Meditsiiniliste gaaside rõhu regulaatorid. Osa 2: Magistraaltoru ja harutoru rõhuregulaatorid

Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 10524-2:2006 sisaldab Euroopa standardi EN ISO 10524-2:2006 ingliskeelset teksti. Käesolev dokument on jõustatud 29.05.2006 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 10524-2:2006 consists of the English text of the European standard EN ISO 10524-2:2006. This document is endorsed on 29.05.2006 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This part of ISO 10524 specifies requirements for manifold pressure regulators (as defined in 3.6) intended to be connected to cylinders with nominal filling pressures up to 25 000 kPa at 15 °C and for line pressure regulators (as defined in 3.4) for inlet pressures up to 3 000 kPa and intended for use in pipeline systems.	**Scope:** This part of ISO 10524 specifies requirements for manifold pressure regulators (as defined in 3.6) intended to be connected to cylinders with nominal filling pressures up to 25 000 kPa at 15 °C and for line pressure regulators (as defined in 3.4) for inlet pressures up to 3 000 kPa and intended for use in pipeline systems.

ICS 11.040.10

Võtmesõnad: gaasiballoonid, gaasisegu jaotamine, hindamine, jõudluse hindamine, konstruktsioon, meditsiinilised gaasid, märgistus, ohutusnõuded, pakkimine, rõhuregulaatorid, tehnilised andmed, testimine

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10524-2

April 2006

ICS 11.040.10

Supersedes EN 738-2:1998

English Version

Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators (ISO 10524-2:2005)

Détendeurs pour l'utilisation avec les gaz médicaux - Partie 2: Détendeurs de rampes et de canalisations (ISO 10524-2:2005)

Druckminderer zur Verwendung mit medizinischen Gasen - Teil 2: Hauptstellendruckregler und Leitungsdruckminderer (ISO 10524-2:2005)

This European Standard was approved by CEN on 20 March 2006.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

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Ref. No. EN ISO 10524-2:2006: E

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Foreword

The text of ISO 10524-2:2005 has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 10524-2:2006 by 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 October 2006, and conflicting national standards shall be withdrawn at the latest by October 2006.

This document supersedes EN 738-2: 1998.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

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

Endorsement notice

The text of ISO 10524-2:2005 has been approved by CEN as EN ISO 10524-2:2006 without any modifications.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC Medical Devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC Medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in table ZA confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA — Correspondence between this European Standard and Directive 93/42/EEC Medical devices

Clause(s)/sub-clause(s) of this EN	Essential requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
5	1	
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5.4.5.6	7.3, 9.3	
5.4.6.1	9.1, 12.7.4	
5.4.6.2	9.1, 12.7.4	
5.4.6.3	7.5	

Clause(s)/sub-clause(s) of this EN	Essential requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
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7.3.2	13.1, 13.3 b)	
8.1	13.1, 13.3 a, 13.4, 13.6 a)	
8.2	9.1, 9.2, 9.3, 13.1, 13.6 c), 13.6 d), 13.6 k)	
8.3	13.6 b)	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 10524-2

First edition
2005-05-01

Pressure regulators for use with medical gases —

Part 2: Manifold and line pressure regulators

Détendeurs pour l'utilisation avec les gaz médicaux —

Partie 2: Détendeurs de rampes et de canalisations

Reference number
ISO 10524-2:2005(E)

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Published in Switzerland

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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.

ISO 10524-2 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*.

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*

— *Part 4: Low-pressure regulators*

Introduction

Manifold pressure regulators are used to reduce cylinder pressure to a lower pressure within a source of supply of a medical gas pipeline system.

Line pressure regulators are used to reduce the pressure supplied by manifold pressure regulators or by cryogenic vessels to the lower pressure required at the terminal units of medical gas pipeline systems.

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 manifold and line pressure regulators are specified and tested in a defined manner.

It is essential that regular inspection and maintenance be undertaken to ensure that the pressure regulators continue 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);

— 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 2: Manifold and line pressure regulators

1 Scope

1.1* This part of ISO 10524 specifies requirements for manifold pressure regulators (as defined in 3.6) intended to be connected to cylinders with nominal filling pressures up to 25 000 kPa at 15 °C and for line pressure regulators (as defined in 3.4) for inlet pressures up to 3 000 kPa and intended for use in pipeline systems for the following medical gases:

— oxygen;

— nitrous oxide;

— air for breathing;

— carbon dioxide;

— oxygen/nitrous oxide mixtures;

— air for driving surgical tools;

— nitrogen for driving surgical tools;

— oxygen produced by an oxygen concentrator.

1.2* This part of ISO 10524 applies to manifold pressure regulators and line pressure regulators supplied as individual units or to the relevant components incorporated within an assembly.

1.3 This part of ISO 10524 does not apply to pressure regulators for use with vacuum pipeline systems.

NOTE Requirements for pressure regulators for use with vacuum pipeline systems are covered in ISO 10079-3.

2 Normative references

The following referenced documents are indispensable for the application 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 32:1977, *Gas cylinders for medical use — Marking for identification of content*

ISO 7396-1:2002, *Medical gas pipeline systems — Part 1: Pipelines for compressed medical gases and vacuum*

ISO 14971:2000, *Medical devices — Application of risk management to medical devices*

ISO 15001:2003, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

EN 837-1:1996, *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.

3.1
closure pressure
P_4
stabilized outlet pressure, after cessation of the flow, from a pressure regulator when the flow has been set to standard discharge

3.2
double-stage pipeline distribution system
pipeline distribution system in which gas is initially distributed from the supply system at a higher pressure than the nominal distribution pressure

NOTE This higher pressure (nominal supply system pressure) is then reduced to the nominal distribution pressure by additional line pressure regulators.

3.3
flow characteristic
variation of outlet pressure in relation to flow with the inlet pressure remaining constant

3.4
line pressure regulator
pressure regulator intended to be installed within a medical gas pipeline system downstream of a manifold pressure regulator or cryogenic gas supply system

3.5
manifold
device for connecting the outlet(s) of one or more cylinders or cylinder bundles of the same medical gas to a pipeline system

3.6
manifold pressure regulator
pressure regulator intended to be installed within sources of supply containing cylinders or cylinder bundles

3.7
medical gas pipeline system
complete system which comprises a supply system, a monitoring and alarm system, a pipeline distribution system with terminal units at the points where medical gases or vacuum may be required

3.8
nominal distribution pressure
pressure of gas which the pipeline system is intended to deliver at the terminal units

3.9
nominal inlet pressure
P_1
upstream pressure (specified as a single value by the manufacturer) for which the pressure regulator is intended to be used

NOTE P_1 for manifold pressure regulators is the maximum cylinder filling pressure at 15 °C.