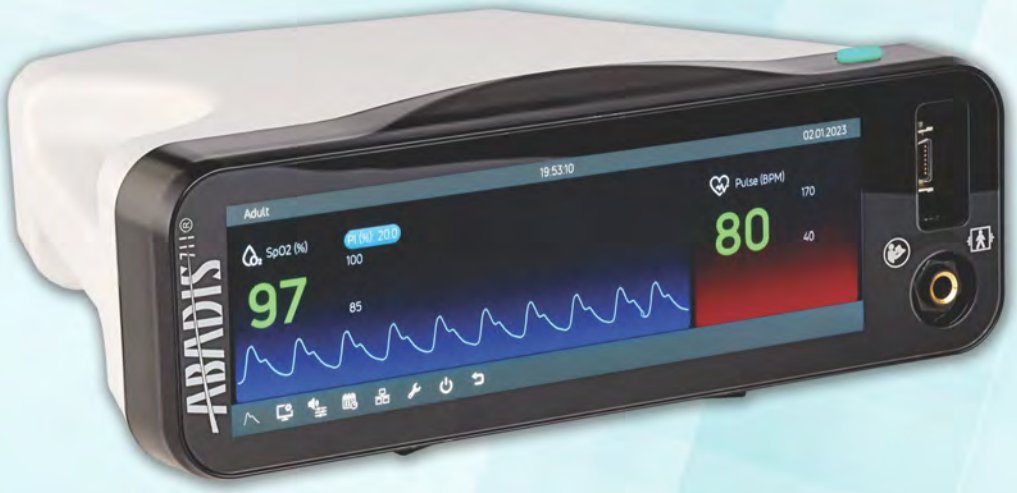
ABADIS 711®

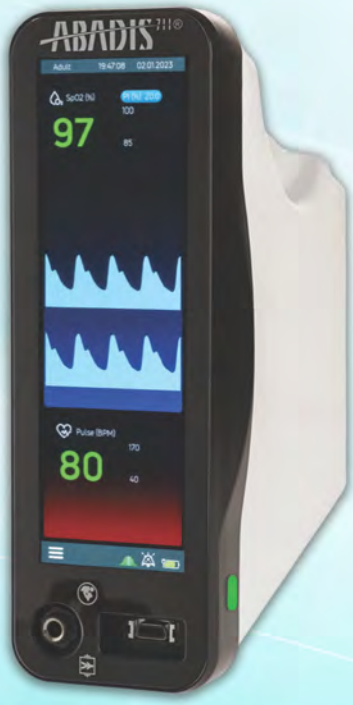
Digital Pulse Oximeter

PARSIAN MEDICAL Co.

Digital Pulse Oximeter Including Following Parameters:

- SpO2 (%)
- Pulse Rate (BPM)
- Perfusion Index (%)
- Photo-Plethysmography Waveform
- Body Temperature (°C)





Technical Specification:

- Self-designed PM2019™ digital oximetry module
- Configurable patient profile settings for: Adult, Pediatric, and Neonate
- Remove motion artifacts
- Record and save measured parameters (Trend)
- Internal rechargeable Li-ion battery, within 5 hours of continuous monitoring
- Ethernet out complying HL7 protocols
- USB connection with computer software
- Rotating and adjustable 7.8" widescreen with capacitive touch
- Audible and visual alarms based on IEC standard
- Variable pitch pulse tone for change in saturation

Electrical Characteristic

Power Requirement	80~264 VAC
Frequency Range	47~63 Hz
Rated Power	30 W
Fuse	2 x 500 mA/250 VAC, 5 x 20 mm

Sensor's LEDs

Nominal wavelength and nominal power output values	(RED) 660 nm - 1.8 mW (IR) 905 nm - 2.0 mW

Parameters Measurement Range

SpO2	30% - 100%
Pulse Rate	30 - 240 BPM (Beat per Minute)
Temperature	0.0° - 60.0°C (32.0° - 138.9°F)
Perfusion	0.2% - 20%

Resolution

SpO2	1%
Pulse Rate	1 BPM
Temperature	0.1°C

Internal Battery

Type	Li-Ion 7.4 V, Rechargeable, Maximum Protection
Operating Time	5 Hours
Charging Time	3 Hours

Display

Type	TFT Liquid Crystal Display (LCD), 400 x 1280 pixels, 7.8 inches
Data Displayed	SpO2, Pulse Rate, Plethysmograph waveform, Temperature, Alarms and Status Messages

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

Physical Dimension

Dimensions (WHD)	25 x 8 x 22 cm
Weight	1 Kg

Alarm Limits

Low SpO2	0% - 99%
High SpO2	1% - 100%
Low Pulse Rate	30 - 229 BPM
High Pulse Rate	31 - 230 BPM

Accuracy

SpO2 (functional)	No motion and Normal Perfusion	(70-100 %) ± 2 %
Pulse Rate	No motion and Normal Perfusion	(30-250 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%	(35-245 BPM) ± 5 BPM
Temperature	Not including sensor accuracy	(0- 40 °C) 1 – 2 %

* Neonatal testing was completed on healthy adult subjects and 1% was added to the % Arms on account of fatal hemoglobin effects.

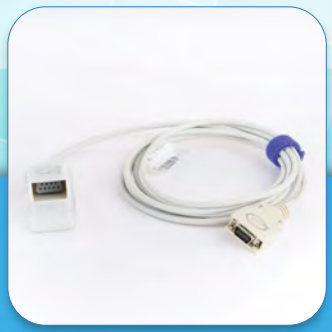
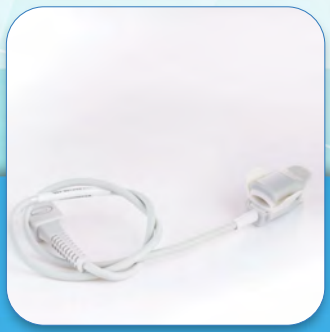
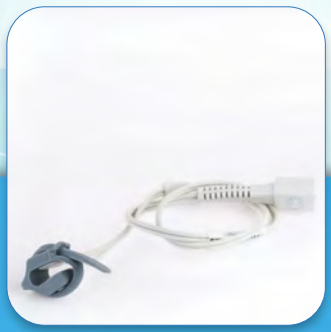
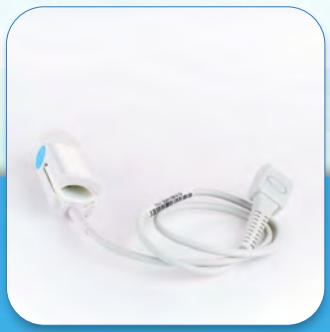
Classification IEC (International Electrotechnical Commission)

Type of protection	CLASS I
Degree of protection	Type BF
Mode of operation	Continuous
Degree of protection against ingress of liquids	Ordinary (IP42)
Recommended methods of sterilization or disinfection	Use 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 pulse oximeter probes and monitor.

List of Relevant Standards

IEC 60601-1:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-8:2006	Medical electrical equipment - Part 1-8: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
ISO 80601-2-61:2017	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 14971:2019	Medical devices - Application of risk management to medical devices
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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ABADIS 711®

CERTIFIED ISO 13485

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