INTERNATIONAL STANDARD

ISO 8835-3

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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

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Contents

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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.

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.

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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.

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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.

8.4 The connector at the outlet of the receiving system shall be type 1L for receiving systems to be connected to a low-flowrate disposal system or type 1H for receiving systems to be connected to a high-flowrate disposal system.

NOTE — Specifications for types 1L and 1H connectors are under consideration by ISO/TC 121/SC 6. The use of differing connectors is intended to prevent connection to an inappropriate disposal system (see ISO 7396-2 and ISO 9170-2).

9 Extract flow

9.1 Transfer and receiving systems intended for use with low-flowrate disposal systems shall meet the requirements of this part of ISO 8835 with extract flowrates not exceeding 50 l/min.

9.2 Transfer and receiving systems intended for use with high-flowrate disposal systems shall meet the requirements of this part of ISO 8835 with an extract flowrate of 75 l/min.

9.3 The resistance to extract flow of a transfer and receiving system intended for use with a low-flowrate disposal system shall not exceed 2 kPa (20 cmH_2O) at 25 l/min, and be not less than 1 kPa (10 cmH_2O) at 50 l/min when tested as described in annex D.

9.4 The resistance to extract flow of a transfer and receiving system intended for use with a high-flowrate disposal system shall not exceed 2 kPa (20 cmH_2O) at a flowrate of 75 l/min when tested as described in annex D.

10 Electrical requirements

If the transfer or receiving systems incorporate electrically powered components, the systems shall comply with IEC 601-1.

11 Information to be supplied by the manufacturer

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

a) operating instructions, details of functional tests to be carried out and a statement of the maximum constant and intermittent flowrates before spillage occurs;

b) warning statements and instructions to the operator to review the specifications of the AGSS transfer and receiving systems and the breathing system with which it is intended to be used, to ensure compatibility;

c) warning statements and instructions to the operator to review the performance specifications of the disposal system with which the transfer and receiving systems are to be used, to ensure compatibility;

d) installation instructions, if applicable;

e) range of flowrates and, if possible, pressures of the disposal system(s) with which the transfer and receiving systems are intended to be used;

f) recommended methods of cleaning, disinfection or sterilization;

g) maintenance recommendations, including instructions for changing filters, if applicable.

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 601-1:1988 that shall include at least the following:

a) the direction of flow, if applicable, e.g. by means of an arrow:

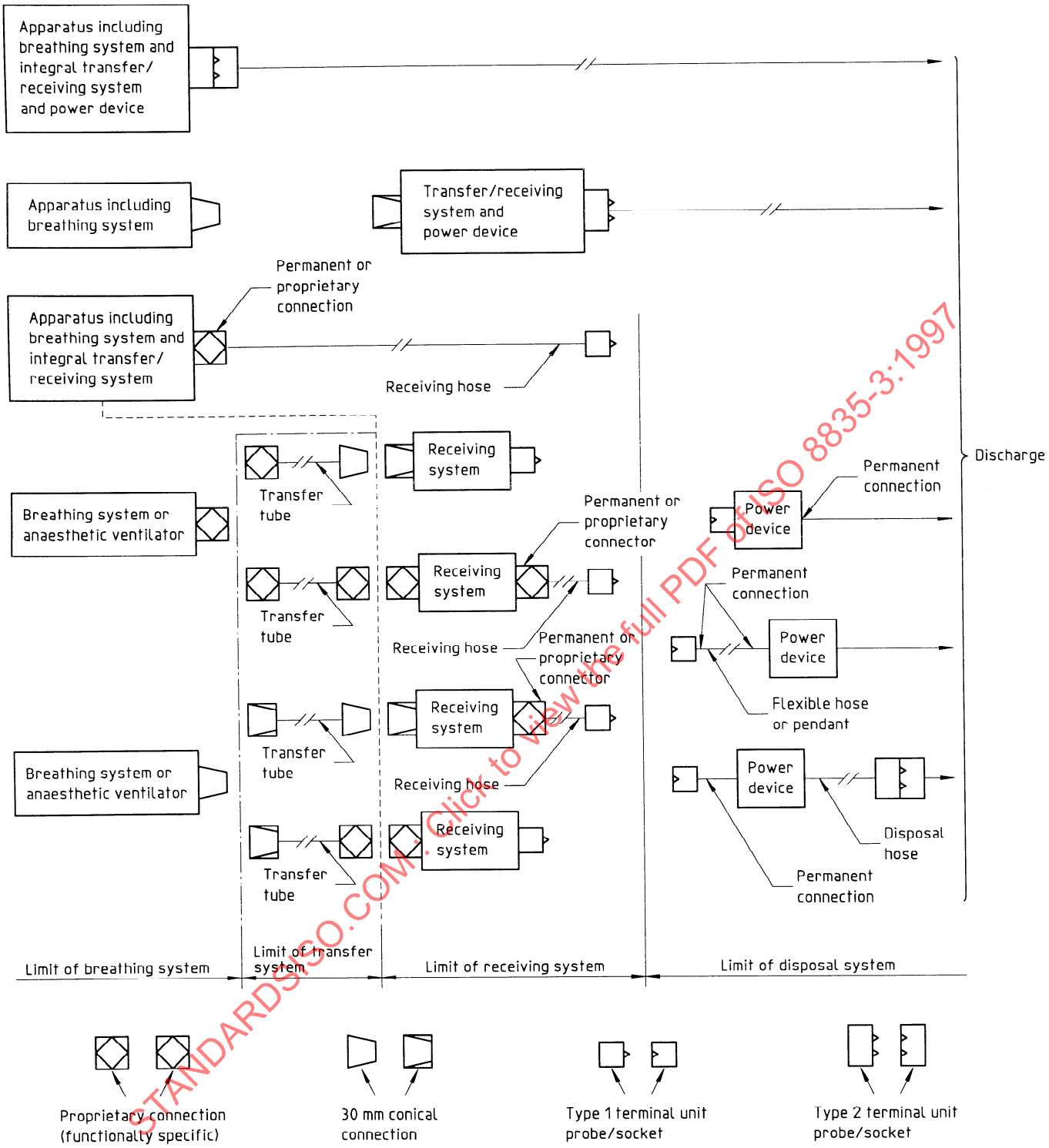
b) an identification of the manufacturer/supplier;

c) if applicable, symbol number 14 specified in table D.1 of IEC 601-1:1988;

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

13 Identification

If colour coding is used to identify components as being specific for use with AGSS, the components of the transfer system and the connector of the receiving system that connects with the transfer system shall be colour-coded with a colour within the range of 10P hue/4/10 to 10P hue/5/10 as specified in the Munsell Book of Color.



NOTES

1 Type 1 terminal unit probe/socket is for negative pressure; type 2 terminal unit probe/socket is for positive pressure.

2 The limit between the receiving system and the disposal system as shown may not coincide with an actual physical limit such as a wall. In the arrangement shown, a terminal unit on a wall would be located on the inlet to the power device.

Figure 1 — Schematic diagram of typical AGSS connections

Annex A
(normative)

Test for pressure rise at inlet to AGSS

A.1 Apparatus

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

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

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 Render the means of pressure relief, if provided, inoperative.

A.2.3 Adjust the air flowrate to 30 l/min and record the pressure.

A.2.4 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.

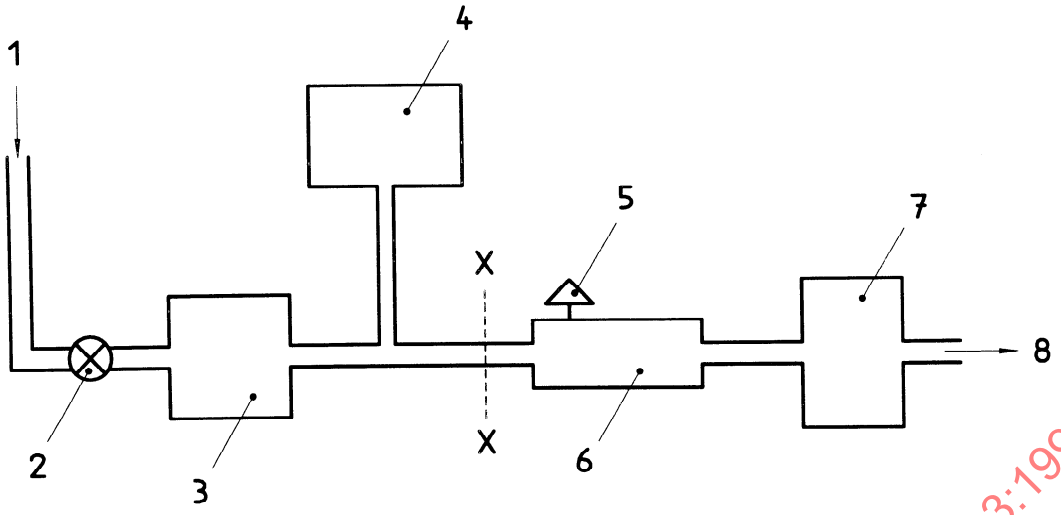
A.2.5 Record the pressure, and calculate the pressure difference by subtracting the pressure recorded in A.2.3 from that recorded in A.2.4.

A.2.6 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 described in A.2.3 to A.2.5 inclusive.

A.2.7 Repeat the test procedure described in A.2.3 to A.2.6 inclusive, but with an air flowrate of 75 l/min.

A.2.8 Disconnect the AGSS at X-X. Return the means of pressure relief, if provided, to the operative condition.

A.2.9 Repeat the test procedure described in A.2.3 to A.2.5 inclusive, introducing single faults, one at a time.

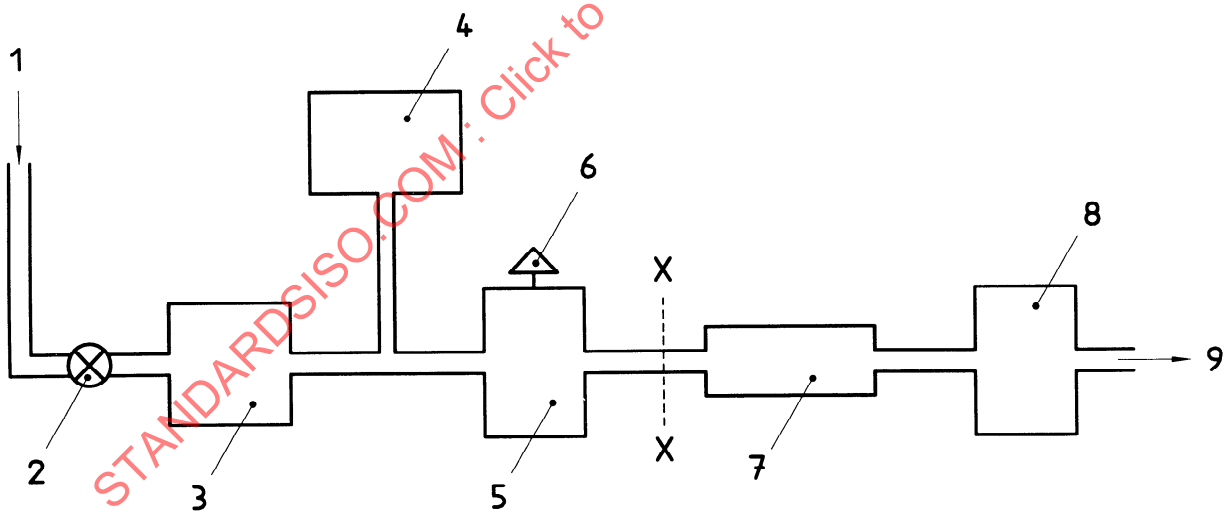


1 Air supply
2 Flow-control valve
3 Flow-measuring device
4 Pressure-measuring device
5 Means of pressure relief

X - - - -X entry to the AGSS

6 AGSS transfer and receiving systems with integrated means of pressure relief
7 Disposal system or equivalent test device
8 Discharge

Figure A.1 — Test apparatus for measurement of pressure rise at the inlet of interchangeable AGSS with integrated means of pressure relief



1 Air supply
2 Flow-control valve
3 Flow-measuring device
4 Pressure-measuring device
5 Breathing system with integrated means of pressure relief

X - - - - X entry to AGSS

6 Means of pressure relief
7 Noninterchangeable AGSS
8 Disposal system or equivalent test device
9 Discharge

Figure A.2 — Test apparatus for resistance to flow of noninterchangeable AGSS with a means of pressure relief integrated into the breathing system

Annex B
(normative)

Test for induced flow

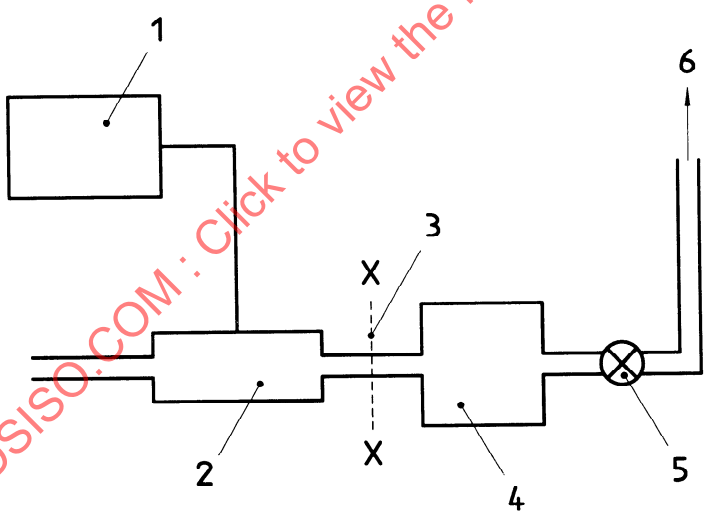
B.1 Apparatus

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

B.2 Test procedure

B.2.1 Connect the flow-measuring device to the inlet of the AGSS at X-X as shown in figure B.1. Test at the maximum extract flowrate specified by the manufacturer for the AGSS transfer and receiving system, or if no maximum outlet flowrate is specified, at 50 l/min or 75 l/min, according to its designation for use with a low- or high-flowrate disposal system.

B.2.2 Measure the induced flowrate.



1 Recording instrument
2 Flow-measuring device
3 Inlet of AGSS
4 AGSS transfer and receiving systems
5 Flow-control valve
6 Suction flow

Figure B.1 — Test apparatus for induced flow

Annex C
(normative)

Test for spillage

C.1 Apparatus

The test apparatus consists of a test enclosure (see figure C.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 at a constant flowrate. 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 actual reading.

C.2 Calibration procedure

C.2.1 Set up the apparatus as shown in figure C.1

C.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 flowrate between 20 l/min and 30 l/min. Set and maintain a flowrate of 100 ml/min of the calibration gas into the calibration-gas injection site (see figure C.1).

C.2.3 When the calibration-gas concentration reading has reached steady-state, record this reading and the outlet gas flowrate.

NOTE — Gas samples should be taken from the centre of the enclosure outlet.

C.2.4 Turn off the flow of calibration gas into the calibration-gas injection site at the completion of the calibration procedure.

C.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 C.2.

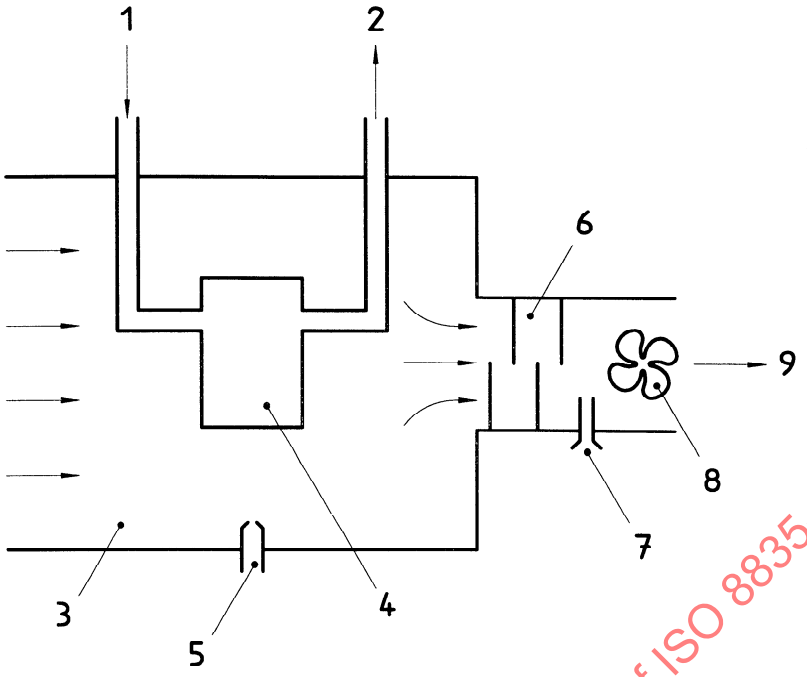
C.4 Test procedure

C.4.1 Set the extract flowrate to the minimum value for which the components under test have been designed. Set and maintain the outlet gas flowrate to the same value used for calibration.

C.4.2 When the reading of the calibration-gas concentration has reached steady-state, record this reading and the outlet gas flowrate.

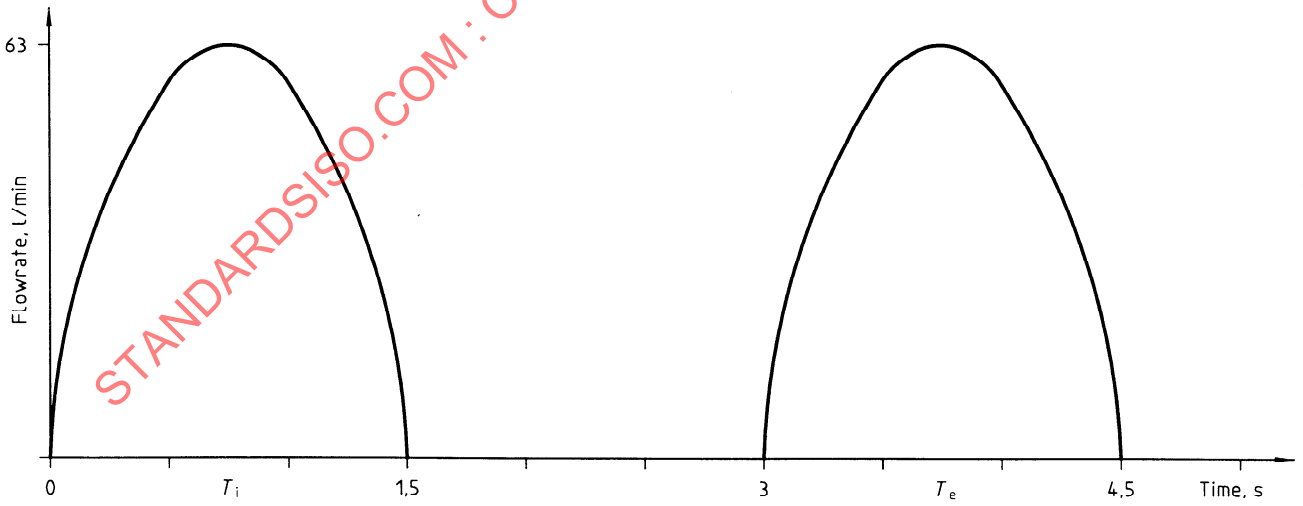
C.5 Calculation of results

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



1 Test gas flow
2 Extraction flow
3 Test enclosure
4 AGSS transfer and receiving system
5 Calibration-gas injection site
6 Mixing device
7 Test-gas sampling site
8 Fan
9 Outlet gas flow

Figure C.1 — Test apparatus for measurement of spillage



Inspiratory time: T_i: 1,5 s
Expiratory time T_e: 1,5 s.
Inspiratory:expiratory ratio I:E = 1:1
Tidal volume: 1 litre
Waveform: half-sine

Figure C.2 — Flow pattern for testing of spillage