



SLOVENSKI STANDARD
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Sistemi napeljav za medicinske pline - 3. del: Proporcionirne enote za proizvodnjo sintetičnega medicinskega zraka (ISO/DIS 7396-3:2023)

Medical gas pipeline systems - Part 3: Proportioning units for the production of synthetic medical air (ISO/DIS 7396-3:2023)

Systèmes de distribution de gaz médicaux - Partie 3: Unités mélangeurs pour la production d'air médical reconstitué (ISO/DIS 7396-3:2023)

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Medical gas pipeline systems —

Part 3: Proportioning units for the production of synthetic medical air

ICS: 11.040.10

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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**

104

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107 **Foreword**

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

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116 matters of electrotechnical standardization.

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130 adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following
131 URL: [Foreword - Supplementary information](#)

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

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

135

136

137 **Introduction**

138

139 **Proportioning units** are components of a supply system intended to supply **synthetic**
140 **medical air** to a medical gas pipeline distribution system complying with ISO 7396-1.
141 Such a standard requires that a supply system consists of at least three sources of supply
142 which can typically be, in addition to a **proportioning unit**, cylinder manifolds with associated
143 pressure regulators.

144

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

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

151

152 This part of ISO 7396 pays particular attention to:

153

154 - use of suitable materials;

155

156 - safety (mechanical strength, leakage, safe relief of excess pressure);

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157
158 - compliance of the product gas with specification;

159
160 - monitoring of the production process;

161
162 - cleanliness;

163
164 - testing;

165
166 - marking;

167
168 - packaging;

169
170 - information supplied by the manufacturer.

171
172 **Annex C** contains rationale statements for some of the requirements of this part of ISO 7396.

173
174 The clauses and sub-clauses marked with an asterisk (*) after their number have
175 corresponding rationale included to provide additional insight into the reasoning that led to the
176 requirements and recommendations that have been incorporated into this part of ISO 7396. It
177 is considered that knowledge of the reasons for the requirements will not only facilitate the
178 proper application of this part of ISO 7396, but will expedite any subsequent revisions.

179
180 **NOTE:** synthetic medical air is referred to as “air, synthetic medicinal” in the European
181 Pharmacopoeia monograph.

182 183 184 **1 Scope**

185
186 **1.1** This standard applies to **proportioning units** intended to produce **synthetic medical air**
187 **and air for driving surgical tools** by mixing in defined proportions oxygen and nitrogen.

188
189 **1.2** This standard applies to **proportioning units** intended to be components of a medical gas
190 supply system for **medical air** which supplies a medical gas pipeline distribution system
191 complying with **ISO 7396-1**.

192
193 **1.3** The number of **proportioning units** within the **medical air** supply system and their
194 combination with other sources of supply (e.g. cylinder manifolds) to ensure that the supply
195 system consists of at least three sources of supply is outside the scope of this standard.
196 Requirements for the supply systems for **medical air** are given in **ISO 7396-1**.

197 198 199 **2 Normative references**

200
201 **ISO 20417** Information to be supplied by the manufacturer

202
203 **EN 62304** Medical device software – Software life cycle processes

204
205 **ISO 4126-1** Safety devices for protection against excessive pressure. Safety valves.

206
207 **ISO 7396-1** Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical

208 gases and vacuum.

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

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

211 **IEC 60529-1** Degrees of protection provided by enclosures (IP Code)

212 **IEC 61000-6-2** Electromagnetic compatibility (EMC) – Part 6-2- Generic standards- Immunity

213 standard for industrial environments

214 **IEC 61000-6-4** Electromagnetic compatibility (EMC) – Part 6-4 - Generic standards - Emission

215 standard for industrial environments

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

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

218 **IEC/TR 62366-2:** Medical devices – Part 2: Guidance on the application of usability

219 engineering to medical devices

220 **EN 331:** Manually operated ball valves and closed bottom taper plug valves for gas

221 installations for buildings

222 **EN 62304:** Medical device software — Software life cycle processes

223 **IEC 60529:** Degrees of protection provided by enclosures

224 3 Terms and definitions

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

226 3.1 air for driving surgical tools

227 natural or synthetic mixture of gases, mainly composed of oxygen and nitrogen in

228 specified proportions, with defined limits for the concentration of contaminants, supplied by

229 a medical gas pipeline system and intended for driving surgical tools

230 3.2 control system

231 device or set of devices to manage, command, direct or regulate the behaviour of

232 other device(s) or system(s)

233 3.3 double-stage pipeline distribution system

234 pipeline distribution system in which gas is initially distributed from the supply system at a

235 pressure higher than the nominal distribution pressure, and is then reduced to the

236 nominal distribution pressure by line pressure regulator(s)

237 **NOTE** This initial higher pressure is the nominal supply system pressure

238 3.4 information signal

239 signal that is not an alarm signal or a reminder signal

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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).