

## Blood Glucose Monitoring System

## **User Manual**

This product contains a rechargeable internal battery. To conserve battery power this product will turn off the screen after one minute of non-use. To turn on the product either insert a test strip or press any side button.

Not Intended for Sale Within the EU

ART-161 Rev. 6

### **Contents**

- A Intended Use (pg. 2)
- B Important Safety Instructions (pg. 2)
- C Getting Started (pg. 3)
- D Your BioTel Care BGM™ (pg. 5)
  - D.1 Testing Your Blood Glucose (pg. 10)
  - D.2 Testing With Control Solution (pg. 17)
  - D.3 Functions and Settings (pg. 21)
- E Classic Mode (pg. 31)
  - E.1 Testing Your Blood Glucose (pg. 32)
  - E.2 View Your History on the Meter (pg. 35)
  - E.3 Testing With Control Solution (pg. 35)
  - E.4 Setting Up Your BioTel Care BGM™ (pg. 39)
- F Maintenance of Your BioTel Care BGM™ and Lancing Device (pg. 40)
- G Storing Your BioTel Care BGM™ and Test Strips (pg. 45)
- H Troubleshooting (pg. 45)
- I About Your System (pg. 50)
- J Terms of Service/Use (pg. 55)
- K Privacy Policy (pg. 69)

## A. Intended Use

The BioTel Care™ 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 BioTel Care™ Blood Glucose Monitoring System consists of the BioTel Care BGM™ Blood Glucose Meter, BioTel Care™ Blood Glucose Test Strips, and BioTel Care™ Glucose Control Solutions. The BioTel Care™ 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 BioTel Care™ Blood Glucose Meter uses cellular data transmission to send test results to Telcare's remote database. Telserve, and to receive messages from Telserve. The BioTel Care™ 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.

## **B. Important Safety Instructions**

The BioTel Care™ Blood Glucose Monitoring System and lancing device are for single patient use.

Do not share them with anyone, including family members! Do not use on multiple patients! Do not transfer ownership.

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. Dispose of in accordance with local regulations.

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 (pg. 42).

For Technical Support, contact Telcare, LLC 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 Bloodborne 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).

## C. Getting Started

Thank you for choosing the BioTel Care™ Blood Glucose Monitoring System. The BioTel Care™ system is comprised of the BioTel Care™ 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 to the meter. This manual will provide you with all you need to know to use your new meter. So let's get started!



All images for reference only

## Unboxing the BioTel Care BGM™ for the first time

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

- BioTel Care BGM<sup>™</sup> (battery included)
- AC Charger
- Quick Start Guide
- · User Manual
- Test Strip Insert

- Control Solution Levels 1 & 2 (2.5 mL)
- · Lancing Device
- BioTel Care<sup>™</sup> Lancets (10 count)
- BioTel Care™ Test Strips (10 count)

## Using your new meter:

Make sure you charge your glucose meter for at least 6 hours before first use. To charge your glucose meter, use the AC Charger included in your kit.

**Important:** Please remove the protective film over the screen. Please wait for the meter to finish the boot process to start a test when it powers on.

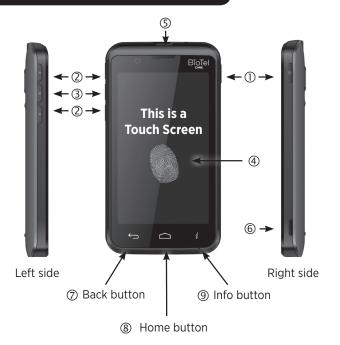
## You should use the BioTel Care BGM™ for:

- Testing Blood Glucose
- Testing only with fresh capillary whole blood samples

### You should NOT use the BioTel Care BGM™ for:

- The diagnosis of Diabetes
- · Testing blood glucose on newborn infants
- · Testing of arterial blood
- · Testing of venous blood

## D. Your BioTel Care BGM™



### ① Power (PWR) Button ©

- Short-press of power button turns on/off the screen.
- Long-press of power button when screen is on pops out a window with the following options: Power Off, Restart, and Airplane Mode / Silent, Vibrate, and Sound.
- ② UP/Down
  - Buttons to scroll through menus
- ③ Enter Button
- ④ Display Touch Screen
- (5) Insert Test Strip (white side up)
- 6 Battery Access Notch
  - Use the notch to remove the battery cover and replace the battery

## ⑦ Back button

· Press of back button returns to the previous screen except in Test Mode.

### Home button

• Press of home button returns to the Home screen except in Test Mode.

### Info button

 Press of info button displays a dialog box with helpful information for the current screen.

## BioTel Care™ Test Strips





Contact End (put into device)

## Important Notes on Test Strips:

- Because of the auto coding 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.

## **Preparation and Safety**

## Before you begin, make sure to:

- Set up your BioTel Care BGM™ Blood Glucose Meter properly.
- Run a control test before first use. (See Step-by-Step Guide to Control Testing - pg. 18.)
- 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" for more information - pg. 45.)
- Keep away from direct sunlight and heat. Store the test strip bottle in a dry cool place. 6

- 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 BioTel Care BGM™ is compatible with Telcare® Test Strips and Telcare® Glucose Control Solutions.

## You will need:

- Your BioTel Care BGM™ A new BioTel Care™ 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 and lancing device 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.

### The Home Screen



On the Home Screen, you can see the following:

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



In this Home Screen, swipe up/down OR use the **UP/ DOWN** buttons (located on the left of your meter) to access the meter's options:

- Test Mode Logs
- SummaryMessages
- SupportSettings
- Apps
   Reminders

# Icon Definitions

Symbol	Descriptions
Carrier Name	The name of the cellular carrier to which the meter is currently connected.
	Indicates that the current battery charge status. The battery energy remaining is depicted in a standard manner, familiar to most users, in which red indicates near-total discharge, which additional levels of white indicate progressively more complete charge states.
8 8 8 8 8 8 8 8	Indicates that the battery is actively charging. These items are displayed in an animated fashion from top to bottom in order to depict active charging of the meter battery.
- <u>5</u>	Indicates the battery is getting low and needs to be charged.
364 1X4 111 111	Indicates the strength of the wireless signal between base station and the meter in a manner familiar to most users. Additional bars of signal depict increased signal strength. The user manual instructs users that two bars or less of signal may result in unreliable transmission and reception of data. The 3G or 1X icon may be displayed with the wireless icon based on the network in use.
	The letter "R" or triangle icon indicates that the meter is roaming on the network of a cellular carrier different from the home carrier. The user manual does not need to describe roaming features since Telcare has negotiated national roaming agreements for the product.
XII	The letter "X" is used to indicate no wireless signal connectivity.

### Descriptions



The airplane icon is used to indicate that wireless function is disabled by user selection of "airplane" mode from the setup menu



The status bar shows this icon when charging is shut off because battery temperature is too high/low.





The screen displays this icon when charging is shut off because battery temperature is too high/low.

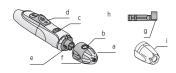
## **D.1 Testing Your Blood Glucose**

- Power on the BioTel Care BGM™ with the PWR (Power) button on the right side of the BGM. Long press if it is in OFF mode, short press if it is in SLEEP mode. The device will automatically display the Home Screen.
- Press on the TEST MODE icon OR use the three buttons on the left side of the BGM to enter BG Test Mode.

When ready to check blood, Insert a new test strip will be displayed.

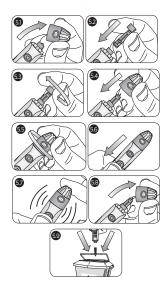


- Take out a BioTel Care<sup>™</sup>
  Test Strip from the bottle, and close the bottle immediately. (Some meters require the user to enter a code from the vial. BioTel Care<sup>™</sup> and Telcare® strips do not require a code.)
- 4. Firmly insert the test strip into your BioTel Care BGM™ until it is fully seated. The strip port light will turn on.
- **5.** Prepare Your Lancing Device (Refer to Components Illustration)
  - **5.1** Remove the lancing device cap (f) by snapping it off at an angle.
  - 5.2 Insert a new lancet (h) into the lancet holder(e). This action will cock the device.
  - **5.3** Hold the lancing device firmly in one hand, use your other hand to twist off the lancet cap (g).



#### **AUTOLET PLUS COMPONENTS**

- a. Depth adjuster
- b. Depth setting indicator window
- c. Activation button
- d. Cocking/lancet release slider
- e. Lancet holder
- f. Lancing device cap
- g. Lancet cap
- h. Lancet
- i. Optional alternate site testing cap (Not included/Can be special ordered)



**5.4** Place the lancing device cap (f) back on the device with the depth setting indicator window (b) aligned with the activation button (c).

- **5.5** Set the depth adjuster (a). The lancing device offers 9 depth settings. Level 1 is the shallowest depth; Level 9 is the deepest.
- **5.6** To prime the device pull back on the grey slider until it clicks (d), (You may have already cocked/primed the device in Step 5.2). You are now ready to obtain a blood sample.
- **5.7** To lance your finger hold the lancing device firmly against the side of your fingertip. Press the activation button (c). Apply gentle pressure near the puncture site if needed, until a blood drop appears.
- **5.8** To release the used lancet, first remove the lancing device cap (f), push the lancet release slider forward/downward (d). If the lancet does not detach, push the slider foward and carefully hold the sides of the exposed lancet. Firmly pull the lancet away from the device.
- **5.9** The lancet should be removed and disposed in accordance with local waste regulations.

### Important Information for Lancing Device

- Use the BioTel Care<sup>™</sup> or Telcare® Lancing Device included in your BioTel Care<sup>™</sup> Blood Glucose Monitoring System to obtain a blood sample. The minimum blood sample volume is 0.8 microliters.
- Purchase an additional BioTel Care<sup>™</sup> Lancing Device by calling Telcare, LLC at (888) 666-4530 (US) or (1) (978) 610-4688 (International). (9AM - 9PM EST, M-F).
- If using another type of lancing device, please refer to its user manual.

## Important Safety Procedures Regarding Lancets

To avoid contamination, use a new lancet every time you test.
 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.

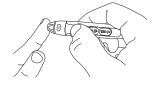
- If alcohol wipes are used to clean your finger or palm, make sure your skin is dry before the blood sample is obtained.
- Lancing devices should NEVER be used by more than one person.
- If the seal is broken, discard the lancet.

## 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.



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.

**6.** Testing Using an Alternate Test Site

This package does NOT include an alternate site cap. If you require one, please contact Telcare, LLC.

Important Information on Alternate Site Testing

You BioTel Care BGM™ is capable of testing your blood glucose from your palm, usually referred to as an

alternate site test, or AST.



13

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 a 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 guite 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. Lift the lancing device straight up. 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.

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

- 7. 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.
- 8. Tagging Your Data
  The screen will start to count
  down. After 6 seconds, your
  glucose level will appear on the
  display screen. You can select
  a Reading Tag (e.g., "Before
  Breakfast") from the list displayed
  during or after countdown. Swipe
  down OR use the DOWN key to
  select the correct tag. Press on
  the CONTINUE button OR use the
  ENTER key to confirm.

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 tag".

- 9. Sending Your Results After pressing the CONTINUE button, your BioTel Care BGM™ will send the results to Telcare's secure server.
- **10.** Remove the used test strip and discard it properly.





### CLINICAL RESPONSE SCREEN:

During data transmission, you will see a dial that compares your reading to your set target. To change your set target, call your doctor or 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.

## Important steps to follow 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 the server, you may receive a multiple choice question to answer. This may be a question from your caregiver or relate to reordering supplies. Swipe up/down OR use the **UP/DOWN** buttons to select the appropriate answer. Press on the option OR use the **ENTER** button to transmit.

### If Your Data Transmission is Not Successful

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

No network connection. Reading will be sent when a connection returns.

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

The meter will attempt to forward unsent readings automatically. Readings that have not been transmitted to the server will be marked with a yellow triangular hazard icon in the Logs 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<sup>1</sup>:

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

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

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

 Treat your diabetes according to the instructions from your doctor.

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

- Test your BioTel Care BGM<sup>™</sup> with a control solution: refer to"Step-by- Step Guide to Control Testing." (pg. 18)
- 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

 American Diabetes Association. Standards of Medical Care in Diabetes—2008. Diabetes Care. 2008;31:S12–S54.

## **D.2 Testing With Control Solution**

Control solution testing will confirm that your BioTel Care BGM<sup>™</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 BioTel Care<sup>™</sup> Test Strips
- · You left the test strip bottle cap open
- · You dropped the meter
- You suspect the meter and test strip are not working properly
- The test results do not reflect how you feel
- · Practice 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, LLC at (888) 666-4530 (US) or

(1) (978) 610-4688 (International) (9AM-9PM EST, M-F)

## Step-by-Step Guide to Control Solution Testing



 Power on the BioTel Care BGM™ with the PWR button on the right side of the BGM. The device will automatically display the Home Screen with the last reading as shown



Press on the TEST MODE
icon OR use the three
buttons on the left side of
the BGM to enter Test Mode.
 Switch modes from Normal
Test Mode to L1 Control
Solution Mode.

To test Level 1 (L1) control solution, press on the L1 CONTROL button OR use the UP/DOWN buttons to highlight L1 CONTROL button.







Again, press on the TEST MODE icon OR use the three buttons on the left side of the BGM to enter Test Mode. Switch modes from Normal Test Mode to L2 Control Solution Mode.

To test Level 2 (L2) control solution, press on the L2 CONTROL button OR use the UP/DOWN buttons to highlight L2 CONTROL button.

**3.** Take out a BioTel Care<sup>™</sup> Test Strip from the test strip bottle. Close the bottle immediately.

### 4. IMPORTANT:

- Firmly insert the test strip into your BioTel Care BGM™ until it is fully seated. The strip port light will turn on.
- The term "BioTel Care" or "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
- **5.** Use Level 1 solution for L1 mode. Use Level 2 solution for L2 mode. Squeeze a drop of control solution onto a clean, dry, non-absorbent surface. Immediately replace the bottle cap on the control solution bottle. Do not apply control solution to the test strip directly from the bottle.
- **6.** 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.

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

- **7.** The screen will start to count down. After 6 seconds, the control test result will appear on the meter's display screen.
- 8. 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" (pg. 20).

Control Solution readings are stored on the meter but are not included in the Blood Glucose testing logs.

## **Important Tips About Control Solution**

- Only use BioTel Care™ or Telcare® Glucose Control Solution with the BioTel Care™ or Telcare® Test Strips. Other brands of control solution or test strips may produce inaccurate results.
   Always check the expiration date. DO NOT use expired
- 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 than 3 months since first opened.

## **Control Solution Troubleshooting**

control solution.

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

## **D.3 Functions and Settings**

## View Your Logs on the Meter

## View your logs on your meter

Your BioTel Care  $\mathsf{BGM}^\mathsf{TM}$  can store a lifetime of logs. Each log is stored with date and time.

- Power on the BioTel Care BGM<sup>™</sup> by using the PWR button.
- Press on the LOGS icon OR use the UP/DOWN /ENTER buttons to access logs.
- **3.** Swipe up/down OR use the **UP/ DOWN** buttons to scroll through stored readings and other entries.
- Press the Filter button to select a subset of log types for display.
- **5**. To exit the Logs menu, press the **BACK** button.



This icon indicates that the associated log has not been uploaded to the server. You can select the log and retry to send it.





## Blood Glucose Readings

Blood glucose readings are displayed in a colored (blue, green, orange, or red) circle. Each color indicates in which target range the reading falls:

**Green:** on target **Orange:** above target **Red:** high above target

Blue: below target

### **Control Solution and other Logs**

- Control solution logs are displayed in a grey circular box.
- Non-Glucose logs are displayed in a grey rectangular box.

## **List of Log Icons**

The following 7 different categories can be displayed in the Logs Screen: Blood Glucose, Carbs, Medicine, Activity, Weight, Blood Pressure, A1C. Each category has its unique icon as shown in the picture.



## Add Logs on the Meter

## Add your logs on your meter

Your BioTel Care BGM™ allows you to manually add Blood Glucose, Carbs, Medicine, Activity, Weight, Blood Pressure and A1C.

- You can enter the Add Log mode from the Logs Screen or Home Screen by pressing on the Add Log button.
- 2. Select the log type by pressing on the option OR use the UP/DOWN button.
- **3.** Press the **CREATE A LOG** button OR use the **ENTER** button to enter the Add Log Screen where you can enter log details.

Press the **EDIT** button to edit or create a new log type. (See step 5)

- **4.** You can enter the log details such as amount, tag and timestamp and press SUBMIT to save and upload this log to the server.
- 5. Create New Log Type You can enter the Create New Log Type screen by pressing the New Log Type button, where you can enter new type name and unit.
- **6.** Press **SAVE** to save the log type.









## View Messages

### Display messages on your meter

Your BioTel Care BGM<sup>™</sup> allows you to check historical messages. The messages will be displayed in chronological order with most recent at the top.

- **1.** You can enter the Message Screen from the Home Screen by swiping up and pressing the **MESSAGES** icon or use the buttons to select and enter.
- **2.** You can swipe up/down OR use the **UP/DOWN** buttons to navigate through each message.
- To return to the Home Screen, press the BACK or HOME button.

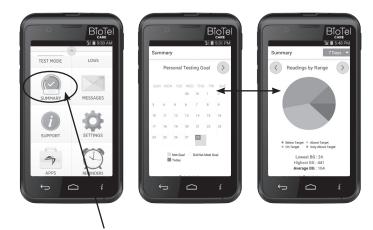




## **Summary of Past Readings**

## Display statistics of your past readings on your meter

Your BioTel Care BGM<sup>™</sup> allows you to check the statistic result of your past blood glucose readings. The summary screen has 5 graphs: Personal Testing Goal, Readings by Range, Hourly Averages, Readings out of Range, and Average Result by Tag.



- 1. You can enter the Summary Screen from the Home Screen by swiping up and pressing the **SUMMARY** icon or use the buttons to select and enter.
- **2.** You can swipe left/right, press the "<" and ">" icons OR use the **UP/DOWN** buttons to navigate to each graph.
- **3.** You can also select one of the following timeframes to generate the graph: Today, 7, 14, 30, 90 days, All.



### Reminders

Your BioTel Care BGM $^{\rm TM}$  allows you to create and manage reminders for blood glucose readings, medications or activities, etc.

1. You can enter the Reminders Screen from the Home Screen by swiping up and pressing the **REMINDERS** icon or use the buttons to select and enter.



You can create a new reminder by pressing the CREATE REMINDER button.

You can edit an existing reminder by pressing on it; this will bring up the reminder detailed information.

In the detailed information, you can change the time, title, and days which the reminder are active by pressing on each area. Pressing the **SAVE** button saves the reminder setting. Pressing the **DELETE REMINDER** button deletes the reminder.

To return to the Home Screen, press the BACK or HOME button.

## Support

Get on-screen support from your tutorials on your meter.

Your BioTel Care  $\mathsf{BGM}^\mathsf{TM}$  allows you to view video tutorials and the user manual on your meter.

- You can enter the Support Screen from the Home Screen by swiping up and pressing the SUPPORT icon or use the buttons to select and enter.
- You can open a page-by-page slideshow of the user manual by pressing the VIEW button OR use the UP/DOWN buttons to highlight user manual and then press the ENTER button.

You can swipe up/down and press on the video tutorial you want to watch OR use the **UP/DOWN** buttons to highlight the video and then press the **ENTER** button.

**3.** To return to the Home Screen, press the **BACK** or **HOME** button.





## Setting Up Your BioTel Care BGM™

Your BioTel Care 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.

### **Navigating to the Settings Screen**

- **1.** Power **(PWR)** your BioTel Care BGM<sup>™</sup> device on.
- **2.** Swipe up OR use the **DOWN** button to navigate to the Settings option.

**3.** Press on the **SETTINGS** icon or use the **ENTER** button to enter the Settings Menu.





## **Setting Options**

### Volume

Change the volume of your meter by moving the slider thumb.

### **Brightness**

Change the brightness of your meter's screen.

### 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.



### Languages

Change the language displayed by your meter.

### **Time Format**

Change the time display as 24-hour or 12-hour.

### Date Format

Change the date display format.

### 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.

### Reminders

Press here to manage test reminders.

## Personal Testing Goal

Display and set your goal for number of tests per day.

### Mode

This changes the user interface styles among "Normal" and "Classic" views.

### **Meter Name**

You may enter a Name on this screen that can help identify your meter and will be displayed on your home screen.

### **About**

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

### **Check Connectivity**

You may check whether it connects to server.

### **Version Information**

Press here to check the current software versions.

## **Apps**

# Download software updates for your BGM from the App Store.

Your BioTel Care BGM™ allows you to download software updates available for your BGM from the App Store. You can enter the Apps Screen from the Home Screen by swiping up and pressing the **APPS** icon or use the buttons to select and enter.

### **Critical Updates**

When a critical software update is available, an **INSTALL NOW** prompt will appear on your screen. This prompt will take you to the App Store to select and install the update. You will not be able to use other meter functions until a critical update has been installed.

\*Please see details in Section D.1 - Testing Your Blood (pg. 10)

### Non-Critical Updates

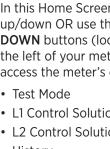
When a non-critical software update is available, an **INSTALL** NOW or TRY LATER prompt will appear on your screen. The INSTALL NOW prompt will take you to the App Store to select and install the update. The TRY LATER prompt will display the software update prompt again after 24 hours, until the update has been completed.

## **E. Classic Mode**

You can select the Classic Mode under the Mode option on the Settings screen, and the Classic style main menu screen will be displayed. It mimics the User Interface in Telcare's previous models.

### Main Menu





In this Home Screen, swipe up/down OR use the UP/ **DOWN** buttons (located on the left of your meter) to access the meter's options:

- L1 Control Solution Mode
- L2 Control Solution Mode
- History
- · Settings Menu

## **E.1 Testing Your Blood Glucose**

 Power on the BioTel Care BGM<sup>™</sup> device with the PWR button on right side of meter. The device will automatically start in the Main Menu. Select Test Mode to test your blood glucose. When ready to check blood, Insert test strip will be displayed.



On the Test Mode Screen, you can see the following:

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

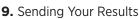
- 2. Take out a BioTel Care<sup>™</sup> Test Strip from the bottle, and close the bottle immediately. (Some meters require the user to enter a code from the vial. BioTel Care<sup>™</sup> and Telcare® strips do not require a code.)
- **3.** Firmly insert the test strip into your BioTel Care BGM™ until it is fully seated.
- 4. Prepare Your Lancing Device\*

- 5. 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
- 6. Testing Using an Alternate Test Site\*

complete.

- **7.** 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.
- 8. Tagging Your Data The screen will start to count down. After 6 seconds, your glucose level will appear on the display screen. You can select a Reading Tag (e.g., "Before Breakfast") from the list displayed during or after countdown. 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



As soon as you select the tag, your BioTel Care BGM™ will send the results to Telcare's secure server.

will automatically be tagged as "No tag". \*Please see details in Section D.1 - Testing Your Blood Glucose (pg. 10)





**10.** You can remove the test strip. Discard the used test strip properly.

# Important steps to follow 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 the server, you may receive a multiple choice question to answer. This may be a question from your caregiver or relate to reordering supplies. Swipe up/down OR use the UP/DOWN buttons to select the appropriate answer. Press on the option OR use 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, call your doctor or Customer Support at (888) 666-4530 (US) or (1) (978) 610-4688 (International). You may also seek helpful guidance from your caregiver regarding this reading to manage your diabetes.





## **E.2 View Your History on the Meter**

### View your logs on your meter

Your BioTel Care BGM<sup>™</sup> can store at least 1000 logs. Each result is stored with date and time.

- Power on the BioTel Care BGM<sup>™</sup> by using the PWR button.
- 2. Use the UP/DOWN keys to access History.
- **3.** 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 BACK button.)



## **E.3 Testing With Control Solution**

Control solution testing will confirm that your BioTel Care BGM™ 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 test strips
- · You left the test strip bottle cap open
- You dropped the meter
- You suspect the meter and test strip are not working properly
- · The test results do not reflect how you feel
- Practice 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 Solution Testing

1. Power on the BioTel Care BGM<sup>™</sup> by using the **PWR** button on the right side of the BGM.

The device starts on the Main Menu. Once start up is completed, press Test Mode and the device will be 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.
- **4.** Take out a BioTel Care<sup>™</sup> Test Strip from the test strip bottle. Close the bottle immediately.

#### 5. IMPORTANT:

- Firmly insert the test strip into your BioTel Care BGM™ until it is fully seated.
- The term "BioTel Care" or "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
- **6.** Use Level 1 solution for L1 mode. Use Level 2 solution for L2 mode. Squeeze a drop of control solution onto a clean, dry, non-absorbant surface. Immediately replace the bottle cap on the control solution bottle. Do not apply control solution to the test strip directly from the bottle.
- **7.** 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.



Apply Level 1

**Control Solution** 

BioTel

- **8.** The screen will start to count down. After 6 seconds, the control test result will appear on the meter's display screen.
- 9. 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" (pg. 20).

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

## Important Tips About Control Solution

 Only use BioTel Care<sup>™</sup> Glucose Control Solution with the BioTel Care<sup>™</sup> Test Strips. The BioTel Care BGM<sup>™</sup> is also compatible with the Telcare<sup>®</sup> Glucose Control Solution and Telcare<sup>®</sup> Test Strips. Other brands of control solution or test strips may produce inaccurate results.



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

- 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 than 3 months since first opened.

## E.4 Setting Up Your BioTel Care BGM™

Your BioTel Care 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.

#### Navigating to the Settings Screen

- 1. Power (PWR) your BioTel Care BGM<sup>™</sup> device on.
- 2. Use the **UP/DOWN** buttons to reach the Settings Menu.

## **Setting 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.

#### **Brightness**

Change the brightness of your meter's screen.

#### Languages

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.

#### Mode

This changes the user interface styles among "Normal" and "Classic" views.

## 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.

#### 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** 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.

#### About

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

# F. Maintenance of Your BioTel Care BGM™ and Lancing Device

## **Charging Your BioTel Care BGM™**

Your BioTel Care 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

- 1. Plug the power cord into an electrical outlet.
- 2. Plug the other end of the cord into the BGM's charging port.

#### **Charging Troubleshooting**

If your device does not turn on when you press the power button on, your battery may not be fully charged. If after 6 hours of charging the device the device does not turn on, contact Telcare technical support at (888) 666-4530 or (1)(978) 610-4688 (International).

#### Warning:

- Please only use the included charger to charge your meter;
   other chargers may result in excessive heating of the device.
- Please call customer support if you feel the meter is heating up significantly when charging.

## **Cleaning and 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 device. 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 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 Cleaning your Lancing Device section (pg. 44) for instructions on cleaning your lancing device. If using a different brand lancing device, see your device's user manual for decontamination/cleaning instructions.

To acquire canisters of Caltech DISPATCH towels, please contact:

Amazon - www.amazon.com

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

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

A full list of authorized dealers of Caltech DISPATCH towels is at www.telcare.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:

- **1.** 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.
- 5. Disinfect the meter with the second towel by wiping all outside surfaces.6. Discard used towel in a sealed container where it will not be
- touched by others.

  7. Wait at least one minute and make sure device is completely
- The BioTel Care BGM<sup>™</sup> 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 Cleaning Dos and Don'ts

air dried before next blood test.

• Do not allow cleaning solution to run in or around the strip port. Doing so may cause a malfunction.

meter (5 years) has been reached, whichever comes first.

- Do not let the meter come in contact with water.
- Do not use any glass or household cleaners on the meter.
- IMPORTANT: Avoid getting cleaning solution, dust, dirt, blood, control solution, water, or any other substance in the meter's openings, including the test strip port, USB port, headphone jack, strip port LED light and thermistor hole.
- 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 is damaged or has stopped working.
  - The meter's screen has been cracked or has become clouded.

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

#### **Cleaning Your Lancing Device**

**Important:** Do not immerse the body of the lancing device in water or any other liquid. Use isopropyl alcohol or soap and water to wipe the outside of the lancing device. If you wish, remove the cap, wash it in warm water, and rinse. Store lancing device in carry case or in a clean and dry environment.

#### 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.

#### **Warranty Information**

Please refer to Terms of Warranty section (pg. 49) of this user manual. Please read this warranty in full. Your rights under the laws of your country are not affected.

# G. Storing Your BioTel Care BGM<sup>™</sup> 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
- Do not 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.
- Dispose of in accordance with local waste regulations.

## H. 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 Detected! Please insert a new strip."

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: "The temperature of the environment is too high!" or "The temperature of the environment is too low!"

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.

5. Error Message: "No network connection. Reading will be sent when a connection returns."

What it means: The meter is unable to connect to the server.

**Action to take:** See "Communication Errors" below (pg. 48). If this is not resolved and you have more than 1 bar of cellular signal strength, call customer service.

6. Error Message: "Reading is below the minimum 20 mg/dL. It may be caused by meter failure. Please insert another test strip and take a new reading."

**What it means:** The reading is below the minimum test range.

**Action to take:** Remove test strip, insert another one and take a new reading. If the problem continues, please contact Telcare customer service.

## Other Messages

Icon Message: Low Battery icon Displayed
 What it means: The meter is about to lose power.

**Action to take:** Charge the battery

**Action to take:** Charge the battery

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 right of the meter's screen.

3. Message: "High" Displayed

What it means: If you see High displayed on your device, your blood sugar level may be out of range (in excess of 600 mg/dL [High])

Action to take: See "Troubleshooting" (pg. 45), 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.

4. Message: Software updates are available in the App Store for your BGM

What it means: A critical or non-critical software update is available on the App Store. If the update is critical, you won't be able to use other meter functions until the software update is completed.

**Action to take:** See "Apps" section (pg. 30). Follow the prompts to install the software update.

#### 5. Error: Meter freezes or restarts

**What it means:** Your meter may require rebooting or software updates.

Action to take: Check your meter's battery charge level. Charge your meter if low or very low battery. Turn off your device, wait 10 seconds, and turn your device back on. If the issue persists, check if your meter has pending software updates and install them. Power cycle the meter again if necessary. If the issue still persists, contact Telcare Technical Support.

#### **Communication Errors**

If you are having trouble sending your results, 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 Logs.

If your meter has had an extended period of inactivity or excessive data usage for ancillary applications, your cellular service may have been discontinued in accordance with the Telcare Terms of Service. Contact Telcare Technical Support for re-activation options.

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

#### **Patient Consent**

Upon initial boot up, you will be prompted to accept the Telcare Terms of Service included in this user manual. You will not be able to start a test or use the meter functions until the terms have been accepted. If you do not wish to accept the terms, contact Telcare Technical Support for opt-out options.

## Terms of Warranty

Telcare warrants the BioTel Care BGM™ 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, LLC 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. Lost, stolen, or irretrievable devices are also specifically excluded from this warranty.

Transfer of ownership will render this warranty null and void.

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

Telcare, LLC

150 Baker Ave. 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:** BioTel Care<sup>™</sup> or Telcare<sup>®</sup> 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: 10,000 blood test results with date and time stamp

Result Averaging: 7, 14, 30, and 90 days averaging displayed on

BioTel Care BGM™

Dimensions: 121L x 65W x 13H (mm)

Weight: 145 grams

Battery: Rechargeable, Lithium Ion 1800mA hour battery,

replaceable.

Battery Life: 1 year, call Telcare to replace your battery or if you

have battery life issues.

Automatic Sleep Mode: After 1 minute of nonuse (2 minutes for

Apply Blood)

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

Relative Humidity: Less than 85%

Storage Conditions: Meter at  $39^{\circ}F^{-1}22^{\circ}F$  ( $4^{\circ}C^{-5}0^{\circ}C$ ). Test Strips at  $39^{\circ}F^{-8}6^{\circ}F$  ( $4^{\circ}C^{-3}0^{\circ}C$ ). Control Solution at  $39^{\circ}F^{-8}6^{\circ}F$  ( $4^{\circ}C^{-3}0^{\circ}C$ )

## I. About Your System

Contact Telcare, LLC

Telcare, LLC

150 Baker Ave. 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.telcare.com

For any medical questions, contact your health care professional.

#### **Product and Safety Information**

#### Information on Health

The U.S. Food and Drug Administration (FDA) and the U.S. Federal Communications Commission (FCC) published statements and questions and answers concerning mobile devices and health. Telcare, LLC encourages you to visit these websites for updated information. The BioTel Care BGM™ is not a cell phone but is considered a similar wireless device. You can access the FDA website at http://www.fda.gov/Radiation-EmittingProducts/ RadiationEmittingProductsandProcedures/ HomeBusinessandEntertainment/CellPhones/default.htm and the FCC website at transition.fcc.gov/oet/rfsafetv/rffags.html. Additional health related information is available from the World Health Organization (WHO) at www.who.int/ mediacentre/factsheets/fs193/en/ and The National Cancer Institute ("NCI") at http://www.cancer.gov/publications/ blogs-newsletters/cancer-bulletin/. In the event that you are concerned about possible health effects, the FDA suggests that you limit your own or your children's radio frequency (RF) exposure by limiting the length of your calls or by using hands free devices.

#### **Implanted Medical Devices**

To avoid potential interference, manufacturers of implanted medical devices recommend a minimum separation of six (6) inches (15.3 centimeters) between a wireless device and the medical device. Persons who have such devices should:

- Always keep the wireless device more than six (6) inches (15.3 centimeters) from the medical device.
- Do not carry the wireless device in a breast pocket.
- Hold the wireless device to the ear opposite the medical device.
- Turn the wireless device off if there is any reason to suspect that interference is taking place.
- Follow the manufacturer directions for the implanted medical device.

If you have any questions about using your wireless device with an implanted medical device, consult your health care provider.

## Wireless Technology Information

The BioTel Care BGM™ is a wireless medical device which encompasses wireless technologies and functions. This device is a data only device and does not incorporate voice service. The BioTel Care BGM™ meets the Verizon Wireless and Sprint Network standards and has been certified to function on their networks. You can only use your device on CDMA 850, CDMA 1900, CDMA 1xRTT, and CDMA EVDO.

This EUT (Equipment Under Test) has been shown to be capable of complying with the requirements set forth in the following standards:

- FCC 47 CFR Part 2, 22(H), 24(E)
- FCC Part 15, Subpart B
- ANSI/TIA/EIA-603-C-2004
- FCC KDB 971168 D01 Power Meas. License Digital Systems v01

This device functions on CDMA 2000 BC0 (850mHz) and BC1 (1900mHz) and uses CDMA 2000 1x and EVDO. The following are operating characteristics of the BioTel Care BGM $^{\text{TM}}$ :

- Effective RF Radiated Power Output and Operating Range: Less than 24 dBm
- Modulation: QPSK. (Quadrature Phase-Shift Keying)
- Antenna Type: PIFA Antenna
- Bandwidth of Receiving Section Is in accordance with FCC Rule Parts 24H and 24E for Frequency Range
- Part 24H = 824.7-848.31 (mHz)
- Part 24E = 1851.25-1908.75 (mHz)

## Electromagnetic Emitted Interference According to IEC 61326

The BioTel Care  $BGM^{TM}$  is suitable for operation in the indicated electromagnetic environment. The customer and/or operator of the BioTel Care  $BGM^{TM}$  should make sure that it is used in an electromagnetic environment as described.

IEC 61326-1: 2013, IEC 61326-2-6:2013	
Test Condition	Compliance
Radiated Emission (30MHz to 1000MHz)	Complies
Conducted Emission on AC 150kHz to 30MHz	Complies
Harmonic Class A	Complies
Flicker	Complies

IEC 61326-1: 2013, IEC 61326-2-6:2013	
Immunity Tests	Compliance
Electrostatic Discharge (IEC 61000-4-2) ±4kV ±8kV	Complies
Radiated Immunity (IEC 61000-4-3) 80MHz to 1000MHz 3V/m (rms) 1400MHz to 2000MHz 3V/m (rms)2000MHz to 2700MHz 1V/m (rms)	Complies
Electrical Fast Transient (IEC 61000-4-4) ±1kV	Complies
Surge (IEC 61000-4-5) ±0.5kV (Line to line) ±1kV (Line to ground)	Complies
Conducted Immunity (IEC 61000-4-6) 150KHz to 80MHz 3Vrms	Complies
Voltage Dips and Interruption (IEC 61000-4-11) 0%, 70% of Ut	Complies

## **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 complies with FCC radiation exposure limits set forth for an uncontrolled environment when used with Telcare, LLC accessories supplied or designated for this product. Use of other accessories may not ensure compliance with FCC RF exposure guidelines. 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.

## RF Exposure Information (SAR)

This device meets the government's requirements for exposure to radio waves.

This device is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government.

The exposure standard for wireless mobile devices employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6W/kg. Tests for SAR are conducted using standard operating positions accepted by the FCC with the device transmitting at its highest certified power level in all tested frequency bands. Although the SAR is determined at the highest certified power level, the actual SAR level of the device while operating can be well below the maximum value. This is because the device is designed to operate at multiple power levels so as to use only the power required to reach the network. In general, the closer you are to a wireless base station, the lower the power output.

The highest SAR value for the model device as reported to 54

the FCC when tested for use at the ear is 1.176 W/kg and when worn on the body, as described in this user guide, is 1.084 W/kg (body-worn measurements differ among device models, depending upon available accessories and FCC requirements). While there may be differences between the SAR levels of

various devices and at various positions, they all meet the

government requirement.

The FCC has granted an Equipment Authorization for this model device with all reported SAR levels evaluated as in compliance with the FCC RF exposure guidelines. SAR information on this model device is on file with the FCC and can be found under the Display Grant section of www.fcc.gov/oet/ea/fccid after

searching on FCC ID: YPTTELCBGM03

For body worn operation, this device has been tested and meets the FCC RF exposure guidelines for use with an accessory that contains no metal and that positions the handset a minimum of 1.5 cm from the body. Use of other accessories may not ensure compliance with FCC RF exposure guidelines. If you do not use a body-worn accessory and are not holding the device at the ear, position the handset a minimum of 1.5 cm from your body when the device is switched on.

## J. Terms of Service/Use

#### Telcare. LLC

Terms of Use (Last Updated May 16, 2018)

#### General

# THESE TERMS OF USE SHALL BE DEEMED TO BE ACCEPTED UPON YOUR OPENING OF AND USE OF THE METER.

The following terms constitute an agreement between you and Telcare, LLC, its subsidiaries and affiliates (collectively, the "Company" or "Telcare" or "we" or "us"), the operator of www. mytelcare.com, www.telcaresupplies.com and related websites (collectively, the "Sites"). This Agreement governs your use of the Sites, both as a visitor and a registered member as described below, and purchase, use of the BioTel Care™ blood glucose 55

meter (the "Meter") and/or access to the Telcare service (collectively, the "Service"). By accessing or using the Sites, the Meter and the Service, you agree to be bound by the terms of this Agreement.

THIS AGREEMENT, WE HEREBY REQUEST THAT YOU DO NOT OPEN THE METER AND RETURN THE METER TO TELCARE PURSUANT TO THE INSTRUCTIONS TO BE PROVIDED TO YOU BY TELCARE SUPPORT AS INDICATED BELOW.

To access certain parts of the Sites and the Service, including but not limited to the e-commerce section and forum section, you

IF YOU DO NOT AGREE TO THE TERMS AND CONDITIONS OF

## Membership Eligibility

must become a member. To become a member and access the area on the Sites reserved for members (the "Member Area"), the Company requires that you are either (a) a diagnosed patient of the particular community you are joining, (b) a caregiver for a patient eligible to join such community, (c) a health care professional (e.g. doctor, nurse, health researcher, etc.), (e) registered user for forum pages, (f) registered e-commerce user, or (d) a guest as authorized by a Telcare employee.

#### The Sites and the Services Do Not Provide Medical Advice.

ALL OF THE MATERIAL PROVIDED ON THE SITES, THE METER AND AS PART OF THE SERVICE, SUCH AS TEXT, TREATMENTS, DOSAGES, OUTCOMES, CHARTS, PATIENT PROFILES, GRAPHICS, PHOTOGRAPHS, IMAGES, ADVICE, MESSAGES, FORUM POSTINGS, AND ANY OTHER MATERIAL PROVIDED ON THE SITES, THE METER AND AS PART OF THE SERVICE ARE FOR INFORMATIONAL PURPOSES ONLY AND ARE NOT A SUBSTITUTE FOR PROFESSIONAL MEDICAL ADVICE OR TREATMENT. YOU HEREBY AGREE AND ACKNOWLEDGE THAT SUCH INFORMATION SHALL NOT CONSTITUTE MEDICAL ADVICE, DIRECTLY OR INDIRECTLY, WHATSOEVER. 56

YOU SHOULD ALWAYS SEEK THE ADVICE OF YOUR PHYSICIAN OR OTHER QUALIFIED HEALTH PROVIDER WITH ANY QUESTIONS YOU MAY HAVE REGARDING YOUR HEALTH. NEVER DISREGARD PROFESSIONAL MEDICAL ADVICE OR DELAY IN SEEKING IT BECAUSE OF SOMETHING YOU HAVE READ ON THE SITES OR RECEIVED AS PART OF THE SERVICE.

IF YOU THINK YOU MAY HAVE A MEDICAL EMERGENCY, CALL YOUR DOCTOR OR 911 IMMEDIATELY. TELCARE DOES NOT RECOMMEND OR ENDORSE ANY SPECIFIC TESTS, PHYSICIANS, PRODUCTS, PROCEDURES, OPINIONS, OR OTHER INFORMATION THAT MAY BE MENTIONED ON THE SITES OR AS PART OF THE SERVICE. RELIANCE ON ANY INFORMATION PROVIDED BY TELCARE, BY PERSONS APPEARING ON THE SITES OR AT THE PART OF THE SERVICE AT THE INVITATION OF TELCARE, OR BY OTHER MEMBERS IS SOLELY AT YOUR OWN RISK.

#### Acceptable and Lawful Use of the Sites by Members

Members shall not post or upload any information or other

content on the Sites that (a) is false, inaccurate or misleading; (b) is obscene or indecent; (c) infringes any copyright, patent, trademark, trade secret or other proprietary rights or rights of publicity or privacy of any party; or (d) is defamatory, libelous, threatening, abusive, hateful, or contains pornography. Members shall not interfere with other members' use and enjoyment of Sites (for example, by harassing, threatening or stalking another participant of a chat room, forum, seminar, or threaded message, including the use of expressions of bigotry, racism, hatred, or profanity). Members may not use the Sites to conduct any activity that is illegal or violates the rights of others, provide instructional information about illegal activities, or promote physical harm or injury against any group or individual.

All members represent and warrant that the information they provided when registering as a member, and all information that they subsequently provide regarding themselves and 57

their membership, is true and accurate and not misleading.

#### Use of Sites by Members and Non-Members.

You may not use any robot, spider, scraper, or other automated means to access the Sites, the Service or content or services provided on the Sites for any purposes. You may not post content on the Sites or as part of the Service that contains any viruses, Trojan horses, worms, time bombs, spiders, or other computer programming routines that are intended to damage, detrimentally interfere with, surreptitiously intercept or expropriate any system, data or personal information. You shall not attempt to make the Sites or the Service unavailable through denial-of-service attacks or similar means. You shall not use contact information provided by members, or collect information about our members, to facilitate the sending of unsolicited bulk communications such as SPAM or SPIM or allow others use of your membership account to take such actions.

### Non-Commercial Use by Members.

The member area of the Sites and the Service (the "Member Area") and the content and information contained in such Member Area is for the personal use of individual members only and may not be used in connection with any commercial endeavors. Organizations, companies, and/or businesses may not become members and should not use the Sites or any part of the Service without the prior express written consent from the Company.

## **Privacy and Your Data.**

You agree that you have read, understood and accept the terms of Telcare's Privacy Policy. This policy governs the collection, use and sharing of personal and non-personal information from you when using the Sites, the Meter and the Service. As detailed in our Privacy Policy, we use personal information collected through our Services to:

58

(a) set up and establish your account and activate your Meter, including recording your initial A1c results from your physician or health care provider; (b) operate and improve our Services: (c) respond to your comments and questions and provide customer service; (d) provide and deliver products and services you request; (e) send you related information, including confirmations, invoices, technical notices, updates, security alerts, supply alerts and reminders and support and administrative messages, including messages from our authorized distributors; (f) better understand you so that we may tailor messaging and services based on your interests. preferences, needs and specialties; (g) communicate with you via email, mobile alerts. SMS text messages and other messaging services about commercial, non-commercial, sponsored and non-sponsored clinical information, messaging regarding your blood glucose readings and testing frequencies. FDA and product safety alerts and our selected partners (if you do not wish to receive these kinds of communications, you may choose to opt out by updating your profile); (h) link or combine your information with other personal information we get from third parties, to help understand your needs and provide you with better service; and (i) to comply with our obligations under applicable laws and regulations.

As part of the Service, in addition to your physician or health care provider (collectively, "Health Care Provider") and health care insurance carrier (and its licensed health care professionals, agents and personnel) (collectively, "Insurance Carrier"), your data will be shared with only those individuals whom you designate to receive such data. You hereby waive and release the Health Care Provider and Insurance Carrier and its respective affiliates from any and all damages, losses, actions, costs and claims in connection with the access of your data resulting from your use of the Service and the Meter and in connection with the administration of your participation in the Insurance Carrier's health care plan.

If you share your data generated by the Service, then you

agree that anyone you've shared such data with may access and use that data which such use shall not be subject to Telcare's Privacy Policy. You agree that SMS and email messages sent to authorized users are for informational purposes only.

Furthermore, you hereby acknowledge and agree that Telcare shall be permitted to view any and all of your data ("End User Data") for the sole purpose of complying with FDA regulations and its obligations therein. In addition, Telcare may, in its discretion, extract from the End User Data information on an aggregated and anonymous basis, including without limitation your age, gender, and prescription protocols (the "De-Identified Information") from which identifiers have been removed pursuant to 45 C.F.R. § 164.514 (together with any other relevant statutes or regulations, as amended from time to time), such that the De-Identified Information is not Protected Health Information ("PHI") and is not subject to the privacy restrictions of HIPAA and any and all related privacy regulations. Without limiting Telcare's obligation to preserve the confidentiality of your PHI, Telcare may use your De-Identified Information for statistical, analytical, and any academic or commercial purposes on an aggregated basis.

Telcare shall not use or disclose the De-Identified Information in any manner inconsistent with HIPAA or any other statute or regulation.

You hereby agree and acknowledge that your testing data and blood glucose readings ("Testing Data") will not be automatically sent to or monitored by your physician, medical advisor or any health personnel that you seek or receive health services from in connection with your health management needs (collectively, "Health Agents") Accordingly, you hereby waive and release any such Health Agents and any respective affiliates from any and all liability, damages, losses, actions, costs and claims in connection with the access of your Testing Data resulting from your use of the Service.

#### Posting and Use of Content in the Member Area.

The Member Area includes community areas, such as forums and member areas, where members may post messages, images, and other content. If you are a member, you (or the author) owns the copyright in the messages, images, and other content you post in the Member Area, but by posting such content to the Member Area you grant Telcare and our affiliates the right and irrevocable, unlimited, worldwide, and royalty free license to use, copy, display, perform, distribute, translate, edit, and create derivative works of your postings, subject to the terms of the Privacy Policy.

While some community areas in the Member Area are monitored periodically for topicality, Telcare has no obligation to prescreen postings and is not responsible for their content. We encourage you to notify us of inappropriate or illegal content and we reserve the right to remove postings for any reason.

You agree not to disclose to any person or entity personally identifiable information about other members that you learn using the Sites or the Service (whether posted in the Member Area by a member or emailed to you by a member) without the express consent of such member. You may disclose information of a general nature (that could not identify the member who provided such information or whom such information is about) to third parties outside the Sites and the Service, subject to the above restriction on non-commercial use.

#### Member Password and Login Identity.

You are responsible for maintaining the confidentiality of your member password and login for the Sites and the Service, and are fully responsible for all activities that occur under your password or account with or without your knowledge. If you knowingly provide your login and password information to another person, your membership privileges to the Sites and the Service may be suspended temporarily or terminated. You agree to immediately notify Telcare of any unauthorized use of your membership password or login or any other breach of security.

61

## Links to Other Websites.

The Sites may contain links to other websites that are not under the control of Telcare. The inclusion of any link does not imply endorsement by Telcare of such website and Telcare is not responsible for the content of such linked websites.

## Membership Termination.

You agree that the Company may, with or without cause, immediately terminate your Telcare membership and access to the Member Area, the Sites, the Meter and the Service without prior notice. Without limiting the foregoing, the following may lead to a termination by the Company of a member's membership and use of the Sites and the Service: (a) breaches or violations of this Agreement or other incorporated agreements or guidelines, (b) requests by law enforcement or other government agencies, (c) a request by you (self-initiated membership cancellation), (d) unexpected technical issues or problems, and (e) extended periods of inactivity or excessive data usage for ancillary applications. Telcare has no obligation to maintain, store, or transfer to you information or data that you have posted on or uploaded to the Member Area.

## Modifications to this Agreement.

time, and without prior notice, by posting amended terms on the Sites. Any use of the Meter, Sites, and the Service by you after such update shall be deemed to constitute acceptance of the revised version of the Agreement. If at any time you are no longer able to comply with the terms of the thencurrent Agreement, you must terminate this Agreement and immediately stop using the Meter, Sites, and the Service. Telcare may change, modify, suspend, or discontinue any aspect of the Service at any time. Telcare may also impose limits on certain features or restrict your access to parts or all of the Service without notice or liability. You have no interest, monetary or otherwise, in any feature or content contained in the Service covered in this Agreement. We advise you to frequently consult the Terms of Service for changes.

Telcare may update this Agreement at its sole discretion, at any

Please check the webpage www.telcare.com for changes from time to time to make sure you are aware of our latest Terms of Service. If we make any changes to the Terms of Service, we will change the "Last Updated" date.

Membership to the Sites is currently free. Telcare reserves the right to from time to time change the terms of this Agreement and charge for membership and/or to provide additional optional services for a fee in connection with the Sites and/or the Service. Products may be purchased from mytelcare.com.

#### **Purchases; Other Terms and Conditions.**

The Company obligations, if any, with regard to the Services are governed solely by the agreements pursuant to which they are provided, and nothing on the Sites should be construed to alter such agreements.

Prices and availability of goods and services are subject to change without notice. Telcare may make changes to any Services offered on the Sites, or to the applicable prices for any such products or services, at any time, without notice. The materials and content on the Sites with respect to products and services may be out of date, and Telcare makes no commitment to update the materials or content on the Sites with respect to such products and services.

The Company reserves the right to revoke any stated offer and to correct any errors, inaccuracies or omissions including after an order has been submitted and whether or not the order has been confirmed and your credit card charged. If your credit card has already been charged for the purchase and your order is cancelled, Telcare will issue a credit to your credit card account in the amount of the charge. Individual bank policies will dictate when this amount is credited to your account. If you are not fully satisfied with your purchase, you may return it in accordance with the Company Return Policy.

## Paying for Your Order.

Generally, credit and debit cards are not charged until we either ship the item(s) to you or confirm availability (at which 63

shipped along with any appropriate taxes or shipping charges). However, we may pre-authorize your order amount with your credit or debit card issuer at the time you place the order, which may have an effect on your available credit line. Please contact your credit card issuer for more information.

time you will be charged only for the goods we have actually

If you ordered a special delivery item, you will be charged once a delivery time is confirmed. For digitally delivered orders, your credit or debit card will be charged at the time that you initiate the download of the product.

#### Validating Your Order.

After you place an order using our shopping cart, we will check the information you give us for validity, by verifying your method of payment or shipping address. We reserve the right to reject any order you place with us, and/or to limit quantities on any order, without giving any reason. If we reject your order, we will attempt to notify you using the e-mail address you have given us with the order.

Your credit or debit card will normally not be charged if we reject an order, but we will process a refund if the charge has been made against your card.

#### Order Acceptance/Confirmation.

Your receipt of an electronic or other form of order confirmation does not signify our acceptance of your order, nor does it constitute confirmation of our offer to sell. Telcare reserves the right at any time after receipt of your order to accept or decline vour order for any reason.

### Return Policy.

All sales made through the Sites are subject to Company return policy. For a complete explanation of the return policy, please see our Return Policy.

## Order Limitations.

We reserve the right to reject any order you place with us, and/ 64

or to limit quantities on any order, without giving any

reason. If we reject your order, we will generally attempt to notify you using the e-mail address you gave us when you placed the order.

Telcare may, at its own discretion, limit or cancel quantities purchased per person, per household or per order. Telcare also reserves the right to reject any order you place with us. These restrictions may include orders placed by the same Sites account, the same credit card, and orders that use the same billing and/or shipping address. In the event we make a change to an order, we will attempt to notify you by contacting the e-mail and/or billing address provided at the time the order was made. Telcare reserves the right to limit or prohibit sales to distributors.

#### Shipping.

All orders placed on the Sites are subject to product availability and will be shipped according to Company shipping policies. In the rare event that your order never arrives, notification of lost items must be received within 60 days from receipt of the shipping confirmation e-mail.

Please review the Shipping page for additional information on shipping times, rates, and policies.

#### **Disclaimer of Warranties**

THE SITES, THEIR APPLICABLE CONTENT, THE METER AND SERVICES ARE PROVIDED ON AN "AS IS" AND "AS AVAILABLE" BASIS. TELCARE DOES NOT MAKE, AND DISCLAIMS ALL EXPRESS AND IMPLIED WARRANTIES AND REPRESENTATIONS, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE, WITH REGARD TO THE SITES, THE METER AND THE SERVICE, THE SITES' CONTENT, OR ANY ADVICE OR SERVICES PROVIDED THROUGH THE SITES TO THE EXTENT PERMITTED BY LAW. TELCARE DOES NOT WARRANT THAT ACCESS TO THE SITES, THE METER, THEIR APPLICABLE CONTENT, OR THE SERVICES WILL BE UNINTERRUPTED OR ERROR-FREE OR THAT DEFECTS IN THE SITES OR THE SERVICES WILL BE CORRECTED.

THE ADVICE, RECOMMENDATIONS, INFORMATION, AND CONCLUSIONS POSTED OR EMAILED BY OTHER MEMBERS OF THE SITES ARE NOT IN ANY WAY VETTED, APPROVED OR ENDORSED BY TELCARE, AND YOU USE SUCH INFORMATION AT YOUR OWN RISK.

WARRANTIES ARE LIMITED TO INDIVIDUAL PRODUCTS WHEN APPLICABLE. REFER TO THE PRODUCT FOR WARRANTY INFORMATION.

NOT ALL PRODUCTS SOLD ON THIS SITES HAVE WARRANTIES.

## Limitation of Liability.

EXCEPT WHERE PROHIBITED BY LAW, UNDER NO CIRCUMSTANCES SHALL TELCARE BE LIABLE FOR ANY INDIRECT, PUNITIVE, INCIDENTAL, SPECIAL, OR CONSEQUENTIAL DAMAGES (EVEN IF IT HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES) DUE TO YOUR USE OF THIS SITES, THE METER, AND THE SERVICES OR DUE TO YOUR RELIANCE ON ANY OF THE CONTENT CONTAINED OR THE SERVICES.

#### Indemnification.

You agree to indemnify and hold harmless the Company, its officers, employees, agents, subsidiaries, affiliates and other partners, from and against any claims, actions or demands, liabilities and settlements including without limitation, reasonable legal and accounting fees, resulting from, or alleged to result from, your violation of this Agreement.

#### International Users.

Telcare makes no claims that information on the Sites is appropriate or may be used or downloaded outside of the United States. Personal information ("Information") that is submitted to the Sites and the Service will be collected, processed, stored, disclosed and disposed of in accordance with applicable U.S. law and our Privacy Policy. If you are a non-U.S. user, you acknowledge and agree that the Company may collect and use your Information and disclose it to other entities outside your resident jurisdiction. In addition, such Information

outside your resident jurisdiction as detailed in our Privacy Policy. If you do not consent to such transfer, you may not use the Sites or the Service.

## Member Notices.

If you register as a member, you agree that Telcare may send notices to you by email at the email address you provide when registering to become a member (or which you later update using the functionality of the Sites or the Service).

## Governing Law and Venue.

This Agreement shall be governed by the laws of the state of Delaware and the applicable federal laws of the United States of America. All disputes arising under, or in any way connected with membership in or use of the Sites, shall be litigated exclusively in the state and federal courts residing in the state of Delaware, and in no other court or jurisdiction.

You hereby submit to the jurisdiction of the state and federal courts sitting in the state of Delaware.

#### Miscellaneous Terms.

Telcare and the Telcare logo are trademarks of Telcare, LLC. You agree not to display or use these trademarks in any manner without a prior, written permission from Telcare.

Telcare may assign this Agreement at any time to a subsidiary or parent company or to a successor to its business as part of a merger or sale of substantially all of its assets. You may not assign or transfer this Agreement.

If any provision of this Agreement is held to be unenforceable for any reason, the remaining provisions will be unaffected and remain in full force and effect.

Some of the treatment information provided on the Sites and the Service is from third party sources. Every effort has been made to ensure that the information provided is accurate, upto-date, and complete, but no guarantee is made to that effect. The absence of a warning for a given drug or drug combination in no way should be construed to indicate that the drug or 67

or drug combination is safe, effective or appropriate for any given patient.

For any returns, questions or comments, or to report violations of this Agreement contact us at:

Telcare, LLC
150 Baker Avenue Extension, Suite 300
Concord, MA 01742
(888) 666-4530
support@telcare.com

IF YOU DO NOT AGREE TO THE TERMS AND CONDITIONS OF THIS AGREEMENT, PLEASE DO NOT OPEN OR USE THE METER AND PROMPTLY CONTACT TELCARE SUPPORT EITHER AT THE EMAIL OR ADDRESS PROVIDED ABOVE.

## K. Privacy Policy

Telcare, LLC

Privacy Policy (Last Updated May 17, 2018)

General

## THESE TERMS OF USE SHALL BE DEEMED TO BE ACCEPTED UPON YOUR OPENING OF AND USE OF THE METER.

At Telcare, LLC, we are committed to respecting your privacy. This privacy policy describes how Telcare, LLC and its subsidiaries and affiliated companies ("Telcare," "we" or "our") may collect, use and disclose information about customers who use our websites, including telcare.com, mytelcare.com and our mobile applications displaying this policy ("Services"). This policy does not cover websites, applications or services displaying different privacy statements.

#### 1. What information do we collect?

Information you provide us.

- When you order, we ask you for your name, email address, postal addresses, telephone number, and credit card information so that we can complete the transaction.
- When you register for a mobile application, we ask for information including your name, email address, date of birth, and postal code.
- We may ask you for other types of information like demographics information, for example, when you participate in a survey or product test or when you enter a contest or other promotional event.

Information we may automatically collect.

• When you visit our websites, some information is automatically collected. For example, when you visit our web sites your computer's operating system, Internet Protocol (IP) address, access times, browser type and language, and the website you visited before our site are logged automatically. We also collect information about your usage and activity on our Sites. For more information about this practice please refer to "How are 'cookies' and 'web beacons' used on our website?" (pg. 73). Additionally, when you use our mobile applications, we may automatically collect data about your device such as your device ID and how you use our application including pages you view.

Information we receive from third parties.

• We may also collect additional information about you from third parties in providing you with the Services.

### 2. How do we use the information we collect?

We use personal information collected through our Services for purposes described in this Policy or disclosed to you in our Services. For example, we may use your information to:

- · operate and improve our Services;
- respond to your comments and questions and provide customer service;
- provide and deliver products and services you request;
- send you related information, including confirmations, invoices, technical notices, updates, security alerts, and support and administrative messages;
- better understand you so that we may tailor messaging and services based on your interests, preferences, needs and specialties;

- communicate with you via email, mobile alerts, SMS text messages and other messaging services about commercial, non-commercial, sponsored and non-sponsored clinical information, messaging regarding your blood glucose readings and testing frequencies, FDA and product safety alerts and our selected partners (if you do not wish to receive these kinds of emails, you may choose to opt out by updating your profile;
- link or combine your information with other personal information we get from third parties, to help understand your needs and provide you with better service.

Telcare may store and process information in the United States and other countries.

#### 3. How does Telcare protect your information?

We take appropriate measures to protect the information that we receive about you from unauthorized access, disclosure, alteration, or destruction. No method of transmission over the Internet or electronic storage is 100% secure; as a result, we cannot guarantee absolute security.

#### 4. Will Telcare share the information it collects with others?

Telcare may share aggregated or de-identified information such as statistics about our customers, sales, product usage or traffic patterns, and related website information. In addition, without limiting Telcare's obligation to preserve the confidentiality of your personal health information, Telcare may use your deidentified information for any academic or commercial purpose on an aggregated basis. This information will not include any information directly identifying you.

If you post a comment or message in our blog or other public forums on mytelcare.com, it will be shared publicly.

We may share personal information under the following circumstances:

- with third party vendors, consultants and other service providers as needed to perform their job functions;
- to (i) comply with laws or to respond to lawful requests and legal process, (ii) to protect the rights and property of our agents, customers, and others including to enforce our agreements, policies and terms of use or (iii) in an emergency to protect the personal safety of Telcare, its customers, or any person;
- in connection with or during negotiation of any merger, financing, acquisition or bankruptcy transaction or proceeding involving sale or transfer of all or a portion of our business or assets to another company, when such use is permitted by law.

## 5. What access does Telcare give you to your personal information?

You may amend any inaccuracies or update your Telcare profile, including your personal information and email preferences, at any time.

You have the option of correcting, updating and/or changing contact and demographic information and other information previously provided and stored in our database. If you wish to correct, update or change your information, simply update your profile.

You may opt-out of any of promotional emails at any time by following the unsubscribe instructions in the promotional emails you receive from us, by updating your profile as described below or by sending an email to support@telcare.com.

How to update your profile: Please visit the home page of our website at www.telcare.com, click on "Mytelcare Login", and then sign in using your email address and password. To opt in or out of email communications, go to the bottom of the form and make the selection of your choices. If you select a box, you will NOT receive emails of the type listed. You may also request profile changes by sending an email to support@telcare.com.

## 6. How are "cookies" and Web beacons used on our websites?

"Cookies" are small pieces of information that are stored by

your browser on your computer's hard drive. We use both session cookies and persistent cookies on our website to help us provide you with a more personalized experience and improve our services. We may also use third party cookies to collect anonymous traffic data. Most web browsers automatically accept cookies, but you can usually change your browser settings to remove or reject cookies. Disabling cookies in your browser, however, may prevent access to some features of our website. If you register with our Service, we may elect to associate your information with our cookies to provide you with more customized content and enhanced functionality of our Services.

We may also collect information using Web beacons. Web beacons are electronic images used on our Sites and in our emails. We use Web beacons to deliver cookies, count visits, understand usage and campaign effectiveness and to tell if an email has been opened and acted upon.

## 7. Children

We understand the importance of protecting the privacy of children younger than 13 years old, who may need special safeguards and privacy protection and may not understand all the provisions of our privacy policy or be able to make informed decisions about the choices available to our users. We do not collect personal information from anyone who we know is younger than 13. However, we may not be able to ascertain 73

the user's real age if the information provided to us is not correct. All personal information of minors younger than 13 years old may only be provided, used and shared by us, with the consent and guidance of, their parents or guardians. The parent or guardian is responsible for supervising the child's use of, and access to, our Services.

#### 8. Is this privacy statement subject to change?

Yes. The Telcare Privacy Policy is subject to change at any time.

Please check the webpage www.telcare.com for changes from time to time to make sure you are aware of our latest privacy practices. If we make any changes to this Policy, we will change the "Last Updated" date.

#### 9. How to send us feedback

Our goal is to respect your privacy and we encourage user feedback to help us improve our privacy policies. If you have any questions or suggestions about this privacy statement, please contact us at: support@telcare.com.

Telcare, LLC 150 Baker Avenue Extension, Suite 300 Concord, MA 01742 (888) 666-4530 support@telcare.com