INTERNATIONAL STANDARD

ISO 7396-2

Second edition
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Medical gas pipeline systems —

Part 2: Anaesthetic gas scavenging disposal systems

Réseaux de distribution de gaz médicaux —

Partie 2: Réseaux d'évacuation de gaz d'anesthésie non réutilisables

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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 7396-2 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in collaboration with Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 7396-2:2000), which has been technically revised.

ISO 7396 consists of the following parts, under the general title *Medical gas pipeline systems*:

— *Part 1: Pipeline systems for compressed medical gases and vacuum*

— *Part 2: Anaesthetic gas scavenging disposal systems*

Introduction

Anaesthetic gas scavenging systems (AGSS) are used to reduce occupational exposure to anaesthetic gases and vapours.

The anaesthetic gas scavenging system comprises three main parts:

— a transfer system,

— a receiving system, and

— a disposal system.

A schematic diagram of typical anaesthetic gas scavenging systems is shown in Figure 1. Requirements for receiving systems and transfer systems are specified in ISO 8835-3. Type-specific connections for terminal units are specified in ISO 9170-2. In this part of ISO 7396, specifications and test procedures are given to ensure compatibility between the components of the system.

This part of ISO 7396 specifies requirements for pipelines for anaesthetic gas scavenging systems for anaesthetic gases and vapours. It is intended for use by those persons involved in the design, construction, inspection and operation of healthcare facilities treating human beings. It is advisable that those persons involved in the design, manufacture and testing of equipment intended to be connected to pipeline systems also be aware of the contents of this part of ISO 7396.

Specific components are used for scavenging terminal units and for other connectors which are intended to be used by the operator. In addition, the system is tested and certified to operate at safe flows and without leakage. It is also intended to address issues of patient safety.

The objectives of this part of ISO 7396 are to ensure the following:

a) avoidance of cross connections between different pipeline systems;

b) continuity of function of the system;

c) use of suitable materials;

d) cleanliness of components;

e) correct installation;

f) provision of indicating system(s);

g) correct marking of the pipeline system and components;

h) testing, commissioning and certification;

i) correct operational management.

Annex E contains rationale statements for some of the requirements of this part of ISO 7396. It is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this part of ISO 7396. The clauses and subclauses marked with (*) after their number have corresponding rationale contained in Annex E.

Medical gas pipeline systems —

Part 2:
Anaesthetic gas scavenging disposal systems

1 Scope

This part of ISO 7396 specifies requirements for the design, installation, function, performance, documentation, testing and commissioning of anaesthetic gas scavenging disposal systems to ensure patient safety and to minimize exposure of the operator and other persons to anaesthetic gases and vapours. It includes requirements for the power device, pipeline system, performance, non-interchangeability between key components and avoidance of cross connections between anaesthetic gas scavenging (AGS) disposal systems and medical gas and vacuum pipeline systems.

NOTE In this part of ISO 7396, the term “pipeline” refers exclusively to pipelines that are part of a dedicated anaesthetic gas scavenging system (AGSS).

This part of ISO 7396 is applicable only to those disposal systems intended to be connected via AGSS terminal units conforming to ISO 9170-2 and to AGSS receiving systems conforming to ISO 8835-3.

This part of ISO 7396 also applies to:

— extensions of existing AGSS disposal systems;

— modifications of existing AGSS disposal systems;

— modifications or replacement of power devices.

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

ISO 7396-1:2007, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 8835-3:—[1)], *Inhalational anaesthesia systems — Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems*

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

1) To be published. (Revision of ISO 8835-3:1997.)

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

ISO 15001, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

EN 1041, *Information supplied by the manufacturer with medical devices*

EN 13348, *Copper and copper alloys — Seamless, round copper tubes for medical gases or vacuum*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
AGSS socket
female part of a terminal unit which is either integral or attached to the base block by a type-specific interface, and which contains the type-specific connection point

3.2
AGSS terminal unit
inlet assembly in an AGSS at which the operator makes connections and disconnections

3.3
AGSS terminal unit base block
part of an AGSS terminal unit which is attached to the pipeline disposal system

3.4
AGSS type 1 terminal unit
connection point between the receiving system and the disposal system at which an operator makes connections and disconnections

See Figure 1.

3.5
AGSS type 1H terminal units
AGSS type 1 terminal unit to be used in high-flow disposal systems

3.6
AGSS type 1L terminal units
AGSS type 1 terminal unit to be used in low-flow disposal systems

3.7
AGSS type 2 terminal unit
connection point between the power device or the disposal hose and the remainder of the disposal system at which an operator makes connections and disconnections

See Figure 1.

3.8
AGSS type-specific
having characteristics which prevent interchangeability and thereby allow assignment to one AGSS type only

3.9
AGSS type-specific connection point
part of the AGSS socket which is the receptor for an AGSS type-specific probe

3.10
air compressor system
source of supply with compressor(s) designed to provide medical air and/or air for driving surgical tools and/or air for AGSS

NOTE Different names or symbols are used for air for driving surgical tools, such as: instrument air, surgical air, air motor, air - 700 and air - 800.

3.11
anaesthetic gas scavenging system
AGSS
complete system which is connected to the exhaust port(s) of a breathing system or other equipment for the purpose of conveying expired and/or excess anaesthetic gases and vapours to an appropriate point of discharge

NOTE Functionally, an AGSS 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 AGSS can be combined with a breathing system or other equipment (e.g. an anaesthetic ventilator) to include the transfer system, or transfer and receiving systems.

3.12
commissioning
proof of function to verify that the agreed specification is met and is accepted by the user or his representative

3.13
disposal hose
part of an AGSS which transfers expired and/or excess anaesthetic gases and vapours from the power device to the probe of an AGSS type 2 terminal unit

3.14
disposal system
means by which the expired and/or excess anaesthetic gases and vapours are conveyed from the receiving system to an appropriate point of discharge

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

3.15
diversity factor
factor which represents the maximum proportion of terminal units in a defined clinical area which will be used at the same time, at flowrates defined in agreement with the management of the healthcare facility

3.16
high-flow disposal system
disposal system which is intended to operate with a high-flow transfer and receiving system complying with ISO 8835-3

3.17
high-flow transfer and receiving system
transfer and receiving system complying with ISO 8835-3 which connects through an AGSS type 1H terminal unit as specified in ISO 9170-2 to a high-flow disposal system complying with this part of ISO 7396

3.18
low-flow disposal system
disposal system which is intended to operate with a low-flow transfer and receiving system complying with ISO 8835-3

3.19
low-flow transfer and receiving system
transfer and receiving system complying with ISO 8835-3 which connects through an AGSS type 1L terminal unit as specified in ISO 9170-2 to a low-flow disposal system complying with this part of ISO 7396

3.20
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party

3.21
maximum operating pressure
maximum pressure at which a terminal unit is designed to operate

NOTE Operating pressure for a type 1 terminal unit is negative and for a type 2 terminal unit it is positive.

3.22
maximum test pressure
maximum pressure to which a terminal unit is designed to be subjected during pipeline pressure testing

3.23
non-return valve
valve which permits flow in one direction only

3.24
power device
part of an AGS disposal system that provides flow and pressure for scavenging

3.25
probe
non-interchangeable male component designed for acceptance by, and retention in, a socket

3.26
quick connector
pair of type-specific components which can be easily and rapidly joined together by a single action of one or both hands without the use of tools

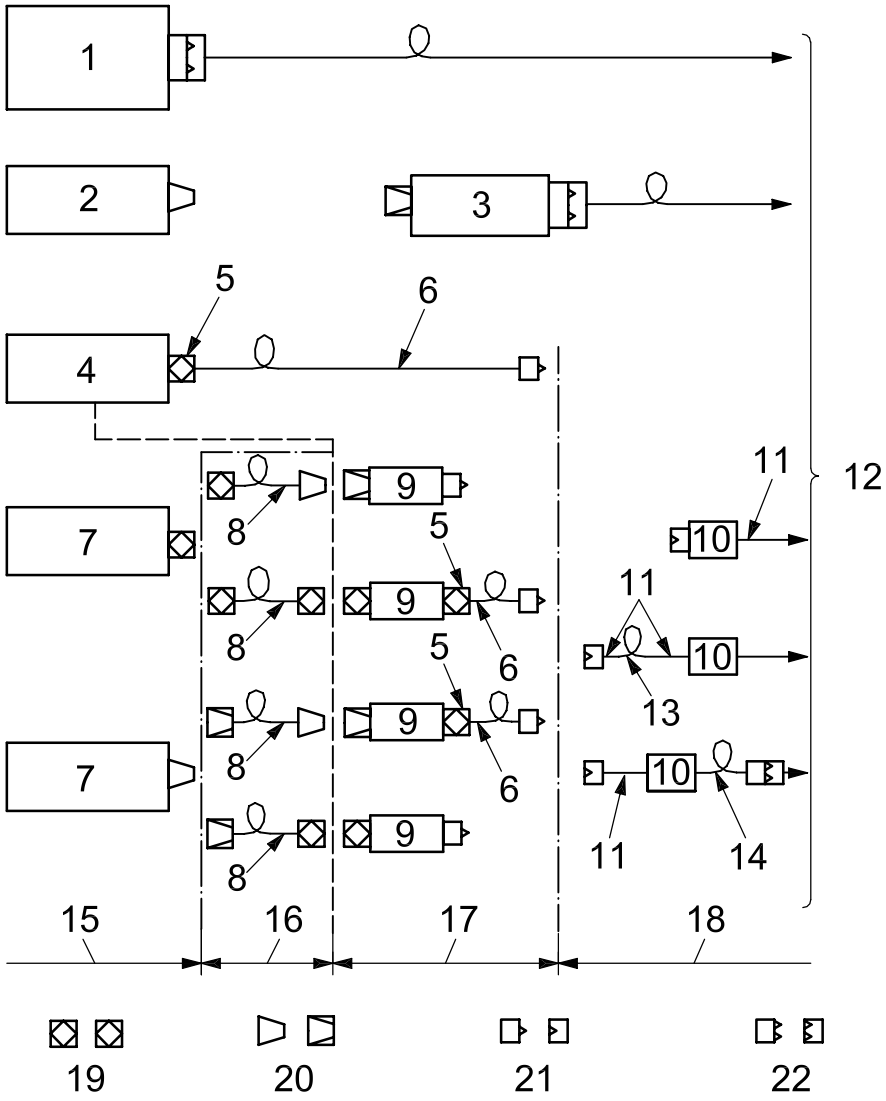
3.27
receiving hose
part of an AGSS which transfers expired and/or excess anaesthetic gases and vapours from the receiving system to the disposal system

3.28
receiving system
part of an AGSS which provides an interface between the transfer system and the disposal system

3.29
shut-off valve
valve which prevents flow in both directions when closed

3.30
single fault condition
condition in which a single means for protection against a safety hazard in equipment is defective or a single external abnormal condition is present

NOTE Maintenance of equipment is considered a normal condition.



Key

1 apparatus such as anaesthetic breathing system or anaesthetic ventilator and integral transfer/receiving system and power device
2 apparatus such as anaesthetic breathing system or anaesthetic ventilator
3 transfer/receiving system and power device
4 apparatus such as anaesthetic breathing system and integral transfer/receiving system
5 permanent or proprietary connector
6 receiving hose
7 breathing system or anaesthetic ventilator
8 transfer tube
9 receiving system
10 power device
11 permanent connection
12 point of discharge
13 flexible hose or pendant
14 disposal hose
15 limit of breathing system or anaesthetic ventilator
16 limits of transfer system
17 limits of receiving system
18 limit of disposal system
19 proprietary connection (functionally specific)
20 30 mm conical connection
21 type 1 terminal unit probe/socket
22 type 2 terminal unit probe/socket

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

NOTE 2 The limit between the receiving system and the disposal system as shown does not necessarily 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

3.31
system design flow
flow calculated from the maximum flow requirement of the healthcare facility and corrected by the diversity factor(s)

3.32
transfer system
part of an AGSS which transfers expired and/or excess anaesthetic gases from the exhaust port of the breathing system or other equipment to the receiving system

3.33
transfer tube
part of an AGSS which transfers expired and/or excess anaesthetic gases from the breathing system to the receiving system

4 General requirements

4.1 Safety

AGS disposal systems shall, when installed, extended, modified, commissioned, operated and maintained in accordance with the instructions of the manufacturer, present no risks that are not reduced to an acceptable level using risk management procedures in accordance with ISO 14971 and which are connected with their intended application, in normal condition and in single fault condition.

NOTE 1 A situation in which a fault is not detected is considered a normal condition. Fault conditions/hazardous situations can remain undetected over a period of time and as a consequence can lead to an unacceptable risk. In that case, a subsequent detected fault condition needs to be considered as a single fault condition. Specific risk control measures need to be determined within the risk management process to deal with such situations.

NOTE 2 Typical safety hazards (discontinuity of operation, incorrect pressure and/or flow, etc.) are listed in Annex D.

4.2 Alternative construction

AGS disposal systems and components, or parts thereof, using materials or having forms of construction different from those detailed in this part of ISO 7396, shall be presumed to be in compliance with the safety objectives of this part of ISO 7396 if it can be demonstrated that an equivalent degree of safety is obtained (i.e. compliance with requirements presumes that risks have been mitigated to acceptable levels) unless objective evidence to the contrary becomes available.

NOTE 1 Objective evidence can be obtained by post-market surveillance.

Evidence of an equivalent degree of safety shall be provided by the manufacturer.

NOTE 2 Regional or national regulations can require the provision of evidence to the competent authority or a conformity assessment body, e.g. notified body in the European Economic Area (EEA), upon request.

4.3 Materials

4.3.1 The materials used for pipelines and other components of the disposal system shall be corrosion-resistant and compatible with anaesthetic gases and vapours under the operating conditions specified by the manufacturer.

NOTE 1 Corrosion resistance includes resistance against the influence of moisture and the surrounding materials.

Evidence shall be provided by the manufacturer.

NOTE 2 Regional or national requirements can require the provision of evidence to the competent authority or a conformity assessment body, e.g. notified body in the European Economic Area (EEA), upon request.

4.3.2 If copper pipes are used, they shall comply with the requirements given in EN 13348.

Evidence shall be provided by the manufacturer.

NOTE 1 Regional or national regulations can require the provision of evidence to the competent authority or a conformity assessment body, e.g. notified body in the European Economic Area (EEA), upon request.

NOTE 2 The requirement in 4.3.2 allows the use of the same stock of copper pipes as is used for the installation of pipeline systems for compressed medical gases and vacuum in accordance with ISO 7396-1.

4.3.3 The potential hazards arising from the use of non-metallic pipes and components shall be taken into account, using risk management procedures in accordance with ISO 14971.

NOTE Experience shows that non-metallic pipes and their junctions used in AGS disposal systems need to be carefully evaluated for their durability following exposure to volatile anaesthetic agents.

4.3.4 All components of the system, other than copper pipes, which come in contact with anaesthetic gases and vapours shall be cleaned in accordance with ISO 15001.

Evidence shall be provided by the manufacturer.

NOTE Regional or national regulations can require the provision of evidence to the competent authority or a conformity assessment body, e.g. notified body in the European Economic Area (EEA), upon request.

4.3.5 If lubricants are used, they shall be compatible with anaesthetic gases and vapours at the operating conditions specified by the manufacturer.

Evidence shall be provided by the manufacturer.

NOTE Regional or national regulations can require the provision of evidence to the competent authority or a conformity assessment body, e.g. notified body in the European Economic Area (EEA), upon request.

4.3.6 Precautions shall be taken to maintain the cleanliness of components during transportation, storage and installation.

4.4 Continuity of operation

The AGS disposal system shall be designed so to achieve continuity of operation in normal condition and in single fault condition.

NOTE Loss of mains electrical power is a single fault condition. A fault in control equipment is a single fault condition.

In order to achieve these objectives, the AGS disposal system shall comprise at least two sources of supply of air to drive exhaust ejectors or at least two fans, blowers or dedicated vacuum pumps.

The AGS disposal system shall be such that the system design flow can be supplied with any one source of supply for air or any one fan, blower or dedicated vacuum pump out of service.

Means shall be provided so that each power device can be isolated for maintenance or repair.

5 Power device

5.1 The power device shall be used solely to power the AGS disposal system.

5.2 The power device shall be one of the following:

a) an exhaust ejector, for one or more AGSS type 1 terminal unit(s), driven by compressed air from a supply system for air and a pipeline distribution system complying with ISO 7396-1, provided with a means of adjusting the flow from the receiving system through the type 1 terminal unit to meet the requirements specified in 8.1.1 and 8.1.2 [see Figure 2 a)];

b) an exhaust ejector for each AGSS type 2 terminal unit, driven by compressed air from a supply system for air and a pipeline distribution system complying with ISO 7396-1, provided with a means of adjusting the flow from the receiving system to meet the requirements specified in 8.1.3 [see Figure 2 b)];

NOTE 1 Due to the high air flow required by the AGS disposal system, it is advisable to use a supply system with compressor(s) or proportioning units.

c) at least two fans, blowers or dedicated vacuum pumps.

NOTE 2 National and regional regulations concerning noise within medical environment levels can exist.

NOTE 3 See Annex A for guidelines for power devices consisting of fans, blowers or dedicated vacuum pumps.

If dedicated vacuum pumps are installed as power device(s), they shall be compatible with oxygen and the anaesthetic gases and vapours.

(*) A vacuum supply system in accordance with ISO 7396-1 shall not be used as AGSS power device.

5.3 Means shall be provided to adjust pressure and flow in the disposal system to meet the requirements given in 8.1.1 and 8.1.2 for type 1 terminal units, regardless of the number of terminal units in use [see Figure 2 c)].

NOTE Such means can be located either within the pipeline and/or in combination with the terminal unit(s).

5.4 Means for adjusting the pressure and flow shall be arranged so that they can be maintained without interruption of operation.

Evidence shall be provided by the manufacturer.

NOTE Regional or national regulations can require the provision of evidence to the competent authority or a conformity assessment body, e.g. notified body in the European Economic Area (EEA), upon request.

5.5 Power devices consisting of fans, blowers or dedicated vacuum pumps shall not be located in the same room as gas and non-cryogenic liquid cylinder supply systems.

5.6 The locations of power devices complying with this part of ISO 7396 and supply systems complying with ISO 7396-1 shall be decided by risk management process in accordance with ISO 14971 in order to minimize the risk arising from hazards such as fire, contamination with oil, grease, and increased oxygen and nitrous oxide concentrations.

6 Indicating systems

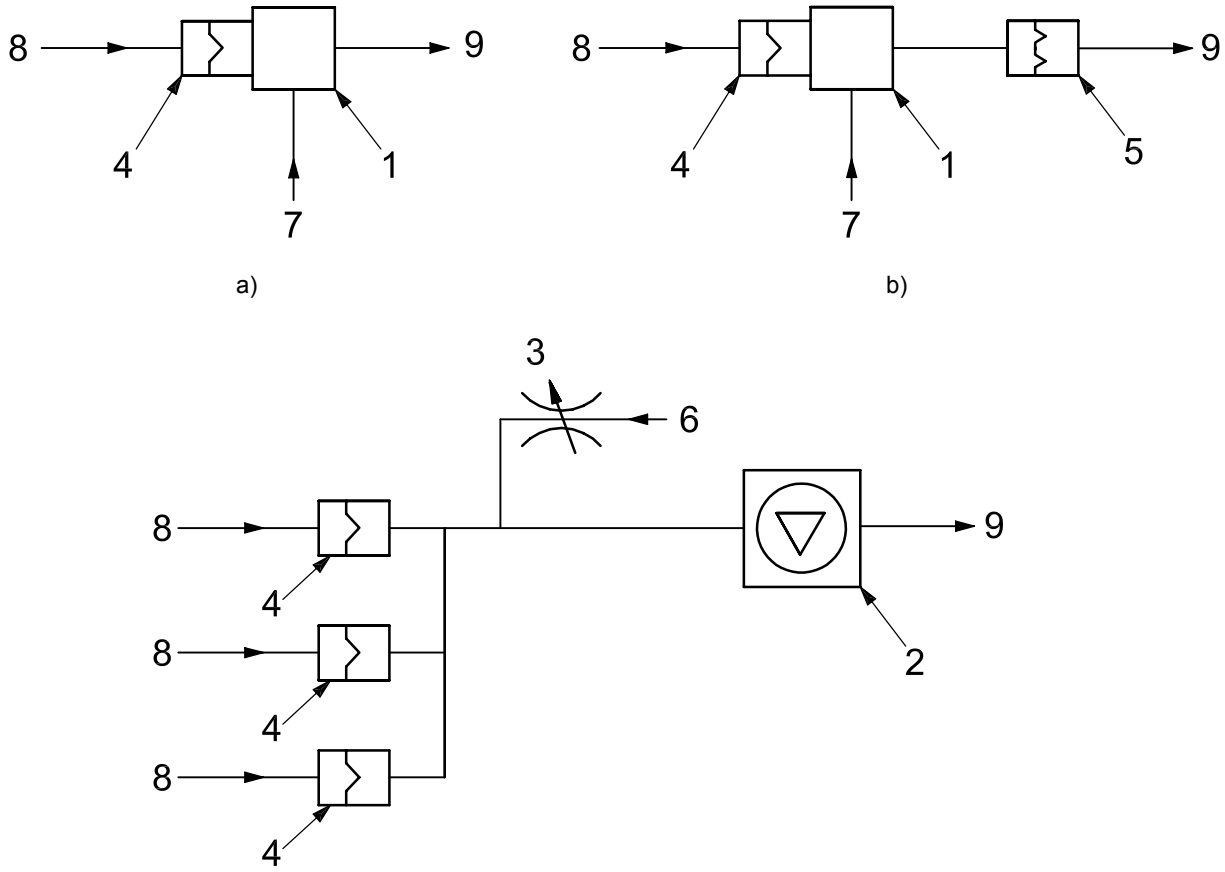
Means shall be provided to indicate to the operator that the AGS disposal system is operating.

7 Pipelines, connecting assemblies and disposal hoses

7.1 If connecting assemblies or disposal hoses are readily accessible to the operator, their connectors shall be type-specific. The dimensions of the connectors shall be different from those specified in ISO 5359.

7.2 If flexible connecting assemblies or disposal hoses are used between components of the disposal system and they are not readily accessible to the operator without significant disassembly of fixed components or not normally replaced during their lifetime, the connectors of the assembly need not be type-specific. The dimensions of the connectors shall be different from those specified in ISO 5359.

NOTE Examples of such connecting assemblies are those in hinged-arm booms, tracks and ceiling pendants, and those used for isolation of vibration, building movement and relative movement of the pipelines.



Key

1 compressed-air-driven power device
2 vacuum pump/fan/blower power device
3 means to adjust pressure and flow
4 type 1 terminal unit
5 type 2 terminal unit
6 ambient air
7 compressed air
8 receiving system
9 point of discharge

Figure 2 — Typical examples of power devices

8 Disposal system characteristics and test methods for pressure and flow

8.1 Requirements

8.1.1 Requirements for the AGS disposal system with type 1L terminal units

The flowrate through each type 1L terminal unit or, if not provided, at the interface point upstream of the power device (see Figure 1) shall not exceed 50 l/min when the resistance to flow, which is provided to simulate the resistance of the receiving system, is such as to produce a pressure drop of 1 kPa at 50 l/min, and shall not be lower than 25 l/min when the resistance to flow, which is provided to simulate the resistance of the receiving system, is such as to produce a pressure drop of 2 kPa at 25 l/min (see also ISO 8835-3:—, 10.1).

8.1.2 Requirements for the AGS disposal system with type 1H terminal units

The flowrate through each type 1H terminal unit or, if not provided, at the interface point upstream of the power device (see Figure 1) shall not exceed 80 l/min when the resistance to flow, which is provided to simulate the resistance of the receiving system, is such as to produce a pressure drop of 1 kPa at 80 l/min, and shall not be lower than 50 l/min when the resistance to flow, which is provided, is such as to produce a pressure drop of 2 kPa at 50 l/min (see also ISO 8835-3:—, 10.2).

8.1.3 Requirements for the AGS disposal system with type 2 terminal units

With a flowrate of 50 l/min through the socket of each AGSS type 2 terminal unit, the pressure drop shall not exceed 7,5 kPa.

8.2 Test methods for pressure and flow

8.2.1 General

8.2.1.1 All means for adjusting pressure and flow shall be adjusted to control the flow at each terminal unit. Each terminal unit on the system shall be tested as follows:

a) with only the terminal unit under test in use;

b) for systems with more than one terminal unit, with all terminal units in use which are required to provide the system design flow at the specified diversity factor.

8.2.1.2 Testing shall be carried out using ambient air.

8.2.1.3 The resolution and accuracy of all measuring devices used for testing shall be appropriate for the values to be measured. All measuring devices used for certification shall be calibrated at appropriate intervals.

8.2.2 Test methods for flow in disposal systems fitted with type 1L terminal units

8.2.2.1 Test devices

In order to simulate the resistance to flow of a receiving system complying with ISO 8835-3, calibrated test devices which are fitted with type 1L probes and which produce a pressure drop of 1 kPa at a flowrate of 50 l/min (test device 1/50) and 2 kPa at a flowrate of 25 l/min (test device 2/25) shall be used.

NOTE A typical test device is shown in Figure 3.

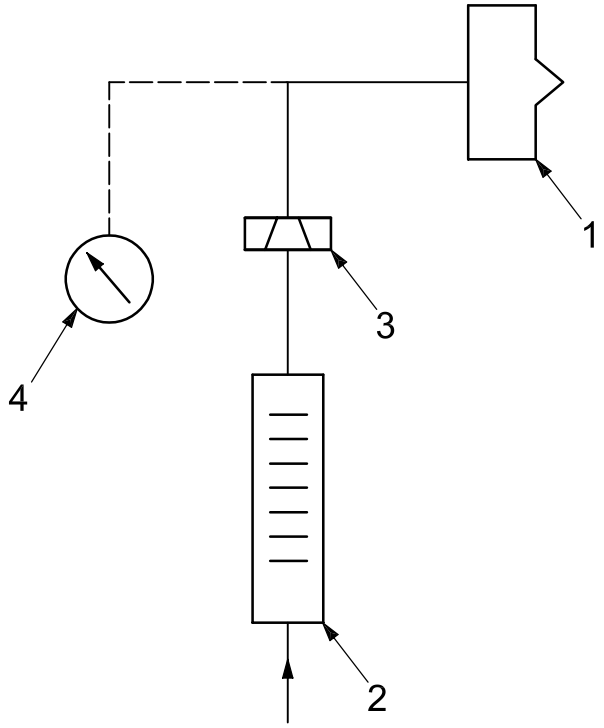
8.2.2.2 Procedure

8.2.2.2.1 Activate the power device on the AGS disposal system to be tested.

8.2.2.2.2 A test device fitted with type 1L probe which produces a pressure drop of 1 kPa at 50 l/min shall be inserted into each type 1L terminal unit in turn with all the other terminal units closed. The flowrate on the test device at each terminal unit shall be recorded.

8.2.2.2.3 A test device fitted with type 1L probe which produces a pressure drop of 2 kPa at 25 l/min shall be inserted into each type 1L terminal unit in turn with all the other terminal units closed. The flowrate on the test device at each terminal unit shall be recorded.

8.2.2.2.4 Type 1L probes which produce a pressure drop of 1 kPa at 50 l/min shall be inserted into each of several type 1L terminal units up to the system design flow of the AGS disposal system with all the other terminal units closed. A test device with type 1L probe which produces a pressure drop of 2 kPa at 25 l/min shall be inserted into each terminal unit in turn. The flowrate at each terminal unit when this test device is connected shall be recorded.



Key

1 type 1 probe
2 flowmeter
3 fixed orifice
4 pressure measuring device (for calibration only)

Figure 3 — Typical test device for AGS disposal system characteristics (with type 1 terminal units)

8.2.2.2.5 The tests in 8.2.2.2.2, 8.2.2.2.3 and 8.2.2.2.4 shall be carried out at the same setting of the means of pressure and flow adjustment. The results shall be recorded on a form such as Form C.7.1 (see Annex C).

8.2.3 Test methods for flow in disposal systems fitted with type 1H terminal units

8.2.3.1 Test devices

In order to simulate the resistance to flow of a receiving system complying with ISO 8835-3, calibrated test devices which are fitted with type 1H probes and which produce a pressure drop of 1 kPa at a flowrate of 80 l/min (test device 1/80) and 2 kPa at a flowrate of 50 l/min (test device 2/50) shall be used.

NOTE A typical test device is shown in Figure 3.

8.2.3.2 Procedure

8.2.3.2.1 Activate the power device on the AGS disposal system to be tested.

8.2.3.2.2 A test device fitted with type 1H probe, which produces a pressure drop of 1 kPa at 80 l/min, shall be inserted into each type 1H terminal unit in turn with all the other terminal units closed. The flowrate on the test device at each terminal unit shall be recorded.

8.2.3.2.3 A test device fitted with type 1H probe, which produces a pressure drop of 2 kPa at 50 l/min, shall be inserted into each type 1H terminal unit in turn with all the other terminal units closed. The flowrate on the test device at each terminal unit shall be recorded.

8.2.3.2.4 Type 1H probes, which produce a pressure drop of 1 kPa at 80 l/min, shall be inserted into each of several type 1H terminal units up to the system design flow of the AGS disposal system with all the other terminal units closed. A test device with type 1H probe, which produces a pressure drop of 2 kPa at 50 l/min, shall be inserted into each terminal unit in turn. The flowrate at each terminal unit when this test device is connected shall be recorded.

8.2.3.2.5 The tests in 8.2.3.2.2, 8.2.3.2.3 and 8.2.3.2.4 shall be carried out at the same setting of the means of pressure and flow adjustment. The results shall be recorded on a form such as Form C.7.2 (see Annex C).

8.2.4 Test method for pressure in disposal systems fitted with type 2 terminal units

8.2.4.1 Test devices

Test devices fitted with a type 2 probe and providing flowrates up to 50 l/min shall be used.

8.2.4.2 Procedure

8.2.4.2.1 Activate the power device.

8.2.4.2.2 The probe of the test device shall be inserted into each terminal unit in turn with all the other terminal units closed. The flowrate shall be adjusted to (50 $\pm$ 5) l/min. The pressure shall be recorded at the inlet to the terminal unit.

8.2.4.2.3 If individual piping to each terminal unit is not provided, test devices shall be inserted into each of several terminal units up to the system design flow of the AGS disposal system with all the other terminal units closed. Each flowrate shall be adjusted to (50 $\pm$ 5) l/min. The pressure at the inlet to each terminal unit shall be recorded.

8.2.4.2.4 The results shall be recorded on a form such as Form C.7.3 (see Annex C).

8.3 Means to prevent backflow

For disposal systems with exhaust ejectors driven by compressed air, means shall be provided to prevent backflow of waste anaesthetic gases and vapours through terminal units.

NOTE This can be achieved by, for example, individual piping or non-return valves.

9 Terminal units

Terminal units shall comply with ISO 9170-2.

10 Marking and colour coding

10.1 Marking

10.1.1 Pipelines shall be marked “AGSS” or national equivalent and shall have arrows denoting the direction of flow adjacent to valves (if fitted) at junctions and changes of direction, before and after walls and partitions, etc., at intervals of no more than 10 m and adjacent to terminal units.

10.1.2 Connecting assemblies and disposal hoses shall be marked “AGSS” or national equivalent.

10.1.3 Marking shall be:

a) durable;

b) with letters not less than 6 mm high for the pipelines and not less than 2,5 mm high for connecting assemblies and disposal hoses.

10.2 Colour coding

10.2.1 If colour coding is used, it shall be red magenta or in accordance with the national standard.

NOTE An example of red magenta is 3050-R40B, in accordance with SS 01 91 02.

10.2.2 If colour coding is used, it shall be durable.

10.3 Test for durability

The test for durability of markings and colour coding is given in 12.4.10.

11 Pipeline installation

11.1 Pipelines and electrical services shall be either:

a) run in separate compartments; or

b) separated by more than 50 mm.

NOTE Regional or national regulations which apply to electrical installations in buildings can exist.

11.2 Metallic pipelines, if applicable, shall be bonded to an earth terminal as near as possible to the point at which the pipeline enters the building. Pipelines shall not be used for earthing the electrical equipment.

NOTE 1 Regional or national regulations which apply to electrical installations in buildings can exist.

NOTE 2 Regional or national regulations, which apply to continuity of earthing across all joints within the same building and to electrical isolation of different buildings from each other, can exist.

11.3 Pipelines shall be protected from physical damage, for example damage which might be sustained from the movement of portable equipment such as trolleys, stretchers and trucks, in corridors and in other locations.

11.4 Unprotected pipelines containing gas under positive pressure shall not be installed in areas of special hazard. If installation of pipelines in such a location is unavoidable, the pipeline shall be protected by an enclosure which will prevent the liberation of gases within the room should leaks occur in the pipeline installed in the area.

NOTE 1 An area where flammable materials are stored is an example of an area of special hazard.

NOTE 2 Regional or national regulations which apply to building requirements and fire prevention can exist.

11.5 If pipelines are placed underground they shall be placed in tunnels or ducts. The tunnel or duct shall be provided with adequate drainage to prevent the accumulation of water. If pipelines are placed in the same tunnel, trench or duct with fuel pipelines, steam lines or other services, they shall be separated by more than 50 mm. Ducts in which pipelines are installed shall be ventilated.

If pipelines for an AGS disposal system are placed in a tunnel or duct along with other services or with pipelines for other fluids or gases, the potential hazard arising from this situation shall be assessed using risk management procedures in accordance with ISO 14971. The risk assessment shall take into account that a leak which is not detected (e.g. by an alarm or other means such as periodic inspection recommended by the

manufacturer) shall be considered a normal condition and not a single fault condition. The route of pipes placed underground should be indicated at the site by appropriate means, e.g. by continuous marking tape above the pipeline at approximately one-half the depth of burial.

11.6 Pipelines shall not be installed in elevator shafts.

11.7 Damage due to contact with corrosive materials shall be minimised, e.g. by the use of impermeable non-metallic materials applied to the outer surface of the pipe in the area where the contact can occur.

11.8 Allowances shall be made for expansion and contraction of pipelines.

11.9 If condensation is likely to occur in the pipelines, means shall be provided to remove condensation from the system.

11.10 Pipelines shall be supported at intervals to prevent sagging or distortion. Recommended intervals for rigid metallic pipes are given in Table 1.

Table 1 — Recommended intervals between supports for rigid metallic pipes

Outside diameter mm	**Maximum intervals between supports**[a] m
up to 15	1,5
22 to 28	2,0
35 to 54	2,5
greater than 54	3,0
[a] Shorter intervals may be required when using rigid non-metallic pipes.	

11.11 The supports shall ensure that the pipeline cannot be displaced accidentally.

The supports shall either be of corrosion-resistant material, or shall be treated to prevent corrosion. Means shall be provided to prevent electrolytic corrosion.

Where pipelines cross electric cables, the pipes shall be supported adjacent to the cables.

Pipelines shall not be used as support for, nor shall they be supported by, other pipelines or conduits.

11.12 Except for mechanical joints used for certain components, all metallic pipeline joints shall be brazed or welded. The methods used for brazing or welding shall permit the joints to maintain their mechanical characteristics up to an ambient temperature of 600 °C. Filler metals for brazing shall be nominally cadmium-free (less than 0,025 % mass fraction cadmium).

NOTE Mechanical joints (e.g. flanged or threaded connections) can be used to connect components such as shut-off valves, terminal units, pressure regulators, controls and monitoring and alarm sensors to the pipeline.

11.13 The exhaust from the disposal system shall be piped to the outside or into the exhaust conduit of a non-recirculating ventilation system and shall be provided with a means to prevent the ingress of insects, debris and precipitation.

The location of the exhaust outlet shall be remote from the air intake for medical air compressor systems, air intakes, doors, windows or other openings in buildings.

Consideration should be given to the potential effects of prevailing winds when considering the location of the exhaust outlet.

If the exhaust outlet is accessible to personnel, a warning against the inhalation of noxious gas shall be affixed at the point of discharge.

12 Testing, commissioning and certification

12.1 General

Tests after completion of installation shall be carried out, documented and certified by the manufacturer.

NOTE Regional or national regulations requiring the manufacturer to have an approved quality system can exist.

An example of a procedure for testing and commissioning is given in Annex B.

12.2 General requirements for tests

12.2.1 Testing shall be carried out with ambient air.

12.2.2 Before any testing is carried out, every terminal unit in a system under test shall be labelled to indicate that the system is under test and shall not be used.

12.2.3 The resolution and accuracy of all measuring devices used for testing shall be appropriate for the values to be measured. All measuring devices used for certification shall be calibrated at appropriate intervals.

12.3 Tests, inspections and checks

The following tests, inspections and checks shall be carried out before use of the system:

a) inspection and tests for leakage;

b) inspection for marking and support intervals of the pipeline system;

c) check of mechanical function and cleanliness of the terminal units;

d) test for cross connection;

e) tests for function of power devices;

f) tests for pressure and flow at the terminal units;

g) check of the indicating system;

h) check of the AGS disposal system exhaust;

i) check of identification and labelling of the terminal units.

12.4 Requirements for tests, inspections and checks listed in 12.3

12.4.1 Inspection and leakage

12.4.1.1 Pipelines downstream of the power device shall be visually inspected for the integrity of all connections.

12.4.1.2 Pipelines between a type 1 terminal unit and a power device shall be tested at a pressure of 70 kPa $\pm$ 10 %. The pressure drop in these sections, after a test period of 15 min with the terminal units blanked off, shall be less than 10 kPa.

12.4.2 Marking and support intervals of the pipeline system

The marking of the pipeline system shall meet the requirements of 10.1. The colour coding of the pipeline system, if used, shall meet the requirements of 10.2. The support intervals shall meet the requirements of 11.10.

12.4.3 Mechanical function and cleanliness of the terminal units

It shall be demonstrated for each terminal unit that the appropriate probe can be inserted, captured and released. All terminal units shall be inspected for the absence of visible particulate matter.

12.4.4 Cross connection

There shall be no cross connection to any other pipeline system.

12.4.5 Function of power devices

All power devices shall operate in accordance with the manufacturer's manuals and specifications.

12.4.6 Pressure and flow at the terminal units

It shall be demonstrated that the flow at each AGSS type 1L terminal unit is in accordance with 8.1.1.

It shall be demonstrated that the flow at each AGSS type 1H terminal unit is in accordance with 8.1.2.

It shall be demonstrated that the pressure drop at each AGSS type 2 terminal unit is in accordance with 8.1.3.

12.4.7 Indicating system

The indicating system shall comply with Clause 6.

12.4.8 AGS disposal system exhaust

The exhaust from the disposal system shall comply with 11.13.

12.4.9 Identification and labelling of the terminal units

On satisfactory completion of the tests, inspections and checks described in 12.4.1 to 12.4.8, the construction labels indicating that the system is under test shall be removed. At the same time, the correct identification and labelling (marking and, if used, colour coding) of each terminal unit shall be checked.

12.4.10 Test for durability of markings and colour coding

Rub markings and colour coding by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with ethanol and then for 15 s with a cloth rag soaked with isopropanol. Carry out this test at ambient temperature. The markings shall remain legible.

12.5 Certification of the system

Before an AGS disposal system is used, it shall be certified in writing to the healthcare facility that all tests, inspections and checks given in 12.3 have been satisfactorily carried out and all the requirements of 12.4 have been met. The results of tests showing details of the areas tested should be part of the permanent record of the healthcare facility.

NOTE Typical forms for this purpose are given in Annex C.

The system manufacturer shall certify that all drawings and manuals, as required in Clause 13, have been supplied to the owner or client.

12.6 Extensions or modifications

When extensions or modifications are made to the system, the appropriate tests, inspections and checks in 12.3 shall be carried out before the system is returned to service.

13 Information to be supplied by the manufacturer

13.1 General

The information to be provided by the manufacturer shall be in accordance with EN 1041 or equivalent national standards.

13.2 Instructions for use

13.2.1 The manufacturer of the complete system or the manufacturer(s) of each component of the AGS disposal system (i.e. power device, terminal units and pipeline system) shall provide the healthcare facility with instructions for use.

NOTE 1 The power device, terminal units and pipeline system can be supplied by one or several different manufacturers.

NOTE 2 Regional or national regulations which apply to manufacturers of medical devices can exist.

13.2.2 The instructions for use shall contain the following:

— the name or trade name and address of the manufacturer;

— year of manufacture and, where appropriate, the lifetime of the system and its components, any special storage and/or handling conditions;

— any special operating instructions;

— any warnings and/or precautions to be taken, in particular the danger of fire or explosion due to the use of oil and grease in oxygen-enriched atmospheres or the use of flammable anaesthetic agents;

— batch or serial number;

— a technical specification including the performance of the system, and how to connect and disconnect detachable parts and accessories;

— a description of the indicating system;

— the position in normal condition (i.e. open or closed) of all shut-off valves, if fitted;

— instructions for recommended periodic checks of function of the system;

— instructions for recommended maintenance tasks and their frequency, and a list of recommended spare parts, if applicable;

— adequate information regarding which anaesthetic gases and vapours the system is designed to be used with;

— instructions for the disposal of components or consumables (e.g. oil used in compressors and vacuum pumps).

13.2.3 The instruction for use given in 13.2.2 shall take into account the possibility that several different organisations are involved in operation, use and maintenance.

13.3 Operational management information

13.3.1 The manufacturer(s) of each component of the AGS disposal system (i.e. power device, terminal units and pipeline system) shall provide operational management information to the healthcare facility to enable it to draft its Operational management document.

13.3.2 The system manufacturer(s) shall provide instructions to the healthcare facility for recommended maintenance tasks and their frequency, and a list of recommended spare parts.

NOTE Informative guidelines for the preparation of the Operational management document are given in Annex G of ISO 7396-1:2007. Informative guidelines for carrying out a risk management procedure are given in Annex D.

13.4 “As-installed” drawings

13.4.1 A separate set of “as-installed” mechanical drawings which show the actual locations of the pipelines, the diameters of the pipelines, shut-off valves and all other components shall be maintained during construction, and shall be brought up to date as changes are made. These drawings shall include details which will enable buried or concealed pipelines to be located.

13.4.2 A complete set of “as-installed” drawings of the pipeline system as specified in 13.4.1 shall be presented to the healthcare facility of the pipeline system, for inclusion as part of the permanent record of the pipeline system.

13.5 Electrical diagrams

Electrical diagrams for the components supplied shall be provided by the system manufacturer to the healthcare facility.

Annex A
(informative)

Guidelines for power devices consisting of fans, blowers or dedicated vacuum pumps

A.1 Services containing combustible gases or liquids should not be permitted within the power device area.

A.2 All electrical fittings in power device rooms should be located in fixed positions to minimize the risk of physical damage.

A.3 Fire fighting equipment should be provided within the power device area.

NOTE Regional or national regulations which apply to fire protection can exist.

A.4 The power device area should be well ventilated to the open air. Ducting for such ventilation should not be connected to ducting servicing any other building.

A.5 The doors or gate should be capable of being locked. An emergency exit should be provided which should be free from obstructions at all times. It should be possible to open any door from the inside without a key at all times. All doors should open outwards.

A.6 Power device rooms should:

a) comply with local building codes;

b) have a warning notice “NO SMOKING”, or similar, clearly displayed on both sides of each door or gate.

A.7 Clauses A.1 to A.6 apply to power devices which are centrally located. Power devices that are not centrally located and may or may not be connected to a pipeline system should be installed and serviced in accordance with the instructions supplied by the manufacturer.

Annex B
(informative)

Example of procedure for testing and commissioning

B.1 General

This test procedure is given as an example of how the specifications of Clause 12 can be verified so that the system may be commissioned and certified. Other procedures may be devised which validly test these specifications. In this procedure the given sequence of tests is important and should be followed. The general requirements of 12.3 should be followed.

When the results of a test do not meet the pass criteria, remedial work shall be carried out and previous tests repeated as necessary.

Typical forms for certification of the system are given in Annex C. A summary of typical tests required which lists the specification, procedure and form for each test is given in Form C.1.

B.2 Inspection and tests for leakage

B.2.1 Inspection

Visually inspect the exhaust pipeline system for the integrity of all connections.

B.2.2 Tests for leakage

B.2.2.1 General conditions

Isolate the power device from the pipeline. Open all shut-off valves (if fitted) and blank off all type 1 terminal units. If necessary, remove all means of adjusting the flow and blank their connection points.

B.2.2.2 Example of procedure

Connect a suitable pressure-measuring device to the system under test. Fill the system with clean, oil-free, dry compressed gas at a pressure of 70 kPa ± 10 %. Record the pressure and, after a period of 15 min, record the pressure again. The pressure drop shall not exceed 10 kPa.

NOTE There is no allowance for temperature variation in this test.

B.2.2.3 Test results

Record the results on a form such as Form C.2.

B.3 Inspection for marking and support intervals of the pipeline system

B.3.1 Example of procedure

Visually inspect that marking has been correctly placed on the pipeline system, especially adjacent to T-connections and where the pipeline system passes through walls or partitions. Check that marking complies with 10.1 and colour coding, if used, complies with 10.2. Check that the support intervals comply with 11.10.

B.3.2 Test results

Record the results on a form such as Form C.3.

B.4 Check of mechanical function and inspection for cleanliness of the terminal units

B.4.1 Example of procedure

B.4.1.1 Inspect the test probes to ensure that they conform to ISO 9170-2. Insert a test probe into each terminal unit in turn. Check that the probe can be inserted, captured and released.

B.4.1.2 Check each terminal unit for the absence of visible particulate matter.

B.4.2 Test results

Record the results on a form such as Form C.4.

B.5 Test for cross connection

B.5.1 Example of procedure

Test the pipeline system of the AGS disposal system for cross connection to any other medical gas or vacuum pipeline system. With all power devices switched off and with pressure in all other medical gas or vacuum pipeline systems, check at all AGSS terminal units that there is no positive or negative pressure.

B.5.2 Test results

Record the results on a form such as Form C.5.

B.6 Tests for function of power devices

B.6.1 Example of procedure

Test all power devices for operation in accordance with the manufacturer's manuals and specifications.

B.6.2 Test results

Record the results on a form such as Form C.6.

B.7 Test for pressure and flow at the terminal units

B.7.1 Example of procedures

Procedures for testing for flow at the type 1L terminal units are given in 8.2.2.

Procedures for testing for flow at the type 1H terminal units are given in 8.2.3.

Procedures for testing for pressure at the type 2 terminal units are given in 8.2.4.

B.7.2 Test results

Record the results on forms such as Forms C.7.1, C.7.2 and C.7.3.

B.8 Check of the indicating system

B.8.1 Example of procedure

Check functioning of the means provided to indicate to the operator that the power device is operating.

B.8.2 Test results

Record the results on a form such as Form C.8.

B.9 Check of the AGS disposal system exhaust

B.9.1 Example of procedure

Verify that the exhaust from the AGS disposal system:

— is piped either to the outside or into the exhaust conduit of a non-recirculating ventilation system;

— is provided with a means to prevent the ingress of insects;

— that the exhaust is in a position where the risk of contamination of occupied buildings is minimized; and

— that the exhaust warning label (if fitted) is legible

B.9.2 Test results

Record the results on a form such as Form C.9.

B.10 Check of identification and labelling of the terminal units

B.10.1 Example of procedure

Check that the tests in B.2 to B.9 have been completed satisfactorily.

Remove the construction label on each terminal unit which indicates that the system is not to be used. Do not remove these labels unless all preceding tests have been completed satisfactorily. At the same time, check for the correct identification and labelling (marking and, if used, colour coding) of each terminal unit.

B.10.2 Test results

Record the results on a form such as Form C.10.

Annex C
(informative)

Typical forms for certification of AGS disposal systems

The forms given in this annex are to be completed during testing and commissioning of AGS disposal systems in accordance with Annex B.

Form C.1 — Summary of tests

Healthcare facility_____ Area identification _____

This is to certify that the following tests and procedures have been carried out satisfactorily on the anaesthetic gas scavenging disposal system at _____ healthcare facility.

(Sheet ..... of ..... sheets)

Form	Description of tests and procedures	Test required Yes/No	Procedure	Specification	Date of completion of tests and procedures
C.1	Summary of tests				
C.2	Leakage		B.2	12.4.1	
C.3	Marking and support intervals of the pipeline system		B.3	12.4.2	
C.4	Mechanical function and cleanliness of the terminal units		B.4	12.4.3	
C.5	Cross connection		B.5	12.4.4	
C.6	Function of power devices		B.6	12.4.5	
C.7	Pressure and flow at the terminal units		B.7	12.4.6	
C.7.1	— for type 1L terminal units		8.2.2		
C.7.2	— for type 1H terminal units		8.2.3		
C.7.3	— for type 2 terminal units		8.2.4		
C.8	Indicating system		B.8	12.4.7	
C.9	AGS disposal system exhaust		B.9	12.4.8	
C.10	Identification and labelling of the terminal units		B.10	12.4.9	

Manufacturer's Representative

Position_____ Signature _____

Date _____ Name _____

Authorized Person

Position_____ Signature _____

Date _____ Name _____

Form C.2 — Inspections and tests for leakage

Healthcare facility_____ Area identification _____

(Sheet ..... of ..... sheets)

This is to certify that the pipeline system was inspected and tested for leakage. At a test pressure of 70 kPa the pressure drop after 15 min was ..... kPa (maximum permitted is 10 kPa).

Measuring instrument(s) used _____

Manufacturer's Representative

Position _____ Signature _____

Date _____ Name _____

Authorized Person

Position _____ Signature _____

Date _____ Name _____

Form C.3 — Inspection for marking and support intervals of the pipeline system

Healthcare facility_____ Area identification _____

(Sheet ..... of ..... sheets)

This is to certify that the pipeline system was inspected for marking and support intervals. The marking and, if used, colour coding have been tested for durability.

Manufacturer's Representative

Position _____ Signature _____

Date _____ Name _____

Authorized Person

Position _____ Signature _____

Date _____ Name _____

Form C.4 — Check of mechanical function and cleanliness of the terminal units

Healthcare facility_____ Area identification _____

(Sheet ..... of ..... sheets)

This is certify that all terminal units were checked for mechanical function and inspected for cleanliness.

Manufacturer's Representative

Position _____ Signature _____

Date _____ Name _____

Authorized Person

Position _____ Signature _____

Date _____ Name _____

Form C.5 — Test for cross connection

Healthcare facility_____ Area identification _____

(Sheet ..... of ..... sheets)

This is to certify that the pipeline system was tested for cross connection to any other pipeline system.

Measuring instrument(s) used _____

Manufacturer's Representative

Position _____ Signature _____

Date _____ Name _____

Authorized Person

Position _____ Signature _____

Date _____ Name _____

Form C.6 — Tests for function of power devices

Healthcare facility_____ Area identification _____

(Sheet ..... of ..... sheets)

This is to certify that all power devices have been tested in accordance with the manufacturer's manuals and specifications.

Measuring instrument(s) used _____

Manufacturer's Representative

Position _____ Signature _____

Date _____ Name _____

Authorized Person

Position _____ Signature _____

Date _____ Name _____

Form C.7.1 — Tests for flow for AGSS type 1L terminal units

Healthcare facility_____ Area identification _____

(Sheet ..... of ..... sheets)

This is to certify that the AGSS type 1L terminal units were tested in accordance with 8.2.2 with test device 1/50, (pressure drop 1 kPa, maximum flowrate 50 l/min) and with test device 2/25 (pressure drop 2 kPa, minimum flowrate 25 l/min).

One terminal unit in use				... terminal units in use [a]			
Terminal unit number	Room number	Flowrate measured		Terminal unit number	Room number	Flowrate measured	
		Test device 1/50	Test device 2/25			Test device 1/50	Test device 2/25

[a] Number to correspond to system design flow of the AGS system.

Measuring instrument(s) used _____

Manufacturer's Representative

Position _____ Signature _____

Date _____ Name _____

Authorized Person

Position _____ Signature _____

Date _____ Name _____

Form C.7.2 — Tests for flow for AGSS type 1H terminal units

Healthcare facility_____ Area identification _____

(Sheet ..... of ..... sheets)

This is to certify that the AGSS type 1H terminal units were tested in accordance with 8.2.3 with test device 1/80, (pressure drop 1 kPa, maximum flowrate 80 l/min) and with test device 2/50 (pressure drop 2 kPa, minimum flowrate 50 l/min).

One terminal unit in use				... terminal units in use [a]			
Terminal unit number	Room number	Flowrate measured		Terminal unit number	Room number	Flowrate measured	
		Test device 1/80	Test device 2/50			Test device 1/80	Test device 2/50

[a] Number to correspond to system design flow of the AGS system.

Measuring instrument(s) used _____

Manufacturer's Representative

Position _____ Signature _____

Date _____ Name _____

Authorized Person

Position _____ Signature _____

Date _____ Name _____

Form C.7.3 — Tests for pressure for AGSS type 2 terminal units

Healthcare facility_____ Area identification _____

(Sheet ..... of ..... sheets)

This is to certify that the type 2 terminal units were tested in accordance with 8.2.4 (test flowrate 50 l/min, maximum pressure drop 7,5 kPa).

One terminal unit in use			... terminal units in use [a]		
Terminal unit number	**Room number**	**Pressure measured**	**Terminal unit number**	**Room number**	**Pressure measured**

[a] Number to correspond to system design flow of the AGS system.

Measuring instrument(s) used _____

Manufacturer's Representative

Position _____ Signature _____

Date _____ Name _____

Authorized Person

Position _____ Signature _____

Date _____ Name _____

Form C.8 — Check of the indicating system

Healthcare facility_____ Area identification _____

(Sheet ..... of ..... sheets)

This is to certify that the indicating system has been checked for proper operation.

Manufacturer's Representative

Position _____ Signature _____

Date _____ Name _____

Authorized Person

Position _____ Signature _____

Date _____ Name _____

Form C.9 — Check of the AGS disposal system exhaust

Healthcare facility_____ Area identification _____

(Sheet ..... of ..... sheets)

This is to certify that the AGS disposal system exhaust has been checked.

Manufacturer's Representative

Position _____ Signature _____

Date _____ Name _____

Authorized Person

Position _____ Signature _____

Date _____ Name _____

Form C.10 — Check of identification and labelling of the terminal units

Healthcare facility_____ Area identification _____

(Sheet ..... of ..... sheets)

This is to certify that all terminal units have been checked for identification and labelling (marking and, if used, colour coding), and labels indicating that the system is not to be used have been removed.

Manufacturer's Representative

Position _____ Signature _____

Date _____ Name _____

Authorized Person

Position _____ Signature _____

Date _____ Name _____

Annex D
(informative)

Risk management checklist

D.1 General

Risk management should be carried out in accordance with ISO 14971.

This annex gives the recommended risk management procedure and checklist used to identify the root causes and the hazardous situations (i.e. causes of harm) related to defined safety objectives and appropriate risk control measures for the AGS disposal system.

The risk management procedure and the risk control checklist should be used by both the manufacturer (M) of the AGS disposal system and the healthcare facility (H) representative(s) during:

— design, installation, commissioning and operation of new AGS disposal systems;

— ongoing operation and monitoring of existing AGS disposal systems.

D.2 Risk management procedure

When managing the risks associated with the AGSS, it is first necessary to complete a risk assessment of the overall system.

Having assessed the risks (i.e. the combination of severity and probability of occurrence of the harm), the design should endeavour to mitigate the risks by using procedures in the order of priority:

a) inherently safe design;

b) protective measures in the medical device itself or in the manufacturing process;

c) information for safety.

D.3 Risk management checklist

Tables D.1 and D.2 give a list of typical safety objectives, root causes, hazardous situations and appropriate risk control measures to mitigate the risk to acceptable levels, and identify the organizations responsible for action.

Table D.1 — Risk management checklist — Systems with blowers, fans or vacuum pumps

Safety objective	Root cause	Hazardous situation	Risk control measures	Responsible organizations
1) Continuity of operation	a) Blockage/partial blockage of the pipeline	Loss or reduction of flow	Flow tests at every terminal unit before use	M
	b) Loss of flow and/or pressure from the power device in operation	System supplied from the secondary power device Loss of flow at all terminal units if all systems fail	Ensure that a secondary power device is included in the layout design of the disposal system	H+M
			Preventive maintenance system for each power device set up	H
			Operational procedures to ensure continuity of flow for emergency situations established	H
			Routine testing of the secondary power device to ensure its proper functioning when the primary power device fails	H
			Routine testing of the indicating means	H
			Operational management document to address failure of flow	H
	c) Poor power device location/housing	Mechanical damage to the power device leading to loss of flow Power device affected by incident involving an adjacent building	Ensure that plant rooms have adequate temperature control and ventilation	H+M
			Adequate physical protection from mechanical damage	H+M
			Routine review of power device location to ensure system remains safe	H
	d) Failure of indicating means	Abnormal condition of the power device not detected	UPS (uninterrupted power supply) to ensure continuity of electrical supply to indicating system	H+M
			Routine testing of the indicating system	H
	e) Electricity supply failure	Failure of operation of electrical components potentially leading to loss of flow	UPS or emergency electrical supply to ensure continuity of electrical system	H
			Check capacity of the emergency electrical supply	H
			Routine testing of the emergency electrical supply	H
			Operational management document addresses issues of electrical supply failure	H
			Procedure to ensure that all components are restored to an operating condition following restoration of normal power supply	H

Table D.1 *(continued)*

Safety objective	Root cause	Hazardous situation	Risk control measures	Responsible organizations
	f) Component failure	Potential loss of flow with failure of critical components	Review and identification of critical components	M
			Specific preventive maintenance for critical components	H+M
			Specification for the critical components from approved suppliers	M
			Indicating means routinely checked to ensure that the power device is operating in accordance with the manufacturer's specifications	H
			Adequate spares/redundancy for critical components	H
			Operational management document addresses issues of critical component failure	H
		Ignition of components	Ensure that AGS disposal system is used only with anaesthetic gases and vapours as specified by the manufacturer	H
	g) Failure of the maintenance system	Potential failure of components and subsequent failure of power device	Operational management document addresses issues of critical component failure	H
2) System performance	a) Incorrect design/specification of components and pipeline systems	Inadequate flow	Design validation in accordance with Clause 12	M
			Commissioning checks following installation	H+M
			Provide usage information	H
			Operational management document addresses periodic checks of usage	H
		Ignition of components	Selection of components to ensure they are compatible with anaesthetic gases and vapours as specified by the manufacturer	M
			Operational management document to ensure that all replacement parts used are compatible with anaesthetic gases and vapours	H+M
	b) Inadequate corrosion protection of pipelines/components	Failure of pipelines/components. Leakages. Collapse of supports	Correct design/protection of pipelines/components	M
			Operational management document addresses periodic inspection and maintenance of pipelines	

Table D.1 *(continued)*

Safety objective	Root cause	Hazardous situation	Risk control measures	Responsible organizations
	c) Backflow of gases	Incorrect flow to the receiving system	Correct design of the AGS disposal system to prevent backflow of anaesthetic gases and vapours into type 2 terminal units	M
			Commissioning checks to demonstrate performance of any means to prevent backflow	H+M
	d) Cross connections between medical gas or vacuum pipeline systems and AGS disposal system	Positive pressure in AGS disposal system pipelines	Correct design of AGS disposal system to prevent cross connections	M
			Commissioning of AGS disposal system to demonstrate no cross connections	H+M
			Operational management document addresses avoidance of cross connections when system is modified/extended	H
3) System operation	a) Incorrect operation or maintenance of the AGS disposal system	Loss or reduction of flow Failure of components	Define responsibilities for all associated staff/users of the AGS disposal system	H
			Training for all associated staff/users of the AGS disposal system	H+M
			Operational management document to specify the need to assess competency of all associated staff/users of the AGS disposal system and specify the retraining requirements. Recording of training	H

Table D.2 — Risk management checklist — Systems with exhaust ejector(s) driven by compressed air

Safety objective	Root cause	Hazardous situation	Risk control measures	Responsible organizations
1) Continuity of operation	a) Blockage/partial blockage of the pipeline	Loss or reduction of flow	Flow tests at every terminal unit before use	M
	b) Failure of the power device	Loss or reduction of flow	Preventive maintenance program set up for each power device	H
			Operational procedures established for emergency situations to ensure continuity of scavenging	H
			Routine testing of each terminal unit to ensure it is operating in accordance with the manufacturer's specifications	H
			Operational management document to address failure of power device	H
	c) Loss of the AGS disposal system compressed air or variation of its pressure rate/flowrate	Loss or reduction of flow	Provide alarm systems for compressed air	M+H
			Routine testing of the alarm systems for compressed air	H
			Routine testing of the indicating means	H
			Check capacity of the AGS disposal system compressed air supply system	M+H
			Routine testing of each terminal unit to ensure it is operating in accordance with the manufacturer's specifications	H
			Operational management document addresses issues of AGS disposal system compressed air supply system failure	H
	d) Loss of the AGS disposal system compressed air or variation of its pressure rate/flowrate	Loss or reduction of flow	Procedure to ensure that all components are restored to an operating condition following reestablishment of the compressed air supply	H
			Operational procedures established for emergency situations to ensure continuity of flow to the patient	H
	e) Poor power device location/housing	Mechanical damage to the power device leading to loss of flow	Adequate physical protection from mechanical damage	H+M

Table D.2 *(continued)*

Safety objective	Root cause	Hazardous situation	Risk control measures	Responsible organizations
	f) Failure of indicating means	Abnormal condition of the power device not detected	Routine testing of the indicating system	H
	g) Failure of AGS disposal system compressed air alarm system	Loss or reduction of the AGS disposal system compressed air pressure not detected	Routine testing of the alarm systems for compressed air	H
	h) Component failure	Potential loss or variation of flow with failure of critical components	Review and identification of critical components	M
			Specific preventive maintenance for critical components	H+M
			Specification for the critical components from approved suppliers	M
			Routine testing of each terminal unit to ensure it is operating in accordance with the manufacturer's specifications	H
			Adequate spares/redundancy for critical components	H
			Operational management document addresses issues of critical component failure	H
	i) Component failure	Ignition of components	Selection of dedicated vacuum pumps (if fitted) which are compatible with oxygen and anaesthetic gases and vapours	M
			Ensure that AGS disposal system is used only with anaesthetic gases and vapours as specified by the manufacturer	H
	j) Failure of the maintenance system	Potential failure of components and subsequent failure of power device	Operational management document addresses issues of critical component failure	H

Table D.2 *(continued)*

Safety objective	Root cause	Hazardous situation	Risk control measures	Responsible organizations
2) System performance	a) Incorrect design/specification of components and pipeline systems	Inadequate flow	Design validation in accordance with Clause 12	M
			Commissioning checks following installation	H+M
			Provide usage information	M+H
			Operational management document addresses periodic inspection and maintenance of pipelines	H
		Ignition of components	Selection of components to ensure they are compatible with anaesthetic gases and vapours as specified by the manufacturer	M
			Operational management document to ensure that all replacement parts used are compatible with anaesthetic gases and vapours	H+M
	b) Inadequate corrosion protection of pipelines/components	Failure of pipelines/components. Leakages. Collapse of supports	Correct design/protection of pipelines/components	M
			Operational management document addresses periodic inspection or maintenance of pipelines	H
	c) Backflow of gases	Incorrect supply to the patient	Correct design of the AGS disposal system to prevent back feeding of waste gases into type 1 and type 2 terminal units	M
			Commissioning checks to demonstrate performance of any means to prevent backflow	H+M

Table D.2 *(continued)*

Safety objective	Root cause	Hazardous situation	Risk control measures	Responsible organizations
	d) Cross connections between medical gas or vacuum pipeline systems and AGS disposal system	Positive pressure in AGS disposal system pipelines Incorrect flow	Correct design of AGS disposal system to prevent cross connections	M
			Commissioning of AGS disposal system to demonstrate no cross connections	H+M
			Operational management document addresses avoidance of cross connections when system is modified/extended	H
	e) Power device contamination from visible particulate matter	Loss or reduction of flow	Design validation in accordance with Clause 12 Commissioning of AGS disposal system to demonstrate absence of particulate matter	M
	f) Incorrect pressure of AGS disposal system compressed air	Loss or variation of flow	Correct design specification to ensure compressed air pressure	M
			Commissioning of AGS disposal system to demonstrate the means of pressure control/regulation are operating in accordance with the manufacturer's specifications	M+H
			Operational management document addresses periodic inspection and maintenance of the means of pressure control/regulation	H
3) System operation	a) Incorrect operation or maintenance of the AGSS	Loss or reduction of flow Failure of components	Define responsibilities for all associated staff/users of the AGS disposal system	H
			Training for all associated staff/users of the AGS disposal system	H+M
			Operational management document to specify the need to assess competency of all associated staff/users of the AGS disposal system and to specify the retraining requirements. Recording of training	H
	b) Incompatibility of the AGS system with other medical devices	Impossibility of use or incorrect use	Define characteristics of the device intended to be connected to AGS disposal system before its purchase	H
			Check compatibility before use	H
	c) Incorrect operation or maintenance of the AGS disposal system	Loss or reduction of flow Failure of components	Define responsibilities for all associated staff/users of the AGS disposal system	H
			Training for all associated staff/users of the AGS disposal system	H+M
			Operational management document to specify the need to assess competency of all associated staff/users of the AGS disposal system and specify the retraining requirements. Recording of training	H

Annex E
(informative)

Rationale

The clauses in this Annex have been so numbered as to correspond to the clauses in this part of ISO 7396 to which they refer.

E.5.2 c) Vacuum pumps generate high temperatures in the compression process which can lead, in combination with anaesthetic gases and vapours, to fires within the vacuum pumps.

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