

# 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
<b>1 Scope.....</b>	<b>1</b>
<b>2 Normative references.....</b>	<b>1</b>
<b>3 Terms and definitions.....</b>	<b>2</b>
<b>4 General requirements.....</b>	<b>6</b>
4.1 General.....	6
4.2 <i>Essential performance</i> .....	6
4.3 <i>ME equipment or ME system parts that contact the patient</i> .....	6
4.4 <i>Single fault condition for ME equipment</i> .....	6
<b>5 General requirements for testing of ME equipment.....</b>	<b>6</b>
5.1 General.....	6
5.2 <i>Infant cardiorespiratory monitor testing errors</i> .....	6
<b>6 Classification of ME equipment and ME systems.....</b>	<b>7</b>
6.1 General.....	7
6.2 Additional requirements for classification of <i>ME equipment</i> and <i>ME systems</i> .....	7
<b>7 ME equipment identification, marking and documents.....</b>	<b>7</b>
7.1 General.....	7
7.2 <i>Information to be supplied by the manufacturer</i> .....	7
7.3 Additional requirements for <i>accessories</i> .....	7
7.4 Additional requirements for <i>marking</i> on the outside of <i>ME equipment</i> or <i>ME equipment parts</i> .....	8
7.5 <i>General instructions for use</i> .....	8
7.6 Additional requirements for warnings and safety notices.....	8
7.7 Additional requirements for <i>start-up procedure</i> .....	9
7.8 Additional requirements for operating instructions.....	9
7.8.1 General.....	9
7.8.2 <i>Lay operator</i> operating instructions.....	9
7.8.3 <i>Healthcare professional operator</i> operating instructions.....	10
7.9 <i>Cleaning, disinfection, and sterilization</i> .....	10
7.10 Additional requirements for maintenance.....	10
7.11 Additional requirements for <i>accessories</i> , supplementary equipment, used material.....	10
7.12 Additional requirements for the <i>technical description</i> .....	10
<b>8 Protection against electrical hazards from ME equipment.....</b>	<b>11</b>
<b>9 Protection against mechanical hazards of ME equipment and ME systems.....</b>	<b>11</b>
9.1 General.....	11
9.2 Additional requirements for instability from unwanted lateral movement.....	11
9.3 Grips and other handling devices.....	11
<b>10 Protection against unwanted and excessive radiation hazards.....</b>	<b>11</b>
<b>11 Protection against excessive temperatures and other hazards.....</b>	<b>11</b>
11.1 General.....	11
11.2 <i>Cleaning and disinfection of ME equipment or ME system</i> .....	12
11.3 <i>Sterilization of ME equipment or ME system</i> .....	12
11.4 <i>Biocompatibility of ME equipment and ME systems</i> .....	12
11.5 Interruption of the power supply / <i>supply mains to ME equipment</i> .....	13
11.5.1 General.....	13
11.5.2 Power sources.....	13
11.5.3 Alternative power supply/ <i>supply mains</i> .....	14
<b>12 Accuracy of controls and instruments and protection against hazardous outputs.....</b>	<b>14</b>

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 <i>patient alarm condition</i> .....	16
	12.3.7 Sensor fault.....	17
	12.3.8 Clinical performance evaluation.....	17
12.4	<i>Usability of ME equipment</i> .....	17
<b>13</b>	<b><i>Hazardous situations and fault conditions for ME equipment</i></b> .....	<b>18</b>
<b>14</b>	<b><i>Programmable electrical medical systems (PEMS)</i></b> .....	<b>18</b>
<b>15</b>	<b><i>Construction of ME equipment</i></b> .....	<b>18</b>
	15.1 General.....	18
	15.2 Mode of operation.....	18
	15.3 Pre-use check.....	18
<b>16</b>	<b><i>ME systems</i></b> .....	<b>19</b>
<b>17</b>	<b><i>Electromagnetic compatibility of ME equipment and ME systems</i></b> .....	<b>19</b>
<b>18</b>	<b><i>Requirements for the accessories</i></b> .....	<b>19</b>
	18.1 General.....	19
	18.2 Labelling.....	19
<b>19</b>	<b><i>Training</i></b> .....	<b>19</b>
<b>20</b>	<b><i>Functional connection</i></b> .....	<b>19</b>
	20.1 General.....	19
	20.2 Connection to an electronic health record.....	19
	20.3 Connection to a <i>distributed alarm system</i> .....	19
<b>21</b>	<b><i>Electromagnetic disturbances – Requirements and tests</i></b> .....	<b>20</b>
	21.1 General.....	20
	21.2 Compliance criteria.....	20
	21.3 Requirements applicable to all <i>ME equipment</i> and <i>ME systems</i> .....	20
	21.4 Additional general requirements.....	20
<b>22</b>	<b><i>Usability</i></b> .....	<b>20</b>
	22.1 General.....	20
	22.2 <i>Primary operating functions</i> .....	21
<b>23</b>	<b><i>General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems</i></b> .....	<b>21</b>
	23.1 General.....	21
	23.2 Volume and characteristics of auditory <i>alarm signals</i> and <i>information signals</i> .....	21
	23.3 Additional requirements for termination of <i>alarm signal</i> inactivation.....	21
	23.4 Additional requirements for <i>alarm system</i> logging.....	22
<b>24</b>	<b><i>Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment</i></b> .....	<b>22</b>
<b>Annex A</b>	<b>(informative) <i>General guidance and rationale</i></b> .....	<b>23</b>
<b>Annex B</b>	<b>(informative) <i>Sequence of testing</i></b> .....	<b>28</b>
<b>Annex C</b>	<b>(informative) <i>Guide to marking and labelling requirements for ME equipment and ME systems</i></b> .....	<b>29</b>
<b>Annex D</b>	<b>(informative) <i>Symbols on marking</i></b> .....	<b>32</b>

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