SLOVENSKI STANDARD
SIST EN 738-4:2000

01-januar-2000

Tlaļ ni regulatorji za medicinske pline - 4. del: Nizkotlaļ ni regulatorji za vgradnjo v medicinske naprave

Pressure regulators for use with medical gases - Part 4: Low-pressure regulators intended for incorporation into medical equipment

Druckminderer zur Verwendung mit medizinischen Gasen - Teil 4: Niederdruckminderer zum Einsetzen in medizinische Geräte

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Détendeurs pour l'utilisation avec les gaz médicaux - Partie 4: Détendeurs basse pression conçus pour le matériel médical

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Ta slovenski standard je istoveten z: **EN 738-4:1998**

ICS:

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

SIST EN 738-4:2000 **en**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 738-4

October 1998

ICS 11.040.10; 23.060.40

Descriptors: medical equipment, utilization, medical gases, pressure regulators, safety, materials, design, performance evaluation, flow rate, mechanical strength, tests, marking, packing

English version

Pressure regulators for use with medical gases - Part 4: Low-pressure regulators intended for incorporation into medical equipment

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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.

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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of an identical text or by endorsement, at the latest by April 1999, and conflicting national standards shall be withdrawn at the latest by April 1999.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.

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Introduction

Pressure regulators are fitted within medical equipment to maintain a constant outlet pressure irrespective of variation of inlet pressure or flow.

To enable correct application of these devices it is important that the operating characteristics are specified and tested in a defined manner.

As pressure regulators of this type are often derived from products designed for industrial applications, this European standard pays particular attention to:

- suitability of materials;
- safety (mechanical strength and resistance to ignition);
- cleanliness;
- testing;
- identification;
- information supplied.

It is also essential that regular inspection and maintenance procedures are recommended.

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

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1 Scope

1.1 This European Standard applies to low-pressure regulators suitable for inlet pressures between 280 kPa and 600 kPa, supplied and packaged as for use in medical equipment intended for the administration of medical gases in the treatment, management, diagnostic evaluation and care of patients for use with the following medical gases:

- oxygen;
- nitrous oxide;
- air for breathing;
- helium;
- carbon dioxide;
- xenon;
- specified mixtures of the gases listed above.

1.2 This European Standard does not apply to pressure regulators supplied as spare parts for a specific application.

1.3 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 publications are listed hereafter. For dated references, subsequent amendments to or revision 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.

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EN 737-1 Medical gas pipeline systems - Part 1: Terminal units for compressed medical gases and vacuum

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prEN 737-6 Medical gas pipeline systems - Part 6: Dimensions of probes for terminal units for compressed medical gases and vacuum

EN 739 Low-pressure hose assemblies for use with medical gases

EN 1441 Medical devices - Risk analysis

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 bleed flow: Intended small flow of gas to the atmosphere for the purpose of the correct operation of the regulator.

3.3 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.

3.4 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.

3.5 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.

3.6 low pressure: Pressure of 1 400 kPa or less.

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

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

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

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

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

3.14 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.

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

3.16 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.

3.17 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.

3.18 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 B.1.

Table 1: Notations, symbols and designations

P_1	rated inlet pressure
P_2	rated outlet pressure
P_3	test inlet pressure (2 P_2 + 100) kPa
P_4	closure pressure
$P_{4\ max}$	maximum closure pressure
Q_1	standard discharge
Q_{max}	maximum discharge

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5 General requirements

5.1 Safety

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Pressure regulators shall, when stored, installed, operated in normal use and maintained according to the recommendations 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 applications, 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 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.

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 pressure regulator and its components to meet the requirements of 5.4 in the temperature range of 0 °C to +40 °C.

If the pressure regulator is suitable for use outside this temperature range, the range shall be specified by the manufacturer.

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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.

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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 *Inlet pressure*

5.4.1.1 R Pressure regulators shall operate and meet the requirements of this European standard when supplied with an inlet pressure ranging from 280 kPa to 600 kPa.

5.4.1.2 R Pressure regulators shall meet the requirements of 5.4.1.1 following exposure to an inlet pressure of 1 000 kPa for 10 min.

5.4.2 *Inlet connection*

See annex A for special national conditions.

If the inlet connection of the pressure regulator is intended to be used as the inlet connection to the equipment, it shall be either a probe complying with prEN 737-6 or a NIST body complying with EN 739. Cylinder valve connections shall not be used.

5.4.3 *Outlet connection*

See annex A for special national conditions.

If a gas-specific outlet connection of the pressure regulator is intended to be used as the outlet connection of the equipment, it shall be either a socket complying with EN 737-1 or a NIST body complying with EN 739.

In this case it shall not be possible for the operator to set the outlet pressure below 280 kPa.

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5.4.4 *Pressure adjusting device*

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.

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Compliance shall be tested by visual inspection.

5.4.5 ***Performance, functional and flow characteristics***

The performance, functional and flow characteristics shall be in accordance with the values stated by the manufacturer.

The tests are given in 6.2.

5.4.6 ***Over-pressure relief***

If a means for over-pressure relief is provided, its characteristics shall be specified by the manufacturer.

The test is given in 6.3.

5.4.7 ***Leakage***

The maximum external leakage (to the atmosphere) and internal leakage (through the regulator valve) shall not exceed the values specified by the manufacturer.

The test for leakage is given in 6.4.

5.4.8 ***Bleed flow***

The bleed flow shall not exceed the value specified by the manufacturer.

The test for bleed flow is given in 6.5.

5.4.9 ***Mechanical strength***

The inlet and outlet sides of the pressure regulator shall be capable of withstanding 1 400 kPa without rupturing.

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The test for mechanical strength is given in 6.6.

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5.4.10 R ***Resistance to ignition***

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For pressure regulators for all gases the autoignition temperature of the non-metallic components in contact with the gas, including the sealing materials and lubricants (if used) shall not be lower than 160 °C.

Evidence of conformity with this requirement shall be provided by the manufacturer.

The test for the determination of the autoignition temperature is given in 6.7.