SLOVENSKI STANDARD
SIST EN 737-1:2000

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Sistemi napeljav za medicinske pline - 1. del: Končni deli za stisnjene medicinske pline in podtlak

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

Rohrleitungssysteme für medizinische Gase - Teil 1: Entnahmestellen für medizinische Druckgase und Vakuum

Systemes de distribution de gaz médicaux - Partie 1: Prises murales pour gaz médicaux comprimés et pour le vide (aspiration)

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11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

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Descriptors: gas distribution, medical gases, compressed gas, junctions, definitions, design, equipment specifications, mechanical properties, tests, marking, colour codes, packing

English version

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

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Rohrleitungssysteme für medizinische Gase - Teil 1: Entnahmestellen für medizinische Druckgase und Vakuum

This European Standard was approved by CEN on 5 July 1997.

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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 Central Secretariat has the same status as the official versions.

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

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

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Contents **Page**

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of an identical text or by endorsement, at the latest by July 1998, and conflicting national standards shall be withdrawn at the latest by July 1998.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

1.1 This Part of this European Standard specifies requirements for terminal units intended for use in medical gas pipeline systems specified in prEN 737-3 for use with the following medical gases:

- 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).

3.4 low-pressure hose assembly: Assembly which consists of a flexible hose with permanently-attached gas-specific inlet and outlet connectors which is designed to conduct a medical gas at pressures between 300 kPa and 1400 kPa and for use with a vacuum service at pressures above 10 kPa absolute (see EN 739).

3.5 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.

3.6 medical gas pipeline system: Central supply system with control equipment, a pipeline distribution system and terminal units at the points where medical gases or vacuum are required.

3.7 medical gas supply system: Either:

a) a medical gas pipeline system; or

b) any other installation having no permanent pipeline system but employing a medical gas supply source complete with pressure regulators.

3.8 NIST connectors; non-interchangeable screw-threaded connectors: Range of male and female components intended to maintain gas-specificity by the allocation of a set of different diameters and a left or right hand screw thread to the mating components for each particular gas.

3.9 nominal distribution pressure: Pressure which the pipeline distribution system is intended to deliver at the terminal units.

3.10 probe: Non-interchangeable male component designed for acceptance by and retention in the socket.

3.11 quick connector: Pair of non-threaded gas-specific components which can be easily and rapidly joined together by a single action of one or both hands without the use of tools.

3.12 single fault condition: Condition in which a single means for protection against a safety hazard in equipment is defective or a single external abnormal condition is present.

3.13 socket: That part of a terminal unit which is either integral or attached to the base block by a gas-specific interface and which contains the gas-specific connection point.

3.14 terminal unit: Outlet assembly (inlet for vacuum) in a medical gas supply system at which the operator makes connections and disconnections.

3.15 terminal unit base block: That part of a terminal unit which is attached to the pipeline distribution system.

3.16 terminal unit check valve: Valve which remains closed until opened by insertion of an appropriate probe and which then permits flow in either direction.

3.17 terminal unit for supply and disposal of air for driving tools: Combination of an outlet assembly (for the supply) and an inlet assembly (for disposal) which are connected to a supply system and to a disposal system respectively and at which the operator makes connections and disconnections by means of a combined probe.

3.18 terminal unit maintenance valve: Valve which permits maintenance of the terminal unit without shutting down the pipeline system to other terminal units.

4 Terminology

A diagram of a typical terminal unit with examples of terminology is given in figure 1.

5 General requirements

5.1 Safety

Terminal units shall, when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, cause no safety hazard which could be foreseen using risk analysis procedures in accordance with prEN 1441 and which is connected with their intended application, in normal condition and in single fault condition.

5.2 R Alternative construction

Terminal units and components or parts thereof, using materials or having forms of construction different from those detailed in clause 5 of this Part of this Standard shall be accepted if it can be demonstrated that an equivalent degree of safety is obtained.

Such evidence shall be provided by the manufacturer.

See annex C for special national conditions and transition periods.

5.3 Materials

5.3.1 The materials in contact with the gas shall be compatible with oxygen, the other medical gases and their mixtures in the temperature range specified in 5.3.2.

NOTE 1: Corrosion resistance includes resistance against moisture and surrounding materials.

NOTE 2: Compatibility with oxygen involves both combustibility and ease of ignition. Materials which burn in air will burn violently in pure oxygen. Many materials which do not burn in air will do so in pure oxygen, particularly under pressure. Similarly, materials which can be ignited in air require lower ignition energies for ignition in oxygen. Many such materials may be ignited by adiabatic compression produced when oxygen at high pressure is rapidly introduced into a system initially at low pressure.

NOTE 3: A standard '*Compatibility of medical equipment with oxygen*' is in preparation by ISO/TC 121/SC6.

5.3.2 The materials shall permit the terminal units and their components to meet the requirements of 5.4 in the temperature range of -20 °C to +60 °C.

5.3.3 Terminal units shall be capable, while packed for transport and storage, of being exposed to environmental conditions as stated by the manufacturer.

***5.3.4* R** Evidence of conformity with the requirements of 5.3.1, 5.3.2 and 5.3.3 shall be provided by the manufacturer.

5.4 Design requirements

5.4.1 *Medical gas supply pressure*

5.4.1.1 R Terminal units for oxygen, nitrous oxide, air for breathing, carbon dioxide and oxygen/nitrous oxide mixture 50/50 % (V/V) shall operate and meet the requirements of this Part of this European Standard for a medical gas supply having a pressure range from 320 kPa to 600 kPa.

5.4.1.2 R Terminal units for oxygen, nitrous oxide, air for breathing, carbon dioxide and oxygen/nitrous oxide mixture 50/50 % (V/V) shall not create a hazard to the patient or operator at an inlet pressure of 1000 kPa.

Evidence shall be provided by the manufacturer.

5.4.1.3 R Terminal units for oxygen, nitrous oxide, air for breathing, carbon dioxide and oxygen/nitrous oxide mixture 50/50 % (V/V) shall meet the requirements of 5.4.1.1 following exposure to an inlet pressure of 1000 kPa for 10 min.

5.4.1.4 R Terminal units for air for driving surgical tools and nitrogen for driving surgical tools shall operate and meet the requirements of this Part of this European Standard for a medical gas supply having a pressure range from 640 kPa to 1200 kPa.

5.4.1.5 R Terminal units for air for driving surgical tools and nitrogen for driving surgical tools shall not create a hazard to the patient or operator at an inlet pressure of 2000 kPa.

Evidence shall be provided by the manufacturer.

5.4.1.6 R Terminal units for air for driving surgical tools and nitrogen for driving surgical tools shall meet the requirements of 5.4.1.4 following exposure to an inlet pressure of 2000 kPa for 10 min.

5.4.1.7 R Terminal units for vacuum shall operate and meet the requirements of this Part of this European standard for a vacuum supply having a minimum absolute pressure of 10 kPa.

5.4.2 ***Terminal units for different pressures***

Terminal units for the same gas at different nominal operating pressures shall have gas-specific connection points for each pressure (e.g. the supply of air for driving surgical tools and air for breathing).

5.4.3 ***Incomplete assembly***

If any gas-specific component is removed from the terminal unit, either the terminal unit shall be rendered inoperable or the gas-specificity of the terminal unit shall be maintained.

If the terminal unit can be dismantled, the components shall not be capable of being reassembled in such a way that the fully-assembled terminal unit is no longer gas-specific.

5.4.4 ***Gas-specific connection point***

Each terminal unit shall include a gas-specific connection point which shall accept the appropriate gas-specific probe only. This connection point shall be included in a socket.

5.4.5 ***Terminal unit check valve***

Each terminal unit shall include a check valve which shall open the gas supply when the probe is connected and which shall shut off automatically when the probe is disconnected. The check valve shall be a separate component or assembly from the maintenance valve specified in 5.4.6.

5.4.6 ***Terminal unit maintenance valve***

Except for vacuum services, each terminal unit shall be equipped with a maintenance valve, which can be manual or automatic. The maintenance valve shall be a separate component or assembly from the check valve specified in 5.4.5.