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Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices (ISO 10524-1:2018)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 10524-1:2019 sisaldab Euroopa standardi EN ISO 10524-1:2019 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 10524-1:2019 consists of the English text of the European standard EN ISO 10524-1:2019.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 30.01.2019.	Date of Availability of the European standard is 30.01.2019.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

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English Version

Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices (ISO 10524-1:2018)

Détendeurs pour l'utilisation avec les gaz médicaux- Partie 1: Détendeurs et détendeurs-débitmètres (ISO 10524-1:2018)

Druckminderer zur Verwendung mit medizinischen Gasen - Teil 1: Druckminderer und Druckminderer mit Durchflussmessgeräten (ISO 10524-1:2018)

This European Standard was approved by CEN on 13 December 2018.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 10524-1:2019) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 2019, and conflicting national standards shall be withdrawn at the latest by July 2019.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 10524-1:2006.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 10524-1:2018 has been approved by CEN as EN ISO 10524-1:2019 without any modification.

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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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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 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 the following URL: 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 systems*.

This second edition cancels and replaces the first edition (ISO 10524-1:2006), which has been technically revised.

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

— the common requirements have been aligned with ISO 10524-2 and ISO 10524-3;

— this document has been restructured according to the new ISO template and associated renumbering;

— a complete schedule has been introduced;

— all type tests have been reviewed.

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

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 FLOWMETER or by a FLOWGAUGE.

It is essential that regular inspection and maintenance be undertaken to ensure that the PRESSURE REGULATOR continues to meet the requirements of this document.

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, and

— information supplied by the manufacturer.

Annex A contains rationale statements for some of the requirements of this document. 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 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.

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.

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: in smaller type. Normative text of tables is also in a smaller type;

— *test specifications: italic type*;

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

Pressure regulators for use with medical gases —

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

1 Scope

This document specifies the design, construction, type testing, and marking requirements for PRESSURE REGULATORS (as defined in 3.18) intended for the administration of medical gases and their mixtures 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 PRESSURE REGULATORS:

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

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

c) 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 30 000 kPa (300 bar) and can be provided with devices which control and measure the flow of the medical gas delivered.

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

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

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

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

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

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

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

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

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 https://www.electropedia.org/

3.1
ACCURACY OF FLOW
difference between the indicated value and the actual value of the flow

Note 1 to entry: It is expressed in per cent.

3.2
ADJUSTABLE PRESSURE REGULATOR
PRESSURE REGULATOR (3.18) that is provided with a means of operator adjustment of the outlet pressure

3.3
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 or cylinder pressure.

3.4
FLOWGAUGE
device that measures pressure and which is calibrated in units of flow

Note 1 to entry: The FLOWGAUGE does not measure flow. It indicates flow by measuring the pressure upstream of a fixed *ORIFICE* (3.13).

3.5
FLOWMETER
device that measures and indicates the flow of a specific gas or gas mixture

3.6
FLOW SELECTOR
means for selecting the flow and indicating the flow selected

3.7
FLOW OUTLET
outlet intended to deliver a controlled flow of gas

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

3.9
GAS-SPECIFIC CONNECTION POINT
part of the terminal unit which is the receptor for a *GAS-SPECIFIC* (3.8) probe