Medical gas pipeline systems —
Part 1: Pipeline systems for compressed medical gases and vacuum

Réseaux de distribution de gaz médicaux —
Partie 1: Réseaux de distribution de gaz médicaux comprimés et de vide
PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.
## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foreword</td>
<td>v</td>
</tr>
<tr>
<td>Introduction</td>
<td>vi</td>
</tr>
<tr>
<td>1 Scope</td>
<td>1</td>
</tr>
<tr>
<td>2 Normative references</td>
<td>2</td>
</tr>
<tr>
<td>3 Terms and definitions</td>
<td>2</td>
</tr>
<tr>
<td>4 General requirements</td>
<td>7</td>
</tr>
<tr>
<td>4.1 (* Safety</td>
<td>7</td>
</tr>
<tr>
<td>4.2 (* Alternative construction</td>
<td>7</td>
</tr>
<tr>
<td>4.3 Materials</td>
<td>8</td>
</tr>
<tr>
<td>4.4 System design</td>
<td>9</td>
</tr>
<tr>
<td>5 Supply systems</td>
<td>10</td>
</tr>
<tr>
<td>5.1 System components</td>
<td>10</td>
</tr>
<tr>
<td>5.2 General requirements</td>
<td>10</td>
</tr>
<tr>
<td>5.3 Supply systems with cylinders or cylinder bundles</td>
<td>12</td>
</tr>
<tr>
<td>5.4 Supply systems with mobile or stationary cryogenic or non-cryogenic vessels</td>
<td>13</td>
</tr>
<tr>
<td>5.5 Supply systems for air</td>
<td>13</td>
</tr>
<tr>
<td>5.6 Supply systems with oxygen concentrator(s)</td>
<td>17</td>
</tr>
<tr>
<td>5.7 Supply systems for vacuum</td>
<td>18</td>
</tr>
<tr>
<td>5.8 Location of supply systems</td>
<td>18</td>
</tr>
<tr>
<td>5.9 Location of cylinder manifolds</td>
<td>19</td>
</tr>
<tr>
<td>5.10 Location of stationary cryogenic vessels</td>
<td>19</td>
</tr>
<tr>
<td>6 Monitoring and alarm systems</td>
<td>19</td>
</tr>
<tr>
<td>6.1 General</td>
<td>19</td>
</tr>
<tr>
<td>6.2 Installation requirements</td>
<td>19</td>
</tr>
<tr>
<td>6.3 Monitoring and alarm signals</td>
<td>20</td>
</tr>
<tr>
<td>6.4 Provision of operating alarms</td>
<td>21</td>
</tr>
<tr>
<td>6.5 Provision of emergency clinical alarms</td>
<td>22</td>
</tr>
<tr>
<td>6.6 (* Provision of emergency operating alarms</td>
<td>22</td>
</tr>
<tr>
<td>7 Pipeline distribution systems</td>
<td>22</td>
</tr>
<tr>
<td>7.1 Mechanical resistance</td>
<td>22</td>
</tr>
<tr>
<td>7.2 Distribution pressure</td>
<td>22</td>
</tr>
<tr>
<td>7.3 Low-pressure hose assemblies and low-pressure flexible connections</td>
<td>23</td>
</tr>
<tr>
<td>7.4 Double-stage pipeline distribution systems</td>
<td>24</td>
</tr>
<tr>
<td>8 Shut-off valves</td>
<td>24</td>
</tr>
<tr>
<td>8.1 General</td>
<td>24</td>
</tr>
<tr>
<td>8.2 Service shut-off valves</td>
<td>25</td>
</tr>
<tr>
<td>8.3 Area shut-off valves</td>
<td>25</td>
</tr>
<tr>
<td>9 Terminal units, gas-specific connectors, medical supply units, pressure regulators and pressure gauges</td>
<td>26</td>
</tr>
<tr>
<td>10 Marking and colour coding</td>
<td>27</td>
</tr>
<tr>
<td>10.1 Marking</td>
<td>27</td>
</tr>
<tr>
<td>10.2 Colour coding</td>
<td>27</td>
</tr>
<tr>
<td>11 Pipeline installation</td>
<td>27</td>
</tr>
<tr>
<td>11.1 General</td>
<td>27</td>
</tr>
<tr>
<td>11.2 Pipeline supports</td>
<td>28</td>
</tr>
<tr>
<td>11.3 Pipeline joints</td>
<td>29</td>
</tr>
</tbody>
</table>
11.4 Extensions and modifications of existing pipeline systems.......................................................... 29
12 Testing, commissioning and certification.......................................................................................... 29
12.1 General........................................................................................................................................ 29
12.2 General requirements for tests..................................................................................................... 30
12.3 Inspections and checks before concealment............................................................................... 30
12.4 Tests, checks and procedures before use of the system.............................................................. 30
12.5 Requirements for inspections and checks before concealment.................................................. 31
12.6 Requirements for tests, checks and procedures before use of the system.................................... 31
12.7 Certification of the systems........................................................................................................ 36
13 Information to be supplied by the manufacturer............................................................................. 37
13.1 General....................................................................................................................................... 37
13.2 Instructions for use....................................................................................................................... 37
13.3 Operational management information.......................................................................................... 38
13.4 “As-installed” drawings.............................................................................................................. 38
13.5 Electrical diagrams..................................................................................................................... 38
Annex A (informative) Schematic representations of typical supply systems and area distribution systems.................................................................................................................................................................................................................................................. 39
Annex B (informative) Guidelines for location of cylinder manifolds, cylinder storage areas and stationary vessels for cryogenic or non-cryogenic liquids.................................................................................................................................................................................................................................................................................................................. 62
Annex C (informative) Example of procedure for testing and commissioning.................................. 63
Annex D (informative) Typical forms for certification of the medical gas pipeline system.................. 75
Annex E (informative) Temperature and pressure relationships.......................................................... 105
Annex F (informative) Risk management checklist............................................................................. 107
Annex G (informative) Operational management................................................................................. 120
Annex H (informative) Rationale......................................................................................................... 138
Bibliography........................................................................................................................................ 140
Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 7396-1 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, Respiratory and anaesthetic equipment, in collaboration with Technical Committee ISO/TC 121, Anaesthetic and respiratory equipment, Subcommittee SC 6, Medical gas systems, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 7396-1:2002), which has been technically revised.

ISO 7396 consists of the following parts, under the general title Medical gas pipeline systems:

— Part 1: Pipeline systems for compressed medical gases and vacuum
— Part 2: Anaesthetic gas scavenging disposal systems
Introduction

Many healthcare facilities use pipeline systems to deliver medical gases and to provide vacuum to areas where they are used in patient care or to power equipment such as ventilators and surgical tools.

This part of ISO 7396 specifies requirements for pipeline systems for compressed medical gases, gases for driving surgical tools and vacuum. It is intended for use by those persons involved in the design, construction, inspection and operation of healthcare facilities treating human beings. Those persons involved in the design, manufacture and testing of equipment intended to be connected to pipeline systems should also be aware of the contents of this document.

This part of ISO 7396 seeks to ensure that medical gas pipelines contain only the specific gas (or vacuum) 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 (or vacuum).

The objectives of this part of ISO 7396 are to ensure the following:

a) non-interchangeability between different pipeline systems by design;

b) continuous supply of gases and vacuum at specified pressures by providing appropriate sources;

c) use of suitable materials;

d) cleanliness of components;

e) correct installation;

f) provision of monitoring and alarm systems;

g) correct marking of the pipeline system;

h) testing, commissioning and certification;

i) purity of the gases delivered by the pipeline system;

j) correct operational management.

Annex H contains rationale statements for some of the requirements of this part of ISO 7396. It is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this part of ISO 7396. The clauses and subclauses marked with (*) after their number have a corresponding rationale contained in Annex H.
Medical gas pipeline systems —

Part 1:
Pipeline systems for compressed medical gases and vacuum

1 Scope

This part of ISO 7396 specifies requirements for design, installation, function, performance, documentation, testing and commissioning of pipeline systems for compressed medical gases, gases for driving surgical tools and vacuum in healthcare facilities to ensure continuous delivery of the correct gas and the provision of vacuum from the pipeline system. It includes requirements for supply systems, pipeline distribution systems, control systems, monitoring and alarm systems and non-interchangeability between components of different gas systems.

This part of ISO 7396 is applicable to:

a) pipeline systems for the following medical gases:
   — oxygen;
   — nitrous oxide;
   — medical air;
   — carbon dioxide;
   — oxygen/nitrous oxide mixtures (see Note 1);

b) pipeline systems for the following gases:
   — (*) oxygen-enriched air;
   — air for driving surgical tools;
   — nitrogen for driving surgical tools;

c) pipeline systems for vacuum.

This part of ISO 7396 also applies to:

— extensions of existing pipeline distribution systems;
— modifications of existing pipeline distribution systems;
— modifications or replacement of supply systems or sources of supply.

NOTE 1 Regional or national regulations can prohibit the distribution of oxygen/nitrous oxide mixtures in medical gas pipeline systems.

(*') NOTE 2 EN 14931 [23] defines additional or alternative requirements for the specific application, in particular for flows and pressures of compressed air required to pressurize the hyperbaric chambers and to drive other connected services and of oxygen and other treatment gases administered to patients.
2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3746, Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane

ISO 5359, Low-pressure hose assemblies for use with medical gases

ISO 8573-1:2001, Compressed air — Part 1: Contaminants and purity classes

ISO 9170-1, Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum

ISO 10083, Oxygen concentrator supply systems for use with medical gas pipeline systems

ISO 10524-2, Pressure regulators for use with medical gases — Part 2: Manifold and line pressure regulators

ISO 11197, Medical supply units

ISO 14971, Medical devices — Application of risk management to medical devices

ISO 15001:2003, Anaesthetic and respiratory equipment — Compatibility with oxygen

ISO 21969, High-pressure flexible connections for use with medical gas systems

IEC 60601-1-8, Medical electrical equipment — Part 1-8: General requirements for safety — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

EN 286-1, Simple unfired pressure vessels designed to contain air or nitrogen — Part 1: Pressure vessels for general purposes

EN 1041, Information supplied by the manufacturer with medical devices

EN 13348, Copper and copper alloys — Seamless, round copper tubes for medical gases or vacuum

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1 air compressor system
supply system with compressor(s) designed to provide medical air or air for driving surgical tools or both

3.2 air for driving surgical tools
natural or synthetic mixture of gases, mainly composed of oxygen and nitrogen in specified proportions, with defined limits for the concentration of contaminants, supplied by a medical gas pipeline system and intended for driving surgical tools

NOTE Different names or symbols are used for air for driving surgical tools, such as instrument air, surgical air, air motor, air - 700 and air - 800.
3.3 **branch**
portion of the pipeline distribution system which supplies one or more areas on the same floor of the facility

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 medical gas pipeline system within the specified operating parameters

NOTE Examples of control equipment are pressure regulators, pressure-relief valves, alarms, sensors, manual or automatic valves and non-return valves.

3.6 **cryogenic liquid system**
supply system containing a gas stored in the liquid state in a vessel at temperatures lower than \(-150 {^\circ}C\)

3.7 **cylinder bundle**
pack or pallet of cylinders linked together with one or more connectors 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 flowrates defined in agreement with the management of the healthcare facility

3.9 **double-stage pipeline distribution system**
pipeline distribution system in which gas is initially distributed from the supply system at a pressure higher than the nominal distribution pressure, and is then reduced to the nominal distribution pressure by line pressure regulator(s)

NOTE This initial higher pressure is the nominal supply system pressure (see 3.32).

3.10 **emergency clinical alarm**
alarm to indicate to medical and technical staff that there is abnormal pressure within a pipeline that requires an immediate response

3.11 **emergency inlet point**
inlet point which allows the connection of an emergency supply

3.12 **emergency operating alarm**
alarm to indicate to technical staff that there is abnormal pressure within a pipeline that requires an immediate response

3.13 **emergency supply**
source of supply intended to be connected to an emergency inlet point

3.14 **gas-specific**
having characteristics which prevent connections between different gas services
3.15 **gas-specific connector**
connector with dimensional characteristics which prevent connections between different gas services

**NOTE** Examples of gas-specific connectors are quick connectors, screw-threaded connectors, diameter-indexed safety system (DISS) connectors or non-interchangeable screw-threaded (NIST) connectors.

3.16 **high-dependency patient**
patient with a continual need of a medical gas/vacuum supply, who will be adversely affected by a medical gas/vacuum supply failure to such a degree that his/her clinical condition or his/her safety can be compromised

3.17 **information signal**
visual indication of normal status

3.18 **line pressure regulator**
pressure regulator intended to supply the nominal distribution pressure to the terminal units

3.19 **low-pressure hose assembly**
assembly consisting of a flexible hose with permanently attached gas-specific inlet and outlet connectors and designed to conduct a medical gas at pressures less than 1 400 kPa

3.20 **main line**
portion of the pipeline distribution system connecting the supply system to risers and/or branches

3.21 **maintenance supply assembly**
inlet point which allows the connection of a maintenance supply

3.22 **maintenance supply**
source of supply intended to supply the system during maintenance

3.23 **manifold**
device for connecting the outlet(s) of one or more cylinders or cylinder bundles of the same gas to the pipeline system

3.24 **manifold pressure regulator**
pressure regulator intended to be installed within sources of supply containing cylinders or cylinder bundles

3.25 **manufacturer**
natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party

3.26 **maximum distribution pressure**
pressure at any terminal unit when the pipeline system is operating at zero flow
3.27 medical air
natural or synthetic mixture of gases, mainly composed of oxygen and nitrogen in specified proportions, with defined limits for the concentration of contaminants, supplied by a medical gas pipeline system and intended for administration to patients

NOTE 1 Medical air can be produced by supply systems with air compressors or by supply systems with proportioning units.

NOTE 2 Medical air produced by air compressor systems is called “medicinal air” by European Pharmacopoeia 2005.

NOTE 3 Medical air produced by proportioning systems is called “synthetic medicinal air” by European Pharmacopoeia 2005.

3.28 medical gas
any gas or mixture of gases intended for administration to patients for anaesthetic, therapeutic, diagnostic or prophylactic purposes

3.29 medical gas pipeline system
complete system which comprises a supply system, a monitoring and alarm system and a distribution system with terminal units at the points where medical gases or vacuum are required

3.30 minimum distribution pressure
lowest pressure occurring at any terminal unit when the pipeline system is operating at the system design flow

3.31 nominal distribution pressure
pressure which the medical gas pipeline system is intended to deliver at the terminal units

3.32 nominal supply system pressure
pressure which the supply system is intended to deliver at the inlet to the line pressure regulators

3.33 non-cryogenic liquid system
supply system containing a gas stored under pressure in the liquid state in a vessel at temperatures not lower than $-50\, ^\circ C$

3.34 non-return valve
valve which permits flow in one direction only

3.35 operating alarm
alarm to indicate to technical staff that it is necessary to replenish the gas supply or to correct a malfunction

3.36 oxygen concentrator
device which produces oxygen-enriched air from ambient air by extraction of nitrogen

3.37 oxygen-enriched air
gas produced by an oxygen concentrator

3.38 pipeline distribution system
portion of a medical gas or vacuum pipeline system linking the sources of supply of the supply system to the terminal units
3.39 **pressure regulator**
device which reduces the inlet pressure and maintains the set outlet pressure within specified limits

3.40 **pressure-relief valve**
device intended to relieve excess pressure at a preset pressure value

3.41 **primary source of supply**
portion of the supply system which supplies the pipeline distribution system

3.42 **proportioning unit**
device in which gases are mixed in a specified ratio

3.43 **reserve source of supply**
that portion of the supply system which supplies the complete, or a portion(s) of the, pipeline distribution system in the event of failure or exhaustion of both the primary and secondary sources of supply

3.44 **riser**
portion of the pipeline distribution system traversing one or more floors and connecting the main line with branch lines on various levels

3.45 **secondary source of supply**
portion of the supply system which supplies the pipeline distribution system in the event of exhaustion or failure of the primary source of supply

3.46 **shut-off valve**
valve which prevents flow in both directions when closed

3.47 **silencing**
temporary stopping of an auditory alarm signal by manual action

**NOTE** This is also referred to as audio pausing.

3.48 **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

**NOTE** Maintenance of equipment is considered a normal condition.

3.49 **single-stage pipeline distribution system**
pipeline distribution system in which gas is distributed from the supply system at the nominal distribution pressure

3.50 **source of supply**
portion of the supply system with associated control equipment which supplies the pipeline distribution system
3.51 supply pressure regulator
pressure regulator fitted within a source of supply and intended to regulate the pressure supplied to the line
pressure regulator(s)

NOTE For a source of supply with cylinders or cylinder bundles, this is referred to as the manifold pressure regulator.

3.52 supply system
assembly which supplies the pipeline distribution system and which includes all sources of supply

3.53 system design flow
flow calculated from the maximum flow requirement of the healthcare facility and corrected by the diversity
factor(s)

3.54 terminal unit
outlet assembly (inlet for vacuum) in a medical gas pipeline system at which the operator makes connections
and disconnections

3.55 vacuum supply system
supply system equipped with vacuum pumps designed to provide a flow at negative pressure

4 General requirements

4.1 (*) Safety

Medical gas pipeline systems shall, when installed, extended, modified, commissioned, operated and
maintained according to the instructions of the manufacturer, present no risks that are not reduced to an
acceptable level using risk management procedures in accordance with ISO 14971 and which are connected
with their intended application, in normal condition and in single fault condition.

NOTE 1 A situation in which a fault is not detected is considered a normal condition. Fault conditions/hazardous
situations can remain undetected over a period of time and as a consequence can lead to an unacceptable risk. In that
case, a subsequent detected fault condition needs to be considered as a single fault condition. Specific risk control
measures to deal with such situations need to be determined within the risk management process.

NOTE 2 Typical safety hazards (including discontinuity of supply, incorrect pressure and/or flow, wrong gas supply,
wrong gas composition, contamination, leakage, fire) are listed in Annex F.

4.2 (*) Alternative construction

Pipeline installations and components, or parts thereof, using materials or having forms of construction
different from those detailed in this part of ISO 7396, shall be presumed to be in compliance with the safety
objectives of this part of ISO 7396 if it can be demonstrated that an equivalent degree of safety is obtained
(i.e. compliance with requirements presumes that risks have been mitigated to acceptable levels) unless
objective evidence to the contrary becomes available.

NOTE 1 Objective evidence can be obtained by post-market surveillance.

Evidence of an equivalent degree of safety shall be provided by the manufacturer.

NOTE 2 Regional or national regulations can require the provision of evidence to a competent authority or a conformity
assessment body, e.g. to a notified body in the European Economic Area (EEA) upon request.
4.3 Materials

4.3.1 (*) The manufacturer shall disclose, upon request, evidence of the corrosion resistance of the materials used for pipes and fittings.

NOTE Corrosion resistance includes resistance against the influence of moisture and the surrounding materials.

4.3.2 (*) The manufacturer shall disclose, upon request, evidence that the materials used in components of the medical gas pipeline system which come into contact with the actual gas shall be compatible with the actual gas and oxygen under normal and single fault condition. If lubricants are used, except within air compressors and vacuum pumps, they shall be compatible with oxygen during normal and single fault condition of the pipeline system.

Evidence shall be provided by the manufacturer.

NOTE 1 Criteria for the selection of metallic and non-metallic materials are given in ISO 15001.

NOTE 2 Regional or national regulations can require the provision of evidence to a notified body or competent authority upon request.

NOTE 3 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 less energy to ignite in oxygen. Many such materials can be ignited by friction at a valve seat or by adiabatic compression produced when oxygen at high pressure is rapidly introduced into a system initially at low pressure.

4.3.3 The specific hazards of toxic products from combustion or decomposition of non-metallic materials (including lubricants, if used) and potential contaminants shall be addressed. Some potential products of combustion and/or decomposition for some commonly available non-metallic materials are listed in Table D.7 of ISO 15001:2003.

NOTE Typical “oxygen-compatible” lubricants can generate toxic products on combustion or decomposition.

Annex E of ISO 15001:2003 gives details of suitable test and quantitative analysis methods for the products of combustion of non-metallic materials. Data from such tests shall be considered in any risk evaluation.

4.3.4 (*) Components of systems which can be exposed to cylinder pressure in normal or single fault condition shall function according to their specifications after being exposed to a pressure of 1.5 times the cylinder working pressure for 5 min.

Evidence shall be provided by the manufacturer.

NOTE Regional or national regulations can require the provision of evidence to a notified body or competent authority upon request.

4.3.5 (*) Components of systems which can be exposed to cylinder pressure in normal or single fault condition shall not ignite or show internal scorching damage when submitted to oxygen pressure shocks. The test for resistance to ignition shall be in accordance with ISO 10524-2.

Evidence shall be provided by the manufacturer.

NOTE Regional or national regulations can require the provision of evidence to a notified body or competent authority upon request.

4.3.6 (*) Except for low-pressure hose assemblies and low-pressure flexible connections, metallic materials shall be used for compressed medical gas pipelines. If copper pipes of ≤ 108 mm diameter are used for pipelines, they shall comply with EN 13348 or equivalent national standards. Copper pipes of > 108 mm diameter and pipes of materials other than copper which are used for compressed medical gases shall comply with the cleanliness requirements of EN 13348 or equivalent national standards. If non-metallic materials are used for vacuum pipelines, these materials shall be compatible with the potential contaminants that can be present in the vacuum system.
Evidence shall be provided by the manufacturer.

NOTE 1 Regional or national regulations can require the provision of evidence to a notified body or competent authority upon request.

NOTE 2 Copper pipes of >108 mm diameter are not covered by EN 13348.

NOTE 3 Copper is the preferred material for all medical gas pipelines, including vacuum.

4.3.7 Pipeline components which come in contact with the actual gas shall be supplied in a clean condition (see 4.3.8) and protected from contamination prior to, and during, installation.

4.3.8 (*) Components of the system other than pipes, which are liable to come in contact with the actual gas, shall meet the cleanliness requirements of ISO 15001.

NOTE Examples of cleaning procedures are described in ISO 15001.

4.3.9 Materials for pipelines and components installed in the vicinity of strong magnetic or electromagnetic fields [e.g. Nuclear Magnetic Resonance (NMR), Magnetic Resonance Imaging (MRI)] shall be selected for compatibility with these applications.

4.4 System design

4.4.1 General

The number of terminal units per bed-space/work-space and their location in each department or area of the healthcare facility, together with the corresponding flowrates required and the diversity factors, shall be defined by the management of the healthcare facility in consultation with the system manufacturer.

NOTE 1 Typical examples of locations of terminal units, flow requirements and diversity factors are given in HTM 02 [25], [26], FD S 90-155 [24], AS 2896-1998 [16] and SIS HB 370 [30].

The sizing of the pipelines shall take into account the potential hazards arising from high gas velocity.

NOTE 2 Examples of maximum recommended gas velocity are given in FD S 90-155 [24] and SIS HB 370 [30].

4.4.2 Extensions and modifications of existing pipeline systems

Extensions and modifications of existing pipeline systems shall comply with the relevant requirements of this part of ISO 7396. In addition, the following requirements apply:

a) the flow capacity of the supply system shall continue to meet the flow requirements of the extended or modified pipeline system. For this purpose, the existing supply system might need to be upgraded;

b) the flow and pressure drop characteristics of the existing pipeline distribution system shall continue to meet at least the original design specifications;

c) the flow and pressure drop characteristics of the extension or modification to the existing pipeline distribution system shall meet the requirements of 7.2. For this purpose, modifications of the existing pipeline distribution system might be needed.
5 Supply systems

5.1 System components

5.1.1 Except for air or nitrogen for driving surgical tools, each supply system shall comprise at least three independent sources of supply which can be a combination of the following:

a) gas in cylinders or cylinder bundles;
b) non-cryogenic liquid in cylinders;
c) cryogenic or non-cryogenic liquid in mobile vessels;
d) cryogenic or non-cryogenic liquid in stationary vessels;
e) an air compressor system;
f) a proportioning system;
g) an oxygen concentrator system (see ISO 10083).

5.1.2 A supply system for air or nitrogen for driving surgical tools shall comprise at least two sources of supply.

5.1.3 A supply system for vacuum shall consist of at least three vacuum pumps.

5.1.4 Schematic representations of typical supply systems are given in Annex A (Figures A.1 to A.27).

5.2 General requirements

5.2.1 Capacity and storage

The capacity and storage of any supply system shall be based on the estimated usage and frequency of delivery. The location and the capacity of the primary, secondary and reserve sources of supply of all supply systems and the number of full cylinders held in storage, as defined by the management of the healthcare facility in consultation with the gas supplier using risk management principles, shall be taken into account by the system manufacturer. Appropriate undercover storage facilities for cylinders should be provided to ensure that the cylinders are maintained in a safe, secured and clean condition.

5.2.2 Continuity of supply

5.2.2.1 The supply systems for compressed medical gases and vacuum shall be designed to achieve continuity of system design flow at a distribution pressure complying with 7.2 in normal condition and in single fault condition.

NOTE Loss of mains electrical power or water supply is a single fault condition. A fault in control equipment is a single fault condition.

In order to achieve this objective,

a) the supply systems for compressed medical gases and vacuum shall comprise at least three sources of supply, i.e. primary source of supply, secondary source of supply and reserve source of supply, and

b) the layout and the location of the pipelines shall reduce the risk of mechanical damage of the pipeline to an acceptable level.

Failure of the pipeline is considered a catastrophic event and not a single fault condition, and should be managed in accordance with the emergency procedure (see Annex G).
5.2.2 Control equipment shall be designed so that components can be maintained without interrupting the gas supply.

5.2.3 Primary source of supply

The primary source of supply shall be permanently connected and shall be the main source of supply to the medical gas pipeline.

5.2.4 Secondary source of supply

The secondary source of supply shall be permanently connected and shall automatically supply the pipeline in the event that the primary source of supply is unable to supply the pipeline.

5.2.5 Reserve source of supply

The reserve source of supply shall be permanently connected. Activation of the reserve supply in the event of both the primary and the secondary sources of supply being unable to supply the pipeline or for maintenance can be automatic or manual. A reserve source of supply can also be required for air or nitrogen for driving surgical tools.

The manufacturer together with the healthcare facility management shall determine the location of the reserve source(s) of supply to cover the complete pipeline system.

NOTE This can result in a number of reserve sources of supply, some or all of which could be close to the terminal units.

5.2.6 Means of pressure relief

5.2.6.1 For all compressed medical gases except air, pressure-relief valves shall be vented to the outside of the building and the vents shall be provided with means to prevent the ingress of, for example, insects, debris and water. The vents shall be located remote from any air intakes, doors, windows or other openings in buildings. Consideration shall be given to the potential effects of prevailing winds on the location of the vents.

5.2.6.2 All pressure-relief valves shall close automatically when excess pressure has been released.

5.2.6.3 It shall not be possible to isolate a means of pressure relief, for example by a shut-off valve, 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 fully opened by the insertion of the means of pressure relief.

NOTE Attention is drawn to regional, national and international standards for pressure-relief valves, e.g. ISO 4126-1.[1]

5.2.6.4 Means shall be provided to protect the pressure-relief valve from tampering.

5.2.6.5 Any portion of a pipeline within a supply system where gas in liquid phase can be entrapped between two shut-off valves shall be provided with means to relieve excess pressure resulting from vaporization of the liquid.

5.2.7 Maintenance supply assembly

5.2.7.1 Except for pipelines for vacuum and air or nitrogen for driving surgical tools, one or more maintenance supply assemblies shall be provided downstream of the main shut-off valve(s).

The manufacturer together with the healthcare facility management shall determine the location of the maintenance supply assembly.
5.2.7.2 The maintenance supply assembly shall have a gas-specific inlet connector, a means of pressure relief, a non-return valve and a shut-off valve. The design of the supply assembly shall take into account the flow which can be required under maintenance conditions. The supply assembly shall be physically protected to prevent tampering and unauthorized access.

The maintenance supply assembly should be located outside of the area of the supply system and should allow access by vehicles.

5.2.8 Pressure regulators

For single-stage pipeline distribution systems, the pressure regulators within the supply systems shall be capable of controlling pipeline pressure at levels which meet the requirements specified in Table 2, 7.2.2 and 7.2.3.

5.3 Supply systems with cylinders or cylinder bundles

5.3.1 A supply system with cylinders or cylinder bundles shall comprise:

a) a primary source of supply which supplies the pipeline;

b) a secondary source of supply which shall automatically supply the pipeline when the primary source of supply becomes exhausted or fails;

c) a reserve source of supply (except for air or nitrogen for driving surgical tools).

Except for air and nitrogen for driving surgical tools, the supply system with cylinders or cylinder bundles shall be such that the system design flow can be supplied with any two sources of supply out of service.

5.3.2 The primary and secondary sources of supply which alternately supply the pipeline shall each consist of one bank of cylinders or cylinder bundles. When an exhausted bank of cylinders or cylinder bundles is replaced, it shall be possible to reset the automatic change-over either manually or automatically. Each bank shall have its cylinders or cylinder bundles connected to a manifold with its own pressure regulator. Except for air, vent valves, if fitted on manifolds, shall be vented outside of the building.

5.3.3 Except for banks with only one cylinder or cylinder bundle, a non-return valve shall be installed at the manifold end of each flexible connection between the cylinder or cylinder bundle and the manifold.

5.3.4 A filter having a pore size no greater than 100 µm shall be provided between the cylinder(s) and the first pressure regulator.

5.3.5 (*) The flexible connections between each cylinder or cylinder bundle and the manifold shall comply with ISO 21969. Non-metallic (polymer-lined or rubber-reinforced) flexible hoses shall not be used.

5.3.6 Means shall be provided to individually secure all cylinders located within the supply system to prevent them from falling over. The flexible connections between each cylinder and the manifold shall not be used for this purpose.

5.3.7 All supply systems with cylinders shall comply with 5.2.2.1.
5.4 Supply systems with mobile or stationary cryogenic or non-cryogenic vessels

NOTE Regional or national regulations applying to mobile and stationary cryogenic and non-cryogenic vessels can exist.

5.4.1 Except for nitrogen for driving surgical tools, a supply system with stationary cryogenic or non-cryogenic vessels shall consist of one of the following:

a) one stationary cryogenic or non-cryogenic vessel with associated equipment and two banks of cylinders or cylinder bundles;

b) two stationary cryogenic or non-cryogenic vessels with associated equipment and one bank of cylinders or cylinder bundles;

c) three stationary cryogenic or non-cryogenic vessels with associated equipment.

The sources-of-supply management procedure (see Annex G) should take into account the natural vaporization of liquid contained in cryogenic and non-cryogenic vessels.

5.4.2 All supply systems with mobile or stationary cryogenic or non-cryogenic vessels shall comply with 5.2.2.1.

5.5 Supply systems for air

5.5.1 General requirements

5.5.1.1 A supply system for medical air or air for driving surgical tools shall be one of the following:

a) a supply system with cylinders or cylinder bundles as specified in 5.3;

b) a supply system with air compressor(s) as specified in 5.5.2;

c) a supply system with proportioning unit(s) as specified in 5.5.3.

NOTE Air for driving surgical tools can be supplied from the same sources as medical air.

5.5.1.2 (*) If medical air or air for driving surgical tools is provided for other purposes, such as operation of ceiling columns, anaesthetic gas scavenging systems, breathing air for medical personnel or testing or drying of medical devices, means shall be provided to prevent backflow into the pipeline. The flow requirements of these applications shall be taken into account by the manufacturer of the system.

5.5.1.3 Medical air and air for driving surgical tools shall not be provided for applications such as general workshop use, motor repair workshop use, spray painting, tyre inflation, reservoirs for pressurization of hydraulic fluids, sterilizing systems and pneumatic control of air conditioning, which can impose unforeseen demands and could compromise the availability and/or quality of air for normal patient care purposes.

NOTE Such uses could increase service interruptions, reduce service life and introduce contamination.

5.5.1.4 Where the medical air supply system is required to pressurize a hyperbaric chamber, an assessment shall be made to ensure that there is adequate capacity of the medical gas pipeline system to meet the total demand.

5.5.1.5 All supply systems for air shall comply with 5.2.2.1. All compressor units and all proportioning units shall be connected to an emergency electrical power supply.