SLOVENSKI STANDARD
SIST EN 738-2:2000

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Tlaļ ni regulatorji za medicinske pline - 2. del: Tlaļ ni regulatorji v razdelilnikih in ceveh

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

Druckminderer zur Verwendung mit medizinischen Gasen - Teil 2: Hauptstellendruckregler und Leitungsdruckminderer

Détendeurs pour l'utilisation avec les gaz médicaux - Partie 2: Détendeurs de rampes et de canalisations

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ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
23.060.40	Tlaļ ni regulatorji	Pressure regulators

SIST EN 738-2:2000 **en**

EUROPEAN STANDARD
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Descriptors: gas distribution, gas cylinders, medical gases, pressure regulators, specifications, safety requirements, design, performance evaluation, tests, marking, packing

English version

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

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This European Standard was approved by CEN on 2 October 1998.

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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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

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Foreword

This European Standard has been prepared 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of an identical text or by endorsement, at the latest by April 1999, and conflicting national standards shall be withdrawn at the latest by April 1999.

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 Directive(s), see informative Annex ZA, which is an integral part of this standard.

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 see annex A.

Annex A forms a normative part of this European Standard. Annexes B, C, D 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

Manifold pressure regulators are used to reduce the high cylinder pressure to a lower pressure suitable for the supply of medical gas pipeline systems.

Line pressure regulators are used to reduce the pressure supplied by manifold pressure regulators or by cryogenic vessels (complete with control and monitoring equipment) to the lower pressure available at the terminal units of medical gas pipeline systems which is 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 manifold and line pressure regulators are specified and tested in a defined manner.

This European Standard specifies the provision of information for:

- installation and testing;
- inspection, maintenance and the frequency of such activities.

Testing after installation is critical to patient safety and it is essential that manifold and line pressure regulators are not used until full testing in accordance with EN 737-3 has been completed.

This European Standard pays particular attention to:

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

Clauses and sub clauses marked with **R** after their numbers have corresponding rationales contained in annex D.

1. Scope

1.1 This European Standard applies to manifold pressure regulators and line pressure regulators intended for the supply of pipeline systems for the following medical gases:

- oxygen;
- nitrous oxide;
- air for breathing;
- carbon dioxide;
- oxygen/nitrous oxide mixture (50/50% (v/v));
- air for driving surgical tools;
- nitrogen for driving surgical tools.

1.2 This European Standard does not apply to pressure regulators for use with suction services (see EN ISO 10079-3).

2. Normative references

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 publication 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.

EN 737-3	Medical gas pipeline systems - Part 3: Pipelines for compressed medical gases and vacuum.
EN 837-1	Pressure gauges - Part 1: Bourdon tube pressure gauges - Dimensions, metrology, requirements and testing
EN 1441	Medical devices - Risk analysis
ISO 32	Gas cylinders for medical use - Marking for identification of content

3 Definitions

For the purposes 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 normal use.

3.2 closure pressure, P_4: Stabilized outlet pressure, one minute after cessation of the flow, 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 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.

3.5 line pressure regulator: Pressure regulator with a maximum inlet pressure of 3 000 kPa intended to be fitted within a medical gas pipeline system.

3.6 manifold pressure regulator: Pressure regulator with a maximum inlet pressure of 20 000 kPa intended to be installed within sources of supply containing cylinders.

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

3.8 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.

3.9 medical gas pipeline system: Central supply system with control equipment, a pipeline distribution system and terminal units at the points where medical gases or vacuum are required.

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

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

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

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

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

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

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

3.17 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.

3.18 source of supply: Supply system with associated control equipment which supplies the pipeline.

3.19 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.

3.20 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).

3.21 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.

4. Symbols and terminology

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

A diagram of a typical manifold pressure regulator with examples of terminology is given in figure B.1.

A diagram of a typical line pressure regulator with examples of terminology is given in figure B.2.

Table 1: Notations, 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 $\frac{P_4 - P_2}{P_2}$
i	irregularity coefficient $\frac{P_5 - P_2}{P_2}$

5. General requirements

5.1 Safety

Manifold and line pressure regulators shall, when stored, installed, operated in normal 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 EN 1441 and which is connected with their intended application, in normal condition and in single fault condition.

5.2 R Alternative construction

Manifold and line pressure regulators and components or parts thereof, using materials or having forms of construction different from those detailed in clause 5 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 A 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 can 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 prEN 13159 "*Compatibility of medical equipment with oxygen*" is in preparation by CEN/TC 215/WG3.

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

5.3.3 Manifold and line 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 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

5.4.1.1 If Bourdon tube pressure gauges are used, they shall conform to EN 837-1 and meet the requirements specified in 5.4.1.2 to 5.4.1.4.

5.4.1.2 The indicated value of pressure gauges (if fitted) shall be legible to an operator having visual acuity of 1 (corrected if necessary) seated or standing 1 m from gauges with an illuminance of 215 lux.

5.4.1.3 The scale of inlet pressure gauges (if fitted) shall extend to a pressure at least 33 % greater than the rated inlet pressure.

5.4.1.4 The inlet and outlet pressure gauges (if fitted) shall be class 2.5 or better according to EN 837-1.

NOTE: The maximum permissible error for accuracy class 2.5 is ± 2.5 % of the maximum scale value.

5.4.2 Pressure adjusting device

The pressure adjusting device shall be captive and shall be removable only by the use of a tool. The regulator shall be designed so that the regulator valve cannot be held in the open position as a consequence of the pressure regulator spring being compressed to its solid length and thereby allowing gas to pass from the inlet to the outlet side.

Compliance shall be tested by visual inspection.

5.4.3 R Filtration

Manifold and line pressure regulators shall be fitted on the inlet side with a filter with openings no greater than 100 mμ or equivalent mesh.

Evidence shall be provided by the manufacturer.

NOTE: The filter can be a separate item.

5.4.4 Mechanical strength

The inlet side of manifold and line pressure regulators shall be capable of withstanding 2,25 times its rated inlet pressure P_1 without rupturing. The outlet side of manifold and line pressure regulators shall be capable of withstanding 4 times its rated outlet pressure P_2 without rupturing.

The tests for mechanical strength are given in 6.2.7 and 6.3.3.

5.4.5 Requirements for manifold pressure regulators

5.4.5.1 R Inlet port

Cylinder valve connections shall not be used.

The choice of dimensions of the inlet port is at the manufacturer's discretion.

5.4.5.2 Outlet port

The choice of dimensions of the outlet port is at the manufacturer's discretion.

5.4.5.3 Leakage

The maximum internal leakage (through the regulator valve) shall not exceed 1 ml/min (0,1010 kPa l/min) at inlet pressure P_1 and P_3.

The maximum external leakage (to the atmosphere) shall not exceed 0,2 ml/min (0,0202 kPa l/min) at inlet pressure P_1 and outlet pressure P_4.

The test for leakage is given in 6.2.6.

5.4.5.4 Performance, functional and flow characteristics

5.4.5.4.1 The performance, functional and flow characteristics shall be in accordance with the values stated by the manufacturer. Q_{max} shall not exceed 2 x Q_1.

The tests for performance and function are given in 6.2.1 and the test for flow characteristic is given in 6.2.2.

5.4.5.4.2 Coefficient of pressure increase upon closure *R*.

The coefficient R shall be less than 0,3 after exposure of the pressure regulator to an inlet pressure of 1,5 P_1 and to an outlet pressure of 2 P_2 as described in 6.2.3.

The test for the coefficient R is given in 6.2.3.