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# THG001

Blood Glucose Monitoring System

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## Owner's Manual



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# Dear THG001 System Owner:

Thank you for purchasing the Tula Health THG001 Blood Glucose Monitoring System. This manual provides important information to help you use the system properly. Before using this product, please read the following instructions thoroughly and attentively.

Regular monitoring of your blood glucose levels can help you and your doctor gain better control of your diabetes. You can use the Tula Health THG001 to easily monitor your blood glucose levels by yourself anywhere and anytime.

If you have other questions regarding this product, please contact the local customer service at 1-855-352-7884 (24 hours a day, 7 days a week) or place of purchase.

## Intended Use

The Tula Health THG001 Blood Glucose Monitoring System consists of the Tula Health THG001 meter, Tula Health THG001 test strips, and the Tula Health THG001 mobile application as the display component of the Tula Health THG001 Blood Glucose Monitoring System. The Tula Health THG001 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the finger. This blood glucose monitoring system is intended to be used by a single person and should not be shared. The Tula Health THG001 Blood Glucose Monitoring System is intended for self-testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system should not be used for the diagnosis of or screening for diabetes, nor for use on neonates.

# **IMPORTANT SAFETY PRECAUTIONS**

## **READ BEFORE USE**

- The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

For more information, please visit the following:

1. “FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication” (2010)  
<http://webarchive.it.org/7993/2017011013014/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>
2. “CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens” (2010)  
<http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>

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. Do NOT, under any circumstances, use the device on neonates or infants.
5. This device does NOT serve as a cure for any symptoms or diseases. The data measured is for reference only.

6. Before using this device to test blood glucose, read all instructions thoroughly. 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 test strips, lancets and vial caps are choking hazards.
8. Use this device in a dry environment. Be aware of the presence of synthetic materials, such as clothing, carpets and so on, which might give rise to damaging static discharges that may produce incorrect results.
9. Do NOT use this instrument in close proximity to sources of strong electromagnetic radiation (ex: an alternator) as these may interfere with the accuracy.
10. This instrument is designed for handheld or remote use only. It is NOT a cell phone. Do NOT use this device held against the ear or head or within in 10mm distance.
11. Proper maintenance and periodic control solution tests are essential to the durability of your device. If you are concerned about its accuracy, please contact Tula Health at 855-352-7884 or place of purchase for help.

**KEEP THESE INSTRUCTIONS IN A SAFE PLACE**

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## LIMITATION

- Not for the screening or diagnosis of diabetes mellitus.
- Severe dehydration and excessive water loss may cause inaccurate readings.
- Do NOT use the Tula Health THG001 Blood Glucose Monitoring System on severely hypotensive individuals or patients in shock.
- Do NOT use the Tula Health THG001 Blood Glucose Monitoring System on neonates, patients who are critically ill or patients in hyperglycemic-hyperosmolar state, with or without ketosis.
- Use only fresh capillary whole blood from the fingertip.
- If your blood glucose results are lower or higher than expected, 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 expected, follow the treatment advice of your healthcare professional.

## BEFORE YOU BEGIN

### Test Principle

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

# Meter Overview



## 1. **USB Port (only for charging)**

For battery recharge

## 2. **Cellular Connection and Battery Level Indicator**

## 3. **Display Window and Touchscreen**

The touchscreen allows users to interact with what is displayed directly by the finger.

## 4. **Volume Button**

## 5. **Power Button**

Press to turn on/off the meter.

## 6. **Test Strip Slot**

# Contents of System

Your new Tula Health THG001 system kit includes:

1. Meter
2. Owner's Manual
3. Protective Wallet
4. Micro-USB cable
5. Adapter

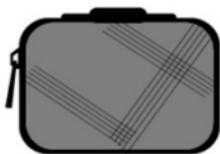
1



2



3



4



5



## NOTE:

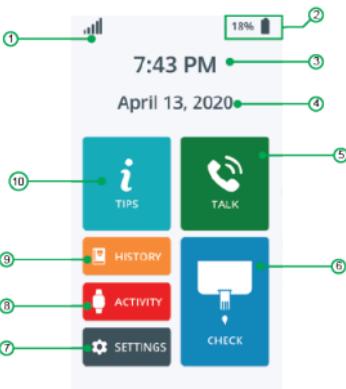
If any items are missing from your kit or opened prior to use, please contact Tula Health at 855-352-7884 for assistance.

# Display Screen

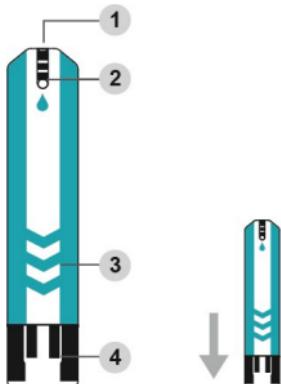
The display window and touchscreen allows you to interact with what is displayed. The meter features 3 main functions: measuring/check, memory/history and setting, which are shown on the main page.

Other icons on the Main Page are introduced as below:

1. Cellular Signal
2. Battery Capacity
3. Time
4. Date
5. Call/Talk
6. Measuring/Check
7. Settings
8. Activity
9. History
10. Tips



# Test Strip



## 1. Absorbent Hole

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

## 2. Confirmation Window

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

## 3. Test Strip Handle

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

## 4. Contact Bars

Insert this end of the test strip into the meter. Push it in firmly until it will go no further.

## 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 **Tula Health THG001** monitor should only be used with **Tula Health THG001** Test Strips. Using other test strips with this meter can produce

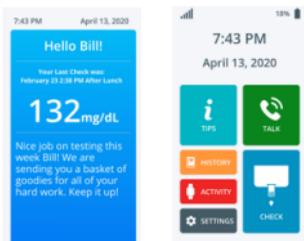
# SETTING THE METER

Before using your meter for the first time, you should check and update these settings. The touchscreen allows users to communicate with the meter by simply tapping on the screen with fingers.

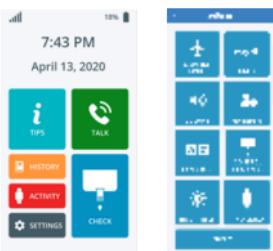
## 1. Start with the system off.

Press the power button for 1 second to activate the meter.

The meter displays the Tula Health logo then a welcome page. Continuing past the welcome page, at the main page, there are 6 features:  (check or measuring),  (tips),  (talk or call),  (history),  (activity) and  (setting), on the display.



## 2. Tap on , and there are nine sections: airplane mode, units, volume, reminders, language, control readings, brightness, find moko and about.



# Airplane Mode

In the airplane mode, the meter's cellular telephony and transmitting functions will be terminated.

1. Tap on  to enter its setting page.
2. Tap on the preferred mode (on or off) and then tap "OK" to save and exit.
  - airplane mode Off: activate the meter's telecommunication
  - airplane mode On: apply as necessary



## NOTE:

The airplane mode allows users to measure their blood glucose values in flight or in places where radio-frequency signal transmission must be suspended.

The measuring result will be saved in the memory, and later be transmitted to the server when the meter's telecommunication function is resumed.

# Units

1. Tap on  to set the measuring unit: mg/dL or mmol/L.
2. Tap on the preferred one and then  to save and exit.



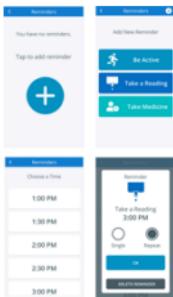
## Volume

1. Tap  to set up the volume.
2. Slide the bar  up and down to adjust the volume.
3. Tap on  to save and exit.



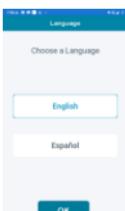
## Reminders

1. Tap on  to set the reminder.
2. Tap on  to create a new reminder.
3. Select the appropriate category for the reminder.
4. Select the appropriate time for the reminder.
4. Select whether to repeat the reminder and then  to save and exit.



## Language

1. Tap on  to set the displayed language. The default language is English.
2. Tap on the preferred language bar.
3. Tap  to save and exit.



## Control Readings

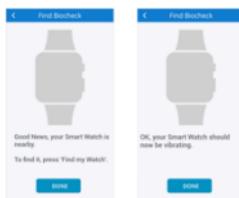
1. Tap on  to view and test control solution (see Quality Control Testing).



2. Tap on “<” to exit.

## Find MOKO

1. Tap on  to find the biocheck.
2. Tap on “Find My Watch”.
3. The watch will vibrate. Tap  to exit.



## Brightness

1. Tap on  to set the brightness.
2. Slide the bar  to adjust the brightness.
3. Tap  to save and exit.



## About

1. Tap on  to view device info.
2. Tap  to exit.



**Congratulations! You have completed all settings!**

### NOTE:

These parameters can ONLY be changed in the setting mode.

# Calling

Tula Health THG001 Blood Glucose Monitoring System is equipped with cellular service that allows users to call Tula's service center directly, receive calls, or stream data to the server. Calling feature is activated under the following conditions.

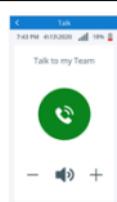
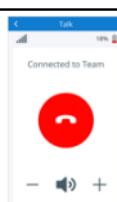
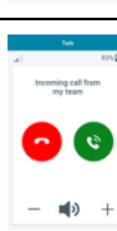
## 1. After every blood glucose measurement:

To transmit the test result to the server. Tula will contact you if the uploaded result is atypical.

## 2. Talk:

Whenever the  button on the home screen is pressed.

Appears when a call comes in. Tap on  to take or  to reject. The following display will be shown in the calling page:

MESSAGE	WHAT IT MEANS
	Press the green button to talk with the service center.
	Appears when a call is connected. Tap on the red button to end the call.
	Appears when a call comes in. Tap on the green button to take or the red button to reject. Tap on “-” or “+” to adjust the volume.

**NOTE:**

- The phone number of the service center is programmed prior to your receipt of the meter. If not, please contact Tula Health at 855-352-7884 for assistance.
- The connection quality may vary from each service provider.
- The calling and data transmission features are disabled when the meter is set in the airplane 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 blood glucose test results are not consistent with how you feel,
- 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, control solutions, lancing device, or sterile lancets are optional and may not come with 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.

# Performing a Control Solution Check

Please have your meter, strip, and control solution ready before you perform a control solution test.

## 1. Activate the meter

Start with the meter off. Press the power button for 1 second to turn on the meter. Wait for the main page to appear.

## 2. Start measuring

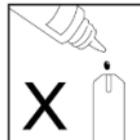
On the settings page, tap on  to enter the measuring page. Tap "+" and wait for the meter to display the test strip symbol.

## 3. Apply control solution

Shake the control solution vial thoroughly before use.

Squeeze out a 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**

The control solution test result will appear on the display in seconds. 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.

#### **Out-of-range Results**

If you continue to have test results fall outside the range printed on the test strip vial, the meter and strips may not be working properly. Do NOT test your blood. Contact the service center for help.

#### **WARNING:**

- 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 glucose level.
- See the **MAINTENANCE** section for important information about your control solutions.

# TESTING WITH BLOOD SAMPLE

## **Warning:**

To reduce the chance of infection:

- The meter and lancing device are for single use. 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.
- Wash and dry your hands thoroughly after handling the meter, lancing device, and test strips to prevent infection. For more information, please refer to the “Cleaning and Disinfection” section.
- If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be decontaminated (see “MAINTENANCE” section) prior to use by the second person.
- If patient is being assisted with glucose meter testing, the assistant should wear gloves throughout. Additionally, the assistant should clean and disinfect meter between each use.

**Sharing the lancing device and lancets may increase the risk of contracting infectious disease. Lancing device must not be used for more than one person.**

## **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 glucose value obtained. Blood from a site that has not been rubbed exhibits a measurably different glucose 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 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**

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 the pharmacy.
- Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.
- It is recommended that you discard the first drop of blood as it might contain tissue fluid, which may affect the test result.

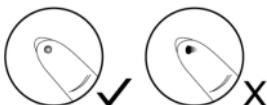
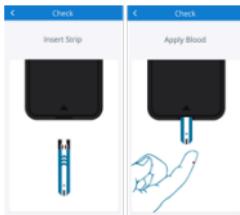
## Performing a Blood Test

Please have the meter, test strip, lancets and lancing device ready before you start performing blood glucose tests.

1. Start with the meter off. Press the power button to activate the meter. At the main page, tap on  to start the measurement.
2. Perform the blood glucose test as directed on the display.
3. Obtaining a blood sample

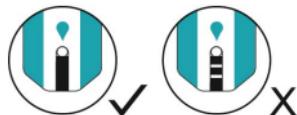
Use the pre-set lancing device to puncture the desired site.

After penetration, discard the first drop of blood with a clean cotton swab. Gently squeeze the punctured area to obtain another drop of blood. Be careful NOT to smear the blood sample.



#### 4. Apply blood onto the strip

Hold the blood drop to touch the absorbent hole of the test strip and blood will be drawn in automatically.



Make sure to provide the minimum required sample volume to fill the confirmation window completely with blood before your finger leaves the absorbent hole or meter to prevent inaccurate glucose results.

#### 5. Wait a few seconds for the measurement to process.

When the page of measuring mode appears, choose the mode that fits you the best: before / after breakfast, lunch or dinner respectively. Then you will see the measuring result on the display.



#### 6. Tap to save and exit.

#### 7. Remove the used test strip and remove the lancet. Dispose of the used test strip in a sharp bin.

**NOTE:**

- Do not press the punctured site against the test strip or try to smear the blood.
- Do not leave the absorbent hole until the confirmation window is filled with blood.
- **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.

**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.
- Wash and dry your hands thoroughly after handling the meter, lancing device, and test strips to avoid contamination. For more information, please refer to the **MAINTENANCE** section.

# METER HISTORY

The meter stores the most recent blood glucose test results, up to 90 days, along with respective dates and times in the memory feature.

## Reviewing Test Results

### 1. Turn on the Meter

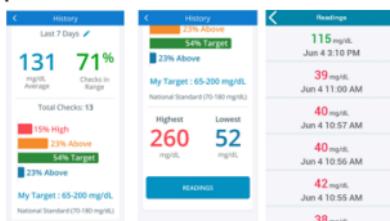
Start with the meter off. Press the power button for 1 second to activate the meter. Wait for the main page to show up.

### 2. Enter the history feature

Tap on  to enter the history feature.

### 3. Review Records

Tap on range drop down , and select the desired range. The average along with the percent of checks in range are displayed at the top. The Checks in Range is the percentage of the checks in the given time period that are within your Target Range. Your target range can be customized on either your personal web portal or your mobile app.



To view the individual readings tap on  button at the bottom of the page.

### 4. Exit

Tap the  icon at the top left of the screen to exit.

# MAINTENANCE

## Battery

### **Recharging the Battery**

Use an AC power adapter. Plug the meter into a wall outlet to initiate the charging process.

### **Battery Charging Indicator**

Refer to the battery icon on the upper right for battery capacity.

## Caring for Your Meter

To avoid the meter and test strips attracting dirt, dust or other contaminants, please wash and dry your hands thoroughly before and after the measurement.

### **Why the cleaning and disinfection should be performed?**

Cleaning and disinfection are different. Cleaning is the process of removing dirt (e.g. food debris, grease, dust), while disinfection is the process of killing germs (e.g. bacteria and viruses).

### **When to clean and disinfect the meter?**

Clean the meter when you see any dirt on it. You should disinfect the meter at least once a week to prevent infection.

### **How to clean and disinfect the meter?**

The meter must be cleaned prior to the disinfection. Use one disinfecting wipe to clean exposed surfaces of the meter thoroughly and remove any visible dirt or blood or any other body fluid with the wipe. Use a second wipe to disinfect the meter. **Do NOT use organic solvents to clean the meter.**

We recommend for meter cleaning and disinfection you should use the disinfecting wipes / towelettes from below. The following product with isopropyl alcohol as the active ingredient has been shown to be safe for use with the Tula Health THG001 Blood Glucose Monitoring System:

Micro-Kill+™ (Micro-Kill Plus™) by Medline (EPA Reg. No. 59894-10-37549)

To obtain disinfecting wipes and other information, please contact Medline at 1-800-MEDLINE (1-800-633-5463) or visit [www.medline.com](http://www.medline.com). You can also purchase it at Amazon ([www.amazon.com](http://www.amazon.com)) or Walmart ([www.walmart.com](http://www.walmart.com)).

### **Disinfecting Procedures**

1. Wipe all meter's exterior surface display and buttons by three passes vertically and three passes horizontally with a folded disinfecting towelette. Hold the meter with the test strip slot pointing down and wipe the area around the test slot but be careful not to allow excess liquid to get inside. Keep meter wet with disinfection solution contained in the wipe for a minimum of 2 minutes for Micro-Kill+™ wipes.
2. Remove the wipe. Allow the meter surface to dry completely.
3. Discard the used wipes and never reuse them. Users should wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

Improper system cleaning and disinfection may result in meter malfunction. If you have a question, please contact local customer service at 1-855-352-7884.

This device has been validated to withstand up to 10950 cleaning and disinfection cycles using the recommended disinfecting wipe/towelette. The tested number of cycles is estimated by 10 cleaning and disinfection cycles per day over 3 years. The meter should be replaced after the validated number of cleaning and disinfection cycles or the warranty period, whichever comes first.

Stop using the meter if you see any signs of deterioration. For example:

- Meter cannot be turned on
- LCD display cracks or becomes cloudy
- Buttons no longer function
- Meter outer casing cracks
- Scratches or abrasions on meter are higher than acceptable

**Please contact the customer service for a replacement meter if any of the signs of deterioration are noticed.**

**NOTE:**

- Do NOT clean and disinfect the meter while performing tests.
- If the meter is being operated by a second person, the meter and lancing device should be decontaminated prior to use by the second person.
- Do NOT allow cleaning and disinfecting solution to get in the test slot.
- If you do get moisture in the test strip slot, wipe it away with a corner of tissue.
- Always dry the meter thoroughly before using it.
- Do not spray the meter directly with cleaning solutions especially those containing water (i.e. soapy water), as this could cause the solution to enter the case inside and damage the electronic components or circuitry.

## Caring for Your Test Strips

- Storage conditions: 35.6°F to 86°F (2°C to 30°C) and between 10% to 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.
- 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.
- Do not reuse test strips.

**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 Tula Health 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 68°F to 77°F (20°C to 25°C). 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 35.6°F to 86°F (2°C to 30°C). Do NOT freeze.

# SYSTEM TROUBLESHOOTING

If you have followed the recommended actions but the problem persists, or error messages other than the ones listed below appear, please call your local customer service. Do not attempt to try to repair the meter yourself and never try to disassemble the meter under any circumstances.

## Error Messages

MESSAGE	WHAT IT MEANS	WHAT TO DO
Please Insert New Strip	Appears when a used test strip is applied.	Repeat the test with a new test strip. Contact the service center if the problem persists.
Not Enough Blood on Test Strip	Appears when the amount of blood taken is not enough.	
Internal Memory Error	Problem with the meter.	Reboot the meter, or contact the service center for assistance if the problem persists.
Internal Error		
BGM Firmware Ver. Error		
EEPROM Internal Error		
R code Error	Problem with the meter or the strip.	Repeat the test with a new test strip. Contact the service center if the problem persists.

MESSAGE	WHAT IT MEANS	WHAT TO DO
Invalid Strip	Appears when the strip is not inserted correctly.	Please re-insert the strip and make sure its front side is facing up.
Ambient Temperature Too Low	Appears when ambient temperature is above or below system operation range.	System operation range is 50°F to 104°F (10°C to 40°C). Repeat the test after the meter and test strip are in the above temperature range.
Ambient Temperature Too High		
Charging Cable Detected	Blood glucose tests are prohibited in battery charging procedure.	Please plug out the micro-USB cable.

## Troubleshooting

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

POSSIBLE CAUSE	WHAT TO DO
Battery 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 service.

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.
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 service.
Improper working of meter and test strip.	Please contact customer service.

# DETAILED INFORMATION

## Reference Values

Blood glucose monitoring plays an important role in diabetes control. A long-term study showed that maintaining blood glucose levels close to normal can reduce the risk of diabetes complications by up to 60%\*<sup>1</sup>. The results provided by this system can help you and your healthcare professional monitor and adjust your treatment plan to gain better control of your diabetes.

Time of day	Normal plasma glucose range for people without 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)

\*<sup>1</sup>: American Diabetes Association. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2020 Jan; 43(Supplement 1): S14-S31. <https://doi.org/10.2337/dc20-S002>

## Comparing Meter and Laboratory Results

The meter provides you with whole blood equivalent results. The result you obtain from your meter may differ somewhat from your laboratory result due to normal variation. Meter results may be affected by factors and conditions that do not affect laboratory results in the same way. To make an accurate comparison between meter and laboratory results, follow the guidelines below.

### **Before going to the laboratory**

- Perform a control solution test to make sure that the meter is working properly.
- Fast for at least eight hours before doing comparison tests, if

possible.

- Take your meter with you to the lab.

**NOTE:**

Please consult with your healthcare professional regarding instructions for conducting a fasting blood glucose test.

**While staying at the laboratory**

Make sure that the samples for both tests are taken and tested within 15 minutes of each other.

- Wash your hands before obtaining a blood sample.

You may still have a variation from the result because blood glucose levels can change significantly over short periods of time, especially if you have recently eaten, exercised, taken medication or experienced stress<sup>\*2</sup>. In addition, if you have eaten recently, the blood glucose level from a finger prick can be up to 70 mg/dL (3.9 mmol/L) higher than blood drawn from a vein (venous sample) used for a lab test<sup>\*3</sup>. Therefore, it is best to fast for eight hours before doing comparison tests. Factors such as the amount of red blood cells in the blood (a high or low hematocrit) or the loss of body fluid (dehydration) may also cause a meter result to be different from a laboratory result.

\*2: Surwit, R.S., and Feinglos, M.N.: Diabetes Forecast (1988), April, 49-51.

\*3: Sacks, D.B.: "Carbohydrates. " Burtis, C.A., and Ashwood, E.R. (ed.), Tietz Textbook of Clinical Chemistry. Philadelphia: W.B. Saunders Company (1994), 959.

# SPECIFICATIONS

**Model No.:** THG001

**Dimension:** 127 mm(L) x 54 mm(W) x 15 mm(H)

**Weight:** 107 g

**Power Source:** Li- Ion rechargeable battery

**Display:** LCD

**Memory:** 90 days measurement results with respective date and time

Auto sample uploading

detection Auto reaction

time count-down

Temperature Warning

**Operating Condition:** 50°F to 104°F (10°C to 40°C), 10% to 85%

R.H. (non-condensing)

**Meter Storage / Transportation Conditions:**

-4°F to 140°F (-20°C to 60°C), 10% to 93% R.H.

**Strip Storage / Transportation Condition:** 35.6°F to 86°F (2°C to 30°C), 10% to 85% R.H. (non-condensing)

**Measurement Units:** mg/dL or mmol/L

**Measurement Range:** 20 to 600mg/dL (1.1 to 33.3mmol/L)

**Expected Service Life:** 3 Years

This device has been tested to meet the electrical and safety requirements of: IEC/EN 61010-1

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.(For only one antenna)
2. This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 5mm between the radiator and your body.

**FCC**

# NOTE

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# NOTE

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Hours of Operation: 24 hours, 7 days/week

For self-testing.

Read instructions before use.