Meditsiiniliste gaaside rõhuregulaatorid. Osa 1: Rõhuregulaatorid ja gaasivoolu mõõteseadmega rõhuregulaatorid

Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 10524-1:2006 sisaldab Euroopa standardi EN ISO 10524-1:2006 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 10524-1:2006 consists of the English text of the European standard EN ISO 10524-1:2006. 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 is applicable to the types of pressure regulators listed in 1.3 intended for the administration of the following medical gases in the treatment, management, diagnostic evaluation and care of patients:- oxygen; - nitrous oxide; - air for breathing; - helium; - carbon dioxide; - xenon; - mixtures of the gases listed above; - air for driving surgical tools; - nitrogen for driving surgical tools.	**Scope:** This part of ISO 10524 is applicable to the types of pressure regulators listed in 1.3 intended for the administration of the following medical gases in the treatment, management, diagnostic evaluation and care of patients:- oxygen; - nitrous oxide; - air for breathing; - helium; - carbon dioxide; - xenon; - mixtures of the gases listed above; - air for driving surgical tools; - nitrogen for driving surgical tools.

ICS 11.040.10

Võtmesõnad: gaasiballoonid, gaasijaotus, katsed, konstruktsioon, kulumõõturid, meditsiinilised gaasid, mehaaniline tugevus, rõhukindlus, rõhuregulaatorid, spetsifikatsioon, süttivuse katsetamine, tähistamine

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10524-1

February 2006

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Supersedes EN 738-1:1997

English Version

Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices (ISO 10524-1:2006)

Détendeurs pour l'utilisation avec les gaz médicaux - Partie 1: Détendeurs et détendeurs à débitmètre intégré (ISO 10524-1:2006)

Druckminderer zur Verwendung mit medizinischen Gasen - Teil 1: Druckminderer und Druckminderer mit Durchflussmessgeräten (ISO 10524-1:2006)

This European Standard was approved by CEN on 30 November 2005.

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.

CEN members are the national standards bodies of 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.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN ISO 10524-1:2006: E

Foreword

This document (EN ISO 10524-1:2006) 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 August 2006, and conflicting national standards shall be withdrawn at the latest by August 2006.

This document supersedes EN 738-1:1997.

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 10524-1:2006 has been approved by CEN as EN ISO 10524-1:2006 without any modifications.

ANNEX ZA
(informative)

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

This International Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide one 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 normative clauses of this standard given in Table ZA.1 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.1 — Correspondence between this International Standard and Directive 93/42/EEC

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8.2	13.6 b)	
8.3	13.6 b)	
8.4	9.1, 9.2, 9.3, 13.1, 13.6 c), 13.6 d)	

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 10524-1

First edition
2006-02-01

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 à débitmètre intégré

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

This first edition cancels and replaces ISO 10524:1995 and ISO 10524:1995/Cor 1:1996, which has been technically revised.

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*

For the purposes of this part of ISO 10524, the CEN annex regarding fulfilment of European Council Directives has been removed.

Introduction

A pressure regulator is 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 the pressure regulators are specified and tested in a defined manner.

A pressure regulator often has coupled to it a device which controls the flow, such as a flow control valve or a fixed orifice. The flow can be indicated by a flowmeter or by a flowgauge.

It is essential that regular inspection and maintenance are undertaken to ensure that 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);

— 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 asterix (*) after their number have corresponding rationale, contained in Annex B, included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in 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

1.1 This part of ISO 10524 is applicable to the types of pressure regulators listed in 1.3 intended for the administration of the following medical gases in the treatment, management, diagnostic evaluation and care of patients:

— oxygen;

— nitrous oxide;

— air for breathing;

— helium;

— carbon dioxide;

— xenon;

— mixtures of the gases listed above;

— air for driving surgical tools;

— nitrogen for driving surgical tools.

1.2* These pressure regulators are intended to be fitted to cylinders with nominal filling pressures up to 25 000 kPa at 15 °C and can be provided with devices which control and measure the flow of the medical gas delivered.

1.3 The types of pressure regulators covered by this part of ISO 10524 are as follows:

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

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

c) pressure regulators that are an integral part of medical equipment (e.g. anaesthetic workstations, lung ventilators, resuscitators).

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

ISO 5145:2004, *Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning*

ISO 5359:2000, *Low-pressure hose assemblies for use with medical gases*

ISO 9170-1:1999, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with 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*

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

SS 01 91 02, *Colour Atlas*

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
flow outlet
outlet intended to deliver a controlled flow of gas

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

NOTE The flowgauge does not measure flow. It indicates flow by measuring the pressure upstream of a fixed orifice.

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

3.6
gas-specific connection point
that part of the terminal unit that is the receptor for a gas-specific probe