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Pressure regulators for use with medical gases —

Part 4: Low-pressure regulators intended for incorporation into medical equipment

Régulateurs de pression pour systèmes de gaz médicaux —

Partie 4: Régulateurs de pression à faible pression destinés à être incorporés dans du matériel médical

ICS 11.040.10

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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 3.

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 part of ISO 10524 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 for medical gas systems*

— *Part 2: Manifold and line pressure regulators*

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

— *Part 4: Low-pressure regulators intended for incorporation into medical equipment*

Introduction

Pressure regulators are fitted within medical equipment to maintain a constant outlet pressure irrespective of variation of inlet pressure or flow.

To enable correct application of these devices it is important that the operating characteristics are specified and tested in a defined manner.

As pressure regulators of this type are often derived from products designed for industrial applications, this part of ISO 10524pays particular attention to:

- suitability of materials;

- safety (mechanical strength and resistance to ignition);

- cleanliness;

- testing;

- identification;

- information supplied.

It is also essential that regular inspection and maintenance procedures are recommended.

Annex B contains rationale statements for some of the requirements of this part of ISO 10524. It is 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. The clauses and subclauses marked with **R** after their number have corresponding rationale contained in Annex B.

Pressure regulators for use with medical gases - Part 4 : Low-pressure regulators intended for incorporation into medical equipment

1 Scope

1.1 This part of this ISO 10524 applies to low-pressure regulators suitable for inlet pressures between 280 kPa and 600 kPa, supplied and packaged as for use in medical equipment 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.

1.2 This part of ISO 10524 does not apply to pressure regulators supplied as spare parts for a specific application.

1.3 This part of ISO 10524 does not apply to pressure regulators for use with suction services (see ISO 10079-3).

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 10524. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 10524 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

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

prEN 737-6, *Medical gas pipeline systems - Part 6: Dimensions of probes for terminal units for compressed medical gases and vacuum.*

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

ISO 14971, *Medical devices – - Application of risk management to medical devices.*

3 Terms and definitions

For the purposes of this part of ISO 10524, the following terms and definitions apply.

3.1
adjustable pressure regulator
regulator which has been provided with a means of operator adjustment of the delivery pressure under normal use

3.2
bleed flow
intended small flow of gas to the atmosphere for the purpose of the correct operation of the regulator

3.3
closure pressure, P_4
stabilized outlet pressure, one minute after cessation of the flow, from a regulator where the flow has been set to standard discharge

3.4
flow characteristic
variation of the outlet pressure in relation to the rate of flow from zero to maximum capacity flow of the regulator with the inlet pressure remaining constant

3.5
hysteresis
lagging of the outlet pressure (effect) when the flow (cause) is varied so that at a constant inlet pressure the values of outlet pressure measured with increasing flow do not coincide with the values of outlet pressure measured with decreasing flow

3.6
low pressure
pressure of 1 400 kPa or less

3.7
maximum closure pressure, $P_{4\,max}$
stabilized outlet pressure, one minute after cessation of the flow, from a regulator where the flow has been set to maximum discharge

3.8
maximum discharge, Q_{max}
maximum flow which is delivered by the regulator at the rated outlet pressure, P_2 at test inlet pressure, P_3

3.9
preset pressure regulator
regulator which has not been provided with a means of operator adjustment of the delivery pressure under normal use

3.10
pressure characteristic
variation of the outlet pressure with inlet pressure under constant flow conditions

3.11
pressure regulator
device for regulation of a generally variable inlet pressure to as constant as possible an outlet pressure

3.12
rated inlet pressure, P_1
rated maximum upstream pressure for which the pressure regulator is designed

3.13
rated outlet pressure, P_2
rated downstream pressure for the standard discharge Q_1 specified in the instructions for use

3.14
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

3.15
single stage pressure regulator
regulator that reduces the inlet pressure in a single stage to the required pressure

3.16
standard discharge, Q_1
flow, specified in the instructions for use for which the regulator is designed to maintain a rated outlet pressure, P_2 at test inlet pressure P_3

3.17
test inlet pressure, P_3
minimum inlet pressure at which the standard discharge of the regulator Q_1 is measured and which is equivalent to twice the rated outlet pressure P_2 plus 100 kPa, i.e. $P_3 = (2\ P_2 + 100)$ kPa

3.18
two-stage pressure regulator
regulator that reduces the inlet pressure in two stages to the required pressure

4 Symbols (and abbreviated terms)

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

A diagram of typical pressure regulators with examples of terminology is given in Figure A.1.

Table 1 - Notations, symbols and designations

P_1	Rated inlet pressure
P_2	Rated outlet pressure
P_3	Test inlet pressure ($2P_2$ + 100) kPa
P_4	Closure pressure
P_{4max}	Maximum closure pressure
Q_1	Standard discharge
Q_{max}	Maximum discharge

5 General requirements

5.1 Safety

Pressure regulators shall, when stored, installed, operated in normal use and maintained according to the recommendations of the manufacturer, cause no safety hazard which could be foreseen using risk analysis procedures in accordance with ISO 14971-1 and which is connected with their intended applications, in normal condition and in single fault condition.

5.2 R Alternative construction

Pressure regulators and components or parts thereof, using materials or having forms of construction different from those detailed in clause 5 of this part of ISO 10524 shall be accepted if it can be demonstrated that an equivalent degree of safety is obtained.

Such evidence shall be provided by the manufacturer.

5.3 Materials

5.3.1 The materials in contact with the gas shall be 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 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.

NOTE 3 ISO 15001, *Anaesthetic and respiratory equipment --- compatibility with oxygen* is in preparation by ISO/TC 121/SC6.

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 0 °C to +40 °C.

If the pressure regulator is suitable for use outside this temperature range, the range shall be specified by the manufacturer.

5.3.3 Pressure regulators shall be capable, while packed for transport and storage, of 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 R Evidence of conformity with the requirements of 5.3.1, 5.3.2, 5.3.3 and 5.3.4 shall be provided by the manufacturer.

5.4 Design requirements

5.4.1 Inlet pressure

5.4.1.1R Pressure regulators shall operate and meet the requirements of this part of ISO 10524 when supplied with an inlet pressure ranging from 280 kPa to 600 kPa.

5.4.1.2 R Pressure regulators shall meet the requirements of 5.4.1.1 following exposure to an inlet pressure of 1 000 kPa for 10 min.

5.4.2 Inlet connection

If the inlet connection of the pressure regulator is intended to be used as the inlet connection to the equipment, it shall be either a probe complying with prEN 737-6 or a NIST body complying with ISO 5359. Cylinder valve connections shall not be used.

5.4.3 Outlet connection

If a gas-specific outlet connection of the pressure regulator is intended to be used as the outlet connection of the equipment, it shall be either a socket complying with ISO 9170-1 or a NIST body complying with ISO 5359.

In this case it shall not be possible for the operator to set the outlet pressure below 280 kPa.

5.4.4 Pressure adjusting device

The regulator shall be designed so that the regulator valve cannot be held in the open position, as a consequence of the pressure regulator spring being compressed to its solid length and thereby allowing gas to pass from the inlet to the outlet side.

Compliance shall be tested by visual inspection.

5.4.5 Performance, functional and flow characteristics

The performance, functional and flow characteristics shall be in accordance with the values stated by the manufacturer.

The tests are given in 6.2.

5.4.6 Over-pressure relief

If a means for over-pressure relief is provided, its characteristics shall be specified by the manufacturer.

The test is given in 6.3.

5.4.7 Leakage

The maximum external leakage (to the atmosphere) and internal leakage (through the regulator valve) shall not exceed the values specified by the manufacturer.

The test for leakage is given in 6.4.

5.4.8 Bleed flow

The bleed flow shall not exceed the value specified by the manufacturer.

The test for bleed flow is given in 6.5.