

ISO 80601-2-80:2018-07 (E)

Medical electrical equipment - Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency

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	3
201.3 Terms and definitions.....	5
201.4 General requirements.....	7
201.4.3 Essential performance	7
201.4.3.101 * Additional requirements for ESSENTIAL PERFORMANCE	7
201.4.6 * ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT.....	7
201.4.11.101 * Additional requirements for pressurized gas input	8
201.5 General requirements for testing of ME EQUIPMENT	9
201.5.101 * Additional requirements for the general requirements for testing of ME EQUIPMENT	9
201.5.101.1 Ventilatory support equipment test conditions.....	9
201.5.101.2 * Gas flowrate and leakage specifications	9
201.5.101.3 * VENTILATORY SUPPORT EQUIPMENT testing errors	9
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	10
201.6.101 * Additional requirements for classification of ME EQUIPMENT and ME SYSTEMS	10
201.7 ME EQUIPMENT identification, marking and documents	10
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	17
201.9 Protection against mechanical hazards of ME EQUIPMENT and ME SYSTEMS	17
201.10 Protection against unwanted and excessive radiation HAZARDS	19
201.11 Protection against excessive temperatures and other HAZARDS.....	19
201.11.7 Biocompatibility of ME EQUIPMENT and ME SYSTEMS	20
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 ALARM CONDITION	21
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 Other breath types	28
201.12.2.101 Usability of me equipment	29
201.12.4 Protection against hazardous output.....	29
201.12.4.101 * Measurement of AIRWAY PRESSURE	29
201.12.4.102 Measurement of expired volume	31
201.12.4.103 * Maximum limited pressure protection device.....	31
201.12.4.104 Hypoventilation ALARM CONDITION.....	31
201.12.4.105 * High leakage ALARM CONDITION	31
201.12.4.106 * CO ₂ rebreathing	32
201.12.101 * Protection against accidental adjustments.....	32

201.13 Hazardous situations and fault conditions for ME EQUIPMENT.....	33
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	34
201.15 Construction of ME EQUIPMENT	34
201.15.101 Mode of operation	34
201.15.102 Pre-use check	34
201.16 ME SYSTEMS	34
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS.....	35
201.101 Gas connections	35
201.101.1 VBS connectors.....	35
201.101.1.1 General	35
201.101.1.2 Other named ports	35
201.102 Requirements for the VBS and ACCESSORIES.....	36
201.102.1 * General	36
201.102.2 Labelling	37
201.102.3 Breathing sets	37
201.102.4 * Humidification.....	37
201.102.4.1 HUMIDIFIER.....	37
201.102.4.2 HEAT AND MOISTURE EXCHANGER (HME).....	37
201.102.5 BREATHING SYSTEM FILTERS (BSF)	37
201.103 * Spontaneous breathing during loss of power supply	37
201.104 * Training	38
201.105 * Indication of duration of operation.....	38
201.106 Functional connection.....	38
201.106.1 General.....	38
201.106.2 * Connection to an electronic health record	39
201.106.3 * Connection to a distributed alarm system	39
201.106.4 Connection for remote control	39
201.107 Display loops	39
201.107.1 Pressure-volume loops.....	39
201.107.2 Flow-volume loops.....	39
201.108 Power supply cords.....	40
201.109 Ventilatory support equipment security.....	40
202 Electromagnetic disturbances — Requirements and tests.....	40
206 Usability	41
208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.....	43
211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	44
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS.....	45
Annex D (informative) Symbols on marking	52
Annex AA (informative) Particular guidance and rationale	54
Annex BB (informative) Data interface requirements	69
Annex CC (informative) Reference to the ESSENTIAL PRINCIPLES	76
Annex DD (informative) Terminology — Alphabetized index of defined terms.....	80
Bibliography	84