

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

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Committees responsible for this British Standard

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- 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

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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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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
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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.

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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, 5.4.2.1.2c) 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 1.1a), b), and c) and to the types of flow metering devices given in 1.1d) and e) for use with the following medical gases:

- oxygen;
- nitrous oxide;
- air for breathing;
- helium;
- carbon dioxide;
- xenon;
- NO/N_2 mixtures ($\text{NO} \leq 1\,000\ \mu\text{l/l}$); A_1
- 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 1.1a) and 1.1c);

e) flow metering devices that are not integral with the types of pressure regulator described in 1.1a) and 1.1c) 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*.

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

prEN 1441, *Medical devices — Risk analysis*.

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

Ⓐ Reference deleted. Ⓐ

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

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

3 Definitions

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

3.1

adjustable pressure regulator

regulator which has been provided with a means of operator adjustment of the delivery pressure under intended use

3.2

closure pressure, P_4

stabilized outlet pressure, on cessation of the flow after one minute, from a regulator where the flow has been set to standard discharge

3.3

flow characteristic

variation of the outlet pressure in relation to the rate of flow from zero to maximum capacity flow of the regulator with the inlet pressure remaining constant

3.4**flowgauge**

gauge which measures pressure differential using ambient pressure as the datum point but which is calibrated in units of flow

NOTE The flowgauge does not measure flow, but it indicates flow by measuring the pressure upstream of a fixed orifice.

3.5**flowmeter**

device that measures and indicates the flow of a specific gas

NOTE It may incorporate a flow adjustment control.

3.6**gas-specific connection point**

that part of the socket which is the receptor for a gas-specific probe

3.7**high pressure**

pressure greater than 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