
**Terminal units for medical gas
pipeline systems —**

Part 1:

**Terminal units for use with
compressed medical gases and vacuum**

Prises murales pour systèmes de distribution de gaz médicaux —

Partie 1: Prises murales pour les gaz médicaux comprimés et le vide

STANDARDSISO.COM : Click to view the full PDF of ISO 9170-1:2017



STANDARDSISO.COM : Click to view the full PDF of ISO 9170-1:2017



COPYRIGHT PROTECTED DOCUMENT

© ISO 2017, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

	Page
Foreword	v
Introduction	vi
1 Scope	1
2 *Normative references	2
3 Terms and definitions	2
4 General requirements	7
4.1 Safety	7
4.2 *Alternative construction	7
4.3 Materials	7
5 Design requirements	8
5.1 Medical gas supply	8
5.2 Terminal units for different pressures	9
5.3 Retention of gas specificity	9
5.4 Gas-specific connection point	9
5.5 Terminal unit check valve	9
5.6 Terminal unit maintenance valve	9
5.7 Connection of terminal units to the pipeline (see also 9.2)	10
5.8 Socket	10
5.9 Compliance	10
5.10 Endurance (connection/release)	10
5.10.1 Socket	10
5.10.2 Probe	10
5.11 *Pressure drop	10
5.12 Connection force and torque	11
5.13 Disconnection force and torque	11
5.14 Mechanical strength	11
5.15 Leakage	12
5.16 Gas specificity	12
5.17 Effective connection of probes	12
5.18 Electrical requirements	12
6 Constructional requirements	12
6.1 Cleaning	12
6.2 Lubricants	12
7 Test methods	12
7.1 General	12
7.2 Test for endurance	13
7.3 Test for pressure drop	13
7.4 Test for connection force and torque	15
7.5 Test for disconnection force and torque	15
7.6 Test for mechanical strength	16
7.7 Test for leakage	16
7.8 Test for gas specificity	17
7.9 Test for effective connection of probe	17
7.10 Test for durability of markings and colour coding	17
8 Marking, colour coding and packaging	17
8.1 Marking	17
8.2 Colour coding	17
8.3 Packaging	18
9 Information to be supplied by the manufacturer	18
9.1 Technical description	18
9.2 Instructions	18

Annex A (informative) Rationale	19
Annex B (informative) Environmental aspects	20
Annex C (informative) Special national and regional conditions for electrical installations	22
Bibliography	24

STANDARDSISO.COM : Click to view the full PDF of ISO 9170-1:2017

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC6, *Medical gas systems*.

This third edition cancels and replaces the second edition (ISO 9170-1:2008), which has been technically revised.

This edition includes the following significant changes with respect to the previous edition:

- a) oxygen 93, detailing marking and colour coding, was introduced;
- b) figures for test conditions were clarified.

A list of all parts in the ISO 9170 series can be found on the ISO website.

Introduction

Terminal units are the points on a medical gas pipeline system where the operator makes connections and disconnections for the supply of specified medical gases to anaesthetic machines, lung ventilators or other items of medical equipment. Terminal units are also used for vacuum pipeline systems. A wrong connection can create a hazard to the patient or operator. It is important that terminal units and their components be designed, manufactured, installed and maintained in such a way as to meet the requirements specified in this document.

This document pays particular attention to

- suitability of materials,
- gas-specificity,
- cleanliness,
- testing,
- identification, and
- information supplied.

This document contains information for the installation and testing of terminal units prior to use. 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 7396-1 has been completed.

[Annex A](#) contains rationale statements for some of the requirements of this document. 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 document. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this document, but will also expedite any subsequent revisions.

[Annex B](#) contains environmental aspects that should be considered.

Terminal units for medical gas pipeline systems —

Part 1:

Terminal units for use with compressed medical gases and vacuum

1 Scope

This document is intended especially to ensure the gas-specific assembly, mechanical resistance, flow, leakage and pressure drop of terminal units and to prevent their interchange between different gases and services and applies to terminal units:

- a) intended for use in medical gas pipeline systems in accordance with ISO 7396-1;
- b) used as pressure outlets on pressure regulators in accordance with ISO 10524-1;
- c) used as pressure outlets on pressure regulators integrated with cylinder valves (VIPR) in accordance with ISO 10524-3.

This document applies to terminal units for use with the following gases for administration to patients or for medical uses (A):

- oxygen (A);
- nitrous oxide (A);
- medical air (A);
- carbon dioxide (A);
- oxygen/nitrous oxide mixture (A);
- helium/oxygen mixtures (A);
- oxygen 93 (A);
- gases and gas mixtures classified as medical device (A);
- gases delivered to medical devices or intended for medical purposes (A);
- gases and gas mixtures for medicinal use not specified above (A).

This document applies to terminal units for use with the following gases (B):

- air for driving surgical tools (B);
- nitrogen for driving surgical tools (B).

This document applies to terminal units for use with vacuum systems (C).

NOTE The requirements of this document can be used as guidelines for terminal units for other gases. These other gases will be considered for inclusion in this document when they come into general use.

This document specifies requirements for terminal units for supply and disposal of nitrogen and air for driving surgical tools.

This document specifies requirements for probes intended to be connected to the gas-specific connection point.

This document does not specify the dimensions of probes or of the gas-specific connection points.

NOTE Regional or national standards specifying dimensions of probes and gas-specific connection points are given in the Bibliography.

Other connection systems in national use may be acceptable under this document. Dimensioning for such connections will be specified by their respective national standards.

This document does not specify the requirements for terminal units for anaesthetic gas scavenging systems (AGSS), which are specified in ISO 9170-2.

2 *Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 32, *Gas cylinders for medical use — Marking for identification of content*

ISO 5359:2014, *Low-pressure hose assemblies for use with medical gases*

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

ISO 7396-1:2016, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 11114-3, *Transportable gas cylinders — Compatibility of cylinder and valve materials with gas contents — Part 3: Autogenous ignition test in oxygen atmosphere*

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

ISO 15001:2010, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

NOTE A diagram of a typical terminal unit and probe, with an example of terminology, is shown in [Figure 1](#).

3.1 diameter-index safety system connector DISS connector

any of a range of male and female components intended to maintain gas specificity by allocation of a set of different diameters to the mating connectors for each particular gas

3.2 gas specific

having characteristics which prevent connections between different gas services or vacuum services

3.3 gas-specific connection point

part of the socket which is the receptor for a gas-specific probe

3.4**gas-specific connector**

connector with dimensional characteristics that prevent connections between different gas services

Note 1 to entry: Examples of gas-specific connectors are *quick connectors* (3.14), screw-threaded connectors, *diameter-index safety system (DISS) connectors* (3.1), *non-interchangeable screw-threaded (NIST) connectors* (3.11) or *sleeve indexed (SIS) connectors* (3.16).

3.5**low-pressure hose assembly**

assembly consisting of a flexible hose with permanently attached gas-specific inlet and outlet connectors and designed to conduct a *medical gas* (3.7) at pressures less than 1 400 kPa and vacuum

3.6**medical device gas**

any gas or mixture of gases intended by the manufacturer to be used for human beings for the purpose of

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

Note 1 to entry: In Europe, these gases are classified as a medical device in accordance with Directive 93/42/EC.

3.7**medical gas**

any gas or mixture of gases having properties for treating or preventing disease in human beings which may be used in or administered either with a view to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis

Note 1 to entry: This is also sometimes referred to as medicinal gas.

Note 2 to entry: In Europe, this is classified as a medicinal product in accordance with Directive 2001/83/EC.

3.8**medical gas pipeline system**

complete system which comprises a supply system, a monitoring and alarm system and a distribution system with terminal units at the points where *medical gases* (3.7) or vacuum may be required

3.9**medical gas supply system**

either

- a) a medical gas pipeline system, or
- b) an installation having no permanent pipeline system but employing a *medical gas* (3.7) supply source complete with pressure regulator(s)

3.10**nominal distribution pressure**

pressure which the *medical gas pipeline system* (3.8) is intended to deliver at the terminal units

Note 1 to entry: Unless otherwise specified, pressures in this document are expressed as gauge pressures (i.e. atmospheric pressure is defined as 0 kPa gauge pressure).

3.11

non-interchangeable screw-threaded connector

NIST connector

range of male and female components intended to maintain gas specificity by the allocation of a set of different diameters and a left- or right-hand screw thread to the mating components for each particular gas

3.12

pressure regulator integrated with cylinder valve

VIPR

combination of a pressure regulator and cylinder valve intended to be fitted to a *medical gas* (3.7) cylinder

3.13

probe

gas-specific male component designed for acceptance by and retention in the socket

3.14

quick connector

pair of non-threaded gas-specific components which can be easily and rapidly joined together by a single action of one or both hands without the use of tools

3.15

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 1 to entry: Planned maintenance of equipment is considered a normal condition.

3.16

sleeve index system connector

SIS connector

range of male and female components intended to maintain gas specificity by the allocation of a set of different diameters to the mating connectors for each particular gas

3.17

socket

female part of a *terminal unit* (3.18) which is either integral or attached to the terminal unit base block by a gas-specific interface and which contains the gas-specific connection point

3.18

terminal unit

outlet assembly (inlet for vacuum) in a *medical gas pipeline system* (3.8) at which the operator makes connections and disconnections

3.19

terminal unit base block

part of a *terminal unit* (3.18) which is attached to the pipeline distribution system

3.20

terminal unit check valve

valve which remains closed until opened by insertion of an appropriate probe and which then permits flow in either direction

3.21

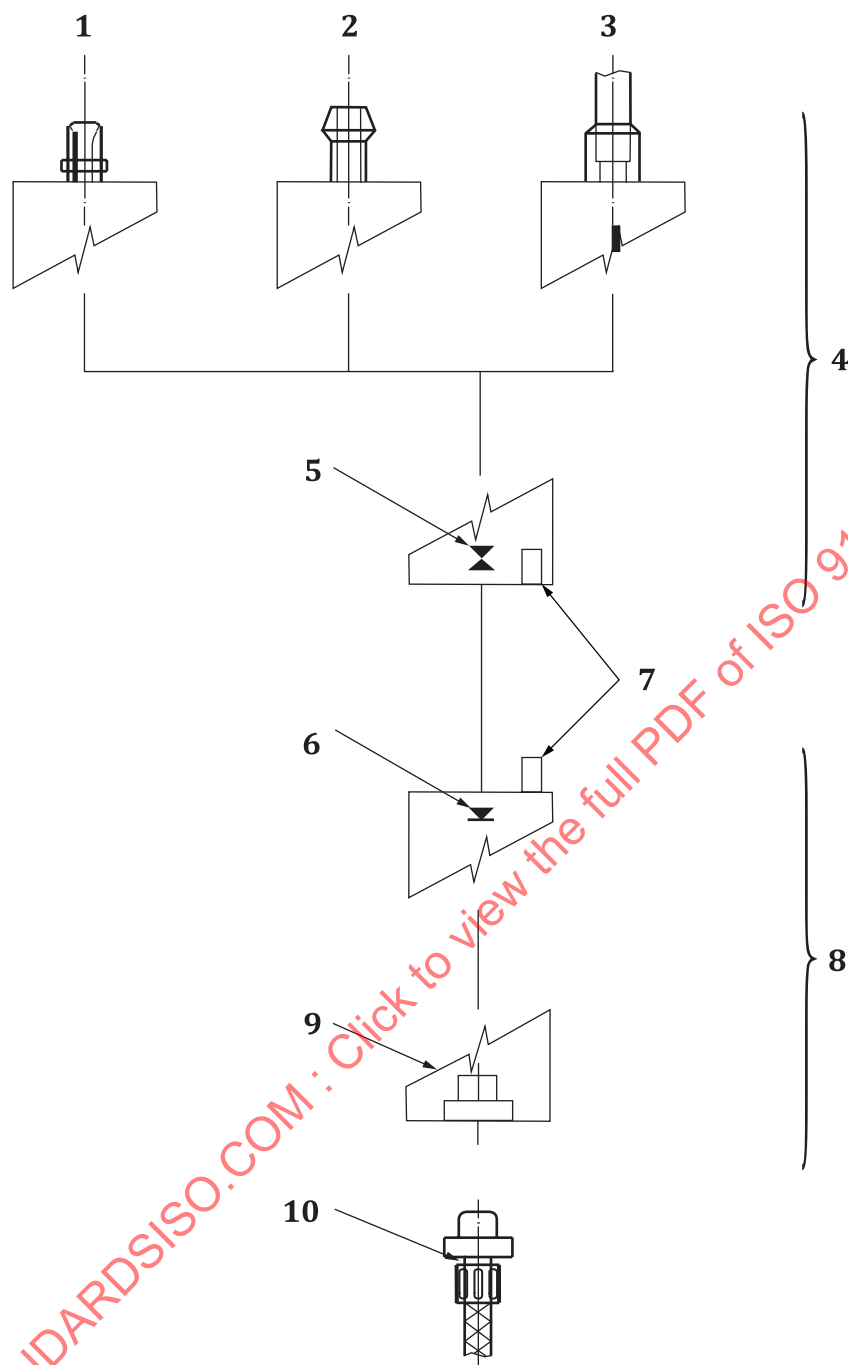
terminal unit maintenance valve

valve that permits maintenance of the terminal unit without shutting down the pipeline system to other terminal units

3.22**terminal unit for supply and disposal of nitrogen or air for driving surgical tools**

combination of an outlet assembly (for supply) and an inlet assembly (for disposal) which are connected to a *medical gas pipeline system* (3.8) and to a gas disposal system respectively and at which the operator makes connections and disconnections by means of a combined probe

STANDARDSISO.COM : Click to view the full PDF of ISO 9170-1:2017



Key

- 1 gas-specific connector
- 2 hose insert
- 3 point for brazed connection
- 4 base block
- 5 maintenance valve
- 6 check valve
- 7 gas-specific interface
- 8 socket
- 9 gas-specific connection point
- 10 probe

Figure 1 — Typical components of a terminal unit and probe

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 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 Maintenance of equipment is considered a normal condition.

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 fault condition subsequently detected needs to be considered as a single fault condition. Specific risk control measures to deal with such situations need to be determined within the risk management process.

Measures should be taken to minimize electrical and mechanical hazards. National or regional regulations concerning such hazards may exist.

4.2 *Alternative construction

Terminal units and components, or parts thereof, which use materials or have forms of construction different from those detailed in this document, shall be presumed to be in compliance with the safety objectives of this document 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.

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

NOTE Objective evidence can be obtained by postmarket surveillance.

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.

4.3 Materials

4.3.1 Materials in contact with the gases listed in the Scope, during normal use shall be resistant to corrosion and compatible with oxygen, the other gases and their mixtures in the temperature range specified in [4.3.2](#).

NOTE 1 Corrosion resistance includes resistance against moisture and surrounding materials.

NOTE 2 Oxygen compatibility is usually defined as the ability of a material to coexist with oxygen and a moderate ignition source. The aim of using oxygen-compatible materials is to develop a system design which has a low probability of ignition and low consequences based on the use of materials exhibiting good compatibility, low energy release if ignited or by minimizing the quantities of non-metallic components.

NOTE 3 Many materials which do not burn in air will do so in an oxygen enriched atmosphere, particularly under pressure. Similarly, materials which can be ignited in air require lower ignition energies to ignite in oxygen. Many such materials can be ignited by friction at a valve seat or by adiabatic compression produced when oxygen at high pressure is rapidly introduced into a system initially at low pressure.

NOTE 4 Design considerations and criteria for the selection of metallic and non-metallic materials are given in ISO 15001.

4.3.2 The materials shall permit the terminal units and their components to meet the requirements of ISO 9170-1 in the temperature range of $-20\text{ }^{\circ}\text{C}$ to $+60\text{ }^{\circ}\text{C}$.

4.3.3 Terminal units shall meet the requirements of ISO 9170-1 after being exposed, while packed for transport and storage, to environmental conditions as specified by the manufacturer.

4.3.4 Materials that are liable to shed particles which come in contact with the medical gas in normal condition or single-fault condition shall not be used for highly strained components and parts liable to wear.

EXAMPLE Springs.

NOTE See ISO 15001:2010, Annex C.

4.3.5 For terminal units for all gases, the auto-ignition temperature of the non-metallic components in contact with the gas, including the sealing materials and lubricants (if used), shall not be lower than 160 °C.

The determination of the auto-ignition temperature shall be carried out in accordance with ISO 11114-3.

NOTE The maximum permitted operating temperature of tested material is 100 °C lower than the auto-ignition temperature at the corresponding oxygen pressure. This safety margin is necessary because it covers both an unforeseen increase in the operating temperature and the fact that the auto-ignition temperature is not a constant. Values of the auto-ignition temperature always depend on the test method used, which may not exactly simulate all possible operating conditions.

4.3.6 Evidence of conformity with the requirements of [4.3.1](#) to [4.3.5](#) shall be provided by the manufacturer upon request.

NOTE There is a possibility that regional or national regulations 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 Design requirements

5.1 Medical gas supply

[Table 1](#) defines the pressure requirements for terminal units in accordance with their specific intended use.

5.1.1 Terminal units shall

- be designed to operate and meet the requirements of this document within the nominal distribution pressure range given in [Table 1](#),
- be designed to operate and meet the requirements of this document within the distribution pressure range given in [Table 1](#),
- not cause a hazard at the test pressure given in [Table 1](#), and
- be able to withstand the test pressure given in [Table 1](#) for 5 min and continue to meet the requirements of this document within the distribution pressure range given in [Table 1](#).

Table 1 — Terminal outlet pressure requirements

Medical gas supply system	Nominal distribution pressure range (kPa)	Distribution pressure range (kPa)	Test pressure (kPa)
Pipeline and/or pressure regulators for medical gases (A)	400 to 500	320 to 600	1 200
Pipeline and/or pressure regulators for gases for driving surgical tools (B)	700 to 1 000	560 to 1200	2 400
Pipeline for vacuum (C)	-40 (60 absolute)	-90 to -40 (10 to 60 absolute)	500

5.1.2 Evidence of conformity with the requirements of [5.1.1](#) shall be provided by the manufacturer upon request.

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

5.2 Terminal units for different pressures

Terminal units for the same gas at different nominal distribution pressures (e.g. medical air and air for driving surgical tools) shall have gas-specific connection points for each pressure range.

5.3 Retention of gas specificity

If any gas-specific component is removed from the terminal unit, the gas 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 re-assemble the components in such a way that the fully assembled terminal unit is no longer gas specific.

5.4 Gas-specific connection point

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

5.5 Terminal unit check valve

Each terminal unit shall include a check valve that shall open the gas supply when the probe is connected and shall shut off automatically when the probe is disconnected. The check valve shall be a component or assembly separate from the maintenance valve specified in [5.6](#).

5.6 Terminal unit maintenance valve

Except for vacuum services and terminal units for the supply and disposal of nitrogen or air for driving surgical tools, each terminal unit shall be equipped with a maintenance valve that may be manual or automatic. The maintenance valve shall be a separate component or assembly from the check valve specified in [5.5](#).

Rationale:

Terminal units for the supply and disposal of nitrogen or air for driving surgical tools do not need a maintenance valve. Regarding the ISO 7396-1, an area shut-off valve shall be provided in each gas and vacuum pipeline serving for each operating theatre. In the case of maintenance, the operator has to shut off the drive gas with this area shut off valve.

A leakage from the terminal unit maintenance valve is permitted provided it causes no unacceptable risk to the operator while changing the socket under nominal distribution pressure.

Evidence shall be provided by the manufacturer upon request.

5.7 Connection of terminal units to the pipeline (see also 9.2)

5.7.1 Except for connection to a disposal system for nitrogen or air for driving surgical tools, the base block of a terminal unit shall be designed and manufactured for either permanent (e.g. by brazing or welding) or gas-specific (e.g. by means of an NIST, DISS or SIS body) connection to a pipeline distribution system. The connection shall comply with ISO 7396-1.

5.7.2 Connection to a low-pressure hose shall be either by direct ferruling on to a hose insert or by means of a gas-specific connector and shall comply with ISO 5359 (see [Figure 1](#)).

5.8 Socket

The attachment of a socket to its base block shall be gas specific.

5.9 Compliance

Compliance with [5.2](#) to [5.8](#) shall be tested by visual inspection, functional testing and/or measurement.

5.10 Endurance (connection/release)

5.10.1 Socket

The socket shall retain gas specificity and meet the requirements given in [Table 2](#) after testing in accordance with [7.2.1](#).

5.10.2 Probe

The probe shall retain gas specificity and meet the requirements given in [Table 2](#) after testing in accordance with [7.2.2](#).

5.11 *Pressure drop

The pressure drop across the terminal unit and its probe, measured at the test pressures and with the test flows given in [Table 2](#), shall not exceed the values given in [Table 2](#).

For terminal units for supply and disposal of nitrogen or air for driving surgical tools, the pressure drop across the outlet assembly shall not exceed the value given in [Table 2](#); the pressure drop across the inlet assembly shall not exceed 25 kPa with a back pressure not exceeding 15 kPa.

The test for pressure drop is given in [7.3](#).

Table 2 — Requirements for flow and pressure drop across terminal units with probe inserted

Terminal unit nominal distribution pressure range kPa	Test pressure kPa	Test flow l/min	Maximum pressure drop across a terminal unit kPa
400 to 500	320	40	15
400 to 500	320	200	70
700 to 1 000	560	350	100
Vacuum	–40 (60 absolute)	25	15

NOTE The values in [Table 1](#) are in accordance with the requirements in ISO 7396-1:2016, 7.2.1, 7.2.2, 7.2.3, 7.2.4 and Table 2 and ISO 5359:2014, 4.4.14.

5.12 Connection force and torque

The force and the torque required to insert and lock the probe into the terminal unit shall be

- a) a torque not exceeding 1 Nm, and
- b) axial force according to [Table 3](#).

Table 3 — Axial force requirements for connections

Terminal unit nominal distribution pressure range kPa	Test pressure kPa	Maximum allowed axial connection force N
700 to 1 000	1 200	200
400 to 500	600	100
Vacuum	–40 (60 absolute)	100

The test for connection force and torque is given in [7.4](#).

5.13 Disconnection force and torque

5.13.1 The force and the torque required to release the locking mechanism shall be

- a) a push or pull of not more than 110 N and not less than 20 N, and/or
- b) a torque of not more than 1 Nm and not less than 0,1 Nm.

5.13.2 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.

5.13.3 The test for disconnection force and torque is given in [7.5](#).

NOTE Danger to personnel can arise as a result of the rapid expulsion of probes from terminal units. The design can prevent this from occurring.

5.14 Mechanical strength

The terminal unit shall withstand the application of a steady axial tensile force of at least 500 N. The test for mechanical strength is given in [7.6](#).

5.15 Leakage

5.15.1 The leakage from a terminal unit with or without the probe inserted shall not exceed 0,296 ml/min (which is equivalent to 0,03 kPal/min).

The test for leakage is given in [7.7](#).

5.16 Gas specificity

The terminal unit shall only accept the probe for the gas for which it is intended. The test for gas specificity is given in [7.8](#).

National or regional regulations may allow the use of the terminal unit and the probe for oxygen to also be used for oxygen 93 provided they are identified with the relevant symbol and/or colour coding.

5.17 Effective connection of probes

A tactile and/or audible indication of locking shall be perceived on retention of the gas-specific probe. The test for effective connection of probes is given in [7.9](#).

5.18 Electrical requirements

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

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

NOTE 2 [Annex C](#) lists some regional and national regulations for electrical installations.

6 Constructional requirements

6.1 Cleaning

Terminal units for all services shall be cleaned to meet the requirements of ISO 15001. Evidence shall be provided by the manufacturer upon request.

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

6.2 Lubricants

If lubricants are used, they shall be compatible with oxygen, the other medical gases and their mixtures in the temperature range specified in [4.3.2](#).

Evidence shall be provided by the manufacturer upon request.

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

7 Test methods

7.1 General

The test methods given below are type tests. Production test methods and sampling criteria are outside the scope of this document.

7.1.1 Ambient conditions

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

7.1.2 Test gas

All positive pressure 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.

Tests for the pressure drop across terminal units for vacuum using the apparatus shown in [Figure 3](#) shall use ambient air.

7.1.3 Reference conditions

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

7.2 Test for endurance

7.2.1 Socket

Fix the terminal unit to be tested to a horizontal or vertical surface, as appropriate, using the procedure recommended by the manufacturer. Apply a test pressure at the inlet to the base block of the terminal unit. Use a test pressure of 1 200 kPa for terminal units for nitrogen or air for driving surgical tools, a test pressure of 600 kPa for all other terminal units for compressed gases or a test pressure of -40 kPa for vacuum.

Using a test probe made of corrosion-resistant steel of minimum chromium content of 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, with the seals being changed every 1 000 operations or according to the manufacturer's instructions, whichever is the greater interval.

Test the socket for compliance with [Table 1](#).

7.2.2 Probe

Fix a terminal unit complying with this document to a horizontal or vertical surface, as appropriate, using the procedure recommended by the manufacturer. Apply a test pressure at the inlet to the base block of the terminal unit. Use a test pressure of 1 200 kPa for terminal units for nitrogen or air for driving surgical tools, a test pressure of 600 kPa for all other terminal units for compressed gases or a test pressure of -40 kPa for vacuum.

Connect and release the probe 10 000 times at a frequency of not more than 10 operations per minute, with the seals being changed every 1 000 operations or according to the manufacturer's instructions, whichever is the greater interval.

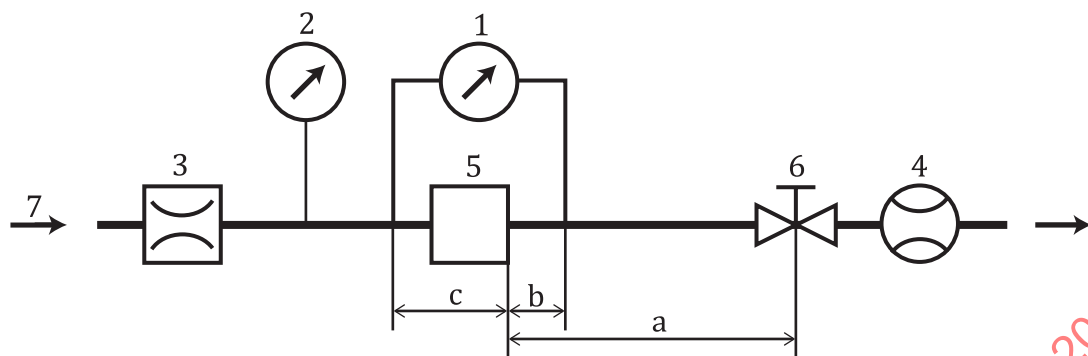
Test the probe for compliance with [Table 1](#).

7.3 Test for pressure drop

Using an apparatus of typical configuration as shown in [Figure 2](#) for terminal units for compressed medical gases, [Figure 3](#) for terminal units for vacuum or [Figure 4](#) for terminal units for supply and disposal of nitrogen or air for driving surgical tools, set the test pressure and flow at the inlet of the terminal unit to the appropriate values given in [Table 1](#).

Measure the pressure drop across the terminal unit with the probe inserted.

For terminal units for the supply and disposal of nitrogen or air for driving surgical tools, measure the pressure drops across the outlet and inlet assemblies simultaneously.



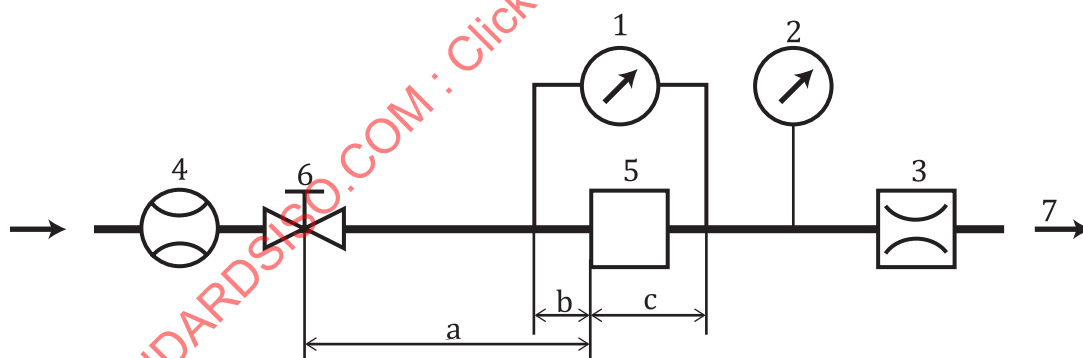
Key

- | | | | |
|---|--|---|--------------------|
| 1 | pressure-differential measuring device | 6 | flow control valve |
| 2 | pressure gauge | 7 | pressure supply |
| 3 | pressure regulator | a | 100 cm |
| 4 | flowmeter | b | 10 cm |
| 5 | terminal unit with probe inserted | c | 20 cm |

NOTE Dimensions a, b and c are given as the typical configuration. Other dimensions can be used and the effect of the pressure drop is taken into account when choosing measurement equipment.

Figure 2 — Typical apparatus for measuring pressure drop across a terminal unit for compressed medical gases

Rationale: Reference dimensions noted in [Figure 2](#) are used for consistency in testing.

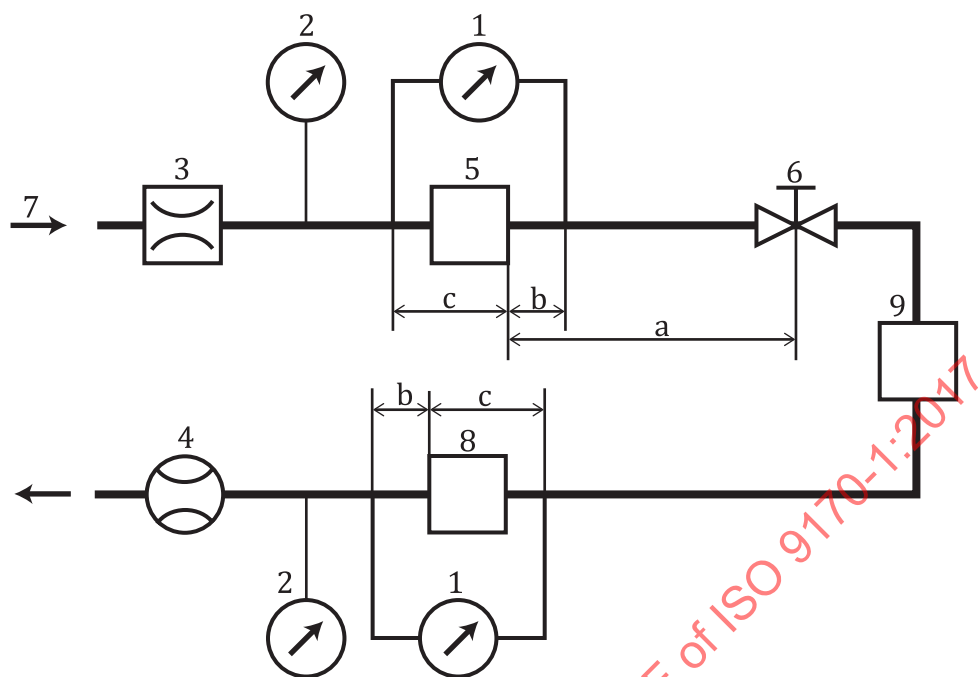


Key

- | | | | |
|---|--|---|--------------------|
| 1 | pressure-differential measuring device | 6 | flow control valve |
| 2 | pressure gauge | 7 | vacuum supply |
| 3 | vacuum regulator | a | 100 cm |
| 4 | flowmeter | b | 10 cm |
| 5 | terminal unit with probe inserted | c | 20 cm |

NOTE Dimensions a, b and c are given as the typical configuration. Other dimensions can be used and the effect of the pressure drop is taken into account when choosing measurement equipment.

Figure 3 — Typical apparatus for measuring pressure drop across a terminal unit for vacuum

**Key**

1	pressure-differential measuring device	7	pressure supply
2	pressure gauge	8	inlet assembly of terminal unit with probe inserted
3	pressure regulator	9	connection between supply and disposal side of the probe
4	flowmeter	a	100 cm
5	outlet assembly of terminal unit with probe inserted	b	10 cm
6	flow control valve	c	20 cm

NOTE Dimensions a, b and c are given as the typical configuration. Other dimensions can be used and the effect of the pressure drop is taken into account when choosing measurement equipment.

Figure 4 — Typical apparatus for measuring pressure drop across a terminal unit for supply and disposal of nitrogen or air for driving tools

Rationale: Reference dimensions noted in [Figure 2](#) are used for consistency in testing.

7.4 Test for connection force and torque

Adapt a blank 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.

Apply a test pressure at the inlet to the base block of the terminal unit. Use a test pressure of 1 200 kPa for terminal units for nitrogen or air for driving surgical tools, a test pressure of 600 kPa for all other terminal units for compressed gases or a test pressure of –40 kPa for vacuum.

In accordance with the manufacturer's instructions, insert the adapted blank probe into the terminal unit and record the force and/or torque required to insert and lock the probe.

7.5 Test for disconnection force and torque

Adapt a blank 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.

Apply a test pressure at the inlet to the base block of the terminal unit. Use a test pressure of 640 kPa for terminal units for nitrogen or air for driving surgical tools, a test pressure of 320 kPa for all other terminal units for compressed gases or a test pressure of –60 kPa for vacuum.

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 and disconnect the probe in accordance with the manufacturer's instructions. Record the force and/or torque required to release each locking mechanism. If the recommended disconnection method involves applying, for example, a compressive force to reduce the effort required to disengage the locking mechanism, measure each separate force/torque involved.

7.6 Test for mechanical strength

Adapt a blanked probe in order to apply tensile force.

Fix the terminal unit to a suitable surface using the procedure recommended by the manufacturer.

Apply a test pressure at the inlet to the base block of the terminal unit. Use a test pressure of 1 200 kPa for terminal units for nitrogen or air for driving surgical tools, a test pressure of 600 kPa for all other terminal units for compressed gases or a test pressure of –40 kPa for vacuum.

Insert the adapted probe.

Apply a tensile force of 500 N and hold it for 1 min.

Remove the tensile force and check that the terminal unit is completely functional and the leakage is in accordance with [Table 1](#).

Dismantle the terminal unit and check that no damage or distortion has occurred to either the terminal unit components or the probe.

7.7 Test for leakage

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

Apply a test pressure at the inlet of the base block of the terminal unit. Use the following test pressures:

- a) 320 kPa and 600 kPa for terminal units for compressed medical gases;
- b) 560 kPa and 1 200 kPa for terminal units for nitrogen or air for driving surgical tools;
- c) –90 kPa and –40 kPa for vacuum.

Measure the leakage under the conditions of maximum test pressure and minimum test pressure.

7.7.2 Keep the terminal unit pressurized as described in [7.7.1](#) and insert a gas-specific blanked probe.

Measure the leakage under the conditions of maximum and minimum test pressures.

7.7.3 Apply a force of 20 N perpendicular to the long axis of the probe, 50 mm from the outermost surface of the terminal unit. Measure the leakage while the force is applied to the probe under the conditions of maximum and minimum test pressures.

7.8 Test for gas specificity

Carry out the test by attempting to connect gas-specific test probes for all other medical gases, in turn, to the gas-specific connection point of each socket.

7.9 Test for effective connection of probe

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

7.10 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 markings required in 8.1 and 8.2 are still legible.

8 Marking, colour coding and packaging

8.1 Marking

8.1.1 Terminal units, probes and their gas-specific components shall be durably and legibly marked with the symbol of the relevant gas in accordance with Table 4.

The test for the durability of markings is given in 7.10.

NOTE In addition to the symbol, the name of the gas can be used.

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

8.1.3 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.

8.2 Colour coding

8.2.1 If colour coding is used, it shall be in accordance with Table 4 or the appropriate regional or national standard.

8.2.2 Colour coding shall be durable.

The test for the durability of colour coding is given in 7.10.

Table 4 — Symbols and colour coding for medical gases

Medical gas or mixture	Symbol	Colour coding ^{a, b}
Oxygen	O ₂	White
Oxygen 93	O ₂ 93	White-Emerald green
Nitrous oxide	N ₂ O	Blue
Medical air	Air ^c	Black-White
^a According to ISO 32, except vacuum.		
^b An example of yellow is given by NCS 0060Y in SS 01 92 02.		
^c National languages may be used for air and vacuum.		

Table 4 (continued)

Medical gas or mixture	Symbol	Colour coding ^{a, b}
Air for driving surgical tools	Air – 800 ^c	Black-White
Air for driving surgical tools (with disposal)	Air motor ^c	Black-White
Nitrogen for driving surgical tools	N ₂ – 800	Black
Nitrogen for driving surgical tools (with disposal)	N ₂ motor	Black
Carbon dioxide	CO ₂	Grey
Oxygen/nitrous oxide mixtures	O ₂ /N ₂ O	White-blue
Helium/Oxygen mixtures	He/ O ₂	Brown-White
Vacuum	Vac ^c	Yellow
^a According to ISO 32, except vacuum.		
^b An example of yellow is given by NCS 0060Y in SS 01 92 02.		
^c National languages may be used for air and vacuum.		

8.3 Packaging

8.3.1 Terminal units, gas-specific probes and spare parts shall be sealed to protect against particulate contamination and packaged to prevent damage during storage and transportation.

8.3.2 Packages shall provide a means of identification of the contents.

9 Information to be supplied by the manufacturer

9.1 Technical description

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

9.2 Instructions

9.2.1 The manufacturer shall provide instructions for installation and a reference to the testing procedures for terminal units given in ISO 7396-1.

9.2.2 Instructions for use shall include information necessary for the operation of the terminal unit in accordance with its specification and shall include 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.

9.2.3 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

A.1 General

This annex provides a rationale for some requirements of this document and is intended for those who are familiar with the subject of this document 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 document necessitated by those developments.

The following correspond to clauses and subclauses marked with an asterisk (*) in this document. The numbering is, therefore, not consecutive.

A.2 References

A.2.1 Only dated references are used in this document. As stated in the preamble of the European Medical Device Directive 93/42/EEC, manufacturers shall take account of technology and practice existing at the time of design and of technical and economic 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 that 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 amendment of existing standards.

A.2.2 SG1 of the Global Harmonization Task Force (GHTF) (www.ghtf.org) is developing a guideline, SG1/N044^[15], which addresses the need to use dated references.

A.2.3 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.2.3 The testing of vacuum pipeline systems given in ISO 7396-1 requires exposure of vacuum terminal units to a positive pressure of 500 kPa for 5 min as a test of mechanical integrity.

A.2.4 Lung ventilators can require peak flows of 200 l/min for up to 3 s. Experience shows that such ventilators can be supplied by terminal units that meet the requirements of 5.11.

A.2.5 Terminal units for different gases are often made with interchangeable components or subassemblies. The requirement for compatibility with oxygen should, therefore, be applied to terminal units for all gases.