



BSI Standards Publication

Medical gas pipeline systems

Part 1: Pipeline systems for compressed medical gases and vacuum

National foreword

This British Standard is the UK implementation of EN ISO 7396-1:2016+A1:2019. It is identical to ISO 7396-1:2016, incorporating amendment 1:2017. It supersedes [BS EN ISO 7396-1:2016](#), which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment A1 is indicated by A1 A1.

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English Version

**Medical gas pipeline systems - Part 1: Pipeline systems
for compressed medical gases and vacuum (ISO
7396-1:2016)**

Systèmes de distribution de gaz médicaux - Partie
1: Systèmes de distribution de gaz médicaux
comprimés et de vide (ISO 7396-1:2016)

Rohrleitungssysteme für medizinische Gase -
Teil 1: Rohrleitungssysteme für medizinische
Druckgase und Vakuum (ISO 7396-1:2016)

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European foreword

This document (EN ISO 7396-1:2016) has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” in collaboration with 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of an identical text or by endorsement, at the latest by September 2016, and conflicting national standards shall be withdrawn at the latest by March 2019.

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This document supersedes EN ISO 7396-1:2007.

This document 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 document.

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Endorsement notice

The text of ISO 7396-1:2016 has been approved by CEN as EN ISO 7396-1:2016 without any modification.

Foreword to amendment A1

This document (EN ISO 7396-1:2016/A1:2019) has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” in collaboration with Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

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Endorsement notice

The text of ISO 7396-1:2016/Amd 1:2017 has been approved by CEN as EN ISO 7396-1:2016/A1:2019 without any modification.

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide one means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on Medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in [Table ZA.1](#) confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC, Medical devices

Clause(s)/Sub-clause(s) of this European Standard	Essential Requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
4	1, 2, 7.1, 7.3	
4.3.2	9.3	
4.3.3	7.1	
4.3.4	9.2, 9.3, 12.7.1	
4.3.5	9.3	
4.3.6	7.1, 9.3, 12.7.1	
4.3.7	7.2, 7.6	
4.3.8	9.2	
4.4.1	2, 3	
4.4.2	1, 2, 3, 4	
5.1 to 5.2.9	1, 2, 3, 4, 7.6, 12.8.1, 12.8.2	
5.3.1 to 5.3.3	2, 3, 7.6	
5.3.4	7, 12.7.1	
5.3.5	7, 12.7.1	
5.3.6	7.1, 9.3	
5.3.7	2, 3	
5.4	3	
5.5.1	3, 12.8	
5.5.2.1 to 5.5.2.11	3, 7.2, 12.8	
5.5.2.12	7.6	
5.5.2.13	3, 9.2	
5.5.2.14	12.7.2	
5.5.2.15	3, 7.2	
5.5.3	3, 7.2, 7.6, 12.8	
5.6	2, 3, 7.2, 7.3, 7.6, 9.3, 12.8	
5.7.1 to 5.7.7	3, 8.1, 12.8.1	

Clause(s)/Sub-clause(s) of this European Standard	Essential Requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
5.7.8 to 5.7.9	7,6, 8.1	
5.7.10	12.7.2	
5.7.11	7.2	
5.7.12	3, 7.2, 7.6	
5.7.13	3, 9.3	
5.7.14	3, 9.3	
5.7.15	3, 12.8	
5.8 to 5.10	2, 3	
6	1, 2, 3, 4, 12.3, 12.8.1, 12.8.2, 12.9	
7	1, 2, 3	
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7.2.6	9.2	
7.3	2,3,4	
7.4	2, 3, 12.8	
8	1, 2	
9	9.1, 12.7.4, 13.6 c)	
9.3	9.2, 12.5, 12.6	
10	13.2	
11	1, 2, 3, 4, 9	
11.1.5	12.6	
12.1 to 12.4	1, 2, 3	
12.5.1	9.3, 12.7.1, 9.2	
12.5.2	7.5, 9.3, 12.7.1, 9.2	
12.6.1	7.5, 12.7.1	
12.6.2 to 12.6.9	2, 3, 7.5, 12.8	
12.6.10	7.2	
12.6.11	7.2	
12.6.12	7.2	
12.6.13	7.2	
12.6.14	7.2	
12.6.15 to 12.6.16	12.7.4, 12.8.1	
13	4, 13.1, 13.3, 13.6 c), 13.6 d), 13.6 e), 13.6 k), 13.6 l), 13.6 m), 13.6 n), 13.6 q)	

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*.

This third edition cancels and replaces the second edition ([ISO 7396-1:2007](#)) and ISO 10083:2006, which have been technically revised. It also incorporates the Amendments ISO 7396-1:2007/Amd1:2010, ISO 7396-1:2007/Amd2:2010, and ISO 7396-1:2007/Amd3:2013.

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 gases for medicinal use, medical device 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 these pipeline systems should also be aware of the contents of this part of ISO 7396.

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, installation and testing;
- b) continuous supply of gases and vacuum at specified quality, pressures and specified flows 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 and commissioning;
- i) quality of the gases delivered by the pipeline system;
- j) correct operational management;
- k) safety features of the sources to ensure the quality of the gases according to specification.

The responsibility for the quality of the medical gas supplied via the medical gas pipeline system should be assigned to a nominated person within the healthcare facility. This role would usually be assigned to the Head Pharmacist, who may in turn nominate other responsible person(s) on site to manage the day-to-day requirements.

Where the medical gas is supplied by a third party (in some jurisdictions under licence from the national, regional or local regulatory body), the supplier is responsible for ensuring that the medical gas as delivered meets the relevant specification requirements. In this case, the healthcare facility is responsible under local regulations for ensuring that the product meets the specifications as ordered, that the product administered to patients is not adulterated and complies with specifications and regulations, and that the product manufacturer is informed immediately of any undesirable effects or defects in the quality of the product.

Where the healthcare facility manufactures the gas on site, e.g. for medical air produced by air compressor systems, medical air produced by proportioning systems or oxygen 93 produced by oxygen concentrator systems, the healthcare facility is responsible for all aspects of the medical gas quality.

NOTE Vacuum is also the responsibility of the healthcare facility.

[Annex G](#) provides guidance for the assignment of responsibility for production and quality control of the gases and vacuum.

National, regional or local regulatory bodies may require the manufacture of medical gases on the healthcare facility site to be licenced.

[Annexes G and K](#) provide some guidance as to how the quality of the gas should be managed to maintain patient safety at the highest level.

[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 into this part of ISO 7396. The clauses and subclauses marked with (*) after their number have a corresponding rationale 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, testing, commissioning and documentation of pipeline systems used in healthcare facilities for the following:

- oxygen;
- nitrous oxide;
- medical air;
- carbon dioxide;
- oxygen/nitrous oxide mixtures (see Note 1);
- helium/oxygen mixtures;
- (*) oxygen 93;
- gases and gas mixtures classified as medical device, gases delivered to medical devices or intended for medical purposes or gases and gas mixtures for medicinal use not specified above;
- air for driving surgical tools;
- nitrogen for driving surgical tools;
- vacuum.

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

NOTE 2 Anaesthetic gas scavenging disposal systems are covered in [ISO 7396-2](#).

This part of ISO 7396 includes requirements for supply systems, pipeline distribution systems, control systems, monitoring and alarm systems and non-interchangeability between components of different gas/vacuum systems.

This part of ISO 7396 specifies safety requirements for pipeline systems used in healthcare facilities, both public and private. It applies to all facilities providing healthcare services regardless of type, size, location or range of services, including, but not limited to:

- a) acute care healthcare facilities;
- b) internal patient continuing care healthcare facilities;
- c) long-term care facilities;
- d) community-based providers;
- e) ambulatory and external patient care clinics (e.g. day surgery, endoscopy clinics and doctors' offices).

NOTE 3 This part of ISO 7396 may also be used as reference for pipeline systems for medical gases and vacuum intended to be installed in places other than healthcare facilities.

This part of ISO 7396 applies to the following different types of oxygen supply systems:

- supply systems in which all sources of supply deliver oxygen; in this case the concentration of the oxygen will be greater than 99%;
- supply systems in which all sources of supply deliver oxygen 93; in this case the concentration of the oxygen may vary between 90% and 96%;

NOTE 4 A mixture of oxygen 93 and oxygen may be delivered by a medical gas supply system. In this case the concentration of the gas can vary between 90% and >99%.

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.

Oxygen concentrators for domiciliary use are excluded from the scope of this part of ISO 7396.

NOTE 5 Requirements for oxygen concentrators for domiciliary use are specified in [ISO 80601-2-69](#).

(*) [EN 14931](#) defines additional requirements for hyperbaric application, in particular for flows and pressures of compressed air required to pressurize the hyperbaric chamber and to drive other connected services. Also included are requirements for oxygen and other treatment gases administered to patients.

This part of ISO 7396 does not apply to vacuum systems intended to be used in dentistry.

This part of ISO 7396 does not apply to filling systems for transportable cylinders and transportable cylinder bundle systems.

2 Normative references

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

NOTE Additional references are listed in the Bibliography.

[ISO 3746:2010](#), *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 5359:2014](#), *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases*

[ISO 8573-1:2010](#), *Compressed air — Part 1: Contaminants and purity classes*

[ISO 9170-1:2008](#), *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*

[ISO 10524-2:2005](#), *Pressure regulators for use with medical gases — Part 2: Manifold and line pressure regulators*

[ISO 11197:2004](#), *Medical supply units*

[ISO 14644-1:1999](#), *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness*

[ISO 14971:2007](#), *Medical devices — Application of risk management to medical devices*

[ISO 15001:2010](#), *Anaesthetic and respiratory equipment — Compatibility with oxygen*

[ISO 17672:2010](#), *Brazing — Filler metals*

[ISO 18082:2014](#), *Anaesthetic and respiratory equipment — Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases*

[ISO 21969:2009](#), *High-pressure flexible connections for use with medical gas systems*

ISO 29463-1:2011, *High-efficiency filters and filter media for removing particles in air — Part 1: Classification, performance testing and marking*

[ISO 80601-2-69:2014](#), *Medical electrical equipment — Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment*

[IEC 60601-1-8:2006](#), *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

[EN 286-1:1998](#), *Simple unfired pressure vessels designed to contain air or nitrogen — Part 1: Pressure vessels for general purposes*

[EN 1041:2008](#), *Information supplied by the manufacturer of medical devices*

[EN 1254-1:1998](#), *Copper and copper alloys — Plumbing fittings — Fittings with ends for capillary soldering or capillary brazing to copper tubes*

[EN 1254-4:1998](#), *Copper and copper alloys — Plumbing fittings — Fittings combining other end connections with capillary or compression ends*

[EN 13348:2008](#), *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 1 to entry: 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

audio paused

state of limited duration in which the alarm system or part of the alarm system does not generate an auditory alarm signal

Note 1 to entry: This is sometimes referred to as silencing.

[SOURCE: IEC 60601-1-8]

3.4

booster compressor

compressor used to raise an elevated pressure to a higher pressure

Note 1 to entry: As used herein, the term applies to compressors used to fill high-pressure reservoir(s).

3.5

branch

portion of the pipeline distribution system which supplies one or more areas on the same floor of the facility

3.6

commissioning

proof of function to verify that the agreed system specification is met and is accepted by the user or the user's representative

3.7

control equipment

items necessary to maintain the medical gas pipeline system within the specified operating parameters

Note 1 to entry: Examples of control equipment are pressure regulators, pressure-relief valves, sensors, manual or automatic valves and non-return valves.

3.8

control system

device or set of devices to manage, command, direct or regulate the behaviour of other device(s) or system(s)

3.9

cryogenic liquid system

supply system containing a gas stored in the liquid state in a vessel at temperatures lower than $-150\text{ }^{\circ}\text{C}$

3.10

cylinder bundle

pack or pallet of cylinders linked together with one or more connectors for filling and emptying

3.11

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.

3.12

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 1 to entry: This initial higher pressure is the nominal supply system pressure (see [3.38](#)).

3.13

emergency clinical alarm

alarm to indicate to medical and technical staff that there is a deviation from a monitored parameter which requires an immediate response

3.14

emergency inlet point

inlet point which allows the connection of an emergency supply

3.15

emergency operating alarm

alarm to indicate to technical staff that there is a deviation from a monitored parameter which requires an immediate response

3.16

emergency supply

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

3.17

gas-specific

having characteristics which prevent connections between different gas services or vacuum services

3.18

gas-specific connector

connector with dimensional characteristics which prevent connections between different gas services

Note 1 to entry: Examples of gas-specific connectors are quick connectors, screw-threaded connectors, diameter-indexed safety system (DISS) connectors, non-interchangeable screw-threaded (NIST) connectors and sleeve indexed system (SIS) connectors.

3.19

gas for medicinal use

gas or mixture of gases having properties for treating or preventing disease in human beings which may be used in or administered either with a view to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis

Note 1 to entry: This is also sometimes referred to as medicinal gas.

Note 2 to entry: In Europe this is classified as a medicinal product in accordance with Directive 2001/83/EC.

3.20

medical device gas

gas or mixture of gases intended by the manufacturer to be used for human beings for the purpose of: — diagnosis, prevention, monitoring, treatment or alleviation of disease; — investigation, replacement or modification of the anatomy or of a physiological process; — control of conception; and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

Note 1 to entry: In Europe these gases are classified as a medical device in accordance with Directive 93/42/EEC.

3.21

healthcare facility

hospital, clinic or similar facility that provides patients with their healthcare needs

3.22

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 safety can be compromised

3.23

high pressure

pressures greater than 3 000 kPa

[SOURCE: ISO 15001:2010]

3.24

high-pressure reservoir

permanently installed container(s) with nominal working pressures ranging from 3 000 kPa to 25 000 kPa at 15 °C

3.25

information signal

signal that is not an alarm signal or a reminder signal

3.26

line pressure regulator

pressure regulator used in a double-stage pipeline distribution system to reduce the nominal supply system pressure to the nominal distribution pressure

3.27

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

3.28

main line

portion of the pipeline distribution system connecting the supply system to risers and/or branches

3.29

maintenance supply assembly

inlet point which allows the connection of a maintenance supply

3.30

maintenance supply

source of supply intended to supply the system during maintenance

3.31

manifold

device for connecting the outlet(s) of one or more cylinders, cylinder bundles or high-pressure reservoir(s) of the same gas to the pipeline system

3.32

manifold pressure regulator

pressure regulator intended to be installed within sources of supply containing cylinders, cylinder bundles, or high-pressure reservoir(s)

3.33

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

3.34

maximum distribution pressure

pressure at any terminal unit when the pipeline system is operating at zero flow

3.35

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 to entry: Medical air may be produced by supply systems with air compressors or by supply systems with proportioning units. Medical air produced by air compressor systems is called “medicinal air”, and medical air produced by proportioning systems is called “synthetic medicinal air” by the European Pharmacopoeia.

3.36

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

3.37

minimum distribution pressure

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

3.38

nominal distribution pressure

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

3.39

nominal supply system pressure

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

3.40

non-cryogenic liquid system

supply system containing a gas stored under pressure in the liquid state in a vessel at temperatures not lower than $-50\text{ }^{\circ}\text{C}$

3.41

non-return valve

valve which permits flow in one direction only

3.42

operating alarm

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

3.43

oxygen concentrator supply system

supply system containing one or more oxygen concentrator units

3.44

oxygen concentrator unit

component of source of supply that produces oxygen 93 from ambient air by extraction of nitrogen

3.45

oxygen

gas for medicinal use where the oxygen concentration is at least the minimum specified in the relevant pharmacopoeial monograph

3.46

oxygen 93

gas produced by an oxygen concentrator unit whose concentration is within the limits specified in the relevant pharmacopoeial monograph

3.47

peak demand

maximum foreseeable gas flowrate required by a healthcare facility

Note 1 to entry: This is commonly expressed in litres per minute.

3.48

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

3.49

pressure regulator

device which reduces the inlet pressure and maintains the set outlet pressure within specified limits

3.50

pressure-relief valve

device intended to relieve excess pressure at a preset pressure

3.51

primary source of supply

portion of the supply system which supplies the pipeline distribution system

3.52

proportioning unit

device in which gases are mixed in a specified ratio

3.53

receiver

permanently installed container(s) designed for vacuum application

Note 1 to entry: See also reservoir ([3.56](#)).

3.54

reserve source of supply

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

3.55

riser

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

3.56

reservoir

permanently installed container(s) designed for storing gas at pressures up to 3 000 kPa

Note 1 to entry: See also receiver ([3.53](#)).

3.57

safety

freedom from unacceptable risk

3.58

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

3.59

shut-off valve

valve which prevents flow in both directions when closed

3.60

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 1 to entry: Planned maintenance of equipment is considered a normal condition.

3.61

single-stage pipeline distribution system

pipeline distribution system in which gas is distributed from the supply system at the nominal distribution pressure

3.62

source of supply

portion of the supply system with associated control equipment which supplies the pipeline distribution system

3.63

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 1 to entry: For a source of supply with cylinders, cylinder bundles or high-pressure reservoir(s), this is referred to as the manifold pressure regulator.

3.64

supply system

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

3.65

system design flow

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

3.66

terminal unit

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

3.67

uninterruptible power system

UPS

combination of convertors, switches and energy storage devices (such as batteries), constituting a power system for maintaining continuity of load power in case of input power failure

Note 1 to entry: Healthcare facility emergency electrical power supply may not ensure continuity of supply.

3.68

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 with an unacceptable level under 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 fault condition subsequently detected 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](#).

Supply systems and alarm systems should be designed and manufactured to:

- a) minimize the risk arising from emitted electromagnetic fields which could disturb other equipment and medical devices used within the healthcare facility and

- b) have the appropriate level of electromagnetic immunity to operate safely within the electromagnetic environment of healthcare facilities

National or regional regulations may exist. [IEC 60601-1-2](#) may apply to equipment classified as medical devices.

NOTE 3 Loss of mains electrical power or water supply is a single fault condition. A fault in control equipment is a single fault condition.

Measures should be taken to minimize electrical and mechanical hazards. National or regional regulations concerning such hazards may exist.

NOTE 4 Planned maintenance of equipment is considered a normal condition.

4.2 (*) Alternative construction

Supply system, monitoring and alarm systems, pipeline distribution systems 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 at least 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 may be obtained by post-market surveillance.

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

NOTE 2 Regional or national regulations may 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 materials used in components for the actual gas.

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 are compatible with the actual gas and oxygen under normal and single fault conditions. If lubricants are used, except within air compressors and vacuum pumps, they shall be compatible with the actual gas and oxygen during normal and single fault condition of the pipeline system. See [4.3.6](#).

Evidence shall be provided by the manufacturer.

NOTE 1 Criteria for the selection of metallic and non-metallic materials are given in [ISO 15001](#), [ISO 11114-1](#) and [ISO 11114-2](#).

NOTE 2 Regional or national regulations may require the provision of evidence to a competent authority or a conformity assessment body 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 high concentrations of oxygen, particularly under pressure. Similarly, materials which can be ignited in air require less energy to ignite in oxygen. Less energy is required as the pressure increases. 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 abnormal heating, combustion or decomposition of non-metallic materials (including lubricants, if used) and potential contaminants shall be addressed.

Annex E of [ISO 15001:2010](#) 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.

NOTE 1 Some potential products of combustion and/or decomposition for some commonly available non-metallic materials are listed in Table D.7 of [ISO 15001:2010](#).

NOTE 2 See [Annex I](#), Rationale for compressor hazards.

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 may 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 pressure greater than 3 000 kPa 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 10524-2:2005.

Evidence shall be provided by the manufacturer.

NOTE Regional or national regulations may 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 ≤ 133 mm diameter are used for pipelines, they shall comply with [EN 13348](#). Copper pipes of >133 mm diameter and pipes of materials other than copper which are used for compressed medical gases shall comply with all applicable requirements of [EN 13348](#) (in particular the requirements concerning cleanliness, marking and packaging) 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.

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

NOTE 2 Copper is the preferred material for all medical gas pipelines. For vacuum, copper and plastic tubes are in common use.

4.3.7 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 15001:2010](#).

NOTE Examples of cleaning procedures are described in [ISO 15001:2010](#).

4.3.8 (*) 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

At the time of project design, the management of the healthcare facility, in consultation with the system manufacturer, shall determine essential characteristics for system construction, which should include at least:

- the type of sources of supply;
- the location of the sources of supply;
- the flow and storage capacity of the sources of supply;
- the number of terminal units per bed-space/work-space;
- the location of terminal units in each department or area of the healthcare facility;
- the corresponding flow rate at each terminal unit;
- the diversity factors;
- the location and elevation of area shut-off valves;
- the need of additional local sources of supply in designated departments (e.g. in departments where high-dependency patients are treated, an independent vacuum unit or an independent source(s) of oxygen or oxygen 93, and medical air in case of a catastrophic event).

NOTE 1 Regional or national regulations applying to the number of cylinders or quantity of gas within each department may exist.

NOTE 2 Typical examples of locations of terminal units, flow requirements and diversity factors are given in HTM 02 [33], [34], FD S 90-155 [32], AS 2896-1998 [22] and SIS/HB 370 [38].

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

NOTE 3 Examples of maximum recommended gas velocity are given in FD S 90-155 [32] and SIS/HB 370 [38].

4.4.2 Extensions and modifications of existing pipeline systems

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

NOTE Typical examples of locations of terminal units, flow requirements and diversity factors are given in HTM 02-01 [33], [34], FD S 90-155 [32], AS 2896-1998 [22] and SIS/HB 370 [38].

- 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, nominal distribution pressure and pressure drop characteristics of the existing pipeline distribution system shall continue to meet at least the original design specifications;
- c) the flow, nominal distribution pressure 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;
- d) When extensions or modification are required, the design characteristics of the existing piping systems shall continue to meet at least the original design characteristics.

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 may be a combination of the following:

- a) gas in cylinders, cylinder bundles or high-pressure reservoir(s);
- 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 unit;
- f) a proportioning unit;
- g) an oxygen concentrator unit.

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.21).

5.2 General requirements

5.2.1 Capacity and storage

The capacity and storage of any supply system shall be based on the estimated flow profile, 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 and cylinder bundles 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. Cylinders and cylinder bundles should be maintained in a safe, secured location and clean condition.

Portable equipment, cylinders and cylinder bundles shall be stored under cover and protected from adverse weather conditions, to ensure that they are kept clean until the point of use inside the healthcare facility.

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.

Damage to the pipeline is considered a catastrophic event and not a single fault condition, and shall be managed in accordance with the emergency procedure (see [G.5.3](#)).

5.2.2.2 Control equipment shall be designed to allow maintenance without interrupting the gas/vacuum supply.

5.2.2.3 Where the continuity of supply is not a requirement, application of risk management procedures in accordance with [ISO 14971](#) and in concurrence with the healthcare facility management system shall be performed and documented by the healthcare facility (see [Annex G](#)).

The manufacturer shall provide the documentation thereof, validated by the healthcare facility, on request

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 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(s) of supply

The reserve source(s) of supply shall be permanently connected to the pipeline distribution system. The activation of the reserve source(s) of supply, in the event of both the primary and the secondary sources of supply being unavailable, may be automatic or manual but shall ensure continuity of supply to the pipeline.

The activation of the reserve source(s) of supply depends upon the type of component of the sources of supply:

- a) if all sources of supply are with gas in cryogenic vessels, cylinders or cylinder bundles, then the activation may be manual or automatic;
- b) if the primary and the secondary sources of supply are dependent upon the electrical power supply, then the activation shall be automatic;
- c) if all sources of supply are dependent upon the electrical power supply, then the connection of the reserve source(s) of supply to the emergency electrical power supply shall be automatic and the subsequent activation shall be automatic.

The manufacturer together with the healthcare facility management, on the basis of risk management procedures in accordance with [ISO 14971](#) shall determine:

- a) whether it is acceptable for the reserve source(s) of supply to be dependent on an electrical supply;

If an air compressor unit, a proportioning unit or an oxygen concentrator unit is used as a reserve source of supply, the design of the supply system and the emergency electrical supply should take into consideration the time required to start the reserve source(s) of supply and obtain the specified quality of the gas supplied to the pipeline distribution system.

- b) the size of the reserve source(s) of supply such that the system design flow may be supplied continuously when both the primary and secondary sources of supply are unavailable;

- c) the location of the reserve source(s) of supply in order to supply the complete pipeline system and whether to provide for more than a single reserve source of supply;
- d) the location of the reserve source(s) of supply which should be such as to allow access to and use of at least the reserve source(s) of supply in case of fire inside the room(s) housing the primary and secondary sources of supply;

NOTE Risk management procedures may consider the need to have separate locations for the reserve source(s) of supply.

- e) whether to provide reserve source(s) of supply for air or nitrogen for driving surgical tools.

5.2.6 Means of pressure relief

5.2.6.1 Venting outdoors is not required for air. For all other compressed medical gases the location of the vents of the pressure-relief valves shall be determined in consultation with the healthcare facility management using risk management principles. If the vents are located outside of the building, the vents shall be provided with means to prevent the ingress of, for example, insects, debris and water and 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 or other components 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](#) [3].

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.

5.2.6.6 If a pressure-relief valve is removed, e.g. for maintenance, the pipeline shall be protected from overpressure by another means of pressure relief.

5.2.6.7 Pressure-relief valves shall comply with the supply system manufacturer's design specifications, taking into account that national or regional regulations may exist. Evidence shall be made available by the manufacturer upon request.

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).

5.2.7.2 The manufacturer together with the healthcare facility management shall determine the location of each maintenance supply assembly.

The location of each maintenance supply assembly should be such as to allow the supply of gas to the pipeline in case of fire inside the room(s) of the sources of supply. Risk management procedures should consider the need for multiple maintenance supply assemblies.

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

5.2.7.3 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.

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 [7.2.1](#), [Table 2](#), [7.2.2](#) and [7.2.3](#).

5.2.9 (*)Ozone Sterilizers

Ozone sterilizers shall not be connected to the oxygen/oxygen 93 pipeline system in order to prevent backflow into the oxygen/oxygen 93 pipeline system.

5.3 Supply systems with cylinders, cylinder bundles or high-pressure reservoir(s)

5.3.1 A supply system with cylinders, cylinder bundles or high-pressure reservoir(s) 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, cylinder bundles or high-pressure reservoir(s) 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, cylinder bundles or high-pressure reservoir(s). When an exhausted bank of cylinders, cylinder bundles or high-pressure reservoir(s) is replaced, it shall be possible to reset the automatic changeover. Each bank shall have its cylinders, cylinder bundles or high-pressure reservoir(s) connected to a manifold with its own pressure regulator. Except for air, vent valves shall be vented outside of the building.

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

5.3.4 (*) 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.

5.3.5 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.

5.3.6 All supply systems with cylinders shall comply with [5.2.2.1](#).

5.3.7 Where the oxygen reserve consists of only one cylinder or cylinder bundle, the manifold shall have at least one additional inlet in order to be able to change the cylinder or cylinder bundle without affecting the continuity of supply.

5.4 Supply systems with cryogenic or non-cryogenic vessels

NOTE Regional or national regulations applying to cryogenic and non-cryogenic vessels may exist.

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

- a) one cryogenic or non-cryogenic vessel with associated equipment and two banks of cylinders or high-pressure reservoir(s);
- b) two cryogenic or non-cryogenic vessels with associated equipment and one bank of cylinders, cylinder bundles or high-pressure reservoir(s);
- c) three cryogenic or non-cryogenic vessels with associated equipment.

The sources of supply management procedure (see [G.5.8](#)) should take into account the natural vaporization of liquid contained in cryogenic and non-cryogenic vessels.

5.4.2 (*) Where materials subject to cold embrittlement are used downstream of the vaporizer system, means shall be provided to prevent the ingress of cryogenic liquid into the pipeline system and to initiate an alarm when this means is activated.

5.4.3 All supply systems with mobile or stationary cryogenic or non-cryogenic vessels shall comply with [5.2.2.1](#).

5.4.4 A supply system with mobile or stationary cryogenic or non-cryogenic vessels shall be such that the system design flow can be supplied with any two sources of supply out of service.

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 or a combination thereof:

- a) a supply system with cylinders, cylinder bundles or high-pressure reservoir(s) 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 may 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, 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/or pneumatic control of air conditioning. Medical air and air for driving surgical tools shall also not be provided for any other application which

can impose unforeseen demands and could compromise the availability and/or quality of air for the intended 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 in the source and adequate pipe sizing to meet the total demand.

NOTE [EN 14930](#) provides information about hyperbaric chambers.

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.

5.5.2 Supply systems with air compressor(s)

A compressor used in the supply system with air compressors shall not be used in a supply system with oxygen concentrator(s).

5.5.2.1 (*) Regional or national regulations applying to medical air produced by a supply system with air compressor(s) may exist. Where such regulations do not exist, medical air produced by a supply system with air compressor(s) shall comply with the following:

- a) oxygen concentration $\geq 20,4$ % (volume fraction) and $\leq 21,4$ % (volume fraction);
- b) total oil concentration $\leq 0,1$ mg/m³ measured at ambient pressure;
- c) carbon monoxide concentration ≤ 5 ml/m³;
- d) carbon dioxide concentration ≤ 500 ml/m³;
- e) water vapour content ≤ 67 ml/m³;
- f) sulfur dioxide concentration ≤ 1 ml/m³;
- g) NO + NO₂ concentration ≤ 2 ml/m³.

NOTE 1 Oil can be present as liquid, aerosol and vapour.

NOTE 2 These values are taken from the European Pharmacopoeia monograph for “medicinal air”.

5.5.2.2 (*) Medical air and air for driving surgical tools supplied by compressor systems shall be filtered to maintain the particulate contamination below the following levels:

Maximum number of particles per cubic metre as a function of particle size

From 0,1 µm to 0,5 µm : < 400 000

From 0,5 µm to 1,0 µm : < 6 000

From 1,0 µm to 5,0 µm : < 100

NOTE These values are taken from [Table 2](#), Class 2 of [ISO 8573-1:2010](#).

Evidence of compliance with [5.5.2.2](#) shall be provided by the manufacturer.

5.5.2.3 If periodic change of the filter element(s) is not scheduled, then means shall be provided to verify the status of filter elements.

Compliance shall be confirmed by inspection.

NOTE Regional or national requirements applying to particulate contamination may exist.

5.5.2.4 (*) Regional or national regulations applying to air for driving surgical tools produced by a supply system with air compressor(s) may exist. Where such regulations do not exist, air for driving surgical tools shall comply with the following:

- a) total oil concentration $\leq 0,1 \text{ mg/m}^3$ measured at ambient pressure;
- b) water vapour content $\leq 67 \text{ ml/m}^3$.

NOTE 1 Oil can be present as liquid, aerosol and vapour.

NOTE 2 For air for driving surgical tools, a low water vapour content is necessary to prevent the formation of water or ice (from cooling due to adiabatic expansion) which can damage tools.

Consideration should be given to the use of oil-less compressor technologies for producing medical air. See [Annex I](#).

5.5.2.5 A supply system with compressor(s) for medical air shall comprise at least three sources of supply, at least one of which shall be a compressor unit. The supply system shall be such that the system design flow can be supplied continuously with any two sources of supply out of service.

The source of supply shall be one of the following:

- a) a compressor unit; or
- b) a bank of cylinders, cylinder bundles or high-pressure reservoir(s); or
- c) a proportioning unit.

The compressor unit(s) shall be provided with reservoir(s) and conditioning unit(s), as required.

If a supply system includes two or more sources of supply fed from compressor units, at least two conditioning units shall be provided.

Where the medical air supply system consists of three or more compressor units, which can be switched between the different sources of supply to provide adequate capacity, these shall be arranged so that during maintenance on any compressor unit and during a subsequent single fault condition of any component of the system (e.g. the control system), the remaining compressor units and components shall be capable of supplying the system design flow to ensure continuity of supply.

Where the medical air supply system consists of more than two conditioning units which can be switched between the different sources of supply to provide adequate capacity, these shall be arranged so that during maintenance on any conditioning unit and during a subsequent single fault condition of any component of the system (e.g. the control system), the remaining conditioning unit(s) and components shall be capable of supplying the system design flow to ensure continuity of supply of the appropriate product quality.

Each compressor unit shall have an automatic means to prevent backflow through off-cycle units and a shut-off valve to isolate it from the pipeline system and other compressors.

Each compressor unit shall be protected from overheating. Means shall be provided to avoid the release of toxic product into the pipeline in case of overheating (e.g. by shutting off and isolating the affected compressor from the pipeline).

At least one dew-point and one CO alarm sensor shall be fitted to the pipeline system downstream of all conditioning units. Recording capability should be provided.

NOTE 1 Other parameters of the medical air quality may be monitored or recorded. Regional or national regulations may exist.

NOTE 2 A supply system with compressors for medical air typically comprises one of the following:

- a) one compressor unit with one reservoir, one conditioning unit and two banks of cylinders, cylinder bundles or high-pressure reservoir(s);
- b) two compressor units with at least two reservoirs, two conditioning units and one bank of cylinders, cylinder bundles or high-pressure reservoir(s);
- c) three compressor units with two reservoirs and two conditioning units.

NOTE 3 A compressor unit for medical air typically comprises the following:

- a) an inlet filter;
- b) one or more compressors;
- c) an after-cooler with shut-off valve and automatic drain;
- d) an oil separator with shut-off valve and automatic drain for oil lubricated compressors;
- e) a pressure sensor to ensure that the compressor operates within the range specified by the manufacturer.

NOTE 4 A conditioning unit for medical air typically comprises the following:

- a) a dryer with shut-off valves and automatic drain;
- b) an adsorber, a catalyst and filter(s) as required to remove contaminants;
- c) a dew-point sensor with an alarm and display, fitted to the pipeline system downstream of all conditioning units.

5.5.2.6 If an independent supply system with compressors for air for driving surgical tools is provided, it shall comprise at least two sources of supply, at least one of which shall be a compressor unit.

At least one dew-point alarm sensor shall be fitted to the pipeline system downstream of all conditioning units.

NOTE 1 A supply system with compressors for air for driving surgical tools typically comprises either one compressor unit with one reservoir, one conditioning unit and one bank of cylinders, cylinder bundles or high-pressure reservoir; or two compressor units with one or more reservoirs fitted with a means of bypass and two conditioning units.

NOTE 2 A compressor unit for air for driving surgical tools typically comprises an inlet filter, one or more compressors, an after-cooler with shut-off valve and automatic drain, an oil separator with shut-off valve and automatic drain for oil lubricated compressors, and a pressure sensor to ensure that the compressor operates within the range specified by the manufacturer.

NOTE 3 A conditioning unit for air for driving surgical tools typically comprises a dryer with shut-off valves and automatic drain, filter(s) as required, a dew-point sensor fitted with an alarm and display, connected to the pipeline system downstream of all conditioning units.

5.5.2.7 (*) Reservoirs shall

- a) comply with [EN 286-1](#) or equivalent national standards, and
- b) be fitted with shut-off valve(s), an automatic drain, a pressure gauge and a pressure-relief valve.

5.5.2.8 Each group of reservoirs shall be arranged so as to allow each reservoir in that group to be maintained separately.

NOTE The reservoir(s) may be fitted upstream or downstream of the conditioning unit(s).

5.5.2.9 If two or more conditioning units are fitted, they shall allow the components to be maintained separately.

5.5.2.10 A sample port with a shut-off valve shall be provided immediately downstream of the conditioning system(s).

5.5.2.11 When more than one compressor unit is provided, each compressor shall have a control system arranged so that shutting off, or failure, of one compressor will not affect the operation of other compressor(s). The control system for multiple compressors shall be arranged so that all the units supply the system in turn or simultaneously. This requirement shall be met in normal condition and in single fault condition.

Each reservoir or group of reservoirs shall be fitted with a means of pressure control, e.g. pressure switch(es) or pressure transducer(s).

Means shall be provided to ensure the continuity of supply following a failure of any control system (if fitted).

5.5.2.12 The inlet of the ambient air for compressors shall be located where there is minimal contamination (e.g. from internal combustion engine exhaust, vehicle parking, access areas, healthcare facility waste and disposal systems, vacuum or plume evacuation system exhausts, vents from medical gas pipeline or anaesthetic gas scavenging systems, ventilation system discharges, chimney outlets).

The inlet shall be provided with means to prevent the ingress of, for example, insects, debris and water. Consideration should be given to the potential effects of prevailing winds on the location of the intake(s) which should be remote from chimney outlets.

Where more than one air supply source is an air compressor, pollution of the intake air is a common mode of failure. This risk should be addressed with risk analysis as required in [5.2.5](#).

5.5.2.13 A supply system with compressors intended to supply a single-stage pipeline distribution system shall include at least two permanently fitted pressure regulators. The design flow of the pipeline distribution system shall be supplied with at least one pressure regulator isolated for maintenance.

The instructions for use and maintenance shall specify how the permanently fitted pressure regulators are intended to operate.

NOTE The manufacturer may choose between various means of risk control, e.g. automatic switch-over and alarms, manual switch-over and proper emergency procedures, training and local reserve supplies.

5.5.2.14 Means shall be provided to prevent transmission of vibration between each compressor and the pipeline.

5.5.2.15 (*) If one of the sources of supply comprises (a) permanently attached high-pressure reservoir(s), it may be replenished using a high-pressure compressor fed from the medical air supply system.

5.5.3 Supply systems with proportioning unit(s)

5.5.3.1 Regional or national regulations applying to medical air produced by proportioning unit(s) may exist. Where such regulations do not exist, medical air produced by proportioning unit(s) shall comply with the following:

- a) oxygen content between 95,0 percent to 100 per cent of the nominal value which is between 21,0 percent V/V to 22,5 percent V/V [$\geq 19,95\%$ (volume fraction) and $\leq 23,63\%$ (volume fraction)];

b) water vapour content $\leq 67 \text{ ml/m}^3$.

NOTE These values are taken from the European Pharmacopoeia monograph for “synthetic medicinal air”.

5.5.3.2 A supply system with proportioning unit(s) shall comprise of at least three sources of supply, at least one of which shall be a proportioning unit. The supply system shall be such that the system design flow can be supplied with any two sources of supply out of service.

5.5.3.3 A supply system with proportioning units typically consists of one of the following:

- a) sources of oxygen and nitrogen, one proportioning unit and two banks of cylinders, cylinder bundles or high-pressure reservoir(s) or air compressor units; or
- b) sources of oxygen and nitrogen, two proportioning units and one bank of cylinders, cylinder bundles or high-pressure reservoir(s) or air compressor unit; or
- c) sources of oxygen and nitrogen, one proportioning unit, one air compressor unit and one bank of cylinders, cylinder bundles or high-pressure reservoir(s).

The source of oxygen to the proportioning unit shall not be a supply system including an oxygen concentrator.

5.5.3.4 A proportioning unit typically comprises the following:

- a) a mixer unit connected to an oxygen and nitrogen source of supply;
- b) an automatic shut-off valve controlled by the pressure of the supply gas, a pressure regulator and a non- return valve for each of the supply gases;
- c) a process control analyser fitted between the mixer and the reservoir;
- d) a medical air reservoir fitted with a pressure-relief valve, a pressure gauge and a means of purging;
- e) an automatic shut-off valve fitted to prevent medical air out of specification (see [5.5.3.1](#)) being delivered at the outlet of the supply system.

5.5.3.5 A proportioning source of supply shall consist of at least one proportioning unit. Each proportioning source of supply shall be capable of supplying the design flow.

5.5.3.6 The source(s) of oxygen and nitrogen for proportioning systems shall conform to the requirements of [5.2](#) and [5.4](#) and may be the same sources as those supplying the medical gas pipelines separately.

The source of oxygen shall not be an oxygen concentrator.

Means shall be provided to prevent cross-contamination between gases supplying the proportioning unit.

5.5.3.7 A proportioning system shall operate automatically.

The oxygen concentration of the mixture shall be analysed continuously by an oxygen analyser independent from that referred to in [5.5.3.4](#) c) and fitted on or downstream of the reservoir. Recording capability for oxygen concentration shall be provided. Where the proportioning system consists of more than one proportioning unit, only one independent oxygen analysing system is required.

If the oxygen concentration of the mixture or the pressure supplied to the pipeline distribution system goes out of specification, an emergency operating alarm shall be activated and the proportioning system shall be automatically isolated by closing the shut-off valve fitted to the pipeline. The secondary source of supply shall then automatically supply the pipeline.

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.

Means shall be provided to purge the medical air reservoir.

5.5.3.8 Each oxygen analyser shall ensure an accuracy of $\pm 1\%$ of the measured value. The accuracy shall be specified by the manufacturer

NOTE 1 National or regional regulations concerning the oxygen analyser may exist.

NOTE 2 Additional monitoring may be required to show compliance of medical air produced by proportioning unit(s) with national or regional regulations.

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

5.5.3.10 A proportioning system shall include means for calibrating the analysing system(s) by reference to mixture(s) of known composition.

5.5.3.11 A sample port with a shut-off valve shall be provided immediately upstream of the main shut-off valve(s).

5.6 Supply systems with oxygen concentrator(s)

5.6.1 General requirements

Compressor units included in supply systems with oxygen concentrators shall be connected to an emergency electrical supply.

Compressor units included in supply systems with oxygen concentrators shall not be used as air compressors for medical air.

NOTE National or regional regulations concerning the use of oxygen 93 may exist.

A supply system with concentrator unit(s) shall comprise of at least three sources of supply, at least one of which shall be a concentrator unit. The supply system shall be such that the system design flow can be supplied with any two sources of supply out of service.

5.6.2 Primary source of supply

The primary source of supply shall include the following:

- a) at least an oxygen concentrator unit;
- b) at least one oxygen 93 reservoir;
- c) a sample port with a shut-off valve immediately downstream of the oxygen 93 reservoir;
- d) pressure regulator(s);
- e) filter(s) (see [5.6.5.1](#));
- f) means to verify the status of filter element(s) if periodic change of the filter element(s) is not scheduled;
- g) oxygen analyser(s).

Compliance of the installation shall be checked by inspection.

5.6.3 Secondary source of supply

If the secondary source of supply consists of an oxygen concentrator, it shall include the same components as the primary source of supply. If the secondary source of supply consists of only cylinders, cylinder bundles or high-pressure oxygen 93 reservoirs, the following requirements apply:

- a) the source of supply shall consist of at least one bank of cylinders, cylinder bundles or high-pressure oxygen 93 reservoirs;
- b) if there is more than one bank of cylinders, cylinder bundles or high-pressure oxygen 93 reservoirs, gas shall be supplied from one bank of cylinders, cylinder bundles or high-pressure oxygen 93 reservoirs at a time and on depletion of one bank switch automatically to another bank or reservoir.

NOTE This configuration is needed to facilitate replenishment of the secondary source of supply without interruption of supply.

- c) the secondary source of supply shall be connected parallel to the primary source of supply.

The determination of how to ensure the continuity of supply shall be made together with the healthcare facility management in accordance with risk management procedures

5.6.4 Reserve source of supply

If the reserve source of supply consists of an oxygen concentrator, it shall include the same components as the secondary source. If the reserve source of supply consists of only cylinders, cylinder bundles or high-pressure oxygen 93 reservoirs, the following requirements apply:

- a) the source of supply shall consist of at least one bank of cylinders, cylinder bundles or high-pressure oxygen 93 reservoirs;
- b) if there is more than one bank of cylinders, cylinder bundles or high-pressure oxygen 93 reservoirs, gas shall be supplied from one bank of cylinders, cylinder bundles or high-pressure oxygen 93 reservoirs at a time and on depletion of one bank switch automatically to another bank or reservoir.

NOTE This configuration is needed to facilitate replenishment of the reserve source of supply without interruption of supply.

- c) the reserve source of supply shall be connected downstream of the oxygen 93 reservoir(s).

5.6.5 Specifications for oxygen 93

5.6.5.1 National or regional regulations which apply to oxygen 93 produced by an oxygen concentrator supply system may exist. Where such regulations do not exist, the oxygen 93 shall comply with the following at system design flow:

- a) nominal oxygen concentration 93% +/- 3% V/V;
- b) carbon monoxide concentration $\leq 5 \text{ ml/m}^3$;
- c) carbon dioxide concentration $\leq 300 \text{ ml/m}^3$;
- d) oil concentration $\leq 0,1 \text{ mg/m}^3$ measured at ambient temperature and pressure and corrected to 0°C;
- e) water vapour content $\leq 67 \text{ ml/m}^3$;
- f) nitrous gases NO/NO₂ concentration $\leq 2 \text{ ml/m}^3$;
- g) sulfur dioxide concentration $\leq 1 \text{ ml/m}^3$.

NOTE 1 These values are taken from the European Pharmacopoeia.

NOTE 2 In accordance with the European and US pharmacopoeias, oxygen 93 is oxygen between 90% and 96%, the balance of the gas being predominantly argon and nitrogen.

NOTE 3 Other terms may be used by national or regional regulations.

5.6.5.2 Oxygen 93 shall be filtered before the supply source shut-off valve to maintain the particulate contamination below the level provided by [Table 2](#), class 2 of [ISO 8573-1:2010](#) (see [5.5.2.2](#))

5.6.5.3 If periodic change of the filter element(s) is not scheduled, then means shall be provided to verify the status of filter elements.

Evidence shall be provided by the manufacturer.

5.6.5.4 Each concentrator unit included in a supply system shall be capable of supplying a product gas of the required composition over the entire range of specified flow rates.

5.6.6 Oxygen concentrator unit

5.6.6.1 An oxygen concentrator unit consists of:

- a) a compressed air supply with at least one air compressor;
- b) at least one sieve bed;
- c) switching valves as required;
- d) at least one CO alarm sensor fitted to the pipeline system downstream of all conditioning units.

NOTE Other parameters of the oxygen 93 quality may be monitored or recorded. Regional or national regulations may exist.

5.6.6.2 An air compressor may be connected to an air reservoir.

5.6.6.3 An air reservoir (if fitted) may be served by more than one compressor.

5.6.6.4 Air reservoirs (if fitted) shall:

- a) comply with [EN 286-1](#) or equivalent national standards;
- b) be fitted with shut-off valve(s), an automatic drain, a pressure gauge and a pressure-relief valve;
- c) be fitted with a means of pressure control, e.g. pressure switch(es) or pressure transducer(s).

Evidence shall be provided by the manufacturer upon request.

5.6.6.5 When waste gases generated during production of oxygen 93 are vented to the outside of the building, the vent(s) shall be provided with means to prevent the ingress of insects, debris and precipitation. The vent(s) 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.

Compliance of the installation shall be checked by visual inspection.

5.6.7 Oxygen 93 reservoirs

Each oxygen 93 reservoir or group of oxygen 93 reservoir(s) shall:

- a) comply with relevant international, regional or national standards;

- b) be fitted with shut-off valve(s), a pressure gauge and a pressure-relief valve;
- c) be fitted with a means of pressure control, e.g. pressure switch(es) or pressure transducer(s);
- d) be arranged so that each reservoir can be maintained separately.

NOTE An oxygen 93 reservoir may be supplied by more than one oxygen concentrator.

5.6.8 Oxygen analysers

5.6.8.1 An oxygen analyser(s) shall be provided to continuously measure the oxygen concentration from each source of supply incorporating an oxygen concentrator.

Means to display and record oxygen concentration shall be provided.

5.6.8.2 An additional oxygen analyser shall be provided to permit the oxygen concentration of the product gas supplied to the pipeline distribution system to be continuously monitored.

5.6.8.3 Controls shall be provided such that each source of supply incorporating an oxygen concentrator unit shall be automatically isolated from the system if the oxygen concentration of the oxygen 93 produced by that source of supply falls below that specified in [5.6.5 a\)](#) taking into account the accuracy of the analysers.

The oxygen analyser and automatic isolating valve on the oxygen 93 reservoir shall be located upstream of the oxygen 93 reservoir.

5.6.8.4 Each oxygen analyser shall be equipped with a low concentration emergency alarm and a high concentration information signal. The setting of the alarm limit(s) shall take into account the accuracy of the analysers. Means shall be provided to prevent unauthorized changes of the alarm setting.

5.6.8.5 Where justified by the specifications of the analyser manufacturer, each oxygen analyser shall include compensation for temperature and barometric pressure variations to ensure an accuracy of within $\pm 1\%$. The actual accuracy shall be specified by the manufacturer.

NOTE 1 National or regional regulations concerning the oxygen analyser may exist.

NOTE 2 Additional monitoring may be required to show compliance of oxygen 93 with national or regional regulations.

5.6.8.6 A sample port with a shut-off valve shall be provided immediately upstream of the supply system shut-off valve.

5.6.8.7 A supply system with oxygen concentrators shall include means for calibrating the analysing system(s) by reference to mixture(s) of known composition.

5.6.9 Local filling of permanently attached high-pressure reservoir(s), acting as reserve source of supply

5.6.9.1 Caution shall be taken in filling high-pressure oxygen 93 reservoir(s) as the practice has inherent risks of fire due to the high oxidising capacity of materials, which at ambient pressure are fully compatible with oxygen, but at higher pressures can easily ignite and burn easily in high concentrations of oxygen. These risks may be mitigated by following relevant standards.

5.6.9.2 If oxygen 93 is compressed by a booster compressor into (a) permanently attached high-pressure oxygen 93 reservoir(s), for use as the reserve source of supply the following requirements shall be met:

- a) Means shall be provided to ensure that the filling of reserve high-pressure reservoir(s) does not affect delivery of oxygen 93 to the pipeline distribution system.
- b) A sample port with a shut-off valve shall be provided adjacent to the filling system.

NOTE Regional or national regulations that apply to the filling system may exist (e.g. Pressure Equipment Directive in Europe).

5.6.9.3 The following safety measures shall be implemented:

- a) means (e.g. a non-return valve) to ensure that there is no back flow to the oxygen concentrator supply system;
- b) appropriate barrier(s) to protect personnel;
- c) in order to ensure safety of patients in the event of temperature build-up, the high-pressure booster compressor shall have a temperature sensor on each compression stage, which may activate an alarm for high temperature thresholds recommended by the manufacturer of the compressor, and may stop the compressor;
- d) the following operating alarms shall be provided, set to activate at thresholds as defined by the manufacturer:
 - an enclosure temperature sensor;
 - an output gas temperature sensor;
 - a power sensor;
 - a high-pressure sensor.

In the event of actuation of any of these alarms, the compressor unit shall be automatically stopped in order to avoid contamination of the reserve source of supply.

- e) a means shall be provided to purge the oxygen 93 high-pressure reservoir.

5.7 Supply systems for vacuum

5.7.1 A supply system for vacuum shall comprise at least three sources of supply, one receiver, two parallel bacterial filters and one drainage trap. A source of supply typically comprises one or more vacuum pumps.

5.7.2 A supply system for vacuum shall be such that the system design flow can be supplied with any two sources of supply out of service.

5.7.3 Where the supply system for vacuum consists of more than three pumps, which can be switched between the different sources of supply to provide adequate capacity, these shall be arranged so that during maintenance on any pump and during a subsequent single fault condition of any component of the system (e.g. the control system), the remaining pumps and components shall be capable of supplying the system design flow to ensure continuity of supply.

NOTE Typical examples of flow requirements are given in HTM 02 [33], [34], FD S 90-155 [32] and AS 2896:1998 [22].

5.7.4 Each pump shall have a control circuit arranged so that shutting off, or failure, of one pump will not affect the operation of other pumps. The controls shall be arranged so that all the pumps supply the system in turn or simultaneously. This requirement shall be met in normal condition and in single fault condition of the control system.

5.7.5 All sources of supply shall be connected to the emergency power supply.

5.7.6 Means shall be provided to ensure correct vacuum to the pipeline system when the mains power is interrupted for a period determined by risk management.

5.7.7 Each receiver shall be fitted with maintenance shut-off valve(s), a drain valve and a vacuum gauge. If only one receiver or one drainage trap is fitted, means of bypass shall be provided. Receivers shall comply with appropriate regional or national standards.

5.7.8 The exhaust(s) from the vacuum pumps shall be piped to the outside and shall be provided with means to prevent the ingress of, for example, insects, debris and water. The exhaust(s) shall be located remote from any air intakes, doors, windows or other openings in buildings. Exhaust locations should be chosen after consideration of the dispersal by prevailing winds of the exhaust plume.

5.7.9 The exhaust line shall be provided with a drain at its lowest point.

5.7.10 If necessary, means shall be provided to prevent the transmission of vibration from the vacuum pumps to the pipeline.

NOTE 1 National or regional regulations regarding noise may exist.

5.7.11 Each bacterial filter shall be rated as HEPA [ISO 35H](#) or better under ISO 29463-1 and capable of passing the system design flow under normal operating conditions.

5.7.12 Total filtration capacity shall ensure that the system design flow is sustained at normal operating conditions when at least one bacteria filter is isolated during maintenance, e.g. filter cartridge replacement.

5.7.13 (*) Vacuum supply systems complying with this part of ISO 7396 shall not be used as anaesthetic gas scavenging (AGS) power devices (see [ISO 7396-2 \[8\]](#)).

5.7.14 Vacuum supply systems complying with this part of ISO 7396 shall not be used in dentistry.

5.7.15 Supply systems for vacuum shall comply with [5.2.2.1](#).

5.8 Location of supply systems

The location of a supply system should be defined by the management of the healthcare facility in consultation with the system supplier, using risk management principles.

5.8.1 Gas and liquefied gas cylinder supply systems shall not be located:

- a) in the same room as equipment with electrically driven motors (e.g. air compressors, vacuum pumps, water pumps). An exception may be made for equipment (e.g. fans, blowers) directly ventilating the enclosure and for locations open to the outside without risk of confinement;
- b) in the same room as equipment with open flames (e.g. boilers, gas water heaters).

NOTE National or regional regulations may require that air compressors, oxygen concentrators and vacuum supply systems be located in separate technical areas.

5.8.2 (*) The location of supply systems shall take into account potential hazards (e.g. contamination and fires) arising from the location of other equipment or other supply systems within the same room. The location shall be provided with means of fire detection.

Drainage facilities shall be provided for compressor unit(s) and vacuum pump(s).

The ambient temperature in rooms for supply systems shall be maintained in the range of 10°C to 40°C.

Supply systems installed in open air need to be suitable for the environmental conditions to which they will be exposed.

[A1] Locations of supply systems which contain gases other than CO₂, medical air and air for driving surgical tools, and in which the gas can accumulate, shall be provided with an oxygen monitor with an indicator at the entry to warn of oxygen concentrations below 19,5 % or above 23,5 %. The monitor shall activate an alarm with audible and visual signals outside the entrance to warn of oxygen concentrations below 19,5 % or above 23,5 %. The O₂ sensor should be installed at a height of approximately 1 m. Labelling information on risks (anoxia, hypoxia) shall be placed on the outside of the entrance door. In case of supply system for CO₂, a CO₂ sensor with an indicator shall be installed at the entry to ensure the safety of personnel. In this case, the threshold level for CO₂ is 1,5 % in ambient air. The monitor shall activate an alarm with audible and visual signals outside the entrance, to warn of CO₂ concentrations equal to or above 1,5 %. The CO₂ sensor shall be installed at height of approximately 1 m.

For CO₂, complementary to these requirements labelling, information on risks (anoxia, hypoxia) shall be placed outside of the room in a position that is clearly visible to anyone entering the room. **[A1]**

NOTE 1 National or regional regulations may require monitoring for other gases e.g. CO₂ and N₂O.

NOTE 2 National and regional regulations concerning noise levels may exist. Mechanical equipment (e.g. compressors and pumps) may generate noise in excess of 70 dBA.

5.9 Location of cylinder manifolds

The location of cylinder manifolds shall be defined in collaboration with the relevant authorities and in accordance with the relevant national standards. Informative guidelines are given in [Annex B](#).

5.10 Location of stationary cryogenic vessels

The location of stationary cryogenic vessels shall be defined in collaboration with the relevant authorities and the gas supplier and in accordance with the relevant national standards. Informative guidelines are given in [Annex B](#).

6 Monitoring and alarm systems

6.1 General

Monitoring and alarm systems have four different purposes which are fulfilled by operating alarms, emergency operating alarms, emergency clinical alarms and information signals.

- a) Operating alarms notify the technical staff that one or more sources of supply within a supply system are no longer available for use and it is essential that action be taken.
- b) Emergency operating alarms indicate abnormal pressure within a pipeline or gas quality out of range and could require immediate response by the technical staff.
- c) Emergency clinical alarms indicate abnormal pressure within a pipeline and could require immediate response by both the technical and the clinical staff.
- d) Information signals indicate any status of the system, with exception of alarms and reminders.

The control panel, the monitoring and the alarm system shall be designed in accordance with [IEC 60601-1-8](#). Except if a single or dual tone is used as an auditory signal, the emergency clinical alarm may be exempt from the auditory requirements of [IEC 60601-1-8](#) (see [Table 1](#)).

6.2 Installation requirements

6.2.1 If not specified in this part of ISO 7396, the location of indicator panels shall be determined in consultation with the healthcare facility management using risk management principles.

6.2.2 Monitoring and alarm systems shall comply with the following requirements:

- a) the design and location of the indicator panels shall allow continuous observation;
- b) an indicator panel displaying all operating alarm signals specified in [6.4](#) shall be installed in at least one location allowing continual observation or communication;
- c) the indicator panel(s) for the emergency clinical alarm signals specified in [6.5](#) shall be installed in the clinical and critical care areas. An additional panel indicating the area monitored may be installed near the area shut-off valve;
- d) an indicator panel displaying all emergency operating alarm signals specified in [6.6](#) shall be installed at the location of the source(s) of supply;
- e) visual indicators shall be provided for each condition monitored and shall be marked according to function;
- f) the sensing devices for emergency clinical alarms listed in [6.5](#) shall be located on the patient side of each area shut-off valve;
- g) means shall be provided for testing the activation mechanism and functioning of visual and auditory alarm signals;
- h) it shall not be possible to isolate a pressure-sensing device, for example by a manually operated shut-off valve, while it is connected to the pipeline. If a valve is incorporated for maintenance purposes, it shall be opened by the insertion of the sensing device;
- i) the operating tolerance on the set point of any pressure-sensing device shall not exceed $\pm 4\%$.

6.2.3 (*) Monitoring and alarm systems shall be connected to both the normal and the emergency electrical power supplies and shall be individually electrically protected. Risk assessment shall be performed to determine the advisability of additional batteries or Uninterruptable Power Supplies (UPS).

6.2.4 Alarm systems shall be designed so that an alarm is initiated if there is communication failure between the sensor and the indicator.

6.3 Monitoring and alarm signals

6.3.1 General

The categories and the characteristics of the monitoring and alarm signals shall comply with [Table 1](#).

6.3.2 Auditory signals

6.3.2.1 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 minimum volume shall be at least 2 dB above a white background level of 55 dB when tested in accordance with [ISO 3746](#).

6.3.2.2 If an auditory alarm signal can be audio paused by the operator, the audio pausing shall not prevent the auditory signal from being activated by a new alarm condition.

6.3.2.3 (*) If an emergency auditory alarm signal can be audio paused by the operator, the period of audio pausing shall not exceed 15 min.

6.3.2.4 If means to disable the auditory signal are provided, such means shall only be accessible to authorized persons.

6.3.3 Visual signals

6.3.3.1 The indicator colours and the characteristics of visual signals shall comply with [Table 1](#).

6.3.3.2 Visual indications shall be perceived correctly and discriminated between under the following conditions (see [IEC 60601-1-8](#)):

- a) operator with a visual acuity of 1 (corrected if necessary);
- b) viewpoint 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;
- c) under an ambient illuminance throughout the range of 100 lx to 1 500 lx.

6.3.4 Emergency and operating alarm characteristics

6.3.4.1 For emergency clinical alarms and emergency operating alarms (see [Table 1](#)), there shall be a visual and a simultaneous auditory signal.

6.3.4.2 For operating alarms (see [Table 1](#)), there shall be at least a visual signal.

6.3.4.3 When the condition which has caused the alarm has cleared, the auditory signal and the visual signal shall reset automatically or by deliberate operator action.

Table 1 — Alarm categories and signal characteristics

Category	Operator response	Indicator colour	Visual signal	Auditory signal
Emergency clinical alarm	Immediate response to deal with a hazardous situation	Complying with IEC 60601-1-8	Complying with IEC 60601-1-8	Complying with IEC 60601-1-8 ^a
Emergency operating alarm	Immediate response to deal with a hazardous situation	Red	Flashing ^b	Yes
Operating alarm	Prompt response to a hazardous situation	Yellow	Flashing ^b	Optional
Information signal	Awareness of normal status	Not red Not yellow	Constant	No

^a If a pattern of more than two tones or frequencies is used.

^b 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 %.

6.3.5 Information signals

Information signals shall be provided to indicate normal status and shall consist of a visual signal (see [Table 1](#)).

6.3.6 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.

6.4 Provision of operating alarms

Operating alarm signals shall be provided to indicate the following:

- a) change-over from primary to secondary cylinder supplies;
- b) any primary, secondary or reserve cylinder supply below minimum pressure or content;
NOTE For nitrous oxide and carbon dioxide cylinders, pressure might not indicate the content.
- c) pressure in any cryogenic vessel below the minimum specified by the management of the healthcare facility in consultation with the gas supplier;
- d) liquid level in any cryogenic vessel below the minimum specified by the management of the healthcare facility in consultation with the gas supplier;
- e) malfunctioning of an air compressor system;

NOTE The compressor overheating alarm threshold is defined by the compressor manufacturer.

- f) for air supplied by a compressor system, water vapour content above the level specified in [5.5.2.1](#) or [5.5.2.4](#);
- g) for medical air supplied from a compressor system and oxygen 93 supplied from a concentrator system, when the CO level exceeds 10 ppm or a lower limit where regional or local regulation specifies a lower value.

5 ppm V/V is the value specified in the European Pharmacopoeia Medicinal Air monograph. 0.001% V/V (10 ppm V/V) is the limit value specified in the USP Medicinal Air monograph. In areas where intermittent high levels of atmospheric CO are present (e.g., near a busy highway), healthcare facilities should consider installing a treatment system to remove CO from the compressed medical air supply. To reduce transient nuisance alarms the value of 10 ppm V/V was selected based on North American experience with these monitors.

Additional operating alarms may be required by regional or national regulations e.g. for air supplied by a compressor system or oxygen 93 supplied from a concentrator system.

NOTE This could include e.g. monitoring of concentration of O₂, CO, CO₂, NO, NO₂ and oil.

- h) malfunctioning of a proportioning system;
- i) malfunctioning of a cryogenic system;
- j) malfunctioning of a vacuum system;
- k) malfunctioning of a supply system for oxygen 93;
- l) malfunctioning of a supply system with an oxygen concentrator;
- m) reserve source of supply in use;
- n) content of reserve source of supply below 50% of capacity for compressed gas(es) in cylinders (e.g. oxygen, air, nitrogen) or less than 40 bar for liquefied gas(es) in cylinders (e.g. nitrous oxide and carbon dioxide);
- o) failure of external power supply.

6.5 Provision of emergency clinical alarms

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

- a) deviation of the pipeline pressure downstream of any area shut-off valve by more than $\pm 20\%$ from the nominal distribution pressure;
- b) an increase of pipeline pressure for vacuum upstream of any area shut-off valve above 66 kPa absolute.

6.6 (*) Provision of emergency operating alarms

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

- a) for a single-stage distribution system, deviation of the pipeline pressure downstream of the main shut-off valve by more than $\pm 20\%$ from the nominal distribution pressure;
- b) for a double-stage distribution system, deviation of the pipeline pressure downstream of the main shut-off valve by more than $\pm 20\%$ from the nominal supply system pressure;
- c) increase of pipeline pressure for vacuum on the patient side of the main shut-off valve above 44 kPa absolute;

NOTE Regional or national regulations/standards may require a different value for the vacuum alarm.

- d) temperature of any air compressor exceeding the threshold defined by the manufacturer;
- e) medical air supplied from a compressor system, when CO level exceeds 25 ppm or lower if required by regional or national regulation;

NOTE The 25 ppm alarm set point was selected from the American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit value for CO. Other values may be established by local or regional regulations.

- f) for systems supplied from oxygen concentrator supply units, an oxygen concentration below 90%;
- g) for systems supplied from proportioning units, an oxygen concentration outside the specified limits.

The location of the pressure sensors shall be consistent with the location and the intended use of ring shut-off valves, if fitted.

7 Pipeline distribution systems

7.1 Mechanical resistance

All sections of pipeline distribution systems for compressed medical gases shall withstand a pressure of 1,2 times the maximum pressure which can be applied to that section in single fault condition.

7.2 Distribution pressure

NOTE Unless otherwise specified, pressures in this part of ISO 7396 are expressed as gauge pressure (i.e. atmospheric pressure is defined as 0).

7.2.1 The nominal distribution pressure shall be within the ranges given in [Table 2](#). Different gases may be delivered at different nominal distribution pressures in the same healthcare facility.

Table 2 — Ranges of nominal distribution pressure

Pressure in kilopascals

Compressed medical gases other than air or nitrogen for driving surgical tools	400 ⁺¹⁰⁰ ₀
Air or nitrogen for driving surgical tools	800 ⁺²⁰⁰ ₋₁₀₀ ^a
Vacuum	<60 ^b
^a Regional or national regulations/standards may require a different range.	
^b Absolute pressure.	

If gases are delivered at different nominal distribution pressures, nitrous oxide should be delivered at a nominal distribution pressure lower than that for oxygen and medical air in order to prevent flow of nitrous oxide into the oxygen or medical air pipeline when gas mixers or other equipment are used.

If gases are delivered at different nominal distribution pressures, medical air may be delivered at a nominal distribution pressure lower or higher from that for oxygen. A risk analysis should be conducted to determine appropriate pressure settings.

NOTE National or regional regulations may apply.

7.2.2 For compressed medical gases other than air or nitrogen for driving surgical tools, the pressure at any terminal unit shall not be greater than 110 % of the nominal distribution pressure with the system operating at zero flow. The pressure at any terminal unit shall not be less than 90 % of the nominal distribution pressure with the system operating at system design flow.

NOTE 1 System design flow is calculated in accordance with appropriate diversity factors. Examples of diversity factors are given in HTM 02 [33], [34], FD S 90-155 [32] and AS 2896-1998 [22].

NOTE 2 The following factors will contribute to the pressure change: performance of pressure regulators, pressure drop in the pipeline downstream of the pressure regulator and pressure drop across the terminal unit.

7.2.3 For air or nitrogen for driving surgical tools, the pressure at any terminal unit shall not be greater than 115 % of the nominal distribution pressure with the system operating at zero flow. The pressure at any terminal unit shall not be less than 85 % of the nominal distribution pressure with the system operating at system design flow.

NOTE 1 System design flow is calculated in accordance with appropriate diversity factors. Examples of diversity factors are given in HTM 02 [33], [34], FD S 90-155 [32] and AS 2896-1998 [22].

NOTE 2 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 and pressure drop across the terminal unit.

7.2.4 For vacuum systems, the pressure at any terminal unit shall not be greater than 60 kPa absolute with the system operating at system design flow.

NOTE System design flow is calculated in accordance with appropriate diversity factors. Examples of diversity factors are given in HTM 02 [33], [34], FD S 90-155 [32] and AS 2896-1998 [22].

7.2.5 (*) For compressed medical gases other than air or nitrogen for driving surgical tools, the pressure at any terminal unit shall not exceed 1 000 kPa in a single fault condition of any pressure regulator installed within the system. Means for this purpose (e.g. pressure-relief valves) shall be provided. If fitted, pressure- relief valves shall comply with 5.2.6. Bursting discs shall not be used for this purpose.

Evidence shall be provided by the manufacturer.

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

NOTE 2 Attention is drawn to regional, national and international standards for pressure-relief valves, e.g. [ISO 4126-1](#) [3].

7.2.6 (*) For air or nitrogen for driving surgical tools, the pressure at any terminal unit shall not exceed 2 000 kPa in a single fault condition of any pressure regulator installed within the system. Means for this purpose (e.g. pressure-relief valves) shall be provided. If fitted, pressure-relief valves shall comply with [5.2.6](#). Bursting discs shall not be used for this purpose.

Evidence shall be provided by the manufacturer.

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

NOTE 2 Attention is drawn to regional, national and international standards for pressure-relief valves, e.g. [ISO 4126-1](#) [3].

7.3 Low-pressure hose assemblies and low-pressure flexible connections

7.3.1 If a flexible connection is not intended to be replaced during the life of the pipeline system and is part of the pipeline (e.g. when used for isolation of vibration, seismic isolation, building movement and relative movement of the pipelines) the following requirements shall be met:

- a) the low pressure flexible connection shall be metallic;
- b) the low pressure flexible connection need not be gas-specific;
- c) the materials used for the components shall meet the requirements in [4.3](#);
- d) the low pressure flexible connection shall be tested as part of the permanent piping.

7.3.2 If a low-pressure hose assembly is used to connect moving parts of fixed equipment to a pipeline, (e.g. as part of permanently fixed equipment such as booms, pendants, pendant tracks or to electrically isolate terminal units installed close to Magnetic Resonance Imaging (MRI) systems it shall comply with the following:

- a) it shall comply with [ISO 5359](#);
- b) it shall be tested in accordance with [Clause 12](#);
- c) it shall be accessible for inspection and maintenance (see also [8.1.2](#)).

The use of low-pressure hose assemblies and low-pressure flexible connections in the pipeline distribution system should be limited because of the potential hazard arising from their rupture and the subsequent risk of loss of gas supply.

7.4 Double-stage pipeline distribution systems

7.4.1 (*) Alternative arrangements for line pressure regulators are shown in [Annex A](#) ([Figures A.23](#) and [A.24](#)). Each bed space/patient space shall be supplied from at least two permanently fitted line pressure regulators to ensure continuity of supply. The design flow of the area served shall be supplied by each line pressure regulator. The inlet pressure of the line pressure regulator shall not exceed 3 000 kPa (see [ISO 10524-2](#)).

NOTE 1 The line pressure regulators may be combined with the area shut-off valve (see [8.3](#)).

The instructions for use and maintenance shall specify how the two permanently fitted line pressure regulators are intended to operate.

NOTE 2 The manufacturer may choose between various means of risk control, e.g. automatic switch-over and alarms, manual switch-over and proper emergency procedures, training and local reserve supplies.

In order to ensure continuity of supply the two line pressure regulators should not be in use at the same time. If in use at the same time they may both fail.

7.4.2 For emergency and maintenance purposes, shut-off valves shall be fitted both upstream and downstream, adjacent to each line pressure regulator.

8 Shut-off valves

8.1 General

8.1.1 Shut-off valves are provided to isolate sections of the pipeline distribution system for maintenance, repair, planned future extensions and to facilitate periodic testing.

The nomenclature for shut-off valves shall be as follows:

- a) source shut-off valve;
- b) main shut-off valve;
- c) riser shut-off valve;
- d) branch shut-off valve;
- e) area shut-off valve;
- f) ring shut-off valve;
- g) maintenance shut-off valve;
- h) inlet shut-off valve.

NOTE Examples of nomenclature of shut-off valves are given in [Annex A](#).

8.1.2 If not specified, the location of all shut-off valves and the extent of the area served by each area shut-off valve shall be determined by the manufacturer together with the healthcare facility management, using risk analysis procedures in accordance with [ISO 14971](#).

The risk assessment shall also take into account the hazards arising from the possible rupture of low-pressure hose assemblies fitted within any medical supply units.

Consideration should be given to providing a shut-off valve at the point where the pipeline enters a building unless the main, riser or branch shut-off valve is accessible within the building.

8.1.3 All shut-off valves shall be identified by indicating:

- a) the gas or vacuum service name or symbol; and
- b) the risers, branches or areas controlled.

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

8.1.4 For all shut-off valves in a medical gas pipeline system, it shall be apparent by observation whether the valve is open or closed.

8.1.5 A source shut-off valve shall be provided downstream (upstream for vacuum) of each source of supply.

8.1.6 A main shut-off valve shall be provided on the pipeline immediately upstream of the maintenance supply assembly, if provided.

8.1.7 Either shut-off valves shall be capable of being lockable in the open and closed positions or they shall be protected from operation by unauthorized personnel.

8.2 Service shut-off valves

8.2.1 Typical uses of service shut-off valves are

- a) as shut-off riser valves,
- b) as shut-off branch valves,
- c) as shut-off maintenance valves, or
- d) as shut-off ring valves.

8.2.2 Service shut-off valves shall be used only by authorized personnel and should not be accessible to unauthorized persons.

8.2.3 Each riser shall be provided with a shut-off valve adjacent to the connection to the main line.

8.2.4 Each branch shall be provided with a shut-off valve adjacent to the connection to the riser or main line.

8.3 Area shut-off valves

8.3.1 All terminal units in the pipeline system other than those provided only for emergency, system test purposes or maintenance of components (e.g. line pressure regulators) shall be on the patient side of an area shut-off valve (upstream for vacuum). An area shut-off valve shall be provided in each gas and vacuum pipeline serving each operating theatre, general ward area and all other departments, e.g. Intensive Care Unit (ICU), Neonatal Intensive Care Unit (NICU) and emergency treatment area.

8.3.2 Area shut-off valves shall be located on the same floor as the terminal units they serve.

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

8.3.4 Area shut-off valves shall be housed in boxes with covers or doors. The boxes shall be labelled with the following or similar wording:

For compressed gases:

CAUTION — Medical Gas Valves for (description of area controlled) Do not close valve(s) except in emergency.

For vacuum:

CAUTION — Vacuum Valves for (description of area controlled) Do not close valve(s) except in emergency

8.3.5 Each box shall contain the following:

- a) area shut-off valve(s) for one or more gases;
- b) except for vacuum systems, means to allow physical isolation of the service(s). These means shall be clearly visible when deployed. A closed valve shall not be considered an adequate physical isolation when modifications are carried out to existing systems.

8.3.6 Each box shall be vented to the room to prevent accumulation of gas and shall have a cover or door which may be secured in the closed position. The cover or door shall allow quick access in case of emergency.

8.3.7 All boxes shall be visible and accessible at all times.

Consideration shall be given to prevent access by unauthorized personnel, especially in psychiatric or paediatric units.

8.3.8 Except for pipelines for vacuum and for air or nitrogen for driving surgical tools, an emergency and maintenance inlet point shall be provided downstream of each area shut-off valve. The emergency and maintenance inlet point shall be gas-specific (either a NIST, DISS or SIS body or the socket of a terminal unit). The dimensions of the inlet point shall take into account the flow required during emergency and maintenance activities. The emergency and maintenance inlet point may be located within the box containing the area shut-off valve.

8.3.9 No components shall be installed between an area shut-off valve and the terminal unit except for:

- sensors or indicators (e.g. for pressure and flow),
- emergency and maintenance inlet points,
- means to allow physical isolation of the service,
- maintenance shut-off valves (if fitted),
- operator-adjustable low-pressure regulators for air or nitrogen for driving surgical tools (see [ISO 10524-4](#) [19]),
- low pressure hose assemblies complying with [ISO 5359](#) within medical supply units.

8.3.10 No area shut-off valve shall be fitted downstream of the sensor activating the emergency pressure alarm.

9 Terminal units, gas-specific connectors, medical supply units, pressure regulators and pressure gauges

9.1 Terminal units shall be gas specific and comply with [ISO 9170-1](#).

9.2 Gas-specific connectors shall be either the gas-specific connection point of a terminal unit complying with [ISO 9170-1](#) or the body of a NIST, DISS or SIS connector.

9.3 Medical supply units (e.g. ceiling pendants, bedhead units, booms) shall comply with [ISO 11197](#).

9.4 Manifold and line pressure regulators shall comply with [ISO 10524-2](#).

9.5 Pressure gauges shall comply with the requirements given in [ISO 10524-2](#).