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 80601-2-70:202 0)

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 *Essential performance* 15
201.4.3.101 * Additional requirements for *essential performance* 15
201.4.6 * *ME equipment* or *ME system* parts that contact the *patient* 15

201.5 General requirements for testing of *ME equipment* **16**
201.5.101 Additional requirements for general requirements for testing of *ME equipment* 16
201.5.101.1 Gas flowrate and pressure specifications 16
201.5.101.2 * *Sleep apnoea breathing therapy equipment* testing errors 16

201.6 Classification of *ME equipment* and *ME systems* **16**

201.7 *ME equipment* identification, marking and documents **16**
201.7.1.2 * Legibility of markings 17
201.7.2.4.101 Additional requirements for *accessories* 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 *ME equipment* or *ME equipment* 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 *ME equipment* description 20
201.7.9.2.9.101 Additional requirements for operating instructions 20
201.7.9.2.12 *Cleaning*, *disinfection*, and *sterilization* 21
201.7.9.2.14.101 Additional requirements for *accessories*, supplementary equipment, used material 21
201.7.9.3.1.101 * Additional general requirements 21

201.8 Protection against electrical *hazards* from *ME equipment* **22**

201.9 Protection against *mechanical hazards* of *ME equipment* and *ME systems* **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 *Applied parts* not intended to supply heat to a *patient* 24
201.11.6.6 * *Cleaning* and *disinfection* of *ME equipment* or *ME system* 25
201.11.7 *Biocompatibility* of *ME equipment* and *ME systems* 25
201.11.8 Additional requirements for interruption of the power supply/*supply mains* to *ME equipment* 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 *airway pressure accuracy* (long-term accuracy) 27
201.12.1.102 Stability of dynamic *airway pressure accuracy* (short-term accuracy) 28
201.12.1.102.1 *CPAP* mode 28
201.12.1.102.2 *Bi-level positive airway pressure* 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 *airway pressure* 33
201.12.4.102 * *Maximum limited pressure protection device* 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 *ME equipment* **34**
201.15.101 Mode of operation 34

201.16 *ME systems* **35**

201.17 Electromagnetic compatibility of *ME equipment* and *ME systems* **35**

201.101 *Breathing gas pathway* connectors **35**
201.101.1 General 35
201.101.2 Other named ports 35
201.101.2.1 *Patient-connection port* 35
201.101.2.2 *Gas output port* 35
201.101.2.3 *Flow-direction-sensitive components* 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 *breathing gas pathway* and *accessories* **36**
201.102.1 * General 36
201.102.2 Labelling 37
201.102.3 Humidification 37
201.102.4 *Breathing system filter (BSF)* 37

201.103 *Functional connection* **37**
201.103.1 General 37
201.103.2 * *Functional connection* 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 *ME equipment* and *ME systems* 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 *ME equipment* and *ME systems* **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 *essential principles* and labelling guidances **59**
Annex DD (informative) Reference to the *essential principles* **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**