SLOVENSKI STANDARD
oSIST prEN ISO 10524-1:2017

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Tlačni regulatorji za medicinske pline - 1. del: Tlačni regulatorji in tlačni regulatorji s pretočnimi merilniki (ISO/DIS 10524-1:2017)

Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices (ISO/DIS 10524-1:2017)

Druckminderer zur Verwendung mit medizinischen Gasen - Teil 1: Druckminderer und Druckminderer mit Durchflussmessgeräten (ISO/DIS 10524-1:2017)

Détendeurs pour l'utilisation avec les gaz médicaux- Partie 1: Détendeurs et détendeurs-débitmètres (ISO/DIS 10524-1:2017)

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ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
23.060.40	Tlačni regulatorji	Pressure regulators

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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. www.iso.org/directives

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 10524-1 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*.

This is the second edition of ISO 10524-1, and should be read in conjunction with ISO 10524-2, 10524-3, and 10524-4.

ISO 10524 consists of the following parts, under the general title PRESSURE REGULATORS 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 (VIPRs)*

— *Part 4: Low-PRESSURE REGULATORS*

This edition includes the following significant changes with respect to the previous edition:

a) Alignment of common requirements with ISO 10524-2 and ISO 10524-3.

b) Restructuring with the new ISO template and associated renumbering.

c) Introduction of a complete test schedule.

d) 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: in 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 A.

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.

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 FLOW METER or by a FLOW GAUGE.

It is essential that regular inspection and maintenance be undertaken to ensure that the PRESSURE REGULATOR 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 1: PRESSURE REGULATORS and PRESSURE REGULATORS with flow-metering devices

1 Scope

This International Standard specifies design, type testing, and marking requirements for PRESSURE REGULATORS (as defined in 3.17) 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 PRESSURE REGULATORS

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

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

g) 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 25 000 kPa (250 bar) and can be provided with devices which control and measure the flow of the medical gas delivered.

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 407:2004, *Small medical gas cylinders — Pin-index yoke-type valve connections*

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 14971:2007, Medical devices — Application of risk management to medical devices

ISO 15001:2010, Anaesthetic and respiratory equipment — Compatibility with oxygen

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 62366-1:2015, 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 value and the actual value of the flow, expressed in percent

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 1 to entry: the content can be expressed either in percentage of content~~, volume of gas~~ or cylinder pressure.

3.4

FLOW GAUGE

Device that measures pressure and which is calibrated in units of flow

NOTE The FLOW GAUGE does not measure flow. It indicates flow by measuring the pressure upstream of a fixed ORIFICE.

3.5

FLOW METER

Device that measures and indicates the flow of a specific gas or gas mixture

231 **3.6**
232 **FLOW OUTLET**
233 Outlet intended to deliver a controlled flow of gas
234

235 **3.7**
236 **GAS SPECIFIC**
237 Having characteristics that prevent connection between different gas services
238

239 **3.8**
240 **GAS SPECIFIC CONNECTION POINT**
241 That part of the terminal unit which is the receptor for a GAS SPECIFIC probe

242 **3.9**
243 **NOMINAL INLET PRESSURE**
244 **$P_{1(15)}$**
245 Upstream **WORKING PRESSURE** specified by the manufacturer for which the pressure regulator is
246 intended to be used

247 **3.10**
248 **NIPPLE**
249 That portion of a connector which is pushed into and secured within the bore (lumen) of a hose

250 **3.11**
251 **NOMINAL OUTLET PRESSURE**
252 **P_2**
253 Nominal downstream pressure under flow conditions specified by the manufacturer

254 **3.12**
255 **ORIFICE**
256 Restriction of known cross-section that delivers a constant flow of gas when supplied with gas at a
257 constant upstream pressure

258 **3.13**
259 **OXIDISING GAS**
260 Any gas or gas mixture more oxidizing than air, i.e. any gas or gas mixture that is able, at atmospheric
261 pressure, to support the combustion more than a reference oxidizer consisting of 23,5 % oxygen in
262 nitrogen
263 [derived from ISO 10156:2010]

264 **3.14**
265 **PRE-SET PRESSURE REGULATOR**
266 PRESSURE REGULATOR that is not provided with a means of operator adjustment of the outlet pressure

267 **3.15**
268 **PRESSURE GAUGE**
269 Device that measures and indicates pressure

