

# ISO 7396-3:2025-07 (E)

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

---

<b>Contents</b>		<b>Page</b>
Foreword .....		v
Introduction .....		vi
1	Scope .....	1
2	Normative references .....	1
3	Terms and definitions .....	2
4	Nomenclature .....	5
4.1	General .....	5
4.2	Components of a proportioning unit .....	5
5	General requirements .....	6
5.1	Safety .....	6
5.2	Usability .....	6
5.3	Materials .....	6
6	Design requirements .....	7
6.1	Environmental conditions .....	7
6.2	Specification for synthetic medical air .....	7
6.3	Management of the conformity of supply .....	7
6.4	Sample port .....	8
6.5	Outlet connector .....	8
6.6	Inlet connectors: Pressure-equalizing system .....	8
6.6.1	Inlet connectors .....	8
6.6.2	Pressure-equalizing system .....	8
6.7	Requirements for outlet pressure .....	8
6.8	Indication of the functional parameters .....	9
6.9	Monitoring and alarm systems .....	9
6.10	Record capability .....	9
6.11	Leakage .....	10
6.12	Manual shut-off valves .....	10
6.13	Automatic shut-off valves .....	10
6.14	Non-return valves .....	10
6.15	Pressure-relief valves .....	10
6.16	Mechanical strength .....	10
6.17	Filtration .....	11
6.18	Electromagnetic compatibility .....	11
6.19	Electrical safety .....	11
6.20	Oxygen analysers .....	11
6.21	Software .....	12
6.22	Enclosure .....	12
7	Constructional requirements .....	12
7.1	Cleanliness .....	12
7.2	Lubricants .....	12
8	Type test methods .....	12
8.1	General .....	12

8.2	Test method for compliance of synthetic medical air to specification .....	12
8.3	Test method for leakage .....	12
8.4	Test method for alarms .....	13
8.5	Test method for mechanical strength .....	13
8.6	Test method for performance .....	13
8.7	Electromagnetic compatibility test .....	13
8.8	Electrical safety test .....	13
8.9	Test method for automatic shut-off valve .....	13
8.10	Test for enclosure .....	13
9	Marking and packaging .....	14
9.1	Marking .....	14
9.2	Packaging .....	14
10	Information supplied by the manufacturer .....	14
10.1	General .....	14
10.2	Information for installation .....	14
10.3	Instructions for use .....	15
10.4	Information for maintenance .....	15
	Annex A (informative) Typical example of a proportioning unit with terminology .....	16
	Annex B (informative) Typical forms for documenting compliance of the proportioning unit with the requirements of this document .....	17
	Annex C (informative) Rationale .....	24
	Annex D (informative) List of potential hazards .....	25
	Bibliography .....	26