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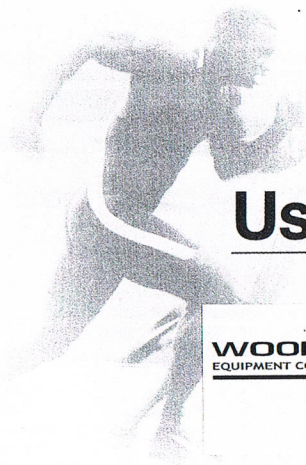
CE

P/N 65015010012
Rev.11/06

THE EDGE™

Blood Lactate Monitoring System



User's Guide

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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.

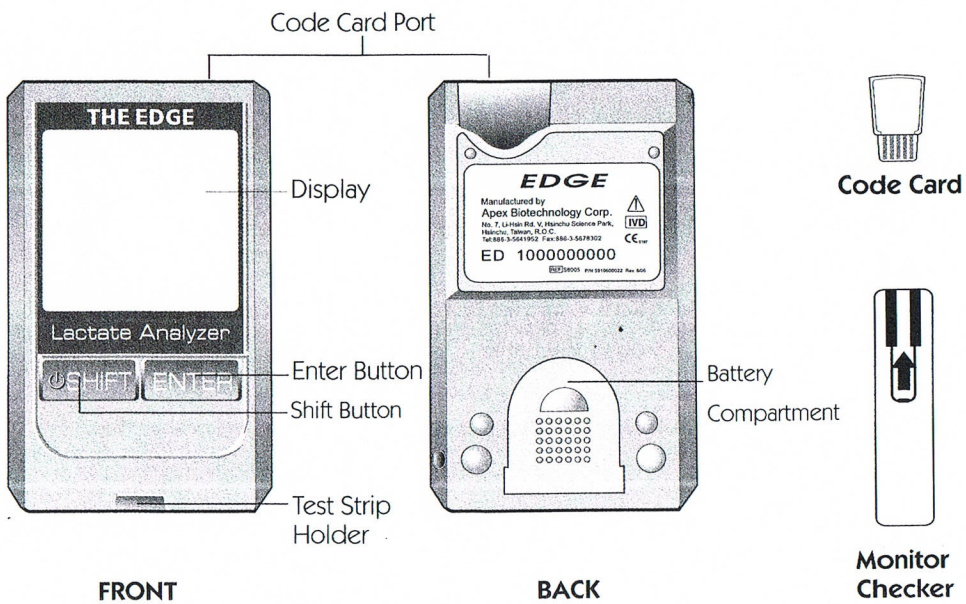
The EDGE Blood Lactate Analyzer provides an easy and precise method for measuring the level of lactate in whole blood at specific points in time. This portable battery operated meter is intended for use outside the body ***(In Vitro).*** The EDGE Blood Lactate Analyzer is designed for professional use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

Contents of Kit

The EDGE kit package includes the following items.

- The EDGE Blood Lactate Meter
- 3V Lithium Coin Cell Batteries (CR 2032)
- Monitor Checker
- The EDGE Blood Lactate Test Strips
- Code Card
- User's Guide
- Log Book
- Wallet
- Puncturer
- Lancets

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



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.

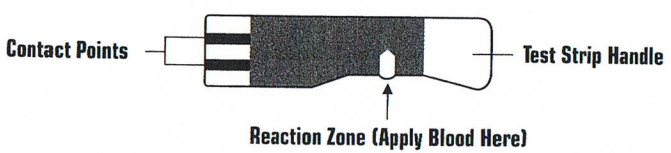
Monitor Checker --------- Used to confirm that the ***EDGE*** meter is functioning properly.

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.



⚠ **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 " " will flash on screen. Press "SHIFT" button to skip this selection.

Step 5: A symbol of cable " " will flash on screen. Press "SHIFT" button to skip this selection.

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

Step 5: A symbol of cable " " 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.

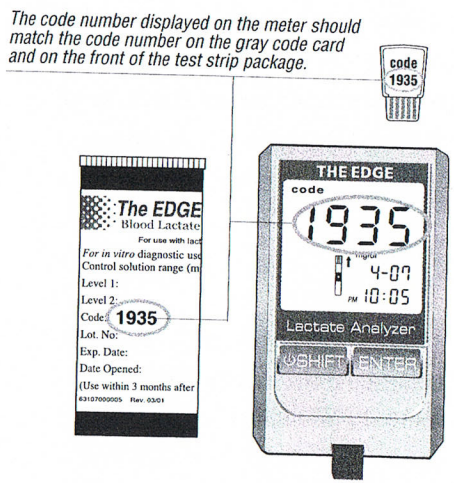
⚠ **NOTE:** There is a code card packaged in each box of test strips. The code card is designed specifically for use with the test strips in that particular package.The code card should have same code number as that indicated on the package of the test strips.

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.



⚠ **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:

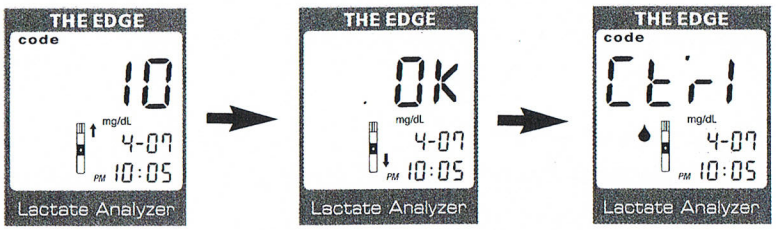
It is recommended that the EDGE Meter is checked using this method when the meter is new and when the performance of the system needs to be confirmed.

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 The Edge 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:**

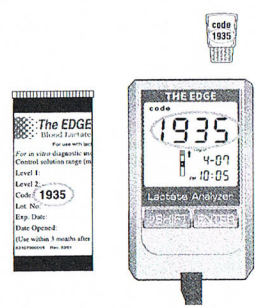
- The acceptable range for the control solution is listed on the package of test strips.
- Use only the Edge Lactate Control Solution and the Edge Blood Lactate Test Strip.
- Always check the expiration date for both the Edge Lactate Control Solution and the Edge Blood Lactate Test strips. **DO NOT** use 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.

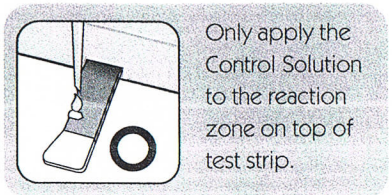
To check the meter using control solution, perform the following steps.

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

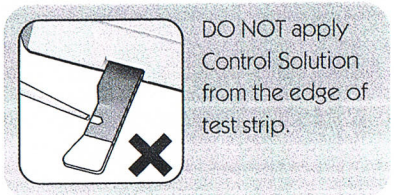
Step 2: The screen will display "Ctrl", and then insert an Edge Blood Lactate Test Strip.

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.

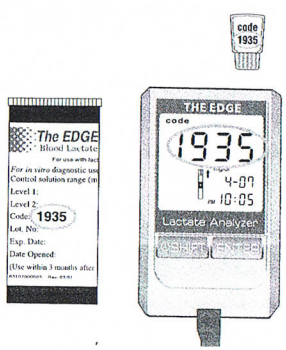
TIP: To avoid soreness, select a site on the side of your fingertips. To avoid calluses, choose a different site each time for obtaining the blood sample.

How to Perform a Test

⚠**IMPORTANT**: Always use the Edge Blood Lactate Test Strips with the Edge Blood Lactate Analyzer.

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

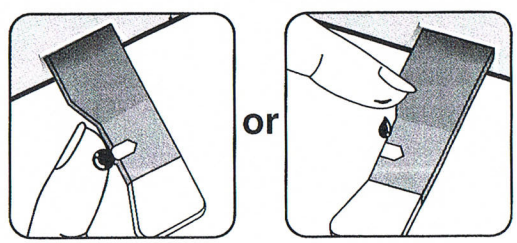
⚠**NOTE:** If the screen shows "Code ---", or if the CODE number on the screen does not match the CODE number on the test strip package, refer to 📖Page 15 for details of (re)coding the Meter.



Step 2: The Meter will self-test the environment temperature. If the temperature is out of range, the screen will show a symbol of thermometer" ▬● ". If the temperature is within the testing range of 10°C 40°C 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 40°C 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.



Performing a Blood Lactate Test

Obtaining a Drop of Blood

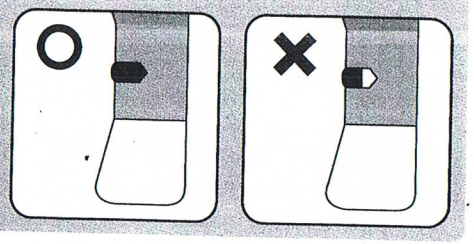
⚠**IMPORTANT**: When performing a blood lactate test, use a new sterile lancet every time. If alcohol wipes are used to cleanse the fingers, make sure the area is dry before the blood sample is obtained.

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.

⚠**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 and lancets. Used test strips and lancets should be treated as biological waste and dispose of properly.

Using the Meter Memory

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 " Ⓜ " 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 " Ⓜ " will flash on screen. Press "SHIFT" button to skip this selection.

Step 4: A symbol of cable " ⌇ " will flash on screen. Press "SHIFT" button to skip this selection.

Step 5: A symbol of speaker " 🔊 " will flash on screen. Press "ENTER" button to skip this selection.

Step 6: 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 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.
- **DO NOT** try to clean the test strip holder.
- **DO NOT** contaminate the strip holder with blood or control solution.

Storage

- The meter is designed to be used within the temperature ranges between 10°C 40°C 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.

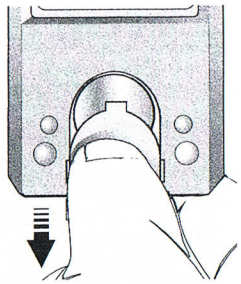
⚠**NOTE:** To save battery power, the EDGE Meter will turn itself off after one minute of non-use. All results stored in memory will be saved even if the meter shuts off automatically. Remove The battery if equipmeut is not likely to be used for some time.

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

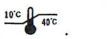
To clean the outside of the EDGE Meter, use a lint-free cloth dampened with soap water or alcohol.

⚠**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.
"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 6mg/dL (0.7 mmol/L).	Repeat the test to confirm the test result. If it reads LO again, contact your healthcare professional.
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:	6 - 200 mg/dL (0.7 - 22.2 mmol/L)
Blood Source:	Finger tip capillary whole blood
Sample Volume:	Approximately than 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, Operating and Transportation)
Storage / Transport 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
Power Suppy:	3V Lithium coin cell battery (CR2032, powered internal)

Dimension:	90Lx55Wx20H (mm)
Weight:	63 g
Electromagnetic Compatibility:	This equipment is complying with EMC requirement of EN 60601-1-2
Classification according to IEC/EN 60601-1:	IPXO, not evaluated as AP/APG equipment, continuous operation.

Symbols Used in this Manual

- (EXP) Expiration date (use by last day of month)
- (LOT) Batch code
- Temperature limitations
- Consult instructions for use
- In vitro diagnostic device
- Caution / warning, consult accompanying documents
- Product code number
- Keep away from sunlight/direct light
- Do not re-use
- Manufactured by
- Authorised Representative in the European Community

Supplies

S54108	The EDGE Blood Lactate Monitoring System
S5638025	The EDGE Test Strips 25's
S5638053	The EDGE Test Strips 2 X 25's
S5800024	The EDGE Lactate control solution

THE EDGE

LACTATE CONTROL SOLUTION

For use with The Edge Blood Lactate Monitoring System

Summary

The purpose of the control solution test is to validate the performance of the Edge Blood Lactate Monitoring System using a standard solution with a known range of lactate. A control solution test that falls within the acceptable range means the user's technique is an appropriate and both of the meter and test strip are functioning properly.

Control solution should be used in the following instances:

- Before you test with the Edge Blood Lactate Monitoring System for the first time.
- Every time you open a new bottle of test strips.
- Whenever you suspect that the meter or test strips are not working properly.
- When your blood Lactate results do not reflect how you feel.
- If you drop the meter.
- If your readings appear to be abnormally high or low.

Chemical Composition

The Edge Control Solution is an aqueous solution containing lactate as the reactive ingredient in approximate concentration of 0.02 %.

⚠Warnings and Precautions

- **Control solution is for In Vitro diagnostic use only and is not intended for human consumption or injection.**
- Warm up the Edge Control Solution to room temperature and shake the Solution well before used.
- **DO NOT** apply a second drop of control solution to the yellow reaction zone of the test strip.
- **DO NOT** smear the solution with the tip of the bottle of control solution.
- **DO NOT** touch the yellow reaction zone of the test strip with the bottle of control solution.
- Replace the cap of the control solution immediately after used.
- Only use the Edge Lactate Control Solution.
- Always check ⌛ the expiration date. **DO NOT use control solution if it has expired.**

⚠Storage and Handling

- Control solution should be stored in 2~8 °C (36~46 °F) 2°C 8°C refrigerator. **DO NOT FREEZE**.

QC (1)

- **DO NOT** use if the expiration date has passed.
- Discard any unused control solution 90 days after first opened.

Control Solution Test Procedure

1. Pre-warm control solution to room temperate before use.
2. Refer to the "Control Solution Method" procedure in user's guide.

Expected Values

THE EDGE Control Solution testing should provide results within the expected range indicated on the Test Strip bottle. If results are not within the acceptable range, the user should carefully review each step of their technique before performing anther test. Any error in technique or meter usage could cause results to be outside the acceptable range. If the control test values continue to be outside the acceptable range and technique is proper, use a strip from a previously unopened bottle and repeat the test. If reading is still not within the acceptable range, please call our authorized dealer in your country.

⚠Caution:

If results continue to be out of range after all instructions have been followed, the system is not functioning properly. **DO NOT** use the system to test your blood Lactate until you get a reading that is within the acceptable range.

	(EXP) Expiration date (use by last day of month)
2°C 8°C	Temperature limitations
	Consult instructions for use
IVD	In vitro diagnostic device
	Caution / warning
REF	Product code number
	Manufactured by

REF S5800024

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P/N 65015110011
Rev.4/ 07

QC (2)

EDGE™

EDGE™ Blood Lactate Test Strips

For the quantitative measurement of Lactate in whole blood for use with the THE EDGE™ Blood Lactate Meter

Before You Begin

- Carefully read this entire insert.
- If you have any question and/or need assistance, please contact our authorized dealer in your country.

Summary

The EDGE™ Blood Lactate Monitoring System is designed to provide an easy, accurate method for the determination of capillary whole blood lactate values. This analysis employs the enzyme Lactate Oxidase which couples with biosensor-based test strip that is specific for lactate measurement. When blood is applied to the reaction zone of the test strip, a signal that correlates with the concentration of lactate in the blood sample is transmit to the Edge Blood Lactate Anlyzer for analysis. The meter analyzes the signal and displays a quantitative result on its large, easy to read LCD screen.

Reagent Composition

Each cm^2 of test strip contains the following reactive ingredients in the approximate concentrations listed below:

Lactate oxidase	0.11 mg
Electron shuttle	0.55 mg
Non-reactive ingredients	0.34 mg

⚠ Warnings and Precautions

The EDGE™ Blood Lactate Test Strips are for IVD IN VITRO diagnostic use only (external use only). The EDGE™ Blood Lactate Test Strips supplied can be used by health-care personnel.

- Do not use test strips after their expiration date.
- Do not use test strips that are wet, bent, scratched, or damaged in any way.
- Do not touch the target area of the test strip.
- Do not re-use the strips.
- You must calibrate your meter with the code card that is packaged with the test strips for each new package of test strips.
- The screen will show "LO" when the whole blood lactate value is less than 6mg/dL, or" HI" when the value is more than 200 mg/dL.

Storage

The EDGE™ Blood Lactate Test Strips are packaged in a moisture proof, light protected bottle.

- Store at temperatures between 4°C to 30°C (39°F to 86°F).
- Keep away from direct heat and sunlight.
- Do not freeze.
- Do not bend, cut, or alter the EDGE™ Blood Lactate Test Strips in any way.

The EDGE™ Test Strips are supplied in a dehumidifying black bottle which protects from moisture and sunlight. Keep the bottle sealed until use.

Sample Collection and Preparation

The EDGE™ Blood Lactate Test Strips are designed specifically for use with fresh capillary whole blood taken from a fingertip. Plasma or serum samples are not to be used. Testing must be performed immediately after the sample is obtained. Prolong aging of blood will led to in blood and endogenous increade of lactate concentration will cause an incorrect result. Common anticoagulants and preservatives such as heparin and sodium EDTA may be used.

Materials Needed to Test Your Blood Lactate

To test your blood Lactate, you will need the EDGE Test Strips provided in this package and the following materials:

- THE EDGE™ Blood Lactate Meter
- THE EDGE™ User's Guide
- Lancet and/or Lancing Device (puncturer)
- Log Book

Testing Procedure

Refer to the EDGE User's Guide, "Performing a Test," for testing procedures.

Quality Control

It is recommended that the performance of the EDGE™ Blood Lactate Monitoring System be tested:

- When your test result do not agree with how you feel.
- When your test strips have been exposed to temperatures outside the specified storage conditions (4°C to 30°C or 39°F to 86°F).

Test Results

Blood Lactate test results are shown on the monitor display as either mg/dL or mmol/L.

Before or during testing, make sure the following:

1. Check if the drop of blood completely filled the reaction zone.
2. Check if the test strip in use is within the expiration date printed on the test strip box label.
3. Check if the code number of the test strip in use matches the number programmed in the meter.
4. Check meter performance with the monitor checker.
5. Check meter and test strip performance with control solutions when test results are still questionable or inconsistent.

Limitations

The EDGE™ Test Strips are designed for use with fresh capillary whole blood samples. DO NOT use serum or plasma samples.

- Hematocrit: variation in sample hematocrit between 35% to 50% have no significant effect on test results. Very high (above 50%) and very low (below 35%) hematocrit can cause inaccurate results.
- Neonates: Do not use EDGE™ test strips to test neonates.

Test strips ①

The performance of this system has not been validated with neonatalsamples.

- Abnormal blood specimens (i.e., high, ascorbic acid, uric acid and hemolysis, etc.) may affect the results. Blood lactate readings from these cases should be interpreted with caution.
- Altitudes up to 2,000 meters (6,562 feet) do not affect test results.

Expected Values

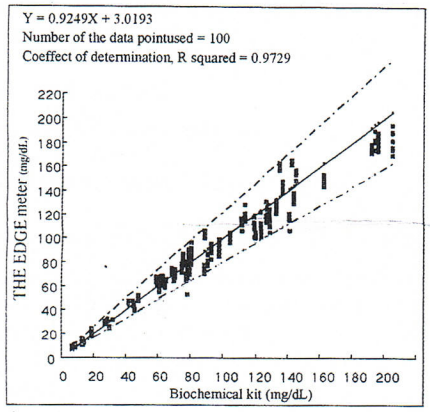
Expected blood Lactate levels for:
At rest: 5.4~18 mg/dL
Anaerobic threshold (IAT): 22.5 -54 mg/dL.

Performance Characteristics

The performance characteristics of the EDGE™ Meter, used with the EDGE™ Test Strips, have been determined in both clinical and laboratory evaluations.

Accuracy:

Accuracy describes how well the readings from a testing system (meter and test strips) agree with the readings from an accepted reference system. The accuracy of the EDGE™ System was assessed in studies using biochemical lactate oxidase-peroxidase method.
The data are presented in the figure below.



Precision:

Precision describes the variation between readings in the test system. A test system with little variation is defined as being precise. A laboratory study was conducted with the EDGE™ System using fresh heparin-venous blood which was adjusted to a broad range of lactate levels. Ten strip readings were obtained with each blood sample. In order to thoroughly verify the precision performance of the EDGE™ System, this study was repeated several times.
The results from a single typical run of this study, shown in the table, exhibit excellent precision characteristics for the EDGE™ System. From all the studies taken together, estimates of mean system precision were calculated to be:
Within run precision ,2.5%.
Between run precision ,2.6%.

Number of readings:	10	10	10	10
Average (mg/dL):	20.0	69.2	101.2	154.2
S.D. (mg/dL):	1.0	1.1	1.5	2.5
C.V. %:	5.1	1.6	1.5	1.6

Reference:

1. Brooks, G.A. (1985) Anaerobic threshold: review of the concept and directions for future research. Medicine Science for Sports and Exercise. 17(1), 6-21. Review.
2. Smith, E. W., Skelton, M. S., Kremer, D. E., Pascoe, D. D., & Gladden, L. B. (1998). Lactate distribution in the blood during steady-state exercise. Medicine and Science in Sports and Exercise, 30(9), 1424-1429.
3. Mader, A., & Heck, H. (1986). A theory of the metabolic origin of "anaerobic threshold". International Journal of Sports Medicine, 7(Sup), 45-65.

Symbols :

(**EXP**) Expiration date (use by last day of month)

(**LOT**) Batch code

4°C 30°C Temperature limitations

IVD In vitro diagnostic device

Consult instructions for use

Caution/warning, consult accompanying documents

REF Product code number

Keep away from sunlight/direct light

Do not re -use

Manufactured by

REF S54108
S5638025
S5638053

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Test Strips (2)