Pressure regulators for use with medical gases —

Part 2: Manifold and line pressure regulators

The European Standard EN ISO 10524-2:2006 has the status of a British Standard

ICS 11.040.10

British Standards

National foreword

This British Standard was published by BSI. It is the UK implementation of EN ISO 10524-2:2006. It is identical with ISO 10524-2:2005. It supersedes BS EN 738-2:1999 which is withdrawn.

The UK participation in its preparation was entrusted by Technical Committee CH/121, Anaesthetic and respiratory equipment, to Subcommittee CH/121/6, Medical gas supply systems.

A list of organizations represented on CH/121/6 can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

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Foreword

The text of ISO 10524-2:2005 has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 10524-2:2006 by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2006, and conflicting national standards shall be withdrawn at the latest by October 2006.

This document supersedes EN 738-2: 1998.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

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Endorsement notice

The text of ISO 10524-2:2005 has been approved by CEN as EN ISO 10524-2:2006 without any modifications.

INTERNATIONAL STANDARD

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Pressure regulators for use with medical gases —

Part 2: Manifold and line pressure regulators

Détendeurs pour l'utilisation avec les gaz médicaux —

Partie 2: Détendeurs de rampes et de canalisations

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 10524-2 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*.

ISO 10524 consists of the following parts, under the general title *Pressure regulators for use with medical gases*:

— *Part 1: Pressure regulators and pressure regulators with flow-metering devices*

— *Part 2: Manifold and line pressure regulators*

— *Part 3: Pressure regulators integrated with cylinder valves*

— *Part 4: Low-pressure regulators*

Introduction

Manifold pressure regulators are used to reduce cylinder pressure to a lower pressure within a source of supply of a medical gas pipeline system.

Line pressure regulators are used to reduce the pressure supplied by manifold pressure regulators or by cryogenic vessels to the lower pressure required at the terminal units of medical gas pipeline systems.

These functions cover a wide range of inlet and outlet pressures and flows which require specific design characteristics.

It is important that the operating characteristics of manifold and line pressure regulators are specified and tested in a defined manner.

It is essential that regular inspection and maintenance be undertaken to ensure that the pressure regulators continue to meet the requirements of this part of ISO 10524.

This part of ISO 10524 pays particular attention to:

— use of suitable materials;

— safety (mechanical strength, leakage, safe relief of excess pressure and resistance to ignition);

— cleanliness;

— type testing;

— marking;

— information supplied by the manufacturer.

Annex B contains rationale statements for some of the requirements of this part of ISO 10524. The clauses and subclauses marked with an asterisk (*) after their number have corresponding rationale included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated into this part of ISO 10524. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this part of ISO 10524, but will expedite any subsequent revisions.

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Pressure regulators for use with medical gases —

Part 2:
Manifold and line pressure regulators

1 Scope

1.1* This part of ISO 10524 specifies requirements for manifold pressure regulators (as defined in 3.6) intended to be connected to cylinders with nominal filling pressures up to 25 000 kPa at 15 °C and for line pressure regulators (as defined in 3.4) for inlet pressures up to 3 000 kPa and intended for use in pipeline systems for the following medical gases:

— oxygen;

— nitrous oxide;

— air for breathing;

— carbon dioxide;

— oxygen/nitrous oxide mixtures;

— air for driving surgical tools;

— nitrogen for driving surgical tools;

— oxygen produced by an oxygen concentrator.

1.2* This part of ISO 10524 applies to manifold pressure regulators and line pressure regulators supplied as individual units or to the relevant components incorporated within an assembly.

1.3 This part of ISO 10524 does not apply to pressure regulators for use with vacuum pipeline systems.

NOTE Requirements for pressure regulators for use with vacuum pipeline systems are covered in ISO 10079-3.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 7396-1:2002, *Medical gas pipeline systems — Part 1: Pipelines for compressed medical gases and vacuum*

ISO 14971:2000, *Medical devices — Application of risk management to medical devices*

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

EN 837-1:1996, *Pressure gauges — Part 1: Bourdon tube pressure gauges — Dimensions, metrology, requirements and testing*

3 Terms and definitions

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

3.1
closure pressure
P_4
stabilized outlet pressure, after cessation of the flow, from a pressure regulator when the flow has been set to standard discharge

3.2
double-stage pipeline distribution system
pipeline distribution system in which gas is initially distributed from the supply system at a higher pressure than the nominal distribution pressure

NOTE This higher pressure (nominal supply system pressure) is then reduced to the nominal distribution pressure by additional line pressure regulators.

3.3
flow characteristic
variation of outlet pressure in relation to flow with the inlet pressure remaining constant

3.4
line pressure regulator
pressure regulator intended to be installed within a medical gas pipeline system downstream of a manifold pressure regulator or cryogenic gas supply system

3.5
manifold
device for connecting the outlet(s) of one or more cylinders or cylinder bundles of the same medical gas to a pipeline system

3.6
manifold pressure regulator
pressure regulator intended to be installed within sources of supply containing cylinders or cylinder bundles

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

3.8
nominal distribution pressure
pressure of gas which the pipeline system is intended to deliver at the terminal units

3.9
nominal inlet pressure
P_1
upstream pressure (specified as a single value by the manufacturer) for which the pressure regulator is intended to be used

NOTE P_1 for manifold pressure regulators is the maximum cylinder filling pressure at 15 °C.

3.10
nominal outlet pressure
P_2
downstream pressure for the standard discharge, Q_1, specified by the manufacturer

3.11
pressure characteristic
variation of the outlet pressure in relation to inlet pressure under constant flow conditions

3.12
pressure gauge
device that measures and indicates pressure

3.13
pressure regulator
device that reduces the inlet pressure and maintains the set outlet pressure within specified limits

3.14
pressure-relief valve
device intended to relieve excess pressure at a pre-set value

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

[IEC 60601-1:1988, 2.10.11]

3.16
single-stage pipeline distribution system
pipeline distribution system in which gas is distributed from the supply system at the nominal distribution pressure

3.17
source of supply
that portion of the supply system with associated control equipment, which supplies the pipeline distribution system

3.18
standard discharge
Q_1
flow for which the pressure regulator is designed to maintain a nominal outlet pressure, P_2, at test inlet pressure, P_3

3.19
supply system
system that supplies the pipeline distribution system and which includes two or more sources of supply

3.20
test inlet pressure
P_3
minimum inlet test pressure

NOTE See Table 1.

3.21
test outlet pressure
P_5
highest or lowest value of the outlet pressure resulting from a variation in the inlet pressure between P_1 and P_3 at previously adjusted conditions P_1, P_2, Q_1

4 Symbols

The symbols used for the functional characteristics are given in Table 1.

Table 1 — Symbols

P_1	Nominal inlet pressure
P_2	Nominal outlet pressure
P_3	Test inlet pressure
P_4	Closure pressure
P_5	Test outlet pressure
Q_1	Standard discharge
R	Coefficient of pressure increase upon closure
i	Irregularity coefficient
NOTE $P_3 = 2P_2 + 100$ kPa	

Examples of a line pressure regulator and a manifold pressure regulator with terminology are given in Annex A.

5 General requirements

5.1 Safety

Manifold and line pressure regulators 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 management procedures in accordance with ISO 14971 and which is connected with their intended application, in normal condition and in single fault condition.

5.2 Alternative construction

Manifold and line pressure regulators and components or parts thereof, using materials or having forms of construction different from those detailed in Clause 5 shall be accepted if it can be demonstrated that an equivalent degree of safety is obtained.

Such evidence shall be provided by the manufacturer upon request.

NOTE Attention is drawn to ISO 14971 on risk management.

5.3 Materials

5.3.1* The materials in contact with the medical gases listed in 1.1, during normal use shall be resistant to corrosion and compatible with oxygen, the other medical gases and their mixtures in the temperature range specified in 5.3.2.

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

NOTE 2 Compatibility with oxygen involves both combustibility and ease of ignition. Materials which burn in air will burn violently in pure oxygen. Many materials that do not burn in air will do so in pure oxygen, particularly under pressure. Similarly, materials that can be ignited in air require lower ignition energies for ignition 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 3 Criteria for the selection of metallic and non-metallic materials are given in ISO 15001.

5.3.2 The materials shall permit the manifold and line pressure regulators and their components to meet the requirements of 5.4 in the temperature range of – 20 °C to + 60 °C.

NOTE Regional or national environmental conditions may require deviation from this range of temperatures.

5.3.3 Manifold and line pressure regulators shall meet the requirements of this part of ISO 10524 after being packed for transport and storage and being exposed to environmental conditions as stated by the manufacturer.

5.3.4 Springs, highly strained components and parts liable to wear, which come in contact with the medical gas shall not be plated.

NOTE Any plating could detach from the component surface.

5.3.5* Aluminium or aluminium alloys shall not be used for components of manifold pressure regulators whose surfaces come into contact with gas at cylinder pressure in normal or single-fault condition.

5.3.6 Evidence of conformity with the requirements of 5.3.1, 5.3.2, 5.3.3, 5.3.4 and 5.3.5 shall be provided by the manufacturer upon request.

5.4 Design requirements

5.4.1 Pressure gauges

5.4.1.1 If a Bourdon tube pressure gauge is used, it shall conform to EN 837-1 (except for the minimum nominal size) and shall meet the requirements given in 5.4.1.2 to 5.4.1.7. The requirements in 5.4.1.2 to 5.4.1.7 also apply to other types of pressure gauge.

5.4.1.2 The connector shall be a thread complying with EN 837-1 or a proprietary connector.

5.4.1.3 The indicated value of a pressure gauge shall be legible to an operator having a visual acuity of 1 (corrected if necessary) 1 m from the gauge with an illuminance of 215 lx.

5.4.1.4 The scale of the inlet pressure gauge shall extend to a pressure at least 33 % greater than nominal inlet pressure, P_1.

NOTE A pressure gauge with a scale range of 0 to 31 500 kPa (315 bar) can be used for a pressure regulator with a nominal inlet pressure, P_1, of up to 23 000 kPa.

5.4.1.5 The inlet pressure gauge and outlet pressure gauge shall be class 2,5 or better in accordance with EN 837-1:1996.

5.4.1.6 The connector for a pressure gauge with a scale range greater than 4 000 kPa shall be fitted with an orifice with an area no greater than 0,1 mm^2.

5.4.1.7 Evidence of conformity with the requirements of 5.4.1.1 and 5.4.1.5 shall be provided by the manufacturer upon request. Compliance with the requirements of 5.4.1.2, 5.4.1.3, 5.4.1.4 and 5.4.1.6 shall be checked by visual inspection or measurement as required.

5.4.2 Pressure-adjusting device

5.4.2.1 The pressure regulator shall be provided with a pressure-adjusting device.

5.4.2.2 Except for a line pressure regulator to a single terminal unit for air or nitrogen for driving surgical tools, the pressure-adjusting device shall be designed so that it can be locked into position and adjusted only with the use of a tool.

Compliance shall be tested by attempting to adjust the pressure without the use of a tool.

5.4.2.3 The pressure-adjusting device shall be captive or removable only with the use of a tool.

Compliance shall be tested by attempting to remove the pressure-adjusting device without the use of a tool.

5.4.2.4 The pressure regulator shall be designed so that the pressure regulator valve cannot be held in the open position as a consequence of the pressure regulator spring being compressed to its solid length.

Compliance shall be tested by inspection.

5.4.2.5 Using the pressure-adjusting device it shall not be possible to set a pressure at which the pressure- relief valve opens.

Compliance shall be tested by inspection.

5.4.3 Filtration

Manifold and line pressure regulators shall be fitted on the inlet side with a filter that prevents particles greater than 100 μm from entering the pressure regulator.

Evidence of conformity shall be provided by the manufacturer upon request.

NOTE The filter can be a separate item.

5.4.4 Mechanical strength

5.4.4.1 The inlet side of a manifold or line pressure regulator shall be capable of withstanding × 2,25 its nominal inlet pressure, P_1, without rupturing. The outlet side of a manifold or line pressure regulator shall be capable of withstanding × 4 its nominal outlet pressure, P_2, without rupturing.

5.4.4.2 Components of the manifold pressure regulator shall not be ejected if the low-pressure chamber of the pressure regulator is exposed to nominal inlet pressure P_1 (for instance if the pressure regulator valve is held in the open position and the outlet connector is closed). The high-pressure gas shall either be safely retained or vented.

The tests for mechanical strength of manifold pressure regulators are given in 6.2.6. The tests for mechanical strength for line pressure regulators are given in 6.3.3.

5.4.5 Manifold pressure regulators

5.4.5.1* Inlet connector

The dimensions of the inlet connector shall be at the discretion of the manufacturer.

A cylinder valve connector shall not be used as an inlet connector.

5.4.5.2 Outlet connector

The dimensions of the outlet connector shall be at the discretion of the manufacturer.

5.4.5.3 Leakage

5.4.5.3.1 The total external leakage to the atmosphere shall not exceed 0,2 ml/min (equivalent to a pressure decay of 0,020 2 kPa·l/min) at nominal inlet pressure P_1 and closure pressure P_4.

The test for external leakage is given in 6.2.5.1.

5.4.5.3.2 The internal leakage through the pressure regulator valve shall not exceed 1 ml/min (equivalent to a pressure decay of 0,101 0 kPa·l/min) at nominal inlet pressure P_1 and test inlet pressure P_3.

The test for internal leakage is given in 6.2.5.2.

5.4.5.4 Functional and flow characteristics

5.4.5.4.1 Standard discharge, Q_1

The standard discharge, Q_1, shall be in accordance with the value(s) stated by the manufacturer.

If the manifold pressure regulator is designed for a range of nominal outlet pressures, P_2, the manufacturer shall specify values of standard discharge, Q_1, for the upper and lower limits of the nominal outlet pressure.

The test to demonstrate compliance to the manufacturer's declared value(s) of Q_1 is given in 6.2.1.

5.4.5.4.2 Coefficient of pressure increase upon closure, R

The coefficient of pressure increase upon closure, R, is calculated using the formula:

$$R = \frac{P_4 - P_2}{P_2} \qquad (1)$$

The coefficient, R, shall be less than 0,3.

The test for determining the coefficient of pressure increase upon closure, R, is given in 6.2.2.

5.4.5.4.3 Irregularity coefficient, i

The irregularity coefficient (i) is calculated using the formula:

$$i = \frac{P_5 - P_2}{P_2} \qquad (2)$$

The irregularity coefficient, i, shall fall within the limit $\pm$ 0,3.

The test for determining the irregularity coefficient, i, is given in 6.2.3.

5.4.5.5 Pressure-relief valve

Each manifold pressure regulator shall be provided with a pressure-relief valve which may be integral with or separate from the manifold pressure regulator. Bursting discs shall not be used.

The pressure-relief valve shall automatically relieve excess pressure and shall reset at a pressure equal to or above the nominal outlet pressure, P_2, or the set pressure.

The leakage from the pressure-relief valve shall comply with the requirements of 5.4.5.3.1 up to a pressure of 1,6 × P_2 or 1,6 times the set pressure.

The discharge of the pressure-relief valve shall be equal to or greater than the standard discharge, Q_1, at a pressure of 2 P_2.

The pressure-relief valve shall be fitted in such a way that gas will be discharged safely.

The test for the pressure-relief valve is given in 6.2.4.

Additional pressure relief valves may be required to protect the pipeline distribution system. See ISO 7396-1.

NOTE The pressure-relief valve need not be integral with the pressure regulator.

5.4.5.6* Resistance to ignition

Manifold pressure regulators for the medical gases listed in 1.1 shall not ignite or show internal scorching damage when subjected to oxygen pressure shocks.

The test for resistance to ignition is given in 6.2.7.

5.4.5.7 Nominal inlet pressure

Manifold pressure regulators for all the medical gases listed in 1.1 shall have nominal inlet pressures, P_1, not less than the maximum filling pressure of the medical gas cylinder at 15 °C as specified in national or regional regulations.

5.4.6 Line pressure regulators

NOTE ISO 7396-1 specifies the functions that are required when line pressure regulators are installed in a double-stage distribution system. The devices which fulfil these functions (e.g. pressure gauges, shut-off valves, pressure alarm switches, emergency and maintenance inlet point) can be either integral to the line pressure regulator or be separate items.

5.4.6.1* Inlet connector

The dimensions of the inlet connector shall be at the discretion of the manufacturer.

A cylinder valve connector shall not be used as an inlet connector.

5.4.6.2 Outlet connector

The dimensions of the outlet connector shall be at the discretion of the manufacturer.

5.4.6.3 Leakage

5.4.6.3.1 The total external leakage to the atmosphere shall not exceed 0,2 ml/min (equivalent to a pressure decay of 0,020 2 kPa·l/min) at nominal inlet pressure, P_1, and nominal outlet pressure, P_2.

5.4.6.3.2 The internal leakage through the pressure regulator valve shall not exceed 0,2 ml/min (equivalent to a pressure decay of 0,020 2 kPa·l/min) at nominal inlet pressure, P_1, and at the minimum inlet pressure specified by the manufacturer.

The tests for leakage are given in 6.2.5.

5.4.6.4 Outlet pressure variation limits

The outlet pressure shall not vary by more than + 0 % and − 10 % when the flow is varied from zero to Q_1 at the nominal inlet pressure, P_1, and at the minimum inlet pressure specified by the manufacturer.

The test for measuring variation of outlet pressure is given in 6.3.1.

5.4.6.5* Resistance to ignition of sealing materials and lubricants

For line pressure regulators the auto-ignition temperature of the non-metallic components in contact with the gas at the inlet side of the pressure regulator, including the sealing materials and lubricants (if used) shall not be lower than 200 °C. The auto-ignition temperature of the non-metallic components in contact with the gas at the outlet side of the pressure regulator, including the sealing materials and lubricants (if used) shall not be lower than 160 °C.

Evidence of conformity with this requirement shall be provided by the manufacturer upon request.

The test for the determination of the auto-ignition temperature of non-metallic components is given in 6.4.

NOTE Values of the auto-ignition temperature always depend on the test method used, which does not exactly simulate all possible operating conditions.

5.4.6.6 Nominal inlet pressure

A line pressure regulator for any medical gas listed in 1.1 shall not have a nominal inlet pressure, P_1, greater than 3 000 kPa.

5.5 Constructional requirements

5.5.1* Cleanliness

Components of manifold and line pressure regulators in contact with the medical gases listed in 1.1 shall meet the cleanliness requirements of ISO 15001.

Evidence of conformity with this requirement shall be provided by the manufacturer upon request.

5.5.2 Lubricants

If lubricants are used, they shall be compatible with oxygen, the other medical gases listed in 1.1 and their mixtures in the temperature range specified in 5.3.2.

Evidence of conformity with this requirement shall be provided by the manufacturer upon request.

NOTE Attention is drawn to Annex D of ISO 15001:2003.

6 Test methods

6.1 Conditions

6.1.1 General

These tests are type tests.

6.1.2 Ambient conditions

Except where otherwise stated, carry out tests at ambient conditions.

6.1.3 Test gas

In all cases carry out tests with clean, oil-free air or nitrogen with a maximum moisture content of 50 µg/g corresponding to a dewpoint of – 48 °C at atmospheric pressure.

When a pressure regulator is tested with a gas other than that for which it is intended, the flows shall be converted using the conversion coefficients given in Table 2.

Table 2 — Conversion coefficients

Intended gas [a]	Conversion coefficient	
	Test gas air	Test gas nitrogen
Air	1	0,98
Oxygen	0,95	0,93
Nitrogen	1,02	1
N_2O	0,81	0,79
CO_2	0,81	0,79
Oxygen from an oxygen concentrator	0,95	0,93

[a] Flow of intended gas = Flow of test gas x conversion coefficient.

6.1.4 Reference conditions

Correct flows to 15 °C and 101,3 kPa.

6.1.5 Test equipment for functional and flow characteristics

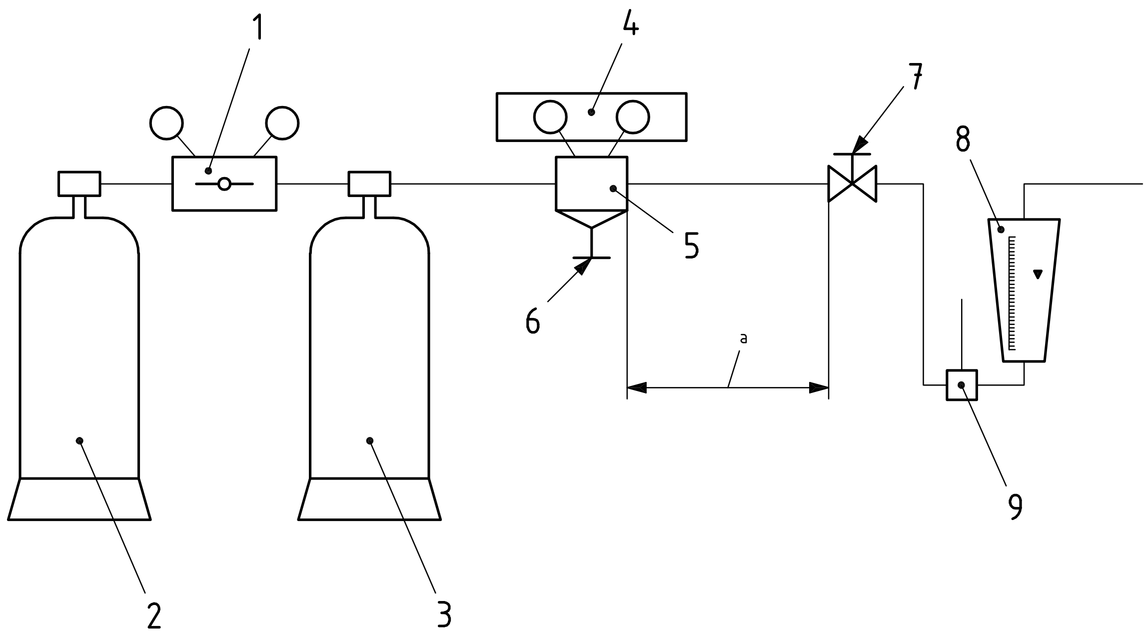
Construct the test equipment in such a way that the inlet and outlet pressures may be regulated separately. The equipment may be operated by remote control. Ensure that the gas supply for the nominal inlet pressure, P_1, and the test inlet pressure, P_3, has sufficient capacity for the test.

Ensure that all the components of the test equipment have a flow capacity greater than that of the pressure regulator to be tested.

6.2 Test methods for manifold pressure regulators

6.2.1 Test method for determining standard discharge, Q_1

The equipment for this test is shown in Figure 1. The gas can be supplied from a buffer cylinder.



Key

1 auxiliary pressure regulator
2 gas supply
3 buffer cylinder
4 calibrated pressure gauges
5 pressure regulator under test
6 pressure-adjusting device
7 flow control valve
8 flowmeter
9 thermometer

[a] Maximum 1 m.

Figure 1 — Equipment for performance and functional tests

Set and hold constant the test inlet pressure, P_3, by means of an auxiliary pressure regulator (1 in Figure 1) or any equivalent device. Using the pressure-adjusting device (6 in Figure 1) on the pressure regulator under test, set the outlet pressure to the manufacturer's upper value of P_2. Gradually open the flow control valve (7 in Figure 1) until the manufacturer's upper value of standard discharge, Q_1 (taking into account the corrections given in Table 2) is attained on the flowmeter (8 in Figure 1). If the outlet pressure has decreased, re-adjust it to P_2 and re-adjust the flow to Q_1. Lock the pressure-adjusting device.

This test shall be carried out at the minimum and maximum limits of P_2 and Q_1 specified by the manufacturer.

The values recorded shall be in accordance with the manufacturer's specification.

6.2.2 Test method for determining the coefficient of pressure increase upon closure, R

Use the test equipment shown in Figure 1. This test is carried out with the pressure regulator set and locked as described in 6.2.1

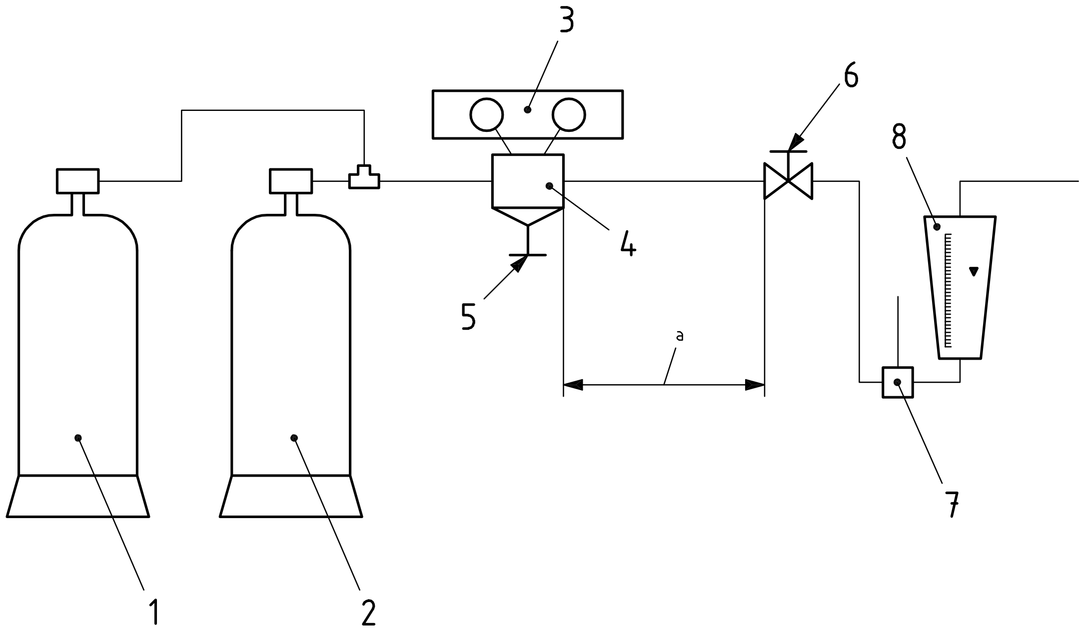
Apply pressure P_3 to the inlet of the pressure regulator being tested (5 in Figure 1). Adjust the flow to Q_1 (taking into account the corrections given in Table 2), using the flow control valve (7 in Figure 1). Stop the flow by closing the flow control valve (7 in Figure 1). Allow the outlet pressure to stabilize for 60 s and record the value P_4.

Determine the value of the coefficient of pressure increase, R.

This test shall be carried out at the minimum and maximum limits of P_2 and Q_1 specified by the manufacturer.

6.2.3 Test method for determining the irregularity coefficient, i

The equipment for this test is shown in Figure 2. Ensure that sufficient gas is available in the gas supply to be able to complete the test in one session.



Key

1 auxiliary gas cylinder
2 primary gas cylinder
3 calibrated pressure gauges
4 pressure regulator under test
5 pressure-adjusting device
6 flow control valve
7 thermometer
8 flowmeter

[a] Maximum 1 m.

Figure 2 — Equipment for determination of pressure characteristics

For the determination of the irregularity coefficient, i, and correct mechanical functioning, plot a curve (see Figures 3 and 4). The curve indicates the variation of outlet pressure as a function of the inlet pressure.

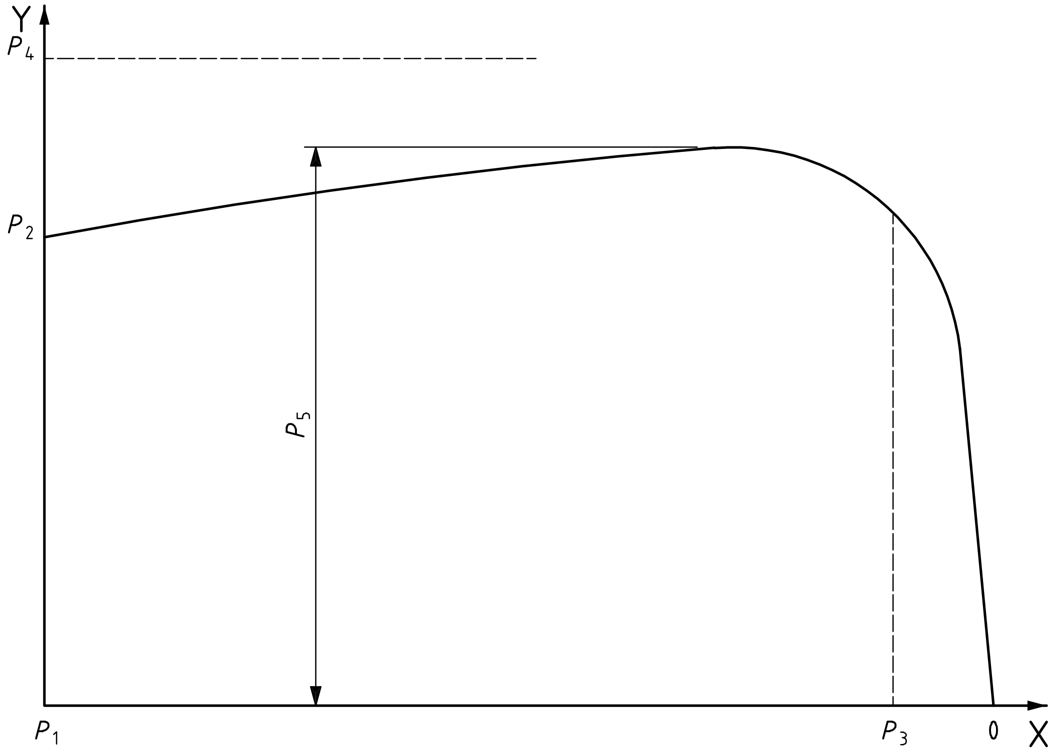
Equip the pressure regulator under test (4 in Figure 2) with two calibrated gauges or recording equipment. Unlock the pressure-adjusting device on the pressure regulator under test. Apply pressure P_1 to the pressure regulator inlet. Operate the pressure-adjusting device on the pressure regulator under test and the flow control valve (6 in Figure 2) to obtain the standard discharge, Q_1 at the outlet pressure, P_2 (taking into account the corrections given in Table 2). Lock the pressure-adjusting device.

Record the values of the inlet and outlet pressures whilst the inlet pressure is varied through the range P_1 to P_3.

Plot the values of the inlet and outlet pressure. The graph should be a curve, either rising to a maximum (see Figure 3) or falling (see Figure 4).

From the graph determine the value of P_5 that is the highest (see Figure 3) or the lowest (see Figure 4) value of the outlet pressure during the test in which the inlet pressure was varied from P_1 to P_3.

Determine the value of the irregularity coefficient, i.

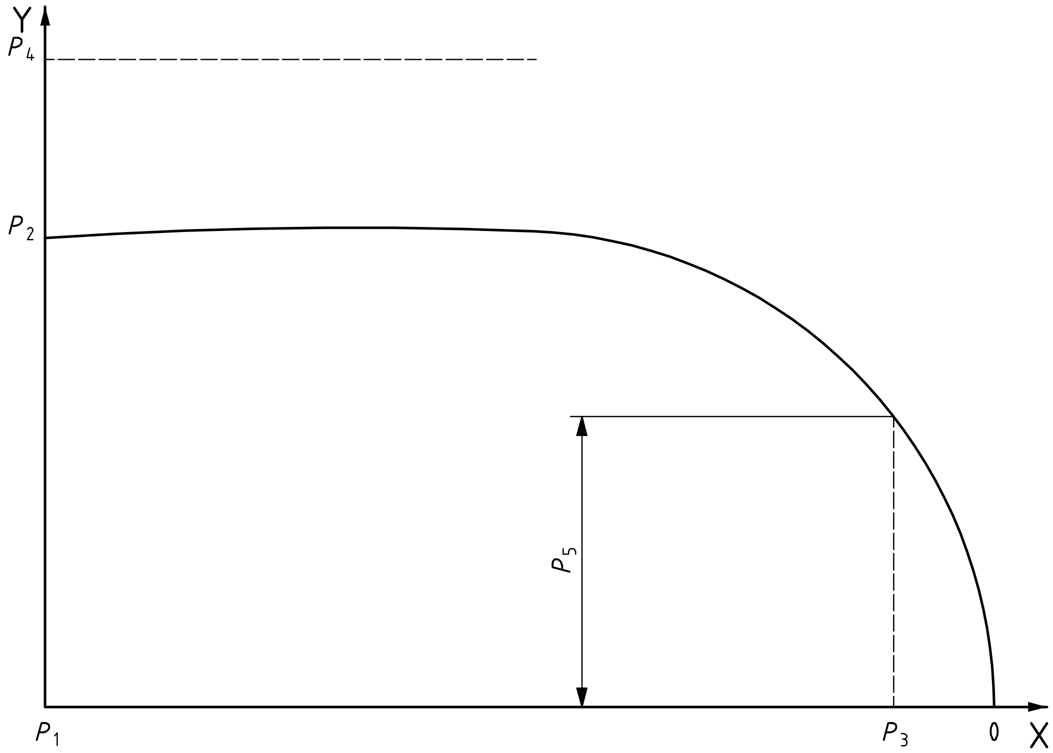


Key

X inlet pressure

Y outlet pressure

Figure 3 — Typical rising pressure characteristic



Key

X inlet pressure

Y outlet pressure

Figure 4 — Typical falling pressure characteristic

6.2.4 Test method for pressure-relief valve

Apply an increasing pressure through the outlet connector up to a pressure of 1,6 × P_2. At this pressure the leakage from the pressure-relief valve shall comply with the requirements of 5.4.5.3.1. Then increase the pressure until the pressure-relief valve opens. Note this pressure. Increase the pressure to 2 × P_2. At this pressure measure the discharge of the pressure-relief valve. The discharge shall be equal to or greater than Q_1. Decrease the pressure and check that the pressure-relief valve reseats at a pressure equal to or above the nominal outlet pressure P_2 or the set pressure.

For this test the value of P_2 shall be the upper limit of the range of P_2 specified by the manufacturer.

6.2.5 Test methods for leakage

6.2.5.1 External leakage

Measure the external leakage of the pressure regulator at the nominal inlet pressure, P_1, and closure pressure, P_4, with the outlet plugged.

For this test the value of P_4 shall relate to the upper limit of P_2 specified by the manufacturer.

6.2.5.2 Internal leakage

Measure the internal leakage at the nominal inlet pressure, P_1, with the pressure-adjusting device set to zero pressure and the outlet open.

Repeat the test at the test inlet pressure, P_3.

For this test the value of P_3 shall relate to the lower limit of P_2 specified by the manufacturer.

6.2.6 Test method for mechanical strength

6.2.6.1 High-pressure side

Ensure that the pressure-adjusting device is set to zero pressure.

Replace the high-pressure gauge, with a plug. Hydraulically pressurize the high-pressure side of the pressure regulator to × 2,25 its nominal inlet pressure, P_1, for 5 min.

Verify that the requirements of 5.4.4.1 are met.

6.2.6.2 Low-pressure side

6.2.6.2.1 This test shall be carried out on the complete pressure regulator. The pressure regulator valve shall be in the fully open position and the outlet(s) plugged throughout the test. Rapidly apply a pneumatic pressure of P_1 to the inlet of the pressure regulator.

Verify that the requirements of 5.4.4.2 are met.

6.2.6.2.2 Replace the pressure-relief valve and outlet pressure gauge, if fitted, with plugs. If necessary, in order to hold the test pressure, replace the diaphragm with a blank. Pressurize the outlet chamber of the pressure regulator to × 4 times its nominal outlet pressure, P_2, for 5 min.

For this test the value of P_2 shall be the upper limit of P_2 specified by the manufacturer.

Verify that the requirements of 5.4.4.1 are met.

6.2.7 Test method for resistance to ignition

Expose a pressure regulator to pressure shocks from industrial oxygen (minimum 99,5 % purity and hydrocarbons less than or equal to 10 µg/g) through the inlet connector. The test equipment is shown in Figure 5. Before starting the test the test pressure regulator shall be at room temperature.

Apply a pressure shock by increasing the pressure from atmospheric pressure to the test pressure in a time of 20^{+0}_{-5} ms measured upstream (at 10 in Figure 5) of the pressure regulator under test. Use an initial test pressure of × 1,2 nominal inlet pressure, P_1, at 60 °C ± 3 °C. During the test the inlet (test) pressure shall not decrease by more than 3 %.

Apply to the pressure regulator under test a series of 20 pressure shocks at intervals of 30 s with the pressure regulator valve fully open and the outlet closed.

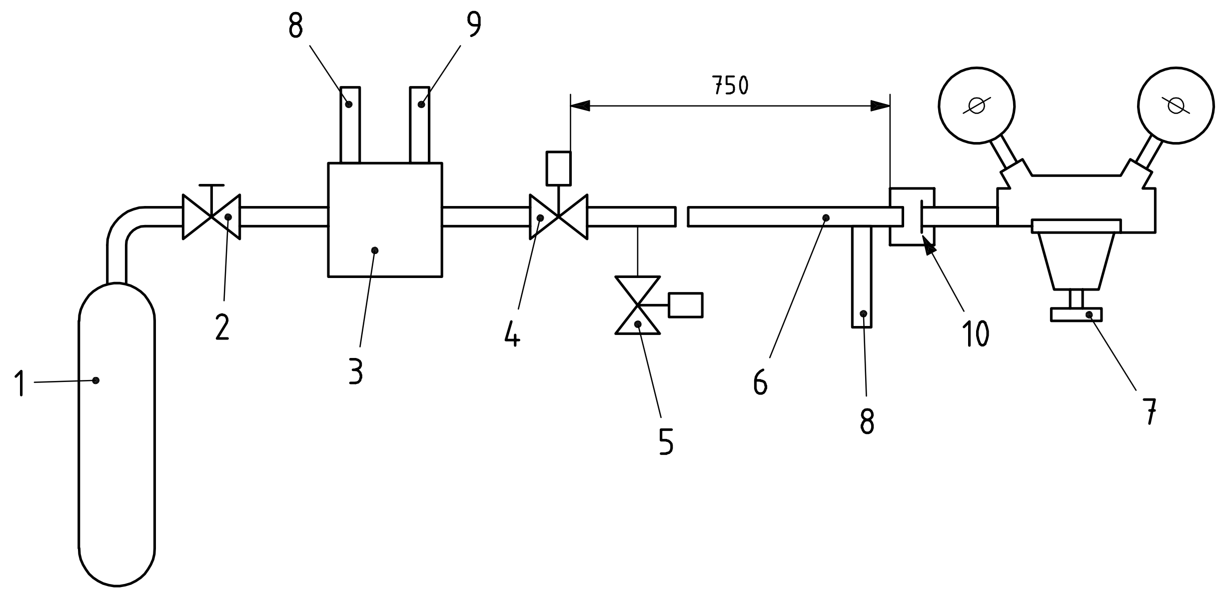
After each pressure shock maintain the test pressure for 10 s and then bring the pressure back to atmospheric pressure by means of the upstream outlet valve (5 in Figure 5) and hold at atmospheric pressure for at least 3 s (see Figure 6).

After the test has been completed, dismantle the pressure regulator under test and inspect all internal parts and areas for damage (e.g. evidence of ignition or scorching).

Repeat this test on two additional pressure regulators.

NOTE This test method is derived from ISO 7291.

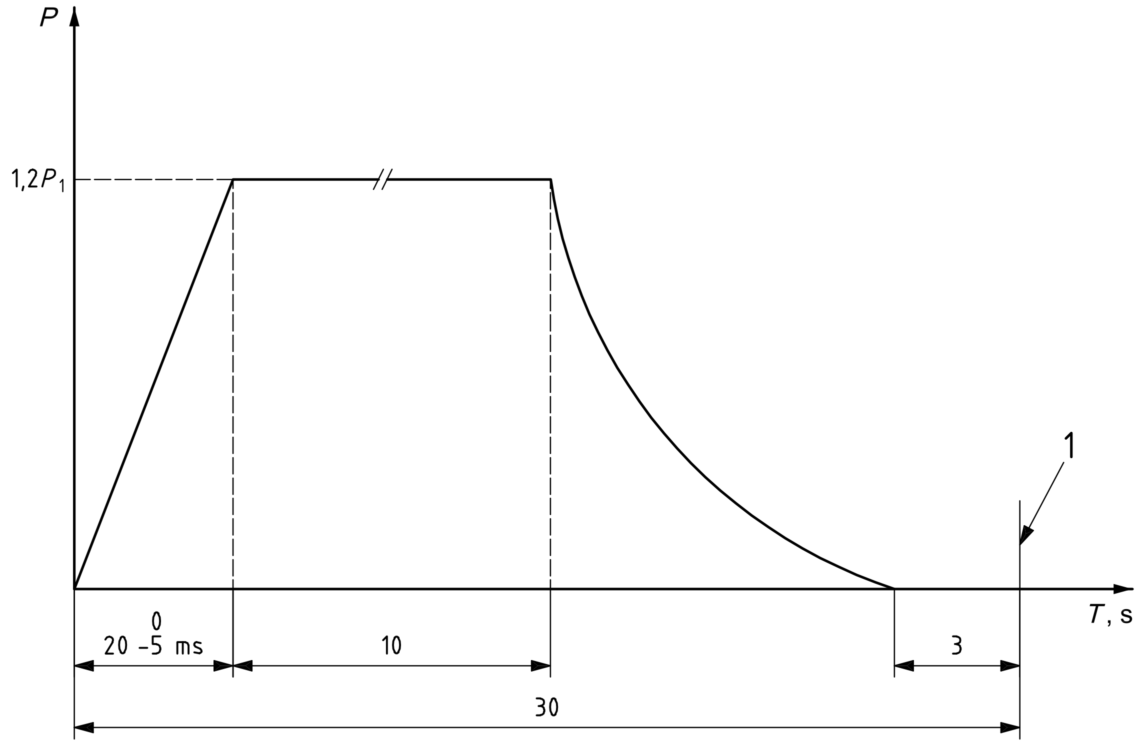
Dimensions in millimetres



Key

1 oxygen supply
2 inlet valve
3 vessel with device for pre-heating oxygen to 60 °C ± 3 °C
4 quick opening valve
5 outlet valve
6 connection tube with internal diameter of 14 mm
7 pressure regulator under test
8 pressure transducer
9 thermometer
10 measuring point

Figure 5 — Test bench for ignition test on manifold pressure regulators



Key

1 next pressure shock

Figure 6 — Test interval

6.3 Test methods for line pressure regulators

6.3.1 Test method for measuring the variation of the outlet pressure

The equipment for this test is shown in Figure 1. The pressure regulator under test (5 in Figure 1) can be supplied by a buffer cylinder (3 in Figure 1). Hold the upstream pressure constant by use of an auxiliary pressure regulator (1 in Figure 1) or any equivalent device.

With the flow control valve (7 in Figure 1) closed, apply the minimum inlet pressure specified by the manufacturer. Set the outlet pressure to P_2. Gradually open the flow control valve until the standard discharge, Q_1, is attained. Readjust the outlet pressure to P_2 if necessary and lock the pressure-adjusting device in this position. Stop the flow by closing the flow control valve. Record the highest and lowest outlet pressure whilst the flow is varied from zero to Q_1.

At the same setting of the pressure-adjusting device, apply an inlet pressure of P_1. Record the highest and lowest outlet pressure whilst the flow is varied from zero to Q_1. Verify that the lowest pressure is not less than 90 % of the highest pressure.

This test shall be carried out at the upper and lower limits of P_2 specified by the manufacturer.

6.3.2 Test methods for leakage

6.3.2.1 External leakage

Measure the external leakage of the pressure regulator at the nominal inlet pressure, P_1, and outlet pressure, P_2, with the outlet plugged. For this test the value of P_2 shall be the upper limit of P_2 specified by the manufacturer.

Verify that the leakage does not exceed 0,2 ml/min.

6.3.2.2 Internal leakage

Measure the internal leakage at the nominal inlet pressure, P_1, with the pressure-adjusting device set to zero pressure and the outlet open. Repeat the test at the minimum inlet pressure specified by the manufacturer.

Verify that the leakage does not exceed 0,2 ml/min.

6.3.3 Test method for mechanical strength

6.3.3.1 High-pressure side

Ensure that the pressure-adjusting device is set to zero pressure. Replace the inlet pressure gauge, if fitted, with a plug. Hydraulically pressurize the high-pressure side of the pressure regulator to × 2,25 its nominal inlet pressure, P_1, for 5 min.

Verify that the requirements of 5.4.4.1 are met.

6.3.3.2 Low-pressure side

6.3.3.2.1 This test is carried out on the complete pressure regulator. The pressure regulator valve shall be in the fully open position and the outlet(s) plugged throughout the test. Rapidly apply a pneumatic pressure of P_1 to the inlet of the pressure regulator.

Verify that the requirements of 5.4.4.2 are met.

6.3.3.2.2 Remove the pressure-relief valve and outlet pressure gauge, if fitted, and replace with plugs. If necessary to hold the test pressure, replace the diaphragm with a blank. Pneumatically pressurize the outlet chamber of the pressure regulator to × 4 its nominal outlet pressure, P_2, for 5 min.

Verify that the requirements of 5.4.4.1 are met

For this test the value of P_2 shall be the upper limit of P_2 specified by the manufacturer.

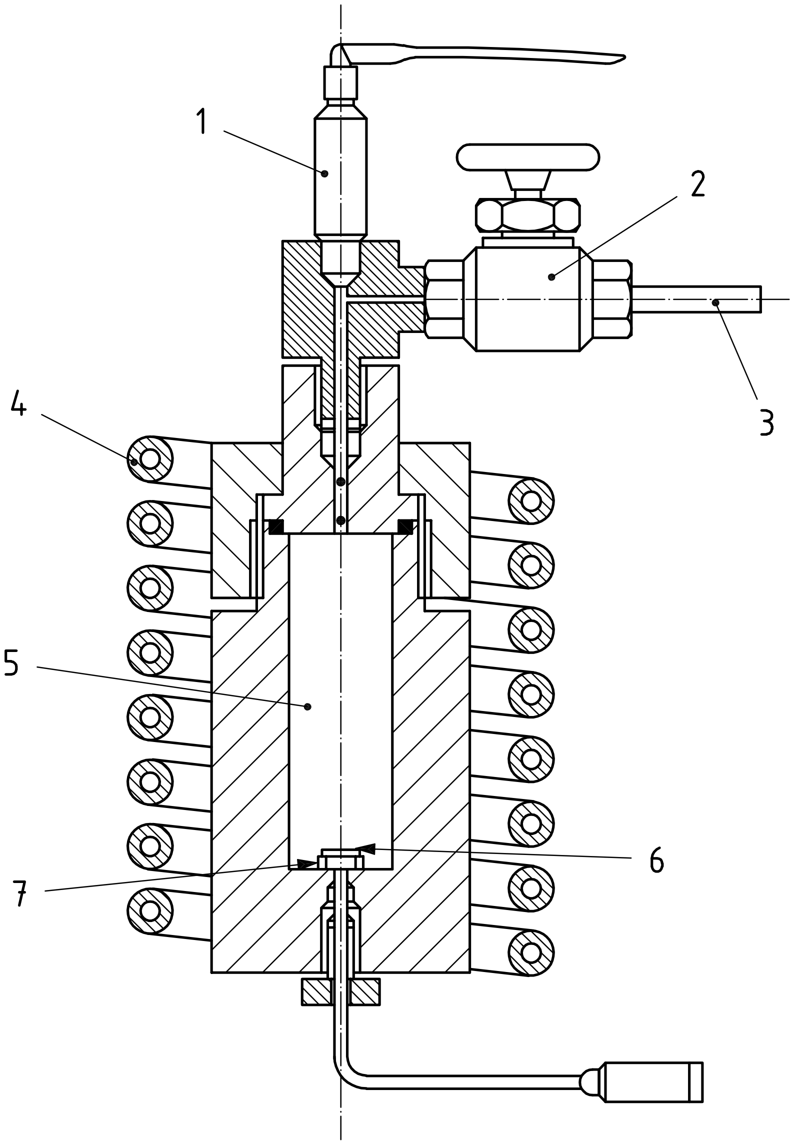
6.4 Test method for determination of the auto-ignition temperature of sealing materials and lubricants

Measure the auto-ignition temperature of the non-metallic materials including sealing materials and lubricants (if used) using the apparatus shown in Figure 7.

Place finely divided test material in quantities of about 0,3 g to 0,5 g into a stainless steel tube with a chrome-nickel steel cladding. To obtain large reactive surfaces, coat liquids as well as pasty substances on fibrous ceramic material. Fill the gas-tight tube containing the sample, with oxygen at a specified pressure (see NOTE 2) and then inductively heat it, using a low frequency heater in an approximately linear manner, at 120 °C/min. Monitor the temperature of the sample as a function of time by use of a thermocouple, and monitor the pressure using a pressure transducer. Record both pressure and temperature using a dual channel recorder. The point at which spontaneous ignition occurs is denoted by a sudden rise in temperature and pressure. The auto-ignition temperature and the corresponding final oxygen pressure can be seen from the record (see Figure 8).

NOTE 1 Auto-ignition temperatures in compressed oxygen can generally be reproduced with variations of ± 5 °C in the range up to 200 °C. Variations of about ± 10 °C and in some cases even higher, are known to occur in the range from 200 °C to 500 °C. Usually five tests at the same pressure are performed.

NOTE 2 Data on auto-ignition temperatures of non-metallic materials depend upon the test method and there are differences in the values obtained by different test laboratories. The measurement of the auto-ignition temperature of non-metallic materials is typically carried out at a pressure of 4 000 kPa and data are unavailable for pressures of 1 400 kPa. The typical relationship is that the auto-ignition temperature of non-metallic materials decreases with increasing oxygen pressure to an approximately constant value above pressures of 4 000 kPa. However, it is known that this typical relationship is not evident with some non-metallic materials. Care should therefore be taken to investigate the properties of new non-metallic materials that may be used for oxygen service.



Key

1 pressure transducer

2 valve

3 oxygen supply

4 inductive heater

5 reaction vessel

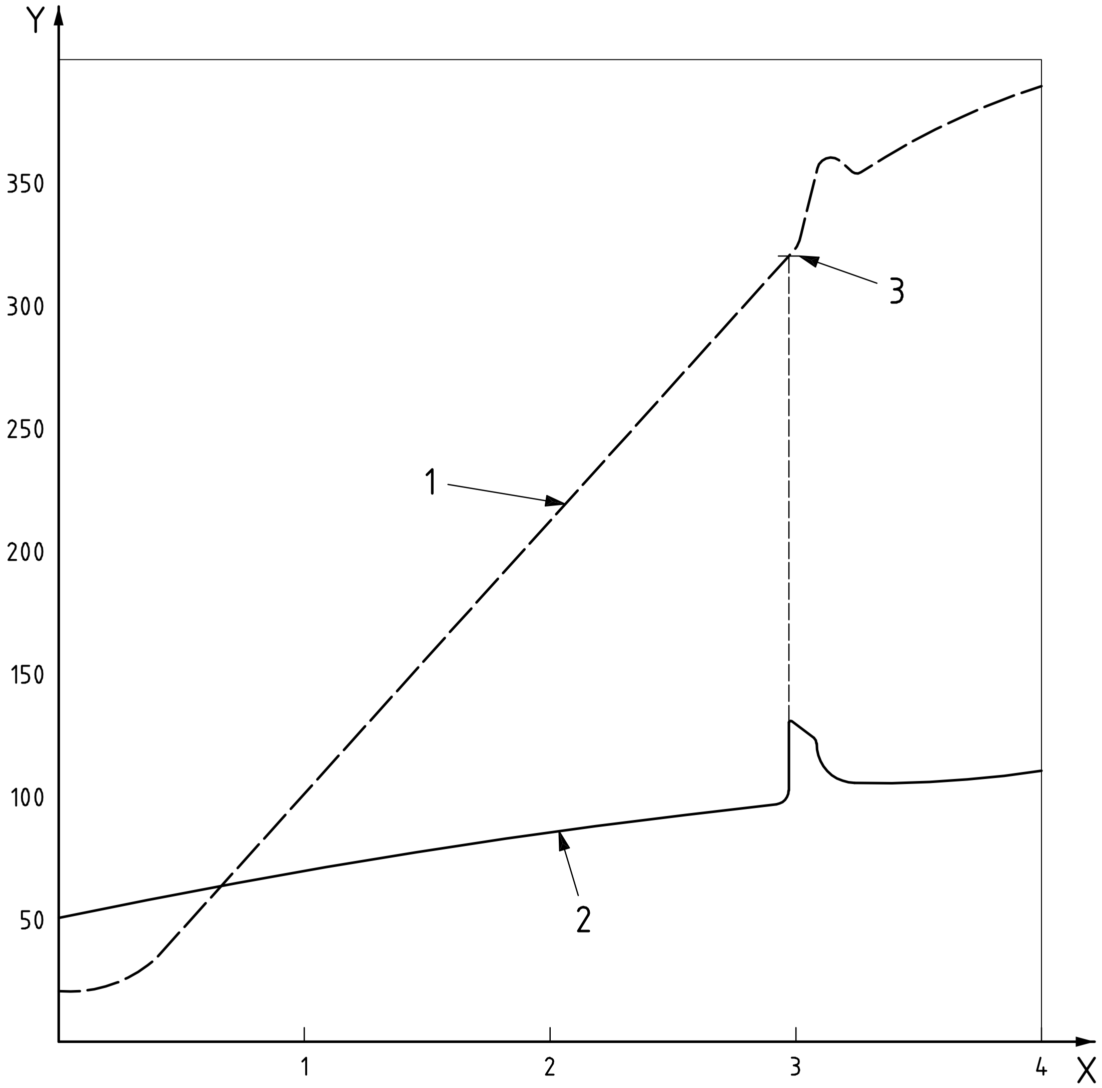
6 test sample

7 thermocouple

Figure 7 — Equipment for determining the autoignition temperature of non-metallic components

6.5 Test method for durability of markings and colour coding

Rub 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.



Key

X time (min)

Y pressure/temperature

1 temperature (°C)

2 pressure (kPa/100)

3 auto-ignition temperature

Figure 8 — Typical record of an auto-ignition temperature determination in compressed oxygen

7 Marking, colour coding, packaging

7.1 Marking

7.1.1 Manifold and line pressure regulators shall be durably and legibly marked with the symbol of the relevant gas in accordance with Table 3. The test for the durability of markings is given in 6.5.

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

7.1.2 In addition to the requirements of 7.1.1, the pressure regulator shall be marked with the following:

a) the name and/or the trademark of the manufacturer or distributor;

b) the model or type designation;

c) means to ensure traceability such as type, batch or serial number or year of manufacture;

d) the nominal inlet pressure, P_1;

e) for manifold pressure regulators the designation 'HP' at all ports connected to inlet pressure;

f) an arrow showing the direction of the flow.

Table 3 — Medical gases, marking and colour coding

Name	Symbol	Colour coding [a]
Oxygen	O_2	White [b]
Nitrous oxide	N_2O	Blue [b]
Air for breathing	Air [c]	Black-white [b]
Air for driving surgical tools	Air-800	Black-white [b]
Nitrogen for driving surgical tools	N_2-800	Black [b]
Carbon dioxide	CO_2	Grey [b]
Oxygen from an oxygen concentrator	Under consideration	Under consideration
Mixture oxygen/nitrous oxide	O_2/N_2O	White-blue [b]

[a] See Annex C for regional and national deviations of colour coding and nomenclature for medical gases.

[b] In accordance with ISO 32.

[c] National languages can be used for air.

7.1.3 Pressure gauges shall be marked with the following:

a) name and/or trademark of the manufacturer and/or distributor;

b) the words “USE NO OIL” or the symbol shown in Figure 9;

c) the units of pressure.

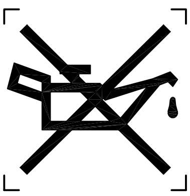


Figure 9 — Symbol for “use no oil” (Application of ISO 7000-0248)

7.2 Colour coding

7.2.1 If colour coding is used, it shall be in accordance with Table 3 or regional or national standards.

NOTE Annex C shows regional and national deviations of colour coding and nomenclature for medical gases.

7.2.2 Colour coding shall be durable. The test for the durability of colour coding is given in 6.5.

7.3 Packaging

7.3.1 Manifold and line pressure regulators and spare parts shall be sealed to protect against contamination and packaged to prevent damage during storage and transportation.

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

8 Information to be supplied by the manufacturer

8.1 Manifold and line pressure regulators shall be accompanied by documents containing at least a technical description, instructions for installation and use and an address to which the user can refer. The accompanying documents shall be regarded as a component part of pressure regulators.

8.2 Instructions for installation shall make reference to the procedures for testing, commissioning and certification given in ISO 7396-1.

Instructions for use shall contain all information necessary to operate the pressure regulator in accordance with its specification and shall include an explanation of the function of controls, the sequence of operation and connection and disconnection of detachable parts and accessories. Instructions for use shall give detailed instructions for the safe performance of cleaning, inspection and preventive maintenance to be performed by the operator or by authorized persons, and shall indicate the recommended frequency of such activities. A list of recommended spare parts shall be provided. The meaning of figures, symbols, warning statements and abbreviations on the pressure regulator shall be explained in the instructions for use.

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

— the danger of fire or explosion arising from the use of lubricants not recommended by the manufacturer;

— the danger of fire or explosion arising from oxygen pressure shocks;

— the danger which can arise from changing the setting of the pressure-relief valve;

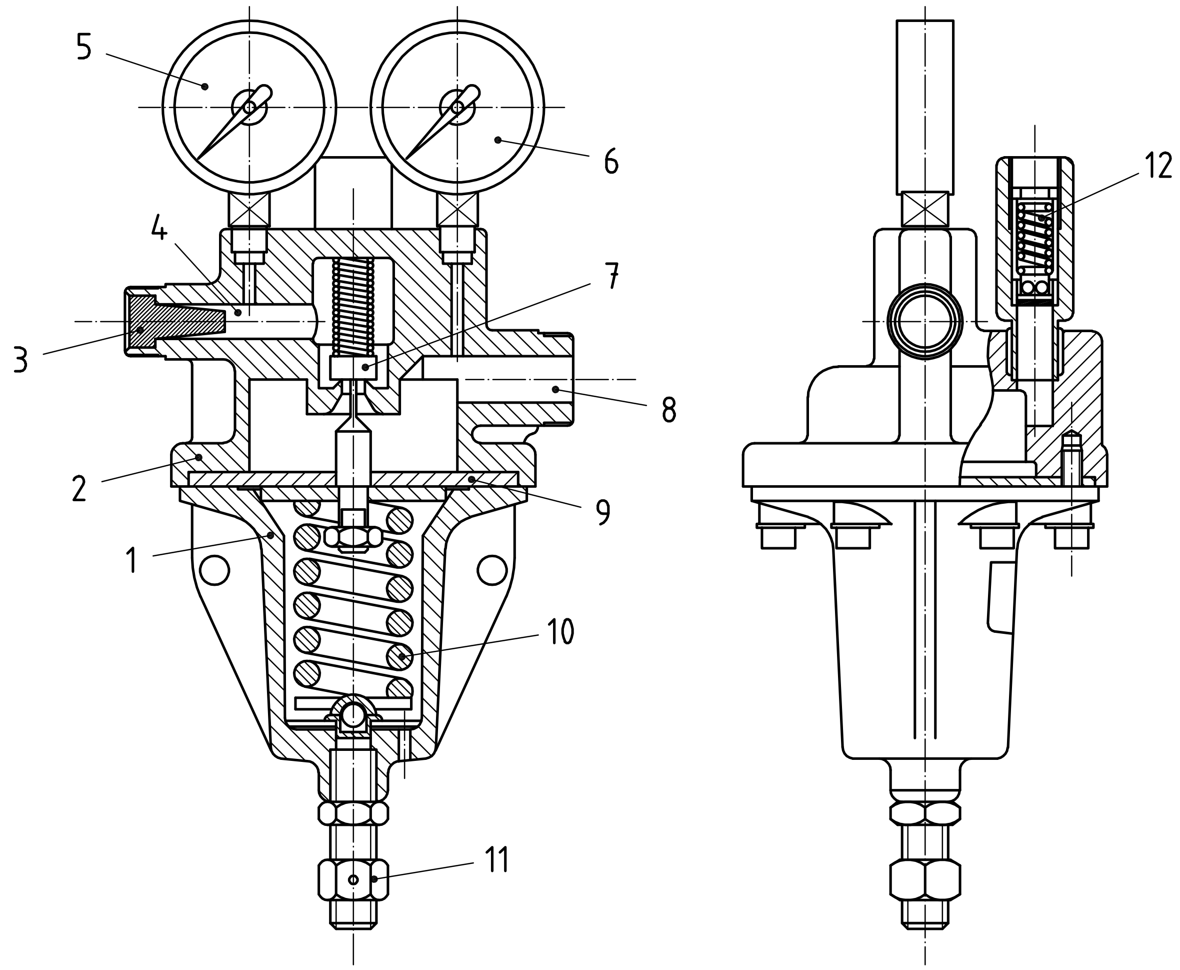
— the danger of fire arising from allowing the pressure regulator to come into contact with oils, greases or other combustible substances.

8.3 The performance of the manifold and line pressure regulators shall be stated by assigning values to the range of inlet pressure, to the range of nominal outlet pressure, P_2, and to the related standard discharge, Q_1.

Annex A
(informative)

Examples of pressure regulators

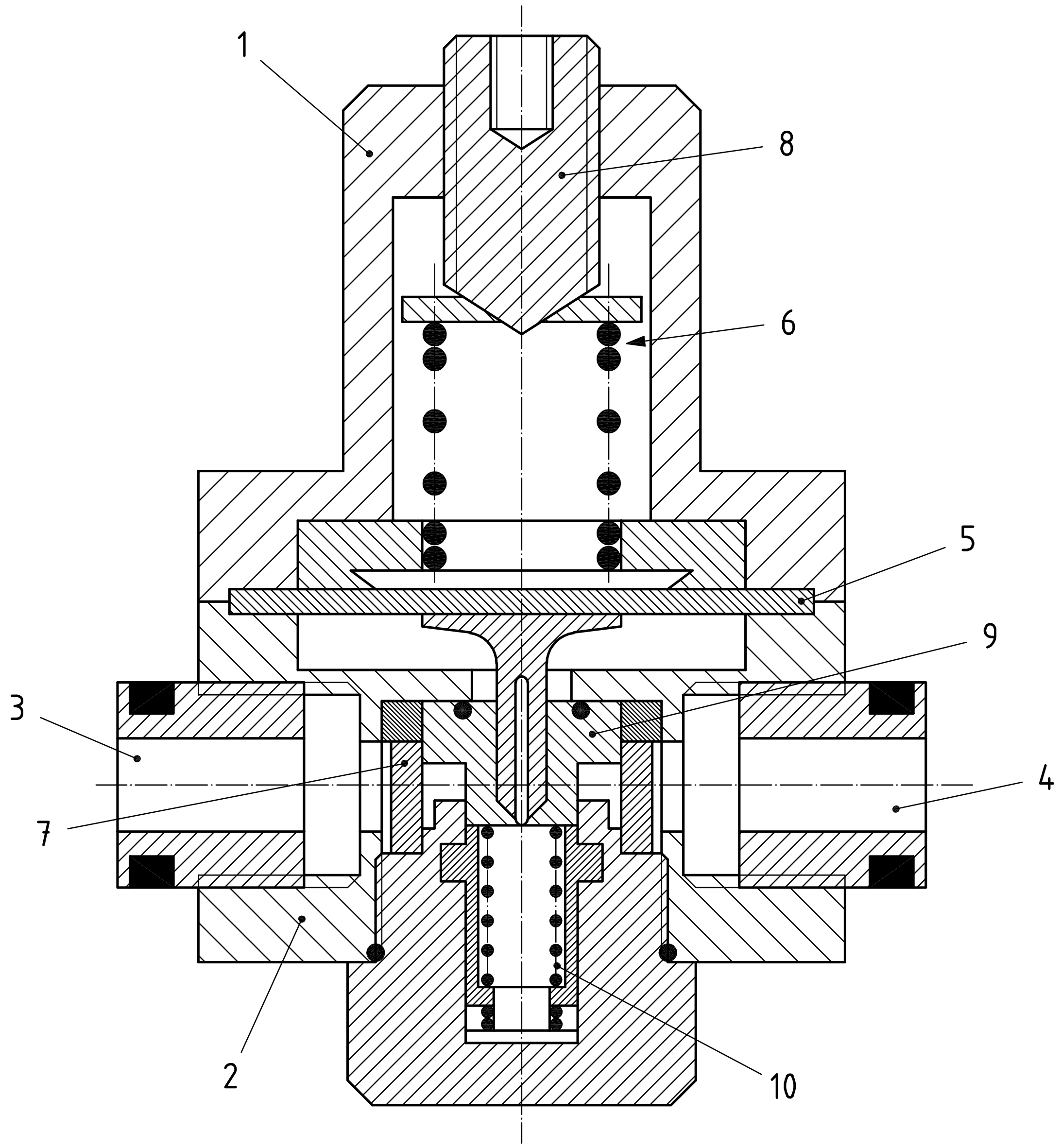
Figures A.1 and A.2 provide examples of pressure regulators.



Key

1 cover
2 body
3 filter
4 inlet port
5 inlet pressure gauge
6 outlet pressure gauge
7 pressure regulator valve
8 outlet port
9 diaphragm
10 pressure regulator spring
11 pressure-adjusting device
12 pressure-relief valve

Figure A.1 — Diagram of a typical manifold pressure regulator



Key

1	cover	6	pressure regulator spring
2	body	7	filter
3	inlet port	8	pressure-adjusting device
4	outlet port	9	pressure regulator valve
5	diaphragm	10	pressure regulator valve spring

Figure A.2 — Diagram of a typical line pressure regulator

Annex B
(informative)

Rationale

The following correspond to subclauses marked with * in this part of ISO 10524. The numbering is, therefore, not consecutive.

B.1.1 Cylinders used to supply medical gas pipeline systems are currently filled to nominal filling pressures of up to 25 000 kPa. Cylinders exist that can be filled to higher pressures (currently up to 30 000 kPa) and these are already in use for certain applications. Although these higher-pressure cylinders have been used in non-medical applications, there is only limited knowledge of the requirements for their safe operation. At present there are no gas-specific cylinder valve outlets specified for use with medical gas cylinders with pressures above 25 000 kPa. Therefore the scope of this part of ISO 10524 has been restricted to the use of cylinders filled at pressures up to 25 000 kPa. Once experience has been gained and standards for medical gas-specific cylinder valve outlets for higher pressures have been developed it is anticipated that this part of ISO 10524 will be amended to include pressure regulators for use with cylinders with nominal filling pressures of up to 30 000 kPa.

B.1.2 In a single-stage pipeline distribution system it is common practice to regulate the supply of medical gas from a cylinder manifold or from a cryogenic vessel using a control panel that integrates the manifold pressure regulator with pressure-relief valves, shut-off valves, pressure gauges, pressure switches for alarms and the line pressure regulator into a single unit. In a double-stage distribution system the line pressure regulator may be assembled or integrated with other components. The requirements of this part of ISO 10524 are intended to cover the design requirements for line and manifold pressure regulators as components of these assemblies as well as those that are supplied as individual items.

B.5.3.1 Pressure regulators for different gases are often made with interchangeable components or sub-assemblies. The requirement for compatibility with oxygen should therefore be applied to manifold pressure regulators for all gases.

B.5.3.5 Most pressure regulators are made of brass or aluminium. Aluminium and its alloys are more likely to ignite in oxygen than is brass. In standard tests, aluminium can burn vigorously even at low pressures, while brass burns only at pressures many times higher than cylinder filling pressures. Although there are some reported instances of ignition in brass pressure regulators, these pressure regulators have a long history of safe use and are believed to be safer than aluminium pressure regulators for use with high-pressure oxygen. Therefore components on the high-pressure side of a manifold pressure regulator are required by this International Standard to be composed of a material other than aluminium, e.g., brass. However, aluminium pressure regulators are widely and safely used as line pressure regulators.

Pressure regulators for different gases are often made with interchangeable components or sub-assemblies. This requirement should therefore be applied to manifold regulators for all gases.

B.5.4.5.1 Cylinder pressure regulators that are specified in ISO 10524-1 are tested for resistance to ignition by a less stringent test than that given for manifold pressure regulators in this part of ISO 10524. Therefore cylinder pressure regulators are not suitable for connection to a manifold. In order to reduce the possibility of fitting cylinder pressure regulators to manifolds, cylinder valve connectors are not permitted to be fitted to the inlet port of manifold pressure regulators.

B.5.4.5.6 Manifold pressure regulators for different gases are often made with interchangeable components or sub-assemblies. The requirement for resistance to ignition should therefore be applied to manifold pressure regulators for all gases.

B.5.4.6.1 Line pressure regulators are not tested for resistance to ignition. Therefore line pressure regulators are not suitable for connection to a cylinder. In order to reduce the possibility of fitting line pressure regulators to cylinders, cylinder valve connectors are not permitted at the inlet port of line pressure regulators.

B.5.4.6.5 Line pressure regulators are normally supplied with gas at inlet pressures up to 3 000 kPa. Higher pressures can be applied in single fault condition of the equipment installed upstream, e.g. manifold pressure regulators or control equipment of cryogenic vessels. However, these higher pressures (which can be expected, in particular, for air or nitrogen for driving surgical tools) are not applied suddenly and the compression ratio between the higher pressure and the nominal inlet pressure is such that only a negligible increase of temperature would be expected. For this reason, line pressure regulators do not need to be subjected to oxygen pressure shocks and the requirement specifying the minimum ignition temperature of the non-metallic components in contact with the gas is considered sufficient to ensure safety.

Line pressure regulators for different gases are often made with interchangeable components or sub-assemblies. The requirement for resistance to ignition should therefore be applied to line pressure regulators for all gases.

The permitted operating temperatures of tested material are 140 °C and 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 of the operating temperature and the fact that the auto-ignition temperature is not a constant.

B.5.5.1 Manifold and line pressure regulators for different gases are often made with interchangeable components or sub-assemblies. The requirement for cleanliness should therefore be applied to pressure regulators for all gases.

Annex C
(informative)

Reported regional and national deviations of colour coding and nomenclature for medical gases

Table 3 of this part of ISO 10524 contains requirements for colour coding of medical gases in accordance with ISO 32. Although many countries comply with ISO 32, some countries have colour coding requirements that differ from those specified in ISO 32. Often these alternative colour codes are mandated by standards in force within the respective countries.

Tables C.1 to C.5 list some of the known specific colour coding requirements which differ from ISO 32. For the countries in which the relevant national condition applies the provisions shown below are normative, for other countries they are informative.

Table C.1 — European Union

Medical gas	Colour coding
Oxygen	White
Nitrous oxide	Blue
Medicinal air	Black and white
Nitrogen	Black
Carbon dioxide	Grey
Helium	Brown
Mixtures of gases	Combination of colours from individual gases, e.g. white/blue
NOTE See EN 1089-3[2].	

Table C.2 — United States of America

Medical gas	Colour coding
Oxygen	Green
Nitrous oxide	Blue
Medical air	Yellow
Nitrogen	Black
Carbon dioxide	Grey
Helium	Brown
Mixtures of gases	Combination of colours from individual gases, e.g. green/blue
NOTE See CGA C-9:1988[13].	

Table C.3 — Australia and New Zealand

Medical gas	Colour coding
Oxygen	White
Nitrous oxide	Ultramarine
Medical breathing air	Black and white
Surgical tool gas	Aqua
Nitrous oxide/oxygen 50/50	Ultramarine and white
Carbon dioxide	Green-grey
Carbon dioxide in oxygen — nominal 5 %	White and green-grey
Spare medical gas	Sand
NOTE See AS 4484-1997[11] and AS 2896-1998[10].	

Table C.4 — Canada

Medical gas	Colour coding
Oxygen	White
Nitrous oxide	Blue
Medical breathing air	Black and white
Nitrogen	Black
Carbon dioxide	Grey
Helium	Brown
Mixtures of gases	Combination of colours from individual gases
NOTE See CAN/CGSB 24.2-M86[12].	

Table C.5 — Japan

Medical gas	Colour coding
Oxygen	Green
Nitrous Oxide	Blue
Air for breathing	Yellow
Nitrogen	Grey
Carbon dioxide	Orange
Air for driving surgical tools	Brown
Nitrogen for driving surgical tools	Grey
NOTE See JIS T 7101:1997[14].	

Bibliography

[1] EN 738-2, *Pressure regulators for use with medical gases — Part 2: Manifold and line pressure regulators*

[2] EN 1089-3, *Transportable gas cylinders — Cylinder identification — Part 3: Colour coding*

[3] ISO 10079-3, *Medical suction equipment — Part 3: Suction equipment powered from a vacuum or pressure source*

[4] ISO 4135, *Anaesthetic and respiratory equipment — Vocabulary*

[5] EN 737-3, *Medical gas pipeline systems — Part 3: Pipelines for compressed medical gases and vacuum*

[6] ISO 7291, *Gas welding equipment — Pressure regulators for manifold systems used in welding, cutting and allied processes up to 300 bar*

[7] ASTM G175:2003, *Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications*

[8] IEC 60601-1:1998, M*edical electrical equipment — Part 1: General requirements for safety*

[9] ISO 4126-7, *Safety devices for protection against excessive pressure – Part 7: Common dat*a

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

[11] AS 4484-1997, *Gas cylinders for industrial, scientific, medical and refrigerant use — Labelling and colour coding*

[12] CAN/CGSB 24.2-M86, *Identification of Medical Gas Containers, Pipelines and Valves*

[13] CGA C-9:1988, *Standard Color Marking of Compressed Gas Containers Intended for Medical Use*

[14] JIS T 7101:1997, *Medical gas pipeline systems*

[15] ISO 10524-1, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC Medical Devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC Medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in table ZA confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA — Correspondence between this European Standard and Directive 93/42/EEC Medical devices

Clause(s)/sub-clause(s) of this EN	Essential requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
5	1	
5.1	2, 6	
5.2	2	
5.3	2	
5.3.1	7.1, 7.3, 9.3	
5.3.2	4, 7.1, 9.2	
5.3.3	3, 5	
5.3.4	7.1, 7.2	
5.4	2, 3, 4	
5.4.1.1	10	
5.4.1.3	10.2	
5.4.2.	12.7.1	
5.4.3	7.2, 7.6	
5.4.4	9.2	
5.4.5.1	9.1, 12.7.4	
5.4.5.2	9.1, 12.7.4	
5.4.5.3	7.5	
5.4.5.4	3	
5.4.5.5	7.5, 9.2, 12.7.1	
5.4.5.6	7.3, 9.3	
5.4.6.1	9.1, 12.7.4	
5.4.6.2	9.1, 12.7.4	
5.4.6.3	7.5	

Clause(s)/sub-clause(s) of this EN	Essential requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
5.4.6.4	3	
5.4.6.5	7.3, 9.3	
5.5.1	7.2, 9.3	
5.5.2	7.2, 9.3	
6	3, 7.5, 9.2, 9.3, 12.8.1, 12.8.2	
7.1	13.1, 13.2	
7.1.2, a)	13.1, 13.3 a)	
7.1.2, b)	13.3 b)	
7.1.2, c)	13.3 d)	
7.1.3, a)	13.1, 13.3 a)	
7.2	13.2	
7.3	3, 5	
7.3.1	5, 7.2, 7.6	
7.3.2	13.1, 13.3 b)	
8.1	13.1, 13.3 a, 13.4, 13.6 a)	
8.2	9.1, 9.2, 9.3, 13.1, 13.6 c), 13.6 d), 13.6 k)	
8.3	13.6 b)	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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