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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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 7396-2:2007(E)

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