INTERNATIONAL STANDARD

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Terminal units for use in medical gas pipeline systems

Prises murales utilisées dans des réseaux de distribution de gaz médicaux

Reference number
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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.

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 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*.

Annexes A, B, C, D and E form an integral part of this International Standard. Annexes F, G and H are for information only.

Introduction

Terminal units are the points on a medical gas pipeline system where the user makes connections and disconnections in the supply of a variety of medical gases to anaesthetic machines or other items of medical equipment, and where a wrong connection may create a hazard to the life of a patient.

It is important therefore that terminal units and their components are designed, manufactured and installed in such a way as to provide the necessary safety requirements and this International Standard pays particular attention to:

— cleanliness and suitability of materials;

— testing;

— gas-specificity;

— identification and labelling;

— maintenance.

In any one health care facility, gas-specific connection points of only one design should be used for any particular gas. Terminal units of more than one design, which are compatible with these gas-specific connection points, may be installed.

Where medical gas is distributed throughout health care facilities at different pressures, it is essential that the gas-specific components are specific for each pressure.

During hospital renovation it may be desirable to upgrade existing medical gas installations rather than completely renew them. For terminal units this may be achieved via conversion or modification kits. It is recognized that with terminal units modified in this way, it may not be possible to achieve the flow and pressure drop requirements of this International Standard, due to limitations imposed by those components of the original terminal units that remain in the pipeline system or by the pipeline system itself.

This International Standard does not specify the installation, testing and certification of terminal units. Testing is critical to patient safety and it is essential that terminal units are not used until full testing in accordance with ISO 7396 has been completed.

The manufacturer should supply installation and maintenance instructions. The purchaser of the system should ensure correct installation and testing. The owner or user of the system should ensure that proper maintenance is carried out under an effective method of control.

In many countries, there are national standards, regulations or legal requirements dealing with one or more matters referred to in this Inter-

national Standard, for example building, fire and electrical regulations. These often vary in their details and it is recognized that these may have to take precedence over the requirements of this International Standard.

Annex A to annex E describe test methods used to verify compliance with performance requirements.

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Terminal units for use in medical gas pipeline systems

1 Scope

This International Standard specifies minimum performance and safety requirements for terminal units intended for use in non-flammable medical gas pipeline systems specified in ISO 7396 for use with the following medical gases:

— oxygen;

— nitrous oxide;

— medical air;

— nitrogen;

— helium;

— carbon dioxide;

— specified mixtures of the above gases;

— medical vacuum.

It is intended especially to ensure the gas-specific assembly of terminal units and to prevent their interchange between different gases.

This International Standard also specifies requirements for conversion and modification kits for use with terminal units in existing installations.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 32:1977, *Gas cylinders for medical use — Marking for identification of content.*

ISO 5359:1989, *Low-pressure flexible connecting assemblies (hose assemblies) for use with medical gas systems.*

ISO 7396:1987, *Non-flammable medical gas pipeline systems.*

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 non-flammable medical gas pipeline system: Central supply system with control equipment, a pipeline distribution system and terminal units at the points where non-flammable medical gases may be required.

3.2 terminal unit: Outlet assembly (inlet for vacuum) in a piped medical gas distribution system at which the user makes connections and disconnections.

3.3 terminal unit check valve: Valve which remains closed until opened by insertion of an appropriate probe and which then permits flow in either direction.

3.4 terminal unit maintenance valve: Valve within the terminal unit assembly which permits maintenance of the terminal unit without shutting down the pipeline system to other terminal units.

3.5 terminal unit base block: That part of a terminal unit which is attached to the pipeline distribution system.

3.6 gas-specific: Having characteristics which prevent interchangeability and thereby allow assignment to one gas or vacuum service only.

3.7 gas-specific connection point: That part of a terminal unit which is the receptor for a non-interchangeable gas-specific connector and which is either integral or attached to the base block by the appropriate non-interchangeable gas-specific device.

3.8 gas-specific connector: Screw-threaded connector [either NIST (non-interchangeable screw-threaded) or DISS (diameter-index safety system)], or a non-interchangeable quick connector. (See ISO 5359.)

3.9 low-pressure flexible connecting assembly (hose assembly): Assembly which consists of a hose with permanently attached gas-specific supply and equipment connectors which is designed to conduct a medical gas at pressures between 300 kPa and 1 400 kPa and for use with a vacuum service at pressures between 40 kPa and 90 kPa below atmospheric pressure.

3.10 maximum operating pressure: Maximum pressure at which the terminal unit is designed to operate.

3.11 maximum test pressure: Maximum pressure to which the terminal unit is designed to be subjected during pipeline pressure testing.

3.12 conversion kit: Gas-specific assembly of components supplied by a manufacturer that is intended to change the configuration of a terminal unit made by another manufacturer.

3.13 modification kit: Gas-specific assembly of components supplied by a manufacturer that is intended to change the configuration of a terminal unit of his own manufacture.

3.14 quick connector: Pair of 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, usually consisting of a probe and socket with check valve.

4 Materials and cleaning

The components of terminal units for all services shall be supplied clean and free from oil, grease and particulate matter.

NOTES

1 Any method of cleaning and degreasing may be used which effectively removes all surface dirt and hydrocarbons, and which leaves no residue itself. Chemical cleaning methods will normally require a subsequent washing and drying process to remove residues.

2 Recommendations for materials are given in annex F.

3 Lubricants recommended for use in oxygen atmospheres at the appropriate pressure may be used.

5 Design

The principal components of a terminal unit are shown in figure 1.

Terminal units of the quick-connect design should permit single-handed insertion and release of the quick-connect probe when the terminal unit is rigidly mounted.

If the axis of an installed terminal unit of the quick-connect design is horizontal, the terminal unit may include a non-swivel feature for the quick-connect probe. If the axis is vertical, as in a pendant, the non-swivel feature may be omitted.

5.1 Incomplete assembly

If any component is removed from the terminal unit, it shall either render the terminal unit inoperable or shall maintain its gas-specificity. (See also 5.5.1 and 5.6.1.)

5.2 Gas-specific connection

Each terminal unit shall include a gas-specific connection point which shall accept only the appropriate gas-specific connector. This connection point on the terminal unit shall be either a quick-connect socket or the body of a DISS or NIST connector complying with ISO 5359.

Terminal units for the same gas at different pressures shall have specific connection points for each pressure.

5.3 Terminal unit check valve

Each terminal unit shall include a check valve which shall open the gas supply when the connection is made and which shall shut off automatically when the connection is broken. The check valve shall be a separate component or assembly from the maintenance valve specified in 5.4.

5.4 Terminal unit maintenance valve

Except for vacuum services, each terminal unit shall be equipped with a maintenance valve, which may be manual or automatic. The maintenance valve shall be a separate component or assembly from the check valve specified in 5.3.

5.5 Connection or terminal units

5.5.1 The base block of a terminal unit shall be designed and manufactured for either permanent or gas-specific connection to a pipeline.

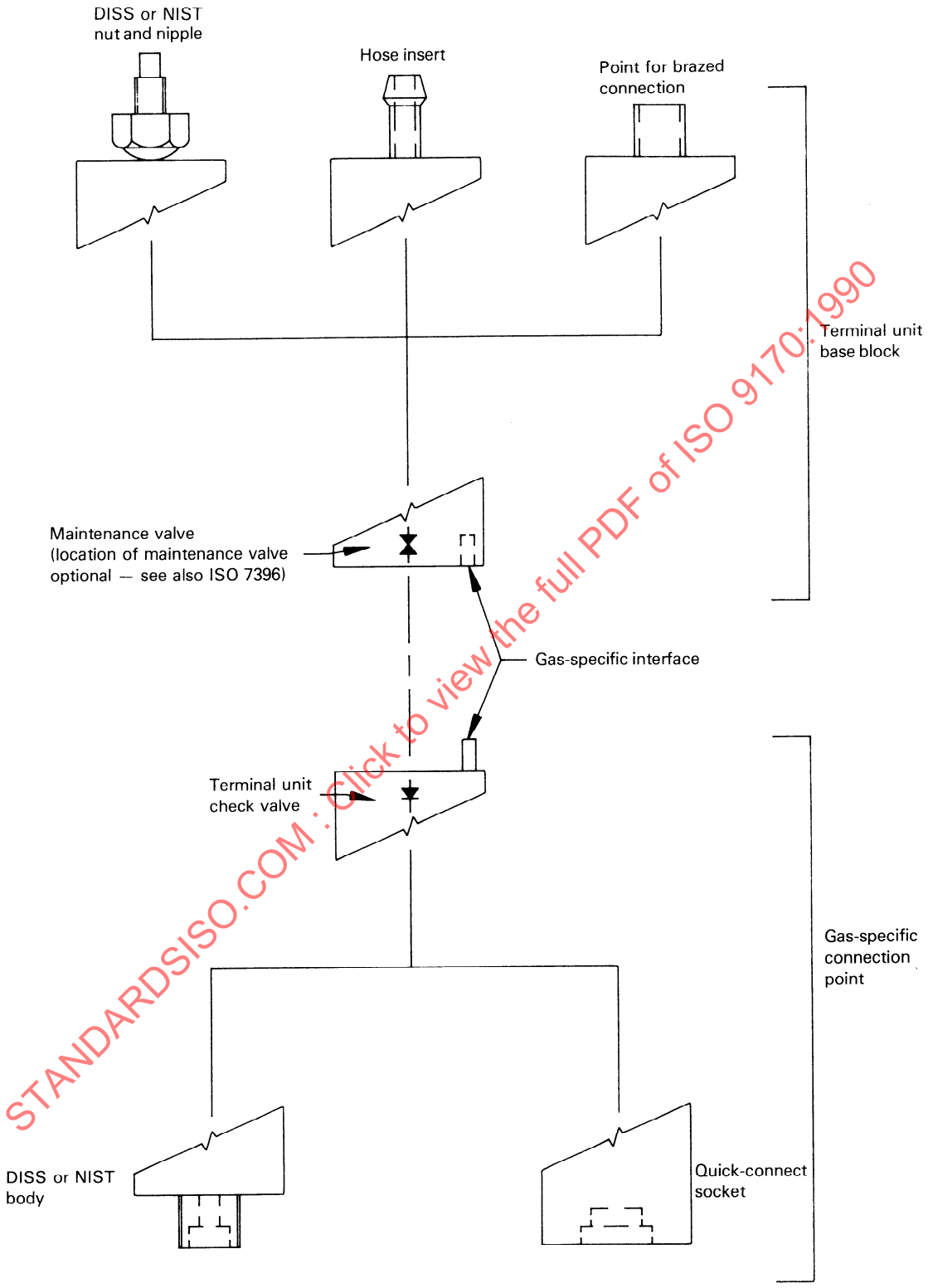

Figure 1 — Typical diagram of a terminal unit showing inlet and outlet connections

5.5.2 Connection to a permanent pipeline distribution system shall be either by brazing or by means of a DISS or NIST connector complying with ISO 5359.

5.5.3 When connected to a low-pressure flexible connecting assembly, connection shall be either by direct ferruling (see ISO 5359) or by a gas-specific connector.

5.6 Non-interchangeable gas-specific connection point (socket assembly)

5.6.1 The arrangement for attaching a gas-specific connection point (socket assembly) to its terminal unit base block for a particular service shall be of a design which prevents interchangeability with the base block of any other service.

5.6.2 If the base block can be dismantled, the components shall not be capable of being reassembled in such a way that the fully-assembled terminal unit is no longer gas-specific.

5.6.3 The gas-specific connection point shall be accessible for maintenance. If the assembly can be dismantled, the components shall not be capable of being reassembled in such a way that the fully-assembled terminal unit is no longer gas-specific.

5.7 Installation

The design of flush-mounted terminal units shall allow for variations in wall thickness.

NOTES

4 If boxes are used, they should be resistant to corrosion.

5 Each surface-mounted terminal unit should be protected from damage.

6 Terminal units for suspension on a flexible connecting assembly should either be buffered to prevent damage to adjacent terminal units or be manufactured from materials which will avoid such damage.

5.8 Conversion kits

5.8.1 Conversion kits shall comply with the requirements given in 5.1, 5.2, 5.3, 5.6 and clause 6.

5.8.2 A conversion kit shall be designed to ensure that after conversion a terminal unit shall comply with the requirements given in 7.2.2 to 7.3.3.

When a conversion kit is type-tested by converting a terminal unit with the kit and testing the converted terminal unit as described in annex A, the following requirements shall be met.

Either

a) if the pressure drop across the terminal unit before conversion is lower than that given in table 2, the pressure drop after conversion shall not be higher than that given in table 2; or

b) if the pressure drop across the terminal unit before conversion is higher than that given in table 2, the pressure drop after conversion shall be no higher than that before conversion.

5.9 Modification kits

5.9.1 Modification kits shall comply with the requirements given in 5.1, 5.2, 5.3, 5.4, 5,6 and clause 6.

5.9.2 A modification kit shall be designed to ensure that after modification a terminal unit shall comply with the requirements given in 7.2.2 to 7.3.3.

When a modification kit is type-tested by modifying a terminal unit with the kit and testing the modified terminal unit as described in annex A, the following requirements shall be met.

Either

a) if the pressure drop across the terminal unit before modification is lower than that given in table 2, the pressure drop after modification shall not be higher than that given in table 2; or

b) if the pressure drop across the terminal unit before modification is higher than that given in the table 2, the pressure drop after modification shall be no higher than that before modification.

6 Marking, labelling, packaging

6.1 Marking

6.1.1 Terminal units and their gas-specific components or assemblies shall, unless it is prevented by their size, be permanently and legibly marked with the medical gas name or the identification symbol of the relevant gas, in accordance with table 1. The height of the lettering shall be at least 2,5 mm.

Table 1 — Symbols used for medical gases

Medical gases or mixture name	Symbol
Oxygen	O_2
Nitrous oxide	N_2O
Medical air	Air[1]
Nitrogen	N_2
Helium	He
Carbon dioxide	CO_2
Mixtures of the above gases	[2]
Medical vacuum	Vac[1]

1) The symbols "air" and "vac" may be used in the appropriate language.

2) See ISO 32.

6.1.2 If the same gas is supplied at two different pressures, the operating pressure shall be marked on each terminal unit.

6.1.3 Gas-specific connection points shall be marked with the manufacturer's name or identification mark.

6.2 Colour coding

6.2.1 If colour coding is applied, the gas-specific connection point or the fascia plate shall be colour-coded in accordance with either ISO 32 or the appropriate national standard.

6.2.2 Materials used for colour coding shall be of a permanent nature, e.g. coloured plastics, vitreous enamel or similar material.

6.3 Packaging

6.3.1 Components shall be packaged or sealed to maintain cleanliness during transportation and storage. Packages shall provide a means of identification of the contents.

6.3.2 Components or assemblies that are intended to be installed at different stages of a project, or which are for use in subsequent maintenance, shall be packaged separately.

7 Performance and testing

7.1 General

Testing shall be carried out using clean, oil-free, dry air or nitrogen as the test gas.

7.2 Type tests

Type tests shall be carried out on terminal units and repeated on any change of design or material.

7.2.1 Pressure drop

When tested as described in annex A, the pressure drop across the terminal unit and its connector shall not exceed the values given in table 2.

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

Terminal unit operating pressure kPa	Test pressure kPa	Terminal unit flow l/min	Maximum pressure drop across a terminal unit kPa
0 to 500	500	200	70
501 to 1 400	1 400	550	70
Vacuum	− 60	40	15

7.2.2 Operation (connection/release)

The terminal unit shall retain gas-specificity and shall meet the requirements given in 7.2.1, 7.2.3, 7.2.4, 7.2.5 and 7.2.6, following pressurization to the appropriate test pressure given in table 2, and connection then release of the connector 10 000 times, with the seals being changed every 1 000 operations.

7.2.3 Connection force

When tested as described in annex B, the maximum force required shall be

a) an axial force not exceeding 100 N, and/or

b) a torque not exceeding 1 N·m.

7.2.4 Mechanical strength

When tested as described in annex C, the attachment shall withstand application of a steady axial tensile force of not less than 500 N.

7.2.5 Disconnection forces

7.2.5.1 When tested as described in annex D, release of the locking mechanisms shall require

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 N·m and not less than 0,1 N·m.

7.2.5.2 When tested as described in annex D, when all locking provisions have been released according to the manufacturer's instructions, disconnection of a terminal unit and connector shall require an axial tensile force of not more than 100 N.

7.2.6 Leakage

When tested as described in annex E, the leakage from a terminal unit shall not exceed 0,48 l/24 h (0,333 ml/min).

7.3 Production tests

NOTE 7 The manufacturer's quality control system should ensure continuing compliance with the requirements given in 7.3.1, 7.3.2 and 7.3.3. Documentation of such compliance should be retained.

7.3.1 Leakage

When tested as described in annex E, the leakage from a terminal unit shall not exceed 0,48 l/24 h (0,333 ml/min).

7.3.2 Gas-specificity

When tested by insertion/connection of all gas-specific test connectors for terminal units of the particular design, the terminal unit shall accept only that test connector for the medical gas for which it is intended.

7.3.3 Effective connections

When tested by insertion of a gas-specific test connector, there shall be a tactile or audible indication of locking.

NOTE 8 This test may be carried out at the same time as the test in 7.3.2.

8 Information to be supplied by the manufacturer

8.1 The manufacturer shall provide the following information:

a) with every shipment of terminal units, conversion kits and modification kits or separately packed sub-assemblies:

   Installation instructions with a statement of the maximum test pressure.

b) on request:

   1) assembly and operating instructions;

   2) a statement of conformity with this International Standard;

   3) a statement of the maximum operating pressure;

   4) recommended maintenance tasks and frequency;

   5) a list of recommended spare parts;

   6) a statement of oxygen compatibility at maximum operating pressure (see also annex F).

Annex A
(normative)

Test method for pressure drop

Using an apparatus of typical configuration shown in figure A.1 for pressure or figure A.2 for vacuum, set test pressure and flow to the values given in table 2. Read the pressure drop across the terminal unit.

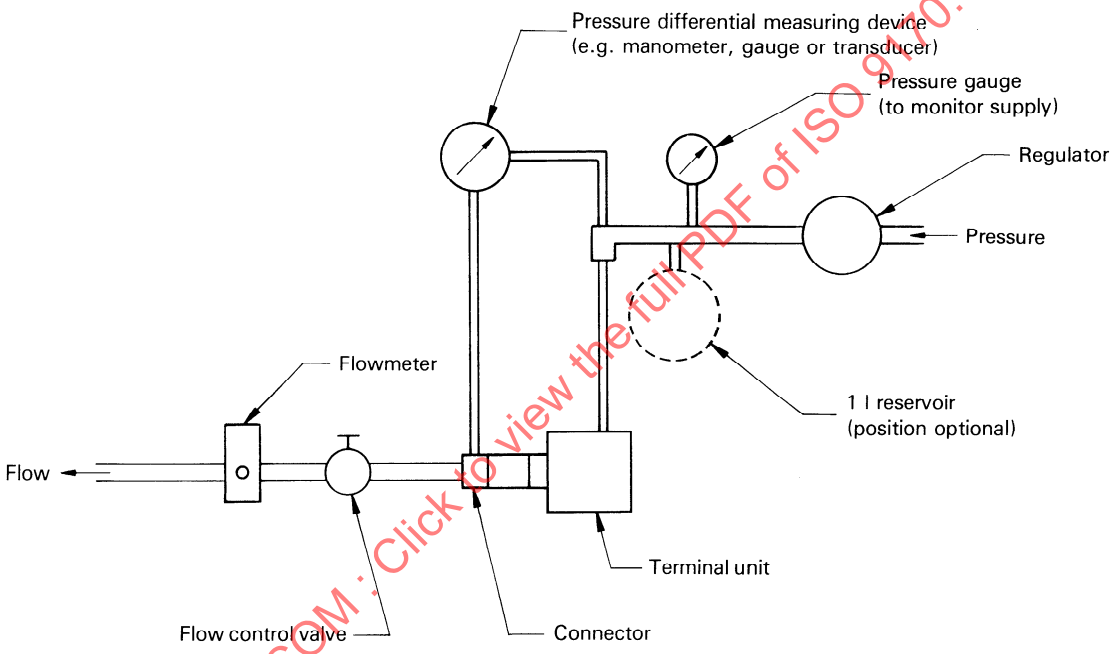

Figure A.1 — Typical apparatus for measuring pressure drop across pressurized gas terminal units

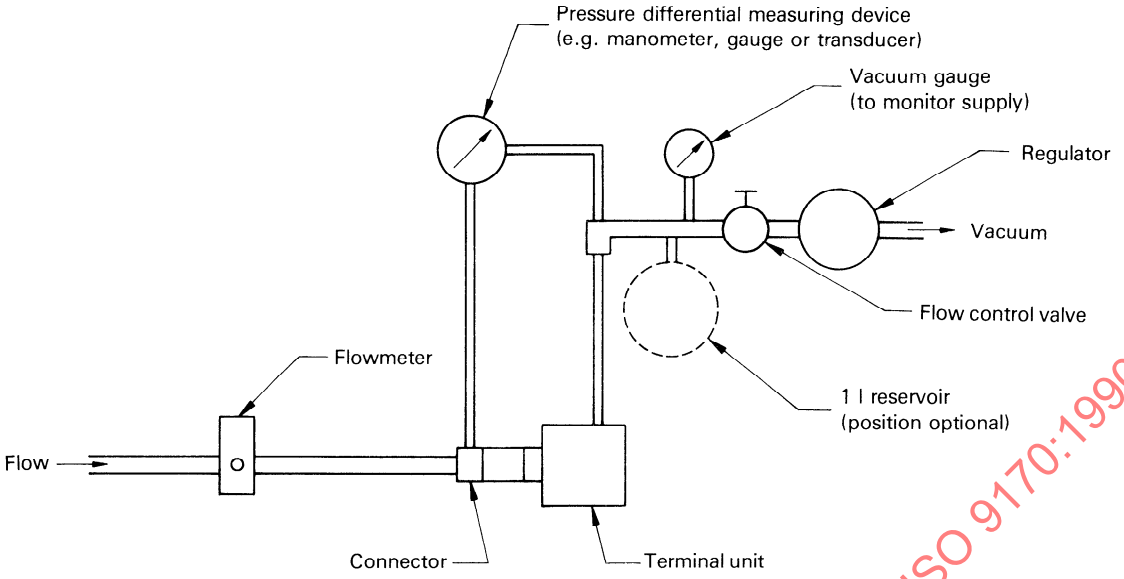

Figure A.2 — Typical apparatus for measuring pressure drop across vacuum terminal units

Annex B
(normative)

Test method for connection force

B.1 Fix the terminal unit to a horizontal or vertical surface, as appropriate, using the procedure recommended by the manufacturer.

B.2 Apply the maximum operating pressure.

B.3 Adapt a connector to accommodate a suitable measuring device.

B.4 In accordance with the manufacturer's instructions, insert the connector into the terminal unit and record the force and/or torque required to insert and engage fully the connector.

Annex C
(normative)

Test method for mechanical strength

C.1 Fix the terminal unit complete with the inlet piping to a suitable surface using the procedure recommended by the manufacturer.

C.2 Apply the maximum operating pressure.

C.3 Insert a blanked connector adapted for application of a tensile force.

C.4 Apply a tensile force of 500 N and hold it for 1 min.

C.5 Remove the tensile force. Check that the terminal unit is completely functional and not leaking.

C.6 Dismantle the terminal unit and check that no damage or distortion has occurred to either the terminal unit components or the connector.

Annex D
(normative)

Test method for disconnection force

D.1 Fix the terminal unit to a horizontal or vertical surface, as appropriate, using the procedure recommended by the manufacturer.

D.2 Apply the maximum operating pressure.

D.3 Adapt a connector to accommodate a suitable measuring device.

D.4 Insert the adapted connector into the terminal unit in accordance with the manufacturer's instructions and ensure that it is fully engaged.

D.5 Disconnect the connector in accordance with the manufacturer's instructions and record the force and/or torque required.

If the recommended disconnection method involves applying, for example, compressive force to the connector to reduce the effort required to disengage the latching mechanism, the total force/torque involved should be measured.

Annex E
(normative)

Test method for leakage

E.1 Fix the terminal unit to a horizontal or vertical surface, as appropriate, using the procedure recommended by the manufacturer.

E.2 Apply the maximum operating pressure and shut off the gas source. Measure the rate of pressure loss and calculate the leakage.

E.3 Repressurize the terminal unit and insert a gas-specific blanked connector. Shut off the gas source and again measure the rate of pressure loss and calculate the leakage.

NOTE 9 There are number of ways in which this test may be carried out. The main consideration is the extremely low leakage rate.

This can be addressed via, at one extreme, highly accurate pressure decay measurement techniques which can be complete in a few seconds.

At the other extreme, to avoid the use of expensive test equipment, the test may have to be carried out over many hours so that the measured pressure loss or volume change can be recorded with the accuracy of available instrumentation.

E.4 Apply a force of 20 N perpendicular to the long axis of the gas-specific connector, 50 mm from the outermost surface of the terminal unit. Repeat the procedure given in clause E.3.

Annex F
(informative)

Recommendations for materials

Components of terminal units should be made of materials which, where appropriate, are oxygen-compatible and which will provide the durability, corrosion-resistance and performance required from these components.

Compatibility with oxygen involves both combustibility and ease of ignition. Materials which burn in air will burn violently in pure oxygen. Many materials which do not burn in air will do so in pure oxygen, particularly under pressure. Similarly, materials which can be ignited in air have lower ignition energies in oxygen. Many such materials may be ignited by friction at a valve seat by adiabatic compression produced when oxygen at high pressure is rapidly introduced into a system initially at low pressure.

Corrosion-resistance includes resistance against moisture and surrounding materials.