BRITISH STANDARD

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738-1:1997
Incorporating
Amendment No. 1

Pressure regulators for use with medical gases —

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

The European Standard EN 738-1:1997, with the incorporation of amendment A1:2002, has the status of a British Standard

ICS 11.040.10; 23.060.40

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/44, Anaesthetic machines, breathing attachments, medical gas pipeline systems and hose assemblies, upon which the following bodies were represented:

Association of Anaesthetists of Great Britain and Ireland

Association of British Health-care Industries

British Anaesthetic and Respiratory Equipment Manufacturers' Association

Department of Health

The following bodies were also represented in the drafting of the standard, through a subcommittee:

Institute of Health-care Engineering and Estate Management

Safety Equipment Association

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on 15 July 1997

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Contents

National foreword

This British Standard has been prepared by Technical Committee CH/44 and is the English language version of EN 738-1:1997, including amendment A1:2002, *Pressure regulators for use with medical gases — Pressure regulators and pressure regulators with flow metering devices*, published by the European Committee for Standardization (CEN).

The start and finish of text introduced or altered by amendment is indicated in the text by tags [A1⟩ ⟨A1]. Tags indicating changes to CEN text carry the number of the amendment. For example, text altered by CEN amendment A1 is indicated by [A1⟩ ⟨A1].

The Technical Committee has reviewed the provisions of prEN 737-1:1992, prEN 737-3, prEN 737-6, prEN 739, EN 837-1, EN 850, prEN 1441, ISO 554 and ISO 5145, to which reference is made in the text and has decided that they are acceptable for use in conjunction with this British Standard.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the *BSI Catalogue* under the section entitled "International Standards Correspondence Index", or by using the "Search" facility of the *BSI Electronic Catalogue* or of British Standards Online.

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 33 and a back cover.

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EUROPEAN STANDARD
NORME EUROPÉENNE
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EN 738-1

February 1997

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ICS 11.040.10; 23.060.40

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

(including amendment A1:2002)

Détendeurs pour l'utilisation avec les gaz médicaux —
Partie 1: Détendeurs et détendeurs-débitmètres
(inclut l'amendement A1:2002)

Druckminderer zur Verwendung mit medizinischen Gasen —
Teil 1: Druckminderer und Druckminderer mit Durchflußmeßgeräten
(enthält Änderung A1:2002)

This European Standard was approved by CEN on 1997-01-05. Amendment A1 was approved by CEN on 2002-03-04. 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.

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CEN

European Committee for Standardization
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Europäisches Komitee für Normung

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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. Annex A, Annex B, Annex C and Annex 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.

Foreword to amendment A1

This document EN 738-1:1997/A1:2002 has been prepared by Technical Committee CEN/TC 215, Respiratory and anaesthetic equipment, the Secretariat of which is held by BSI. It has been prepared so as to accommodate the use of nitric oxide admixed with nitrogen as a medical gas.

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 October 2002, and conflicting national standards shall be withdrawn at the latest by October 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).

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, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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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;

[A1⟩ — NO/N_2 mixtures ($NO \leq 1\,000$ µl/l); ⟨A1]

— 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 1 400 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.*

⟩A1⟨ EN 1089-3, *Transportable gas cylinders — Cylinder identification — Part 3: Colour coding.* ⟩A1⟨

prEN 1441, *Medical devices — Risk analysis.*

ISO 32, *Gas cylinders for medical use — Marking for identification of content.*

⟩A1⟨ *Reference deleted.* ⟩A1⟨

⟩A1⟨ ISO/DIS 407:2001, *Small medical gas cylinders — Pin-index yoke-type valve connections.* ⟩A1⟨

⟩A1⟨ ISO/DIS 5145:2001, *Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning.* ⟩A1⟨

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 1 400 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 1 400 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

〚A1〛 **3.29**
accuracy of flow
difference in percent between the indicated value and the true value of the flow 〈A1〉

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 (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 $R = \frac{P_4 - P_2}{P_2}$
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.

[A1] NOTE 4 Guidance for the selection of metallic and non-metallic materials for use with NO/N_2 mixtures ($NO \leq 1\,000$ µl/l) is given in CEN Report CR 13903. [A1]

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**, **5.4.1.3**, **5.4.1.4** and **5.4.1.5**.

5.4.1.2 The thread shall be G 1/8 B, G1/4 B, 1/8-27 NPT EXT or 1/4-18 NPT EXT, in accordance with EN 837-1.

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 lx.

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.

5.4.1.5 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 ***Requirements for pressure regulators, pressure regulators with flowmeters, pressure regulators with flowgauges, pressure regulators with fixed orifices***

5.4.2.1 *Connectors.*

5.4.2.1.1 *Inlet connector.*

See Annex D for special national conditions.

There shall be an inlet connector. For connection to cylinders the inlet connector shall conform to EN 850, ISO 5145 or the relevant national standard (see ISO/TR 7470 for information).

For connection to terminal units the inlet connector shall conform to prEN 737-1 and prEN 737-6.

〖A1〉 For connection to cylinders of NO/N_2 mixtures ($NO \leq 1\,000$ µl/l) the inlet connector shall conform to ISO/DIS 407:2001 (Figure E-F) or to ISO/DIS 5145:2001 (30-RH/15,2-20,8). 〈A1〗

5.4.2.1.2 *Outlet connector*

There shall be an outlet connector. Except for pressure regulators described in **1.1**b), the outlet connector 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 prEN 737-1:1992 (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 Non Interchangeable Screw Threaded (NIST) body in accordance with prEN 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 D for special national conditions.

⟨A1⟩ For pressure regulators for NO/N_2 mixtures ($NO \leq 1\,000$ µl/l) the outlet connector shall be one of the following:

d) a proprietary fitting permanently connected to the delivery system. If a hose is used, the hose and the method of attachment to the proprietary fitting shall comply with EN 739;

e) a quick connector.

NOTE An example of outlet connector suitable for use with NO/N_2 mixtures ($NO \leq 1\,000$ µl/l) is the body of the quick-connector "Swagelok – QC4 DESO – Stainless steel 316".[1)] ⟨A1⟩

5.4.2.2 R *Rated outlet pressure*

The rated outlet pressure shall be one of the following:

— below 280 kPa for pressure regulators with outlet connectors complying with clause **5.4.2.1.2**a);
— in accordance with the nominal operating pressures specified in prEN 737-3 for pressure regulators with outlet connectors complying with clause **5.4.2.1.2**b);
— in the range 280 kPa to 500 kPa for pressure regulators with outlet connectors complying with clause **5.4.2.1.2**c).

⟨A1⟩ For pressure regulators for NO/N_2 mixtures ($NO \leq 1\,000$ µl/l) the rated outlet pressure shall be 400 kPa. ⟨A1⟩

5.4.2.3 *High pressure gauges*

High pressure regulators shall be fitted with a high pressure gauge.

5.4.2.4 *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.

1) ⟨A1⟩ This information is given for the convenience of users of this standard and does not constitute an endorsement by CEN of the product named. ⟨A1⟩

5.4.2.5 *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.

Compliance shall be tested by visual inspection.

[A1] For pressure regulators for NO/N_2 mixtures ($NO \leq 1\,000$ µl/l) it shall not be possible to set a pressure greater than the rated outlet pressure. [A1]

5.4.2.6 R *Filtration*

High pressure regulators shall incorporate on the inlet side a filter with openings no greater than 100 µm or equivalent mesh.

Evidence shall be provided by the manufacturer.

NOTE Filters should be sited as close as possible to the gas inlet of the pressure regulator.

5.4.2.7 *Performance, functional and flow characteristics*

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

The tests for performance and function are given in **6.2.2** and the test for flow characteristics is given in **6.2.3**.

[A1] Q_{max} shall not exceed $2 \times Q_1$. [A1]

5.4.2.7.2 *Coefficient of pressure increase upon closure R*

The coefficient R shall be less than 0,2 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 **6.2.4**.

[A1] This clause does not apply to pressure regulators with flowmeters, pressure regulators with flowgauges and pressure regulators with fixed orifices. [A1]

5.4.2.7.3 *Irregularity coefficient i*

The coefficient i shall fall within the limits ±0,2 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 **6.2.5**.

[A1] This clause does not apply to pressure regulators with flowmeters, pressure regulators with flowgauges and pressure regulators with fixed orifices. [A1]

5.4.2.8 *Relief valve*

A relief valve shall be provided as a component part of high pressure regulators. Bursting disks shall not be used. The setting of the relief valve shall be either:

a) non-adjustable by the operator; or

b) non-adjustable without the use of a special tool.

The relief valve shall lift automatically to relieve excess pressure and shall reset at a pressure equal to or above the rated outlet pressure P_2 or the set pressure.

The leakage from the relief valve shall comply with the requirement of clause **5.4.2.9** up to a pressure of 1,4 P_2, or 1,4 times set pressure.

The minimum discharge of the relief valve Q_{RV} shall be equal to or greater than the standard discharge Q_1 at a pressure $P_{RV} = 2\ P_2$ [A1] or two times the set pressure specified by the manufacturer. [A1]

The test for the relief valve is given in **6.3**.

NOTE The relief valve should be fitted in such a way that gas will be discharged safely.

[A1] For pressure regulators with outlet connectors complying with **5.4.2.1.2** b) and c), the outlet pressure in single fault condition of the pressure regulator shall not exceed 2 000 kPa for air for driving surgical tools or nitrogen for driving surgical tools or 1 000 kPa for all other uses. [A1]

5.4.2.9 *Leakage*

The maximum external leakage (to the atmosphere) and internal leakage (through the regulator valve) shall not exceed 0,2 ml/min (0,0202 kPa l/min) each.

The test for leakage is given in **6.4**.

[A1] For pressure regulators for NO/N_2 mixtures ($NO \leq 1\,000$ µl/l) the external leakage (to atmosphere) and internal leakage (through the regulator valve) shall not exceed 0,1 ml/min (0,010 1 kPa·l/min) each. [A1]

5.4.2.10 *Mechanical strength*

The inlet side of the regulator shall be capable of withstanding 2,25 times its rated inlet pressure P_1 without rupturing.

The outlet side of the regulator shall be capable of withstanding 4 times its rated outlet pressure P_2 without rupturing.

The test for mechanical strength is given in **6.5**.

5.4.2.11 *Resistance to ignition*

5.4.2.11.1 R *High pressure regulators*

High pressure regulators for all gases shall not ignite or show internal scorching damage when submitted to oxygen pressure shocks.

The test for ignition is given in **6.6.1** and **6.6.2**.

5.4.2.11.2 R *Low pressure regulators*

For low pressure regulators for all gases, the ignition temperature of the non-metallic components in contact with the gas at the inlet side of the regulator, including the sealing materials and lubricants (if used) shall not be lower than 200 °C. For low pressure regulators for all gases the ignition temperature of the non-metallic components in contact with the gas at the outlet side of the regulator, 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 ignition temperature is given in **6.6.3**.

NOTE The permitted operating temperatures of tested material are 140 °C and 100 °C respectively lower than the ignition temperature at the corresponding oxygen pressure. This safety margin is necessary because it covers both an unforeseen increase of the operating temperature and the fact that the ignition temperature is not a constant. In this connection, it should be emphasized that values of the ignition temperature always depend on the test method used, which does not exactly simulate all possible operating conditions.

5.4.3 ***Requirements for pressure regulators with flowmeters***

5.4.3.1 *Scale and indicators of flowmeters*

Flowmeters shall be graduated in units of litres per minute (l/min) or millilitres per minute (ml/min) for flows equal to or less than 1 l/min.

Compliance is checked by visual inspection.

5.4.3.2 *Accuracy of flow*

The accuracy of the flow at any flow graduation of a flowmeter shall be within ±10 % of the indicated value for flows between 10 % and 100 % of full scale or ±0,5 l/min, whichever is greater when discharged into ambient atmosphere at reference conditions (see **6.1.3**).

The accuracy of the flow at any flow graduation of a flowmeter with a maximum flow of 1 l/min shall be within ±10 % of full scale.

The test for accuracy of flow is given in clause **6.8**.

NOTE To enhance accuracy and to reduce the hazard of static discharge, means should be provided to minimize the build up of electrostatic charges both inside and outside the flowmeter tube and its housing.

5.4.3.3 *Legibility*

The indicated value of the flowmeter shall be legible to an operator having visual acuity, (corrected if necessary) of 1, seated or standing 1 m from the flowmeter with an illuminance of 215 lx.

5.4.3.4 *Flowmeter performance*

The flowmeter shall meet the requirements of clause **5.4.3.2** after exposure to an inlet pressure of 2 P_2.

5.4.3.5 *Mechanical strength*

The flowmeter shall be capable of withstanding without rupture a pressure of 4 P_2 for 5 min.

The test for the mechanical strength of the flowmeters is given in **6.7**.

[A1] **5.4.3.6** *Stability of flow*

The true flow, at the maximum flow specified by the manufacturer, shall not vary by more than ±20 % with the inlet pressure decreasing from P_1 to 10 % of P_1.

The test for stability of flow is given in **6.12**. [A1]

5.4.4 ***Requirements for pressure regulators with flowgauges***

5.4.4.1 *Calibration*

The flowgauge shall be calibrated for the identified fixed orifice.

5.4.4.2 *Accuracy of flow*

The accuracy of the flow at any flow graduation of a flowgauge shall be within ±10 % of the indicated value for flows between 10 % and 100 % of full scale or ± 0,5 l/min whichever is greater when discharged into ambient atmosphere at reference conditions (see **6.1.3**).

The accuracy of the flow at any flow graduation of a flowgauge with a maximum flow of 1 l/min shall be within ±10 % of full scale.

The test for accuracy of flow is given in [A1] **6.8**. [A1]

[A1] **5.4.4.3** *Stability of flow*

The true flow, at the maximum flow specified by the manufacturer, shall not vary by more than ±20 % with the inlet pressure decreasing from P_1 to 10 % of P_1.

The test for stability of flow is given in **6.12**. [A1]

5.4.5 ***Requirements for pressure regulators with fixed orifices***

5.4.5.1 *Low pressure setting*

The regulators shall be preset.

[A1] **5.4.5.2** *Stability and accuracy of flow*

The true flow shall be within ±20 % of each stated value or ±30 % of each stated value for flows of 1,5 l/min or less with the inlet pressure decreasing from P_1 to 10 % of P_1.

The test for stability and accuracy of flow is given in **6.9**. [A1]

5.4.5.3 *Flow setting torque*

[A1] If there are multiple orifices, the tangential force required at the maximum radius of the selecting device to change from the "off" position to another and from one setting to another shall be not less than 5 N and not more than 50 N. The control shall self-centre at each setting. [A1]

The test is given in **6.10**.

5.4.5.4 *Removable fixed orifice*

If a fixed orifice is intended to be removed, means shall be provided to prevent inadvertent removal.

5.5 Constructional requirements

5.5.1 R *Cleaning*

The components of pressure regulators for all gases shall be supplied clean and free from oil, grease and particulate matter.

Evidence shall be provided by the manufacturer.

NOTE 1 Any method of cleaning and degreasing can be used which effectively removes all surface dirt and hydrocarbons, and which leaves no residue itself. Chemical cleaning methods normally require a subsequent washing and drying process to remove residues.

NOTE 2 Examples of cleaning procedures will be described in a standard *"Compatibility of medical equipment with oxygen"* which is in preparation by ISO/TC 121/SC6.

5.5.2 R *Lubricants*

If lubricants are used, they shall be compatible with oxygen, the other medical gases and their mixtures in the temperature range specified in **5.3.2**.

Evidence shall be provided by the manufacturer.

5.5.3 *Loosening torques*

5.5.3.1 The torque required to remove the inlet connection from the regulator body shall be greater than or equal to 35 N·m.

5.5.3.2 The torque required to remove the outlet connection from the regulator body shall be greater than or equal to 20 N·m.

5.5.3.3 If a pressure regulator is fitted with a flow control valve, the torque required to remove the valve from the regulator body shall be greater than or equal to 20 N·m.

5.5.3.4 The torque required to remove the pressure gauges and the flowgauges from the regulator body or from the flow control valve body shall be greater than or equal to 20 N·m.

5.5.3.5 The torque required to remove the flowmeter from the regulator body shall be greater than or equal to 20 N·m.

5.5.3.6 The test for loosening torques is given in **6.10**.

6 Test methods

6.1 General

6.1.1 *Ambient conditions*

Except where otherwise stated, carry out tests at (23 ± 2) °C.

6.1.2 *Test gas*

Carry out tests [A1] *Text deleted* [A1] with clean, oil-free, dry air or nitrogen.

[A1] In all cases carry out tests with dry gas with a maximum moisture content of 50 µg/g (50 ppm). [A1]

When a pressure regulator is tested with a gas other than that for which it is intended, convert the flows.

NOTE Conversion coefficients are given in Table 2.

6.1.3 *Reference conditions*

Correct flows to 23 °C and 101,3 kPa.

6.2 Test methods for performance, functional and operating characteristics

6.2.1 *Test bench*

Construct the test bench in such a way that the inlet and outlet pressures can be regulated separately. The equipment can be operated by remote control. Ensure that the gas supply for rated inlet pressure P_1 and test inlet pressure P_3 has sufficient capacity for the test.

Ensure that all the pipelines of the test installation together with the valve controlling the flow have a flow capacity greater than that of the regulator to be tested.

6.2.2 *Test method for performance and function*

The equipment for this test is shown in Figure 1. The regulator can be supplied by a buffer cylinder. Hold the upstream pressure P_3 constant by means of an auxiliary regulator or any equivalent device. Carry out the test at the standard discharge Q_1 stated by the manufacturer.

With the flow control valve closed, apply an inlet pressure P_3. Set the outlet pressure to P_2. Gradually open the flow control valve until the standard discharge Q_1 is attained. If the outlet pressure has decreased, readjust it to the value P_2 on an adjustable regulator. This is not possible with a preset regulator.

6.2.3 *Test methods for flow characteristic*

The equipment for this test is shown in Figure 1. A flow characteristic curve shows the change of outlet pressure caused by variation of the flow from zero to full flow (limited by the outlet restriction) at a constant inlet pressure. Different curves are obtained at different starting pressures and different inlet pressures (see Figure 3 and Figure 4).

6.2.3.1 *Adjustable regulators*

Record a flow characteristic under the following initial conditions:

a) starting with a test inlet pressure P_3, outlet pressure P_2 and standard discharge Q_1, close the flow control valve and record the closure pressure P_4 after 60 s;

b) starting with the rated inlet pressure P_1, outlet pressure P_2 and standard discharge Q_1 , close the flow control valve and record the closure pressure P_4 after 60 s;

c) starting with a test inlet pressure P_3, outlet pressure P_2 and maximum discharge Q_{max} , close the flow control valve and record the maximum closure pressure $P_{4\,max}$ after 60 s.

In each case, at the end of the initial conditions given in a), b) and c) above, gradually open the flow control valve in steps and record the outlet pressure and flow at each step until the flow control valve is fully opened.

Plot the values of flow and pressure as in Figure 3.

NOTE Values of flow and pressure measured with increasing outlet pressure (which results from a decreasing flow) can produce a curve at higher pressures due to hysteresis.

Table 2 — Conversion coefficients

Test Gas[1)]	Air	Oxygen	Nitrogen	N_2O	CO_2	Helium	Xenon
Air	1	0,95	1,02	0,81	0,81	2,69	0,47
Nitrogen	0,98	0,93	1	0,79	0,79	2,65	0,46

[1)] Flow of intended gas = Flow of test gas × conversion coefficient.
〈A1〉 NOTE For NO/N_2 mixtures (NO ≤ 1 000 µl/l) the conversion coefficient for nitrogen can be used. 〈A1〉

6.2.3.2 *Preset regulators*

Record a flow characteristic using the procedure described in clause **6.2.3.1** under the following conditions:

a) starting at the closure pressure P_4 resulting from the test inlet pressure P_3 and the standard discharge Q_1;

b) starting at the closure pressure P_4 resulting from the rated inlet pressure P_1 and the standard discharge Q_1.

NOTE 1 The closure pressure obtained will depend on the pressure characteristic of the regulator (rising or falling).

Plot the values of flow and pressure as in Figure 4.

NOTE 2 Figure 4 shows a typical flow characteristic for a preset regulator with a rising pressure characteristic in which an increasing inlet pressure tends to hold the regulator valve closed.

6.2.4 *Test method for coefficient of pressure increase upon closure R*

6.2.4.1 For an adjustable regulator, ensure that the pressure adjusting device is in the position where the regulator valve is closed. For a preset regulator, plug the outlet.

Pressurize the high pressure chamber of the complete regulator to 1,5 times its rated inlet pressure P_1 for 5 min. Return the pressure to atmospheric pressure.

Replace the low pressure gauge and the relief valve, if fitted, by plugs. Pressurize the low pressure chamber of the complete regulator through the outlet port to twice its rated outlet pressure P_2 for 5 min. Return the pressure to atmospheric pressure.

6.2.4.2 Use the test equipment shown in Figure 1. Adjust the test regulator to the standard initial conditions, inlet pressure P_3, outlet pressure P_2 and standard discharge Q_1. Stop the discharge by closing the flow control valve. The indicator on the low pressure gauge will move to a higher value and stabilize. Note the closure pressure P_4 after 60 s and from it determine the value of coefficient R, using the expression:

$$R = \frac{P_4 - P_2}{P_2}$$

6.2.5 *Test method for irregularity coefficient i*

6.2.5.1 Proceed as described in **6.2.4.1**.

6.2.5.2 Use the test equipment shown in Figure 2. For the determination of the irregularity coefficient i and correct mechanical functioning, plot a curve (see Figure 5 and Figure 6). The curve indicates the variation of outlet pressure as a function of the inlet pressure.

Equip the test regulator with two calibrated gauges or recording equipment. Control the discharge of the test regulator by the flow control valve and measure it by a flowmeter. With the inlet pressure P_1, operate the pressure adjusting device (if fitted) on the test regulator and the flow control valve to obtain the standard discharge Q_1 at the outlet pressure P_2, taking into account the corrections given in Table 2.

Record the value of the inlet and outlet pressures whilst the inlet pressure is varied through the range P_1 to P_3. Ensure that sufficient gas is available in the gas supply to complete the test in one session.

NOTE During this test there should be a smooth regular curve, either rising to a maximum (see Figure 5) or falling (see Figure 6).

The pressure P_5 for the irregularity coefficient i is the highest or lowest value of the outlet pressure during the test in which the inlet pressure varies from P_1 to P_3. Determine the value of coefficient i using the expression:

$$i = \frac{P_5 - P_2}{P_2}$$

6.3 Test method for relief valve

[A1] Apply, through the outlet connection of all types of preset pressure regulators, an increasing pressure up to a pressure 1,4 P_2 or, for all types of adjustable pressure regulators, an increasing pressure up to a pressure 1,4 times the set pressure specified by the manufacturer. At this pressure the leakage from the relief valve shall comply with the requirements of **5.4.2.9**. Then increase the pressure until the relief valve opens. Note this pressure. For all types of preset pressure regulators increase the pressure further to the pressure $P_{RV} = 2\ P_2$; for all types of adjustable pressure regulators increase the pressure further to the pressure P_{RV} = 2 times the set pressure specified by the manufacturer. At this pressure measure the discharge Q_{RV} of the relief valve. [A1]

6.4 Test methods for leakage

6.4.1 *Internal leakage*

6.4.1.1 *Adjustable pressure regulators*

Measure the internal leakage at the rated inlet pressure P_1 with the adjusting device unscrewed and the outlet open.

Repeat the test at the test inlet pressure P_3.

If the outlet pressure cannot be set at zero, the test procedure given in clause **6.4.1.2** applies.

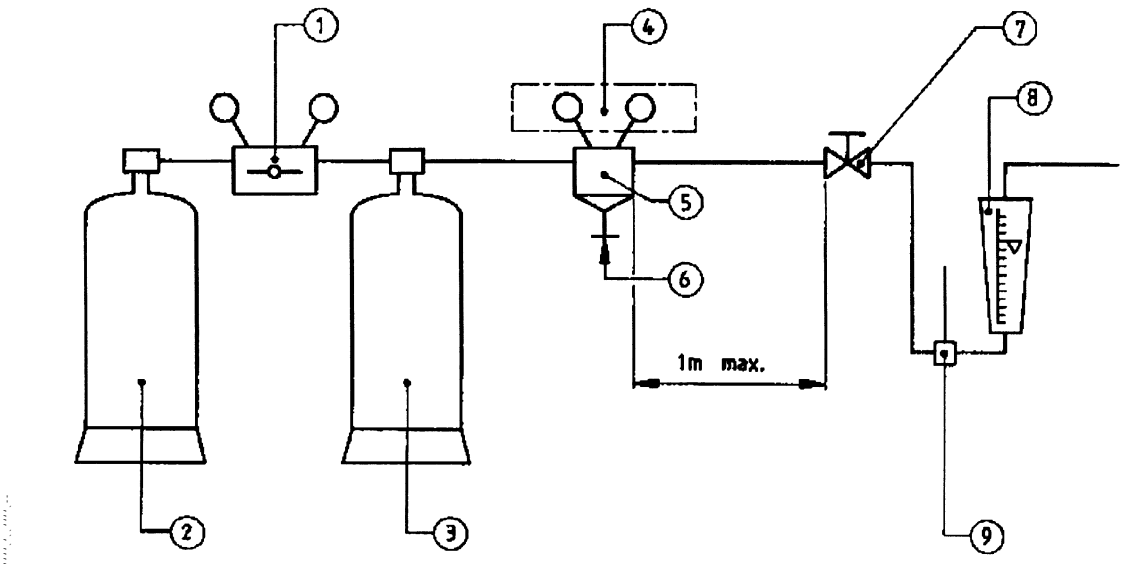
6.4.1.2 *Preset pressure regulators*

Measure the internal leakage at the rated inlet pressure P_1 with the outlet closed.

Repeat the test at the test inlet pressure P_3.

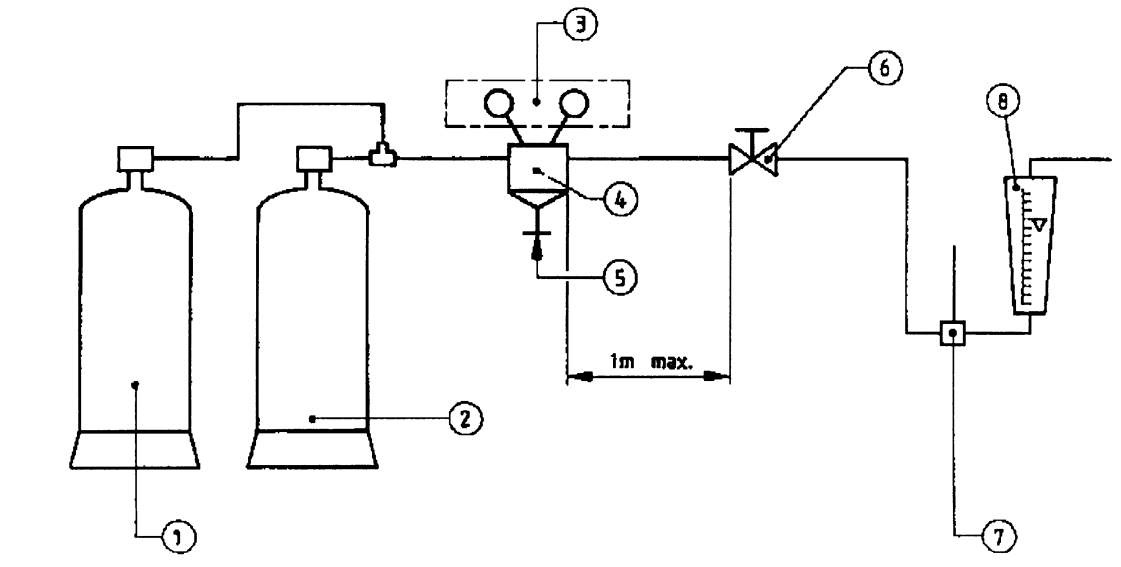
6.4.2 *External leakage*

Measure the external leakage of the regulator at the rated inlet pressure P_1 and closure pressure P_4 with the outlet closed.



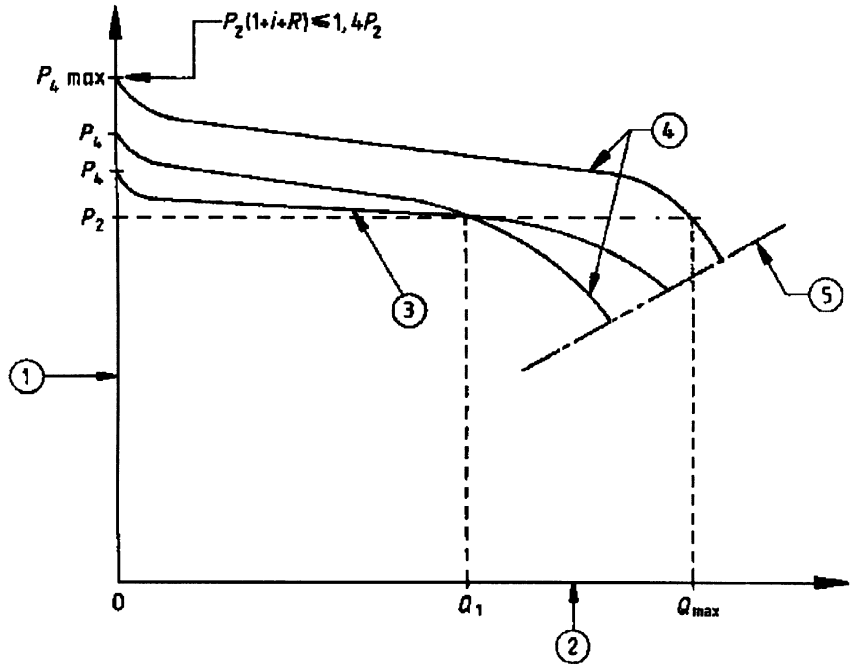
1. Auxiliary pressure regulator
2. Gas supply
3. Buffer cylinder
4. Calibrated gauges
5. Test sample
6. Pressure adjusting device
7. Flow control valve
8. Flowmeter
9. Thermometer

Figure 1 — Equipment for performance and functional tests



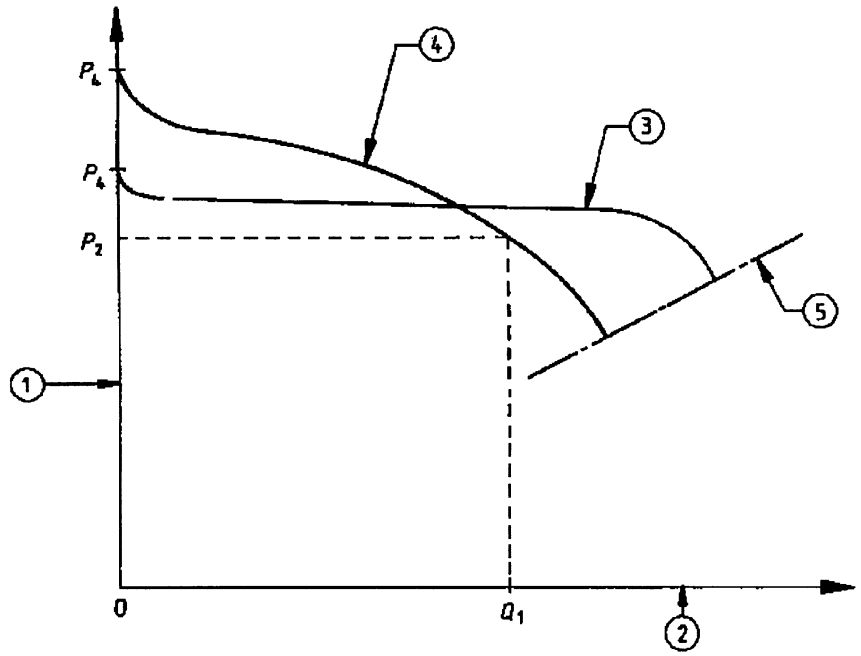
1. Auxiliary gas cylinder
2. Primary gas cylinder
3. Calibrated gauges
4. Test sample
5. Pressure adjusting device
6. Flow control valve
7. Thermometer
8. Flowmeter

Figure 2 — Equipment for determination of pressure characteristics



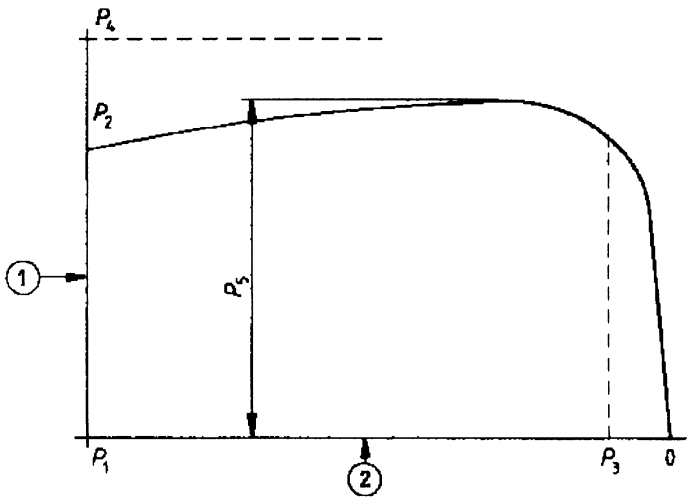
1. Outlet pressure
2. Flow
3. Inlet pressure P_1
4. Inlet pressure P_3
5. Outlet restriction

Figure 3 — Typical flow characteristic for an adjustable pressure regulator



1. Outlet pressure
2. Flow
3. Inlet pressure P_1
4. Inlet pressure P_3
5. Outlet restriction

Figure 4 — Typical flow characteristic for a preset pressure regulator



1. Outlet pressure
2. Inlet pressure

Figure 5 — Typical rising pressure characteristic

6.5 Test method for mechanical strength

6.5.1 For an adjustable regulator, ensure that the pressure adjusting device is in the position where the regulator valve is closed. For a preset regulator, plug the outlet.

6.5.2 Hydraulically pressurize the high pressure chamber of the complete regulator through the inlet port to 2,25 times its rated inlet pressure P_1 for 5 min. For this test replace the high pressure gauge, if fitted, by a plug.

6.5.3 Pressurize the low pressure chamber of the complete regulator through the outlet port to 4 times its rated outlet pressure P_2 for 5 min.

For this test replace the diaphragm, relief valve and low pressure gauge, if fitted, by plugs.

6.6 Test method for ignition

6.6.1 *Adjustable high pressure regulators*

Carry out this test at room temperature. Expose three samples of the regulator through the inlet to pressure shocks from industrial oxygen [minimum 99,5 % purity; hydrocarbons less than or equal to [A1] 10 µg/g (10 ppm)] [A1]. Use the test equipment shown in Figure 7.

Increase the pressure from atmospheric pressure to the test pressure in a time of $(20\ ^{0}_{-5})$ ms, measured prior to the test regulator (see Figure 7). Use a test pressure in all cases of 24 000 kPa at (60 ± 3) °C.

Apply a series of 20 pressure shocks at intervals of 30 s. Apply each pressure shock for 10 s. After each pressure shock return the test regulator to atmospheric pressure, not by means of the regulator but by an upstream outlet valve. Between pressure shocks hold atmospheric pressure for at least 3 s (see Figure 8).

During one test series do not decrease the inlet pressure (test pressure) by more than 3 %. Carry out the tests under the following conditions:

a) regulator valve fully open and outlet closed;

b) regulator valve closed.

After the test has been completed, dismantle the three test regulators and inspect all internal parts and areas for damage.

NOTE This test procedure is derived from EN 585.

6.6.2 *Preset high pressure regulators*

Test preset regulators as described in **6.6.1** in the normal delivery condition (with the regulator valve opened) with the outlet closed. For regulators with flowmeters, repeat the test with the flow control valve fully opened.

6.6.3 *Low-pressure regulators*

For inlet pressures below 1 400 kPa, measure the ignition temperature of the non-metallic materials including the sealing materials and lubricants (if used) as follows, using the apparatus shown in Figure 9.

Place finely divided test material into a stainless steel tube with a chrome nickel steel cladding, in quantities of about 0,3 g to 0,5 g. To obtain large reactive surfaces, coat liquids as well as pasty substances on fibrous ceramic material. Fill the gas-tight tube, containing the sample, with oxygen at a specified pressure (see Note 2) and then inductively heat it by a low frequency heater in an approximately linear manner at 120 °C/min. Monitor the temperature of the sample as a function of time by use of a thermocouple, and monitor the pressure by a pressure transducer. Record both pressure and temperature by a dual channel recorder. The point at which spontaneous ignition occurs is denoted by a sudden rise in temperature and pressure. The ignition temperature and the corresponding final oxygen pressure can be seen from Figure 10.

NOTE 1 Ignition temperatures in compressed oxygen can generally be reproduced with variations of ±5 °C in the range up to 200 °C. Variations of about ±10 °C and in some cases even higher, can be expected in the range from 200 °C to 500 °C. Usually five tests at the same pressure are performed on each sample.

NOTE 2 Data on ignition temperature of non-metallic materials depend upon the test method and there are differences in the values obtained by different test laboratories. The measurement of the ignition temperature of non-metallic materials is typically carried out at a pressure of 4 000 kPa and data is unavailable for pressures of 1 400 kPa. The typical relationship is that ignition temperature of non-metallic materials decreases with increasing oxygen pressure to an approximately constant value above pressures of 4 000 kPa. It is, however, known that this typical relationship is not followed by some non-metallic materials.

Care should therefore be taken to investigate the properties of new non-metallic materials which may be used for oxygen service.

6.7 Test method for flowmeter mechanical strength

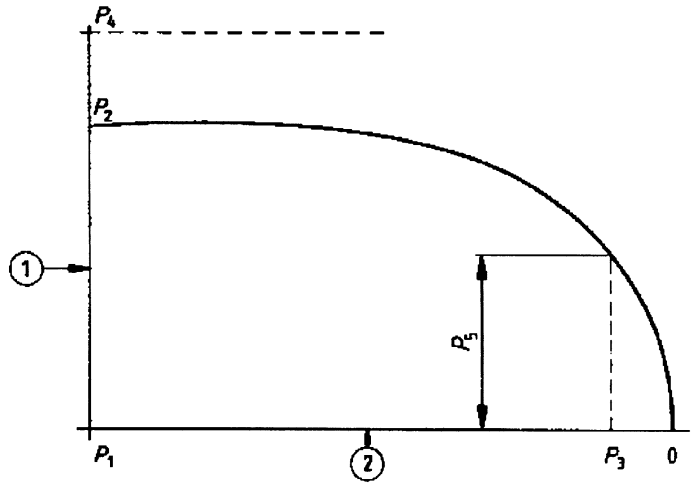
Apply an increasing pressure to the flowmeter up to the value 4 P_2. After 5 min check that the flowmeter has not ruptured. If a relief valve is fitted to the flowmeter and it limits the pressure below 4 P_2, the flowmeter is considered to comply with **5.4.3.5**.

[A1] 6.8 Test method for accuracy of pressure regulators with flowmeters and pressure regulators with flowgauges [A1]

Test the accuracy of flow using the equipment shown in Figure 1. Repeat this test after exposure of the flowmeter to an inlet pressure of 2 P_2.

[A1] 6.9 Test method for stability and accuracy of pressure regulators with fixed orifices

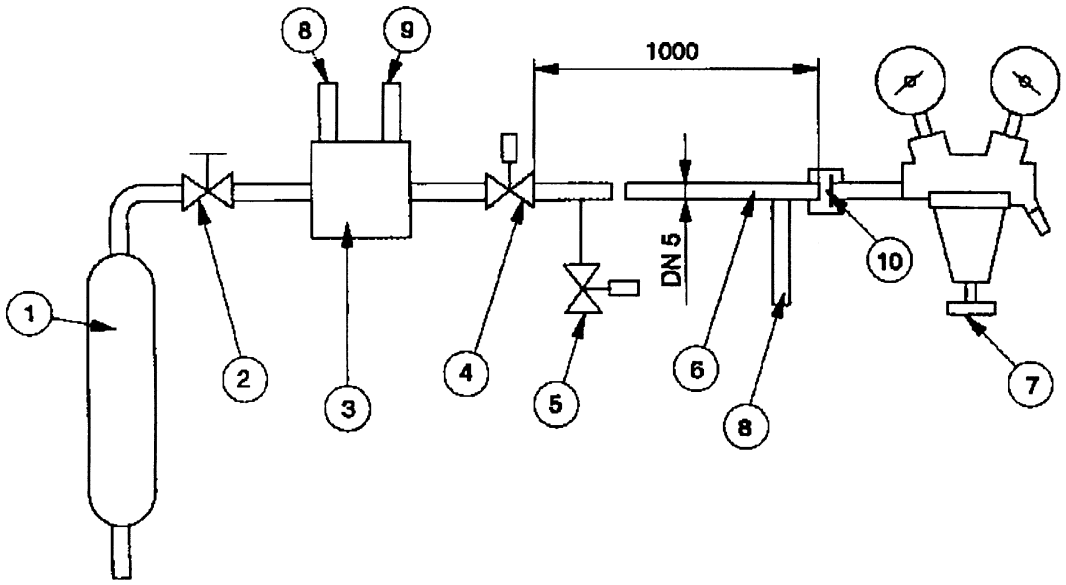
Use the equipment described in Figure 1 with the flow control valve (7) fully open. For each fixed orifice record the true flow as indicated by the flowmeter (8) with the inlet pressure decreasing from P_1 to 10 % of P_1. [A1]



1. Outlet pressure
2. Inlet pressure

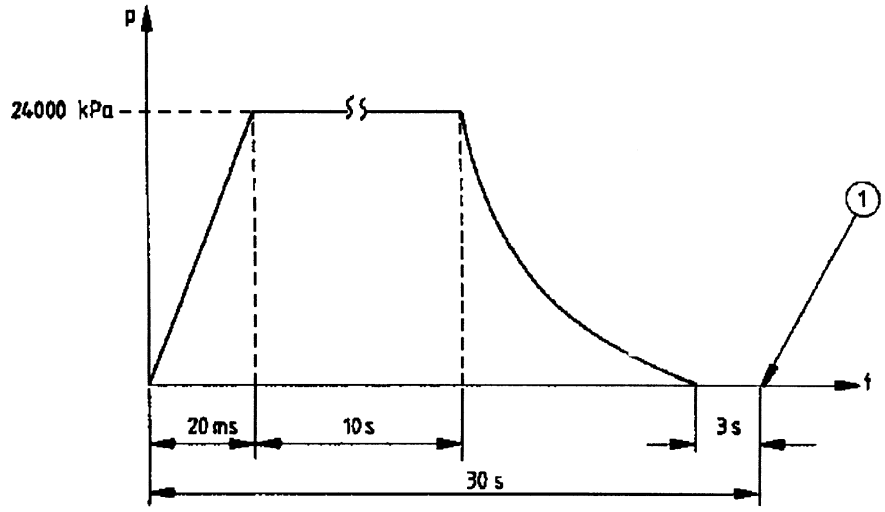
Figure 6 — Typical falling pressure characteristic

Dimensions in mm



1. Oxygen supply
2. Inlet valve
3. Vessel with device to pre-heat oxygen to (60 ± 3) °C
4. Quick-opening valve
5. Outlet valve
6. Connection tube
7. Test sample
8. Pressure transducer
9. Temperature sensor
10. Pressure measuring point

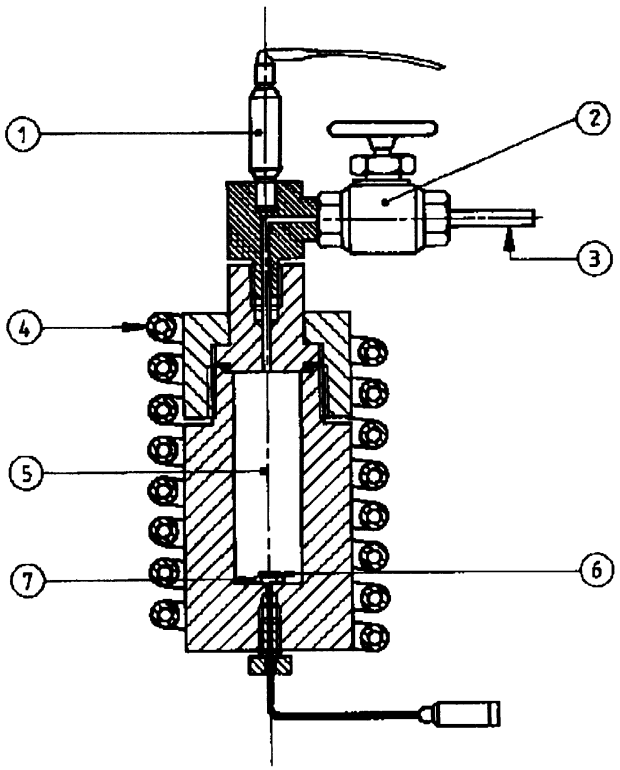
Figure 7 — Test bench for ignition test



1. Next pressure shock

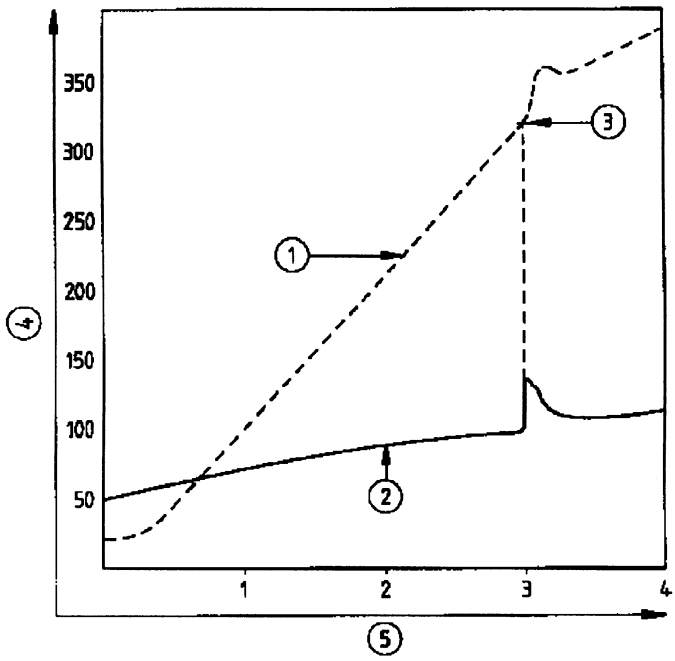
Figure 8 — Test interval

Dimensions in mm



1. Pressure transducer
2. Valve
3. Oxygen supply
4. Inductive heater
5. Reaction vessel
6. Test sample
7. Thermocouple

Figure 9 — Equipment for ignition temperature of non-metallic components



1. Temperature (°C)
2. Pressure (kPa/100)
3. Ignition temperature
4. Pressure/temperature
5. Time (min)

Figure 10 — Typical record of an ignition temperature determination in compressed oxygen

6.10 Test method for operating and loosening torques

Measure the torques using an appropriate torque spanner.

6.11 Test method for durability of markings and colour coding

Rub markings and colour coding by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with methylated spirit and then for 15 s with a cloth rag soaked with isopropyl alcohol. Carry out this test at ambient temperature.

[A1] 6.12 Test method for the stability of the flow

Using the equipment described in Figure 1 with the flow control valve (7) fully open, adjust the test sample (5) until the flowmeter (8) shows the maximum flow value specified by the manufacturer at an inlet pressure of P_1. Record the true flow as indicated by the flowmeter (8) with the inlet pressure decreasing from P_1 to 10 % of P_1. [A1]

7 Marking, colour coding, packaging

7.1 Marking

7.1.1 Pressure regulators and their gas-specific components shall be durably and legibly marked with the symbol of the relevant gas in accordance with Table 3. The test for the durability of markings is given in **6.11**.

NOTE In addition to the symbol, the name of the gas may be used.

Table 3 — Medical gases, marking and colour coding

Name	Symbol	Colour coding
Oxygen	O_2	White[1)]
Nitrous oxide	N_2O	Blue[1)]
Air for breathing	Air[4)]	White and black[1)]
Air for driving surgical tools	Air-800	White and black[1)]
Nitrogen for driving surgical tools	N_2-800	Black[1)]
Helium	He	Brown[1)]
Carbon dioxide	CO_2	Grey[1)]
Xenon	Xe	Light brown[2)]
[A1] Nitric oxide/nitrogen mixture (NO $\leq$ 1 000 µl/l)	NO/N_2	Black-bright green[5)] [A1]
Mixtures of the above gases	[3)]	[3)]

[1)] According to ISO 32.
[2)] An example of light brown is NCS 3030-Y30 R in accordance with SS 01 91 02.
[3)] According to the components.
[4)] National languages may be used for air.
[A1] [5)] According to EN 1089-3. [A1]

7.1.2 In addition, the regulators shall be marked with the following:

a) the name and/or the trademark of the manufacturer or distributor;

b) the model or type designation;

c) means to ensure traceability such as type, batch or serial number or year of manufacture;

d) the rated inlet pressure P_1;

e) the standard discharge Q_1, except for pressure regulators with flow metering devices as listed in **1.1**d) and e);

f) the designation “HP” at all high pressure ports.

7.1.3 The flowmeter shall be marked with the symbol and/or the name of the medical gas for which the regulator with flowmeter is designed and with the calibrated inlet pressure.

7.1.4 The body of the fixed orifice shall be marked with the corresponding flow in units of l/min.

7.1.5 The pressure gauges and flowgauges shall be marked with the following:

a) the name and/or the trademark of the manufacturer and/or supplier;

b) the symbol and/or the name of the gas or the gas mixture (for flowgauges and oxygen pressure gauges);

c) the note “USE NO OIL” or the symbol shown in Figure 11;

d) the symbol of the unit of pressure (for pressure gauges);

e) the symbol of the unit of flow (for flowgauges);

f) the identity of the fixed orifice for which the flowgauge is calibrated.

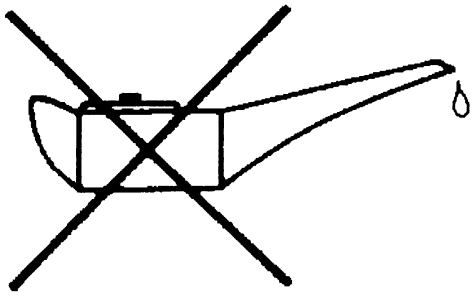


Figure 11 — Symbol for "use no oil"

7.1.6 Pressure adjusting devices and flow control valves (if fitted) shall be clearly and durably marked with the direction for increasing pressure and flow.

7.1.7 Compliance with clauses **7.1.1**, **7.1.2**, **7.1.3**, **7.1.4**, **7.1.5**, **7.1.6** and **7.1.7** shall be checked by visual inspection.

7.2 Colour coding

7.2.1 If colour coding is used, it shall be in accordance with Table 3. Annex D specifies special national conditions.

7.2.2 Colour coding shall be durable. The test for the durability of colour coding is given in **6.11**.

7.3 Packaging

7.3.1 Pressure regulators, pressure regulators with flow metering devices and spare parts shall be sealed to protect against particulate contamination and packaged to prevent damage during storage and transportation.

7.3.2 Packages shall provide a means of identification of the contents.

8 Information to be supplied by the manufacturer

8.1 Pressure regulators [A1] and pressure regulators with flow metering devices [A1] shall be accompanied by documents containing at least a technical description, instructions for use and an address to which the user can refer. The accompanying documents shall be regarded as a component part of pressure regulators.

[A1] For pressure regulators for NO/N_2 mixtures ($NO \leq 1\ 000$ µl/l) the instructions for use shall include a procedure for purging the pressure regulator before use. [A1]

8.2 Instructions for use shall contain all information necessary to operate the pressure regulator in accordance with its specification and shall include explanation of the function of controls, the sequence of operation and connection and disconnection of detachable parts and accessories. Instructions for use shall include indications on recognized accessories and detachable parts if the use of other accessories and parts can degrade the minimum safety. Instructions for use shall give detailed instructions for the safe performance of cleaning, inspection and preventive maintenance to be performed by the operator or by authorized persons, and shall indicate the frequency of such activities. A list of recommended spare parts shall be provided. The meaning of figures, symbols, warning statements and abbreviations on the pressure regulator and the flowmetering device shall be explained in the instructions for use.

Particular attention shall be given to the following safety related items:

— the danger of fire or explosion arising from the use of lubricants not recommended by the manufacturer;

— instructions to open the cylinder valve slowly, due to the danger of fire or explosion arising from oxygen pressure shocks;

— the danger which can arise from changing the setting of the relief valve.

8.3 [A1] For pressure regulators the performances [A1] shall be stated by assigning values to the range of inlet pressure P_1 and P_3, to the rated outlet pressure P_2 and to the standard discharge Q_1.

8.4 For [A1] pressure [A1] regulators, the manufacturer shall state the variation of the outlet pressure P_2 when the inlet pressure is varied from P_1 to P_3 at the flow of Q_1.

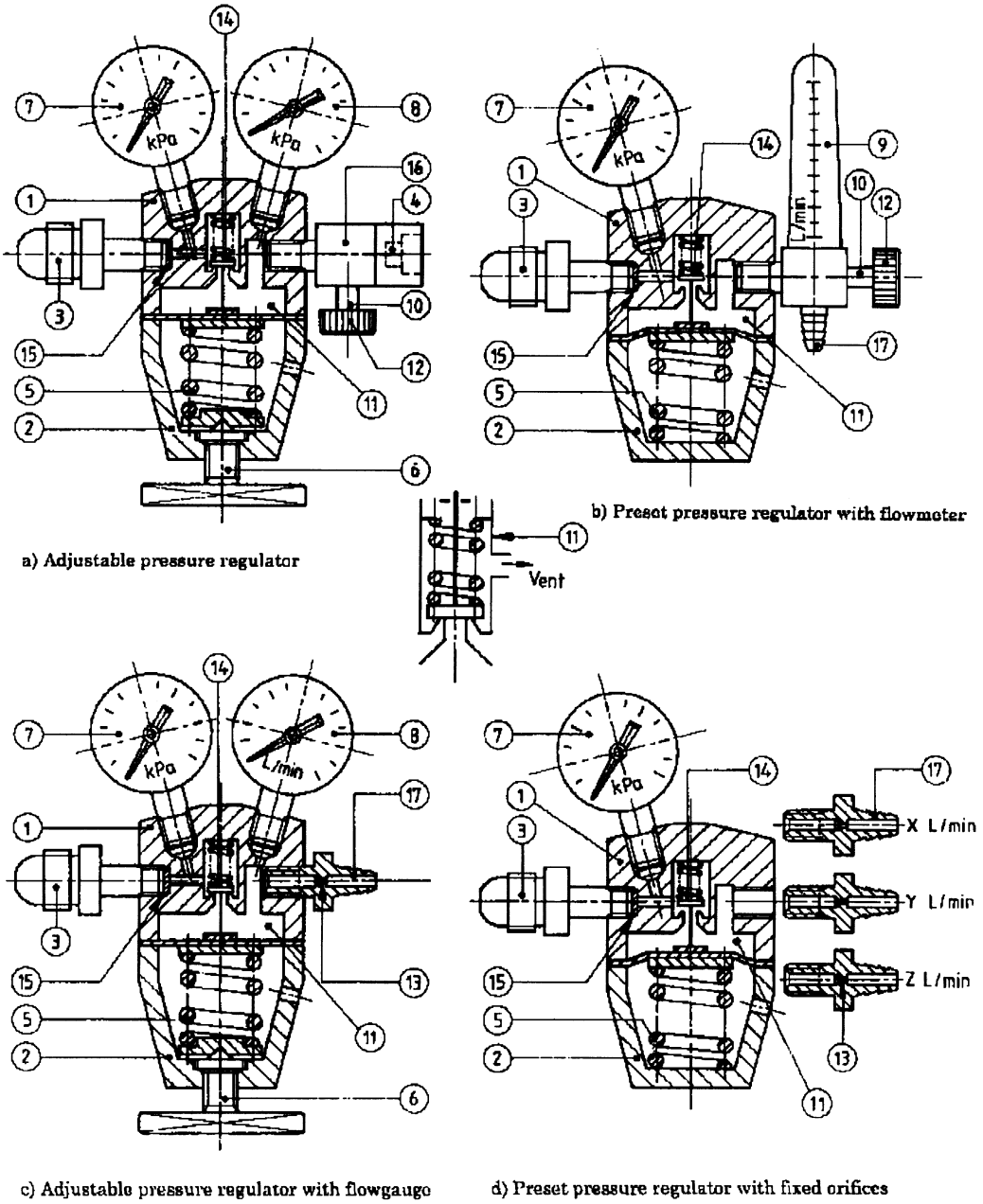
NOTE This variation can be expressed as % of P_2 or as a diagram.

8.5 [A1] For pressure regulators with flow metering devices the manufacturer shall state the rated inlet pressure P_1 and the accuracy of flow. [A1]

NOTE 1 The accuracy of flow will depend on the characteristics of the pressure regulator, the tolerances on any fixed orifices and the accuracy of the flowmeter or the flow gauge.

NOTE 2 The accuracy can be expressed as % of the actual reading or setting.

Annex A (informative)
Examples of pressure regulators and their applications



a) Adjustable pressure regulator

b) Preset pressure regulator with flowmeter

c) Adjustable pressure regulator with flowgauge

d) Preset pressure regulator with fixed orifices

1. Body
2. Cover
3. Inlet connection
4. Socket or NIST body
5. Pressure regulator spring
6. Pressure adjusting device
7. High pressure gauge
8. Low pressure gauge (or flowgauge)
9. Flowmeter
10. Flow control valve spindle
11. Relief valve
12. Flow control knob
13. Fixed orifice
14. Pressure regulator valve
15. Filter
16. Flow control valve
17. Hose insert

Figure A.1 — Typical diagram of pressure regulators

Table A.1 — Typical applications of pressure regulators

Type	P_1[1] kPa	P_2[2] kPa	Q_1[3] l/min	Supply	Typical application
Regulators	up to 20 000	400	60	HP gas cylinders	Single medical equipment[4]
Regulators	up to 20 000	800	300	HP gas cylinders	Single surgical tool
Regulators with flowmeter	up to 20 000	—	40	HP gas cylinders	Patient use
Regulators with flowgauge and fixed orifice	up to 20 000	—	20	HP gas cylinders	Home care, emergency transport
Regulators	up to 1 400	400	60	Pipeline systems	Single medical equipment[4]
Regulators with flowmeter	up to 1 400	—	40	Pipeline systems	Patient use

[1] Rated inlet pressure.
[2] Rated outlet pressure.
[3] Standard discharge.
[4] Some medical equipment may require higher flows for a short period of time.

Annex B (informative)
Bibliography

EN 585, *Gas welding equipment — Pressure regulators for gas cylinders used in welding, cutting and allied processes up to 200 bar*.

ISO 407, *Small medical gas cylinders — Yoke-type valve connections*.

EN ISO 10079-3, *Medical suction equipment — Part 3: Suction equipment powered from vacuum or pressure source*
(ISO 10079-3:1992).

SS 01 91 02, *Colour atlas*.

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

〈A1〉 CR 13903:2000, *General guidance on the equipment used for inhaled nitric oxide therapy*. 〈A1〉

Annex C (informative)
Rationale

C.5.2 Evidence will be provided to e.g. a Notified Body during CE conformity assessment and upon request to the Competent Authority. Attention is drawn to prEN 1441 on risk analysis and to the standards under development by ISO/TC 210 on risk evaluation and risk control.

C.5.3.5 Evidence of such compatibility will be provided e.g. to a Notified Body during CE conformity assessment and Competent Authority upon request.

C.5.4.2.2 The rated outlet pressure for pressure regulators has been linked to the type of outlet connector for the following reasons.

— When a terminal unit or a gas-specific connection point is used as an outlet connector, that pressure regulator may be connected to a cylinder for use as a medical gas supply system. Such a system should have essentially the same performance as a medical gas pipeline system so that the nominal operating pressure should be as specified in prEN 737-3 (400 kPa to 500 kPa except for air for driving surgical tools and nitrogen for driving surgical tools). The various limits given in prEN 737-3 for all compressed medical gases (except air for driving surgical tools and nitrogen for driving surgical tools) would permit a pressure variation in the range from 280 kPa to 1 000 kPa under single fault condition. All pneumatically powered medical equipment covered by CEN/TC 215 is specified to function with these variations of pressure input.

— It is intended that pressure regulators with proprietary fittings or hose inserts should not be used to operate medical equipment which normally requires a minimum supply pressure of 280 kPa. The pressure output of such pressure regulators has therefore been limited to below 280 kPa.

— Pressure regulators fitted with NIST connectors are intended for the supply of certain medical gases which are normally not piped but which may be used for therapy or measurement.

— NIST connectors for those medical gases which are normally supplied by medical gas pipeline systems are not permitted by this Part of this European Standard so that only one system for gas-specific connectors is used for any one medical gas.

C.5.4.2.6 Evidence will be provided e.g. to a Notified Body during CE conformity assessment and Competent Authority upon request.

C.5.4.2.11.1 High pressure regulators for different gases are often made with interchangeable components or sub-assemblies. The requirement for resistance to ignition should therefore be applied to high pressure regulators for all gases.

C.5.4.2.11.2 Low pressure regulators for different gases are often made with interchangeable components or sub-assemblies. The requirement for the ignition temperature of non-metallic components should therefore be applied to low pressure regulators for all gases.

Evidence of compliance with the requirement that the non-metallic materials used have ignition temperature above 160 °C and 200 °C respectively will be provided e.g. to a Notified Body during CE conformity assessment and Competent Authority upon request.

C.5.5.1 Pressure regulators for different gases are often made with interchangeable components or sub-assemblies. The requirement for cleaning should therefore be applied to pressure regulators for all gases.

Evidence of such compatibility will be provided e.g. to a Notified Body during CE conformity assessment and Competent Authority upon request.

C.5.5.2 Evidence of such compatibility will be provided e.g. to a Notified Body during CE conformity assessment and Competent Authority upon request.

Annex D (normative)
Special national conditions

Special national condition: National characteristic or practice that cannot be changed even over a long period, e.g. climatic conditions, electrical earthing conditions. If it affects harmonization, it forms part of the European Standard. In the countries in which the relevant national condition applies these provisions are normative, for other countries they are informative.

Clause **5.4.2.1.1**: Special national condition for all CEN members utilizing terminal units and probes which comply with the National Standards of Austria (ÖNORM 7387-4), France (NF S 90-116), Germany (DIN 13260 Part 2), Italy (UNI 9507), Sweden (SS 87 524 30) and United Kingdom (BS 5682).

The requirement to comply with prEN 737-6 does not apply until the latest date of withdrawal of the special national condition (2012-12-01), subject to review taking into account e.g. the results of a forthcoming European study.

Clause **5.4.2.1.2**c): Special national conditions for all CEN members.

The requirement to use NIST connectors in accordance with prEN 739 does not apply until the latest date of withdrawal of the special national condition (1998-06-13), subject to review taking into account e.g. the results of a forthcoming European study.

Clause **7.2.1** and Table 3: Special national condition for Austria, Germany, Switzerland.

The requirement to comply with Table 3 does not apply until the latest date of withdrawal of the special national condition (2006-07-01), subject to review taking into account e.g. the results of a forthcoming European study and the ongoing European standardization activities of the future EN 1089 series.

Annex ZA (informative)
Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This European Standard has been prepared under a mandate given to CEN/CENELEC by the European Commission and the European Free Trade Association and supports essential requirements of EU Directive 93/42/EEC.

WARNING. Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The clauses of this standard, as given in Table ZA.1, are likely to support requirements of Directive 93/42/EEC.

Compliance with these clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and EU Directives

Clause/subclause of this European Standard	Corresponding essential requirement of Directive 93/42/EEC	Comments
Section **5**	1	
Section **6**	1	
5.1	2, 6	
5.2	1	
5.3	1	
5.3.1	7.1, 7.3, 9.3	
5.3.2	4, 7.1, 9.2	
5.3.3	3, 5	
5.3.4	7.1, 7.2	
5.3.5	1, 3, 4, 5, 7.1, 7.2, 7.3, 9.2, 9.3	
5.4	1, 3, 4	
5.4.1.1	10.3	
5.4.1.3	10.2	
5.4.2.1	9.1, 12.7.4	
5.4.2.2	9.1, 12.7.4	
5.4.2.5	12.7.1	
5.4.2.6	7.2, 7.6	
5.4.2.7	10.1	
5.4.2.8	7.5, 9.2, 12.7.1	
5.4.2.9	7.5	
5.4.2.10	9.2	
5.4.2.11	7.3, 9.3	
5.4.3.1	10.3, 12.8.1, 12.8.2	
5.4.3.2	10.1, 12.8.1, 12.8.2	
5.4.3.3	10.2	
5.4.4.1	12.8.1, 12.8.2	
5.4.4.2	10.1, 12.8.1, 12.8.2	
5.4.5.2	10.1, 12.8.1	
5.5.1	7.2, 9.3	
5.5.2	9.3	
6.2	10.1	
6.3	7.5, 9.2, 12.7.1	

Table ZA.1 — Correspondence between this European Standard and EU Directives *(continued)*

Clause/subclause of this European Standard	Corresponding essential requirement of Directive 93/42/EEC	Comments
6.4	1, 3, 4, 7.5	
6.5	1, 3, 4, 9.2	
6.6	1, 3, 4, 7.3, 9.3	
6.7	1, 3, 4	
6.8	1, 3, 4, 10.1, 12.8.1, 12.8.2	
6.9	1, 3, 4, 10.1, 12.8.1, 12.8.2	
6.10	1, 3, 4	
6.11	13.2	
7.1	13.1, 13.2	
7.1.2 1st dash	13.1, 13.3d)	
7.1.2 2nd dash	13.3d)	
7.1.2 3rd dash	13.5	
7.1.5 1st dash	13.3a)	
7.1.6	12.9	
7.2	13.2	
7.3	3	
7.3.1	5, 7.2, 7.6	
7.3.2	13.1, 13.3b)	
8.1	13.1, 13.3a), 13.4, 13.6a)	
8.2	1, 13.1, 13.2, 13.6c), 13.6d), 13.6k)	
8.2 1st dash	9.3, 13.6l)	
8.2 3rd dash	9.2	
8.3	13.6b)	
8.4	13.6b)	
8.5	13.6b), 13.6p)	

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