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# I1

## Multi-Functional Monitoring System

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### Owner's Manual





# Dear I1 System Owner:

Thank you for purchasing the **I1** Multi-Functional 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) to quantitatively measure the blood glucose,  $\beta$ -ketone or lactate levels in whole blood. It is for home use or for healthcare professional use. It should not be used for diagnosis or screening of diseases.

The blood glucose test strip uses fresh capillary whole blood samples from fingertips, and from venous, arterial and neonatal whole blood. Professionals may use the test strips to test capillary, venous, arterial and neonatal blood sample; home use is limited to capillary whole blood testing.

The  $\beta$ -ketone test strip uses fresh capillary whole blood samples from the fingertips, and from venous whole blood. Professionals may use the test strips to test capillary and venous blood sample; home use is limited to capillary whole blood testing.

The lactate test strip uses fresh capillary whole blood samples from the fingertips, and from venous whole blood. Professionals may use the test strips to test capillary and venous blood sample immediately; home use is limited to capillary whole blood testing immediately.

## **Test Principle**

Your system measures the amount of blood glucose/ $\beta$ -ketone/lactate in whole blood. The blood glucose/ $\beta$ -ketone/lactate testing is based on the measurement of electrical current generated by the reaction of blood glucose/ $\beta$ -ketone/lactate with the reagent of the strip. The meter measures the current, calculates the blood glucose/ $\beta$ -ketone/lactate level, and displays the result. The strength of the current produced by the reaction depends on the amount of blood glucose/ $\beta$ -ketone/ lactate in the blood sample.

# IMPORTANT SAFETY PRECAUTIONS

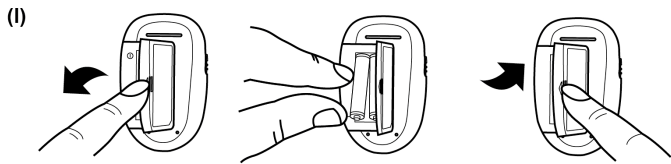
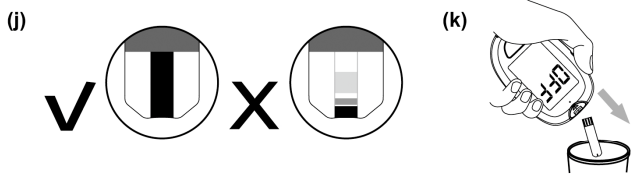
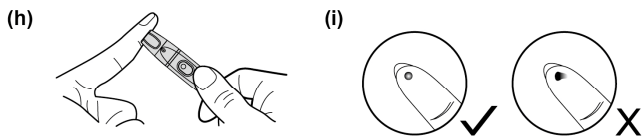
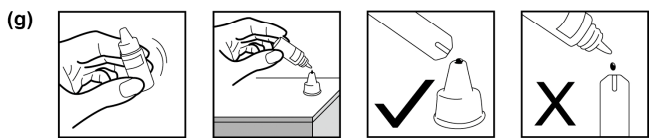
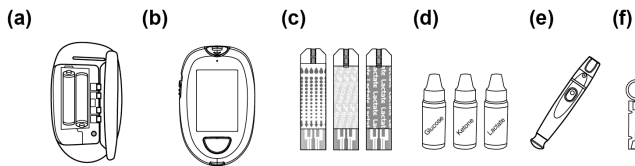
## READ BEFORE USE

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. The blood glucose test strip can be used for the testing of newborns; the  $\beta$ -ketone/lactate test strip must not be used for the testing of newborns.
5. 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.
6. Before using this device to test blood glucose,  $\beta$ -ketone or lactate, read all instructions thoroughly and practice the test. Carry out all the quality control checks as directed.
7. 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.
8. Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, and carpets etc.) may cause damaging static discharges that may cause erroneous results.
9. Do **NOT** use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with the accurate operation.
10. 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**

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# 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 blood glucose,  $\beta$ -ketone or lactate 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 blood glucose,  $\beta$ -ketone or lactate. Using other substances will lead to incorrect results.
- If you are experiencing symptoms that are inconsistent with your 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.
- The measurement unit used for indicating the concentration of blood or plasma glucose can either have a weight dimension (mg/dL) or a molarity (mmol/L). The approximate calculation rule for conversion of mg/dL in mmol/L is:

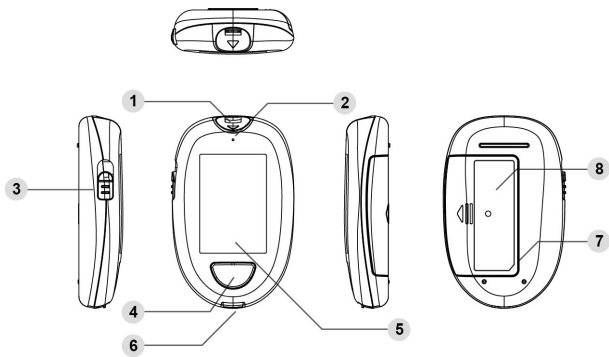
mg/dL	Divided by 18	= mmol/L
mmol/L	Times 18	= mg/dL

For example:

1)  $120 \text{ mg/dL} \div 18 = 6.6 \text{ mmol/L}$

2)  $7.2 \text{ mmol/L} \times 18 = 129 \text{ mg/dL}$  approximately.

# Meter Overview

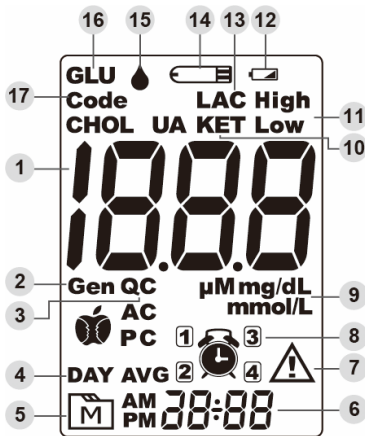


- 1 Test Strip Slot with Strip Indication Light**  
Insert test strip here to turn the meter on for testing.
- 2 Bluetooth Indication Light**  
**(Bluetooth is available for alternative data transmission)**
- 3 Test Strip Ejector**  
Eject the used strip by sliding up this button.
- 4 M Button (M)**  
Enter the meter memory and silence a reminder alarm.
- 5 Display Screen**
- 6 Data Port**  
Download test results with a cable connection.
- 7 SET Button (S)**  
Enter and confirm the meter settings.
- 8 Battery Compartment**

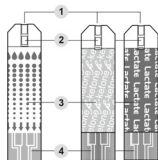
# Display Screen

- 1 **Test Result**
- 2 **Measuring Mode**  
Gen – any time of day  
AC – before meal  
PC – after meal
- 3 **Auto QC Mode/ QC Mode**  
QC – control solution test
- 4 **Day Average**
- 5 **Memory Mode**
- 6 **Date / Time**
- 7 **Error Message /  
Ketone Warning**
- 8 **Alarm Symbol**
- 9 **Measurement Unit**
- 10  **$\beta$ -Ketone Symbol**
- 11 **High / Low Indicator**
- 12 **Low Battery Symbol**
- 13 **Lactate Symbol**
- 14 **Test Strip Symbol**

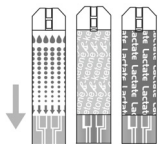
- 15 **Blood Drop Symbol**
- 16 **Blood Glucose Symbol**
- 17 **Code**



# 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 I1 monitor should only be used with I1 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 **S**.

### **1. Setting the date**

The sequence of the date setting is: YEAR → MONTH → DAY. With the YEAR / MONTH / DAY flashing in sequence, press **M** to select the correct number. Press **S**.

### **2. Setting the time format**

Press **M** to select the desired time format (12h or 24h). Press **S**.

### **3. Setting the time**

With the HOUR / MINUTE flashing in sequence, press **M** to select the correct number. Press **S**.


### **4. Setting the blood glucose measuring unit**

With the measuring unit flashing, press **M** to switch between mg/dL and mmol/L. Press **S**.


### **5. Setting the buzzer**

With the buzzer displays, press **M** to switch between “On” and “Off”. Press **S**.

### **6. Deleting the memory**

With “dEL” and “M” on the display, press **M** to select “no” to keep the results in memory then press **M** to skip. To delete all the results, press **M** and select “yes” to delete all the memory records.

## 7. Setting the reminder alarm

Your meter has four reminder alarms. The meter will display “On” or “OFF” and “”. If you don’t want to set an alarm, press **S** to skip this step. Or press **M** to select “On”, then press **S**.

With the hour/minute flashing in sequence, press **M** to select the correct hour/minute. Press **S** and go to the next alarm setting.

### NOTICE:

When the alarm beeps, press **M** to switch it off. Otherwise, it will beep for 2 minutes then switch off.

## 8. Setting the Bluetooth function (alternative to USB)

With “bt” on the display, press **M** to select “On” or “OFF”. Press **S**.

### NOTICE:

This function is referring to the Bluetooth data transmission. If “On” is selected, your result will be transmitted automatically right after the test.

**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 MEASURING MODES

## For Blood Glucose Testing

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



1. Start with the meter switched off. Insert a test strip to turn on the meter. The screen will display “”, a flashing “” and “GLU”.
2. Press **M** to switch between General, AC and PC mode.

## For $\beta$ -Ketone Testing

The meter provides you with one mode for measuring, General. You can start with the meter switched off. Insert a test strip to turn on the meter. The screen will display “”, a flashing “”, and “KET”.

## For Lactate Testing

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

1. Start with the meter switched off. Insert a test strip to turn on the meter. The screen will display “”, a flashing “”, and “LAC”.
2. Press **M** to switch between General and QC mode.

# 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 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 **(c)**, control solutions **(d)**, lancing device **(e)** or sterile lancets **(f)** 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 test beforehand.

## Performing a Control Solution Test

To perform a control solution test, you will need: **(b)**, **(c)** and **(d)**.

### 1. Insert the test strip to turn on the meter

Insert the test strip into the meter. Wait for the meter to display “” and a flashing “”.

### 2. Press **M** to mark this test as a control solution test (for the lactate test)

With “**QC**” displayed, the meter will store your test result in memory under “**QC**”. If you press **M** again, the “**QC**” will disappear and this test is no longer a control solution test.

#### **Warning:**

Make sure to perform the control solution test in QC mode.



### 3. **Apply control solution (g)**

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:**

- For the blood glucose or  $\beta$ -ketone test, your device will tag this measurement as QC test automatically.
- 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 vial and it should fall within this range. If not, please read the instructions again and repeat the control solution test.

With “**QC**” displayed, the meter will store your test result in memory under “**QC**”.

#### **NOTE:**

- The control solution range printed on the test strip vial is for control solution use only. It is not a recommended range for your blood test 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 test value obtained.

Blood from a site that has not been rubbed exhibits a measurably different blood glucose/ $\beta$ -ketone/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.
- 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 (h)**

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:**

Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.

## Performing a Blood Test

To perform a blood test, you will need: **(b)**, **(c)**, **(e)** and **(f)**.

### 1. Insert the test strip to turn on the meter

Wait for the meter to display the “”, “”, and “GLU”/“KET”/“LAC”.

### 2. Select the appropriate measuring mode by pressing M.

### 3. Obtaining a blood sample (i)

Use the pre-set lancing device to puncture the desired site. The size of the drop should be at least as big as • (actual size) which is 0.5 microliter ( $\mu\text{L}$ ) of volume for a blood glucose test; 0.8 microliter ( $\mu\text{L}$ ) of volume for both the  $\beta$ -ketone test and the lactate test. Gently squeeze the punctured area to obtain another drop of blood. Be careful **NOT** to smear the blood sample.

### 4. Apply the sample (j)

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:**

- For a lactate test, make sure to perform a test immediately after drawing the sample.
- 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 test will appear after the meter counts down to 0. The result will be stored in the memory automatically.

## 6. **Eject the used test strip (k)**

Eject the test strip by pushing the eject button on the side. Use a sharp bin to dispose of used test strips. 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 1000 most recent test results along with respective dates and times in its memory. To enter the meter memory, **start with the meter switched off.**

## Reviewing Test Results

### 1. **Press and release M.**

“**M**” will appear on the display. Press **M** again, and the first reading you see is the last result along with date, time and the measuring mode.

### 2. **Press M** to recall the test results stored in the meter each time you press. Press and hold **M** to switch off the meter.

## Reviewing Blood Glucose Day Average Results

### 1. **Press and release M** to enter memory mode for average results with “**M**” and “**DAY AVG**” displayed on the screen. Release **M** and then your 7-day average result measured in general mode will appear on the display.

### 2. **Press M to review** 14-, 21-, 28-, 60- and 90- day average results stored in each measuring mode in the order of General, AC, then PC.

### 3. **Exit the meter memory.**

Keep pressing the **M** and the meter will turn off after displaying the last test result.

#### **NOTE:**

- Any time you wish to exit the memory, keep pressing **M** for 3 seconds or leave it without any action for 3 minutes. The meter will switch off automatically.
- Control solution results are **NOT** included in the day average.

# DOWNLOADING RESULTS ONTO A COMPUTER

## **Data Transmission via Cable**

You can use the meter with a USB cable (optional) 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](http://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. The "USB" 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 test.

# BLUETOOTH PAIRING

## **Data Transmission via Bluetooth (alternative to USB)**

You can transmit your data from the meter to your device via Bluetooth. The **ProCheck app** is designed to assist you easily monitoring your blood glucose,  $\beta$ -ketone and lactate levels.

## **How to Install and Update the ProCheck App**

You must connect to the internet to download the app. The App Store or Google Play can be accessed by tapping the App Store or Play Store icon on your iOS or Android devices.

It is simple and intuitive to use, for better understanding of your current condition and to achieve better diabetes control.

## **System Requirement**

For the requirement of OS version, please find on App Store or Google Play when you download the app. Please contact your local customer service or place of purchase for assistance. Please note that you must complete the pairing between meter and Bluetooth receiver before transmitting data.

## **Pairing with your mobile device**

1. Turn on the Bluetooth function on your mobile device.
2. Follow the instructions of the ProCheck app to pair the device. (Ex. Search to find the meter and then add it into the app.)
3. After successfully pairing the app with the device, the Bluetooth function of meter shall be on before transmitting data to the ProCheck app.

## Bluetooth Indicator on the Meter:

BLUETOOTH INDICATOR	STATUS
Flashing Blue	The Bluetooth function is on and waiting for connection.
Solid Blue	The Bluetooth connection is established.

### WARNING:

- If a cable connects to the data port on your meter and computer, the data will be transmitted via USB; If a cable does not connect to the data port on your meter and computer, the data will be transmitted via Bluetooth.
- While the meter is in transmission mode, it will be unable to perform a test.
- Make sure your device supports Bluetooth Smart Technology. Also make sure the Bluetooth setting on your device is turned on and the meter is within the receiving range before transmitting the data. Please find OS version requirement on App Store or Google Play when you download the app.
- The Bluetooth functionality is implemented in different ways by the various mobile device manufacturers; the compatibility issue between your mobile device and the meter maybe occur.






# MAINTENANCE

## Battery

Your meter comes with two 1.5V AAA size alkaline batteries.

### Low Battery Signal

The meter will display one of the messages below to alert you when the meter power is getting low.

1. **The “” symbol appears** along with display messages: The meter is functional and the result remains accurate, but it is time to change the batteries.
2. **The “” symbol appears with E-b,  and Low:** The power is not enough to do a test. Please change the batteries immediately.

## Replacing the Battery

**To replace the batteries (I), make sure the meter is turned off.**

1. Press the edge of the battery cover and lift it up to remove.
2. Remove the old batteries and replace with two 1.5V AAA size alkaline batteries.
3. Close the battery cover. If the batteries are inserted correctly, you will hear a “beep” afterwards.

### NOTE:

- Replacing the batteries does not affect the test results stored in the memory.
- As with all small batteries, these batteries should be kept away from children. If swallowed, promptly seek medical assistance.
- Batteries might leak chemicals if unused for a long time. Remove the batteries if you are not going to use the device for an extended period (i.e., 3 months or more).
- Properly dispose of the batteries according to your local environmental regulations.

## Caring for Your Meter

### Cleaning

- To clean the meter exterior, wipe it with a cloth moistened with tap water or a mild cleaning agent, then dry the device with a soft dry cloth. Do **NOT** rinse with water.
- Do **NOT** use organic solvents to clean the meter.

### Meter Storage

- Storage conditions: -20°C to 60°C (-4°F to 140°F), between 10% and 93% relative humidity (non-condensing).
- 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 86.0°F) and 10% to 90% relative humidity for blood glucose test strips; 2°C to 30°C (35.6°F to 86.0°F) and 10% to 85% relative humidity for  $\beta$ -ketone and lactate test strips. 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.
- 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 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.

## 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.

# MEASUREMENT RESULT READINGS

## For Blood Glucose Testing

MESSAGE	WHAT IT MEANS		
<b>Lo</b>	< 10 mg/dL (0.56 mmol/L)		
Low	10 to 69 mg/dL (0.56 and 3.8 mmol/L)		
<small>GLU</small> 	<b>AC</b>	<b>PC</b>	<b>Gen</b>
	70 to 129 mg/dL (3.8 to 7.1 mmol/L)	70 to 179 mg/dL (3.8 to 9.9 mmol/L)	70 to 119 mg/dL (3.8 to 6.6 mmol/L)
High	<b>AC</b>	<b>PC</b>	<b>Gen</b>
	130 to 239 mg/dL (7.2 to 13.2 mmol/L)	180 to 239 mg/dL (10 to 13.2 mmol/L)	120 to 239 mg/dL (6.6 to 13.2 mmol/L)
<small>GLU</small> 	≥ 240 mg/dL (13.3 mmol/L)  Ketone Warning: This is shown when your blood glucose result is equal to or higher than 240 mg/dL (13.3 mmol/L).  What to Do: Check blood ketone if checking ketones is part of your diabetes management program.		
<b>H,</b>	> 800 mg/dL (44.44 mmol/L)		

## For $\beta$ -Ketone Testing

MESSAGE	WHAT IT MEANS
Lo	< 0.1 mmol/L
<sup>KET</sup> 0.5 mmol/L	0.1 to 8.0 mmol/L
Hi	> 8.0 mmol/L

## For Lactate Testing

MESSAGE	WHAT IT MEANS
Lo	< 0.3 mmol/L
<sup>LAC</sup> 1.2 mmol/L	0.3 to 22 mmol/L
Hi	> 22 mmol/L

## Reference Values

### Blood Glucose Test

The blood glucose readings deliver plasma equivalent results and are displayed either in milligrams of glucose per deciliter of blood (mg/dL) or in millimoles of glucose per liter of blood (mmol/L).

Time of day	Normal plasma glucose range for people <b>without</b> diabetes (mg/dL)
Fasting and before meal	< 100 mg/dL (5.6 mmol/L)
2 hours after meals	< 140 mg/dL (7.8 mmol/L)

Source: American Diabetes Association. Standards of Medical Care in Diabetes- 2018 Jan; 41(Supplement 1): S1-S2

### $\beta$ -Ketone Test

The  $\beta$ -Ketone readings deliver plasma equivalent results and are displayed in millimoles of ketone per liter of blood (mmol/L).

The  $\beta$ -Ketone test measures Beta-Hydroxybutyrate ( $\beta$ -OHB), the most important of the three  $\beta$ -Ketone bodies in the blood. Normally, levels of  $\beta$ -OHB are expected to be less than 0.6 mmol/L<sup>1</sup>.

$\beta$ -OHB levels may increase if a person fasts, exercises vigorously or has diabetes and becomes ill. If your  $\beta$ -Ketone result is “Lo”, repeat the  $\beta$ -Ketone test with new test strips. If the same message appears again or the result does not reflect how you feel, contact your healthcare professional. Follow your healthcare professional’s advice before you make any changes to your diabetes medication program. If your  $\beta$ -Ketone result is between 0.6 and 1.5 mmol/L, this may indicate development of a problem that could require medical assistance. Follow your healthcare professional’s instructions. If your  $\beta$ -Ketone result is higher than 1.5 mmol/L, contact your healthcare professional promptly for advice and assistance. You may be at risk of developing diabetic ketoacidosis (DKA).

1: Wiggam MI, O'Kane MJ, Harper R, Atkinson AB, Hadden Dr, Trimble ER, Bell PM. **Treatment of diabetic ketoacidosis using normalization of blood 3-hydroxybutyrate concentration as the endpoint of emergency management.** Diabetes Care 1997; 20: 1347-52.

## Lactate Test

The meter provides you with plasma equivalent results and are displayed in millimoles of lactate per liter of blood (mmol/L).

Desirable range:

Lactate	0.3 to 2.4 mmol/L
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Source: Mary A. Williamson, L. Michael Snyder, 10th ed, 2015. Wallach's interpretation of diagnostic tests :pathways to arriving at a clinical diagnosis. Philadelphia : Wolters Kluwer.

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

# SYSTEM TROUBLESHOOTING

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

## Error Messages

MESSAGE	WHAT IT MEANS	WHAT TO DO
E-b	Appears when the batteries are too low.	Replace the battery immediately.
E-U	Appears when a used test strip is inserted.	Repeat with a new test strip.
E-2	Appears when the strip/code chip is expired.	Make sure the date you set on the meter is correct and check the expiry date shown on the packaging. If the problem persist, repeat with a new code chip.
E-t	Appears when ambient temperature is above or below system operation range.	System operation range is 8°C to 45°C (46.4°F to 113°F). Repeat the test after the meter and test strip are in the above temperature range.
E-0 E-A E-E E-C	Problem with the meter.	Repeat the test with a new test strip. If the meter still does not work, please contact the customer service for assistance.
E-F	Appears when test strip is removed while counting down, or 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.
E-8	Appears when the code chip is not inserted before testing or the meter does not support certain parameters.	Check the code chip is inserted for coding correctly. Make sure the code chip you used supports the parameter. If the problem persists, please contact the local customer service for help.



# Troubleshooting

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

POSSIBLE CAUSE	WHAT TO DO
Batteries exhausted.	Replace the batteries.
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.

# SYMBOL INFORMATION

SYMBOL	REFERENT	SYMBOL	REFERENT
	<i>In vitro</i> diagnostic medical device		Manufacturer
	Consult instructions for use		Catalogue number
	Temperature limit		Caution
	Use-by date		Humidity limitation
	Batch code		CE mark
	Serial number		RoHS compliance
	Authorized representative in the European Community		
	This device does not belong to household waste and must be returned to a collection point for recycling electric and electronic devices according to local laws. If it contains batteries, the batteries should be removed and disposed in accordance with locations for separate collection of spent batteries.		

# SPECIFICATIONS

**Model No.:** I1

**Dimension & Weight:** 90.3 (L) x 52.3 (W) x 18 (H) mm, 58 g

**Power Source:** Two 1.5V AAA alkaline batteries

**Display:** LCD with backlight

**Memory:** 1000 measurement results with respective date and time

**External Output:** USB and Bluetooth

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:** 8°C to 45°C (46.4°F to 113°F), between 10% and 85% R.H. (non-condensing)

**Meter Storage/Transportation Conditions:** -20°C to 60°C (-4°F to 140°F), between 10% and 93% R.H. (non-condensing)

**Strip Storage/Transportation Conditions:**

Blood Glucose: 2°C to 30°C (35.6°F to 86°F), between 10% and 90% R.H. (non-condensing)

β-Ketone/ Lactate: 2°C to 30°C (35.6°F to 86°F), between 10% and 85% R.H. (non-condensing)

**Measurement Units:**

Blood Glucose Test: Either mg/dL or mmol/L

β-Ketone Test: Fixed mmol/L

Lactate Test: Fixed mmol/L

**Measurement Range:**

Blood Glucose Test: 10 to 800 mg/dL (0.56 to 44.4 mmol/L)

$\beta$ -Ketone Test: 0.1 to 8.0 mmol/L

Lactate Test: 0.3 to 22 mmol/L

**Expected Service Life:** 5 years

**Operating Altitude:** Up to 2000m, for indoor use

**Degree of Pollution:** Pollution degree 2

This device has been tested to meet the electrical and safety requirements of: IEC/EN 61010-1, IEC/EN 61010-2-101, IEC/EN 61326-1, IEC/EN 61326-2-6, EN 300 328.













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TD-4289

For self-testing

