shall comply with the requirements for hoses for vacuum services given in 5.1 (test conditions), 4.4.6 (resistance to kinking) and 5.7 (resistance to occlusion) of ISO 5359:2000, and shall have connectors complying with 8.2.1 of this part of ISO 8835.

When a power device is integral with the transfer and receiving system, it shall comply with the applicable requirements of ISO 7396-2 and the outlet of the system or the disposal hose shall be a type 2 connector as specified in ISO 9170-2:1999.

9 Extract flow resistance

9.1 Low-flow transfer and receiving systems

The resistance to extract flow of a low-flow transfer and receiving system shall not exceed 2 kPa (20 cm H_2O) at 25 l/min and shall be not less than 1 kPa (10 cm H_2O) at 50 l/min.

9.2 High-flow transfer and receiving systems

The resistance to extract flow of a high-flow transfer and receiving system shall not exceed 2 kPa (20 cm H_2O) at 50 l/min and shall be not less than 1 kPa (10 cm H_2O) at 80 l/min.

10 Electrical requirements

If the transfer and receiving system incorporate electrically-powered components, the system shall comply with IEC 60601-1.

* 11 Information to be supplied by the manufacturer

The manufacturer shall provide the following information in the accompanying documents:

a) operating instructions, functional tests to be carried out and a statement of the maximum constant and intermittent flows into the transfer system before the 100 ml/min spillage limit is exceeded;

b) installation instructions, if applicable;

c) range of flow and pressures of the disposal system(s) with which the transfer and receiving systems are intended to be used (e.g. high flow or low flow);

d) recommended methods of cleaning, disinfection or sterilization;

e) maintenance recommendations, including instructions for changing the filter(s), if applicable;

f) the functional characteristics of any particle filter(s);

g) intended use.

12 Marking

The receiving system of an AGSS, if physically discrete, shall have permanently affixed and clearly legible marking as specified in Clause 6 of IEC 60601-1:2005 that shall include at least the following:

a) if required, the direction of flow, e.g. by means of an arrow;

b) the identity of the manufacturer/supplier;

c) if applicable, symbol number 1641 (see operating instructions) specified in ISO 7000:2004;

d) an indication of suitability for use with high- or low-flow disposal systems.

NOTE Such indication could be as follows: $>$ 75 l/min, high-flow, or $<$ 50 l/min, low-flow identification.

* 13 Colour coding

If colour coding is used to identify components as being specific for use with an AGSS transfer system, it shall be magenta.

NOTE Magenta can be, for example, 10P hue/4/10 specified in the Munsell Book of Color [3].

Annex A
(informative)

Typical test arrangement and method for pressure measurement at inlet to AGSS

A.1 Apparatus

A.1.1 **Flow-measuring device**, accurate to within ± 5 % of actual value.

A.1.2 **Pressure-measuring device**, accurate to within ± 5 % of actual value.

A.2 Test procedure

A.2.1 Set up the test apparatus and AGSS as shown in Figure A.1 or Figure A.2, but do not connect the inlet of the AGSS at X-X.

A.2.2 As shown in Figure A.1 or Figure A.2, connect the inlet of the transfer system to the test apparatus at X-X and the outlet of the receiving system to an active disposal system as recommended by the manufacturer in the accompanying documents or to a test device simulating the performance of the recommended disposal system.

A.2.3 Adjust the air flow to 75 l/min and record the pressure.

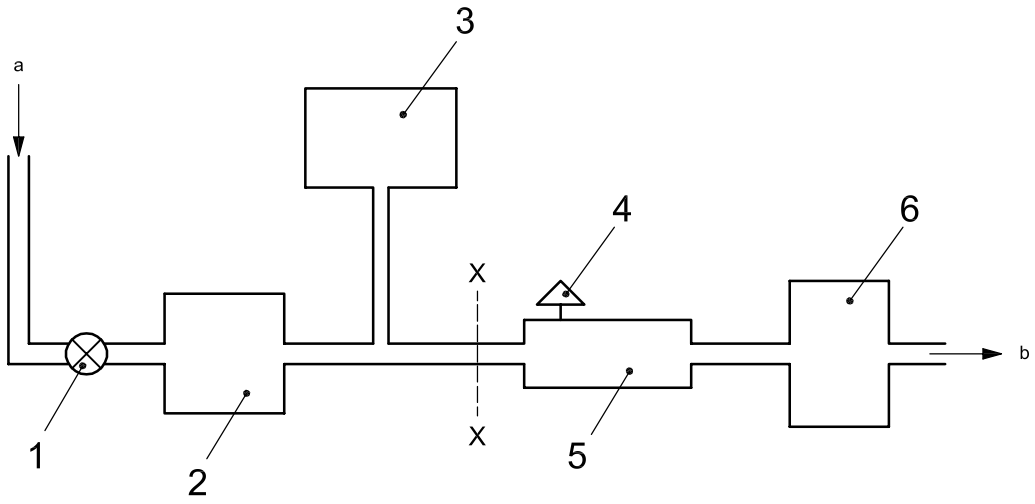
A.2.4 Disconnect the receiving system hose, if any, from the disposal system or test device, or switch off the power device, and repeat the test procedure.

A.3 Test procedure for single fault condition

A.3.1 Set up the test apparatus and AGSS as shown in Figure A.1 or Figure A.2, but do not connect the inlet of the AGSS at X-X.

A.3.2 As shown in Figure A.1 or Figure A.2, connect the inlet of the transfer system to the test apparatus at X-X. If applicable, apply force to the transfer tube as shown in Figure A.3. The force shall be applied as proximal to the outlet of the transfer system as possible.

A.3.3 Adjust the flow to 75 l/min and allow steady state conditions to be achieved. Record the pressure.



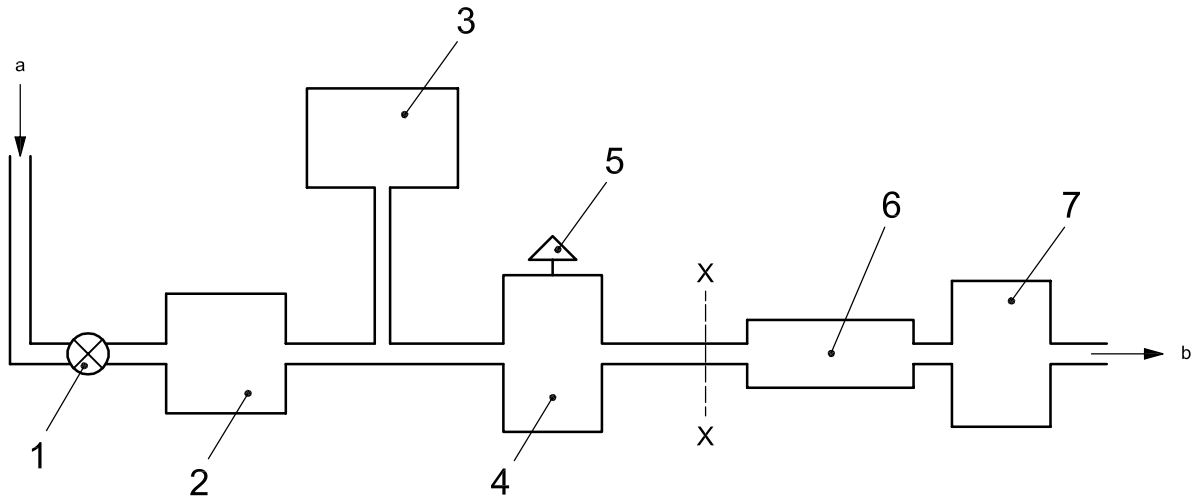
Key

1 flow control valve
2 flow-measuring device
3 pressure-measuring device
4 means of pressure relief
5 AGSS transfer and receiving system with integrated means of pressure relief
6 disposal system or equivalent test device

[a] Air supply.
[b] Discharge.

X-X Entry to AGSS (inlet to transfer system).

Figure A.1 — Typical test arrangement for pressure measurement at the inlet of the AGSS



Key

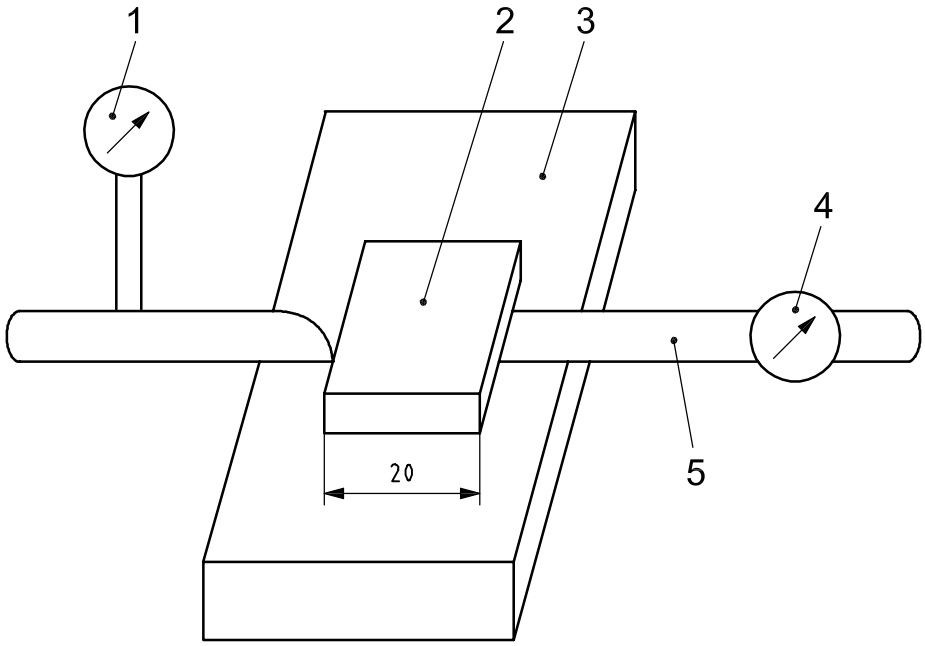
1 flow control valve
2 flow-measuring device
3 pressure-measuring device
4 breathing system with integrated means of pressure relief
5 means of pressure relief
6 non-interchangeable AGSS
7 disposal system or equivalent test device

[a] Air supply.
[b] Discharge.

X-X Entry to AGSS (inlet to transfer system).

Figure A.2 — Typical test arrangement for pressure measurement at the inlet of an AGSS with a means of pressure relief integrated into the breathing system

Dimensions in millimetres



Key

1 pressure gauge
2 applied force (200 N)
3 test pad
4 flow-measuring device
5 hose under test

Figure A.3 — Typical test arrangement for occlusion of an AGSS transfer hose

Annex B
(informative)

Typical test arrangement and method for sub-atmospheric pressure limitation

B.1 Apparatus

B.1.1 Pressure-measuring device, accurate to within ± 5 Pa at 50 Pa.

B.2 Test procedure

Connect the pressure-measuring device (B.1.1) to the inlet of the transfer system as shown in Figures A.1 and A.2 as appropriate and connect the receiving and transfer system(s) to the disposal system but with the flow control valve at the inlet fully closed; operate the power device at maximum extract flow. Measure the sub-atmospheric pressure.

Annex C
(informative)

Typical test arrangement and method for testing of induced flow

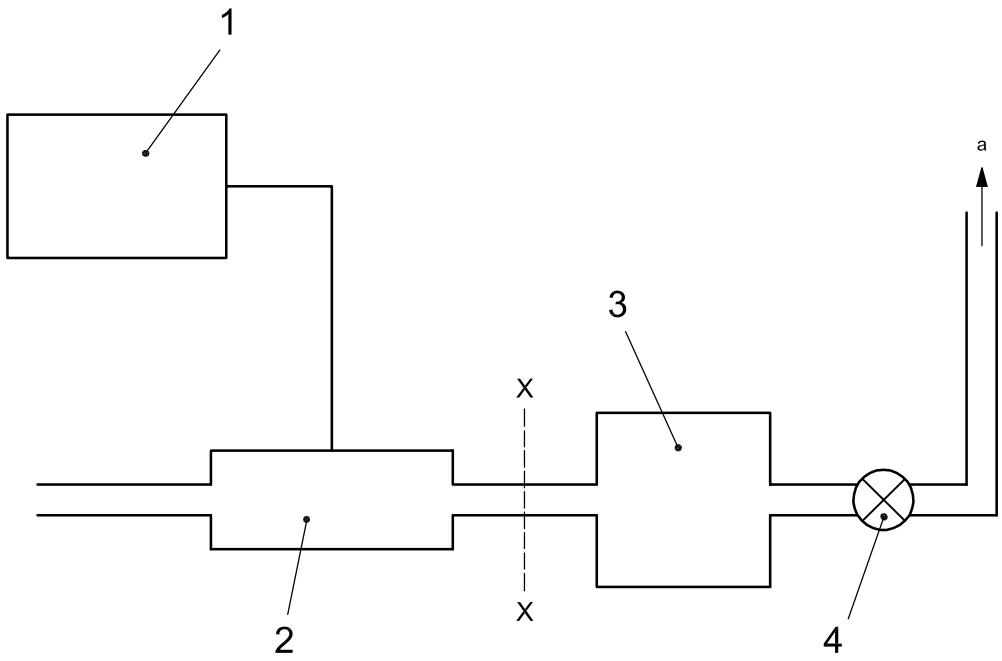
C.1 Apparatus

C.1.1 **Flow-measuring device**, accurate to within ± 10 ml/min.

C.2 Test procedure

C.2.1 Connect the flow-measuring device (C.1.1) to the inlet of the AGSS at X-X as shown in Figure C.1. Test at the maximum extract flow specified by the manufacturer for the AGSS transfer and receiving system. If no maximum outlet flow is specified, test at 50 l/min or 75 l/min according to whether it is designed for use with a low- or high-flow disposal system.

C.2.2 Measure the induced flow.



Key

1 recording instrument
2 flow-measuring device
3 AGSS transfer and receiving system
4 flow control valve

[a] Suction flow.

X-X Inlet of AGSS.

Figure C.1 — Typical test arrangement for induced flow

Annex D
(informative)

Typical test arrangement and method for resistance to extract flow

D.1 Apparatus

D.1.1 **Test rig**, as shown in Figure D.1.

D.1.2 **Flow- and pressure-measuring devices**, as specified in A.1.

D.2 Test procedure

D.2.1 Assemble the test apparatus as shown in Figure D.1, but do not connect the transfer and receiving system.

D.2.2 Adjust the air flow to 25 l/min and record the pressure.

D.2.3 Connect the low-flow transfer and receiving system to the test apparatus.

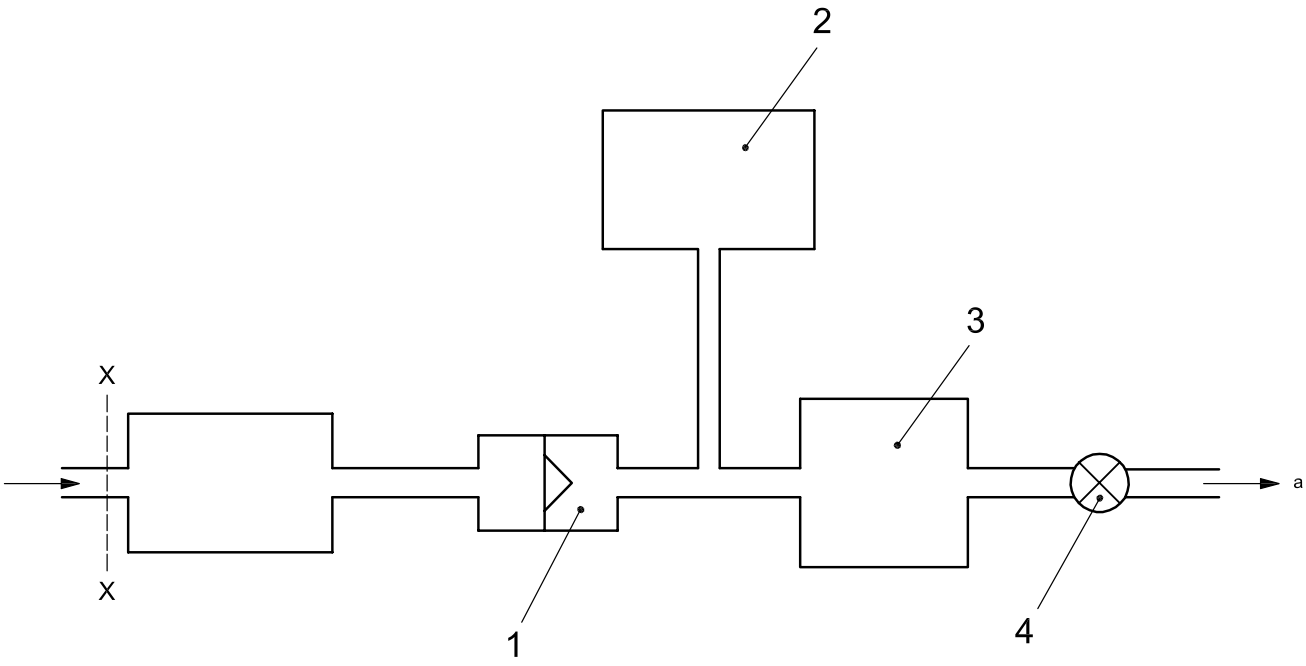
D.2.4 Re-adjust the air flow to 25 l/min and record the pressure.

D.2.5 Subtract the pressure measured in D.2.2 from the pressure measured in D.2.4 and verify that the pressure drop complies with the appropriate requirement in 9.1.

D.2.6 Disconnect the transfer and receiving system from the test apparatus.

D.2.7 Repeat the procedure described in D.2.2 to D.2.5 with an air flow of 50 l/min and verify that the pressure drop complies with the requirement in 9.1

D.2.8 For high-flow transfer and receiving systems carry out the test procedure described in D.2.1 to D.2.5 but with an air flow of 80 l/min and verify that the pressure drop complies with the requirement in 9.2.



Key

1 outlet of receiving system/inlet to disposal system (see 7.2)
2 pressure-measuring device
3 flow-measuring device
4 flow control device

[a] Suction flow.

X-X Inlet of AGSS.

Figure D.1 — Typical test arrangement for measurement of resistance to flow

Annex E
(informative)

Typical test arrangement and method for spillage

E.1 Apparatus

The test apparatus consists of a test enclosure (see Figure E.1) in which the appropriate parts of an AGSS transfer and receiving system can be installed. To ensure free flow, the air inlet of the enclosure is open to atmosphere and, by a fan or other suitable means, air is drawn through the enclosure box at a constant flow rate. Means are provided to ensure mixing of any spilled test gas with entrained air and to measure the calibration gas concentration with an accuracy of within ± 10 % of the actual value.

E.2 Calibration procedure

E.2.1 Set up the apparatus as shown in Figure E.1.

E.2.2 Place the AGSS components in the test enclosure and connect the tubing for the test gas flow and the extract flow. Set and maintain the outlet gas flow between 20 l/min and 30 l/min. Set and maintain a flow of 100 l/min of the calibration gas into the calibration gas injection site. See Figure E.1.

E.2.3 When the calibration gas concentration has reached steady-state, record this value and that of the outlet gas flow rate.

E.2.4 Turn off the flow of calibration gas into the calibration gas injection site on completion of the calibration procedure.

E.3 Test flow pattern

Apply a flow of a test gas, consisting of the calibration gas at a known concentration, in the form of a half-sine wave pulse, to the inlet of the AGSS, the pulse being as shown in Figure E.2.

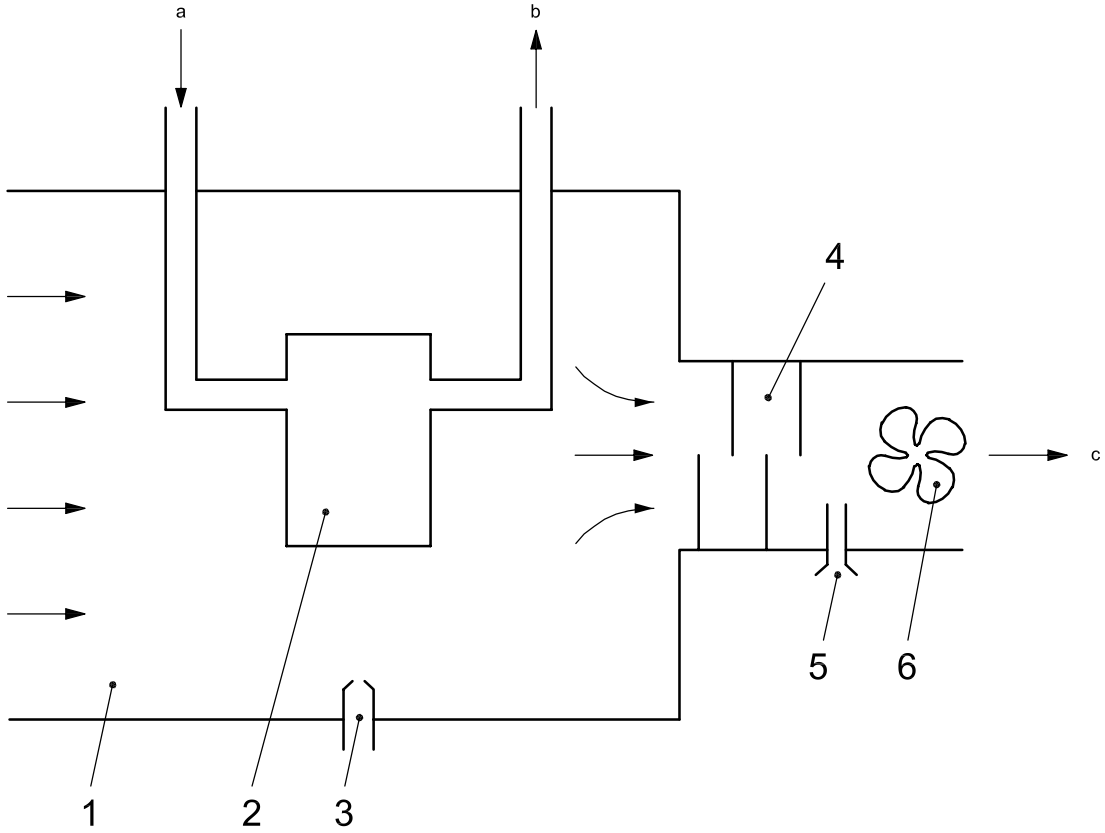
E.4 Test procedure

E.4.1 Set the extract flow to the minimum value for which the components are designed. Set and maintain the outlet gas flow to the same value used for calibration.

E.4.2 When the value of the calibration gas concentration has reached steady-state, record this value and the outlet gas flow rate.

E.5 Calculation of results

Derive the spillage by calculating the difference between the results obtained in E.2 and E.4.

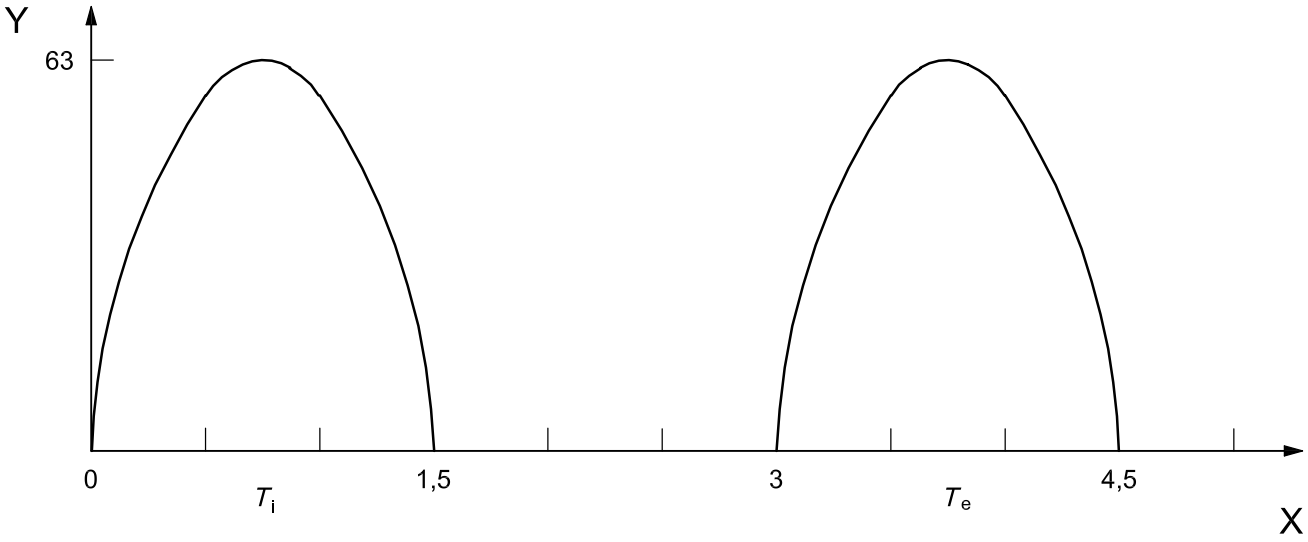


Key

1 test enclosure
2 AGSS transfer and receiving system
3 calibration gas injection site
4 mixing device
5 test gas sampling site
6 fan

a Test gas flow.
b Extract flow.
c Outlet gas flow.

Figure E.1 — Typical test arrangement for spillage



Key

X time in seconds

Y flow in litres per minute

Figure E.2 — Typical test flow pattern for spillage

Annex F
(informative)

Rationale

This annex provides a rationale for some requirements of this part of ISO 8835 and is intended for those who are familiar with the subject of this part of ISO 8835 but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this part of ISO 8835 necessitated by those developments.

The numbering of the following rationale corresponds to the numbering of the clauses in this part of ISO 8835. The numbering, therefore, is not consecutive.

F.1 Scope

An anaesthetic gas scavenging system is defined in this specification as the complete system connected at the exhaust port of a breathing system, anaesthetic ventilator or other equipment for the purpose of conveying expired or excess anaesthetic gases, or both, to an appropriate place of discharge. This specification is intended to establish requirements for only two components of the total anaesthetic gas scavenging system — the transfer system and the receiving system. The requirements for other parts of the complete system (breathing system and disposal system) are covered by other standards.

The primary reason for using an AGSS is to reduce the exposure of healthcare personnel to anaesthetic gases and vapours. During the creation of this specification, the subcommittee recognised that there are many factors affecting conditions within the working environment of healthcare workers, which are not included in this part of ISO 8835 because they are outside the control of manufacturers of anaesthetic gas scavenging transfer and receiving systems. These include the room ventilation, leakage from equipment, and many different clinical treatment procedures. Furthermore, the amount of pollutant taken up by personnel is affected by other factors such as the duration of exposure and their position in relation to the sources of pollution. Recommendations on permissible levels of atmospheric pollution by anaesthetic gases have not been included in this specification because they are the subject of considerable discussion and opinions differ as to the limits that should be allowed in the healthcare workers' environment.

The requirements appearing in this specification are those that the subcommittee believes will reduce the risk to patients that an AGSS transfer system and receiving system of an anaesthetic gas scavenging system might introduce. Where applicable, the subcommittee addresses these risks under both normal conditions and single fault conditions.

Non-active AGSS systems should comply with the positive pressure requirements in 5.1.1 and 5.2.1. Charcoal filters and a high rate of room air exchange can also be used to reduce the exposure of hospital personnel to anaesthetic gases and vapour.

F.5 Patient and environmental protection

The location and performance of devices to limit pressure have been specified because as they are essential for limiting or preventing harmful pressure changes in the breathing system under normal conditions and for providing protection against excessive pressure under single fault conditions.

F.5.1.1 The subcommittee chose to limit the pressure rise at the inlet of the AGSS under normal conditions to no more than 350 Pa (3,5 cm H_2O) since the addition of the AGSS transfer and receiving system under normal conditions should not add excessive amounts of resistance to gas flow. The subcommittee chose a positive pressure limit under single fault conditions of 2,0 kPa (20 cm H_2O) since the most likely scenario to cause pressure rise to occur at the inlet to the transfer system of the AGSS would be the partial or complete occlusion of the transfer tube/system. The subcommittee recognises that designs exist where a partial or complete occlusion of the transfer tube/system cannot be considered possible. However, for those

systems where this is not the case, the subcommittee believes that limiting the pressure rise at the inlet to transfer tube/system to less than 2,0 kPa (20 cm H_2O) under single fault conditions will not cause serious patient injury in all but extremely rare cases. Also, this value has been the acceptable limit for a number of years in the USA, and there are no known reports of adverse incidents.

F.5.1.2 Experience has shown that sub-atmospheric pressure at the inlet to the AGSS can induce gas flow from the breathing system under specific conditions. This can be hazardous to the patient because it can reduce the gas flow in the breathing system to below the minimum required for patient and/or alter the composition of the inspired gas mixture and/or affect the proper functioning of respiratory measuring equipment or alarms. Unfortunately, it is impractical to design an AGSS system to prevent the generation of this flow in all conditions. Therefore the subcommittee chose to impose limits on this flow under both normal and single fault conditions.

F.5.1.3 The subcommittee chose to limit the sub-atmospheric pressure at the inlet to the AGSS under normal conditions to no more than 50 Pa (0,5 cm H_2O). Sub-atmospheric pressure within the AGSS is reported to have raised the opening pressure on some adjustable pressure-limiting valves and lowered it on others. These changes in opening pressure can cause the reservoir bag to collapse, thereby altering the delivered anaesthetic concentrations and the ability to assist or control ventilation.

F.6 Connectors

A connector for scavenging the sample gas from a respiratory gas monitor is not mandated. Connectors to be used for this purpose are still being developed and will most likely be standardized at some point in the future (see ISO 21647). Manufacturers are encouraged to provide a connection to allow the scavenging of sample gas from a diverting respiratory gas monitor.

F.7 and F.8 Transfer and receiving systems — Inlet and outlet connections

The subcommittee established requirements for both interchangeable transfer systems and interchangeable receiving systems, as well as transfer systems and receiving systems that are not interchangeable. These requirements were thought necessary since it should be expected that interchangeable transfer tube/systems should be provided with pressure relief regardless of what device/system (e.g. anaesthetic system, breathing system, etc.) it is connected to.

Transfer systems and receiving systems that are not interchangeable are required to have inlet and outlet connections that are either permanently attached or proprietary, so as to avoid misconnections.

The subcommittee recognised that there are a wide variety of proprietary terminal units and probes that will provide the connection from the receiving system to the disposal system including a diameter index safety system (DISS) 2220 connector.

F.11 Information to be supplied by the manufacturer and F.12 Marking

The requirements for marking in this specification are intentionally minimal, since the equipment will most likely not be large in size. The subcommittee recognises that statements in the accompanying documents are probably the least effective method of reducing risks. However, providing the operator with the necessary information to set up, test and use the equipment is properly considered a necessity. Many of the requirements for accompanying documents are generic statements and subject to determination of applicability and interpretation.

F.13 Identification

Magenta was chosen as the colour code for AGSS systems and components, when colour coding is used, since this is already used internationally.

Annex G
(informative)

Environmental aspects

Planning and design of products applying to this part of ISO 8835 should consider the environmental impact of the product during its life cycle. The environmental impact generated by a transfer and receiving system of active anaesthetic gas scavenging systems is mainly restricted to the following occurrences:

— impact on local environment during normal use;

— use, cleaning and disposal of consumables during testing and normal use;

— scrapping at the end of the life cycle.

To highlight the importance of reducing the environmental burden, this part of ISO 8835 addresses requirements or recommendations intended to decrease the environmental impact caused by those aspects.

See Table G.1 for a mapping of the life cycle of a transfer and receiving system of active anaesthetic gas scavenging systems to aspects of the environment.

Table G.1 — Environmental aspects addressed by clauses of this International Standard

Environmental aspects (inputs and outputs)		**Product life cycle**			
		Production and preproduction Stage A	**Distribution** (including packaging) Stage B	**Use** Stage C	**End of life** Stage D
		Addressed in Clause:			
1	Resource use	1	—	4 12 13	4
2	Energy consumption	1	—	11	—
3	Emissions to air	1	—	5	5
4	Emissions to water	1	—	12	5
5	Waste	1	1 5	12	12
6	Noise	1	—	—	—
7	Migration of hazardous substances	1	—	—	—
8	Impacts on soil	1	—	12	—
9	Risks to the environment from accidents or misuse	1	—	—	—

Bibliography

[1] ISO 14971, *Medical devices — Application of risk management to medical devices*

[2] ISO/TS 18835, *Inhalational anaesthesia systems — Draw-over vaporizers and associated equipment*

[3] Munsell Book of Color[2)]

[4] IEC 60079-4, *Electrical apparatus for explosive gas atmospheres — Part 4: Method of test for ignition temperature*

[5] IEC 60079-11:2006, *Explosive atmospheres — Part 11: Equipment protection by intrinsic safety "i"*

2) Available from Munsell Color, 2441 N. Calvert Street, Baltimore, MD 21218, USA. This information is given for the convenience of users of this part of ISO 8835 and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same results.

ICS 11.040.10

Price based on 23 pages