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Sistemi napeljav za medicinske pline - 1. del: Sistemi napeljav za stisnjene medicinske pline in podtlak (ISO/FDIS 7396-1:2026)

Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum (ISO/FDIS 7396-1:2026)

Rohrleitungssysteme für medizinische Gase - Teil 1: Rohrleitungssysteme für medizinische Druckgase und Vakuum (ISO/FDIS 7396-1:2026)

Systèmes de distribution de gaz médicaux - Partie 1: Systèmes de distribution de gaz médicaux comprimés et de vide (ISO/FDIS 7396-1:2026)

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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

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 document 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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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

This fourth edition cancels and replaces the third edition (ISO 7396-1:2016), which has been technically revised. It also incorporates the Amendment ISO 7396-1:2016/Amd 1:2017.

The main changes are as follows:

— Compared to previous editions, there are few major changes to the pipeline system. Most updates are improvements and clarifications based on practical experience, such as better drawings.

— Compressors have now been added as an integrated part of the standard, and oxygen concentrators have been added as a subsystem. When reading this standard, it is important to note which section you are in: the pipeline, packaged gases (manifolds and cryogenic supply), compressor section, or the oxygen concentrator section.

— The number of annexes with additional information has increased. However, Annex D with typical forms for test results is now available separately for download from the ISO portal (add link!).

— Annex G, which covered operations, has been removed. Such management topics are now included in quality management standards. Annex G will become the foundation of a new document for operational management.

— The revision of this standard was delayed by the COVID pandemic. During the pandemic, many healthcare facilities discovered problems because the medical gas pipeline system had been designed with too little capacity, was not well maintained, or had been expanded until the design limits were fully reached. For this reason, the role of hospital management in the design, planning, construction, and future strategy of the medical gas pipeline systems has been made more explicit.

— Clause 12 still covers the testing and commissioning of the installation, which should make becoming familiar with this standard easier.

A list of all parts in the ISO 7396 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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 document 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 document.

This document 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 document 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.

It is normal practice to assign responsibility for the quality of the medical gas supplied to a nominated person within the *healthcare facility* such as the head pharmacist. 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*.

EN 14931:2006[37] defines additional requirements for hyperbaric application, in particular for flow rates and pressures of compressed air required to pressurize hyperbaric chambers and to drive other connected services. Also included are requirements for oxygen and other treatment gases administered to patients during hyperbaric therapies. 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 document. It is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated into this document.

Medical gas pipeline systems —

Part 1:
Pipeline systems for compressed medical gases and vacuum

1 Scope

This document specifies requirements for design, installation, function, performance, testing, commissioning and documentation of medical gas pipeline systems used in healthcare facilities for the following:

— argon;

— pharmacopeial 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.2

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

This document 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 document 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). This document may also be used as reference for medical gas pipeline systems intended to be installed in places other than healthcare facilities.

This document 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

Oxygen concentrators for domiciliary use are excluded from the scope of this document. This document 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.

This document does not apply to vacuum systems intended to be used in dentistry (A rationale is discussed in Annex I.2)

This document does not apply to filling systems for transportable cylinders and transportable cylinder bundle systems.

This document does not apply to cryogenic pipeline systems conveying liquified gases.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

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

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

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

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

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

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

ISO 11197, *Medical supply units*

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

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

ISO 17672, *Brazing — Filler metals*

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

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

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

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

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

IEC 60601-1-8, *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, *Medical device software — Software life cycle processes*

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

EN 837-1, *Pressure gauges, Bourdon tube pressure gauges, Dimensions, metrology, requirements and testing*

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

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

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

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

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

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

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 can be established by the authority having jurisdiction.

Note 2 to entry: The applicable policy can 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.

3.4
audio off
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 2006 3.12]

3.5
booster compressor unit
compressor unit 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 a 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

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 unit).

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
dedicated setting where health care professionals deliver services for patient care

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

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