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

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English version

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

Régulateurs de pression pour systèmes de gaz médicaux -
Partie 1: Regulateurs de pression avec ou sans débitmètre

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 215.

If this draft becomes a European Standard, 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.

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

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

Foreword

This document (prEN ISO 10524-1:2004) 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 document is currently submitted to the parallel Enquiry.

This document will supersede EN 738-1:1997, EN 738-1:1997/A1:2002, EN 738-4:1998, and EN 738-4:1998/A1:2002.

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).

Endorsement notice

The text of ISO/DIS 10524-1:2004 has been approved by CEN as prEN ISO 10524-1:2004 without any modifications.

DRAFT INTERNATIONAL STANDARD ISO/DIS 10524-1

ISO/TC **121**/SC **6** Secretariat: **ANSI**

Voting begins on: **2004-06-03** Voting terminates on: **2004-11-03**

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Pressure regulators for use with medical gas systems —

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

Régulateurs de pression pour systèmes de gaz médicaux —

Partie 1: Régulateurs de pression avec ou sans débitmètre

(Revision of ISO 10524:1995 and its Corrigendum 1:1996)

ICS 11.040.10

ISO/CEN PARALLEL ENQUIRY

The CEN Secretary-General has advised the ISO Secretary-General that this ISO/DIS covers a subject of interest to European standardization. **In accordance with the ISO-lead mode of collaboration as defined in the Vienna Agreement, consultation on this ISO/DIS has the same effect for CEN members as would a CEN enquiry on a draft European Standard.** Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month FDIS vote in ISO and formal vote in CEN.

In accordance with the provisions of Council Resolution 15/1993 this document is circulated in the English language only.

Conformément aux dispositions de la Résolution du Conseil 15/1993, ce document est distribué en version anglaise seulement.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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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 second edition cancels and replaces the first edition (ISO 10524), 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.*

Annexes A, B and C are for information only.

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 is normally coupled to 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 a boldface capital **R** 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 standard. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this International Standard, but will expedite any subsequent revisions.

Pressure regulators for use with medical gas systems —

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

1 Scope

1.1 This part of ISO 10524 applies 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;

- air for driving surgical tools;

- nitrogen for driving surgical tools;

- specified mixtures of the gases listed above.

1.2 R 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:

- high-pressure regulators intended to be connected to cylinders by the operator;

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

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

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 10524. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 10524 are encouraged to investigate the possibility of applying the most recent editions of the normative documents

indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

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

ISO 407:1991, *Small medical gas cylinders – Pin-index, yoke-type valve connections.*

ISO 5145:2004, *Cylinder valve outlets for gases and mixtures -- Selection and dimensioning.*

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

ISO/TR 7470:1988, *Valve outlets for gas cylinders -- List of provisions which are either standardized or in use.*

ISO 9170-1:1999, *Terminal units for medical gas pipeline systems -- Part 1: Terminal units for use with compressed medical gases and vacuum.*

EN ISO 14971:2000, *Medical devices -- Application of risk management to medical devices.*

EN 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 part of ISO 10524, 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 which 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 which measures pressure and which 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 which measures and indicates the flow of a specific gas or gas mixture

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

3.7
gas-specific
having characteristics which prevent connection between different gas services

3.8
nipple
that portion of a connector which is pushed into and secured within the bore (lumen) of a hose

3.9
nominal inlet pressure
P_1
upstream pressure specified by the manufacturer for which the pressure regulator is intended to be used

NOTE P_1 is related to the cylinder filling pressure at 15 °C.

3.10
nominal outlet pressure
P_2
Nominal downstream pressure

NOTE P_2 is specified by the manufacturer in the instructions for use.

3.11
pre-set pressure regulator
pressure regulator which is not provided with a means of operator adjustment of the outlet pressure

3.12
pressure gauge
device which measures and indicates pressure

3.13
pressure outlet
outlet intended to deliver gas at a controlled pressure

3.14
pressure regulator
device which reduces the inlet pressure and maintains the set outlet pressure within specified limits

3.15
pressure-relief valve
device intended to relieve excess pressure at a pre-set value

3.16
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

NOTE This definition is taken from IEC 60601-1.

4 Symbols

The symbols used are given in Table 1.