Meditsiinilise gaasi torusüsteemide liitmikega ühendatavad voolamise mõõteseadmed

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 15002:2008 sisaldab Euroopa standardi EN ISO 15002:2008 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 15002:2008 consists of the English text of the European standard EN ISO 15002:2008.
Standard on kinnitatud Eesti Standardikeskuse 18.08.2008 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 18.08.2008 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 01.07.2008.	Date of Availability of the European standard text 01.07.2008.
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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 (ISO 15002:2008)

Dispositifs de mesure de débit pour raccordement aux prises murales des systèmes de distribution de gaz médicaux (ISO 15002:2008)

Durchflussmesseinrichtungen zum Anschluss an Entnahmestellen von Rohrleitungssystemen für medizinische Gase (ISO 15002:2008)

This European Standard was approved by CEN on 21 June 2008.

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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

Foreword

This document (EN ISO 15002:2008) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with 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of an identical text or by endorsement, at the latest by January 2009, and conflicting national standards shall be withdrawn at the latest by July 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 13220:1998.

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 EC Directive.

For relationship with EC Directive, see informative Annex ZA, which is an integral part of this document.

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

Endorsement notice

The text of ISO 15002:2008 has been approved by CEN as a EN ISO 15002:2008 without any modification.

Annex ZA
(informative)

Correspondence between this International Standard and Directive 93/42/EEC

This International Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide one means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC Medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this International Standard and Directive 93/42/EEC

Clause(s)/Sub-clause(s) of this International Standard	Corresponding essential requirements of EU Directive 93/42/EEC	Qualifying remarks/Notes
5	1	
5.1	2, 6	
5.2	2	
5.3	2	
5.3.1	7.1, 7.3, 9.3	
5.3.2	7.3, 9.3	
5.3.3	4, 7.1, 9.2	
5.3.4	3, 5	
5.3.5	7.1, 7.2	
5.4	2, 3, 4	
5.4.1	9.2, 12.7.4	
5.4.1.2	7.2, 7.6	
5.4.2	9.2, 12.7.4	
5.4.3	9.2, 12.7.1	
5.4.4	7.5	
5.4.5	9.1	
5.4.6.1	10.3, 12.8.2	
5.4.6.2	10.2	
5.4.6.3	10.1, 12.8.1, 12.8.2	
5.4.6.4	12.8.1	

Table ZA.1 (*continued*)

Clause(s)/Sub-clause(s) of this International Standard	Corresponding essential requirements of EU Directive 93/42/EEC	Qualifying remarks/Notes
5.4.7.1	10.3, 12.8.2	
5.4.7.2	10.2	
5.4.7.3	10.1, 12.8.1, 12.8.2	
5.4.7.4	12.8.1	
5.4.7.5	10	
5.4.8.1	10.2	
5.4.8.2	10.1, 12.8.1, 12.8.2	
5.4.8.3	10.2	
5.5.1	7.2, 9.3	
5.5.2	7.3, 9.3	
6.2	9.2, 12.7.1, 12.7.4	
6.3	7.5	
6.4	13.2	
7.1	13.1, 13.2, 13.3 a), 13.3 d), 13.5	
7.2	13.2	
7.3	3, 5	
7.3.1	5, 7.2, 7.6	
7.3.2	13.1, 13.3 b)	
8.1	13.1, 13.3 a), 13.4, 13.6 a)	
8.2	13.6 c), 13.6 d)	
8.3 1st dash	9.3	
8.3 2nd dash	9.1, 12.7.4, 13.6 c)	
8.3 3rd dash	9.3	
8.3 4th dash	10.1, 12.8.1, 12.8.2	
8.3 5th dash	10.1, 12.8.1, 12.8.2	
8.3 6th dash	10.1, 12.8.1, 12.8.2	
8.3 7th dash	10.1, 12.8.1, 12.8.2	
8.3 8th dash	10.1, 12.8.1, 12.8.2	
8.3 9th dash	10.1, 12.8.1, 12.8.2	

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.

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Introduction

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

This International Standard pays particular attention to:

— safety (mechanical strength, safe relief of excess pressure, resistance to ignition);

— gas specificity;

— cleanliness;

— suitability of materials;

— accuracy;

— testing;

— identification;

— information supplied.

Annex A contains rationale statements for some of the requirements of this International Standard. The clauses and subclauses marked with an asterix (*) after their number have corresponding rationale contained in informative Annex A, included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this International Standard. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this International Standard, but will expedite any subsequent revisions.

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

1 Scope

1.1 This International Standard is applicable to:

— flow-metering devices that are connected, either directly or by means of flexible connecting assemblies, and disconnected by the operator at terminal units of a medical gas pipeline system for flow adjustment, measurement and delivery of medical gases;

— flow-metering devices that are connected and disconnected by the operator at gas-specific connection points of devices such as pressure regulators.

1.2 This International Standard applies to:

a) flow-metering devices intended to be used with the following medical gases:

— oxygen;

— nitrous oxide;

— medical air;

— carbon dioxide;

— oxygen/nitrous oxide mixture [50 %/50 % (by volume)];

— specified mixtures of the gases listed above;

b) flow-metering devices intended to be used with the following gases:

— oxygen-enriched air;

— helium;

— xenon.

NOTE Regional or national regulations might permit use of oxygen-specific connection points for oxygen-enriched air.

1.3 This International Standard does not apply to electrical or electronic flow-metering devices.

1.4 This International Standard does not apply to gases used for driving surgical tools.

2 *Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 5359:2008, *Low-pressure hose assemblies for use with medical gases*

ISO 7396-1, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 9170-1, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*

ISO 11114-3:1997, *Transportable gas cylinders — Compatibility of cylinder and valve materials with gas contents — Part 3: Autogenous ignition test in oxygen atmosphere*

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

ISO 15001:2003, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

ISO 19054, *Rail systems for supporting medical equipment*

EN 837-1:1996, *Pressure gauges — Part 1: Bourdon tube pressure gauges — Dimensions, metrology, requirements and testing*

EN 1089-3:2004, *Transportable gas cylinders — Gas cylinder identification (excluding LPG) — Part 3: Colour coding*

EN 13544-2, *Respiratory therapy equipment — Part 2: Tubing and connectors*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
diameter index safety system connectors
DISS connectors
any of a range of male and female components intended to maintain gas-specificity by allocation of a set of different diameters to the mating connectors for each particular gas

3.2
flowgauge
device that measures pressure and is calibrated in units of flow

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

3.3
flowmeter
device that measures and indicates the flow of a specific gas

3.4
flow-metering device
device fitted with an inlet connector and an outlet connector and which incorporates one of the following:

a) a flowmeter with a flow control valve;

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

