SLOVENSKI STANDARD
SIST EN 738-1:2000

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Tlaļ ni regulatorji za medicinske pline - 1. del: Tlaļ ni regulatorji in tlaļ ni regulatorji s pretoļ nimi merilniki

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

Druckminderer zur Verwendung mit medizinischen Gasen - Teil 1: Druckminderer und Druckminderer mit Durchflußgeräten

Détendeurs pour l'utilisation avec les gaz médicaux - Partie 1: Détendeurs et détendeurs -débitmetres

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23.060.40	Tlaļ ni regulatorji	Pressure regulators

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Descriptors: gas distribution, gas cylinders, medical gases, flowmeters, pressure regulators, design, specification, mechanical strength, pressure resistance, flammability testing, tests, marking

English version

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

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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.

The European Standards exist 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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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart,36 B-1050 Brussels

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Annexes

Foreword

This European Standard has been prepared by CEN Technical Committee 215 'Respiratory and anaesthetic equipment' the secretariat of which is held by BSI.

EN 738 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 intended for incorporation into medical equipment.*

For special national conditions and transition periods for clauses 5.4.2.1.1, 5.4.2.1.2 c) and 7.2.1, see annex D.

This European Standard 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 Directives, see informative annex ZA, which is an integral part of this standard.

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 1997, and conflicting national standards shall be withdrawn at the latest by June 1998.

Annex D forms a normative part of this Part of this European Standard. Annexes A, B, C and ZA are given for information only.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

Pressure regulators are widely used on medical gas cylinders to reduce the high cylinder pressure to a lower pressure suitable for use with medical equipment or for delivery of gas directly to a patient. They may also be used to control pressure and flow supplied by a medical gas pipeline system.

These functions cover a wide range of inlet and outlet pressures and flows which require specific design characteristics for the appropriate regulator.

It is important that the operating characteristics of the pressure regulators are specified and tested in a defined manner.

Pressure regulators are normally coupled to devices which control the flow, such as a flow control valve or a fixed orifice; the flow may be indicated by a flowgauge or by a flowmeter.

It is essential that regular inspection and maintenance are undertaken to ensure that the pressure regulators continue to meet the requirements of this Part of this European Standard.

This Part of this European Standard pays particular attention to:

- suitability of materials.
- safety (mechanical strength, safe relief of excess pressure and resistance to ignition).
- gas-specificity.
- cleanliness.
- testing.
- identification.
- information supplied.

Clauses and subclauses marked with R after their number have corresponding rationales contained in annex C.

1 Scope

1.1 This Part of this European Standard applies to pressure regulators intended for the administration of medical gases in the treatment, management, diagnostic evaluation and care of patients and applies to the types of pressure regulator given in 1.1 a), b) and c) and to the types of flow metering devices given in 1.1 d) and e) for use with the following medical gases:

- oxygen
- nitrous oxide
- air for breathing
- helium
- carbon dioxide
- xenon
- specified mixtures of the gases listed above
- air for driving surgical tools
- nitrogen for driving surgical tools

a) High pressure regulators (up to 20 000 kPa) intended to be connected by the operator to high pressure gas cylinders;

b) High pressure regulators (up to 20 000 kPa) that are an integral part of, or are permanently connected to, medical equipment (e.g. anaesthetic workstations, lung ventilators, resuscitators);

c) Low pressure regulators (up to 1400 kPa) intended to be connected by the operator to the terminal units of medical gas pipeline systems;

d) Flow metering devices that are integral with the types of pressure regulator described in 1.1 a) and 1.1 c);

e) Flow metering devices that are not integral with the types of pressure regulator described in 1.1 a) and 1.1 c) but are not intended to be detached from the pressure regulator by the operator.

1.2 This standard does not apply to the following types of pressure regulator:

a) High pressure and low pressure regulators that are an integral part of medical gas pipeline systems (see prEN 738-2);

b) Pressure regulators integrated with cylinder valves (see prEN 738-3);

c) Low pressure regulators, with or without flow metering devices that are an integral part of medical equipment (see prEN 738-4);

d) Pressure regulators for use with suction services. (See EN ISO 10079-3)

2 Normative references

This Part of this European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

prEN 737-1:1992	Medical gas pipeline systems Part 1: Terminal units for compressed medical gases and vacuum
prEN 737-3	Medical gas pipeline systems Part 3: Pipelines for compressed medical gases and vacuum - Basic requirements
prEN 737-6	Medical gas pipeline systems Part 6: Dimensions of probes for terminal units for compressed medical gases and vacuum
prEN 739	Low-pressure flexible connecting assemblies (hose assemblies) for use with medical gas supply systems
EN 837-1	Pressure gauges Part 1: Bourdon tube pressure gauges - Dimensions, metrology, requirements and testing
EN 850	Transportable gas cylinders - Pin-index, yoke-type valve outlet connections for medical use
prEN 1441	Medical devices - Risk analysis
ISO 32	Gas cylinders for medical use - Marking for identification of content
ISO 554	Standard atmospheres for conditioning and/or testing - Specifications
ISO 5145	Cylinder valve outlets for gases and gas mixtures - Selection and dimensioning

3 Definitions

For the purposes of this Part of this European Standard, the following definitions apply:

3.1 adjustable pressure regulator: Regulator which has been provided with a means of operator adjustment of the delivery pressure under intended use.

3.2 closure pressure, P_4: Stabilized outlet pressure, on cessation of the flow after one minute, from a regulator where the flow has been set to standard discharge.

3.3 flow characteristic: Variation of the outlet pressure in relation to the rate of flow from zero to maximum capacity flow of the regulator with the inlet pressure remaining constant.

3.4 flowgauge: Gauge which measures pressure differential using ambient pressure as the datum point but which is calibrated in units of flow.

NOTE: The flowgauge does not measure flow, but 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.

NOTE: It may incorporate a flow adjustment control.

3.6 gas-specific connection point: That part of the socket which is the receptor for a gas-specific probe.

3.7 high pressure: Pressure greater than 1400 kPa.

3.8 hose insert: That portion of a connector which is pushed into and secured within the bore (lumen) of the hose.

3.9 hysteresis: Lagging of the outlet pressure (effect) when the flow (cause) is varied so that at a constant inlet pressure the values of outlet pressure measured with increasing flow do not coincide with the values of outlet pressure measured with decreasing flow.

3.10 low pressure: Pressure of 1400 kPa or less.

3.11 maximum closure pressure, $P_{4\,max}$: Stabilized outlet pressure, on cessation of the flow after one minute, from a regulator where the flow has been set to maximum discharge.

3.12 maximum discharge, Q_{max}: Maximum flow which is delivered by the regulator at the rated outlet pressure P_2 at test inlet pressure P_3.

3.13 preset pressure regulator: Regulator which has not been provided with a means of operator adjustment of the delivery pressure under intended use.

3.14 pressure characteristic: Variation of the outlet pressure with inlet pressure under constant flow conditions.

3.15 pressure gauge: Gauge which measures and indicates a pressure.

3.16 pressure regulator: Device for regulation of a generally variable inlet pressure to as constant as possible an outlet pressure.

3.17 pressure regulator with fixed orifice(s): Preset regulator which incorporates one or more fixed orifices to control the flow.

3.18 pressure regulator with flowgauge: Regulator which incorporates a flowgauge and a fixed orifice downstream of the flowgauge.

3.19 pressure regulator with flowmeter: Regulator equipped with a flowmeter to measure and indicate flow.

3.20 rated inlet pressure, P_1: Rated maximum upstream pressure for which the pressure regulator is designed.

3.21 rated outlet pressure, P_2: Rated downstream pressure for the standard discharge Q_1 specified in the instructions for use.

3.22 relief valve: Device designed to relieve excess pressure from the low pressure side at a preset value.

3.23 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.

3.24 single stage pressure regulator: Regulator that reduces the inlet pressure in a single stage to the required pressure.

3.25 standard discharge, Q_1: Flow, specified in the instructions for use for which the regulator is designed to maintain a rated outlet pressure P_2 at test inlet pressure P_3.

3.26 test inlet pressure, P_3: Minimum inlet pressure at which the standard discharge of the regulator Q_1 is measured and which is equivalent to twice the rated outlet pressure P_2 plus 100 kPa (i.e. $P_3 = (2\ P_2 + 100)$ kPa).

3.27 test outlet pressure, P_5: Highest or lowest value of the outlet pressure resulting from a variation in the inlet pressure between P_1 and P_3 at previously adjusted conditions P_1, P_2, Q_1.

3.28 two stage pressure regulator: Regulator that reduces the inlet pressure in two stages to the required pressure.

4 Symbols and Terminology

The symbols used for the physical characteristics are given in table 1.

A diagram of typical pressure regulators with examples of terminology is given in figure A.1, and typical applications of regulators are given in table A.1.

Table 1: Symbols and designations

P_1	rated inlet pressure
P_2	rated outlet pressure
P_3	test inlet pressure $(2P_2 + 100)$ kPa
P_4	closure pressure
$P_{4\ max}$	maximum closure pressure
P_5	test outlet pressure
Q_1	standard discharge
Q_{max}	maximum discharge
Q_{RV}	discharge of the relief valve
R	coefficient of pressure increase upon closure $R = \frac{P_4 - P_2}{P_2}$
i	irregularity coefficient $i = \frac{P_5 - P_2}{P_2}$

5 General requirements

5.1 Safety

Pressure regulators shall, when transported, stored, installed, operated in intended use and maintained according to the instructions of the manufacturer, cause no safety hazard which could be foreseen using risk analysis procedures in accordance with prEN 1441 and which is connected with its intended application, in normal condition and in single fault condition.

5.2 R Alternative construction

Pressure regulators and components or parts thereof, using materials or having forms of construction different from those detailed in clause 5 of this Part of this European Standard shall be accepted if it can be demonstrated that an equivalent degree of safety is obtained.

Such evidence shall be provided by the manufacturer.

See annex D for special national conditions.

5.3 Materials

5.3.1 The materials in contact with the gas shall be compatible with oxygen, the other medical gases and their mixtures in the temperature range specified in 5.3.2.

NOTE 1: Corrosion resistance includes resistance against moisture and surrounding materials.

NOTE 2: Compatibility with oxygen involves both combustibility and ease of ignition. Materials which burn in air will burn violently in pure oxygen. Many materials which do not burn in air will do so in pure oxygen, particularly under pressure. Similarly, materials which can be ignited in air require lower ignition energies for ignition in oxygen. Many such materials may be ignited by friction at a valve seat or by adiabatic compression produced when oxygen at high pressure is rapidly introduced into a system initially at low pressure.

NOTE 3: A Standard "*Compatibility of medical equipment with oxygen*" is in preparation by ISO/TC 121/SC6.

5.3.2 The materials shall permit the pressure regulator and its components to meet the requirements of 5.4 in the temperature range of -20 °C to +60 °C.

5.3.3 Pressure regulators shall be capable, while packed for transport and storage, of being exposed to environmental conditions as stated by the manufacturer.

5.3.4 Springs, highly strained components and parts liable to wear, which come in contact with the medical gas, shall not be plated.

NOTE: Plating could come off.

5.3.5 R Evidence of conformity with the requirements of clauses 5.3.1, 5.3.2, 5.3.3 and 5.3.4 shall be provided by the manufacturer.

5.4 Design requirements

5.4.1 ***Requirements for pressure gauges and flowgauges***

5.4.1.1 If Bourdon tube pressure gauges and flowgauges are used, they shall conform to EN 837-1 (except for the minimum nominal size) and meet the requirements specified in 5.4.1.2 to 5.4.1.5.