

# ISO 80601-2-85:2021-03 (E)

## Medical electrical equipment - Part 2-85: Particular requirements for the basic safety and essential performance of cerebral tissue oximeter 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.....	10
201.4.3.101 * Additional requirements for <i>essential performance</i> .....	11
201.4.102 Additional requirements for acceptance criteria.....	11
201.4.103 Additional requirements for <i>cerebral tissue oximeter equipment, parts and accessories</i> .....	11
201.5 General requirements for testing of <i>ME equipment</i> .....	12
201.6 Classification of <i>ME equipment</i> and <i>ME systems</i> .....	12
201.7 <i>ME equipment</i> identification, marking and documents.....	12
201.7.1.101 <i>Information to be supplied by the manufacturer</i> .....	12
201.7.2.3 Consult <i>accompanying documents</i> .....	12
201.7.2.9.101 IP classification.....	12
201.7.2.101 Additional requirements for marking on the outside of <i>ME equipment</i> parts.....	13
201.7.4.3 Units of measurement.....	13
201.7.9.2 Instructions for use.....	13
201.7.9.2.1.101 Additional general requirements.....	13
201.7.9.2.2.101 Additional requirements for warnings and safety notices.....	15
201.7.9.2.9.101 Additional requirements for operating instructions.....	15
201.7.9.2.14.101 Additional requirements for <i>accessories, supplementary equipment, used material</i> .....	15
201.7.9.3.1.101 * Additional general requirements.....	16
201.8 Protection against electrical <i>hazards</i> from <i>ME equipment</i> .....	16
201.8.3.101 Additional requirements for classification of <i>applied parts</i> .....	16
201.8.5.5.1.101 Defibrillation protection.....	16
201.8.7.4.7.101 Additional requirements for measurement of the <i>patient leakage current</i> .....	16
201.9 Protection against mechanical <i>hazards</i> of <i>ME equipment</i> and <i>ME systems</i> .....	17
201.10 Protection against unwanted and excessive radiation <i>hazards</i> .....	17
201.10.4 Lasers.....	17
201.11 Protection against excessive temperatures and other <i>hazards</i> .....	17
201.11.1.2.2 <i>Applied parts</i> not intended to supply heat to a <i>patient</i> .....	17
201.11.6.5.101 * Additional requirements for ingress of water or particulate matter into the <i>ME equipment</i> or <i>ME system</i> .....	18
201.11.6.7 <i>Sterilization</i> of <i>ME equipment</i> or <i>ME system</i> .....	18
201.11.8.101 Additional requirements for interruption of the power supply/ <i>supply mains</i> to <i>ME equipment</i> .....	18

201.11.8.101.1	<i>Technical alarm condition for power supply failure</i>	18
201.11.8.101.2	Settings and data storage following short interruptions or automatic switchover	19
201.11.8.101.3	Operation following long interruptions	19
201.12	Accuracy of controls and instruments and protection against hazardous outputs	19
201.12.1.101	* <i>StO<sub>2</sub> accuracy of cerebral tissue oximeter equipment</i>	19
201.12.1.101.1	* Specification	19
201.12.1.101.2	* Data collection for determination of <i>StO<sub>2</sub> accuracy</i>	21
201.12.1.101.3	* Data analysis for determination of <i>StO<sub>2</sub> accuracy</i>	22
201.12.1.101.4	Characteristics of the study used for determination of <i>StO<sub>2</sub> accuracy</i>	23
201.12.4	Protection against hazardous output	23
201.12.4.101	* <i>Data update period</i>	23
201.12.4.102	* Signal inadequacy	23
201.13	<i>Hazardous situations and fault conditions for ME equipment</i>	24
201.13.101	Detection of <i>probe faults</i> and <i>probe cable extender faults</i>	24
201.14	<i>Programmable electrical medical systems (PEMS)</i>	24
201.15	Construction of <i>ME equipment</i>	24
201.15.3.5.101	* Additional requirements for rough handling	25
201.15.3.5.101.1	* Shock and vibration (robustness)	25
201.15.3.5.101.2	* Shock and vibration for a <i>transit-operable cerebral tissue oximeter</i> during operation	26
201.15.101	Mode of operation	27
201.16	<i>ME systems</i>	27
201.17	Electromagnetic compatibility of <i>ME equipment</i> and <i>ME systems</i>	27
201.101	* <i>Cerebral tissue oximeter probes and probe cable extenders</i>	27
201.101.1	General	27
201.101.2	Labelling	28
201.102	<i>Functional connection</i>	28
201.102.1	General	28
201.102.2	* Connection to an electronic health record or <i>integrated clinical environment</i>	28
201.102.3	Connection to a <i>distributed alarm system</i>	28
202	Electromagnetic disturbances — Requirements and tests	29
202.4.3.1	Configurations	29
202.5.2.2.1	Requirements applicable to all <i>ME equipment</i> and <i>ME systems</i>	29
202.8.1.101	Additional general requirements	29
202.8.2	<i>Patient</i> physiological simulation	29
206	Usability	30
208	General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	30
208.6.1.2.101	* Additional requirements for <i>alarm condition</i> priority	30
208.6.5.4.101	* Additional requirements for <i>default alarm preset</i>	31
208.6.8.5.101	Additional requirements for <i>alarm signal</i> inactivation states, indication and access	31
211	Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	31
212	Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment	31

<b>Annex C (informative) Guide to marking and labelling requirements for <i>ME</i> equipment and <i>ME</i> systems.....</b>	<b>32</b>
<b>Annex D (informative) Symbols on marking.....</b>	<b>36</b>
<b>Annex AA (informative) Particular guidance and rationale .....</b>	<b>37</b>
<b>Annex BB (informative) Skin temperature at the <i>cerebral tissue oximeter probe</i> .....</b>	<b>48</b>
<b>Annex CC (informative) Determination of <i>accuracy</i> .....</b>	<b>50</b>
<b>Annex DD (informative) Characteristics of a <i>tissue haemoglobin phantom</i> for the verification of the <i>accuracy</i> of <i>cerebral tissue oximeter equipment</i>.....</b>	<b>56</b>
<b>Annex EE (informative) Guideline for evaluating and documenting <i>StO<sub>2</sub> accuracy</i> in human subjects.....</b>	<b>66</b>
<b>Annex FF (informative) <i>Functional testers</i> for <i>cerebral tissue oximeter equipment</i>.....</b>	<b>72</b>
<b>Annex GG (informative) Concepts of <i>ME equipment</i> response time .....</b>	<b>75</b>
<b>Annex HH (normative) Data interface requirements.....</b>	<b>80</b>
<b>Annex II (informative) Comparison of methods of performance evaluation.....</b>	<b>84</b>
<b>Annex JJ (informative) Reference to the <i>IMDRF essential principles</i> and labelling guidances .....</b>	<b>89</b>
<b>Annex KK (informative) Reference to the <i>essential principles</i>.....</b>	<b>92</b>
<b>Annex LL (informative) Reference to the general safety and performance requirements.....</b>	<b>95</b>
<b>Annex MM (informative) Terminology — alphabetized index of defined terms.....</b>	<b>98</b>
<b>Bibliography .....</b>	<b>102</b>