

ISO 80601-2-61:2026-04 (E)

Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

Contents	Page
Foreword.....	v
Introduction.....	vii
201.1 Scope, object, and related standards.....	1
201.2 Normative references.....	3
201.3 Terms and definitions.....	3
201.4 General requirements.....	17
201.5 General requirements for testing of <i>ME equipment</i>	19
201.6 Classification of <i>ME equipment</i> and <i>ME systems</i>	19
201.7 <i>ME equipment</i> identification, <i>marking</i> and documents.....	19
201.8 Protection against electrical <i>hazards</i> from <i>ME equipment</i>	24
201.9 Protection against mechanical <i>hazards</i> of <i>ME equipment</i> and <i>ME systems</i>	24
201.10 Protection against unwanted and excessive radiation <i>hazards</i>	24
201.11 Protection against excessive temperatures and other <i>hazards</i>	24
201.12 <i>Accuracy</i> of controls and instruments and protection against hazardous outputs.....	26
201.13 <i>Hazardous situations</i> and fault conditions for <i>ME equipment</i>	41
201.14 <i>Programmable electrical medical systems (PEMS)</i>	42
201.15 Construction of <i>ME equipment</i>	43
201.16 <i>ME systems</i>	44
201.17 Electromagnetic compatibility of <i>ME equipment</i> and <i>ME systems</i>	44
201.101 <i>Pulse oximeter probes</i> and <i>probe cable extenders</i>	44
201.102 Saturation pulse <i>information signal</i>	45
201.103 <i>Functional connection</i>	45
202 Electromagnetic disturbances – Requirements and tests.....	46
206 Usability.....	47
208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.....	48
211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.....	48
212 Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment.....	49
Annex C (informative) Guide to <i>marking</i> and labelling requirements for <i>ME equipment</i> and <i>ME systems</i>	50

Annex D (informative) <i>Symbols on marking</i>	54
Annex AA (informative) Particular guidance and rationale	55
Annex BB (informative) Skin temperature at the <i>pulse oximeter probe</i>	76
Annex CC (informative) Determination of <i>accuracy, pigmentation differential bias, sample size, and study design considerations</i>	80
Annex DD (normative) Method for invasive studies for evaluating and documenting <i>SpO₂ accuracy</i> in human participants	100
Annex EE (informative) Simulators, calibrators, and <i>functional testers</i> for <i>pulse oximeter equipment</i>	106
Annex FF (informative) Concepts of <i>ME equipment</i> response time	115
Annex GG (normative) Data interface requirements	119
Annex HH (informative) Clinical context and rationales of data interface requirements	125
Annex II (informative) Using a <i>functional tester</i> to assess <i>pulse oximeter equipment</i> conditions of signal inadequacy over a range of transmitted light and optical modulation	126
Annex JJ (informative) Using a <i>transfer standard</i> in <i>pulse oximeter equipment</i> development ...	130
Annex KK (informative) Reference to the <i>IMDRF essential principles</i> and labelling guidances	135
Bibliography	138
Terminology — Alphabetized index of defined terms	147