DIN EN ISO 80601-2-70:2026-10 (E)

Medical electrical equipment - Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment (ISO 80601-2-70:2025)

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 *Essential performance* 20
201.4.3.101 Additional requirements for *essential performance* 20
201.4.6 *ME equipment* or *ME system* parts that contact the *patient* 21

201.5 General requirements for testing of *ME equipment* 21
201.5.101 Additional requirements for general requirements for testing of *ME equipment* 21
201.5.101.1 Gas flowrate specifications 21
201.5.101.2 *Sleep apnoea breathing therapy equipment* testing errors 21

201.6 Classification of *ME equipment* and *ME systems* 22

201.7 *ME equipment* identification, *marking* and documents 22
201.7.1.2 Legibility of *markings* 22
201.7.2.4.101 Additional requirements for *accessories* 22
201.7.2.101 Additional requirements for *marking* on the outside of *ME equipment* or *ME equipment* parts 23
201.7.4.3 Units of measurement 23
201.7.9.2 *Instructions for use* 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 *ME equipment* description 25
201.7.9.2.9.101 Additional requirements for operating instructions 25
201.7.9.2.12 *Cleaning*, *disinfection*, and *sterilization* 25
201.7.9.2.13.101 Additional requirements for maintenance 25
201.7.9.2.14.101 Additional requirements for *accessories*, supplementary equipment, used material 26
201.7.9.3.1.101 Additional general requirements 26

201.8 Protection against electrical *hazards* from *ME equipment* 27

201.9 Protection against *mechanical hazards* of *ME equipment* and *ME systems* 27
201.9.6.2.1.101 Additional requirements for audible acoustic energy 28

201.10 Protection against unwanted and excessive radiation *hazards* 30

201.11 Protection against excessive temperatures and other *hazards* 30
201.11.1.2.2 *Applied parts* not intended to supply heat to a *patient* 30
201.11.6.6 *Cleaning* and *disinfection* of *ME equipment* or *ME system* 30

201.11.7 *Biocompatibility* of *ME equipment* and *ME systems* 31
201.11.8 Additional requirements for interruption of the power supply/*supply mains* to *ME equipment* 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 *airway pressure accuracy* (long-term accuracy) 32
201.12.1.102 Stability of dynamic *airway pressure accuracy* (short-term accuracy) 34
201.12.1.102.1 *CPAP* mode 34
201.12.1.102.2 *Bi-level positive airway pressure* mode, pressure stability 35
201.12.1.103 Maximum flowrate 38
201.12.4 Protection against hazardous output 41
201.12.4.101 Measurement of *airway pressure* 41
201.12.4.102 *Maximum limited pressure protection device* 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 *Breathing gas pathway connectors* 44
201.101.1 General 44
201.101.2 Other named ports 44
201.101.2.1 *Patient-connection port* 44
201.101.2.2 *Gas output port* 44
201.101.2.3 *Flow-direction-sensitive components* 45
201.101.2.4 *Accessory* access connection port 45
201.101.2.5 Oxygen *inlet connector* 45
201.101.2.5.1 Low pressure 45
201.101.2.5.2 High pressure 46

201.102 Requirements for the *breathing gas pathway* and *accessories* 46
201.102.1 General 46
201.102.2 Labelling 46
201.102.3 Humidification 47
201.102.4 *Breathing system filter* (*BSF*) 47

201.103 *Functional connection* 47
201.103.1 General 47
201.103.2 *Functional connection* 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 *marking* and labelling requirements for *ME equipment* and *ME systems* 50
201.C.1 *Marking* on the outside of *ME equipment*, *ME systems* or their parts 50
201.C.2 *Accompanying documents*, general 50
201.C.3 *Accompanying documents*, *instructions for use* 51
201.C.4 *Accompanying documents*, *technical description* 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 — *Auto CPAP* 57
AA.2.3 — 201.3.208 — *Automatic start/stop function* 58
AA.2.4 — 201.3.254 — *Ramp mode* 58
AA.2.5 — 201.4.3.101 — Additional requirements for *essential performance* 58
AA.2.6 — 201.4.6 — *ME equipment* or *ME system* parts that contact the *patient* 59
AA.2.7 — 201.5.101.2 — *Sleep apnoea breathing therapy equipment* testing errors 59
AA.2.8 — 201.7.1.2 — Legibility of *markings* 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 — *Cleaning* and *disinfection* of *ME equipment* or *ME system* 60
AA.2.12 — 201.12.1 — Accuracy of controls and instruments 63
AA.2.13 — 201.12.1.102.2 — *Bi-level positive airway pressure* mode, pressure stability 63
AA.2.14 — 201.12.1.103 — Maximum flowrate 63
AA.2.15 — 201.12.4.102 — *Maximum limited pressure protection device* 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 *essential principles* and labelling guidances 69

Annex DD (informative) Terminology — alphabetized index of defined terms 73

Bibliography 77