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Pressure regulators for use with medical gases —

Part 4: Low-pressure regulators

Détendeurs pour l'utilisation avec les gaz médicaux —

Partie 4: Détendeurs basse pression

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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 10524-4 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

A low-pressure regulator is used to reduce the pressure in a medical gas pipeline system to a lower pressure suitable for use with medical equipment or for delivery of gas directly to a patient.

These functions cover a range of inlet and outlet pressures and flows which require specific design characteristics. It is important that the operating characteristics of low-pressure regulators are appropriately specified for their intended use and then tested in a defined manner.

A low-pressure regulator may be coupled to a device that 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 low-pressure regulators continue to meet the requirements of this part of ISO 10524.

This part of ISO 10524 pays particular attention to:

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

— suitability of materials;

— gas specificity;

— accuracy;

— cleanliness;

— 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 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 document. 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 4: Low-pressure regulators

1 Scope

1.1 This part of ISO 10524 applies to the types of low-pressure regulators listed in 1.2 and intended to be used with the following medical gases in the treatment, management, diagnostic evaluation and care of patients:

— oxygen;

— nitrous oxide;

— medical air;

— helium;

— carbon dioxide;

— xenon;

— specified mixtures of the gases listed above;

— air for driving surgical tools;

— nitrogen for driving surgical tools;

— oxygen-enriched air.

1.2 The types of low-pressure regulators covered by this part of ISO 10524 are as follows:

a) low-pressure regulators intended to be connected to terminal units of medical gas pipeline systems complying with ISO 7396-1;

b) low-pressure regulators with integral flow-metering devices intended to be connected to terminal units of medical gas pipeline systems complying with ISO 7396-1;

c) low-pressure regulators intended to be connected to terminal units attached to pressure regulators complying with ISO 10524-1 or ISO 10524-3;

d) operator-adjustable low-pressure regulators for air or nitrogen for driving surgical tools that are an integral part of a medical gas pipeline system complying with ISO 7396-1.

1.3 This part of ISO 10524 does not apply to low-pressure regulators integrated within anaesthetic and respiratory equipment.

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

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

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

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

ISO 10524-3, *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves*

ISO 11114-3:1997, *Transportable gas cylinders — Compatibility of cylinder and valve materials with gas contents — Part 3: Autogenous ignition test in oxygen atmosphere*

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

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

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

EN 1089-3:2004, *Transportable gas cylinders — Gas cylinder identification (excluding LPG) — Part 3: Colour coding*

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

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
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
flow-metering device
device fitted with an inlet connector and an outlet connector and that incorporates one of the following:

a) a flowmeter with a flow control valve;

b) a flowgauge and a fixed orifice with a flow control valve;

c) one or more fixed orifices with a means of selection

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 that is the receptor for a gas-specific probe

3.9
low pressure
pressure of 2 000 kPa or less

3.10
maximum inlet pressure
p_m
maximum upstream pressure specified 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 for a pressure regulator with pressure outlet(s).

3.12
medical gas pipeline system
complete system that comprises a supply system, a monitoring and alarm system and a distribution system with terminal units at the points where medical gases or vacuum may be required

3.13
nipple
that portion of a connector that is pushed into and secured within the bore (lumen) of a hose

3.14
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.

3.15
pipeline distribution system
that portion of a medical gas or vacuum pipeline system linking the sources of supply of the supply system to the terminal units

3.16
preset pressure regulator
pressure regulator that is not provided with a means of operator adjustment of the outlet pressure

3.17
pressure gauge
device that measures and indicates pressure

3.18
pressure outlet
outlet intended to deliver gas at a controlled pressure

3.19
pressure regulator
device that reduces the inlet pressure and maintains the set outlet pressure within specified limits

3.20
single-fault condition
condition in which a single means for reducing a risk is defective or a single abnormal condition is present

[IEC 60601-1:2005, definition 3.116]

4 Nomenclature

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

5 General requirements

5.1 Safety

5.1.1 Low-pressure regulators shall, when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, present no risks that are not reduced to an acceptable level 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.

5.1.2 Following exposure for 5 min to the maximum pressure under single-fault condition allowed by ISO 7396-1, a low-pressure regulator shall meet the requirements of this part of ISO 10524 when the pressure is reduced to maximum inlet pressure, p_m. These pressures are 1 000 kPa for gases other than air or nitrogen for driving surgical tools and 2 000 kPa for air or nitrogen for driving surgical tools.

5.2 Alternative construction

Low-pressure regulators and components or parts thereof, using materials or having forms of construction different from those detailed in 5.3 shall be presumed to be in compliance with the safety objectives of this part of ISO 10524 if it can be demonstrated that 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. Evidence of an equivalent degree of safety shall be provided by the manufacturer upon request. Objective evidence may be obtained by postmarket surveillance.

NOTE 1 Regional or national regulations might require the provision of evidence to a competent authority or conformity assessment body (e.g. notified body in the European Economic Area) upon request.

NOTE 2 Attention is drawn to ISO 14971 on risk management and to the International Standards, under development by ISO/TC 210, on risk evaluation and risk control.

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 5.3.3.

NOTE 1 Corrosion resistance includes resistance to 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 require lower ignition energies 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. For low-pressure regulators the risk of ignition by adiabatic compression is reduced in comparison with pressure regulators covered in other parts of ISO 10524 because of the lower pressures involved.

NOTE 3 ISO 15001 contains information on selection of metallic and non-metallic materials and other aspects of compatibility of equipment with oxygen.

5.3.2* For low-pressure regulators for all gases, the auto-ignition temperature of the non-metallic components in contact with the gas, 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.

NOTE 1 Regional or national regulations might require the provision of evidence to a competent authority or conformity assessment body (e.g. notified body in the European Economic Area) upon request.

The determination of the auto-ignition temperature shall be carried out in accordance with ISO 11114-3.

NOTE 2 The maximum permitted operating temperature of tested material is 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 in the operating temperature and the fact that the auto-ignition temperature is not a constant. Values of the auto-ignition temperature always depend on the test method used, which does not exactly simulate all possible operating conditions.

5.3.3 The materials shall permit the low-pressure regulator 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 might require deviation from this range of temperatures.

5.3.4 Low-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.

5.3.5 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.

5.3.6 Evidence of conformity with the requirements of 5.3.1 to 5.3.5 shall be provided by the manufacturer upon request.

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

5.4 Design requirements

5.4.1 Inlet pressure limits

The maximum inlet pressures for low-pressure regulators covered by this part of ISO 10524 are the maximum pressures under single-fault condition as specified in ISO 7396-1, ISO 10524-1 and ISO 10524-3. These pressures are 1 000 kPa for gases other than air or nitrogen for driving surgical tools and 2 000 kPa for air or nitrogen for driving surgical tools.

5.4.2 Pressure gauges and flowgauges

5.4.2.1 If a Bourdon tube pressure gauge is used to measure pressure or flow, it shall conform to EN 837-1 (except for the minimum nominal size) and shall meet the requirements given in 5.4.2.2 to 5.4.2.5.

The requirements given in 5.4.2.2 to 5.4.2.5 also apply to other types of pressure gauge and flowgauge.

5.4.2.2 If a threaded connector is used, it shall comply with EN 837-1 or a regional or national standard.

5.4.2.3 The indicated value of a pressure gauge or flowgauge shall be legible to an operator having a visual acuity of 1 (corrected if necessary) 1,0 m from the gauge with an illuminance of 215 lx.

5.4.2.4 The inlet pressure gauge, outlet pressure gauge or flowgauge shall be class 2,5 or better in accordance with EN 837-1.

5.4.2.5 Compliance with the requirements of 5.4.2.2 to 5.4.2.4 shall be checked by visual inspection or measurement as required.

5.4.2.6 Evidence of conformity with the requirements of 5.4.2 shall be provided by the manufacturer upon request.

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

5.4.3 Connectors

5.4.3.1 * Inlet connector

For low-pressure regulators intended to be connected to terminal units, the inlet connector shall be a probe complying with ISO 9170-1 or the relevant regional or national standards.

For operator-adjustable low-pressure regulators for air or nitrogen for driving surgical tools that are an integral part of a medical gas pipeline system, the dimensions of the inlet connector is at the discretion of the manufacturer. A cylinder valve connector shall not be used as an inlet connector.

5.4.3.2 Outlet connector

5.4.3.2.1 General

For low-pressure regulators intended to be connected to terminal units, the outlet connector shall be a pressure outlet.

For low-pressure regulators with integral flow-metering devices intended to be connected to terminal units, the outlet shall be a flow outlet.

For operator-adjustable low-pressure regulators for air or nitrogen for driving surgical tools that are an integral part of a medical gas pipeline system, the outlet shall be a pressure outlet.

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

5.4.3.2.2 * Flow outlet

A flow outlet shall be either:

a) a permanently connected hose insert with a nipple with dimensions in accordance with EN 13544-2 or in accordance with regional or national standards or

b) a proprietary fitting or

c) for oxygen and medical air, a weight-bearing screw-threaded connector in accordance with EN 13544-2 or in accordance with regional or national standards.