

# ISO 10651-6:2004-07 (E)

## Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 6: Home-care ventilatory support devices

---

<b>Contents</b>		<b>Page</b>
Foreword .....		vi
Introduction .....		vii
1	Scope .....	1
2	Normative references .....	1
3	Terms and definitions .....	2
4	General requirements and general requirements for tests .....	3
5	Classification .....	3
6	Identification, marking and documents .....	3
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
6.101	Test method for legibility .....	7
7	Power input .....	8
7.101	Pneumatic power .....	8
8	Basic safety categories .....	8
9	Removable protective means .....	8
10	Environmental conditions .....	8
10.101	Pneumatic driving power supplies .....	9
11	Not used .....	9
12	Not used .....	9
13	General .....	9
14	Requirements related to classification .....	9
14.2	* Class II Equipment .....	9
15	Limitation of voltage and/or energy .....	9
16	Enclosures and protective covers .....	9
17	Separation .....	9
18	Protective earthing, functional earthing and potential equalization .....	9
19	Continuous leakage currents and patient auxiliary currents .....	10
19.4	* Tests .....	10
20	Dielectric strength .....	10

21	<b>Mechanical strength</b> .....	10
22	<b>Moving parts</b> .....	10
23	<b>Surfaces, corners and edges</b> .....	10
24	<b>Stability in normal use</b> .....	10
25	<b>Expelled parts</b> .....	10
26	<b>Vibration and noise</b> .....	10
27	<b>Pneumatic and hydraulic power</b> .....	10
28	<b>Suspended masses</b> .....	11
29	<b>X-radiation</b> .....	11
30	<b>Alpha, beta, gamma, neutron radiation and other particle radiation</b> .....	11
31	<b>Microwave radiation</b> .....	11
32	<b>Light radiation (including lasers)</b> .....	11
33	<b>Infra-red-radiation</b> .....	11
34	<b>Ultra-violet radiation</b> .....	11
35	<b>Acoustical energy (including ultrasonics)</b> .....	11
36	<b>Electromagnetic compatibility</b> .....	11
37	<b>Locations and basic requirements</b> .....	11
38	<b>Marking, accompanying documents</b> .....	12
39	<b>Common requirements for category AP and category APG equipment</b> .....	12
40	<b>Requirements and tests for category AP equipment, parts and components thereof</b> .....	12
41	<b>Requirements and tests for category APG equipment, parts and components thereof</b> .....	12
42	<b>Excessive temperatures</b> .....	12
43	<b>Fire prevention</b> .....	12
43.2	<b>Oxygen enriched atmospheres</b> .....	12
43.101	<b>Compatibility with pressurized oxygen</b> .....	13
44	<b>Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility</b> .....	13
44.3	<b>Spillage</b> .....	13
44.7	<b>Cleaning, sterilization and disinfection</b> .....	13
44.8	<b>Compatibility with substances used with the equipment</b> .....	13
45	<b>Pressure vessels and parts subject to pressure</b> .....	13
46	<b>Human errors</b> .....	14
47	<b>Electrostatic charges</b> .....	14
48	<b>Biocompatibility</b> .....	14

<b>49</b>	<b>Interruption of the power supply .....</b>	<b>14</b>
<b>49.101</b>	<b>* Internal electrical power source .....</b>	<b>14</b>
<b>49.102</b>	<b>Spontaneous breathing during power failure .....</b>	<b>14</b>
<b>49.103</b>	<b>Accidental operation of the on/off-switch .....</b>	<b>15</b>
<b>50</b>	<b>Accuracy of operating data .....</b>	<b>15</b>
<b>51</b>	<b>Protection against hazardous output .....</b>	<b>15</b>
<b>51.101</b>	<b>Maximum ventilator breathing system pressure limitation .....</b>	<b>15</b>
<b>51.102</b>	<b>Measurement of airway pressure .....</b>	<b>15</b>
<b>51.103</b>	<b>* High-inspiratory pressure alarm condition .....</b>	<b>15</b>
<b>51.104</b>	<b>Expiratory monitoring .....</b>	<b>15</b>
<b>51.105</b>	<b>Respiration rate alarm condition .....</b>	<b>16</b>
<b>52</b>	<b>Abnormal operation and fault conditions .....</b>	<b>17</b>
<b>53</b>	<b>Environmental tests .....</b>	<b>17</b>
<b>54</b>	<b>General .....</b>	<b>17</b>
<b>54.3</b>	<b>Protection against inadvertent adjustments .....</b>	<b>17</b>
<b>55</b>	<b>Enclosures and covers .....</b>	<b>17</b>
<b>56</b>	<b>Components and general assembly .....</b>	<b>17</b>
<b>56.3</b>	<b>Connections -- General .....</b>	<b>17</b>
<b>56.101</b>	<b>Reservoir bags and breathing tubes .....</b>	<b>19</b>
<b>57</b>	<b>Mains parts, components and layout .....</b>	<b>19</b>
<b>57.3</b>	<b>* Power supply cords .....</b>	<b>19</b>
<b>58</b>	<b>Protective earthing -- Terminals and connections .....</b>	<b>19</b>
<b>59</b>	<b>Construction and layout .....</b>	<b>20</b>
<b>101</b>	<b>Alarm systems .....</b>	<b>20</b>
<b>102</b>	<b>Appendices of IEC 60601-1:1988 .....</b>	<b>20</b>
<b>Annex AA (informative) Rationale .....</b>		<b>21</b>
<b>Annex BB (informative) Reference to the Essential Principles .....</b>		<b>25</b>
<b>Bibliography .....</b>		<b>26</b>