
**Pressure regulators for use with medical
gases —**

Part 1:

**Pressure regulators and pressure
regulators with flow-metering devices**

iTeh STANDARD PREVIEW
Détendeurs pour l'utilisation avec les gaz médicaux —
(standards.iteh.ai) **Partie 1: Détendeurs et détendeurs à débitmètre intégré**

[ISO 10524-1:2006](https://standards.iteh.ai/catalog/standards/sist/7a091723-dd22-4ed9-a9ab-8086bb218644/iso-10524-1-2006)

<https://standards.iteh.ai/catalog/standards/sist/7a091723-dd22-4ed9-a9ab-8086bb218644/iso-10524-1-2006>



PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO 10524-1:2006

<https://standards.iteh.ai/catalog/standards/sist/7a091723-dd22-4ed9-a9ab-8086bb218644/iso-10524-1-2006>

© ISO 2006

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword.....	iv
Introduction	v
1 Scope	1
2 Normative references	2
3 Terms and definitions.....	2
4 Nomenclature	4
5 General requirements.....	4
5.1 Safety	4
5.2 Alternative construction	4
5.3 Materials	4
5.4 Design requirements	5
5.5 Constructional requirements.....	12
6 Test methods.....	12
6.1 General.....	12
6.2 Test methods for outlet pressure.....	13
6.3 Test method for pressure-relief valve.....	14
6.4 Test methods for leakage.....	14
6.5 Test method for mechanical strength.....	15
6.6 Test method for resistance to ignition	15
6.7 Test method for accuracy of flow of pressure regulators fitted with flowmeters or flowgauges.....	16
6.8 Test method for the stability of flow of pressure regulators fitted with flowmeters or flowgauges	16
6.9 Test method for stability and accuracy of flow of pressure regulators fitted with fixed orifices	16
6.10 Test method for flow setting and loosening torques.....	16
6.11 Test method for durability of markings and colour coding.....	16
7 Marking, colour coding, packaging	16
7.1 Marking	16
7.2 Colour coding.....	18
7.3 Packaging	18
8 Information to be supplied by the manufacturer.....	18
Annex A (informative) Typical examples of pressure regulators and pressure regulators with flow-metering devices.....	22
Annex B (informative) Rationale	26
Annex C (informative) Reported regional and national deviations of colour coding and nomenclature for medical gases.....	28
Bibliography	30

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 10524-1 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*.

This first edition cancels and replaces ISO 10524:1995 and ISO 10524:1995/Cor 1:1996, which has been technically revised.

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*

For the purposes of this part of ISO 10524, the CEN annex regarding fulfilment of European Council Directives has been removed.

Introduction

A pressure regulator is used to reduce high cylinder pressure to a lower pressure suitable for use with medical equipment or for delivery of gas directly to a patient.

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 the pressure regulators are specified and tested in a defined manner.

A pressure regulator often has coupled to it a device which controls the flow, such as a flow control valve or a fixed orifice. The flow can be indicated by a flowmeter or by a flowgauge.

It is essential that regular inspection and maintenance are undertaken to ensure that 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);
- gas specificity;
- cleanliness;
- type testing; <https://standards.iteh.ai/catalog/standards/sist/7a091723-dd22-4ed9-a9ab-8086bb218644/iso-10524-1-2006>
- 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 asterix (*) after their number have corresponding rationale, contained in Annex B, included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in 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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO 10524-1:2006

<https://standards.iteh.ai/catalog/standards/sist/7a091723-dd22-4ed9-a9ab-8086bb218644/iso-10524-1-2006>

Pressure regulators for use with medical gases —

Part 1:

Pressure regulators and pressure regulators with flow-metering devices

1 Scope

1.1 This part of ISO 10524 is applicable to the types of pressure regulators listed in 1.3 intended for the administration of the following medical gases in the treatment, management, diagnostic evaluation and care of patients:

- oxygen;
- nitrous oxide;
- air for breathing; iTeh STANDARD PREVIEW
(standards.iteh.ai)
- helium;
- carbon dioxide; [ISO 10524-1:2006](https://standards.iteh.ai/catalog/standards/sist/7a091723-dd22-4ed9-a9ab-8086bb218644/iso-10524-1-2006)
- xenon; <https://standards.iteh.ai/catalog/standards/sist/7a091723-dd22-4ed9-a9ab-8086bb218644/iso-10524-1-2006>
- mixtures of the gases listed above;
- air for driving surgical tools;
- nitrogen for driving surgical tools.

1.2* These pressure regulators are intended to be fitted to cylinders with nominal filling pressures up to 25 000 kPa at 15 °C and can be provided with devices which control and measure the flow of the medical gas delivered.

1.3 The types of pressure regulators covered by this part of ISO 10524 are as follows:

- a) pressure regulators intended to be connected to cylinders by the operator;
- b) pressure regulators with integral flow-metering devices intended to be connected to cylinders by the operator;
- c) pressure regulators that are an integral part of medical equipment (e.g. anaesthetic workstations, lung ventilators, resuscitators).

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 407:2004, *Small medical gas cylinders — Pin-index, yoke-type valve connections*

ISO 5145:2004, *Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning*

ISO 5359:2000, *Low-pressure hose assemblies for use with medical gases*

ISO 9170-1:1999, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with 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*

EN 13544-2:2002, *Respiratory therapy equipment — Part 2: Tubing and connectors*

SS 01 91 02, *Colour Atlas*

ITEH STANDARD PREVIEW
(standards.iteh.ai)

3 Terms and definitions

ISO 10524-1:2006

[https://standards.iteh.ai/catalog/standards/sist/7a091723-dd22-4ed9-a9ab-](https://standards.iteh.ai/catalog/standards/sist/7a091723-dd22-4ed9-a9ab-8096fb218644/iso-10524-1-2006)

[8096fb218644/iso-10524-1-2006](https://standards.iteh.ai/catalog/standards/sist/7a091723-dd22-4ed9-a9ab-8096fb218644/iso-10524-1-2006)

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

3.1

accuracy of flow

difference between the indicated value and the actual value of the flow expressed in percent

3.2

adjustable pressure regulator

pressure regulator that is provided with a means of operator adjustment of the outlet pressure

3.3

flow outlet

outlet intended to deliver a controlled flow of gas

3.4

flowgauge

device that measures pressure and that is calibrated in units of flow

NOTE The flowgauge does not measure flow. It indicates flow by measuring the pressure upstream of a fixed orifice.

3.5

flowmeter

device that measures and indicates the flow of a specific gas or gas mixture

3.6

gas-specific connection point

that part of the terminal unit that is the receptor for a gas-specific probe

3.7**gas-specific**

having characteristics that prevent connection between different gas services

3.8**nipple**

that portion of a connector that is pushed into and secured within the bore (lumen) of a hose

3.9**nominal inlet pressure**

p_1

upstream pressure specified by the manufacturer for which the pressure regulator is intended to be used

NOTE For compressed gases (e.g. oxygen) p_1 is related to the cylinder filling pressure at 15 °C.

3.10**nominal outlet pressure**

p_2

nominal downstream pressure

NOTE p_2 is specified by the manufacturer in the instructions for use.

3.11**orifice**

restriction of known cross-section that delivers a constant flow of gas when supplied with gas at a constant upstream pressure

NOTE An orifice does not provide an indication of flow.

3.12**preset pressure regulator**

pressure regulator that is not provided with a means of operator adjustment of the outlet pressure

3.13**pressure gauge**

device that measures and indicates pressure

3.14**pressure outlet**

outlet intended to deliver gas at a controlled pressure

3.15**pressure regulator**

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

3.16**pressure-relief valve**

device intended to relieve excess pressure at a preset 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

[IEC 60601-1]

4 Nomenclature

Examples of pressure regulators with terminology are given in Annex A.

5 General requirements

5.1 Safety

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 14971:2000 and which is connected with their intended application, in normal condition and in single fault condition.

5.2 Alternative construction

Pressure regulators and components or parts thereof, using materials or having forms of construction different from those detailed in this clause 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 Regional or national regulations can require the provision of evidence to a notified body or competent authority upon request.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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.

<https://standards.iteh.ai/catalog/standards/sist/7a091723-dd22-4ed9-a9ab-8086bb218644/iso-10524-1-2006>

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 goal of using oxygen-compatible materials is to develop system designs with low probability of ignition and low consequence of ignition based on the use of materials exhibiting good compatibility and low energy release if ignited. Many materials which do not burn in air will do so in pure oxygen, particularly under pressure. Similarly, materials which can be ignited in air 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 15001:2003.

5.3.2 The materials shall permit the pressure regulator and its components to meet the requirements of 5.4 in the temperature range of $-20\text{ }^{\circ}\text{C}$ to $+60\text{ }^{\circ}\text{C}$.

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

5.3.3 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 Plating could come off.

5.3.5* Aluminium or aluminium alloys shall not be used for components 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.

NOTE Regional or national regulations might require the provision of evidence to a notified body or competent authority upon request.

5.4 Design requirements

5.4.1 Pressure gauges and flowgauges

5.4.1.1 If a Bourdon tube pressure gauge or flowgauge is used, it shall conform to EN 837-1:1996 (except for the minimum nominal size) and shall meet the requirements in 5.4.1.2, 5.4.1.3, 5.4.1.4, 5.4.1.5 and 5.4.1.6.

The requirements in 5.4.1.2, 5.4.1.3, 5.4.1.4, 5.4.1.5, 5.4.1.6 and 5.4.1.7 also apply to other types of pressure gauges and flowgauges.

5.4.1.2 If the gauge connector is threaded, it shall comply with EN 837-1:1996 or a regional or national standard.

5.4.1.3 The indicated value of a pressure gauge or flowgauge 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 cylinder pressure gauge shall extend to a pressure at least 33 % greater than nominal inlet pressure p_1 .

NOTE In addition to the scale ranges in EN 837-1:1996, a pressure gauge with a scale range of 0 kPa to 31 500 kPa (315 bar) can also be used.

5.4.1.5 The cylinder pressure gauge, outlet pressure gauge or flowgauge 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 mm².

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.

NOTE Regional or national regulations might require the provision of evidence to a notified body or competent authority upon request.

5.4.2 Connectors

5.4.2.1 Inlet connector

There shall be an inlet connector. The inlet connector for connection to cylinders shall comply with either ISO 407:1991, ISO 5145:2004 or the relevant regional or national standards. See ISO/TR 7470:1988 for information.

5.4.2.2 Outlet connector

Except for pressure regulators that are an integral part of medical equipment, the outlet connector(s) shall be in accordance with 5.4.2.2.1 and/or 5.4.2.2.2.

NOTE A pressure regulator can have multiple outlets and can have both a pressure outlet and a flow outlet.

5.4.2.2.1* Flow outlet

A flow outlet shall be fitted with a fixed nipple or a threaded connector.

Nipples, if used, shall be in accordance with EN 13544-2:2002.

Threaded connectors for oxygen or air for breathing, if used, shall be in accordance with EN 13544-2:2002 or equivalent regional or national standards or shall be manufacturer-specific connectors. Threaded connectors, if used for other gases, shall be in accordance with regional or national standards or shall be manufacturer-specific connectors.

A flow outlet shall not be fitted on a pressure regulator intended for use with air or nitrogen for driving surgical tools.

5.4.2.2.2 Pressure outlet

A pressure outlet shall be fitted with one of the following:

- a) a terminal unit or a gas-specific connection point in accordance with ISO 9170-1:1999, for the following medical gases:
 - oxygen;
 - nitrous oxide;
 - air for breathing;
 - carbon dioxide;
 - oxygen/nitrous oxide mixture 50/50 (volume fraction, %);
 - air for driving surgical tools;
 - nitrogen for driving surgical tools;
 - other gases for which terminal units in national standards exist (the connection of the terminal unit or the gas-specific connection point to the pressure regulator body need not be gas-specific).
- b) a NIST or DISS body in accordance with ISO 5359:2000, unless a national standard exists for terminal units, for the following medical gases:
 - helium;
 - xenon;
 - mixtures of oxygen and nitrous oxide [except 50/50 (volume fraction, %)];
 - mixtures of oxygen and helium;
 - mixtures of oxygen and carbon dioxide;
- c) a connector in accordance with regional or national standards.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO 10524-1:2006
<https://standards.iteh.ai/catalog/standards/sist/7a091723-dd22-4ed9-a9ab-8086bb218644/iso-10524-1-2006>