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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
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (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.	

DRAFT INTERNATIONAL STANDARD

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ISO/TC 121/SC 6

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Medical gas pipeline systems —

Part 3:

Proportioning units for the production of synthetic medical air

ICS: 11.040.10

This document is circulated as received from the committee secretariat.

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ISO/CEN PARALLEL PROCESSING



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97 **Annex A (informative) - Typical examples of a proportioning unit with**
98 **terminology (To be drafted if necessary)**

99 **Annex B (Informative) – Typical forms for documenting compliance of**
100 **the proportioning unit with the requirements of this standard.**

101 **Annex C (Informative) – Rationale (To be drafted)**

102 **Annex D - List of potential hazards**

103 **Annex E (Informative) – Bibliography**
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work.

ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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

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

This is the first edition of this part of ISO 7396.

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. Such a standard 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 part of ISO 7396 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 part of ISO 7396.

The clauses and sub-clauses marked with an asterisk (*) after their number have corresponding rationale 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. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this part of ISO 7396, but will expedite any subsequent revisions.

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

1 Scope

1.1 This standard applies to **proportioning units** intended to produce **synthetic medical air and air for driving surgical tools** by mixing in defined proportions oxygen and nitrogen.

1.2 This standard applies 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**.

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

2 Normative references

ISO 20417 Information to be supplied by the manufacturer

EN 62304 Medical device software – Software life cycle processes

ISO 4126-1 Safety devices for protection against excessive pressure. Safety valves.

ISO 7396-1 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

IEC 60529-1 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 60204-1 Electrical equipment of machines – Part 1: General requirements

IEC 62366-1: Medical devices – Part 1: Application of usability engineering to medical devices

IEC/TR 62366-2: Medical devices – Part 2: Guidance on the application of usability engineering to medical devices

EN 331: Manually operated ball valves and closed bottom taper plug valves for gas installations for buildings

EN 62304: Medical device software — Software life cycle processes

IEC 60529: Degrees of protection provided by enclosures

3 Terms and definitions

NOTE These definitions are taken from ISO 7396-1:2019.

3.1 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

3.2 control system

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

3.3 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 This initial higher pressure is the nominal supply system pressure

3.4 information signal

signal that is not an alarm signal or a reminder signal

3.5 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

3.6 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

3.7 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 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.

3.8 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

3.9 nominal distribution pressure

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

3.10 non-return valve

valve which permits flow in one direction only

3.11 operating alarm

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

3.12 oxygen

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

3.13 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

3.14 pressure regulator

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

3.15 pressure-relief valve

device intended to relieve excess pressure at a pre-set pressure

3.16 primary source of supply

portion of the supply system which supplies the pipeline distribution system

3.17 proportioning unit

device in which gases are mixed in a specified ratio

3.18 reserve source of supply

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

3.19 reservoir

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

3.20 safety

freedom from unacceptable risk

3.21 secondary source of supply

portion of the supply system which supplies the pipeline distribution system in the event of exhaustion or failure of the primary source of supply

3.22 shut-off valve

valve which prevents flow in both directions when closed

3.23 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 Planned maintenance of equipment is considered a normal condition.

3.24 single-stage pipeline distribution system

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

3.25 source of supply

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

3.26 supply system

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

4 Nomenclature

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

4.1 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.

5 General Requirements

5.1 (*) Safety

Proportioning units shall, when transported, installed, commissioned, operated and maintained according to the instructions of the manufacturer, present no risks with an unacceptable level in normal condition and in single fault condition.