INTERNATIONAL STANDARD

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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

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Foreword

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

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

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

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

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

– *Part 1: Pipeline systems for compressed medical gases and vacuum*

– *Part 2: Anaesthetic gas scavenging disposal systems*

Introduction

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

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

This part of ISO 7396 seeks to ensure that medical gas pipelines contain only the specific gas (or vacuum) intended to be supplied. For this reason, gas-specific components are used for terminal units and for other connectors which are intended to be used by the operator. In addition, each system is tested and certified to contain only the specific gas (or vacuum).

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

a) non-interchangeability between different pipeline systems by design, installation and testing;

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

c) use of suitable materials;

d) cleanliness of components;

e) correct installation;

f) provision of monitoring and alarm systems;

g) correct marking of the pipeline system;

h) testing and commissioning;

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

j) correct operational management;

k) safety features of the sources to ensure the quality of the gases according to specification.

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

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

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

NOTE Vacuum is also the responsibility of the healthcare facility.

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

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

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

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

Medical gas pipeline systems —

Part 1:
Pipeline systems for compressed medical gases and vacuum

1 (*) Scope

This part of ISO 7396 specifies requirements for design, installation, function, performance, testing, commissioning and documentation of pipeline systems used in healthcare facilities for the following:

— oxygen;

— nitrous oxide;

— medical air;

— carbon dioxide;

— oxygen/nitrous oxide mixtures (see Note 1);

— helium/oxygen mixtures;

— (*) oxygen 93;

— gases and gas mixtures classified as medical device, gases delivered to medical devices or intended for medical purposes or gases and gas mixtures for medicinal use not specified above;

— air for driving surgical tools;

— nitrogen for driving surgical tools;

— vacuum.

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

NOTE 2 Anaesthetic gas scavenging disposal systems are covered in ISO 7396-2.

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

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

a) acute care healthcare facilities;

b) internal patient continuing care healthcare facilities;

c) long-term care facilities;

d) community-based providers;

e) ambulatory and external patient care clinics (e.g. day surgery, endoscopy clinics and doctors' offices).

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

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

— supply systems in which all sources of supply deliver oxygen; in this case the concentration of the oxygen will be greater than 99%;

— supply systems in which all sources of supply deliver oxygen 93; in this case the concentration of the oxygen may vary between 90% and 96%;

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

This part of ISO 7396 also applies to:

— extensions of existing pipeline distribution systems;

— modifications of existing pipeline distribution systems;

— modifications or replacement of supply systems or sources of supply.

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

NOTE 5 Requirements for oxygen concentrators for domiciliary use are specified in ISO 80601-2-69.

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

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

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

2 Normative references

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

NOTE Additional references are listed in the Bibliography.

ISO 3746:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane*

ISO 5359:2014, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases*

ISO 8573-1:2010, *Compressed air — Part 1: Contaminants and purity classes*

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

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

ISO 11197:2004, *Medical supply units*

ISO 14644-1:1999, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness*

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

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

ISO 17672:2010, *Brazing — Filler metals*

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

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

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

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

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

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

EN 1041:2008, *Information supplied by the manufacturer of medical devices*

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

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

EN 13348:2008, *Copper and copper alloys — Seamless, round copper tubes for medical gases or vacuum*

3 Terms and definitions

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

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

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

Note 1 to entry: Different names or symbols are used for air for driving surgical tools, such as instrument air, surgical air, air motor, air - 700 and air - 800.

3.3
audio paused
state of limited duration in which the alarm system or part of the alarm system does not generate an auditory alarm signal

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

[SOURCE: IEC 60601-1-8]

3.4
booster compressor
compressor used to raise an elevated pressure to a higher pressure

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

3.5
branch
portion of the pipeline distribution system which supplies one or more areas on the same floor of the facility

3.6
commissioning
proof of function to verify that the agreed system specification is met and is accepted by the user or the user's representative

3.7
control equipment
items necessary to maintain the medical gas pipeline system within the specified operating parameters

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

3.8
control system
device or set of devices to manage, command, direct or regulate the behaviour of other device(s) or system(s)

3.9
cryogenic liquid system
supply system containing a gas stored in the liquid state in a vessel at temperatures lower than −150 °C

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

3.11
diversity factor
factor which represents the maximum proportion of terminal units in a defined clinical area which will be used at the same time, at flowrates defined in agreement with the management of the healthcare facility.

3.12
double-stage pipeline distribution system
pipeline distribution system in which gas is initially distributed from the supply system at a pressure higher than the nominal distribution pressure, and is then reduced to the nominal distribution pressure by line pressure regulator(s)

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

3.13
emergency clinical alarm
alarm to indicate to medical and technical staff that there is a deviation from a monitored parameter which requires an immediate response

3.14
emergency inlet point
inlet point which allows the connection of an emergency supply

3.15
emergency operating alarm
alarm to indicate to technical staff that there is a deviation from a monitored parameter which requires an immediate response

3.16
emergency supply
source of supply intended to be connected to an emergency inlet point

3.17
gas-specific
having characteristics which prevent connections between different gas services or vacuum services

3.18
gas-specific connector
connector with dimensional characteristics which prevent connections between different gas services

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

3.19
gas for medicinal use
gas or mixture of gases having properties for treating or preventing disease in human beings which may be used in or administered either with a view to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis

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

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

3.20
medical device gas
gas or mixture of gases intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease;

— investigation, replacement or modification of the anatomy or of a physiological process;

— control of conception;

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

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

3.21
healthcare facility
hospital, clinic or similar facility that provides patients with their healthcare needs

3.22
high-dependency patient
patient with a continual need of a medical gas/vacuum supply, who will be adversely affected by a medical gas/vacuum supply failure to such a degree that his/her clinical condition or safety can be compromised

3.23
high pressure
pressures greater than 3 000 kPa

[SOURCE: ISO 15001:2010]

3.24
high-pressure reservoir
permanently installed container(s) with nominal working pressures ranging from 3 000 kPa to 25 000 kPa at 15 °C

3.25
information signal
signal that is not an alarm signal or a reminder signal

3.26
line pressure regulator
pressure regulator used in a double-stage pipeline distribution system to reduce the nominal supply system pressure to the nominal distribution pressure

3.27
low-pressure hose assembly
assembly consisting of a flexible hose with permanently attached gas-specific inlet and outlet connectors and designed to conduct a medical gas at pressures less than 1 400 kPa

3.28
main line
portion of the pipeline distribution system connecting the supply system to risers and/or branches

3.29
maintenance supply assembly
inlet point which allows the connection of a maintenance supply

3.30
maintenance supply
source of supply intended to supply the system during maintenance

3.31
manifold
device for connecting the outlet(s) of one or more cylinders, cylinder bundles or high-pressure reservoir(s) of the same gas to the pipeline system

3.32
manifold pressure regulator
pressure regulator intended to be installed within sources of supply containing cylinders, cylinder bundles, or high-pressure reservoir(s)

3.33
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party

3.34
maximum distribution pressure
pressure at any terminal unit when the pipeline system is operating at zero flow

3.35
medical air
natural or synthetic mixture of gases, mainly composed of oxygen and nitrogen in specified proportions, with defined limits for the concentration of contaminants, supplied by a medical gas pipeline system and intended for administration to patients

Note 1 to entry: Medical air may be produced by supply systems with air compressors or by supply systems with proportioning units. Medical air produced by air compressor systems is called “medicinal air”, and medical air produced by proportioning systems is called “synthetic medicinal air” by the European Pharmacopoeia.

3.36
medical gas pipeline system
complete system which comprises a supply system, a monitoring and alarm system and a distribution system with terminal units at the points where medical gases or vacuum are required

3.37
minimum distribution pressure
lowest pressure occurring at any terminal unit when the pipeline system is operating at the system design flow

3.38
nominal distribution pressure
pressure which the medical gas pipeline system is intended to deliver at the terminal units

3.39
nominal supply system pressure
pressure which the supply system is intended to deliver at the inlet to the line pressure regulators

3.40
non-cryogenic liquid system
supply system containing a gas stored under pressure in the liquid state in a vessel at temperatures not lower than −50 °C

3.41
non-return valve
valve which permits flow in one direction only

3.42
operating alarm
alarm to indicate to technical staff that it is necessary to replenish the gas supply or to correct a malfunction

3.43
oxygen concentrator supply system
supply system containing one or more oxygen concentrator units

3.44
oxygen concentrator unit
component of source of supply that produces oxygen 93 from ambient air by extraction of nitrogen

3.45
oxygen
gas for medicinal use where the oxygen concentration is at least the minimum specified in the relevant pharmacopoeial monograph

3.46
oxygen 93
gas produced by an oxygen concentrator unit whose concentration is within the limits specified in the relevant pharmacopoeial monograph

3.47
peak demand
maximum foreseeable gas flowrate required by a healthcare facility

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

3.48
pipeline distribution system
portion of a medical gas or vacuum pipeline system linking the sources of supply of the supply system to the terminal units

3.49
pressure regulator
device which reduces the inlet pressure and maintains the set outlet pressure within specified limits

3.50
pressure-relief valve
device intended to relieve excess pressure at a preset pressure