SLOVENSKI STANDARD
SIST EN 738-3:2000

01-januar-2000

Tlaļ ni regulatorji za medicinske pline - 3. del: Tlaļ ni regulatorji v sklopu ventilov jeklenk

Pressure regulators for use with medical gases - Part 3: Pressure regulators integrated with cylinder valves

Druckminderer zur Verwendung mit medizinischen Gasen - Teil 3: Druckminderer in Flaschenventilen

Détendeurs pour l'utilisation avec les gaz médicaux - Partie 3: Détendeurs intégrés dans les robinets de bouteilles

Ta slovenski standard je istoveten z: **EN 738-3:1998**

ICS:

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

SIST EN 738-3:2000 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 738-3

October 1998

ICS 11.040.10; 23.060.40

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

English version

Pressure regulators for use with medical gases - Part 3: Pressure regulators integrated with cylinder valves

Détendeurs pour l'utilisation avec les gaz médicaux - Partie 3: Détendeurs intégrés dans les robinets de bouteilles

Druckminderer zur Verwendung mit medizinischen Gasen - Teil 3: Druckminderer in Flaschenventilen

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

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, 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

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

Contents **Page**

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

Pressure regulators integrated within cylinder valves are used 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.

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.

Pressure regulators are normally coupled to devices which control 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 the pressure regulators continue to meet the requirements of this European standard.

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 numbers have corresponding rationales contained in annex D

1 Scope

This European Standard applies to pressure regulators integrated with cylinder valves 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;
- air for driving surgical tools;
- nitrogen for driving surgical tools.

The pressure regulators are intended to be fitted to high pressure cylinders with filling pressure up to 20 000 kPa, and can be provided with devices which control and measure the flow of the medical gas delivered to the patient.

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.

EN 629-1	Transportable gas cylinders - 25 E taper thread for connection of valves to gas cylinders - Part 1: Specification.
prEN ISO 11116	Gas cylinders - 17 E taper thread for connection of valves to gas cylinders - Part 1: Specifications (ISO/DIS 11116:1996)
EN 737-1:1998	Medical gas pipeline systems - Part 1 : Terminal units for compressed medical gases and vacuum.
EN 739	Low-pressure hose assemblies for use with medical gases .
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
EN 1441	Medical devices - Risk analysis.
EN ISO 13341:1997	Transportable gas cylinders - Fitting of valves to gas cylinders (ISO 13341:1997)
ISO 32	Gas cylinders for medical use - Marking for identification of content.
ISO 5145	Cylinder valve outlets for gases and mixtures - Selection and dimensioning.

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 filling port: Point on the pressure regulator through which the cylinder is filled.

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

NOTE: The flowgauge indicates flow by measuring the pressure upstream of a fixed orifice.

3.6 flowmeter: Device which measures and indicates the flow of a specific gas.

NOTE: It can incorporate a flow adjustment control.

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

3.8 high pressure: Pressure greater than 1 400 kPa.

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

3.10 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.

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

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

3.13 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.

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

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

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

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

3.18 pressure regulator integrated with a cylinder valve: Regulator intended to be permanently fitted to the conical connection of a medical gas cylinder.

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

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

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

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

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

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

3.25 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.

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

3.27 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.

3.28 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.

3.29 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.

3.30 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.

Diagrams of typical pressure regulators integrated with cylinder valves with examples of terminology are given in annex B.

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
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

Pressure regulators shall, when transported, 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

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 gases 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 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 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.

5.4.1.2 The connection shall be a thread complying with EN 837-1 or a proprietary connection.

5.4.1.3 The indicated value of pressure gauges and flowgauges 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.

5.4.1.4 The scale of the high pressure gauges shall extend to a pressure at least 33% greater than either the "full" indication position or the filling pressure of the cylinder at a temperature of (23 ± 2) °C.

The high pressure gauges, low pressure gauges and flowgauges 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 R ***Filling port***

A filling port shall be provided. The filling port shall comply with EN 850, ISO 5145, the relevant National Standard (see ISO/TR 7470 for information) or be a proprietary connection. If the filling port is not provided with a check valve, it shall be provided with a pressure-tight device which can be removed only by the use of a proprietary tool.

The check valve, if fitted, shall comply with the requirements of 5.4.12.1 after 1 000 opening and closing cycles. The test is given in 6.14.

Means shall be provided to prevent the filling port being used for any other purpose. Evidence shall be provided by the manufacturer.

NOTE: In order to prevent particulate contamination the filling port should be protected.

5.4.3 ***Connectors***

5.4.3.1 R *Cylinder connection*

If conical connectors to the cylinder are used, they shall be either 25E in accordance with EN 629-1 or 17E in accordance with prEN ISO 11116. If other connectors are used, evidence shall be provided by the manufacturer that an equivalent mechanical strength is achieved.

5.4.3.2 *Outlet connector*

5.4.3.2.1 R Except for pressure regulators permanently connected to equipment, each outlet shall be fitted with an outlet connector, which shall be one of the following :

a) a proprietary fitting with or without a hose insert to supply all medical gases except air for driving surgical tools and nitrogen for driving surgical tools;

b) a terminal unit or a gas-specific connection point in accordance with EN 737-1:1998 (except for 5.4.6 and 5.4.7) to supply 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.

NOTE: The connection of the terminal unit or the gas-specific connection point to the pressure regulator body need not be gas-specific.

c) a NIST body in accordance with EN 739 to supply the following medical gases:

- helium;
- xenon;
- mixtures of oxygen and nitrous oxide (except 50/50 % (V/V)
- mixtures of oxygen and helium;
- mixtures of oxygen and carbon dioxide.

See annex A for special national conditions.

5.4.3.2.2 When the pressure regulator is fitted with a proprietary fitting as outlet connector, as specified in 5.4.3.2.1 a), a flowmeter, or a flowgauge, or a fixed orifice(s) shall be provided.

5.4.4 R ***Rated outlet pressure***

The rated outlet pressure shall be one of the following:

a) below 280 kPa for pressure regulators with outlet connectors complying with clause 5.4.3.2.1 a);

b) in the range of 305 kPa to 500 kPa for pressure regulators with outlet connectors complying with 5.4.3.2.1b) and c).

c) in the range of 305 kPa to 500 kPa for pressure regulators with two different outlet connectors complying with 5.4.3.2.1a) and b) or 5.4.3.2.1a) and c).

Means shall be provided to prevent the use of the proprietary fitting described in 5.4.3.2.1a) to supply medical equipment.

Evidence shall be provided by the manufacturer.

5.4.5 *High pressure indicators*

The regulator shall be fitted with a high pressure gauge or with an equivalent means to indicate the cylinder gas content.

5.4.6 *Flow control valve*

If a flow control valve is fitted, the flow control knob and the valve spindle shall be captive such that they cannot be disengaged without the use of a tool.

Compliance shall be tested by attempting to remove the knob and spindle without the use of a tool.

5.4.7 *Pressure adjusting device*

The pressure adjusting device, if fitted, 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 high pressure to the low pressure side.

Using the adjusting device it shall not be possible to set a pressure at which the relief valve lifts and pressures above the upper limit of the ranges specified in 5.4.4.

Compliance shall be tested by visual inspection.

5.4.8 R *Filtration*

The regulator valve shall be protected by a filter with openings no greater than 100 µm or equivalent mesh.

Evidence shall be provided by the manufacturer.

5.4.9 *Shut-off valve*

A shut-off valve shall be provided between the connection to the cylinder and the regulator valve. The shut-off valve shall be a separate item from the regulator valve.