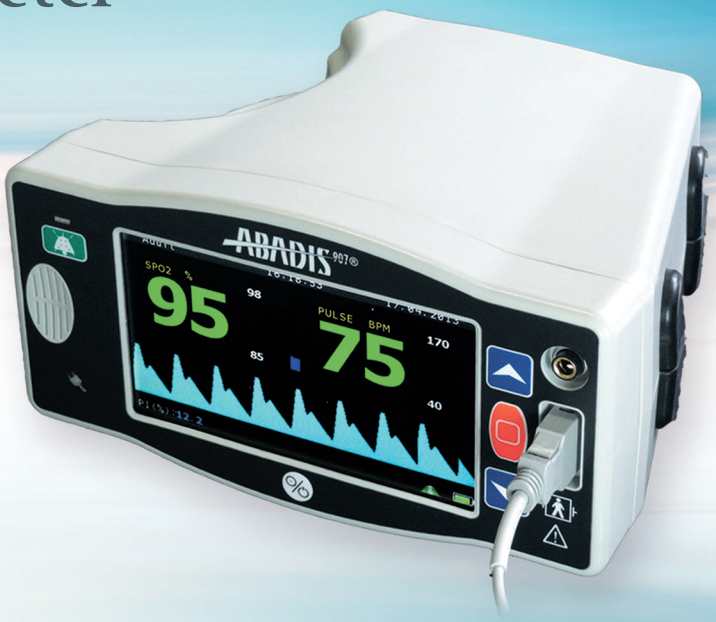
ABADIS 907®

Digital Pulseoximeter

PARSIAN MEDICAL Co.



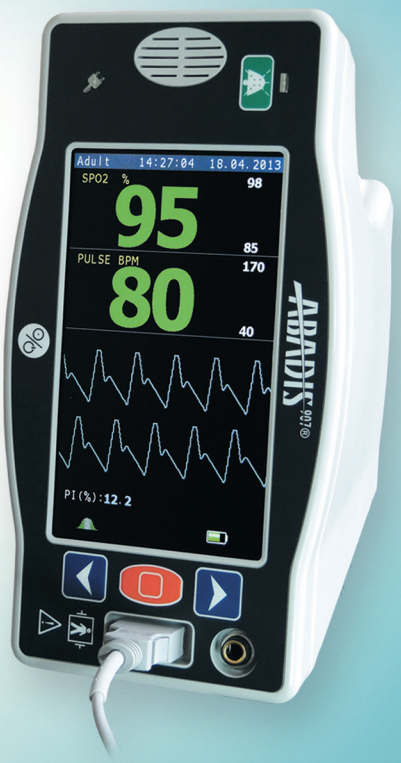
Digital Pulseoximeter Including:

- Oxygen Saturation (SpO2)
- Pulse Rate (PR)
- Plethysmograph Waveform
- Perfusion Index (PI)
- Temperature

High Accuracy and Precision of Parameters on Low Perfusion Condition

Setting for all Patient Type :

- Adult
- Pediatric
- Neonate



Technical Specification

- Internal Rechargeable Battery with 6 Hours Working Capacity
- ETHERNET Connector Complying HL7 Protocols
- USB Connector
- Arm Processor Design
- Unlimited Trend for Several Patients
- 7 Inch Full Color TFT LCD
- Auto-rotate Sensor for Detecting Horizontal or Vertical Positions

Oximetry performance is the most critical right when conditions are most difficult. That's when you can count on Dolphin Medical's ONE™ (Oximetry Noise Elimination) technology.

Dolphin Medical's ONE™ technology is the first and only system that uses a patented digital sensor – all others still use an analog sensor.

Dolphin ONE™ sensors both amplify and digitize the signal in the sensor, resulting in a stronger and higher quality signal. Dolphin's OEM oximetry modules are designed to substantially improve performance and eliminate nuisance alarms associated with motion and low perfusion. Dolphin's OEM modules interface directly with the Dolphin ONE™ family of sensors and the host platform to-calculate the SpO2 and pulse rate.

Electrical Characteristics	
Power Requirements (AC Line)	100-240VAC; 50-60 Hz; 23-30VA
Battery	7.6 VDC; Li-Ion, Rechargeable Maximum Protection Battery Operating Time: 4 hours Battery Charging Time: 4 hours
Fuse	500 mA

Measurment Range	
SpO2	0% - 100%
Pulse Rate	30 - 240 bpm (beat per minute)
Temperature	0.0° - 60.0°C (32.0° - 138.9°F)
Perfusion	0.02% - 20%

Resolution	
SpO2	1%
Pulse Rate	1 bpm
Temperature	0.1°C

Accuracy		
SpO2 (Functional)	No Motion and Normal Perfusion	(70-100%) ±2%
Pulse Rate	No Motion and Normal Perfusion	(30-240 bpm) ±3 bpm
SpO2 (Functional)	Neonatal* No Motion and Normal Perfusion	(70-100%) ±2%
SpO2 (Functional)	Motion, Low Perfusion <0.2%	(70-100%) ±3%
Pulse Rate	Motion, Low Perfusion <0.2%	(30-240 bpm) ±5 bpm
Temperature	Not Including Sensor Accuracy	(0-70°C) 1-2%

*Neonatal testing was completed on healthy adult subject and 1% was added to the % arms to account for fatal haemoglobin effects.

IEC (International Electrotechnical Commission) Classifications	
Type of Protection	CLASS II
Degree of Protection	Type BF
Mode of Protection	Continuous
Degree of Protection Against Ingress of Liquids	Ordinary (IPX2)
Recommended Methods of Sterilization or Disinfection	Using a soaked swab with alcohol for the external parts of system, SpO2 sensor and extension cable for appropriate cleaning instructions.
Degree of Safety of Application in the Presence of a Flammable Anesthetic	Not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.

⚠ Do not use functional tester to assess the accuracy of pulseoximeter probes and monitor.

Sensor LEDs	
Nominal wavelenght and nominal power output values	(RED) 660 nm - 1.8 mw and (IRED) 905 nm - 2.0 mw

Display	
Type	High Quality TFT Full Colors Liquid Crystal Display (LCD) with LED Backlight
Data Displayed	SpO2, Pulse Rate, Plethysmograph waveform, Temperature, Alarms and Status Message

Note: There is no display delay for the calculated value.

Alarm Limits	
Low SpO2	0% - 99%
High SpO2	1% - 100%
Low Pulse Rate	30 bpm - 229 bpm
High Pulse Rate	31 bpm - 230 bpm

Unit Dimensions & Weight	
Dimensions	30 x 25 x 10 cm
Weight	1.5 kg

List of Relevant Standard		
1	EN ISO 80601-2-61:2011	Medical electrical equipment Part 2-61: Particular requirements for basic safety and essential performance of pulseoximeter equipment
2	EN 80601-1-8:2006	Medical electrical equipment - Part 1-8: General requirements for safety - Collateral standard: 2. General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
3	EN 60601-1:2006	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
4	EN ISO 14971:2007	Medical devices - Application of risk management to medical devices (ISO 14971:2007)
5	EN 60601-1-2:2001	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
6	ASTM F2761-09	Medical Devices and Medical Systems – Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) – Part 1: General requirements and conceptual model

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