

DIN ISO 10083:2008-12 (E)

Oxygen concentrator supply systems for use with medical gas pipeline systems (ISO 10083:2006)

Contents		Page
National foreword		3
National Annex NA (informative) Bibliography		4
National Annex NB (informative) Relationship between this International Standard and the essential requirements of EU Directive 93/42/EEC on medical devices		5
Introduction		6
1	Scope	8
2	Normative references	8
3	Terms and definitions	9
4	General requirements	11
4.1	Safety and continuity of supply	11
4.2*	Alternative constructions	12
4.3	Materials	13
4.4	System design	14
4.5	Specifications for oxygen-enriched air	14
4.6	Cylinder filling	15
5	Sources of supply	15
5.1	General	15
5.2	Primary source of supply	15
5.3	Secondary source of supply	16
5.4	Reserve source of supply	17
5.5	Sources of supply with cylinders	17
5.6	Location of oxygen concentrator supply systems	17
6	Requirements for components	18
6.1	Oxygen concentrator unit	18
6.2	Oxygen-enriched air storage vessels	19
6.3	Oxygen analysers	19
6.4	Pressure-relief valves	19
6.5	Shut-off valves	20
6.6	Sample port	20
6.7	Pressure regulators	20
7	Monitoring and alarm systems	20
7.1	General	20
7.2	Monitoring and alarm signals	20
7.3	Operating alarms	21
7.4	Information signals	21
8	Marking	21
9	Installation	22
9.1	General	22
9.2	Electrical systems	22

10	Testing, commissioning and certification	22
10.1	General	22
10.2	Tests and procedures	22
10.3	Specific tests	23
10.4	Commissioning and certification	25
11	Information to be supplied by the manufacturer	25
11.1	Instructions for installation	25
11.2	Instructions for use	25
11.3	Instructions for preventive maintenance	26
11.4	Operational management information	26
11.5	"As installed" drawings	26
11.6	Electrical schematics	26
11.7	Disclosure by the manufacturer	26
12	Implementation of use of oxygen-enriched air	26
12.1	Acceptance of oxygen-enriched air	26
12.2	Timing	26
12.3	Mixing of oxygen-enriched air and oxygen	27
12.4	Calibration of medical equipment	27
12.5	Labelling	27
12.6	Compliance with ISO 7396-1	27
Annex A (informative)	Schematic representations of oxygen concentrator supply systems	28
Annex B (informative)	General guidelines for location of supply systems	37
Annex C (informative)	Guidelines for emergency procedures	39
Annex D (informative)	Procedure for testing and commissioning	41
Annex E (informative)	Typical forms for certification of an oxygen concentrator supply system	43
Annex F (informative)	Recommended minimum requirements for preventive maintenance	46
Annex G (informative)	Recommendations for installation	48
Annex H (informative)	Risk and risk management	49
Annex I (informative)	Recommendations for sizing and capacity	50
Annex J (informative)	Recommendations for filling cylinders with oxygen-enriched air	52
Annex K (informative)	Rationale	53