ABC, Inc.

Operator's Manual

EZ-Arm®

Wrist Oximeter

CE 0123

CAUTION! Federal law (USA) restricts this device to sale by or on the order of a physician.
CAUTION! Read this entire manual carefully before using the EZ-Arm.

The information in this manual has been checked carefully and is believed to be accurate. In the interest of continued product development, ABC, Inc. reserves the right to make changes and improvements to this manual and the products it describes at any time, without notice or obligation.

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Precautions for Use

Read and follow all safety instructions before using the EZ-Arm.

Contraindications

- Do not use the EZ-Arm in a magnetic resonance imaging (MRI) environment.
- Explosion Hazard: Do not use the EZ-Arm in an explosive atmosphere or in the presence of flammable anesthetics or gases.

Warnings

- The EZ-Arm is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
- General operation of the EZ-Arm might be affected by the presence of an electrosurgical unit (ESU).
- As with all medical equipment, carefully route patient cables and connections to reduce the possibility of patient entanglement or strangulation.
- Use the EZ-Arm only within the specified temperature ranges: +32°F to +122°F (0°C to 50°C) for operating, and 14°F to 122°F (-10°C to +50°C) for storage and transportation.

- Use only ABC-manufactured pulse oximeter sensors. These sensors are manufactured to meet the accuracy specifications for ABC products. Using other manufacturers' sensors can result in improper product performance.
- Discontinue use of adhesive tape strips if the patient exhibits an allergic reaction to the adhesive material.
- Do not stretch the adhesive tape while applying the sensor.
- Ensure that the wrist band fits comfortably on the patient's arm. Do not over-tighten the wrist band.
- Product readings might be affected while patients are being defibrillated.
- This device should not be used adjacent to other equipment. If adjacent use is necessary, the device should be observed carefully to verify normal operation.
- The use of accessories, sensors, and cables other than those listed in this manual may result in increased emission and/or decreased immunity of this device.

Cautions

- Federal law (USA) restricts this device to sale by or on the order of a physician.
- Read this entire manual carefully before using the EZ-Arm.
- Before using any sensor, carefully read the Directions for Use.
- Do not, under any circumstances, perform any testing or maintenance on the EZ-Arm while it is being used to monitor a patient.
- Verify that all visible indicators appear during the start-up sequence. If any indicator does not appear, do not use the EZ-Arm. Contact ABC Customer Support for assistance.
- This equipment complies with International Standard EN 60601-1-2:2001 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. 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. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information specified in this manual.

- Portable and mobile RF communications equipment can affect electrical equipment.
- If the EZ-Arm fails to respond as described, refer to “Troubleshooting” or discontinue use until the situation has been corrected by qualified personnel.
- Do not remove any covers other than the battery cover when replacing batteries. There are no user-serviceable parts inside.
- Batteries might leak or explode if used or disposed of improperly.
- Follow local governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
- Do not immerse the EZ-Arm or sensors in water or any other liquids.
- Do not place or pour liquids on top of the EZ-Arm.
- The EZ-Arm is a precision electronic instrument. It must be repaired by trained ABC, Inc. personnel only.
- Check the application site frequently to determine the positioning of the sensor and the circulation and skin sensitivity of the patient. Patient sensitivity varies depending on medical status or skin condition.
- This device has not been tested for immunity to electromagnetic disturbances.
- Some nail polish colors or artificial nails can reduce light transmission and affect SpO2 accuracy.

Unpacking and Inspecting the EZ-Arm

Contact the carrier immediately if the shipping carton for the EZ-Arm is damaged. Confirm that the items listed below are packed with the EZ-Arm:

- EZ-Arm Wrist Oximeter
- Two 1.5V Alkaline N-cell Batteries
- EZ-Arm Operator's Manual
- Reusable Fingerclip Sensor
- 1 Reusable Wristband

Using the EZ-Arm

Indications for Use

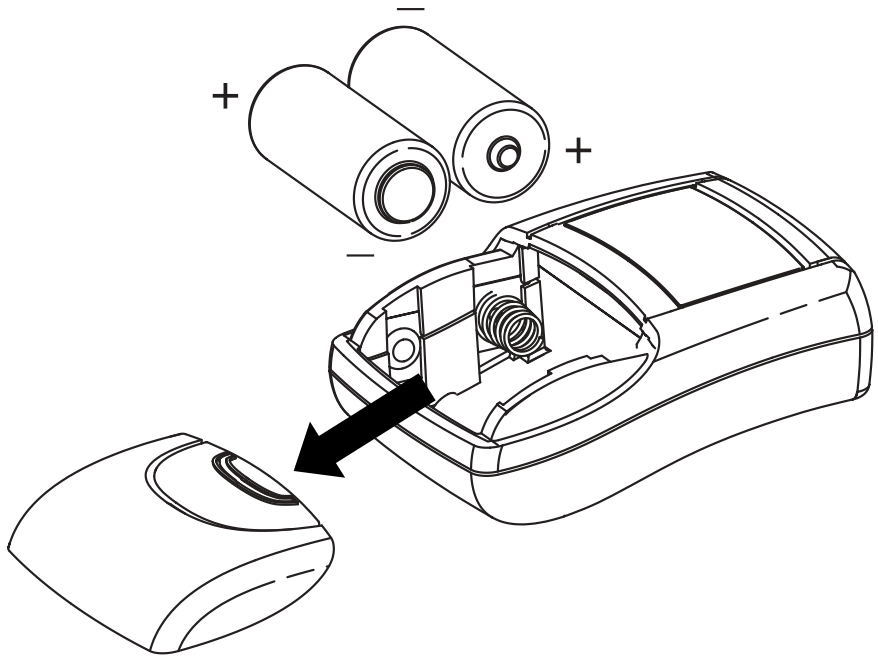
The ABC, Inc. EZ-Arm® is a small, wrist-worn device indicated for use in measuring, displaying, and storing functional saturation of arterial hemoglobin and pulse rate. It may be used for spot-checking and/or data collection and recording of adult and pediatric patients in hospitals, medical facilities, ambulatory, subacute, and sleep study environments.

WARNING! Do not use the EZ-Arm when alarms are required!

The EZ-Arm comes packaged in Spot Check mode. In Spot Check mode, inserting a finger in the sensor turns on the EZ-Arm automatically, and removing a finger turns off the EZ-Arm automatically. Advanced memory and programming features are only available with ABC, Inc.'s Beur® software. See "Accessing Advanced Features" to learn more about using the EZ-Arm with Beur software.

Installing the Batteries

1. Use your thumb to loosen the lower front cover of the EZ-Arm, and carefully remove the battery door by sliding it downward.



2. Remove the old batteries and discard or recycle them according to local governing ordinances.
3. Insert two new 1.5V alkaline N-cell batteries. *Correct battery positioning is essential for proper operation.*
4. Carefully re-position the battery door. Do not force the door into place; it fits only when positioned properly.
5. If the EZ-Arm does not turn on when a sensor is plugged into the unit, reinsert the batteries or refer to “Troubleshooting.”

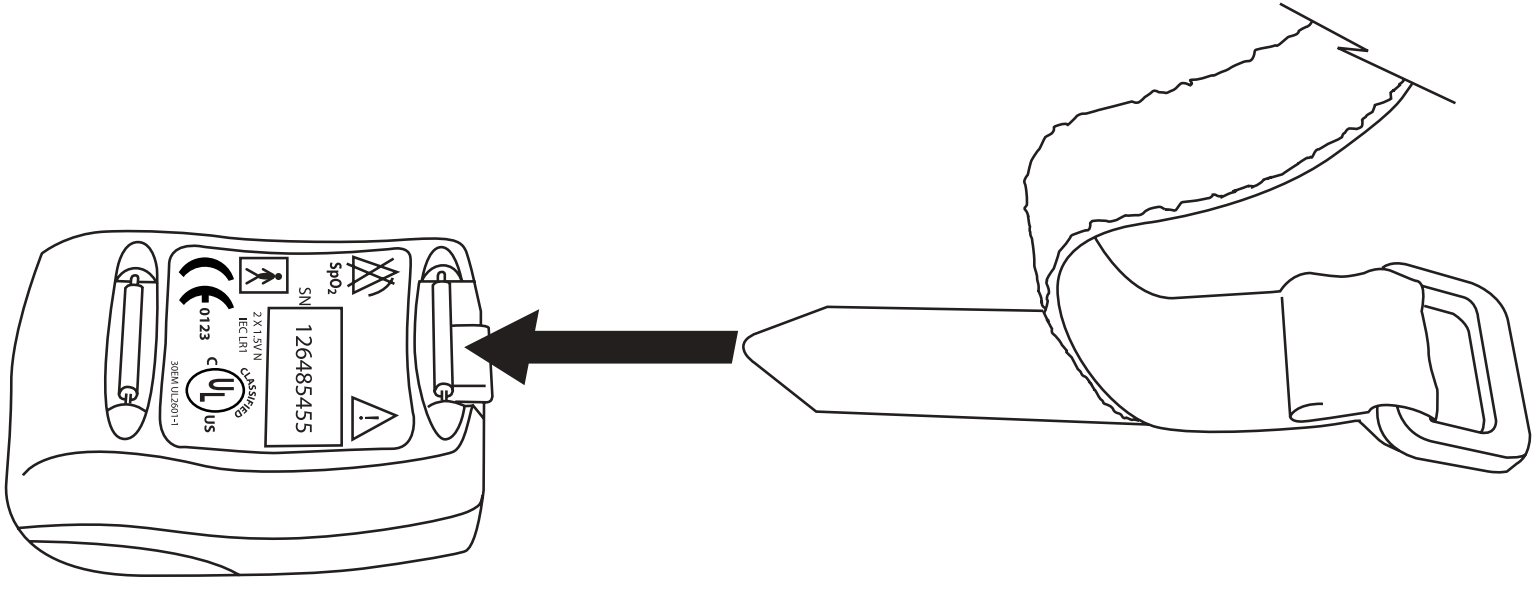
Important Notes about Battery Use

The Battery Indicator will begin to flash approximately 30 minutes before entering critical battery mode. *In critical battery mode, the EZ-Arm no longer monitors or records patient data.* Replace low batteries as soon as possible.

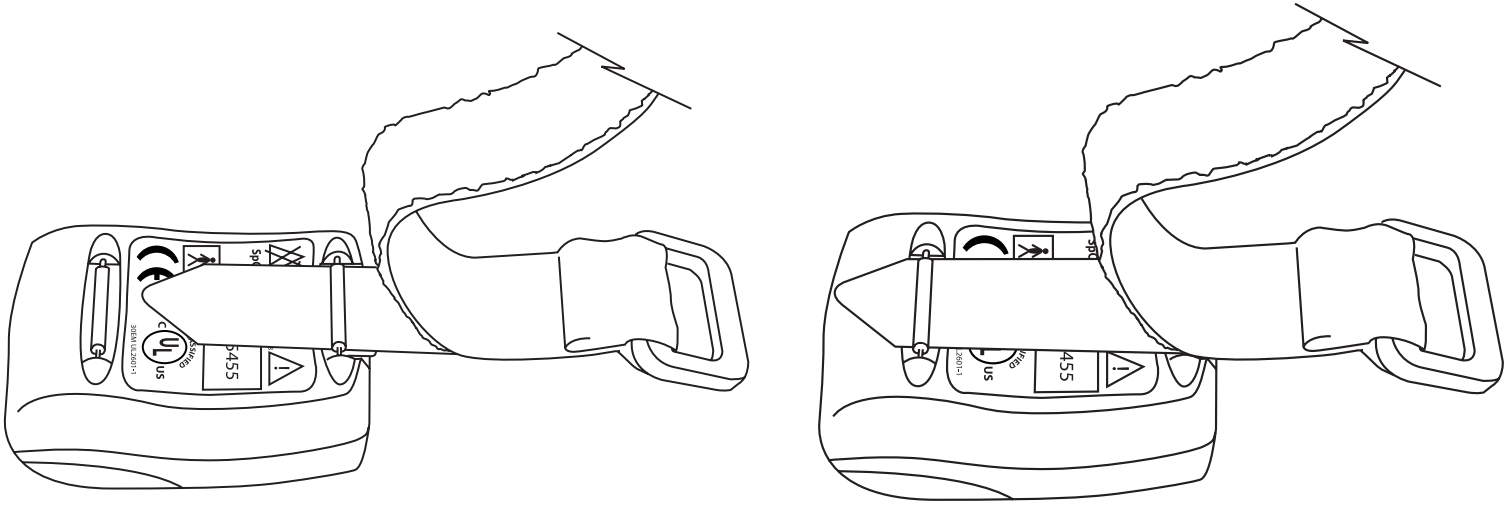
NOTE: The EZ-Arm contains non-volatile memory, so removing or replacing batteries will not affect the data stored in EZ-Arm memory. Stored data will remain in memory until overwritten by newer data or cleared from memory with Beur software.

Setting Up the EZ-Arm and Attaching the Sensor

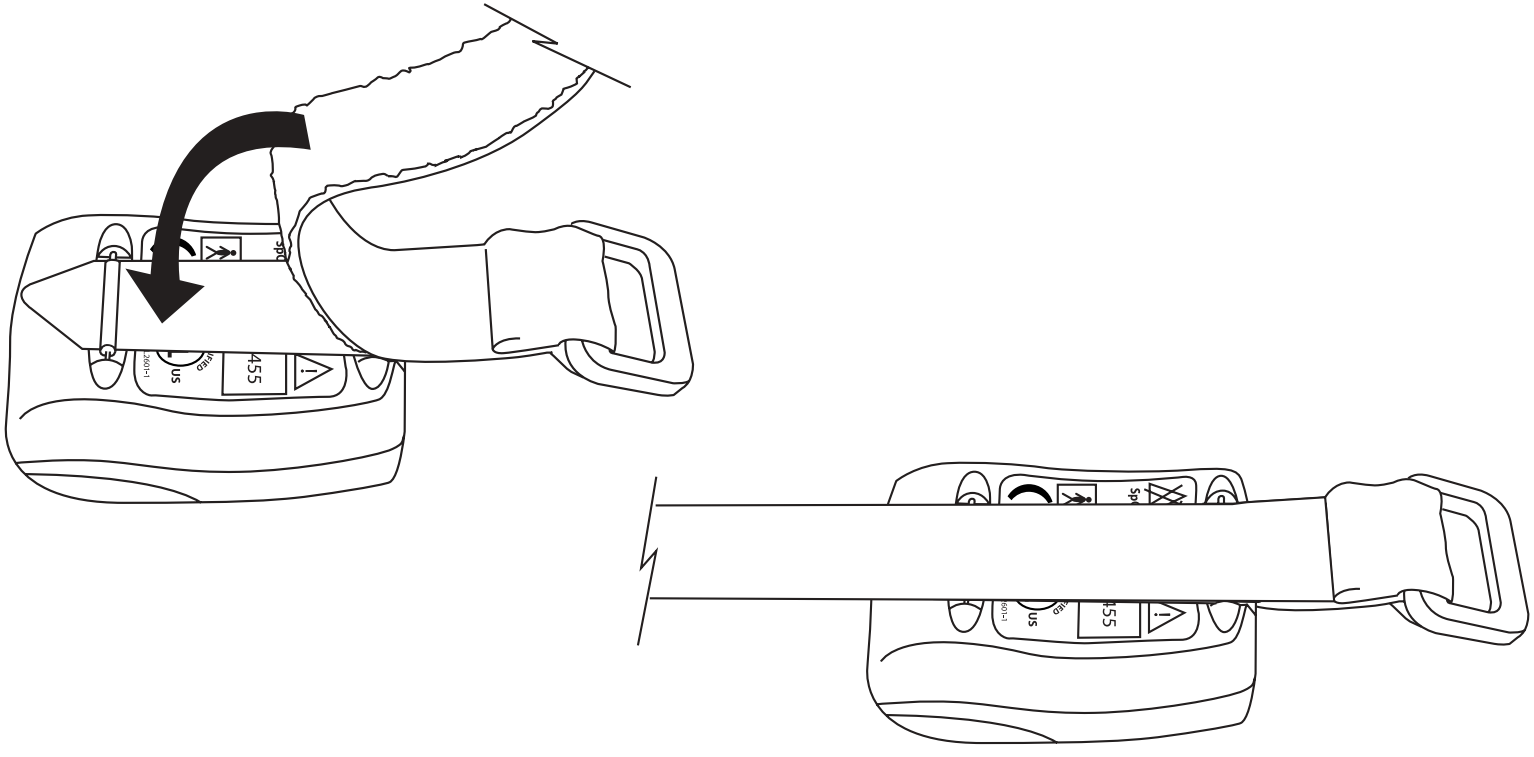
Use this procedure to thread the wrist strap, attach the sensor, and begin taking readings.



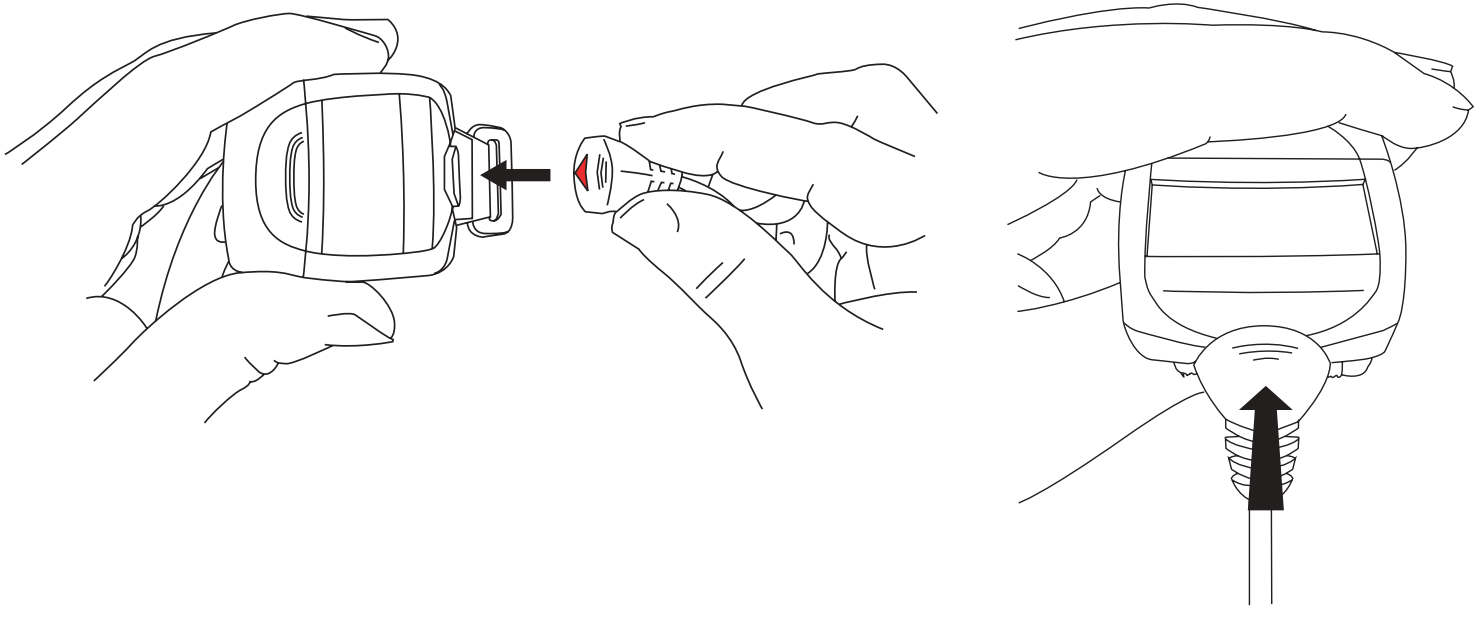
1. Begin threading the short segment of the wrist strap through the spring bars on the rear of the EZ-Arm. As illustrated above, the spring bar near the top of the EZ-Arm should be threaded first.



2. Continue threading the wrist strap until it is pulled securely through both spring bars on the rear of the EZ-Arm.

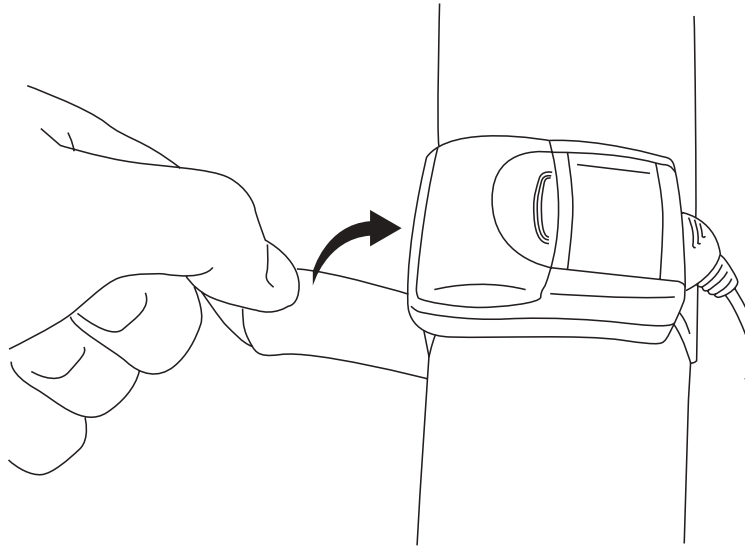


3. Press the long segment of the wrist strap securely against the already-threaded strap. The EZ-Arm is now securely mounted on the wrist strap.



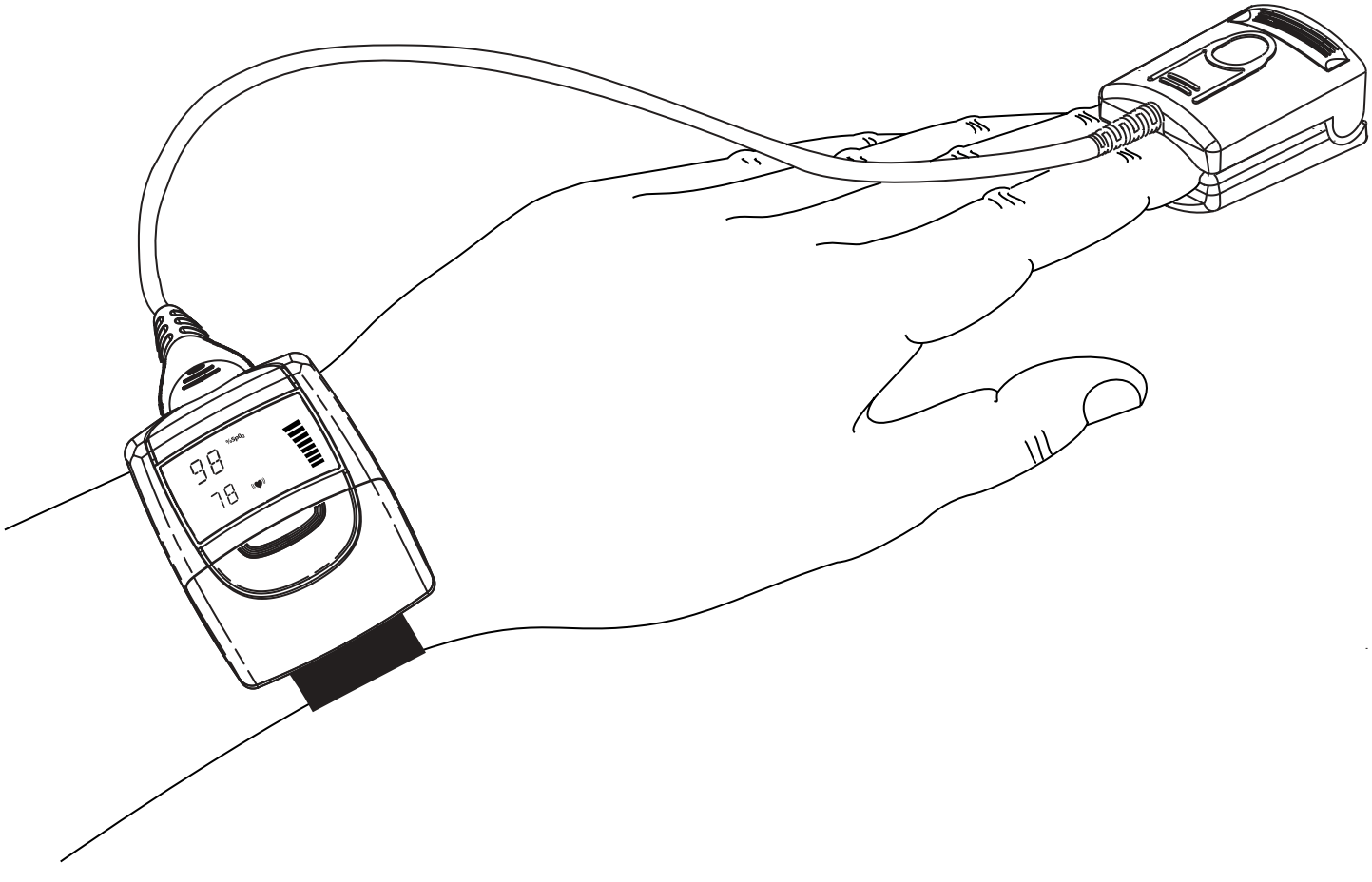
4. Plug the sensor into the connector at the top of the EZ-Arm, ensuring that all indicators appear during the first phase of the startup sequence.

NOTE: When the sensor is completely connected, the red triangle on the sensor connector should not be visible.



5. Apply the wrist band securely and comfortably around the patient's wrist.
6. Place the patient's finger inside the sensor. Refer to the respective sensor instructions for specific information about placement and patient safety.

NOTE: In Spot Check mode (default), the patient finger acts as the ON/OFF switch. See "Accessing Advanced Features" for more information about other modes that are available with the EZ-Arm.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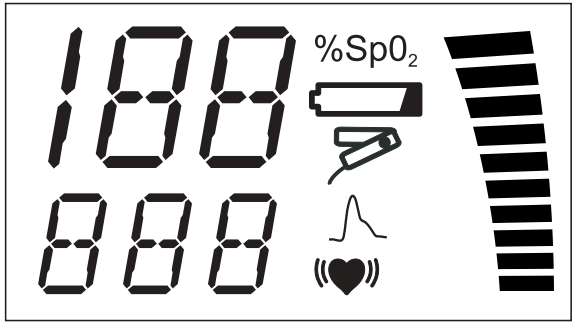
Verifying EZ-Arm Operation

The EZ-Arm performs an automatic startup (initialization) sequence and self-test when a sensor is plugged in. Verify that all indicators display during the first phase of the startup sequence. If any indicator is not displayed, do not use the EZ-Arm. Contact ABC, Inc. Customer Support for assistance.



NOTE: If the device cannot track the pulse or finger removal is not detected, the EZ-Arm will shut off automatically after 3 minutes.

System Features

%SpO_2 Display

Numeric indicators on the upper left-hand corner of the EZ-Arm display blood saturation in percent (indicated by the %SpO_2 icon).

Pulse Rate Display

The pulse rate display is the lower numeric display on the left side of the EZ-Arm (identified by the symbol). This 3-digit indicator display shows the pulse rate in beats per minute.

Sensor Indicator

The Sensor Indicator indicates when a sensor has become disconnected, has failed, or has not been applied correctly.

Pulse Strength Bargraph Indicator

This 10-segment bargraph indicates pulse strength as determined by the oximeter. The height of the Pulse Strength Bargraph is proportional to the pulse amplitude.

Pulse Quality Indicator

This Indicator blinks to indicate a poor pulse. If there is a sustained series of poor pulses (approximately 10 seconds), the Pulse Quality Indicator will display solid.

Battery Indicator

Any time the EZ-Arm batteries are low or critical, this Indicator blinks, providing early warning to replace them. After critical battery capacity is met, the display turns off and monitoring is stopped.

Numeric Indicators

Numeric Indicators appear after an %SpO_2 or pulse rate reading is complete, providing results of the measurement.

Accessing Advanced Features

To access additional modes of operation and advanced features for the EZ-Arm, Beur software is required. Beur is a flexible and convenient data management and oximetry screening tool that allows users to record, transfer, analyze, report, and archive patient data. Beur is compatible with many ABC products.

NOTE: Data is stored in the EZ-Arm regardless of which mode the device is in.

Using the EZ-Arm with Beur Software

The EZ-Arm can be used with Beur® software to set various features and options according to user needs. A EZ-Arm accessory package, which includes Beur software and a computer cable, is available from ABC, Inc..

The following advanced settings can be programmed in EZ-Arm with Beur software:

- Date
- ID
- Display Options
- Time
- Patient Data Storage Rate
- Activation Options

In addition, information about device model number, revision, and parameters can be retrieved; patient data can be downloaded and stored; EZ-Arm memory can be cleared; and the EZ-Arm date and time can be synchronized to the date and time of the computer.

Full and Partial Display modes are also programmable with Beur software. Partial Display mode can be used if visible %SpO_2 and pulse rate data might add to patient anxiety in longer-term studies. In Partial Display mode, %SpO_2 and pulse rate data are not displayed on the EZ-Arm, but the Pulse Strength Bargraph is still visible.

Activation Options

The EZ-Arm features Spot Check mode, Sensor Activation mode, and Programmed mode.

Spot Check Mode

Spot Check mode is the EZ-Arm default activation setting. In Spot Check mode, inserting a finger in the sensor turns ON the EZ-Arm automatically, and removing a finger turns OFF the EZ-Arm automatically. In this mode, the sensor can be left attached (plugged in) to the EZ-Arm.

NOTE: If the device cannot track the pulse or finger removal is not detected, the EZ-Arm will shut off automatically after 3 minutes.

Sensor Activation Mode

Sensor Activation mode can be selected with Beur software. In this mode, connecting and disconnecting the sensor from the EZ-Arm functions like an ON/OFF switch (whether or not a finger is in the sensor). In Sensor Activation mode, the EZ-Arm shuts off automatically after 30 minutes of no use or invalid pulse detection.

NOTE: When the EZ-Arm shuts off automatically after 30 minutes, the sensor must be unplugged and then reattached in order to turn on the EZ-Arm.

Programmed Mode

In Programmed mode, the EZ-Arm turns on and off at user-defined intervals that are selected using Beur software. Programmed mode allows users to select up to three start and stop times and dates. *The sensor must be connected in order for Programmed mode to function.*

NOTE: In Programmed mode, the EZ-Arm turns on and off ONLY at pre-programmed intervals. The device cannot be used at unprogrammed times until exiting Programmed mode with Beur software.

Connecting the EZ-Arm to a Computer

To use the EZ-Arm with Beur software, a EZ-Arm-compatible computer cable is needed. This cable can be connected to a computer for data downloading and editing with Beur software. Use the instructions below to connect the EZ-Arm to a computer:

1. Connect the cable to the appropriate COM port on the computer.
2. Plug the cable to the top of the EZ-Arm.
3. Wait until “CP” appears in the EZ-Arm display. The EZ-Arm is now ready for use with Beur software.
4. For more information about capturing and saving data, refer to Beur software’s online help.

NOTE: When the cable is connected completely and securely, the red triangle on the cable connector should not be visible.

Memory Features

The EZ-Arm collects and stores up to 33 hours of SpO_2 and pulse rate information with a 4-second data storage rate. When the memory fills up, the unit begins overwriting the oldest data with the new data. Each time the EZ-Arm is turned on, data are automatically collected in memory.

NOTE: Only recording sessions longer than one minute are stored.

Each time the EZ-Arm is turned on, the current oximeter time and date (if the clock is set properly) are stored in memory to allow quick differentiation of recording sessions. Patient SpO_2 and pulse rate are stored every four seconds (default), or every one or two seconds if programmed using Beur software (version 5.0 or greater). The saturation values are stored in 1% increments in the range of 0 to 100%.

NOTE: Storage rates do not affect battery life; however, data storage capacity is reduced when using a 1- or 2-second storage rate.

Using a 2-second storage rate, data storage capacity is reduced to approximately 16 hours. Using a 1-second storage rate, data storage capacity is reduced to approximately 8 hours.

The stored pulse rate ranges from 18 to 300 pulses per minute. The stored values are in increments of one pulse per minute in the interval from 18 to 200 pulses per minute, and in increments of 2 pulses per minute in the interval from 201 to 300 pulses per minute.

NOTE: Playing back data in memory does not clear any data from memory.

Cleaning and Storing the EZ-Arm

NOTE: Do not immerse the EZ-Arm in liquid, and do not use caustic or abrasive cleaning agents on the EZ-Arm.

Clean the EZ-Arm separately from its associated sensors. For instructions regarding cleaning sensors, refer to the appropriate sensor package inserts.

Clean the EZ-Arm with a soft cloth dampened with isopropyl alcohol. Do not pour or spray any liquids onto the EZ-Arm, and do not allow any liquid to enter any openings in the device. Allow the EZ-Arm to dry thoroughly before reusing.

Store the EZ-Arm within the stated environmental specifications. See “Specifications” for additional information.

Specifications

OXIMETER SPECIFICATIONS

Oxygen Saturation Range (%SpO_2)	0% to 100%
Pulse Rate Range	18 to 300 pulses per minute
Displays	
Numeric Displays	3-digit Indicators
Pulse Indicator	Pulse Strength Bargraph
Measurement Wavelengths and Output Power	
Red	660 nanometers @ 3 mw nominal
Infrared	910 nanometers @ 3 mw nominal
Altitude	
Operating Altitude	Up to 40,000 feet
Hyperbaric Pressure	Up to 4 atmospheres

SYSTEM SPECIFICATIONS

Temperature	
Operating	+32° to +122°F (+0° to +50°C)
Storage/Transportation	14° to +122°F (-10° to +50°C)
Humidity	
Operating	10% to 90% noncondensing
Storage/Transportation	10% to 95% noncondensing
Battery Life	
Operating	minimum 24 hours of continuous operation
Storage	9 months
Dimensions (without sensor or strap)	2 in H x 1.75 in W x 0.75 in D (5.08 cm H x 4.445 cm W x 1.905 cm D)
Weight	~0.88 oz. without batteries or wrist strap (~24.95 g without batteries or wrist strap)

Parts and Accessories

EZ-CC	EZ-Arm Carrying Case
EZ-OP	Operator's Manual for the EZ-Arm
EZ-COM	Computer cable
	Pulse Oximeter Reusable Sensors
AFCS	Adult Finger Clip Sensor
FAS	Flexible Adult Sensor
	Other Accessories
BEUR	Beur software for Windows® 95/98/00/NT
WRAP	Adult Flexible Sensor Wrap
EZ-WB	10" Reusable Wrist Band (elastic material)
EZ-WBE	5" Reusable Wrist Band Extender for Larger Wrists (elastic material)

For more information about ABC parts and accessories, contact your distributor, or contact ABC, Inc. at (555) 555-2345 (USA and Canada) or (555) 222-1234.

Service and Support

The EZ-Arm performs all computations from internal software stored in microprocessor chips. Thus, there are no critical parts to drift, and no calibration is required.

For information about the EZ-Arm and accessories, contact your sales representative or distributor. For the representative or distributor in your area, contact ABC at (555) 555-1234

Warranty

ABC, Inc. (ABC) warrants to the purchaser the pulse oximetry module of the EZ-Arm for three years from the date of purchase. ABC shall repair or replace any EZ-Arm found to be defective in accordance with this warranty, free of charge, for which ABC has been notified by the purchaser by serial number that there is a defect, provided notification occurs within the warranty period. This warranty shall be the sole and exclusive remedy by the purchaser hereunder for any EZ-Arm delivered to the purchaser that is found to be defective in any manner.

This warranty excludes cost of delivery to and from ABC. All repaired units shall be received by the purchaser at ABC. ABC reserves the right to charge a fee for a warranty repair request on any unit found to be within specifications. The EZ-Arm is a precision electronic instrument and must be repaired by knowledgeable and specially trained ABC personnel only. Accordingly, any evidence of opening the EZ-Arm, field service by non-ABC personnel, tampering, or any kind of misuse of the EZ-Arm shall void the warranty. All non-warranty work shall be done according to ABC standard rates and charges in effect at the time of delivery to ABC.

DISCLAIMER/EXCLUSIVITY OF WARRANTY:

The warranties in this manual are exclusive, and no other warranties of any kind, whether statutory, written, oral, or implied, shall apply.

Troubleshooting

Problem	Possible Cause	Possible Solution
Device won't activate.	Batteries inserted wrong.	Check batteries.
	Batteries are dead.	Replace batteries and try again.
	Sensor is disconnected.	Re-connect sensor and try again.
	EZ-Arm set in Programmed mode.	Use Beur software to reset EZ-Arm in Spot Check or Sensor Activation mode.
No %SpO_2 or pulse rate display.	EZ-Arm set in Partial Display mode.	Use Beur software to reset EZ-Arm in Full Display mode.

Problem	Possible Cause	Possible Solution
No pulse display on bargraph.	Low patient pulse strength.	Reposition or replace finger; keep sensor motionless.
		Remove and re-connect sensor.
	Sensor applied incorrectly.	Refer to sensor instructions to apply sensor correctly.
	Poorly perfused finger.	Reposition or replace finger; keep sensor motionless.
		Warm application site.
	Finger positioned wrong.	Reposition or replace finger; keep sensor motionless.

Problem	Possible Cause	Possible Solution
No pulse display on bargraph, *cont'd*.	Possible interference from: • arterial catheter • blood pressure cuff • electrosurgical procedure • infusion line	Reduce or eliminate interference.
	Reduced circulation from excess pressure on sensor.	Allow hand to rest without squeezing or pressing sensor.
	Excessive ambient light.	Shield sensor from light source.
	Sensor applied to polished or artificial nail.	Apply sensor to finger without fingernail polish or an artificial nail.

Problem	Possible Cause	Possible Solution
No pulse display on bargraph, *cont'd*.	Finger is cold.	Warm the finger.
	Finger is wet.	Dry the finger and inside of sensor.
	Indicator not lit in finger insertion area.	Call ABC Customer Support.
	Excessive patient motion.	Reduce patient motion.
Pulse Oximeter Sensor indicator appears.	Poor signal detected from finger.	Reposition or replace finger; keep sensor motionless.
		Warm the application site.
	The EZ-Arm needs repair.	Call ABC Customer Support.

Problem	Possible Cause	Possible Solution
EZ-Arm doesn't record in Programmed mode.	Start and stop times set inconsistently.	Use Beur software to set start and stop times correctly.
	EZ-Arm date and time settings are incorrect (or lost after removing batteries).	Use Beur software to set date and time correctly.

If these solutions do not correct the problem, please contact ABC Customer Support at **(555) 555-1234** (USA and Canada) or **(555) 222-9789.**

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