

ISO 7396-3:2025-07 (E)

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

Contents		Page
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