

FORA G71a Blood Glucose Monitoring System

Owner's Booklet ver 5.0 2018/10

FORA Control Solution contains a known amount of glucose that reacts working together correctly.

- you suspect the meter or test strips are not working properly,
- your blood glucose test results are not consistent with how you feel,
- practicing the testing process, or
- you have dropped or think you may have damaged the meter.

How to Perform a Control Solution Test

Step 1 Insert Test Strip

Insert a test strip into the test port with the contact bars end first and facing up. (Contact bars must be inserted all the way into the meter or you may get an inaccurate test result.) The meter will turn on automatically and display the followings in sequence:

LCD full display → flashing " ▲ "



APPEARANCE AND KEY FUNCTIONS OF THE METER



1 Test Slot

Is where you insert the test strip. The meter will turn on automatically after insertion.

2 Display Screen

Guides you through the test using symbols and simple messages.

Located at the front of the monitor and marked with an "M", is used to turn on the monitor and enter the memory.

Replace the battery when the power is low.

5 Set Button

"CTL" sign will disappear.

Is used to set up the meter.

NOTE

The meter will turn off automatically after 120 seconds without any action of ou can press and hold the main button for 3 seconds to turn off the meter.

"CTL" will appear on the display. When the "CTL" sign is displayed, the

meter will not store your test result in the memory. If you decide not to

Every time you perform a control solution test you must enter "CTL" test

Step 2 Apply Control Solution

Shake the control solution vial well. Remove

the cap from the control solution bottle. Place

the cap on a flat surface. Squeeze the bottle.

discard the first drop, and wipe the dispenser

tip clean to prevent contamination. Squeeze

out another drop and place it on the tip of the

Hold the meter to touch the drop with the

filled. The meter begins to count down.

test strip's absorbent hole and the drop will

automatically drawn into the test strip. Make sure the confirmation window is completely

mode so that the test result will not be stored in the meter memory.

perform a control solution test, press the main button again and the

DISPLAY SCREEN



1 Blood Drop Symbol

Flashes when meter is ready for sample application.

2 Test Result Area

Test results are displayed here.

3 Error Warning

Appears with error messages. 4 Month / Day / Hour / Minute

Indicates a test result stored in memory.

6 Measurement Unit

The measurement unit is fixed as mg/dL.

7 Battery Symbol

Appears when the battery is low.

FORA G71a TEST STRIPS

Your system measures the amount of sugar (glucose) in whole blood. Blood is applied to the absorbent hole on the test strip and is automatically drawn into the reaction cell where the reaction takes

The test strip consists of the following parts:



1 Test Strip Handle

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

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

3 Confirmation Window

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

4 Absorbent Hole

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

IMPORTANT SAFETY INSTRUCTIONS

Read Before Use

Dear owner of a FORA G71a Blood Glucose Monitoring System,

The system consists of three main products: the meter, test strips, and control solutions. These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. Only use FORA G71a test strips and control solutions with the FORA G71a blood glucose monitoring system.

This system is intended for external use (in vitro diagnostic use) only. It is used for the quantitative measurement of glucose in samples of fresh capillary whole blood taken from the palm, forearm, upper arm, calf, thigh, or fingers. It is not intended to diagnose or screen for diabetes mellitus, or to be used on neonates. This system provides you with plasma equivalent results.

The Standard Kit for This System Includes

Meter

5 Warranty Card

2 Owner's Booklet 6 Control Solutions (optional)

 Storage Case 4 Lancets

Test Strips

S Lancing Device with a Clear Cap

Check your system to ensure that it is unopened prior to use and that it contains all parts listed above. If anything is missing or damaged, please return your system to the place of purchase.

CHECKING THE SYSTEM WITH FORA CONTROL SOLUTIONS

with test strips and is used to ensure your meter and test strips are

Do a control solution test when:

- · vou 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,
- or if you think the results are not accurate,



When the " • " symbol appears on the display, press the main button and

To avoid contaminating the control solution with the content of the test strip, it is recommended that you discard the first drop and place another drop of control solution on a clean surface first. Then touch the drop with the test

Step 3 Check Results

After the meter counts 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.

TESTING YOUR BLOOD

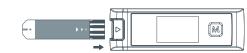
Before testing, be sure to read this section and the test strip insert found in the test strip box carefully. Make sure you have all the items needed

Test Steps

Step 1 Insert the Test Strip

Insert the test strip into the test port with the contact bars end first and facing up. The bars must be fully inserted into the port for an accurate result. The meter turns on automatically and displays the blood drop symbol.

LCD full display → flashing " • "



Step 2 Apply Blood Sample

Obtain a drop of blood of at least 0.5 µL using a lancing device. To obtain blood from other sites other than the fingertip, use the clear cap provided and refer to the strip package insert for more details.

When the "

" symbol appears on the display, touch the drop of blood with the absorbent hole of the test strip. Do not rub the test strip with your finger or try to apply a smeared sample.

The blood should completely fill the confirmation window before the meter begins to count down. If the confirmation window is not filled completely before the meter begins to count down, do not add more blood to the test strip. Discard the test strip and start again. If you have trouble filling the test strip, please call your local customer service number for assistance.

SPECIFICATIONS

Dimension: 86.9 (L) x 27.0 (W) x 11.3 (H) mm

Weight: 19 g (excluding battery)

One CR2032 3V Lithium battery (for at least 500 measurements)

Display: LCD

Memory: 20 measurement results with date and time

Automatic detection of electrode insertion Automatic reaction time count-down Temperature warning

Operating Conditions:

10°C to 40°C (50°F to 104°F), below 85% R.H.

Storage/Transport Conditions:

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

Measurement Units: mg/dL

Measurement Range: 20-600 mg/dL (1.1-33.3 mmol/L)

When the battery is low, you can still do up to 50 tests.

The device has been tested to meet the requirements of ISO 15197, and electrical and safety requirements of:

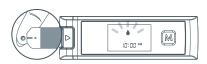
IEC/EN 61010-1, IEC/EN 61010-2-101, EN 61326-1, EN 61326-2-6.

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311-4274100-040









NOTE

If you do not apply a blood sample within 3 minutes, the meter will turn itself off. You must remove the test strip and insert it back into the meter to restart the test.

Step 3 Get Results

The result of your blood glucose test will appear after the meter counts to 0. Blood glucose test results are automatically stored in the meter's memory.



NOTE

Please do not change your treatment based on the result without first consulting your healthcare provider. Turn the meter off by removing the test strip. Discard the used test strip and lancet carefully according to your local regulations.

Announcement of Test Result by Universal Tone

The blood glucose results will be broken down into individual digits and each digit represents the corresponding number of beeps.

The result is announced three times in succession and each time is preceded by two quick beeps. So you will hear: 2 quick beeps – results – 2 quick beeps – results – 2 quick beeps – result.

For mg/dL meters, the hundreds are always announced, even when the result is below 100

Examples:

80 mg/dL is announced as 1 long beep (0) – 1 single pause – 8 single beeps (8) – 1 single pause – 1 long beep (0)

182 mg/dL is announced as 1 single beep (1) – 1 single pause – 8 single beeps (8) – 1 single pause – 2 single beeps (2)

For mmol/L meters, the tens are always announced, even when the result is below 10. The decimal point is represented by 1 quick beep.

xamples:

6.0 mmol/L is announced as 1 long beep (0) – 1 single pause – 6 single beeps (6) – 1 single pause – 1 quick beep (.) – 1 single pause – 1 long beep (0)

NOTE

Information or warnings in the form of symbols displayed together with the results are not announced acoustically.

USING THE METER MEMORY

Viewing Results

Your Meter stores the latest 20 blood glucose test results with date and time in its memory. You can review the test results easily by the following steps.



Step 1 Enter the Memory Mode

With the meter turned off, press the main button twice. The first test result will appear, indicating that you are in the memory mode. If you continue to press the main button, you can then review the last 20 tests in the memory.

When using the meter for the first time or if the results have been deleted, "—" will appear, indicating that there are no test results in the memory.



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MESSAGE WHAT IT MEANS

Step 2 Recall Test Results

After the last test result, the most recent test result appears with the date and time. Press the main button to review your last 20 test results in order. When the memory is full, the oldest result will be deleted when the newest is added.

Announcement of Memory Result by Universal Tone

Only the most recent result that was saved can be announced acoustically. If you press **M** button to turn the meter on, you will first hear the Long-Beep which stands for power-on and then the most recent result.

Step 3 Exit The Memory Mode

Press the main button for three seconds to turn off the meter.



NOTE

The results of control solution tests are NOT stored in the memory. Stored results are blood glucose results only.

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Step 1 Set the Year

back. The meter is now in the setting mode.

SETTING THE METER AND DELETING THE MEMORY

Start with the meter off. Then press the setting button located on the

The year will appear first, with the year flashing. Press and release the main button to add one year. To go faster, press the main button down longer. Once the correct year is displayed, press the setting button and the date will appear on the display with the month segment flashing.



Step 2 Set the Month

Press and release the main button until the correct month appears. To go faster, press the main button down longer. Once the correct month is displayed, press the button and the day will flash.



Step 3 Set the Date

Press and release the main button until the correct day appears. To go faster, press the main button down longer. Once the correct day is displayed, press the setting button and the time will appear on the display with the hour flashing. (To set the time, you must first set the date.)



Step 4 Select 12h or 24h Clock

Press and release the main button to select the 12h or 24h clock. These are different time presentation formats. If you select 12h, AM and PM will be shown alongside the time. If you select 24h, the time format will be from 00:00 to 23:59 without showing AM or PM.

After you have finished selecting the 12h or 24h clock, press the setting button and then the hour will flash on the screen.

SYMBOL INFORMATION

SYMBOL	REFERENT
IVD	For in vitro diagnostic use only
2	Do not reuse
mi	Read instructions before use
*	Keep away from sunlight
Ť	Keep dry
1	Temperature limitation
	Use by / Expiry date
6M	Use within 6 months after opening
LOT	Batch code
	Manufacturer
SN	Serial number
<u></u>	Caution, consult accompanying documents
STERILE R	Sterilized using irradiation
(E ₀₁₂₃	CE mark
®	Do not use if package is damaged
<u></u>	Humidity limitation
(+ 1	Battery
3V ===	3 Volts DC
ŭ i	Dispose of the packaging properly after use
REF	Model No.



Step 5 Set the Hour

Press and release the main button to add one hour. To go faster, press the main button down longer. Once the correct hour is displayed, press the setting button and the minute will flash.



Step 6 Set the Minute

Press and release the main button to add one minute. To go faster, press the main button down longer. Once the correct minute is displayed, press the setting button to enter the memory deleting mode.



Step 7 Universal Tone

Press \mathbf{M} button to select Beep On, Universal Tone On or Beep Off.

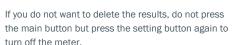


When Universal Tone is turned on, the meter guides you through the blood glucose test in a series of beep tones; it also outputs the result as a series of beeps.



Step 8 Delete Results and Exit the Setting Mode

With the "no" symbol flashing on the display, you can easily delete all the results stored in the memory by pressing the main button once. The meter will display "yes". Then press the setting button to delete all the results and "--" will be displayed. The meter will then automatically turn off.



When the meter is in the setting mode, it will also turn off automatically after being idle for two minutes.

DISPLAY MESSAGES AND PROBLEM-SOLVING GUIDE

The following is a summary of the display messages. If your meter displays an error message, please follow the actions for the error message as described in the table below. If the problem persists, please contact your local customer service agent for help.

WHAT TO DO

E-b	The " or " symbol appears with this message. This means that the battery does not have enough power remaining for a test.	Replace the battery immediately.
E-U	A used test strip is inserted, or there is an electrical problem.	Repeat test with a new test strip. If the error message re-appears, please contact your local customer service agent for help.
E-Ł	The temperature of the environment, meter, or test strip is outside the system's operating range. You cannot perform a test until the meter and test strip are within the operating range of 10°C to 40°C (50°F to 104°F).	Repeat the test after the meter and test strip are within the operating temperatures.

MESSAGE	WHAT IT MEANS	WHAT TO DO
E-E E-U	Problem with the meter.	Review the instructions and try again with a new test strip. If the problem persists, please contact your local customer service agent for help.
E-F	You may have removed the strip after applying blood to the absorbent hole.	Keep the test strip in the meter after it has absorbed the blood until the meter displays the test result.
E-R	Memory error.	Please contact your local customer service agent for help.
Lo	Result is below the measurement limit of 20 mg/dL (1.1 mmol/L).	This indicates hypoglycemia (low blood glucose.) Please seek medical assistance immediately.
н.	Result is above the measurement limit of 600 mg/dL (33.3 mmol/L).	This indicates severe hyperglycemia (high blood glucose). Please seek medical assistance immediately.

Announcement of Error Message by Universal Tone Hi or Lo Result:

Results larger than 600 mg/dL (33.3 mmol/L) are represented as 999, i.e. three groups of nine short beeps with pauses between the groups. Results lower than 20 mg/dL (1.1 mmol/L) are represented as 000, i.e. three long beeps.

Low Battery Warning:

When the batteries are about to be exhausted, 2 quick beeps are announced three times in succession. This warning is sounded when the meter is switched on.

Other Errors:

Other Error Messages are announced by 2 quick beeps four times in succession.

For questionable results, please see test strip package insert for important information.