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Pressure regulators for use with medical gases —

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

Détendeurs pour l'utilisation avec les gaz médicaux —
Partie 1: Détendeurs et détendeurs-débitmètres

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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 10524-1:2006), which has been technically revised.

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

— the common requirements have been aligned with ISO 10524-2 and ISO 10524-3;

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

— a complete schedule has been introduced;

— all type tests have been reviewed.

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

Introduction

PRESSURE REGULATORS 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 are 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 device 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 REGULATOR continues 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),

— GAS SPECIFICity,

— cleanliness,

— type testing,

— marking, and

— information supplied by the manufacturer.

Annex A 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 A.

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 1:
Pressure regulators and pressure regulators with flow-metering devices

1 Scope

This document specifies the design, construction, type testing, and marking requirements for PRESSURE REGULATORS (as defined in 3.18) intended for the administration of medical gases and their mixtures in the treatment, management, diagnostic evaluation and care of patients or for gases used for driving surgical tools.

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

This document applies to PRESSURE REGULATORS:

a) intended to be connected to cylinders by the operator;

b) with integral flow-metering devices intended to be connected to cylinders by the operator;

c) that are an integral part of medical equipment (e.g. anaesthetic workstations, lung ventilators, resuscitators).

A PRESSURE REGULATOR can be provided with PRESSURE OUTLET or FLOW OUTLET, and can be adjustable or pre-set.

PRESSURE REGULATORS are intended to be fitted to refillable cylinders with a WORKING PRESSURE up to 30 000 kPa (300 bar) and can be provided with devices which control and measure the flow of the medical gas delivered.

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 407, *Small medical gas cylinders — Pin-index yoke-type valve connections*

ISO 5145, *Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning*

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

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

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

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
ACCURACY OF FLOW
difference between the indicated value and the actual value of the flow

Note 1 to entry: It is expressed in per cent.

3.2
ADJUSTABLE PRESSURE REGULATOR
PRESSURE REGULATOR (3.18) that is provided with a means of operator adjustment of the outlet pressure

3.3
CONTENT INDICATOR
device that displays the amount of gas remaining in the cylinder

Note 1 to entry: The content can be expressed either in percentage of content or cylinder pressure.

3.4
FLOWGAUGE
device that measures pressure and which is calibrated in units of flow

Note 1 to entry: The FLOWGAUGE does not measure flow. It indicates flow by measuring the pressure upstream of a fixed *ORIFICE* (3.13).

3.5
FLOWMETER
device that measures and indicates the flow of a specific gas or gas mixture

3.6
FLOW SELECTOR
means for selecting the flow and indicating the flow selected

3.7
FLOW OUTLET
outlet intended to deliver a controlled flow of gas

3.8
GAS-SPECIFIC
quality of having characteristics that prevent connection between different gas services

3.9
GAS-SPECIFIC CONNECTION POINT
part of the terminal unit which is the receptor for a *GAS-SPECIFIC* (3.8) probe

3.10
NIPPLE
portion of a connector which is pushed into and secured within the bore (lumen) of a hose

3.11
NOMINAL INLET PRESSURE
P_1
upstream *WORKING PRESSURE* (3.21) specified by the manufacturer for which the *PRESSURE REGULATOR* (3.18) is intended to be used

3.12
NOMINAL OUTLET PRESSURE
P_2
nominal downstream pressure under flow conditions specified by the manufacturer

3.13
ORIFICE
restriction of known cross-section that delivers a constant flow of gas when supplied with gas at a constant upstream pressure

3.14
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]

3.15
PRE-SET PRESSURE REGULATOR
PRESSURE REGULATOR (3.18) that is not provided with a means of operator adjustment of the outlet pressure

3.16
PRESSURE GAUGE
device that measures and indicates pressure

3.17
PRESSURE OUTLET
outlet intended to deliver gas at a controlled pressure

3.18
PRESSURE REGULATOR
device that reduces the inlet pressure and maintains the set outlet pressure within specified limits

3.19
PRESSURE-RELIEF DEVICE
device intended to relieve excess pressure at a pre-set value

3.20
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

3.21
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 PRESSURE REGULATORS (see figures) with terminology are given in Annex A.

5 General requirements

5.1 Safety

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 the PRESSURE REGULATOR should be such that in the event of 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[6] and IEC/TR 62366-2[7].

5.3 Alternative construction

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, 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 PRESSURE REGULATOR and its components to meet the requirements of Clause 5 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 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 5 shall be provided by the manufacturer upon request.

6 Design requirements

6.1 General

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

NOTE Regional or national regulations can specify additional design requirements.

6.2 Indicator for cylinder pressure or cylinder content

6.2.1 General

The PRESSURE REGULATOR shall be fitted with a PRESSURE GAUGE or with an equivalent means to indicate the cylinder pressure or cylinder content.

NOTE In a cylinder with liquefiable gas (e.g. nitrous oxide), the pressure might not indicate the content.

6.2.2 PRESSURE GAUGES, pressure indicators, and FLOWGAUGES

6.2.2.1 If a Bourdon tube PRESSURE GAUGE or FLOWGAUGE 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 their requirements are applicable to other types of gauges, e.g. direct drive gauges.

6.2.2.2 PRESSURE GAUGES, CONTENT INDICATORS, and FLOWGAUGES should be designed to resist moisture ingress (e.g. IP 44 of IEC 60529).

6.2.2.3 The casings of PRESSURE GAUGES, CONTENT INDICATORS and FLOWGAUGES 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.

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

6.2.2.5 The pressure, flow 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.

6.2.2.6 The scale of the cylinder PRESSURE GAUGE and CONTENT INDICATOR shall extend to at least 133 % of P_1.

6.2.2.7 PRESSURE GAUGES and FLOWGAUGES shall be class 2.5 or better in accordance with EN 837-1.

6.2.2.8 The inlet connection of a PRESSURE GAUGE and CONTENT INDICATOR, 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 electronic device

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 Connections

6.4.1 Inlet connector

The inlet connector for connection to cylinders shall comply with either ISO 407, ISO 5145 or the relevant regional or national standards. See ISO TR 7470 for information. The inlet connection should be selected in order to ensure that the PRESSURE REGULATOR will not be subjected to an upstream pressure higher than the pressure, P_1, specified.

6.4.2 Outlet connectors

6.4.2.1 General

The outlet connector(s) shall be in accordance with 6.4.2.2 or 6.4.2.3.

NOTE A PRESSURE REGULATOR can have multiple outlets and can have both a PRESSURE OUTLET and a FLOW OUTLET.

6.4.2.2 * FLOW OUTLET

A FLOW OUTLET shall either be:

a) a NIPPLE in accordance with EN 13544-2;

b) a threaded connector in accordance with EN 13544-2:

— thread for oxygen: 9/16-18UNF-2A-RH;

— thread for medical air: 3/4-16UNF-2A-RH.

Threaded connectors, if used for other medical gases, shall be in accordance with regional or national standards.

A FLOW OUTLET shall not be fitted to a PRESSURE REGULATOR intended for use with air or nitrogen for driving surgical tools.

6.4.2.3 PRESSURE OUTLET

A PRESSURE OUTLET shall be fitted with a GAS-SPECIFIC CONNECTION POINT, in accordance with ISO 9170-1 for the gases specified or with a GAS-SPECIFIC CONNECTOR in accordance with regional or national standards for the other medical gases.

NOTE The connection of the GAS-SPECIFIC CONNECTION POINT to the PRESSURE REGULATOR body need not be GAS-SPECIFIC.

6.5 * Requirements for outlet pressure

6.5.1 PRESSURE OUTLET

6.5.1.1 General

If a PRESSURE REGULATOR is fitted with a PRESSURE OUTLET, the outlet pressure shall be pre-set.

6.5.1.2 NOMINAL OUTLET PRESSURE (P_2)

The NOMINAL OUTLET PRESSURE (P_2) shall either be:

a) $\left(400\ {}^{100}_{0}\right)$ kPa for medical gases other than air or nitrogen for driving surgical tools;

b) $\left(800\ {}^{200}_{100}\right)$ kPa for air or nitrogen for driving surgical tools.

For special applications (e.g. NO/N_2 mixtures), different outlet pressures from a) may be required.

6.5.1.3 * Outlet pressure limits

The outlet pressure from a PRESSURE REGULATOR fitted with a PRESSURE OUTLET (except for air or nitrogen for driving surgical tools) shall be not less than 360 kPa and no greater than 550 kPa at any flow between zero and 40 l/min for all inlet pressures between P_1 and 1 500 kPa.