Specifications

1. Display Type: **OLED display**

2. SpO_2:

Display range: 0%~100%
Measurement range: 70~100%
Accuracy: 70%~100% ±2 digits; 0%~69% no definition
Resolution: 1%

Note: A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor. Clinical testing is used to establish the SpO_2 accuracy. The measured arterial hemoglobin saturation value (SpO_2) of the sensors is compared to arterial hemoglobin oxygen (SaO_2) value, determined from blood samples with a laboratory CO-oximeter. The accuracy of the sensors in comparison to the CO-oximeter samples measured over the SpO_2 range of 70%~100%. Accuracy data is calculated using the root-mean-squared (Arms value) for all subjects, per ISO 80601-2-61, Medical Electrical Equipment–Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.
A functional tester is used to measure how accurately fingertip pulse oximeter is reproducing the specified calibration curve and the PR accuracy.

3. Pulse Rate:

Display range: 0bpm~250bpm
Measurement range: 30~250BPM
Accuracy: 30bpm~99bpm, ±2bpm; 100bpm~250bpm, ±2% bpm
Resolution: 1bpm

4. Probe LED Specifications:

	Wavelength	Radiant Power
RED	660±3nm	3.2mW
IR	905±10nm	2.4mW

The information about wavelength range can be especially useful to clinicians.

5. Power Requirements:

Two AAA alkaline batteries
Power consumption: Less than 40mA
Battery life: Two AAA 1.5V, 1200mAh alkaline batteries could be continuously operated as long as 24 hours.

6. Dimensions:

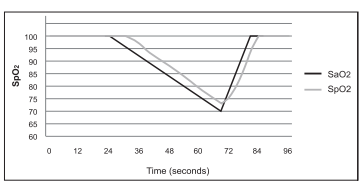
Length: 2.19'' (5.5cm)
Width: 1.13'' (2.9cm)
Height: 1'' (2.5cm)
Weight: 1.76 oz (50g) (including two AAA batteries)

7. Environmental Requirements:

Operation temperature: 41°F~104F (5°C~40°C)
Storage temperature: -13°F~158°F (-25°C~70°C)
Ambient humidity: 15%~93% no condensation in operation; ≤93% no condensation in storage/transport
Atmosphere pressure: 70kPa~106kPa

8. Equipment data update period:

As shown right, the average data update period is 8s.



9. Classification:

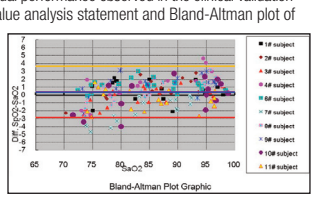
According to the type of protection against electric shock: Internally powered equipment.
According to the degree of protection against electric shock: Type BF Applied Part (applied part: the rubber hole of the device);
According to the degree of protection against ingress of water: IP22
According to the mode of operation: Continuous operation.

Clinical Study Summary

The following details are provided to disclose actual performance observed in the clinical validation study of healthy adult volunteers. The ARMS value analysis statement and Bland-Altman plot of data are shown as follows:

ARMS Value Analysis Statement

Item	90~100	80~<90	70~<80
#pts	78	66	63
Bias	1.02	0.4	-0.48
ARMS	1.66	1.46	1.93



Bland-Altman Plot Graphic

Standards

This equipment complies with IEC 60601-1-2:2014 for electromagnetic compatibility for medical electrical equipment and/or systems.

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 work normally when mixed noise produced by BIO-TEK INDEX Pulse Oximeter tester.

Electromagnetic Compatibility

The device conforms to IEC60601-1-2:2014 Electromagnetic Compatibility (EMC) standard. Essential performance is defined as SpO_2 accuracy and pulse rate accuracy or an indication of abnormal operation. Accuracies may be affected as a result of exposure to electromagnetic disturbances that are outside of the environments listed in the intended use. If issues are experienced, move the device away from the source of electromagnetic disturbances.

Table 1: Electromagnetic Emissions Limits and Compliance

Emissions Test	Compliance
RF Emissions CISPR 11	Group 1, Class B
Note: Harmonics Emissions (IEC 61000-3-2), Voltage Flicker Emissions (IEC 61000-3-3 are not applicable.	

Table 2: Electromagnetic Immunity

Immunity Test	Compliance	
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	
Rated Power Frequency Magnetic Fields IEC 61000-4-8	30 A/m 50 Hz and 60 Hz	
Radiated RF IEC 61000-4-3	80 MHz - 2.7 GHz	10 V/m 80% AM 1kHz
	380 - 390 MHz	27 V/m Pulse mod. 18Hzn
	430 - 470 MHz	28 V/m FM±5Hz deviation 1kHz sine
	704 - 787 MHz	9 V/m Pulse mod. 217Hz
	800 - 960 MHz	28 V/m Pulse mod. 18Hz
	1.7 - 1.99 GHz	28 V/m Pulse mod. 217Hz
	2.4 - 2.57 GHz	28 ZV/m Pulse mod. 217Hz
	5.1 - 5.8 GHz	9 V/m Pulse mod. 217Hz
Note: Electrical Fast Transients (IEC 61000-4-4), Surge (IEC 61000-4-5), Voltage dips (IEC61000-4-1), Conducted Immunity (IEC 61000-4-6) are not applicable.		

Troubleshooting Solutions

Troubleshooting Possible Problems		
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 shown unstably.	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. The battery power is too low to operate.	1. Normal. 2. Replace batteries.
"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

ADC® Adimals® 2150 Pediatric Fingertip Pulse Oximeter

Instructions for Use

AMERICAN DIAGNOSTIC CORPORATION

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 years from date of purchase.

What Is Covered: Replacement of parts, and labor.

What Is Not Covered: Transportation charges to ADC. Batteries where supplied. 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.

To register your product visit us at
www.adctoday.com/support/warranty-registration

FOR QUESTIONS, COMMENTS, OR SUGGESTIONS CALL TOLL FREE:
1-800-ADC-2670
OR VISIT
www.adctoday.com/feedback

This manual is available online in a variety of languages, follow the links for language options.
www.adctoday.com/care

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REF 2150
Model: MD300C52

CE 0123

IB p/n 93-2150-00 rev 10 (8/11/2021)
Printed in China

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 pulse oximeter will provide many years of dependable service.

Device Description and Intended Use

This device is intended for medical diagnostic purposes only. The fingertip pulse oximeter is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate of adult, adolescent and child patients in hospitals, hospital-type facilities and homecare. 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 905nm near infrared light) can be focused onto the human nail tip through a finger-tip sensor. These two LEDs 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 carbonxyhemoglobin 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 (e.g., 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 SpO_2 readings.

Symbol Definitions

Symbol	Definition
⚠	Important warning/caution
LATEX	Not made with natural rubber latex
DEHP	Phthalate free
	Type BP applied part
% SpO_2	Hemoglobin saturation
PRbpm	Pulse rate (BPM)
	Refer to instruction manual/booklet
	Storage temperature and relative humidity
LOT	Lot number
R_x	Rx only

Symbol	Definition
	Low power indication
SpO2	Not for continuous monitoring
EC REP	Authorized European represenative's information
	Manufacturer's information
	Date of manufacture
SN	Serial number
	Recyclable
IP22	Protected against dripping water
?	Indicates the signal is not stable
CE 0123	Meets essential requirements of European Medical Device Directive 93/42/EEC

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.

⚠ **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 30 minutes.

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

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

⚠ **CAUTION:** This equipment complies with IEC 60601-1-2:2014 for electromagnetic compatibility for medical electrical equipment and/or systems. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device.

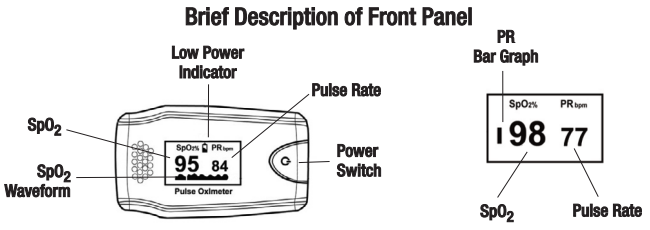
⚠ **CAUTION:** Portable and mobile RF communications equipment can affect medical electrical equipment.

⚠ **CAUTION:** The portable and mobile RF communications equipment should be used no closer than 30cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ **CAUTION:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

⚠ **CAUTION:** When the signal is not stable, the reading may be inaccurate, please do not refer.

Brief Description of Front Panel



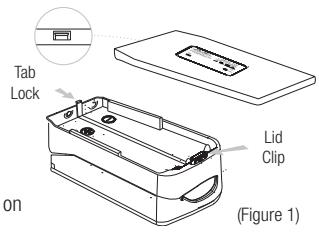
The PR bar graph displays corresponding with the patient's pulse beat.
The height of the bar graph shows the patient's pulse strength.

Included Pulse Oximeter Accessories

- One lanyard
- Two AAA batteries
- One user manual
- One safety bumper
- One carry case

Battery Installation

1. Using a pointed object, remove battery compartment lid by pushing in the tab lock located in the small window and lifting 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 snapping opposite end downward until tab lock closes securely (Figure 1).

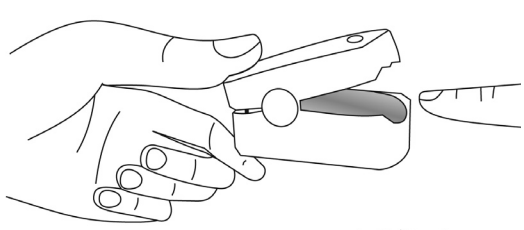


(Figure 1)

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.

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.


(Figure 2)

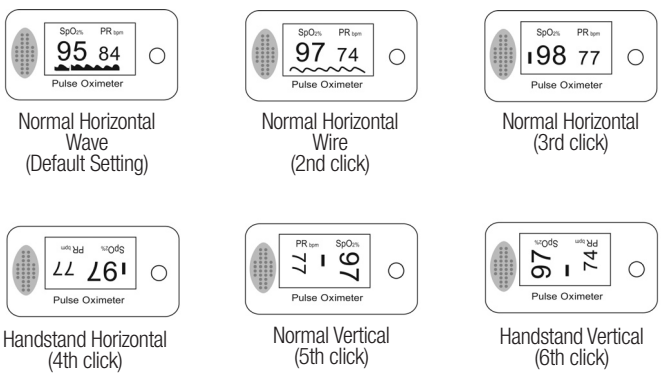
Changing Oximeter Display Mode

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.

To alter the display mode:

1. 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.

Display Mode Cycle



Changing the Display Brightness

There are ten adjustable brightness settings.
To change the brightness setting:

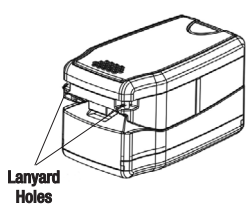
1. After the unit is powered on, press and hold the power switch for 2 seconds. The brightness will then change by degrees.

   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

1. Replace the batteries promptly when low battery indicator appears.
2. Clean surface of the fingertip and oximeter with 70% isopropyl alcohol before using.
3. Remove the batteries if unit will not be operated for extended period of time.
4. Store product in a place where ambient temperature is -13°F -158°F (-25°C -70°C) and humidity is ≤ 93%.
5. The product should be kept in a dry environment at all times.
6. 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.