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