



SLOVENSKI STANDARD
SIST EN 738-1:2000/A1:2002
01-november-2002

Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow metering devices

Druckminderer zur Verwendung mit medizinischen Gasen - Teil 1: Druckminderer und Druckminderer mit Durchflussmessgeräten

Détendeurs pour l'utilisation avec les gaz médicaux - Partie 1: Détendeurs et détenteurs -débitmetres

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Ta slovenski standard je istoveten z: EN 738-1:1997/A1:2002

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ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
23.060.40	V æ } ã^* ~ æ[kã	Pressure regulators

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 738-1:1997/A1

April 2002

ICS 11.040.10; 23.060.40

English version

**Pressure regulators for use with medical gases - Part 1:
Pressure regulators and pressure regulators with flow metering
devices**

Détendeurs pour l'utilisation avec les gaz médicaux - Partie
1: Détendeurs et détendeurs-débitmètres

Druckminderer zur Verwendung mit medizinischen Gasen -
Teil 1: Druckminderer und Druckminderer mit
Durchflussmessgeräten

This amendment A1 modifies the European Standard EN 738-1:1997; it was approved by CEN on 4 March 2002.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This amendment 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 Management Centre 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, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

EN 738-1:1997/A1:2002 (E)**Foreword**

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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REVISED TEXT

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1 Scope

Add to the list of medical gases:

'NO/N₂ mixtures (NO ≤ 1000 µl/l)'

2 Normative references

Add the following:

'ISO/DIS 407:2001 Small medical gas cylinders - Pin-index yoke-type valve connections'

'EN 1089-3 Transportable gas cylinders – Cylinder identification – Part 3: Colour coding'

Delete the following:

'ISO 554 Standard atmospheres for conditioning and/or testing – Specifications'

Change 'ISO 5145' to 'ISO/DIS 5145:2001'

3 Definitions

Add a new definition:

3.29 accuracy of flow:

difference in percent between the indicated value and the true value of the flow.'

5.3.1

Add a new Note 4:

NOTE 4 'Guidance for the selection of metallic and non-metallic materials for use with NO/N₂ mixtures (NO ≤ 1000 µl/l) is given in CEN Report CR 13903.'

5.4.2.1.1

Add the following:

'For connection to cylinders of NO/N₂ mixtures (NO ≤ 1000 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).'

5.4.2.1.2

Add the following:

'For pressure regulators for NO/N₂ mixtures (NO ≤ 1000 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 739:2002

e) a quick connector.

NOTE ¹⁾: An example of outlet connector suitable for use with NO/N₂ mixtures (NO ≤ 1000 µl/l) is the body of the quick-connector "Swagelock - QC4 DESO -Stainless steel 316.'

Add footnote:

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

5.4.2.2

Add the following:

'For pressure regulators for NO/N₂ mixtures (NO ≤ 1000 µl/l) the rated outlet pressure shall be 400 kPa.'

5.4.2.5

Add the following:

'For pressure regulators for NO/N₂ mixtures (NO ≤ 1000 µl/l) it shall not be possible to set a pressure greater than the rated outlet pressure.'

5.4.2.7.1

Add the following:

'Q_{max} shall not exceed 2 x Q₁.'

EN 738-1:1997/A1:2002 (E)**5.4.2.7.2**

Add the following:

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

5.4.2.7.3

Add the following:

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

5.4.2.8

Add the following to the penultimate sentence:

'or 2 times the set pressure specified by the manufacturer.'

Add the following new sentence:

'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.'

5.4.2.9

Add the following:

'For pressure regulators for NO/N_2 mixtures ($\text{NO} \leq 1000 \mu\text{l/l}$) the external leakage (to atmosphere) and internal leakage (through the regulator valve) shall not exceed 0,1 ml/min (0,0101 kPa·l/min) each.'

5.4.3

Add the following new subclause:

5.4.3.6 Stability of flow

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

The test for stability of flow is given in 6.12.'

5.4.4.2

Amend last sentence as follows:

'The test for accuracy of flow is given in 6.8.'

Add the following new subclause:

5.4.4.3 Stability of flow

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

The test for stability of flow is given in 6.12.'

5.4.5.2

Amend as follows:

‘5.4.5.2 Stability and accuracy of flow

The true flow shall be within $\pm 20\%$ of each stated value or $\pm 30\%$ 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.’

5.4.5.3

Amend as follows:

‘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.’

6.1.2

Amend the first two sentences as follows:

‘Carry out tests with clean, oil-free, dry air or nitrogen.

In all cases carry out tests with dry gas with a maximum moisture content of 50 $\mu\text{g/g}$ (50 ppm).’

6.3

Amend as follows:

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‘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.’

6.6.1

In the third line change ‘ 10×10^{-6} ’ to 10 $\mu\text{g/g}$ (10 ppm).’

6.8

Amend the title as follows:

‘6.8 Test method for accuracy of pressure regulators with flowmeters and pressure regulators with flowgauges’

6.9

Amend as follows:

‘6.9 Test method for stability and accuracy of pressure regulators with fixed orifices

Use the equipment described in Fig.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 .’

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Add the following new subclause:

‘6.12 Test method for the stability of the flow

Using the equipment described in Fig.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 .’

Table 2

Add the following note:

‘For NO/N₂ mixtures (NO ≤ 1000 µl/l) the conversion coefficient for nitrogen can be used.’

Table 3

Add the following new row:

‘Nitric oxide/nitrogen mixture (NO ≤ 1000 µl/l); NO/N₂; Black-bright green⁵⁾,’

Add new footnote:

⁵⁾ according to EN 1089-3.

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8.1

In the first line change ‘Pressure regulators’ to ‘Pressure regulators and pressure regulators with flow metering devices’

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Add the following:

‘For pressure regulators for NO/N₂ mixtures (NO ≤ 1000 µl/l) the instructions for use shall include a procedure for purging the pressure regulator before use.’

8.3

In the first line change ‘The performance of the regulator’ to ‘For pressure regulators the performances’.

8.4

In the first line change ‘For regulators’ to ‘For pressure regulators’.

8.5

Amend the first sentence as follows:

‘For pressure regulators with flow metering devices the manufacturer shall state the rated inlet pressure P_1 and he accuracy of flow.’

Annex B

Add ‘CEN Report CR 13903:2000, “General guidance on the equipment used for inhaled nitric oxide therapy”.’