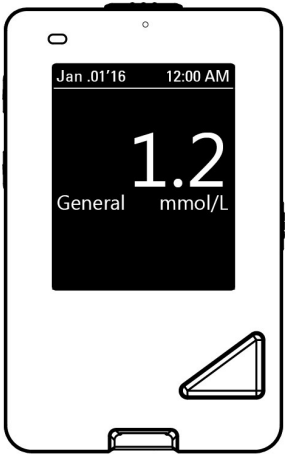
L1

Lactate Monitoring System

Owner's Manual



Dear L1 System Owner:

Thank you for purchasing the **L1** Lactate Monitoring System. This manual provides important information to help you to use the system properly. Before using this product, please read the following contents thoroughly and carefully.

If you have other questions regarding this product, please contact the local customer service or place of purchase.

Intended Use

This system is intended for use outside the body (*in vitro* diagnostic use) by people with suspecting of having lactic acidosis at home and by healthcare professionals in clinical settings as an aid to monitoring the effectiveness of acid-base control. It is intended to be used for the quantitative measurement of lactate in fresh capillary whole blood samples from the fingertips. It should not be used for diagnosis or screening of diseases.

Version 2.0 2018/05
311-4261100-008

IMPORTANT SAFETY PRECAUTIONS
READ BEFORE USE

1. Use this device **ONLY** for the intended use described in this manual.
2. Do **NOT** use accessories which are not specified by the manufacturer.
3. Do **NOT** use the device if it is not working properly or if it is damaged.
4. This device does **NOT** serve as a cure for any symptoms or diseases. The data measured is for reference only. Always consult your doctor to have the results interpreted.
5. Before using this device to test lactate, read all instructions thoroughly and practice the test. Carry out all the quality control checks as directed.
6. Keep the device and testing equipment away from young children. Small items such as the battery cover, batteries, test strips, lancets and vial caps are choking hazards.
7. Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging static discharges that may cause erroneous results.
8. Do **NOT** use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with the accurate operation.
9. Proper maintenance and periodically control solution test are essential to the longevity of your device. If you are concerned about your accuracy of measurement, please contact the local customer service or place of purchase for help.

KEEP THESE INSTRUCTIONS IN A SAFE PLACE

TABLE OF CONTENTS

BEFORE YOU BEGIN 1

Important Information..... 1

Meter Overview..... 2

Display Indicators 3

Test Strip..... 4

SETTING THE METER 4

THE TWO MEASURING MODES..... 6

BEFORE TESTING..... 6

Calibration..... 6

How to Code Your Meter..... 7

Checking the Code Number 7

QUALITY CONTROL TESTING 8

When Should the Control Solution Test be Performed? 8

Performing a Control Solution Test 8

TESTING WITH BLOOD SAMPLE..... 10

Preparing the Lancing Device for Blood Testing..... 10

Preparing the Puncture Site 10

Performing a Lactate Test..... 11

METER MEMORY..... 13

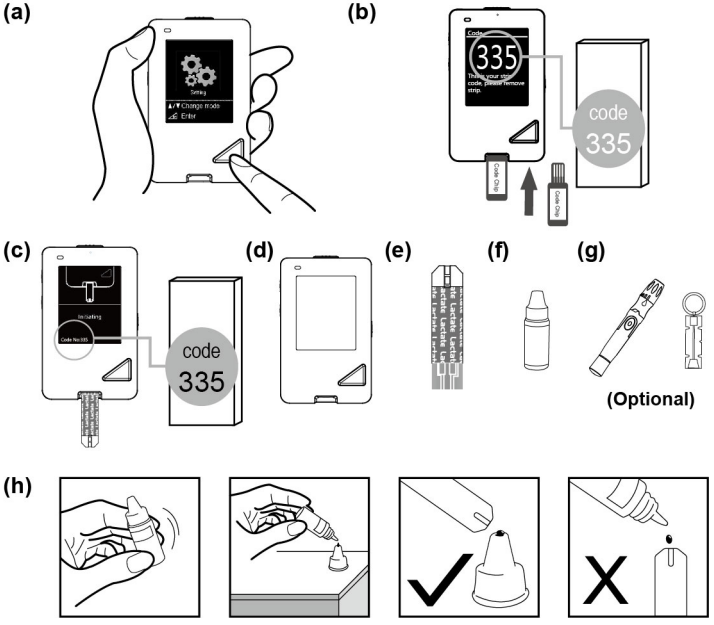
Reviewing Test Results..... 13

DOWNLOADING RESULTS ONTO A COMPUTER..... 14

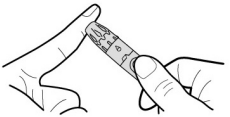
MAINTENANCE..... 15

Battery 15

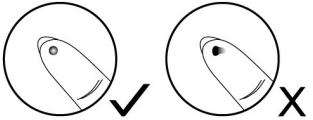
Charging the Battery 15
Caring for Your Meter 16
Caring for Your Test Strips 16
Cleaning Your Lancing Device 17
Important Control Solution Information 18
SYSTEM TROUBLESHOOTING 19
Result Readings 19
Error Messages 19
Troubleshooting 21
DETAILED INFORMATION 22
SYMBOL INFORMATION 22
SPECIFICATIONS 23


(a)
Setup
Change mode
Enter
(b)
335
code
335
(c)
Code No.335
code
335
(d)
(e)
(f)
(g)
(Optional)
(h)

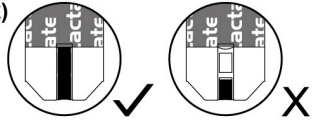
(i)



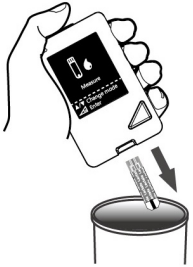
(j)



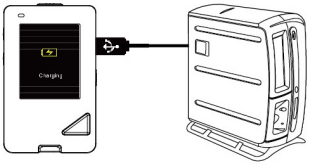
(k)



(l)



(m)

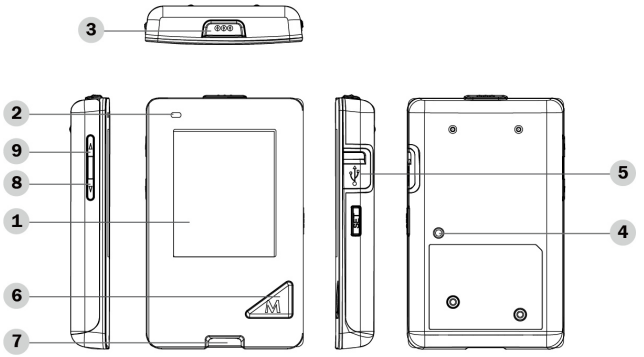


BEFORE YOU BEGIN

Important Information

- Severe dehydration and excessive water loss may cause readings which are lower than actual values. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.
- If your test results are lower or higher than usual, and you do not have any symptoms of illness, first repeat the test. If you have symptoms or continue to get results which are higher or lower than usual, follow the treatment advice of your healthcare professional.
- Use only fresh whole blood samples to test your lactate. Using other substances will lead to incorrect results.
- If you are experiencing symptoms that are inconsistent with your lactate test results and you have followed all the instructions given in this owner's manual, contact your healthcare professional
- We do not recommend using this product on severely hypotensive individuals or patients in shock. Please consult the healthcare professional before use.

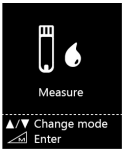
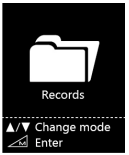
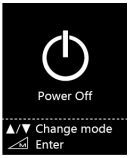
Meter Overview



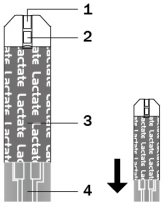
1. **Display Screen**
2. **Charger Indicator**
3. **Test Strip Ejector**
   Eject the used strip by pushing up this button.
4. **Reset Button**
5. **Data Port**
6. **M Button (M)**
   Enter the meter memory
7. **Test Strip Slot**
   Insert test strip here to turn the meter on for testing
8. **Down Button (▼)**
9. **Up Button (▲)**

Display Indicators

The screen displays several indicators to help you use this meter. Press **M** to turn on the meter. Press ▲ or ▼ to select from the modes below:

Indicator	Meaning/ You can do this
	Lactate Measuring Mode: Perform your lactate tests.
	Memory Recall Mode: Review your lactate test results in the meter memory.
	Setting Mode: Set up your meter.
	System Power Off: Turn off the meter.

Test Strip



1 **Absorbent Hole** 2 **Confirmation Window**
3 **Test Strip Handle** 4 **Contact Bars**

ATTENTION:
The front side of test strip should face up when inserting test strip.

Test results might be wrong if the contact bar is not fully inserted into the test slot.

NOTE:
- The **L1** monitor should only be used with **L1** Test Strips. Using other test strips with this meter can produce inaccurate results.

SETTING THE METER

Before using your meter for the first time or if you change the meter battery, you should check and update these settings.

Entering the Setting Mode (a)
Start with the meter off (no test strip inserted). Press **M** to turn on the meter. Press ▲ or ▼ to select Setting mode and press **M**.

1. **Setting the date format**

   Press ▲ or ▼ to select the desired date format --- month/day/year or day/month/year. Press **M**.

2. **Setting the date**

   The sequence of the date setting is: YEAR → MONTH → DAY. Press ▲ or ▼ until the correct year / month / day appears. Press **M**. The meter displays the full date and “Date is set” message.

3. **Setting the time format**

   Press ▲ or ▼ to select the desired time format --- 12h or 24h.
   Press **M**.

4. **Setting the time**

   The sequence of the time setting is: HOUR → MINUTE.
   Press ▲ or ▼until the correct hour / minute appears. Press **M**.
   The meter displays the complete time and “Time is set” message.

5. **Deleting the memory**

   To delete all the results, press ▲ or ▼ to switch to ”yes” and press **M**. The meter displays “Memory cleared” which indicates that all data stored is deleted.

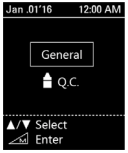
Congratulations! You have completed all settings!

NOTE:

- These parameters can ONLY be changed in the setting mode.
- If the meter is idle for 3 minutes during the setting mode, it will switch off automatically.

THE TWO MEASURING MODES

The meter provides you with two modes for measuring, General and QC. You can switch between each mode by:

Modes		Use when
General		testing with the blood sample
QC		testing with the control solution

You can switch between each mode by: In the measuring mode, after a test strip is inserted, press ▲ or ▼ to select a suitable measuring mode when the meter displays the list. Press **M** and proceed with a lactate testing.

BEFORE TESTING

Calibration

You must calibrate the meter every time you begin to use a new box of lactate test strips by setting the meter with the correct code. Test results may be inaccurate if the code number displayed on the monitor does not match the number printed on your test strip vial or individual foil packet.

How to Code Your Meter

1. Insert the code chip when the monitor is off. Wait until the number appears on the display. (b)

NOTE:
Make sure the number on display, code chip, and test strip vial (or individual foil package) are the same.

2. Remove the code chip, the display will show “OFF”. This tells you that the meter has been updated and is ready for measurement.

Checking the Code Number

You need to make sure that the code number displayed on the meter matches the number on the test strip vial or box of foil package before you proceed **(b)**. If it matches, you can proceed with your test. If the codes do not match, please stop testing and contact Customer Service for help.

NOTICE:
The code number on the display from picture (b) is only for your reference, it may not be an actual code for this meter.

WARNING:
- It is important to make sure that the LCD displayed code is the same as the code on the test strip vial or box of foil package before testing. Failure to do so will get inaccurate results.
- If the LCD displayed code is not the same as the code on the test strip vial or box of foil package, and the code number cannot be updated, please contact Customer Service for assistance.

QUALITY CONTROL TESTING

When Should the Control Solution Test be Performed?

- if it is mandatory following the local regulations in your country,
- if you suspect the meter or test strips are not working properly,
- if your lactate test results are not consistent with how you feel, or if you think the results are not accurate,
- to practice the testing process, or
- if you have dropped or think you may have damaged the meter.

Test strips **(e)**, control solutions **(f)**, lancing device **(g)** or sterile lancets may not be included in the kit (please check the contents on your product box). They can be purchased separately. Please make sure you have those items needed for a lactate test beforehand.

Performing a Control Solution Test

To perform a control solution test, you will need: **(d)**, **(e)** and **(f)**.
When the meter is off, you can enter the measuring mode by two ways:

1. **Insert the test strip to turn on the meter**
   Insert the test strip into the meter. Wait for the meter to display the initiating animation. Or,

   Press M to turn on the meter
   Select the measuring mode. Press **M** to enter. Insert a test strip when the meter displays test strip inserting animation. Wait for the meter to display the initiating animation.

2. Select Q.C. and press M to perform this test in the control solution measuring mode.

Warning:

- When doing the control solution test, you have to mark it so that the test results will **NOT** mix with the lactate **TEST RESULTS** stored in the memory. Failure to do so will mix up the lactate test results with the control solution test results in memory.

3. Apply control solution (h)

Shake the control solution vial thoroughly before use. Squeeze out the first drop and wipe it off, then squeeze out another drop and place it on the tip of the vial cap. Hold the meter to move the absorbent hole of the test strip to touch the drop. Once the confirmation window fills completely, the meter will begin counting down.

NOTE:

- To avoid contaminating the control solution, do not directly apply control solution onto a strip.

4. Read and compare the result

After counting down to 0, the control solution test result will appear on the display. Compare this result with the range printed on the test strip box or test strip vial and it should fall within this range. If not, please read the instructions again and repeat the control solution test.

NOTE:

- The control solution range printed on the test strip box is for control solution use only. It is not a recommended range for your lactate level.
- See the **MAINTENANCE** section for important information about your control solutions.

TESTING WITH BLOOD SAMPLE

Warning:
To reduce the chance of infection:
- Never share a lancet or the lancing device.
- Always use a new, sterile lancet. Lancets are for single use only.
- Avoid getting hand lotion, oils, dirt, or debris in or on the lancets and the lancing device.

Preparing the Lancing Device for Blood Testing

Please follow the instructions in the lancing device insert for collecting a blood sample.

Preparing the Puncture Site

Stimulating blood perfusion by rubbing the puncture site before blood extraction has a significant influence on the lactate value obtained. Blood from a site that has not been rubbed exhibits a measurably different lactate concentration than blood from the finger. When the puncture site was rubbed prior to blood extraction, the difference was significantly reduced.

Please follow the suggestions below before obtaining a drop of blood:

- **Wash and dry your hands before starting.**
- Select the puncture site either at fingertips.
- Rub the puncture site for about 20 seconds before penetration.
- Clean the puncture site using cotton moistened with 70% alcohol and **let it air dry**.
- **Fingertip testing (i)**
  Press the lancing device's tip firmly against the lower side of your fingertip. Press the release button to prick your finger, then a click indicates that the puncture is complete.

NOTE:

- Alcohol swabs with 70% alcohol can be purchased in pharmacy.
- Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.

Performing a Lactate Test

To perform a lactate test, you will need: **(d), (f)** and **(g).**

1. **Insert a test strip to turn on the meter**
   The meter displays the initiating animation.
2. **Select general mode by pressing ▲ or ▼.**
   Press **M** to perform this test.
3. **Obtaining a blood sample (j)**
   Use the pre-set lancing device to puncture the desired site. The size of the drop should be at least as 0.8 microliter (μL) of volume. Gently squeeze the punctured area to obtain another drop of blood. Be careful **NOT** to smear the blood sample.
4. **Apply the sample (k)**
   Gently apply the drop of blood to the absorbent hole of the test strip at a tilted angle. Confirmation window should be completely filled if enough blood sample has been applied. Do **NOT** remove your finger until you hear a beep sound.

NOTE:

- Do not press the punctured site against the test strip or try to smear the blood.
- If you do not apply a blood sample to the test strip within 3 minutes, the meter will automatically turn off. You must remove and reinsert the test strip to start a new test.
- The confirmation window should be filled with blood before the meter begins to count down. **NEVER** try to add more blood to the test strip after the drop of blood has moved away. **Discard the used test strip and retest with a new one.**
- If you have trouble filling the confirmation window, please contact your health care professional or the local customer service for assistance.

5. **Read Your Result**
   The result of your lactate test will appear after the meter counts down to 0. The lactate result will be stored in the memory automatically.
6. **Eject the used test strip (I)**
   Eject the test strip by pushing the eject button on the top. The meter will switch itself off automatically.

Always follow the instructions in the lancing device insert when removing the lancet.

WARNING:

- The used lancet and test strip may be biohazardous. Please discard them carefully according to your local regulations.

METER MEMORY

The meter stores the 450 most recent test results along with respective dates and times in its memory. To enter the meter memory, **start with the meter switched on**.

Reviewing Test Results

1. **Select the records mode by pressing ▲ or ▼.**
   Press **M** to enter. The first reading you see is the last lactate result along with test number, date, time and the measuring mode.

2. **Press ▲ or ▼** to recall the test results stored in the meter each time you press. Press **M** again and the meter returns to the main page of record mode.

NOTE:

- Any time you wish to exit the memory, press **M** to exit or leave it without any action for 3 minutes. The meter will switch off automatically.

DOWNLOADING RESULTS ONTO A COMPUTER

Data Transmission via Cable

You can use the meter with a USB cable and the Health Care Software System to view test results on your personal computer. To learn more about the Health Care Software System or to obtain a USB cable separately, please contact the local customer services or place of purchase for assistance.

1. **Obtaining the required cable and installing the software**
   To download the Health Care Software System, please visit the TaiDoc's website: www.taidoc.com
2. **Connecting to a personal computer**
   Connect the cable to a USB port on your computer. With the meter switched off, connect the other end of the USB cable to the meter data port. "PC link" will appear on the meter display, indicating that the meter is in communication mode.
3. **Data transmission**
   To transmit data, follow the instructions provided with the software. Results will be transmitted with date and time. Remove the cable and the meter will automatically switch off.

WARNING:

- While the meter is connecting to the PC, it will be unable to perform a lactate test.

MAINTENANCE

Battery

Your meter comes with a built-in rechargeable 3.7V Li-polymer battery.

Low Battery Signal

When the meter displays “Battery empty” message:
The power is not enough to do a test. Please charge the battery immediately.

Charging the Battery

To charge the battery (m), make sure the meter is turned off.

1. Connect the USB adapter to the side of the meter.
2. Plug the USB adapter to a wall outlet or connect the other end of USB cable to the USB port on your personal computer.
3. The recharge symbol shows when battery is recharging. After the battery is fully charged, remove the USB cable and then the meter will automatically turn off.

NOTE:

- Recharging the battery does not affect the test results stored in the memory.
- The USB cable is for meter recharging and data transmission with a computer. If you wish to recharge through wall outlet, please obtain a USB adapter.
- Generally, the expected battery life can last for at least 50 measurements with 3 minutes in each measurement, or at least for 4 months of standby until the meter runs out of power.
- Properly dispose of the batteries according to your local environmental regulations.

Caring for Your Meter

Cleaning

1. To clean the meter exterior, wipe it with a cloth moistened with tap water or an alcohol swab with 70% alcohol, then dry the device with a soft dry cloth. Do **NOT** rinse with water.
2. Do **NOT** use organic solvents to clean the meter.

Meter Storage

- Storage conditions: -20°C to 60°C (-4°F to 140°F), below 95% relative humidity.
- Always store or transport the meter in its original storage case.
- Avoid dropping and heavy impact.
- Avoid direct sunlight and high humidity.

Meter Disposal

The used meter should be treated as contaminated that may carry a risk of infection during measurement. The batteries in this used meter should be removed and the meter should be disposed in accordance with local regulations.

The meter falls outside the scope of the European Directive 2002/96/EC-Directive on waste electrical and electronic equipment (WEEE).

Caring for Your Test Strips

- Storage conditions: 2°C to 30°C (35.6°F to 86°F) and below 85% relative humidity. Do **NOT** freeze.
- Store your test strips in their original vial only. Do not transfer to another container.
- Store test strip packages in a cool dry place. Keep away from direct sunlight and heat.

- After removing a test strip from the vial, immediately close the vial cap tightly.
- Touch the test strip with clean and dry hands. Use each test strip immediately after removing it from the vial or the foil package.
- Do not use test strips beyond the expiration date. This may cause inaccurate results.
- Do not bend, cut, or alter a test strip in any way.
- Keep the strip vial or single foil package away from children since the cap and the test strip may be a choking hazard. If swallowed, promptly see a doctor for help.

For further information, please refer to the test strip package insert.

Cleaning Your Lancing Device

Cleaning Procedures

1. Take out one alcohol swab with 70% alcohol from the package and squeeze out any excess liquid in order to prevent damage to the meter.
2. Wipe all lancing device's exterior surface and release button.
3. Remove the alcohol swab. Allow the lancing device surface to dry completely.
4. Discard the used alcohol swabs and never reuse them. Users should wash hands thoroughly with soap and water after handling the lancing device.

The lancing device should be cleaned after each use.

Important Control Solution Information

- Use only our control solutions with your meter.
- Do not use the control solution beyond the expiration date or 3 months after first opening. Write the opening date on the control solution vial and discard the remaining solution after 3 months.
- It is recommended that the control solution test be done at room temperature 20°C to 25°C (68°F to 77°F). Make sure your control solution, meter, and test strips are at this specified temperature range before testing.
- Shake the vial before use, discard the first drop of control solution, and wipe off the dispenser tip to ensure a pure sample and an accurate result.
- Store the control solution tightly closed at temperatures between 2°C to 30°C (35.6°F to 86°F). Do **NOT** freeze.

SYSTEM TROUBLESHOOTING

If you follow the recommended action but the problem persists, please call your local customer service.

Result Readings

MESSAGE	WHAT IT MEANS
Reading below detection range	< 0.3 mmol/L
Reading above detection range	> 22 mmol/L

Error Messages

MESSAGE	WHAT IT MEANS	WHAT TO DO
Error 01	Appears when the battery cannot provide enough power for a test.	Charge the battery immediately.
Error 23	Appears when there is a system error	Repeat the test with a new test strip. If the meter still does not work, please contact the customer service for assistance.
Error 24	Appears when a used test strip is inserted.	Repeat with a new test strip.
Error 25 Error 26	Appears when ambient temperature is above or below system operation range.	System operation range is 10°C to 40°C (50°F to 104°F). Repeat the test after the meter and test strip are in the above temperature range.
Error 28	Appears when inserting the wrong code chip	Check the code chip and insert the correct code chip.

Error 29 Error 30	Problem with the test strip	Repeat the test with a new test strip.
Error 41	Meter error	Contact the local customer service for help.
Error 40	Appears when removing the strip during a measurement	Repeat the test with a new test strip. If this error persists, please the customer service for assistance.
Error 45	Appears when there is insufficient blood volume.	Review the instructions and repeat test with a new strip. If the problem persists, please contact the local customer service for help.
Error 46	Appears when HCT value exceeds the measurement range	Repeat the test with a new test strip.
Notice 01	Measuring result is above the limited range.	
Notice 02	Measuring result is below the limited range!!	
Notice 03	Measuring record is empty.	

Troubleshooting

1. If the meter does not display a message after inserting a test strip:

POSSIBLE CAUSE	WHAT TO DO
Batteries exhausted.	Recharge the battery.
Test strip inserted upside down or incompletely.	Insert the test strip with contact bars end first and facing up.
Defective meter or test strips.	Please contact customer services.

2. If the test does not start after applying the sample:

POSSIBLE CAUSE	WHAT TO DO
Insufficient blood sample.	Repeat the test using a new test strip with larger volume of blood sample.
Defective test strip.	Repeat the test with a new test strip.
Sample applied after automatic switch-off (3 minutes after last user action).	Repeat the test with a new test strip. Apply sample only when flashing "🩸" appears on the display.
Defective meter.	Please contact customer services.

3. If the control solution testing result is out of range:

POSSIBLE CAUSE	WHAT TO DO
Error in performing the test.	Read instructions thoroughly and repeat the test again.
Control solution vial was poorly shaken.	Shake the control solution vigorously and repeat the test again.
Expired or contaminated control solution.	Check the expiry date of the control solution.
Control solution that is too warm or too cold.	Control solution, meter, and test strips should be at room temperature 20°C to 25°C (68°F to 77°F) before testing.
Defective test strip.	Repeat the test with a new test strip.
Meter malfunction.	Please contact customer services.
Improper working of meter and test strip.	Please contact customer services.

DETAILED INFORMATION

The meter provides you with plasma equivalent results.

Desirable range:

Lactate	0.7 - 2.5 mmol/L

Source: Burtis, Carl A. and Ashwood, Edward R., ed. 1994. Tietz Textbook of Clinical Chemistry. Philadelphia, PA: W. B. Saunders Co.

Please consult your doctor to determine a target range that works best for you.

SYMBOL INFORMATION

SYMBOL	REFERENT	SYMBOL	REFERENT
IVD	*In vitro* diagnostic medical device		Caution, consult accompanying documents
	Consult instructions for use		Humidity Limitation
	Temperature limitation		Collection for electrical and electronic equipment
	Use by	CE 0123	CE mark
LOT	Batch code		Manufacturer
SN	Serial number	EC REP	Authorized representative in the European

SPECIFICATIONS

Model No.: L1
Dimension & Weight: 96 (L) x 61 (W) x 26 (H) mm, 67.2 g
Power Source: One 3.7V Li-polymer battery
Display: LCD
Memory: 450 measurement results with respective date and time
External Output: Mini USB cable

Auto sample loading detection
Auto electrode insertion detection
Auto reaction time count-down
Auto switch-off after 3 minutes without action
Temperature Warning

Operating Condition: 10°C to 40°C (50°F to 104°F), below 85% R.H. (non-condensing)
Meter Storage/Transportation Conditions: -20°C to 60°C (-4°F to 140°F), below 95% R.H.
Strip Storage/Transportation Conditions: 2°C to 30°C (35.6°F to 86°F), below 85% R.H.
Measurement Units: fixed mmol/L
Measurement Range: 0.3 to 22 mmol/L
Expected service life: 5 years

This device has been tested to meet the electrical and safety requirements of: IEC/EN 61010-1, IEC/EN 61010-2-101, EN 61326-1, IEC/EN 61326-2-6.

TaiDoc Technology Corporation
B1-7F, No.127, Wugong 2nd Rd.,
Wugu Dist., 24888 New Taipei City, Taiwan
www.taidoc.com

EC REP **MedNet GmbH**
Borkstraβe 10, 48163 Münster, Germany

For self-testing

CE 0123 IVD REF TD-4261