Meditsiinilise gaasi torusüsteemid. Osa 1: Torustikud meditsiiniliste surugaaside ja vaakumi jaoks

Medical gas pipeline systems - Part 1: Pipelines for compressed medical gases and vacuum

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 7396-1:2007 sisaldab Euroopa standardi EN ISO 7396-1:2007 ingliskeelset teksti. Käesolev dokument on jõustatud 22.06.2007 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 7396-1:2007 consists of the English text of the European standard EN ISO 7396-1:2007. This document is endorsed on 22.06.2007 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: Käesolev Euroopa standard määratleb põhinõuded meditsiiniliste surugaaside ja vaakumtorustike süsteemide paigaldamise, toimimise, läbilaskevõime, dokumentatsiooni, kontrollimise ja kasutussevõtmise jaoks eesmärgiga tagada patsiendi ohutus, varustades teda torusüsteemi abil pidevalt õige gaasiga.	**Scope:** This part of ISO 7396 specifies requirements for design, installation, function, performance, documentation, testing and commissioning of pipeline systems for compressed medical gases, gases for driving surgical tools and vacuum in healthcare facilities to ensure continuous delivery of the correct gas and the provision of vacuum from the pipeline system. It includes requirements for supply systems, pipeline distribution systems, control systems, monitoring and alarm systems and non-interchangeability between components of different gas systems.

ICS 11.040.10

Võtmesõnad: abrasion, compressed gases, definitions, gas distribution, gas installation, gas pipelines, information, junctions, marking, medical equipment, medical gases, safety, specifications, suction hoses, tests, warning systems

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 7396-1

April 2007

ICS 11.040.10

Supersedes EN 737-3:1998

English Version

Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum (ISO 7396-1:2007)

Réseaux de distribution de gaz médicaux - Partie 1: Réseaux de distribution de gaz médicaux comprimés et de vide (ISO 7396-1:2007)

Rohrleitungssysteme für medizinische Gase - Teil 1: Rohrleitungenssyteme für medizinische Druckgase und Vakuum (ISO 7396-1:2007)

This European Standard was approved by CEN on 24 February 2007.

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

This European Standard 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 CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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 United Kingdom.

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

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

Ref. No. EN ISO 7396-1:2007: E

Foreword

This document (EN ISO 7396-1:2007) has been prepared by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI, in collaboration with Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment".

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 2007, and conflicting national standards shall be withdrawn at the latest by April 2009.

This document supersedes EN 737-3:1998.

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 EU Directive(s).

For relationship with EU Directive(s), 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 United Kingdom.

Annex ZA
(informative)

Relationship between this International Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical devices

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 on 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 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, Medical devices

Clause(s)/Sub-clause(s) of this International Standard	Essential Requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
4	1, 2, 7.1, 7.3	
4.3.2	9.3	
4.3.3	7.1	
4.3.4	9.2, 9.3, 12.7.1	
4.3.5	9.3	
4.3.6	7.1, 9.3, 12.7.1	
4.3.7	7.2, 7.6	
4.3.8	7.2, 7.6	
4.3.9	9.2	
5.5.2.12	3, 9.2	
4.4.1	2, 3	
4.4.2	1, 2, 3, 4	
5.1 to 5.2.7	1, 2, 3, 4, 7.6, 12.8.1, 12.8.2	
5.2.8	3	
5.3.1 to 5.3.4	2, 3, 7.6	
5.3.5	7, 12.7.1	
5.3.6	7, 12.7.1	
5.3.7	7.1, 9.3	
5.3.8	7.1	
5.4	3	
5.5.1	3, 12.8	
5.5.2.1 to 5.5.2.10	3, 7.2, 12.8	
5.5.2.11	7.6	
5.5.2.13	12.7.2	
5.5.3	3, 7.2, 7.6, 12.8	
5.6	3, 7.2, 7.6, 9.3, 12.8	

Clause(s)/Sub-clause(s) of this International Standard	Essential Requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
5.7.1 to 5.7.7	3, 8.1, 12.8.1	
5.7.8 to 5.7.9	7,6, 8.1	
5.7.10	12.7.2	
5.8 to 5.10	2, 3	
6	1, 2, 3, 4, 12.3, 12.8.1, 12.8.2, 12.9	
7	1, 2, 3	
7.1	9.3, 12.7.1	
7.2.1 to 7.2.4	2, 3	
7.2.5	9.2	
7.2.6	9.2	
7.3	2, 3, 4	
7.4	2, 3, 12.8	
8	1, 2	
9	9.1, 12.7.4, 13.6 c)	
9.3	9.2, 12.5, 12.6	
10	13.2	
11	1, 2, 3, 4, 9	
11.1.3	12.6	
12.1 to 12.4	1, 2, 3	
12.5.1	9.3, 12.7.1, 9.2	
12.5.2	7.5, 9.3, 12.7.1, 9.2	
12.6.1	7.5, 12.7.1	
12.6.2 to 12.6.9	2, 3, 7.5, 12.8	
12.6.10	7.2	
12.6.11	7.2	
12.6.12	7.2	
12.6.13	7.2	
12.6.14	7.2	
12.6.15 to 12.6.16	12.7.4, 12.8.1	
13	4, 13.1, 13.3, 13.6 c), 13.6 d), 13.6 e), 13.6 k), 13.6 l), 13.6 m), 13.6 n)	

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

INTERNATIONAL STANDARD

ISO 7396-1

Second edition
2007-04-01

Medical gas pipeline systems —

Part 1: Pipeline systems for compressed medical gases and vacuum

Réseaux de distribution de gaz médicaux —

Partie 1: Réseaux de distribution de gaz médicaux comprimés et de vide

Reference number
ISO 7396-1:2007(E)

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Published in Switzerland

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 7396-1 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in collaboration with Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 7396-1:2002), which has been technically revised.

ISO 7396 consists of the following parts, under the general title *Medical gas pipeline systems*:

— *Part 1: Pipeline systems for compressed medical gases and vacuum*

— *Part 2: Anaesthetic gas scavenging disposal systems*

Introduction

Many healthcare facilities use pipeline systems to deliver medical gases and to provide vacuum to areas where they are used in patient care or to power equipment such as ventilators and surgical tools.

This part of ISO 7396 specifies requirements for pipeline systems for compressed medical gases, gases for driving surgical tools and vacuum. It is intended for use by those persons involved in the design, construction, inspection and operation of healthcare facilities treating human beings. Those persons involved in the design, manufacture and testing of equipment intended to be connected to pipeline systems should also be aware of the contents of this document.

This part of ISO 7396 seeks to ensure that medical gas pipelines contain only the specific gas (or vacuum) intended to be supplied. For this reason, gas-specific components are used for terminal units and for other connectors which are intended to be used by the operator. In addition, each system is tested and certified to contain only the specific gas (or vacuum).

The objectives of this part of ISO 7396 are to ensure the following:

a) non-interchangeability between different pipeline systems by design;

b) continuous supply of gases and vacuum at specified pressures by providing appropriate sources;

c) use of suitable materials;

d) cleanliness of components;

e) correct installation;

f) provision of monitoring and alarm systems;

g) correct marking of the pipeline system;

h) testing, commissioning and certification;

i) purity of the gases delivered by the pipeline system;

j) correct operational management.

Annex H contains rationale statements for some of the requirements of this part of ISO 7396. It is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this part of ISO 7396. The clauses and subclauses marked with **(*)** after their number have a corresponding rationale contained in Annex H.

Medical gas pipeline systems —

Part 1: Pipeline systems for compressed medical gases and vacuum

1 Scope

This part of ISO 7396 specifies requirements for design, installation, function, performance, documentation, testing and commissioning of pipeline systems for compressed medical gases, gases for driving surgical tools and vacuum in healthcare facilities to ensure continuous delivery of the correct gas and the provision of vacuum from the pipeline system. It includes requirements for supply systems, pipeline distribution systems, control systems, monitoring and alarm systems and non-interchangeability between components of different gas systems.

This part of ISO 7396 is applicable to:

a) pipeline systems for the following medical gases:

— oxygen;

— nitrous oxide;

— medical air;

— carbon dioxide;

— oxygen/nitrous oxide mixtures (see Note 1);

b) pipeline systems for the following gases:

— **(*)** oxygen-enriched air;

— air for driving surgical tools;

— nitrogen for driving surgical tools;

c) pipeline systems for vacuum.

This part of ISO 7396 also applies to:

— extensions of existing pipeline distribution systems;

— modifications of existing pipeline distribution systems;

— modifications or replacement of supply systems or sources of supply.

NOTE 1 Regional or national regulations can prohibit the distribution of oxygen/nitrous oxide mixtures in medical gas pipeline systems.

(*) NOTE 2 EN 14931 [23] defines additional or alternative requirements for the specific application, in particular for flows and pressures of compressed air required to pressurize the hyperbaric chambers and to drive other connected services and of oxygen and other treatment gases administered to patients.

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 3746, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane*

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

ISO 8573-1:2001, *Compressed air — Part 1: Contaminants and purity classes*

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

ISO 10083, *Oxygen concentrator supply systems for use with medical gas pipeline systems*

ISO 10524-2, *Pressure regulators for use with medical gases — Part 2: Manifold and line pressure regulators*

ISO 11197, *Medical supply units*

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

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

ISO 21969, *High-pressure flexible connections for use with medical gas systems*

IEC 60601-1-8, *Medical electrical equipment — Part 1-8: General requirements for safety — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

EN 286-1, *Simple unfired pressure vessels designed to contain air or nitrogen — Part 1: Pressure vessels for general purposes*

EN 1041, *Information supplied by the manufacturer with medical devices*

EN 13348, *Copper and copper alloys — Seamless, round copper tubes for medical gases or vacuum*

3 Terms and definitions

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

3.1
air compressor system
supply system with compressor(s) designed to provide medical air or air for driving surgical tools or both

3.2
air for driving surgical tools
natural or synthetic mixture of gases, mainly composed of oxygen and nitrogen in specified proportions, with defined limits for the concentration of contaminants, supplied by a medical gas pipeline system and intended for driving surgical tools

NOTE 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.