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Standard Specification for Pulse Oximeters[1]

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INTRODUCTION

The approximation of hemoglobin saturation through the use of pulse oximetry has become an increasingly common practice in many areas of clinical medicine. These areas include, but are not limited to anesthesia, respiratory therapy, pediatrics, and intensive care. A variety of devices are currently available that are intended for these applications. This specification covers minimum safety and performance requirements based on parameters that are believed to be achievable within the limits of existing technology.

Appendix X1 contains a rationale for the most important requirements. It is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this specification.

This specification references IEC 601-1 for many of the general requirements for safety. Requirements specific to pulse oximeters not included in IEC 601-1.

1. Scope

1.1 The scope given in Clause 1 of IEC 601-1 applies except that 1.1 shall be replaced by the following:

1.1.1 This specification includes requirements for the safety and performance of pulse oximeters, as defined in 3.2.9 intended for use in approximating the saturation of arterial hemoglobin, non-invasively, from a light signal transmitted through the tissue, taking into account the pulsatile nature of volume changes with blood flow.

1.2 The field of application includes, but is not limited to: intraoperative and perioperative use; adult critical care application; pediatric and neonatal application; and general determination of saturation on hospitalized and non-hospitalized patients.

1.3 Pulse oximeters intended for use in laboratory research applications and "bench" type oximeters that require a blood sample from the patient are outside the scope of this specification.

2. Referenced Documents

2.1 The following standards contain provisions that, through reference in this text, constitute provisions of this specification. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this specification are encouraged to investigate the possibility of applying the most recent editions of the standards listed below.

2.2 *ASTM Standards:*

F 1463 Specification for Alarm Signals in Medical Equipment Used in Anesthesia and Respiratory Care[2]

2.3 *ISO Standards:*

ISO 7249 Controls—Terms, Suitability, Design Requirements[3]

ISO 7250 Basic List of Anthropomorphic Measurements[3]

2.4 *IEC Standards:*

IEC 79-3:1972 Electrical Apparatus for Explosive Atmospheres Part III: Spark Test Apparatus for Intrinsically Safe Units[3]

IEC 79-4:1975 Electrical Apparatus for Explosive Atmosphere Part IV: Method of Test for Ignition Temperature[3]

IEC 601-1:1988 Safety of Medical Electrical Equipment—Part I: General Safety Requirements[3]

IEC 801-2 Electromagnetic Compatibility for Industrial Process Measurement and Control Equipment Part 2: Electrostatic Discharge Requirements (August, 1990—TC65 (Secreteriat) 136[3]

3. Terminology

3.1 *Definitions:*

3.1.1 For the purposes of this specification, the definitions given in Clause 2 of IEC 601-1 apply together with the following additional terms.

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[1] This specification is under the jurisdiction of ASTM F29 on Anesthetic and Respiratory Equipment and is the direct responsibility of Subcommittee F29.11 on Gas Monitors.

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[2] *Annual Book of ASTM Standards*, Vol 13.01.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *alarm*—a warning signal.

3.2.2 *alarm set point*—the setting of the adjustment control, or display value that indicates the SpO_2, at or beyond which the alarm is intended to be activated.

3.2.2.1 *Discussion*—Terms such as *alarm limits* or *alarm threshold* are frequently used to describe the same function.

3.2.3 *alarm system*—those parts of the pulse oximeter that establish the alarm set point(s); and activate an alarm when the SpO_2 is less than or equal to the low alarm set point, if provided, or is equal to or greater than the high alarm set point, if provided.

3.2.4 *calibration range*—the range of SpO_2 values over which the pulse oximeter has been tested and calibrated.

3.2.5 *display range*—the range of the SpO_2 values that may be displayed by the pulse oximeter.

3.2.6 *display update frequency*—the number of seconds or events, that is, pulses, between possible changes in the displayed value.

3.2.7 *probe*—the portion of the applied part of the pulse oximeter intended to come in direct contact with the patient. With some oximeters, the probe may be considered an accessory.

3.2.8 *probe fault*—a condition including, but not limited to, a probe component failure or disconnection of the probe from either the pulse oximeter or the patient.

3.2.9 *pulse oximeter*—a device for determination of saturation of hemoglobin non-invasively from a light signal transmitted through the tissue, taking into account the pulsatile nature of volume changes with blood flow.

3.2.10 *total Hb*—the sum of all hemoglobin species including, but not limited to, O_2Hb, Meth Hb, HHb, and COHb.

3.3 *Symbols:*

3.3.1 *$O_2Hb/(total\ Hb)$*—fractional saturation.

3.3.2 *$O_2Hb/(O_2\ Hb + HHb)$*—functional saturation.

3.3.2.1 *Discussion*—HHb = deoxyHb.

3.3.3 *SaO_2*—hemoglobin saturation with oxygen in systemic arteries.

3.3.4 *SpO_2*—hemoglobin saturation with oxygen as measured by a pulse oximeter.

4. Classification

4.1 The requirements given in Clause 5 of IEC 601-1 apply except as follows:

4.1.1 In Clause 5.6 delete all but “continuous operation.”

5. Relationship of This Specification to IEC 601-1

5.1 *Section One—General*:

	(A)	(N/A)	(AM/R)*
1. Scope and Object			X
2. Terminology and definitions			+X
3. General requirements	X		
4. General requirements for tests			X
5. Classification			X
6. Identification, marking and documents			X
7. Power input	X		

*A = Applies, NA = Not Applicable, AM/R - applies with an amendment, addition, or revision to the requirements in IEC 601-1.

5.2 *Section Two—Environmental Conditions*:

	(A)	(N/A)	(AM/R)*
8. (Not used)			
9. (Not used)			
10. Environmental conditions	X		
11. (Not used)			
12. (Not used)			

5.3 *Section Three—Protection Against Electric Shock Hazards*:

13. General	X		
14. Requirements related to classification	X		
15. Limitation of voltage and/or energy	X		
16. Enclosures and PROTECTIVE COVERS	X		
17. Separation	X		
18. Protective earthing, functional earthing, and potential equalization	X		
19. PATIENT AUXILIARY CURRENTS			X
20. Dielectric strength			X

5.4 *Section Four—Protection Against Mechanical Hazards*:

21. Mechanical strength			X
22. Moving parts	X		
23. Surfaces, corners, and edges	X		
24. Stability in NORMAL USE	X		
26. Vibration and Noise	X		
27. Pneumatic and hydraulic power		X	
28. Suspended masses		X	

5.5 *Section Five—Protection Against Hazards from Unwanted or Excessive Radiation*:

29. X-radiation		X					
30. Alpha, beta, gamma, neutron radiation and other particle radiation				X			
31. Microwave radiation		X					
32. Light radiation (including visual radiation and lasers)		X					
33. Infra-red radiation		X					
34. Ultra-violet radiation		X					
35. Acoustical energy (including ultrasonics)		X					
36. Electromagnetic compatibility						X	

5.6 *Section Six—Protection Against Hazards of Ignition of Flammable Anaesthetic Mixtures*:

37. Locations and basic requirements		X					
38. Marking and ACCOMPANYING DOCUMENTS		X					
		(A)		(N/A)		(AM/R)*	
39. Common requirements for Category AP and Category APG EQUIPMENT		X					
40. Requirements and tests for Category AP EQUIPMENT, parts or components thereof		X					
41. Requirements and tests for Category APG EQUIPMENT, parts or components thereof		X					

5.7 *Section Seven—Protection Against Excessive Temperatures and Other Safety Hazards*:

42. Excessive temperatures		X					
43. Fire prevention		X					
44. Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, and disinfection		X					
45. Pressure vessels and parts subject to PRESSURE		X					
46. Human errors						X	
47. Electrostatic charges		X					
48. Materials in APPLIED PARTS in contact with the body of the PATIENT		X					
49. Interruption of the power supply		X					

5.8 *Section Eight—Accuracy of Operating Data and Protection Against Hazardous Output*:

50. Accuracy of operating data		X					
51. Protection against hazardous output						X	

5.9 *Section Nine—Abnormal Operations and Fault Conditions: Environmental Tests*:

		(A)		(N/A)		(AM/R)*	
52. Abnormal operation and fault conditions		X					
53. Environmental tests		X					

5.10 *Section Ten—Constructional Requirements*:

54. General		X					
55. ENCLOSURES and covers		X					
56. Components and general assembly		X					
57. MAINS PARTS, components and layout		X					
58. Protective earthing—Terminals and connections		X					
59. Construction and layout		X					

5.11 *Section Eleven—Additional Clauses Specific to Pulse Oximeters*:

60. Pulse amplitude or pulse strength display		X					

5.11.1 Clauses containing amendments, additions or replacements to the text in IEC 601-1.

NOTE 1—The clause numbers used reference the specific section in IEC 601-1.

6. General Requirements and General Requirements for Tests

6.1 Clauses 3 and 4 of IEC 601-1 apply together with the following addition:

6.1.1 Test methods other than those specified in this specification but of equal or greater accuracy may be used to verify compliance with the requirements of this specification. However, in the event of dispute, the methods specified in this specification shall be used as the reference methods.

7. Identification, Marking, and Documents

7.1 The requirements given in Clause 6 of IEC 601-1 apply with the following additions and modifications:

7.1.1 In 4.1, replace Item B by the following:

7.1.1.1 If the size of the pulse oximeter does not permit the complete marking as specified throughout this clause, at least the following shall be marked on the pulse oximeter: the name

of the manufacturer, a serial number or lot or batch identifying number, Symbol Number 14 in Table D1 of IEC 601-1, and if the pulse oximeter is not provided with a low SpO_2 alarm, the words "NOT FOR MONITORING."

7.1.2 In 4.1, add the following item to Item F:

7.1.2.1 A serial number or other lot or batch identifying number.

7.1.3 In 4.1, add additional items as follows:

7.1.3.1 Displays of percent saturation shall be displayed in units of "% SpO_2." The units of measure shall be marked by (adjacent to) the display, or displayed on demand.

7.1.3.2 Marking shall be provided on the probe package or on the probe itself if the probe is for "single patient use."

7.1.3.3 If the pulse oximeter is not provided with a low SpO_2 alarm, the words "NOT FOR MONITORING."

7.2 Clause 6.7 of IEC 601-1 shall apply with the following modification:

7.2.1 Dot matrix, alphanumeric displays, and computer-generated graphics are not considered to be indicator lights.

7.2.2 Compliance shall be checked by functional tests and inspections.

7.3 In 6.8.2 delete Subclause b and add the following items:

7.3.1 The instructions for use shall additionally include the following information:

7.3.1.1 If the pulse oximeter is provided with adjustable alarm levels, the range of adjustment;

7.3.1.2 A method of disinfection or sterilization, or both, of both the probe and the body of the pulse oximeter, where applicable;

7.3.1.3 The display update interval of the pulse oximeter and the method by which the displayed value is determined;

7.3.1.4 The calibration range of the pulse oximeter;

7.3.1.5 The display range of the pulse oximeter;

7.3.1.6 Any types of interference known to influence the function of the pulse oximeter at the time that the instructions for use were prepared;

7.3.1.7 If the pulse oximeter requires in-service calibration, a suitable calibration procedure;

7.3.1.8 The mechanism and nature of alarm silencing, that is, during probe disconnection, probe off the finger, etc., and a method for manual self-testing of the alarm circuitry if an automatic self-test is not provided;

7.3.1.9 The default parameters for the alarm that occur upon pulse oximeter activation, if applicable;

7.3.1.10 If not provided with a low SpO_2 alarm, the statement "NOT FOR MONITORING"; and

7.3.1.11 The accompanying documents shall specify probes that may be used with the pulse oximeter.

7.3.2 In 6.8.2, add the following to Item D:

7.3.2.1 The manufacturer shall also state in the accompanying documents the maximum application time for each probe at a single site.

7.4 In 6.8.3 add the following:

7.4.1 *Accuracy*:

7.4.1.1 The accuracy and the range of hemoglobin saturation with oxygen over which the accuracy of the pulse oximeter is claimed shall be disclosed. The manufacturer shall also disclose whether the calibration was to functional or fractional saturation. Test methods shall be available from the manufacturer upon request.

7.4.1.2 If provided, the manufacturer shall disclose in the accompanying documents the accuracy and range for the pulse rate and the range over which this accuracy is claimed.

7.4.1.3 The test methods shall be available from the manufacturer upon request.

8. Continuous Leakage Currents and Patient Auxiliary Currents

8.1 The requirements given in Clause 19 of IEC 601-1 apply except for the following modification:

8.1.1 Replace the alternate saline test with the following:

8.1.1.1 Probes marked as watertight (using Symbol 13 in Table D1 of IEC 601-1) shall comply with the following test: immerse the probe for 1 min in a saline solution containing 0.9% sodium chloride that is maintained at a temperature between 20 and 25°C. While the probe is still immersed, perform the tests for patient leakage current as specified in Clause 19.4 g) 5) of IEC 601-1.

9. Dielectric Strength

9.1 The requirements given in Clause 20 of IEC 601-1 apply except for the following addition:

9.1.1 Probes marked as watertight (using Symbol 13 in Table D1 of IEC 601-1) shall comply with the following test: immerse the probe for 1 min in a saline solution containing 0.9 % sodium chloride that is maintained at a temperature between 20 and 25°C. While the probe is still immersed, perform the tests for dielectric strength as specified in Clause 20.4 a) of IEC 601-1.

10. Mechanical Strength

10.1 The requirements given in Clause 21 of IEC 601-1 apply except add the following to 21.5:

10.1.1 Patient probes that are hand held during normal use and cord-connected control switches shall not present a safety hazard as a result of a free fall from a height of 1 m onto a hard surface.

10.2 Compliance shall be checked by the following test:

10.2.1 Allow the sample to be tested to fall freely once from each of three different starting orientations from a height of 1 m onto a 50 mm thick hardwood board (that is, hardwood having a density of >700 kg/m^3) that lies flat on a rigid base (concrete block). After this test no live parts shall become accessible. Cracks not visible to the naked eye and surface cracks in fiber-reinforced moldings and the like shall be ignored. If the sample appears operational after the fall, a dielectric strength test, according to Clause 20 of IEC 601-1 shall be carried out.

11. Electromagnetic Compatibility

11.1 The requirements in Clause 36 of IEC 601-1 apply with the following addition (the test method in 36.1 is derived from IEC 801-2):

11.1.1 *Protection from Electrostatic Discharge*—The pulse oximeter should continue to function and meet the requirements of this specification or should fail without causing a

safety hazard. The discharges shall have a potential of 3 kV ± 5 % DC for a contact discharge and 8 kV ± 5 % DC for an air discharge from a network as described in IEC 801-2 (TC 65 Sec 136). If an anomaly occurs, such as, display interrupt, alarm activation, etc., it should be possible to restore normal operation within 30 s after the electrostatic discharge has been applied. (Silencing of an activated alarm should not be considered a failure.)

12. Human Errors

12.1 Twin-pole or multi-pole plugs and sockets for extra low voltage patient circuits shall not be interchangeable with plugs and sockets for mains connections and further shall minimize any electrical connection that may result in a safety hazard.

13. Protection Against Hazardous Output

13.1 The requirements given in Clause 51 of IEC 601-1 are replaced by the following:

13.1.1 *Control Function and Position*—If the intended test control function is not clearly distinguishable when displayed on the pulse oximeter, the corresponding control(s) shall automatically return from such control function position(s). The positions of measurement and test controls shall be clearly distinguishable. Calibration controls shall include a means to prevent inadvertent change from the intended position.

NOTE 2—User-operable function checks other than "power on" for test controls such as battery condition or signal operation should automatically return from the check, test, or override position.

NOTE 3—All other controls should also include means to prevent inadvertent changes from the intended position and should have clearly distinguishable positions.

13.1.2 *Movement of Controls*—For controls that consist of a movable part and a non-movable part, movement upwards, to the right, or in a clockwise direction shall increase the control function. Movement downwards, to the left, or in an anti-clockwise direction shall decrease the control function.

NOTE 4—The separation between control knobs, switches, toggles, pinwheels, or push buttons should conform to the recommendations given in ISO 7249 and ISO 7250.

NOTE 5—Controls and their associated markings should be visible or legible, or both, to a user having a visual acuity (corrected if necessary) of at least 1.0 when the user is located at least 1 m in front of the pulse oximeter and the illuminance level is 215 Lx. Markings should be clearly identified with their associated controls.

14. Alarms

14.1 *Alarm Prioritization*:

14.1.1 The alarm characteristics of monitors specified in this specification shall be grouped in three categories: high priority, medium priority, and low priority (see Table 1).

14.1.2 The audible components of these alarms should be designed to allow silencing until the PULSE OXIMETER is placed in use (that is, connected to the patient) in order to reduce nuisance alarms.

14.1.3 There shall be a visual indication that an audible alarm has been silenced.

14.1.4 The set points of adjustable alarms shall be indicated continuously or on user demand.

TABLE 1 Alarm Characteristics

Alarm Category	Operator Response	Audible Indicators*	Indicator Color***	Flashing Frequency (Hz)**
High priority	Immediate	Not medium or low priority I	Red	1.4 to 2.8 Hz (F_2)
Medium priority	Prompt	Not high or low priority	Yellow	0.4 to 0.8 Hz (F_1)
Low priority	Awareness	Nor high or medium priority	Yellow	Constant (On)

14.2 *High Priority Alarms*:

14.2.1 There shall be a visual indication of the high priority alarm. It shall be different and distinguishable from the visual signals specified in 14.3 and 14.4.

14.2.2 There shall be a simultaneous audible indication of the high priority alarm. This audible indication shall be different and distinguishable from the audible signals specified in 14.3 and 14.4.

14.2.3 The audible indicators shall reset automatically when the condition causing the alarm has cleared.

14.3 *Medium Priority Alarms*:

14.3.1 There shall be a visual indication of the medium priority alarm. It shall be different and distinguishable from the visual signals specified in 14.2 and 14.4.

14.3.2 There shall be a simultaneous audible indication of the medium priority alarm. This audible indication shall be different and distinguishable from the audible signals in 14.2 and 14.4.

14.3.3 The audible indicator shall reset automatically when the condition causing the alarm has cleared.

14.4 *Low Priority Alarms*:

14.4.1 There shall be a visual indication of the low priority alarm. It shall be different and distinguishable from the visual signals in 14.2 and 14.3.

14.4.2 There may be a simultaneous audible indication of the low priority alarm. This audible indication, if provided, shall be a low priority alarm. This audible indication shall be different and distinguishable from the audible signals specified in 14.2 and 14.3.

14.4.3 The audible indicator shall reset automatically when the condition causing the alarm has cleared.

NOTE 6—An ASTM standard (see Specification F 1463) is presently being developed for the general characteristics (audible and visual) of all alarms on anesthetic and respiratory care equipment.

14.5 *Alarm Characteristics*:

14.5.1 If intended for continuous monitoring, the pulse oximeter shall have a low SpO_2 alarm.

NOTE 7—In certain clinical applications a high saturation alarm may provide an additional safety feature.

14.5.2 The difference between the alarm set point and the SpO_2 when the alarm is activated shall not exceed 2 "% SpO_2."

14.5.2.1 Compliance shall be checked by the test given in 14.6.

14.6 *Method of Test for SpO_2 Alarm Set Point Accuracy*:

14.6.1 Generate at least four stable SpO_2 readings that span the range of the alarm system in approximately equal steps by

varying the input to the pulse oximeter, or by adjusting the calibration control (if provided).

14.6.2 For each SpO_2 reading, adjust the alarm set point so that the alarm is deactivated. Incrementally adjust the alarm set point until the alarm is activated and record the SpO_2 reading at which the alarm is activated. The difference between the alarm set point and the corresponding SpO_2 reading shall not exceed 2 "% SpO_2."

NOTE 8—An alarm may be of a type that is activated at a SpO_2 reading above (high alarm) or below (low alarm) the alarm set point. A pulse oximeter may have either or both types of alarm.

14.6.3 If alarms are provided, alarm set points shall be operator adjustable. Operator adjustment of alarm set points or default parameters shall require a deliberate sequence of actions on the part of the operator.

14.6.4 Default limits on low SpO_2 alarms shall be 80 "% SpO_2" or greater.

14.6.5 Temporary silencing of audible alarms, if provided, shall not exceed 2 min. The visual signal shall remain until the condition is corrected. If permanent silencing of the audible alarm is provided, it shall require deliberate action on the part of the operator if the silencing is performed after the pulse oximeter is ready for use. The visual signal shall remain until the condition is corrected.

14.6.6 If intended for continuous monitoring, a probe fault alarm shall be provided, and its function shall be checked by the test given in 14.6.7.

14.6.7 Disconnect the probe from the pulse oximeter and replace it with a circuit with which each probe wire can be opened or shorted to any other probe wire. Verify that the alarm is activated.

15. Additional Clauses Specific to Pulse Oximeters

15.1 *Pulse Amplitude or Pulse Strength Display*—If a normalized pulse waveform display is provided, a visual display of pulse strength shall also be provided.

NOTE 9—Visual indication of the signal adequacy should be provided.

NOTE 10—If a variable pitch audible annunciation is provided for the pulse signal, a pitch or amplitude change in the sound indicator should be provided parallel to the reading, for example, as the SpO_2 reading lowers the sound pitch should also be lowered.

ANNEX

(Mandatory Information)

A1.

A1.1 Annexes A to M in IEC 601–1 together with Appendix X1 of this specification apply.

APPENDIX

(Nonmandatory Information)

X1. GENERAL

X1.1 Pulse oximetry facilitates patient care management by providing an approximation of arterial hemoglobin saturation with oxygen, and allows for the possibility of early detection of the catastrophic events associated with patient hypoxemia.

X1.2 The present technology requires an adequate concentration of hemoglobin, a volume change in blood flow, and light transmission through a tissue bed in order to provide effective in vivo approximation of human hemoglobin saturation with oxygen.

X1.3 Pulse oximeters may not function effectively during cardiopulmonary bypass or at extreme low-flow states, and are not at present intended as a means for the measurement of blood flow or blood volume.

X1.4 With the limitations of the present technology, pulse oximetry is not a precision measurement device. The presently marketed in vivo pulse oximeters are not a replacement for measurement of in vitro blood samples by bench-type oximeters.

X1.5 The values derived from pulse oximetry are not a measurement of blood or tissue oxygen tension.