

ISO 80601-2-84:2023-11 (E)

Medical electrical equipment - Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

Contents

	Page
Foreword	vi
Introduction.....	viii
201. 1 Scope, object and related standards.....	1
201. 1.1 Scope.....	1
201. 1.2 Object.....	2
201. 1.3 Collateral standards.....	2
201. 1.4 Particular standards	3
201. 2 Normative references.....	4
201. 3 Terms and definitions	5
201. 4 General requirements	23
201. 4.3 <i>Essential performance</i>	23
201. 4.3.101 Additional requirements for <i>essential performance</i>	23
201. 4.3.102 <i>System recovery</i>	23
201. 4.4 Additional requirements for <i>expected service life</i>	24
201. 4.5 Alternative <i>risk control</i> measures or test methods for <i>ME equipment</i> or <i>ME system</i>	25
201. 4.6 <i>ME equipment</i> or <i>ME system</i> parts that contact the <i>patient</i>	25
201. 4.11.101 Additional requirements for pressurized gas input.....	25
201. 4.11.101.1 Overpressure requirement	25
201. 4.11.101.2 Compatibility requirement for <i>medical gas pipeline systems</i>	25
201. 4.11.101.3 Compatibility requirements for pressure regulators	26
201. 5 General requirements for testing of <i>ME equipment</i>.....	26
201. 5.101 Additional requirements for general requirements for testing of <i>ME equipment</i>	27
201. 5.101.1 <i>EMS ventilator</i> test conditions	27
201. 5.101.2 Gas flowrate and leakage specifications.....	27
201. 5.101.3 <i>EMS ventilator</i> testing errors	27
201. 6 Classification of <i>ME equipment</i> and <i>ME systems</i>	27
201. 7 <i>ME equipment</i> identification, marking and documents	28
201. 7.1.101 <i>Information to be supplied by the manufacturer</i>	28
201. 7.2.3 Consult <i>accompanying documents</i>	28
201. 7.2.4.101 Additional requirements for <i>accessories</i>	28
201. 7.2.18 External gas source	28
201. 7.2.101 Additional requirements for <i>marking</i> on the outside of <i>ME equipment</i> or <i>ME equipment</i> parts.....	29
201. 7.4.2 Control devices	30
201. 7.4.3 Units of measurement	30
201. 7.4.101 Labelling of units of measurement	30
201. 7.9.2.1 General	30
201. 7.9.2.1.101 Additional general requirements	30
201. 7.9.2.2.101 Additional requirements for warnings and safety notices	30
201. 7.9.2.8.101 Additional requirements for start-up <i>procedure</i>	31
201. 7.9.2.9.101 Additional requirements for operating instructions	32
201. 7.9.2.12 <i>Cleaning, disinfection, and sterilization</i>	33
201. 7.9.2.14.101 Additional requirements for <i>accessories</i> , supplementary <i>equipment</i> , used material.....	33

201. 7.9.3.1.101	Additional general requirements	33
201. 7.9.3.101	Additional requirements for the <i>technical description</i>	34
201. 8	Protection against electrical <i>hazards</i> from <i>ME equipment</i>	34
201. 9	Protection against <i>mechanical hazards</i> of <i>ME equipment</i> and <i>ME systems</i>	34
201. 9.4.3.101	Additional requirements for instability from unwanted lateral movement.....	34
201. 9.4.4	Grips and other handling devices	35
201. 9.6.2.1.101	Additional requirements for audible acoustic energy	35
201. 10	Protection against unwanted and excessive radiation <i>hazards</i>.....	36
201. 11	Protection against excessive temperatures and other <i>hazards</i>	36
201. 11.1.2.2	<i>Applied parts not intended to supply heat to a patient</i>	37
201. 11.6.6	<i>Cleaning and disinfection of ME equipment or ME system</i>	37
201. 11.6.7	<i>Sterilization of ME equipment or ME system</i>	38
201. 11.7	<i>Biocompatibility of ME equipment and ME systems</i>	38
201. 12	Accuracy of controls and instruments and protection against hazardous outputs	38
201. 12.1.101	<i>Volume-control inflation-type</i>	38
201. 12.1.102	<i>Pressure-control inflation-type</i>	42
201. 12.1.103	<i>Other inflation-types</i>	45
201. 12.1.104	<i>Inspiratory volume monitoring equipment</i>	45
201. 12.4	Protection against hazardous output.....	45
201. 12.4.101	Oxygen monitor	45
201. 12.4.102	Measurement of <i>airway pressure</i>	46
201. 12.4.103	Measurement of expired volume and low volume <i>alarm conditions</i>	47
201. 12.4.104	<i>Maximum limited pressure protection device</i>	48
201. 12.4.105	High <i>airway pressure alarm condition and protection device</i>	48
201. 12.4.106	Expiratory end-tidal CO ₂ <i>monitoring equipment</i>	50
201. 12.4.107	Protection against inadvertent setting of high <i>airway pressure</i>	50
201. 13	Hazardous situations and fault conditions for <i>ME equipment</i>	50
201. 13.2.101	Additional specific <i>single fault conditions</i>	50
201. 13.102	Failure of one gas supply to an <i>EMS ventilator</i>	51
201. 13.103	Independence of <i>ventilation control function</i> and related <i>risk control measures</i>	51
201. 14	Programmable electrical medical systems (PEMS).....	52
201. 14.1	General	52
201. 14.101	<i>Cybersecurity capabilities of EMS ventilators</i>	52
201. 15	Construction of <i>ME equipment</i>	53
201. 15.3.5.101	Additional requirements for rough handling.....	53
201. 15.4.1	Construction of <i>connectors</i>	53
201. 15.101	Mode of operation	54
201. 15.102	Delivered oxygen concentration	54
201. 15.103	<i>Accessory self-check</i>	54
201. 16	<i>ME systems</i>	54
201. 16.1.101	Additional general requirements for <i>ME systems</i>	54
201. 16.2.101	Additional requirements for power supply.....	55
201. 17	Electromagnetic compatibility of <i>ME equipment</i> and <i>ME systems</i>	55
201. 101	Gas connections	55
201. 101.1	Protection against reverse gas leakage	55
201. 101.2	Connection to a <i>high-pressure inlet</i>	56
201. 101.2.1	<i>Low-pressure hose assembly</i>	56
201. 101.2.2	Filter	56
201. 101.3	<i>VBS connectors</i>	56
201. 101.3.1	General.....	56
201. 101.3.2	Other named ports	56

201. 101.3.2.1	<i>Patient-connection port</i>	56
201. 101.3.2.2	<i>Gas output port and gas return port</i>	57
201. 101.3.2.3	<i>Flow-direction-sensitive components</i>	57
201. 101.3.2.4	<i>Gas pathway connection port</i>	57
201. 101.3.2.5	<i>Gas exhaust port</i>	58
201. 101.3.2.6	<i>Gas intake port</i>	58
201. 102 Requirements for the VBS and accessories	58
201. 102.1	General	58
201. 102.2	Labelling	58
201. 102.3	Breathing sets.....	59
201. 102.4	Water vapour management	59
201. 102.4.1	Humidification system	59
201. 102.4.2	<i>Heat and moisture exchanger (HME)</i>	59
201. 102.5	<i>Breathing system filters</i>	59
201. 102.6	Leakage from complete VBS.....	59
201. 103 Spontaneous breathing during loss of ventilation	60
201. 104 Indication of duration of operation	60
201. 105 Functional connection	60
201. 105.1	General	60
201. 105.2	Connection to an electronic health record	61
201. 105.3	Connection to a <i>distributed alarm system</i>	61
201. 106 Display loops	61
201. 106.1	Pressure-volume loops	61
201. 106.2	Flow-volume loops.....	61
201. 107 Timed ventilatory pause	61
201. 107.1	<i>Expiratory pause</i>	62
201. 107.2	<i>Inspiratory pause</i>	62
202 Electromagnetic disturbances — Requirements and tests	63
206 Usability	64
206.101	<i>Primary operating functions</i>	64
206.102	Training.....	66
208 General requirements, tests and guidance for <i>alarm systems in medical electrical equipment and medical electrical systems</i>	66
212 Requirements for <i>medical electrical equipment and medical electrical systems</i> intended for use in the <i>emergency medical services environment</i>	68
Annex C (informative) Guide to <i>marking and labelling requirements for ME equipment and ME systems</i>	71
201.C.1	<i>Marking on the outside of ME equipment, ME systems or their parts</i>	71
201.C.2	<i>Accompanying documents, general</i>	72
201.C.3	<i>Accompanying documents, instructions for use</i>	72
201.C.4	<i>Accompanying documents, technical description</i>	74
Annex D (informative) Symbols on marking	76
Annex AA (informative) Particular guidance and rationale	78
AA.1	General guidance	78
AA.2	Rationale for particular clauses and subclauses.....	78
Annex BB (informative) Data interfaces	114
BB.1	Background and purpose.....	114
BB.2	Data definition	115
Annex CC (informative) Reference to the IMDRF <i>essential principles</i> and labelling guidances	122
Annex DD (informative) Reference to the <i>essential principles</i>	126
Bibliography	129
Terminology — Alphabetized index of defined terms	133