Meditsiinilise gaasi torusüsteemide liitmikega ühendatavad voolamise mõõteseadmed

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

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA

Käesolev Eesti standard EVS-EN 13220:1999 sisaldab Euroopa standardi EN 13220:1998 ingliskeelset teksti. Käesolev dokument on jõustatud 23.11.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 13220:1999 consists of the English text of the European standard EN 13220:1998. This document is endorsed on 23.11.1999 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

NATIONAL FOREWORD

Käsitlusala: Käesolev standard kehtib: - Voolamise mõõteseadmete kohta, mis on operaatori kaasabil kokku- ja lahtiühendatavad meditsiinilise gaasi torusüsteemi liitmikega meditsiiniliste gaaside mõõtmiseks ja väljastamiseks. Nad võivad olla ühendatavad otse või elastsete ühendusdetailide abil. - Voolamise mõõteseadmete kohta, mis on operaatori kaasabil kokku- ja lahtiühendatavad seadmete, nagu näiteks surveregulaatorite gaasispetsiifiliste ühenduspunktidega. Standard kehtib vaid selliste voolamise mõõteseadmete kohta, mis on ette nähtud järgmiste meditsiiniliste gaaside jaoks: hapnik, dilämmastikoksiid, õhk hingamiseks, süsinikdioksiid, heelium, ksenoon, eespool loetletud gaaside kindlaksmääratud segud, hapniku / dilämmastikoksiidi segu (50/50 % (mahuprotsent)). Elektrilised ja elektroonilised voolamise mõõteseadmed on käesoleva standardi reguleerimisalast välja jäetud.	**Scope:**

ICS 11.040.10

Võtmesõnad: anesteesiaaparatuur, gaasitorud, kunstliku hingamise aparaat, meditsiiniaparatuur, meditsiinilised gaasid, mõõteriistad, määratlused, voolamise mõõtmised, ühenduskohad

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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 1998-10-02.

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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.

The European Standards exist in one official version (English), 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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CEN

European Committee for Standardization
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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.