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