

# ISO 80601-2-72:2015-09 (E)

## Medical electrical equipment - Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients

---

### Contents

	Page
<b>Foreword</b>	<b>vii</b>
<b>Introduction</b>	<b>ix</b>
<b>201.1 Scope, object and related standards</b>	<b>1</b>
<b>201.1.1 *Scope</b>	<b>1</b>
<b>201.1.2 Object</b>	<b>2</b>
<b>201.1.3 Collateral standards</b>	<b>2</b>
<b>201.1.4 Particular standards</b>	<b>2</b>
<b>201.2 Normative references</b>	<b>3</b>
<b>201.3 Terms and definitions</b>	<b>5</b>
<b>201.4 General requirements</b>	<b>7</b>
<b>201.4.3 ESSENTIAL PERFORMANCE</b>	<b>7</b>
<b>201.4.3.101 *Additional requirements for ESSENTIAL PERFORMANCE</b>	<b>8</b>
<b>201.4.6 *ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT</b>	<b>8</b>
<b>201.4.10.2 *SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS</b>	<b>8</b>
<b>201.4.11.101 *Additional requirements for pressurized gas input</b>	<b>9</b>
<b>201.4.11.101.1 Overpressure requirement</b>	<b>9</b>
<b>201.4.11.101.2 Compatibility requirement</b>	<b>9</b>
<b>201.5 General requirements for testing of ME EQUIPMENT</b>	<b>10</b>
<b>201.5.101 *Additional requirements for general requirements for testing of ME EQUIPMENT</b>	<b>10</b>
<b>201.5.101.1 VENTILATOR test conditions</b>	<b>10</b>
<b>201.5.101.2 *Gas flowrate and leakage specifications</b>	<b>10</b>
<b>201.5.101.3 *VENTILATOR testing errors</b>	<b>10</b>
<b>201.6 Classification of ME EQUIPMENT and ME SYSTEMS</b>	<b>10</b>
<b>201.7 ME EQUIPMENT identification, marking and documents</b>	<b>10</b>
<b>201.7.2.3 *Consult ACCOMPANYING DOCUMENTS</b>	<b>10</b>
<b>201.7.2.4.101 Additional requirements for ACCESSORIES</b>	<b>11</b>
<b>201.7.2.13.101 Additional requirements for physiological effects</b>	<b>11</b>
<b>201.7.2.17.101 Additional requirements for protective packaging</b>	<b>11</b>
<b>201.7.2.101 Additional requirements for marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts</b>	<b>11</b>
<b>201.7.4.2 Control devices</b>	<b>12</b>
<b>201.7.4.3 *Units of measurement</b>	<b>12</b>
<b>201.7.9.1 Additional general requirements</b>	<b>12</b>
<b>201.7.9.2 Instructions for use</b>	<b>12</b>
<b>201.7.9.2.1.101 Additional general requirements</b>	<b>12</b>
<b>201.7.9.2.1.102 Additional general requirements</b>	<b>13</b>
<b>201.7.9.2.2.101 *Additional requirements for warnings and safety notices</b>	<b>13</b>

201.7.9.2.8.101 *Additional requirements for start-up PROCEDURE .....	14
201.7.9.2.9.101 *Additional requirements for operating instructions .....	15
201.7.9.2.9.101.1 *LAY OPERATOR operating instructions .....	15
201.7.9.2.9.101.2 *Supervising clinician operating instructions .....	15
201.7.9.2.12 Cleaning, disinfection, and sterilization.....	16
201.7.9.2.13.101 Additional requirements for maintenance.....	17
201.7.9.2.14.101 *Additional requirements for ACCESSORIES, supplementary equipment, used material .....	17
201.7.9.3.1.101 *Additional general requirements .....	17
201.7.9.3.101 Additional requirements for the technical description.....	18
<b>201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....</b>	<b>18</b>
201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS .....	18
201.9.4.3.101 Additional requirements for instability from unwanted lateral movement.....	18
201.9.4.4 Grips and other handling devices .....	18
201.9.6.2.1.101 Additional requirements for audible acoustic energy .....	18
201.10 Protection against unwanted and excessive radiation HAZARDS .....	19
201.11 Protection against excessive temperatures and other HAZARDS.....	19
201.11.1.2.2 *APPLIED PARTS not intended to supply heat to a PATIENT.....	19
201.11.6.4 Leakage .....	20
201.11.6.6 *Cleaning and disinfection of ME EQUIPMENT or ME SYSTEM .....	20
201.11.6.7 Sterilization of ME EQUIPMENT or ME SYSTEM .....	21
201.11.8 Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT.....	21
201.11.8.101 Additional requirements for interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT .....	21
201.12 *Accuracy of controls and instruments and protection against hazardous outputs.....	21
201.12.1 Accuracy of controls and instruments .....	21
201.12.1.101 Breath types.....	22
201.12.1.102 Volume-controlled breath type .....	22
201.12.1.103 Pressure-controlled breath type.....	25
201.12.1.104 DELIVERED VOLUME MONITORING EQUIPMENT .....	28
201.12.4 Protection against hazardous output.....	29
201.12.4.4 Incorrect output .....	29
201.12.4.101 Oxygen monitor .....	29
201.12.4.102 *Measurement of AIRWAY PRESSURE .....	30
201.12.4.103 *Measurement of expired volume and low-volume ALARM CONDITIONS .....	30
201.12.4.104 *Expiratory end-tidal CO <sub>2</sub> MONITORING EQUIPMENT .....	31
201.12.4.105 *MAXIMUM LIMITED PRESSURE PROTECTION DEVICE .....	31
201.12.4.106 High-pressure ALARM CONDITION and PROTECTION DEVICE .....	31
201.12.4.107 *Obstruction ALARM CONDITION .....	32
201.12.4.108 *Partial-occlusion ALARM CONDITION .....	32
201.12.4.109 Hypoventilation ALARM CONDITION.....	32
201.12.4.110 Continuing positive-pressure ALARM CONDITION.....	33
201.12.4.111 *Leakage ALARM CONDITION.....	33
201.12.101 *Protection against accidental adjustments .....	33

<b>201.13 HAZARDOUS SITUATIONS and fault conditions.....</b>	<b>33</b>
<b>201.13.2.101 *Additional specific SINGLE FAULT CONDITIONS .....</b>	<b>33</b>
<b>201.13.101 Failure of one gas supply to a VENTILATOR.....</b>	<b>34</b>
<b>201.13.102 *Independence of ventilation control function and related RISK CONTROL measures.....</b>	<b>34</b>
<b>201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) .....</b>	<b>34</b>
<b>201.14.1 General .....</b>	<b>34</b>
<b>201.15 Construction of ME EQUIPMENT .....</b>	<b>34</b>
<b>201.15.101 Mode of operation.....</b>	<b>34</b>
<b>201.15.102 ACCESSORY pre-use check.....</b>	<b>34</b>
<b>201.15.103 Integrated dual-limb VBS .....</b>	<b>34</b>
<b>201.16 ME SYSTEMS.....</b>	<b>35</b>
<b>201.16.1.101 Additional general requirements for ME SYSTEMS.....</b>	<b>35</b>
<b>201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS .....</b>	<b>35</b>
<b>201.101 Gas connections .....</b>	<b>35</b>
<b>201.101.1 Connection to the MEDICAL GAS PIPELINE SYSTEM .....</b>	<b>35</b>
<b>201.101.2 VBS connectors .....</b>	<b>35</b>
<b>201.101.2.1 *General .....</b>	<b>35</b>
<b>201.101.2.2 Other named ports .....</b>	<b>35</b>
<b>201.101.2.2.1 PATIENT-CONNECTION PORT .....</b>	<b>35</b>
<b>201.101.2.2.2 GAS OUTPUT PORT and GAS RETURN PORT.....</b>	<b>35</b>
<b>201.101.2.2.3 *MANUAL VENTILATION PORT .....</b>	<b>36</b>
<b>201.101.2.2.4 FLOW-DIRECTION-SENSITIVE COMPONENTS .....</b>	<b>36</b>
<b>201.101.2.2.5 ACCESSORY port.....</b>	<b>36</b>
<b>201.101.2.2.6 Monitoring probe port.....</b>	<b>36</b>
<b>201.101.2.2.7 Gas EXHAUST PORT .....</b>	<b>36</b>
<b>201.101.2.2.8 Oxygen inlet port .....</b>	<b>36</b>
<b>201.102 Requirements for the VBS and ACCESSORIES .....</b>	<b>37</b>
<b>201.102.1 *General .....</b>	<b>37</b>
<b>201.102.2 Labelling .....</b>	<b>37</b>
<b>201.102.3 Breathing tubes .....</b>	<b>37</b>
<b>201.102.4 *Humidification.....</b>	<b>37</b>
<b>201.102.4.1 HUMIDIFIER.....</b>	<b>37</b>
<b>201.102.4.2 HEAT AND MOISTURE EXCHANGER (HME) .....</b>	<b>37</b>
<b>201.102.5 BREATHING SYSTEM FILTERS (BSF) .....</b>	<b>37</b>
<b>201.102.6 VENTILATOR BREATHING SYSTEMS .....</b>	<b>38</b>
<b>201.102.6.1 Leakage from VBS .....</b>	<b>38</b>
<b>201.102.6.2 *Non-invasive ventilation .....</b>	<b>38</b>
<b>201.103 *Spontaneous breathing during loss of power supply.....</b>	<b>38</b>
<b>201.104 *Training .....</b>	<b>38</b>
<b>201.105 *Indication of duration of operation.....</b>	<b>39</b>
<b>201.106 FUNCTIONAL CONNECTION .....</b>	<b>39</b>
<b>201.106.1 General .....</b>	<b>39</b>
<b>201.106.2 *Connection to an electronic health record .....</b>	<b>39</b>
<b>201.106.3 *Connection to a DISTRIBUTED ALARM SYSTEM .....</b>	<b>39</b>
<b>201.106.4 Connection for remote control .....</b>	<b>39</b>
<b>201.107 Display loops.....</b>	<b>39</b>
<b>201.107.1 Pressure-volume loops.....</b>	<b>39</b>
<b>201.107.2 Flow-volume loops .....</b>	<b>39</b>

<b>201.108</b>	<b>POWER SUPPLY CORDS .....</b>	<b>40</b>
<b>201.109</b>	<b>VENTILATOR security .....</b>	<b>40</b>
<b>202</b>	<b>Electromagnetic disturbances – Requirements and tests .....</b>	<b>40</b>
<b>202.4.3.1</b>	<b>*Compliance criteria .....</b>	<b>40</b>
<b>202.5.2.2.1</b>	<b>Requirements applicable to all ME EQUIPMENT and ME SYSTEMS .....</b>	<b>40</b>
<b>202.8.1.101</b>	<b>Additional general requirements .....</b>	<b>41</b>
<b>206</b>	<b>Usability.....</b>	<b>41</b>
<b>208</b>	<b>General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems .....</b>	<b>42</b>
<b>208.6.8.3.101</b>	<b>Additional requirements for global indefinite ALARM SIGNAL inactivation states .....</b>	<b>42</b>
<b>208.6.8.4.101</b>	<b>*Additional requirements for termination of ALARM SIGNAL inactivation .....</b>	<b>42</b>
<b>208.6.12.101</b>	<b>*Additional requirements for ALARM SYSTEM logging .....</b>	<b>42</b>
<b>211</b>	<b>Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment .....</b>	<b>43</b>
<b>211.8.4.101</b>	<b>*Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT .....</b>	<b>43</b>
<b>211.10.1.1</b>	<b>General requirements for mechanical strength.....</b>	<b>44</b>
<b>Annex C</b> (informative)	<b>Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS .....</b>	<b>45</b>
<b>Annex D</b> (informative)	<b>Symbols on marking.....</b>	<b>52</b>
<b>Annex AA</b> (informative)	<b>Particular guidance and rationale .....</b>	<b>53</b>
<b>Annex BB</b> (informative)	<b>Data interface requirements .....</b>	<b>72</b>
<b>Annex CC</b> (informative)	<b>Reference to the Essential Principles.....</b>	<b>79</b>
<b>Annex DD</b> (informative)	<b>Alphabetized index of defined terms used in this particular standard .....</b>	<b>81</b>
<b>Bibliography</b>	<b>.....</b>	<b>85</b>