



FINAL DRAFT International Standard

ISO/FDIS 7396-3

Medical gas pipeline systems — Part 3: Proportioning units for the production of synthetic medical air

Systèmes de distribution de gaz médicaux —

*Partie 3: Unités mélangeurs pour la production d'air médical
reconstitué*

ISO/TC 121/SC 6

Secretariat: **ANSI**

Voting begins on:
2025-04-01

Voting terminates on:
2025-05-27

[ISO/FDIS 7396-3](https://standards.iteh.ai/catalog/standards/iso/7520ad31-1f0c-441a-a6cd-bfd0d7844971/iso-fdis-7396-3)

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Published in Switzerland

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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 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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This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas supply systems*, in collaboration with 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).

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Introduction

Proportioning units are components of a supply system intended to supply synthetic medical air to a medical gas pipeline distribution system complying with ISO 7396-1.

ISO 7396-1 requires that a supply system consists of at least three sources of supply which can typically be, in addition to a proportioning unit, cylinder manifolds with associated pressure regulators.

The selection of the components to be associated to a proportioning unit within the supply system, included the reservoir, is therefore the responsibility of the manufacturer of the pipeline system.

When a proportioning unit is used as primary source of supply, the other sources of supply are used as the secondary and/or reserve source to supply the pipeline distribution system in the event of failure of the proportioning unit.

This document pays particular attention to:

- use of suitable materials;
- safety (mechanical strength, leakage, safe relief of excess pressure);
- compliance of the product gas with specification;
- monitoring of the production process;
- cleanliness;
- testing;
- marking;
- packaging;
- information supplied by the manufacturer.

[Annex C](#) contains rationale statements for some of the requirements of this document.

NOTE Synthetic medical air is referred to as “air, synthetic medicinal” in the most current European Pharmacopoeia monograph.

Medical gas pipeline systems —

Part 3:

Proportioning units for the production of synthetic medical air

1 Scope

1.1 This document specifies requirements relating to the construction and operation of devices producing air through the blending of oxygen and nitrogen for use as sources of supply in supply systems for medical gases.

1.2 This document is applicable to proportioning units intended to produce synthetic medical air and air for driving surgical tools by mixing in defined proportions oxygen and nitrogen.

1.3 This document is applicable to proportioning units intended to be components of a medical gas supply system for medical air which supplies a medical gas pipeline distribution system complying with ISO 7396-1.

1.4 The number of proportioning units within the medical air supply system and their combination with other sources of supply (e.g. cylinder manifolds) to ensure that the supply system consists of at least three sources of supply is outside the scope of this document.

Requirements for the supply systems for medical air are given in ISO 7396-1.

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

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

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

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

ISO 20417, *Information to be supplied by the manufacturer*

IEC 60204-1, *Safety of machinery - Electrical equipment of machines - Part 1: General requirements*

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

IEC 61000-6-2, *Electromagnetic compatibility (EMC) – Part 6-2: Generic standards - Immunity standard for industrial environments*

IEC 61000-6-4, *Electromagnetic compatibility (EMC) – Part 6-4: Generic standards - Emission standard for industrial environments*

IEC 61439-1, *Low-voltage switchgear and control gear assemblies - Part 1: General rules*

IEC 62304, *Medical device software - Software life cycle processes*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in in ISO 7396-1 and the following 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* (3.7)

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.

Note 3 to entry: Applicable policies can include regulations or guidelines and local laws.

3.2

air for driving surgical tools

natural or synthetic mixture of gases, mainly composed of *oxygen* (3.13) and nitrogen in specified proportions, with defined limits for the concentration of contaminants, supplied by a *medical gas pipeline system* (3.9) and intended for driving surgical tools

[SOURCE: ISO 7396-1:2016, 3.2, modified — Note to entry deleted.]

3.3

control system

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

[SOURCE: ISO 7396-1:2016, 3.8]

3.4

double-stage pipeline distribution system

pipeline distribution system (3.14) in which gas is initially distributed from the *supply system* (3.26) at a pressure higher than the *nominal distribution pressure* (3.10), and is then reduced to the nominal distribution pressure by *line pressure regulator(s)* (3.6)

Note 1 to entry: This initial higher pressure is the nominal supply system pressure.

[SOURCE: ISO 7396-1:2016, 3.12]

3.5

information signal

signal that is not an alarm signal or a reminder signal

[SOURCE: ISO 7396-1:2016, 3.25]

3.6

line pressure regulator

pressure regulator (3.15) used in a *double-stage pipeline distribution system* (3.4) to reduce the nominal supply system pressure to the *nominal distribution pressure* (3.10)

[SOURCE: ISO 7396-1:2016, 3.26]

3.7

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 their own name, regardless of whether these operations are carried out by that person themselves or on their behalf by a third party

[SOURCE: ISO 7396-1:2016, 3.33, modified — Definition made gender neutral.]

3.8

medical air

natural or synthetic mixture of gases, mainly composed of *oxygen* (3.13) and nitrogen in specified proportions, with defined limits for the concentration of contaminants, supplied by a *medical gas pipeline system* (3.9) and intended for administration to patients

Note 1 to entry: Medical air may be produced by *supply systems* (3.26) with air compressors or by supply systems with *proportioning units* (3.18). 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.

[SOURCE: ISO 7396-1:2016, 3.35]

3.9

medical gas pipeline system

complete system which comprises a *supply system* (3.26), a monitoring and alarm system and a distribution system with terminal units at the points where medical gases or vacuum are required

[SOURCE: ISO 7396-1:2016, 3.36]

3.10

nominal distribution pressure

pressure which the *medical gas pipeline system* (3.9) is intended to deliver at the terminal units

[SOURCE: ISO 7396-1:2016, 3.38]

3.11

non-return valve

valve which permits flow in one direction only

[SOURCE: ISO 7396-1:2016, 3.41]

3.12

operating alarm

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

[SOURCE: ISO 7396-1:2016, 3.42]

3.13

oxygen

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

[SOURCE: ISO 7396-1:2016, 3.45]

3.14

pipeline distribution system

portion of a medical gas or vacuum pipeline system linking the sources of supply of the *supply system* (3.26) to the terminal units

[SOURCE: ISO 7396-1:2016, 3.48]

3.15

pressure regulator

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

[SOURCE: ISO 7396-1:2016, 3.49]

3.16

pressure-relief valve

device intended to relieve excess pressure at a preset pressure

[SOURCE: ISO 7396-1:2016, 3.50]

3.17

primary source of supply

portion of the *supply system* (3.26) which supplies the *pipeline distribution system* (3.14)

[SOURCE: ISO 7396-1:2016, 3.51]

3.18

proportioning unit

device in which gases are mixed in a specified ratio

[SOURCE: ISO 7396-1:2016, 3.52]

3.19

reserve source of supply

that portion of the *supply system* (3.26) which supplies the complete, or portion(s) of the *pipeline distribution system* (3.14) in the event of failure or exhaustion of both the primary and *secondary sources of supply* (3.22)

[SOURCE: ISO 7396-1:2016, 3.54]

3.20

reservoir

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

[SOURCE: ISO 7396-1:2016, 3.56, modified — Note to entry deleted.]

3.21

safety

freedom from unacceptable risk

[SOURCE: ISO 7396-1:2016, 3.57]

3.22

secondary source of supply

portion of the *supply system* (3.26) which supplies the *pipeline distribution system* (3.14) in the event of exhaustion or failure of the *primary source of supply* (3.17)

[SOURCE: ISO 7396-1:2016, 3.58]

3.23

shut-off valve

valve which prevents flow in both directions when closed

[SOURCE: ISO 7396-1:2016, 3.59]

3.24

single fault condition

condition in which a single means for protection against a safety hazard in equipment is defective or a single external abnormal condition is present

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

[SOURCE: ISO 7396-1:2016, 3.60]

3.25

source of supply

portion of the *supply system* (3.26) with associated control equipment which supplies the *pipeline distribution system* (3.14)

[SOURCE: ISO 7396-1:2016, 3.62]

3.26

supply system

assembly which supplies the *pipeline distribution system* (3.14) and which includes all sources of supply

[SOURCE: ISO 7396-1:2016, 3.64]

4 Nomenclature

4.1 General

A typical example of a proportioning unit with the terminology used for its components is given in [Annex A](#).

Typical forms for documenting compliance of the proportioning unit with the requirements of this document are given in [Annex B](#).

4.2 Components of a proportioning unit

A proportioning unit typically comprises of the following components:

- a) inlet filters for oxygen and nitrogen;
- b) non-return valves for oxygen and nitrogen;
- c) automatic shut-off valves controlled by the inlet pressure of oxygen and nitrogen;
- d) pressure regulators for oxygen and nitrogen;
- e) shut-off valves and pressure-relief valve, as required;
- f) a pressure-equalizing system;
- g) a mixer connected to the oxygen and nitrogen sources of supply;
- h) a control system with two independent oxygen analysers and two independent control panels;
- i) a buffer reservoir;
- j) a synthetic medical air reservoir fitted with a pressure-relief valve(s), a pressure gauge and a means of purging;
- k) an automatic shut-off valve, to prevent synthetic medical air out of specification being delivered by the supply system to the pipeline distribution system.

NOTE The synthetic medical air reservoir is a mandatory component of the source of supply consisting of a proportioning unit. However, for certification purposes (e.g. for the CE marking in the European Union) the synthetic medical air reservoir cannot be always considered as part of the proportioning unit because the number of reservoirs, their size, their characteristics and their interconnection will depend upon the design and the destination of use of the pipeline distribution system to be supplied by a supply system with proportioning unit. These items are the responsibility of the pipeline distribution system manufacturer. When the synthetic medical air reservoir is not supplied as a component of the proportioning unit, the manufacturer, together with other information concerning the installation of the proportioning unit, will recommend to the pipeline distribution system manufacturer the characteristics and the minimum requirements to be met by the synthetic medical air reservoir.