



# Telcare Blood Glucose Monitoring System

## **User Manual**

Thank you for choosing the Telcare Blood Glucose Monitoring System.

The Telcare system is comprised of the Telcare meter and the online website.

The meter provides accurate readings sent immediately to your online account to store, track and chart. Personalized messages are also sent from www.mytelcare.com to the meter.

This manual will provide you with all you need to know to use your new meter. So let's get started.

<sup>\*</sup>Not intended for sale within the EU.

## Intended Use

The Telcare Blood Glucose Monitoring system is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. It is intended for lay use by persons with diabetes to aid in diabetes management. It is indicated for use at home (over the counter [OTC]) and should be used only by a single patient and should not be shared. Test results are plasma-calibrated for easy comparison to clinical laboratory methods. Testing is done outside the body (in vitro diagnostic use). The Telcare Blood Glucose Monitoring System consists of the Telcare BGM® Blood Glucose Meter, Telcare Blood Glucose Test Strips, and Telcare Glucose Control Solutions. The Telcare Blood Glucose Monitoring system is not indicated for the diagnosis or screening of diabetes or for neonatal use. Palm and forearm testing should be done only during steady-state times when glucose is not changing rapidly. The Telcare BGM Blood Glucose Meter uses cellular data transmission to send test results to Telcare's remote database, Telserve, and to receive messages from Telserve. The Telcare Blood Glucose Monitoring System is not intended to provide automated treatment guidance or decisions, nor is it to be used as a substitute for professional healthcare judgment.



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# **Important Safety Instructions**

The Telcare Blood Glucose Monitoring System and lancing device is for single patient use. Do not share it with anyone, including family members! Do not use on multiple patients!

Because all parts of the kit may come in contact with your blood, all parts are considered biohazardous. Kit parts can potentially transmit infectious diseases, even after cleaning and disinfection.

Users should wash hands thoroughly with soap and water and dry thoroughly after handling the meter, test strips, and any lancing device.

For Cleaning and Disinfecting procedures to prevent the spread of diseases such as Hepatitis B, see Cleaning and Disinfecting Your Meter (page. 32).

For Technical Support, contact Telcare at (888) 666-4530 (US) or (1) (978) 610-4688 (International).

Hours of Operation: Monday - Friday, 9AM - 9PM EST

#### References

"FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010)

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm

"CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Blood-borne Pathogens" (2010)

http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

"Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline–Third Edition. Clinical and Laboratory Standards Institute (CLSI), document M29-A3, (ISBN 1-56238-567-4).



# Getting started

## Unboxing the Telcare BGM' for the first time

Before we begin, take a moment to go over the contents of your Telcare BGM kit. Your kit should include:

- Telcare BGM (battery included)
- AC Charger
- Quick Start Guide
- Instruction Manual
- Test Strip Insert

- Control Solution Levels 1 & 2 (2.5 mL)
- Lancing Device
- Telcare Lancets (10 Count)
- Telcare Test Strips (10 Count)

## Using your new meter

Make sure you charge your glucose meter for at least 3 hours before first use. To charge your glucose meter, use the AC Charger included in your kit.

IMPORTANT: Slight delays occur when meter powers on. If delay is greater than 20 seconds, do not use meter. Contact technical support at (888) 666-4530 (US) or (1) (978) 610-4688 (International).

You should use the Telcare BGM for:

- Testing blood glucose
- Testing only with fresh capillary whole blood samples

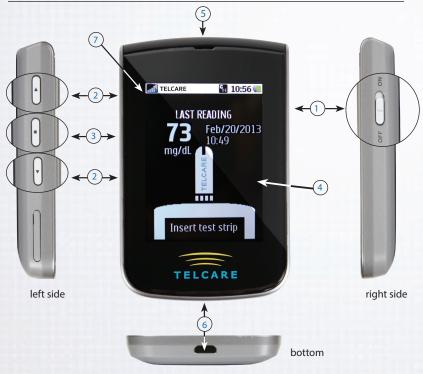
You should NOT use the Telcare BGM for:

- The diagnosis of diabetes Testing of arterial blood
- ■Testing blood glucose on newborn infants ■Testing of venous blood



## The Telcare BGM°

- 1 Power Button
- 2 UP / DOWN Keys to scroll through the menus
- 3 Enter Button
- 4 Display Screen
- 5 Insert Test Strip (white side up)
- 6 Charging Port (do not attempt to insert strip here)
- 7 Wireless Signal Indicator (Other carrier names may appear here.)





## **Telcare Test Strips**



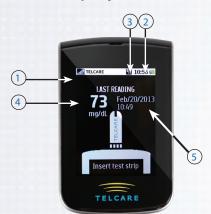
## Important notes on test strips:

- Because of the autocoding feature of this meter, the strip insertion will be snug. This is to be expected and users find it easy after a few attempts.
- Check the expiration date printed on the test strip bottle and its package.

  Do Not use expired test strips.
- Use each test strip immediately after removing it from the bottle.
- Do not use wet or damaged test strips.
- Keep away from direct sunlight and heat. Store the test strip bottle in a dry, cool place.
- Record the "date opened" on the bottle label. Discard the bottle and any remaining test strips 6 months after the date of opening.
- Do not operate the meter outside the temperature range of 50°F (10°C) to 104°F (40°C).



# The Display Screen



On the Display Screen, you can see the following:

- 1 Wireless Signal Strength
- 2 Current Time
- 3 Battery Level
- 4 Last Test Reading
- 5 Date and Time of Last Reading

In this Display Screen, use the UP/ DOWN buttons (located on the left of your meter) to access the meter's options:

- Test Mode
- L1 Control Solution Mode (Low)
- L2 Control Solution Mode (High)
- History
- Settings Menu





# Setting Up Your Telcare BGM°

Your Telcare BGM time is automatically updated with the local date and time when a cellular connection is established.

If you would like to view your meter's preset settings, navigate to the Settings screen.

## Getting to the Settings Screen

1 Power (PWR) your Telcare BGM device on.

2 Use the UP/DOWN buttons to reach the Settings Screen.



## **Settings Options**

### Alarms

Create up to 3 alarms to help remind yourself when to test next.

#### Date and Time

This page allows you to view the Date and Time settings of your device.

#### Volume

This page allows you to select the volume of your meter. Use the UP/DOWN keys to select the appropriate volume. There are six possible volumes you may select from.

## **Brightness**

Change the brightness of your meter's screen.

### Language Settings

Change the language displayed by your meter.

## **BG Tag Timeout**

BG tag timeout determines the duration of the tagging time before a new blood glucose reading is automatically sent to the server if no selection is made.

## Airplane Mode

Turning on Airplane Mode disables cellular network access. You will not be able to transmit your readings while Airplane Mode is turned on. Your meter's clock will continue to work properly while in this mode.



If a time zone change occurs, your meter will not automatically update to the new time until Airplane Mode has been disabled. The meter will reset the time from the new network.

#### About

This screen provides a listing of current software and related information about your meter. This is helpful if you need technical support.

### Personalize

You may enter a Name on this screen that can help identify your meter and will be displayed on your screen in Test, L1 and L2 mode. Use the up and down arrow keys to choose a character and the Enter button to enter it. When you are done entering your Name, press the Enter button again after entering the last character.



## **Control Solution Testing**

Control solution testing will confirm that your Telcare BGM<sup>a</sup> and Test Strips are working properly. You should perform control solution testing when:

- Using the meter for the first time
- Using a new bottle of Telcare Test Strips
- You left the test strip bottle cap open
- You dropped the meter
- You suspect the meter and test strips are not working properly
- The test results do not reflect how you feel
- Practicing the testing
- The test strips are exposed to environmental conditions outside the temperature requirements printed on the label

Purchase additional control solution by calling Telcare at (888) 666-4530 (US) or (1) (978) 610-4688 (International) (9AM – 9PM EST, M-F).



# Step-by-Step Guide to Control Testing

Power on the Telcare BGM with the PWR button on the right side of the BGM.

The device will automatically start in Normal Test Mode, ready to check blood glucose. You will see the "Insert test strip" screen as shown.



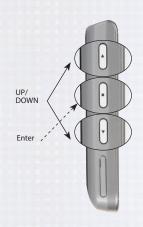
To access the main menu, use the UP/DOWN keys on the left side of the BGM. Switch modes from Normal Test Mode to L1 Control Solution Mode.

To test Level 1 (L1) control solution, use the UP/DOWN buttons to highlight L1 mode. Press the middle (ENTER) button to select L1 mode.

Upon successful completion of Level 1 (L1), test Level 2 (L2) control solution:

Again use the UP/DOWN keys on the left side of the BGM to access the main menu. Switch modes from Normal Test Mode to L2 Control Solution Mode.

To test Level 2 (L2) control solution, use the UP/DOWN buttons to highlight L2 mode. Press the middle (ENTER) button to select L2 mode.

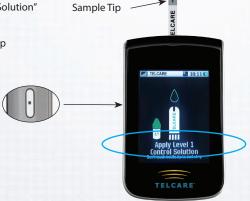






- You can select any Mode you want by pushing the ENTER button.
- Take out a Telcare Test Strip from the test strip bottle. Close the bottle immediately.
- IMPORTANT:
  - Firmly insert the test strip into your Telcare BGM until it is fully seated.
  - The word "Telcare" should be facing up.
  - The sample tip should be facing up.
  - Continue to push the strip in until "Apply Level 1 (2) Control Solution" appears.
  - Do not touch the sample tip







- Squeeze a drop of control solution onto a clean, dry, non-absorbing surface. Use Level 1 solution for L1 mode. Use Level 2 solution for L2 mode.

  Do not apply control solution to the test strip directly from the bottle. Immediately replace the bottle cap on the control solution bottle.
- Gently touch the tip of the test strip to the drop of control solution. You should see the sample end of the test strip fill.
- The screen will start to count down. After 6 seconds, the control test result will appear on the meter's display screen.



Compare the reading on the screen to the "L1 Control Solution" or "L2 Control Solution" range printed on the test strip bottle or package. If the reading on the meter falls within the appropriate range, select the YES tag. If not, select the NO tag. If the reading falls outside the level printed on the bottle or package that you used, please see "Control Solution Troubleshooting" on page 13.

Control Solution readings are stored on the meter but are not transmitted and displayed in Telserve.



Control Solution Range (Images are for reference only. Actual numbers may vary.)

## Important tips about control solution:

- Only use Telcare Glucose Control Solution with the Telcare Test Strips. Other brands of control solution or test strips may produce inaccurate results.
- 2. Always check the expiration date. DO NOT use expired control solution.
- 3. DO NOT FREEZE. Store the control solution at room temperature.
- 4. Never touch the tip of the control solution bottle to the test strip. It will damage all remaining solution in the bottle.
- 5. Record the "date opened" on the bottle label.
- 6. Do not use the control solution if more that 3 months since first opened.



## **Control Solution Troubleshooting**

If your control solution testing is out of range (too high or too low), it may be caused by the following:

- Wrong brand of control solution
- Control solution not at room temperature
- Expired or contaminated control solution
- Damaged test strip
- Touched the tip of solution bottle to test strip
- Meter malfunction
- Testing outside of meter operating temperatures (50°F 104°F) (10°C 40°C)

Check the expiration date and open bottle date on the control solution and on the test strips. Repeat testing using a new test strip. If the result is still out of range, use a new bottle of control solution and retest

If the problem persists, call Telcare at (888) 666-4530 (US) or (1) (978) 610-4688 (International). Do not perform any blood glucose tests until you resolve this issue.

# **Preparation and Safety**

## Before you begin, make sure to:

- Set up your Telcare BGM® Blood Glucose Meter properly.
- Run a control test before first use. (See Step-by-Step Guide to Control Testing on page 8.)
- Wash your hands and testing site thoroughly with warm water and soap. Dry your hands well.
- Test in a place where the temperature range is between 50°F (10°C) and 104°F (40°C). (See "Troubleshooting" on page 37 for more information.)

#### You will need:

- Your Telcare BGM Blood Glucose Meter
- A new Telcare Test Strip
- A lancing device with a clean, unused lancet (or safety lancets)

#### IMPORTANT WARNINGS ABOUT INACCURATE RESULTS:

Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.



#### FOLLOW THESE IMPORTANT SAFETY GUIDELINES

- Please follow cleaning and disinfecting instructions for the meter (page 32) and lancing device (page 34) to prevent the risk of blood-borne pathogen transmission!
- Follow any cleaning/disinfection instructions that may come with the lancing device you use.
- The meter and lancing device are intended for a single user and should not be shared.
- Make sure you wash with soap and water and dry hands thoroughly before and after handling the meter, lancing device, or test strips.



## Step-by-Step Blood Glucose Testing

- Power on the Telcare BGM° device with the PWR button on right side of meter. The device will automatically start in Normal Test Mode. When ready to check blood, Insert test strip will be displayed.
- Take out a Telcare Test Strip from the bottle, and close the bottle immediately.

  (Some meters require the user to enter a code from the vial. Telcare's strips do not require a code.)
- Firmly insert the test strip into your Telcare BGM until it is fully seated.





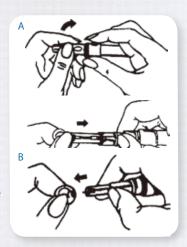


# Prepare Your Lancing Device

A Twist off the lancing device cover. Insert a new lancet firmly into the lancet carrier.

B Hold the lancet needle cover and gently twist it off of the lancet.

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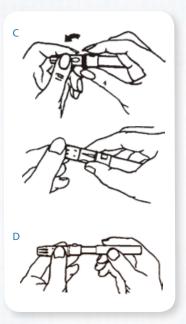
### IMPORTANT SAFETY PROCEDURES REGARDING LANCETS:

- Use a new lancet every time you test, to avoid contamination. It is important to discard the used lancet carefully after each use to avoid unintended lancet stick injuries. Used lancets may be considered biohazardous waste in your area. Be sure to follow your local regulations for proper disposal.
- If alcohol wipes are used to clean your finger or palm, make sure your skin is dry before the blood sample is obtained.
- Lancing devices should <u>NEVER</u> be used by more than one person.
- If the seal is broken, discard the lancet.

C Replace the lancing device cover.
The adjustable tip offers 5 levels of skin penetration. To select the desired depth, twist the adjustable tip in either direction until the number lines up with the arrow.

To select the best depth:

- 1-2 for soft or thin skin
- 3 for average skin
- 4-5 for thick or callused skin
- D Hold the lancing device cover in one hand. Using the other hand, slowly pull the sliding barrel away from the lancing device cover. You will hear a click, indicating that the lancet carrier is locked into position. Release the sliding barrel to return it to its original position.



## How to choose the cap

- For fingertip testing, use the colored cap included on the lancing device.
- For alternate site testing on your palm, use the clear cap.



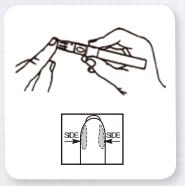
## Tips for fingertip testing

- Gently massage your hand and finger toward the puncture site to form a drop of blood. Do not "milk" or squeeze around the puncture site.
- Lance the side of your fingertip to avoid soreness. To avoid calluses, choose a different lancing site each time.

## Fingertip Testing

Position the end of the adjustable comfort tip against the side of the fingertip. Press the trigger button, and then lift the lancing device away from the finger after the puncture is complete.

Continued on next page



# 6

## Testing Using an Alternate Test Site

# Important Information on Alternate Site Testing

Your Telcare BGM\* is capable of testing your blood glucose from your palm, usually referred to as an alternate site test, or AST.

Alternate site testing can be less painful than fingertip testing.

However, because of the physiological differences between your fingertip and palm, AST results may be significantly different.

Alternate site testing should not be used to calibrate continuous glucose monitor nor should it be used in insulin dose calculations.

Alternate site testing should only be used during steady state blood glucose conditions when glucose is not changing rapidly.

You should consult with your doctor before using alternate site testing.





## Testing on Your Palm

Prepare the lancing device with a new lancet and clear cap. Cock the lancing device so that it is ready to use. Select a site on your palm that does not have veins, moles, excessive hair, or bone. Vigorously rub the side of your palm with your other hand for at least 10 seconds. You should feel it get quite warm.

Press the opening of the clear cap against a fleshy area of the palm. Press the lancing device up and down in a slow pumping motion for several seconds to help the flow of blood.

Keep steady pressure on the area and press the release button. Do not be afraid to apply pressure to the area with the lancing device to assist the flow of blood. Continue to press the cap against the area for a few seconds to allow blood to come to the surface. You can see the blood drop through the clear cap. Do not smear the blood when removing the lancing device. If the blood drop is too small, the meter will show Error: Not Enough Blood. Insert a new strip and obtain a new blood drop.

### Choosing Lancet guage

Telcare users have found that a 26-gauge lancet or thicker (a number lower than 26) is needed in order to obtain an adequate blood drop for palm testing. Ultra-fine lancets that are adequate for finger testing will often fail to yield enough blood for palm testing.

If the results from alternate site testing differ from how you feel, use fingertip testing instead.

#### IMPORTANT SAFFTY INFORMATION ON AST

A We recommend that Alternate Site Testing SHOULD NOT BE USED WHEN:

- You have hypoglycemic unawareness (not able to tell if you have low blood sugar).
- You are within 2 hours of eating a meal, exercising, or taking medication.
- You will be operating machinery or driving a car.
- You are sick.
- You think your blood glucose is low.
- Your Alternate Site Testing results do not match the way you feel.
- You are testing for hyperglycemia.
- B Alternate Site Testing should not be used for patients who are dehydrated, hypotensive, in shock, critically ill, or in a hyperosmolar state.
- C Alternate Site Testing measurements should never be used for insulin dose calculations.
- D Please see your lancing device's user manual for further instructions.

Note: If not using Telcare's provided lancing device, please refer to your lancing device's instruction for use.



#### IMPORTANT INFORMATION FOR LANCING DEVICE

- A Use the Telcare Lancing Device included in your Telcare Blood Glucose

  Monitoring System to obtain a blood sample. The minimum blood sample
  volume is 0.8 microliters.
- B Purchase an additional Telcare Lancing Device by calling Telcare at (888) 666-4530 (US) or (1) (978) 610-4688 (International). (9AM - 9PM EST, M-F).
- C If using another type of lancing device, please refer to its user manual.



- Applying Blood to the Test Strip
  Gently touch the test strip to the drop of blood.
  The test strip will absorb the blood. Keep the
  test strip in the blood drop until you see the
  blood sample end of the test strip fill.
- Tagging Your Data
  The screen will start to count down. After
  6 seconds, your glucose level will appear on the
  display screen. You will then have time to select
  a Reading Tag (e.g., "Before Breakfast") from the
  list displayed. Use the DOWN button to scroll to
  the correct tag. Press the ENTER button to select
  that tag.

Your test result will be automatically stored into the meter history. If a Reading Tag is not selected in the allotted time, it will automatically be tagged as "No Selection."

Remove the Test Strip
In order to send results to the Telcare server,
remove the test strip from the meter when you
see the screen shown here.









Sending Your Results
As soon as you remove the test strip, your Telcare
BGM\* will send the results to Telserve, Telcare's
secure server. Telserve data can be viewed at
MyTelcare.com.

## Important steps to follow if If you see High or Low

If you see High or Low displayed, your blood glucose level may be above 600 mg/dL or below 20 mg/dL. Wash your hands. Dry your hands completely. Test again using fingertip testing. DO NOT test on your palm or forearm. If you still receive the same message, call your caregiver immediately.



OPTIONAL: After successful data transmissions to Telserve, you may receive a multiple choice question to answer. This may be a question from your caregiver or relate to reordering supplies. Use the UP/DOWN buttons to select the appropriate answer. Press the ENTER button to transmit.



#### CLINICAL RESPONSE SCREEN: After

data transmission, you will see a graph that compares your reading to your set target. To change your set target, go to MyTelcare.com or call Customer Support at (888) 666-4530 (US) or (1) (978) 610-4688 (International). You may also see helpful guidance from your caregiver regarding this reading to manage your diabetes.





## If Your Data Transmission Is Not Successful

If the device cannot communicate with Telserve, the following message will appear:

No data connection, Data will be stored

Your test results will be stored in your device. You can send the reading on your own by going into History from the main menu. See page 29. For the transmission to be successful, network connection is required.

The meter will attempt to forward unsent readings automatically. Readings that have been transmitted to Telserve will be marked with a green check in the History List.

IF DATA TRANSFER FAILS, YOU MAY USE THIS PRODUCT LIKE ANY OTHER GLUCOSE METER. FOLLOW YOUR HEALTH CARE PROFESSIONAL'S INSTRUCTIONS ON TREATMENT.

## **Understanding Your Blood Glucose Test Results**

Blood glucose value will vary depending on food intake, medication, health, stress, and exercise. The ideal ranges for people without diabetes are as follows:

- 70 to 100 mg/dL before meals, and
- 70 to 140 mg/dL after meals

# What to do if you get a high or low reading AND you feel ill.

If the Telcare BGM° displays results that are "High" or "Low," or you get a result that is more than 250 mg/dL or below 50 mg/dL <u>AND</u> you feel ill:

■ Treat your diabetes according to the instructions from your doctor.

If the Telcare BGM displays results that are "High" or "Low," or you get a result that is more than 250 mg/dL or below 50 mg/dL <u>AND</u> you <u>DO NOT</u> feel ill:

- Test your Telcare BGM with a control solution: refer to page 8, "Step-by-Step Guide to Control Testing."
- Wash your hands, dry thoroughly and test again using your fingertip.

If you still get a high or low reading, contact your doctor immediately.

#### References

<sup>1.</sup> American Diabetes Association. Standards of Medical Care in Diabetes—2008. Diabetes Care. 2008;31:S12-S54.



## View Your History on the Meter or Online

## View your history on your meter

Your Telcare BGM\* stores up to 300 test and control results. Each result is stored with date and time.

- Power on the Telcare BGM by using the PWR button.
- Use the UP/DOWN keys to access History.
- Use the UP/DOWN keys to scroll through the stored readings.

To exit the History menu, scroll to the bottom of your reading history and select "BACK." (Shortcut: Press the UP button when your most recent reading is highlighted. Doing so will display the BACK option.)

## Access Your readings at www.MyTelcare.com

Access your readings at www.MyTelcare.com. Use the log in credentials that you can obtain by calling (888) 666-4530 (US) or (1) (978) 610-4688 (International). For additional questions or login support, turn your meter off and contact Telcare by phone or e-mail at support@MyTelcare.com.





# Charging Your Telcare BGM°

Your Telcare BGM uses a rechargeable battery. It can be charged and discharged hundreds of times, but eventually the battery will lose its charge. If you notice significant reduction in the duration of your meter's operating time, please contact Telcare technical support at (888) 666-4530 (US) or (1) (978) 610-4688 (International), or e-mail support@MyTelcare.com.

If left unused, a fully charged battery will lose its charge over time.

Always charge indoors.

## To Charge Your Device

- Plug the power cord into an electrical outlet.
- Plug the other end of the cord into the BGM's Charging Port.



#### **Charging Troubleshooting**

If your device does not turn on when you switch the power button on, your battery may not be fully charged. Charge the battery. If after 3 hours of charging the device does not turn on, contact Telcare technical support at (888) 666-4530 or (1) (978) 610-4688 (International).



# Cleaning & Disinfecting

# What is the difference between cleaning and disinfecting?

Cleaning and disinfecting are not the same thing. Cleaning simply removes blood and dirt. Disinfecting kills germs and provides an extra level of safety. In the following procedure, the first disinfectant towel is used for cleaning, and the second towel provides for disinfection.

You should disinfect areas where there are both high concentrations of germs and a possibility that they will be spread to others. The Caltech DISPATCH Cleaner/ Disinfectant with Bleach Premoistened Towels™ have ingredients that clean and disinfect your meter, lancing device, and endcaps. While surfaces may look clean, many infectious germs may be lurking around. Some germs can live on surfaces for hours and even for days! The disinfection process shown in the pages that follow is effective in destroying dangerous Hepatitis B viruses.

If the meter or lancing device is being operated by a second person who is providing testing assistance to the user, the meter should be disinfected prior to assistance from the second person. See your lancing device's user manual for instructions on decontaminating your lancing device.

## To acquire canisters of Caltech DISPATCH towels, please contact:

Medex Supply - www.medexsupply.com - (888) 433-2300

Sears - www.sears.com - (800) 349-4358

Berktree - www.berktree.com - (866) 505-5333

Optics Planet - www.opticsplanet.com - (800) 504-5897

Amazon - www.amazon.com

A full list of authorized dealers of Caltech DISPATCH towels is at www.MyTelcare.com.



## Cleaning and Disinfecting Your Meter

Clean and disinfect your meter at least 1 time per week using Caltech DISPATCH
Cleaner/Disinfectant with Bleach Premoistened Towels™ using the following method:



Dispense the DISPATCH towel from its package or container.



Clean the outside of the meter to remove any blood or dirt.



Discard used towel in a sealed container where it will not be touched by others.



Dispense a second DISPATCH towel from its package or container.



Disinfect the meter with the second towel by wiping all outside surfaces.



Discard used towel in a sealed container where it will not be touched by others.



Wait at least one minute and make sure device is completely air dried before next blood test.



The Telcare BGM° has been validated for 1,825 cleaning and disinfection cycles. Please obtain a new meter after cleaning and disinfecting the meter 1,825 times or once the lifetime of the meter (5 years) has been reached, whichever comes first.

#### Meter Cleaning Dos and Don'ts

- Do not allow cleaning solution to run in or around the strip port. Doing so may cause a malfunction.
- Do not let the meter come in contact with water.
- Do not use any glass or household cleaners on the meter.
- IMPORTANT: If the meter is being operated by a second person who is providing testing assistance to the user, the meter should ALWAYS be disinfected prior to assistance from the second person.
- Stop using the meter and contact customer service immediately if you notice any of the following signs of deterioration:
  - The meter does not turn on.
  - •The meter's screen has been cracked or has become clouded.
  - The meter is damaged or has stopped working.

For technical support, contact Telcare at (888) 666-4530 (US) or (1) (978) 610-4688 (International).



### Cleaning and Disinfecting Your Lancing Device

Cleaning and disinfecting of your lancing device should be done with the Caltech DISPATCH Cleaner/Disinfectant with Bleach Pre-moistened Towels when it appears dirty or contaminated with blood. The lancing device should be cleaned and disinfected daily. The Telcare Lancing Device has been validated for 1,825 cleaning and disinfection cycles, which corresponds to daily cleaning over a five-year lifetime. Please obtain a new lancing device after five years of daily cleaning or if signs of deterioration are seen. Please follow this cleaning method:



Dispense the DISPATCH towel from its package or container.



Clean the outside of the lancing device and the inside and outside of the cap to remove any blood or dirt.



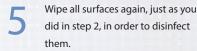
Discard used towel in a sealed container where it will not be touched by others.



Dispense a second DISPATCH towel from its package or container.









Discard the second towel in a sealed container where it will not be touched by others.



Wait at least one minute. Then rinse briefly with water and allow to dry before next use.

#### IMPORTANT LANCING SAFETY MEASURES

If the lancing device is being operated by a second person who is providing testing assistance to the user, the lancing device and endcap should ALWAYS be disinfected prior to assistance from the second person.

Stop using the lancing device and contact customer service immediately for a replacement if you notice any of the following signs of deterioration:

- Any buttons have fallen off or stopped working.
- The device is cracked.
- The device is discolored.
- The device does not yield an adequate blood drop.

# Storing Your Telcare BGM and Test Strips

- Your meter is a delicate electronic device that should be handled with care. Severe shock, such as dropping the meter, could damage it.
- The meter and test strips only work in the temperature range of 50°F (10°C) to 104°F (40°C).
- Store the test strips between 39°F (4°C) and 86°F (30°C). Do not freeze. See the test strip instructions for more details.
- Don't leave the meter in a place that is extremely hot or extremely cold (e.g., anywhere near a heat source or in an extremely hot or cold car).
- Do not expose the meter or test strips to high levels of humidity, such as in the bathroom or kitchen.
- Immediately close the bottle cap tightly after removing a test strip.
- Do not attempt to open the meter. Opening the meter will void the warranty and may cause it to operate improperly. If you have technical problems or questions, turn your meter off and contact Telcare at (888) 666-4530 (US) or (1) (978) 610-4688 (International). Support is available Monday through Friday, 9AM 9PM EST.



## Troubleshooting

#### **Error Codes**

In the event your device experiences an error, you will see the following screen along with an error message.

#### 1. Error Message: "Meter Failure"

What it means: As with any computer device, sometimes the meter may need to be restarted.

Action to take: Restart meter and contact Telcare support if the problem continues. Turn your meter off before calling Telcare at (888) 666-4530 (US) or (1) (978) 610-4688 (International).

### 2. Error Message: "Used Strip Inserted"

What it means: Your test strip may be used or damaged. Action to take: Repeat the test with a new test strip. Remember, add the sample only when you see the prompt on the display screen.

### 3. Error Message: "Not Enough Blood" or

### "Not Enough Control Solution"

What it means: There is not enough blood or too much blood or control solution on the test strip to give a reliable reading.

Action to take: Remove the test strip and repeat the test with a new test strip.

#### 4. Error Message: "No data connection, Data will be stored"

What it means: The meter cannot find a cellular connection.

Action to take: See "Communication Errors" on page 39.



#### 5. Error Message: "Temp. Too Low" or "Temp. Too High"

What it means: The meter is too hot or too cold.

Action to take: Move the meter into an area that is between  $50^{\circ}F$  ( $10^{\circ}C$ ) and  $104^{\circ}F$  ( $40^{\circ}C$ ). After receiving this error, allow the meter to be at room temperature for at least 30 minutes before testing blood or control solution.

#### 6. Error Message: "Unable to Connect, Will Retry at Next Test"

What it means: The meter unable to connect to Telserve.

Action to take: See "Communication Errors" below. If this is not resolved and you have more than 1 bar of cellular signal strength, call customer service.

#### Other Messages

#### 1. Icon Message:

Low Battery icon Displayed

What it means: The meter is about to lose power. Action to take: Charge the battery (see page 30)





#### 2. Icon Message: Wireless Signal Indicator Bars

Two bars or less of wireless signal strength may result in unreliable transmission and reception of data. The strength indicator is located at the top

left of the meter's screen.



#### 3. Message: "High" or "Low" Displayed

What it means: If you see either High or Low displayed on your device, your blood sugar level may be out of range (either in excess of 600 mg/dL [High] or lower than 20 mg/dL [Low]). Action to take: See "Troubleshooting" on page 13, and wash your hands. Dry your hands completely. Test again using fingertip testing. DO NOT test on your palm or forearm. If you still receive the same message, call your caregiver immediately.



#### **Communication Errors**

If you are having trouble uploading your results to Telserve, you may want to try the following:

- If testing indoors, move closer to a window for better cellular reception.
- Check to see if there is cellular coverage in your area. Two bars or less of wireless signal strength may result in unreliable transmission and reception of data.
- Restart meter and send reading within History (see page 29).

If the above actions do not resolve your problem, contact Telcare technical support at (888) 666-4530 (US) or (1) (978) 610-4688 (International), or e-mail support@MyTelcare.com.

## Terms of Warranty

Telcare warrants the Telcare BGM<sup>\*</sup> Blood Glucose Meter to be free of defects in workmanship and materials under normal use for a period of one (1) year from the date of purchase.

The liability of Telcare is limited to repair or replacement. In no event shall Telcare be liable for any collateral or consequential damages or loss.

Instruments subjected to misuse, abuse, neglect, exposure to water, unauthorized repair, or modification are excluded from this warranty.

This guarantee specifically excludes expendables and consumables.

Please direct any questions or claims to the authorized dealer from whom you purchased your system, or to:

Telcare, LLC 150 Baker Avenue Extension Suite 300 Concord, MA 01742, USA

Phone: (888) 666-4530 (US) or (1) (978) 610-4688 (International)

This warranty applies only to the original purchaser of the system.

# **Specifications**

Test Strips: Telcare Blood Glucose Test Strips

Minimum Sample: 0.8 microliters

Test Range: 20 - 600 mg/dL

Calibration: Plasma, calibrated against the YSI Glucose Analyser (YSI, Inc.) reference

instrument, which is traceable to NIST SRM 917c reference standard.

Hematocrit Range: 30 - 55%

Display Type: Color LCD screen

Memory: 300 blood test results with date and time

Result Averaging: 7, 14, and 30 days averaging displayed on Telserve Data System

(not on Telcare BGM°)

Dimensions: 100L x 60W x 15H (mm)

Weight: 115g

Battery: Rechargeable, Lithium Ion 1100 mA hour battery, permanently installed

Battery Life: 1 year

Automatic Sleep Mode: After 2.0 minutes of nonuse

Operating Temperature: 50°F~104°F (10°C~40°C)

Relative Humidity: Less than 85%

Storage Conditions: Meter at 39°F~122°F (4°C~50°C), Test Strips at 39°F~86°F

(4°C~30°C). Control Solution at 39°F~86°F (4°C~30°C)

## About Telcare®

Telcare is committed to creating the very best medical device experience for patients and doctors. Connecting powerful hardware and innovative software via a "no wires" approach, Telcare's offerings aim to provide convenient and effective disease management tools.

The Telcare Blood Glucose Monitoring System won the People's Choice Award at CTIA Wireless 2009, Best in Show at MobiTechFest 2009, was an E-tech Finalist at CTIA Wireless 2010, and won the First Prize 2011 CTIA E-Tech Award for Enterprise Healthcare Solution and the First Prize 2011 CTIA E-Tech Award for Mobile Healthcare Solution.

"I found the Telcare meter a refreshing change, and a significant step toward bringing consumer medical devices closer to the world of modern technology." — Walt Mossberg, Tech Columnist, Wall Street Journal

"Most importantly, the Telcare BGM sends my BG data automatically ... it is also well designed and instantly user friendly, like my iPad and Kindle."

— David Mendosa, Medical Journalist, HealthCentral



## Contact Telcare®

Telcare, LLC

150 Baker Avenue Extension, Suite 300, Concord, MA 01742 USA

Phone: (888) 666-4530 (US) or (1) (978) 610-4688 (International)

Hours: M - F, 9AM - 9PM EST

E-mail: support@MyTelcare.com

Website: www.MyTelcare.com

For any medical questions, contact your health care professional.

### **FCC Interference Statement**

Federal Communication Commission Interference Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 18 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- · Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.
- This device complies with Part 18 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.
- FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

#### **FCC Radiation Exposure Statement**

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator & your body.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.