INTERNATIONAL STANDARD

ISO 9170-2

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Terminal units for medical gas pipeline systems —

Part 2:
Terminal units for anaesthetic gas scavenging systems

Prises murales pour réseaux de distribution de gaz médicaux —

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

Reference number
ISO 9170-2:1999(E)

Contents

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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.

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

This first edition, together with ISO 9170-1, cancels and replaces the first edition of ISO 9170 (ISO 9170:1994), 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*

Annex A of this part of ISO 9170 is for information only.

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 are 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.

Terminal units for medical gas pipeline systems —

Part 2:
Terminal units for anaesthetic gas scavenging systems

1 Scope

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 .

It is intended especially to ensure the type specificity of terminal units and to prevent their interchange between different services.

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

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.

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

NOTE Throughout this part of ISO 9170, clauses for which a rationale is provided in annex A are indicated by a boldface capital **R.**

2 Normative references

The following normative document contains provisions which, through reference in this text, constitute provisions of this part of ISO 9170. 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 9170 are encouraged to investigate the possibility of applying the most recent edition of the normative document 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 6506, *Metallic materials — Hardness test — Brinell test*.

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

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

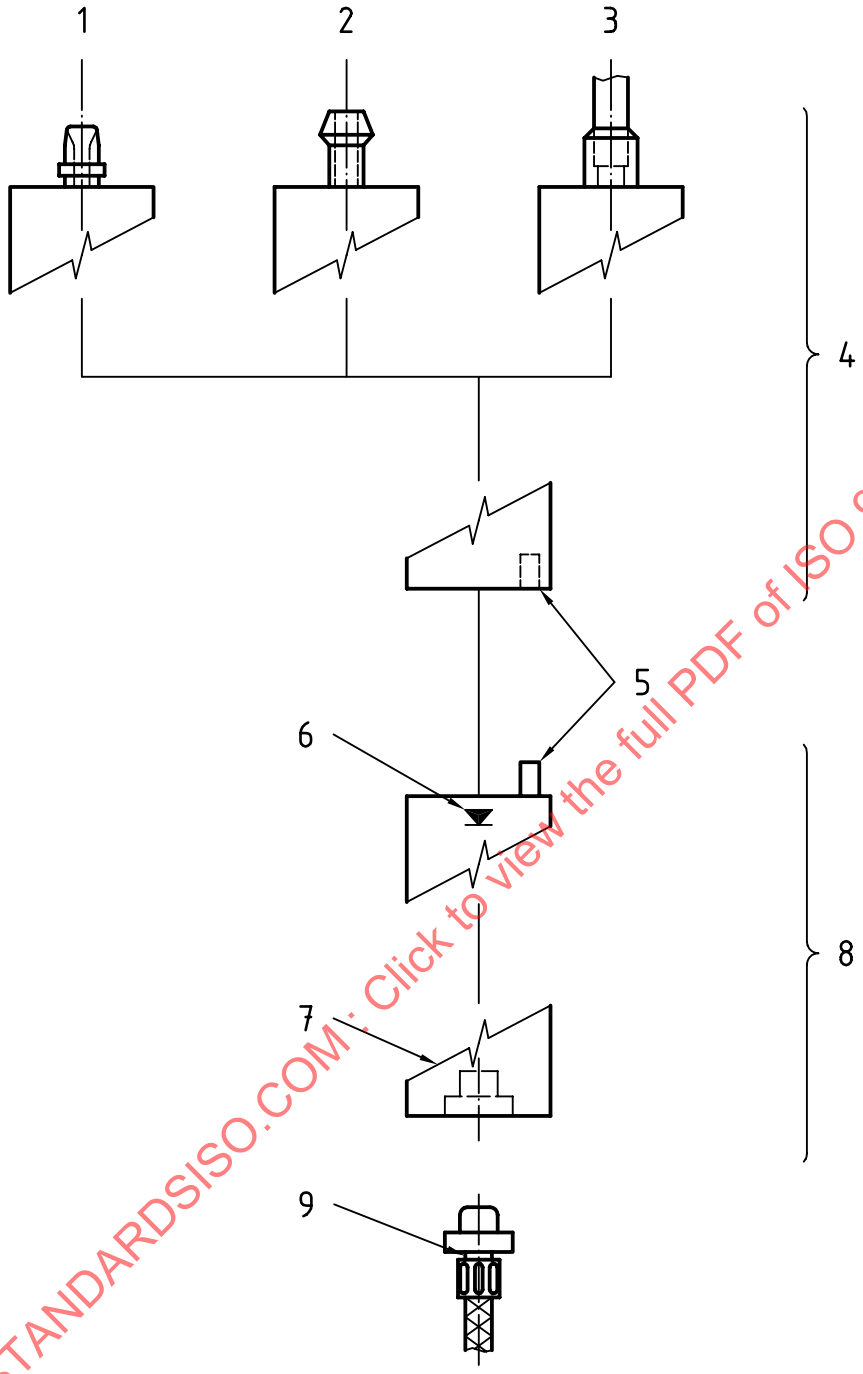
ISO 14971-1, *Medical devices — Risk management — Part 1: Application of risk analysis*.

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

3 Terms and definitions

For the purposes of this part of ISO 9170, the following terms and definitions apply.

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



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

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

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 the disposal hose and the remainder of the disposal system at which the operator makes connections and disconnections

3.5
AGSS type-specific
having characteristics which prevent interchangeability and thereby allows 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 which is connected to the exhaust port(s) of an anaesthetic workstation or which is integrated into an anaesthetic workstation for the purpose of conveying scavenged 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 sequentially combined with a breathing system to include the transfer system or transfer and receiving systems.

See Figure 2.

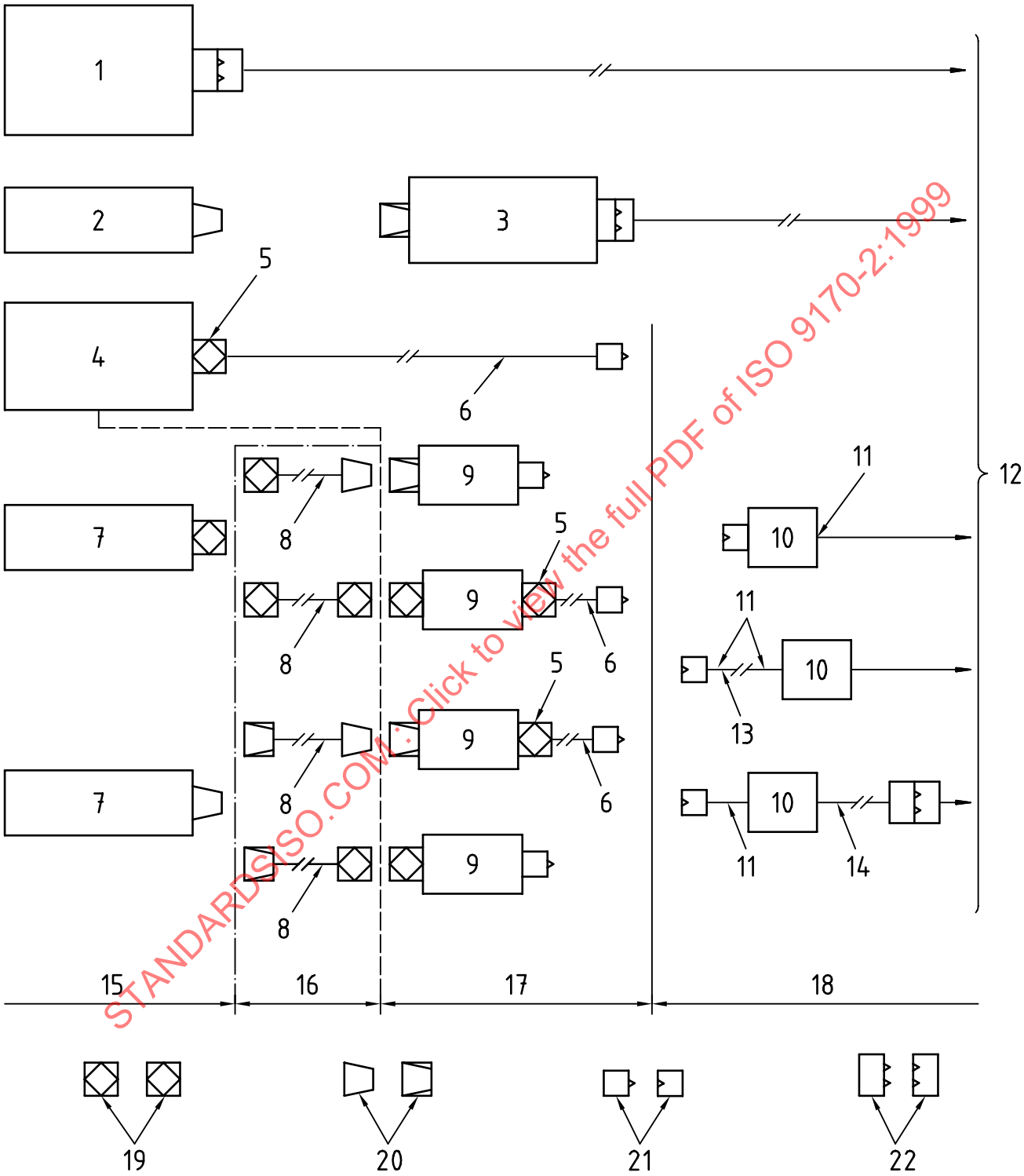
3.8
disposal hose
that part of the AGSS which transfers scavenged gases from the power device to the probe of the AGSS Type 2 terminal unit

3.9
disposal system
means by which the scavenged 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.

3.10
high-flow disposal system
disposal system that generates extract flowrates not lower than 75 l/min from transfer and receiving systems complying with ISO 8835-3

3.11
legible
discernible or identifiable to an operator with 6/6 (20/20) vision (corrected if necessary) from a distance of 1 m at a light level of 215 lx when viewing the information, markings, etc., perpendicular to and including 15° above, below, left and right of the direct line of vision of the operator



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 (see note 2).

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 system

3.12
low-flow disposal system
disposal system that generates extract flowrates not more than 50 l/min from transfer and receiving systems 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 Operating pressure for Type 1 AGSS terminal units is negative; operating pressure for Type 2 AGSS terminal units is positive.

3.15
power device
that part of the disposal system of an AGSS which provides the gas flow for scavenging

3.16
probe
male component designed for acceptance by and retention in the socket

3.17
quick connector
pair of non-threaded 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.

3.18
receiving hose
that part of an AGSS which transfers scavenged 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 which remains closed until opened by 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 the AGSS transfer system which transfers 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, cause no safety hazard which could be foreseen using risk analysis procedures in accordance with ISO 14971-1 and which is related to their intended application, in normal conditions and in single fault condition.

4.2 R Alternative construction

Terminal units and components, or parts thereof, which use materials or have forms of construction (except for dimensions and allocation of probes and the type-specific connection points) different from those detailed in clause 4 of this part of ISO 9170 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 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 against 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 R Evidence of conformity with the requirements of 4.3.1, 4.3.2 and 4.3.3 shall be provided by the manufacturer.

4.4 Design requirements

4.4.1 Incomplete assembly

If any type-specific component is removed from the terminal unit, the type-specificity of the terminal unit shall be maintained, 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 which 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 which shall open when the probe is connected and which shall 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 gas 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 which 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 reuse.

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

The test 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 with 4.4.1 to 4.4.6, except for 4.4.5.3, shall be tested by visual inspection and 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 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 l/min	Maximum pressure drop across a terminal unit kPa
1L and 1H	atmospheric	90	15
2	atmospheric	50	5

4.4.9 Connection force

The axial force required to insert the probe into the terminal unit shall not exceed 100 N.

The test for connection force is given in 5.4.

4.4.10 Disconnection force

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 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 clause 4 following application of a steady axial tensile force of 500 N.

The test for mechanical strength is given in 5.6.1.

4.4.11.2 **R** Terminal units shall meet the requirements of clause 4 following exposure to an inlet pressure of 77 kPa for 10 min.

The test for mechanical strength is given in 5.6.2.

4.4.12 Leakage

The leakage from a terminal unit with and without 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 pressure specified by the manufacturer.

The test 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 for type-specificity is given in 5.8.

4.4.14 Effective connection of probes

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

The test 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

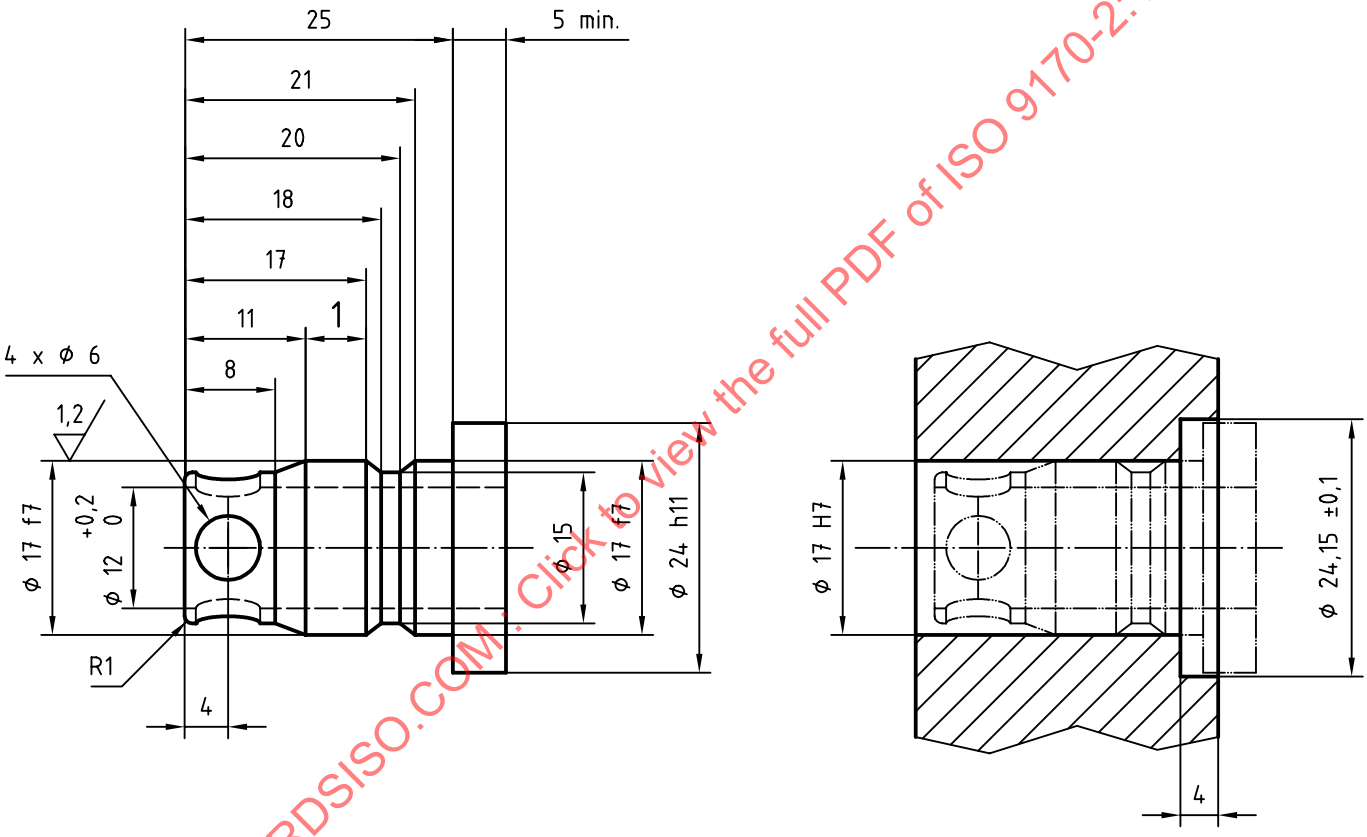
Dimensions of a Type 1L probe and of the corresponding type-specific connection point shall comply with Figure 3.

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

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

Compliance shall be verified by measurement.

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.

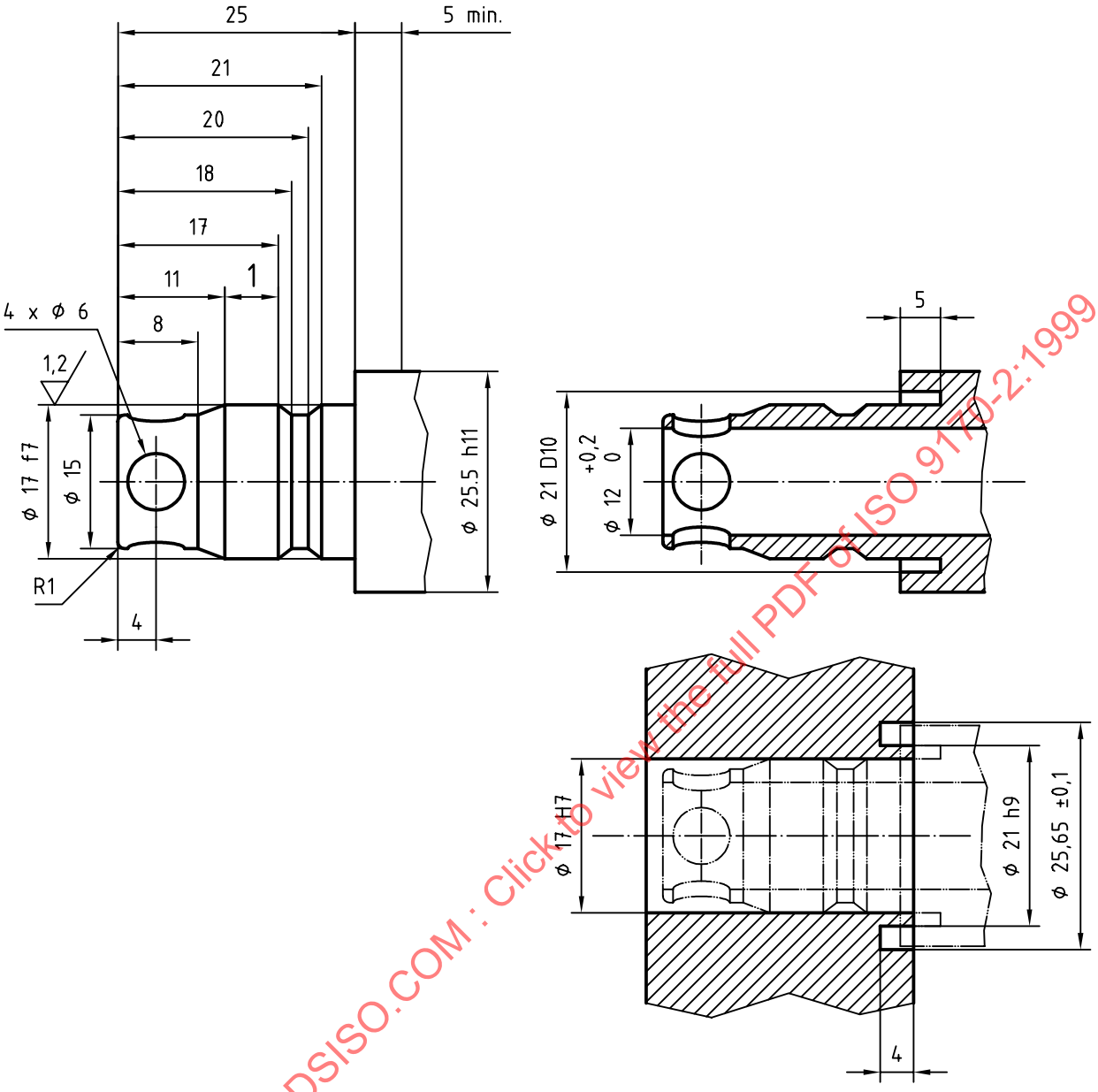
All diameters shall be concentric to within 0,05 mm.

Surface finish shall be 1,6 unless otherwise specified.

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

Figure 3 — Dimensions of Type 1L 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.

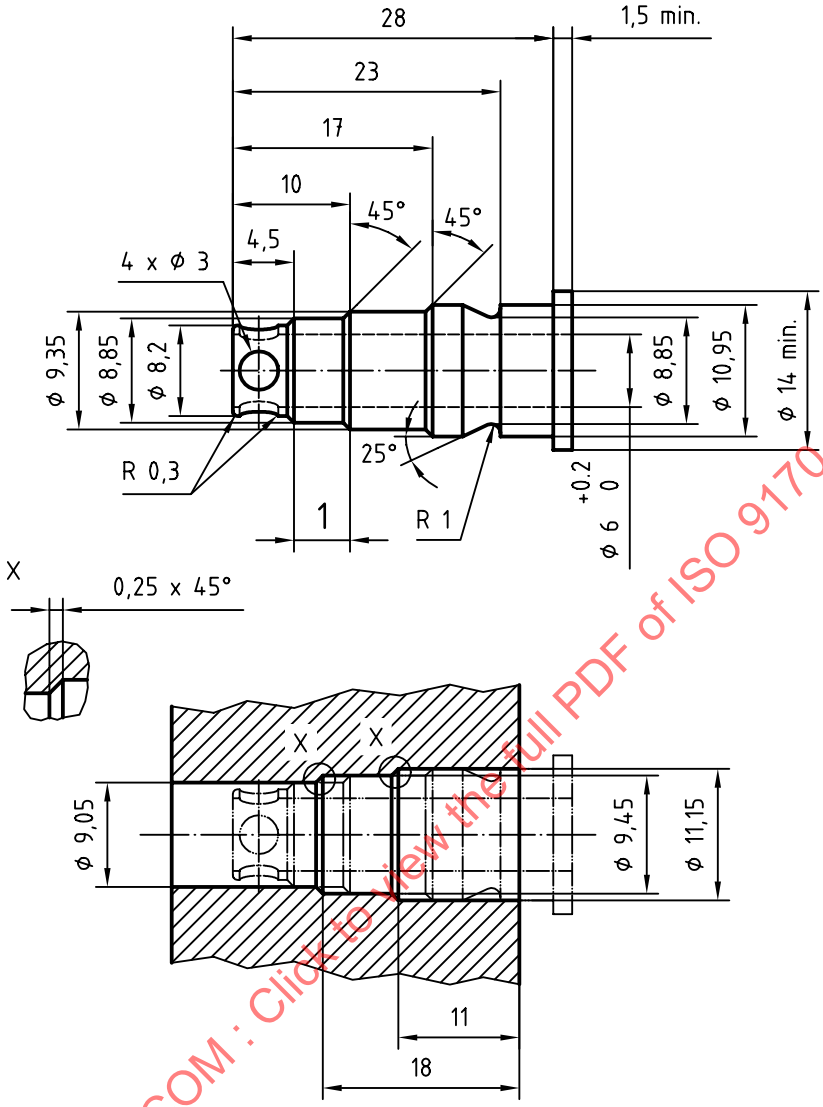
All diameters shall be concentric to within 0,05 mm.

Surface finish shall be 1,6 unless otherwise specified.

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

Figure 4 — Dimensions of Type 1H 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 (max. rad 0,2 mm) unless otherwise specified.

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

4.5 Construction requirements

4.5.1 R Cleaning

Terminal units of all types shall be cleaned to meet the requirements of ISO 15001. Evidence shall be provided by the manufacturer.

4.5.2 R 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 provided by the manufacturer.

5 Test methods

5.1 General

5.1.1 Ambient conditions

Except where otherwise stated, tests shall be carried out at 23 °C ± 2 °C and at atmospheric pressure.

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 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 HB 1/30 (in accordance with ISO 6506), 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, 4.4.9, 4.4.10, 4.4.11, 4.4.12, 4.4.13 and 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 the 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, 4.4.9, 4.4.10, 4.4.11, 4.4.12, 4.4.13 and 4.4.14.

5.3 Test for pressure drop

Using an apparatus of typical configuration 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.

5.4 Test for connection force

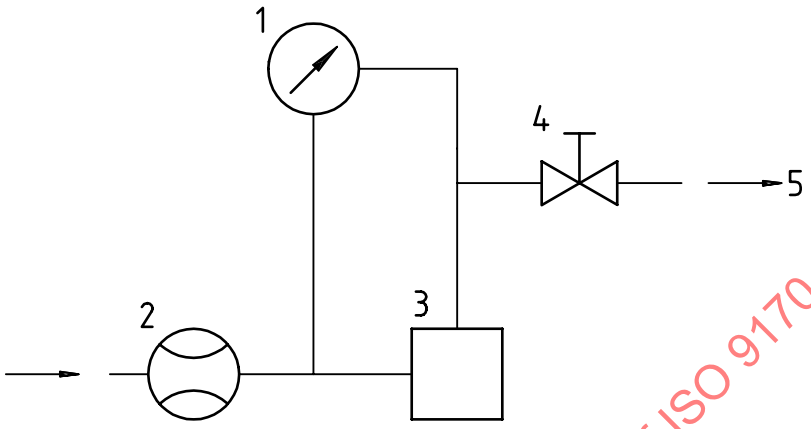
Adapt a probe to accommodate a suitable measuring device.

Fix the terminal unit to a horizontal or vertical surface, as appropriate, using the procedure recommended by the manufacturer. 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 for disconnection force

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. 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.



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 pressure drop across AGSS terminal units

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, 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.