

Medical gas pipeline systems —

Part 3: Pipelines for compressed medical gases and vacuum

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National foreword

This British Standard is the official English language version of EN 737-3:1998 incorporating Amendment EN737-3:1998/A1:1999.

The UK participation in its preparation was entrusted by Technical Committee CH/44, Anaesthetic machines, breathing attachments, medical gas pipeline systems and hose assemblies, to Subcommittee CH/44/2, Medical gas supply systems, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

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Summary of pages

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Rohrleitungssysteme 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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EUROPEAN COMMITTEE FOR STANDARDIZATION
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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of an identical text or by endorsement, at the latest by April 1999, and conflicting national standards shall be withdrawn at the latest by April 1999.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 subclauses 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.

Foreword to EN 737-3:1998/A1:1999

This Amendment EN 737-3:1998/A1:1999 to EN 737-3:1998 has been prepared by Technical Committee CEN/TC 215, Respiratory and anaesthetic equipment, the Secretariat of which is held by BSI.

This Amendment to the European Standard EN 737-3:1998 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2000, and conflicting national standards shall be withdrawn at the latest by June 2000.

This Amendment to the European Standard EN 737-3:1998 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).

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.

The purposes of this amendment are:

- to correct the range of materials (**4.3.8**);
- to delete requirements for air for breathing and air for driving surgical tools that were in conflict with the European Pharmacopoeia (**5.4.1.4/5**);
- to correct errors in pressures and to accommodate pressures used in some member states (Tables 1 and 3).

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;
- e) 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.*

EN 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 3 000 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.

4.2R 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

4.3.1R 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.

4.3.2R 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.

4.3.3R 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 EN 738-2:1998.

Evidence shall be provided by the manufacturer.

4.3.4R 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 EN 738-2:1998 or by providing evidence from published data.

4.3.5R 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.

4.3.6R 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.

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

4.3.8R Metallic materials shall be used for compressed medical gas pipelines. If copper pipes of ≤ 54 mm diameter are used for pipelines, they shall comply with prEN 13348:1998. Pipes of materials other than copper used for compressed medical gases shall comply with the cleanliness requirements of prEN 13348:1998.

Evidence shall be provided by the manufacturer.

NOTE 1 Copper pipes of ≥ 54 mm diameter can be used for vacuum. Such pipes need not comply with prEN 13348:1998.

NOTE 2 Copper is the material normally used for pipelines.

NOTE 3 Non-metallic materials can be used for vacuum 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	0	not applicable	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.

5.1.6R 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.

5.1.7R 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.

5.1.12R 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 EN 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;
- b) a secondary supply which shall operate automatically to supply the pipeline as the primary becomes exhausted;
- c) a reserve supply.

5.2.4 A filter having a pore size no greater than 100 µm shall be provided between the cylinder(s) and the first pressure regulator or within the manifold pressure regulator, if fitted.

5.2.5 The flexible connections between the cylinders and the manifold, intended to be disconnected during cylinder changing operations, shall be gas-specific at the cylinder valve connection in accordance with EN 850, ISO 5145 or with the relevant national standards (see ISO/TR 7470 for information).

5.2.6 The flexible connections between the cylinders and the manifold, intended to be disconnected during cylinder changing operations, shall be marked with the following:

- the name and/or the trademark of the manufacturer and/or supplier;
- the symbol and/or the name of the gas or the gas mixture;
- means to ensure traceability such as batch or serial number or year of manufacture.

5.2.7R Means shall be provided to prevent incorrect replacement of the flexible connections between the cylinders and the manifold, e.g. by the use of gas-specific connections at the manifold.

Evidence shall be provided by the manufacturer.

5.2.8R Polymer-lined flexible hoses shall not be used as flexible connections between the cylinders and the manifolds.

NOTE A standard, "*High pressure flexible connections for use with medical gases*", is under preparation by CEN/TC 215/WG3.

5.3 Supply systems with mobile or stationary cryogenic vessels

NOTE 1 Typical supply systems with mobile cryogenic vessels are shown in Figures A.3 and A.4. Typical supply systems with stationary cryogenic vessels are shown in Figures A.5 to A.8.

NOTE 2 Standards for cryogenic vessels are in preparation by CEN/TC 268, "*Cryogenic vessels*".

5.3.1 The supply system with mobile or stationary cryogenic vessels shall comprise three sources of supply and shall be one of the following:

- a) one vessel and a reserve supply with two banks of cylinders;
- b) two vessels and a reserve supply with one bank of cylinders.

5.3.2 All bulk liquid vessel connectors shall be gas-specific and non-interchangeable between services. Adaptors shall not be used.

NOTE The source of supply should be fitted with an outlet where a sample can be taken for analysis.

5.3.3 A supply system with mobile or stationary cryogenic vessels shall be provided with a means to relieve excess pressure arising from the evaporation of entrapped cryogenic liquid.

NOTE A means of pressure relief can consist of one or more pressure relief valves or bursting discs.

5.4 Air systems

5.4.1 *General Requirements*

5.4.1.1 A supply system for air for breathing and for driving surgical tools shall be one of the following:

- a) an air compressor system as specified in **5.4.2**;
- b) a proportioning system as specified in **5.5**;
- c) a cylinder supply system as specified in **5.2**.

5.4.1.2 If the air for breathing or the air for driving surgical tools is used for purposes such as:

- a) the operation of ceiling columns;
- b) anaesthetic gas scavenging systems;
- c) breathing air for medical personnel;
- d) testing of medical equipment;
- e) hyperbaric chambers,

means shall be provided to prevent back-flow into the pipeline of air for breathing and into the pipeline of air for driving surgical tools. The flow requirements of these applications shall be taken into account.

5.4.1.3 The air for breathing and the air for driving surgical tools shall not be used for applications such as:

- a) sterilizing systems;
- b) pneumatic control of air conditioning;
- c) general workshop use;
- d) motor repair workshop;
- e) spray painting;
- f) tyre inflation;
- g) reservoirs for pressurization of hydraulic fluids;
- h) those applications which can impose unforeseen demands which could prejudice the availability and/or quality of air for normal patient care purposes.

5.4.1.4 Not used.

5.4.1.5 Not used.

5.4.2 Air compressor system

NOTE Typical air compressor systems are shown in Figures A.9 to A.16.

5.4.2.1 The supply system for air for breathing shall contain at least three air sources. An air source is a compressor unit or a single cylinder bank or a proportioning unit.

During normal maintenance on any one air source, a second air source shall provide the system design flow. In the case of a single fault condition on the second air source whilst maintenance is in progress on the first air source, a third air source shall be capable of supplying the pipeline system with the design flow.

In an air compressor system with more than one compressor, there shall be at least two conditioning systems.

NOTE 1 An air compressor system for air for breathing typically comprises one of the following:

- a) one compressor unit with one receiver, a single conditioning system and a reserve supply with two banks of cylinders;
- b) two compressor units with one receiver, a duplex conditioning system and a reserve supply with two banks of cylinders;
- c) two compressor units with two receivers, a duplex conditioning system and a reserve supply with one bank of cylinders;
- d) two compressor units with two receivers, a duplex conditioning system and a proportioning unit as a reserve supply;
- e) three compressor units with two receivers and a duplex conditioning system.

NOTE A compressor unit normally comprises the following:

- a) an inlet filter;
- b) a silencer;
- c) a compressor;
- d) after-cooler with shut-off valve and automatic drain;
- e) a separator with shut-off valve and automatic drain.

NOTE A conditioning system normally comprises the following:

- a) a dryer with shut-off valve and automatic drain;
- b) a pre-filter;
- c) an activated charcoal filter;
- d) a particle filter;
- e) a dew point alarm switch.

5.4.2.2 If the air for driving surgical tools is not derived from an air compressor system for air for breathing and an independent air compressor system for driving surgical tools is provided, it shall contain two air sources.

NOTE An air compressor system for driving surgical tools typically comprises one the following:

- a) one compressor unit with one receiver, a single conditioning system and a reserve supply with a single bank of cylinders;
- b) two compressor units with two receivers and a duplex conditioning system.

5.4.2.3 Receivers shall comply with EN 286-1. Each receiver shall be fitted with a shut-off valve, an automatic drain, a pressure gauge and a pressure-relief valve. Each group of receivers shall be arranged so as to allow each receiver in that group to be maintained separately.

NOTE Means should be provided to prevent corrosion of the receivers.

5.4.2.4 The system shall be fitted with pressure control device(s) to control the operation of the compressor(s).

5.4.2.5 If a duplex conditioning system is fitted, it shall be arranged to allow the components to be maintained separately.

5.4.2.6 When more than one compressor unit is fitted, each compressor shall have a control circuit arranged so that shutting off, or failure, of one compressor will not affect the operation of other compressor(s). The automatic controls for multiple compressors shall be arranged so that all the units will supply the system in turn or simultaneously.

5.4.2.7 All air systems shall comply with **5.1.2**.

NOTE It can be necessary to connect some air sources to the emergency electrical power supply.

5.4.2.8 The intake for the air compressors shall be located in a position where there is minimal contamination from internal combustion engine exhaust, vacuum systems, anaesthetic gas scavenging systems, ventilation system discharge and other contaminants. The air intake shall be provided with means to prevent the intake of insects and particulate matter.

5.4.2.9 Except when supplying a double stage distribution system, an air compressor system shall include a pressure-regulating system to maintain a constant pressure in the pipeline distribution system. In the case of air for breathing, supplied by three or more compressors without a cylinder bank as a reserve supply, the pressure regulating system shall be duplexed.

5.4.2.10 A flexible connection shall be installed between each compressor and the pipeline to prevent transmission of vibration.

5.4.2.11R Means shall be provided to prevent the release of toxic products into the breathing air supplied by air compressors.

Evidence shall be provided by the manufacturer.

5.5 Proportioning systems

NOTE 1 A typical proportioning system, for example for blending oxygen and nitrogen to produce synthetic air for breathing [a mixture of approximately 21 % oxygen and 79 % nitrogen (V/V)], is shown in Figures A.17 and A.18.

NOTE 2 A proportioning system typically consists of a proportioning unit and a reserve supply with two banks of cylinders.

NOTE 3 The proportioning unit normally comprises the following:

- a) a mixer provided with a pressure controlled shut-off valve, a pressure regulator and a non-return valve for each of the gases (e.g. oxygen and nitrogen);
- b) a receiver fitted with a pressure-relief valve;
- c) an analyser connected downstream of the receiver;
- d) a pressure controlled shut-off valve connected downstream of the receiver.

5.5.1 The sources of supply of medical gases for proportioning systems shall conform to the requirements of **5.1** to **5.3** and may be the same sources as those supplying the medical gas pipelines separately. Means shall be used to prevent cross contamination between gases.

5.5.2 A source of supply of air for breathing employing a proportioning system shall include a reserve supply in the form of two banks of cylinders and which shall be permanently connected downstream of the main shut-off valve.

5.5.3 A proportioning system shall operate automatically. The mixture shall be analysed continuously and a recording capability shall be provided, e.g. via a data port. This analysing system shall be completely independent of any analyser, if provided, which is used to control the proportioning system. If the mixture goes out of specification, an alarm shall be activated, the proportioning system shall be automatically disconnected and changed-over to the reserve supply. The system shall be arranged so that manual intervention is necessary to correct the composition of the mixture before reconnecting the proportioning system to the pipeline system.

5.5.4 A proportioning system shall be capable of supplying a mixture of the required composition over the entire range of specified flows.

5.5.5 A proportioning system shall include means for verifying the calibration of the analysing systems by reference to mixture(s) of known composition.

5.6 Vacuum systems

NOTE Typical vacuum systems are shown in Figure A.19.

5.6.1 A source of supply shall comprise three or more vacuum pumps, one or more reservoirs, two or more bacterial filters and one or more drainage traps.

5.6.2 The flow of the source of supply shall be such that the system design flow can be supplied with two units out of service.

5.6.3 Controls for the pump(s) shall be provided to activate the additional pump(s) automatically should the operating pump of the system be incapable of maintaining an adequate vacuum.

5.6.4 Each pump of the source of supply shall have a control circuit arranged so that shutting-off, or failure, of one pump will not affect the operation of other pump(s).

5.6.5 All vacuum systems shall comply with **5.1.2**.

NOTE It will be necessary to connect some vacuum sources to the emergency electrical power supply.

5.6.6 Reservoirs shall comply with appropriate pressure vessel standards.

NOTE Means should be provided to prevent corrosion of the reservoirs.

5.6.7 A drain valve shall be fitted to each reservoir.

5.6.8 The exhaust from the vacuum pumps shall be piped to the outside and shall be provided with a means to prevent the intake of insects and particulate matter. It shall be in a position where risk of contamination of occupied buildings is minimized.

NOTE The exhaust can be provided with a silencer and a drain valve.

5.6.9 A flexible connection shall be installed between the vacuum pump and the pipeline to prevent the transmission of vibrations.

5.7 Location of cylinder manifolds

The location of cylinder manifolds shall be defined in collaboration with the local Authorities and in accordance with the appropriate standards. Informative guidelines are given in annex B.

5.8 Location of stationary cryogenic vessels

The location of stationary cryogenic vessels shall be defined in collaboration with the local authorities and in accordance with the appropriate standards. Informative guidelines are given in annex B.

5.9 General requirements for supply plants

5.9.1 The ambient temperature in enclosures or rooms for supply systems for any gas supplied in cylinders shall not exceed 50 °C.

Means shall be provided to prevent loss of pressure or gas separation in cylinders of nitrous oxide, oxygen/nitrous oxide mixtures and carbon dioxide.

5.9.2 Unless otherwise stated by the manufacturers of air compressors, vacuum pumps and proportioning systems, the temperature in the plant rooms for such equipment shall not exceed 40 °C and shall not be less than 10 °C.

5.9.3 Vacuum and air compressor plants, shall be located separately from other medical gas sources of supply. The location shall be provided with drainage facilities. Guidelines for other requirements are given in annex F.

NOTE Vacuum and air compressor plants should be installed in a well lit, ventilated and clean location.

5.9.4 All sources of supply shall be readily accessible for maintenance.

5.10 Double stage pipeline distribution system

For emergency and maintenance purposes shut-off valves shall be fitted upstream and downstream close to the line pressure regulators together with one of the following:

- a) a gas-specific connector (either a NIST body or the socket of a terminal unit) downstream of the downstream shut-off valve;
- b) a second line pressure regulator with shut-off valves upstream and downstream;
- c) gas-specific connectors (either a NIST body or the socket of a terminal unit) upstream of the upstream shut-off valve and downstream of the downstream shut-off valve.

NOTE Typical double stage pipeline distribution systems are shown in Figures A.2, A.4, A.6, A.8, A.13, A.14, A.15, A.16, and A.18. Alternative arrangements for line pressure regulators in accordance with **5.10** are shown in Figure A.20.

6 Monitoring and alarm systems

NOTE The monitoring and alarm systems have three major functions with different purposes, namely, operating alarms, emergency operating alarms, and clinical emergency alarms. The purpose of the operating alarms is to notify the technical staff that one or more sources within a source of supply is no longer available for use and it is essential that action be taken. Emergency operating alarms indicate abnormal pressure within a pipeline and could require emergency action by the technical staff. Clinical emergency alarms indicate abnormal pressure within a pipeline and could require emergency action by the clinical staff.

6.1 Installation requirements

6.1.1 If not specified in this European Standard, the location of indicator panels shall be determined by the hospital management using risk analysis procedures in accordance with EN 1441.

6.1.2 Monitoring and alarm systems, whether for operating or emergency purposes, shall comply with the following requirements:

- a) the design shall allow continuous observation of the indicator panels;
- b) the indicator panels for the emergency operating alarm signals specified in 6.5d), e) and f) shall also be installed at the same location as the source(s) of supply;
- c) the indicator panel(s) for the clinical emergency alarm signals specified in 6.4a), b) and c) shall be installed near to the area shut-off valve;
- d) pressure gauges or indicators, if provided, shall show deviation from the nominal distribution pressure range and shall be marked to indicate the gas and the area monitored;
- e) each visual indicator shall be marked according to its function;
- f) the sensing devices for operating alarms listed in 6.3 and for the emergency operating alarms listed in 6.5d), e) and f) shall be located at appropriate positions within the source of supply;
- g) the sensing devices for clinical emergency alarms listed in 6.4a), b) and c) shall be located downstream of every line pressure regulator and area shut-off valve;
- h) means shall be provided for testing the activation mechanism and integrity of visual and auditory alarm signals;
- i) a pressure-sensing device shall not be isolated, for example by a manually operated shut-off valve, from the pipeline to which it is connected. If a valve is incorporated for maintenance purposes, it shall be opened by the insertion of the sensing device;
- j) the operating tolerance on the set point of any pressure sensing device shall not exceed $\pm 4\%$.

6.1.3 Monitoring and alarm systems shall be connected to both the normal and the emergency electrical power supplies.

6.1.4 Alarm systems shall be electrically energized under normal conditions so that the alarm is initiated on electrical failure between sensor and indicator.

6.2 Monitoring and alarm signals

6.2.1 The characteristics of the monitoring and alarm signals specified in this European Standard shall be grouped in the following categories as specified in Table 2:

- a) clinical emergency alarms;
- b) emergency operating alarms;
- c) operating alarms;
- d) information signals.

6.2.2 Auditory signals

6.2.2.1 If a pattern of more than two tones or frequencies is used as an auditory signal, the auditory signal(s) for clinical emergency alarms shall conform to the requirements of EN 475.

6.2.2.2 All other auditory signals shall comprise one or two tones modulated equally, e.g. at a rate of 4 Hz between two tones of 440 Hz and 880 Hz. The A-weighted sound pressure level of the auditory components of these alarm signals at a minimum volume shall be at least 2 dB above a white background level of 55 dB when tested as described in ISO 3746.

6.2.2.3 If an auditory signal can be silenced by the operator, the silencing shall not prevent the auditory signal from being activated by a new or different alarm condition.

6.2.2.4 If an emergency auditory signal can be silenced by the operator, the period of silencing shall not exceed 15 min.

6.2.2.5 If means are provided to allow permanent silencing of the auditory signal, such means shall only be accessible to the technical staff.

6.2.3 Visual signals

6.2.3.1 The visual signals for clinical emergency alarms shall conform to the requirements of EN 475.

6.2.3.2 The indicator colour and the characteristics of all other visual signals shall be as given in Table 2.

NOTE Visual indications should be perceived correctly and discriminated between under the following conditions (see EN 475):

- a) the operator having a visual acuity of 1 (corrected if necessary); and
- b) the viewpoint being at a distance of 4 m and at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of display of the visual indication; and
- c) under an ambient illuminance throughout the range of 100 lx to 1 500 lx.

6.2.4 *Emergency and operating alarm characteristics*

6.2.4.1 There shall be a visual and a simultaneous auditory signal for clinical emergency alarms and emergency operating alarms (see Table 2).

6.2.4.2 There shall be at least a visual signal for operating alarms (see Table 2).

6.2.4.3 When the condition which has caused the alarm has cleared, the auditory signal shall reset automatically.

6.2.4.4 When the condition which has caused the alarm has cleared, the visual signal shall reset automatically or manually.

6.2.5 *Information signals*

Information signals shall be provided to indicate normal conditions and shall consist of a visual signal.

6.2.6 *Remote alarm extensions*

If a remote alarm extension is provided, it shall be arranged so that a failure in the external circuit will not affect the correct functioning of the main alarm.

Table 2 — Alarm categories and signal characteristics

Category	Operator response	Indicator colour	Visual signal	Auditory signal
Clinical emergency alarm	Immediate response to deal with a hazardous situation	Complying with EN 475	Complying with EN 475	Complying with EN 475 ¹⁾
Emergency operating alarm	Immediate response to deal with a hazardous situation	red	flashing	yes
Operating alarm	Prompt response to a hazardous situation	yellow	flashing	optional
Information signal	Awareness of normal status	not red/not yellow	constant	no
¹⁾ If a pattern of more than two tones or frequencies is used. NOTE Visual flashing frequencies for operating alarms and emergency operating alarms should be between 0,4 Hz and 2,8 Hz with a duty cycle between 20 % and 60 %.				

6.3 Provision of operating alarms

Operating alarm signals shall be provided to indicate the following:

- a) change-over from primary to secondary cylinder supply, if different from 6.3b);
- b) any primary, secondary or reserve cylinder supply below minimum pressure;
- c) the pressure in any cryogenic vessel has fallen below the minimum;
- d) the liquid level in the operating cryogenic vessel has fallen below the minimum defined by hospital management in consultation with the gas supplier;
- e) the liquid level in the reserve cryogenic vessel has fallen below the minimum defined by hospital management in consultation with the gas supplier;
- f) malfunctioning of air compressors and vacuum pumps as specified by the manufacturer;
- g) not used;
- h) malfunctioning of the proportioning system, as specified by the manufacturer;
- i) malfunctioning of the cryogenic system, as specified by the manufacturer.

6.4 Provision of clinical emergency alarms

Clinical emergency alarm signals shall be provided to indicate the following:

- a) for double stage distribution systems, the pipeline pressure downstream of any line pressure regulator deviates by more than $\pm 20\%$ from the nominal distribution pressure;
- b) the pipeline pressure downstream of any area shut-off valve deviates by more than $\pm 20\%$ from the nominal distribution pressure;
- c) the absolute pipeline pressure for vacuum upstream of any area shut-off valve has risen above 60 kPa.

6.5 Provision of emergency operating alarms

Emergency operating alarm signals shall be provided to indicate the following:

- a) for double stage distribution systems, the pipeline pressure downstream of any line pressure regulator deviates by more than $\pm 20\%$ from the nominal distribution pressure;
- b) the pipeline pressure downstream of any area shut-off valve deviates by more than $\pm 20\%$ from the nominal distribution pressure;
- c) the absolute pipeline pressure for vacuum upstream of any area shut-off valve has risen above 60 kPa.
- d) for single stage distribution systems, the pipeline pressure downstream of the main shut-off valve deviates by more than $\pm 20\%$ from the nominal supply system pressure;
- e) for double stage distribution systems, the pipeline pressure downstream of the main shut-off valve deviates by more than $+20\%$ and -30% from the nominal supply system pressure;
- f) the absolute pipeline pressure for vacuum upstream of the main shut-off valve has risen above 60 kPa.

7 Pipelines

7.1 Except for vacuum systems, all sections of medical gas pipeline systems shall withstand a pressure of 1,2 times the maximum pressure which can be applied to that section of the pipeline in single fault condition.

7.2 The nominal distribution pressure shall be within the ranges given in Table 3.

Table 3 — Ranges of nominal distribution pressure

Gas	Nominal distribution pressure kPa
Compressed medical gases	$400^{+100}_{0} \text{ }^1$
Air and nitrogen for driving surgical tools	$800^{+200}_{-100} \text{ }^1$
Vacuum	$\leq 60 \text{ }^2$
¹⁾ Above atmospheric pressure.	
²⁾ Absolute pressure.	

NOTE 1 Different gases can be delivered at different nominal distribution pressure in the same hospital. In locations such as intensive care units and operating theatres means can be provided to control the nitrous oxide pressure by the oxygen pressure in order to keep the nitrous oxide pressure below the oxygen pressure.

NOTE 2 Flexible connections in pipeline distribution systems are normally used as a part of the pipeline, for example for isolation of vibration, building movement and relative movement of the pipelines.

NOTE 3 Low-pressure hose assemblies in pipeline distribution systems are normally used:

- e) for emergency supply of gas to a pipeline;
- f) as part of permanently fixed equipment such as booms, pendants and pendant tracks.

7.3 The maximum distribution pressure and the minimum distribution pressure shall be within the limits given in Table 1.

7.4 Line pressure regulators shall comply with EN 738-2:1998.

7.5 Low-pressure hose assemblies, if provided, shall comply with EN 739.

7.6 If the flexible connections are part of the pipeline, for example when used for isolation of vibration, building movement and relative movement of the pipelines, and are not normally replaced during their life, the assembly need not be gas-specific.

These flexible connections shall be tested as part of the pipeline in accordance with clause 12.

8 Shut-off valves

8.1 For all shut-off valves in a medical gas pipeline system, except those in the source of supply, it shall be apparent by observation whether the valve is fully open or fully closed.

NOTE 1 Shut-off valves are classified as follows:

- a) service shut-off valves;
- b) area shut-off valves.

NOTE 2 Service shut-off valves are used as:

- a) main shut-off valves;
- b) riser shut-off valves;
- c) equipment shut-off valves.

8.2 All shut-off valves shall be identified:

- a) to indicate the gas service name or symbol;
- b) to indicate, in a manner appropriate to their classification as given in note 1 to **8.1**, the area or section of pipeline being served or their purpose.

This identification shall be secured to the valve, valve box or service pipeline and be readily visible at the valve site.

8.3 Service shut-off valves shall either be lockable in the open or closed position or shall be protected against improper operation.

NOTE Service shut-off valves should only be used by the maintenance and operating staff and should not be accessible to unauthorized persons.

8.4 Each riser shall be provided with a riser shut-off valve.

NOTE 1 Such shut-off valves can be provided for other branches.

NOTE 2 A full-bore purge valve with a preceding lockable shut-off valve can be provided at the bottom of each vertical riser.

8.5 Except for vacuum systems, an area shut-off valve shall be provided in each gas pipeline serving each operating theatre, critical care area, intensive care area and general ward area.

NOTE The extent of the areas served by each area shut-off valve should be assessed in accordance with EN 1441. The risk assessment should also take into account the hazards arising from the possible rupture of low-pressure hose assemblies fitted within any medical supply units.

8.6 All area shut-off valves shall be located in boxes with covers or doors.

NOTE Area shut-off valves should be accessible and should be used to isolate areas within health care facilities for maintenance and emergency purposes. Their operation, in the latter case, should be included as part of the emergency disaster plan.

8.7 Each box shall contain the following:

- a) an area shut-off valve;
- b) a means to allow physical separation of the service(s) when modifications are carried out to existing systems, downstream of the area shut-off valve(s), which shall be clearly visible when deployed. A closed valve is not considered an adequate mechanical disconnection.

8.8 All boxes shall be vented to the room to prevent accumulation of gas and shall have covers or doors, which can be secured in the closed position. The covers or doors shall have a means of quick access in case of emergency.

8.9 All boxes shall be located within normal hand height and shall be accessible at all times.

8.10 Except for pipelines for air and nitrogen for driving surgical tools an emergency and maintenance inlet point shall be provided downstream of each area shut-off valve.

8.11 The emergency and maintenance inlet point shall be gas-specific (either a NIST body or the socket of a terminal unit).

NOTE 1 The emergency and maintenance inlet point can be located within the box.

NOTE 2 The dimensions of the inlet point should take into account the flow required during emergency and maintenance activities.

9 Terminal units, gas-specific connectors and medical supply units

9.1 Terminal units shall comply with EN 737-1.

9.2 Gas-specific connectors shall be either the gas-specific connection point of a terminal unit complying with EN 737-1 or the body of a NIST connector complying with EN 739.

9.3 Medical supply units shall comply with EN 793.

10 Marking and colour coding

10.1 Marking

10.1.1 Pipelines shall be durably marked with the gas name (and/or symbol) adjacent to shut-off valves, at junctions and change of direction, before and after walls and partitions, etc., at intervals of no more than 10 m and adjacent to terminal units.

Such marking may be made, for example, of metal tags, stencilling, stamping or with adhesive markers.

10.1.2 Shut-off valves shall be durably marked with the mode of operation.

10.1.3 Marking shall:

- a) be with letters not less than 6 mm high;
- b) be applied with the gas name and/or symbol to be read along the longitudinal axis of the pipeline;
- c) include arrows denoting direction of flow.

10.2 Colour coding

If colour coding for pipelines is used for all or part of its length, it shall comply with EN 739 and shall be durable.

NOTE An example of test for durability of markings and colour coding is given in EN 739.