

ISO 80601-2-70:2020-11 (E)

Medical electrical equipment - Part 2-70: Particular requirements for the basic safety and essential performance of sleep apnoea breathing therapy equipment

Contents	Page
Foreword.....	vi
Introduction.....	vii
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	4
201.4 General requirements	7
201.4.3 <i>Essential performance</i>	7
201.4.3.101 * Additional requirements for <i>essential performance</i>	7
201.4.6 * <i>ME equipment</i> or <i>ME system</i> parts that contact the <i>patient</i>	7
201.5 General requirements for testing of <i>ME equipment</i>	8
201.5.101 Additional requirements for general requirements for testing of <i>ME equipment</i>	8
201.5.101.1 Gas flowrate and pressure specifications.....	8
201.5.101.2 * <i>Sleep apnoea breathing therapy equipment</i> testing errors.....	8
201.6 Classification of <i>ME equipment</i> and <i>ME systems</i>	8
201.7 <i>ME equipment</i> identification, marking and documents	8
201.7.1.2 * Legibility of markings.....	8
201.7.2.4.101 Additional requirements for <i>accessories</i>	9
201.7.2.13.101 Additional requirements for physiological effects.....	9
201.7.2.17.101 * Additional requirements for protective packaging.....	9
201.7.2.101 Additional requirements for marking on the outside of <i>ME equipment</i> or <i>ME equipment</i> parts.....	10
201.7.4.3 Units of measurement.....	10
201.7.9.1 * Additional general requirements.....	10
201.7.9.2 Instructions for use.....	11
201.7.9.2.1.101 Additional general requirements.....	11
201.7.9.2.2.101 Additional requirements for warnings and safety notices.....	11
201.7.9.2.5.101 Additional requirements for <i>ME equipment</i> description.....	12
201.7.9.2.9.101 Additional requirements for operating instructions.....	12
201.7.9.2.12 <i>Cleaning, disinfection, and sterilization</i>	12
201.7.9.2.14.101 Additional requirements for <i>accessories</i> , supplementary equipment, used material.....	13
201.7.9.3.1.101 * Additional general requirements.....	13
201.8 Protection against electrical <i>hazards</i> from <i>ME equipment</i>	14
201.9 Protection against <i>mechanical hazards</i> of <i>ME equipment</i> and <i>ME systems</i>	14
201.9.6.2.1.101 * Additional requirements for audible acoustic energy.....	14
201.10 Protection against unwanted and excessive radiation <i>hazards</i>	16
201.11 Protection against excessive temperatures and other <i>hazards</i>	16
201.11.1.2.2 <i>Applied parts</i> not intended to supply heat to a <i>patient</i>	16

201.11.6.6	* <i>Cleaning and disinfection of ME equipment or ME system</i>	17
201.11.7	<i>Biocompatibility of ME equipment and ME systems</i>	17
201.11.8	Additional requirements for interruption of the power supply/ <i>supply mains</i> to <i>ME equipment</i>	18
201.12	Accuracy of controls and instruments and protection against hazardous outputs	18
201.12.1	* Accuracy of controls and instruments	18
201.12.1.101	Stability of static <i>airway pressure accuracy</i> (long-term accuracy)	19
201.12.1.102	Stability of dynamic <i>airway pressure accuracy</i> (short-term accuracy)	20
201.12.1.102.1	<i>CPAP mode</i>	20
201.12.1.102.2	<i>Bi-level positive airway pressure mode, pressure stability</i>	22
201.12.1.103	* Maximum flowrate	24
201.12.4	Protection against hazardous output	25
201.12.4.101	Measurement of <i>airway pressure</i>	25
201.12.4.102	* <i>Maximum limited pressure protection device</i>	25
201.12.4.103	* CO ₂ rebreathing	26
201.13	Hazardous situations and fault conditions	26
201.14	Programmable electrical medical systems (PEMS)	26
201.15	Construction of ME equipment	26
201.15.101	Mode of operation	26
201.16	ME systems	27
201.17	Electromagnetic compatibility of ME equipment and ME systems	27
201.101	Breathing gas pathway connectors	27
201.101.1	General	27
201.101.2	Other named ports	27
201.101.2.1	<i>Patient-connection port</i>	27
201.101.2.2	<i>Gas output port</i>	27
201.101.2.3	<i>Flow-direction-sensitive components</i>	28
201.101.2.4	Ancillary port	28
201.101.2.5	Monitoring probe port	28
201.101.2.6	Oxygen inlet port	28
201.102	Requirements for the breathing gas pathway and accessories	28
201.102.1	* General	28
201.102.2	Labelling	29
201.102.3	Humidification	29
201.102.4	<i>Breathing system filter (BSF)</i>	29
201.103	Functional connection	29
201.103.1	General	29
201.103.2	* <i>Functional connection</i> to support remote supervision	30
201.104	Training	30
202	Electromagnetic disturbances — Requirements and tests	30
202.4.3.1	Configurations	30
202.5.2.2.1	Requirements applicable to all <i>ME equipment and ME systems</i>	30
202.8.1.101	Additional general requirements	30
206	Usability	31
211	Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	31

211.4.2.3.1 Continuous operating conditions	31
Annex C (informative) Guide to marking and labelling requirements for <i>ME equipment</i> and <i>ME systems</i>.....	33
Annex D (informative) Symbols on marking	38
Annex AA (informative) Particular guidance and rationale	39
Annex BB (informative) Data interface requirements.....	48
Annex CC (informative) Reference to the IMDRF <i>essential principles</i> and labelling guidances..	52
Annex DD (informative) Reference to the <i>essential principles</i>.....	56
Annex EE (informative) Reference to the general safety and performance requirements	59
Annex FF (informative) Terminology — alphabetized index of defined terms	63
Bibliography	66