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 *Essential performance* 23
201. 4.3.101 Additional requirements for *essential performance* 23
201. 4.3.102 *System recovery* 23
201. 4.4 Additional requirements for *expected service life* 24
201. 4.5 Alternative *risk control* measures or test methods for *ME equipment* or *ME system* 25
201. 4.6 *ME equipment* or *ME system* parts that contact the *patient* 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 *medical gas pipeline systems* 25
201. 4.11.101.3 Compatibility requirements for pressure regulators 26

201. 5 General requirements for testing of *ME equipment* 26
201. 5.101 Additional requirements for general requirements for testing of *ME equipment* 27
201. 5.101.1 *EMS ventilator* test conditions 27
201. 5.101.2 Gas flowrate and leakage specifications 27
201. 5.101.3 *EMS ventilator* testing errors 27

201. 6 Classification of *ME equipment* and *ME systems* 27

201. 7 *ME equipment* identification, *marking* and documents 28
201. 7.1.101 *Information to be supplied by the manufacturer* 28
201. 7.2.3 Consult *accompanying documents* 28
201. 7.2.4.101 Additional requirements for *accessories* 28
201. 7.2.18 External gas source 28
201. 7.2.101 Additional requirements for *marking* on the outside of *ME equipment* or *ME equipment* 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 *procedure* 31
201. 7.9.2.9.101 Additional requirements for operating instructions 32
201. 7.9.2.12 *Cleaning*, *disinfection*, and *sterilization* 33
201. 7.9.2.14.101 Additional requirements for *accessories*, supplementary equipment, used material 33

201. 7.9.3.1.101 Additional general requirements 33
201. 7.9.3.101 Additional requirements for the *technical description* 34

201. 8 Protection against electrical *hazards* from *ME equipment* 34

201. 9 Protection against *mechanical hazards* of *ME equipment* and *ME systems* 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 *hazards* 36

201. 11 Protection against excessive temperatures and other *hazards* 36

201. 11.1.2.2 *Applied parts* not intended to supply heat to a *patient* 37
201. 11.6.6 *Cleaning* and *disinfection* of *ME equipment* or *ME system* 37
201. 11.6.7 *Sterilization* of *ME equipment* or *ME system* 38
201. 11.7 *Biocompatibility* of *ME equipment* and *ME systems* 38

201. 12 Accuracy of controls and instruments and protection against hazardous outputs 38

201. 12.1.101 *Volume-control inflation-type* 38
201. 12.1.102 *Pressure-control inflation-type* 42
201. 12.1.103 Other *inflation-types* 45
201. 12.1.104 *Inspiratory volume monitoring equipment* 45
201. 12.4 Protection against hazardous output 45
201. 12.4.101 Oxygen monitor 45
201. 12.4.102 Measurement of *airway pressure* 46
201. 12.4.103 Measurement of expired volume and low volume *alarm conditions* 47
201. 12.4.104 *Maximum limited pressure protection device* 48
201. 12.4.105 High *airway pressure alarm condition* and *protection device* 48
201. 12.4.106 Expiratory end-tidal CO_2 *monitoring equipment* 50
201. 12.4.107 Protection against inadvertent setting of high *airway pressure* 50

201. 13 *Hazardous situations* and fault conditions for *ME equipment* 50

201. 13.2.101 Additional specific *single fault conditions* 50
201. 13.102 Failure of one gas supply to an *EMS ventilator* 51
201. 13.103 Independence of *ventilation* control function and related *risk control* measures 51

201. 14 *Programmable electrical medical systems* (*PEMS*) 52

201. 14.1 General 52
201. 14.101 *Cybersecurity* capabilities of *EMS ventilators* 52

201. 15 Construction of *ME equipment* 53

201. 15.3.5.101 Additional requirements for rough handling 53
201. 15.4.1 Construction of *connectors* 53
201. 15.101 Mode of operation 54
201. 15.102 Delivered oxygen concentration 54
201. 15.103 *Accessory* self-check 54

201. 16 *ME systems* 54

201. 16.1.101 Additional general requirements for *ME systems* 54
201. 16.2.101 Additional requirements for power supply 55

201. 17 Electromagnetic compatibility of *ME equipment* and *ME systems* 55

201. 101 Gas connections 55

201. 101.1 Protection against reverse gas leakage 55
201. 101.2 Connection to a *high-pressure inlet* 56
201. 101.2.1 *Low-pressure hose assembly* 56
201. 101.2.2 Filter 56
201. 101.3 *VBS connectors* 56
201. 101.3.1 General 56
201. 101.3.2 Other named ports 56

201. 101.3.2.1 *Patient-connection port* ... 56
201. 101.3.2.2 *Gas output port* and *gas return port* ... 57
201. 101.3.2.3 *Flow-direction-sensitive components* ... 57
201. 101.3.2.4 *Gas pathway* connection port ... 57
201. 101.3.2.5 Gas *exhaust port* ... 58
201. 101.3.2.6 *Gas intake port* ... 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 *Heat and moisture exchanger* (*HME*) ... 59
201. 102.5 *Breathing system filters* ... 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 *distributed alarm system* ... 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 *Expiratory pause* ... 62
201. 107.2 *Inspiratory pause* ... 62

202 Electromagnetic disturbances — Requirements and tests ... **63**

206 Usability ... **64**
206.101 *Primary operating functions* ... 64
206.102 Training ... 66

208 General requirements, tests and guidance for *alarm systems* in *medical electrical equipment* and *medical electrical systems* ... **66**

212 Requirements for *medical electrical equipment* and *medical electrical systems* intended for use in the *emergency medical services environment* ... **68**

Annex C (informative) Guide to *marking* and labelling requirements for *ME equipment* and *ME systems* ... **71**
201.C.1 *Marking* on the outside of *ME equipment*, *ME systems* or their parts ... 71
201.C.2 *Accompanying documents*, general ... 72
201.C.3 *Accompanying documents*, *instructions for use* ... 72
201.C.4 *Accompanying documents*, *technical description* ... 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 *essential principles* and labelling guidances ... **122**

Annex DD (informative) Reference to the *essential principles* ... **126**

Bibliography ... **129**

Terminology — Alphabetized index of defined terms ... **133**