

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 |