INTERNATIONAL STANDARD

ISO 10524-2

Second edition
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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

Reference number
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Contents

Page

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 SC 6, *Medical gas systems*.

This second edition cancels and replaces the first edition (ISO 10524-2:2005), which has been technically revised.

The main changes compared to the previous edition are as follows:

— the scope has been extended to include 30 000 kPa (300 bar) manifold pressure regulators;

— this document has been restructured according to the new ISO template and associated renumbering;

— the common requirements have been aligned with ISO 10524-1 and ISO 10524-3;

— all type tests have been reviewed;

— a complete schedule has been introduced;

— a pressure retention test of the low-pressure side for the line pressure regulators has been introduced.

A list of all parts in the ISO 10524 series can be found on the ISO website.

Introduction

MANIFOLD PRESSURE REGULATORS are used within the supply systems of medical gas pipeline systems to reduce high cylinder pressure to a lower pressure suitable for the supply of medical gases to the inlet of LINE PRESSURE REGULATORS.

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 document.

This document 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, and

— information supplied by the manufacturer.

Annex B 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 included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated into 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 expedite any subsequent revisions.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex B.

In this document, the following print types are used:

— requirements and definitions: roman type.

— informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

— *test specifications: italic type*;

— TERMS DEFINED IN CLAUSE 3 OF THIS DOCUMENT OR AS NOTED: SMALL CAPITALS TYPE.

Pressure regulators for use with medical gases —

Part 2: Manifold and line pressure regulators

1 * Scope

This document specifies design, construction, type testing, and marking requirements for MANIFOLD PRESSURE REGULATORS (as defined in 3.7) and LINE PRESSURE REGULATORS (as defined in 3.5) intended for use in MEDICAL GAS PIPELINE SYSTEMS.

Examples of gases include oxygen, medical air and oxygen/nitrous oxide mixtures.

This document applies to MANIFOLD PRESSURE REGULATORS and LINE PRESSURE REGULATORS supplied as individual units or to the relevant components incorporated within an assembly.

MANIFOLD PRESSURE REGULATORS are intended to be connected to a MANIFOLD system which has a NOMINAL INLET PRESSURE, P_1 of up to 30 000 kPa (300 bar).

LINE PRESSURE REGULATORS are intended to be connected downstream of the MANIFOLD PRESSURE REGULATOR with a supply pressure up to 3 000 kPa (30 bar).

This document 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 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 7000, *Graphical symbols for use on equipment — Registered symbols*

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

ISO 10297:2014, *Gas cylinders — Cylinder valves — Specification and type testing*

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

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

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

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

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:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
CLOSURE PRESSURE
P_4
stabilized outlet pressure, after cessation of the flow, from a *PRESSURE REGULATOR* (3.15) when the flow has been set to *STANDARD DISCHARGE* (3.20)

3.2
DOUBLE-STAGE PIPELINE DISTRIBUTION SYSTEM
pipeline distribution system in which gas is initially distributed from the *SUPPLY SYSTEM* (3.21) at a higher pressure than the *NOMINAL DISTRIBUTION PRESSURE* (3.8), and is then reduced to the NOMINAL DISTRIBUTION PRESSURE by *LINE PRESSURE REGULATOR(S)* (3.4)

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 (3.15) used in a *DOUBLE STAGE PIPELINE DISTRIBUTION SYSTEM* (3.2) to reduce the nominal SUPPLY SYSTEM pressure to the *NOMINAL DISTRIBUTION PRESSURE* (3.8)

3.5
MANIFOLD
device for connecting the outlet(s) of one or more cylinders or cylinder bundles of the same medical gas to a *MEDICAL GAS PIPELINE SYSTEM* (3.7)

3.6
MANIFOLD PRESSURE REGULATOR
PRESSURE REGULATOR (3.15) intended to be installed within *SOURCE OF SUPPLY* (3.19) containing cylinders or cylinder bundles, or high pressure storage vessel(s)

3.7
MEDICAL GAS PIPELINE SYSTEM
complete system which comprises a *SUPPLY SYSTEM* (3.21), 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 *MEDICAL GAS PIPELINE SYSTEM* (3.7) is intended to deliver at the terminal units

3.9
NOMINAL INLET PRESSURE
P_1
upstream *WORKING PRESSURE* (3.24) specified by the manufacturer for which the *PRESSURE REGULATOR* (3.15) is intended to be used

3.10
NOMINAL OUTLET PRESSURE
P_2
pressure downstream of the *PRESSURE REGULATOR* (3.15) under flow conditions specified by the manufacturer

3.11
OXIDIZING GAS
any gas or gas mixture more oxidizing than air, i.e. any gas or gas mixture that is able, at atmospheric pressure, to support the combustion more than a reference oxidizer consisting of 23,5 % oxygen in nitrogen

[SOURCE: ISO 10156:2017, 3.1.5, modified]

3.12
PRE-SET PRESSURE REGULATOR
PRESSURE REGULATOR (3.15) that is not provided with a means of operator adjustment of the outlet pressure

3.13
PRESSURE CHARACTERISTIC
variation of the outlet pressure in relation to inlet pressure under constant flow conditions

3.14
PRESSURE GAUGE
device that measures and indicates pressure

3.15
PRESSURE REGULATOR
device that reduces the inlet pressure and maintains the set outlet pressure within specified limits

3.16
PRESSURE-RELIEF DEVICE
device intended to relieve excess pressure at a pre-set value

3.17
SINGLE FAULT CONDITION
condition in which a single means for protection against a safety hazard in equipment is defective or a single external abnormal condition is present

3.18
SINGLE-STAGE PIPELINE DISTRIBUTION SYSTEM
pipeline distribution system in which gas is distributed from the *SUPPLY SYSTEM* (3.19) at the *NOMINAL DISTRIBUTION PRESSURE* (3.8)

3.19
SOURCE OF SUPPLY
portion of the *SUPPLY SYSTEM* (3.19) with associated control equipment, which supplies the pipeline distribution system

3.20
STANDARD DISCHARGE
Q_1
flow for which the *PRESSURE REGULATOR* (3.15) is designed to maintain a *NOMINAL OUTLET PRESSURE*, P_2 (3.10), at *TEST INLET PRESSURE*, P_3 (3.22)

3.21
SUPPLY SYSTEM
system that supplies the pipeline distribution system and which includes two or more *SOURCES OF SUPPLY* (3.19)

3.22
TEST INLET PRESSURE
P_3
minimum inlet test pressure

3.23
TEST OUTLET PRESSURE
P_5
highest or lowest value of the outlet pressure resulting from a variation in the inlet pressure between P_1 (3.9) and P_3 (3.22) at previously adjusted conditions P_1, P_2 (3.10), Q_1 (3.20)

3.24
WORKING PRESSURE
settled pressure of a compressed gas at a uniform reference temperature of 15 °C in a full gas cylinder

Note 1 to entry: This definition does not apply to liquefied gases (e.g. carbon dioxide) or dissolved gases (e.g. acetylene).

4 Nomenclature

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, present no risks with an unacceptable level, under normal condition or SINGLE FAULT CONDITION, identified using risk management procedures in accordance with ISO 14971.

The risks associated with the ignition of metallic and non-metallic materials, including the potential release of toxic products in an oxygen-enriched environment, shall be assessed according to the principles defined in ISO 15001.

The design of MANIFOLD and LINE PRESSURE REGULATORS should be such that in the event of an internal ignition, the consequences of the ignition are contained and the gas vented safely.

Check compliance by inspection of the risk management file.

NOTE 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.

5.2 Usability

The manufacturer shall address, in a usability engineering process, any risks resulting from poor usability.

Check compliance by inspection of the usability engineering file.

NOTE For information related to usability, see other documents; for example, IEC 62366-1 and IEC/TR 62366-2.

5.3 Alternative construction

MANIFOLD and LINE PRESSURE REGULATORS and components, or parts thereof, using materials or having 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 at least 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.

Objective evidence may be obtained by post-market surveillance.

Evidence of at least an equivalent degree of safety shall be provided by the manufacturer.

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

5.4 Materials

5.4.1 * The materials which come in contact with the medical gas in normal condition shall be resistant to corrosion and compatible with oxygen, the other medical gases and their mixtures in the temperature range specified in 6.1.

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 minimizes consequences based on the use of materials exhibiting good compatibility and 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 an oxygen-enriched atmosphere. Many such materials can be ignited by friction at a valve seat or by adiabatic compression when an oxygen-enriched gas at high pressure is rapidly introduced into a system initially at low pressure.

NOTE 4 Halogenated polymers such as polytetrafluoroethylene (PTFE), polychlorotrifluoroethylene (PTCFE) and fluoroelastomers (FKM) can release highly toxic products during thermal decomposition.

NOTE 5 Design considerations and criteria for the selection of metallic and non-metallic materials are given in ISO 15001.

5.4.2 Materials that are liable to shed particles which can 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.

5.4.3 * Aluminium, aluminium alloys or alloys with aluminium content greater than 2,5 % shall not be used for components whose surfaces come into contact with OXIDIZING GASES or gas mixtures at cylinder pressure in normal or SINGLE FAULT CONDITION.

5.4.4 Consideration should be given to the avoidance of stainless steel and other ferrous alloys for components whose surfaces come into contact with OXIDIZING GASES or gas mixtures at cylinder pressure in normal or SINGLE FAULT CONDITION.

5.4.5 The materials shall permit the MANIFOLD and LINE PRESSURE REGULATORS and their components to meet the requirements of Clause 6 in the temperature range of −20 °C to +60 °C.

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

5.4.6 MANIFOLD and LINE PRESSURE REGULATORS shall meet the requirements of this document after being packed for transport and storage and being exposed to environmental conditions, as stated by the manufacturer.

Evidence of conformity with the requirements of Clause 6 shall be provided by the manufacturer upon request.

6 Design requirements

6.1 General

The operation of the MANIFOLD and LINE PRESSURE REGULATORS shall comply with the requirements of this document between −20 °C and +60 °C.

NOTE Regional or national regulations can specify additional design requirements and certifications or approval.

6.2 PRESSURE GAUGES

6.2.1 If a Bourdon tube PRESSURE GAUGE is used, it shall conform to EN 837-1 (except for the minimum nominal size).

NOTE EN 837-1 is a standard for Bourdon tube PRESSURE GAUGES but not all of its requirements are applicable to other types of gauges, e.g. direct drive gauges.

6.2.2 PRESSURE GAUGES should be designed to resist moisture ingress (e.g. IP 44 of IEC 60529).

6.2.3 The casings of PRESSURE GAUGES should be designed such that the pressure is safely relieved to prevent a hazardous overpressure that could lead to a rupture in the event of a leak within the gauge.

6.2.4 If the gauge connector is threaded, it shall comply with EN 837-1 or a regional or national standard.

6.2.5 The pressure or content indication 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.

6.2.6 The scale of the cylinder PRESSURE GAUGE shall extend to at least 133 % of P_1.

NOTE In addition to the scale ranges in EN 837-1, a PRESSURE GAUGE with a scale range of 0 kPa to 31 500 kPa (315 bar) can also be used.

6.2.7 PRESSURE GAUGES shall be class 2.5 or better, in accordance with EN 837-1.

6.2.8 The inlet connection of 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.

Check compliance with the requirements of 6.2 by visual inspection or measurement as required.

6.3 Integrated digital gauges

Where the risk management process demonstrates that the risk to patient safety is impacted by the use of electrical equipment, IEC 60601-1 shall be used as a normative reference.

6.4 Pressure-adjusting device

6.4.1 MANIFOLD and LINE PRESSURE REGULATORS shall be provided with a pressure-adjusting device.

6.4.2 The pressure-adjusting device shall be designed so that it can be locked into position and adjusted only with the use of a tool.

Check compliance by attempting to adjust the pressure without the use of a tool.

6.4.3 The pressure-adjusting device shall be captive.

Check compliance by attempting to remove the pressure adjusting device

6.4.4 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.

Check compliance by inspection.

6.4.5 Using the pressure-adjusting device it shall not be possible to set a pressure at which the PRESSURE-RELIEF DEVICE opens.

Check compliance by inspection.

6.5 Filtration

Means shall be provided to prevent particles greater than 100 µm in diameter from entering the high-pressure side of the PRESSURE REGULATOR.

If a filter is removable without the use of a tool, or it is a separate item, the test for resistance to ignition shall be carried out with and without the filter.

Check compliance by inspection of the risk management file.

NOTE The filter can be a separate item.

6.6 Mechanical strength

6.6.1 Resistance of the high-pressure side

The inlet side of a MANIFOLD or LINE PRESSURE REGULATOR shall be capable of withstanding 2,25× its NOMINAL INLET PRESSURE [P_1] for 5 min without rupturing.

The test is given in 8.4.3.1.

6.6.2 Resistance of the low-pressure side to pneumatic pressure

The outlet side of a MANIFOLD or LINE PRESSURE REGULATOR shall be capable of withstanding 4× its NOMINAL OUTLET PRESSURE (P_2) without rupturing.

The test is given in 8.4.3.2.

6.6.3 Resistance of the low pressure side to P_1

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 test is given in 8.4.3.2.

6.7 Endurance

The pressure regulating mechanism shall be able to withstand 10 000 operational cycles without impairment of operation, mechanical failure, or the development of leakage in excess of the rates described in 8.5.

The device shall maintain flow accuracy.

6.8 Manifold pressure regulators

6.8.1 * 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.

6.8.2 Outlet connector

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

6.8.3 Leakage

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

The test for total external leakage is given in 8.3.6.1

6.8.3.2 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 8.3.6.2.

6.8.4 Functional and FLOW CHARACTERISTICS

6.8.4.1 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_2s, 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 8.3.2.

6.8.4.2 Coefficient of pressure increase upon closure

The coefficient of pressure increase upon closure, R, is calculated using Formula (1):

$$R = \frac{P_4 - P_2}{P_2} \tag{1}$$

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

The test for determining the coefficient of pressure increase upon closure, R, is given in 8.3.3.

6.8.4.3 Irregularity coefficient, i

The irregularity coefficient (i) is calculated using Formula (2):

$$i = \frac{P_5 - P_2}{P_2} \tag{2}$$

The irregularity coefficient, i, shall fall within the limit ±0,3.

The test for determining the irregularity coefficient, i, is given in 8.3.4.

6.8.5 Pressure-relief device

Each MANIFOLD PRESSURE REGULATOR shall be provided with a PRESSURE-RELIEF DEVICE which may be integral with or separate from the MANIFOLD PRESSURE REGULATOR. Bursting discs shall not be used.

Means shall be provided to limit the outlet pressure of the MANIFOLD PRESSURE REGULATOR to a value not greater than 3 000 kPa.

The PRESSURE-RELIEF DEVICE 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 DEVICE shall comply with the requirement of 6.8.3.1 up to a pressure of 1,6 × P_2 or 1,6 times the set pressure.

The PRESSURE-RELIEF DEVICE shall be fitted in such a way that gas will be discharged safely.

The test for the PRESSURE-RELIEF DEVICE is given in 8.3.5.

6.8.6 * Resistance to ignition

MANIFOLD PRESSURE REGULATORS for all medical gases shall not ignite or show internal scorching damage when subjected to oxygen pressure surge.

The test for resistance to ignition is given in 8.3.8.

6.8.7 Nominal inlet pressure

MANIFOLD PRESSURE REGULATORS for medical gases 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.

6.9 Line pressure regulators

NOTE ISO 7396-1 specifies the functions that are required when LINE PRESSURE REGULATORS are installed in a DOUBLE-STAGE PIPELINE 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 separate items.

6.9.1 * 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.

6.9.2 Outlet connector

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

6.9.3 Leakage

6.9.3.1 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.

6.9.3.2 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 8.4.2

6.9.4 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 the variation of outlet pressure is given in 8.4.1.

6.9.5 * 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 or a test shall be performed to qualify the design of the LINE PRESSURE REGULATOR as described in 8.3.8.

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 8.4.4.

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

6.9.6 NOMINAL INLET PRESSURE

A LINE PRESSURE REGULATOR for medical gases shall not have a NOMINAL INLET PRESSURE, P_1, greater than 3 000 kPa.

7 Construction requirements

7.1 * Cleanliness

Components in contact with the medical gases during normal use of a PRESSURE REGULATOR for all medical gases shall meet the cleanliness requirements of ISO 15001.

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

7.2 Lubricants

If lubricants are used, they shall be compatible with oxygen and the other medical gases and their mixtures in the temperature range specified in 6.1. They shall be resistant to ignition up to the pressure they are intended to be exposed to under normal and SINGLE FAULT CONDITION.

NOTE 1 Attention is drawn to ISO 15001:2010, Annex D.

In case the lubricants used are not rated for P_1, evidence of suitability can be demonstrated by submitting three test samples to resistance to ignition tests according to 8.3.8. after they have been pre-conditioned via the endurance cycling procedure according to 8.5.

NOTE 2 The reason for pre-conditioning by endurance test is to allow the migration of lubricant which occurs during use and which can lead to a worsening condition.

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

8 Test methods for type tests

8.1 General conditions

8.1.1 General

These tests are type tests.

8.1.2 Ambient conditions

Unless otherwise stated, tests shall be performed at room temperature (typically between 15 °C to 30 °C, according to ISO 10297).

8.1.3 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 dew point 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 1.

Table 1 — 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
Nitrous oxide	0,81	0,79
Carbon dioxide	0,81	0,79
Helium	2,69	2,65
Xenon	0,47	0,46

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

8.1.4 Reference conditions

Correct flows to 15 °C and 101,3 kPa.

8.2 Test schedule

The tests for the MANIFOLD PRESSURE REGULATORS shall be carried out in accordance with the schedule given in Table 2.

Table 2 — Schedule of tests for MANIFOLD PRESSURE REGULATORS

Test sequence	Test and relevant subclause	Condition of test sample	Test temp.	Test pressure	Number of tests sample	Number of tests per sample	Total number of tests
1	Test method for mechanical strength high-pressure side (8.3.7.1)	As received	RT	2,25 × P_1	1	1	1
2	Test method for mechanical strength low-pressure side (8.3.7.2 and 8.3.7.3)	As received	RT	8.3.7.2 4 × P_2 8.3.7.3 P_1	1 1	2	2
3	Test methods for leakage (8.3.6)	As received	RT	P_1	3 to 5	2	6
4	Functional testing (8.3.2, 8.3.3 and 8.3.4)	From 3	RT	P_1	3 to 5	3	9
5	Endurance test (8.5)	From 4	RT	0,8 × P_1	3 to 5	1	3
6	Test methods for leakage (8.3.6)	From 5	RT	P_1	3 to 5	2	6
7	Functional testing (8.3.2, 8.3.3 and 8.3.4)	From 6	RT	P_1	3 to 5	3	9
8	Durability of markings (8.6)	From 6	RT	—	3 to 5 (only 1 sample)	—	—
9	Test method resistance to ignition (8.3.8)	As received	See 8.3.8	1,2 × P_1	6 to 8	2	6

The tests for the LINE PRESSURE REGULATORS shall be carried out in accordance with the schedule given in Table 3.

Table 3 — Schedule of tests for LINE PRESSURE REGULATORS

Test sequence	Test and relevant subclause	Condition of test sample	Test temp.	Test pressure	Number of test samples	Number of tests per sample	Total number of tests
1	Test method for mechanical strength high-pressure side (8.4.3.1)	As received	RT	2,25 × P_1	1	1	1
2	Test method for mechanical strength low-pressure side (8.4.3.2)	As received	RT	4 × P_2	2	1	1
3	Test methods for leakage (8.4.2)	As received	RT	P_1	3 to 5	2	6
4	Endurance test (8.5)	From 4	RT	0,8 × P_1	3 to 5	1	3

Table 3 *(continued)*

Test sequence	Test and relevant subclause	Condition of test sample	Test temp.	Test pressure	Number of test samples	Number of tests per sample	Total number of tests
5	Test methods for leakage (8.4.2)	From 5	RT	P_1	3 to 5	2	6
6	Durability of markings (8.6)	From 6	RT	—	3 to 5 (only 1 sample)	—	—
7	Test method for AIT (8.4.4)	As received	—	—	—	—	—

8.3 Test methods for MANIFOLD PRESSURE REGULATORS

8.3.1 Test equipment for functional and FLOW CHARACTERISTICS

All measuring devices used for testing shall have an accuracy and resolution of at least 1 % of the measured value for PRESSURE GAUGES and maximum of ±5 % of the measured value for flow-measuring devices.

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.

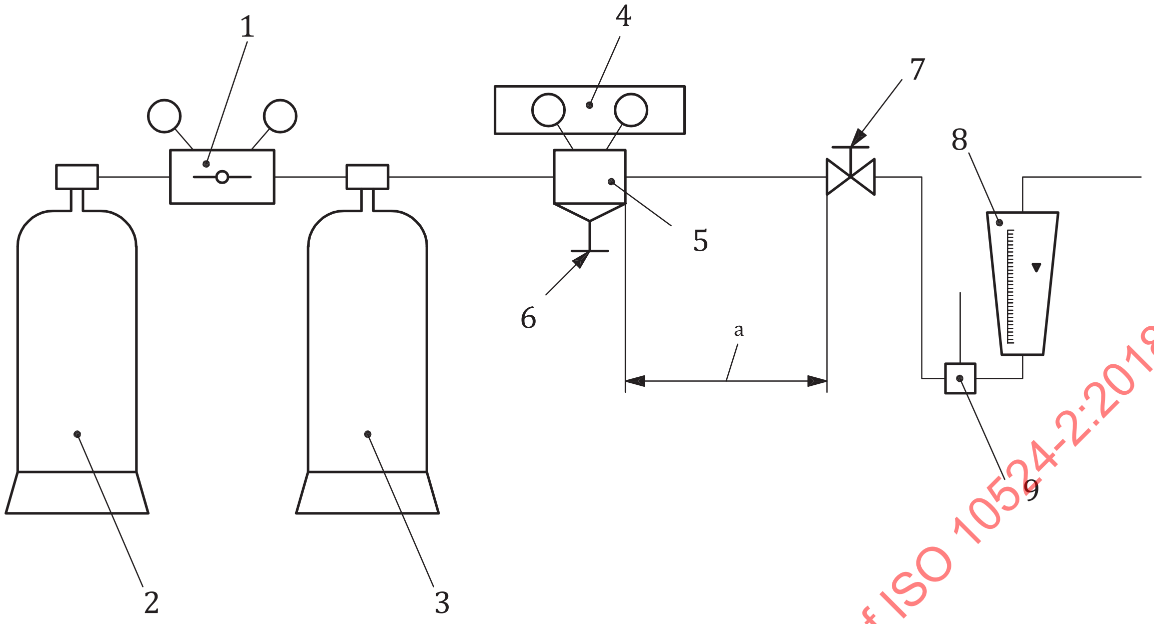
Ensure that all the components of the test equipment have a flow capacity greater than that of the PRESSURE REGULATOR to be tested.

8.3.2 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.

Typical test equipment is shown in Figure 1.

Dimensions in metres



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 (see Figure 1, Key 1) or any equivalent device. Using the pressure-adjusting device (see Figure 1, Key 6) 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 (see Figure 1, Key 7) 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 (see Figure 1, Key 8). If the outlet pressure has decreased, readjust it to P_2 and readjust 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 specifications.

8.3.3 Test method for determining the coefficient of pressure increase upon closure

Use the test equipment shown in Figure 1. This test is carried out with the PRESSURE REGULATOR set and locked as described in 8.3.2.

Apply pressure, P_3, to the inlet of the PRESSURE REGULATOR being tested (see Figure 1, Key 5). Adjust the flow to Q_1 (taking into account the corrections given in Table 2), using the flow control valve (see Figure 1, Key 7).

Rapidly cut off the flow with the flow control valve (see Figure 1, Key 7) (e.g. in less than 1 s) and measure the outlet pressure immediately downstream of the PRESSURE REGULATOR under test (see Figure 1, Key 5).

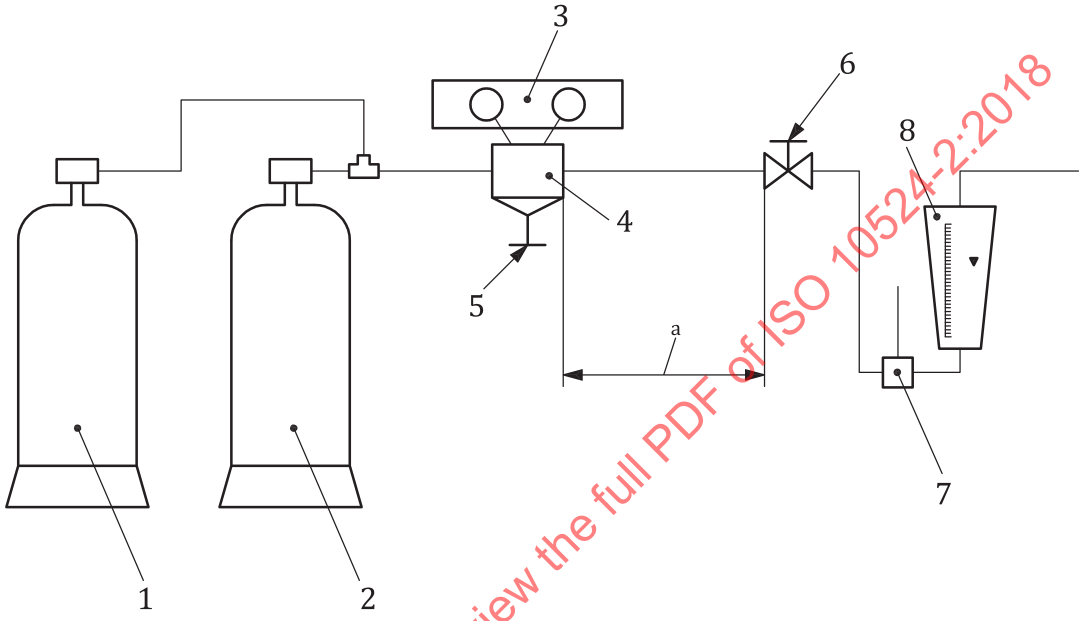
Allow the outlet pressure to stabilize for 60 s and record the value, P_4.

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.

8.3.4 Test method for determining the irregularity coefficient

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.

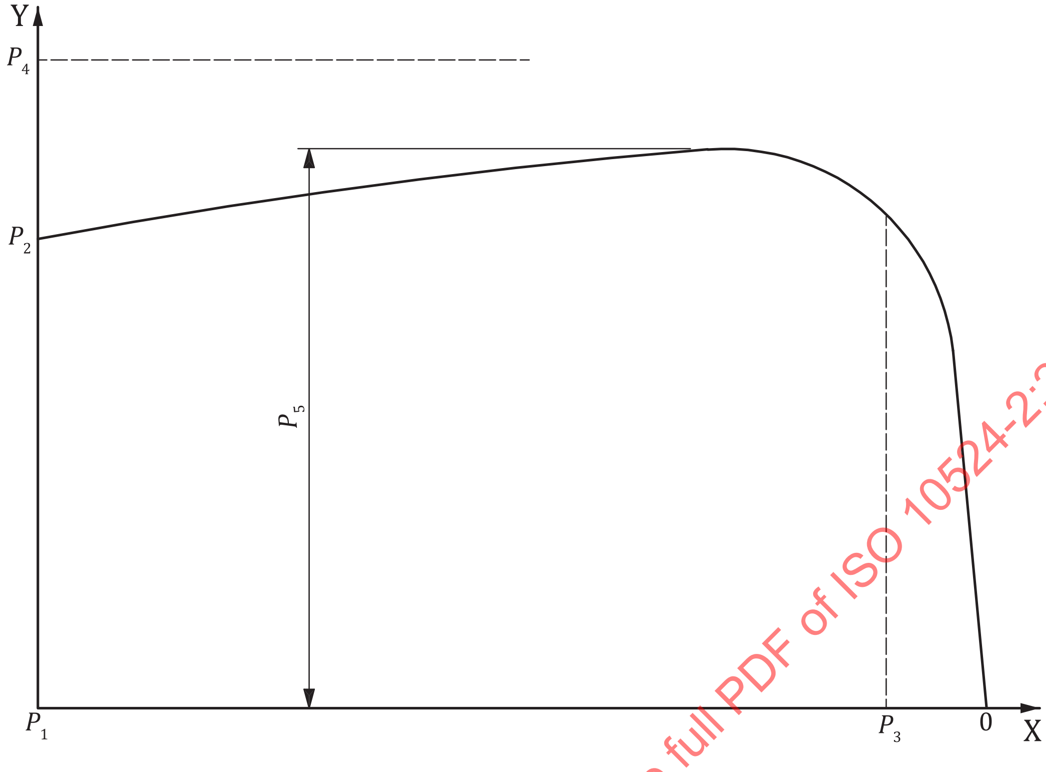
Equip the PRESSURE REGULATOR under test (see Figure 2, Key 4) with two calibrated gauges or recording equipment. Unlock the pressure-adjusting device on the PRESSURE REGULATOR under test. Apply pressure P_1 to the PRESSURE REGULATOR inlet. Operate the pressure-adjusting device on the PRESSURE REGULATOR under test and the flow control valve (see Figure 2, Key 6) 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 while the inlet pressure is varied through the range P_1 to P_3 with a maximum speed of 2 bar/s.

Plot the values of the inlet and outlet pressures. 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 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*.

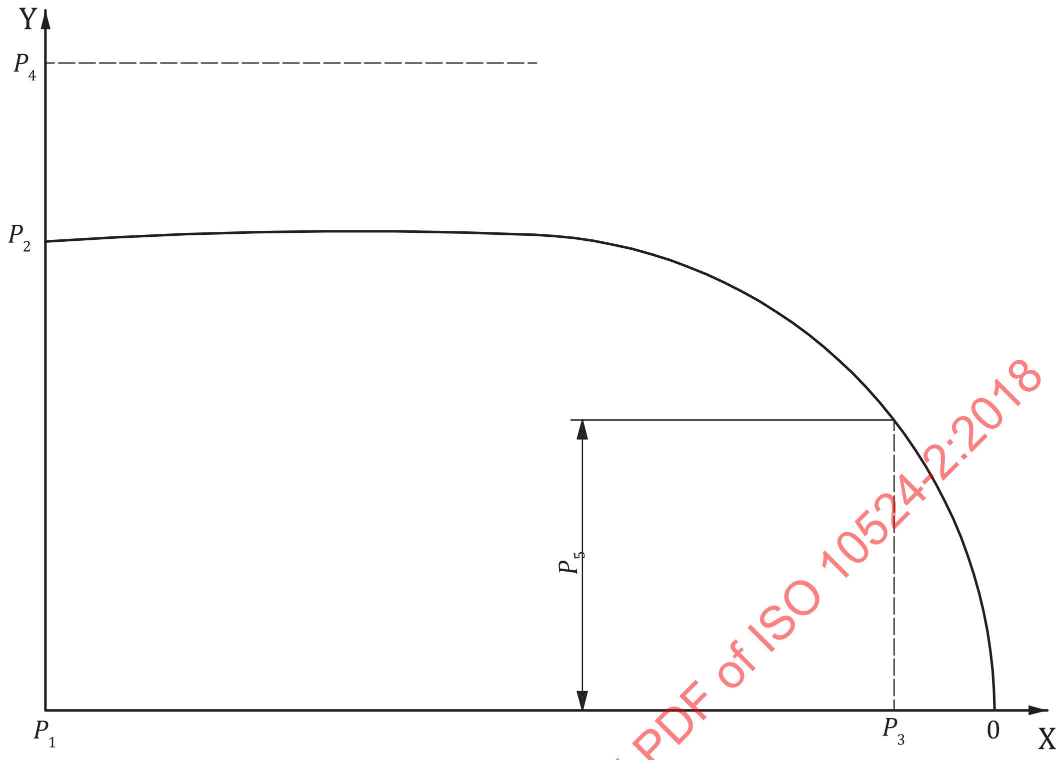


Key

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

8.3.5 Test method for PRESSURE-RELIEF DEVICE

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 DEVICE shall comply with the requirements of 6.8.3.1. Then, increase the pressure until the PRESSURE-RELIEF DEVICE opens. Take note of this pressure. Increase the pressure to 2 × P_2. At this pressure, measure the discharge of the PRESSURE-RELIEF DEVICE. The discharge shall be equal to or greater than Q_1. Decrease the pressure and check that the PRESSURE-RELIEF DEVICE resets at a pressure equal to or above the NOMINAL OUTLET PRESSURE, P_2.

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

8.3.6 Test methods for leakage

8.3.6.1 External leakage

Measure the total 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.

8.3.6.2 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.

8.3.7 Test method for mechanical strength

8.3.7.1 High-pressure side

Ensure the pressure-adjusting device is set to zero.

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 6.8.1 have been met.

8.3.7.2 Low-pressure side

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 6.8.2 are met.

Replace the PRESSURE-RELIEF DEVICE 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 6.8.2 are met.

8.3.7.3 Pressure retention test for the low pressure side (from ISO 7291)

For this test, the PRESSURE REGULATOR valve shall be held permanently open or removed.

The PRESSURE GAUGES shall be replaced by blind plugs and the outlet blanked off.

The PRESSURE-RELIEF DEVICE supplied with the PRESSURE REGULATOR shall be in operation.

A pneumatic pressure of P_1 shall be applied to the PRESSURE REGULATOR inlet through a valve which is manually opened quickly.

If no rupture occurs, the test is satisfactory. If rupture occurs, no pieces shall be ejected.

Venting of gas through the PRESSURE-RELIEF DEVICE, if fitted, is allowed.

During this test, the pressure in the low-pressure side shall not exceed 3 000 kPa (30 bar).

8.3.8 Test method for resistance to ignition

8.3.8.1 General

This test is described in ISO 10297: 2014, Annex C.

Deviations from the referenced test are noted below:

a) the PRESSURE REGULATOR shall be tested via the inlet connection;

b) the dimensions of the connecting tube shall be L = 0,75 m and d = 14 mm.

The test sequences for this document are described in 8.3.8.2

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).

8.3.8.2 Test procedure for MANIFOLD PRESSURE REGULATOR

MANIFOLD PRESSURE REGULATORS shall be tested in the normal delivery condition and with the PRESSURE REGULATOR valve open and the outlet closed (see Table 4).

Table 4 — Oxygen pressure shocks applied to the inlet connector

Sequence	Pressure regulator valve (see Figure 1, Key 5)
1	Closed
2	Open

8.4 Test method for LINE PRESSURE REGULATORS

8.4.1 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 (see Figure 1, Key 5) can be supplied by a buffer cylinder (see Figure 1, Key 3). Hold the upstream pressure constant by use of an auxiliary PRESSURE REGULATOR (see Figure 1, Key 1) or any equivalent device.

With the flow control valve (see Figure 1, Key 7) 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 while 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 while 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.

8.4.2 Test methods for leakage

8.4.2.1 External leakage

Measure the external leakage of the PRESSURE REGULATOR at the NOMINAL INLET PRESSURE, P_1, and NOMINAL 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.

8.4.2.2 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.

8.4.3 Test method for mechanical strength

8.4.3.1 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 6.8.1 are met.

8.4.3.2 Low-pressure side

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 6.8.3 are met.

Remove the PRESSURE-RELIEF DEVICE 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 6.8.3 are met.

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

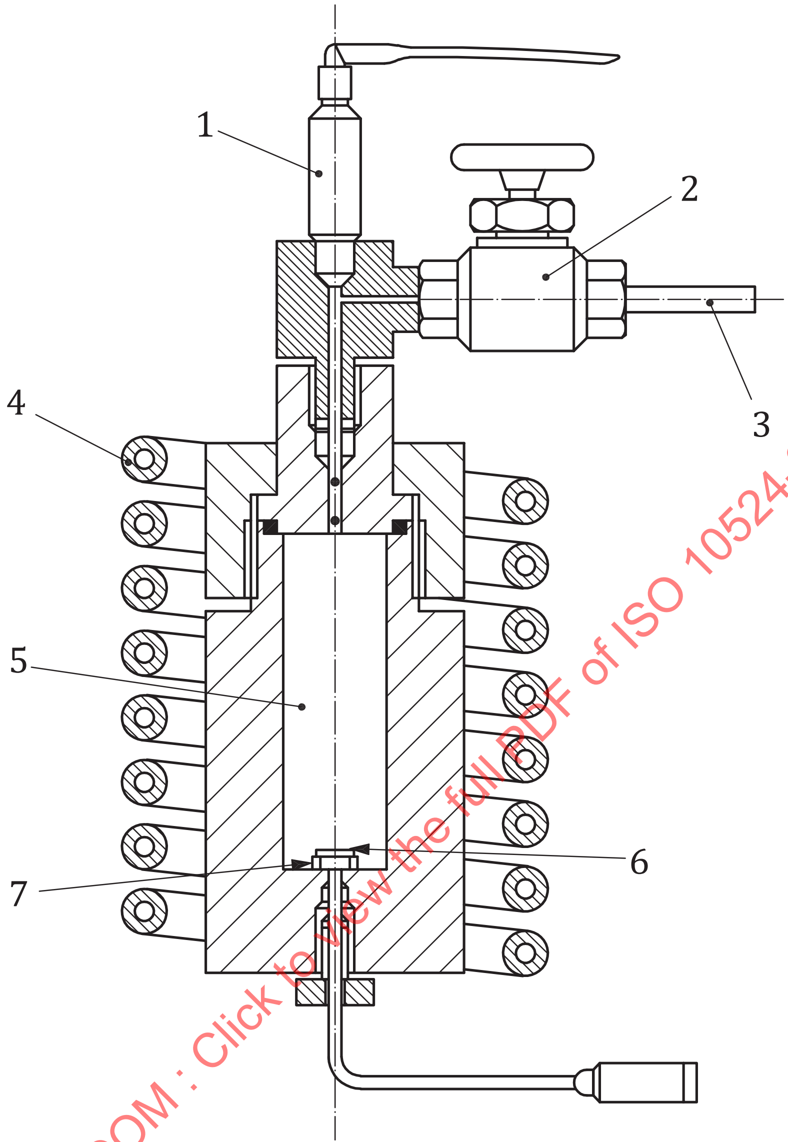
8.4.4 Test method for determination of the auto-ignition temperature of sealing materials and lubricants

Measure the auto-ignition temperature of the non-metallic materials including sealing materials and lubricants (if used) using the apparatus shown in Figure 5.

Place the 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 6).

NOTE 1 Usually, five tests at the same pressure are performed to determine the mean auto-ignition temperature and the standard deviation.

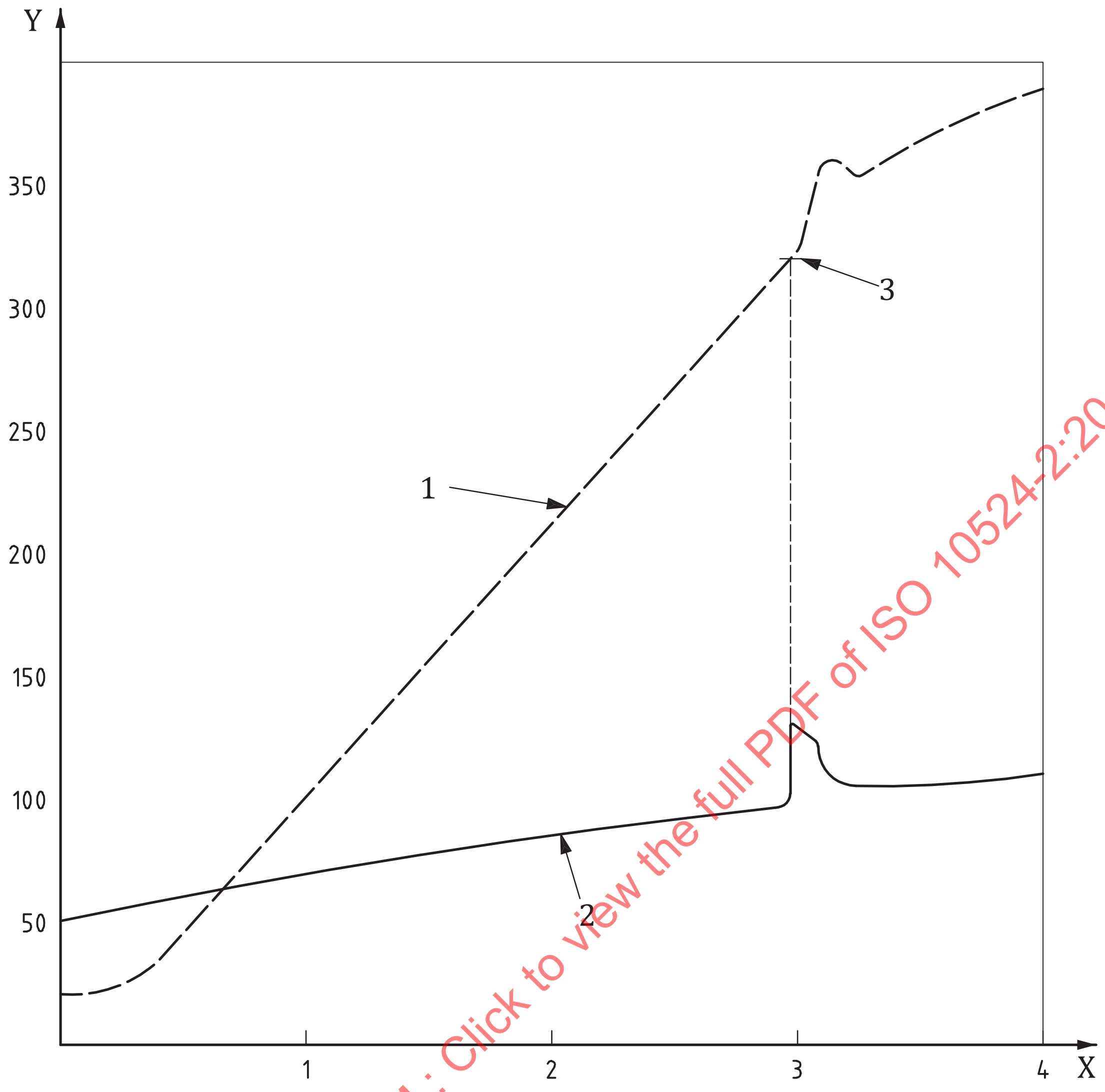
NOTE 2 Data on auto-ignition temperatures of non-metallic materials depend upon the test method and the sample preparation.



Key

1 pressure transducer
2 valve
3 oxygen supply
4 inductive heater
5 reaction vessel
6 test sample
7 thermocouple

Figure 5 — Equipment for determining the auto-ignition temperature of non-metallic components



Key

X time (min)

Y pressure/temperature

1 temperature (°C)

2 pressure (kPa/100)

3 auto-ignition temperature

Figure 6 — Typical record of an auto-ignition temperature determination in compressed oxygen

8.5 Endurance test

Endurance testing shall be carried out with oil-free, dry air or oil-free, dry nitrogen at room temperature.

For this test, the PRESSURE REGULATOR shall be installed so that the inlet is connected to a source of test gas at a minimum of 80 % of the P_1 of the PRESSURE REGULATOR.

The pressure-adjusting mechanism, if used, shall be adjusted to the maximum rated delivery pressure.

The PRESSURE REGULATOR shall then be subjected to the required cyclic testing (see 6.9). Each cycle consists of pressurization to the inlet test pressure then depressurization of both the high and low pressure chambers to atmospheric pressure.

The test apparatus shall incorporate valves upstream and downstream of the PRESSURE REGULATOR being tested to permit the introduction and venting of the test gas.

The cycle rate shall be set to a minimum of five cycles per minute.

The inlet test pressure shall not decrease by more than 5 % during the test period.

After completion of the endurance test, verify the PRESSURE REGULATOR is capable of meeting the leakage requirements specified in 6.8.3.1.

8.6 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.

9 Marking, colour coding, and packaging

9.1 Marking

9.1.1 PRESSURE REGULATORS and their gas-specific components shall be durably and legibly marked with the symbol of the relevant gas in accordance with Table 5.

The test for the durability of markings is given in 8.6.

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

Table 5 — Medical gases, marking and colour-coding

Name	Symbol	Colour coding[a]
Oxygen	O_2	White[b]
Nitrous oxide	N_2O	Blue[b]
Medical air	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]
Helium	He	Brown[b]
Carbon dioxide	CO_2	Grey[b]
Xenon	Xe	Light brown[d]

a See Annex C for national deviations for colour coding for medical gases.

b In accordance with ISO 32.

c National languages can be used for air.

d An example of light brown is NCS 3030-Y30 R in accordance with SS 01 91 02[17].

e According to the components.

9.1.2 In addition to the requirements of 9.1.1, the PRESSURE REGULATOR shall be marked with the following:

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

NOTE Some regional regulatory authorities do not accept that the identification of the distributor replaces the identification of the manufacturer.

b) the model or type designation;

c) a means of individual identification such as a serial number;

d) the value of 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.

9.1.3 PRESSURE GAUGES shall have the following markings:

a) means of identification (e.g. the name and/or the trademark of the manufacturer and/or distributor);

b) the words “USE NO OIL” or the symbol shown in Figure 7;

c) the unit of pressure (for PRESSURE GAUGES).

Figure 7 — Symbol for “use no oil” (Application of ISO 7000)

9.2 Colour coding

9.2.1 If colour coding is used, it shall be in accordance with Table 5 or regional or national standards.

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

9.2.2 Colour coding shall be durable.

The test for the durability of colour coding is given in 8.6.

9.3 Packaging

9.3.1 PRESSURE REGULATORS and spare parts shall be sealed to protect against contamination and packaged to prevent damage during storage and transportation.

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

9.3.3 The package shall be marked with the transport and storage conditions specified by the manufacturer.

10 Information to be supplied by the manufacturer

10.1 In order to provide the necessary information for safe use, the manufacturer of the PRESSURE REGULATOR shall make available to his customer(s) the following information:

— a technical description;

— instructions for installation, operation and maintenance;

— the name and/or the trademark and address of the manufacturer;

— where the manufacturer does not have an address within the locale, an authorized representative within the locale to which the responsible organization can refer.

