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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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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 10524-2:2005), which has been technically revised.

The main changes compared to the previous edition are as follows:

— the scope has been extended to include 30 000 kPa (300 bar) manifold pressure regulators;

— this document has been restructured according to the new ISO template and associated renumbering;

— the common requirements have been aligned with ISO 10524-1 and ISO 10524-3;

— all type tests have been reviewed;

— a complete schedule has been introduced;

— a pressure retention test of the low-pressure side for the line pressure regulators has been introduced.

A list of all parts in the ISO 10524 series can be found on the ISO website.

Introduction

MANIFOLD PRESSURE REGULATORS are used within the supply systems of medical gas pipeline systems to reduce high cylinder pressure to a lower pressure suitable for the supply of medical gases to the inlet of LINE PRESSURE REGULATORS.

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 document.

This document 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, and

— information supplied by the manufacturer.

Annex B contains rationale statements for some of the requirements of this document. 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 document. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this document, but will expedite any subsequent revisions.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex B.

In this document, the following print types are used:

— requirements and definitions: roman type.

— informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

— *test specifications: italic type*;

— TERMS DEFINED IN CLAUSE 3 OF THIS DOCUMENT OR AS NOTED: SMALL CAPITALS TYPE.

Pressure regulators for use with medical gases —

Part 2:
Manifold and line pressure regulators

1 * Scope

This document specifies design, construction, type testing, and marking requirements for MANIFOLD PRESSURE REGULATORS (as defined in 3.7) and LINE PRESSURE REGULATORS (as defined in 3.5) intended for use in MEDICAL GAS PIPELINE SYSTEMS.

Examples of gases include oxygen, medical air and oxygen/nitrous oxide mixtures.

This document applies to MANIFOLD PRESSURE REGULATORS and LINE PRESSURE REGULATORS supplied as individual units or to the relevant components incorporated within an assembly.

MANIFOLD PRESSURE REGULATORS are intended to be connected to a MANIFOLD system which has a NOMINAL INLET PRESSURE, P_1 of up to 30 000 kPa (300 bar).

LINE PRESSURE REGULATORS are intended to be connected downstream of the MANIFOLD PRESSURE REGULATOR with a supply pressure up to 3 000 kPa (30 bar).

This document 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 documents are referred to in the text in such a way that some or all of their content constitutes requirements 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, *Gas cylinders for medical use — Marking for identification of content*

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

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

ISO 10297:2014, *Gas cylinders — Cylinder valves — Specification and type testing*

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

ISO 15001:2010, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

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

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
CLOSURE PRESSURE
P_4
stabilized outlet pressure, after cessation of the flow, from a *PRESSURE REGULATOR* (3.15) when the flow has been set to *STANDARD DISCHARGE* (3.20)

3.2
DOUBLE-STAGE PIPELINE DISTRIBUTION SYSTEM
pipeline distribution system in which gas is initially distributed from the *SUPPLY SYSTEM* (3.21) at a higher pressure than the *NOMINAL DISTRIBUTION PRESSURE* (3.8), and is then reduced to the NOMINAL DISTRIBUTION PRESSURE by *LINE PRESSURE REGULATOR(S)* (3.4)

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 (3.15) used in a *DOUBLE STAGE PIPELINE DISTRIBUTION SYSTEM* (3.2) to reduce the nominal SUPPLY SYSTEM pressure to the *NOMINAL DISTRIBUTION PRESSURE* (3.8)

3.5
MANIFOLD
device for connecting the outlet(s) of one or more cylinders or cylinder bundles of the same medical gas to a *MEDICAL GAS PIPELINE SYSTEM* (3.7)

3.6
MANIFOLD PRESSURE REGULATOR
PRESSURE REGULATOR (3.15) intended to be installed within *SOURCE OF SUPPLY* (3.19) containing cylinders or cylinder bundles, or high pressure storage vessel(s)

3.7
MEDICAL GAS PIPELINE SYSTEM
complete system which comprises a *SUPPLY SYSTEM* (3.21), 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 *MEDICAL GAS PIPELINE SYSTEM* (3.7) is intended to deliver at the terminal units

3.9
NOMINAL INLET PRESSURE
P_1
upstream *WORKING PRESSURE* (3.24) specified by the manufacturer for which the *PRESSURE REGULATOR* (3.15) is intended to be used

3.10
NOMINAL OUTLET PRESSURE
P_2
pressure downstream of the *PRESSURE REGULATOR* (3.15) under flow conditions specified by the manufacturer

3.11
OXIDIZING GAS
any gas or gas mixture more oxidizing than air, i.e. any gas or gas mixture that is able, at atmospheric pressure, to support the combustion more than a reference oxidizer consisting of 23,5 % oxygen in nitrogen

[SOURCE: ISO 10156:2017, 3.1.5, modified]

3.12
PRE-SET PRESSURE REGULATOR
PRESSURE REGULATOR (3.15) that is not provided with a means of operator adjustment of the outlet pressure

3.13
PRESSURE CHARACTERISTIC
variation of the outlet pressure in relation to inlet pressure under constant flow conditions

3.14
PRESSURE GAUGE
device that measures and indicates pressure

3.15
PRESSURE REGULATOR
device that reduces the inlet pressure and maintains the set outlet pressure within specified limits

3.16
PRESSURE-RELIEF DEVICE
device intended to relieve excess pressure at a pre-set 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

3.18
SINGLE-STAGE PIPELINE DISTRIBUTION SYSTEM
pipeline distribution system in which gas is distributed from the *SUPPLY SYSTEM* (3.19) at the *NOMINAL DISTRIBUTION PRESSURE* (3.8)

3.19
SOURCE OF SUPPLY
portion of the *SUPPLY SYSTEM* (3.19) with associated control equipment, which supplies the pipeline distribution system

3.20
STANDARD DISCHARGE
Q_1
flow for which the *PRESSURE REGULATOR* (3.15) is designed to maintain a *NOMINAL OUTLET PRESSURE*, P_2 (3.10), at *TEST INLET PRESSURE*, P_3 (3.22)

3.21
SUPPLY SYSTEM
system that supplies the pipeline distribution system and which includes two or more *SOURCES OF SUPPLY* (3.19)

3.22
TEST INLET PRESSURE
P_3
minimum inlet test pressure

3.23
TEST OUTLET PRESSURE
P_5
highest or lowest value of the outlet pressure resulting from a variation in the inlet pressure between P_1 (3.9) and P_3 (3.22) at previously adjusted conditions P_1, P_2 (3.10), Q_1 (3.20)

3.24
WORKING PRESSURE
settled pressure of a compressed gas at a uniform reference temperature of 15 °C in a full gas cylinder

Note 1 to entry: This definition does not apply to liquefied gases (e.g. carbon dioxide) or dissolved gases (e.g. acetylene).

4 Nomenclature

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, present no risks with an unacceptable level, under normal condition or SINGLE FAULT CONDITION, identified using risk management procedures in accordance with ISO 14971.

The risks associated with the ignition of metallic and non-metallic materials, including the potential release of toxic products in an oxygen-enriched environment, shall be assessed according to the principles defined in ISO 15001.

The design of MANIFOLD and LINE PRESSURE REGULATORS should be such that in the event of an internal ignition, the consequences of the ignition are contained and the gas vented safely.

Check compliance by inspection of the risk management file.

NOTE A situation in which a fault is not detected is considered a normal condition. Fault conditions/hazardous situations can remain undetected over a period of time and, as a consequence, can lead to an unacceptable risk. In that case, a fault condition subsequently detected needs to be considered as a SINGLE FAULT CONDITION. Specific risk control measures to deal with such situations need to be determined within the risk management process.

5.2 Usability

The manufacturer shall address, in a usability engineering process, any risks resulting from poor usability.

Check compliance by inspection of the usability engineering file.

NOTE For information related to usability, see other documents; for example, IEC 62366-1 and IEC/TR 62366-2.

5.3 Alternative construction

MANIFOLD and LINE PRESSURE REGULATORS and components, or parts thereof, using materials or having forms of construction different from those detailed in this document, shall be presumed to be in compliance with the safety objectives of this document if it can be demonstrated that at least 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.

Objective evidence may be obtained by post-market surveillance.

Evidence of at least an equivalent degree of safety shall be provided by the manufacturer.

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

5.4 Materials

5.4.1 * The materials which come in contact with the medical gas in normal condition shall be resistant to corrosion and compatible with oxygen, the other medical gases and their mixtures in the temperature range specified in 6.1.

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 aim of using oxygen-compatible materials is to develop a system design which has a low probability of ignition and minimizes consequences based on the use of materials exhibiting good compatibility and low energy release if ignited or by minimizing the quantities of non-metallic components.

NOTE 3 Many materials which do not burn in air will do so in an oxygen-enriched atmosphere, particularly under pressure. Similarly, materials which can be ignited in air require lower ignition energies to ignite in an oxygen-enriched atmosphere. Many such materials can be ignited by friction at a valve seat or by adiabatic compression when an oxygen-enriched gas at high pressure is rapidly introduced into a system initially at low pressure.

NOTE 4 Halogenated polymers such as polytetrafluoroethylene (PTFE), polychlorotrifluoroethylene (PTCFE) and fluoroelastomers (FKM) can release highly toxic products during thermal decomposition.

NOTE 5 Design considerations and criteria for the selection of metallic and non-metallic materials are given in ISO 15001.

5.4.2 Materials that are liable to shed particles which can come in contact with the medical gas in normal condition or SINGLE FAULT CONDITION shall not be used for highly strained components and parts liable to wear.

EXAMPLE Springs.

NOTE See ISO 15001:2010, Annex C.

5.4.3 * Aluminium, aluminium alloys or alloys with aluminium content greater than 2,5 % shall not be used for components whose surfaces come into contact with OXIDIZING GASES or gas mixtures at cylinder pressure in normal or SINGLE FAULT CONDITION.

5.4.4 Consideration should be given to the avoidance of stainless steel and other ferrous alloys for components whose surfaces come into contact with OXIDIZING GASES or gas mixtures at cylinder pressure in normal or SINGLE FAULT CONDITION.

5.4.5 The materials shall permit the MANIFOLD and LINE PRESSURE REGULATORS and their components to meet the requirements of Clause 6 in the temperature range of −20 °C to +60 °C.

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

5.4.6 MANIFOLD and LINE PRESSURE REGULATORS shall meet the requirements of this document after being packed for transport and storage and being exposed to environmental conditions, as stated by the manufacturer.

Evidence of conformity with the requirements of Clause 6 shall be provided by the manufacturer upon request.

6 Design requirements

6.1 General

The operation of the MANIFOLD and LINE PRESSURE REGULATORS shall comply with the requirements of this document between −20 °C and +60 °C.

NOTE Regional or national regulations can specify additional design requirements and certifications or approval.

6.2 PRESSURE GAUGES

6.2.1 If a Bourdon tube PRESSURE GAUGE is used, it shall conform to EN 837-1 (except for the minimum nominal size).

NOTE EN 837-1 is a standard for Bourdon tube PRESSURE GAUGES but not all of its requirements are applicable to other types of gauges, e.g. direct drive gauges.

6.2.2 PRESSURE GAUGES should be designed to resist moisture ingress (e.g. IP 44 of IEC 60529).

6.2.3 The casings of PRESSURE GAUGES should be designed such that the pressure is safely relieved to prevent a hazardous overpressure that could lead to a rupture in the event of a leak within the gauge.

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

6.2.5 The pressure or content indication 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.

6.2.6 The scale of the cylinder PRESSURE GAUGE shall extend to at least 133 % of P_1.

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

6.2.7 PRESSURE GAUGES shall be class 2.5 or better, in accordance with EN 837-1.

6.2.8 The inlet connection of 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.

Check compliance with the requirements of 6.2 by visual inspection or measurement as required.

6.3 Integrated digital gauges

Where the risk management process demonstrates that the risk to patient safety is impacted by the use of electrical equipment, IEC 60601-1 shall be used as a normative reference.

6.4 Pressure-adjusting device

6.4.1 MANIFOLD and LINE PRESSURE REGULATORS shall be provided with a pressure-adjusting device.

6.4.2 The pressure-adjusting device shall be designed so that it can be locked into position and adjusted only with the use of a tool.

Check compliance by attempting to adjust the pressure without the use of a tool.

