INTERNATIONAL STANDARD

**ISO 9170-2**

Second edition
2008-07-01

# Terminal units for medical gas pipeline systems —

## Part 2: Terminal units for anaesthetic gas scavenging systems

*Prises murales pour systèmes de distribution de gaz médicaux —*

*Partie 2: Prises murales pour systèmes d'évacuation des gaz d'anesthésie*

Reference number
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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 9170-2 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*.

This second edition cancels and replaces the first edition (ISO 9170-2:1999) which has been technically revised.

ISO 9170 consists of the following parts, under the general title *Terminal units for medical gas pipeline systems*:

— *Part 1: Terminal units for use with compressed medical gases and vacuum*

— *Part 2: Terminal units for anaesthetic gas scavenging systems*

# Introduction

Anaesthetic gas scavenging system (AGSS) terminal units are the points in an anaesthetic gas scavenging system where the operator makes connections and disconnections for the disposal of medical gases and anaesthetic vapours from anaesthetic machines or other items of medical equipment, and where a wrong connection may create a hazard to the patient. It is important that terminal units and their components be designed, manufactured, installed and maintained in such a way as to meet the basic requirements specified in this part of ISO 9170.

This part of ISO 9170 pays particular attention to:

— suitability of materials;

— type specificity;

— dimensions of probes and type-specific connection points;

— cleanliness;

— testing;

— identification;

— information supplied.

This part of ISO 9170 specifies the provision of information for the installation and subsequent testing of terminal units. Testing of terminal units prior to use is critical to patient safety and it is essential that terminal units are not used until full testing in accordance with ISO 7396-2 has been completed.

Annex A contains rationale statements for some of the requirements of this part of ISO 9170. The clauses and subclauses marked with an asterisk (*) after their number have corresponding rationale contained in Annex A, included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this part of ISO 9170. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this part of ISO 9170, but will expedite any subsequent revisions.

# Terminal units for medical gas pipeline systems —

# Part 2:
# Terminal units for anaesthetic gas scavenging systems

## 1 Scope

**1.1** This part of ISO 9170 specifies the requirements and dimensions for terminal units intended for use in anaesthetic gas scavenging disposal systems in accordance with ISO 7396-2.

**1.2** This part of ISO 9170 specifies two types of terminal unit according to whether the power device is upstream or downstream of the terminal unit.

**1.3** This part of ISO 9170 also specifies requirements and dimensions for the mating counterpart (probe) of the type-specific connection point which is part of the terminal unit.

**1.4** This part of ISO 9170 does not specify the ranges of nominal operating pressure for terminal units, which are defined in ISO 7396-2.

**1.5** This part of ISO 9170 does not specify requirements for terminal units for use with compressed medical gases and vacuum, which are covered in ISO 9170-1.

## 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.

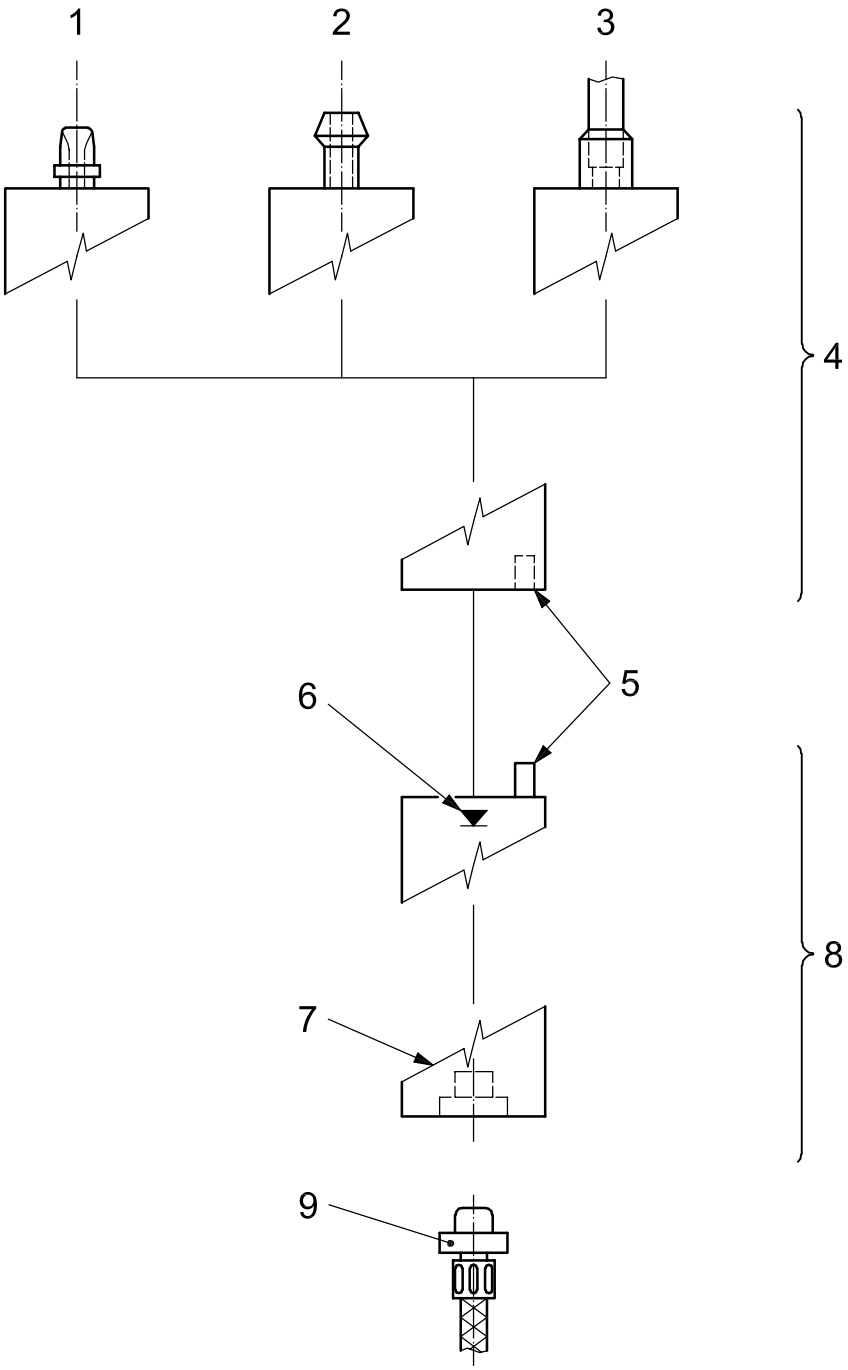
ISO 6506-1:2005, *Metallic materials — Brinell hardness test — Part 1: Test method*

ISO 7396-2:2007, *Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems*

ISO 8835-3:2007, *Inhalational anaesthesia systems — Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems*

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

ISO 15001:2003, *Anaesthetic and respiratory equipment — Compatibility with oxygen*




**Key**

1 type-specific connection
2 hose insert (permanent)
3 point for brazed connection (permanent)
4 terminal unit base block
5 type-specific interface
6 terminal unit check valve (Type 1 only)
7 type-specific connection point
8 socket
9 type-specific probe

**Figure 1 — Diagram of a typical AGSS terminal unit**

## 3 Terms and definitions

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

NOTE A diagram of a typical AGSS terminal unit with an example of terminology is given in Figure 1.

**3.1**
**AGSS Type 1 terminal unit**
connection point between the receiving system and disposal system at which the operator makes connections and disconnections

See Figure 2.

**3.2**
**AGSS Type 1L terminal unit**
terminal unit to be used in low-flow disposal systems

**3.3**
**AGSS Type 1H terminal unit**
terminal unit to be used in high-flow disposal systems

**3.4**
**AGSS Type 2 terminal unit**
connection point between the power device or disposal hose and the remainder of the disposal system at which the operator makes connections and disconnections

See Figure 2.

**3.5**
**AGSS type-specific**
having characteristics which prevent interchangeability and thereby allow assignment to one AGSS type only

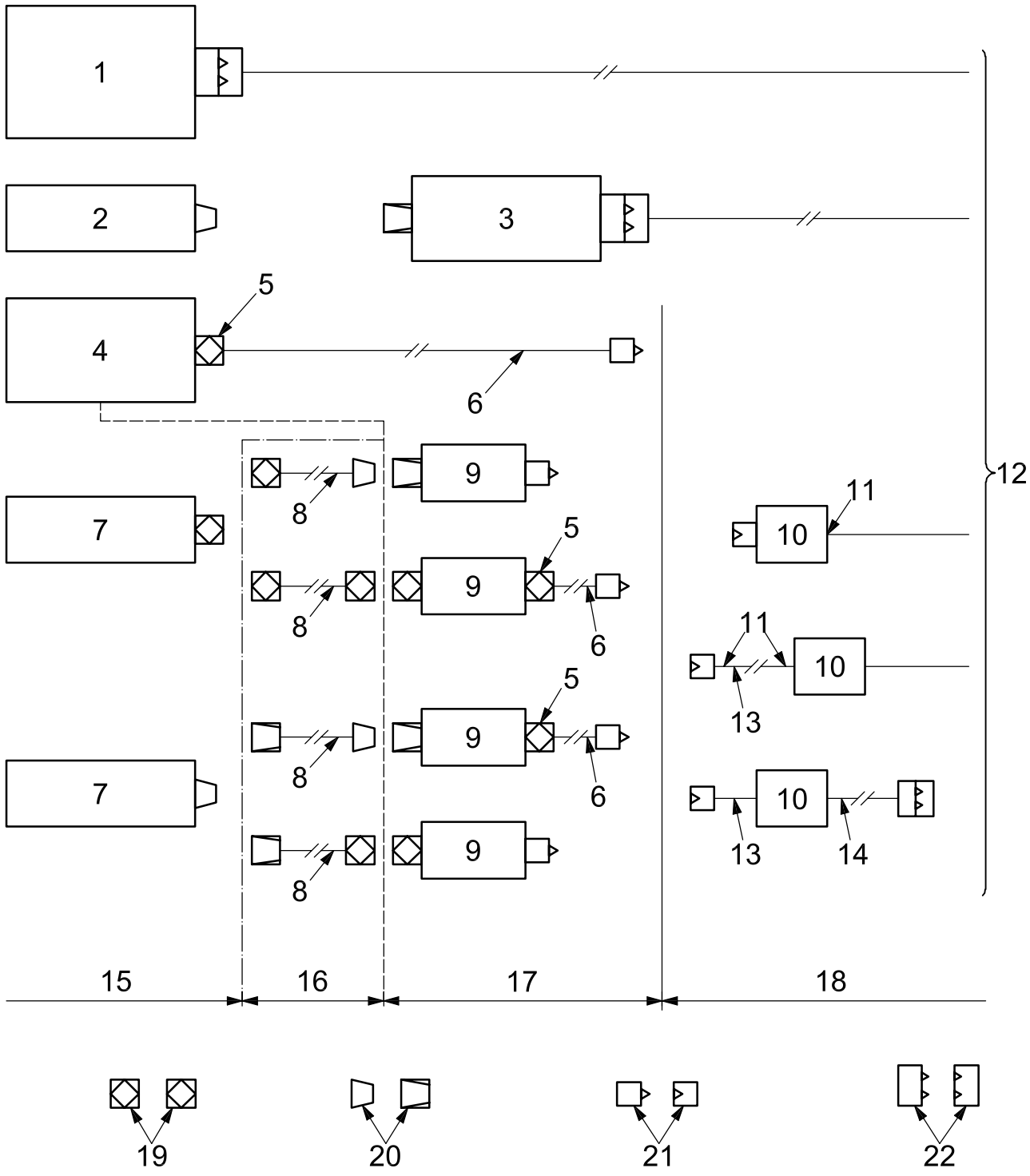
**3.6**
**AGSS type-specific connection point**
that part of the AGSS socket which is the receptor for an AGSS type-specific probe

**3.7**
**anaesthetic gas scavenging system**
**AGSS**
complete system that 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 can be combined with a breathing system or other equipment to include the transfer system or transfer and receiving systems. See Figure 2.

**3.8**
**terminal unit check valve**
valve that remains closed until opened by insertion of an appropriate probe and which then flows in either direction

**3.9**
**disposal hose**
that part of the AGSS which transfers expired and/or excess anaesthetic gases from the power device to the probe of the AGSS Type 2 terminal unit



**Key**

1 apparatus including breathing system, 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 2 — Schematic diagram of typical anaesthetic gas scavenging systems**

**3.10**
**disposal system**
means by which expired and/or excess anaesthetic gases are conveyed from the receiving system to an appropriate place of discharge

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

**3.11**
**high-flow disposal system**
disposal system that is intended to operate with a high-flow transfer and receiving system complying with ISO 8835-3

**3.12**
**low-flow disposal system**
disposal system that is intended to operate with a low-flow transfer and receiving system complying with ISO 8835-3

**3.13**
**maximum test pressure**
maximum pressure to which the terminal unit is designed to be subjected during pipeline pressure testing

**3.14**
**operating pressure**
pressure at which the AGSS terminal unit is designed to operate

NOTE The operating pressure for a Type 1 AGSS terminal unit is negative; the operating pressure for a Type 2 AGSS terminal unit is positive.

**3.15**
**power device**
that part of the AGSS disposal system that provides power for scavenging at specified flows and pressures

**3.16**
**probe**
non-interchangeable male component designed for acceptance by, and retention in, a socket

**3.17**
**quick connector**
pair of non-threaded type-specific components that can be easily and rapidly joined together by a single action of one or both hands without the use of tools

**3.18**
**receiving hose**
that part of an AGSS which transfers expired and/or excess anaesthetic gases from the receiving system to the disposal system

**3.19**
**receiving system**
that part of an AGSS which provides an interface between a transfer system and a disposal system

**3.20**
**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

**3.21**
**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

**3.22**
**terminal unit base block**
that part of a terminal unit which is attached to the disposal system

**3.23**
**terminal unit check valve**
valve that remains closed until opened by the insertion of an appropriate probe and which then permits flow in either direction

**3.24**
**transfer system**
that part of an AGSS which transfers scavenged gases from the exhaust port of a breathing system or other equipment to a receiving system

**3.25**
**transfer tube**
that part of an AGSS that transfers expired and/or excess anaesthetic gases from the breathing system or other equipment to the receiving system

# 4 General requirements

## 4.1 Safety

Terminal units shall, when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, present no risks that are not reduced to an acceptable level using procedures in accordance with ISO 14971 and which are related to their intended application, in normal conditions and in single-fault condition.

NOTE Maintenance of equipment is considered a normal condition.

## 4.2 * Alternative construction

Terminal units and components, or parts thereof, that use materials or have forms of construction (except for dimensions and allocation of probes and type-specific connection points) different from those detailed in this clause, shall be presumed to be in compliance with the safety objectives of this part of ISO 9170 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), and unless objective evidence to the contrary becomes available.

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

NOTE 1 Objective evidence may be obtained by postmarket surveillance.

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

## 4.3 Materials

**4.3.1** The materials in contact with the gas shall be corrosion-resistant and compatible with the medical gases and anaesthetic vapours in the temperature range specified in 4.3.2.

NOTE Corrosion resistance includes resistance to moisture and surrounding materials.

**4.3.2** The materials shall permit the terminal units and their components to meet the requirements of 4.4 in the temperature range −20 °C to +60 °C.

**4.3.3** Terminal units shall be capable of meeting the requirements of 4.4 after being packed, transported and stored as specified by the manufacturer.

**4.3.4** Evidence of conformity with the requirements of 4.3.1, 4.3.2 and 4.3.3 shall be provided by the manufacturer upon request.

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

## 4.4 Design requirements

### 4.4.1 Retention of type specificity

If any type-specific component is removed from the terminal unit, the type specificity of the terminal unit shall be retained, or the terminal unit shall be rendered inoperable. If the terminal unit can be dismantled, it shall not be possible to reassemble the components in such a way that the fully assembled terminal unit is no longer type-specific.

### 4.4.2 Type-specific connection point

Each terminal unit shall include a type-specific connection point that shall accept only the appropriate type-specific probe. This connection point shall be included in a socket.

### 4.4.3 Terminal unit check valve

Each Type I terminal unit shall include a check valve that shall open when the probe is connected and shut off automatically when the probe is disconnected.

### 4.4.4 Connection of terminal units to the disposal system

**4.4.4.1** The base block of the terminal unit shall be designed and manufactured for either permanent or type-specific connection to a pipeline (see also 7.2).

**4.4.4.2** Such type-specific connections shall be incompatible with those used for compressed medical gases and vacuum pipeline systems, hose assemblies, breathing systems and other AGSS components.

### 4.4.5 Connection of receiving or disposal hoses to hose inserts

**4.4.5.1** Hoses shall be attached to the hose inserts of connectors by means of compression swaging, a crimped ferrule or other methods that permit compliance with 4.4.5.2 and 4.4.5.3.

**4.4.5.2** It shall be impossible to remove the fitted sleeve or ferrule without it becoming unfit for re-use.

**4.4.5.3** The connection shall withstand the application of a steady axial tensile force of 600 N for 60 s.

The test method for connection of receiving or disposal hoses to hose inserts is given in 5.10.

### 4.4.6 Socket

The attachment of a socket to its base block for a particular service shall be type-specific.

### 4.4.7 Compliance

Compliance with 4.4.1 to 4.4.6, except for 4.4.5.3, shall be tested by visual inspection and/or functional testing where applicable.

### 4.4.8 Pressure drop

The pressure drop across the terminal unit and its probe, measured at the test pressure and with the test flowrates given in Table 1, shall not exceed the values given in Table 1.

The test method for pressure drop is given in 5.3.

**Table 1 — Requirements for flowrate and pressure drop across terminal units with probe inserted**

| Terminal unit type | Test pressure | Test flowrate<br>l/min | Maximum pressure drop across a terminal unit<br>kPa |
|---|---|---|---|
| 1L and 1H | atmospheric | 90 | 15 |
| 2 | atmospheric | 50 | 5 |

#### 4.4.9 Connection force

Except for screw-threaded connectors, the axial force required to insert the probe into the terminal unit shall not exceed 100 N.

The test method for connection force is given in 5.4.

#### 4.4.10 Disconnection force

Except for screw-threaded connectors the force required to release the locking mechanism shall be a push or pull of not more than 110 N and not less than 20 N. When all locking provisions have been released according to the manufacturer's instructions, disconnection of the probe from the terminal unit shall require a force of not more than 100 N.

The test method for disconnection force is given in 5.5.

#### 4.4.11 Mechanical strength

**4.4.11.1** Terminal units shall comply with the requirements of this clause following application of a steady axial tensile force of 500 N for 60 s.

The test method for mechanical strength is given in 5.6.1.

**4.4.11.2** *Terminal units shall meet the requirements of this clause following exposure to an inlet pressure of 77 kPa for 10 min.

The test method for mechanical strength is given in 5.6.2.

#### 4.4.12 Leakage

The leakage from a terminal unit with and without a probe inserted shall not exceed 2,96 ml/min (which is equivalent to 0,3 kPa l/min) under the conditions of maximum and minimum operating pressures specified by the manufacturer.

The test method for leakage is given in 5.7.

#### 4.4.13 Type specificity

The terminal unit shall accept only the type-specific probe for which it is intended.

The test method for type specificity is given in 5.8.

#### 4.4.14 Effective connection of probes

A tactile and/or audible indication of locking shall be perceived on retention of the type-specific probe.

The test method for effective connection of probes is given in 5.9.

#### 4.4.15 Endurance (connection/release)

##### 4.4.15.1 Socket

The terminal unit shall meet the requirements given in 4.4.8 to 4.4.14 after testing in accordance with 5.2.1.

##### 4.4.15.2 Probe

The probe shall meet the requirements given in 4.4.8 to 4.4.14 after testing in accordance with 5.2.2.

### 4.4.16 Dimensions

Dimensions of a Type 1L ISO probe and of the corresponding type-specific connection point shall comply with Figure 3.

Dimensions of a Type 1H ISO probe and of the corresponding type-specific connection point shall comply with Figure 4 or regional or national standards.

NOTE 1 As far as is known to the Committee at the time of publication of this part of ISO 9170, the set of dimensions defined for probe and type-specific connection point for 1H terminal units is not used in any country.

Dimensions of a Type 2 ISO probe and of the corresponding type-specific connection point shall comply with Figure 5.

Compliance shall be verified by measurement.

NOTE 2 Regional or national standards for the design and dimensions of other type-specific connectors for terminal units for anaesthetic gas scavenging systems might exist.

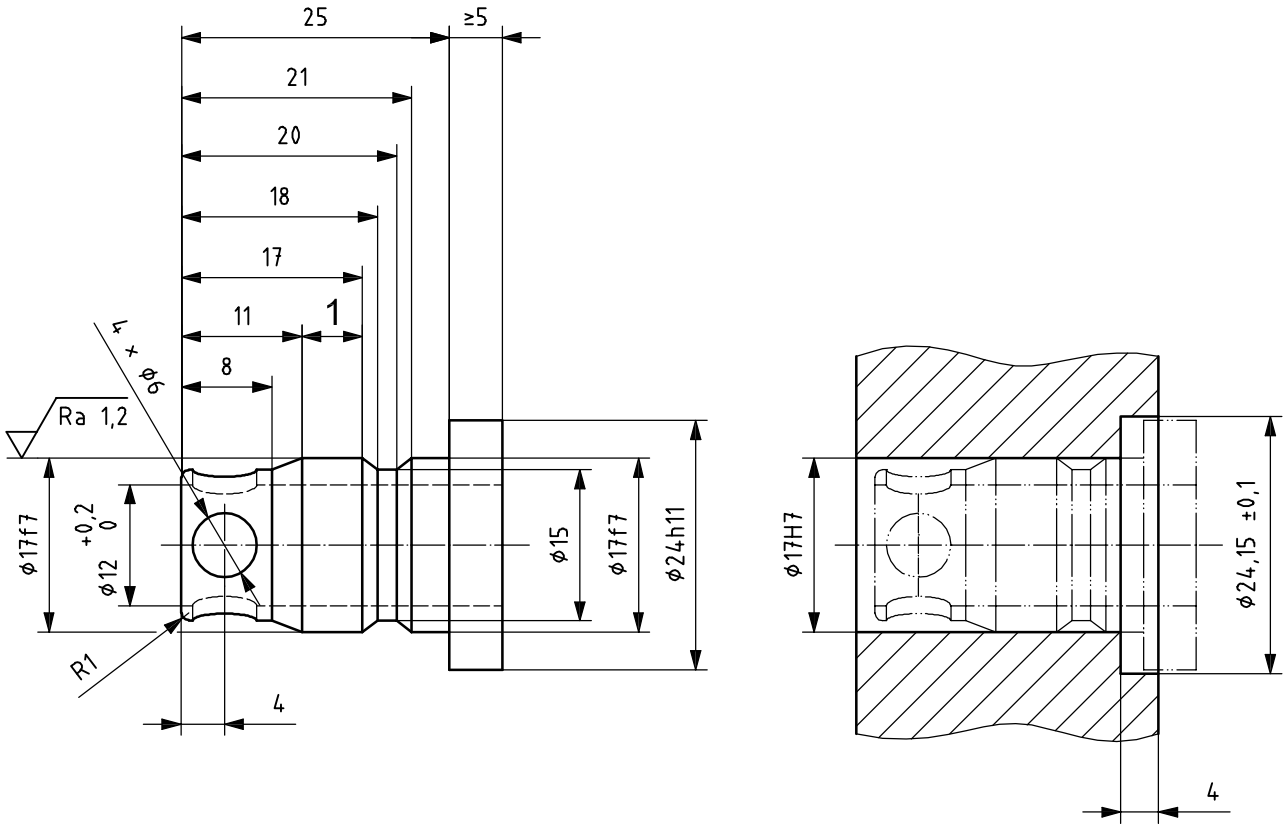
### 4.4.17 Electrical requirements

If required by regional or national regulations, terminal units shall be fitted with means for connection to the equipotential bonding installation.

NOTE 1 Regional or national regulations which apply to electrical installations in medical locations might exist.

NOTE 2 Annex C lists some regional and national regulations for electrical installations.

Dimensions in millimetres




**Key**

1 probe sealing area

All length tolerances shall be ± 0,1 mm.

All diameters shall be ± 0,05 mm unless otherwise stated.

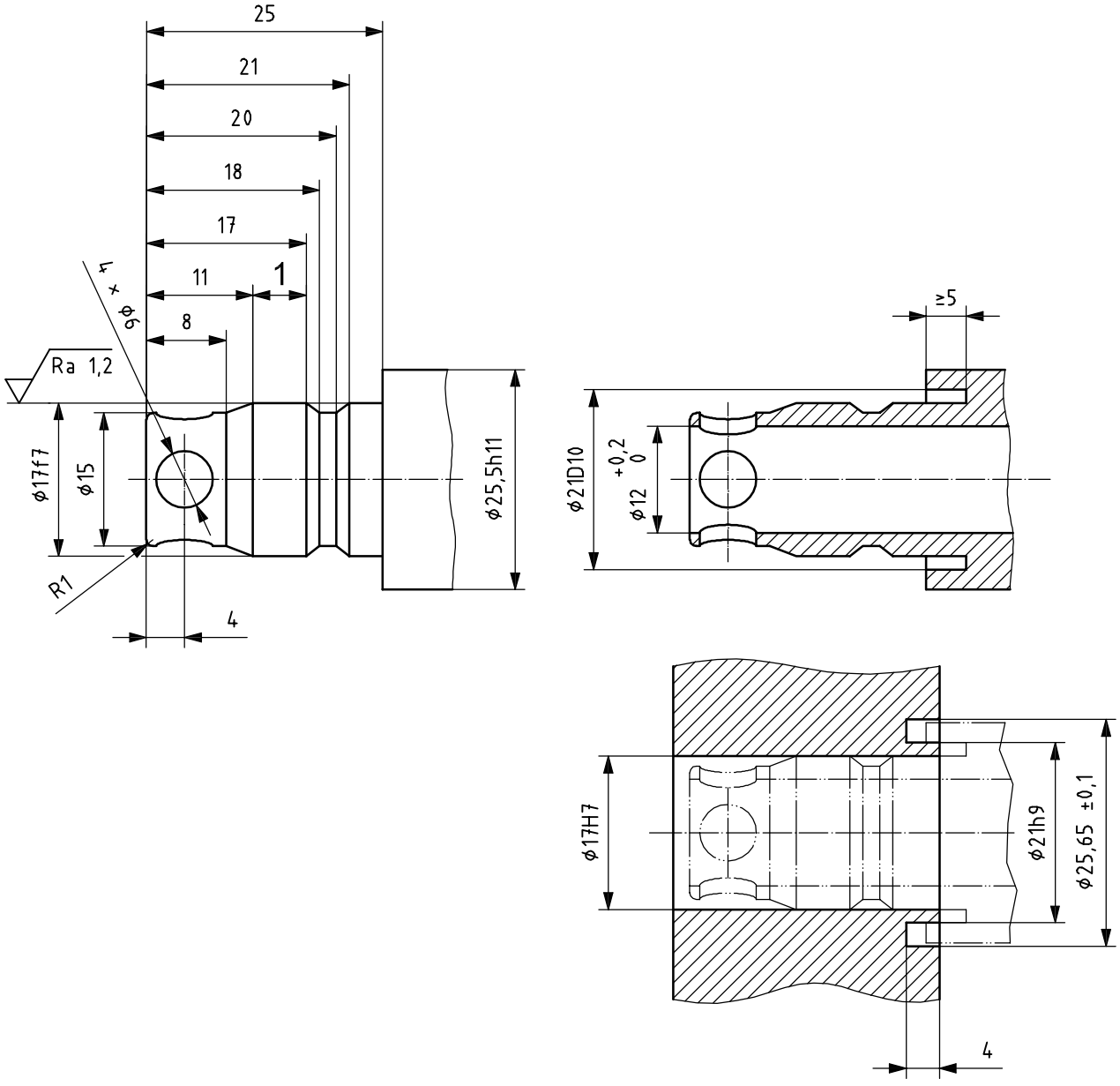
All diameters shall be concentric to within 0,05 mm.

Surface finish shall be 1,6 unless otherwise specified.

All sharp edges and burrs shall be removed (maximum radius 0,2 mm) unless otherwise specified.

**Figure 3 — Dimensions of Type 1L ISO probe and type-specific connection point**

Dimensions in millimetres




**Key**

1 probe sealing area

All length tolerances shall be ± 0,1 mm.

All diameters shall be ± 0,05 mm unless otherwise stated.

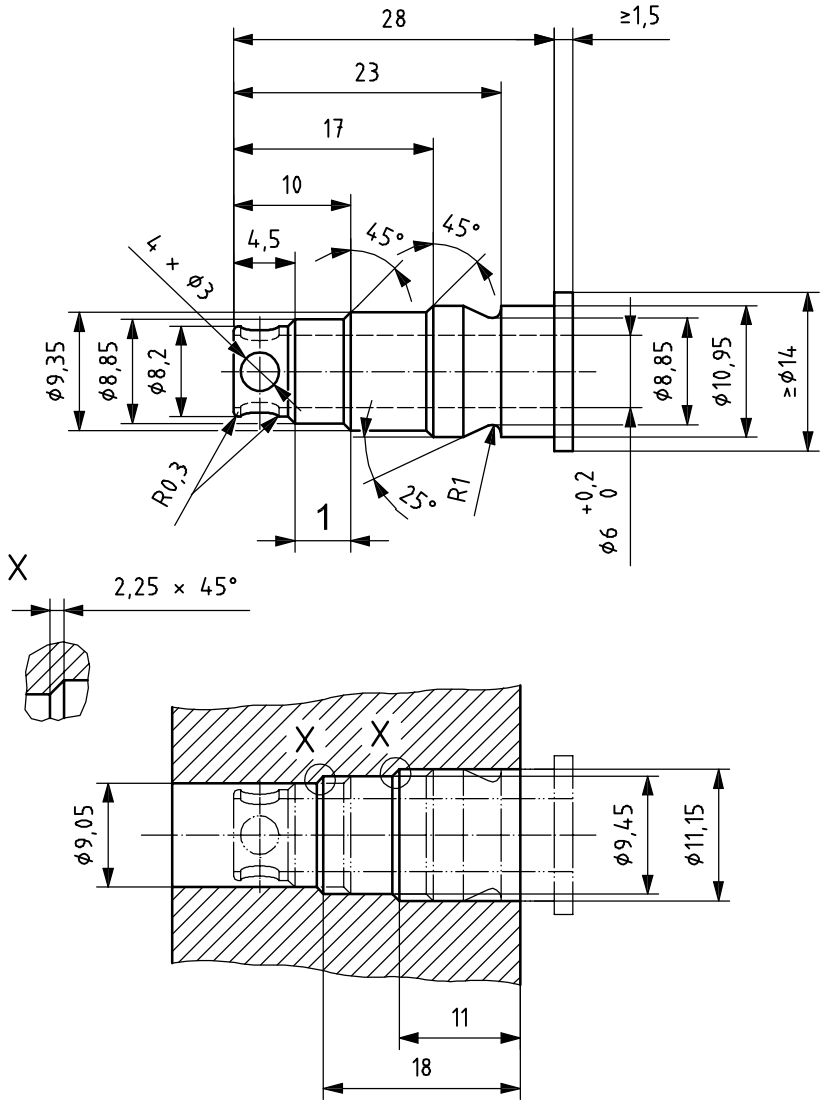
All diameters shall be concentric to within 0,05 mm.

Surface finish shall be 1,6 unless otherwise specified.

All sharp edges and burrs shall be removed (maximum radius 0,2 mm) unless otherwise specified.

**Figure 4 — Dimensions of Type 1H ISO probe and type-specific connection point**

Dimensions in millimetres




**Key**

1 probe sealing area

All length tolerances shall be ± 0,1 mm.

All diameters shall be ± 0,05 mm unless otherwise stated.

All diameters shall be concentric to within ± 0,05 mm.

Surface finish shall be 1,6 unless otherwise specified.

All sharp edges and burrs shall be removed (maximum radius 0,2 mm) unless otherwise specified.

**Figure 5 — Dimensions of Type 2 ISO probe and type-specific connection point**

## 4.5 Construction requirements

### 4.5.1 Cleaning

Terminal units of all types shall be cleaned to meet the requirements of ISO 15001. Evidence shall be made available by the manufacturer upon request.

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

### 4.5.2 Lubricants

If lubricants are used, they shall be compatible with medical gases and anaesthetic vapours in the temperature range specified in 4.3.2. Evidence shall be made available by the manufacturer upon request.

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

# 5 Test methods

## 5.1 General

### 5.1.1 Ambient conditions

Except where otherwise stated, tests shall be carried out at ambient conditions.

### 5.1.2 Test gas

Tests shall be carried out with clean, oil-free dry air or nitrogen. Tests shall be carried out with dry gas with a maximum moisture content of 50 µg/g corresponding to a dew point of –48 °C at atmospheric pressure.

### 5.1.3 Reference conditions

Flowrates shall be corrected to 23 °C and 101,3 kPa.

## 5.2 Endurance test

### 5.2.1 Socket

Fix the terminal unit to a horizontal or vertical surface, as appropriate, using the procedure recommended by the manufacturer. Using a test probe made of corrosion-resistant steel of minimum chromium content 17 % and a surface Brinell hardness of 210 HBW 1/30 (in accordance with ISO 6506-1), connect and release the probe 10 000 times at a frequency of not more than 10 operations per minute, changing the seals every 1 000 operations or according to the manufacturer's instructions, whichever is the greater interval.

Test the socket for compliance with 4.4.8 to 4.4.14.

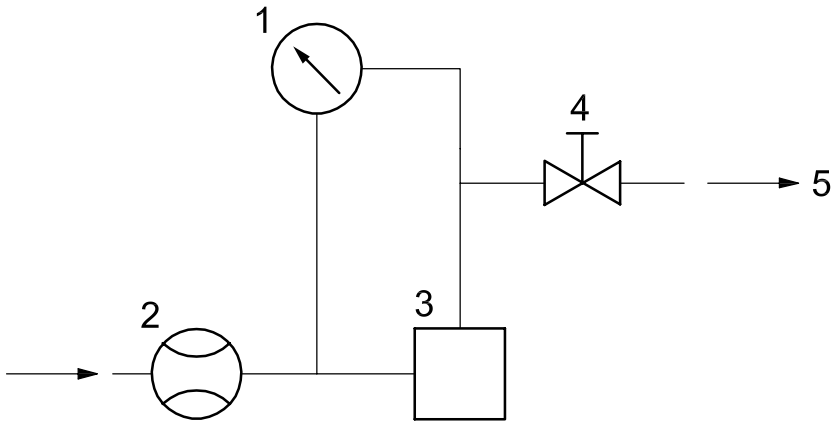
### 5.2.2 Probe

Fix a terminal unit complying with this part of ISO 9170 to a horizontal or vertical surface, as appropriate, using the procedure recommended by the manufacturer. Connect and release a probe 10 000 times at a frequency of no more than 10 operations per minute, changing the seals every 1 000 operations or according to the manufacturer's instructions, whichever is the greater interval.

Test the probe for compliance with 4.4.8 to 4.4.14.

## 5.3 Test method for pressure drop

Using an apparatus of typical configuration as shown in Figure 6, set the test pressure and flowrate to the appropriate values given in Table 1. Measure the pressure drop across the terminal unit.




**Key**

1 pressure-differential measuring device
2 flowmeter
3 terminal unit with probe inserted
4 flow control valve
5 vacuum supply

**Figure 6 — Typical apparatus for measuring the pressure drop across AGSS terminal units**

## 5.4 Test method for connection force

This test method does not apply to screw-threaded connectors.

Adapt a probe to accommodate a suitable measuring device.

Fix the terminal unit to a horizontal or vertical surface, as appropriate, using the procedure recommended by the manufacturer. Where the probe is inserted axially into a socket without any assistance from a threaded handwheel or equivalent connecting mechanism, insert the adapted probe into the terminal unit in accordance with the manufacturer's instructions and record the force required to insert and engage the probe fully.

## 5.5 Test method for disconnection force

This test method does not apply to screw-threaded connectors.

Adapt a probe to accommodate a suitable measuring device.

Fix the terminal unit to a horizontal or vertical surface, as appropriate, using the procedure recommended by the manufacturer. Where the probe is inserted axially into a socket without any assistance from a threaded handwheel or equivalent connecting mechanism, insert the adapted probe into the terminal unit in accordance with the manufacturer's instructions and ensure that it is fully engaged. Release the locking mechanism. Disconnect the probe in accordance with the manufacturer's instructions and record the force required to release the locking mechanism. If the recommended disconnection method involves applying, for example, compressive force to the probe to reduce the effort required to release the locking mechanism, measure each separate force.

### 5.6 Tests for mechanical strength

**5.6.1** Adapt a blanked probe to apply a tensile force.

Fix the terminal unit to a suitable surface using the procedure recommended by the manufacturer. Insert the adapted probe. Apply a tensile force of 500 N and maintain it for 60 s. Remove the tensile force and check that the terminal unit complies with the requirements of Clause 4. Dismantle the terminal unit and check that no damage or distortion has occurred to either the terminal unit or the probe.

**5.6.2** Fix the terminal unit to a suitable surface using the procedure recommended by the manufacturer. Apply a test pressure of 77 kPa and maintain it for 10 min. Remove the test pressure. Check that the terminal unit complies with the requirements of Clause 4. Dismantle the terminal unit and check that no damage or distortion has occurred to the terminal unit.

### 5.7 Tests for leakage

**5.7.1** Fix the terminal unit to a horizontal or vertical surface, as appropriate, using the procedure recommended by the manufacturer. Apply the maximum and then the minimum operating pressure specified by the manufacturer at the inlet to the base block on the terminal unit. Measure the leakage under the conditions of maximum and minimum operating pressures.

**5.7.2** Keep the terminal unit pressurized as described in 5.7.1 and insert a type-specific blanked probe. Measure the leakage under the conditions of maximum and minimum operating pressures specified by the manufacturer.

### 5.8 Test for type specificity

Carry out the test by attempting to connect all type-specific test probes in turn to the type-specific connection points of each socket.

### 5.9 Test for effective connection of probes to sockets

Carry out the test by inserting the type-specific probe and checking that a tactile and/or audible indication of locking is perceived.

### 5.10 Test for connection of receiving or disposal hoses to hose inserts

Subject the hose and connectors of the test specimen to an axial force of 600 N for 60 s. Destroy the hose of the test specimen after testing.

### 5.11 Test for durability of markings and colour coding

Rub the 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. Verify that the requirements of 6.1.1 and 6.2.2 have been met.

## 6 Marking, colour coding and packaging

### 6.1 Marking

**6.1.1** Terminal units, probes and their type-specific components shall be durably and legibly marked with the letters “AGSS” (or the national equivalent) and the type.

The test for durability of markings is given in 5.11.

**6.1.2** The height of the lettering shall be at least 2,5 mm.

**6.1.3** Terminal units and probes shall be marked with the manufacturer's name or identification mark and, if applicable, with additional means to ensure traceability such as type, batch or serial number, or year of manufacture.

### 6.2 Colour coding

**6.2.1** If colour coding is used, it shall be red magenta.

NOTE An example of red magenta is 3050-R40B in accordance with SS 19102.

**6.2.2** Colour coding shall be durable.

The test for the durability of colour coding is given in 5.11.

### 6.3 Packaging

**6.3.1** Terminal units, probes and spare parts shall be sealed to protect against particulate contamination and packaged to prevent damage during storage and transportation.

**6.3.2** Packages shall provide a means of identification of the contents.

## 7 Information to be supplied by the manufacturer

**7.1** Terminal units shall be accompanied by a technical description, instructions for use, storage and transportation, and an address to which the operator can refer.

**7.2** The manufacturer shall provide instructions for installation and a reference to the testing procedures for terminal units given in ISO 7396-2.

**7.3** Instructions for use shall include information necessary for the operation of the terminal unit in accordance with its specification and a description of the procedure for connection and disconnection of probes.

Instructions for use shall give detailed instructions for cleaning, inspection and preventive maintenance to be performed by the operator or by authorized persons, and shall recommend the frequency of such activities. A list of recommended spare parts shall be provided.

**7.4** Particular attention shall be given to the following safety-related items:

— the danger of fire or explosion due to the use of lubricants not recommended by the manufacturer;

— the range of operating pressures;

— the hazard due to the use of improper probes.

# Annex A
(informative)

# Rationale

This annex provides a rationale for some requirements of this part of ISO 9170 and is intended for those who are familiar with the subject of this part of ISO 9170 but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this part of ISO 9170 necessitated by those developments.

The following correspond to subclauses marked with an asterisk (*) in this part of ISO 9170. The numbering is, therefore, not consecutive.

**A.2** Only dated references are used in this part of ISO 9170. As stated in the preamble of the European Medical Device Directive 93/42/EEC, manufacturers have "to take account of technology and practice existing at the time of design and of technical and economical considerations compatible with a high level of protection of health and safety". This is to ensure that a manufacturer does not design against a moving target (i.e. a standard which is revised after completion of the specification), before the device is placed on the market. Having only dated references will ensure that design specifications are developed using clearly defined standards that reflect the generally acknowledged state of the art at the time of design, except for emerging hazards requiring the amendment of existing standards.

SG1 of the Global Harmonization Task Force (GHTF) (www.ghtf.org) is developing a guideline, SG1/N044[6], which addresses the need to use dated references.

**A.4.2** Attention is drawn to ISO 14971 on risk management and to the International Standards under development by ISO/TC 210 on risk evaluation and risk control.

**A.4.4.11.2** The pressure of 70 kPa ± 10 % is specified in ISO 7396-2 as the test pressure for leakage for the AGSS disposal system.

# Annex B
(informative)

# Environmental aspects

Planning and design of products applying to this part of ISO 9170 should consider the environmental impact from the product during its life cycle. The environmental impact generated by terminal units for use with anaesthetic gas scavenging systems is mainly restricted to the following occurrences:

— impact at local environment caused by leakage;

— impact at local environment caused by cross-connection;

— danger of fire or explosion due to the use of unsuitable materials or lubricants;

— cleaning.

To highlight the importance of reducing the environmental burden, this part of ISO 9170 addresses requirements or recommendations intended to decrease environmental impact caused by those aspects.

See Table B.1 for a mapping of the life cycle of a terminal unit for use with an anaesthetic gas scavenging system to aspects of the environment.

**Table B.1 — Environmental aspects addressed by subclauses of this part of ISO 9170**

| Environmental aspects (inputs and outputs) | | Product life cycle | | | |
|---|---|---|---|---|---|
| | | Production and preproduction | Distribution (including packaging) | Use | End of life |
| | | Stage A | Stage B | Stage C | Stage D |
| | | | Addressed in Clause | Addressed in Subclause | |
| 1 | Resource use | — | — | — | — |
| 2 | Energy consumption | — | — | — | — |
| 3 | Emissions to air | — | — | 4.4.3<br>4.4.10<br>4.4.12<br>4.4.14 | — |
| 4 | Emissions to water | — | — | — | — |
| 5 | Waste | — | — | 4.4.3<br>4.4.10<br>4.4.12 | — |
| 6 | Noise | — | — | — | — |
| 7 | Migration of hazardous substances | — | — | 4.1<br>4.2<br>4.3 | — |
| 8 | Impacts on soil | — | — | — | — |
| 9 | Risks to the environment from accidents or misuse | — | 6<br>7 | 4.1<br>4.2<br>4.3<br>4.4.1<br>4.4.2<br>4.4.3<br>4.4.4<br>4.4.5<br>4.4.6<br>4.4.10<br>4.4.11<br>4.4.12<br>4.4.13<br>4.4.14<br>4.4.15<br>4.5<br>7 | — |

# Annex C
(informative)

# Special national and regional conditions for electrical installations

The following table provides some of the known country/market-specific electrical installation requirements. For the countries in which the relevant national condition applies, the provisions shown below are normative; for other countries they are informative.

| Country or region | Relevant regulations |
|---|---|
| Europe | IEC 60364-7-710, Ed. 1[7] |
| Australia | AS/NZS 3000[8], AS/NZS 3003[9] |
| USA | National Electric Code |
| Canada | Canadian Electrical Code |
| Japan | Japanese Industrial Standard |

# Bibliography

[1] ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

[2] ISO 9170-1:2008, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*

[3] SS 19102:2004, *NCS Atlas (NCS Colour Atlas)*

[4] AS 2896-1998, *Medical gas systems — Installation and testing of non-flammable medical gas pipeline systems*

[5] NFPA 99:2005, *Health care facilities*

[6] SG1/N044, *Role of Standards in the Assessment of Medical Devices*

[7] IEC 60364-7-710:2002, *Electrical installations of buildings — Part 7-710: Requirements for special installations or locations — Medical locations*

[8] AS/NZS 3000:2000, *Electrical installations (known as the Australian/New Zealand Wiring Rules)*

[9] AS/NZS 3003:2003, *Electrical installations — Patient treatment areas of hospitals and medical and dental practices and dialyzing locations*

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