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~~DRAFT PROPOSAL FOR A STANDARD ON PROPORTIONING UNITS~~

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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

FDIS stage

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: + 41 22 749 01 11
E-mail: copyright@iso.org
Website: www.iso.org

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Foreword

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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.

~~The~~ ISO 7396-1 ~~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~~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 ~~part of ISO 7396~~document.

NOTE~~: synthetic~~ 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 part of the ISO 7396 gives information~~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 ~~applies~~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 ~~applies~~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 60204-1 *Safety of Machinery - Electrical equipment of machines – Part 1: General requirements*~~

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

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

~~IEC 62304: Medical device software — Software life cycle processes~~

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 ~~following~~ 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/

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

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

~~NOTE~~ 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~~ 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 ~~his~~their own name, regardless of whether these operations are carried out by that person ~~himself~~themself or on ~~his~~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~~ 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~~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]

~~3.14~~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]

~~3.15~~3.16
pressure-relief valve
device intended to relieve excess pressure at a ~~pre-set~~preset pressure

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

~~3.16~~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]

~~3.17~~3.18
proportioning unit
device in which gases are mixed in a specified ratio

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

~~3.18~~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]

~~3.19~~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.]

~~3.20~~3.21
safety
freedom from unacceptable risk

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

~~3.21~~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]

~~3.22~~3.23
shut-off valve
valve which prevents flow in both directions when closed

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

~~3.23~~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~~ Note 1 to entry: Planned maintenance of equipment is considered a normal condition.

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

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

~~3.24~~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]

~~3.25~~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.

5 General ~~Requirements~~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.

The risk management process ~~according to~~in accordance with ISO 14971 should also consider the possibility of undetected faults. Annex D provides a list of potential risks to consider.

In that case, a fault condition subsequently detected ~~needs to~~should be considered as a single fault condition. Specific risk control measures to deal with such situations ~~need to~~should 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.