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Introduction

Thank you for choosing THE EDGE Blood Lactate Monitoring System. All of the information that will be needed to use and maintain THE EDGE Blood Lactate Monitoring System is included in this manual. Please read it carefully before using the system.

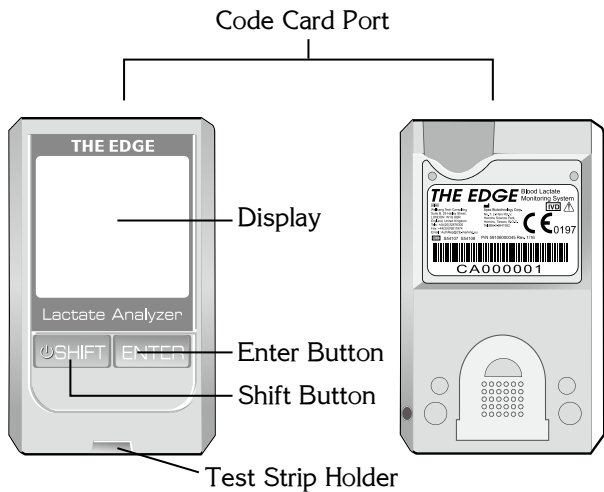
THE EDGE Blood Lactate Monitoring System provides you with important information concerning individual metabolism and oxygen debt. The system is especially designed for an application by in a number of disorders including: liver disease, heart disease, diabetes mellitus, muscular dystrophy, thiamine deficiency, neoplastic disorders. Regardless an application can also be effected by medical specialists in application can also be effected by medical specialist in medial diagnostic. Here it is possible to use measurement results as decision support for following medical treatments of the patient because of the skilled and qualified result evaluation (In Vitro). THE EDGE Blood Lactate Monitoring System is designed for both personal use and professional use.

Contents of the System

THE EDGE system may include the following items.

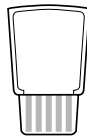
- THE EDGE Blood Lactate Meter
- 3V Lithium Coin Cell Battery (CR 2032)
- Monitor Checker
- EDGE Blood Lactate Test Strips
- Code Card
- User's Guide
- Log Book
- Wallet
- Puncturer
- Lancets (28G)

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.



FRONT

BACK



Code Card



Monitor Checker

Meter Components

- LCD Screen.....Displays information that guides users through testing and setup, and shows test result and error messages.
- Shift Button & Turn meter on and off. Control selection and steps of Enter Button userprogrammable setup in Function Mode.
- Test Strip HolderInsertion 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.

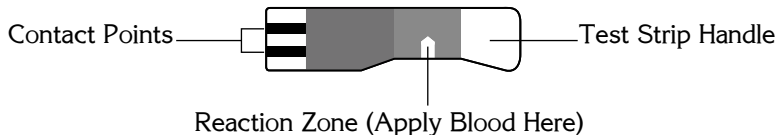
Code Card.....Codes the meter for the test strips that have the same code when inserted into the code card port. Insert the code card with the code number facing up. One code card is packaged with each box of Test Strips.

EDGE Blood Lactate Test Strip

Contact PointsSense 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:

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 "🩸" For additional information on the EDGE Blood Lactate Test 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 confirm. 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 confirm. 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 confirm. 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. Press "SHIFT" button to scroll through the hours and press "ENTER" button to confirm. 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 confirm. Press and hold 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 "ENTER" button to enter setup. Press "SHIFT" button to turn ON/OFF beep sound. 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 "SHIFT" button to skip this selection.

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

Step 8: The pre-set unit of measurement will flash on screen. Press "ENTER" button to enter setup. Press "SHIFT" button to change between mg/dL and mmol/L, and press the "ENTER" button to confirm. 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.

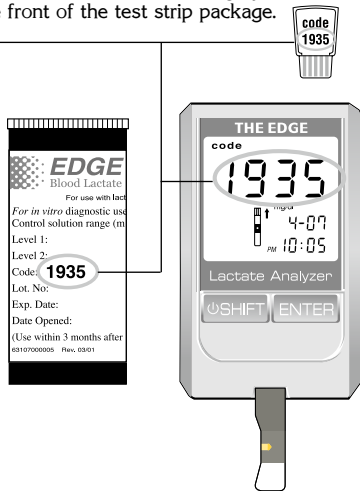
Step 2: Verify that the code number on the code card matches the code number on the test strip package.

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.



⚠NOTE:

Recoding needs to be done when opening a new package of test strips with a different code number.

Checking the System

There are two ways to check performance of THE EDGE Blood Lactate Meter. 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:

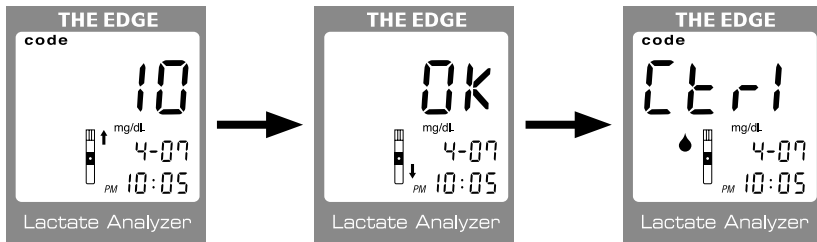
It is recommended that THE EDGE meter is checked using this method when the meter is new and when the performance of the system needs to be confirmed.

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-test.

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" button to exit checking the meter.



⚠NOTE:



If the screen displays "nt OK", repeat the test. If "nt OK" continues to appear, contact the authorized dealer.

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 -20°C (-4°F) or above 50°C (122°F)  -20°C 50°C , or stored in humidity levels above 85%.
- 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)  4°C 30°C and/or light or humidity levels above 85%.
- if the readings appear to be abnormally high or low.

⚠ IMPORTANT:

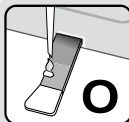
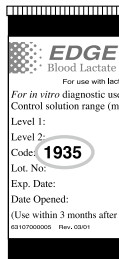
- The acceptable range for the control solution is listed on the package of test strips.
- Use only THE EDGE Lactate Control Solution and EDGE Blood Lactate Test Strips.
- Always check the expiration date  for both THE EDGE Lactate Control Solution and EDGE Blood Lactate Test Strips. **DO NOT** use if expired.
- If a control solution test is not within the expected range that is printed on the test strip package, **DO NOT** use the system. 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.
- **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.

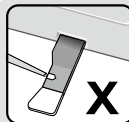
Step 1: Perform Monitor Checker method up to Step 2 (see P.17, Monitor Checker Method) and verify the code number on screen is the same with the code number printed on the bottle.

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 7: Remove and properly discard the used test strip.
- Step 8: 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 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 (puncture) or lancet against the side of the finger and lance the finger. Follow manufacturer's instruction for how the lancing device (puncture) 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


⚠️ IMPORTANT:

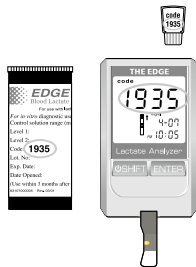
Always use EDGE Blood Lactate Test Strips with THE EDGE Blood Lactate Meter.


Step 1: Follow the instruction on page 14 "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 14 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 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.

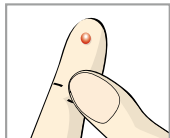
Step 3: Obtain a drop of blood and apply the blood either to the absorbent area at the curved edge of the test strip or the yellow reaction zone on the top of the test strip.



OR

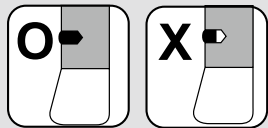


Gently massage your hand and finger toward the puncture site to form a drop of blood (approximately: ●). Do not "milk" or squeeze around the puncture site.



⚠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 number 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.

Understanding the Test Result

Expected blood lactate levels for:

- Normal Range: 9-45 mg/dL(2-5 mmol/L).
- Higher Range: 45 mg/dL to 89.1 mg/dL(5 -9.9 mmol/L) should be considered as severe hyperrlactatemia.

If the result is higher than 45 mg/dL, please contact your physician or healthcare professional immediately.

- Anaerobic threshold (IAT): 22.5 -54 mg/dL About Muscle training.

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 "M" will flash on screen. Press "ENTER" button to view the latest result (with test date and time) in memory. Continue to press the "SHIFT" button to view the previous results.


Step 3: Press the "SHIFT" and "ENTER" buttons 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 "SHIFT" 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 confirm. 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 confirm. 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 confirm. 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. Press "SHIFT" button to scroll through the hours and press "ENTER" button to confirm. Press and hold on the "SHIFT" button for quick searching of the hour.
- Step 11: 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 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 off automatically 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 unused for a long time.

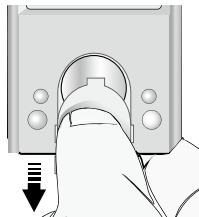
To replace the battery:

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

This section details the significant display screen messages and error codes you may encounter when using THE EDGE Blood Lactate Monitoring System.

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.“ | <ul style="list-style-type: none">• 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. | <ul style="list-style-type: none">• Insert a new code card from a new package of test strips, follow the procedures on p.14 "Coding the Meter".• If problem persists, call the authorized dealer. |
|  | The battery in the meter is running out of power. | Replace the battery. |
|  | The temperature is out of the meter's operating range 10°C to 40°C (50°F to 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) . |

| Message | Problem | What To Do |
|---------|--|--|
| nt OK | <ul style="list-style-type: none">• Monitor Checker result fails.• Used or defective test strip | Repeat the test with a new test strip. If problem persists, 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 the result is still LO, 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 the result is still HI, contact your healthcare professional. |

| Message | Problem | What To Do |
|---------|-----------------------|-----------------------------|
| 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 Meter |
| Test Strips: | EDGE Blood Lactate Test Strips |
| Test Range: | 6 - 200 mg/dL (0.7 - 22.2 mmol/L) |
| Blood Source: | Fingertip capillary whole blood |
| Sample Volume: | Minimum 3 μ L |
| 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: | -20°C to 50°C (-4°F to 122°F) for meter 4°C to 30°C (39.2°F to 86°F) for test strip |
| Power Supply: | 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:

IPX0, not evaluated as AP/APG equipment, continuous operation.

Symbols Used in this Manual



Use-by date



Batch code



Temperature limit



Consult instructions for use



In vitro diagnostic medical device



Caution



Catalogue number



Keep away from sunlight



Do not re-use



Manufacturer



Authorised representative in the European Community

Supplies

| | |
|--------------|--|
| S54108 | THE EDGE Blood Lactate Monitoring System |
| S5638025 | EDGE Test Strips 25's |
| S5638053 | EDGE Test Strips 2 X 25's |
| S5800024 | THE EDGE Lactate control solution |
| 65235010002 | Lancing Device |
| 800500000003 | Lancets (28G) 50's |