ADC® 2200 Advantage™ Pulse Oximeter

Instructions for Use

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 Pulse Oximeter
- Two AAA batteries
- Lanyard
- Instructions for Use

Intended Use

The Advantage 2200 is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO_2) and Pulse Rate of adult, adolescent and child patients in hospitals, hospital-type facilities and homecare.

The device is not intended to be used under low perfusion. It is designed for finger thickness between 0.8 cm and 2.2 cm (0.3 in to 0.9 in).

The use life of the device is five years when it is used for 15 measurements every day and 10 minutes per one measurement.

Contraindications

None found.

Symbol Definitions

The following symbols are associated with your Advantage 2200

Symbol	Definition
	Type BF applied part
IP22	Protected against solid objects >12.5mm and vertically falling water drops when tilted up to 15° from normal position
♡ /Min	PR bmp
SpO₂	Not for continuous monitoring, no SpO_2 alarm
	Storage temperature and relative humidity
	Unstable signal indication
	Date of Manufacture
	Follow instructions for use
℞ Only	Prescription use only

Symbol	Definition
	Important warning/caution
%SpO2	Oxygen saturation
	Low power indication
	Batteries and electronic devices must be disposed of in accordance with the locally applicable regulations, not with domestic waste
NATEX	Not made with natural rubber latex
NO DEHP	Phthalate free
SN	Serial number
LOT	Lot number
REF	Catalog number
MD	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:** 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:** Do not use the pulse oximeter in an MRI or CT environment.

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

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

⚠ **CAUTION:** Operation of the pulse oximeter may be affected by the use of an electrosurgical unit.

⚠ **CAUTION:** The device must be able to measure the pulse properly to obtain an accurate SpO_2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO_2 measurement.

⚠ **CAUTION:** Do not sterilize the device using autoclaving, ethylene oxide sterilizing, or immersing the device in liquid. The device is not intended for sterilization.

⚠ **CAUTION:** The presence of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and various environments may cause high levels of interference. Such interference, whether due to proximity or signal strength, could affect the performance of this device.

⚠ **CAUTION:** Portable and mobile RF communication equipment (e.g., mobile phones, phone base stations, radios) may interfere with medical electrical equipment. To prevent potential performance degradation, such equipment should be kept at least 12 inches (30 cm) away from all parts of the device.

⚠ **CAUTION:** This equipment is not intended for use during patient transport outside the healthcare facility.

⚠ **CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

⚠ **CAUTION:** Only a healthcare professional is qualified to interpret SpO_2 measurements. This device is NOT intended to replace regular medical checkups.

⚠ **CAUTION:** SpO_2 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:** The pulse oximeter is not intended for continuous monitoring.

⚠ **CAUTION:** This pulse oximeter 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 pulse oximeter 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 pulse oximeter will not be used for more than 30 days.

⚠ **CAUTION:** Do not use the pulse oximeter outside the specified operating and storage temperature ranges.

⚠ **CAUTION:** Do not tamper with the pulse oximeter.

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

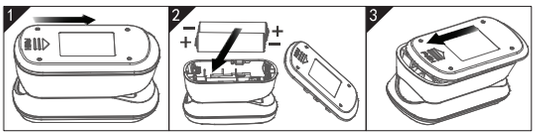
⚠ **CAUTION:** The Advantage 2200 is a precision electronic instrument and must be serviced by ADC's service department.

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.

Battery Installation

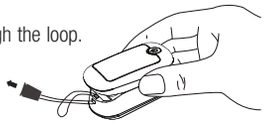
1. Slide off battery cover in direction of arrow.
2. Put the two AAA batteries into battery compartment, observing correct polarity.
3. Close the battery door cover by pushing the cover against the PUSH arrow, towards the finger measurement entry.



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.

Lanyard Installation

1. Thread thinner end of the strap through the loop.
2. Thread thicker end of the strap through the threaded end and pull tightly.

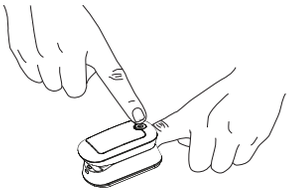


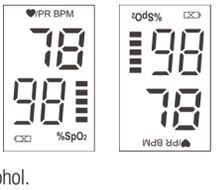
⚠ **WARNING:** Do not hang the lanyard from the device's electrical wire.

⚠ **WARNING:** Please notice that the lanyard which is tied to the oximeter may cause strangulation due to excessive length.

Operation Instructions

1. Hold the Advantage 2200 with the display screen facing toward you as shown below. 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 with nail surface facing up, toward 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.





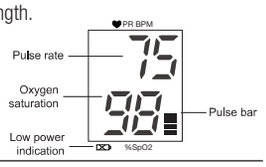
Note:

- Short press the power button to switch the display mode.
- The rubber inside the oximeter that touches the finger may be cleaned with alcohol.
- For best results, keep the Advantage 2200 at heart or chest level.
- The index (pointer) finger is recommended.
- 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.

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. The height of the bar graph shows your pulse strength.
- Pulse rate, displayed as **BPM** or beats per minute.
- The amount of oxygen in your blood, displayed as **%SpO$_2$.**



Changing Display Orientation

Upon powering on the device, the display will automatically orient itself with the numbers facing the wearer. If desired, the display can be adjusted to face the opposite direction. To change the display orientation, press the power button while the device is displaying a reading.

Note: By default, the device presents the readings oriented towards the wearer.

Maintenance and Storage

- Replace the batteries when the low battery indicator is displayed.
- Keep the surface of the pulse oximeter that contacts your finger 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 -13°F to 158°F (-25°C to 70°C), relative humidity ≤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 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.

Specifications

Display Type:	**LED 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: 30mA~70mA **Battery Life:** Two AAA 1.5V, 1,200mAh alkaline batteries could be continuously operated as long as 18 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
SpO2	Display range: 0%~100% Measurement range: 70%~100% Accuracy: 70%~100%±2%; ≤69% no definition Resolution: 1%
Pulse Rate	Display range: 30bpm~250bpm Measure range: 30bpm~250bpm Accuracy: 30bpm~99bpm, ±2bpm; 100bpm~250bpm, ±2% Resolution: 1bpm
Dimensions	Length: 2.19'' (5.5cm) Width: 1.13'' (2.9cm) Height: 1'' (2.5cm)

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 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.

Clinical Study Summary

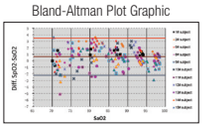
The summary of the clinical study report: The subject demographics included a total of 11 subjects, 6 females and 5 males. The subject ages ranged from 20 to 42 years. The subject weights ranged from 115 to 154 lbs (52 to 70kg). The subject height ranged from 5'1" to 5'9" (154 to 176cm). The skin tones included in the study were as follows: one subject with light skin tone of Caucasians, three subjects with dark 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 as follows:

ARMS Value Analysis Statement

Item	70-100	90-100	80-<90	70-<80	70-<90
#pts	225	89	81	55	136.00
Bias	0.64	0.45	1.12	0.23	0.76
ARMS	1.57	1.12	1.79	1.83	1.81

Bland-Altman Plot Graphic



Electromagnetic Compatibility

The device conforms to IEC60601-1-2 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. 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 (IEC61000-4-11), Conducted Immunity (IEC 61000-4-6) are not applicable.		

Table 3: Electromagnetic Emissions Limits and Compliance

Frequency Test	Modulation	Immunity Test Level (A/m)
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.

Troubleshooting

Problems	Possible reason(s)	Solution(s)
SpO$_2$ or pulse rate cannot be shown normally	1. Finger is not inserted correctly 2. Oxyhemoglobin value is too low to be measured	1. Reinsert / reposition finger 2. Ensure that the sensor is clean and not blocked, or that there is no excessive illumination. 3. Try taking a reading on a different finger or warm your finger by rubbing
SpO$_2$ or pulse rate is shown unstably	1. Finger might not be inserted deep enough 2. Excessive movement during measurement	1. Reinsert / reposition finger 2. Remain still during measurement
The pulse oximeter cannot be powered on	1. Low battery strength 2. Batteries installed incorrectly 3. The pulse oximeter might be damaged	1. Replace batteries 2. Reinstall the batteries 3. Contact ADC Customer Service
Display suddenly powers off.	1. The product is automatically powered off when no signal is detected for longer than 8 seconds 2. Low battery strength	1. Reinsert / reposition finger 2. Replace the batteries
"Err7" is displayed on screen	1. Low power 2. Pulse oximeter is damaged	1. Replace batteries 2. Contact ADC Customer Service

Limited Warranty

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 year from date of purchase (all parts).

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/support/warranty-registration

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

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