

SLOVENSKI STANDARD oSIST prEN ISO 10524-3:2017

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Tlačni regulatorji za medicinske pline - 3. del: Tlačni regulatorji v sklopu ventilov jeklenk (ISO/DIS 10524-3:2017)

Pressure regulators for use with medical gases - Part 3: Pressure regulators integrated with cylinder valves (VIPRs) (ISO/DIS 10524-3:2017)

Druckminderer zur Verwendung mit medizinischen Gasen - Teil 3: Druckminderer in Flaschenventilen (ISO/DIS 10524-3:2017)

Détendeurs pour l'utilisation avec les gaz médicaux - Partie 3: Détendeurs intégrés dans les robinets des bouteilles de gaz (VIPR) (ISO/DIS 10524-3:2017)

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23.060.40	Tlačni regulatorji	Pressure regulators

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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 de gaz

ICS: 11.040.10

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75 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.

⁸³ 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

⁸⁶ editorial rules of the ISO/IEC Directives, Part 2. <u>www.iso.org/directives</u>

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. <u>www.iso.org/patents</u>

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For an explanation on the meaning of ISO specific terms and expressions related to conformity

assessment, as well as information about ISO's adherence to the WTO principles in the Technical

95 Barriers to Trade (TBT) see the following URL: <u>Foreword - Supplementary information</u>

The committee responsible for this document is ISO/TC121 Anaesthetic and Respiratory
 Equipment/SC6 Medical Gas Systems. <u>SCTEN ISO 10524-3-2019</u>

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This is the second edition of ISO 10524-3, and should be read in conjunction with ISO 10524-1, 10524-2 and 10524-4. This replaces standard ISO 10524-3:2005 + A1:2013.

ISO 10524 consists of the following parts, under the general title Pressure regulators integrated with
 cylinder valves for use with medical gases:

- 102 Part 1: Pressure regulators and pressure regulators with flow-metering devices
- 103 Part 2: Manifold and line pressure regulators
- 104 Part 3: Pressure regulators integrated with cylinder valves
- 105 Part 4: Low-pressure regulators
- ¹⁰⁶ This edition includes the following significant changes with respect to the previous edition:
- a) Introduction of the acronym VIPR for designating the Valve with Integrated Pressure Regulator and in ISO 10297 and ISO 22435.
- 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.

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111	d) Removal of the requirements for VIPS fitted with flow metering devices and flow gauges.
112	e) Alignment of the common requirements of ISO 10524-1 and ISO 10524-2.
113	f) Cross-reference to ISO 10297 for all requirements concerning the main shut-off.
114 115	g) Rationalisation of impact test requirements to comply with ISO 10297 and requirements for drop testing in line with ISO 11117.
116	h) Introduction of endurance testing on flow selector, non-return valve, and pressure regulator.
117	i) Introduction of operational testing with the intended gas.
118	j) Introduction of a complete test schedule.
119	k) Review of all type tests.
120	In this standard, the following print types are used:
121	— Requirements and definitions: roman type.
122 123	 Informative material appearing outside of tables, such as notes, examples and references: smaller type. Normative text of tables is also in a smaller type.
124	— Test specifications: italic type iTeh Standards
125	— TERMS DEFINED IN CLAUSE 3 OF THIS STANDARD OR AS NOTED: SMALL CAPITALS TYPE.
126 127	In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.
128 129	The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:
130 131	 "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;
132 133	 "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
134	— "may" is used to describe a permissible way to achieve compliance with a requirement or test.
135 136	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.
137 138 139 140 141	The attention of Member Bodies is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the

content of this publication be adopted for implementation nationally not earlier than 3 years from the
 date of publication for equipment newly designed and not earlier than 5 years from the date of
 publication for equipment already in production.

European Foreword

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard "within the meaning of Annex ZA", the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state - ofart.

When the ISO or IEC standard is referred to in the ISO text standard, this must be understood as a normative reference to the parallel EN standard or dated ISO standard, as outlined below, including the foreword and the Annexes ZZ.

NOTE The way in which these references documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

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144

Table – Correlations between normative references and dated EN and ISO/IEC standards

Normative references as listed	Equivalent dated standard	
in Clause 2	EN	ISO/IEC
ISO XXXXX	EN ISO XXXXX	ISO XXXXX
ISO XXXXX	EN XXXXX Canual US	ISO XXXXX
		1 • >

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158 Introduction

Pressure regulators integrated with cylinder valves (VIPRs) 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 VIPRs 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 FLOW GAUGE.

It is essential that regular inspection and maintenance be undertaken to ensure that the VIPR continues
 to meet the requirements of this part of ISO 10524.

- ¹⁶⁸ This part of ISO 10524 pays particular attention to:
- 169 use of suitable materials;
- ¹⁷⁰ safety (mechanical strength, leakage, safe relief of excess pressure and resistance to ignition);
- 171 gas specificity;
- 172 cleanliness;
- 173 type testing;
- 174 marking;

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information supplied by the manufacturer. SO 10524-3:2019

Annex B contains rationale statements for some of the requirements of this part of ISO 10524. 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 part of ISO 10524. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this part of ISO 10524, but will expedite any subsequent revisions.

Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves (VIPR)

184 **1 * Scope**

This International Standard specifies design, type testing, and marking requirements for cylinder valves with integrated pressure regulators (as defined in 3.22 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 standard applies to VIPR 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 can be adjustable or pre-set and provided with a pressure outlet and/or flow outlet.

¹⁹⁴ **2** Normative References

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

198 ISO 32:1977, Gas cylinders for medical use — Marking for identification of content

199 ISO 5145:2014, Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning

ISO 7000:2014, Graphical symbols for use on equipment — Registered symbols

ISO 7396-1:2016, Medical gas pipeline systems — Part 1: Pipelines for compressed medical gases and vacuum (new

202 edition) https://standards.iteh.ai/catalog/standards/sist/0f84326b-2280-471a-83f4-7b70ac6aca7b/sist-en-iso-10524-3-2019

ISO/TR 7470:1988, Valve outlets for gas cylinders — List of provisions which are either standardized or in use

ISO 9170-1:2008, Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed
 medical gases and vacuum

ISO 10156:2010, Gases and gas mixtures — Determination of fire potential and oxidizing ability for the selection of
 cylinder valve outlets

²⁰⁸ ISO 10297:—1), Transportable gas cylinders — Cylinder valves — Specification and type testing

- ISO 11117:1998, Gas cylinders Valve protection caps and valve guards for industrial and medical gas cylinders —
 Design, construction and tests
- ISO 11361-1:2010, Gas cylinders 17E and 25E taper threads for connection of valves to gas cylinders Part 1:
 Specifications
- ISO 13341:1997, Transportable gas cylinders Fitting of valves to gas cylinders
- ISO 14971:2012, Medical devices Application of risk management to medical devices
- ISO 15001:2010, Anaesthetic and respiratory equipment Compatibility with oxygen
- ISO 15245-1:2001, Gas cylinders Parallel threads for connection of valves to gas cylinders Part 1: Specification

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- ISO 15996: 2005, Gas cylinders -- Residual pressure valves -- General requirements and type testing 217
- ISO 22435:2007, Gas cylinders Cylinder valves with integrated pressure regulators Specification and type 218 testing 219
- EN 837-1:1996, Pressure gauges Part 1: Bourdon tube pressure gauges Dimensions, metrology, requirements 220 and testing 221
- EN 13544-2:2002, Respiratory therapy equipment Part 2: Tubing and connectors 222
- IEC 60529:2013, Degrees of protection provided by enclosures (IP Code) 223
- IEC 60601-1:2005+A1:2012, Medical electrical equipment Part 1: General requirements for safety 224
- IEC 62366, Usability of medical devices 225
- Terms and definitions 3 226
- For the purposes of this document, the following terms and definitions apply. 227
- 3.1 228
- ACCURACY OF FLOW 229
- Difference between the indicated flow and themeasured flow, expressed as a percentage 230
- 3.2 231

https://standards.iteh.ai) ADJUSTABLE PRESSURE REGULATOR 232

- Pressure regulator that is provided with a means of operator adjustment of the outlet pressure 233
- 3.3 234

235

- CONTENT INDICATOR
- Device that displays the amount gas remaining in the cylinder. 314-7b70ac6aca7b/sist-en-iso-10524-3-2019 236
- Note: the content can be expressed either in percentage of content, volume of gas or cylinder pressure. 237
- 3.4 238
- FILLING ADAPTOR 239
- The means of connecting the VIPR FILLING PORT to the filling system allowing the cylinder fitted with a 240 VIPR to be filled or vented. 241
- 242
- Note1: this is not part of the VIPR 243
- Note 2: It may also be referred to as a filling tool. 244

245

- 3.5 246
- **FILLING PORT** 247
- Connector on the pressure regulator through which the cylinder is filled 248
- 3.6 249
- FLOW OUTLET 250
- Outlet intended to deliver a controlled flow of gas 251
- 252

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253	3.7
254	GAS SPECIFIC
255	Having characteristics that prevent connection between different gas services
256	3.8
257	GAS SPECIFIC CONNECTION POINT
258	That part of the terminal unit which is the receptor for a GAS SPECIFIC probe
259	3.9
260	LIFETIME
261	Time period during which a VIPR can be used to refill a cylinder
262	NOTE TO ENTRY the WIDD can be used after its experisional lifetime up to the suming data of the filled medical sea
263	NOTE TO ENTRY-the VIPR can be used after its operational lifetime up to the expiry date of the filled medical gas
264 265	3.10
266	MAIN SHUT-OFF
267	Primary mechanism which closes and opens the valve orifice and which includes the internal and
268	external sealing systems.
269	NOTE 1 to entry: In ISO 10297 the MAIN SHUT-OFF is called valve operating mechanism
270	NOTE 2 to entry: For some VIPR designs the pressure regulating valve acts as the shut-off mechanism.
271	3.11
272	NOMINAL INLET PRESSURE ITCh Standards
273	P ₁₍₁₅₎ (https://stondords.itoh.oi)
274	Upstream WORKING PRESSURE specified by the manufacturer for which the pressure regulator is
275	intended to be used Document Preview
276	3.12
277	NIPPLE SIST EN ISO 10524-3:2019
278 05	That portion of a connector which is pushed into and secured within the bore (lumen) of a hose 524-3-2019
279	3.13
280	NOMINAL OUTLET PRESSURE
281	P ₂
282	Nominal downstream pressure under flow conditions specified by the manufacturer
283	3.14
284	OXIDISING GAS
285	Any gas or gas mixture more oxidizing than air, i.e. any gas or gas mixture that is able, at atmospheric
286	pressure, to support the combustion greater than or equal to a reference oxidizer consisting of 23,5 $\%$
287	oxygen in nitrogen
288	[derived from ISO 10156:2010]
289	3.15
290	PRE-SET PRESSURE REGULATOR
291	Pressure regulator that is not provided with a means of operator adjustment of the outlet pressure
292	3.16

- 293 PRESSURE GAUGE
- ²⁹⁴ Device that measures and indicates pressure

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295	3.17
296	PRESSURE OUTLET
297	Outlet intended to deliver gas at a controlled pressure
298	3.18
299	PRESSURE REGULATOR
300	Device that reduces the inlet pressure and maintains the set outlet pressure within specified limits
500	
301	3.19
302	PRESSURE RELIEF VALVE
303	Device intended to relieve excess pressure at a pre-set value
304	3.20
305	RESIDUAL PRESSURE DEVICE
306	Means for retaining a minimum pressure within a cylinder
307	3.21
308	PRESSURE REGULATOR INTEGRATED WITH CYLINDER VALVE (VIPR)
309	Combination of a PRESSURE REGULATOR and cylinder valve intended to be fitted to a medical gas cylinder
310	3.22
311	single fault condition illen Standards
312	Condition in which a single means for protection against a safety hazard in equipment is defective or a
313	single external abnormal condition is present INCLATORS . Item . al)
314	3.23 Document Preview
314	VALVE INLET CONNECTION
315	Threaded connection of the VIPR which connects it to the cylinder
317 DS:	NOTE 1 to entry: it can also be referred to as the valve stem $a-83$ (4-7b70ac6aca7b/sist-en-iso-10524-3-2019)
318	
319	3.24
320	WORKING PRESSURE
321	Settled pressure of a compressed gas at a uniform reference temperature of 15°C in a full gas cylinder
322	NOTE This definition does not apply to liquefied gases (e.g. carbon dioxide) or dissolved gases (e.g. acetylene).
323	4 Nomenclature
324	Examples of VIPRs with terminology are given in Annex A.

5 General Requirements

326 **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.