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Pressure regulators for use with medical gases —

Part 2: Manifold and line pressure regulators

Détendeurs pour l'utilisation avec les gaz médicaux —

Partie 2: Détendeurs de rampes et de canalisations

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Foreword

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

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

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

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

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

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

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

— *Part 2: Manifold and line pressure regulators*

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

— *Part 4: Low-pressure regulators*

Introduction

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

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

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

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

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

This part of ISO 10524 pays particular attention to:

— use of suitable materials;

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

— cleanliness;

— type testing;

— marking;

— information supplied by the manufacturer.

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

Pressure regulators for use with medical gases —

Part 2:
Manifold and line pressure regulators

1 Scope

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

— oxygen;

— nitrous oxide;

— air for breathing;

— carbon dioxide;

— oxygen/nitrous oxide mixtures;

— air for driving surgical tools;

— nitrogen for driving surgical tools;

— oxygen produced by an oxygen concentrator.

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

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

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

2 Normative references

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

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

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

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

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

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

3 Terms and definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3.12
pressure gauge
device that measures and indicates pressure

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

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

3.15
single-fault condition
condition in which a single means for protection against a safety hazard in equipment is defective or a single external abnormal condition is present

[IEC 60601-1:1988, 2.10.11]

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

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

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

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

3.20
test inlet pressure
P_3
minimum inlet test pressure

NOTE See Table 1.

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

4 Symbols

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

Table 1 — Symbols

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

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

5 General requirements

5.1 Safety

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

5.2 Alternative construction

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

Such evidence shall be provided by the manufacturer upon request.

NOTE Attention is drawn to ISO 14971 on risk management.

5.3 Materials

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

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

NOTE 2 Compatibility with oxygen involves both combustibility and ease of ignition. Materials which burn in air will burn violently in pure oxygen. Many materials that do not burn in air will do so in pure oxygen, particularly under pressure. Similarly, materials that can be ignited in air require lower ignition energies for ignition in oxygen. Many such materials can be ignited by friction at a valve seat or by adiabatic compression produced when oxygen at high pressure is rapidly introduced into a system initially at low pressure.

NOTE 3 Criteria for the selection of metallic and non-metallic materials are given in ISO 15001.

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

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

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

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

NOTE Any plating could detach from the component surface.

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

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

5.4 Design requirements

5.4.1 Pressure gauges

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

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

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

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

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

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

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

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

5.4.2 Pressure-adjusting device

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

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

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

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

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

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

Compliance shall be tested by inspection.

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

Compliance shall be tested by inspection.

5.4.3 Filtration

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

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

NOTE The filter can be a separate item.

5.4.4 Mechanical strength

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

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

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

5.4.5 Manifold pressure regulators

5.4.5.1* Inlet connector

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

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

5.4.5.2 Outlet connector

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