SLOVENSKI STANDARD
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Tlačni regulatorji za medicinske pline - 3. del: Tlačni regulatorji v sklopu cilindričnih ventilov jeklenk (ISO/DIS 10524-3:2025)

Pressure regulators for use with medical gases - Part 3: Pressure regulators integrated with cylinder valves (VIPRs) (ISO/DIS 10524-3:2025)

Druckminderer zur Verwendung mit medizinischen Gasen - Teil 3: Druckminderer in Flaschenventilen (ISO/DIS 10524-3:2025)

Détendeurs pour l'utilisation avec les gaz médicaux - Partie 3: Détendeurs intégrés dans les robinets des bouteilles à gaz (VIPR) (ISO/DIS 10524-3:2025)

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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)

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

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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*, Subcommittee SC 6, *Medical gas supply systems*.

This third edition cancels and replaces the second edition (ISO 10524-3:2019), which has been technically revised.

The main changes are as follows:

- reorganisation of the structure of the document
- Alignment on the requirements of ISO 10297:2024, Gas cylinders — Cylinder valves — Specification and type testing
- Alignment of terms with ISO 10297 and ISO 15002
- New requirement regarding the potential contamination of the gas pathway
- New requirement regarding cleaning and disinfection
- Definition of three temperature ranges
- References to colour coding have been removed
- Specific requirements for *VIPRs* intended to supply air or nitrogen for driving surgical tools moved to an normative annex
- New informative annex on qualification of a *VIPR* for use in an air / road ambulance
- New informative annex on the promoted ignition test (ASTM G175-24)

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

Medicinal gases can be supplied in cylinder fitted with *Valves with Integrated Pressure regulators* (*VIPRs*). High pressure cylinders fitted with a *VIPR* offers the patient and the healthcare professional with a safe and convenient package to administer the gas without having to connect a separate *pressure regulator*.

The *VIPR* is normally fitted with an *integral flow control device* incorporating a *flow outlet* to allow the prescribed flow to be administered and can be fitted with a *pressure outlet*, using a *gas-specific* terminal outlet, as used for medical gas pipeline systems.

In order for the medicinal gas to be administered safely to the patient, the design specifications and characteristics of the *VIPR* need to be controlled to ensure that the flows and pressures are compatible with any medical devices used with the cylinder package.

This standard describes basic requirements for the *VIPRs* used with medical gas cylinder packages including:

- Suitable materials of construction, compatible with the medicinal gases
- Safe design principles, including requirements for:
    - usability and handling;
    - mechanical strength,
    - operational characteristics (flowrates and pressures);
    - pressure relief systems;
    - product integrity (leakage);
    - resistance to ignitions.
- Gas-specificity
- Cleanliness
- Marking
- Information for safe usage by the medical gas supplier and the end user

The standard describes the approved tests for the type testing of the *VIPR* and the acceptance limits for the tests.

VIPRs also act as the “closure” of gas cylinders, and both gas cylinders and closures are subjected to transport regulations. ISO 10297, *Gas cylinders — Cylinder valves — Specification and type testing* standard, developed by ISO/TC 58/SC 2 is the ISO cylinder valve (closure) standard referenced in these regulations. ISO 10297 includes industrial and medical *VIPRs* within its scope and was recently revised,

Medical *VIPRs* are classified as medical devices and have to comply with the medical device regulations. As a medical device standard, ISO 10524-3 is intended to demonstrate conformity with the safety and performance requirements as defined in medical devices regulations and recognised guidelines. As, ISO 10524-3 strives to comprehensively cover all aspects related to safety and performances of the medical *VIPR*, it makes having a general reference to ISO 10297 impractical.

In order to reconcile these regulatory constraints and minimize burden on manufacturers, the chosen approach is to replicate the applicable “medical” requirements common to both standards within ISO 10524-3, along with a note indicating alignment with ISO 10297:2024. Some of the requirements of ISO 10297 are not relevant for medical devices and have not been duplicated.

However, for those tests methods that are relevant, direct reference to ISO 10297:2024 is made, so avoiding duplication.

1 Scope

This document specifies design, type testing, and marking requirements for cylinder valves with integrated *pressure regulator*s [as defined in 3.26 and referred to hereafter as *valves with integrated pressure regulators* (*VIPRs*)].

Medical *VIPRs* are designed to be mounted on medical gas cylinders, allowing them to be filled with medical gases for subsequent use as a supply source for other medical devices, such as emergency ventilators, or for the direct administration of medical gases to a patient via an *integral flow control device*, when fitted.

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

Intended use of *VIPRs* may also encompass the supply of air or nitrogen for driving surgical tools.

NOTE See annex B for their specific requirements

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).

VIPRs used for self-fill systems used in homecare are not covered by this standard, but it can be used as a guide.

NOTE The conditions of use for these *VIPRs* vary significantly, particularly in terms of filling frequency and usage, which can occur daily throughout their lifetime.

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

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

ISO 10297:2024, *Gas cylinders — Cylinder valves — Specification and type testing*

ISO 11114-6, *Gas cylinders — Compatibility of cylinder and valve materials with gas contents — Part 6: Oxygen pressure surge testing*

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*

ISO 17256, *Anaesthetic and respiratory equipment — Respiratory therapy tubing and connectors*

ISO 20417, *Medical devices — Information to be supplied by the manufacturer*

EN 837-1, *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.

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 indicates the cylinder content
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* 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* 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* until opened by insertion of an appropriate means and which then permits flow in either direction