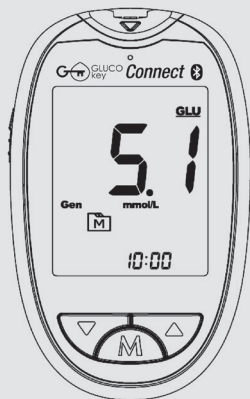




Blood Glucose Plus  $\beta$ -Ketone Monitoring System



## Owner's Manual





# Dear Owner of **GlucoKey Connect** **Blood Glucose Plus $\beta$ -Ketone** **Monitoring System:**

Thank you for purchasing the **GlucoKey Connect** Blood Glucose Plus  $\beta$ -Ketone Monitoring System. This manual provides important information to help you to use the system properly. Before using this product, please read and follow the instructions in this Owner's Manual.

Regular monitoring of your blood glucose levels can help you and your doctor gain better control of your diabetes. Due to its compact size and easy operation, you can use the **GlucoKey Connect** Blood Glucose Plus  $\beta$ -Ketone Monitoring System to easily monitor your blood glucose levels.

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# SAFETY INFORMATION

Read the following Safety Information thoroughly before using the device.

- Use this device **ONLY** for the intended use described in this manual.
- **DO NOT** use accessories which are not specified by the manufacturer.
- **DO NOT** use the device if it is not working properly or if it is damaged.
- 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.
- The blood glucose test strip can be used for testing of newborns.
- The  $\beta$ -Ketone test strip must NOT be used for testing of newborns.
- Before using this device to test blood glucose or  $\beta$ -Ketone, read all instructions thoroughly and practice the test. Carry out all the quality control checks as directed.

- Keep the device and testing supplies away from young children. Small items such as the battery cover, batteries, test strips, lancets and vial caps are choking hazards.
- The 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.
- **DO NOT** use this instrument in close proximity to sources of strong electromagnetic radiation as these may interfere with the correct operation.
- Proper maintenance as well as timely calibration of the device together with the control solution is essential in ensuring the longevity of your device. If you are concerned about the accuracy of the measurement, please contact customer service for assistance on 1800 451 737.

**KEEP THESE INSTRUCTIONS IN A SAFE PLACE**



## 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 or  $\beta$ -Ketone results are lower or higher than usual and you do not have 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 or  $\beta$ -Ketone. Using other substances will lead to inaccurate results.
- If you are experiencing symptoms that are inconsistent with your blood glucose or  $\beta$ -Ketone test results and you have followed all the instructions described in this owner's manual, contact your healthcare professional.
- We do not recommend using this product on severely hypotensive individuals or patients in shock. Readings which are lower than actual values may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. Please consult your healthcare professional before use.

- The measurement unit used for indicating the concentration of blood glucose is mmol/L.
- The measurement unit used for indicating the concentration of  $\beta$ -Ketone is mmol/L.

# INTRODUCTION

## Intended Use

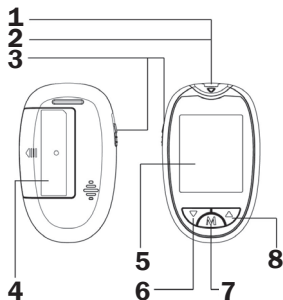
This system is intended for use outside the body (in vitro diagnostic use) by people with diabetes at home and by healthcare professionals in clinical settings as an aid to monitor the effectiveness of diabetes control. It is intended to be used for the quantitative measurement of glucose (sugar) with capillary from fingertip, venous, arterial and to measure  $\beta$ -hydroxybutyrate (Ketone) in fresh whole blood samples from the finger. It should not be used for the diagnosis of diabetes or screening for diabetes mellitus. Professionals may test blood glucose with capillary sampling from a finger tip or with venous, arterial and neonatal blood from the heel. Test  $\beta$ -Ketone with a capillary sampling from the fingertip. Use only heparin for anticoagulation of whole blood.

Home use is limited to capillary blood from the fingertip.

## Test Principle

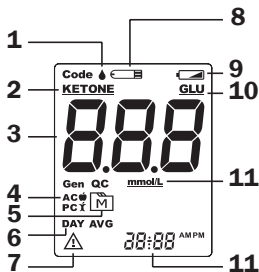
Your system measures the amount of glucose or  $\beta$ -Ketone in whole blood. The glucose or  $\beta$ -Ketone testing is based on the measurement of electrical current generated by the reaction of glucose or  $\beta$ -Ketone with the reagent of the strip. The meter measures the current, calculates the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

## Product Overview



- ① Test Strip Slot
- ② Strip Indication Light
- ③ Test Strip Ejector
- ④ Battery Compartment
- ⑤ Display Screen
- ⑥ Down Button
- ⑦ MAIN Button
- ⑧ UP Button


## Meter Display



- ① Blood Drop Symbol
- ② Ketone Warning / Ketone Symbol
- ③ Test Result
- ④ Measurement Mode
- ⑤ Memory Symbol
- ⑥ Day Average
- ⑦ Warning Symbol
- ⑧ Test Strip Symbol
- ⑨ Low Battery Symbol
- ⑩ Blood Glucose Symbol
- ⑪ Measurement Unit
- ⑫ Date & Time

# GETTING STARTED

## Initial Set-up

Please follow the initial set-up procedure before using the device for the first time or after you have replaced the battery. When the battery power is extremely low and “E-b &  ” appears on the screen, the meter cannot be turned on.

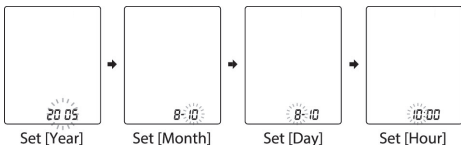


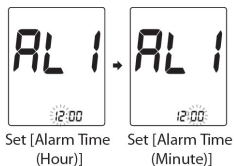
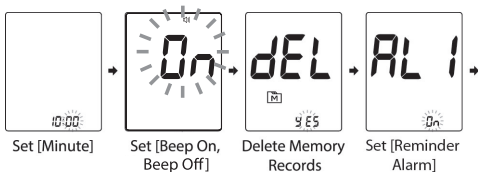
### Step 1: Enter the Setting Mode

1. The meter turns on automatically once a new battery is inserted.
2. Start with the meter off (no test strip inserted). Press ▲ and ▼ at the same time.

### Step 2: Configuring the Settings (Date, Time, Memory Deletion and Reminder Alarm)

Press ▲ or ▼ to adjust the value or enable/disable the setting then press MAIN button to confirm the setting and switch to another field.





### Note:

- Press ▲ to select Beep On or Beep Off then press **MAIN** button to confirm.



- When Beep is turned off, the alarm function will remain effective.
- During memory deletion, select “no” to keep all saved results.
- You may set it up to four reminder alarms.

- To turn off the alarm, press ▲ or ▼ to change On to OFF. Press **MAIN** button to confirm.
- When the alarm goes off, the device will automatically turn on. Press ▲ or ▼ to mute the alarm. If you do not press ▲ or ▼, the device will beep for 2 minutes then switch off.
- If the device is idle for 3 minutes during the setting mode, it will turn off automatically.



# BEFORE TESTING

## Calibration

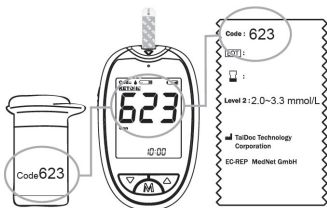
You must calibrate the device every time you begin to use a new box of  $\beta$ -Ketone test strips by setting the meter with the correct code. To ensure test accuracy, make sure the code number displayed on the display screen matches the number printed on the test strip vial or individual foil pack.

## Checking the Code Number

1. Insert the  $\beta$ -Ketone strip into the test strip slot of the device. Wait for the device to display the code number.

### Important

Make sure that the code number displayed on the device matches the number on the test strip vial or individual foil pack before you proceed.



2. Remove the  $\beta$ -Ketone strip, the display will show “OFF” indicating the device has finished coding and ready for  $\beta$ -Ketone or blood glucose testing.

Make sure the code number on display and test strip vial or individual foil pack are the same.

If it matches, you can proceed with your test. Otherwise, please stop testing and repeat the calibration procedure. If the problem persists, contact customer service for further assistance.



### **Important**

It is important to make sure that the LCD display code is the same as the code on the test strip vial or individual foil pack before testing. Failure to do so will cause inaccurate results.

## **Control Solution Testing**



Our Control Solution contains a known amount of glucose or  $\beta$ -Ketone that reacts with test strips and is used to ensure your device and test strips are working together correctly.

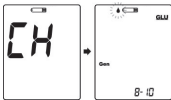
Test strips, control solutions or sterile lancets may not be included in the kit (please check the contents on your product box). They can be purchased separately. Please make sure you have those items needed for a blood glucose test beforehand.

### **Do a control solution test when:**

- ✓ you first receive the device.
- ✓ you begin using a new vial of test strips.
- ✓ you suspect the device or test strips are not working properly.
- ✓ your blood glucose or  $\beta$ -Ketone test results are not consistent with how you feel or if you think the results are not accurate.
- ✓ you have dropped or think you may have damaged the device.

### **Perform a control solution test:**

1. Insert the test strip into the test strip slot of the device. Wait for the device to display the test strip “” and blood drop “”.



2. The meter will detect the difference between control solution and blood samples automatically. It will automatically mark the result as a control solution test with “QC” displayed.
3. Shake the control solution vial thoroughly before use. Squeeze out a drop and wipe it off then squeeze another drop and place it on the tip of the vial cap. Hold the device to move the absorbent hole of the test strip to

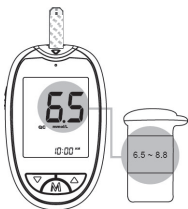
touch the drop of control solution. Once the confirmation window is filled completely, the device will begin counting down.



**Note:**

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

4. Read and compare the result. After counting down to 0, the test result of the control solution will appear on the display. Compare this result with the range printed on the test strip vial or individual foil pack and it should fall within this range. If the test result is out of range, read the instructions again and repeat the control solution test.



**Note:**

- Control solution test results are stored in the memory.
- The control solution range printed on the test strip vial or

individual foil pack is for control solution use only. It is not a recommended range for your blood glucose level.

- Refer to the **Maintenance** section for important information about your control solutions.

**Out of range results:**

If you continue to get results that fall outside the range printed on the test strip vial, it means that the meter and strips may not be working properly.

# TESTING YOUR BLOOD GLUCOSE

## Test Strip Appearance

### Absorbent Hole

Apply a drop of blood here. The blood will be automatically absorbed.

### Test Strip Handle

Hold this part to insert the test strip into the meter slot.



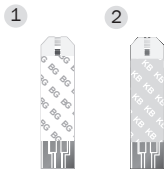
### Confirmation Window

This is where you confirm if enough blood has been applied to the absorbent hole in the strip.

### Contact Bars

Insert this end of the test strip into the meter. Push it in firmly until it stops.

- ① Blood Glucose Test Strip
- ②  $\beta$ -Ketone Test Strip



## Inserting a Test Strip

Insert the test strip into its slot.

### Important

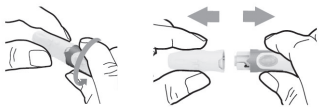
The front side of test strip should face up when inserting the test strip. Test results may be inaccurate if the contact bar is not fully inserted into the test slot.

To reduce the chance of infection:

- Never share a lancet or a lancing device.
- Always use a new, sterile lancet. Lancets are for single use only.
- Avoid getting hand cream, oils, dirt or debris in or on the lancets and the lancing device.

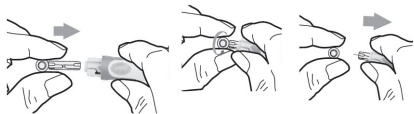
## Preparing the Lancing Device

1. Remove the cap.



2. Insert a new lancet firmly into the white lancet holder cup.

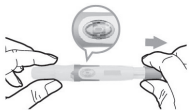
3. Remove the protective disk on the lancet. Hold the lancet firmly in place and twist off the protective disk.



4. Replace the cap until it snaps or clicks into place.
5. Rotate the dial to set the desired lancing depth.



6. Pull the cocking control out until the orange bar appears on the release button window.



## Obtaining a Blood Sample

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

- Wash and dry your hands before starting.
- Select the puncture site either on your fingertips or other body parts.
- Rub the puncture site for about 20 seconds before penetration.

### \* **Blood from the fingertip**

1. Press the lancing device tip firmly against the lower side of your fingertip.



2. Press the release button to prick your finger. A click indicates that the puncture is complete.

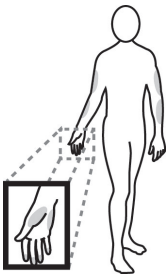


\* **Blood from sites other than the fingertip (For Blood Glucose Test Only)**

**Important**

- AST is not available for  $\beta$ -Ketone test.

Alternative site testing (AST) is when individuals check their blood glucose levels using other areas of the body other than the fingertips. The GlucoKey test strips allow AST to be performed on sites other than the fingertips. Please consult your healthcare professional before you begin AST.



We strongly recommend that you perform AST **ONLY** at the following times:

- During a pre-meal or fasting state (more than 2 hours since the last meal).

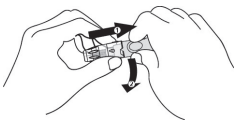
- Two hours or more after taking insulin.
- Two hours or more after exercise.

**DO NOT** use AST if:

- You think your blood glucose is low.
- You may not notice if you are hypoglycemic.
- Your AST results are inconsistent with the way you feel.
- You are testing for hyperglycemia.
- Your routine glucose results often fluctuate.

To obtain a blood sample from the alternative sites, please rub the puncture site for approximately 20 seconds.

1. Replace the lancing device cap with the clear cap.





2. Pull the cocking control out until the orange bar appears on the release button window.



### **Important**

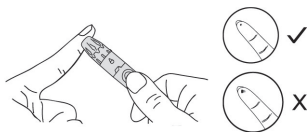
- Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.
- Avoid lancing the areas with obvious veins to avoid excessive bleeding.
- It is recommended to discard the first drop of blood as it might contain tissue fluid which may affect the test result.

## Perform a Blood Glucose or $\beta$ -Ketone Test

1. Insert the test strip into its slot. Wait for the device to display the test strip “”, blood drop “” and **GLU** or **KETONE**.

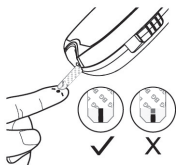


2. Press  or  to adjust the measuring mode, and press **MAIN** button to confirm it.
  - General Tests (Gen) - any time of day without regard to time since the last meal.
  - AC - no food intake for at least 8 hours.
  - PC - 2 hours after a meal.
  - QC - testing with control solution.
3. Obtain a blood sample.



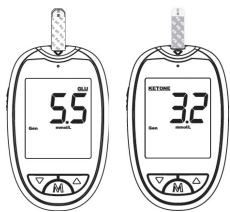
Use the preset lancing device to prick your desired site. After penetration, discard the first drop of blood with a clean tissue or cotton. Gently squeeze the punctured area to obtain another drop of blood. Be careful NOT to smear the blood sample. The volume of blood sample must be at least 0.5 microliter ( $\mu\text{L}$ ) for blood glucose or at least 0.8 microliter ( $\mu\text{L}$ ) for  $\beta$ -Ketone.

4. Apply the blood sample.



Move your finger to meet the absorbent hole of the test strip and the drop will be automatically be drawn onto the test strip. Remove your finger until the confirmation window is filled. The meter begins to countdown. Do not remove your finger until you hear a beep sound.

5. Read your result.



The results of your blood glucose test or the result of your  $\beta$ -Ketone test will appear after the meter counts down to 0. The results will be stored automatically in the meter memory.

## Disposing Used Test Strip and Lancet

To remove the used test strip, simply push the **Test Strip Ejector** button upward to eject the used test strip. The device will automatically turn off after the test strip is removed. Remove the used lancet from the lancing device after you have finished testing. Discard your used strip and lancet properly in a sharps container.

### **Important**

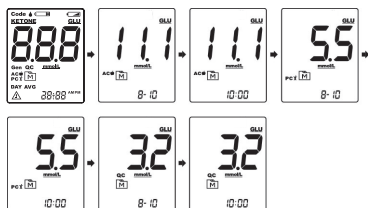
The used lancet and test strip may be a biohazard. Please consult your healthcare provider for proper disposal which complies with your local regulations.

# REVIEWING TEST RESULTS

Your device stores the 1000 most recent test results along with respective dates and times in its memory. To enter the device memory, start with the device switched off.

## To review all test results, do the following:

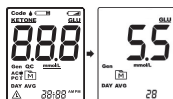
1. Press and release **MAIN** button or ▲. The “**M**” icon appears on the screen.
2. Press **MAIN** to review the test results stored in the device. Press ▲ or ▼ repeatedly to review other test results stored in the device.



After the last test result, press **MAIN** again and the device will be turned off.

## To review the day-average test results, do the following:

1. Press and release ▼ to enter memory mode for average results with “M” and **DAY AVG** displayed on the screen. Release **MAIN** and then your 7-day average result measured in general mode will appear on the display.
2. Press ▲ to review 14, 21, 28, 60 and 90-day average results stored in each measuring mode in the order of Gen, AC, then PC.



**Note:**

- Press and hold **MAIN** for 5 seconds to exit the memory mode or leave it without any action for 3 minutes. The device will turn off automatically.
- If using the device for the first time, the “—” icon will appear when you recall the test results or review the average result. This indicates that there is no test result in the memory.
- Control solution results are **NOT** included in the day average.



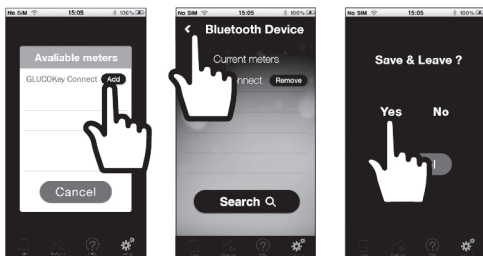
# TRANSFERRING DATA

## Data Transmission Via Bluetooth

You can use your device with an iOS (5.0.1 or higher) or Android (2.3.3 or higher) to download data from your GlucoKey Connect via Bluetooth. Follow the steps below to transmit data from your GlucoKey Connect. Please contact your customer service or place of purchase for assistance.

1. Install the GlucoKey app to your device with an iOS or Android system.
2. Every time the GlucoKey Connect is turned off, the Bluetooth will be initiated for data transmission. The Bluetooth indicator flashes in blue.
3. Make sure your GlucoKey Connect is already paired with your device by following the instructions below:





### Note:

This step is recommended when the user needs to pair this meter to a Bluetooth receiver for the first time or when the user needs to pair this meter to another Bluetooth receiver.


4. If your device with an iOS or Android is within the receiving range, the data transmission will start and the Bluetooth signals in blue. Once it is finished, the GlucoKey Connect will automatically switch off.
5. If your device with an iOS or Android is not within the receiving range, the GlucoKey Connect will automatically switch off in 2 minutes.

### Note:

- While the meter is in transmission mode, it will be unable to perform a blood glucose test.
- Before transmitting data, ensure the meter is within range and your iOS or Android device has Bluetooth turned on.

# MAINTENANCE

## Changing the Battery

You must change the battery immediately and reset the date and time when the battery power is extremely low and “ & E-b” appears on the screen. The meter cannot be turned on.



To change the battery, do the following:

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

### CAUTION

**RISK OF EXPLOSION IF BATTERY IS REPLACED BY AN INCORRECT TYPE.**

**DISPOSE OF USED BATTERIES ACCORDING TO THE INSTRUCTIONS.**

### Note:

- Replacing the battery does not affect the test results stored in the memory.

- Keep the battery away from small children. If swallowed, seek medical assistance immediately.
- Battery may leak chemicals if unused for a long time. Remove the battery if you are not going to use the device for an extended period.
- Properly dispose of the used battery according to your local environmental regulations.

## Caring for Your Device

- To clean the exterior of the device, 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 device.

## Device Storage

- Storage condition:  $-20^{\circ}\text{C}$  to  $60^{\circ}\text{C}$  , below 95% relative humidity.
- Always store or transport the device 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 and 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.

## Caring for Your Test Strips

- Storage condition: 2°C to 30°C , 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 and 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 expiry 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 assistance.

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

## Important Control Solution Information

- Use only our control solutions with your device.
- Do not use the control solution beyond the expiry 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. Make sure your control solution, device 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. **DO NOT** freeze.

## REFERENCE VALUE

The device provides you with plasma equivalent blood glucose results.

Time of day	Normal plasma glucose range for people without diabetes
Fasting and before meals	< 5.6 mmol/L
2 hours after meals	< 7.8 mmol/L

Source: American Diabetes Association (2012). *Clinical Practice Recommendations. Diabetes Care, 35 (Supplement 1): S1-100.*



















- 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.  $\beta$ -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 a development of a problem that may 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 immediately for advice and assistance. You may be at risk of developing diabetic ketoacidosis (DKA).

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



# SYMBOL INFORMATION


SYMBOL	REFERENT	SYMBOL	REFERENT
	<i>In vitro</i> diagnostic medical device		Caution, consult accompanying documents
	Consult instructions for		Humidity Limitation
	Temperature limitation		Collection for electrical and
	Use by		CE mark
	Batch code		Manufacturer
	Serial number		Dispose of the packaging properly after use
	Do not reuse		Sterilized using irradiation
	Keep away from sunlight		Keep dry
	Do not use if package is damaged		Manufacturing date

# TROUBLESHOOTING

If you follow the recommended steps but the problem persists or error messages other than the ones below appear, please call customer service on 1800 451 737.

Do not attempt to repair the device yourself and never try to disassemble the device under any circumstances.

## Result Readings (for glucose test)

MESSAGE	WHAT IT MEANS
<b>Lo</b>	< 0.5 mmol/L
	$\geq 13.3$ mmol/L
<b>Hi</b>	> 33.3mmol/L

## Result Readings (for $\beta$ -Ketone test)


MESSAGE	WHAT IT MEANS
<b>Lo</b>	< 0.1 mmol/L
<b>0.6</b> mmol/L	0.1 to 8.0 mmol/L
<b>Hi</b>	> 8.0 mmol/L

## Error Messages

MESSAGE	Cause	What To Do
E-b	The batteries cannot provide enough power for a test.	Replace the battery immediately and reset date and time on the meter setting.
E-U	Strip has been used.	Repeat the test with a new strip.
E-E E-2 E-0 E-A E-C	Problem in operation.	Review the instructions and repeat the test with a new strip. If problem persists, contact customer service for assistance.
E-F	You may have removed the strip after applying blood, or insufficient blood volume.	Review the instructions and repeat test with a new test strip.
E-t	Ambient temperature is out of the system's operation range.	System operational range is 8°C to 45°C. Repeat the test after the device and test strip have reached the above temperature.

## Blood Glucose Measurement

Symptom	Cause	What To Do
The device does not display a message after inserting a test strip.	Batteries exhausted.	Replace the battery immediately and reset date and time on the meter setting.
	Test strip inserted upside down or incompletely.	Fully insert the test strip with contact bars end first and facing up.
	Defective device or test strips.	Please contact customer service.

The test does not start after applying the sample.	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 the device is automatically turned off.	Repeat the test with a new test strip. Apply sample only when flashing “  The control solution testing result is out of range.	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 solutions.	Check the expiration date of the control solution.			

	Control solution that is too warm or too cold.	Control solution, device and test strips should be at room temperature (20°C to 25°C) before testing.
	Defective test strip.	Repeat the test with a new test strip.
	Device malfunction.	Please contact customer service.

# SPECIFICATIONS

Model No.	TD-4183D / GD82a
Memory	1000 measurement results with respective date and time
Dimensions	89.8 (L) x 54.9 (W) x 18 (H) mm
Power Source	One 1.5V AAA alkaline battery
Weight	46.1 g (without battery)
External output	Bluetooth
Features	Auto electrode insertion detection Auto sample loading detection Auto reaction time count-down Auto switch-off after 3 minutes without action Temperature warning
Operating Condition	8°C to 45°C, below 85% R.H. (noncondensing)
Storage/Transportation Condition	-20°C to 60°C, below 95% R.H
Measurement Units	Fixed mmol/L
Measurement Range	0.5-33.3 mmol/L for glucose test and 0.1~8.0 mmol/L for $\beta$ -Ketone test

Hematocrit range	0~70% for glucose testing and 10~70% for $\beta$ -Ketone test
Test Result	Glucose measurements are reported as plasma equivalents

This device has been tested to meet the electrical and safety requirements of: IEC/EN 61010-1, IEC/EN 61010-2-101, EN 61326-, IEC/EN 61326-2-6, EN 301 489-17, EN 300 328.



# WARRANTY TERMS AND CONDITIONS

With respect to disposable products, the manufacturer warrants to the original purchaser that at time of delivery, each standard product manufactured by the manufacturer shall be free from defects in material and workmanship and when used for the purposes and indications described on the labeling is fit for the purposes and indications described on the labeling. All warranties for a product shall expire as of the product expiration date, or if none, after two (2) years from the original date of purchase, as long as it has not been modified, altered or misused. The manufacturer warranty hereunder shall not apply if:

- (i) a product is not used in accordance with its instructions or if it is used for a purpose not indicated on the labeling;
- (ii) any repairs, alterations or other work has been performed by the buyer or others on such item, other than work performed with the manufacturer's authorization and according to its approved procedures; or
- (iii) the alleged defect is a result of abuse, misuse, improper maintenance, accident or the negligence of any party other than the manufacturer. The warranty set forth herein is

conditioned upon proper storage, installation, use and maintenance in accordance with applicable written recommendations from the manufacturer. The warranty furnished hereunder does not extend to damaged items purchased hereunder resulting in whole or in part from the use of components, accessories, parts or supplies not furnished by the manufacturer.





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