INTERNATIONAL STANDARD

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Pressure regulators for use with medical gases —

Part 3: Pressure regulators integrated with cylinder valves

Détendeurs pour l'utilisation avec les gaz médicaux —

Partie 3: Détendeurs intégrés aux valves des bouteilles de gaz

Reference number
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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

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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 10524-3 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

Pressure regulators integrated with cylinder valves are 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 pressure regulators integrated with cylinder valves be specified and tested in a defined manner.

A pressure regulator normally 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 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);

— gas specificity;

— 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.

Pressure regulators for use with medical gases —

Part 3:
Pressure regulators integrated with cylinder valves

1 Scope

1.1 This part of ISO 10524 applies to pressure regulators integrated with cylinder valves (as defined in 3.16) intended for the administration of medical gases in the treatment, management, diagnostic evaluation and care of patients for use with the following medical gases:

— oxygen;

— nitrous oxide;

— air for breathing;

— helium;

— carbon dioxide;

— xenon;

— specified mixtures of the gases listed above;

— air for driving surgical tools;

— nitrogen for driving surgical tools.

1.2 * These pressure regulators integrated with cylinder valves 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 that control and measure the flow of the medical gas delivered.

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, *Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning*

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

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

ISO/TR 7470:1988, *Valve outlets for gas cylinders — List of provisions which are either standardized or in use*

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

ISO 10297:—[1)], *Transportable gas cylinders — Cylinder valves — Specification and type testing*

ISO 10920:1997, *Gas cylinders — 25E taper thread for connection of valves to gas cylinders — Specification*

EN ISO 11116-1:1999, *Gas cylinders — 17E taper thread for connection of valves to gas cylinders — Part 1: Specifications*

ISO 11117:1998, *Gas cylinders — Valve protection caps and valve guards for industrial and medical gas cylinders — Design, construction and tests*

ISO 13341:1997, *Transportable gas cylinders — Fitting of valves to gas cylinders*

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

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

ISO 15245-1:2001, *Gas cylinders — Parallel threads for connection of valves to gas cylinders — Part 1: Specification*

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*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*

SS 01 91 02, *Colour Atlas*

3 Terms and definitions

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
filling port
connector on the pressure regulator through which the cylinder is filled

3.4
flow outlet
outlet intended to deliver a controlled flow of gas

1) To be published. (Revision of ISO 10297:1999)

3.5
flowgauge
device that measures pressure and which 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.

3.6
flowmeter
device that measures and indicates the flow of a specific gas or gas mixture

3.7
gas-specific
having characteristics that prevent connection between different gas services

3.8
gas-specific connection point
that part of the terminal unit which is the receptor for a gas-specific probe

3.9
nipple
that portion of a connector which is pushed into and secured within the bore (lumen) of a hose

3.10
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

3.11
nominal outlet pressure
P_2
nominal downstream pressure

NOTE P_2 is specified by the manufacturer in the instructions for use.

3.12
pre-set 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 regulator integrated with cylinder valve
combination of a pressure regulator and cylinder valve intended to be permanently fitted to a medical gas cylinder

3.17
pressure-relief valve
device intended to relieve excess pressure at a pre-set value

3.18
residual pressure valve
means for retaining a minimum pressure within a cylinder

3.19
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]

4 Symbols

P_1 Nominal inlet pressure;

P_2 Nominal outlet pressure.

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

5 General requirements

5.1 Safety

Pressure regulators integrated with cylinder valves shall, when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, cause no safety hazard that could be foreseen using risk management procedures in accordance with ISO 14971 and that is connected with their intended application, in normal condition and in single fault condition.

5.2 Alternative construction

Pressure regulators integrated with cylinder valves and components or parts thereof, using materials or having forms of construction different from those detailed in 5.3 to 5.5 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.

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.

Criteria for the selection of metallic and non-metallic materials are given in ISO 15001.

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

NOTE 2 Compatibility with oxygen involves both combustibility and ease of ignition. Materials that burn in air 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, in oxygen require lower ignition energies. 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.

5.3.2 The materials shall permit the pressure regulator, integrated with cylinder valve and its 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 Pressure regulators integrated with cylinder valves 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 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 and flowgauges

5.4.1.1 If a Bourdon tube pressure gauge or flowgauge is used, it shall conform to EN 837-1, except for the minimum nominal size.

The requirements in 5.4.1.2 to 5.4.1.7 shall apply to all types of pressure gauges and flowgauges.

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

5.4.1.3 The indicated value of a pressure gauge or flowgauge shall be legible to any 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, a pressure gauge with a scale range of 0 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.

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 Filling port

5.4.2.1 * The filling port shall be gas-specific for the medical gas for which the pressure regulator is intended to be used.

5.4.2.2 The filling port shall either:

a) comply with either ISO 407, ISO 5145 or the relevant regional or national standard (see ISO/TR 7470 for information) or

b) be a proprietary connector.

5.4.2.3 The filling port shall be fitted with a means (e.g. non-return valve and/or plug or cap) that allows the pressure regulator integrated with cylinder valve to meet the external leakage requirement in 5.4.13.1. Pressure-tight caps and plugs shall be designed to require the use of a proprietary tool for removal.

5.4.2.4 The non-return valve, if fitted, shall comply with the requirement of 5.4.13.1 after 1 000 opening and closing cycles.

The test is described in 6.14

5.4.2.5 Means shall be provided to reduce the likelihood of the filling port becoming contaminated.

NOTE Such means may include a filter or a removable cap.

Evidence shall be provided by the manufacturer upon request.

5.4.2.6 Means shall be provided to reduce the likelihood of the filling port being used for other than its intended purpose.

Evidence shall be provided by the manufacturer upon request.

5.4.3 Connectors

5.4.3.1 Valve stem

If a taper thread is used for the valve stem, it shall be in accordance with ISO 10920 or ISO 11116-1 or regional or national standards. If a parallel thread is used for the valve stem, it shall be in accordance with ISO 15245-1 or regional or national standards.

Evidence shall be provided by the manufacturer upon request.

5.4.3.2 Outlet connector

5.4.3.2.1 General

The outlet connector shall be in accordance with 5.4.3.2.2 and/or 5.4.3.2.3.

NOTE A pressure regulator integrated with cylinder valve can have multiple outlets and can have both a pressure outlet and a flow outlet.

5.4.3.2.2 * 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.

Threaded connectors used for oxygen or air for breathing shall be in accordance with EN 13544-2. Threaded connectors used for other gases shall be in accordance with regional or national standards or shall be proprietary connectors.

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

5.4.3.2.3 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, 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 regional or national standards exist.

NOTE The connection of the terminal unit or the gas-specific connection point to the pressure regulator body need not be gas-specific.

b) an NIST or DISS body in accordance with ISO 5359, unless a regional or 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.

5.4.4 * Outlet pressure

5.4.4.1 General

The pressure requirements for a pressure outlet are given in 5.4.4.2.2 and 5.4.4.2.3.

The pressure requirement for a flow outlet is given in 5.4.4.3.

5.4.4.2 Pressure outlet

5.4.4.2.1 General

If a pressure regulator integrated with cylinder valve is fitted with a pressure outlet, the pressure regulator shall be pre-set.

5.4.4.2.2 Nominal outlet pressure, P_2

The nominal outlet pressure, P_2, shall be either:

— 400 $^{100}_{0}$ kPa for medical gases except for air or nitrogen for driving surgical tools or

— 800 $^{200}_{100}$ kPa for air or nitrogen for driving surgical tools.