Form 36

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx

1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex **(e.g. 3.1)**	Paragraph/ Figure/Table/Note	**Type of comment**	**Commend (justification for change) by the MB**	**Proposed change by the MB**	**Secretariat observations on each comment submitted**
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	

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DRAFT International Standard

ISO/DIS 7396-1

Medical gas pipeline systems —

Part 1: Pipeline systems for compressed medical gases and vacuum

Systèmes de distribution de gaz médicaux —

Partie 1: Systèmes de distribution de gaz médicaux comprimés et de vide

ICS: 11.040.10

ISO/TC **121**/SC **6**

Secretariat: **ANSI**

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2025-04-25

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2025-07-18

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Contents

Page

Foreword ..... **v**

Introduction ..... **vi**

1 Scope **1**

2 Normative References **2**

3 Terms and Definitions **3**

4 General Requirements **9**
4.1 *Safety* and Risk Management 9
4.2 Deviations from the standard 10
4.3 Gases for Medicinal Use 10
4.4 Materials 10
4.5 System Design 12

5 *Supply systems* **15**
5.1 *Supply system* components 15
5.2 General Requirements for *supply systems* 17
5.3 *Supply systems* with cylinders, *cylinder bundles* or *high pressure reservoir*(s) 19
5.4 *Supply systems* with cryogenic or non *Cryogenic vessels* 21
5.5 *Supply systems* for Air 21
5.6 *Supply systems* using oxygen concentrators 27
5.7 *Supply systems* for Vacuum 33
5.8 Location of *supply systems* and sources of supply 35
5.9 Sources of supply and *supply systems* assembled at site 36
5.10 *Sources of supply* and *supply systems* preassembled in a factory 37

6 Monitoring and Alarms **38**
6.1 General 38
6.2 Installation requirements 39
6.3 Monitoring and alarm signals 39
6.4 Provision of *operating alarms* 41
6.5 Provision of *emergency clinical alarms* 42
6.6 Provision of *emergency operating alarms* 42

7 *Pipeline distribution systems* **42**
7.1 Mechanical resistance in *single fault condition* 42
7.2 Distribution pressure 43
7.3 Low-pressure hose assemblies and low-pressure flexible connections 44
7.4 *Double-stage pipeline distribution systems* 44

8 *Shut-off valves* and *non-return valves* **45**
8.1 General 45
8.2 Source *shut-off valve* 45
8.3 Main *shut-off valve* 45
8.4 Service *shut-off valves* 46
8.5 *Riser shut-off valves* 46
8.6 *Pipeline branch shut-off valves* 46
8.7 Area *shut-off valves* 46
8.8 *Non-return valves* 47

9 *Terminal units*, *pressure regulators* and pressure gauges **47**

10 Marking and color coding **48**
10.1 Marking 48
10.2 Colour coding 48

11 Pipeline Installation **48**
11.1 General 48
11.2 Pipeline supports 49

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Full document details: 25/30475284 DC

11.3 Pipeline Joints ... 50
11.4 Extensions and modifications of existing *medical gas pipeline systems* ... 50

12 Testing and *Commissioning* ... **51**
12.1 General ... 51
12.2 General requirements for tests ... 51
12.3 Inspections and tests for sources of supply and *supply systems* ... 51
12.4 Tests for *sources of supply* using oxygen concentrator units ... 53
12.5 Tests of the quality of *air for driving surgical tools* ... 54
12.6 Tests of the quality of medical air produced by supply systems with proportioning unit(s) ... 55
12.7 Tests of the *supply systems* for vacuum ... 55
12.8 Verification of restart after power supply failure ... 55
12.9 Pipeline Tests ... 55
12.10 Statement of compliance to this part of ISO 7396 ... 61

13 Documentation Requirements ... **62**
13.1 Instructions for installation ... 62
13.2 Instructions for use ... 62
13.3 Operational management information ... 63
13.4 "As-installed" drawings ... 63
13.5 Test reports ... 64

Annex A (informative) **Schematic representations of typical *supply systems* and area distribution systems** ... **65**

Annex B (informative) **Guidelines for location of cylinder *manifolds*, cylinder storage areas and stationary vessels for cryogenic or non-cryogenic liquids** ... **98**

Annex C (informative) **Example of procedure for testing and *commissioning*** ... **99**

Annex D (informative) **Typical forms for documenting compliance of the *medical gas pipeline systems*.** ... **112**

Annex E (informative) **Temperature and pressure relationships** ... **141**

Annex F (informative) **Rationale for *Air compressor unit* Hazards** ... **143**

Annex G (informative) **Operational management** ... **145**

Annex H (informative) **Risk management checklist** ... **164**

Annex I (informative) **Rationale** ... **175**

Annex J (informative) **Considerations for implementation and use of oxygen following alternate pharmacopeial specifications** ... **179**

Annex K (informative) **Manufacture of medical gases on site, Responsibility for medical gas quality** ... **181**

Annex L (Informative) **Roles and Responsibilities** ... **184**

Annex M (Informative) **Examples of pharmacopeial requirements for on-site production** ... **187**

Bibliography ... **189**

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Full document details: 25/30475284 DC

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).

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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 fourth edition cancels and replaces the third edition (ISO 7396-1:2016).

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: Anesthetic gas scavenging disposal systems

— Part 3: *Proportioning units*

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Introduction

Many *healthcare facilities* use *medical gas 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 *medical gas 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 *medical gas 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 *medical gas pipeline systems* by design, installation and testing;

b) continuous supply of gases and vacuum at specified quality, pressures and design flow rates 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 and pressure of the gases delivered to the terminals 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 third party 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 medical gas on site the *healthcare facility* is responsible for all aspects of the medical gas quality.

Vacuum for medical suction is also the responsibility of the *healthcare facility*.

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Annex G, J and K provides guidance for the assignment of responsibility for production and quality control of the gases and vacuum.

Annexes G and H provide some guidance as to how the quality of the gas should be managed to maintain patient *safety* at the highest level.

Annex I 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 I.

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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 *medical gas pipeline systems* used in *healthcare facilities* for the following:

— argon;

— oxygen;

— nitrous oxide;

— *medical air*;

— carbon dioxide;

— oxygen/nitrous oxide mixtures;

— helium/oxygen mixtures;

— 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;

— vacuum.

NOTE 1 A rationale for this is contained in Annex I.

NOTE 2 Anesthetic gas scavenging disposal systems are covered in ISO 7396-2[6]

This part of ISO 7396 includes requirements for *supply systems*, medical gas *pipeline distribution systems*, *control system(s)*, monitoring and alarm systems and non-interchangeability between different gas/vacuum systems.

This part of ISO 7396 specifies *safety* requirements for *medical gas pipeline systems* used in *healthcare facilities*. 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).

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NOTE 3 This part of ISO 7396 may also be used as reference for *medical gas pipeline systems* 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 produced off-site;

— *supply systems* in which some or all *sources of supply* deliver oxygen produced on-site; in this case the concentration of the oxygen may vary, depending on the pharmacopeial specification selected by the *healthcare facility*

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.

EN 14931:2006[37] defines additional requirements for hyperbaric application, in particular for flow rates 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.

This part of ISO 7396 does not apply to liquid nitrogen cryogenic piping for cryobanks.

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 4126-1:2013, *Safety devices for protection against excessive pressure — Part 1: Safety valves*

ISO 5011:2020, *Inlet air cleaning equipment for internal combustion engines and compressors — Performance testing*

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 9170-1:2017, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*

ISO 10524-2:2018, *Pressure regulators for use with medical gases — Part 2: Manifold and line pressure regulators*

ISO 11197:2019, *Medical supply units*

ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

ISO 15001:2010, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

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ISO 17672:2024, *Brazing — Filler metals*

ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer*

ISO 21969:2009, *High-pressure flexible connections for use with medical gas systems*

ISO 29463-1:2024, *High efficiency filters and filter media for removing particles in air — Part 1: Classification, performance, testing and marking*

ISO 18562-2:2024, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 2: Tests for emissions of particulate matter*

IEC 60529:2019, *Degrees of protection provided by enclosures (IP Code)*

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*

IEC 62304:2006, *Medical device software — Software life cycle processes*

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

EN 1254-1:2021, *Copper and copper alloys - Plumbing fittings - Fittings with ends for capillary soldering or capillary brazing to copper tubes*

EN 1012-1:2010, *Compressors and vacuum pumps - Safety requirements - Part 1: Air Compressors*

EN 1012-2:2009, *Compressors and vacuum pumps - Safety requirements - Part 2: Vacuum Pumps*

EN 13348:2016, *Copper and copper alloys — Seamless, round copper tubes for medical gases or vacuum*

EN 13445-1:2021, *Unfired pressure vessels - Part 1: General*

3 Terms and Definitions

3.1
applicable policy
set of requirements relating to the medical device or accessory and its attributes such as form, fit, function, process or information to be supplied by the *manufacturer*

Note 1 to entry: The *applicable policy* shall be established by the authority having jurisdiction.

Note 2 to entry: The *applicable policy* may include specification for the format of the information to be supplied by the *manufacturer*.

3.2
air compressor unit
the portion of the *source of supply* including the device for compressing or moving ambient air (typical examples are compressors and blowers). The *air compressor unit* comprises the compressor, a drive system and any component or device which is necessary for operation

3.3
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.

Note 2 to entry: Nitrogen can also be used to drive surgical tools.

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3.4
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]

3.5
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)*.

3.6
commissioning
proof of function to verify that the agreed system specification is met and is accepted by the responsible organization

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 vessel
vacuum jacketed vessel intended for application at low temperature involving liquefied gases

3.10
cylinder bundle
pack or pallet of cylinders linked together with one or more connectors for filling and emptying

3.11
diversity factor
number which represents the maximum proportion of *terminal units* in a defined clinical area which will be used at the same time, at flow rates 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 operating alarm
alarm to indicate to technical staff that there is a deviation from a monitored parameter which requires an immediate response

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3.15
emergency power supply
an *emergency power supply* is an independent source of electrical power that supports important electrical systems on loss of normal power supply. An *emergency power supply* may include a standby generator, batteries and other apparatus

3.16
feed air unit
means of compressing ambient air (e.g.: *air compressor unit*, air blower).

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
healthcare facility
facility where professional health services are provided

3.20
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

3.21
high pressure
pressures greater than 3 000 kPa

[SOURCE: ISO 15001]

3.22
high-pressure reservoir
permanently installed container(s) with nominal working pressures greater than 3 000 kPa and up to 25 000 kPa at 15 °C

Note 1 to entry: installed container include cylinders and cylinders bundles, intended to be permanent in the *healthcare facility*

3.23
information signal
signal that is not an alarm signal or a reminder signal

3.24
line pressure regulator
pressure regulator used in a *pipeline distribution system* to reduce the *nominal supply system pressure* to the *nominal distribution pressure*

3.25
low pressure
pressures lower than 1 400 kPa

3.26
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

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3.27
main line
portion of the *pipeline distribution system* connecting the *supply system* to *risers* and/or *pipeline branches*

3.28
maintenance supply assembly
source of supply intended to supply the system during maintenance

3.29
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

3.30
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 (see also Annex L)

3.31
maximum distribution pressure
pressure at any *terminal unit* when the *medical gas pipeline system* is operating at zero flow

3.32
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 compressor *sources of supply* 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.

3.33
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.

3.34
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

3.35
nominal distribution pressure
pressure which the *medical gas pipeline system* is intended to deliver at the *terminal units*

3.36
nominal supply system pressure
pressure which the *supply system* is intended to deliver at the inlet to the *line pressure regulator* when flowing at the design flow rate for the medical gas pipeline.

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3.37
normal condition
condition in which all means provided for protection against hazards are intact

3.38
non-return valve
valve which permits flow in one direction only

3.39
operating alarm
alarm to indicate to technical staff that it is necessary to replenish the gas supply or to correct a malfunction

3.40
pharmacopeial oxygen
oxygen compliant with the pharmacopeia required by the regulatory authority having jurisdiction or the pharmacopeia selected by the *healthcare facility*.

3.41
pipeline branch
portion of the *pipeline distribution system* which supplies one or more areas on the same floor of the *healthcare facility*

3.42
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*

3.43
pressure regulator
device which reduces the inlet pressure and maintains the set outlet pressure within specified limits

3.44
pressure relief valve
device intended to relieve excess pressure at a pre-set pressure

3.45
primary source of supply
portion of the *supply system* which is the first to be drawn upon to supply the medical gas *pipeline distribution system*

3.46
proportioning unit
device in which gases are mixed in a specified ratio

3.47
reserve source of supply
that *source of supply* which supplies the *pipeline distribution system* (or part(s) thereof) in the event both the primary and secondary *sources of supply* fail, are exhausted or under maintenance.

3.48
riser
portion of the *pipeline distribution system* traversing one or more floors and connecting the *main line* with *pipeline branch* lines on various levels

3.49
reservoir
permanently installed container(s) designed for storing gas at pressures up to 3 000 kPa

Note 1 to entry: See also *vacuum receiver* (3.62)

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3.50
safety
freedom from unacceptable risk

3.51
secondary source of supply
that *source of supply* which supplies the *pipeline distribution system* in the event the *primary source of supply* fails, is exhausted or is under maintenance.

3.52
shut-off valve
valve which prevents flow in both directions when closed

3.53
single fault condition
condition in which a single means for protection against a *safety* hazard in equipment is defective or a single external ab*normal condition* is present

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

3.54
single-stage pipeline distribution system
pipeline distribution system in which gas is distributed from the *supply system* at the *nominal distribution pressure*

3.55
source of supply
portion of the *supply system* with associated *control equipment* which supplies the *pipeline distribution system*

3.56
source of supply using proportioning units
source of supply which employs *proportioning unit*(s) to provide *synthetic medical air* or *air for driving surgical tools* or both

Note 1 to entry: *proportioning unit*(s) are described in ISO 7396-3.*m*

3.57
source of supply using air compressor unit(s)
source of supply which employs *air compressor unit(s)* to provide *medical air* or *air for driving surgical tools* or both

3.58
source of supply using oxygen concentrator(s)
Source of supply that produces *pharmacopeial oxygen* from ambient air by extraction of nitrogen

3.59
supply system
assembly which supplies the *pipeline distribution system* and which includes all *sources of supply*

3.60
system design flow
flow calculated from the maximum flow requirement of the *healthcare facility* and corrected by the *diversity factors*.

3.61
terminal unit
outlet assembly (inlet for vacuum) in a *medical gas pipeline system* at which the operator makes connections and disconnections

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3.62
vacuum receiver
permanently installed container(s) designed for vacuum application

Note 1 to entry: See also *reservoir* (3.49).

3.63
vacuum supply system
supply system equipped with vacuum pumps designed to provide a flow at negative pressure

4 General Requirements

This section describes principles that are used throughout the standard and is intended to enable the user to understand the intent of the standard where interpretation is found to be required.

4.1 *Safety* and Risk Management

The intent of this section is to provide and guarantee the correct gas or vacuum at the *gas-specific* outlet point at the correct pressure and flow to protect patients, users and other personal against unsafe and avoidable risks.

4.1.1 *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*.

Specific risk control measures to deal with such situations need to be determined within the risk management process.

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*.

NOTE 2 A list of risks to be considered and process to be observed as part of the risk analysis is found in Annex H.

4.1.2 All Risk Assessment shall be applied to the systems as a whole and undertaken using the principles set forth in the ISO 14971.

4.1.3 *Supply systems* and alarm systems shall 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 the *healthcare facility*.

NOTE 1 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 2 Planned maintenance of equipment is considered a *normal condition*.

4.1.4 Risk Assessment shall be applied to ensure risks are understood and considered.

4.1.5 Risk Assessments shall consider risks to patients, medical staff, visitors at a first priority, but also risks to the *healthcare facility* and the environment.

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4.1.6 Risk Management principles shall then be applied to mitigate all identified risks below a level acceptable to the *healthcare facility* and the *manufacturer*.

4.1.7 All Risk Assessment shall be documented.

4.1.8 Fire protection measures are not within the scope of this standard. *Healthcare facilities* are responsible for the fire protection concept and shall follow applicable policies on fire protection.

Fire protection for the location(s) of *supply systems* is not considered part of the medical gas system or installation.

Selection of the location(s) for *supply systems* and maintenance supply assemblies shall be made based on joint risk analysis by the *healthcare facility* and *manufacturer*.

4.2 Deviations from the standard

Regulations or guidelines, local laws, (the applicable policies) can take precedence over international standards such as those set by the International Organization for Standardization (ISO). If the applicable policies are more stringent or specific than the corresponding ISO standard, organizations operating in that particular locality are generally required to comply with the stricter local regulations.

This approach is common to ensure that standards are adapted to the specific needs, circumstances, and legal requirements of a particular region or jurisdiction. While ISO standards provide a globally recognized framework for various industries and practices, individual countries or regions may have their own specific laws and regulations that organizations must adhere to, even if they go beyond the requirements of the ISO standard.

NOTE A rationale for this is contained in Annex I.

4.3 Gases for Medicinal Use

4.3.1 The Management of the *healthcare facility*, with reference to the appropriate Regulatory Authority shall determine the appropriate pharmacopeia for use in the facility, and the medical gases shall be procured, produced and managed to the requirements of that pharmacopeia.

NOTE Examples of pharmacopeial specifications are given in Annex M

4.3.2 Where continuous monitoring systems are required in this part of ISO 7396-1 to detect impurities in medical gases, these devices shall be validated.

4.4 Materials

4.4.1 Materials used which come into contact with medical gases under normal or *single fault condition* shall be compatible with the actual gas(es) and oxygen.

NOTE 1 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.

NOTE 2 Criteria for the selection of metallic and non-metallic materials are given in ISO 15001 Annex D and Table D.7, ISO 11114-1[17] and ISO 11114-2[18].

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4.4.2 The materials which come in contact with medical gases shall be resistant to corrosion at the humidity levels expected in normal and *single fault conditions*.

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

4.4.3 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.

4.4.4 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 the appropriate standards, e.g. ISO 10524-2 for regulators or ISO 21969 for *high pressure* flexible connections.

4.4.5 Materials used for permanent medical gas pipelines shall comply with the following

a) be constructed of metallic materials;

b) have a safe operating pressure limit at least equal to EN 13348 copper;

c) have a corrosion resistance equal to or better than copper;

d) have an internal cleanliness equivalent to EN 13348 copper;

e) Flexible corrugated metallic tubing (CMT) shall be permitted for use if:

   i) constructed of material compliant with (a), and;

   ii) having an operating pressure 3x the intended operating pressure, and;

   iii) compliant with (c) and (d)

f) *Low pressure* flexible connections (e.g. for vibration or seismic isolation) shall be permitted for use if compliant with (e).

NOTE A rationale for this is contained in Annex I.

4.4.6 Materials used for permanent vacuum pipelines shall comply with the following

a) be suitable for vacuum service;

b) have a corrosion resistance equal to or better than copper;

c) be compatible with the potential contaminants that can be present in the vacuum system;

d) Flexible corrugated metallic tubing (CMT) shall be permitted for use if compliant with a) to c) above.

e) *Low pressure* flexible connections (e.g. for vibration or seismic isolation) shall be permitted for use if compliant with a) to c) above.

4.4.7 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.

NOTE Examples of cleaning procedures are described in ISO 15001.

4.4.8 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.

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4.4.9 The specific risks of 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 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.

NOTE 2 See also Annex F, "Rationale for *air compressor unit* hazards".

4.4.10 If lubricants are used, they shall be compatible with the gases to which they will be exposed in *normal condition* and in *single fault condition*.

All lubricants, except those used in air compressors and vacuum pumps shall also be compatible with oxygen.

Check compliance by inspection of the technical file.

4.4.11 The *manufacturer* shall ensure compliance of materials with Clause 4.4, including in their Technical documentation a list of materials which are in contact with the medical gases in normal and *single fault conditions*.

The Technical documentation shall specifically include, under both normal and *single fault conditions*:

— Evidence that the materials used are compatible with the actual gas,

— Evidence of the corrosion resistance of materials used,

— Evidence of pressure resistance for the pressures expected,

— Evidence of resistance to ignition must be provided. Compliance must be provided for the appropriate standard,

— Evidence of internal cleanliness to ISO 15001 for medical technical devices other than pipes, and EN 13348 for pipes.

— Where intended for application in strong magnetic or electromagnetic fields, evidence of compatibility

— Where materials are subject to abnormal heating and or decomposition, risk analysis and details of mitigation methods where appropriate.

NOTE 1 Resistance to ignition for *pressure regulators* is defined in ISO 10524-2, for flexible connecting bends in ISO 21969.

NOTE 2 A rationale for this section is contained in Annex I.

4.5 System Design

Whenever a medical gas project (new construction, modification, addition or replacement) is proposed, the *healthcare facility* shall determine the essential characteristics of the system design

4.5.1 Requirements in the Design

Following the design brief, the medical gas and vacuum systems shall be laid out, sized and specified subject to the approval of the *healthcare facility*.

4.5.1.1 At the time of project design, the management of the *healthcare facility*, in consultation with the system *manufacturer*, on the basis of risk management procedures shall determine essential characteristics for system construction, which shall include at least:

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— requirements from the facility's emergency/disaster plan, if available.

— the gas *supply systems*;

— the reserve source(s) of supply;

— the number and location of *terminal units*;

— flows and *diversity factors* by pipeline section;

— valve arrangement, including main, *pipeline branch* and area valves;

— alarm arrangement, including all monitors and alarm panels.

— the type of sources of supply;

— the location of the sources of supply;

— 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 pharmacopeial oxygen, and *medical air* in case of a catastrophic event).

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

— If a *reserve source of supply uses an air compressor unit*, a *proportioning unit* or an *oxygen concentrator unit*, the design of the *supply system* and the emergency electrical supply should take into consideration the time required to start the *reserve source of supply* and obtain the specified quality of the gas supplied to the *pipeline distribution system*;

— 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*;

NOTE 1 Risk management procedures may consider the need to have separate locations for the reserve source(s) of supply.

NOTE 2 pipeline system design may also consider future clinical developments.

4.5.1.2 For each component of the system and for the overall pipeline, the design documents shall show:

— the size, selection and location for the basis of design component(s);

— the piping runs on the architectural plans, especially noting location of sources, valves and alarms;

— the sizes for the piping and the calculation of pressure losses based on section flows, including both standard conditions and the emergency plan;

— for each alarm panel, the specific signals to be displayed.

— the flow and storage capacity of the sources of supply;

— the outlet connector of the *source of supply* taking into account the design flow;

— 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 *pharmacopeial oxygen*, and *medical air* in case of a catastrophic event);

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— 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 power 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*;

— 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;

— 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*;

— the layout and the location of the pipelines shall reduce the risk of mechanical damage of the pipeline to an acceptable level;

— whether to provide reserve source(s) of supply for air or nitrogen for driving surgical tools;

— For double stage *pipeline distribution systems*, the location and elevation of *line pressure regulators*;

— The sustainability of design should be documented and choices and impact analysis on environment and energy resources documented.

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

Note 1 The design flow of each section of the *medical gas pipeline system* can take into consideration an increased flow rate required for each patient and the potential increase in number of patients requiring treatments during exceptional and unforeseen cases (e.g., Covid pandemic). See Annex I for other considerations.

NOTE 2 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).

NOTE 3 Examples of locations of *terminal units*, flow requirements and *diversity factors* are given in HTM 02,[42] FD S 90-155,[40] AS 2896[28] and SIS/HB 370[46].

NOTE 4 Examples of maximum recommended gas velocity are given in FD S 90-155[40] and SIS/HB 370[46].

4.5.2 Extensions and modifications of existing *medical gas pipeline systems*

Extensions and modifications of existing *medical gas 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:

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 rate, *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 rate, *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.

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.

NOTE 1 For this purpose, modifications of the existing *pipeline distribution system* might be needed;

NOTE 2 Examples of locations of *terminal units*, flow requirements and *diversity factors* are given in HTM 02,[42] FD S 90-155[40] and AS 2896[28].and SIS/HB 370[46].

4.5.3 Usability

The risk management process shall include risks related to usability.

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Check compliance by inspection of the usability engineering file.

NOTE For information related to usability see for example IEC 62366-1[26], and IEC/TR 62366-2[27].

4.5.4 Provision for Electrical Supply

NOTE A rationale is contained in Annex I.

4.5.4.1 All medical gas *sources of supply*, *supply systems*, monitoring and alarm systems shall be considered critical life *safety* equipment and shall be supplied from the facility's *emergency power supply*. Loss of main(s) electrical power to the facility is a *single fault condition*.

Note There are alternate strategies which can be applied to deal with this single fault. Risk management can be used to mitigate the risk.

4.5.4.2 In the event of loss of mains electrical power, all medical gas *supply sources*, monitoring and alarm systems shall operate normally.

4.5.5 Biocompatibility

To ensure that no risks related to missing biocompatibility arise, all materials in the gas pathway shall be evaluated at least with regards to particle generation and for the occurrence of volatile organic substances (VOS).

The evaluation shall cover "new condition" as well as evaluations over the life cycle of the system.

Note ISO 18562-1describes the biocompatibility evaluation of breathing gas pathways in healthcare applications.

4.5.6 Software

If software is used in medical gas *supply systems,* its lifecycle shall be managed with the IEC 62304 criteria.

The related hazards and risks shall be treated within the risk management process (4.1).

Evidence shall be provided by the *manufacturer*. Check compliance by inspection of the Technical documentation.

5 *Supply systems*

Note Schematic representations of typical *supply systems* are given in Annex A (Figures A.1 to A.21).

5.1 *Supply system* components

5.1.1 *Supply systems* for medicinal gases shall comprise at least three independent *sources of supply* which may, depending on the gas, be a combination of the following:

a) source providing gas from cylinders, *cylinder bundles*, *high-pressure reservoir(s)*, mobile vessels or stationary *Cryogenic vessels*;

b) source providing gas from an *air compressor unit*;

c) source providing gas from a *proportioning unit*;

d) source providing gas from an oxygen concentrator unit.

5.1.2 *Supply systems* for air or nitrogen for driving surgical tools shall comprise at least two *sources of supply* which may be a combination of the following:

a) source providing gas from cylinders, *cylinder bundles*, *high-pressure reservoir(s)*, mobile vessels or stationary *Cryogenic vessels*;

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b) source providing gas from an *air compressor unit*;

c) source providing gas from a *proportioning unit*;

5.1.3 Combined *supply systems* for air or nitrogen intended for both medicinal gases and for driving surgical tools shall comprise at least three *sources of supply* which may be a combination of the following:

a) source providing gas from cylinders, *cylinder bundles*, *high-pressure reservoir(s)*, mobile vessels or stationary *Cryogenic vessels*;

b) source providing gas from an *air compressor unit*;

c) source providing gas from a *proportioning unit*;

Sources of supply used in combined systems shall be suitable for medicinal gases.

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

5.1.5 A *supply system* equals three (or more) *sources of supply*

NOTE A rationale is contained in Annex I.

5.1.5.1 All *supply systems* for compressed medicinal 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*), except where specific exemption is allowed in this standard.

5.1.5.2 All *supply systems* shall be arranged to sequentially supply the *medical gas pipeline system* from a single *source of supply* as they are exhausted, or failures occur.

NOTE Under normal circumstances, this standard requires the *medical gas pipeline system* to be supplied from a single *source of supply*. In case of a situation (e.g., state of emergency, catastrophic event/incident, health crisis) that results in a higher demand for medical gases than was unforeseeable when the *medical gas pipeline system* was designed, the *healthcare facility* should be able to utilize the capacity of multiple sources of supply simultaneously. Therefore, even though it is not in conformance with this standard to use multiple sources of supply simultaneously under normal circumstances, the technical capability to utilize multiple sources of supply simultaneously can be required.

5.1.5.3 The use of onsite technologies as the *secondary source of supply* or *reserve source of supply* (*medical air*, synthetic *medical air*, and *pharmacopeial oxygen*) shall be evaluated by the system supplier in consultation with the management of the *healthcare facility*, using risk management principles.

5.1.5.4 The use of onsite technologies as the *secondary source of supply* or *reserve source of supply* (*medical air*, synthetic air, and *pharmacopeial oxygen*) shall be only if the switch to the *secondary source of supply* or *reserve source of supply* shall not introduce any interruption of supply or quality.

Note Where it is possible to obtain gases in a format suitable for long term storage (e.g. cylinders), and practical (e.g. in overall capacity and space required) to use it, it is advisable the *reserve source of supply* be of this type.

5.1.5.5 Where long term storage vessels cannot effectively be used as a *reserve source of supply*, it is advisable that *healthcare facility* apply Risk Assessment and Risk Management principles to mitigate consequent risk.

NOTE A rationale is contained in Annex I.

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5.2 General Requirements for *supply systems*

5.2.1 Capacity and Storage

5.2.1.1 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*.

5.2.1.2 Mobile *Cryogenic vessels* and cylinders shall be stored in areas with managed access, under cover and protected from adverse weather conditions.

5.2.1.3 Medical gas *Supply system* output capacities shall be such that the *system design flow* can be supplied whilst maintaining all *terminal unit* pressures above the requirements of 7.2.1 Table 2.

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 *nominal distribution pressure* complying with 7.2.1 Table 2 in *normal condition* and in *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.

c) during maintenance, two sources can be allowed.

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 regular and/or preventative maintenance without interrupting the gas/vacuum supply.

5.2.2.3 Where 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, validated by the *healthcare facility*, on request.

NOTE See Annex L for further information.

5.2.3 *Primary source of supply*

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

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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.

5.2.5.1 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 vessel*s, 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.

5.2.5.2 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;

b) If a *source of supply using air compressor unit(s)*, a *source of supply using proportioning unit(s)* or a *source of supply using oxygen concentrator unit(s)* is used as a *reserve source of supply*, the design of the *supply system* and the emergency electrical supply shall 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*.

c) 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;

d) 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*;

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

5.2.6 Requirements for outlet pressure

The pressure of a single stage system at the outlet port of the *source of supply*, measured at the flow rate specified by the *manufacturer*, shall meet the requirements given in 7.2.1.

For a double stage system, the *manufacturer* shall define *nominal supply system pressure*.

The *manufacturer* shall define the operating pressures within the *source of supply*.

Check compliance by inspection of the technical documentation.

NOTE Please refer to Annex L for roles.

5.2.7 Means of pressure relief

5.2.7.1 *Pressure relief valves*

Pressure relief valves, shall comply with ISO 4126-1.

Check compliance by inspection of the technical documentation.

5.2.7.2 Venting outdoors is not required for *medical air* and *air for driving surgical tools*. 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

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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.

5.2.7.3 All *pressure relief valves* shall close automatically when excess pressure has been released.

5.2.7.4 It shall not be possible to isolate a means of pressure relief, for example by a *shut-off valve*, from the pipeline, *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.

5.2.7.5 Means shall be provided to protect the *pressure relief valve* from tampering.

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

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

NOTE Immediate change of a relief valve is acceptable

5.2.8 *Maintenance supply assembly*

5.2.8.1 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)*.

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

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.

5.2.8.3 The *maintenance supply assembly* shall have a *gas-specific* inlet connector(s), 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 rate which can be required under maintenance conditions. The supply assembly shall be physically protected to prevent tampering and unauthorized access.

5.2.9 *Line pressure regulators*

Line 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, and 7.2.3 through 7.2.7.

5.2.10 Ozone Sterilizers

Ozone sterilizers shall not be connected to the *pharmacopeial oxygen* pipeline system.

NOTE A rationale is contained in Annex I.

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

5.3.1 A *supply system* using cylinders, *cylinder bundles* or *high-pressure reservoir(s)* shall comprise (see 5.2.2.1):

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

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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* using 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)*.

5.3.2.1 When an exhausted bank of cylinders, *cylinder bundles* or *high-pressure reservoir(s)* is replaced, it shall be possible to reset the automatic changeover.

5.3.2.2 Each bank shall have its cylinders, *cylinder bundles* or *high-pressure reservoir(s)* connected to a *manifold* with its own *manifold pressure regulator*.

5.3.3 *Sources of supply* with cylinders, *cylinder bundles* or *high-pressure reservoir(s)*

5.3.3.1 Each *Source of supply* using cylinders, *cylinder bundles* or *high-pressure reservoir(s)* shall be such that the *system design flow* can be supplied.

5.3.3.2 Except for air, vent valves shall be vented outside of the building.

5.3.3.3 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.

Note 1 Anti whip *safety* cables should be provided.

NOTE 2 A rationale is contained in Annex I.

5.3.3.4 Except for *sources of supply* 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* and the *manifold*.

5.3.3.5 Where the *reserve source of supply* 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.

5.3.3.6 Except for *sources of supply* 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* and the *manifold*.

5.3.3.7 Each *source of supply* shall have cylinders, *cylinder bundles* or *high-pressure reservoir(s)* connected to the *supply system* with its own *supply pressure regulator*.

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

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5.4 *Supply systems* with cryogenic or non *Cryogenic vessels*

5.4.1 A *supply system* using cryogenic or non-*Cryogenic vessels* shall consist of one of the following (see 5.2.2.1):

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.

5.4.2 *Sources of supply* using *Cryogenic vessels* (mobile and stationary)

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

5.4.2.1 A *source of supply* using cryogenic or non-*Cryogenic vessels* shall consist of a stationary or mobile cryogenic or non-*Cryogenic vessel* with associated equipment.

5.4.2.2 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*.

5.4.2.3 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.

NOTE A rationale is contained in Annex I.

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 *supply system* with cylinders, *cylinder bundles* or *high-pressure reservoir(s)* as specified in 5.3.3;

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

— 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 (e.g. operation of ceiling columns, anaesthetic gas scavenging systems, breathing air for medical personnel or testing, or drying of medical devices) means shall be provided to prevent backflow into the pipeline. The flow requirements of these applications shall be taken into account by the *manufacturer* of the system.

NOTE A rationale is contained in Annex I.

5.5.1.3 *Medical air* and *air for driving surgical tools* shall 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 medical purposes.

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Note Non-medical purposes includes 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

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 14931[37] provides information about hyperbaric chambers.

5.5.2 *Supply systems* with *air compressor unit(s)*

NOTE A rationale is contained in Annex I.

5.5.2.1 *Medical air* produced by *supply systems* with *air compressor unit(s)* shall comply with the selected pharmacopeial specification (see 4.3.1).

Check compliance to selected pharmacopeia with appropriate validated on-site measurements.

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

Evidence of compliance with 5.5.2.2 shall be provided by the *manufacturer*.

In addition *medical air* shall fulfil the particulate contamination requirements of the Biocompatibility and risk management of ISO 18562-2

NOTE These values are taken from Table 2, Class 2 of ISO 8573-1:2010.

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

Compliance shall be confirmed by inspection.

5.5.2.4 A *supply system* with *air compressor unit(s)* for *medical air* shall comprise at least three *sources of supply*, at least one of which shall be an *air 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.

NOTE examples of typical configurations are given in Annex A

5.5.2.4.1 If a *supply system* with *air compressor unit(s)* for *medical air* includes two or more *sources of supply* fed from compressor units, at least two conditioning units shall be provided.

NOTE Typical conditioning units for *medical air* would be comprised of the following:

— a dryer with *shut-off valves*;

— an adsorber, a catalyst and filter(s) as required to remove contaminants;

— a dew-point sensor with an alarm and display, fitted to the pipeline system downstream of all conditioning units.

5.5.2.4.2 Where the *supply system* with *air compressor unit(s)* for air consists of three or more *source of supply* using compressor units, which can be switched between the different *sources of supply* to provide

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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.

5.5.2.4.3 Where the *supply system* with *air compressor unit(s)* for air 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.

5.5.2.4.4 Each *source of supply* 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 *air compressor unit(s)*.

5.5.2.4.5 Specific attention shall be paid to the connection between *air compressor unit(s)* and conditioning units as any low point may create accumulation of water within the pipe.

5.5.2.5 *Source of supply using air compressor unit(s)*

5.5.2.5.1 A *source of supply using air compressor unit(s)* typically comprises the following:

a) inlet filter(s) for ambient air, which may be integral to the *air compressor unit*;

b) at least one *air compressor unit*;

c) conditioning unit(s);

d) *shut-off valves*, non-return-valves and *pressure relief valve*, as required;

e) a *reservoir* fitted with required accessories such as *pressure relief valve(s)*, a pressure gauge, drain(s), and a means of purging;

f) a filter;

g) a pressure sensor to ensure that the compressor operates within the range specified by the *manufacturer*.

NOTE 1 one source could consist of more than one *air compressor unit*.

NOTE 2 A rationale is contained in Annex I.

5.5.2.5.2 At least one dew point and carbon monoxide alarm sensor shall be fitted downstream of all conditioning units. Recording capability should be provided.

5.5.2.5.3 *An air compressor unit* used in the *supply system using air compressor unit(s)* shall not be used in parallel to feed a *supply system using oxygen concentrator unit(s)*.

5.5.2.5.4 Means shall be provided to prevent transmission of vibration between each *air compressor unit* and the pipeline.

5.5.2.5.5 If the *source of supply using air compressor unit(s)* includes a conditioning unit, it shall comply with 5.5.2.5.13.

5.5.2.5.6 If the *source of supply using air compressor unit(s)* includes a *reservoir*, it shall comply with 5.5.2.5.12.

Where *reservoirs* are grouped, arrangement shall be such that each *reservoir* shall be separately maintainable.

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Check compliance by inspection of the technical documentation.

NOTE if conditioning unit(s) are provided within the *source of supply using air compressor unit(s)*, The *reservoir*(s) may be fitted upstream or downstream of the *conditioning unit(s)*.

5.5.2.5.7 The liquid from condensate drains is potentially contaminated and must be disposed of in accordance with environmental regulations.

Check compliance by inspection of the technical documentation.

5.5.2.5.8 Sample port

A sample port with shut-off functionality shall be fitted immediately upstream of the *source of supply shut-off valve* to enable the *medical air* to be tested.

Check compliance by inspection.

NOTE This could refer to a *terminal unit*.

5.5.2.5.9 *Air compressor units*

5.5.2.5.9.1 The *air compressor unit(s)* shall comply with EN 1012-1.

NOTE Consideration should be given to the use of oil-less compressor technologies for producing *medical air*. See Annex F

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

NOTE Typical compressor units for *medical air* typically would be comprised of the following:

— an inlet filter;

— one or more air compressors;

— for oil lubricated compressors, an oil separator with automatic drain;

— an after-cooler with *shut-off valve* and automatic drain;

— a pressure sensor to ensure that the compressor operates within the range specified by the *manufacturer*.

5.5.2.5.9.3 Each *air 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).

Check compliance by inspection of the technical documentation.

5.5.2.5.10 Inlet

5.5.2.5.10.1 The inlet of the ambient air for *air compressor units* 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).

5.5.2.5.10.2 The inlet shall be provided with means to prevent the ingress of, for example, insects, debris and water (e.g. where they are piped to outside). 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.

5.5.2.5.10.3 Intakes of the *air compressor units* shall be fitted with filters compliant with ISO 5011.

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5.5.2.5.11 Air outlet

Each *air compressor unit* shall be provided with automatic means to prevent backflow through off-cycle units and a *shut-off valve* to isolate itself.

Check compliance by visual inspection and functional test.

5.5.2.5.12 *Reservoirs*

5.5.2.5.12.1 *Reservoirs* shall

— comply with EN 286-1 or equivalent local standards, and

— be fitted with *shut-off valve(s)*, a drain, a pressure gauge and a *pressure relief valve*.

5.5.2.5.12.2 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).

5.5.2.5.13 Conditioning Units

Conditioning units typically include an after-cooler (which may be integral to the *air compressor unit*), a dryer, a drain, an oil separator, filters to remove contaminants, and a purifier.

5.5.2.5.13.1 Conditioning units for *medical air* shall maintain an atmospheric pressure dewpoint in accordance with *applicable policy or selected pharmacopeia.* If there is no *applicable policy* available, the atmospheric pressure dewpoint shall be equal to or below -40 °C.

NOTE A rationale is contained in Annex I.

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

5.5.2.5.13.3 At least one dew point and one carbon monoxide alarm sensor shall be fitted to the pipeline system downstream of all conditioning units. Recording capability should be provided. The *manufacturer* shall take account of the accuracy of all analysers to set the alarm thresholds.

NOTE Other parameters of the *medical air* quality may be monitored or recorded.

5.5.2.5.13.4 A sample port shall be provided immediately downstream of the conditioning system(s).

5.5.2.5.14 Controls

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

5.5.2.5.14.2 Means shall be provided to ensure the continuity of supply following a failure of any *control system*.

5.5.2.6 Where an air supply source is an *air compressor unit*, pollution of the intake air is a common mode of failure. This risk shall be addressed with risk analysis as required in 4.1.2.

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5.5.2.7 A *supply system* with *air compressor unit(s)* intended to supply a *single-stage pipeline distribution system* shall include at least two permanently fitted *line pressure regulators*. The design flow of the *pipeline distribution system* shall be supplied with at least one *line 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

5.5.2.8 Means shall be provided to prevent transmission of vibration between each *source of supply using air compressor unit(s)* and the pipeline.

5.5.2.9 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*.

NOTE A rationale is contained in Annex I.

5.5.3 *Supply systems using proportioning unit(s)*

5.5.3.1 *Medical air* produced by *proportioning unit(s)* shall comply with the with the selected pharmacopeial specification for synthetic medicinal air. (see 4.3.1)

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 *source of supply using proportioning unit(s)* complying with ISO 7396-3.

Note Examples of typical configurations are given in Annex A.

5.5.3.2.1 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 The source of oxygen to the *proportioning units* shall not be an oxygen concentrator.

5.5.3.4 Each *source of supply using proportioning unit(s)* shall be capable of supplying a mixture of the required composition over the entire range of the design flow.

5.5.3.5 The source(s) of oxygen and nitrogen for *source of supply using proportioning unit(s)* shall conform to the requirements of 5.3 or 5.4 and may be the same sources as those supplying the medical gas pipelines separately.

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

5.5.3.6 The oxygen concentration of the mixture shall be analysed continuously by an oxygen analyser fitted on or upstream of the *reservoir*.

5.5.3.6.1 Recording capability for oxygen concentration shall be provided. Where the proportioning system consists of more than one *source of supply using proportioning unit(s)*, only one independent oxygen analysing system is required.

5.5.3.6.2 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

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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.

5.5.3.6.3 Each oxygen analyser shall ensure an accuracy of ±1 % of the measured value. The accuracy shall be documented by the *manufacturer*

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

5.5.3.7 Means shall be provided to purge the *medical air reservoir*(s).

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

5.5.4 Independent *supply systems* for *air for driving surgical tools*

Supply systems providing air only for surgical tools and not connected to the *medical air* piping system shall comply with 5.5 with the exceptions permitted in 5.5.4. Combined systems are not permitted these exceptions.

NOTE A rationale is contained in Annex I.

5.5.4.1 Independent *supply systems* delivering *air for driving surgical tools* shall be permitted to comprise only two *sources of supply*.

NOTE Examples of typical configurations are given in Annex A.

5.5.4.2 Where Applicable Policies do not exist, *air for driving surgical tools* shall comply with the following, measured at ambient pressure downstream of the *source of supply* with *air compressor unit(s)*:

a) total oil concentration ≤ 0,1 mg/m^3;

b) water vapour content ≤67 ml/m^3.

NOTE 1 Oil can be present as liquid, aerosol and vapour. Consideration should be given to the use of oil-less compressor technologies for producing *medical air*. See Annex F.

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.

NOTE 3 A rationale is contained in Annex I.

5.6 *Supply systems* using oxygen concentrators

5.6.1 General requirements

A *supply system using air concentrator unit(s)* shall comprise of at least three *sources of supply*, at least one of which shall be an oxygen 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.

Air compressor units included in *supply systems using oxygen concentrators* shall not be used in parallel to *supply systems using air compressor units* for *medical air*.

Sources of supply for *supply systems* using oxygen concentrators shall comply with:

— if a *source of supply* using oxygen concentrators, 5.6.6;

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— if a *source of supply* using cylinders, *cylinder bundles* or *high-pressure reservoir(s)*, 5.3;

— if a *source of supply* using cryogenic or non-*Cryogenic vessels*, 5.4.

5.6.2 *Primary source of supply*

The *primary source of supply* shall be a *source of supply using oxygen concentrator(s)* compliant with 5.6.6.

Compliance of the installation shall be checked by inspection.

5.6.3 *Secondary source of supply*

If the *secondary source of supply* consists of only cylinders, *cylinder bundles* or *high-pressure reservoirs*, the following requirements apply:

— the *source of supply* shall consist of at least one bank of cylinders, *cylinder bundles* or *high-pressure reservoir*(s);

— if there is more than one bank of cylinders, *cylinder bundles* or *high-pressure reservoir*(s), gas shall be supplied from one bank of cylinders, *cylinder bundles* or *high-pressure reservoir*(s) at a time and on depletion of one bank switch automatically to another bank or *reservoir*.

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 only cylinders, *cylinder bundles* or *high-pressure reservoir*(s), the following requirements apply:

— the *source of supply* shall consist of at least one bank of cylinders, *cylinder bundles* or *high-pressure reservoir*(s);

— if there is more than one bank of cylinders, *cylinder bundles* or *high-pressure reservoirs*, gas shall be supplied from one bank of cylinders, *cylinder bundles* or *high-pressure reservoirs* at a time and on depletion of one bank switch automatically to another bank or *reservoir*.

The *reserve source of supply* shall be connected downstream of the oxygen *reservoir*(s) of *primary* and *secondary source of supply*.

5.6.5 Specifications for *pharmacopeial oxygen*

5.6.5.1 *Pharmacopeial oxygen* shall comply with the selected pharmacopeial specification (see 4.3.1).

5.6.5.2 *Pharmacopeial oxygen* shall be filtered before the *supply systems* with oxygen concentrator(s) *shut-off valve* to maintain the particulate contamination below the level provided by Table 2, class 2 of ISO 8573-1.

5.6.5.3 Each *source of supply* 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 *Sources of supply* using oxygen concentrator(s)

5.6.6.1 The specification for oxygen shall be met across the entire flow range specified by the *manufacturer*. When this specification is not met, the *source of supply using oxygen concentrator(s)* shall:

Case 1: oxygen concentration is below the minimum level

— Activate an *emergency operating alarm*

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— Close the automatic *source of supply shut-off valve* (see 5.6.6.3.5)

Case 2: oxygen concentration is over the maximum level:

— activate an *operating alarm*

Case 3: other monitored contaminants

— Activate an *emergency operating alarm*

Check compliance by functional tests.

5.6.6.2 Components of *sources of supply* using oxygen concentrator units

A *source of supply* using zeolite based oxygen concentrator units typically comprises the following:

— inlet filter(s) for ambient air;

— at least one means of supplying feed air (e.g.: *air compressor unit*, air blower);

— conditioning unit(s), as required, including typically an after-cooler, a dryer, a drain, an oil separator, filters to remove contaminants;

— *shut-off valves* and *pressure relief valves*, as required;

— a compressed air *reservoir*, as required, fitted with a *pressure relief valve*, a pressure gauge and a means of purging;

— one or more means of removing nitrogen (the concentrator);

— a *control system* with an oxygen analyser and a control panel;

— a filter;

— a means to automatically terminate supply from the supply source to prevent out of pharmacopeial specification oxygen being delivered by the *supply system* to the *pipeline distribution system*.

NOTE 1 Some designs of oxygen concentrator unit require an oxygen *reservoir* within each *source of supply*.

NOTE 2 The liquid from condensate drains is potentially contaminated and must be disposed of in accordance with environmental regulations.

5.6.6.3 Oxygen concentrator unit

An oxygen concentrator unit typically consists of:

— an air supply;

— at least one sieve bed;

— switching valves as required;

— Oxygen sensor

5.6.6.3.1 Feed Air

5.6.6.3.1.1 In cases where an *air compressor unit(s)* are used to supply feed air they may be connected to an air *reservoir*.

5.6.6.3.1.2 Air *reservoirs* (if fitted) shall be:

— compliant with EN 286-1 or EN 13445-1 or equivalent local standards;

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— provided with means to temporarily bypass the *reservoir*;

— fitted with a drain, a pressure gauge and a *pressure relief valve*.

Compliance of the installation shall be checked by visual inspection.

5.6.6.3.1.3 *Feed air unit* intakes shall be provided with filters compliant with ISO 5011.

Where intakes are subject to the entrance of insects, debris, or water (e.g. where they are piped to outside), means shall be provided to protect the air intake.

5.6.6.3.1.4 Each *feed air unit* shall be protected from overheating.

Check compliance by inspection of the technical documentation.

NOTE 1 EN 1012-1 can be used for ambient air compression system above 0,5 bar and EN 1012-2 can be used for vacuum system. EN1012-1 is not applicable for air blowers where the working pressure is below 0,5 bar / 0,05 MPa.

5.6.6.3.2 Conditioning Unit

The volume, dryness and cleanliness of the air supplied by the *feed air unit* to the sieve bed shall be maintained as specified by the *manufacturer* of the oxygen concentrator to ensure the continuous production of *pharmacopeial oxygen*.

Check compliance by inspection of the Technical documentation

Note 1 Conditioning of the feed air may be required

Note 2 monitoring of critical parameters in the feed air may be required.

5.6.6.3.3 *Pharmacopeial oxygen reservoirs*

If *pharmacopeial oxygen reservoirs* are required by the design of the *source of supply using oxygen concentrator(s)*, they shall be:

— -fitted with a means of bypassing temporarily the *reservoir* without bypassing the automatic *shut-off valve*;

— fitted with a pressure gauge and a *pressure relief valve* vented to outside;

— arranged so that each *reservoir* can be maintained separately;

— compliant with relevant local standards.

NOTE An *oxygen reservoir* may be supplied by more than one *source of supply using oxygen concentrator unit(s)*.

Check compliance by inspection of the technical documentation

5.6.6.3.4 Automatic *shut-off valves*

In addition to the source valve required in 8.2, a *source of supply using oxygen concentrator(s)* shall be fitted with an automatic source valve at the outlet to isolate all components of the *source of supply using oxygen concentrator(s)* from the *supply system* with the following characteristics:

— the valve shall have both manual and automatic actuation with visual indication of open or closed, or alternatively may be comprised of an automatic valve and separate manual valve;

Note Visual indication may be provided directly on the valve or via *control system(s)* connected to the valve with separate displays.

— the valve shall close automatically whenever the *source of supply using oxygen concentrator(s)* is not producing oxygen of a concentration equal to the selected pharmacopeial specification (see 4.3.1);

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— continuing operation of the *source of supply using oxygen concentrator(s)* through a vent mode is permitted with the isolating valve closed;

— the isolating valve, when automatically closed due to low concentration, shall require manual reset;

— closing the isolating valve, whether automatically or manually, shall activate an *operating alarm* signal indicating that the oxygen concentrator *supply system* is disconnected.

Check by inspection and simulation of low oxygen concentration.

5.6.6.3.5 Filtration

5.6.6.3.5.1 *Sources of supply* using oxygen concentrator(s) shall be fitted with particulate filtration:

a) provided upstream of the *source valve* and downstream of any part of the oxygen concentrator;

b) to maintain the particulate contamination below the level provided by Table 2, class 2 of ISO 8573-1.

Check compliance by inspection of the technical documentation.

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

Check compliance by inspection of the technical documentation.

5.6.6.3.6 Sample port

A sample port shall be fitted immediately upstream of the *source of supply shut-off valve* to enable the product gas to be tested.

Check compliance by visual inspection.

5.6.6.3.7 Outlet connector

The outlet connector of the *source of supply using oxygen concentrator(s)* shall be specified by the *manufacturer*, taking into account the design flow.

5.6.6.3.8 Waste Gases

When waste gases generated during production of *pharmacopeial oxygen* 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.

5.6.6.3.9 Monitors and Alarms for *sources of supply* with oxygen concentrators

5.6.6.3.9.1 Continuous on-line monitoring of oxygen concentration shall be provided to check the conformity of the *pharmacopeial oxygen* to specification.

Check compliance by visual inspection.

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

Check compliance by visual inspection.

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Document Sharing Hub
Full document details: 25/30475284 DC

5.6.6.3.9.3 Oxygen analyser shall ensure an accuracy of at least ±1 % of the measured value. The *manufacturer* shall take account of the accuracy of all analysers to set the alarm thresholds.

Check compliance by inspection of the technical documentation

5.6.6.3.9.4 Oxygen concentration shall be displayed and recorded. The *control system* shall have the capability to allow the *healthcare facility* to define the frequency of sampling and duration of the record.

Check compliance by visual inspection and inspection of the technical documentation

5.6.6.3.9.5 Means shall be provided to enable the analysers to be calibrated.

Check compliance by inspection of the technical documentation

5.6.6.3.9.6 The oxygen analyser shall activate a low concentration *emergency operating alarm*.

Check compliance by functional test.

5.6.6.3.9.7 Each oxygen analyser shall activate a high concentration *operating alarm*.

Check compliance by functional test.

5.6.6.3.9.8 Means shall be provided to prevent unauthorized changes of the alarm setting.

Check compliance by inspection of the technical documentation.

5.6.6.4 Monitoring

5.6.6.4.1 An oxygen analyser, in addition to those on the *sources of supply* with concentrators shall be provided to permit the oxygen concentration of the product gas supplied to the *pipeline distribution system* to be continuously monitored.

5.6.6.4.1.1 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.

5.6.6.4.1.2 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 ±1 %. The actual accuracy shall be specified by the *manufacturer*.

The *manufacturer* shall take account of the accuracy of all analysers to set the alarm thresholds.

5.6.6.4.2 A carbon monoxide sensor shall be fitted to the pipeline system downstream of all conditioning units.

The carbon monoxide (CO) monitor shall continuously display the CO level and activate an emergency alarm if the carbon monoxide level exceeds the level required by the pharmacopeial specification (see 4.3.1).

5.6.6.4.3 A *supply system* with oxygen concentrators shall include means for calibrating the oxygen and carbon monoxide analyzers by reference to mixture(s) of known composition.

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

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

NOTE A rationale is contained in Annex I.

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Full document details: 25/30475284 DC

5.6.7.1 Caution shall be taken in filling high-pressure *pharmacopeial oxygen reservoir*(s) as the practice has inherent risks of fire due to the high oxidizing 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.

5.6.7.2 If *pharmacopeial oxygen* is compressed by a *booster compressor* into (a) permanently attached *high-pressure reservoir(s)*, cylinders and *cylinder bundles* for use as the *reserve source of supply* the following requirements shall be met:

— Means shall be provided to ensure that the filling of reserve *high-pressure reservoir(s)* does not affect delivery of *pharmacopeial oxygen* to the *pipeline distribution system*.

— A sample port with a *shut-off valve* shall be provided downstream of the filling system to allow sampling of the *reservoir* contents.

— the fill compressor shall draw *pharmacopeial oxygen* upstream of the *supply system* oxygen analyzer (see 5.6.6.4.1).

5.6.7.3 The following *safety* measures shall be implemented:

— means (e.g. a *non-return valve*) to ensure that there is no backflow to the oxygen concentrator *supply system*;

— appropriate barrier(s) to protect personnel;

— 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.

5.6.7.4 The following *operating alarms* shall be provided, if applicable, set to activate at thresholds as defined by the *manufacturer*:

— an enclosure temperature alarm;

— an output gas temperature alarm;

— an over current power alarm;

— a high-pressure alarm.

5.6.7.5 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*.

5.6.7.6 A means shall be provided to purge the *high pressure reservoir,* cylinder and *cylinder bundles*.

5.7 *Supply systems* for Vacuum

5.7.1 A *supply system* for vacuum shall comprise at least three *sources of supply*, one *vacuum receiver*, filters and one drainage trap.

The medical gas system designer and *healthcare facility* management should include bacterial filter location in the risk management assessment taking into account the risk to infections control as per definition of responsibilities in annex L.

NOTE 1 It may be preferable to install two parallel bacterial filters on each floor so as to facilitate maintenance on a floor-by-floor basis in case of infection spread. See Annex A.

NOTE 2 A rationale is contained in Annex I.

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Full document details: 25/30475284 DC

5.7.1.1 *Vacuum supply systems* shall not be used for extraction of A.G.S. as described in the ISO 7396-2

5.7.1.2 *Vacuum supply systems* complying with this part of ISO 7396 shall not be used in dentistry, see ISO 22051.

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 Examples of flow requirements are given in HTM 02[42], FD S 90-155[40] and AS 2896[28].

5.7.4 Each pump shall have a control circuit arranged so that shutting off, or failure, of one pump shall 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 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.

5.7.6 Each *vacuum receiver* shall be fitted with maintenance *shut-off valve(s)*, a drain valve and a vacuum gauge. If only one *vacuum receiver* or one drainage trap is fitted, means of bypass shall be provided. *Vacuum receivers* shall comply with appropriate local standards.

Note The liquid from condensate drains is potentially contaminated.

5.7.7 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.

Note Exhaust pipes can be hot.

5.7.8 The exhaust line shall be piped to prevent the accumulation of liquids. Where low points are unavoidable due to site conditions, a drain shall be provided at all low points.

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

5.7.10 Vacuum Filters

NOTE A rationale is contained in Annex I.

5.7.10.1 Filters shall be rated as HEPA ISP 35H or better under ISO 29463-1.

5.7.10.2 Total filtration capacity shall ensure that the *system design flow* can pass the filter(s) with a differential pressure across the filter(s) below the filter *manufacturer's* recommended limit.

5.7.10.3 At least one filter additional to the number required for the design flow shall be provided for use during maintenance (e.g. filter replacement).

5.7.10.4 Filters shall be valved to permit isolation of any one filter for maintenance.

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5.8 Location of *supply systems* and sources of supply

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 (see 4.1.4).

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

NOTE Open air locations for *supply systems* may not be suitable to ensure appropriate environment conditions, prevention of unauthorized access and overall system *safety*.

5.8.1 *Sources of supply* with *high pressure reservoirs* shall be located in a well-ventilated location with managed access, under cover and protected from adverse weather conditions.

5.8.2 Supply equipment shall be installed with sufficient maintenance space as specified by the *manufacturer*.

5.8.3 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 and oxygen 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).

5.8.4 The location of cylinder *manifolds* shall be defined in collaboration with the relevant authorities and in accordance with the relevant local standards. Informative guidelines are given in Annex B.

5.8.5 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 local standards. Informative guidelines are given in Annex B.

5.8.6 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.

NOTE Mechanical equipment (e.g. compressors and pumps) may generate noise in excess of 70 dBA.

5.8.7 Drainage facilities shall be provided for *air compressor unit(s)* and *vacuum pumps*.

5.8.8 The ambient temperature in rooms for *supply systems* shall be maintained in the range of 10 °C to 40 °C when the equipment is in full operation.

The environmental limits in which the *supply systems* may be operated shall be detailed in the instructions for use.

Check compliance by inspection of the technical documentation.

Note 1 Ventilation must account for waste heat from motor driven equipment which must be accounted for in the ventilation of the room.

Note 2 Cylinders containing CO_2 or N_2O can show pressure increases at room temperatures above 30 °C. Therefore a room temperature below this temperature for rooms containing these gases is favourable.

NOTE 3 Local environmental conditions may require deviation from this range of temperatures.

NOTE 4 A rationale is contained in Annex I.

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Full document details: 25/30475284 DC

5.8.9 Locations where cylinders, stationary cryogenic and mobile vessels will be placed shall be provided with ventilation to prevent accumulation of gas.

Mobile *Cryogenic vessels* and cylinders shall be stored in areas with managed access, under cover and protected from adverse weather conditions.

5.8.10 Locations of *supply systems* which contain gases other than CO_2, *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 O_2 sensor should be installed at a height of approximately 1 m.

In case of *supply system* for CO_2, a CO_2 sensor with an indicator shall be installed at the entry to ensure the *safety* of personnel. In this case, the threshold level for CO_2 is 1,5 % in ambient air. The monitor shall activate an alarm with audible and visual signals outside the entrance, to warn of CO_2 concentrations equal to or above 1,5 %. The CO_2 sensor shall be installed at height of approximately 1 m.

For CO_2, complementary to these requirements, labelling information on asphyxiation risks (anoxia, hypoxia) shall be placed outside of the room in a position that is clearly visible to anyone entering the room.

Alarms related to ambient air gas concentrations shall be classified as *emergency operating alarms*.

NOTE A rationale is contained in Annex I.

5.8.11 Locations for *sources of supply using oxygen concentrator(s)* or *sources of supply using proportioning unit(s)* require means to be provided to prevent concentration of nitrogen in the enclosure.

5.9 Sources of supply and *supply systems* assembled at site

5.9.1 General

Systems assembled at site shall be demonstrated to conform to all provisions of this standard regarding installation, operation, and pharmacopeial specification of product gas.

5.9.1.1 If required by applicable policies the *manufacturer* shall provide to the facility or regulatory authority the risk analysis required in 4.1.2, the materials list required in 4.4 and the usability analysis required in 4.5.3.

5.9.1.2 The *manufacturer* shall confirm that each *source of supply* and each *supply system* assembled on site includes all components required by this standard.

5.9.1.3 The *manufacturer* shall demonstrate and confirm that each *source of supply* and each *supply system* assembled on site operates in every respect as described by this standard.

5.9.1.4 The *manufacturer* shall test the *source of supply* and *supply system* per 12.3.

5.9.1.5 For *supply systems* producing *medicinal gas*, the *manufacturer* shall, prior to the opening the main *shut-off valve* from the *supply system* to the pipeline system, test and demonstrate that the *medicinal* gas produced by each *supply system* assembled on site meets the selected pharmacopeial specification (see 4.3.1).

5.9.1.6 The *manufacturer* shall provide instructions for use as per 13.2 and instructions for maintenance as per 13.3.

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5.10 *Sources of supply* and *supply systems* preassembled in a factory

These requirements apply to *sources of supply* and *supply systems* assembled and tested off site (e.g. in a factory setting) and transported to the site as complete assemblies. This includes packaged products which are constructed in modules or partially disassembled for shipment and reassembled at site.

The information to be supplied by the *manufacturer* should be in accordance section 13 of this document.

5.10.1 Leakage

The total leakage to atmosphere of all connection between the components of a pressure *source of supply* shall meet the test for leakage given in 12.3.1.1 at the manufacturing site.

The acceptance test for leakage on-site according to 12.3.1.1 is additionally required to detect any transport or assembly faults or damages.

5.10.2 Marking

The *source of supply* produced in a factory shall be marked with the following:

a) the name and/or the trademark of the *manufacturer* or distributor;

b) the model or type designation;

c) the medical gas produced or controlled;

d) the design flow rate (m3/h);

e) the value of the nominal outlet pressure (kPa);

f) the date of manufacture (can be part of the serial number, recognizable to the user);

g) a means of individual identification such as a serial number;

h) the supply voltage (V) as applicable;

i) the frequency (Hz) as applicable;

j) the power (kW) as applicable;

k) the type of enclosure, in accordance with IEC 60529, as applicable.

5.10.3 Packaging

Packages shall provide a means of identification of the contents.

Means shall be provided to avoid that the source(s) of supply, *supply systems* and/or single components become contaminated during transport and storage; this applies, in particular:

a) to the inlet port and to the outlet port of the *reservoir*,

b) to ensure allow that the cleanliness level achieved during the manufacturing process is maintained until installation.

The type of packaging, the material used, the protection from the shocks of the *source of supply* shall take into account the transport means envisaged (e.g. transport by air, by sea, by train, by road). The *manufacturer* shall define appropriate validated procedures to ensure that this important aspect has been taken into account.

The package shall be marked with the transport and storage limitations conditions specified by the *manufacturer*.

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Evidence that the packaging is appropriate to prevent contamination and damages according to *manufacturer* transport instructions, shall be provided in the technical documentation.

5.10.4 Information for installation

5.10.4.1 The *manufacturer* shall at least provide specific information related to the environmental characteristics for installation (such as minimum dimension, required service access, ventilation, weight, vibration, etc).

5.10.4.2 The *manufacturer* shall at least provide suitable instructions for the installation, reassembly and for its connection to the other components of the *supply system*.

5.10.4.3 The information for installation shall specify the tests that are required after installation; their description shall include test conditions, test methods and results acceptance criteria.

5.10.5 Information for use

The *manufacturer* shall provide instructions for use.

Where local standards concerning information to be provided by the *manufacturer* do not exist, the instructions for use shall contain at least the following:

— a technical specification including the performances of the *source of supply using oxygen concentrator(s)* and how to connect and disconnect to the MGPS;

— a description of all alarm signals and *information signals*;

— the position in *normal condition* (i.e. open or closed) of all valves;

— instructions for recommended periodic checks of function of the system;

— adequate information regarding the product which the system is designed to deliver;

— instructions for the disposal of components or consumables;

— the starting and shut-down procedures.

The instructions for use shall be drafted taking into account the possibility that several different parties are involved in operation, use and maintenance.

5.10.6 Information for maintenance

The *manufacturer* shall provide instructions for periodic testing, preventive maintenance of the *sources of supply* and calibration of analysers, including the recommended frequency of such activities. A list of recommended spare parts shall also be provided.

6 Monitoring and Alarms

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.

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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 ±4 %.

6.2.3 Monitoring and alarm systems shall be connected to both the normal and the *emergency 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).

NOTE A rationale is contained in Annex I.

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.

NOTE A rationale is contained in Annex I.

6.3 Monitoring and alarm signals

The categories and the characteristics of the monitoring and alarm signals shall comply with Table 1.

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Full document details: 25/30475284 DC

6.3.1 Auditory signals

6.3.1.1 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.

6.3.1.2 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.

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

NOTE A rationale is contained in Annex I.

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

6.3.2 Visual signals

6.3.2.1 The indicator colours and the characteristics of visual signals shall comply with Table 1.

6.3.2.2 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.

6.3.3 Emergency and *operating alarm* characteristics

6.3.3.1 For *emergency clinical alarms* and *emergency operating alarms* (see Table 1), there shall be a visual and a simultaneous auditory signal.

NOTE A rationale is contained in Annex I.

6.3.3.2 For *operating alarms* (see Table 1), there shall be at least a visual signal.

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