

# FORA V10 BLOOD GLUCOSE MONITORING SYSTEM

English

311-4244100-016 Version 5.0 2010/07 Thank you for choosing

# FORA V10 BLOOD GLUCOSE MONITORING SYSTEM

Dear FORA V10 System Owner:

This product can assist you in monitoring your blood glucose level. Please visit our website <u>www.foracare.com/usa</u> to view other updated instructions or product information.

This manual contains important information you must know about the system. Please read it thoroughly and carefully.

The most unique feature of this system is its **speaking function**, which is an audible aid for users, especially those with visual impairment.

Another unique feature of this system is its no code function, which means that there is no need to calibrate your meter. You just simply insert the test strip into the meter and begin the test.

For other questions regarding this system, please contact our customer service team at 1-888-307-8188, 1-866-469-2632. You can also visit <u>www.foracare.com/usa</u> for helpful information.

## IMPORTANT SAFETY INSTRUCTIONS READ THIS BEFORE USE

The following basic safety precautions should always be taken.

- 1. Close supervision is necessary when the device is used by, on, or near children, handicapped persons or invalids.
- 2. Use the device only for the intended use described in this manual.
- Do not use accessories which are not supplied by the manufacturer.
- 4. Do not let the device or its cord come into contact with surfaces that are hot to the touch.
- 5. Do not use the device near aerosol sprays, or where oxygen is being administered.
- 6. Do not use device if it is not working properly, or if it had suffered any damages.
- Read all instructions thoroughly and practice the test before using the product to test your blood glucose. Do all quality control checks as directed and consult with a diabetes healthcare professional.

## **KEEP THESE INSTRUCTIONS**

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## 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 results are lower or higher than usual, and you do not have symptoms of illness, first repeat the test. If you have symptoms or continue to get results higher or lower than usual, follow the treatment advice of your healthcare professional.
- Use only capillary whole blood sample to test your blood glucose. Using other substances will cause wrong results.
- If you are experiencing symptoms that are inconsistent with your blood glucose test results and you have followed all instructions described in this owner's manual, call your healthcare professional.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock. Readings which are lower than actual values may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.
- Please refer to your test strip package insert for additional important information.

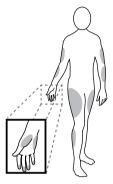
## Alternative Site Testing (AST)

Important: AST results serve as references only.

Please consult your healthcare professional before you begin AST.

## What is AST?

Alternative site testing (AST) refers to when individuals check their blood glucose levels using areas of the body other than the fingertip. This system allows AST at the palm, the forearm, the upper arm, the calf or the thigh with results as reliable as those obtained from fingertip testing.



## What's the advantage?

Fingertips feel pain more readily because they are full of nerve endings (receptors). Since nerve endings are not so condensed at other body sites, tests performed there will be less painful.

## When to use AST?

Food, medication, illness, stress and exercise can affect blood glucose levels.

Capillary blood at the fingertip reflects these changes faster than capillary blood at other sites. Therefore, when testing blood glucose during or immediately after a meal or physical exercise, results from AST and fingertip may be significantly different. We strongly recommend you do AST in the following intervals:

- · In a pre-meal or fasting state (more than 2 hours since the last meal).
- Two hours or more after taking insulin.
- Two hours or more after exercise.

## Do NOT use AST if:

- · You think your blood glucose is low.
- · You are unaware of hypoglycemia.
- · You are testing for hyperglycemia.
- · Your AST results do not correspond with the way you feel.
- · Your routine glucose results are often fluctuating.

## How to increase the accuracy?

Stimulating blood perfusion by rubbing the puncture site prior to blood extraction has a significant influence on the glucose value obtained. Blood from a site that has not been rubbed exhibits a measurably different glucose concentration than blood from the finger. When the puncture site is rubbed prior to blood extraction, the difference is markedly reduced.

## Please follow suggestions below before puncturing the skin:

- · Rub the puncture site approximately 20 seconds before penetration.
- · Use a clear cap (included in the kit) while setting the lancing device.

## INTRODUCTION TO THE SYSTEM

## Intended Use

The system is intended for use outside the body (in vitro diagnostic use). It should be used only for testing glucose (sugar) and only with fresh capillary whole blood samples (from the finger, the palm, the forearm, the upper arm, the calf and the thigh). The system is intended for use in the home and in clinical settings. It should not be used for the diagnosis of diabetes or for the testing of newborns.

AST in this system can be used only during steady-state blood glucose conditions described in the section of "About Alternative Site Testing (AST)."

## Principle of Measurement

The test is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the strip. The meter measures the current and displays the corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

## Contents of the System

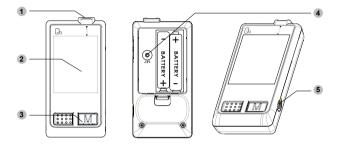
The system consists of three main products: the blood glucose meter, test strips, and a control solution. These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. Use only the FORA V10 test strips and FORA brand control solution with the blood glucose meter.

Your system includes:



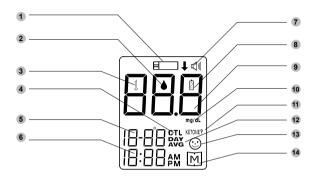
## PLEASE NOTE

- If your system was opened prior to use or it did not contain all the parts listed above, please return your system to the place of purchase.
- Control solutions, lancing device, and lancets are optional. They are not included in the standard kit. Please contact the Customer Care Line at 1-888-307-8188, 1-866-469-2632 or place of purchase for availability.
- 3. Only use the **FORA V10 Blood Glucose Test Strip** with this meter for accurate measurement results.



- TEST SLOT is where you insert the test strip. The meter will turn on automatically after insertion.
- LCD SCREEN guides you through the test using symbols and simple messages.
- MAIN BUTTON located in front of the meter with "M" on it, is used to turn on the meter, enter the memory mode and control steps of setting.
- SET BUTTON (in the back) located in the battery compartment, is used to set up the meter.
- **5 DATA PORT** located at the side, is for cable connection.

## Meter Display



1 TEST STRIP SYMBOL Appears when the meter is turned

on.

- 2 BLOOD DROP SYMBOL Flashes when it is ready to apply the sample.
- 3 TEMPERATURE SYMBOL Appears when ambient temperature is outside operating temperature.
- 4 CTL SYMBOL

Appears when doing a control test and indicates that the result won't be stored in the memory.

- 5 DATE
- 6 TIME

#### 7 VOICE SYMBOL

Indicates speaking function is on/off.

- 8 LOW BATTERY SYMBOL Appears when the battery power is low.
- TEST RESULT AREA Displays glucose results.
- **10 UNIT OF MEASUREMENT**
- **10 KETONE WARNING**

Appears when the test result is equal or higher than 240mg/dL(13.3mmol/L).

#### 12 DAY AVERAGE

Indicates that the displayed test result is an average.

#### **13 FACE SYMBOL**

Appears when memory deletion completed.

#### **14 MEMORY SYMBOL**

Appears when you review the memory.

## Speaking Function

FORA V10 "speaks" aloud step by step instructions to guide you through the process of blood glucose testing. The following table tells you when and what the meter "speaks".

WHEN does the meter speak?	WHAT does the meter speak?	
When you insert the strip into the meter.	Thank you for using this product. Please relax during measurement.	
When room temperature is outside op- erating range, which is 50-104°F(10- 40°C).	Room temperature out of range, unable to measure.	
When the meter is ready to test. (symbol appears on display)	Please apply blood into the strip.	
When the test is completed. (result appears on display)	The blood glucose is (number) milligram per deciliter.	
When the test result is outside measurement range, which is 20-600 mg/dL(1.1-33.3 mmol/L).	The blood glucose out of range, unable to measure.	



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



## Absorbent Hole

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

# <sup>2</sup> Confirmation Window

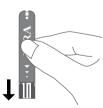
This is where you confirm if enough blood has been applied to the absorbent hole in the strip.

## Test Strip Handle

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

## Contact Bars

Insert this end of the test strip into the meter. Push it in firmly until it will go no further.



## ATTENTION:

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

## NOTE

The **FORA V10** monitor should only be used with **FORA V10** Test Strips. Using other test strips with this meter can produce inaccurate results.

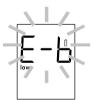
## **BEFORE USE**

## **Battery Replacement**

Your meter comes with two 1.5V AAA alkaline batteries. The meter will alert you when the power is low by displaying two different messages:



1. With **battery exhausted symbol** appears on the display: the meter is functional and the result remains accurate, but battery should be replaced.

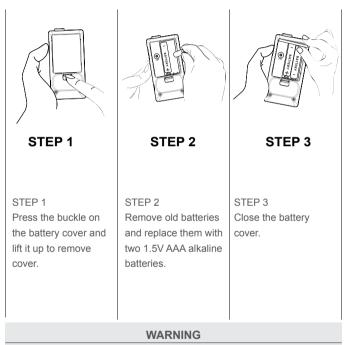


2.With **battery exhausted symbol** [], low and E-b symbols on the display: the batteries can not provide enough power for a test. You must replace the batteries immediately.

## PLEASE NOTE

- 1. Replacing the batteries does not affect the meter's memory (previous test results stored in memory). The time and date settings may need to be updated.
- 2. Batteries might leak chemicals if not used 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).

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



As with all small batteries, these batteries should be kept away from small children. If they are swallowed, promptly see a doctor for help.

## Setting the Meter and Deleting the Memory

Your meter comes with the time, date, memory deletion, voice volume and language preset. If you need to change the time or replace the batteries, you may have to enter the setting mode and reset.

# Please set the time, date, memory deletion, voice volume and language according to the following steps.

To set the time, you must first enter the setting mode. Start with the meter off. Then press the set button located in the battery compartment. The meter is now in the setting mode.

#### STEP 1 Set the Year

The year appears first, with the number flashing. Press and release the M button to advance one year. To move faster, hold the M button down. With the correct year on the display, press the set button and the date will appear on the display with the month flashing.



#### STEP 2 Set the Month

Press and release the M button until the correct month appears. To move faster, hold the M button down. With the correct month on the display press the set button and the date will start flashing.



#### STEP 3 Set the Date

Press and release the M button until the correct date appears. To move faster, hold the M button down. With the correct date on the display, press the set button and the time will appear on the display with the hour flashing.

## STEP 4 Set the Hour

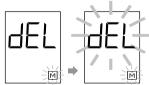
Press and release the M button to advance one hour. To move faster, hold the M button down. With the correct hour on the display press the set button and the minute will start flashing.

## STEP 5 Set the Minutes

Press and release the M button to advance one minute. To move faster, hold the M button down. With the correct minute on the display, press the set button and the memory deletion will start flashing.

## **STEP 6 Delete Memory**

"dEL" and flashing " M " symbol appear on the display. If you didn't want to delete memory, press the set button again to skip this step. If you'd like to delete ALL memory, press M button. Both "dEL" and " m " will flash. Press the M button again to delete all memory. The meter then displays " (2) ", which means that the memory has been deleted.









- The time, date, memory deletion, voice volume and language can ONLY be changed in the setting mode. Therefore, while performing a blood glucose, these parameters cannot be changed.
- Your meter displays 7-, 14-, 21-, 28-, 60- and 90-day averages which you can access from the meter memory. These averages are calculated from results obtained during the 7-, 14-, 21-, 28-, 60-and 90-days preceding the current date and time settings. When the date and time are changed, the 7-, 14-, 21-, 28-, 60- and 90-day averages may change as well.
- 3. If the meter is at the setting mode, and if there is no button pressed for 3 minutes, the meter will turn off automatically.

## **STEP 7 Select Speaking Function**

The meter displays "VOL", " I and flashing number. Press M button to select speaking volume from 0 to 7. Then press the set button to proceed to the next step.

Number 0 indicates that the speaking function is turned off. " I will not display on LCD during testing. Numbers 1 to 7 indicates speaking volume from low to high. At this time " I will be displayed on LCD during test.

## **STEP 8 Select Language**

L1 (English) or L2 (Spanish) and " I display on LCD. Press the M button to select one of the two languages.

After the set-up is complete, press the set button to turn off the meter. "OFF" will be displayed before shut down.

Congratulations! You have finished all settings now!

# 10 1





## Control Test

**FORA** control solution contains a known amount of glucose that reacts with test strips. By comparing your control solution test results with the expected range printed on the test strip vial label, you can ensure that the meter and the test strips are working together as a system and that you are performing the test correctly. It is very important that you do this simple check routinely to make sure your results are accurate.

#### How often should the control solution test be performed?

- When you use this system to test your blood for the first time, practice the procedure using control solution. When you can do three tests in a row that are within the expected range, you are ready to test your blood.
- To routinely check the meter and test strips, perform a single test for each level of control solution at least once a week.

#### When should the control solution test be performed?

- ► When you first get your meter.
- ► When you begin using a new vial of test strips.
- Whenever you suspect that the meter or test strips are not working properly.
- When your blood glucose test results are inconsistent with how you feel, or when you think your results are inaccurate.
- ► When your test strips are exposed to extreme environmental conditions (See section TAKING CARE OF YOUR METER & STRIP ).
- ► When you want to practice running the test.
- ▶ If you drop the meter.

## Important Control Solution Test Information

- Use only FORA control solutions. Check the expiration date on the control solution vial. Do not use if expired.
- Control solution, meter, and test strips should be at room temperature, 68-77°F (20-25°C), before testing.
- Shake the vial before use. Discard the first drop of control solution. After squeezing, wipe off the dispenser tip to avoid contamination. The above tips ensure you to get a clean sample and an accurate result.
- ► Use only 3 months after the first opening date. Record the discard date (date opened plus 90 days) on the control solution vial. Discard the vial after 90 days.
- Store the control solution with lid tightly closed at temperatures 36-86°F (2-30°C). Do not freeze.

#### PLEASE NOTE

The control solution range is printed on FORA test strip vial. Only use FORA control solution with FORA test strips. It is used to evaluate the meter and test strip performance. It is not a recommended range for your blood glucose level.

## Performing a Control Solution Test

#### **STEP 1 Insert Test Strip**

Fully insert the test strip, with the contact bars end first facing up into test slot. The meter will turn on automatically. "CH" and " I will appear first, followed by a flashing " • "symbol.

#### STEP 2 Press the M Button

After the symbol appears on display, press the M button so that "CTL" appears. With the "CTL" sign on the display, the meter will not store your test result in memory. If you decide not to perform a control solution test, press the M button again and the "CTL" sign will disappear.

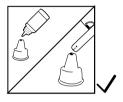


## PLEASE NOTE

- Contact bars must be inserted all the way into the meter or you may receive an inaccurate test result.
- 2. Every time you perform a control solution test, you must enter into the "CTL" test mode so that the test result will not be stored in the meter memory. Failure to do so will cause confusion between the blood glucose test result and the control solution test result in system memory.

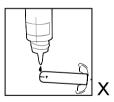
## **STEP 3 Obtain Control Solution**

Shake the control solution vial well. Remove the cap from the control solution bottle and place it on a flat surface. Squeeze the vial, discard the first drop, and wipe off the dispenser tip to prevent contamination. Squeeze the vial again to produce another drop and **place this drop on the top of cap.** 



#### **STEP 4 Apply Control Solution**

Hold the meter up to meet the absorbent hole of the test strip and the drop will be automatically absorbed. Once the confirmation window is completely filled, the meter will start counting down.



To avoid contaminating the control solution with the contents of the test strip, you will have to place a drop of control solution on a clean surface. Do not directly apply control solution to a test strip.

## **STEP 5 Result Appears in 7 Seconds**

After counting down to 0, the control solution test result will appear. Compare the result with the range printed on the test strip vial. The result should fall within this range.



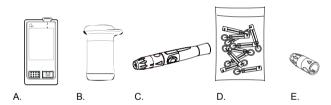
## Out-of-range results

If test results fall outside the printed range, check the "Operational Problem" section in troubleshooting guide and repeat the test. If your results continue to be out-of-range, the system may not be working properly. Do NOT test your blood. Please contact Customer Care Line at 1-888-307-8188, 1-866-469-2632 for help.

## TESTING YOUR BLOOD SUGAR

Be sure to read this section and the test strip package insert included in the test strip box carefully before testing. Make sure you have all items needed to test:

- A.Blood glucose meter
- B. Test strip
- C.Lancing device
- D.Sterile lancet
- E.Clear cap (For AST use)



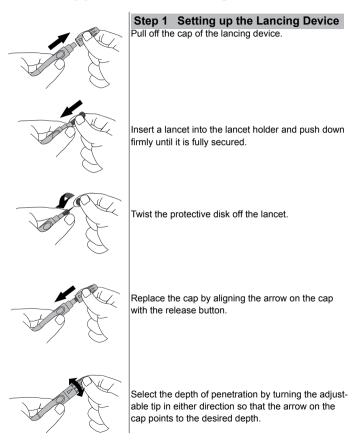
## WARNING

To reduce the possibility of infection:

- · Never share lancets 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.

**Test Procedure** 

## Wash and dry your hands before starting.





Hold your fingers on the body. Not the cap.

Pull the cocking control back until it clicks. You will see a color change inside the release button when it is ready.

If it does not click, the device may have been cocked when the lancet was inserted.

The lancing device is now ready for use. Set aside for later use.

Fully insert test strip face up with contact bars end first, into the test slot. The meter will turn on automatically and display the following in sequence: "CH" and "  $\blacksquare$  "  $\rightarrow$  flashing "  $\blacklozenge$ " with date and time.

## STEP 3 Get A Drop of Blood

Select the puncture site either at fingertips or at other parts of the body (AST). Clean the puncture site with cotton moistened with 70% alcohol and let it air dry.

#### · Fingertip Testing

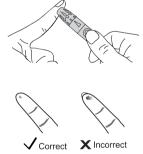
Hold the lancing device firmly against the side of your finger. Press the release button. You will hear a click, indicating that the puncture is complete.

After penetration, discard the first drop of blood with a clean tissue paper or cotton. Gently squeeze the punctured area to obtain blood. Be careful NOT to smear the blood sample. The volume of blood sample must be at least 0.7 microliters in volume (+actual size).

#### · Sites other than fingertips

Please refer to the section of "About Alternative Site Testing (AST)" for possible punctured sites.





## PLEASE NOTE

- Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.
- Before you decide to begin AST, please consult your health professional.
- It is recommended that you discard the first drop of blood as it might contain tissue fluid and serum, which may affect the test result.

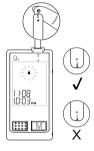
## STEP 4 Apply Blood into the Test Strip

When " **b** " is flashing on the screen, apply your blood to the absorbent hole of the test strip until the confirmation window is **fully covered** with blood. The meter will then begin to count down automatically.

## STEP 5 Obtain AN Accurate Result in 7 Seconds

The result of your blood glucose test will appear after counting down to 0. This reading will automatically be stored in the memory.





## PLEASE NOTE

- Do not push your punctured finger (with blood on it) against the test strip or try to apply a smeared blood sample to the test strip.
- If you do not apply a blood sample to the test strip within 3 minutes, the meter will automatically turn off. You must remove and reinsert the test strip to restart the test procedure.
- The blood should completely fill the confirmation window before the meter begins to count down. If you find that the confirmation window is not filled with blood when the meter is counting. NEVER try to add more blood to the test strip. Discard the test strip and retest with a new one.
- If you have trouble filling the confirmation window, contact Customer Care Line at 1-888-307-8188, 1-866-469-2632 for help.

## **STEP 6 Remove the Lancet**

# Always use caution when removing the lancet.

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



## WARNING!

The used lancet and the used test strip may be biohazardous. Please discard them carefully under your healthcare provider's instructions.

## Expected Test Results

Blood glucose 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%.<sup>1</sup> The results provided by the FORA V10 system can help you and your healthcare professional monitor and adjust your treatment plan to gain better control of your diabetes.

Time of day	blood glucose value (mg/dL) for people without diabetes	Your target range (mg/dL)
Fasting and before meal <sup>*2</sup>	<100.8 mg/dL (Whole blood)	
2 hours after meals*3	<140 mg/dL (plasma)	

your system is calibrated to be equivalent to whole blood. Convert your meter's readings to plasma values by multiplying by 1.1. <sup>\*4</sup>

\*1: American Diabetes Association position statement on the Diabetes Control and Complications Trial (1993).

\*2: Diabetes UK .Early identification of people with Type 2 diabetes. June 2006.

\*3: ADA Clinical Practice Recommendations 2003

\*4: Approved IFCC Recommendation on Reporting Results for Blood Glucose, Clinical Chemistry 51:9 1573–1576 (2005)

## 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 can be affected by factors and conditions that do not affect laboratory results in the same way. (See test strip package insert for typical accuracy and precision data, and for important information on limitations.) To make an accurate comparison between meter and laboratory results, please follow the guidelines below.

#### Before you go 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 at the lab:

Make sure that the samples for both tests (the meter test and the lab test 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 blood only.

You may still have a variation from the result because blood glucose levels can change significantly over short periods of time, especially if you have recently eaten , exercised, taken medication, or experienced stress\*<sup>5</sup>. In addition, if you have eaten recently, the blood glucose level from a finger prick can be up to 70 mg/dL higher than blood drawn from a vein (venous sample) used for a lab test.\*<sup>6</sup> 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.

#### References

\*5: Surwit, R.S., and Feinglos, M.N.: Diabetes Forecast (1988), April, 49-51.
\*6: Sacks, D.B.: "Carbohydrates." Burtis, C.A., and Ashwood, E.R.(ed.), Tietz Textbook of Clinical Chemistry. Philadelphia: W.B. Saunders Company (1994), 959.

## **USING THE METER MEMORY**

## Viewing Results on the Meter

Your meter stores 450 most recent blood glucose test results along with their repective dates and times in its memory. It also provides you with 7-, 14-, 21-, 28-, 60- and 90-day averages of your blood glucose test results. You can review these test result averages in memory through the following easy steps.

#### Read the Average of Blood Glucose Results:

When the meter is off, press and release the M button. The screen shows " M ". Keep pressing the M button for 2-3 seconds, until blinking " XX " appears. Release the M button and then the the 7-day average will appear, indicating that you are in the memory mode. If you continue to press the M button, the 14-, 21-, 28-, 60- and 90- day averages will appear in order.

When using the meter for the first time, "---" will appear to indicate that there are no test results in memory.

The 7- day average is calculated from the blood glucose results obtained during the last 7 days. It also indicates how many blood glucose tests have been performed within this period, e.g., 14 (14 tests in the last 7 days).

The 14- day average is calculated from the blood glucose results obtained during the last 14 days. It also indicates how many blood glucose tests have been performed, e.g., 28 (28 tests in the last 14 days). The same follows for the 21-, 28-, 60- and 90- day averages.







# 35

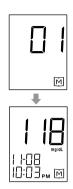
#### Recall the Stored Test Results

- When the meter is off, press and release the M button. The screen shows " M ". Press the M button again, "01" appears first and then the latest glucose result along with date and time will be shown on the screen.
- 2. Press the M button once by once to recall the test results stored in the meter consecutively.
- **3.** After the last test result, press the M button again and the meter will be turned off.

#### Exit the Memory Mode

You can also exit memory mode by pressing M button for 5 seconds to turn off the meter.

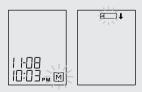




## PLEASE NOTE

• The control solution results are **NOT** stored in the memory (please refer to **NOTE** on page 23 for more information). The list of past results and the result averages are for blood glucose results only.

• When pressing the M button to recall the test results, the meter will first display date and time. If you do not press the M button within 5 seconds, the blinking " — " and "+"will appear. In the meantime, you can choose to insert a test strip to start testing your blood or press the M button again to review the stored test results.



 $\cdot$  If no button is pressed for 3 minutes, the meter will display "OFF" and turn off automatically.

## Viewing Results on a Personal Computer

Results in memory can be transmitted to a personal computer. Health Care Software System and an interface cable are required before installation.

The software can be downloaded from the home page of Fora Care Inc. An interface cable is required for data transmission, but is not included in the standard kit. To learn more about Health Care Software System or to obtain an interface cable separately, please contact Customer Care Line at 1-888-307-8188, 1-866-469-2632 for help.

### STEP 1

#### Install Software

Install Health Care Software System on your Computer by following the instructions provided on Fora Care's website, <u>www.foracare.com/usa</u>

### STEP 2

#### **Connect to Personal Computer**

Connect the interface cable to a serial port of your computer. With the meter turned off, connect the internal cable to the data port of the meter. Then "PC" will appear on the display, indicating that the meter is ready to transmit data.



#### STEP 3

#### Transmit Data

Follow the instructions to transmit data from the meter's memory to your computer. Results transmitted will include date and time. Remove the cable and the meter will automatically turn off.

### PLEASE NOTE

While the meter is connected to the PC, it is unable to perform a blood glucose test.

# TAKING CARE OF YOUR METER AND TEST STRIPS

To protect the monitor and test strips from dirt, dust and other contaminants, please wash and dry your hands thoroughly before use.

### Cleaning

- To clean the meter's exterior, wipe with a cloth moistened with tap water or a mild cleaning agent, then dry the device with a soft and dry cloth. Do not flush with water.
- 2. Do not use organic solvents to clean the meter.

### Storage

#### 1. Meter Storage



- Storage condition: -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 strong impact.
- · Avoid direct sunlight and humidity.



#### 2. Strip Storage

- Storage condition: 39.2°F to 104°F (4°C to 40°C), below 85% relative humidity. 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 and dry place. Keep away from direct sunlight and heat.
- After removing a test strip from the vial, immediately replace the vial cap and close it tightly.
- Handle the test strip with clean and dry hands.



- Use each test strip immediately after removing it from the vial.
- Write the discard date (the date opened plus 90 days) on the vial label when you first open it. Discard the vial along with remaining test strips on this date.



- Do not bend, cut, or alter a test strip in any way.
- Keep the strip vial away from children as the cap and the test strip may be choking hazardous. If swallowed, promptly see a doctor for help.



#### 3. Control solution storage

- Storage condition: Store the control solution tightly closed at temperatures 36 to 86°F (2 to 30°C). Do not freeze.
- Record the discard date (date opened plus 90 days) on the control solution vial. Discard the vial on this date.

# **TROUBLESHOOTING GUIDE**

The following is a summary of various display messages. These messages help to identify certain problems but do not always appear in all cases when a problem has occurred. Improper use may cause an inaccurate result without producing an error message. In the event of a problem, refer to the information under the row "ACTION".

Never try to disassemble the meter under any circumstances. If you encounter any error messages not listed below or if you have followed the actions recommended below but the problem persists unsolved, please call Customer Care Line at 1-888-307-8188, 1- 866-469-2632 for support.

# Risk Message

Special symbols and messages appear together with your test result.

MESSAGE	WHAT IT MEANS	WHAT TO DO
L	Your result is below measurement limit, 20 mg/dL(1.1 mmol/L). This indicates hypoglycemia (low blood glucose.)	You should seek immediate medical assistance.
<b>Н</b> 1 I-08 10:0.3 <sub>РМ</sub>	Your result is above measurement limit, 600 mg/dL(33.3 mmol/L). This indicates severe hyperglycemia (high blood glucose).	You should seek immediate medical assistance.
KETONE?	Your result is equal to or higher than 240 mg/ dL(13.3 mmol/L). This indicates there is a possibility of ketone accumulation If you have type 1 diabetes.	Please seek immediate medical assistance.

## Error Message

MESSAGE	WHAT IT MEANS	WHAT TO DO
	Appears when the battery can not provide enough power for a test.	Replace the battery immediately.
E-E E-0	Problem with the meter.	Review the instructions and re-test with a new test strip.
E-F	You need to remove the strip after applying blood to the absorbent hole.	Re-test with a new test strip.
	Appears when environmental temperature is below system operation range.	System operation range is 50°F to 104°F(10°C to 40°C). Repeat the test
	Appears when environmental temperature is above system operation range.	after the meter and test strip have reached the above temperature.
E-U	Appears when inserting a used test strip.	Test with a new test strip.

# **Operational Problem**

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

POSSIBLE CAUSE	WHAT TO DO
Batteries exhausted.	Replace the batteries.
Batteries incorrectly installed or absent.	Check to see if the batteries are correctly installed.
Test strip inserted upside down or not completely inserted.	Insert the test strip correctly with the contact bars end first.
Defective meter.	Contact Customer Care Line at 1-888- 307-8188, 1- 866-469-2632 for help.

2. The test does not start after applying the sample.

POSSIBLE CAUSE	WHAT TO DO
Insufficient blood sample.	Repeat the test with a new test strip and a larger sample.
Defective test strip.	Repeat the test with a new test strip.
Sample applied after automatic shutdown (3 minutes after last user action).	Repeat the test with a new test strip. Apply sample only when " <b>(</b> " appears on the display.
Defective meter.	Contact Customer Care Line at 1-888- 307-8188, 1- 866-469-2632 for help.

## 3.If the control solution test result is out of range.

POSSIBLE CAUSE	WHAT TO DO
Error in performing the test.	Read instructions thoroughly and repeat the test.
Control solution vial shaken poorly.	Shake the control solution vigor- ously and repeat the test again.
Expired or contaminated control solution.	Check the expiration and disposing dates of the control solution.
Control solution that is too warm or too cold.	Allow control solution, meter and test strips to come to room temperature (68 to 77°F/20 to 25°C) before testing.
Test strip deterioration.	Repeat the test with a new test strip.
Meter malfunction.	Contact Customer Care Line at 1-888-307-8188, 1- 866-469-2632 for help.

# SPECIFICATIONS

Dimension & Weight: 90.7mm(L) x 46.3 mm(W) x 21.5 mm(H), 57.9g Power source: two 1.5V AAA alkaline batteries Battery life: Over 1.000 determinants Display: Large LCD Memory: 450 measurement results with respective dates and times Auto electrode inserting detection Auto sample loading detection Auto reaction time countdown Sleeping mode: Power consumption less than 50uA Auto shutdown after 3 minutes of idleness Temperature warning Operating condition: 50°F to104°F (10°C to 40°C), below 85% R.H. (noncondensing) Meter storage/transportation condition:-4°F to 140°F (-20°C to 60°C), below 95% R H Shelf life: 3 years Measurement units: mg/dL Measurement range: 20 to 600 mg/dL(1.1 to 33.3 mmol/L)

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

### Performance characteristics

#### Accuracy

Within  $\pm 15 \text{ mg/dL}$  (0.83 mmol/L) at glucose concentration < 75 mg/dL (4.2 mmol/L) and within  $\pm 20\%$  at glucose concentration  $\geq 75 \text{ mg/dL}$  (4.2 mmol/L).

### Precision

CVs (%) of intermediate precision and repeatability are less than 5%.

The product has been tested to meet the requirements of ISO 15197.