ISO 18778:2022-06 (E)

Respiratory equipment - Particular requirements for basic safety and essential performance of infant cardiorespiratory monitors

Contents

Page

Foreword ... **vi**

Introduction ... **viii**

1 Scope ... **1**

2 Normative references ... **1**

3 Terms and definitions ... **2**

4 General requirements ... **6**
4.1 General ... 6
4.2 *Essential performance* ... 6
4.3 *ME equipment* or *ME system* parts that contact the *patient* ... 6
4.4 *Single fault condition* for *ME equipment* ... 6

5 General requirements for testing of *ME equipment* ... **6**
5.1 General ... 6
5.2 *Infant cardiorespiratory monitor* testing errors ... 6

6 Classification of *ME equipment* and *ME systems* ... **7**
6.1 General ... 7
6.2 Additional requirements for classification of *ME equipment* and *ME systems* ... 7

7 *ME equipment* identification, *marking* and documents ... **7**
7.1 General ... 7
7.2 *Information to be supplied by the manufacturer* ... 7
7.3 Additional requirements for *accessories* ... 7
7.4 Additional requirements for *marking* on the outside of *ME equipment* or *ME equipment* parts ... 8
7.5 General *instructions for use* ... 8
7.6 Additional requirements for warnings and safety notices ... 8
7.7 Additional requirements for start-up *procedure* ... 9
7.8 Additional requirements for operating instructions ... 9
7.8.1 General ... 9
7.8.2 *Lay operator* operating instructions ... 9
7.8.3 *Healthcare professional operator* operating instructions ... 10
7.9 *Cleaning*, *disinfection*, and *sterilization* ... 10
7.10 Additional requirements for maintenance ... 10
7.11 Additional requirements for *accessories*, supplementary equipment, used material ... 10
7.12 Additional requirements for the *technical description* ... 10

8 Protection against electrical *hazards* from *ME equipment* ... **11**

9 Protection against *mechanical hazards* of *ME equipment* and *ME systems* ... **11**
9.1 General ... 11
9.2 Additional requirements for instability from unwanted lateral movement ... 11
9.3 Grips and other handling devices ... 11

10 Protection against unwanted and excessive radiation *hazards* ... **11**

11 Protection against excessive temperatures and other *hazards* ... **11**
11.1 General ... 11
11.2 *Cleaning* and *disinfection* of *ME equipment* or *ME system* ... 12
11.3 *Sterilization* of *ME equipment* or *ME system* ... 12
11.4 *Biocompatibility* of *ME equipment* and *ME systems* ... 12
11.5 Interruption of the power supply / *supply mains* to *ME equipment* ... 13
11.5.1 General ... 13
11.5.2 Power sources ... 13
11.5.3 Alternative power supply/*supply mains* ... 14

12 Accuracy of controls and instruments and protection against hazardous outputs ... **14**

12.1 General 14
12.2 Accuracy of controls and instruments 14
12.3 Accuracy of controls and instruments 15
12.3.1 General 15
12.3.2 Cardiorespiratory monitoring 15
12.3.3 Direct monitoring - respiration 15
12.3.4 Indirect monitoring – heart rate 15
12.3.5 Indirect monitoring from pulse oximetry 15
12.3.6 Apnoeic *patient alarm condition* 16
12.3.7 Sensor fault 17
12.3.8 Clinical performance evaluation 17
12.4 *Usability* of *ME equipment* 17

13 *Hazardous situations* and fault conditions for *ME equipment* **18**

14 *Programmable electrical medical systems (PEMS)* **18**

15 Construction of *ME equipment* **18**
15.1 General 18
15.2 Mode of operation 18
15.3 Pre-use check 18

16 *ME systems* **19**

17 Electromagnetic compatibility of *ME equipment* and *ME systems* **19**

18 Requirements for the *accessories* **19**
18.1 General 19
18.2 Labelling 19

19 Training **19**

20 *Functional connection* **19**
20.1 General 19
20.2 Connection to an electronic health record 19
20.3 Connection to a *distributed alarm system* 19

21 Electromagnetic disturbances – Requirements and tests **20**
21.1 General 20
21.2 Compliance criteria 20
21.3 Requirements applicable to all *ME equipment* and *ME systems* 20
21.4 Additional general requirements 20

22 *Usability* **20**
22.1 General 20
22.2 *Primary operating functions* 21

23 General requirements, tests and guidance for *alarm systems* in *medical electrical equipment* and *medical electrical systems* **21**
23.1 General 21
23.2 Volume and characteristics of auditory *alarm signals* and *information signals* 21
23.3 Additional requirements for termination of *alarm signal* inactivation 21
23.4 Additional requirements for *alarm system* logging 22

24 Requirements for *medical electrical equipment* and *medical electrical systems* used in the *home healthcare environment* **22**

Annex A (informative) **General guidance and rationale** **23**

Annex B (informative) **Sequence of testing** **28**

Annex C (informative) **Guide to *marking* and labelling requirements for *ME equipment* and *ME systems*** **29**

Annex D (informative) ***Symbols* on *marking*** **32**

Annex E (informative) **Examples of the connection of the measuring device (MD) for measurement of the *patient leakage current* and *patient auxiliary current*** **33**
Annex F (informative) **Suitable measuring supply circuits** **34**
Annex G (informative) **Protection against *hazards* of ignition of flammable anaesthetic mixtures** **35**
Annex H (informative) ***PEMS* structure, *PEMS development life-cycle* and documentation** **36**
Annex I (informative) ***ME systems* aspects** **37**
Annex J (informative) **Survey of insulation paths** **38**
Annex K (informative) **Simplified *patient leakage current* diagrams** **39**
Annex L (informative) **Insulated winding wires for use without interleaved insulation** **40**
Annex M (informative) **Reduction of pollution degrees** **41**
Annex N (informative) **Data interface requirements** **42**
Annex O (informative) **Considerations for a clinical performance study** **45**
Annex P (informative) **Reference to the IMDRF *essential principles* and labelling guidances** **47**
Annex Q (informative) **Reference to the *essential principles*** **49**
Annex R (informative) **Reference to the general safety and performance requirements** **51**
Bibliography **54**
Terminology — Alphabetized index of defined terms **55**