

ISO 9919 :2005-03 (E)

Medical electrical equipment_ - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use

Contents

Page

Foreword	vii
Introduction	viii
1 Scope.....	1
2 Normative references	1
3 Terms and definitions	2
4 General requirements and requirements for tests	7
4.101 Other test methods	7
4.102 Acceptance criteria	8
4.103 Pulse oximeter equipment, parts and accessories	8
5 Classification	8
6 Identification, marking and documents	8
6.1 Marking on the outside of equipment or equipment parts	8
6.8.1 General	9
6.8.2 Instructions for use.....	9
6.8.3 Technical description	11
7 Power input.....	11
8 Basic safety categories	11
9 Removable protective means	11
10 Environmental conditions	12
10.1 Transport and storage	12
11 Not used	12
12 Not used	12
13 General	12
14 Requirements related to classification	12
14.6 Types B, BF and CF equipment.....	12
15 Limitation of voltage and/or energy	12
16 Enclosures and protective covers	12
17 Separation.....	12
18 Protective earthing, functional earthing and potential equalization	12
19 Continuous leakage currents and patient auxiliary currents	13
19.4 Tests	13
20 Dielectric strength.....	13
20.4 Tests	13
21 * Mechanical strength	13
21.5 13	
21.101 * Shock and vibration	13
21.102 * Shock and vibration for transport.....	14
22 Moving parts	15
23 Surfaces, corners and edges	15
24 Stability in normal use.....	15

25	Expelled parts	15
26	Vibration and noise	16
27	Pneumatic and hydraulic power	16
28	Suspended masses	16
29	X-Radiation.....	16
30	Alpha, beta, gamma, neutron radiation and other particle radiation	16
31	Microwave radiation	16
32	Light radiation (including lasers).....	16
33	Infra-red radiation.....	16
34	Ultraviolet radiation.....	16
35	Acoustical energy (including ultrasonics).....	16
36	* Electromagnetic compatibility.....	17
37	Locations and basic requirements	17
38	Marking, accompanying documents	17
39	Common requirements for category AP and category APG equipment	17
40	Requirements and tests for category AP equipment, parts and components thereof	17
41	Requirements and tests for category APG equipment, parts and components thereof	17
42	Excessive temperatures	18
43	Fire prevention.....	18
43.101	* Pulse oximeter equipment used in conjunction with oxidants	18
43.101.1	Ignitable material	18
43.101.2	Sparking.....	19
44	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility.....	19
44.6	* Ingress of liquids	19
44.7	Cleaning, sterilization and disinfection	19
45	Pressure vessels and parts subject to pressure	19
46	Human errors	20
47	Electrostatic charges	20
48	Biocompatibility.....	20
49	Interruption of the power supply	20
49.101	Power-failure alarm condition.....	20
49.102	Pulse oximeter equipment operation following interruption of the power supply.....	20
49.102.1	Settings and data storage following short interruptions or automatic switchover	20
49.102.2	Operation following long interruptions	20
50	Accuracy of operating data	21
50.101	* SpO ₂ accuracy of pulse oximeter equipment	21
50.101.1	* Specification	21
50.101.2	Determination of SpO ₂ accuracy.....	21
50.102	Accuracy under conditions of motion.....	22
50.103	Accuracy under conditions of low perfusion	22
50.104	Pulse rate accuracy.....	23
51	Protection against hazardous output.....	23
51.101	* Data update period	23
51.102	Detection of pulse oximeter probe and probe cable extender fault.....	23

52	Abnormal operation and fault-conditions	23
53	Environmental tests	24
54	General	24
55	Enclosures and covers	24
56	Components and general assembly	24
57	Mains parts, components and layout.....	24
58	Protective earthing — Terminals and connections	24
59	Construction and layout.....	24
101	* Signal inadequacy	24
102	* Pulse oximeter probes and probe cable extenders	25
102.1	General	25
102.2	Labelling.....	25
103	Saturation pulse information signal.....	25
104	Alarm systems.....	25
201.1.2	* Assignment of priority	25
201.5.4	* Default alarm preset	26
201.8	Alarm signal inactivation states	26
201.8.3	Indication and access	26
105	Appendices of IEC 60601-1:1988.....	26
Annex AA (informative) Rationale.....		27
Annex BB (informative) Skin temperature at the pulse oximeter probe		38
Annex CC (informative) Determination of accuracy.....		42
Annex DD (informative) Calibration standards.....		50
Annex EE (informative) Guideline for evaluating and documenting SpO ₂ accuracy in human subjects.....		51
Annex FF (informative) Simulators, calibrators and functional testers for pulse oximeter equipment		58
Annex GG (informative) Concepts of equipment response time.....		68
Annex HH (informative) Reference to the Essential Principles		72
Annex II (informative) Environmental aspects.....		74
Annex JJ (informative) Index of defined terms.....		76
Bibliography		78

Tables

Table AA.1	— Qualitative assessment of pulse oximeter equipment shock and vibration environment.....	28
Table AA.2	— Allowable maximum temperatures for skin contact with medical electrical equipment applied parts (adapted from Table 22, IEC/CDV 60601-1:2004)	30
Table BB.1	— Pulse oximeter probe safe application time and source	40
Table EE.1	— Example of target plateaus and ranges	54
Table HH.1	— Correspondence between this International Standard and the Essential Principles.....	72
Table II.1	— Environmental aspects addressed by clauses of this International Standard.....	75

Figures

Figure CC.1 — Synthesized calibration data (base case)	43
Figure CC.2 — Constant offset has been added to base case	44
Figure CC.3 — Tilt has been added to base case	45
Figure CC.4 — Graphical representation for the definition of local bias (Test sensor SpO_2 as a function of reference S_R)	46
Figure CC.5 — Graphical representation for the definition of local bias and mean bias (Test sensor SpO_2 as a function of reference S_R)	46
Figure EE.1 — Example of desaturation-time profile	54
Figure FF.1 — Sample calibration curve for pulse oximeter equipment	60
Figure FF.2 — Interface of a functional tester that uses a photodiode and LED to interact with a pulse oximeter probe	61
Figure FF.3 — Interface of a functional tester that uses a dye mixture	62
Figure FF.4 — Interface of a functional tester that uses a liquid crystal modulator	63
Figure FF.5 — Absorbency of blue bandage material (measured in reflection) used in a special test pulse oximeter probe with great patient-to-patient variability of calibration	65
Figure FF.6 — Calibration of high-variability pulse oximeter probe in controlled desaturation study on five test subjects	66
Figure FF.6 — Calibration of high-variability pulse oximeter probe in controlled desaturation study on five test subjects (<i>continued</i>)	67
Figure GG.1 — Illustration of fidelity of pulse oximeter equipment performance in tracking saturation changes	68
Figure GG.2 — Illustration of effect of different averaging times on fidelity	69
Figure GG.3 — Graphic representation of components of alarm system delay	70
Figure GG.4 — Illustration of the effects of different averaging times on a more rapid and noisier desaturation signal	71