ADC® Adimals™ 2150 Pediatric Fingertip Pulse Oximeter

MEDGUARD®
Professional Healthcare Supplies

Directions for Use

AMERICAN DIAGNOSTIC CORPORATION

ADC® Fingertip Pediatric Pulse Oximeter

Thank you for purchasing an ADC Adimals™ Brand Fingertip Pediatric Pulse Oximeter. We're proud of the care and quality that goes into the manufacture of every product that bears our name. With proper care and maintenance your Adimals™ Fingertip Pediatric Pulse Oximeter will provide many years of dependable service.

Device Description and Intended Use

This device is intended for medical diagnostic purposes only. It is used to indirectly measure the functional oxygen saturation (SpO2) of a pediatric patient's blood. It is intended for use on fingers with a thickness of 7.64mm - 11.19mm (.3" to .44"). This is the distance between the fingernail (top), and the finger pad (bottom). Functional oxygen saturation refers to the ratio of oxyhemoglobin to all hemoglobin that is capable of carrying oxygen. This oximeter is not intended for continuous monitoring. The pulse oximeter requires no routine calibration or maintenance other than replacement of batteries.

Pulse oximetry combines the principles of optical plethysmography and spectrophotometry to determine arterial oxygen saturation values. Optical plethysmography uses light absorbance technology to reproduce waveforms produced by pulsating blood. Spectrophotometry uses various wavelengths of light to perform quantitative measurements about light absorption. Photoelectric Oxyhemoglobin Inspection Technology is combined with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelengths of light (660nm glow and 940nm near infrared light) can be focused onto the human nail tip through a finger-tip sensor. These two LED's are chosen because the light absorption varies with the oxygen concentration of hemoglobin in these frequencies. The pulse amplitudes of the red and near infrared signals are detected using photoelectric sensors and run through a microprocessor which converts the readings to numerical values.

Contraindications

- The patient suffers from significant levels of dysfunctional hemoglobins (such as carbonxy-hemoglobin or methemoglobin).
- Intravascular dyes such as indocyanine green or methylene blue have been injected into the patient.
- Used in the presence of high ambient light (ie, direct sunlight). Shield the sensor area with a surgical towel if necessary.
- There is excessive patient movement.
- The patient experiences venous pulsations.
- The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
- The patient is in cardiac arrest or is in shock.
- Patients have fingernail polish or false fingernails as they may cause inaccurate SpO2 readings.

Symbol Definitions

Symbol	Definition
	Important Warning/Caution
	Not made with natural rubber latex
	Equipment type is BF
% SpO_2	Hemoglobin Saturation
BPM	Heart Rate (BPM)
	Refer to Instruction Manual/Booklet

Symbol	Definition
	Low Power Indication
	Not for Continuous Monitoring
	Authorized European Represenative's Information
	Manufacturer's Information
SN	Serial Number

General Warnings ⚠

A warning statement in this manual identifies a condition or practice which, if not corrected or discontinued immediately, could lead to patient injury, illness, or death.

⚠ **WARNING:** Before use, carefully read the manual.

⚠ **WARNING:** Do not use the pulse oximeter in an MRI or CT environment.

⚠ **WARNING:** The operation of Pulse Oximeter may be affected by the use of an electrosurgical unit (ESU).

⚠ **WARNING:** Federal law restricts this device to sale by or on the order of a physician or licensed healthcare practitioner.

⚠ **WARNING:** The pulse oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.

⚠ **WARNING:** Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.

⚠ **WARNING:** This product may contain a chemical known to the state of California to cause cancer, birth defects, or other reproductive harm.

⚠ **CAUTION: Do not use the pulse oximeter in an explosive atmosphere.**

⚠ **CAUTION:** SpO2 and pulse rate data is displayed for informational purposes only and does not constitute a diagnosis or medical advice of any kind. Only a qualified healthcare professional should interpret the data obtained on this device.

⚠ **CAUTION:** Check the pulse oximeter sensor application site frequently to determine the positioning of the sensor and circulation and skin sensitivity of the patient.

⚠ **CAUTION:** The pulse oximeter is not for continuous monitoring.

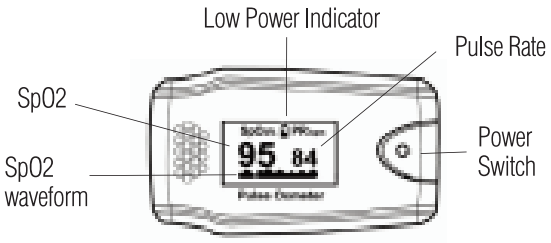
⚠ **CAUTION:** Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.

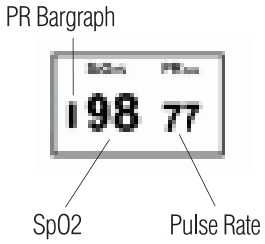
⚠ **CAUTION:** Inaccurate measurements may be caused by autoclaving, ethylene oxide sterilizing, or immersing the sensors in liquid.

⚠ **CAUTION:** The device should not be used on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.

⚠ **CAUTION:** Do not use this pulse oximeter in situations where alarms are required. This device has no alarm.

Brief Description of Front Panel





The PR Bar graph displays corresponding with the patient's pulse beat. The height of the bar graph shows the patient's pulse strength.

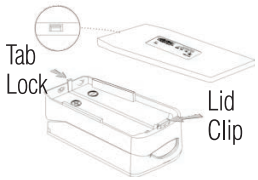
Included Pulse Oximeter Accessories

- One (1) lanyard
- Two (2) AAA batteries
- One (1) user manual
- One (1) Safety Bumper
- One (1) Carry Case

Battery Installation

1. Remove battery compartment lid, by pushing in, the "Tab Lock" located in the small window using a pointed object and lift lid upward.
2. Insert two AAA batteries into battery compartment being sure to observe the correct polarities.
3. Replace the battery cover by hooking lid on "Lid Clip" then snap opposite end downward until tab lock closes securely (Figure 1)

Note: Be sure to observe correct battery polarity. Failure to do so might damage the device. If device will not be used for an extended period of time, remove batteries. Replace batteries when low battery symbol appears on display. Always replace BOTH batteries at the same time.



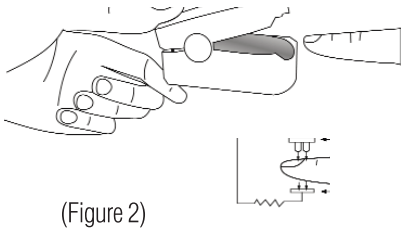
(Figure 1)

Operating Instructions

1. Be sure to insert two AAA batteries before attempting to operate.
2. Clean inside surface of oximeter and patient's finger with 70% isopropyl alcohol before use.
3. Squeeze the end opposite the power switch between the thumb and forefinger in order to open the device (there is a textured surface on the battery cover side to facilitate grip). (Figure 2)
4. Insert patient's finger, nail side up into the device. (Be sure to fully insert the patient's finger so that the sensors are completely covered by the finger.) Index or middle finger is recommended.
5. Release the device allowing it to clamp down on the patient's finger.
6. Press the power switch on the front (top) panel to activate.
7. Have patient keep still for optimal accuracy.
8. Depending upon environmental and patient conditions, the device will begin to display readings in about 4 seconds.
9. Note readings on the display.
10. Remove the patient's finger from the device by squeezing between forefinger and thumb as indicated in Figure 2.
11. The display will indicate finger out.
12. The unit will power off approximately 8 seconds after the patient's finger is removed from the device.

Changing Oximeter Display Mode

There are six different display modes. The display modes alter the orientation of the display to facilitate reading by the observer. Horizontal modes display the pulse wave form along with SPO2 and pulse rate while vertical modes display a pulse rate bar graph along with the SPO2 and pulse rate readings.



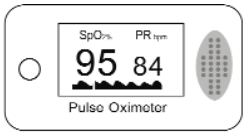
(Figure 2)

To alter the display mode:

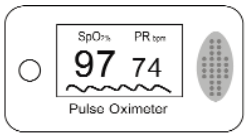
After the unit is powered on each brief press of the power switch will cycle through to the next display mode in the sequence shown.

Note: The default setting is display mode 1.

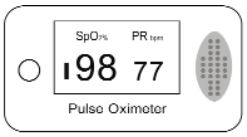
Display Mode Cycle



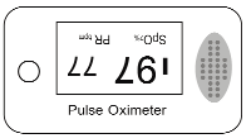
Normal Horizontal
Wave Display
(Default Setting)



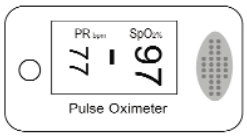
Normal Horizontal
Wire Display
(2nd click)



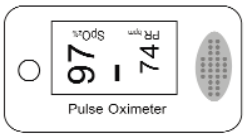
Normal Horizontal
(3rd click)



Handstand Horizontal
(4th click)



Normal Vertical
(5th click)



Handstand Vertical
(6th click)

Changing the Display Brightness (10 adjustable brightness settings)

To change the brightness setting:

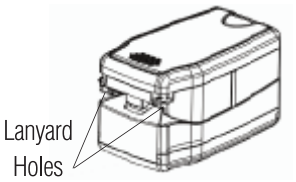
After the unit is powered on, depress and hold the power switch (for 2 seconds), the brightness will then change by degrees. There are 10 levels of brightness.

Note: The default setting is level 4.

Lanyard Attachment

1. Thread thinner end of the lanyard through the hanging hole at either side of the device.
2. Thread thicker end of the lanyard through the threaded end before pulling it tightly.

Note: Unclasping the lanyard connector will facilitate threading thicker end through threaded loop.



Care and Maintenance

- Replace the batteries promptly when low voltage indicator appears.
- Clean surface of the fingertip and oximeter with 70% isopropyl alcohol before it is used in diagnosis of patients.
- Remove the batteries if unit will not be operated for extended period of time.
- It is best to store this product in a place where ambient temperature is -20°C -55°C (-4°F -131°F) and humidity is < 93%.
- It is recommended that the product should be kept in a dry environment at all times.
- Please follow local ordinances when disposing of batteries.

Cleaning the Pulse Oximeter

Clean the rubber touching the finger inside of the oximeter with a soft dampened cloth with 70% isopropyl alcohol, and clean the test finger using alcohol before and after each test.

Note: Do not pour or spray any liquids onto the oximeter, and do not allow any liquids to enter any openings in the device. Allow the oximeter to dry thoroughly before reusing.

Troubleshooting Solutions

Problem	Possible Reason	Solution
SpO2% or pulse rate do not display normally.	1. Finger is not inserted correctly. 2. Patient SpO2 value is too low to be measured.	1. Retry inserting the finger. 2. There is excessive illumination. 3. Measure more times. If you determine the product is working correctly, see your healthcare provider for an exact diagnosis.
SpO2% or pulse rate is shownunstably.	1. Finger might not be inserted deep enough. 2. Excessive patient movement.	1. Retry inserting the finger. 2. Sit calmly and retry.
The monitor cannot be powered on.	1. No battery or low battery power. 2. Battery not installed correctly. 3. The monitor may be damaged.	1. Replace battery. 2. Remove and reinstall battery. 3. Contact customer service center.
Indication is suddenly off.	1. The Oximeter is automatically powered off, when no signal was detected after 8 seconds. 2. Battery power is too low to operate.	1. Normal. 2. Replace batteries.
“Err 3” or “Err 4”	1. Low Power. 2. Recieving tube being shielded or damaged together with broken connector. 3. Mechanical Misplace for recieve-emission tube. 4. Amp Circuit malfunction	1. Change batteries. 2. Return to Service Center 3. Return to Service Center 4. Return to Service Center
“Err 7”	1. Low Power 2. Emission tube damaged 3. Current control circuit malfunction	1. Change batteries. 2. Return to Service Center 3. Return to Service Center

Guidance and Manufacturer's Declaration—Electromagnetic Emissions

Guidance and Manufacturer's declaration - electromagnetic emission.
The Pulse Oximeter is intended for use in the electromagnetic environment specified below.
The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.

Emission Test	Compliance Level	Electronic Environment Guidance
RF Emissions CISPR11	Group 1	The PULSE OXIMETER uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR11	Class B	The PULSE OXIMETER is suitable for use in all establishments,including domestic establishments and those directly connected to the public low-voltage power supply, network that supplies buildings used for domestic purposes.

Technical Specifications

Display Type: OLED Display
SPO2 display range: 70-100%
PR Display Range: 30-235 BPM
PR Display Mode: Bargraph
Data Update Time: < 15 s

LED Wavelengths

Red: 660nm
Infrared: 940nm

Measurement range:

SPO2: 70-100% - 100% ±3%; s 70% no definition
Pulse Rate: 30-235 BPM, ±2 bpm during the pulse rate range of 30-99 bpm and ±2% during the pulse rate range of 100-235 bpm.
Accuracy: ±2% on the stage of 80%-100% ±3% on the stage of 70%-79%
Accuracy: ±2 BPM or ±2% (larger)
Pulse Intensity: Bargraph Indicator
Power Requirements: Two AAA alkaline Batteries
Power consumption: Less than 40mA

Low power indication:

Battery Life: (2) "AAA" 1.5V, 600mAh alkaline batteries could be continuously operated as long as 30 hours.

Dimension:

Length: 1.9" (50mm)
Width: 1.1" (28mm)
Height: 1.1" (28mm)
Weight: 1.2 - 1.7oz. (35 - 50g) (Including 2 AAA batteries)

Environment:

Operation Temperature: 41°F - 104°F (5°C - 40°C)
Storage Temperature: -4°F - 131°F (-20°C - 55°C)
Relative Humidty: 15%-80% in operation / 10%-80% in storage

Finger Range: .3" - .44" (7.64mm-11.19mm)

Standards

Declaration: EMC of this product comply with IEC60601-1-2 standard.

Measurement Performance in Low Perfusion Condition: required the test equipment (BIO-TEK INDEX Pulse Oximeter tester) the pulse wave is available without failure when the simulation pulse wave amplitude is at 6%.

Interference Resistance Capacity against Ambient Light: Device works normally when mixed noise produced by BIO-TEK INDEX Pulse Oximeter tester.

Warranty

American Diagnostic Corporation (ADC®) warrants its products against defects in materials and workmanship under normal use and service as follows:

1.Warranty service extends to the original retail purchaser only and commences with the date of delivery.

2.Your Pulse Oximeter is warranted for two (2) years from date of purchase (all parts).

What is Covered: Replacement of parts, and labor.

What is Not Covered: Transportation charges to and from ADC®. Damages caused by abuse, misuse, accident, or negligence. Incidental, special, or consequential damages. Some states do not allow the exclusion or limitation of incidental, special, or consequential damages, so this limitation may not apply to you.

To Obtain Warranty Service: Send item(s) postage paid to ADC®, Attn: Repair Dept., 55 Commerce Dr., Hauppauge, NY 11788. Please include your name and address, phone no., proof of purchase, and a brief note explaining the problem.

Implied Warranty: Any implied warranty shall be limited in duration to the terms of this warranty and in no case beyond the original selling price (except where prohibited by law). This warranty gives you specific legal rights and you may have other rights which vary from state to state.

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