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Medical gas pipeline systems - Part 3: Pipelines for compressed medical gases and vacuum

Rohrleitungssysteme für medizinische Gase - Teil 3: Rohrleitungen für medizinische Druckgase und Vakuum

Systemes de distribution de gaz médicaux - Partie 3: Systèmes de distribution pour gaz médicaux comprimés et vide (aspiration)

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

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Rohrleitungssysteme für medizinische Gase - Teil 3: Rohrleitungen für medizinische Druckgase und Vakuum

This European Standard was approved by CEN on 4 September 1998.

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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.

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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of an identical text or by endorsement, at the latest by April 1999, and conflicting national standards shall be withdrawn at the latest by April 1999.

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.

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 6 - *Dimensions of probes for terminal units for compressed medical gases and vacuum* (in preparation)

Annexes A, B, C, D, E, F, G, H, J, K, L and ZA are given for information only.

Annex L contains rationale statements for this part of this European Standard. The clause and sub-clauses which have corresponding rationale statements are marked with **R** after their number.

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 specifies basic requirements for compressed medical gases and vacuum pipeline systems.

This European Standard seeks to ensure that medical gas pipelines contain only the specific gas 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.
These specifications and procedures are undermined by the lack of European Standards for gas-specific connections on gas and non-cryogenic liquid cylinders and mobile and stationary cryogenic vessels. Until European Standards for these items are published and implemented, the safety of patients depends upon different National Standards together with manufacturer's specifications.

1 Scope

1.1 This European Standard specifies basic requirements for installation, function, performance, documentation, testing and commissioning of compressed medical gases and vacuum pipeline systems to ensure patient safety by continuous delivery of the correct gas from the pipeline system.

It includes basic requirements for the sources of supply, distribution system, control, monitoring and alarm systems and for non-interchangeability between components of different gas systems.

The objective of this Part of this European Standard is to ensure the following :

a) design of equipment to ensure non-interchangeability between different gas systems;

b) provision of reserve supplies of gas and reserve plant in order to ensure continuous supply;

c) use of correct materials, and their cleanliness;

d) correct installation;

e) control, monitoring and alarm systems;

f) marking of the pipeline system;

g) testing, commissioning and certification;

h) purity of the gases delivered by the system.

The scope of this European Standard does not include the provision of gas-specific connectors for mobile and stationary cryogenic vessels and transport vehicles, nor for the inlet/outlet of non-cryogenic liquid and gas cylinders. Such gas-specific connectors, however, are essential to ensure that only the correct gas can be used for the gas supply to the patient.

1.2 This European Standard applies only to pipeline systems for 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

and to pipeline systems for :

- vacuum.

1.3 This European Standard does not apply to terminal units, dimensions of probes, hose assemblies and colour coding for medical gases which are specified in other parts of this European Standard (EN 737-1 and prEN 737-6 : 1996) and in other European Standards (EN 739).

1.4 This European Standard does not apply to pipeline systems supplied by oxygen concentrators which comply with ISO 10083.

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 143 : 1990	*Respiratory protective devices - Particle filters - Requirements, testing, marking.*
EN 286-1	*Simple unfired pressure vessels designed to contain air or nitrogen - Part 1: Pressure vessel for general purposes.*
EN 475	*Medical devices - Electrically-generated alarm signals.*
EN 737-1	*Medical gas pipeline systems - Part 1 - Terminal units for compressed medical gases and vacuum.*
prEN 738-2:1998	*Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators*
EN 739	*Low-pressure hose assemblies for use with medical gases*
EN 793	*Particular requirements for safety of medical supply units.*
EN 850	*Transportable gas cylinders - Pin-index yoke-type valve outlet connections for medical use.*
EN 1441	*Medical devices - Risk analysis*
EN ISO 9001	*Quality systems - Model for quality assurance in design/development, production, installation and servicing. (ISO 9001:1994)*
EN 46001	*Quality systems - Medical devices - Particular requirements for the application of EN ISO 9001.*
HD 384	*Electrical installations of buildings.*

ISO 3746	*Acoustics - Determination of sound power levels of noise sources using sound pressure - Survey method using an enveloping measurement surface over a reflecting plane*
ISO 5145	*Cylinder valve outlets for gases and gas mixtures - Selection and dimensioning.*

3 Definitions

For the purposes of this standard the following definitions apply :

3.1 air compressor system : Source of supply with compressor(s) designed to provide air for breathing and/or air for driving surgical tools.

3.2 air for breathing : Natural or synthetic mixture mainly composed of nitrogen and oxygen in specified proportions (approximately 21% oxygen and 79% nitrogen (V/V)) with defined limits for the concentration of contaminants, supplied by a pipeline system and intended for administration to patients.

3.3 air for driving surgical tools : Natural or synthetic mixture mainly composed of nitrogen and oxygen in specified proportions (approximately 21% oxygen and 79% nitrogen (V/V)) with defined limits for the concentration of contaminants, supplied by a pipeline system and intended for driving surgical tools.

3.4 commissioning : Proof of function to verify that the agreed system specification is met and is accepted by the user or his representative.

3.5 control equipment : Items necessary to maintain the gas supply at a set pressure within the pipeline distribution system, such as pressure regulators, relief valves, alarm initiators and manual and automatic valves.

3.6 cryogenic liquid system : Source of supply containing liquified gas stored under cryogenic conditions.

3.7 cylinder bundle : Pack or pallet of cylinders linked together with a single connector for filling and emptying.

3.8 diversity factor : Factor which represents the maximum proportion of terminal units in a defined clinical area which will be used at the same time at flows defined in agreement with the hospital management.

3.9 double - stage pipeline distribution system : Pipeline distribution system in which gas is initially distributed from the source of supply at a higher pressure than the nominal distribution pressure; this higher pressure is then reduced by additional line pressure regulators.

3.10 emergency alarm : Visual and auditory alarm to indicate to technical and clinical staff that the supply is outside normal operating limits.

3.11 gas-specific : Having characteristics which prevent interchangeability, thereby allowing assignment to one gas or vacuum service only.

3.12 gas-specific connector : Connectors which are either Non-Interchangeable Screw-Threaded (NIST) or non-interchangeable quick-connectors of terminal units.

3.13 line pressure regulator : Pressure regulator with a maximum inlet pressure of 3000 kPa intended to be fitted within a medical gas pipeline system.

3.14 low-pressure hose assembly : Assembly which consists of a hose with permanently attached gas-specific inlet and outlet connectors.

3.15 manifold : Device for connecting the outlet(s) of one or more sources of the same medical gas within the pipeline system.

3.16 manifold pressure regulator : Pressure regulator with a maximum inlet pressure of 20 000 kPa intended to be installed within sources of supply containing cylinders.

3.17 maximum distribution pressure : Pressure downstream of any terminal unit when the pipeline distribution system is operating at zero flow.

3.18 medical gas pipeline system : Complete system which comprises a source of supply, a pipeline distribution system and terminal units at the points where medical gases or anaesthetic gas scavenging may be required.

3.19 medical oxygen concentrator : System comprising compressor(s), nitrogen adsorber unit(s) and reservoir by means of which oxygen-enriched, clean, dry, oil-free air is generated from atmospheric air.

NOTE : One example is a pressure swing adsorber.

3.20 minimum distribution pressure : Lowest pressure downstream of any terminal unit when the pipeline distribution system is operating at the system design flow.

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

3.22 nominal supply system pressure : Pressure which the supply system is intended to deliver at the inlet to the line pressure regulators.

3.23 non-cryogenic liquid system : Source of supply containing liquified gas stored under non-cryogenic conditions.

3.24 non-return valve : Valve which permits flow in one direction only.

3.25 operating alarm : Visual or visual and auditory alarm to indicate the necessity for technical staff to adjust the supply or to correct a malfunction.

3.26 pipeline distribution system : Part of a pipeline system linking the source of supply to the terminal units, including any necessary branch isolation valves and additional line pressure regulators as required.

3.27 pressure-relief valve : Valve to limit pressure.

3.28 primary supply : Portion of the source of supply which supplies the pipeline distribution system.

3.29 proportioning system : Central supply system in which gases can be mixed in specified ratios.

3.30 reserve supply : Portion of the source of supply which supplies the pipeline distribution system in the event of failure of the primary and secondary supplies or for emergency and maintenance purposes.

3.31 secondary supply : Portion of the source of supply which automatically supplies the pipeline distribution system when the primary supply becomes exhausted or fails and then becomes the primary supply.

3.32 shut-off valve : isolating valve : Manual or automatic valve which prevents flow in both directions when closed.

3.33 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.

3.34 single stage pipeline distribution system : Pipeline distribution system in which gas is distributed from the source of supply at the nominal distribution pressure.

3.35 source of supply : Supply system with associated control equipment which supplies the pipeline.

3.36 system design flow : Flow calculated from the maximum flow requirements of the health care facility corrected by the operational diversity factor.

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

3.38 vacuum system : Source of supply with vacuum pumps designed to provide a vacuum.

4 General Requirements

4.1 Safety

Pipeline systems shall, when installed, commissioned, 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.

4.2 R Alternative construction

Pipeline installation and components or parts thereof, using materials or having forms of construction different from those detailed in 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.

4.3 Materials

4.3.1 R The manufacturer shall disclose, upon request, evidence of the corrosion resistance and of the compatibility of the materials used for pipelines, and for all components of the system, with oxygen under the operating conditions specified by the manufacturer.

NOTE 1 : Corrosion resistance includes resistance against the influence of moisture and the surrounding materials in contact with the components.

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, the ignition energy in oxygen is lower than that in air. Many such materials can 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*' (prEN 13159) is under preparation by CEN/TC 215.

4.3.2 R All components of the systems which can be exposed to cylinder pressure in normal or in single fault condition shall withstand a pressure of 1,5 times the cylinder pressure for 15 min.

Evidence shall be provided by the manufacturer.

4.3.3 R All components of the systems which can be exposed to cylinder pressure in normal or in single fault condition shall not ignite when submitted to oxygen pressure shocks. The test for ignition is given in 6.2.8 of prEN 738-2:1998.

Evidence shall be provided by the manufacturer.

4.3.4 R All non-metallic components of the systems, including lubricants and thread sealants, which in normal condition are exposed to the nominal supply system pressure shall have an autoignition temperature not lower than 200 °C; all non-metallic components of the systems, including lubricants and thread sealants, which in normal condition are exposed to the nominal distribution pressure shall have an autoignition temperature not lower than 160 °C.

Compliance shall be demonstrated by testing in accordance with 6.4 of prEN 738-2:1998 or by providing evidence from published data.

4.3.5 R If lubricants are used, they shall be compatible with oxygen, the other medical gases and their mixtures at the operating conditions specified by the manufacturer.

Evidence shall be provided by the manufacturer.

4.3.6 R All components of the system which are liable to come in contact with the medical gas shall be supplied clean and free from oil, grease and particulate matter.

Evidence shall be provided by the manufacturer.

NOTE 1 : Any method of cleaning and degreasing can be used which effectively removes all surface dirt and hydrocarbons, and which leaves no residue itself. Chemical cleaning methods will normally require a subsequent washing and drying process to remove residues.

NOTE 2 : Examples of cleaning procedures will be described in a standard, '*Compatibility of medical equipment with oxygen*' (prEN 13159) which is under preparation by CEN/TC 215.

4.3.7 Pipeline components which come into contact with the gas shall be protected against the ingress of contaminants prior to and during installation.

4.3.8 R If copper pipes are used for pipelines, they should comply with a standard under preparation (prEN 13348) . Pipes of materials other than copper, used for compressed medical gases, should comply with the cleanliness requirements of a standard under preparation (prEN 13348).

Evidence shall be provided by the manufacturer.

NOTE : Copper is the material normally used for pipelines.

5 Source of Supply

5.1 General requirements

5.1.1 The sizing of the storage capacity of any source of supply and its reserve shall be based on the estimated usage and the frequency of delivery by the gas supplier.

NOTE : The capacity of the primary, secondary and reserve supplies of all sources of supply should be defined by hospital management in consultation with the manufacturer and the gas supplier.

The number of cylinders held in store should also be defined. Appropriate storage facilities for cylinders should be provided in accordance with the relevant requirements.

5.1.2 All sources of supply shall cause no interruption of gas supply in normal condition and in single fault condition.

NOTE : Loss of mains electrical power is a single fault condition.

5.1.3 The source of supply shall consist of one or more of the following :

a) gas in cylinders (figures A.1 and A.2);

b) non-cryogenic liquid in cylinders (figures A.1 and A.2);

c) cryogenic liquid in mobile vessels (figures A.3 and A.4);

d) cryogenic liquid in stationary vessels (figures A.5 to A.8);

e) an air compressor system (figures A.9 to A.16);

f) a proportioning system (figures A.17 and A.18);

g) a vacuum system (figure A.19).

5.1.4 All pressure regulators shall be capable of controlling pipeline pressure at levels which meet the requirements specified in table 1.

TABLE 1 - Change from nominal distribution pressure %

	Maximum distribution pressure %	Minimum distribution pressure %	Test flow (l/min)
Compressed medical gases	+10	-10	40
Air and nitrogen for driving surgical tools	+15	-15	350
Vacuum	+10	-10	25

NOTE 1 : The following factors will contribute to the pressure change :

- performance of line pressure regulators;
- pressure drop in the pipeline downstream of the line pressure regulator;
- pressure drop across the terminal unit.

NOTE 2 : Examples of diversity factors are given in HTM 2022 and NF S 90-155

5.1.5 Control systems shall be designed so that regulators and automatic change-over devices can be maintained without interrupting the gas supply to the pipeline distribution system, e.g. with duplex components or by-pass.

5.1.6 R For pipeline systems for oxygen, nitrous oxide, air for breathing, carbon dioxide and oxygen/nitrous oxide mixture (50/50 (%)V/V) the pressure supplied to the terminal units shall not exceed 1 000 kPa in single fault condition of any pressure regulator installed within the system. Means such as pressure relief valves shall be provided to prevent this from occurring; bursting discs shall not be used.

Evidence shall be provided by the manufacturer.

NOTE : Attention is drawn to a series of European Standards 'prEN 1268 *Safety devices for the protection against excessive pressure*' which is in preparation by CEN/TC 69 .

5.1.7 R For pipeline systems for air and nitrogen for driving surgical tools the pressure supplied to the terminal units shall not exceed 2 000 kPa in single fault condition of any pressure regulator installed within the system. Means such as pressure relief valves shall be provided to prevent this from occurring; bursting discs shall not be used.

Evidence shall be provided by the manufacturer.

NOTE : Attention is drawn to a series of European Standards 'prEN 1268 *Safety devices for the protection against excessive pressure*' which is in preparation by CEN/TC 69 .

5.1.8 For all gases, except for air, the means of pressure relief shall be vented to the outside of the building.

5.1.9 Means of pressure relief shall not be isolated from the pipeline or the pressure regulator to which it is connected.

If a valve or a flow-limiting device is incorporated for maintenance it shall be opened by the insertion of the means of pressure relief.

5.1.10 The pipeline systems shall be provided with a main shut-off valve adjacent to the source of supply.

5.1.11 Except for pipelines for air or nitrogen for driving surgical tools, an emergency and maintenance inlet point shall be provided downstream of the main shut-off valve.

5.1.12 R The emergency and maintenance inlet point shall be gas-specific (e.g. by using one or more Non-Interchangeable Screw Threaded (NIST) bodies) and shall have a means of pressure-relief and a shut-off valve. The inlet shall be physically protected to prevent tampering and unauthorized access.

If NIST bodies are not used, evidence of gas-specificity shall be provided by the manufacturer.

NOTE 1 : See also annex G.

NOTE 2 : The emergency and maintenance inlet point can be located outside of the area of the source of supply and should preferably allow access by vehicles.

NOTE 3 : The dimensions of the inlet point should take into account the system design flow.

5.1.13 The reserve supply shall be permanently connected and shall be operated either manually or automatically in the event of both the primary and the secondary supplies being unable to supply the pipeline or for maintenance purposes. In both cases, this connection shall be downstream of the main shut-off valve.

5.2 Supply system with cylinders

NOTE : Typical supply systems with gas or non-cryogenic liquid cylinders are shown in figures A.1 and A.2.

5.2.1 A cylinder manifold system shall have two banks (or groups) of cylinders or cylinder bundles which alternately supply the pipeline, each bank having its cylinders connected to a common header with a separate manifold pressure regulator complying with prEN 738-2:1998. When the content of the primary bank becomes exhausted, the secondary bank shall come into operation automatically to supply the pipeline system.

NOTE 1: When an exhausted bank of cylinders is replaced, it is permissible for the automatic change-over to be reset either manually or automatically.

NOTE 2 : Vent valves can be fitted on cylinder manifolds; if fitted, the valve outlets should be vented outside of the building.

5.2.2 Except for reserve supplies and cylinder banks with less than two cylinders, a non-return valve shall be installed at the manifold end of each flexible connector between the cylinder and the manifold. Reserve supplies with more than one cylinder shall be fitted with either a manually operated valve or a non-return valve.

5.2.3 A cylinder supply system shall comprise :

a) a primary supply which supplies the pipeline;