

FORA[®] 6 *Connect*

Multi-Functional Monitoring System
Sistema de Monitoreo Multifuncional



Owner's Manual
Manual del Propietario

Dear FORA 6 Connect System Owner:

Thank you for purchasing the **FORA 6 Connect** Multi-Functional Monitoring System. This manual provides important information to help you use the system properly. Before using this system, please read and follow the instructions in this Owner's Manual.

The system measures both blood glucose and β -ketone levels. Regular monitoring of your blood glucose and β -ketone levels can help you and your doctor gain better control of your diabetes. Due to its compact size and easy operation, you can use the **FORA 6 Connect** Multi-Functional Monitoring System to easily monitor your blood glucose and β -ketone levels anywhere, any time.

If you have other questions regarding this product, please contact the place of purchase or call our customer service line at 888.307.8188 (8:30 am - 5:00 pm PST, Mon. - Fri.). For assistance outside these hours, please contact your healthcare professional.

IMPORTANT SAFETY PRECAUTIONS

READ BEFORE USE

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

For more information, please visit

- “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/ucm234889.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>
1. Use this device **ONLY** for the intended use described in this manual.
 2. Do **NOT** use accessories which are not specified by the manufacturer.
 3. Do **NOT** use the device if it is not working properly or if it is damaged.
 4. Do **NOT** under any circumstances use the device on newborns or infants.
 5. This device does **NOT** serve as a cure for any symptoms or diseases. The data measured is for reference only.

6. Before using this device to test blood glucose and β -ketone, read all instructions thoroughly and practice the test. Carry out all the quality control checks as directed.
7. Keep the device and testing equipment away from young children. Small items such as the battery cover, batteries, test strips, lancets and vial caps are choking hazards.
8. 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.
9. Do **NOT** use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with the accurate operation.
10. Proper maintenance and periodical control solution tests are essential to the longevity of your device. If you are concerned about your accuracy of measurement, please contact customer service or place of purchase for help.

KEEP THESE INSTRUCTIONS IN A SAFE PLACE

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BEFORE YOU BEGIN

Important Information

- Severe dehydration and excessive water loss may cause readings which are lower than actual values. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.
- If your blood glucose or β -ketone results are lower or higher than usual, and you do not have symptoms of illness, repeat the test. If you have symptoms or continue to get results which are higher or lower than usual, follow the treatment advice of your healthcare professional.
- Use only fresh whole blood samples to test your blood glucose and β -ketone. Using other substances will lead to inaccurate results.
- If you are experiencing symptoms that are inconsistent with your blood glucose or β -ketone test results and you have followed all the instructions given in this owner's manual, contact your healthcare professional.
- We do not recommend using this product on severely hypotensive individuals or patients who are in shock. Readings which are lower than actual values may occur for individuals in a hyperglycemic-hyperosmolar state, with or without ketosis. Please consult your healthcare professional before use.
- Limitation:
 - For in vitro diagnostic use (for use outside of the body only).
 - For single user only.
 - The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!

- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- Please read your **FORA 6 Connect** Multi-Functional Monitoring System Owner's Manual before you use the test strip. Use only **FORA 6 Connect** Test Strips with **FORA 6 Connect** Multi-Functional Monitoring System to obtain accurate results, and to be covered by the manufacturer's warranty.
- This system is not for use in patients with abnormally low blood pressure or those who are in shock.
- This system is not for use in patients in hyperglycemic-hyperosmolar state, with or without ketosis.
- This system should not be used on critically ill patients.
- This system should not be used on patients with impaired peripheral circulation, severe dehydration as a result of diabetic ketoacidosis or severe hyperglycemia, hyperosmolar non-ketotic coma or shock.
- Keep test strips and lancets away from small children. If swallowed, consult a doctor immediately for advice.
- Hematocrit: The hematocrit level is limited to between 20% and 70%. Please ask your healthcare professional if you do not know your hematocrit level.
- Neonatal Use: These test strips are not for use with neonates.
- Altitude Effects: Altitudes up to 10,742 feet (3,275 m) do not affect test results.

Intended Use

The **FORA 6 Connect** Multi-Functional Monitoring System is intended for use in the quantitative measurement of glucose and β -ketone (beta-hydroxybutyrate) in fresh capillary whole blood from the finger.

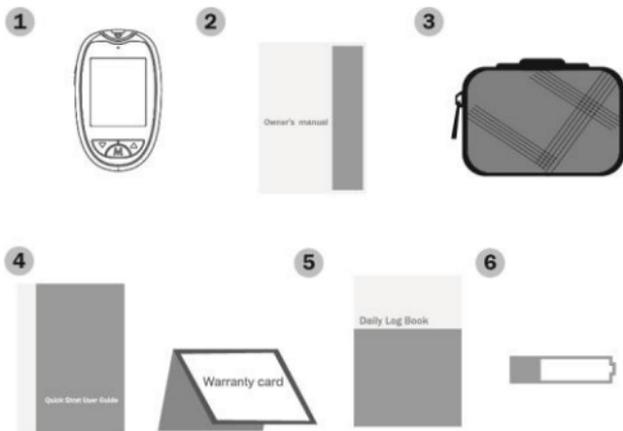
It is intended for *in vitro* diagnostic use by people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. It is intended to be used by a single person and should not be shared.

Test Principle

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

Contents of System

The **FORA 6 Connect** system kit includes:



① **Meter**

② **Owner's Manual**

③ **Protective Wallet**

④ **Quick Start User Guide /**

Warranty Card

⑤ **Daily Log Book**

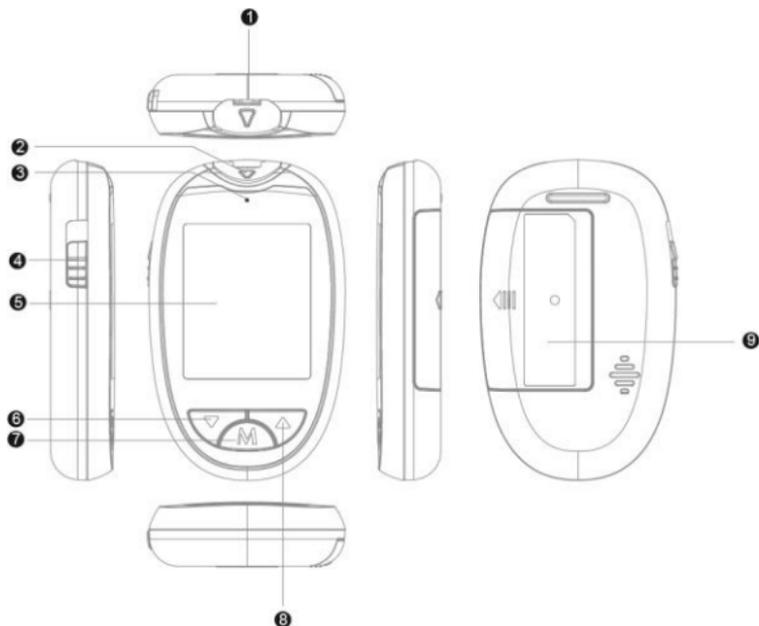
⑥ **1 x 1.5V AAA Battery**

Test strips, control solution, sterile lancets and lancing device may be purchased separately. Please make sure you have those items needed for a blood glucose test beforehand.

NOTE:

- If any items are missing from your kit or opened prior to use, or to obtain test strips and control solutions, please contact the place of purchase or call Customer Service for assistance.

Meter Overview



① **Test strip Slot**

Insert test strip here to turn the meter on for testing.

② **Strip Indication Light**

③ **Bluetooth Indicator**

Download test results with a Bluetooth connection.

④ **Test Strip Ejector**

Eject the used strip by pushing up this button.

⑤ **Display Screen**

⑥ **DOWN Button**

⑦ **MAIN Button**

Enter the meter memory and silence a reminder alarm.

⑧ **UP Button**

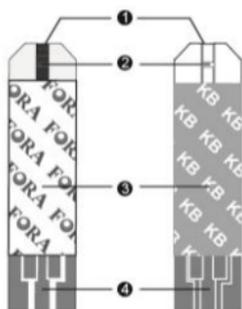
⑨ **Battery Compartment**

Meter Display



- | | |
|----------------------|--------------------|
| ① Code | ⑨ Error Message |
| ② Blood Drop Symbol | ⑩ Memory Symbol |
| ③ Test Strip Symbol | ⑪ Date / Time |
| ④ Low Battery Symbol | ⑫ Measurement Unit |
| ⑤ Ketone Testing | ⑬ Glucose Testing |
| ⑥ Test Result | |
| ⑦ Measuring Mode | |
| ⑧ Day Average | |

Test Strip



1. Absorbent Hole

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

2. Confirmation Window

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

3. Test Strip Handle

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

4. Contact Bars

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



ATTENTION:

The front side of test strip should face up when inserting test strip.

Test results might be wrong if the contact bar is not fully inserted into the test slot.

NOTE:

- The **FORA 6 Connect** Multi-Functional Monitoring System should only be used with **FORA 6 Connect** Test Strips. Using other test strips with this monitoring system can produce inaccurate results.

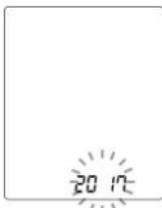
Setting the Meter

Before using your meter for the first time or if you change the meter battery, you should check and update these settings. Make sure you complete the steps below and have your desired settings saved.



Entering the Setting Mode

Start with the meter off (no test strip inserted). Press **UP** and **DOWN** buttons at the same time to enter Setting Mode.



1. Setting the date

With the year flashing, press **UP/DOWN** button until the correct year appears. Press **MAIN**.



With the month flashing, press **UP/DOWN** button until the correct month appears. Press **MAIN**.

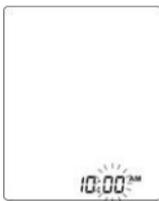


With the day flashing, press **UP/DOWN** button until the correct day appears. Press **MAIN**.

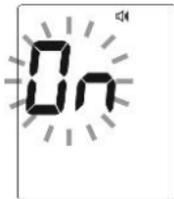


2. Setting the time

With the hour flashing, press **UP/DOWN** button until the correct hour appears. Press **MAIN**.



With the minute flashing, press **UP/DOWN** button until the correct minute appears. Press **MAIN**.



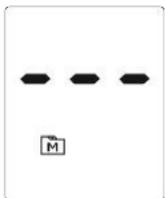
3. Setting the beep

With the speaker symbol displayed, press **UP/DOWN** to select “On” or “OFF”. Press **MAIN**.



4. Deleting the memory

With “dEL” and “” on the display, press **UP** button and select “no” to keep the results in memory then press **MAIN** to skip.



To delete all the results, press **UP** button and “yes” and “” will be displayed on the meter, press **MAIN** to delete the memory.



After the set-up is complete, “OFF” will be displayed before shut down.

Congratulations! You have completed all settings!

NOTE:

- These settings can **ONLY** be changed in the setting mode.
- If the meter is idle for 2 minutes during the setting mode, it will switch off automatically.

MEASURING MODES

Three Measuring Modes for Blood Glucose Testing

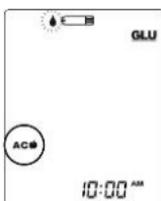
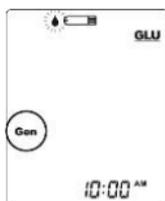
The meter provides you with three modes for blood glucose testing: General, AC, and PC.

MODES	USE WHEN
General tests (GEN)	any time of day without regard to time since last meal
AC	no food intake for at least 8 hours
PC	2 hours after a meal

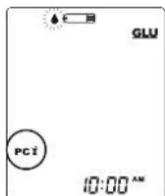


You can switch between each mode by:

1. Start with the meter switched off. Insert a test strip to turn on the meter. The screen will display: "🩸" and "GLU".



2. Press **UP** button to switch between General, AC, and PC modes.



One Measuring Mode for Blood Ketone Testing

The meter provides you with one mode for blood ketone testing:
General.

MODE	USE WHEN
General (GEN)	any time of day without regard to time since last meal

You can enter general mode by:

Start with the meter switched off. Insert a ketone test strip to turn on the meter. The screen will display: “” and “KETONE”.

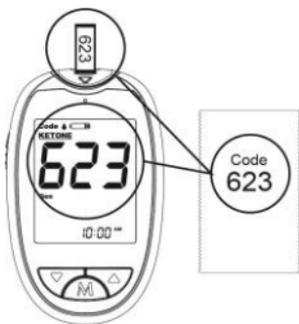


BEFORE TESTING

Calibration for Ketone Testing

You must calibrate the meter every time you begin to use a new vial of β -Ketone test strips by setting the meter with the correct code. Test results may be inaccurate if the code number displayed on the monitor does not match the number printed on the strip vial.

How to Code Your Meter (β -Ketone test)



- 1.** Insert the code strip when the monitor is off. Wait until the code number appears on the display.

NOTICE:

- Make sure the code number on display, code strip, and the individual foil package are the same. The code strip should be within the expiration date; otherwise, an error message may appear.

- 2.** Remove the code strip, the display will show "OK". This tells you that the meter has finished coding and is ready for a β -ketone test.

Checking the Code Number (β -Ketone test)



You need to make sure that the code number displayed on the meter matches the number on the test strip vial before you proceed. If it matches, you can proceed with your test. If the codes do not match, please stop testing and contact Customer Service for help.

NOTICE:

- The code number on this image is only for reference, it may not be actual code for this meter.

WARNING:

- It is important to make sure that the displayed code is the same as the code on the test strip vial before testing. Failure to do so will get inaccurate results.
- The code number for β -Ketone strip is three-digits; please ensure you are using the correct strips for the test.
- If the displayed code is not the same as the code on the test strip vial, and the code number cannot be updated, please contact Customer Service for assistance.

Control Solution Testing

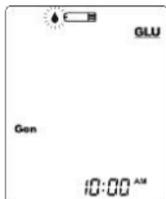
Our control solutions contain a known amount of glucose that reacts with test strips and that are used to ensure your meter and test strips are working together correctly.

Test strips, control solutions, or sterile lancets may not be included in the kit (please check the contents on your product box). They can be purchased separately. Please make sure you have those items needed for a blood glucose test beforehand.

Do a control solution test when:

- you first receive the meter,
- at least once a week to routinely check the meter and test strips,
- you begin using a new vial of test strips,
- you suspect the meter or test strips are not working properly,
- your blood glucose or β -ketone test results are not consistent with how you feel, or if you think the results are not accurate,
- practicing the testing process, or
- you dropped or think you have damaged the meter.

Performing a Control Solution Test

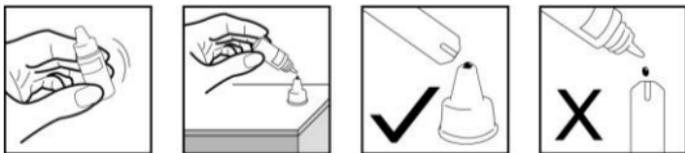


1. Insert the test strip to turn on the meter

Insert a test strip into the meter. Wait for the meter to display a flashing “”.



2. Apply control solution

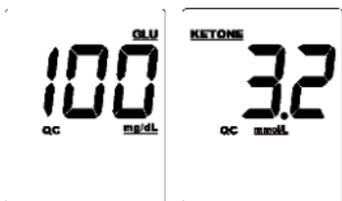


Shake the control solution vial thoroughly before use. Squeeze out a drop and wipe it off, and then squeeze out another drop and place it on the tip of the vial cap. Hold the meter in an angled position so that the absorbent hole of the test strip touches the drop. Once the confirmation window fills completely, the meter will begin counting down. To avoid contaminating the control solution, do not directly apply control solution onto the strip.

3. Read and compare the results

After the meter counts to 0, the result of the control solution test will appear. Compare the result with the range printed on the test strip vial. The result should fall within this range. If not, please read the instructions again and repeat the control solution test.

With “QC” displayed, the meter will store your test result in memory under “QC”.



Out-of-range results

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

NOTE:

- The control solution range printed on the test strip vial is for control solution use only. It is not a recommended range for your blood glucose or β -ketone level.
- See the **MAINTENANCE** section for important information about your control solutions.

TESTING WITH A BLOOD SAMPLE

WARNING:

To reduce the chance of infection:

- Never share a lancet or the lancing device.
- Always use a new, sterile lancet. Lancets are for single use only.
- Avoid getting hand lotion, oils, dirt, or debris in or on the lancets and the lancing device.
- Wash and dry your hands thoroughly after handling the meter, lancing device and test strips to prevent infection. For more information, please refer to the **MAINTENANCE** section.
- If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be decontaminated prior to use by the second person.

Sharing the lancing device and lancets may increase the risk of spreading infectious diseases. Lancing device must not be used on more than one person.

Preparing the Lancing Device for Blood Testing

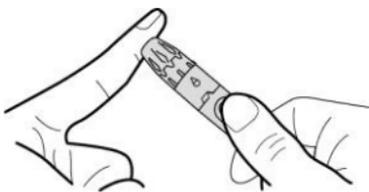
Please refer to the manufacturer's instructions for the lancing device to collect a blood sample.

Preparing the Puncture Site

Stimulating blood perfusion by rubbing the puncture site before blood extraction significantly reduces variations between measurements.

Please follow the suggestions below before obtaining a drop of blood:

- **Wash and dry your hands before starting.**
- Select the puncture site on fingertips.
- Rub the puncture site for about 20 seconds before penetration.
- Clean the puncture site using cotton moistened with 70% alcohol and **let it air dry.**



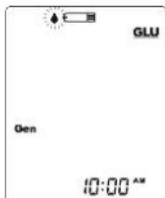
► Fingertip testing

Hold the lancing device firmly against the lower side of your fingertip. Press the release button to puncture your finger; you will hear a click indicating that the puncture is complete.

NOTE:

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

Performing a Blood Glucose or β -ketone Test

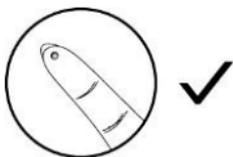


1. Insert the test strip to turn on the meter

Wait for the meter to display "GLU"/"KETONE" and "🩸".

2. Select the appropriate measuring mode by pressing the Main button

For selecting the measurement mode, please refer to "MEASURING MODES".

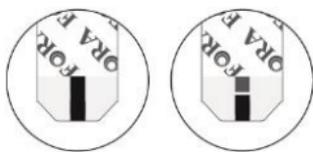


3. Obtaining a blood sample

Use the pre-set lancing device to puncture the desired site. Wipe off the first appeared drop of blood with a clean cotton swab. The size of the drop should be at least 0.5 microliter (μL) for a blood glucose test or 0.8 microliter (μL) for a blood ketone test. Gently squeeze the punctured area to obtain another drop of blood. Be careful **NOT** to smear the blood sample.

4. Bring strip to sample

While holding the meter in an angled position with the strip facing down, gently bring the strip to the sample so that the absorbent hole can sip in the blood.



Confirmation window should be completely filled if enough blood sample has been applied. Do **NOT** remove your finger until you hear a beep sound.

NOTE:

- Do not press the punctured site against the test strip or try to smear the blood.
- If you do not apply a blood sample within 2 minutes, the meter will automatically turn off. You must remove the test strip and insert it back into the meter to start a new test.
- The confirmation window should be filled with blood before the meter begins to count down. **NEVER** try to add more blood to the test strip after the drop of blood has moved away. **Discard the used test strip and retest with a new one.**

- If you have trouble filling the confirmation window, please contact your health care professional or local customer service for assistance.



5. Read your result

The result of your test will appear after the meter counts down to 0. The result will be stored in the memory automatically.

6. Eject the used test strip

Eject the test strip by pushing the eject button on the side. Dispose of the used test strip in a sealed trash container or one that's out of the reach of pets or children. The meter will switch itself off automatically.



Take the lancet out carefully. Place the disk on a hard surface and push the exposed tip into the protective disk.

When removing the lancet, follow the instructions from the lancing device insert.

WARNING:

- The used lancet and test strip may be biohazardous. Please discard them properly.
- Wash and dry your hands thoroughly after handling the meter, lancing device and test strips to prevent infection. For more information, please refer to the **MAINTENANCE** section.

METER MEMORY

Your meter stores the 1,000 most recent test results with date and time in its memory. To enter the meter memory, **start with the meter switched off.**

Reviewing Test Results



- 1. Press and release the MAIN button**
“M” will appear on the display. The first reading you see is the last testing result along with date, time and the measurement mode.
- 2. Press the UP/DOWN button** to recall the test results stored in the meter. Press and hold the **MAIN** button again and the meter will be turned off.

Reviewing Day Average Results



1. Press and release the **DOWN** button

Your 7 day average result measured in general mode will appear on the display.

2. Press the **UP/DOWN** button to review

14, 21, 28, 60 and 90 day average results stored in each measuring mode.

3. Exit the meter memory

Keep pressing the **MAIN** button and the meter will turn off.

NOTE:

- Any time you wish to exit the memory, hold the **MAIN** button for 5 seconds or leave the meter idle for 2 minutes. The meter will turn off automatically.
- Control solution results are **NOT** included in the day average.
- If there are no records in memory, “—” displays when you recall the test results or review the average results.

DOWNLOADING THE RESULTS

Data Transmission via Bluetooth

You can transmit your measurement data from the meter to an App on your mobile device via Bluetooth signal. Please note that you must first pair your meter to your mobile device before attempting to transmit any data. Please contact customer service or the place of purchase for further assistance.

Pairing with your mobile device

1. Start with the meter switched off. Insert a test strip to turn on the meter. Wait for the screen displays "▲" and the Bluetooth indicator starts to flash. Remove and dispose of the test strip. You can also activate Bluetooth function by entering Memory Mode when memory is not empty. Press and release the **M** to enter the memory mode then the Bluetooth indicator will flash.
2. On your mobile device, turn on the Bluetooth function and follow the instruction on the App to pair the device (e.g., Search for meter, and Pair).
3. After successfully pairing the APP to your meter, the Bluetooth function on the meter will then start to transmit the data to your APP.

Bluetooth indicator on the meter

BLUETOOTH INDICATOR	STATUS
Flashing Blue	The Bluetooth function is enabled and waiting for connection.
Solid Blue	The Bluetooth connection is established.

NOTE:

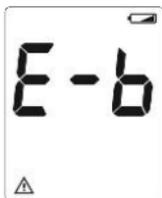
- While the meter is in transmission mode, it will be unable to perform a test.
- Make sure that your Bluetooth enabled device has turned on the Bluetooth signal prior to transmitting the data, and that the meter is within range.
- For OS version requirements please refer to the app description on the Apple App Store or Google Play Store.
- A compatibility issue between your mobile device and the meter might occur due to the way Bluetooth functionality is implemented by the various mobile device manufacturers.

MAINTENANCE

Battery

Your meter comes with one 1.5V AAA size alkaline battery.

Low Battery Signal



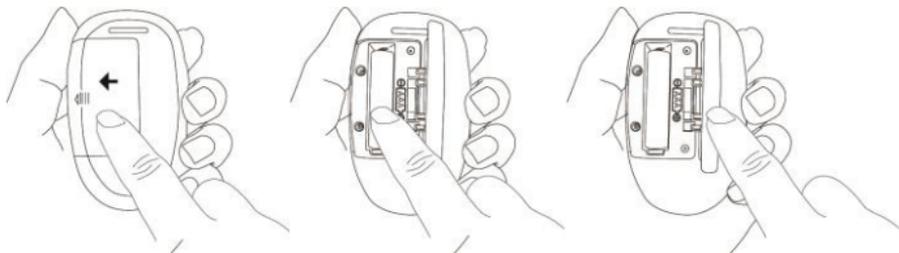
The meter will display the message below to alert you when the meter power is getting low.

The “” appears with E-b and low:

The power is not enough to do a test. Please change the battery immediately.

Replacing the Battery

To replace the battery, make sure that the meter is turned off.



1. Press the edge of the battery cover and lift it up to remove.
2. Remove the old battery and replace it with one 1.5V AAA size alkaline battery.
3. Close the battery cover. If the battery is inserted correctly, you will hear a “beep” afterwards.

NOTE:

- Replacing the batteries does not affect the test results stored in the memory.
- As with all small batteries, these batteries should be kept away from children. If swallowed, promptly seek medical assistance.
- Batteries might leak chemicals if unused for a long time. Remove the batteries if you are not going to use the device for an extended period (i.e., 3 months or more).

- Properly dispose of the batteries according to your local environmental regulations.
- After replacing batteries, the meter will enter the setting mode.

Caring for Your Meter

To avoid the meter and test strips attracting dirt, dust or other contaminants, please wash hands thoroughly with soap and water before and after use.

What is Cleaning and Disinfection?

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

When to clean and disinfect the meter?

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

How to clean and disinfect the meter?

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

We recommend for meter cleaning and disinfection you should use the disinfecting wipe/towelette from below. The following product has been shown to be safe for use with the **FORA 6 Connect** Multi-Functional Monitoring System.

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

To obtain disinfecting wipes and other information, please contact Medline at 1-800-MEDLINE (1-800-633-5463) or visit

www.medline.com.

Disinfecting Procedures



- 1.** Take out one disinfecting wipe from the package and squeeze out any excess liquid in order to prevent damage to the meter.
- 2.** Wipe all meter's exterior surface display and buttons. Hold the meter with the test strip slot pointing down and wipe the area around the test slot but be careful not to allow excess liquid to get inside. Keep the meter surface wet with disinfection solution for a minimum of 2 minutes for Micro-Kill+™ wipes. Follow the instructions on the package label of disinfecting wipe. Use two or more wipes if necessary.
- 3.** Remove the wipe. Allow the meter surface to dry completely.
- 4.** Discard the used wipes and never reuse them. Wash your hands thoroughly with soap and water after handling the meter, lancing device and test strips to avoid contamination.

Improper system cleaning and disinfection may result in meter malfunction. If you have a question, please contact customer service at 1-888-307-8188 for assistance.

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

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

- Meter cannot be turned on
- LCD display cracks or becomes cloudy
- Buttons no longer function
- Meter outer casing cracks
- Data cannot be transmitted
- Color or paint/printing on housing is abnormal
- Scratches or abrasions on meter are higher than acceptable

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

NOTE:

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

Meter Storage

- Storage conditions: -4 °F to 140 °F (-20 °C to 60 °C), below 95% relative humidity.
- Always store or transport the meter in its original storage case.
- Avoid dropping and heavy impact.
- Avoid direct sunlight and high humidity.

Caring for Your Test Strips

- Storage conditions: 35.6°F to 86.0°F (2°C to 30°C), 10% - 90% R.H. for blood glucose test strips; 35.6°F to 86.0°F (2°C to 30°C), 10% - 85% R.H. for blood β -Ketone test strips. Do **NOT** freeze.
- Store your test strips in their original vial only. Do not transfer to another container.
- Store test strip packages in a cool dry place. Keep away from direct sunlight and heat.
- After removing a test strip from the vial, immediately close the vial cap tightly.
- Touch the test strip with clean and dry hands.
- Use each test strip immediately after removing it from the vial.
- Write the opening date on the vial label when you first opened it.
- Discard remaining test strips after expiration.
- Do not use test strips beyond the expiration date. This may cause inaccurate results.
- Do not bend, cut, or alter a test strip in any way.
- Keep the strip vial away from children since the cap and the test strip may be a choking hazard. If swallowed, promptly see a doctor for help.

For further information, please refer to the test strip package insert.

Important Control Solution Information

- Use only FORA control solutions with your meter.
- Do not use the control solution beyond the expiration date or 3 months after first opening. Write the opening date on the control solution vial and discard the remaining solution after 3 months.
- It is recommended that the control solution test be done at room temperature 68°F to 77°F (20°C to 25°C). Make sure your control solution, meter, and test strips are at this specified temperature range before testing.
- Shake the vial before use, discard the first drop of control solution, and wipe off the dispenser tip to ensure a pure sample and an accurate result.
- Store the control solution tightly closed at temperatures between 35.6°F to 86°F (2°C to 30°C). Do **NOT** freeze.

SYSTEM TROUBLESHOOTING

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

Result Readings

Glucose Test

MESSAGE	WHAT IT MEANS
Lo	Appears when your blood glucose test result is below the lower measurement limit, which is less than 10 mg/dL (0.55 mmol/L).
Hi	Appears when your result is higher than the limit of measurement, which is higher than 600 mg/dL (33.3 mmol/L).

β -Ketone test

MESSAGE	WHAT IT MEANS
Lo	Appears when your β -Ketone test result is below the lower measurement limit, which is less than 0.1 mmol/L.
Hi	Appears when your result is higher than the limit of measurement, which is higher than 8.0 mmol/L.

Error Messages

MESSAGE	WHAT IT MEANS	WHAT TO DO
E-b	Appears when the batteries cannot provide enough power for a test.	Replace the batteries immediately.
E-2	Expired code strip.	Repeat the test with a new lot of test strip.
E-U	Appears when a used test strip is inserted.	Repeat with a new test strip.
E-E E-O E-A	Problem in operation.	Repeat the test with a new test strip. If the meter still does not work, please contact the customer service for assistance.
E-F	Appears when test strip is removed while counting down.	Repeat the test with a new test strip.
E-C	Appears when the wrong code strip is inserted or other coding errors.	Make sure to insert the right code strip for the meter. Check if the code numbers on the code strip and the strip vial label are the same.
E-t	Appears when ambient temperature is below or above system operation range.	System operation range is 46.4°F to 113°F (8°C to 45°C). Repeat the test after the meter and test strip are in the above temperature range.

Troubleshooting

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

POSSIBLE CAUSE	WHAT TO DO
Battery exhausted.	Replace the battery.
Test strip inserted upside down or incompletely.	Insert the test strip with contact bars end first and facing up.
Defective meter or test strips.	Please contact customer service.

2. If the test does not start counting down after applying the sample:

POSSIBLE CAUSE	WHAT TO DO
Defective test strip.	Repeat the test with a new test strip.
Sample applied after automatic switch-off (2 minutes after last user action).	Repeat the test with a new test strip. Apply sample only when flashing “  ” appears on the display.
Defective meter.	Please contact customer service.

3. If the control solution testing result is out of range:

POSSIBLE CAUSE	WHAT TO DO
Error in performing the test.	Read instructions thoroughly and repeat the test again.
Control solution vial was poorly shaken.	Shake the control solution vigorously and repeat the test again.
Expired or contaminated control solution.	Check the expiration date of the control solution.
Control solution that is too warm or too cold.	Control solution, meter, and test strips should be at room temperature (68°F to 77°F / 20°C to 25°C) before testing.
Defective test strip.	Repeat the test with a new test strip.
Meter malfunction.	Please contact customer service.

DETAILED INFORMATION

Reference Values

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

Time of day	Normal plasma glucose range for people without diabetes (mg/dL)
Fasting and before meal	< 100 mg/dL (5.6 mmol/L)
2 hours after meals	< 140 mg/dL (7.8 mmol/L)

*¹: American Diabetes Association. Standards of medical care in diabetes- 2016; 39 (supp.1 Diabetes Care): S16.

The β -Ketone test measures Beta-Hydroxybutyrate (β -OHB), the most important of the three β -Ketone bodies in the blood. Normally, levels of β -OHB are expected to be less than 0.6 mmol/L.

β -OHB levels may increase if a person fasts, exercises vigorously or has diabetes and becomes ill. If your β -Ketone result is “Lo”, repeat the β -Ketone test with new test strips. If the same message appears again or the result does not reflect how you feel, contact your healthcare professional. Follow your healthcare professional’s advice before you make any changes to your diabetes medication programme. If your β -Ketone result is between 0.6 and 1.5 mmol/L, this may indicate development of a problem that could require medical assistance. Follow your healthcare professional’s instructions. If your β -Ketone result is higher than 1.5 mmol/L, contact your healthcare professional promptly for advice and assistance. You may be at risk of developing diabetic ketoacidosis (DKA).

Please work with your doctor to determine a target range that works best for you.

Comparing Meter and Laboratory Results

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

Before going to the lab:

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

While staying at the lab:

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

- Wash your hands before obtaining a blood sample.
- Never use your meter with blood that has been collected in a gray-top test tube.
- Use fresh capillary or venous blood only.

You may still have a variation from the result because blood glucose or β -ketone levels can change significantly over short periods of time, especially if you have recently eaten, exercised, taken medication or experienced stress*². In addition, if you have eaten recently, the blood glucose level from a finger prick can be up to 70 mg/dL (3.9 mmol/L) higher than blood drawn from a vein (venous sample) used for a lab test*³.

Therefore, it is best to fast for eight hours before doing comparison tests. Factors such as the amount of red blood cells in the blood (a high or low hematocrit) or the loss of body fluid (dehydration) may also cause a meter result to be different from a laboratory result.

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

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

SPECIFICATIONS

Model No.: FORA 6 Connect

Dimension: 89.8 (L) x 54.9 (W) x 18 (H) mm

Weight: 46.1 g (without battery)

Power Source: one 1.5V AAA alkaline battery

Display: LCD

Memory: 1,000 measurement results with date and time

External Output: Bluetooth

Automatic detection of electrode insertion

Automatic reaction time count-down

Temperature warning

Auto turn-off after 2 minutes without action

Operating Condition:

46.4°F to 113°F (8°C to 45°C), 10% to 85% R.H. (non-condensing)

Meter Storage/Transportation Conditions:

-4°F to 140°F (-20°C to 60°C), below 95% R.H.

Glucose Test Strip Storage / Transportation Conditions:

35.6°F to 89.0°F (2°C to 30°C), 10% to 90% R.H. (non-condensing)

Glucose Measurement Units: mg/dL

Glucose Measurement Range: 10 to 600 mg/dL (0.55 to 33.3 mmol/L)

β-Ketone Test Strip Storage / Transportation Conditions:

35.6°F to 86.0°F (2°C to 30°C), 10% to 85% R.H. (non-condensing)

β-ketone Measurement Units: mmol/L

β-ketone Measurement Range: 0.1 ~ 8.0 mmol/L

This device has been tested to meet the electrical and safety requirements of: IEC/EN 61010-1, IEC/EN 61010-2-101, EN 61326-1, and EN 61326-2-6.

FEDERAL COMMUNICATIONS COMMISSION (FCC) STATEMENT

15.21

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

15.105(b)

Federal Communications Commission (FCC) Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more 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 15 of the FCC Rules. Operation is subject to the following two conditions:

- 1) This device may not cause harmful interference and
- 2) This device must accept any interference received, including interference that may cause undesired operation of the device.

FCC RF Radiation Exposure Statement:

- 1) This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
- 2) This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 centimeters between the radiator and your body.

FORA[®] 6 *Connect*

For Self-Testing. Read instructions before use.
Para automonitoreo. Lea las instrucciones antes de utilizarse.

Distributed by ForCare, Inc. / Distribuido por ForCare, Inc.

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Products made in Taiwan / Productos hechos en Taiwán

Toll Free / Número de Teléfono Gratuito : 1-888-307-8188

(8:30 am-5:00 pm PST, Monday to Friday / 8:30 am-5:00 pm PST, Lunes a Viernes)

For assistance outside of these hours, please contact your healthcare professional. /

Para obtener asistencia fuera de estos horarios, póngase en contacto con un profesional de la salud.

www.foracare.com