

---

---

**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*

**iTeh STANDARD PREVIEW  
(standards.iteh.ai)**

ISO 7396-1:2007

<https://standards.iteh.ai/catalog/standards/sist/b6a92bff-15a4-41cc-8828-c6336254d74e/iso-7396-1-2007>



**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.

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[ISO 7396-1:2007](#)

<https://standards.iteh.ai/catalog/standards/sist/b6a92bff-15a4-41cc-8828-c6336254d74e/iso-7396-1-2007>

© ISO 2007

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Published in Switzerland

# Contents

Page

Foreword.....	v
Introduction .....	vi
<b>1 Scope .....</b>	<b>1</b>
<b>2 Normative references .....</b>	<b>2</b>
<b>3 Terms and definitions.....</b>	<b>2</b>
<b>4 General requirements.....</b>	<b>7</b>
4.1 (*) Safety .....	7
4.2 (*) Alternative construction.....	7
4.3 Materials .....	8
4.4 System design.....	9
<b>5 Supply systems.....</b>	<b>10</b>
5.1 System components.....	10
5.2 General requirements.....	10
5.3 Supply systems with cylinders or cylinder bundles .....	12
5.4 Supply systems with mobile or stationary cryogenic or non-cryogenic vessels .....	13
5.5 Supply systems for air .....	13
5.6 Supply systems with oxygen concentrator(s) .....	17
5.7 Supply systems for vacuum .....	18
5.8 Location of supply systems .....	18
5.9 Location of cylinder manifolds.....	19
5.10 Location of stationary cryogenic vessels .....	19
<b>6 Monitoring and alarm systems.....</b>	<b>19</b>
6.1 General.....	19
6.2 Installation requirements .....	19
6.3 Monitoring and alarm signals .....	20
6.4 Provision of operating alarms .....	21
6.5 Provision of emergency clinical alarms .....	22
6.6 (*) Provision of emergency operating alarms .....	22
<b>7 Pipeline distribution systems.....</b>	<b>22</b>
7.1 Mechanical resistance.....	22
7.2 Distribution pressure.....	22
7.3 Low-pressure hose assemblies and low-pressure flexible connections.....	23
7.4 Double-stage pipeline distribution systems .....	24
<b>8 Shut-off valves .....</b>	<b>24</b>
8.1 General.....	24
8.2 Service shut-off valves.....	25
8.3 Area shut-off valves.....	25
<b>9 Terminal units, gas-specific connectors, medical supply units, pressure regulators and pressure gauges .....</b>	<b>26</b>
<b>10 Marking and colour coding.....</b>	<b>27</b>
10.1 Marking .....	27
10.2 Colour coding.....	27
<b>11 Pipeline installation .....</b>	<b>27</b>
11.1 General.....	27
11.2 Pipeline supports.....	28
11.3 Pipeline joints.....	29

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	..... <a href="https://standards.iteh.ai/catalog/standards/sist/b6c92b8f-15a4-41cc-8828-c6336254d74e/iso-7396-1-2007">https://standards.iteh.ai/catalog/standards/sist/b6c92b8f-15a4-41cc-8828-c6336254d74e/iso-7396-1-2007</a>	140

iteh STANDARD PREVIEW  
(standards.iteh.ai)

ISO 7396-1:2007

## 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 7396-1:2007](https://standards.iteh.ai/catalog/standards/sist/b6c9210f-15a4-41cc-8828-c6336254d74e/iso-7396-1-2007)

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; <https://standards.iteh.ai/catalog/standards/sist/b6a92bff-15a4-41cc-8828-c6336254d74e/iso-7396-1-2007>
  - 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 <sup>[23]</sup> 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* <https://standards.iteh.ai/catalog/standards/sist/b6a92bff-15a4-41cc-8828-c6336254d74e/iso-7396-1-2007>

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  $-150\text{ }^{\circ}\text{C}$

**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

iTeh STANDARD PREVIEW  
(standards.iteh.ai)

<https://standards.iteh.ai/catalog/standards/sist/b6a92bff-15a4-41cc-8828-c6336254d74e/iso-7396-1-2007>

**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  $-50\text{ }^{\circ}\text{C}$

**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

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

**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

[ISO 7396-1:2007](https://standards.iteh.ai/catalog/standards/sist/b6a92bff-15a4-41cc-8828-c6336254d74e/iso-7396-1-2007)

<https://standards.iteh.ai/catalog/standards/sist/b6a92bff-15a4-41cc-8828-c6336254d74e/iso-7396-1-2007>

**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

## iTeh STANDARD PREVIEW (standards.iteh.ai)

**4 General requirements****4.1 (\*) Safety**

[ISO 7396-1:2007](https://standards.iteh.ai/catalog/standards/sist/4c928f15-411e-4828-6336-4474e9a77ac6/iso-7396-1-2007)

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  $\leq 108$  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.