Meditsiinilise gaasi torusüsteemid. Osa 1: Liitmikud kokkusurutud meditsiinilise gaasi ja vaakumi jaoks

Terminal units for medical gas pipeline systems - Part 1: Terminal units for use with compressed medical gases and vacuum

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 9170-1:2008 sisaldab Euroopa standardi EN ISO 9170-1:2008 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 9170-1:2008 consists of the English text of the European standard EN ISO 9170-1:2008.
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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Terminal units for medical gas pipeline systems - Part 1: Terminal units for use with compressed medical gases and vacuum (ISO 9170-1:2008)

Prises murales pour systèmes de distribution de gaz médicaux - Partie 1: Prises murales pour les gaz médicaux comprimés et le vide (ISO 9170-1:2008)

Entnahmestellen für Rohrleitungssysteme für medizinische Gase - Teil 1: Entnahmestellen für medizinische Druckgase und Vakuum (ISO 9170-1:2008)

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

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Foreword

This document (EN ISO 9170-1:2008) 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of an identical text or by endorsement, at the latest by January 2009, and conflicting national standards shall be withdrawn at the latest by July 2010.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 737-1:1998.

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 Directives, 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 9170-1:2008 has been approved by CEN as a EN ISO 9170-1:2008 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
4	1	
4.1	2, 6	
4.2	2	
4.3	2	
4.3.1	7.1, 7.3, 9.3	
4.3.2	4, 7.1, 9.2	
4.3.3	3, 5	
4.3.4	7.1, 7.2	
4.3.5	7.3, 9.3	
4.4	2, 3, 4	
4.4.1	9.1, 9.2	
4.4.1.2	12.7.1	
4.4.1.5	12.7.1	
4.4.1.8	12.7.1	
4.4.2	9.1, 12.7.4	
4.4.3	12.7.4	
4.4.4	9.1, 12.7.4	
4.4.5	12.8.2	
4.4.6	12.8.2	
4.4.7	9.1, 12.7.4	
4.4.8	12.7.4	
4.4.10	12.7.4	

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
4.4.11	9.1	
4.4.12	9.2, 12.7.4	
4.4.13	9.2, 12.7.4	
4.4.14	9.2, 12.7.1, 12.7.4	
4.4.15	7.5	
4.4.16	9.1, 12.7.4	
4.4.17	9.1, 12.7.4	
4.4.18	12.6	
4.5.1	7.2, 9.3	
4.5.2	7.3, 9.3	
5.2	12.7.4	
5.3	9.1	
5.4	9.2, 12.7.4	
5.5	9.2, 12.7.4	
5.6	9.2, 12.7.1, 12.7.4	
5.7	7.5	
5.8	9.1, 12.7.4	
5.9	9.1, 12.7.4	
5.10	13.2	
6.1	13.2	
6.1.3	13.1, 13.3 a), 13.3 d), 13.5	
6.2	13.2	
6.3	3, 5	
6.3.1	5, 7.2, 7.6	
6.3.2	13.1, 13.3 b)	
7.1	13.1, 13.3 a), 13.4, 13.6 a)	
7.2	7.6, 9.1, 12.7.4, 13.6 c), 13.6 d)	
7.3	2, 13.1	
7.4 1st dash	9.3	
7.4 2nd dash	9.2	
7.4 3rd dash	9.1, 12.7.4, 13.6 c)	

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

Terminal units are the points on a medical gas pipeline system where the operator makes connections and disconnections for the supply of specified medical gases to anaesthetic machines, lung ventilators or other items of medical equipment. A wrong connection can create a hazard to the patient or operator. It is important that terminal units and their components be designed, manufactured, installed and maintained in such a way as to meet the basic requirements specified in this part of ISO 9170.

This part of ISO 9170 pays particular attention to:

— suitability of materials;

— gas specificity;

— cleanliness;

— testing;

— identification;

— information supplied.

This part of ISO 9170 specifies the provision of information for the installation and subsequent testing of terminal units prior to use. Testing of terminal units prior to use is critical to patient safety, and it is essential that terminal units are not used until full testing in accordance with ISO 7396-1 has been completed.

Annex A contains rationale statements for some of the requirements of this part of ISO 9170. The clauses and subclauses marked with an asterisk (*) after their number have corresponding rationale contained in Annex A, included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this document. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this part of ISO 9170, but will expedite any subsequent revisions.

Terminal units for medical gas pipeline systems —

Part 1: Terminal units for use with compressed medical gases and vacuum

1 Scope

1.1 This part of ISO 9170 applies to:

a) terminal units intended for use in medical gas pipeline systems in accordance with ISO 7396-1, for use with the following medical gases:

   — oxygen;

   — nitrous oxide;

   — medical air;

   — carbon dioxide;

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

b) terminal units intended for use in medical gas pipeline systems in accordance with ISO 7396-1, for use with the following gases and services:

   — oxygen-enriched air;

   — air for driving surgical tools;

   — nitrogen for driving surgical tools;

   — vacuum.

NOTE 1 Different names or symbols are used for air for driving surgical tools, such as instrument air, surgical air, air motor, air-700 and air-800.

NOTE 2 The requirements of this part of ISO 9170 can be used as guidelines for terminal units for other gases. These other gases will be considered for inclusion in this part of ISO 9170 when they come into general use.

It is intended especially to ensure the gas-specific assembly of terminal units and to prevent their interchange between different gases and services.

1.2 This part of ISO 9170 specifies requirements for terminal units for supply and disposal of nitrogen or air for driving surgical tools.

1.3 This part of ISO 9170 specifies requirements for probes intended to be connected to the gas-specific connection point which is part of the terminal unit.

1.4 This part of ISO 9170 does not specify the dimensions of probes or of the gas-specific connection points of the terminal units.

NOTE Certain regional or national standards specifying dimensions of probes and gas-specific connection points are given in the Bibliography.

1.5 This part of ISO 9170 does not specify the dimensions of NIST connectors, which are defined in ISO 5359.

1.6 This part of ISO 9170 does not specify the dimensions of DISS connectors, which are defined in CGA V-5[1) [12]].

1.7 This part of ISO 9170 does not specify the requirements for terminal units for anaesthetic gas scavenging systems (AGSS), which are covered in ISO 9170-2.

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 32:1977, *Gas cylinders for medical use — Marking for identification of content*

ISO 5359:—[2)], *Low-pressure hose assemblies for use with medical gases*

ISO 6506-1:2005, *Metallic materials — Brinell hardness test — Part 1: Test method*

ISO 7396-1:2007, *Medical gas pipeline systems — Part 1: Pipeline systems for 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*

3 Terms and definitions

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

NOTE A diagram of a typical terminal unit and probe, with an example of terminology, is shown in Figure 1.

3.1
diameter-index safety system connector
DISS connector
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
gas-specific
having characteristics which prevent connections between different gas services

1) CGA = Compressed Gas Association.

2) To be published. (Revision of ISO 5359:2000)