

Note: Short press the power button to switch the display modes. Take out your finger, the screen displays "Finger out". It means the measurement ending.

Lanyard Attachment

- Thread thinner end of the lanyard through the loop.
- Thread thicker end of the lanyard through the threaded end and pull tightly.



- WARNING:** Keep the pulse oximeter away from young children. Small items such as the battery door, battery, and lanyard are choking hazards.
- WARNING:** Do not hang the lanyard from the device's electrical wire.
- WARNING:** Please notice that the lanyard which is tied to the pulse oximeter may cause strangulation due to excessive length.

Maintenance and Storage

- Replace the batteries in a timely manner when low battery indicator is displayed.
- Clean surface of the pulse oximeter before it is used in diagnosis for patients.
- Remove the batteries if the pulse oximeter will not be used for an extended period of time.
- It is best to store the product in -13°F - 158°F (-25°C - 70°C) and ≤93% humidity.
- Store in a dry place. Excessive moisture may shorten the pulse oximeter's lifespan and cause damage.
- Dispose of battery properly; follow any applicable local battery disposal laws.

Cleaning the Pulse Oximeter

- Clean and disinfect the silicone that touches the finger inside the device with a soft, damp cloth using 70% isopropyl or 70% ethanol alcohol before and after each use.
- Do not pour or spray any liquids onto the pulse oximeter, and do not allow any liquids to enter any openings in the device. Allow the device to dry thoroughly before reusing.

CAUTION: Never use EtO (ethylene oxide) or formaldehyde for disinfection.

Troubleshooting

Problem	Possible Reason	Solution
SpO ₂ or pulse rate do not display normally.	<ol style="list-style-type: none"> Finger is not inserted correctly. Patient's SpO₂ value is too low to be measured. 	<ol style="list-style-type: none"> Retry inserting the finger. There is excessive illumination. Take multiple measurements. If you determine the product is working correctly, consult your healthcare provider for an accurate diagnosis.
SpO ₂ or pulse rate is shown unstably.	<ol style="list-style-type: none"> Finger might not be inserted deep enough. Excessive patient movement. 	<ol style="list-style-type: none"> Retry inserting the finger. Sit calmly and retry.
The pulse oximeter cannot be powered on.	<ol style="list-style-type: none"> No battery or low battery power. Battery not installed correctly. The pulse oximeter may be damaged. 	<ol style="list-style-type: none"> Replace the batteries. Remove and reinstall batteries. Contact ADC customer service.
Display suddenly powers off.	<ol style="list-style-type: none"> The pulse oximeter is automatically powered off, when no signal was detected after 8 seconds. The battery power is too low to operate. 	<ol style="list-style-type: none"> Normal. Replace the batteries.
"Err 7" is displayed on screen	Err 7 means all the emission LED or reception diode is damaged.	1. Contact ADC customer service.

Electromagnetic Compatibility

The device conforms to IEC60601-1-2 Electromagnetic Compatibility (EMC) standard. Essential performance is defined as SpO₂ 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: Harmonic Emissions (IEC 61000-3-2, Voltage flicker Emissions (IEC 61000-3-3) are not applicable.	

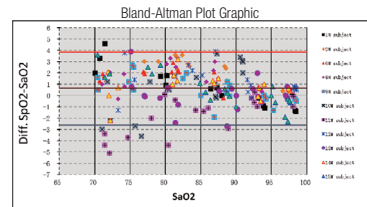
Table 2: Electromagnetic Immunity		
Immunity Test	Compliance	
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air	
Rated Power Frequency Magnetic Fields IEC 61000-4-8	30 A/m 50 Hz and 60 Hz	
Radiated RF IEC 61000-4-3	80 MHz – 2.7 GHz	10 V/m 80% AM 1kHz
	380 – 390 MHz	27 V/m Pulse mod. 18Hz
	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 V/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 (IEC 61000-4-11), Conducted Immunity (IEC 61000-4-6) are not applicable.		

Table 3: Electromagnetic Immunity		
Immunity Test	Modulation	Immunity
0 kHz ^{a)}	CW	8
134.2 kHz	Pulse modulation ^{b)} 2, 1 KHz	65 ^{c)}
13.56 MHz	Pulse modulation ^{b)} 50 kHz	7, 5 ^{c)}
^{a)} This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the home healthcare environment. ^{b)} The carrier shall be modulated using a 50% duty cycle square wave signal. ^{c)} r.m.s., before modulation is applied.		

Clinical Study Summary

The summary of the clinical study report: The subject demographics included a total of 111 subjects, 6 females and 5 males. The subject ages ranged from 20 to 42 years. The subject weights ranged from 115 to 154 lbs (52 to 70kg). The subject height ranged from 5'1" to 5'9" (154 to 176cm). The skin tones represented in the study were as follows: one subject with a light skin tone typical of Caucasians, three subjects with darker pigmentation, and the remaining subjects with yellow skin tones of Asian origins. 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 to the right:

ARMS Value Analysis Statement					
Item	70-100	90-100	80-<90	70-<80	
#pts	225	89	81	55	136.00
Bias	0.62	0.10	1.10	0.76	0.96
ARMS	1.75	0.96	1.93	2.35	2.11



Technical Specifications

Display Type	LCD display
Equipment Data Update Period	The average data update period is 12.4 seconds.
Probe LED Specifications	RED Wavelength: 660±3nm Radiant Power: 3.2mW IR Wavelength: 905±10nm Radiant Power: 2.4mW NOTE: The information about wavelength range can be especially useful to clinicians.
Power Requirements	Two AAA alkaline Batteries Power consumption: Less than 70mA Battery Life: Two AAA 1.5V, 1,200mAh alkaline batteries could be continuously operated as long as 20 hours.
Environment Requirements	Operation Temperature: 32°F–104°F (0°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
NOTE:	When the ambient temperature is 68°F (20°C), it is required 6 hours for the equipment to warm from the minimum storage temperature or 4 hours to cool from the maximum storage temperature between uses until it is ready for its intended use.
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
SpO ₂	Display range: 0%–100% Measurement range: 70%–100% Accuracy: 70%–100% ±2%; 0%–69% no definition Resolution: 1%
Pulse Rate	Display range: 30bpm–250bpm Measure range: 30bpm–250bpm Accuracy: 30bpm–99bpm, ±2bpm; 100bpm–250bpm, ±2% Resolution: 1bpm
Perfusion Index	Display range: 0.1%–20% Measure range: 0.3–20.0% Resolution: 0.1%

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 SpO₂ accuracy. The measured arterial hemoglobin saturation value (SpO₂) of the sensors is compared to arterial hemoglobin oxygen (SaO₂) 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 SaO₂ 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 Pulse Oximeter is reproducing the specified calibration curve and the PR accuracy. The model of functional tester is Index2 FLUKE simulator and the version is 2.1.3. Pulse oximeter equipment measurements are statistically distributed, only about two-thirds of pulse oximeter equipment measurements can be expected to fall within Arms of the value measured by a co-oximeter.

ADC® Diagnostix™ 2100 Fingertip Pulse Oximeter

Instructions for Use



Warranty

ADC® warrants its products against defects in materials and workmanship under normal use and service as follows:

- Warranty service extends to the original retail purchaser only and commences with the date of delivery.
- Your pulse oximeter is warranted for two years from date of purchase.

What Is Covered: Replacement of parts, and labor.

What Is Not Covered: Batteries where supplied. 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.

To register your product visit us at
www.adctoday.com/register

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OR SUGGESTIONS CALL TOLL FREE:

1-800-ADC-2670

OR VISIT

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ADC® Fingertip Pulse Oximeter

Thank you for purchasing an ADC Diagnostix™ brand fingertip 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 Diagnostix fingertip pulse oximeter will provide many years of dependable service.

Device Description and Intended Use

The 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, child and infant patients in hospitals, hospital-type facilities and homecare. The device is not intended to be used under motion and low perfusion. It is designed for finger thickness between 0.8cm and 2.2cm (0.3 inches to 0.9 inches).

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 red light and 905nm infrared-red light) can be focused onto the human nail tip through a fingertip 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.

The device has a service life of five years when used for 15 measurements per day, with each measurement lasting approximately 10 minutes.

Contraindications

None found.

Symbol Definitions

Symbol	Definition	Symbol	Definition
	Important warning/caution		Not for continuous monitoring, no SpO ₂ alarm
	Type BF applied part		Not made with natural rubber latex
% SpO ₂	Oxygen saturation		Phthalate free
	Heart rate (BPM)		Date of manufacture
	Follow instructions for use		Serial number
	Storage temperature and relative humidity		Batteries and electronic devices must be disposed of in accordance with the locally applicable regulations, not with domestic waste
	Lot number		Protected against solid objects >12.5mm and vertically falling water drops when tilted up to 15° from normal position
	Perfusion Index		Prescription use only
	Low power indicator		Catalog number
	Medical device		

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: The device must be able to measure the pulse properly to obtain an accurate SpO₂ measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO₂ measurement. For example, measurement during motion, mental stress, tiredness, cardiac disease, arrhythmia, severe anemia.

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

WARNING: This equipment complies with IEC 60601-1-2 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.

WARNING: The patient is an intended operator. The patient can safely use all functions of the device.

WARNING: Certain activities may pose a risk of injury, including strangulation if the lanyard should become wrapped around your neck. Use the lanyard with caution.

WARNING: It may be unsafe to: use accessories, detachable parts and materials not described in the instructions for use; interconnect this equipment with other equipment not described in the instructions for use; disassemble, repair or modify the equipment.

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

CAUTION: 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: Portable and mobile RF communications equipment (e.g. mobile phone, interphone, Radio) can affect medical electrical equipment. 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: This equipment is not intended for use during patient transport outside the healthcare facility.

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

CAUTION: In order to ensure correct sensor alignment and skin integrity, the maximum application time at a single site for our device should be less than half an hour.

CAUTION: The material of the device has no natural latex.

CAUTION: The pulse oximeter equipment is calibrated to display functional oxygen saturation.

CAUTION: The waveform we provided is normalized.

CAUTION: Do not modify this equipment without authorization of the manufacturer.

CAUTION: Aging infrared-ray detector or insufficient battery level may affect the equipment performance. Please follow the instructions in the manual to maintain the device.

CAUTION: Certain activities may pose a risk of injury, including strangulation, if lanyard should become wrapped around your neck.

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: Do not use the pulse oximeter in situations where alarms are required. The device has no alarms. It is not for continuous monitoring.

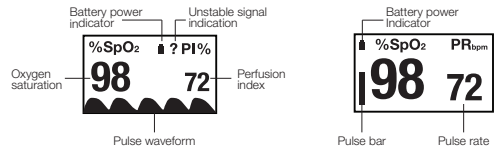
CAUTION: Do not sterilize the device using autoclaving, ethylene oxide sterilizing (a professional sterilization gas), or immersing the device in liquid. The device is not intended for sterilization.

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

Causes of Inaccurate Measurements

- Significant levels of dysfunctional hemoglobin (such as carbonyl-hemoglobin or methemoglobin).
- Any tests recently performed on you that required the injection of Intravascular dyes such as indocyanine green or methylene blue.
- High-frequency electrosurgical interference and defibrillators.
- Apply the pulse oximeter to the same arm as a blood pressure cuff, arterial catheter or infusion line(s).
- The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
- High ambient light. Shield the sensor area, if necessary.
- The patient is in cardiac arrest or is in shock.
- Fingernail polish and/or artificial nails.
- Weak pulse (low perfusion).
- Low hemoglobin.
- Moisture in the device and residue in the light path.
- Venous pulsations.
- Excessive patient movement.
- Finger thickness is outside recommended size range.

Description of Front Panel



Notes: The signal indication “?” displayed on the screen means the signal inadequacy. Keep your hands still and retry.

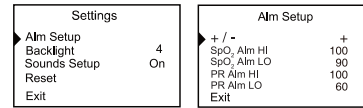
When the battery is empty, the battery icon will blink. Please replace the batteries.

Included Pulse Oximeter Accessories

- Carry lanyard
- 2 AAA batteries
- Rubberized bumper
- Instruction booklet

Settings

1. Turn on the device. Press and hold the power button to enter the Settings interface.
2. Press the power button to select the item on the menu; press and hold the power button to switch the options of the item.



ALM Setup	When “ALM” is selected; press and hold the power button to enter the submenu. Press the power button to select “+/-”; press and hold the power button to switch to “+” or “-”. Press the power button to select the parameter; press and hold the power button to switch the value of the parameter (high limit SpO ₂ range is 71%~100%; low limit SpO ₂ range is 70%~99%; high limit PR range is 35bpm~250bpm; low limit PR range is 30bpm~245bpm). Default limits: SpO ₂ High 100%, low 90%; PR High 100bpm, low 60bpm. SpO ₂ increment: 1; PR increment: 5. When the measurement exceeds the limit, the reading flashes. Press the power button to select Exit; press and hold the power button to return to the main menu.
Backlight	The backlight level is adjustable from 1~10. The default level is 4.
Sounds Setup	The sound setup is ON by default. In that case, when the measurement exceeds the limit, the sound “didi-didi” will be heard.
Reset	When “Reset” is selected, press and hold the power button to choose “Yes”, all settings become defaults.
Exit	When “Exit” is selected, press and hold the power button to go back to the measurement interface.

Note: The device automatically returns to the measurement interface from the setting interface 8 seconds later if no operation is detected. The device will start at the settings used when it was last turned off.

Battery Installation

1. Slide the battery door cover horizontally along the PUSH arrow.
2. Install two AAA batteries into the battery compartment, observing correct polarity.
3. Close the battery door cover by pushing the cover against the PUSH arrow, towards the finger measurement entry.

Note: If the polarities are not matched, damage may be caused to the pulse oximeter. Remove the batteries if the pulse oximeter will not be used for an extended period of time. Replace the batteries when low battery symbol appears on the 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 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.
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 8 stable pulse beats.
9. Note readings on the display.
10. Remove the patient's finger from the device by squeezing between forefinger and thumb as indicated.
11. The display will indicate finger out.
12. The unit will power off approximately 10 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.

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. The default setting is display mode 1.

Display Mode Cycle

