

ADC[®] 2200 Advantage[™] Fingertip Pulse Oximeter



Directions for Use

ADC[®]
AMERICAN DIAGNOSTIC CORPORATION

ADC® Fingertip Pulse Oximeter

Thank you for purchasing an ADC Advantage™ Fingertip Pulse Oximeter. We're proud of the care and quality that goes into the manufacture of every product that bears our name. The ultra-portable Advantage™ 2200 will give you information about oxygen saturation (the amount of oxygen in the blood) and pulse rate at your fingertip. The 2200 is easy to use and needs no routine maintenance except battery replacement. This User's Guide explains how to use and care for your Advantage™ 2200.

Contents of this Package

Advantage™ 2200
Two "AAA" batteries
Lanyard
User Guide

Intended use

The Advantage™ 2200 is intended to measure blood oxygen saturation (%SpO₂) – the amount of oxygen in your blood - and pulse rate. It is designed for use on fingers (not the thumb) with a thickness of .31" to .79" (8mm to 20mm), this is the distance between the fingernail (top) and finger pad (bottom). The index finger is most recommended. This device is intended for sport and aviation purposes only.

Contraindications:

- The patient suffers from significant levels of dysfunctional hemoglobins (such as carboxy-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.

General Warnings

WARNING: Keep the Advantage™ 2200 away from young children. Small items such as the battery cover, battery, and lanyard are choking hazards.

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: Explosion hazard: Do not use the pulse oximeter in an explosive (oxygen enriched) environment.

CAUTION: Only a healthcare professional is qualified to interpret SpO₂ measurements. This device is NOT intended to replace regular medical checkups.

CAUTION: It is recommended that your physician review your procedure for using this device.

CAUTION: SpO₂ readings obtained by this device should be verified before prescribing or making adjustments to any medications. Under no circumstances should YOU alter the dosages of any drugs

prescribed by your doctor.

CAUTION: Excessive movement of the Advantage™ 2200 during measurement may cause inaccurate readings. Limit finger movement as much as possible when using the device.

CAUTION: The Advantage™ 2200 is not intended for continuous monitoring.

CAUTION: Do not place the Advantage™ 2200 on the same hand/arm when using a blood pressure monitor.

CAUTION: The Advantage™ 2200 has NO alarms. It will not sound if the amount of oxygen in your blood is low or if the pulse rate is too high or too low.

CAUTION: The Advantage™ 2200 readings may be adversely affected in the presence of high ambient light. Shield the device if necessary.

CAUTION: Do not immerse the Advantage™ 2200 in liquid or clean with agents that are not listed in this User's Guide.

CAUTION: Any of the following conditions may reduce the performance of the Advantage™ 2200:

- Very bright or flickering light
- Weak pulse
- Low hemoglobin
- Arterial catheters
- Nail polish and/or artificial nails
- Any tests recently performed on you that required the injection of intravascular dyes

CAUTION: The Advantage™ 2200 may not function if you have poor circulation. Rub your fingers to increase circulation or try an alternate finger if you are having trouble obtaining readings.

CAUTION: Batteries can leak or explode if used or disposed of improperly. Remove the battery if the Advantage™ 2200 will not be used for more than 30 days.

CAUTION: Do not use the Advantage™ 2200 outside the specified operating and storage temperature ranges.

CAUTION: Do not use the Advantage™ 2200 for more than 30 minutes without relocating the device to another finger.

CAUTION: Do not tamper with the Advantage™ 2200.

CAUTION: Radios, cell phones or other similar devices may affect the Advantage™ 2200 and should be kept at least 7 feet away from the device.

CAUTION: Use in emergency vehicles with communication systems may affect the accuracy of the Advantage™ 2200.

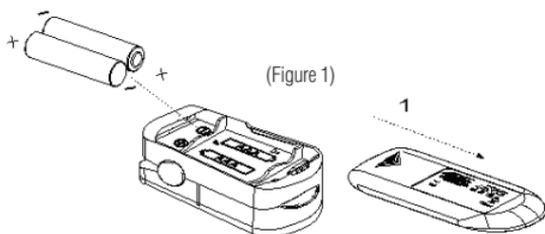
CAUTION: Field strengths from fixed transmitters (radio, phone base stations, AM/FM radio or TV broadcast towers) may affect the accuracy of the Advantage™ 2200.

CAUTION: Follow local ordinances and recycling instructions regarding disposal or recycling of the Advantage™ 2200 including batteries.

CAUTION: The Advantage™ 2200 is a precision electronic instrument and must be serviced by ADC's service department.

Battery Installation (figure 1)

1. Slide off battery cover in direction of arrow.
2. Put the two AAA batteries into battery compartment by observing correct polarity.
3. Slide the battery cover on by reversing Step #1.



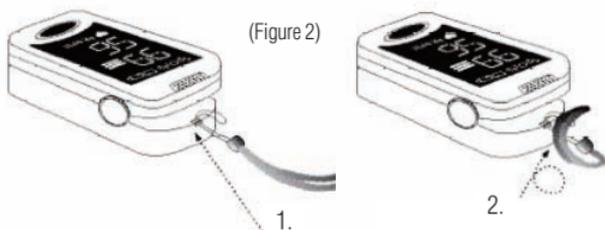
(Figure 1)

Note:

- Battery polarity should be observed to prevent damage to the device.
- When battery is low, the battery indicator symbol on the display will flash. Replace low battery as soon as possible. Remove battery if the device will not be used for more than 30 days.

Strap Installation (figure 2)

1. Thread thinner end of the strap through the loop.
2. Thread thicker end of the strap through the threaded end before pulling it tightly.



(Figure 2)

Operation Instructions (figure 3)

1. Hold the Advantage™ 2200 with the display screen facing toward you as shown in Figure 3. Gently squeeze the hinged end and insert one finger into the device fully. Release hinged end to allow device to clamp down onto finger. Be sure finger is fully inserted. (When your finger is inserted into the device, your nail surface must be facing the same side as the display.)
2. Press the power button on the front panel once.
3. Remain still while taking a measurement and avoid applying pressure to the clamped device while in use.
4. The device will display a reading once it has had a moment to begin measurement.

Note:

- The rubber inside the Oximeter that touches the finger may be cleaned with alcohol.
- For best results, keep the Advantage™ 2200 chest level.
- The index (pointer) finger is recommend
- While on the finger, do not press the Advantage™ 2200 against any surface and do not squeeze it or hold the device.
- The internal spring provides the correct pressure. Additional pressure may affect readings.

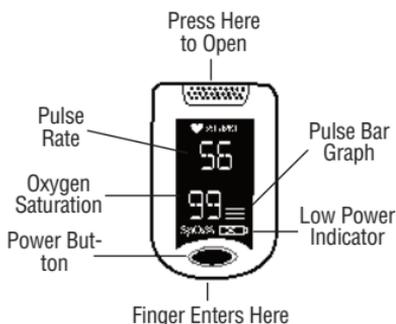


(Figure 3)

Reading Your Results

After measurement begins, you will see three pieces of information displayed on your pulse oximeter:

- A pulse bar graph display corresponding with your pulse beat will be shown. The height of the bar graph shows your pulse strength.
- Your pulse rate will be displayed as BPM or beats per minute.
- The amount of oxygen in your blood will be displayed as SpO2%.



Changing Directions of the Display

When you first power on the unit, the display will orient it with the numbers facing the person wearing the device. The display can be re-orientated to face the other direction, if desired.

To change the direction of the display, press the power button while the unit is displaying a reading.

Note: By default, the unit will always display the readout facing the wearer.

Maintenance and Storage

- When the low power indicator comes on, you must replace the batteries.
- The surface of the pulse oximeter that comes into contact with your finger should be kept clean.
- When storing the pulse oximeter for more than 30 days, remove the batteries.
- When storing the pulse oximeter, ensure that the temperature is between -4°F to 131°F (-20°C to 55°C) with a relative humidity greater than or equal to 93%.
- Store the pulse oximeter in a dry environment. Exposure to moisture may decrease the lifespan of your device.
- Batteries should be disposed of in accordance with local and state laws.

Cleaning the Pulse Oximeter

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

Detailed Description of Product Functions

1. Display Type:	LED	Battery Life:	Two AAA 1.5V, 600mAh alkaline Could continuously operate for 30 hrs.
2. SpO2:		5. Dimensions:	
Measurement range:	70-99%	Length:	2.19" (5.5cm)
Accuracy:	80%-99%, ±2%; 70%-80%, ±3%; ≤ 69% no definition.	Width:	1.13" (2.9cm)
3. Pulse Rate:		Height:	1" (2.5cm)
Measure range:	30-235 BPM	Weight:	1.76oz. (50g) (including two AAA batteries)
Accuracy:	30-99BPM, ±2BPM; 100-235BPM, ±2%	6. Environment Requirements:	
Pulse Intensity:	Bar Graph Indicator	Operation Temperature:	41°F-104°F (5°C - 40°C)
4. Power Requirements:	Two (2) AAA alkaline Batteries	Storage Temperature:	-4°F to 131°F (-20°C - 55°C)
Power consumption:	Less than 40mA	Ambient Humidity:	
Low power indication:		Operation:	±80%, non-condensing
		Storage:	±93%, non-condensing

Troubleshooting

Problem	Possible Reason	Solution
SpO ₂ or pulse rate cannot be shown normally	<ol style="list-style-type: none"> 1. Finger is not inserted correctly. 2. Oxyhemoglobin value is too low to be measured 	<ol style="list-style-type: none"> 1. Re-insert/re-position finger 2. Ensure that sensor is clean and not blocked 3. Try taking a reading on a different finger or warm your finger by rubbing.
SpO ₂ or pulse rate is shown unstably	<ol style="list-style-type: none"> 1. Finger might not be inserted deep enough. 2. Excessive patient movement. 	<ol style="list-style-type: none"> 1. Re-insert/re-position finger. 2. Sit calmly and retry.
The Oximeter cannot be powered on	<ol style="list-style-type: none"> 1. No battery or low battery power. 2. Battery not installed correctly. 3. The Oximeter may be damaged. 	<ol style="list-style-type: none"> 1. Replace battery. 2. Remove and reinstall battery. 3. Contact customer service center.
Display suddenly powers off.	<ol style="list-style-type: none"> 1. The Oximeter is automatically powered off, when no signal was detected after 8 seconds. 2. Low battery strength. 	<ol style="list-style-type: none"> 1. Replace the batteries 2. Re-insert/re-position finger
"Err 3" or "Err 4"	<ol style="list-style-type: none"> 1. Low Power. 2. Mechanical device error near sensor 	<ol style="list-style-type: none"> 1. Replace the batteries. 2. Return to Service Center
"Err 7"	<ol style="list-style-type: none"> 1. Low Power 2. Oximeter is damaged 	<ol style="list-style-type: none"> 1. Change batteries. 2. Return to Service Center

Symbol Definitions

The following symbols are associated with your Advantage™ 2200

	The equipment type is BF		Low Power Indication
	Refer to user manual before use		Manufacturing Date
% SpO ₂	Hemoglobin saturation		Conforms to EU Standards
● PR BPM	Heart Rate (BPM) Beats per Minute		Not for continuous monitoring

Limited 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 one (1) year 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.

Declaration: This product complies with the IEC60601-1-2 standard. The user-contacting materials are non-toxic and comply with ISO10993-1, ISO10993-5 and ISO10993-10.

Guidance and Manufacturer's Declaration- Electromagnetic emissions for all EQUIPMENT and SYSTEMS

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.



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