INTERNATIONAL STANDARD

ISO 10524-3

Second edition
2019-01

Pressure regulators for use with medical gases —

Part 3: Pressure regulators integrated with cylinder valves (VIPRs)

Détendeurs pour l'utilisation avec les gaz médicaux —

Partie 3: Détendeurs intégrés dans les robinets des bouteilles à gaz (VIPR)

Reference number
ISO 10524-3:2019(E)

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

Published in Switzerland

Contents

Page

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 of 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 www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 10524-3:2005), which has been technically revised. It also incorporates the Amendment ISO 10524-3:2005/Amd 1:2013.

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

a) introduction of the acronym VIPR for designating the valve with integrated pressure regulator as in ISO 10297 and ISO 22435[9];

b) extension of the scope to include VIPRs with a nominal inlet pressure up to 30 000 kPa (300 bar);

c) restructuring of the document to the new ISO template and associated renumbering;

d) removal of the requirements for VIPRs fitted with flow-metering devices, flow gauges and adjustable pressure regulators;

e) alignment with the common requirements of ISO 10524-1 and ISO 10524-2;

f) addition of cross-reference to ISO 10297 for all requirements concerning the MAIN SHUT-OFF;

g) rationalization of impact test requirements to comply with ISO 10297 and requirements for drop testing in alignment with ISO 11117;

h) introduction of endurance testing on the flow selector, non-return valve and PRESSURE REGULATOR;

i) introduction of type testing with the intended gas;

j) introduction of a complete test schedule;

k) review of all type tests;

l) reference to ISO 15996 for *residual pressure device* (RPD);

m) introduction of requirements for usability;

n) consideration of avoidance of stainless steel for parts in contact with oxygen.

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

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

VALVES WITH INTEGRATED PRESSURE REGULATORS (VIPRs) are used to reduce high cylinder pressure to a lower pressure suitable for use with medical equipment or for delivery of gas 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 VIPRs are specified and tested in a defined manner.

A VIPR is normally coupled to a device which controls the gas flow, such as a flow control device or a fixed orifice.

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;

— information supplied by the manufacturer.

This document should be read in conjunction with ISO 10524-1, ISO 10524-2 and ISO 10524-4.

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: smaller type. Normative text of tables are also in a smaller type.

— *Test specifications*: *italic type*.

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

In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this document conform to usage described in ISO/IEC Directives, Part 2:2016, Annex H. For the purposes of this document, the auxiliary verb:

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

— "may" is used to describe a permissible way to achieve compliance with a requirement or test.

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. Annex B contains rationale statements for some of the requirements of this document. It provides 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.

Pressure regulators for use with medical gases —

Part 3:
Pressure regulators integrated with cylinder valves (VIPRs)

1 *Scope

This document specifies design, type testing, and marking requirements for cylinder valves with integrated PRESSURE REGULATORS [as defined in 3.26 and referred to hereafter as VALVES WITH INTEGRATED PRESSURE REGULATORS (VIPRs)] intended for the administration of medical gases 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 VIPRs mounted on refillable cylinders with a WORKING PRESSURE up to 30 000 kPa (300 bar) intended to be filled in cylinder filling facilities or on self-filling systems as used in homecare applications.

VIPRs covered by this document are pressure pre-set and provided with a PRESSURE OUTLET and/or pre-set FLOW OUTLET(S).

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

ISO/TR 7470, *Valve outlets for gas cylinders — List of provisions which are either standardized or in use*

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 10297:2014/Amd1:2017, *Pressure drums and tubes*

ISO 11117, *Gas cylinders — Valve protection caps and valve guards — Design, construction and tests*

ISO 11363-1, *Gas cylinders — 17E and 25E taper threads for connection of valves to gas cylinders — Part 1: Specifications*

ISO 13341, *Gas cylinders — Fitting of valves to gas cylinders*

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

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

ISO 15245-1, *Gas cylinders — Parallel threads for connection of valves to gas cylinders — Part 1: Specification*

ISO 15996, *Gas cylinders — Residual pressure valves — Specification and type testing of cylinder valves incorporating residual pressure devices*

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

EN 13544-2:2002+ A1:2009, *Respiratory therapy equipment — Part 2: Tubing and connectors*

IEC 60601-1+ A1:2012, *Medical electrical equipment — Part 1: General requirements for safety*

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 http://www.electropedia.org/

3.1
ACCURACY OF FLOW
difference between the indicated flow and the measured flow

Note 1 to entry: Expressed as a percentage.

3.2
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, volume of gas or cylinder pressure.

3.3
FILLING ADAPTOR
means of connecting the VIPR FILLING PORT to the filling system allowing a cylinder fitted with a *VIPR* (3.26) to be filled or vented

Note 1 to entry: This is not part of the VIPR.

Note 2 to entry: It may also be referred to as a filling tool.

3.4
FILLING PORT
connector on the *VIPR* (3.26) through which the cylinder is filled

3.5
FILLING PORT NON-RETURN VALVE
valve which remains closed in normal use thus preventing the flow out of the *VIPR's filling port* (3.4) until opened by insertion of an appropriate means and which then permits flow in either direction

Note 1 to entry: Some FILLING PORT NON-RETURN VALVES may also be opened by the pressure of the incoming gas.

3.6
FLOW OUTLET
outlet intended to deliver a controlled flow of gas

3.7
FLOW SELECTOR
means for selecting the flow and indicating the flow selected

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

3.9
GAS-SPECIFIC CONNECTION POINT
part of the *pressure outlet* (3.19) which is the receptor for a *gas-specific* (3.8) probe

3.10
MAIN SHUT-OFF
primary mechanism which closes and opens the valve *orifice* (3.14) and which includes the internal and external sealing systems

Note 1 to entry: In ISO 10297, the MAIN SHUT-OFF is called valve operating mechanism.

Note 2 to entry: For some *VIPR* (3.26) designs, the pressure regulating valve acts as the shut-off mechanism.

3.11
NIPPLE
portion of a connector which is pushed into and secured within the bore (lumen) of a hose

3.12
NOMINAL INLET PRESSURE
P_1
working pressure (3.27) of the cylinder specified by the manufacturer of the *VIPR* (3.26) for which the VIPRs is intended to be used

3.13
NOMINAL OUTLET PRESSURE
P_2
pressure downstream of the *pressure regulator* (3.20) under flow conditions specified by the manufacturer

3.14
ORIFICE
restriction of known cross-section that delivers a constant flow of gas when supplied with gas at a constant upstream pressure

3.15
OUTLET PRESSURE
pressure supplied by the *VIPR* (3.26) at the outlet

3.16
OXIDIZING GAS
gas or gas mixture more oxidizing than air

EXAMPLE Any gas or gas mixture that is able, at atmospheric pressure, to support the combustion greater than or equal to a reference oxidizer consisting of 23,5 % oxygen in nitrogen

Note 1 to entry: Derived from ISO 10156.

3.17
PRE-SET PRESSURE REGULATOR
pressure regulator (3.20) that is not provided with a means of operator adjustment of the *outlet pressure* (3.15)

3.18
PRESSURE GAUGE
device that measures and indicates pressure

3.19
PRESSURE OUTLET
outlet intended to deliver gas at a controlled pressure

3.20
PRESSURE REGULATOR
device that reduces the inlet pressure and maintains the set *outlet pressure* (3.15) within specified limits

3.21
PRESSURE-RELIEF DEVICE
device intended to relieve excess pressure at a pre-set value

3.22
RESIDUAL PRESSURE DEVICE
device that is designed to prevent ingress of contaminants by maintaining a positive pressure within the cylinder relative to atmosphere by closing off its internal gas passages in the discharging direction

[SOURCE: ISO 15996:2017, 3.2]

3.23
SERVICE LIFE
time period during which a *VIPR* (3.26) can be used to refill a cylinder

Note 1 to entry: The VIPR can be used after its SERVICE LIFE up to the expiry date of the filled medical gas.

3.24
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

3.25
VALVE INLET CONNECTION
threaded connection of the *VIPR* (3.26) which connects it to the cylinder

Note 1 to entry: It can also be referred to as the valve stem.

3.26
VALVE WITH INTEGRATED PRESSURE REGULATOR
VIPR
combination of a *pressure regulator* (3.20) and cylinder valve intended to be fitted to a medical gas cylinder

3.27
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) (from ISO 10297).

4 Nomenclature

The terminology used in this document for components of VIPRs is given in a labelled diagram in Annex A.

5 General requirements

5.1 Safety

VIPRs 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 VIPR should be such that in the event of internal ignition, the consequences of the ignition are contained and the gas vented safely by the VIPR.

Check compliance by inspection of the risk management file.

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 standards, for example IEC 62366-1[6] and IEC/TR 62366-2[7].

5.3 Materials

5.3.1 *The materials which come in contact with the medical gas in normal condition shall be resistant to corrosion and compatible with the intended medical gas and oxygen, in the temperature range specified in 6.1.

Check compliance by inspection of the list of materials in contact with the gas in normal and SINGLE FAULT CONDITION and associated rationale for compatibility.

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 minor 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 can burn 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 (PCTFE) 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.

NOTE 6 See ISO 11114-1[16] and ISO 11114-2[17] for information concerning chemical and/or physical compatibility of metallic and non-metallic materials with the gas.

5.3.2 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.

5.3.3 *Aluminium, or any 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.

5.3.4 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.

5.3.5 The materials shall permit the VIPR and its components to meet the requirements of Clause 6.

5.3.6 VIPRs 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 in Clause 6 shall be provided by the manufacturer upon request.

5.4 Alternative construction

VIPRs 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 by the manufacturer 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.

NOTE 1 Objective evidence can be obtained by post-market surveillance.

NOTE 2 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.

6 Design requirements

6.1 *General

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

VIPRs, closed in accordance with the instructions for use, shall be leak-tight during transport and storage, within the temperature range between −40 °C and +65 °C.

Check compliance by inspection of the technical file.

NOTE 1 Regional or national environmental conditions can require deviation from this range of temperatures.

NOTE 2 Regional or national regulations concerning transport and medical device regulations can specify additional design requirements and certifications or approval.

6.2 Integrated electronic device

Where the risk management process demonstrates that the risk to patient safety is impacted by the use of an integrated electronic device, the relevant clauses of IEC 60601-1 shall be used as a normative reference.

6.3 FILLING PORT

6.3.1 *The FILLING PORT shall be GAS-SPECIFIC for the medical gas for which the VIPR is intended to be used.

Check compliance by inspection of the technical file.

6.3.2 The FILLING PORT shall either:

a) comply with ISO 5145 or the relevant regional or national standard (see ISO/TR 7470 for information), or

b) be a proprietary connector.

Check compliance by inspection of the technical file.

6.3.3 The FILLING PORT shall be fitted with a means that allows the VIPR to meet the external leakage requirement in 6.12.1 (e.g. non-return valve and/or pressure-tight plug or cap). The cap or plug, if fitted, shall be designed for the design pressure of the VIPR for which it is intended to be used.

Check compliance by inspection of the technical file.

6.3.4 Gas tight caps and plugs shall be designed to require the use of a proprietary tool for removal.

If a gas-tight plug is used, the risk of ejection in case of leak of the non-return valve when removing the plug, shall be addressed to prevent any risk to the operator.

Check compliance by inspection of the technical file.

6.3.5 The non-return valve, if fitted, shall comply with the requirement of 6.16.2 after 1 000 opening and closing cycles.

Check compliance by test described in 8.1.3.

6.3.6 Means shall be provided to reduce the likelihood of the FILLING PORT becoming contaminated either in storage or in use.

NOTE Such means can include a removable plug, cap or cover.

Check compliance by inspection of the technical file.

6.3.7 Means shall be provided to reduce the likelihood of the FILLING PORT being used for other than its intended purpose.

Check compliance by inspection of the technical file.

6.3.8 The FILLING PORT shall be designed for filling activities including both filling and venting the cylinder.

If the cylinder can be purged through the FILLING PORT, the effects of a backflow from the cylinder shall be taken into account in the design to prevent sealing components on the FILLING PORT or the