SLOVENSKI STANDARD
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Pretočni merilniki za priključitev na končne dele napeljav za medicinske pline

Flow-metering devices for connection to terminal units of medical gas pipeline systems

Durchflußmeßeinrichtungen zum Anschluß an Entnahmestellen von Rohrleitungssystemen für medizinische Gase

Dispositifs a débitmetre pour prises murales des réseaux de distribution de gaz médicaux

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11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

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English version

Flow-metering devices for connection to terminal units of medical gas pipeline systems

Dispositifs à débitmètre pour prises murales des réseaux de distribution de gaz médicaux

Durchflußmeßeinrichtungen zum Anschluß an Entnahmestellen von Rohrleitungssystemen für medizinische Gase

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

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This European Standard exists in one official version in accordance with Resolution BT 74/1997, the one language experiment. A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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

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

Contents

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest byApril 1999, and conflicting national standards shall be withdrawn at the latest by April 1999.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard.

For special national conditions for clauses 5.4.1, 7.2.1 and table 2 see annex D.

Annex D forms a normative part of this European Standard. Annexes A, B, C and ZA are given for information only.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

Flow-metering devices are widely used in delivery of medical gases supplied by a medical gas supply system directly to a patient. It is essential that these devices deliver accurate flows under varying conditions of temperature and inlet pressure. It is therefore important that the operating characteristics be specified and tested in a defined manner.

This standard pays particular attention to:

- Suitability of materials
- Safety (mechanical strength, safe relief of excess pressure and resistance to ignition)
- Gas specificity
- Cleanliness
- Accuracy
- 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 European Standard applies to:

- Flow-metering devices which are connected and disconnected by the operator at terminal units of a medical gas pipeline system for measurement and delivery of medical gases. They can be connected either directly or by means of flexible connecting assemblies.
- Flow-metering devices which are connected and disconnected by the operator at gas-specific connection points of devices such as pressure regulators.

1.2 It applies only to flow-metering devices for the following medical gases:

- oxygen
- nitrous oxide
- air for breathing
- carbon dioxide
- helium
- xenon
- specified mixtures of the gases listed above
- oxygen/nitrous oxide mixture (50/50 % V/V).

1.3 Electrical or electronic flow-metering devices are excluded from the scope of this standard.

2 Normative references

This European Standard incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revision of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

prEN 737-6:1996	Medical gas pipeline systems - Part 6: Dimension of probes for terminal units for compressed medical gases and vacuum
EN 739	Low-pressure hose assemblies for use with medical gases

EN 1441	Medical devices - Risk analysis
EN 12218	Rail systems for supporting medical equipment.
ISO 32	Gas cylinders for medical use - Marking for identification of content

3 Definitions

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

3.1 flowgauge: Gauge which measures pressure differential and which is calibrated in units of flow.

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

3.2 flowmeter: Device that measures and indicates the flow of a specific gas.

3.3 flow-metering device: Device fitted with an inlet and an outlet connector and which incorporates one of the following:

a) a flowmeter and a flow control valve

b) a flowgauge and a fixed orifice with a flow control valve

c) multiple fixed orifices with a means of selecting the orifice.

3.4 gas-specific: Having characteristics which prevent interchangeability and thereby allow assignment to one gas or vacuum service only.

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

3.6 medical gas: Any gas or mixture of gases intended to be administered to patients for therapeutic, diagnostic or prophylactic purposes or for surgical tool application.

3.7 medical gas pipeline system: Complete system which comprises a source of supply, a pipeline distribution system and terminal units at the points where medical gases or anaesthetic gas scavenging can be required.

3.8 medical gas supply system: Either:

a) a medical gas pipeline system; or

b) any other installation having no permanent pipeline system but employing a medical gas supply source complete with pressure regulators.

3.9 NIST connectors; non-interchangeable screw-threaded connectors: Range of male and female components intended to maintain gas-specificity by the allocation of a set of different diameters and a left or right hand screw thread to the mating components for each particular gas.

3.10 probe: Non-interchangeable male component designed for acceptance by and retention in the socket.

3.11 rated inlet pressure, P_1: Rated maximum upstream pressure for which the flow-metering device is designed to operate.

3.12 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.

3.13 socket: That part of a terminal unit which is either integral or attached to the base block by a gas-specific interface and which contains the gas-specific connection point.

3.14 terminal unit: Outlet assembly (inlet for vacuum) in a medical gas supply system at which the operator makes connections and disconnections.

NOTE: Terminal units and gas-specific connection points can also be connected to pressure regulators or low-pressure hose assemblies.

4 Terminology

Typical examples of flow-metering systems are shown in annex A.

5 General requirements

5.1 Safety

Flow-metering devices shall, when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, cause no safety hazard which could be foreseen using risk analysis procedures in accordance with EN 1441 and which is connected with their intended application, in normal condition and in single fault condition.

5.2 *R* Alternative construction

Flow-metering devices and components or parts thereof, using materials or having forms of construction different from those detailed in clause 5 of this European Standard (except for dimensions and allocation of NIST connectors and probes used as inlet connectors) 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 in oxygen. Many such materials can be ignited by friction at a valve seat or by adiabatic compression produced when oxygen at high pressure is rapidly introduced into a system initially at low pressure.

NOTE 3: prEN 13159 "Compatibility of medical equipment with oxygen" is in preparation by CEN/TC 215/WG3.

5.3.2 The materials shall permit the flow-metering device and its components to meet the requirements of 5.4 (except 5.4.6) in the temperature range of -20 °C to +60 °C.

5.3.3 Flow-metering devices 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 medical gases, shall not be plated.

NOTE: Plating could come off.

5.3.5 ***R*** Evidence of conformity with the requirements of 5.3.1, 5.3.2, 5.3.3 and 5.3.4 shall be provided by the manufacturer.

5.4 Design Requirements

5.4.1 ***Inlet connector***

5.4.1.1 The inlet connector shall be one of the following:

a) a probe complying with prEN 737-6:1996 [see figure A.2 a)];

b) a NIST nut and nipple complying with EN 739 [see figure A.2 b)];

c) an assembly consisting of a hose insert, a length of hose and a probe complying with prEN 737-6:1996 [see figure A.2 c)];

d) an assembly consisting of a hose insert, a length of hose and a NIST nut and nipple complying with EN 739 [see figure A.2 d)];

5.4.1.2 These assemblies shall comply with EN 739 except that the outlet connector is replaced by the hose insert specified in EN 739.

See annex D for special national conditions.

Compliance shall be checked by visual inspection.

5.4.2 ***Outlet connector***

The outlet connector shall be one of the following:

a) a permanently connected hose insert;

b) a proprietary fitting, with or without a hose insert.

Compliance shall be checked by visual inspection.

5.4.3 ***R Filtration***

A filter shall be provided which:

a) is located upstream of the flow-metering device.

b) is replaceable.

c) has openings not exceeding 100 µm or equivalent mesh.

Evidence shall be provided by the manufacturer.

5.4.4 ***Scales and indicators***

5.4.4.1 All flow-metering devices shall be graduated in units of litres per minute (l/min).

NOTE: For flows of less than 1 l/min the flow-metering devices can be graduated in millilitres per minute (ml/min).

5.4.4.2 Unit graduations in flow-metering device scale increments shall be not less than the stated accuracy at a given flow.

5.4.4.3 The indicator of a flow-metering device shall be visible to the user at all flow rates, including zero flow.

5.4.4.4 The scale of the flow-metering device shall be legible to an operator having visual acuity, corrected if necessary, of 1, sitting or standing l m from the flow-metering device at an illuminance of 215 lux.

5.4.4.5 Compliance with the requirements of 5.4.4.1 to 5.4.4.4 is checked by visual inspection.

5.4.5 ***Mechanical strength***

The flow-metering device shall be capable of either containing for 10 min, or safely relieving, a pressure of 1 000 kPa.

The test for mechanical strength is given in 6.2