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

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



EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 737-	This Estonian standard EVS-EN 737-
1:1999 sisaldab Euroopa standardi EN	1:1999 consists of the English text of the
737-1:1998 ingliskeelset teksti.	European standard EN 737-1:1998.
Käesolev dokument on jõustatud 23.11.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.	This document is endorsed on 23.11.1999 with the notification being published in the official publication of the Estonian national standardisation organisation.

Standard on kättesaadav Eesti standardiorganisatsioonist.

The standard is available from Estonian standardisation organisation.

Käsitlusala:

Standardi käesolev osa esitab nõuded liitmikele, mis on ette nähtud kasutamiseks järgmiste meditsiiniliste gaaside torusüsteemides: hapnik, dilämmastikoksiid, õhk hingamiseks, süsinikdioksiid, hapniku / dilämmastikoksiidi segu (50/50 % (mahuprotsent)), õhk kirurgiariistade käitamiseks, lämmastik kirurgiariistade käitamiseks; ning vaakumi jaoks ettenähtud torusüsteemides.

Scope:

ICS 11.040.10

Võtmesõnad: aparatuuri tehnilised andmed, gaasisegu jaotamine, konstruktsioon, meditsiinilised gaasid, mehaanilised omadused, märgistus, määratlused, pakkimine, surugaas, testimine, värvuskoodid, ühenduskohad

EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

EN 737-1

January 1998

ICS 11.040.10; 23.040.60; 23.060.01

Descriptors: Compressed gas, medical pipeline systems, terminal units, vacuum.

English version

Medical gas pipeline systems

Part 1: Terminal units for compressed medical gases and vacuum

Systèmes de distribution de gaz médicaux – Partie 1: Prises murales pour gaz médicaux comprimés et pour le vide (aspiration) Rohrleitungssysteme für medizinische Gase – Teil 1: Entnahmestellen für medizinische Druckgase und Vakuum

This European Standard was approved by CEN on 1997-07-05.

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 Central Secretariat or to any CEN member.

The European Standards exist 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

CEN

European Committee for Standardization Comité Européen de Normalisation Europäisches Komitee für Normung

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

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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 by July 1998, and conflicting national standards shall be withdrawn at the latest by July 1998.

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 special national conditions and transition periods for clause 7.2.1, see annex C.

EN 737 consists of the following Parts under the general title 'Medical gas pipeline systems'.

Part 1: Terminal units for compressed medical gases and vacuum

Part 2: Anaesthetic gas scavenging disposal systems

Part 3: Pipelines for compressed medical gases and vacuum

Part 4: Terminal units for anaesthetic gas scavenging systems

Part 5 : Oxygen concentrators

Part 6: Dimensions of probes for terminal units for compressed medical gases and vacuum

Dimensions of probes are specified in prEN 737-6, which has a Date of Withdrawal (DoW) of [DOP + 15 yrs].

Until this time, products complying with national standards may continue to be used for the maintenance and repair of probes.

Annex C forms a normative part of this Part of this European Standard. Annexes A, B are informative.

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

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

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, and where a wrong connection may create a hazard to the life of a patient.

It is important that terminal units and their components are designed, manufactured, installed and maintained in such a way as to meet the basic requirements specified in this Part of this European Standard. This Part of this European Standard pays particular attention to:

- suitability of materials;
- gas-specificity;
- cleanliness;
- testing;
- identification;
- information supplied.

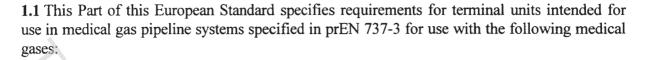
In any health care facility, it is strongly recommended that terminal units of only one type (i.e. with the same set of dimensions for probe and socket) are used for any particular gas. During hospital renovation it may be desirable to upgrade existing medical gas installations rather than renew them completely.

It is recognized that with modified terminal units it may not be possible to achieve the flow and pressure drop requirements of this Part of this European Standard, due to limitations imposed by the pipeline system itself or by those components of the original terminal units that remain in the pipeline system.

This Part of this European Standard specifies the provision of information for the installation and testing of terminal units. Testing after installation is critical to patient safety and it is essential that terminal units are not used until full testing in accordance with prEN 737-3 has been completed.

Rationales for some of the requirements of this Part of this European Standard are given in annex B. These requirements are indicated by the letter 'R' after the clause number.

1 Scope



- oxygen;
- nitrous oxide;
- air for breathing;
- carbon dioxide;
- oxygen/nitrous oxide mixture (50/50 % (V/V))
- air for driving surgical tools;
- nitrogen for driving surgical tools
- vacuum.

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

- 1.2 This Part of this European Standard also specifies requirements for:
 - terminal units for the supply and disposal of air for driving surgical tools;
 - probes intended to be connected to the gas-specific connection point which is part of a terminal unit;
- 1.3 This Part of this European Standard does not specify:
 - the dimensions of probes and of the gas-specific connection points of the terminal unit (see prEN 737-6);
 - the dimensions of NIST connectors (see EN 739);
 - requirements for terminal units for anaesthetic gas scavenging systems (see EN 737-4)

2 Normative references

This Part of 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 revisions 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 737-3	Medical gas pipeline systems Part 3: Pipelines for compressed medical gases and vacuum - Basic requirements
EN 739	Low-pressure hose assemblies for use with medical gases
prEN 1441	Medical devices - Risk analysis
ISO 32	Gas cylinders for medical use - Marking for identification of content
ISO 554	Standard atmospheres for conditioning and/or testing - Specifications

3 Definitions

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

- **3.1 gas-specific:** Having characteristics which prevent interchangeability and thereby allow assignment to one gas or vacuum service only.
- **3.2 gas-specific connection point:** That part of the socket which is the receptor for a gas-specific probe.
- 3.3 gas-specific connector: NIST (non-interchangeable screw-threaded) connector (see EN 739) or a probe (see prEN 737-6).