Table of Contents

Introduction

Thank you for choosing the *EDGE* Blood Lactate Analyzer.

All of the information that will be needed to use and maintain the *EDGE* Blood Lactate Analyzer is included in this manual. Please read it carefully before using the system.

The *EDGE* Blood Lactate Analyzer provides an easy and precise method for measuring the level of lactate in whole blood at specific points in time. This portable battery operated meter is intended for use outside the body *(In Vitro).* The *EDGE* Blood Lactate Analyzer is designed for both personal use and for use by healthcare professionals.

Contents of Kit

*THE EDGE* kit package includes the following items.

- *THE EDGE* Blood Lactate Meter
- 3V Lithium Coin Cell Batteries
- Monitor Checker
- The EDGE Blood Lactate Test Strips
- Code Card

- User's Guide
- Log Book
- Wallet
- Puncturer
- Lancets

In addition to the above items, standard lactate control soltion may also be purchased to check the system (P.20). Please contact your nearest authorised dealer when needed.

Code Card Port

THE EDGE

Display

EDGE

Manufactured by
Apex Biotechnology Corp.

IVD

CE

ED 1000000000

Code Card

Lactate Analyzer

SHIFT   ENTER

Enter Button

Battery
Compartment

Shift Button

Data Protb

Test Strip
Holder
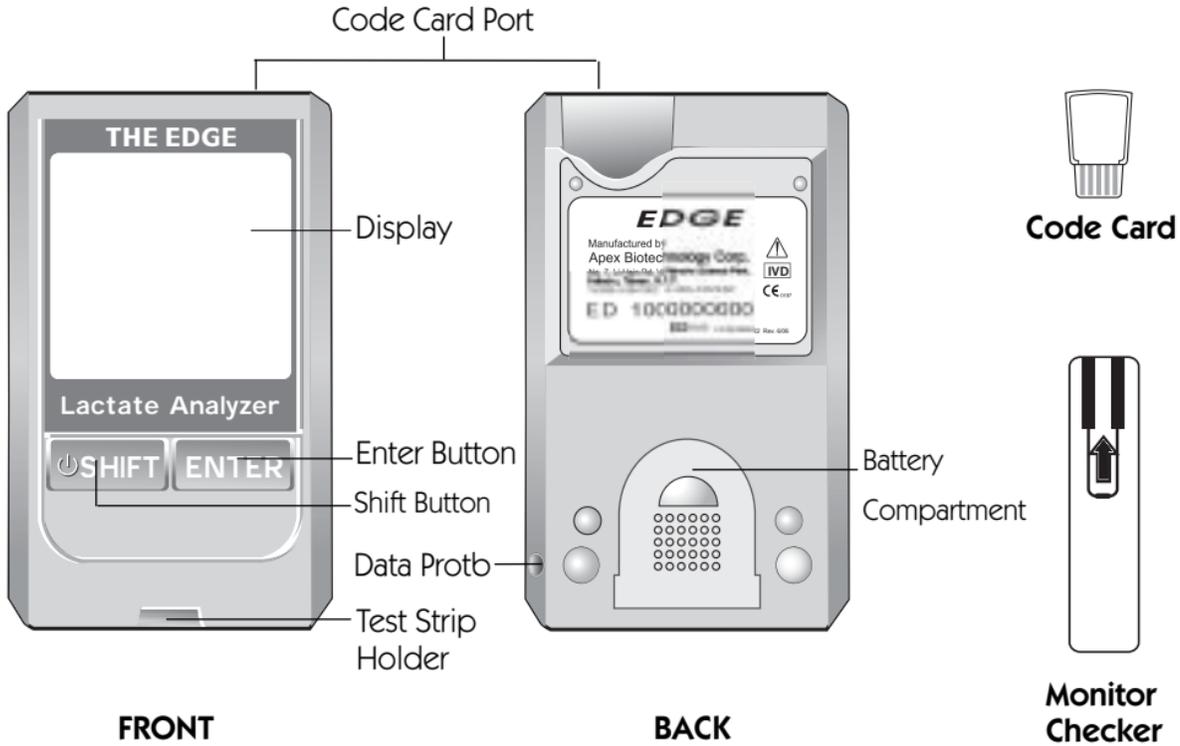
Monitor
Checker

FRONT

BACK

Meter Components

LCD Screen ---------------- Displays information that guides users through testing and setup, and shows test result and error messages.

Shift Button & Enter Button ------------- Turn meter on and off. Control selection and steps of user-programmable setup in Function Mode.

Test Strip Holder -------- Insertion site for test strip. Located on the bottom at front side of the meter.

Battery Compartment --- Holds one 3V Lithium coin cell battery to power the system. Located on the backside of the meter.

Data Port ------------------- Interface for data transmission to computer. Located at the right bottom side of the meter.

Monitor Checker --------- Used to confirm that the *EDGE* meter is functioning properly.

Code Card Port ----------- Insertion site for code card. Located at top of the backside of the meter.

Code Card ---------------- Codes the meter for the test strips that have the same code when inserted into the code card port. Insert the code card with the code number facing up. One code card is packaged with each box of Test Strips.

The EDGE Blood Lactate Test Strip

Contact Points ------------ Sense the position and orientation of the test strip.
Test Strip Handle --------- The area to be held when inserting the test strip.
Reaction Zone ------------ The area where the blood sample or control solution is
applied.

Contact Points — | | — Test Strip Handle

Reaction Zone (Apply Blood Here)
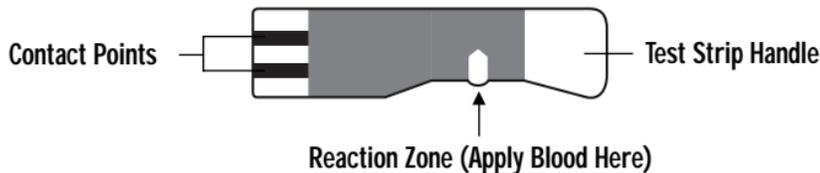
IMPORTANT: The Edge Blood Lactate Test Strips come in a moisture proof
and light protected bottle ☀. Because the test strips are sensitive to moisture
and light, it is important that the bottle is kept well sealed before use. Replace
the cap of the test strip bottle tightly after a test strip is taken out of the bottle.

DO NOT leave any test strips outside the bottle while not in use. When performing a blood test, insert the test strip with the contact points up and towards the meter, then apply blood sample to the reaction zone of the test strip when the display shows a symbol of blood " 🩸 ". For additional information on the *Edge* Blood LactateTest Strips, refer to the package insert 📖.

Using Your Meter for the First Time

Setting the Clock

Step 1: Press any key to turn on the meter.

Step 2: A clock symbol " 🕔 " will flash on screen. Press "ENTER" button to enter setup of the date & time in the order of Year-Month-Day and then Hour-Minute.

Step 3: The pre-set Year will flash on screen. Press "SHIFT" button to scroll through the years and press "ENTER" button to enter the correct Year. Press and hold on the "SHIFT" button for quick searching of the years.THE EDGE Meter provides calendar years from 2005 to 2099.

Step 4: The pre-set Month will flash on screen. Press "SHIFT" button to scroll through the months and press "ENTER" button to enter the correct Month. Press and hold on the "SHIFT" button for quick searching of the Month.

Step 5: The pre-set Day will flash on screen. Press "SHIFT" button to scroll through the days and press "ENTER" button to enter the correct Day. Press and hold

on the "SHIFT" button for quick searching of the day.

Step 6: The pre-set Hour will flash on screen. The *EDGE* Meter uses am/pm time clock. Each Hour is led by AM or PM Press "SHIFT" button to scroll through the hours and press "ENTER" button to enter the correct Hour. Press and hold on the "SHIFT" button for quick searching of the hour.

Step 7: The pre-set Minute will flash on screen. Press "SHIFT" button to scroll through the minutes and press "ENTER" button to enter the correct Minute. Keep pressing on the "SHIFT" button for quick searching of the minute.

Step 8: Press the two buttons on the meter simultaneously to return to the Blood Test Mode during Date or time Setting.

Turning ON/OFF Beep Sound

Step 1: Press any key to turn on the meter.

Step 2: The LCD screen will show a 4-digit code number, unit of measurement, date & time, and a symbol of test strip.

Step 3: Press the two buttons on the meter simultaneously.

Step 4: A symbol of head " $\{M\}$ " will flash on screen. Press "SHIFT" button to skip this selection.

Step 5: A symbol of cable " $\hat{\zeta}$ " will flash on screen. Press "SHIFT" button to skip this selection.

Step 6: A symbol of speaker " $\triangleleft$)) " will flash on screen. Press "SHIFT" button to set ON or OFF for beep sound of the meter. The "speaker" with wave ahead of the speaker means ON; the "speaker" without wave means OFF.

Step 7: Press the two buttons on the meter simultaneously to return to the Blood Test Mode.

Changing Unit of Measurement

Step 1: Press any key to turn on the meter.

Step 2: The LCD screen shows at the Blood Test Mode that contains a 4-digit code number (☐ⓘ Please refer to P.14 "Coding the Meter"), unit of measurement, date & time, and a symbol of test strip.

Step 3: Press the two buttons on the meter simultaneously to enter the Function Mode.

Step 4: A symbol of head " $\{M\}$ " will flash on screen. Press "SHIFT" button to skip this selection.

Step 5: A symbol of cable " $\mathcal{E}$ " will flash on screen. Press "SHIFT" button to skip this selection.

Step 6: A symbol of speaker " ◁)) " will flash on screen. Press "ENTER" button to skip this selection.

Step 7: A symbol of clock " 🕐 " will flash on screen. Press "SHIFT" to skip this section.

Step 8: The pre-set Unit of Measurement will flash on screen. Press "SHIFT" button to change from mg/dL to mmol/L or vice versa, and press the "ENTER" button to confirm the selection. Then, the display will return to the Blood Test Mode.

Coding the Meter

IMPORTANT: After Setting the date and time for the first time, the current CODE will appear on the screen when the meter is turned on each time. Verify that the CODE displayed on screen matches the CODE number on the package of test strip before each use of the meter. The CODE needs to be set only once for each package of test strips. The meter will memorize the CODE until it is changed. The CODE number on the meter screen not matching the CODE number on the test strip package will create an inaccurate blood lactate test result.

To code the meter with a code card, follow these steps.

Step 1: Locate the code card in the package of test strip.

NOTE: There is a code card packaged in each box of test strips. The code card is designed specifically for use with the test strips in that particular package.The code card should have same code number as that indicated on the package of the test strips.

Step 2: Verify that the code number on the code card matches the code number on the test strip package.

Step 3: Insert the code card with the code number facing up firmly and completely into the code card port on the backside of the meter.

Step 4: Press any button to power on the meter.

Step 5: A 4-digit code number will display on the meter screen. Verify the code number on the screen with that on the code card and that on the test strip package. The four numbers on the code card, meter, and test strip bottle should match.

The code number displayed on the meter should match the code number on the gray code card and on the front of the test strip package.

code
1935

THE EDGE

code

1935

mg/dL
4-07
PM 10:05

Lactate Analyzer

SHIFT   ENTER

The EDGE
Blood Lactate
For use with act
For in vitro diagnostic use
Control solution range (m
Level 1:
Level 2:
Code: **1935**
Lot. No:
Exp. Date:
Date Opened:
(Use within 3 months after
63107000005 Rev. 03/01
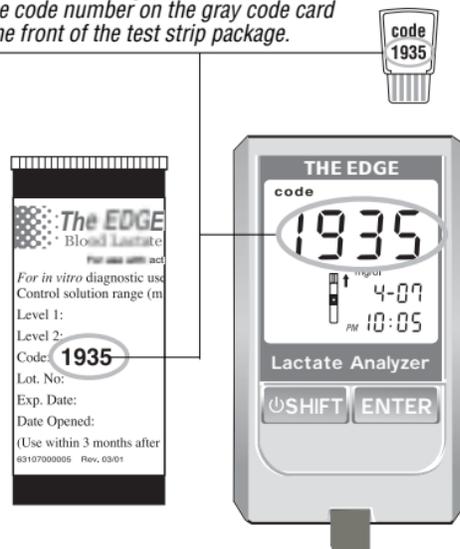
NOTE: Recoding needs to be done when a new package of test strips with a different code number is opened for use.

Checking the System

There are two ways to check performance of the *EDGE* Blood Lactate Analyzer. These checks are simple and very important to ensure accurate lactate readings.

1. The Monitor Checker confirms the meter is operating properly.
2. The Control Solutions confirm the meter and test strips are working together properly.

Monitor Checker Method:

It is recommended that the *EDGE* Meter is checked using this method when the meter is new and when the performance of the system wants to be confirmed.

To check the meter using a monitor checker, perform the following steps.

Step 1: Insert the monitor checker into the test strip holder (when the meter is either turned on or off) , the *EDGE* Meter will now perform a series of self-fest.

Step 2: The meter display screen will show "OK" when self-testing is complete
Remove the monitor checker from the test strip holder and the screen will
then display "Ctrl."

Step 3: Press "ENTER" key to exit checking the meter.
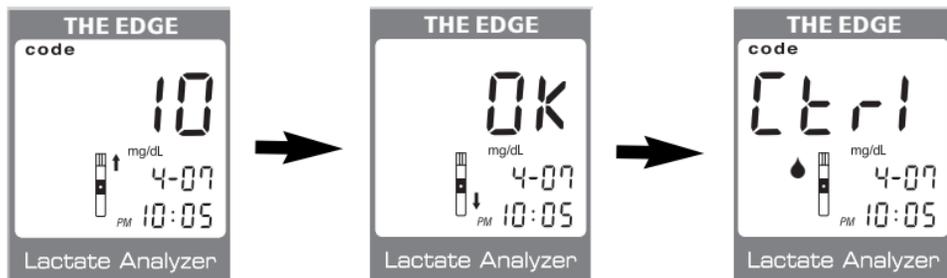
NOTE: If the screen dispalys "nt OK" , repeat the test. If "nt OK" continues to
appear, contact the authorized dealer for service.

Control Solution Method:

Please ask your authorized distributor to purchase standard lactate control solution .

The purpose of the control solution check is to validate the performance of the **EDGE** Blood Lactate Analyzer using a standard solution with a known concentration range of lactate. A control solution test that falls within the acceptable range indicates the user's technique is appropriate and both the meter and the test strip are functioning properly.

When to perform a control solution test -

• whenever there is doubt that the meter or the test strips are not working properly.
• if the meter has been dropped, stored below -10°C (14°F) or above 55°C (131°F), or stored in humidity levels above 95%.
• if the test strip bottle has been left open or has been exposed to temperatures below 4°C (39.2°F) or above 30°C (86°F) and/or light or humidity levels above 85%.
• if the readings appear to be abnormally high or low.

IMPORTANT:

- The acceptable range for the control solution is listed on the package of test strips.
- Use only the recommended lactate control solutions.
- Always check the expiration date ⧖. **DO NOT** use control solutions if expired.
- If a control solution test is not within the expected range that is printed on the test strip package, **DO NOT** use the Meter System to test. Repeat the test until a control solution test performs within the expected range. If the results continue falling outside the expected range, call the authorized dealer for service.
- DO NOT touch the test area with the tip containing control solution.
- DO NOT apply a second drop of control solution to the test strip.
- DO NOT smear the control solution with the tip containing control solution.
- Please refer to your control solution's package insert for additional information.

To check the meter using control solution, perform the following steps.

Step 1: Perform Monitor Checker method up to Step 2
(see P.17, Monitor Checker Method) and verify the code number on screen is the same with the code number printed on the bottle

Step 2: The screen will display "Ctrl", and then insert an Edge Blood Lactate Test Strip.

Step 3: The screen will flash a symbol of liquid drop " 🌢 " instructing applying the control solution.

Only apply the Control Solution to the reaction zone on top of test strip.
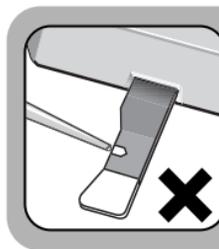
DO NOT apply Control Solution from the edge of test strip.

Step 4: Apply a drop of control solution **on the yellow reaction zone in the middle top of the test strip**.

Step 5: The screen will show timing bars " ____ " that flash and then gradually diminish for countdown.

Step 6: After the timing bars disappear (in approximately 45 seconds), the screen will show test result. Compare the reading on the screen to the range indicated on the test strip package. Remove the test strip.

Step 9: Remove and properly discard the used test strip.

Step 10: The screen will display at blood test mode.

The test result of control solution **will not** be stored in memory.

NOTE: If the test result is not within the expected range, repeat testing of the control solution until the result falls within the range.If the results continue falling outside the expected range, please call your authorized dealer.

Performing a Test

Obtaining a Drop of Blood

IMPORTANT: When performing a blood lactate test, use a new sterile lancet every time. If alcohol wipes are used to cleanse the fingers, make sure the area is dry before the blood sample is obtained.

Step 1: Wash hands with soap and warm water and dry thoroughly. Warm water stimulates blood flow to the fingers making it easier to obtain a sample.

Step 2: Hang the arm down at the side for 10 to 15 seconds massage through the wrist, palm, and then finger. This can stimulate the blood flow to the finger more quickly.

Step 3: Hold the lancing device (puncturer) or lancet against the side of the finger and lance the finger. Follow manufacturer's instruction for how the lancing device (puncturer) or lancet should be used.

TIP: To avoid soreness, select a site on the side of your fingertips. To avoid calluses, choose a different site each time for obtaining the blood sample.

How to Perform a Test

Step 1: Follow the instruction on 📖 page 15 "coding the meter."

NOTE: If the screen shows "Code ---" (meaning that the meter is not coded), or if the CODE number on the screen does not match the CODE number on the test strip package, refer to 📖 Page 15 for details of (re)coding the meter.

Step 2: The meter will self-test the environment temperature. If the temperature is out of range, the screen will show a symbol of

code
1935

The EDGE
Blood Lactate
For in vitro diagnostic use
Control solution range (m
Level 1:
Level 2:
Code: **1935**
Lot. No:
Exp. Date:
Date Opened:
(Use within 3 months after
63107000005 Rev. 03/01

THE EDGE
code
1935
4-07
10:05
Lactate Analyzer
SHIFT   ENTER
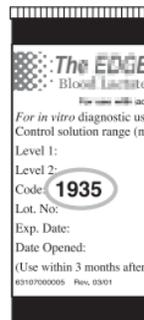
thermometer" ━━● ". If the temperature is within the testing range of ☖ 10°C to 40°C (50°F to 104°F), the screen will show a symbol of blood " ◗ " indicating to apply blood.

NOTE: If the temperature is out of the operating range, the meter needs to be moved to an area that is within the meter's operating range of ☖ 10°C to 40°C (50°F to 104°F). Measurement outside the temperature range will affect accuracy of test result.

Step 3: Obtain a drop of blood and apply the blood either to the absorbent area at the curved edge of the test strip or the yellow reaction zone on the top of the test strip.
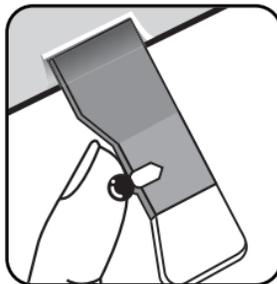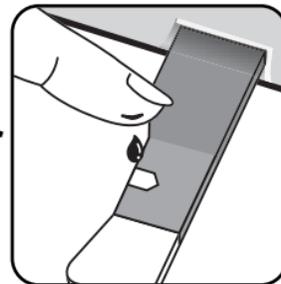
NOTE: • DO NOT touch the target area of the test strip.
- DO NOT smear the blood drop onto the target area.
- DO NOT add or apply a second drop of blood. This may cause false result.
- DO NOT proceed testing if the yellow window is not full of blood sample. Insufficient blood sample may cause inaccurate test result.
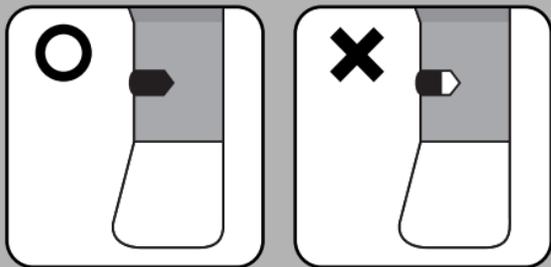
Step 4: The screen will show timing bars " —— ", and the bars will then flash and gradually diminish for countdown.

Step 5: After the timing bars disappear (approximately 45 seconds), the screen will display test result.
- The test result is automatically stored in memory.

• Record test result in the personal Log Book.

Step 6: Remove the used test strip. The LCD screen on the meter will show the code mumber and a flashing arrow next to the test strip icon, indicating the meter is ready for another test.

Step 7: If more tests are to be performed, repeat steps 1 through 5.

NOTE: The measurement done outside the temperature range will show the test result with a flashing symbol of thermometer " ━● ".

IMPORTANT: ⊘ Do not reuse test strips. Used test strip should be treated as biological waste and dispose of properly.

Using the Meter Memory

The *THE EDGE* Meter automatically stores up to 300 test results with date and time. When more than 300 test results have been performed, the oldest result will be dropped from memory each time a new result is added. When the test results are recalled from memory, the most recent result is always displayed first.

To view the results from memory:

Step 1: Press any key to turn on the meter and press the two buttons on the meter simultaneously.

Step 2: A symbol of head " $\{^{M}_{Q}$ " will flash on screen. Press "ENTER" key to view the latest result (with test date and time) in memory. Continue to press the "SHIFT" key to view the previous results.

Step 3: Press the "SHIFT" and "ENTER" keys simultaneously to exit viewing memory.

Setting Time After First Use

Step 1: Press any key to turn on the meter.

Step 2: After the LCD screen shows a code number, unit of measurement, date & time, and a symbol of test strip; press the two buttons on the meter simultaneously to enter the Function Mode.

Step 3: A symbol of head " $\{M\}$ " will flash on screen. Press "SHIFT" button to skip this selection.

Step 4: A symbol of cable " $\overset{\curvearrowright}{\frown}$ " will flash on screen. Press "SHIFT" button to skip this selection.

Step 5: A symbol of speaker " $\triangleleft\!\!\|$ " will flash on screen. Press "ENTER" button to skip this selection.

Step 6: A clock symbol " $\bigcirc$ " will flash on screen. Press "ENTER" button to enter setup of the date & time in the order of Year-Month-Day and then Hour-Minute.

Step 7: The Year will flash on screen. Press "SHIFT" button to scroll through the years

and press "ENTER" button to enter the correct Year. Press and hold on the "SHIFT" button for quick searching of the years.THE EDGE Meter provides calendar years from 2005 to 2099.

Step 8: The Month will flash on screen. Press "SHIFT" button to scroll through the months and press "ENTER" button to enter the correct Month. Press and hold on the "SHIFT" button for quick searching of the Month.

Step 9: The Day will flash on screen. Press "SHIFT" button to scroll through the days and press "ENTER" button to enter the correct Day. Press and hold on the "SHIFT" button for quick searching of the day.

Step10: The Hour will flash on screen. The *EDGE* Meter uses am/pm time clock. Each Hour is led by a.m. or p.m. Press "SHIFT" button to scroll through the hours and press "ENTER" button to enter the correct Hour. Press and hold on the "SHIFT" button for quick searching of the hour.

Step11: The Minute will flash on screen. Press "SHIFT" button to scroll through the minutes and press "ENTER" button to enter the correct Minute.

Caring for the Meter

Caring for the *EDGE* Meter is easy. Follow these simple guidelines to keep the *EDGE* Meter working properly.

Precautions

- DO NOT take the *EDGE* meter apart. If there are technical problems or questions in use of the meter, please call your authorized dealer.
- Handle the meter with care - severe shock, such as dropping the Meter, could damage the electronics.

Storage

- The meter is designed to be used within the temperature ranges between 10°C to 40°C (50°F to 104°F) .

- Avoid leaving the meter in extremely hot or cold places, such as near a heat source or in an extremely hot or cold car.
- Do not store or use the meter or test strips where they may be exposed to high humidity levels, such as in a bathroom or kitchen.
- Never immerse or hold the meter under running water.

Changing the Battery

The *EDGE* Meter operates on one 3V Lithium coin cell battery which should maintain at least 1,000 blood tests. When the LCD screen displays a symbol of " ▯▭▭ ", this indicates the batteries are low and should be replaced as soon as possible.

NOTE: To save battery power, the *EDGE* Meter will turn itself off after one minute of non-use. All results stored in memory will be saved even if the meter shuts off automatically.

To replace the battery:

Step 1: Open battery cover on backside of the meter.

Step 2: Remove the old battery from the battery compartment and replace with a new one.

NOTE: Dispose of used battery properly.

Step 3: Replace the battery cover.
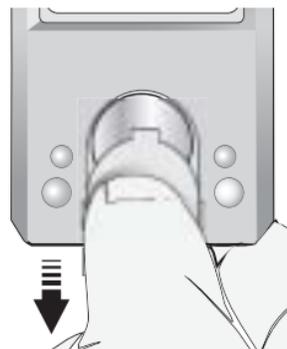
IMPORTANT: You will need to reset time after replacing the battery. 📖 See P.29, "Setting Time After First Use"

Cleaning the Meter

To clean the outside of the *EDGE* Meter, use a lint-free cloth dampened with soap water or isopropyl alcohol.

NOTE: DO NOT get water inside *THE EDGE* Meter. Never immerse the meter or hold it under running water. DO NOT use glass cleaners or household cleaners on the meter.

Solving Problems

If there is a problem with the way you are performing a test or if there is a problem with *THE EDGE* Meter, any of the following messages may appear on the meter screen.

If you have further questions after reviewing these messages, call our authorised dealer.

Message	Problem	What To Do
"code - - - - "	The monitor has not been coded with a code card.	• Insert the code card that is included in the test strip package into the code card port on the top of backside of the meter, and insert a test strip into the test strip holder at the bottom on the front of the meter.

Message	Problem	What To Do
"code ——"	The code card has been damaged.	• Insert a new code card from a new pachage of test strips, follow the procedures on p.14" coding the meter." • If problem persists, call the authorized dealer.
⊏⊢⊒	The batteries in the meter are running out of power.	Replace the batteries.
⊂——●	The temperature of the meter is below its operating range of < 10°C (<50°F).	The meter needs to be moved to an area that is within the meter's operating range, 10°C to 40°C (50°F to 104°F) ⊢●⊣ .

Message	Problem	What To Do
▬▬━●	The temperature of the meter is above its operating range of > 40°C (>104°F).	The meter needs to be moved to an area that is within the meter's operating range, 10°C to 40°C (50°F to 104°F).
nt OK	· Monitor Checker result fails. · Used or defective test strip	Repeat the test with a new test strip. If this message continues, call the authorised dealer.
LO	The blood lactate result is lower than 10mg/dL (1.1mmol/L).	Repeat the test to confirm the test result. If it reads LO again, contact your healthcare professional.

Message	Problem	What To Do
HI	The blood lactate result is higher than 200mg/dL (22.2mmol/L).	Repeat the test to confirm the test result. If it reads HI again, contact your healthcare professional.
Err	The meter is damaged.	Call the authorized dealer.

If you are unable to correct the problem after following the **What To Do** procedures, call your authorised dealer in your country and/or contact your healthcare professional with questions and concerns.

Product Warranty

THE EDGE Blood Lactate Meter is guaranteed to be free of defects in workmanship and materials under normal use for a period of five (5) years from the date of purchase to the consumer.

The liability of Apex Biotechnology Corp is limited to repair or replacement and in no event shall Apex Biotechnology Corp be liable for any collateral or consequential damages or loss.

Instruments subjected to misuse, abuse, neglect, unauthorized repair or modification will be excluded from this warranty.

This guarantee specifically excludes expendables and consumables.

All warranty claims must be directed to the Apex Biotechnology Corp authorized dealer.

The warranty applies only to the original purchaser of the system.

Specifications

Meter Type: THE EDGE Blood Lactate Analyzer
Test Strips: EDGE Blood Lactate Test Strips
Test Range: 10 - 200 mg/dL (1.1 - 22.2 mmol/L)
Blood Source: Finger tip capillary whole blood
Sample Volume: ≧3μL
Reading Time: 45 sec.
Hematocrit Range: 35 - 50%
Memory: 300 sets with date & time
Operating Temperature: 10°C to 40°C (50°F to 104°F)
Relative Humidity: Less than <85%
Storage Condition: -10°C to 55°C (14°F to 131°F) for meter
4°C to 30°C (39.2°F to 86°F) for test strip
Dimension: 90Lx55Wx20H (mm)
Weight: 63 g
Electromagnetic Compatibility: This equipment has been EMC to according
to the requirement of EN 60601-1-2