SLOVENSKI STANDARD
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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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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

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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. 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. 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 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 Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC121 Anaesthetic and Respiratory Equipment/SC6 Medical Gas Systems.

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:

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

— *Part 2: Manifold and line pressure regulators*

— *Part 3: Pressure regulators integrated with cylinder valves*

— *Part 4: Low-pressure regulators*

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.

d) Removal of the requirements for VIPS fitted with flow metering devices and flow gauges.

e) Alignment of the common requirements of ISO 10524-1 and ISO 10524-2.

f) Cross-reference to ISO 10297 for all requirements concerning the main shut-off.

g) Rationalisation of impact test requirements to comply with ISO 10297 and requirements for drop testing in line with ISO 11117.

h) Introduction of endurance testing on flow selector, non-return valve, and pressure regulator.

i) Introduction of operational testing with the intended gas.

j) Introduction of a complete test schedule.

k) Review of all type tests.

In this standard, 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 is also in a smaller type.

— *Test specifications: italic type*

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

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.

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:

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

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

— "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.

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 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-of-art.

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.

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

Normative references as listed in Clause 2	Equivalent dated standard	
	EN	ISO/IEC
ISO XXXXX	EN ISO XXXXX	ISO XXXXX
ISO XXXXX	EN XXXXX	ISO XXXXX

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.

This part of ISO 10524 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.

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)

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.

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.

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

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 edition)*

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*

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*

ISO 15996: 2005, *Gas cylinders -- Residual pressure valves -- General requirements and type testing*

ISO 22435:2007, *Gas cylinders — Cylinder valves with integrated pressure regulators — Specification and type testing*

EN 837-1:1996, *Pressure gauges — Part 1: Bourdon tube pressure gauges — Dimensions, metrology, requirements and testing*

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

IEC 60529:2013, *Degrees of protection provided by enclosures (IP Code)*

IEC 60601-1:2005+A1:2012, *Medical electrical equipment — Part 1: General requirements for safety*

IEC 62366, *Usability of medical devices*

3 Terms and definitions

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

3.1

ACCURACY OF FLOW

Difference between the indicated flow and themeasured flow, expressed as a percentage

3.2

ADJUSTABLE PRESSURE REGULATOR

Pressure regulator that is provided with a means of operator adjustment of the outlet pressure

3.3

CONTENT INDICATOR

Device that displays the amount gas remaining in the cylinder.

Note: the content can be expressed either in percentage of content, volume of gas or cylinder pressure.

3.4

FILLING ADAPTOR

The means of connecting the VIPR FILLING PORT to the filling system allowing the cylinder fitted with a VIPR to be filled or vented.

Note1: this is not part of the VIPR
Note 2: It may also be referred to as a filling tool.

3.5

FILLING PORT

Connector on the pressure regulator through which the cylinder is filled

3.6

FLOW OUTLET

Outlet intended to deliver a controlled flow of gas

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

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**

273 **$P_{1(15)}$**

274 Upstream **WORKING PRESSURE** specified by the manufacturer for which the pressure regulator is
275 intended to be used

276 **3.12**

277 **NIPPLE**

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

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

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 VALVE

Device intended to relieve excess pressure at a pre-set value

3.20

RESIDUAL PRESSURE DEVICE

Means for retaining a minimum pressure within a cylinder

3.21

PRESSURE REGULATOR INTEGRATED WITH CYLINDER VALVE (VIPR)

Combination of a PRESSURE REGULATOR and cylinder valve intended to be fitted to a medical gas cylinder

3.22

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

3.23

VALVE INLET CONNECTION

Threaded connection of the VIPR which connects it to the cylinder

NOTE 1 to entry: it can also be referred to as the valve stem

3.24

WORKING PRESSURE

Settled pressure of a compressed gas at a uniform reference temperature of 15°C in a full gas cylinder

NOTE This definition does not apply to liquefied gases (e.g. carbon dioxide) or dissolved gases (e.g. acetylene).

4 Nomenclature

Examples of VIPRs with terminology are given 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.

