

Blood Glucose Meter LTEM-BGM 0031

USER MANUAL





Blood Glucose Monitor

Thanks for choosing the Greater Goods blood glucose monitoring system. This system is designed for simplistic blood glucose testing and assisting in keeping blood glucose under control. Read this user manual carefully before using your system. This manual is for helping you understand how to comfortably use the Greater Goods blood glucose monitoring system and get reliable test results. Please keep this user manual in a safe place for later reference and thanks again for choosing Greater Goods.

Intended Use and Principle

Greater Goods blood glucose monitoring system consists of the Greater Goods blood glucose meter (LTEM-BGM 0031) and Greater Goods test strips (TTS01). Greater Goods blood glucose monitoring system is intended to quantitatively measure the glucose concentration in fresh capillary whole blood samples drawn from the fingertips. It is intended for use by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It is not intended for neonatal use or for the diagnosis of or screening for diabetes. This system is intended for self-testing outside the body (*in vitro diagnostic use*), and should only be used by a single person and should not be shared.

This meter is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this meter on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

TABLE OF CONTENTS

| 1. Understanding Your Testing Tools | |
|---|----|
| Your Meter System Overview | |
| Your Meter Display | |
| Meter Use and Precautions | 3 |
| Important Safety Information | 4 |
| Limitations | 5 |
| 2. Setting Up Your System | 6 |
| Set the Date and Time | 6 |
| Set the Audio Feature | |
| Set the Meal Marker | 8 |
| Set the Hypoglycemia (Hypo) Warning | 8 |
| Set the Ketone Warning | 9 |
| 3. Performing a Test | |
| Preparing the Test Strip | |
| Preparing the Lancing Device | |
| Getting a Blood Drop for Testing | |
| Questionable or Inconsistent Results | 15 |
| Testing with Control Solution | 15 |
| Using the Meter Memory | 18 |
| Viewing Your Test Results | 18 |
| 4. Maintenance and Troubleshooting | |
| Charging the Battery | 20 |
| Caring for Your Glucose Monitoring System | |
| Cleaning and Disinfection | 21 |
| Troubleshooting Guide | 23 |
| Symptoms of High or Low Blood Glucose | 25 |
| 5. Specification Information | 26 |
| System Specifications | 26 |
| Warranty | 27 |
| EMC Guidance | 28 |
| FCC Requirement | |

CHARPTER 1: UNDERSTANDING YOUR TESTING TOOLS

Meter System Overview

Greater Goods Blood Glucose Test Strip



Greater Goods Blood Glucose Meter



Turns the meter on and off and switches between functions.

Meter Display



Above are all the icons your meter can display. Ensure the display works correctly before using the meter. When the meter is off, press and hold the

to see all the icons. All of the icons should be clear and easy to see—just like the image above. If any of the icons are not working, please contact Greater Goods customer service.

| Icon | What It Means |
|----------|---|
| 88/88 | Indicates date. |
| 88:88 | Indicates year or time. |
| AM PM | Indicates morning or afternoon. |
| d/m/d | Indicates either day and month (d/m) or month and day (m/d). |
| ② | Indicates data transmitted successfully. |
| 8 | Indicates data not transmitted. |
| M | Indicates test result history. |
| Α | Indicates average value. |
| | Indicates battery level. |
| Ketone? | Ketone warning; the "Ketone?" symbol appears when the test result is equal to or above 300 mg/dL. |

| Нуро | Indicates that a low glucose test result may cause hypoglycemia |
|-------|--|
| atl | Indicates signal strength |
| 88.8 | Indicates the result of a test or displays error codes |
| | Indicates the room temperature is not suitable for testing. |
| mg/dL | Test results are displayed as mg/dL. |
| | When the strip is inserted, the drop will flash, indicating the system is ready to test. |
| • | Indicates pre-meal marker. |
| Ì | Indicates post-meal marker. |
| ē | Indicates control test result. |

Notes:

Your Greater Goods blood glucose meter is preset with a beep function. The meter will beep when:

- · the meter turns on.
- · setting date and time (in setup mode).
- the test strip is inserted and ready for application of blood or control solution.
- sufficient blood or control solution is added to the test strip.
- the test is complete.
- · any error occurs during operation.

Meter Use and Precautions

- The meter is for indoor use.
- The meter is preset to display blood glucose concentration in milligrams per deciliter (mg/dL) by default.
- Meter will shut off by itself after 2 minutes of inactivity.
- · Do not get water or other liquids inside the meter.
- Keep the strip port area clean.
- Keep your meter dry and avoid exposing it to extremes in temperature or humidity. Do not leave it in your car.
- Do not drop the meter or get it wet. If you do drop the meter or get it wet, check the meter by running a quality control test. Refer to **Testing with Control Solution** for instructions.
- Do not take the meter apart. Taking the meter apart will void the warranty.
- Refer to the Cleaning and Disinfection section for details on cleaning the meter.
- Keep the meter and all associated parts out of reach of children.
- Pollution degree: 2

Note: Follow proper precautions and all local regulations when disposing of the meter.

Important Safety Information

- The meter is for single patient use. Do not share it with anyone. including family members.
- Always keep the test strips in the original vial. Tightly close the vial immediately after you have removed the test strip.
- Do not use the meter if it has been dropped in water or water has been spilled on it
- Wash and dry your hands well before and after testing.
- Do not drop blood directly on the flat surface of the test strip.
- Check the expiration dates and discard dates on your test strips via the label and control solution vial label.
- Use only Greater Goods blood glucose test strips with your Greater Goods blood glucose meter.
- Use only Greater Goods control solution with your Greater Goods blood glucose meter and Greater Goods blood glucose test strips.
- Please contact your physician or diabetes healthcare professional if you want to make a change to your current medical treatment or diet based on test results.
- If the system is used in a manner not specified by the manufacturer, the protection provided by the system can be impaired.



/I Potential Biohazard

All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

Note:

- 1. 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!
- 2. All parts of the kit are considered biohazardous. They can potentially transmit infectious diseases from blood borne pathogens, even after you have performed cleaning and disinfection. Please follow proper precautions when handing your meter and lancing device.
- 3. For more information, please refer to the FDA Public Health Notification: "Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) at https://wayback.archive it.org/7993/20170111013014/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm. You may also refer to the CDC Clinical Reminder: "Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010) at http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html.

Limitations

- · For single-patient use only.
- Very high (above 70%) and very low (below 20%) hematocrit levels can cause false results. Talk to your healthcare professional to find out your hematocrit level.
- If you are taking vitamin C (ascorbic acid in your blood>3mg/dL) then your glucose results using this meter may not be reliable.
- If your oxygen partial pressure is below 40mmHg or above 120mmHg (for example, undergoing an oxygen therapy), or if you undergo a treatment related to Mannitol, it may affect the test result.
- · Not for use on critically ill patients.
- Not for use on patients in shock or with severe dehydration.
- Not for use on patients in a hyperosmolar state (with or without ketosis).
- The system should not be used following xylose absorption procedures.
- Not for neonatal use.
- Not for screening for or diagnosis of diabetes mellitus.
- · Not for use in hypotensive individuals.
- Do not use at altitudes above 10,413 ft (3,174 meters) above sea level.
- This meter is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this meter on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

Note:

 The system is tested to accurately read the measurement of glucose in whole blood within the range of 20 to 600 mg/dL.

CHAPTER 2: SETTING UP YOUR SYSTEM

Before using your meter for the first time, make sure to set it up properly.

Set the Date and Time

When the meter is off, press and hold ⊚ until the meter beeps to enter setup mode. Set the clock for either 24 or 12 hour mode by pressing ⊚ to adjust it. Press and hold ⊚ to save your selection.



The year will start flashing. Press
to adjust a digit, press and hold
until the meter beeps to set it, and then do the same for the next digit, continuing until the year setting is completed.



The day and month icon will start flashing. Press

to set the display as m/d or d/m and hold

until it beeps to confirm selection.



The month icon will start flashing next. Press ⊚ to adjust the month, and press and hold ⊚ to confirm your selection.



Then the day icon will start flashing. Press ⊚ to adjust the day, and press and hold ⊚ to confirm your selection.



After you finish setting the date, time will be next. First, press ⊕ to adjust the hour, and press and hold ⊕ to confirm your selection. Then it will shift to the next digit.



Set the minutes the same way as you set the hour.



Note:

 Before using your meter for the first time, make sure to set the correct date and time, so results will be stored correctly.

Set the Audio

After setting time, you will be prompted to turn sound on or off. Press ● to rotate between on and off, and hold ● to confirm your selection.





Set the Meal Marker

After setting audio, the ♠ will flash along with the word "On".

Press ● to rotate between on and off for the meal marker mode function. Press and hold ● to confirm your selection.





Set the Hypoglycemia (Hypo) Warning

After setting meal marker mode, it's time to set the hypo alarm, which indicates a possible hypoglycemic condition (blood glucose level too low).

The words "Hypo" and "On" will flash on the screen.

Press ● to rotate between on and off, and hold ● to confirm your selection. If you select "On" the screen will display 70 mg/dL, press and hold ● move to the next step.







Notes:

 Consult with your healthcare provider to help determine the right hypo level setting for you.

Set the Ketone Warning

After setting the hypo warning, the "Ketone?" symbol and "On" will flash on the screen. Press
to switch between having the ketone warning on or off, and hold to confirm your selection.





A flashing strip symbol will appear on the screen, indicating that you've successfully finished setting up your meter. Press and hold
for 5 seconds to confirm the settings you selected.



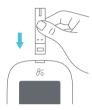
After setting up your meter for the first time to change settings, with the meter off, press and hold for 5 seconds to enter setup mode.

CHAPTER 3: PERFORMING A TEST

After setting up your meter, gather all the materials you will need for testing, including: Greater Goods blood glucose meter, Greater Goods blood glucose test strips, and Greater Goods lancing device and lancets.

Preparing the Test Strip

- 1. Wash and dry your hands well before testing.
- 2. Remove a test strip from the test strip vial. Tightly close the vial cap immediately after you have removed the test strip.
- 3. Insert the test strip into the meter in the direction of the arrows. The meter will turn on after this, indicated by a beep.



A symbol with a flashing blood drop will appear on the screen, indicating the meter is ready to test.



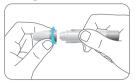
Note:

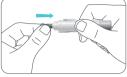
Check the expiration and discard dates on the test strip vial. All expiration dates are printed in Year-Month-Day format. 2023-01-01 indicates 1st, January, 2023. Your Greater Goods test strips have a 6 month shelf life after you first open a test strip vial. Write the discard date on the vial label when you first open it. Make sure the test strip does not appear damaged. Prior to testing, wipe the test site with an alcohol swab or soapy water. Wash your hands with warm, soapy water to increase blood flow, if necessary. Dry your hands and the test site thoroughly. Make sure there is no cream or lotion on the test site.

Preparing the Lancing Device

For fingertip sampling, adjust the penetration depth to reduce discomfort.

 Unscrew the lancing device cover from the body of the lancing device. Insert a sterile lancet into the lancing device and push it until the lancet comes to a complete stop in the lancing device.



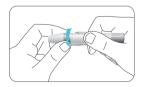


Note: The Greater Goods lancing device uses **ONLY** Greater Goods sterile lancets.

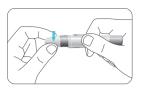
2. Hold the lancet firmly in the lancing device and twist the safety tab of the lancet until it loosens, then pull the safety tab off the lancet. Save the safety tab for disposing the used lancet.



3. Carefully screw the cover back onto the lancing device. Avoid contact with the exposed lancet. Make sure the cover is fully sealed on the lancing device.



 Adjust the puncture depth by rotating the lancing device cover. There are 5 puncture depth settings. To reduce discomfort, use the lowest setting that still produces an adequate drop of blood.





Adjustment:

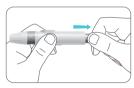
1 for delicate skin 2 and 3 for normal skin

4 and 5 for calloused or thick skin

Note: Applying more pressure to the lancing device against the puncture site will also increase the depth of the puncture.

Getting a Blood Drop for Testing

Pull the cocking barrel back to set the lancing device. You
may hear a click to indicate the lancing device is now loaded
and ready for obtaining a drop of blood.



Press the lancing device against the side of the finger to be lanced with the cover resting on the finger. Push the release button to prick your fingertip. You should hear a click as the lancing device activates.

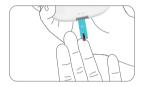


3. Remove the first drop of blood with a clean paper towel to ensure a more accurate result. Gently massage from the base of the finger to the tip of the finger to obtain the required blood volume (half the size of a match head). Avoid smearing the drop of blood. For the least amount of pain, lance on the side of the fingertip. Test immediately after a good blood drop has formed.





4. Touch the tip of the test strip to the drop of blood. The blood will be pulled into the test strip through the tip. Make sure that the blood sample has fully filled the check window of the tip of the strip. Hold the tip of the test strip in the blood drop until the meter beeps.



Note: If the blood sample does not fill the check window, do not add a second drop. Discard the test strip and start over with a new test strip.

5. The meter counts down 5 seconds and your result appears on the display after a beep. The test result will automatically be stored in the meter memory. Please do not touch the test strip during the countdown as this may result in an error.

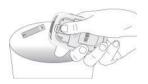




After the testing is completed, the measurement data will be transmitted.

Discard the Used Test Strip

Eject and discard the used test strip by utilizing the strip ejector.



Potential Biohazard

Dispose of used test strips as medical waste.

Note:

- 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! Please follow proper precautions when handling your meter and lancing device.
- All parts of the kit are considered biohazardous. They can potentially transmit infectious diseases from blood borne pathogens, even after you have performed cleaning and disinfection

Warning:

- If your blood glucose reading is under 50 mg/dL or you see LO (less than 20 mg/dL) on the meter display, contact your healthcare professional as soon as possible.
- If your test result is above 250 mg/dL or you see HI (greater) than 600 mg/dL) on the meter display, contact your healthcare professional as soon as possible.
- Please contact your physician if you think that you should change your medical routine based on the results of the Greater Goods blood glucose meter.

Expected Diabetes Control Goal:

Expected blood glucose values for most non-pregnant adults with diabetes:

| Time | Range,mg/dL | Range,mmol/L |
|------------------------|-------------|--------------|
| Before a meal | 80 - 130 | 4.4 - 7.2 |
| 1-2 hours after a meal | < 180 | < 10.0 |

Reference: American Diabetes Association; Standards of

Medical Care in Diabetes—2021 Abridged for Primary Care Providers. Clin Diabetes 1 January

2021; 39 (1): 14–43.

Note: Please work with your healthcare professional to

determine a target range that works best for you.

Questionable or Inconsistent Results:

If your blood glucose result does not match how you feel, please:

- Check the expiration date and the discard date of the test strip.
- Make sure that the test strip vial has not been opened for more than 6 months.
- Confirm the temperature in which you are testing is between 41-113°F.
- Make sure that the test strip vial has been tightly capped.
- Make sure the test strip has been stored at 36-86°F, 10-90% humidity.
- Make sure the test strip was used immediately after removal from the test strip vial.
- Make sure that you followed the test procedure correctly.
- Perform a control solution test (See Testing with Control Solution for instructions).

After checking all of the conditions listed above, repeat the test with a new test strip. Please contact Greater Goods Customer Support for technical support or questions.

Testing with Control Solution / Why Perform Control Tests

Performing a control test lets you know that your meter and test strips are working properly to give reliable test results. You should perform a control test:

- Once a week.
- Before using a new box of test strips.
- When you suspect that the meter and test strips are not working together properly.
- · If you suspect your meter is damaged.
- · After cleaning your meter.
- · If you dropped the meter.
- Always perform a control test if you suspect your results are inaccurate or do not match how you are feeling.

About the Control Solutions

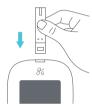
- Only use Greater Goods control solutions (1,2, or 3) to test the system.
- Your meter automatically recognizes the control solution.
- Control solution results are not included in the average value calculation.
- Store the control solution at 36-86°F, 10-90% humidity.

- All expiration dates are printed in Year-Month-Day format. 2023-01-01 indicates 1st January, 2023.
- Do not use control solution that is outside the expiration or discard date (the control solution will expire 6 months after the bottle is opened for the first time).
- Shake the bottle well before use.
- · Close the bottle tightly after use.

Performing a Control Test

 Remove a test strip from the test strip vial. Tightly close the vial cap immediately after you have removed the test strip.
 Note: Check the expiration and discard dates of the test strips.
 Do not use an expired test strip.

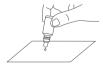
2. Insert a test strip into the meter in the direction of the arrows.



3. The meter turns on after a beep. An image of a test strip with a flashing blood drop will appear, letting you know the meter is ready to test.



4. Shake the control solution vial thoroughly. Squeeze the control solution vial gently and discard the first drop. Squeeze out a second small drop on a clean nonabsorbent surface.



Note: Do not apply control solution to the test strip directly from the vial.

5. Immediately touch the tip of the test strip to the drop of control solution. The control solution is pulled into the test strip through the strip tip.



Note: If the control solution sample does not fill the check window, do not add a second drop. Discard the test strip and start over with a new test strip.

6. The meter will beep, followed by a countdown on the screen, and then the control test result will display on the screen.





Note: The meter will automatically recognize and mark the control result for you. Control results are not included in the 7, 14, and 30 day average calculations.

Understand Your Control Test Result

Compare your control test result with the ranges printed on the test strip yial label.



Note:

If your control test result is out of range:

- Check the expiration dates and discard dates of the test strip and control solution. Make sure that the test strip vial and the control solution vial have not been opened for more than 6 months.
 Discard any expired test strips or control solution.
- Confirm the temperature in which you are testing is between 50-104°F.
- Make sure your test strips and control solution are stored between 36-86°F, 10-90% humidity.
- Make sure that the test strip vial and the control solution vial have been tightly capped.
- Make sure the test strip was used immediately after removal from the test strip vial.
- Make sure the control solution was mixed well.
- Confirm that you are using Greater Goods brand control solution.
- Make sure that you followed the test procedure correctly.

After checking all of the conditions listed above, repeat the control solution test with a new test strip. If your results still fall out of the range indicated on the test strip vial label, your meter or test strips may not be working properly. DO NOT use the system to test blood. Contact Greater Goods Customer Support at 800.481.0233. Please contact your healthcare professional if you need help.

To turn your meter off, just remove the test strip. Dispose of the used test strips as medical waste. The result will be automatically marked and stored in the meter memory. Control results will be not included in your blood glucose averages.

Using the Meter Memory

Your meter automatically stores up to 500 results with time, date, and meal marker. Test results are stored from the newest to the oldest. The meter will also calculate the average values of blood glucose records from the last 7, 14, and 30 days.

Notes:

- If there are already 500 records in memory, the oldest record will be erased to make room for a new one.
- Control results of blood glucose are not included in the 7, 14, and 30 day average calculation.

Viewing Your Test Results

When your meter is off, press • to turn the meter on. After a beep, a symbol of a test strip will flash on the display. Press • to review previous results in order.

Press and hold ● for 2 seconds to see your 7 day average for blood glucose results. If you want to review memory immediately after taking a test, with the test result on the display, press ● to see your 7 day average.



Press • again to view the 14 day average, and press it one more time to view the 30 day average.



When "End" appears on the display, you have viewed all of the results in memory.



CHARTER 4: MAINTENANCE AND TROUBLESHOOTING

Proper maintenance is recommended.

Charging the Battery

When the meter needs to be charged, the Empty Battery symbol () will appear.

When the Empty Battery symbol () and 'E11' appear on the screen, the meter cannot be used. You must charge the battery before using your meter.

The meter battery may be charged using one of the following options:

- Micro USB cable (computer charging)
- Micro USB cable with the AC adapter (wall charging) (AC adapter, Input: 100-240V~, 50/60Hz, 0.2A Max; Output: 5.0V, 1.0A; OVERVOLTAGE CATEGORY: II)

If you need the AC adapter which is not included in your kit, please contact your local distributor.



Caution:

- Do Not charge the meter outdoors or in a wet area.
- Do Not use the Micro USB cable, AC adapter or meter if it is damaged, discolored, abnormally hot, or has an unusual odour. Contact your local distributor.
- Do Not plug the AC adapter into a wall socket and leave it unattended.
- · Verify that the wall socket voltage matches the AC adapter voltage.
- Do Not allow unsupervised children to charge the meter battery.



Caution:

Do Not insert a test strip when the meter is connected to a computer or wall outlet.

NOTE:

- Using the Micro USB cable or AC adapter charges the battery in about 3 hours.
- When using the USB port on your computer to charge the battery, be sure the computer is turned on and not in standby mode. If the meter does not charge, try using another USB port on your computer.
- To optimise battery life, it is best to charge the battery when the Empty Battery symbol (___) appears.



Caution:

- If you use an ac adapter, which is not provided by Greater Goods, ensure it meets the standard ANSI/AAMI ES 60601-1.
- If you use the USB port on your computer to charge the battery, please ensure the computer meets the standard IEC 60950.

Warning

Please note that the battery is not removable. If the battery needs to be separated for sorting and discarding due to scrap of the product, please keep it away from children. A lithium hatteny is poisoppus. If swallowed impediately contact your doctor.

of the product, please keep it away from children. A lithium battery is poisonous. If swallowed, immediately contact your doctor or poison control center. Discard battery according to your local environmental regulations.

Caring for Your Glucose Monitoring System

- Store meter in the carrying case provided whenever possible.
- Wash and dry hands well before handling to keep the meter and test strips free of water and other contaminants.
- Greater Goods blood glucose meter is a precision electronic instrument. Please handle it with care.
- Avoid exposing meter and test strips to excessive humidity, heat, cold, dust, or dirt.

Cleaning and Disinfection

Your Greater Goods blood glucose meter should be cleaned and disinfected a minimum of once per week. Use only Clorox $^{\!\top\!\!M}$ Healthcare Bleach Germicidal Wipes, which have been proven to be safe with the Greater Goods blood glucose meter.

Cleaning is part of your normal care and maintenance and should be performed prior to disinfection, but cleaning does not kill germs. After use and exposure to blood, all parts of this kit can potentially transmit infectious diseases. Disinfecting reduces the risk of transmitting infectious diseases.

Note: If the meter is being operated by a second person who is providing testing assistance to you, the meter should be cleaned and disinfected prior to use by the second person.

Cleaning Your Meter

Step 1:

Take one piece of Clorox™ Healthcare Bleach Germicidal Wipes (EPA Registration No. 67619-12) from the container.

Step 2:

Clean the entire meter surface including front side, back side, right side, and left side.



The meter should be cleaned whenever it is visibly dirty or a minimum of once per week. This cleaning is to prepare the meter surface for a disinfection process.

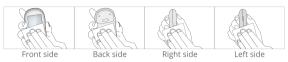
Disinfecting Your Meter

Step 1:

After cleaning your meter, take out another new piece of Clorox[™] Healthcare Bleach Germicidal Wipes.

Step 2:

Wipe the entire surface including the front side, back side, right side, and left side of the meter with a back and forth movement.



Step 3:

Keep the meter surface wet for at least one minute.

Step 4:

Wait for the surface of the meter to dry.

Clorox™ Healthcare Bleach Germicidal Wipes containing sodium hypochlorite 0.55% has been proven safe to use with the Greater Goods system. Clorox™ Healthcare Germicidal Bleach Wipes are available by visiting and purchasing at http://www.walmart.com, http://www.staples.com/ and https://www.staples.com/ and https://www.staples.com/ and https://www.amazon.com/. The meter should be disinfected a minimum of once per week. The meter disinfection process has been validated for 608 disinfection cycles, which is equivalent cleaning and disinfecting your meter every 3 days for 5 years. This is to ensure that your

Notes:

- Do not use alcohol or any other solvent.
- Do not allow liquid, dirt, dust, blood, or control solution to enter the test strip port or the USB port.

meter will operate properly over the 5-year life of the meter.

- Do not squeeze the wipe or gauze into test strip port.
- Do not spray cleaning solution on the meter.
- · Do not immerse the meter in any liquid.

Notes:

Although it has not been observed, some alterations may appear on your meter due to the cleaning and disinfection procedure, such as: a cloudy display window, cracks in the plastic housing, a lack of function in the meter's button, a partially visible display, inability to perform the meter's initial setup, etc. If you notice any of these external changes to your meter or any changes to the performance of your meter stop using the meter and please contact Customer Support for help.

If you have questions about cleaning or disinfection, or if you see evidence of physical damage, contact Greater Goods Customer Support at 800.481.0233. Additionally, you can reach out to your healthcare professional if you need help.

Troubleshooting Guide

| What You See | What It Means | What You Should Do |
|--------------|--|---|
| E 1 | Blood or control solution was applied to the test strip before the flashing blood drop appeared on the screen. | Discard the test strip and repeat the test with a new test strip. Wait until you see the flashing blood drop on the display before testing. |
| E Ž | The meter is sensing a used or contaminated test strip. | Discard the test strip and repeat the test with a new test strip. Wait until you see the flashing blood drop on the display before testing. |
| Ē 3 | Incorrect test strip. | Discard the test strip and repeat the test with a new test strip. Make sure that you are using a Greater Goods test strip. |
| Ę Ý | Incorrect sample. | Discard the test strip and repeat the test with a new test strip. Make sure that only human capillary blood and Greater Goods control solution are used for the test. |
| ξŚ | Temperature out of range. | Move to an area that is within the operating range for the meter. Let the meter adjust to this temperature for 20 minutes before performing a test. |

| | Potential | Restart the meter. If the |
|---------|--|--|
| E 5 E 1 | hardware error. | problem continues, contact Greater Goods Customer Support at 800.481.0233. |
| E B | A test strip was inserted while the meter was connected to a computer or wall outlet. | When the charge is completed (about 3 hours for charging an empty battery), remove the Micro USB cable from the meter, and then take a test. |
| E 10 | Insufficient sample. | Repeat the test and apply enough sample to fill the test strip check window. |
| E ! أ | Running out of battery. | Charge the battery. |
| 8 | Data not transmitted. | Please check your network connection, discard the test strip, and repeat the test with a new test strip. If the problem continues, contact Greater Goods Customer Support at 800.481.0233. |
| ăII | Network not connected. | Restart the meter. Please check if your SIM data is used up. If the problem continues, contact Greater Goods Customer Support at 800.481.0233. |



The test result is above 600 mg/dL.

Wash and dry your hands well and the test site. Repeat the test using a new test strip. If your result still flashes "HI", contact your healthcare professional as soon as possible.



Caution:

Glucose levels above 250 mg/dL may indicate a potential serious medical condition.



The test result is below 20 mg/dL.

Wash and dry your hands well and the test site. Repeat the test using a new test strip. If your result still flashes "LO", contact your healthcare professional as soon as possible.



Caution:

Glucose levels below 50 mg/dL may indicate a potential serious medical condition

Symptoms of High or Low Blood Glucose

You can better understand your test results by being aware of the symptoms of high or low blood glucose. According to the American Diabetes Association, some of the most common symptoms are:

Low blood glucose (Hypoglycemia):

- shakiness
- sweating
- fast heartbeat
- blurred vision
- confusion
- · passing out
- irritability
- seizure
- extreme hunger
- dizziness

High blood glucose (Hyperglycemia):

- · frequent urination
- excessive thirst
- blurred vision
- increased fatigue
- hunger

Ketones (ketoacidosis):

- shortness of breath
- nausea or vomiting
- very dry mouth

Warning:

If you are experiencing any of these symptoms, test your blood glucose. If your test result is under 50 mg/dL or above 250 mg/dL, contact your healthcare professional immediately.

CHAPTER 5: SPECIFICATION INFORMATION

System Specifications:

| Feature | Specification |
|--------------------------------|---|
| Measurement Range | 20 - 600 mg/dL |
| Measurement Result | Plasma Glucose |
| Sample | Fresh capillary whole blood |
| Sample Volume | 0.8 μL |
| Test Time | 5 seconds |
| Power Source | Rechargeable 3.7 Volt Lithium Ion Battery |
| Charging Time | ≤3h, direct current |
| Battery Type | Rechargeable, 800 mAh, 3.7 Volt DC nominal, lithium polymer battery (5V input charge voltage) |
| Units of Measure | The meter is preset to milligrams per deciliter (mg/dL) |
| Memory | 500 records |
| Automatic Shutoff | 2 minutes after last action |
| Dimensions | 95.5 mm x 59.1 mm x 20.5 mm |
| Display Size | 47 mm x 37.5 mm |
| Weight | Approximately 70g |
| Operating Temperature | 41 - 113°F |
| Operating Relative Humidity | 10-90% (non-condensing) |
| Hematocrit Range | 20 - 70% |
| Charging Port | Micro USB |
| Data Transmission | 4G |

The Greater Goods LTE-BGM 0031 blood glucose monitoring system was tested by 353 lay users using capillary blood samples and three Greater Goods test strip lots. The results were compared to the YSI Model 2300 STAT PLUS glucose analyzer, a laboratory instrument. The tables below show how well the two methods compared.

Table 1- Linear Regression Results

| Slope | 0.9971 |
|-----------------------------|---------------|
| Intercept | -0.2597 mg/dL |
| Correlation coefficient (R) | 0.9950 |

Number of sample 353

Range tested 48.4 to 448.5 mg/dL

Table 2 - Consumers Accuracy Results
The numbers and percentages represented in this table are the number of meter results compared to a laboratory result.

| Difference range between the true blood qlucose level and the Greater Goods LTEM-BGM 0031 Blood Glucose meter result. | Within | Within | Within | Within |
|---|----------|----------|----------|----------|
| | ±5% | ±10% | ±15% | ±20% |
| The percent (and number) of meter results that match true blood glucose level within x%. | 240/353(| 337/353(| 353/353(| 353/353(|
| | 68.0%) | 95.5%) | 100%) | 100%) |

| Accurate Results (Meter result is +/-15% of laboratory result) | 353 out of 353 (100% of results) |
|--|-----------------------------------|
| More Accurate Results (Meter result is +/-10% of laboratory result) | 337 out of 353 (95.5% of results) |
| Most Accurate Results (Meter result is +/-5% of laboratory result) | 240 out of 353 (68.0% of results) |

Activate Your Warranty

Please visit *greatergoods.com/0031* to activate your product's warranty and access lifetime product support.

Your blood glucose meter is warranted by the manufacturer against defects in materials and workmanship for three (3) years from the original purchaser from the date of purchase. Proof of purchase is required. The warranty is void if the product has been subjected to mechanical damage or mistreatment, such as immersion. This warranty is in lieu of all other warranties and limits the liability of the manufacturer. This warranty gives you certain legal rights, and you may have other rights depending on which state the product was purchased in.

If your blood glucose meter is defective, please contact Greater Goods, LLC:

800.481.0233 | info@greatergoods.com | greatergoods.com/0031

FMC Guidance:

Warning: Don't use near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Portable RF communications equipment(including peripherals such as antenna cables and external antennas)should be used no closer than 12 in(30 cm)to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

| Guidance and Manufacturer s Declaration Electromagnet- ic Emissions | | |
|--|------------|--|
| Emissions test | Compliance | |
| RF emissions CISPR 11 | Group 1 | |
| RF emissions CISPR 11 | Class B | |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/flicker emissions IEC 61000-3-3 | Complies | |

Note:

This warranty applies only to the meter in the original purchase, and does not apply to the battery supplied with the meter.

| Guidance and Manufacturer's Declaration Electromagnetic Immunity | | | | |
|--|--|--|--|--|
| Immunity Test | IEC 60601-1-2 Test L evel Compliance Level | | | |
| Electrostatic discharge(ESD) IEC 61000-4-2 | ±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air | ±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air | | |
| Electrical fast transient/burst IEC 61000-4-4 | ±2 kV for power supply lines | ±2 kV for power supply lines | | |
| Surge IEC 61000-4-5 | ± 0.5 kV, ± 1 kV line(s) to line(s) | ± 0.5 kV, ± 1 kV line(s) to line(s) | | |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | 0% U ₁ ; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U ₁ ; 1 cycle 70% U ₁ ; 25/30 cycle Single phase: at 0° 0% U ₁ : 250/300 cycle | 0% Ur; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% Ur; 1 cycle 70% Ut; 25/30 cycle Single phase: at 0° 0% Ur; 250/300 cycle | | |
| Power frequency magnetic field IEC 61000-4-8 | 30 A/m 50Hz/60Hz | 30 A/m 50Hz/60Hz | | |
| Conduced RF IEC 61000-4-6 | 3 V r.m.s. 150 kHz to 80 MHz 6 V RMS in the ISM and amateur bands between 0.15 MHz and 80 MHz | 3 V r.m.s. 150 kHz to 80 MHz 6 V RMS in the ISM and amateur bands between 0.15 MHz and 80 MHz | | |
| Radiated RF IEC 61000-4-3 | 10 V/m 80 MHz - 2.7 GHz 80 % AM at 1 kHz | 10 V/m 80 MHz - 2.7 GHz 80 % AM at 1 kHz | | |

Guidance and Manufacturer's Declaration-IMMUNITY to proximity fields from RF wireless communications equipment

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

| Immunity Test | IEC60601 Test Level | | | | Compliance |
|---------------------------------|---------------------|---|------------------|------------------------|------------|
| | Test Frequency | Modulation | Maximum Power | Immunity Test Level | |
| Radiated RF IEC 61000-4-3 | 385 MHz | **Pulse Modulation: 18Hz | 1.8W | 27 V/m | 27 V/m |
| | 450 MHz | *FM+ 5 kHz deviation: 1kHz sine | 2W | 28 V/m | 28 V/m |
| | 710 MHz | | 0.2W | 9 V/m | 9 V/m |
| | 745 MHz | **Pu l se Modu l ation: 217Hz | | | |
| | 780 MHz | | | | |
| | 810 MHz | | 2W | 28 V/m | 28 V/m |
| | 870 MHz | **Pulse Modulation: 217Hz | | | |
| | 930 MHz | | | | |

| Radiated RF IEC 61000-4-3 | 1720 MHz | **Pulse Modulation: 217Hz | 2W | 28 V/m | 28 V/m |
|---------------------------------|----------|---------------------------------|------|--------|--------|
| | 1845 MHz | | | | |
| | 1970 MHz | | | | |
| | 2450 MHz | **Pulse Modulation: 217Hz | 2W | 28 V/m | 28 V/m |
| | 5240 MHz | **Pulse Modulation: 217Hz | 0.2W | 9 V/m | 9 V/m |
| | 5500 MHz | | | | |
| | 5785 MHz | | | | |

Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. Note** - The carrier shall be modulated using a 50 % duty cyde square wave signal.

FCC Requirement

RF Exposure Compliance

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End user must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

The portable device is designed to meet the requirements for exposure to radio waves established by the Federal Communications Commission(USA). These requirements set a SAR limit of 1.6 W/kg averaged over one gram of tissue. The highest SAR value reported under this standard during product certification for use when properly worn on the extremity, with 00mm separation.

Frequency Requirement

| Frequency Band | Max Power | Min Power |
|----------------|-----------|-----------|
| Band 2 | 1850-1910 | 1930-1990 |
| Band 4 | 1710-1755 | 2110-2155 |
| Band 12 | 699-716 | 729-746 |
| Band 13 | 777-787 | 746-756 |

TX POWER

| Frequency Band | Max Power | Min Power |
|----------------|-------------------|-----------|
| Band 2/4/12/13 | 21 dBm +1.7/-3 dB | <39 dBm |



Greater Goods, LLC. 4427 Chouteau Ave. St. Louis, MO 63110

Customer Support: 800.481.0233