INTERNATIONAL STANDARD

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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

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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

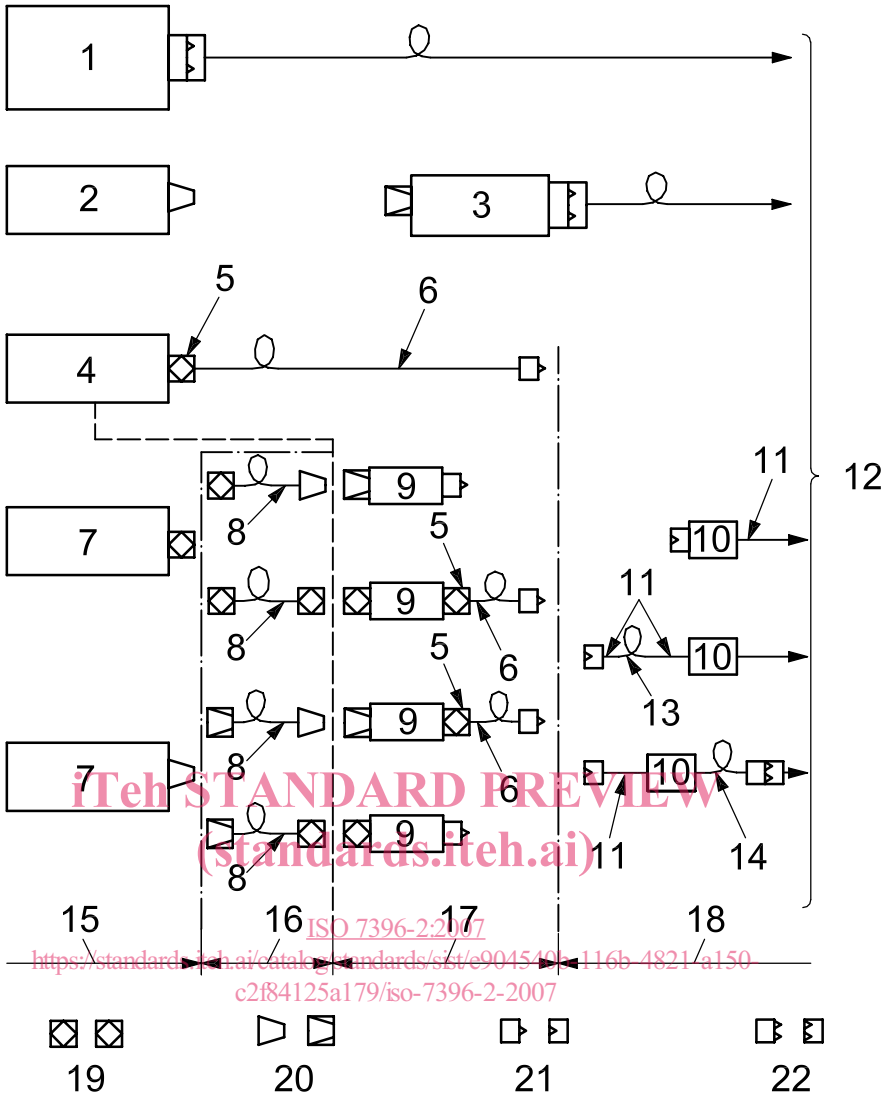
3.27
receiving hose
part of an AGSS which transfers expired and/or excess anaesthetic gases and vapours from the receiving system to the disposal system

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

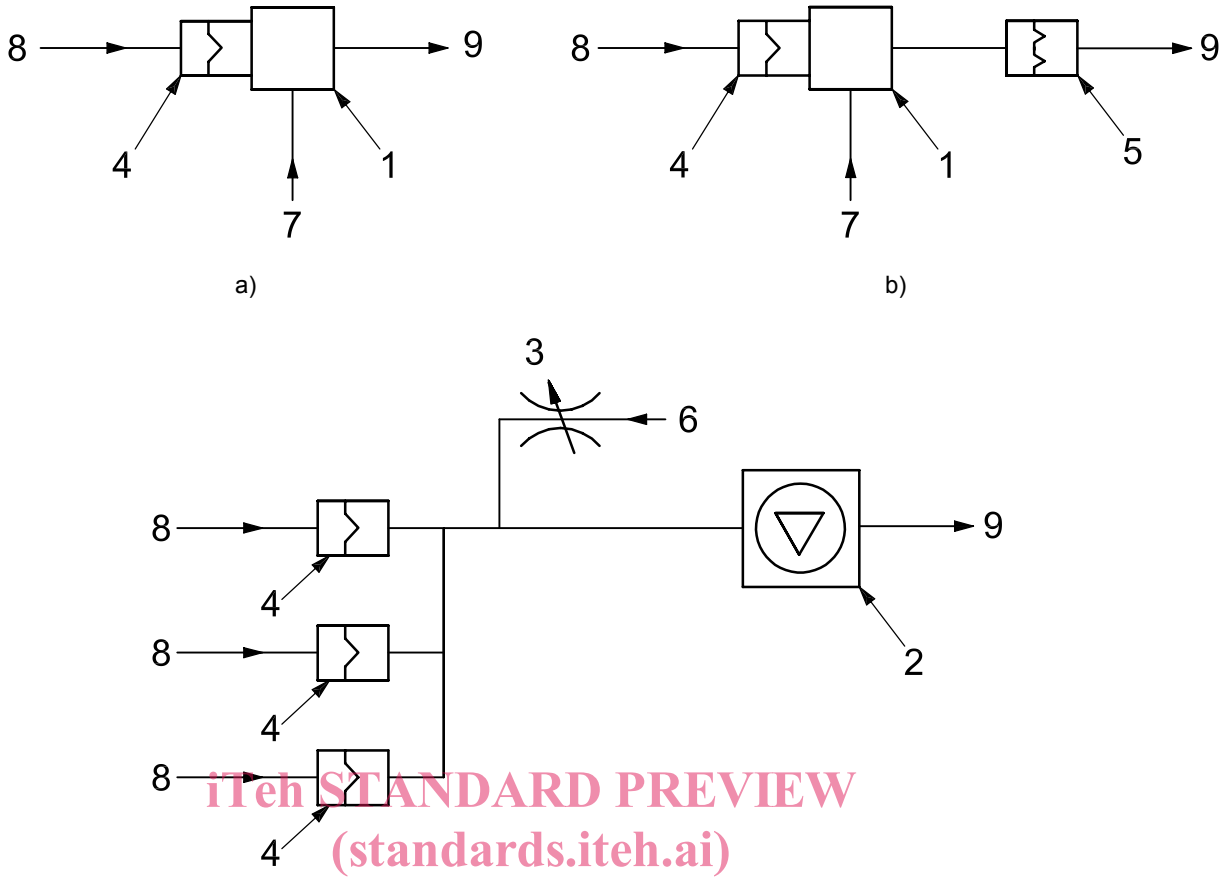
Means shall be provided to indicate to the operator that the AGS disposal system is operating.

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).