

# DIN EN ISO 80601-2-61:2019-09 (E)

Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO 80601-2-61:2017, Corrected version 2018-02)

---

<b>Contents</b>		<b>Page</b>
European foreword.....		4
Foreword.....		5
Introduction.....		6
201.1	Scope, object and related standards.....	8
201.1.1	* Scope.....	8
201.1.2	Object.....	9
201.1.3	Collateral standards.....	9
201.1.4	Particular standards.....	9
201.2	Normative references.....	10
201.3	Terms and definitions.....	11
201.4	General requirements.....	16
201.4.3	Essential performance.....	16
201.4.102	Additional requirements for acceptance criteria.....	16
201.4.103	Additional requirements for PULSE OXIMETER EQUIPMENT, parts and ACCESSORIES.....	17
201.5	General requirements for testing of ME EQUIPMENT.....	17
201.6	Classification of ME EQUIPMENT and ME SYSTEMS.....	17
201.7	ME EQUIPMENT identification, marking and documents.....	18
201.8	Protection against electrical HAZARDS from ME EQUIPMENT.....	22
201.9	Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	22
201.10	Protection against unwanted and excessive radiation HAZARDS.....	22
201.10.4	Lasers.....	22
201.11	Protection against excessive temperatures and other HAZARDS.....	22
201.12	Accuracy of controls and instruments and protection against hazardous outputs.....	24
201.12.1	Accuracy of controls and instruments.....	24
201.12.4	Protection against hazardous output.....	27
201.13	HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT.....	28
201.13.101	Detection of PROBE FAULTS and PROBE CABLE EXTENDER faults.....	28
201.14	Programmable electrical medical systems (pems).....	28
201.15	Construction of ME EQUIPMENT.....	28
201.15.101	Mode of operation.....	29
201.16	ME SYSTEMS.....	30
201.17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS.....	30
201.101	* Pulse oximeter probes and probe cable extenders.....	30
201.101.1	General.....	30
201.101.2	Labelling.....	30

201.102	Saturation pulse INFORMATION SIGNAL.....	30
201.103	Functional connection .....	31
201.103.1	General.....	31
201.103.2	* Connection to electronic health record.....	31
201.103.3	Connection to a DISTRIBUTED ALARM SYSTEM.....	31
202	Electromagnetic disturbances – Requirements and tests .....	31
202.8.2	PATIENT physiological simulation .....	32
206	Usability.....	32
206.5	Replacement of requirements given in IEC 62366 <sup>[19]</sup> .....	33
208	General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.....	33
211	Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.....	33
212	Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment.....	34
Annex C (informative)	Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS.....	35
Annex D (informative)	Symbols on marking .....	38
Annex AA (informative)	Particular guidance and rationale .....	39
Annex BB (informative)	Skin temperature at the PULSE OXIMETER PROBE.....	47
Annex CC (informative)	Determination of ACCURACY .....	51
Annex DD (informative)	Calibration standards.....	60
Annex EE (informative)	Guideline for evaluating and documenting SpO <sub>2</sub> ACCURACY in human subjects .....	61
Annex FF (informative)	Simulators, calibrators and FUNCTIONAL TESTERS for PULSE OXIMETER EQUIPMENT .....	68
Annex GG (informative)	Concepts of ME EQUIPMENT response time .....	77
Annex HH (normative)	Data interface requirements .....	81
Annex II (informative)	Reference to the ESSENTIAL PRINCIPLES .....	85
Annex JJ (informative)	Terminology — alphabetized index of defined terms .....	89
Bibliography	.....	92