

On·Call[®] Extra Mobile

Blood Glucose Monitoring System

User's Manual



IVD

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On Call[®] Extra Mobile

Blood Glucose Monitoring System

Self monitoring of blood glucose (SMBG) is an important part of diabetes care. But the high cost of testing can make this impossible. At **ACON**, our goal is to provide high quality glucose monitoring systems at a price that allows you to test as often as necessary. Together, we can better manage your diabetes and help you live a longer and healthier life.

Welcome, and thank you for choosing the On Call[®] Extra Mobile Blood Glucose Monitoring System. The *On Call[®] Extra Mobile* Blood Glucose Monitoring System will give you accurate blood glucose results in just a few simple steps.

To ensure accurate results from your *On Call[®] Extra Mobile* Blood Glucose Monitoring System, please follow these instructions:

- Read instructions before use.
- Use only *On Call[®] Extra* Blood Glucose Test Strips with the *On Call[®] Extra Mobile* Blood Glucose Meter.
- For *in vitro* diagnostic use only. Your blood glucose monitoring system is to be used only outside the body. It is for monitoring the effectiveness of diabetes control. It should not be used for the diagnosis of diabetes.
- For self-testing and professional use.
- Test only whole blood samples with the *On Call[®] Extra* Blood Glucose Test Strips and *On Call[®] Extra Mobile* meter.
- For self-testers, consult your physician or diabetes healthcare professional before making any adjustments to your medication, diet or activity routines.
- Keep out of reach of children.
- Keep this User's Manual in a safe place, do not discard it.

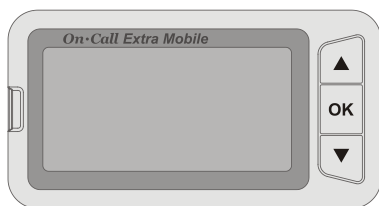
By following the instructions outlined in this User's Manual, you will be able to use your *On Call[®] Extra Mobile* Blood Glucose Monitoring System to monitor your blood glucose and better manage your diabetes.

Table of Contents

Getting Started	1
Component Descriptions	2
<i>On Call® Extra Mobile</i> Blood Glucose Meter.....	3
Meter Display.....	4
<i>On Call® Extra</i> Blood Glucose Test Strips	6
<i>On Call® Extra</i> Glucose Control Solution	8
Installing the Battery	10
Meter Setup Before Testing	11
Device Pairing	14
Performing a Quality Control Test	16
Testing Your Blood	19
Step 1 – Getting a Drop of Blood	19
Step 2 – Testing Blood Glucose.....	24
“HI” and “LO” Messages.....	27
Using the Meter Memory	28
Viewing Stored Records.....	28
Clearing the Memory	29
Manually Transferring Records by <i>Bluetooth®</i> Wireless Technology	30
Maintenance	32
Replacing the Battery	32
Caring for Your <i>On Call® Extra Mobile</i> Blood Glucose Monitoring System	33
Suggested Testing Times and Target Goals	34
Comparing Meter and Laboratory Results	35
Troubleshooting Guide	36
Specifications	38
Warranty	39
Index of Symbols	40
Index	41

Getting Started

Before testing, read the instructions carefully and learn about all the components of your *On Call® Extra Mobile* Blood Glucose Monitoring System. Depending on the *On Call® Extra Mobile* product you purchased, some of the components may need to be purchased separately. Please check the list of contents on the outer box for details on which components are included with your purchase.



Blood Glucose Meter



Test Strip



Control Solution



Steril Lancet



Lancing Device



Clear Cap

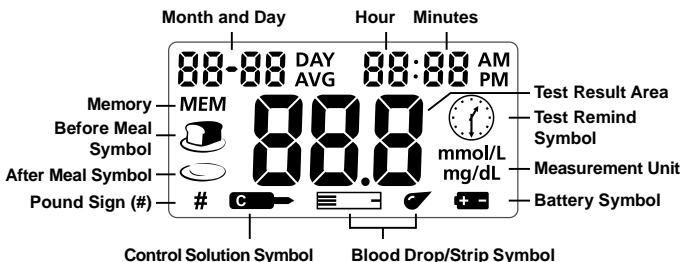


Carrying Case

Component Descriptions

1. Blood Glucose Meter: Reads the test strips and displays the blood glucose concentration.
2. Test Strips: Strips with a chemical reagent system used with the meter to measure glucose concentration in blood.
3. Lancing Device: Used with sterile lancets to prick the fingertip, palm (at the base of the thumb) or forearm for blood sample collection. The packaged lancing device has multiple depth settings, allowing users to adjust the depth of the puncture to minimize discomfort. It can also eject the used lancets.
4. Clear Cap: Used with the lancing device and sterile lancet to draw a blood sample from the forearm or palm.
5. Sterile Lancets: Used with the lancing device to draw a blood sample. Sterile lancets are inserted into the lancing device with each blood draw and discarded after use.
6. Control Solution: Verifies the proper operation of the blood glucose monitoring system by checking the test strips and meter against a pre-calibrated control solution. Control Solution 1 is all you need most of the time. Control Solution 0 and Control Solution 2 are also available if you want to do a level 0 or level 2 test. The three levels of control solution, CTRL 0, CTRL 1 and CTRL 2 are available in the *On Call® Extra* Glucose Control Solution package which is sold separately.
7. Carrying Case: Provides portability for blood glucose testing wherever you go.
8. User's Manual: Provides detailed instructions on using the blood glucose monitoring system.
9. Quick Reference Guide: Provides a brief overview of the blood glucose monitoring system and testing procedures. This small guide can be kept in your carrying case.
10. Warranty Card: Should be completed and returned to the distributor to qualify for the 5-year meter warranty.

Meter Display



Battery Symbol: Warns you when you should replace the battery.

Blood Drop / Strip Symbol: Wait for the Blood Drop / Strip Symbol to appear before applying the sample. These two symbols appear at the same time.

Pound Sign (#): Appears with the control solution test result or when you mark an invalid result to prevent it from being included in the average.

Control Solution Symbol: Indicates a control test result. A pound sign (#) will also be displayed when control solution symbol appears.

Test Result Area: Indicates a test result.

Measurement Unit: Only one unit will be displayed on your meter. It cannot be adjusted.

Before Meal Symbol: Appears when before-meal test results are displayed.

After Meal Symbol: Appears when after-meal test results are displayed.

Test Remind Symbol: Appears to remind you to test your blood glucose.

MEM: Shows a test result stored in memory.

Meter Use and Precautions

- Wait for the Blood Drop/Strip Symbol to appear before applying the sample.
- The meter is preset to display blood glucose concentration in either millimoles per liter (mmol/L) or milligrams per deciliter (mg/dL). This depends on your country's standard unit of measurement. This unit of measure cannot be adjusted.
- The meter will shut off automatically after 2 minutes of inactivity.
- Do not get water or other liquids inside the meter.
- Keep the strip port area clean.
- Keep your meter dry and avoid exposing it to extreme temperatures or humidity. Do not leave it in your car. Please use the meter indoor.
- Do not drop the meter or get it wet. If you do drop the meter or get it wet, check the meter by running a quality control test. Refer to **Quality Control Test** on page **16** for instructions.
- Do not take the meter apart. This will void the warranty.
- Refer to the **Caring for Your Meter** section on page **33** for details on cleaning the meter.
- Keep the meter and all associated parts out of the reach of children.

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

All Glucose Systems Preventive Warnings with Regard to EMC:

1. This instrument is tested for immunity to electrostatic discharge as specified in IEC 61000-4-2. However, use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets, etc.) may cause damaging static discharges that may cause erroneous results.
2. This instrument complies with the emission and immunity requirements described in EN61326-1 and EN61326-2-6. Do not use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with proper operation of the meter.
3. For professional use, the electromagnetic environment should be evaluated prior to operation of this device.

On Call® Extra Blood Glucose Test Strips

The *On Call® Extra* Blood Glucose Test Strips are thin strips. The strips have a chemical reagent system. They work with the *On Call® Extra Mobile* Blood Glucose Meter to measure the glucose concentration in whole blood. After the strip is inserted into the meter, blood is applied to the sample tip of the test strip. The blood is then automatically absorbed into the reaction cell where the reaction takes place. A transient electrical current is formed during the reaction. The blood glucose concentration is calculated based on the electrical current detected by the meter. The result is shown on the meter display. The meter is set to display plasma equivalent results.

Sample Tip

Apply blood or control solution here.



Check Window

Check to confirm that a sufficient sample has been applied.

Contact Bars

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

IMPORTANT: Apply sample only to the sample tip of the test strip. Do not apply blood or control solution to the top of the test strip. This may result in an inaccurate reading.

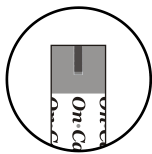


Correct

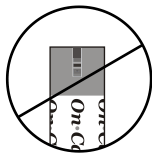


Incorrect

Hold the blood drop to the sample tip of the test strip until the check window is completely full. The meter will then begin to count down. If you applied blood but do not see the countdown start, you may reapply a second drop of blood within 3 seconds. If the check window does not fill and the meter starts to count down, then do not add more blood to the test strip. If you do then you may get an E-5 message or an inaccurate test result. In this case, if the meter begins to count down and the check window does not fill, discard the strip and begin the test again with a new test strip.



Correct



Incorrect

Storage and Handling

Please review the following storage and handling instructions:

- Store test strips in a cool, dry place at 2-35 °C (36-95 °F). Store them away from heat and direct sunlight.
- Do not freeze or refrigerate.
- Do not store or use test strips in a humid place such as a bathroom.
- Do not store the meter, the test strips or control solution near bleach or cleaners that contain bleach.
- The test strip should be used immediately after removing it from container.
- Repeated insertion and removal of a test strip into the meter strip port may result in reading errors.
- Do not use your test strips past the unopened expiration date printed on the label. Using test strips past the unopened expiration date may produce incorrect test results.

Note: The expiration date is printed in Year-Month-Date format.

Special Instructions for Test Strips in the Vial

- Test strips must be stored in the original vial with the cap tightly closed. This keeps them in good working condition.
- Do not transfer test strips to a new vial or any other container.
- Replace the cap on the test strip vial immediately after removing a test strip.
- A new vial of test strips may be used for 12 months after being first opened. Write the opened expiration date on the vial label after opening. Discard the vial 12 months after you first open it. Usage after this period may result in inaccurate readings.

Special Instructions for Test Strips in the Foil Pouch

- Tear the pouch carefully starting from the tear gap. Avoid damaging or bending the test strip.
- Use test strip immediately after removing it from the pouch.

Test Strips Precautions

- For *in vitro* diagnostic use. Test strips are to be used only outside the body for testing purposes.
- Do not use test strips that are torn, bent, or damaged in any way. Do not reuse test strips.
- Keep the test strips vial or the foil pouch away from children and animals.
- Consult your physician or healthcare professional before making any changes in your treatment plan based on your blood glucose test results.

See the test strip insert for more details.

On Call[®] Extra Glucose Control Solution

The *On Call[®] Extra* Glucose Control Solution contains a known concentration of glucose. It is used to confirm that your *On Call[®] Extra Mobile* Blood Glucose Meter and *On Call[®] Extra* Blood Glucose test strips are working together properly. It also confirms that you are performing the test correctly. It is important to run a quality control test regularly to make sure you are getting correct results.

You should run a quality control test:

- Before you first use your meter, to familiarize yourself with its operation.
- Before using a new box of test strips.
- When you suspect that the meter or test strips are not working properly.
- When you suspect that your test results are inaccurate, or if they are inconsistent with how you feel.
- When you suspect that your meter is damaged.
- After cleaning your meter.
- At least once a week.



Refer to **Quality Control Test** on page 16 for instructions on running a quality control test.

Storage and Handling

Please review the following storage and handling instructions:

- Store the control solution at 2-35 °C (36-95 °F).
- Do not refrigerate or freeze.
- If the control solution is cold, do not use until it has warmed to room temperature.
- Use before the unopened expiration date that is shown on the bottle.
Note: The expiration date is printed in Year-Month-Date format.
- Each bottle of control solution can be used for 6 months after you first open it. Record the opened and the resulting expiration date on the bottle label.

Control Solution Precautions

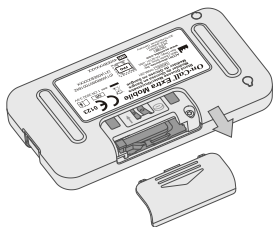
- For *in vitro* diagnostic use. The control solution is for testing only outside the body. Do not swallow or inject.
- Shake well before using.
- Control solution tests are designed to be accurate only when tested between 10 and 40 °C (50-104 °F).
- The control ranges shown on the test strip vial (or on the foil pouch) are not recommended ranges for your blood glucose level. Your personal blood glucose target ranges should be determined by your diabetes healthcare professional.
- Do not touch the test strip with the tip of the control solution bottle.
- Use only the same brand of control solution that was provided with your kit.

See the control solution insert for more details.

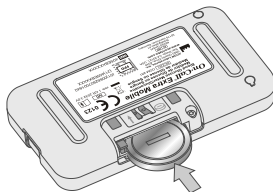
Installing the Battery

The battery may not be preinstalled in the meter. The meter requires one CR 2032 3.0 V coin cell battery. Please find the battery in your carrying case and install it according to the following steps:

1. Turn over the meter and slide the battery cover off the top of the meter.



2. Insert one CR 2032 3.0 V coin cell battery into the battery carrier. Make sure it is aligned with the plus (+) facing down.



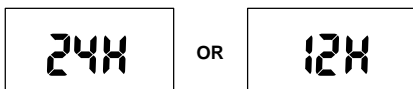
3. Slide the battery cover back on and make sure that it snaps shut.

Meter Setup Before Testing

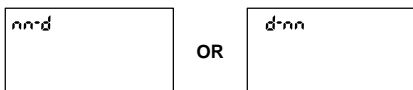
Before using your meter for the first time, you will need to adjust the settings that are listed in detail below.

- Meter Setup Mode:** Press the OK button for 2 seconds to enter the meter setup mode. The meter will automatically enter the setup mode when turned on for the first time or every battery change.
- Clock:** Set the clock to 12 or 24 hour mode. Press the ▲ or ▼ button to switch between the two settings. Then press the OK button to save your choice. Now you can start to set the Date Format.

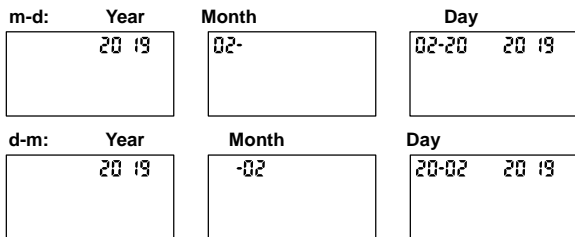
Note: The clock needs to be reset after replacing the battery.



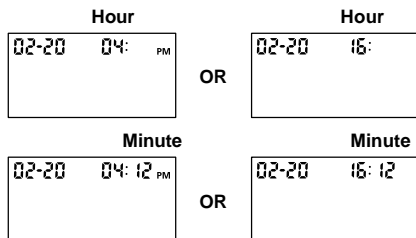
- Date Format:** m-d or d-m will appear at the top of the display to indicate either a month-day-year format or a day-month-year format. Press the ▲ or ▼ button to switch between the two settings. Then press the OK button to save your choice.



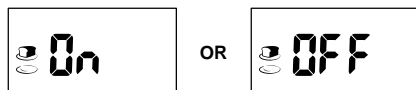
- Date:** The year will appear at the top of the display. Press the ▲ or ▼ button to increase or decrease the year. Once you have selected the correct year, press the OK button to save your choice. Then you can start to set the month. Press the ▲ or ▼ button to increase or decrease the month. Then press the OK button to save your choice. You can now select the day. Press the ▲ or ▼ button to increase or decrease the date. Then press the OK button to save your choice. Then you can start to set the time.



5. **Time:** The hour will appear at the top of the display. Press the ▲ or ▼ button to change to the correct hour. Press the OK button to save your choice and set the minutes. Press the ▲ or ▼ button to change to the correct minute. Press the OK button to save your choice. You can then start to set the meal marker feature.

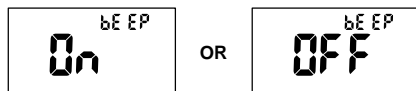


6. **Meal Marker:** The meter comes with the meal marker feature disabled. The meter allows the user to enable or disable this option. The words “On” or “Off” will be displayed on the large center segments of the display. The before meal symbol together with the after meal symbol will be displayed as shown below.



Press the ▲ or ▼ button to switch between turning the meal marker “On” and “Off”. Press the OK button to confirm your selection.

7. **Audio Feature:** The meter comes with the meter audio feature enabled. There will be a short beep when it is turned on, after sample detection and when the result is ready. The meter will sound three short beeps to sound a warning when an error has occurred. Please check the error number on the display to confirm what kind of error has occurred.

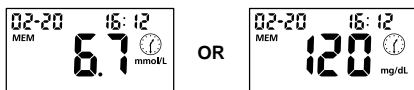


Press the ▲ or ▼ button to turn the meter beep “On” or “Off”. Press the OK button to confirm your selection.

8. **Test Reminder:** Test reminders are a useful way to remind you when to test. You can set 1 to 5 reminders per day. Your meter is preset with the test reminder disabled. You must turn it on to use this feature.

- Press the ▲ or ▼ button to turn the first Test Reminder “On” or “Off”. Press the OK button to confirm your selection. When the Test Reminder is “Off”, pressing the OK button will go to the set up of the second Test Reminder. When the Test Reminder is “On”, pressing the OK button will go to the set up of the time for the first Test Reminder. Press the ▲ or ▼ button to adjust the first Test Reminder time. Press the OK button to confirm the first Test Reminder time and then go to the second Test Reminder set up.
- When the Test Reminder is “Off” during the second Test Reminder set up, pressing the OK button will go to the set up of the third Test Reminder. When the Test Reminder is “On”, pressing the OK button will go to the set up of the time for the second Test Reminder. Press the ▲ or ▼ button to adjust the second Test Reminder time. Press the OK button to confirm the second Test Reminder time and then go to the third Test Reminder set up.
- Repeat the same set up procedure for Test Reminder 3, 4 and 5.

If one or more test reminders have been set, the reminder symbol will always appear on the LCD screen when the meter is turned on. The display sample is shown below.



The meter beeps 5 times when it is first set. It will beep again two minutes later, and two minutes after that unless you insert a test strip. This function will still work with Audio feature turned off.

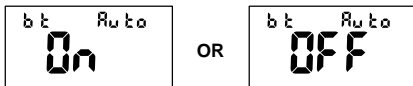
When the meter beeps at the time set by the Test Reminder feature, the date, time and strip symbols will be displayed, and the test reminder symbol will flash. The display sample is shown below.



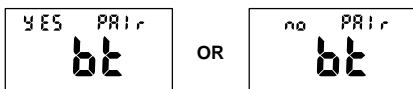
Note: For any step of the setup, if the ◀ button is pressed and held, it will allow a faster adjustment.

Device Pairing

1. **Bluetooth® Auto-Send:** The meter comes with the *Bluetooth®* auto-send feature enabled. This feature will allow your glucose result to automatically be sent to your mobile device if the glucose meter and the mobile device are paired and within range. The meter allows the user to enable or disable this option. Press the ▲ or ▼ button to select whether data is automatically sent to the default paired device after each test. The words “bt” “Auto” “On” or “bt” “Auto” “Off” will be shown on the display. Press the OK button to confirm your selection.

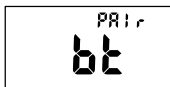


2. **Bluetooth® Pairing:** Before any data can be sent via *Bluetooth®* wireless with either the Auto-send option or manual *Bluetooth®* transmission, the glucose meter and the mobile device must be paired. From this setting, “bt” will appear on the screen with either “yes” or “no” and “PAIR” at the top of the display. Press the ▲ or ▼ button to change the setting.



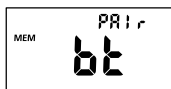
If no new devices need to be paired, select the “no” option and press the OK button to exit the setup. If you have a new device that needs to be paired with the glucose meter or you have a new meter that has never been paired with a mobile device, select the “yes” option and press the OK button to enter pairing mode.

In pairing mode, “bt” displays along with the word “PAIR” blinking at the top of the display. The green Status Light on the side of the meter will also blink to indicate the meter is attempting to connect with the mobile device. When prompted to pair by your mobile device, proceed to enter in the last 6 digits of the meter serial number (located on the back of the Bluetooth meter).



Once the pairing is completed successfully, the word “PAIR” stops blinking and the “MEM” symbol displays to show that the device is paired and stored in the

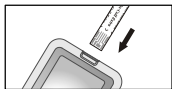
meter's memory. Press the OK button to exit the setup or the meter will automatically shut off after 30 seconds of inactivity.



Performing a Quality Control Test

The quality control test confirms that the test strips and meter are working together properly; it also confirms that you are performing the test correctly. It is important to perform this test:

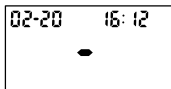
- Before you first use your meter.
 - Before using a new box of test strips.
 - When you suspect that the meter or test strips are not working properly.
 - When you suspect that your test results are inaccurate, or if they are inconsistent with how you feel.
 - When you suspect your meter is damaged.
 - After cleaning your meter.
 - At least once a week.
1. Insert a test strip into the strip port, contact bars end first and facing up. It will turn on the meter and display all the display segments. If the audio option is on, the meter will beep, signaling that the meter is turned on.
 2. Check the display to confirm that all the display segments turn on. Next, a dash will move across the display.



NOT READY



NOT READY



NOT READY

3. Following this display check, the system will enter the test mode. The display will show the date time and the strip icon with the blood sample icon blinking to indicate that the test strip is inserted correctly.



NOT READY

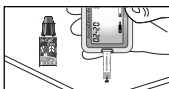
Note: If the test strip has been inserted incorrectly, the meter will not turn on.

4. Press the ▲ button to mark the test as a control solution test. Once the ▲ button is pressed, the control solution symbol will appear on the display. It indicates that a drop of control solution can be added.



READY TO TEST

- Shake the control solution bottle well. Squeeze it gently and discard the first drop. If the tip clogs, tap the tip gently on a clean, hard surface. Then shake again and use. Squeeze out a second small drop on a clean nonabsorbent surface. Touch the sample tip of the test strip to the control solution drop. If the audio option is turned on, the meter will beep to indicate a sufficient sample has been applied.



Notes:

- Do not apply control solution to the test strip directly from the bottle.
 - If you applied the control solution sample but do not see the starting of the count down, you may reapply a second drop within 3 seconds.
- Once a sufficient sample has been applied, the meter display will count down from 3 to 1. Then the result and a control solution symbol will be displayed on the screen. The control solution test results should be within the control range (CTRL 1) printed on the test strip vial (or on the foil pouch). This means that your blood glucose monitoring system is working properly and that you are performing the procedure correctly.



OR



Test results are displayed either in mmol/L or mg/dL depending on the unit of measure most common in your country.

Note: The control solution range is the expected range for the control solution results. It is not a recommended range for a blood glucose level.

7. Remove and discard the used test strip.

The display should also show a pound sign (#) indicating the test is a control solution test. This shows that the number will not be counted in the 7, 14, 30, 60 and 90-day averages. The pound sign (#) will also be displayed when reviewing the results stored in memory.

If the result falls outside the indicated control range:

- Confirm you are matching the correct range. Control Solution 1 results should be matched to the CTRL 1 range printed on the test strip vial (or on the foil pouch).
- Check the expiration date of the test strip and control solution. Discard any test strips or control solution that has expired.
- Confirm the temperature in which you are testing is between 50-104°F (10-40°C).
- Make sure that the test strip vial and control solution bottle have been tightly capped.
- Confirm that you are using the same brand of control solution that was provided with your kit.
- Make sure that you followed the test procedure correctly.

After checking all of the conditions listed above, repeat the quality control test with a new test strip. If your results still fall outside of the control range shown on the test strip vial (or on the foil pouch), your meter may be defective. Please contact your local distributor.

Three levels of control solution are available labeled Control Solution 0, Control Solution 1 and Control Solution 2. Control Solution 1 is sufficient for most all self-testing needs. If you think your meter or strips may not be working correctly, you may also want to do a level 0 or level 2 test. The ranges for CTRL 0, CTRL 1 and CTRL 2 are displayed on the test strip vial (or on the foil pouch). Simply repeat step 4 through 6, using Control Solution 0 or Control Solution 2.

To confirm your results, Control Solution 0 tests should fall within the CTRL 0 range, Control Solution 1 tests should fall within the CTRL 1 range and Control Solution 2 tests should fall within the CTRL 2 range. If the control solution test results do not fall within their respective ranges, DO NOT use the system to test blood, as the system may not be working properly. If you cannot fix the problem, please contact your local distributor for help.

Please contact your local distributor for information on ordering the *On Call® Extra* Glucose Control Solution kit. The kit contains Control Solution 0, Control Solution 1 and Control Solution 2.

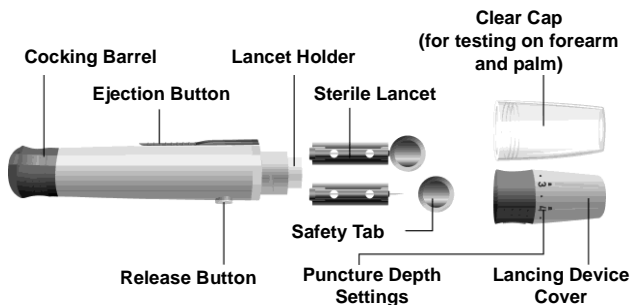
Testing Your Blood

The following steps will show you how to use the meter, test strips, lancing device and sterile lancets together to measure your blood glucose level.

Step 1 – Getting a Drop of Blood

The *On Call® Extra Mobile* Blood Glucose Monitoring System requires a very small drop of blood. The blood may be obtained from the fingertip, palm (at base of the thumb) or forearm. Before testing, choose a clean, dry work surface. Familiarize yourself with the procedure and make sure you have all the items needed to obtain a drop of blood.

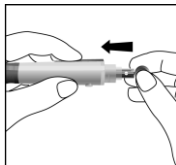
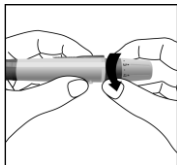
IMPORTANT: Prior to testing, wipe the test site with an alcohol swab or soapy water. Use warm water to increase blood flow if necessary. Dry your hands and the test site thoroughly. Make sure there is no alcohol, soap or lotion on the test site.



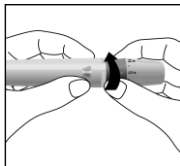
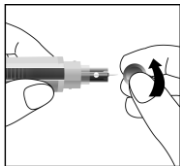
Fingertip Testing

For fingertip sampling, adjust the depth penetration to reduce the discomfort. You do not need the clear cap for fingertip sampling.

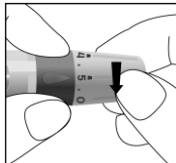
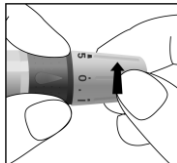
1. Unscrew the lancing device cover from the body of the lancing device. Insert a sterile lancet into the lancet holder and push it until the lancet comes to a complete stop in the lancing device.



2. Hold the lancet firmly in the lancet holder and twist the safety tab of the lancet until it loosens, then pull the safety tab off the lancet. Save the safety tab for lancet disposal.
3. Carefully screw the cover back onto the lancing device. Avoid contact with the exposed needle. Make sure the cover is fully sealed on the lancing device.



4. Adjust the puncture depth by rotating the lancing device cover. There are a total of 11 puncture depth settings. To reduce discomfort, use the lowest setting that still produces an adequate drop of blood.

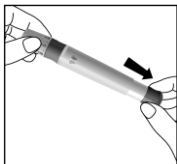


Adjustment:

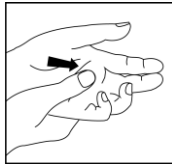
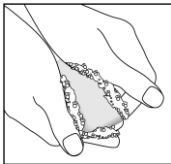
- 0 - 1.5 for delicate skin
- 2 - 3.5 for normal skin
- 4 - 5 for calloused or thick skin

Note: Greater pressure of the lancing device against the finger will also increase the puncture depth.

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

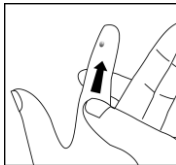
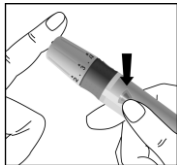


6. Prior to testing, wipe your hands with an alcohol swab or wash your hands with soap. Use warm water to increase blood flow in your fingers if necessary. Dry your hands thoroughly. Massage the hand from the wrist up to the fingertip a few times to encourage blood flow.



7. Hold the lancing device against the side of the finger to be lanced with the cover resting on the finger. Push the release button to prick your fingertip. You should hear a click as the lancing device activates. Gently massage from the base of the finger to the tip of the finger to obtain the required amount of blood. Avoid smearing the drop of blood.

Note: For the greatest reduction in pain, lance on the sides of the fingertips. Rotation of sites is recommended. Repeated punctures in the same spot can make your fingers sore and callused.



Forearm and Palm Testing

The forearm and palm areas have less nerve endings than the fingertip, for that reason, you may find that obtaining blood from these sites is less painful than from the fingertip. The procedure for forearm and palm sampling is different. You need the clear cap to draw blood from these sites. The clear cap is not adjustable for puncture depth.

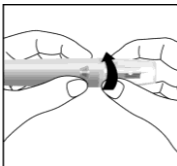
IMPORTANT: There are important differences among forearm, palm and fingertip samples that you should know. Important information about forearm and palm glucose testing:

- You should consult your healthcare professional before choosing to perform forearm or palm testing.
- When blood glucose levels are changing rapidly such as after a meal, an insulin dose or exercise, blood from the fingertips may show these changes more rapidly than blood from other areas.

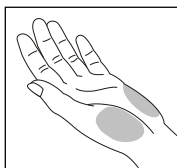
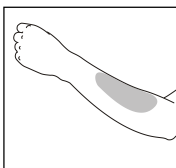
- Fingertips should be used if testing is within 2 hours of a meal, an insulin dose or exercise and any time you feel your glucose levels are changing rapidly.
- You should test with the fingertips anytime there is a concern for hypoglycemia or you suffer from hypoglycemia unawareness.

Please refer to **Fingertip Testing** to insert the lancet and load the lancing device.

1. Screw the clear cap onto the lancing device.

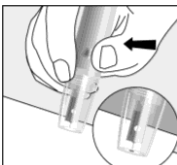


2. Choose a puncture site on the forearm or palm. Select a soft, fleshy area of the forearm or palm that is clean and dry, away from bone, and free of visible veins and hair.



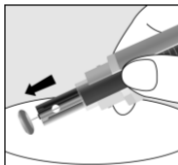
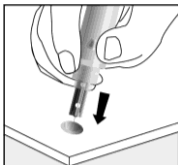
Note: To bring fresh blood to the surface of the puncture site, massage the puncture site vigorously for a few seconds until you feel it getting warm.

3. Place the lancing device against the puncture site. Press and hold the clear cap against the puncture site for a few seconds. Press the release button of the lancing device. **Do not immediately lift the lancing device** from the puncture site. Continue to hold the lancing device against the puncture site until you can confirm a sufficient blood sample has formed.



Disposal of the Lancet

1. Unscrew the lancing device cover. Place the safety tab of the lancet on a hard surface. Carefully insert the lancet needle into the safety tab.
2. Press the release button to make sure that the lancet is in the extended position. Slide the ejection button forward to discard the used lancet. Place the lancing device cover back on the lancing device.



Lancet Precautions

- Do not use the lancet if the safety tab is missing or loose when you take the lancet out of the bag.
- Do not use the lancet if the needle is bent.
- Use caution whenever the lancet needle is exposed.
- Never share lancets or the lancing device with other people.
- In order to reduce the risk of infection from prior use of the instrument, always use a new, sterile lancet. Do not reuse lancets.
- Avoid getting the lancing device or lancets dirty with hand lotion, oils, dirt or debris.

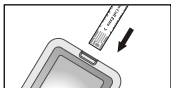
Specimen collection and preparation by healthcare professionals

Please refer to test strip insert

Step 2 – Testing Blood Glucose

Note: Insertion of a new test strip at any time, except while in the data transfer mode (See page 30) will cause the meter to automatically enter the test mode.

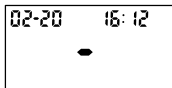
1. Insert a test strip into the strip port, contact bars end first and facing up. This will turn on the meter and display all the display segments. If the audio option is on, the meter will beep when the meter is turned on.
2. Check the display to confirm that all the display segments turn on with no missing components. The display will then show only the date and time, with a dash moving across the display. Check the display to ensure no inappropriate segments or icons are permanently turned on.



NOT READY



NOT READY



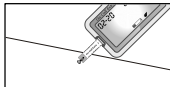
NOT READY

3. Following this display check, the system will enter the test mode. The display will show the date and time, and the strip icon with the blood sample icon blinking, to indicate that the test strip is inserted correctly and that a drop of blood can be added. If the test strip has been inserted incorrectly, the meter will not turn on. The meter is ready for testing when the blinking blood drop and strip icon appears. At this time a blood drop can be added.



READY TO TEST

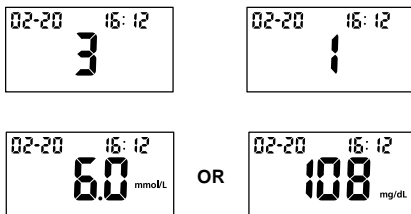
4. Touch the blood drop to the sample tip at the end of the test strip. If the audio option is turned on, the meter will beep to indicate that the sample is sufficient and the measurement has started. If you applied a drop of blood, but do not see the countdown begin, you may reapply a second drop of blood within 3 seconds.



DO NOT:

- Apply the sample to the front or back of the test strip.
- Smear the blood drop onto the test strip.
- Press your finger against the test strip.

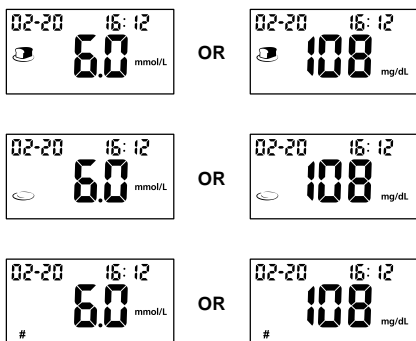
5. The meter will count down from 3 to 1 and then display the measurement's result. The meter will also beep to indicate that the measurement is complete, then your blood glucose level will display on the screen. The measurement's unit, date, and time of the test will also be displayed.



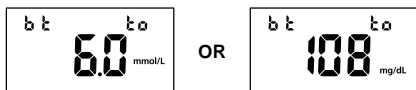
Blood Glucose results are automatically stored in the memory. To mark invalid results and prevent them from being included in the 7, 14, 30, 60 and 90-day averages, press the ▲ or ▼ button. A pound sign (#) will appear on the display to show that the result will not be included when calculating the 7, 14, 30, 60 and 90-day averages. If a result is marked by accident, press the ▲ or ▼ button to unmark the result. After marking the invalid result with a pound sign (#), press the OK button to confirm the invalid result. After marking the invalid result, run the test again with a new test strip.

When the meal marker feature is turned on, the test result will be displayed along with the suggested default meal marker based upon current time. The “before meal” or “after meal” symbol is flashing until confirmed by pressing the OK button. The meter allows the user to change the meal marker. Press the ▲ or ▼ button to switch the marker from “before meal”, “after meal”, no marker or invalid result. After deciding the selection, press the OK button to confirm the selection for either “before meal marker”, “after meal marker”, “invalid result pound sign” or none of these three symbols. If an invalid result is marked, run the test again with a new test strip.

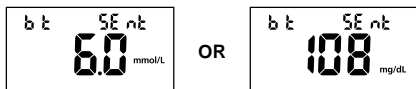
When the *Bluetooth*® Auto-Send feature is turned on and the meal marker feature is turned on, the meter allows the user 15 seconds to change the meal marker before going into automatic *Bluetooth*® transmission. If the *Bluetooth*® Auto-Send feature is turned on but the meal marker feature is not, the meter will instantly go into automatic *Bluetooth*® transmission after displaying the glucose result.



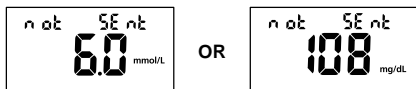
When the meter begins automatic *Bluetooth*[®] transmission, the glucose reading remains on the display and the words “bt” and “to” appear at the top of the display.



Once the transmission has finished, the words “bt” and “SEnt” appear at the top of the display.



If the transmission was interrupted and the data transfer failed, the words “not” and “SEnt” appear at the top of the display.



Notes:

- The default “before meal” time periods are 5:00 - 7:59, 10:00 - 11:59 and 15:00 - 17:59
- The default “after meal” time periods are 8:00 - 9:59, 12:00 - 14:59 and 18:00 - 20:59

If an error message appears on the display, refer to the **Troubleshooting Guide** on page 36. If a “HI” or “LO” error appears on the display, refer to “HI” and “LO” messages below.

- Record valid results in your logbook with the date and time, and compare them to the target goals set by your diabetes healthcare professional. Refer to **Suggested Testing Times and Target Goals** on page 34 or your logbook for more details on your target blood glucose level goals.
- Remove and discard the used test strip.

Note: Dispose of blood samples and materials carefully. Treat all blood samples as if they are infectious materials. Follow proper precautions and obey all local regulations when disposing of blood samples and materials.

“HI” and “LO” Messages

The meter can accurately measure blood glucose concentrations between 0.6 to 33.3 mmol/L (10 to 600 mg/dL). “HI” and “LO” messages indicate results outside of this range.

If “HI” appears on the display, the measured concentration value is above 33.3 mmol/L (600 mg/dL). The test should be retaken to ensure that no mistake was made in the procedure. If you are certain the meter is functioning properly and no mistakes were made in the procedure, and your blood glucose is still consistently measured as “HI”, it indicates severe hyperglycemia (high blood glucose). You should contact your healthcare professional immediately.

If “LO” appears on the display, the measured concentration value is below 0.6 mmol/L (10 mg/dL). The test should be retaken to ensure that no mistake was made in the procedure. If you are certain the meter is functioning properly and no mistakes were made in the procedure, and your blood glucose is still consistently measured as “LO”, it may indicate severe hypoglycemia (low blood glucose). You should treat yourself for hypoglycemia immediately as recommended by your healthcare professional.



Precautions and Limitations

Please refer to test strip insert.

Using the Meter Memory

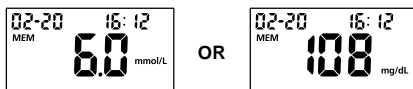
The meter automatically stores up to 500 test records. Each record includes the test result, time and date. If there are already 500 records in memory, the oldest record will be erased to make room for a new one.

The meter will also calculate the average values of records from the last 7, 14, 30, 60 and 90 days.

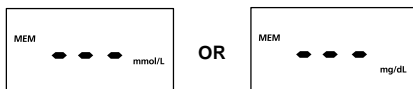
Viewing Stored Records

To view stored records:

1. Press the ▲ button to turn the meter on and enter memory mode. The most recent value and the word "MEM" will appear on the display.



2. If you are using the meter for the very first time, the meter display will show three dashed lines (---), the word "MEM" and the unit of measure. This shows that no data have been stored in memory.



3. The date and time will be displayed together with the results stored in memory. A pound sign (#) indicates records that will be omitted from the 7, 14, 30, 60 and 90-day averages.

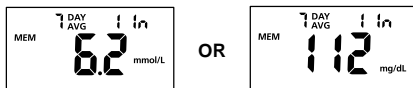
4. Press the ▲ or ▼ button to view the previous or next stored records.

Press the OK button to view the data averages. The words "DAY AVG" will appear on the screen.

5. While in data average mode:

- If the meal marker feature is off, press the ▲ or ▼ button to switch between the general 7, 14, 30, 60 and 90-day averages.
- If the meal marker feature is on, press the ▲ or ▼ button to switch between the 7, 14, 30, 60 and 90-day general, pre-meal and post-meal averages.
- The meter will calculate the average that you selected. The number of records used in the DAY AVG will also appear in the display.

Note: Only test results that have been marked as “before meal” or “after meal” are included in pre-meal and post-meal averages. All blood glucose results are included in the general 7, 14, 30, 60 and 90-day averages.



6. If there are fewer than 7, 14, 30, 60 and 90 days in memory, all the readings without the pound (#) sign currently stored in memory will be averaged instead.

If you are using the meter for the very first time, no value will appear on the display. This means that no records have been stored in memory. If you have not marked any results as “before meal” or “after meal”, no value will appear on the display for the pre-meal or post-meal averages. This means that no records have been stored as “before meal” or “after meal” in memory.

7. Press the OK button to turn off the display.

Note: Results from quality control tests will not be included in the averages. When viewing results in memory, these values are marked with a pound sign (#) to show that they will not be included in the 7, 14, 30, 60 and 90-day averages.

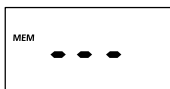
Clearing the Memory

Take extreme caution when clearing the memory as this is not a reversible operation. To clear the memory:

1. With the meter off, press and hold the ▲ button for two seconds. This will turn on the meter and enter the delete mode.



2. To clear the memory, press and hold both the ▲ and ▼ buttons for two seconds.
3. The display will show “MEM” and “- - -”. The meter will clear its memory and turn itself off after a moment.

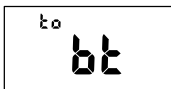


4. If you entered the delete mode but want to exit without deleting the recorded data, press the OK button. This will turn the meter off without deleting any data.

Manually Transferring Records by *Bluetooth*[®] Wireless Technology

Instead of transferring data immediately after completing the blood glucose measurement when auto-send function is on, the meter can also wirelessly transfer your stored diabetes information manually when you choose to send the data. You will need a mobile application on your mobile device to accept the meter's data. Consult your local distributor for current mobile app compatibility.

1. Turn on *Bluetooth*[®] to the discoverable state and launch the app in your mobile device to connect to the glucose meter. Press and hold both the ▼ and ▲ buttons for two seconds. The meter will display "bt" mode along with word "to" blinking. The green Status Light on the side of the meter will also blink to indicate the meter is attempting to connect wirelessly to the mobile device. After several seconds, the word "to" will stop blinking, indicating a successful connection to the mobile device.



Note: When meter is in "bt" mode, sample application mode cannot be activated after a strip is inserted into the meter. Do not insert test strips and attempt to test blood glucose while the meter is in "bt" mode.

2. Once the data transfer is complete, the meter will display "SEnt" and "bt".



3. After data transfer from meter to your device is complete, press the OK button to turn off the meter. If nothing else happens 2 minutes after data transfer is completed, the meter will automatically turn off. In this case press both the ▼ and ▲ buttons to enter "bt" mode again if needed.

Warning: Never break the connection between the meter and mobile device while *Bluetooth*[®] data transfer is in progress, for example by turning off the meter or removing the battery. Do not put the *On Call*[®] *Extra Mobile* Meter on a metal surface or in a metal box or enclosure. This may affect its ability to transfer data.

Note: Peripheral equipment which is intended to be connected with meter shall conform to relevant safety standard.

Compliance Information

Bluetooth® Notice


The *Bluetooth®* word mark and logos are registered trademarks owned by the Bluetooth SIG, Inc. and any use of such marks by **ACON** is under license. Other trademarks and trade names are those of their respective owners.

Maintenance

Proper maintenance is recommended for best results.

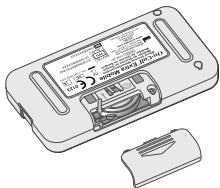
Replacing the Battery

Your *On Call*[®] *Extra Mobile Meter* uses one 3.0 Volt CR 2032 lithium battery.

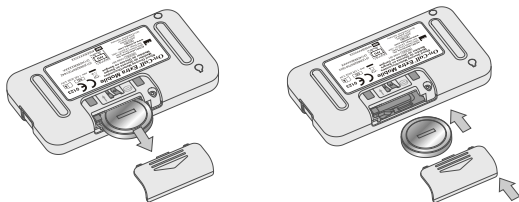
When the battery icon () is blinking, it means the battery is running low. You should replace the battery as soon as possible. An “E-6” error message will appear if the battery is too low to perform any more blood glucose tests. The meter will not function until the battery is replaced.

Instructions:

1. Turn the meter off before removing the battery.
2. Turn the meter over to locate the battery cover. Slide the battery cover off the top of the meter to get the battery.
3. Press the “+” symbol on the white plastic battery holder to loosen the old battery.



4. Pull out and discard the old battery. Insert one new CR 2032 3.0 V coin cell battery. Make sure the plus (+) side is facing down.



5. Close the battery cover and make sure that it snaps shut.
6. Recheck and reset the clock setting after battery replacement, if necessary. To set the meter clock, see **Meter Setup before Testing** on page 11.

Caring for Your *On Call*[®] *Extra Mobile* Blood Glucose Monitoring System

Blood Glucose Meter

Your *On Call*[®] *Extra Mobile* Blood Glucose Meter does not require special maintenance or cleaning. A cloth dampened with water and a mild detergent solution can be used to wipe the outside of the meter. Take care to avoid getting liquids, dirt, blood or control solution into the meter through the strip port. It is recommended that you store the meter in the carrying case after each use.

The *On Call*[®] *Extra Mobile* Blood Glucose Meter is a precision electronic instrument. Please handle it with care.

Lancing Device

Use mild soap and warm water to clean with a soft cloth as required. Carefully dry the device thoroughly. Do not immerse the lancing device.

Please refer to the lancing device insert for more details.

Suggested Testing Times and Target Goals

Tracking your blood glucose concentration through frequent testing is an important part of proper diabetes care. Your healthcare professional will help you decide the normal target range for your glucose levels. They will also help you to determine when and how often you should test your blood glucose.

Some suggested times are:

- When you wake up (fasting level)
- Before breakfast
- 1-2 hours after breakfast
- Before lunch
- 1-2 hours after lunch
- Before or after exercise
- Before dinner
- 1-2 hours after dinner
- Before bedtime
- After a snack
- At 2 or 3 AM, if taking insulin

You may need to test more often whenever: ¹

- You add or adjust your diabetes medication.
- You think your blood glucose levels may be too low or too high.
- You are ill, or feeling uncomfortable over long periods of time.

Expected blood glucose levels for people without diabetes:²

Time	Range, mg/dL	Range, mmol/L
Fasting and Before Meals	70-100	3.9 – 5.6
2 hours after meals	Less than 140	Less than 7.8

Talk to your doctor to set your own daily target ranges.

Time of Day	Your Target Range
Waking up (Fasting level)	
Before meals	
2 hours after meals	
Bedtime	
2 AM to 3 AM	
Other	

(Note: 1 mmol/L = 18 mg/dL)

Use the logbook to record your blood glucose measurements and related information. Bring the logbook with you when you visit your doctor. Together, you can determine how well your blood glucose is being controlled. This can help you and your doctor make the best decisions about your glucose control plan.

1. Jennifer Mayfield and Stephen Havas, "Self-Control: A Physician's Guide to Blood Glucose Monitoring in the Management of Diabetes – An American Family Physician Monograph"
2. ADA Clinical Practice Recommendations, 2013. Diabetes Care, 2013, Vol.36, Supplement 1, S67-S74

Comparing Meter and Laboratory Results

Your *On Call® Extra Mobile* Blood Glucose System and laboratory results both report the glucose concentration in the serum or plasma component of your blood. However, the results may differ somewhat due to normal variation. The meter results can be affected by factors and conditions that do not affect laboratory results in the same way. See *On Call® Extra Test Strips'* package insert for typical accuracy and precision data, and for important information on limitations.

To ensure a reasonable comparison, follow these guidelines.

Before you go to the lab:

- Bring your meter, test strips and control solution with you.
- Make sure your meter is clean.
- Perform a quality control test to make sure the meter is working properly.
- Comparisons will be more accurate if you do not eat for at least four hours before testing. Eight hours is preferable.








At the lab:

- Wash your hands before obtaining a blood sample.
- Take the blood samples for a laboratory test and for your meter within 10 minutes of each other. This will ensure an accurate comparison of results.
- Never test blood that has been placed in test tubes containing fluoride or other anticoagulants which is not suggested. This will cause falsely low results.

Troubleshooting Guide

The meter has built-in messages to alert you of problems. When error messages appear, note the error number. Turn off the meter and then follow these instructions.

Display	Causes	Solution
Meter fails to turn on	Battery may be damaged or empty	Replace the battery.
	Meter is too cold	If the meter has been exposed to or stored in cold conditions, wait 30 minutes. Allow the meter to reach room temperature then repeat the test.
E-0	Power On self check error	Remove the battery for 30 seconds and then put the battery back and turn meter on again. If the problem persists, please contact your local distributor.
E-1	Internal calibration check error	If a cell phone, radio frequency source or a high power electrical source is nearby, place more distance between the meter and any of these sources then retest. If the problem persists, please contact your local distributor.
E-2	Test strip was removed during the test	Repeat the test and ensure that the test strip remains in place.
E-3	Sample was applied to the test strip too soon	Repeat the test and apply the sample after the blood drop/test strip symbol appears.
E-4	Test strip is contaminated or used	Repeat the test with a new test strip.
	Sample was applied to the test strip too soon	Repeat the test and apply the sample the after blood drop/test strip symbol appears.
E-5	Insufficient sample	Repeat the test and apply enough sample to fill the test strip check window.
	Sample application error due to late sample re-dosing	Repeat the test and apply enough sample to fill the test strip check window within 3 seconds.

Display	Causes	Solution
	Temperature has exceeded the operating temperature of the system	Move to a cooler environment and repeat the test.
	Temperature is below the operating temperature of the system	Move to a warmer environment and repeat the test.
	Battery is low but has enough power to run 20 more tests.	Test results will still be accurate, but replace the battery as soon as possible.
	Battery is discharged and the meter does not allow for more tests until replacement with a new battery.	Replace the battery and repeat the test.
	Meter electronics failure.	If the problem persists, please contact your local distributor.
	Improper type of test strip used.	Please make sure you use the <i>On Call® Extra</i> test strip with the <i>On Call® Extra Mobile</i> Blood Glucose Meter. If the problem persists, please contact your local distributor.
	Test strip damaged or calibration error.	Please test again using a new strip. If the problem persists, please contact your local distributor.
	Communications failure.	There is an error in transferring data to the device. Check your device. Make sure that Bluetooth® communication is carried out within 10 meters, and there is no interference from metal shields and other Bluetooth® devices.

Specifications

Feature	Specification
Meter Model Number	OGM-281
Measurement Range	0.6 - 33.3 mmol/L (10 - 600 mg/dL)
Result Calibration	Plasma-equivalent, calibrated by using YSI (Model 2300 STAT PLUS) Glucose Analyzer reference instrument, which is traceable to NIST reference standard.
Sample	Fresh capillary whole blood
Minimum Sample Size	0.4 μ L
Test Time	4 seconds
On/Off Source	One (1) CR 2032 3.0 V coin cell battery
Battery Life	500 tests for glucose testing (<i>Bluetooth</i> [®] auto send function is off, manual sending data via Bluetooth once every 10 glucose measurements).
Glucose Units of Measure	The meter is preset to either millimoles per liter (mmol/L) or milligrams per deciliter (mg/dL) depending on the standard of your country.
Memory	Up to 500 records with time and date
Automatic shutoff	2 minutes after last action
Meter Size	75.0 mm \times 40.0 mm \times 13.0 mm
Display Size	50.0 mm \times 25.0 mm
Weight	36.0 g (with battery installed)
Operation Environmental Conditions	Temperature: 5 - 45 $^{\circ}$ C (41 - 113 $^{\circ}$ F); Relative Humidity: 10 - 90% (non-condensing); Altitude: \leq 3048m
Meter storage and transportation conditions	Temperature: -20 - 50 $^{\circ}$ C (-4 - 112 $^{\circ}$ F); Relative humidity: 10% - 93% (non-condensing); Air pressure: 500 hPa - 1060 hPa
Hematocrit Range	25 - 60%
Pollution Degree	2
Means of protection	Class III
Marked degree of protection	IPX0
Wireless Frequency	2.4 GHz worldwide ISM band (Instrumentation, Scientific and Medical)

Warranty









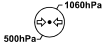

Please complete the warranty card that came with this product and mail it to your distributor to register your purchase.

If the meter fails to work for any reason other than obvious abuse within the first five (5) years from purchase, we will replace it with a new meter free of charge. For your records, also write the purchase date of your product here.

Date of purchase: _____

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


Index of Symbols

	Consult instructions for use
IVD	<i>In vitro</i> diagnostic medical device
	Temperature limit
	Contains sufficient for <n> tests
	Do not reuse
	Use by
LOT	Lot Number
	Manufacturer
EC REP	Authorized representative in the European Community
STERILE R	Sterilized using irradiation
CTRL	Control Range
REF	Catalogue number
MODEL	Model Number
SN	Serial Number
	Do not dispose along with household waste
	Humidity limitation
	Atmospheric pressure limitation
	Direct Current

Index

Averaging Results	27	Specifications.....	38
Battery, Replacing the	10,32	Procedure	
Carrying Case	1	Precautions and Limitations....	27
Clearing the Memory	29	Testing Your Blood.....	19
Date Format	7,9	Quality Control Test	16
Device Pairing	14	Control Solution.....	8
Guidelines	i	How to Run.....	16
Hematocrit	38	Results	
Lancing Device	1,18,33	Blood Glucose.....	25
Lancets	1,18	Control Solution.....	17
Maintenance	5,32	Meter vs. Lab Results.....	35
Measure, Unit of	5,16	Target Goals.....	34
Meter	3	Unit of Measure.....	17,38
▲ Button.....	3	Status Light	3,14
▼ Button.....	3	Suggested Testing Times	34
Audio feature.....	12	Symbols, Index of	40
Cleaning.....	33	Test Strip	6
Display.....	4	Expiration.....	7
Error Messages.....	36,37	Precautions.....	8
"HI" and "LO" Messages.....	27	Testing Your Blood	19
Memory.....	28	Get a Drop of Blood.....	19
Meter Use and Precautions....	5	Test Blood Glucose.....	24
Meter Setup.....	11	Troubleshooting	36
Set the Clock.....	11	Viewing Stored Records	28
OK Button.....	3	Warranty	2,39



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