

ISO 80601-2-12:2011-04 (E)

Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators

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.....	2
201.2 Normative references.....	3
201.3 Terms and definitions	6
201.4 General requirements	9
201.4. 3 ESSENTIAL PERFORMANCE	9
201.4. 3.101 * Additional requirements for ESSENTIAL PERFORMANCE	9
201.4. 6 * ME EQUIPMENT OR ME SYSTEM parts that contact the PATIENT	9
201.4. 11.101 * Additional requirements for pressurized gas input	9
201.4. 11.101.1 Overpressure requirement	9
201.4. 11.101.2 Compatibility requirement.....	10
201.5 General requirements for testing of ME EQUIPMENT.....	10
201.5. 101 * Additional requirements for general requirements for testing of ME EQUIPMENT	10
201.5. 101.1 VENTILATOR test conditions	10
201.5. 101.2 * Gas flowrate and leakage specifications.....	11
201.5. 101.3 * VENTILATOR testing errors	11
201.6 Classification of ME EQUIPMENT and ME SYSTEMS.....	11
201.7 ME EQUIPMENT identification, marking and documents.....	11
201.7. 2.3 * Consult ACCOMPANYING DOCUMENTS	11
201.7. 2.101 Additional requirements for marking on the outside of ME EQUIPMENT OR ME EQUIPMENT parts.....	11
201.7. 2.4.101 Additional requirements for ACCESSORIES	12
201.7. 2.13.101 Additional requirements for physiological effects	12
201.7. 2.17.101 Additional requirements for protective packaging	13
201.7. 4.3 * Unit of measure	13
201.7. 9.1 Additional general requirements	13
201.7. 9.2.1.101 Additional general requirements	14
201.7. 9.2.2.101 * Additional requirements for warnings and safety notices	14
201.7. 9.2.8.101 * Additional requirements for start-up procedure.....	15
201.7. 9.2.9.101 * Additional requirements for operating instructions	15
201.7. 9.2.12 Cleaning, disinfection, and sterilization	16
201.7. 9.2.14.101 * Additional requirements for ACCESSORIES, supplementary equipment, used material.....	16
201.7. 9.2.16.101 * Additional requirements for reference to the technical description	16
201.7. 9.3.1.101 * Additional general requirements.....	16
201.7. 9.3.101 Additional requirements for the technical description	17
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	17
201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	17
201.9. 6.2.1.101 Additional requirements for audible acoustic energy.....	17
201.9. 101 * Additional requirements for suction procedures	18
201.10 Protection against unwanted and excessive radiation HAZARDS	20

201.11	Protection against excessive temperatures and other HAZARDS	20
201.11. 6.4	Leakage.....	20
201.11. 6.5.101 *	Additional requirements for ingress of water or particulate matter into ME EQUIPMENT or ME SYSTEM	21
201.11. 6.6 *	Cleaning and disinfection of ME EQUIPMENT or ME SYSTEM.....	21
201.11. 6.7	Sterilization of ME EQUIPMENT or ME SYSTEM.....	21
201.11. 8.101	Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT	22
201.11. 8.101.1	TECHNICAL ALARM CONDITION for power supply failure	22
201.11. 8.101.2	INTERNAL ELECTRICAL POWER SOURCE or external reserve electrical power source	22
201.12	Accuracy of controls and instruments and protection against hazardous outputs.....	23
201.12. 1 *	Accuracy of controls and instruments	23
201.12. 1.101	Volume-controlled breath type.....	23
201.12. 1.102	Pressure-controlled breath type	26
201.12. 1.103 *	DELIVERED VOLUME MONITORING.....	29
201.12. 1.104 *	Response of the VENTILATOR to an increase in O ₂ concentration	29
201.12. 4	Protection against hazardous output.....	31
201.12. 4.101	Oxygen monitor	31
201.12. 4.102 *	Measurement of AIRWAY PRESSURE	31
201.12. 4.103 *	Measurement of expired volume and low-volume ALARM CONDITIONS	32
201.12. 4.103.1	VENTILATORS intended to provide a DELIVERED VOLUME > 50 ml	32
201.12. 4.103.2	VENTILATORS intended to provide a DELIVERED VOLUME u 50 ml	32
201.12. 4.104 *	MAXIMUM LIMITED PRESSURE PROTECTION DEVICE	33
201.12. 4.105	High-pressure ALARM CONDITION and PROTECTION DEVICE.....	33
201.12. 4.106	PEEP ALARM CONDITIONS.....	33
201.12. 4.107 *	Obstruction ALARM CONDITION.....	33
201.12. 4.108 *	Partial-occlusion ALARM CONDITION.....	34
201.12. 101 *	Protection against accidental adjustments	34
201.13	HAZARDOUS SITUATIONS and fault conditions	34
201.13. 2.101 *	Additional specific SINGLE FAULT CONDITIONS	34
201.13. 102 *	Failure of one gas supply to a VENTILATOR.....	35
201.13. 103 *	Independence of ventilation control function and related RISK CONTROL measures	35
201.14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....	35
201.14. 101	Software life cycle	35
201.15	Construction of ME EQUIPMENT.....	35
201.15. 3.5.101	Additional requirements for rough handling	35
201.15. 3.5.101.1 *	Shock and vibration	35
201.15. 3.5.101.2 *	Shock and vibration for a MOBILE VENTILATOR	36
201.15. 101	Mode of operation.....	37
201.15. 102	Delivered Oxygen concentration	38
201.15. 103	ACCESSORY self-check	38
201.16	ME SYSTEMS	38
201.16. 1.101	Additional general requirements for ME SYSTEMS	38
201.17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS.....	38
201.17. 101	Additional requirements for electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	38
201.101	Gas connections	38
201.101. 1 *	Protection against reverse gas leakage.....	38
201.101. 2	Connection to the MEDICAL GAS PIPELINE SYSTEM	39
201.101. 3	Vbs connectors	39
201.101. 3.1 *	General	39
201.101. 3.2	Other named ports.....	39
201.101. 3.2.1	PATIENT-CONNECTION PORT.....	39
201.101. 3.2.2	GAS OUTPUT PORT and GAS RETURN PORT	39
201.101. 3.2.3	MANUAL ventilation port.....	39
201.101. 3.2.4	EMERGENCY INTAKE PORT	40

201.101. 3.2.5 FLOW-DIRECTION-sensitive components	40
201.101. 3.2.6 ACCESSORY port.....	40
201.101. 3.2.7 Monitoring probe port.....	40
201.101. 3.2.8 Gas EXHAUST PORT	40
201.102 Requirements for the VBS and ACCESSORIES	40
201.102. 1 * General.....	40
201.102. 2 Labelling.....	40
201.102. 3 Breathing tubes	41
201.102. 4 * Water management.....	41
201.102. 4.1 Humidification system	41
201.102. 4.2 HEAT AND MOISTURE EXCHANGER (HME).....	41
201.102. 5 Gas mixers	41
201.102. 6 BREATHING SYSTEM FILTERS	41
201.102. 7 VENTILATOR BREATHING SYSTEMS	41
201.102. 7.1 Leakage from complete VBS	41
201.102. 7.2 * Non-invasive ventilation.....	42
201.103 * Spontaneous breathing during loss of power supply.....	42
201.104 * Training	43
201.105 * Indication of duration of operation	43
201.106 SIGNAL INPUT/OUTPUT PART	43
201.106. 1 General	43
201.106. 2 * Connection to an electronic health record.....	43
201.106. 3 * Connection to a DISTRIBUTED ALARM SYSTEM	43
201.106. 4 * Connection for remote control	43
201.107 Display loops	43
201.107. 1 Pressure-volume loops.....	43
201.107. 2 Flow-volume loops	44
201.108 * Timed ventilatory pause.....	44
201.108. 1 Expiratory pause	44
201.108. 2 Inspiratory pause.....	44
202 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.....	45
202.6.2.1.10 * Compliance criteria.....	45
206 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability.....	46
208 Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	47
208.6.3.3.2.101 * Additional requirements for characteristics of ALARM CONDITION logging	47
208.6.8.3.101 Additional requirements for global indefinite ALARM SIGNAL inactivation states.....	47
208.6.8.4.101 * Additional requirements for termination of ALARM SIGNAL inactivation	47
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS.....	48
Annex D (informative) Symbols on marking	53
Annex AA (informative) Particular guidance and rationale	55
Annex BB (informative) Reference to the Essential Principles.....	72
Bibliography.....	74
Alphabetized index of defined terms used in this particular standard.....	77