leadcare® II

Quick Reference Guide

NOTE: For use with Analyzer Firmware Version 1.09 or higher.
Please check the label on the bottom of your analyzer to determine firmware version.

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Precautions

⚠ Caution

- The LeadCare® II Blood Lead Analyzer is a CLIA-waived device. Facilities that perform tests with the LeadCare II System must have a CLIA Certificate of Waiver as issued under the authority of the Public Health Service Act (PHSA) (42 U.S.C. 263(a). In addition to a waiver certificate, laboratories performing this test must comply with all applicable state and local laws.
- Any modifications by the laboratory to the test system or the manufacturer's instructions will result in the test no longer meeting the requirements of the waived category.
- All laboratories eligible for a CLIA Certificate of Waiver must follow the manufacturer's instructions as specified in the LeadCare II User's Guide, LeadCare II Quick Reference Guide and LeadCare II Test Kit Package Insert.
- Observe universal precautions for handling blood samples as defined by the U.S. Public Health Service, Centers for Disease Control. Refer to the LeadCare II User's Guide for information about where to find this document.
- The LeadCare treatment reagent contains dilute hydrochloric acid solution which may cause eye, skin, and respiratory system irritation. In case of accidental contact immediately flush skin and eyes with running water for up to 15 minutes and move to fresh air. Seek medical assistance in situations where eye contact; skin irritation or burn; or difficulty breathing occurs.
- Do NOT mix components from different lots of test kits.
- Test kit components (kit box, sensors, controls, and treatment reagent tubes) are labeled with expiration dates. Using any item with an expired date may produce inaccurate results. Do not use any component with an expiration date that has passed. Check the expiration on the kit box as this is the earliest date.
- Proper sample preparation is essential for accurate results. Take precautions to ensure that the sample collection area is not contaminated by environmental sources of lead. Refer to Collecting and Handling Blood Lead Samples–2004 published by the Department of Health and Human Services, Centers for Disease Control.
- Use only fresh, whole blood. Mix the blood with treatment reagent within 24 hours of collection. Follow sample collection instructions exactly.

Wear protective gloves, safety glasses and lab coats.

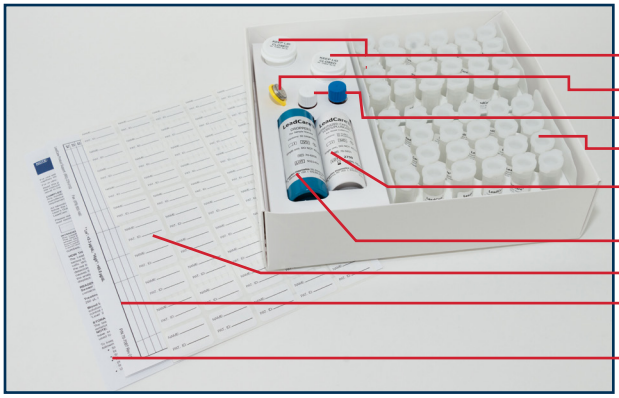
Dispose of materials in appropriate biohazard containers.

Allow analyzer, test kit and samples to reach room temperature before testing.

Required Materials

Analyzer Kit Contents

- Calibration Button Reader
- LeadCare II Blood Lead Analyzer
- AC Adapter and Plug Set
- LeadCare II Flash Drive containing User's Guide & Instructional Videos (not pictured)
- AA Batteries
- Quick Reference Guide (not pictured)

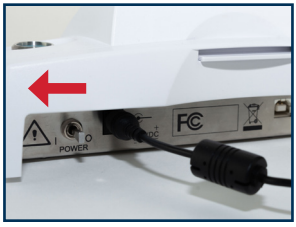


Test Kit Contents

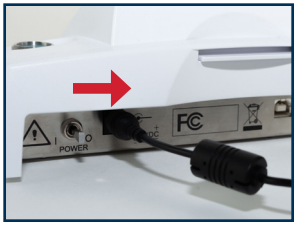
- Blood Lead Sensors
- Calibration Button
- Control Solutions
- Treatment Reagent Tubes
- Capillary Tubes and Plungers
- Droppers
- Labels
- LeadCare II Worksheet & Assay Control Sheet
- Package Insert

Power on the Analyzer

Connect the analyzer to an outlet using the AC power cord or install batteries as shown below.



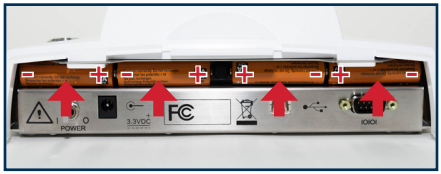
To turn ON the analyzer, move the switch to the left.



To turn the analyzer OFF, move the switch to the right.

Battery Installation (Optional)

Push white tab up and pull cover off.



Insert batteries as shown and replace cover.

Analyzer Calibration and Quality Control

Perform this calibration procedure each time you open a new test kit.

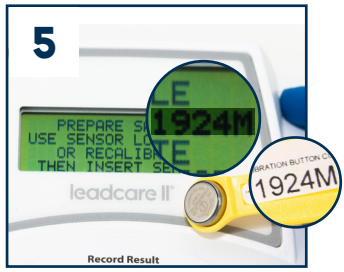
The first time you turn on the analyzer, you will see the **PLEASE CALIBRATE** message.

Remove the calibration button from the test kit.

Hold the calibration button to the button reader until you **hear a beep**.

NOTE: Button must touch both the center contact and metal side of button reader.

Test two levels of quality control on each new kit lot. Refer to the 'Quality Control' section for further instructions on when to run controls.



Make sure the number on the button matches the display.

The analyzer is ready when the PREPARE SAMPLE message appears.

Quality Control

LeadCare II Blood Lead controls are intended to monitor the accuracy and precision of your blood lead testing using the LeadCare II Blood Lead Testing System.

How Often to Test with Controls

Test two levels of quality control:[1]

- on each new lot, or on each new shipment of materials
- with each new operator
- monthly, as a check on continued storage condition
- when problems (storage, operator, instrument, or other) are suspected or identified
- if required by your laboratory's standard QC procedure

Results obtained on control samples that are within the expected ranges means that your LeadCare II System is operating properly. Refer to the LeadCare II User's Guide for additional important information on quality control.

1. Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of in Vitro Diagnostic Devices, Guidance for Industry and FDA Staff:, p. 34, viewed 17 August 2017, ‹https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070890.pdf›.

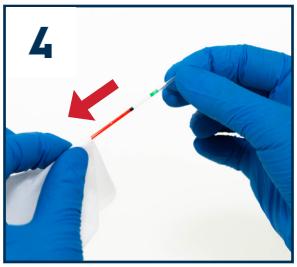
Using the Controls (See Prepare the Sample for Additional Information)

Treat the controls as you would a patient blood sample. Refer to the LeadCare II User's Guide for detailed instructions on how to perform blood lead testing.

Label a fresh treatment reagent tube "**Level 1 Control**".

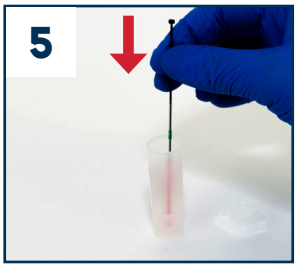
After thorough mixing, remove the cap from the Level 1 control vial and place it top down on a clean surface.

Holding the capillary tube almost horizontally with the green band on top, fill the tube to the 50 µL black line. Replace the cap on the control vial.

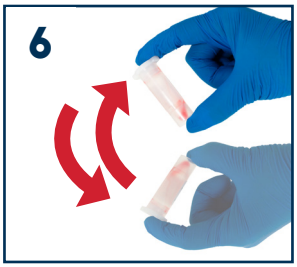


Wipe the outside of the capillary tube to remove any excess control.

Inspect the capillary tube to confirm that it is properly filled (see step 5 on page 7).



Place the capillary tube into the treatment reagent tube. Insert a plunger into the top of the capillary tube and push down, ensuring the entire volume of control is dispensed into the treatment reagent.



Replace the tube cap. Invert the tube 8 to 10 times to mix the sample completely. Control material in treatment reagent tube will appear red.

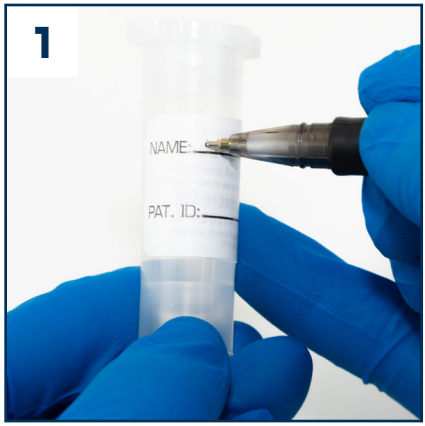
Analyze the control sample according to the instructions provided in the **Analyze the Sample** section. Repeat this process for the Level 2 control.

Lead Control Test Results: Expected Results

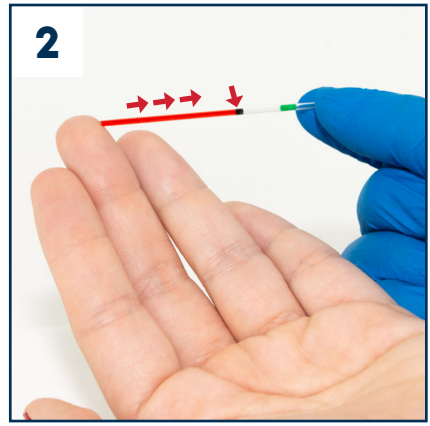
Control target values and acceptable ranges are provided on the control vial label. The blood lead result you obtain for a control should be within the acceptable range. If the results are not within the listed range, refer to the Troubleshooting section of the User's Guide. If, after following the instructions, the controls are still out of range, call Product Support.

CAUTION: Do NOT proceed to patient samples unless both Level 1 and Level 2 control results are within the acceptable ranges.

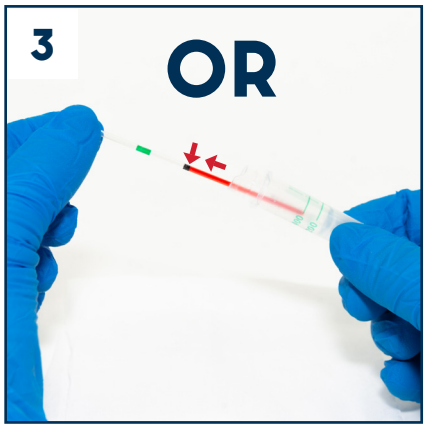
Prepare the Sample



Label the tube with the patient ID using the labels provided.



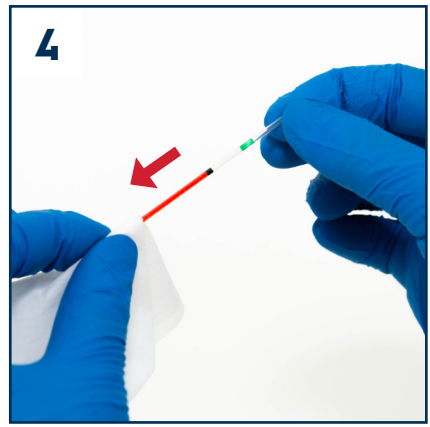
Holding the capillary tube almost horizontally with the green band on top, fill the capillary to the 50 µL black line.



If using blood from a microcollection tube, make sure the blood is well mixed by inverting the tube 8 to 10 times before sampling.

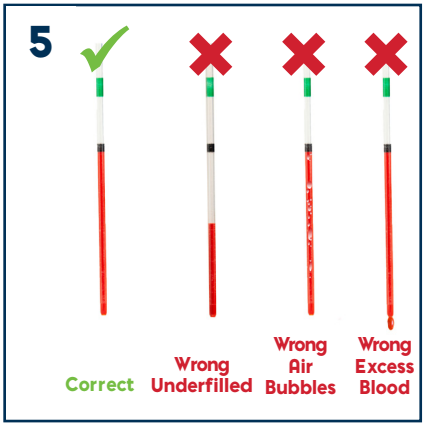
Hold the capillary tube almost horizontally with the green band on top, fill the tube to the 50 µL black line.

Do NOT use venous blood samples.

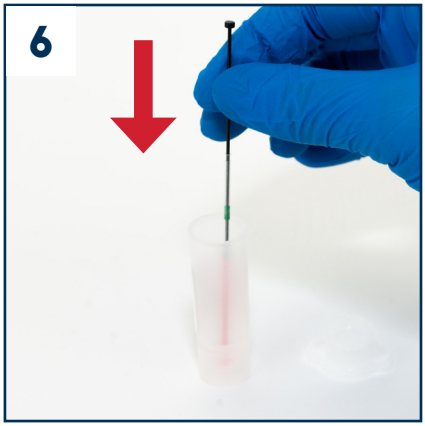


Remove excess blood from the outside of the tube with a clean wipe or gauze.

Use caution not to drain the blood from the end of the capillary tube.



Inspect the capillary tube for proper filling. Make sure there are no gaps, air bubbles, or any excess blood on the outside of the capillary.



Place the capillary tube into the treatment reagent tube. Insert a plunger into the top of the capillary tube and push down, ensuring the entire volume of sample is dispensed into the treatment reagent.

Replace the tube cap. Invert the tube 8 to 10 times to mix the sample completely.

NOTE: The mixture of blood and treatment reagent is stable for up to 48 hours at room temperature and up to 7 days refrigerated.
If refrigerated, bring to room temperature prior to analysis.

The sample is ready when the mixture turns brown. Samples may be stored up to one week if refrigerated.

CAUTION: Any visual impairment, such as color blindness may affect the operator's ability to detect the sample color change. Operators with vision deficiencies should invert the tube 8 to 10 times to ensure that the sample is properly mixed.

Analyze the Sample

Remove a sensor from the sensor container. Close the container.

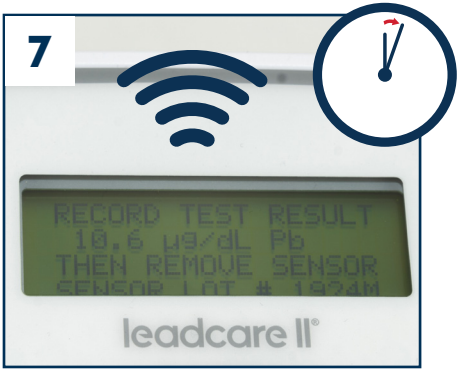
Insert the sensor (with black bars facing up) under the sensor guides on the sensor deck. Insert completely into the analyzer until you hear a beep.

Make sure the sensor lot number matches the display.

Make sure the sample is thoroughly mixed. Allow samples that were stored refrigerated to reach room temperature before use.

Remove the cap from the treatment reagent tube. Squeeze the walls of the dropper and insert into the sample. Release the pressure to draw some sample into the dropper.

Touch the dropper tip to the **X** on the sensor and squeeze the walls to dispense the sample. The analyzer will "beep" and begin the 3 minute countdown.



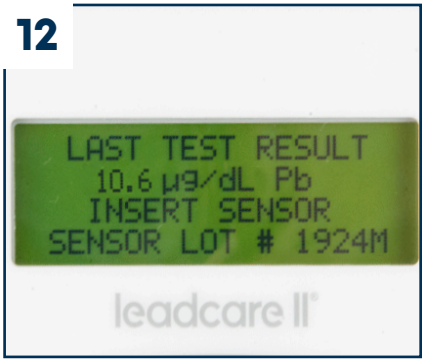
Wait 3 minutes until the test is done. The analyzer will beep and display the lead result in µg/dL Pb.

Record the test results on the LeadCare II worksheet provided.

Remove the used sensor immediately after recording the test result.

Discard materials in appropriate containers.

A beep will sound if you do not remove the sensor after the result is displayed. Once the sensor is removed, the beep will stop.



The analyzer is ready for the next sample.

Interpreting Patient Test Results

Interpreting Patient Test Results

The analyzer's display window shows the blood lead result. The result is in micrograms (µg) of lead per deciliter (dL) of whole blood. No calculation is needed. Results are displayed to one decimal place. The reportable range of the test is 3.3 to 65 µg/dL.

"Low" in the display window indicates a blood lead test result less than 3.3 µg/dL. When this occurs, report the blood lead result as less than (‹) 3.3 µg/dL.

"High" in the display windows indicates a blood lead test result greater than 65 µg/dL. When this occurs, report the blood lead result as greater than (›) 65 µg/dL. **"High" results on LeadCare II should be followed up immediately as an emergency laboratory test.**

According to the US Centers for Disease Control (CDC), there is no known safe level of lead. Consult your local public health department and/or CDC recommendations for information on the management of blood lead levels.

Blood lead test results should be shared with the patient's physician for interpretation and to determine when retesting and follow-up care are necessary. A capillary blood sample that generates an elevated lead level should be confirmed with a venous sample. The venous sample should be run at a reference laboratory using a high complexity testing method.

For the most current information regarding blood lead testing guidelines, please refer to the CDC's website and specific regulations in your State.

In cases where the capillary specimen demonstrates an elevated lead level but the confirmation venous sample does not, it is important to recognize that the child may live in a lead-contaminated environment that resulted in contamination of the fingertip. Efforts should be made to identify and eliminate the source of lead in these cases.[2]

Report all blood lead test results to the appropriate state or federal agency.

2. Newman, N., et al. PEHSU Lead Working Group, June 2013. Recommendations on Medical Management of Childhood Lead Exposure and Poisoning. Retreived from: http://wwwpehsu.net/_Library/facts/medical-mgmnt-childhood-lead-exposure-June-2013.pdf.

Maintenance

Maintaining the Analyzer

- Remove used sensors from the analyzer as soon as a result is recorded.
- Clean the analyzer with a damp cloth and warm, soapy water.
  Do NOT immerse in water.
- Disinfect with dilute (10%) bleach solution.
- Do NOT leave any soap film on the analyzer.
- Do NOT allow liquid of any kind into the sensor connector.
- Do NOT get the metal pins in the sensor connector wet.
- Do NOT wash the inside of the calibration button reader.

ADDITIONAL INFORMATION

- To extend operating time of the system, 1.5V AA alkaline or lithium batteries can be used instead of alkaline batteries.
- Batteries can damage the environment and cause health problems if discarded improperly. Please dispose of dead batteries responsibly.

- This device complies with the Waste Electrical and Electronic Equipment (WEEE) directive of the European Union (EU). For information regarding the proper disposal procedure for this product, please contact Magellan Diagnostics. Instruments labeled with the associated symbol (see left) **must not** be disposed of as regular waste material.

Troubleshooting

STARTUP MESSAGES	DEFINITION	WHAT TO DO
PLEASE CALIBRATE ANALYZER WITH BUTTON	Analyzer must be calibrated the first time you use it.	Calibrate the analyzer. Refer to the calibration instructions in this guide.
TEMP IS TOO HOT PLEASE WAIT UNTIL ANALYZER IS IN TEMP RANGE	The temperature is too hot for testing.	Wait until the screen displays the PREPARE SAMPLE message.
TEMP IS TOO COLD PLEASE WAIT UNTIL ANALYZER IS IN TEMP RANGE	The temperature is too cold for testing.	Wait until the screen displays the PREPARE SAMPLE message.
ELECTRONIC QC CHECK FAILED CALL TECH SERVICE ERROR X	The internal quality control check failed.	Record the error number and call Product Support.
PROCESSING MESSAGES	**DEFINITION**	**WHAT TO DO**
WARNING TEMP IS UNSTABLE TEST MAY FAIL	The temperature is changing rapidly. This message flashes for 2 seconds.	Allow system temperature to stabilize.
THIS IS A USED SENSOR PLEASE REMOVE SENSOR	The sensor in the analyzer is wet or previously used.	Remove the used sensor or adjust the new sensor until the screen displays the PREPARE SAMPLE message.
PLEASE REMOVE SENSOR	A sensor was left in the analyzer.	Remove the sensor.
SENSOR OUT OF VIAL TOO LONG PLEASE REMOVE SENSOR	The sensor in the analyzer has been out of the container too long and cannot be used.	Remove the sensor and insert a new sensor.
TEST FAILED PLEASE REMOVE SENSOR	There is not enough sample on the sensor or the sensor failed.	Remove the sensor, discard it and insert a new sensor. When adding the sample to the sensor, make sure the sample covers the X area.
SENSOR REMOVED TOO SOON	The sensor was removed from the analyzer before the end of the test.	Remove the sensor, discard it, insert a new sensor and add sample. Wait 180 seconds (3 minutes) for the test to finish.
TEMP IS UNSTABLE RESULT DISCARDED PLEASE REMOVE SENSOR	The temperature in the room is too unstable to yield accurate test results.	Move the analyzer to an area where there are fewer temperature changes (away from sources of cold or heat). The temperature is stable enough when the PREPARE SAMPLE message indicates that the analyzer is ready.
PLEASE RECALIBRATE	There was a problem with transferring the calibration data to the analyzer from the calibration button.	Repeat the calibration procedure.
SYSTEM FAILURE CALL TECH SERVICE	One of the main system components failed.	Power analyzer off & on. If error persists, call Product Support.
PLEASE CALIBRATE ANALYZER WITH BUTTON	The analyzer must be calibrated before you can use it.	Calibrate the analyzer. Refer to the calibration instructions in this guide. The PREPARE SAMPLE message indicates that the analyzer is ready to use.
SENSOR LOT TOO OLD PLEASE RECALIBRATE	The analyzer is calibrated to a sensor lot that has expired.	Discard the expired lot. Recalibrate the analyzer to a new lot.
CHANGE BATTERIES SOON	Message flashes before or after a test. Voltage is too low for the analyzer to run a test.	Change the batteries.

If an error message is encountered repeatedly, call Product Support.

Troubleshooting of Inaccurate Results

Scenario 1: Troubleshooting results below the target or expected value

- Make sure the analyzer is calibrated to the sensor lot in use.
- Make sure the sensor is inserted under the sensor guides and sits flush on the sensor deck.
- Check the expiration date on the test kit box. Do NOT use a test kit that is beyond the expiration date. Note: the analyzer will not perform a test when it is calibrated for a sensor lot that has expired.
- Use only fresh, whole blood from patients. Do NOT use plasma or serum.
- Less than 50 µL in the capillary tube will tend to produce lower blood lead results.
- Make sure that there are no clots or bubbles in the capillary tube.
- Always mix the blood sample with treatment reagent. Results generated with untreated blood are not accurate.
- Do NOT use clotted blood. If there are clots in the blood, obtain a new sample.
- Operate the analyzer only within the specified humidity range - 12 to 80% relative humidity.
- Make sure that the analyzer, test kit, and sample are all at the same temperature before testing. Note: The analyzer will not initiate a test if the temperature is changing too rapidly, or if the temperature is outside of the operating range.
- Avoid operating the LeadCare II System in drafts.
- Make sure the blood and treatment reagent are thoroughly mixed before placing onto the sensor.
- Keep the lid on the sensor container closed to protect unused sensors.
- Do NOT touch the sensor while running a test.

Scenario 2: Troubleshooting results above the target or expected value

- To avoid contamination of the skin's surface, wash patient's hands thoroughly with warm soapy water prior to collecting a fingerstick sample. Use clean gloves during testing and keep your gloved hands clean.
- Make sure the analyzer is calibrated to the sensor lot in use.
- Check the expiration date on the test kit box. Do NOT use a test kit that is beyond the expiration date.
- Make sure you are using lead-free collection devices.
- Do NOT touch the ends of the capillary tubes or the plungers. This could cause contamination.
- Excess blood on capillary tube. Be sure to wipe excess blood from the tube with a downward motion. The accuracy of the test depends on filling the capillary tube with 50 µL. Excess blood on the outside of the tube may produce higher blood lead results.
- Do NOT use clotted blood. If there are clots in the blood, obtain a new sample.
- Do NOT leave the treatment reagent tube uncapped other than to add the blood sample and remove the blood sample/treatment reagent mixture.
- Make sure to thoroughly mix blood with the treatment reagent. The mixture should turn brown before you place it on the sensor.
- Operate the analyzer only within the specified humidity range - 12 to 80% relative humidity.
- Make sure that the analyzer, test kit, and sample are all at the same temperature before testing.
- Do NOT use a sensor that has been dropped on the floor or exposed to contaminants.
- Do NOT touch the sensor while running a test.

After following the instructions, if the problem persists, call Product Support.

Analyzer:

LeadCare® II Analyzer Kit	70-6760

Reagents:

LeadCare® II Test Kit	70-6762

Parts and Accessories:

Label Printer (U.S. only)	70-3447
Printer Labels	80-0195
Quick Reference Guide	70-6552
User's Guide	Call to inquire
Instructional Video	Visit LeadCare2.com/training
CDC Blood Collection Video	Visit LeadCare2.com/training
AC Adapter and Plug Set	70-9500

LeadCare II Serial Number: _____

Contact Us

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Product Support: 1.800.275.0102
Email: leadcaresupport@meridianbioscience.com

Part Number: 70-6552 Rev. 06

IVD

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