

ISO 80601-2-70:2025-11 (E)

Medical electrical equipment - Part 2-70: Particular requirements for 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.....	3
201.2 Normative references.....	4
201.3 Terms and definitions.....	5
201.4 General requirements.....	20
201.4.3 <i>Essential performance</i>	20
201.4.3.101 Additional requirements for <i>essential performance</i>	20
201.4.6 <i>ME equipment</i> or <i>ME system</i> parts that contact the <i>patient</i>	21
201.5 General requirements for testing of <i>ME equipment</i>	21
201.5.101 Additional requirements for general requirements for testing of <i>ME equipment</i>	21
201.5.101.1 Gas flowrate specifications.....	21
201.5.101.2 <i>Sleep apnoea breathing therapy equipment</i> testing errors	21
201.6 Classification of <i>ME equipment</i> and <i>ME systems</i>.....	22
201.7 <i>ME equipment</i> identification, marking and documents.....	22
201.7.1.2 Legibility of <i>markings</i>	22
201.7.2.4.101 Additional requirements for <i>accessories</i>	22
201.7.2.101 Additional requirements for <i>marking</i> on the outside of <i>ME equipment</i> or <i>ME equipment</i> parts.....	23
201.7.4.3 Units of measurement	23
201.7.9.2 <i>Instructions for use</i>	23
201.7.9.2.1.101 Additional general requirements.....	24
201.7.9.2.2.101 Additional requirements for warnings and safety notices	24
201.7.9.2.5.101 Additional requirements for <i>ME equipment</i> description.....	25
201.7.9.2.9.101 Additional requirements for operating instructions.....	25
201.7.9.2.12 <i>Cleaning, disinfection, and sterilization</i>	25
201.7.9.2.13.101 Additional requirements for maintenance	25
201.7.9.2.14.101 Additional requirements for <i>accessories</i> , supplementary equipment, used material.....	26
201.7.9.3.1.101 Additional general requirements.....	26
201.8 Protection against electrical <i>hazards</i> from <i>ME equipment</i>.....	27
201.9 Protection against <i>mechanical hazards</i> of <i>ME equipment</i> and <i>ME systems</i>	27
201.9.6.2.1.101 Additional requirements for audible acoustic energy	28
201.10 Protection against unwanted and excessive radiation <i>hazards</i>	30
201.11 Protection against excessive temperatures and other <i>hazards</i>.....	30
201.11.1.2.2 <i>Applied parts</i> not intended to supply heat to a <i>patient</i>	30
201.11.6.6 <i>Cleaning</i> and <i>disinfection</i> of <i>ME equipment</i> or <i>ME system</i>	30

201.11.7	<i>Biocompatibility of ME equipment and ME systems</i>	31
201.11.8	Additional requirements for interruption of the power supply/supply mains to <i>ME equipment</i>	32
201.12	Accuracy of controls and instruments and protection against hazardous outputs	32
201.12.1	Accuracy of controls and instruments	32
201.12.1.101	Stability of static <i>airway pressure accuracy</i> (long-term accuracy).....	32
201.12.1.102	Stability of dynamic <i>airway pressure accuracy</i> (short-term accuracy)	34
201.12.1.102.1	<i>CPAP mode</i>	34
201.12.1.102.2	<i>Bi-level positive airway pressure mode, pressure stability</i>	35
201.12.1.103	Maximum flowrate.....	38
201.12.4	Protection against hazardous output.....	41
201.12.4.101	Measurement of <i>airway pressure</i>	41
201.12.4.102	<i>Maximum limited pressure protection device</i>	41
201.12.4.103	CO ₂ rebreathing.....	42
201.13	Hazardous situations and fault conditions	42
201.14	Programmable electrical medical systems (PEMS)	42
201.15	Construction of ME equipment	43
201.15.101	Mode of operation.....	43
201.16	ME systems	43
201.17	Electromagnetic compatibility of ME equipment and ME systems	43
201.101	<i>Breathing gas pathway connectors</i>	44
201.101.1	General.....	44
201.101.2	Other named ports	44
201.101.2.1	<i>Patient-connection port</i>	44
201.101.2.2	<i>Gas output port</i>	44
201.101.2.3	<i>Flow-direction-sensitive components</i>	45
201.101.2.4	<i>Accessory access connection port</i>	45
201.101.2.5	<i>Oxygen inlet connector</i>	45
201.101.2.5.1	Low pressure.....	45
201.101.2.5.2	High pressure.....	46
201.102	Requirements for the <i>breathing gas pathway and accessories</i>	46
201.102.1	General.....	46
201.102.2	Labelling.....	46
201.102.3	Humidification	47
201.102.4	<i>Breathing system filter (BSF)</i>	47
201.103	<i>Functional connection</i>	47
201.103.1	General.....	47
201.103.2	<i>Functional connection</i> to support remote supervision	47
202	Electromagnetic disturbances — Requirements and tests	48
202.4.3.1	Configurations	48
202.5.2.2.1	Requirements applicable to all ME equipment and ME systems	48
202.8.1.101	Additional general requirements	48
206	Usability	48

211	Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	49
211.4.2.3.1	Continuous operating conditions.....	49
Annex C (informative)	Guide to <i>marking</i> and labelling requirements for <i>ME equipment</i> and <i>ME systems</i>	50
201.C.1	<i>Marking on the outside of ME equipment, ME systems or their parts.....</i>	50
201.C.2	<i>Accompanying documents, general</i>	50
201.C.3	<i>Accompanying documents, instructions for use</i>	51
201.C.4	<i>Accompanying documents, technical description.....</i>	53
Annex AA (informative)	Particular guidance and rationale.....	55
AA.1	General guidance	55
AA.2	Rationale for particular clauses and subclauses.....	56
AA.2.1	— 201.1.1 — Scope.....	56
AA.2.2	— 201.3.207 — <i>Auto CPAP</i>	57
AA.2.3	— 201.3.208 — <i>Automatic start/stop function</i>	58
AA.2.4	— 201.3.254 — <i>Ramp mode</i>	58
AA.2.5	— 201.4.3.101 — Additional requirements for <i>essential performance</i>	58
AA.2.6	— 201.4.6 — <i>ME equipment</i> or <i>ME system</i> parts that contact the <i>patient</i>	59
AA.2.7	— 201.5.101.2 — <i>Sleep apnoea breathing therapy equipment</i> testing errors.....	59
AA.2.8	— 201.7.1.2 — Legibility of <i>markings</i>	59
AA.2.9	— 201.7.9.3.1.101 — Additional general requirements	59
AA.2.10	— 201.9.6.2.1.101 — Additional requirements for audible acoustic energy	60
AA.2.11	— 201.11.6 — <i>Cleaning</i> and <i>disinfection</i> of <i>ME equipment</i> or <i>ME system</i>	60
AA.2.12	— 201.12.1 — Accuracy of controls and instruments	63
AA.2.13	— 201.12.1.102.2 — <i>Bi-level positive airway pressure</i> mode, pressure stability.....	63
AA.2.14	— 201.12.1.103 — Maximum flowrate.....	63
— c) 2)	63	
AA.2.15	— 201.12.4.102 — <i>Maximum limited pressure protection device</i>	63
Annex BB (informative)	Data interface requirements	65
BB.1	Background and purpose.....	65
BB.2	Data definition	66
Annex CC (informative)	Reference to the IMDRF <i>essential principles</i> and labelling guidances.....	69
Annex DD (informative)	Terminology — alphabetized index of defined terms	73
Bibliography	77