

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