

DIN EN ISO 80601-2-70:2021-06 (E)

Medical electrical equipment - Part 2-70: Particular requirements for the basic safety and essential performance of sleep apnoea breathing therapy equipment (ISO 80601-2-70:2020)

Contents	Page
European foreword	5
Foreword.....	6
Introduction.....	7
201.1 * Scope, object and related standards	9
201.1.1 Scope.....	9
201.1.2 Object	10
201.1.3 Collateral standards	10
201.1.4 Particular standards	10
201.2 Normative references	11
201.3 Terms and definitions.....	12
201.4 General requirements.....	15
201.4.3 <i>Essential performance</i>	15
201.4.3.101 * Additional requirements for <i>essential performance</i>	15
201.4.6 * <i>ME equipment</i> or <i>ME system</i> parts that contact the <i>patient</i>	15
201.5 General requirements for testing of <i>ME equipment</i>	16
201.5.101 Additional requirements for general requirements for testing of <i>ME equipment</i>	16
201.5.101.1 Gas flowrate and pressure specifications.....	16
201.5.101.2 * <i>Sleep apnoea breathing therapy equipment</i> testing errors	16
201.6 Classification of <i>ME equipment</i> and <i>ME systems</i>	16
201.7 <i>ME equipment</i> identification, marking and documents	16
201.7.1.2 * Legibility of markings	17
201.7.2.4.101 Additional requirements for <i>accessories</i>	17
201.7.2.13.101 Additional requirements for physiological effects.....	17
201.7.2.17.101 * Additional requirements for protective packaging	17
201.7.2.101 Additional requirements for marking on the outside of <i>ME equipment</i> or <i>ME equipment</i> parts.....	18
201.7.4.3 Units of measurement.....	18
201.7.9.1 * Additional general requirements.....	19
201.7.9.2 Instructions for use	19
201.7.9.2.1.101 Additional general requirements	19
201.7.9.2.2.101 Additional requirements for warnings and safety notices	19
201.7.9.2.5.101 Additional requirements for <i>ME equipment</i> description.....	20
201.7.9.2.9.101 Additional requirements for operating instructions.....	20
201.7.9.2.12 <i>Cleaning, disinfection, and sterilization</i>	21
201.7.9.2.14.101 Additional requirements for <i>accessories</i> , supplementary equipment, used material	21
201.7.9.3.1.101 * Additional general requirements.....	21
201.8 Protection against electrical <i>hazards</i> from <i>ME equipment</i>.....	22

201.9	Protection against <i>mechanical hazards</i> of <i>ME equipment</i> and <i>ME systems</i>	22
	201.9.6.2.1.101 * Additional requirements for audible acoustic energy	22
201.10	Protection against unwanted and excessive radiation hazards	24
201.11	Protection against excessive temperatures and other hazards	24
	201.11.1.2.2 <i>Applied parts</i> not intended to supply heat to a <i>patient</i>	24
	201.11.6.6 * <i>Cleaning</i> and <i>disinfection</i> of <i>ME equipment</i> or <i>ME system</i>	25
	201.11.7 <i>Biocompatibility</i> of <i>ME equipment</i> and <i>ME systems</i>	25
	201.11.8 Additional requirements for interruption of the power supply/ <i>supply mains</i> to <i>ME equipment</i>	26
201.12	Accuracy of controls and instruments and protection against hazardous outputs	27
	201.12.1 * Accuracy of controls and instruments	27
	201.12.1.101 Stability of static <i>airway pressure accuracy</i> (long-term accuracy)	27
	201.12.1.102 Stability of dynamic <i>airway pressure accuracy</i> (short-term accuracy)	28
	201.12.1.102.1 <i>CPAP</i> mode	28
	201.12.1.102.2 <i>Bi-level positive airway pressure</i> mode, pressure stability	30
	201.12.1.103 * Maximum flowrate	32
	201.12.4 Protection against hazardous output.....	33
	201.12.4.101 Measurement of <i>airway pressure</i>	33
	201.12.4.102 * <i>Maximum limited pressure protection device</i>	33
	201.12.4.103 * CO ₂ rebreathing	34
201.13	Hazardous situations and fault conditions	34
201.14	Programmable electrical medical systems (PEMS)	34
201.15	Construction of <i>ME equipment</i>	34
	201.15.101 Mode of operation	34
201.16	<i>ME systems</i>	35
201.17	Electromagnetic compatibility of <i>ME equipment</i> and <i>ME systems</i>	35
201.101	<i>Breathing gas pathway connectors</i>	35
	201.101.1 General	35
	201.101.2 Other named ports	35
	201.101.2.1 <i>Patient-connection port</i>	35
	201.101.2.2 <i>Gas output port</i>	35
	201.101.2.3 <i>Flow-direction-sensitive components</i>	36
	201.101.2.4 Ancillary port.....	36
	201.101.2.5 Monitoring probe port.....	36
	201.101.2.6 Oxygen inlet port	36
201.102	Requirements for the <i>breathing gas pathway</i> and <i>accessories</i>	36
	201.102.1 * General	36
	201.102.2 Labelling	37
	201.102.3 Humidification.....	37
	201.102.4 <i>Breathing system filter (BSF)</i>	37
201.103	<i>Functional connection</i>	37
	201.103.1 General	37
	201.103.2 * <i>Functional connection</i> to support remote supervision.....	38
201.104	Training	38
202	Electromagnetic disturbances — Requirements and tests	38
	202.4.3.1 Configurations.....	38
	202.5.2.2.1 Requirements applicable to all <i>ME equipment</i> and <i>ME systems</i>	38
	202.8.1.101 Additional general requirements.....	38
206	Usability	39

211	Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.....	39
	211.4.2.3.1 Continuous operating conditions	39
Annex C (informative)	Guide to marking and labelling requirements for <i>ME equipment</i> and <i>ME systems</i>.....	40
Annex D (informative)	Symbols on marking	45
Annex AA (informative)	Particular guidance and rationale	46
Annex BB (informative)	Data interface requirements.....	55
Annex CC (informative)	Reference to the IMDRF <i>essential principles</i> and labelling guidances..	59
Annex DD (informative)	Reference to the <i>essential principles</i>.....	63
Annex EE (informative)	Reference to the general safety and performance requirements	66
Annex FF (informative)	Terminology — alphabetized index of defined terms	70
Bibliography	73