INTERNATIONAL STANDARD

**ISO 7396-2**

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# Medical gas pipeline systems —

## Part 2: Anaesthetic gas scavenging disposal systems

*Réseaux de distribution de gaz médicaux —*
*Partie 2: Systèmes d'évacuation de gaz d'anesthésie non réutilisables*



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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 3.

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 part of ISO 7396 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 7396-2 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*.

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



— *Part 1: Pipelines for compressed medical gases and vacuum*

— *Part 2: Anaesthetic gas scavenging disposal systems.*



Annexes A to E of this part of ISO 7396 are for information only.

NOTE Throughout this part of ISO 7396, a clause for which a rationale is provided in annex B is indicated by a boldface capital **R.**

## Introduction

This part of ISO 7396 specifies requirements for anaesthetic gas scavenging (AGS) disposal systems.

The anaesthetic gas scavenging system (AGSS) 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.

# Medical gas pipeline systems —

# Part 2: Anaesthetic gas scavenging disposal systems

## 1 Scope

This part of ISO 7396 specifies requirements for the installation, function, performance, documentation, testing and commissioning of anaesthetic gas scavenging disposal systems to ensure patient and operator safety. It includes requirements for the power device, pipeline system, performance and for non-interchangeability between key components.

This part of ISO 7396 specifies:

a) the compatibility between and safe performance of the disposal system and the other components of the AGSS by design, installation and commissioning;

b) the use of appropriate materials;

c) the testing for correct installation of the completed system to ensure achievement of the performance intended by the manufacturer;

d) the marking of pipeline and components.



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

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

## 2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 7936. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 7936 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

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

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

ISO 8835-3:1997, *Inhalational anaesthesia systems — Part 3: Anaesthetic gas scavenging systems — Transfer and receiving systems.*

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

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

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

## 3 Terms and definitions

For the purposes of this part of ISO 7936, the following terms and definitions apply.

**3.1**
**AGSS socket**
that 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 AGS system at which the operator makes connections and disconnections

**3.3**
**AGSS terminal unit base block**
that 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 disposal system at which an operator makes connections and disconnections



**3.5**
**AGSS type 1L terminal unit**
terminal unit to be used in low-flow disposal systems



**3.6**
**AGSS type 1H terminal unit**
terminal unit to be used in high-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

**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**
that 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 air for breathing and/or air for driving surgical tools

**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 to an appropriate place 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 may be either separate or sequentially combined in part or in total. In addition, one or more parts of an AGSS may be combined with a breathing system or other equipment .

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

**3.13**
**design capacity**
total flow of an AGS disposal system taking into account the diversity factor, i.e. the number of AGSS terminal units which may be in use at the same time

**3.14**
**disposal hose**
that part of an AGSS which transfers expired and/or excess gases from the power device to the probe of an AGSS type 2 terminal unit

**3.15**
**disposal system**
means by which the expired and/or excess anaesthetic gases are conveyed from the receiving system to an appropriate place of discharge

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



**3.16**
**high-flow disposal system**
disposal system that generates extract flows not lower than 75 l/min from transfer and receiving systems complying with ISO 8835-3



**3.17**
**low-flow disposal system**
disposal system that generates extract flows not more than 50 l/min from transfer and receiving systems complying with ISO 8835-3

**3.18**
**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

**3.19**
**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.

**3.20**
**maximum test pressure**
maximum pressure to which a terminal unit is designed to be subjected during pipeline pressure testing

**3.21**
**non-return valve**
valve which permits flow in one direction only

**3.22**
**placing on the market**
making available for the first time, in return for payment or free of charge, a device other than a device intended for clinical investigation, with a view to distribution and/or use

**3.23**
**power device**
that part of a disposal system of an AGSS which provides the gas flow for scavenging

**3.24**
**probe**
non-interchangeable male component designed for acceptance by, and retention in, a socket

**3.25**
**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

**3.26**
**receiving hose**
that part of an AGSS which transfers expired and/or excess gases from the receiving system to the disposal system

**3.27**
**receiving system**
that part of an AGSS which provides an interface between the transfer system and the disposal system

**3.28**
**shut-off valve, isolating valve**
manual or automatic valve which prevents flow in both directions when closed



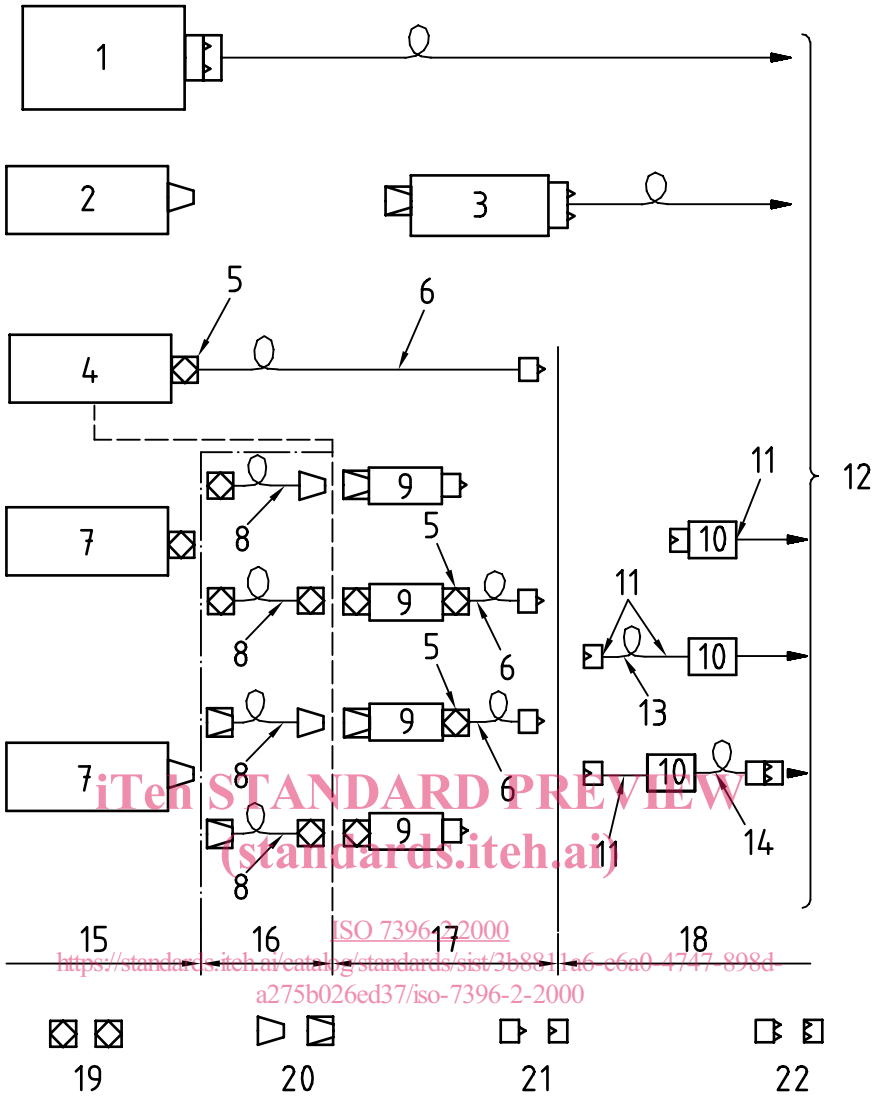
**3.29**
**single fault condition**
condition in which a single means for protection against a safety hazard in equipment is defective or a single external abnormal condition is present



**3.30**
**terminal unit check valve**
valve which remains closed until opened by insertion of an appropriate probe and which then permits flow in either direction

**3.31**
**transfer system**
that part of an AGSS which transfers expired and/or excess anaesthetic gases from the exhaust port of the breathing system to the receiving system

**3.32**
**transfer tube**
that part of an AGSS which transfers expired and/or excess gases from the breathing system to the receiving system






**Key**

1 Apparatus including breathing system and integral transfer/receiving system and power device
2 Apparatus including breathing system
3 Transfer/receiving system and power device
4 Apparatus including 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 Discharge
13 Flexible hose or pendant
14 Disposal hose
15 Limit of breathing system
16 Limit of transfer system
17 Limit 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 may not coincide with an actual physical limit such as a wall.

**Figure 1 — Schematic diagram of typical AGSS connections**

# 4 General requirements

## 4.1 Safety

AGS disposal systems shall, when installed, commissioned, operated in normal use and maintained according to the instructions of the manufacturer, cause no safety hazard which could be foreseen using risk analysis procedures in accordance with ISO 14971 and which is connected with their intended application, in normal condition and in single fault condition.

## 4.2 R Alternative construction

AGS disposal system installations and components or parts thereof, using materials or having forms of construction different from those detailed in this part of ISO 7396, shall be accepted if it can be demonstrated that an equivalent degree of safety is obtained.

Such evidence shall be provided by the manufacturer.

## 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.

Evidence shall be provided by the manufacturer.

**4.3.2 R** If copper pipes are used, they shall comply with the requirements for copper tubing for pipelines given in ISO 7396-1.



NOTE 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.



Evidence shall be provided by the manufacturer.

**4.3.3 R** All components of the system which come in contact with anaesthetic gases and vapours shall be cleaned in accordance with ISO 15001.

**4.3.4 R** If lubricants are used, they shall be compatible with anaesthetic gases and vapours at the operating conditions.

Evidence shall be provided by the manufacturer.

**4.3.5** All precautions shall be taken to maintain cleanliness during transportation, storage and installation.

# 5 Power device

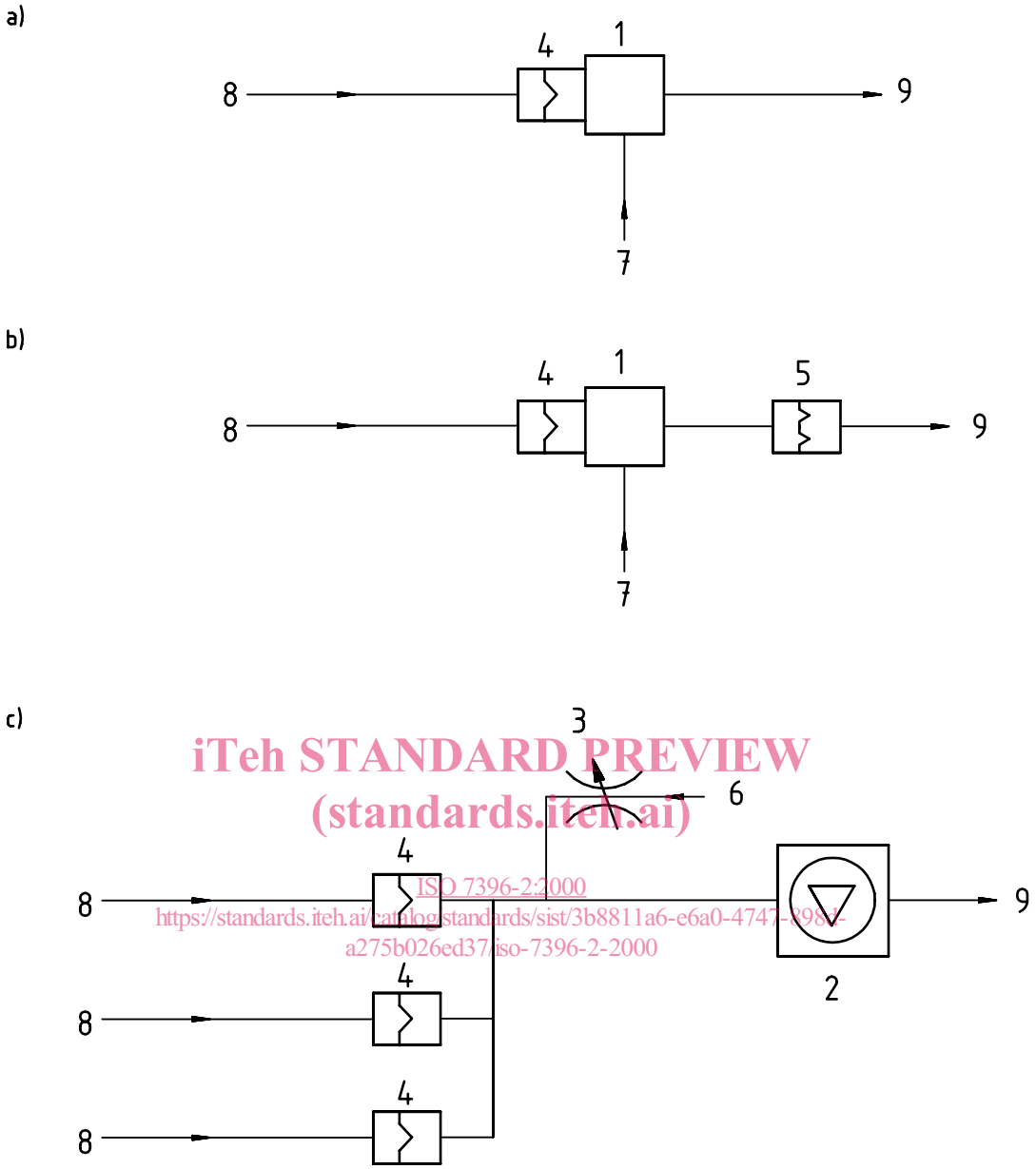
**5.1** The power device shall be used solely to power the AGS disposal system.

**5.2** The power device shall be one of the following:

a) an exhaust ejector, for each type 1 terminal unit, driven by compressed air from an air compressor system and a pipeline 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 a) or b); see Figure 2a);

b) an exhaust ejector for each type 2 terminal unit, driven by compressed air from an air compressor system and a pipeline 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 c); see Figure 2b);

c) one or more fans, blowers or dedicated vacuum pumps, provided with means of adjusting and controlling the vacuum level in the pipeline system and therefore the flow through each type 1 terminal unit within the limits specified in 8.1 a) or b), regardless of the number of terminal units in use; see Figure 2 c).






**Key**

| | | | |
|---|---|---|---|
| 1 | Compressed-air-driven power device | 6 | Ambient air |
| 2 | Vacuum pump/fan/blower power device | 7 | Compressed medical air |
| 3 | Flow regulating valve | 8 | Receiving system |
| 4 | Type 1 terminal unit | 9 | Discharge |
| 5 | Type 2 terminal unit | | |

**Figure 2 — Typical examples of power devices**