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Standard Specification for Pulse Oximeters¹

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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 Care²

2.3 *ISO Standards:*

ISO 7249 Controls—Terms, Suitability, Design Requirements³

ISO 7250 Basic List of Anthropomorphic Measurements³

2.4 *IEC Standards:*

IEC 79-3:1972 Electrical Apparatus for Explosive Atmospheres Part III: Spark Test Apparatus for Intrinsically Safe Units³

IEC 79-4:1975 Electrical Apparatus for Explosive Atmosphere Part IV: Method of Test for Ignition Temperature³

IEC 601-1:1988 Safety of Medical Electrical Equipment—Part I: General Safety Requirements³

IEC 801-2 Electromagnetic Compatibility for Industrial Process Measurement and Control Equipment Part 2: Electrostatic Discharge Requirements (August, 1990—TC65 (Secretariat) 136³

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.

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	+	(A)	(N/A)	(AM/R)*
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		+
39. Common requirements for Category AP and Category APG EQUIPMENT	+	(A)	(N/A)	(AM/R)*
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	+		+	+

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		+
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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