SLOVENSKI STANDARD
SIST EN 739:2000

01-januar-2000

Nizkotlačne povezovalne cevi za delo z medicinskimi plini

Low-pressure hose assemblies for use with medical gases

Niederdruck-Schlauchleitungssysteme zur Verwendung mit medizinischen Gasen

Flexibles de raccordement a basse pression pour utilisation avec les gaz médicaux

Ta slovenski standard je istoveten z: **EN 739:1998**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
83.140.40	Gumene cevi	Hoses

SIST EN 739:2000 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 739

January 1998

ICS 11.040.10; 23.040.70

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

English version

Low-pressure hose assemblies for use with medical gases

Flexibles de raccordement à basse pression pour utilisation avec les gaz médicaux

Niederdruck-Schlauchleitungssysteme zur Verwendung mit medizinischen Gasen

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

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.

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

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

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.

For special national conditions and transition periods for clauses 5.4.8 and 7.2.1 see annex A.

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

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

Dimensions of probes are specified in prEN 737-6, which has a Date of Withdrawal (DoW) of [DOP + 15 yrs]. Until this time, national standards specifying dimensional requirements for the gas-specific connection point of the terminal unit may continue to be used for the maintenance and repair of systems.

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

This European Standard has been prepared in response to the need for a safe method of connecting medical equipment to a fixed medical gas pipeline system or other medical gas supply system such that hose assemblies carrying different gases, or the same gas at different pressures, cannot be interchanged. Fixed medical gas pipelines once installed are rarely disturbed and are subjected to commissioning procedures to avoid the possibility of cross-connections or contamination of the medical gas conveyed. However, hose assemblies are subjected to physical wear and tear, misuse and abuse throughout their relatively short service life and are frequently connected to, and disconnected from, the medical equipment and the fixed pipeline.

While recognizing that no system is absolutely safe, this standard includes those requirements considered necessary to prevent foreseeable hazards arising from the use of hose assemblies. Operators should be continually alert to the possibility of damage being caused by external factors and it is therefore essential that regular inspection and repair is undertaken to ensure that hose assemblies continue to meet the requirements of this European Standard.

This European Standard pays particular attention to:

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

Rationales for some of the requirements of this European Standard are given in annex B. Such requirements are indicated by the letter "***R***" after the clause number.

1 Scope

1.1 This European Standard specifies requirements for low-pressure hose assemblies intended for use with the following medical gases:

- oxygen;
- nitrous oxide;
- air for breathing;
- helium;
- carbon dioxide;
- xenon;
- specified mixtures of the gases listed above;
- air for driving surgical tools;
- nitrogen for driving surgical tools;
- vacuum.

It is intended especially to ensure gas-specificity and to prevent cross-connection between different gases.

These hose assemblies are intended to be used in the pressure range between 300 kPa and 1400 kPa for compressed medical gases and between 10 kPa and 100 kPa absolute pressure for vacuum.

1.2 This European Standard does not specify the intended uses of hose assemblies. Some examples of the intended uses specified in other standards are as follows:

a) between a terminal unit and medical equipment (see EN 737-1, prEN 740, EN 794-1);

b) between the fixed pipeline system and a terminal unit of that system (see prEN 737-3, EN 793);

c) between a terminal unit and a second terminal unit (see prEN 737-3);

d) between an emergency supply and an emergency and maintenance inlet point of a pipeline system (see EN 738-1, prEN 737-3);

e) between an emergency supply and medical equipment (see EN 738-1, prEN 740, EN 794- 1).

1.3 This European Standard specifies the dimensions of non-interchangeable screw-threaded (NIST) connectors.

1.4 This European Standard does not specify:

- dimensions of probes and of the mating parts of the socket (see prEN 737-6);

- requirements for hose assemblies for anaesthetic gas scavenging systems;

- requirements for coaxial hoses used for the supply and disposal of air for driving surgical tools;

- requirements for electrical conductivity.

2 Normative references

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.

EN 737-1:1998	Medical gas pipeline systems Part 1: Terminal units for compressed medical gases and vacuum
prEN 737-6	Medical gas pipeline systems Part 6: Dimensions of probes for terminal units for compressed medical gases and vacuum
EN 1441	Medical devices - Risk analysis
ISO 1402	Rubber and plastic hoses and hose assemblies - Hydrostatic testing
ISO 32	Gas cylinders for medical use - Marking for identification of content
ISO 554	Standard atmospheres for conditioning and/or testing - Specifications
ISO 1307	Rubber and plastic hoses for general-purpose industrial application - Bore diameters and tolerances, and tolerances on length
ISO 8033	Rubber and plastic hose - Determination of adhesion between components

3 Definitions

For the purposes 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 hose assembly check valve: Valve which is normally closed and which allows flow in either direction when opened by the insertion of an appropriate gas-specific connector.

3.3 hose insert: That portion of a connector which is pushed into and secured within the bore (lumen) of the hose.

3.4 inlet connector: Gas-specific part of a hose assembly which is connected to a medical gas supply system.

3.5 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 pressure.

3.6 maximum operating pressure: Maximum pressure for which the hose assembly is intended for use.

3.7 medical gas: Any gas or mixture of gases intended to be administered to patients for therapeutic, diagnostic or prophylactic purposes, or for surgical tool applications.

3.8 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.

3.9 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 source complete with pressure regulators.

3.10 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.

3.11 outlet connector: Gas-specific part of a hose assembly which is connected to the point where gas is delivered.

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

3.13 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.

3.14 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.

3.15 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.

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

4 Terminology

A diagram of the permitted inlet and outlet connectors on hose assemblies with examples of terminology is given in figure 1.

5 General requirements

5.1 Safety

Hose assemblies 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 EN 1441 and which is connected with their intended application, in normal condition and in single fault condition.

5.2 *R* Alternative construction

Hose assemblies and components or parts thereof, using materials or having forms of construction different from those detailed in this standard (except for dimensions and allocation of NIST connectors and of probes and the mating parts of the socket) 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 A 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 can be ignited by adiabatic compression produced when oxygen 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 hose assemblies and their components to meet the requirements of 5.4 in the temperature range of -10 °C to +40 °C.

5.3.3 Hose assemblies 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 ***Hose internal diameter***

5.4.1.1 The internal diameter (bore) of hoses shall be in accordance with ISO 1307.

5.4.1.2 Hoses for compressed medical gases shall have a nominal internal diameter of at least 5 mm.

5.4.1.3 Hoses for vacuum shall have a nominal internal diameter of at least 6,3 mm.

5.4.2 ***Mechanical strength***

5.4.2.1 ***R*** The minimum bursting pressure of hoses used for all services (except vacuum) shall be not less than 5600 kPa at 23 °C and not less than 4000 kPa at 40 °C. Evidence shall be provided by the manufacturer.

5.4.2.2 The hose assemblies shall resist the following axial tensile forces for 60 s:

a) hoses for compressed medical gases: 600 N;

b) hoses for vacuum: 300 N.

The test for mechanical strength is given in 6.5.

5.4.3 ***Deformation under pressure***

5.4.3.1 When the pressure is increased from 50 kPa to 1400 kPa, the increase in outside diameter shall not exceed 5 % of the original diameter.

5.4.3.2 When the pressure is increased from 50 kPa to 1400 kPa, the change in length shall not exceed 5 % of the original length.

The test for deformation under pressure is given in 6.6.

5.4.4 ***Resistance to occlusion***

The reduction of a flow of 20 l/min shall not exceed 10 % and the hose shall show no visible deformation under the following conditions:

a) hoses for compressed medical gases:

test pressure: 320 kPa
test force: 400 N;

b) hoses for vacuum:

test pressure: 10 kPa absolute pressure
test force: 300 N.

The test for resistance to occlusion is given in 6.7.

5.4.5 ***Adhesion strength***

The adhesion strength, according to ISO 8033, shall be at least 1,5 kN/m for rubber hoses and at least 4 kN/m for plastic hoses.

5.4.6 ***Flexibility of hoses***

The unsupported and unpressurized hose shall be capable of being formed to an inner radius of ten times the internal diameter of the hose without visible kinking.

5.4.7 ***Gas-specificity***

5.4.7.1 Hose assemblies for different gases shall have gas-specific connectors for each gas.

5.4.7.2 Hose assemblies for the same gas for different nominal operating pressures shall have gas-specific connectors for each pressure (e.g. the supply of air for driving surgical tools and air for breathing).

The test for gas-specificity is given in 6.4.

5.4.8 ***End connectors***

Hose assemblies shall terminate at one end with an inlet connector and at the other end with an outlet connector (see figure 1).

See annex A for special national conditions and transition periods.