

ISO 10651-2:2004-07 (E)

Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 2: Home care ventilators for ventilator-dependent patients

Contents

	Page
Foreword	vi
Introduction	vii
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 General requirements and requirements for tests	3
5 Classification	4
6 Identification, marking and documents	4
6.1 Marking on the outside of equipment or equipment parts	4
6.3 Marking of controls and instruments	5
6.6 Identification of medical gas cylinders and connections	5
6.8.2 Instructions for use	6
6.8.3 Technical description	7
6.101 Test method for legibility	8
7 Power input	8
7.101 Pneumatic power	8
8 Basic safety categories	8
9 Removable protective means	9
10 Environmental conditions	9
10.2.1 Environment	9
10.2.2 Power supply	9
10.101 Pneumatic driving-power supplies	9
11 Not used	9
12 Not used	9
13 General	9
14 Requirements related to classification	10
14.2 * Class II Equipment	10
15 Limitation of voltage and/or energy	10
16 Enclosures and protective covers	10
17 Separation	10

18	Protective earthing, functional earthing and potential equalization	10
19	Continuous leakage currents and patient auxiliary currents	10
19.4	* Tests	10
20	Dielectric strength	10
21	Mechanical strength	10
22	Moving parts	11
23	Surfaces, corners and edges	11
24	Stability in normal use	11
25	Expelled parts	11
26	Vibration and noise	11
27	Pneumatic and hydraulic power	11
28	Suspended masses	11
29	X-radiation	11
30	Alpha, beta, gamma, neutron radiation and other particle radiation	11
31	Microwave radiation	11
32	Light radiation (including lasers)	11
33	Infra-red-radiation	12
34	Ultraviolet radiation	12
35	Acoustical energy (including ultrasonics)	12
36	Electromagnetic compatibility	12
37	Locations and basic requirements	12
38	Marking, accompanying documents	12
39	Common requirements for category AP and category APG equipment	12
40	Requirements and tests for category AP equipment, parts and components thereof	12
41	Requirements and tests for category APG equipment, parts and components thereof	12
42	Excessive temperatures	12
43	Fire prevention	13
43.2	* Oxygen-enriched atmospheres	13
43.101	Compatibility with pressurized oxygen	13
44	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility	13
44.3	Spillage	13
44.7	Cleaning, sterilization and disinfection	13
44.8	Compatibility with substances used with the equipment	14
45	Pressure vessels and parts subject to pressure	14

46	Human errors	14
47	Electrostatic charges	14
48	Biocompatibility	14
49	Interruption of the power supply	14
49.101	*Internal electrical power source	15
49.102	Additional external backup power source	15
49.103	Spontaneous breathing during power failure	15
49.104	Accidental operation of the on/off-switch	15
50	Accuracy of operating data	15
51	Protection against hazardous output	16
51.101	Failure of air and oxygen supply systems	16
51.102	Adjustable ventilator breathing system pressure limitation	16
51.103	Maximum ventilator breathing system pressure limitation	16
51.104	Measurement of airway pressure	16
51.105	*High-inspiratory pressure alarm condition	16
51.106	Expiratory monitoring	17
51.107	Hypoventilation alarm condition	18
51.108	Continuing pressure alarm condition	18
51.109	Respiration-rate alarm condition	18
52	Abnormal operation and fault conditions	18
53	Environmental tests	19
54	General	19
54.3	Protection against inadvertent adjustments	19
55	Enclosures and covers	19
56	Components and general assembly	19
56.3	Connections -- General	19
56.101	Reservoir bags and breathing tubes	21
56.102	Humidifiers and heat and moisture exchangers	21
56.103	Pulse oximeters and capnometers	21
56.104	Oxygen monitor and alarm condition	21
56.105	Integrated monitoring equipment	21
57	Mains parts, components and layout	22
57.3	* Power supply cords	22
58	Protective earthing -- Terminals and connections	22
59	Construction and layout	22
101	Alarm systems	22
201.8.3	Indication and access	22
201.12	Alarm condition logging	22
102	Appendices of IEC 60601-1:1988	23
	Annex AA (informative) Rationale	24
	Annex BB (informative) Reference to the essential principles	28
	Bibliography	30