

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)

Contents		Page
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 ^[19]	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 ₂ 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