FORA®

Diamond MINI

Blood Glucose Monitoring System

Owner's Manual

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English

Version 1.0 2012/05
311-4283000-005

IMPORTANT SAFETY INSTRUCTIONS

READ BEFORE USE

Dear owners of **FORA Diamond MINI** 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 Diamond MINI** test strips and control solutions with the **FORA Diamond MINI** Blood Glucose Monitoring System.

INTENDED USE

This system is intended for external use (in vitro diagnostic use) only. It is used for the quantitative measurement of glucose in samples of venous whole blood and 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.

Professionals may test with capillary and venous blood sample; home use is limited to capillary whole blood testing. Use only heparin for anticoagulation of whole blood.

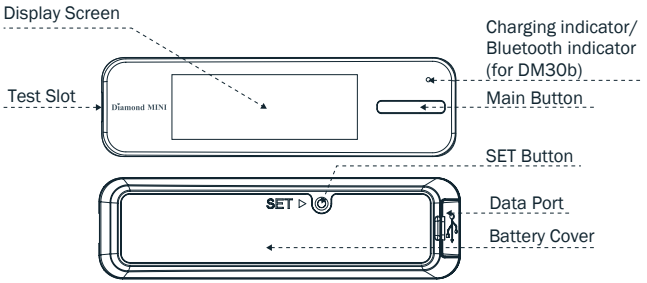
This system provides you with plasma equivalent results.

The measurement unit used for indicating the concentration of blood or plasma glucose can either have a weight dimension (mg/dL) or a molarity (mmol/L). The approximate calculation rule for conversion of mg/dL in mmol/L is:

mg/dL	Divided by 18	= mmol/L
mmol/L	Times 18	= mg/dL

For example;
1) 120 mg/dL ÷ 18 = 6.6 mmol/L
2) 7.2 mmol/L x 18 = 129 mg/dL approximately.

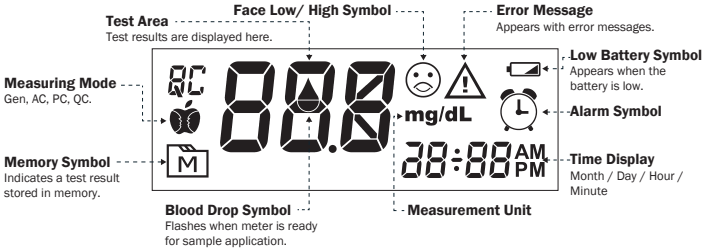
APPEARANCE AND KEY FUNCTIONS OF THE METER



NOTE:

The meter will turn off automatically after 180 seconds without any action or you can press and hold the Main button for 3 seconds to turn off the meter.

METER DISPLAY



FORA Diamond MINI 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 place.

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

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.

SETTING THE METER AND DELETING THE MEMORY

Start with the meter off (no test strip inserted). **Press SET.**

1. Setting the date

With the year flashing, press Main button until the correct year appears. Press SET.

With the month flashing, press Main button until the correct month appears. Press SET.

With the day flashing, press Main button until the correct day appears. Press SET.

2. Setting the time format

Press Main button to select the desired time format --- 12h or 24h. Press SET.

3. Setting the time

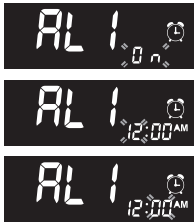
With the hour flashing, press Main button until the correct hour appears. Press SET.

With the minute flashing, press Main button until the correct minute appears. Press SET.

4. Deleting the memory

With “dEL” and a flashing “ M ” on the display, press Main button and select “no” to keep the results in memory then press SET to skip.

To delete all the results, press Main button and “yes” and “ M ” are displayed on the meter, press SET to delete the memory.



5. Setting the reminder alarm

You may set up any or all of the reminder alarms (1-4). The meter displays “On” or “OFF” and “ ① ” , press Main button to turn on or turn off to set the first reminder alarm.

Press Main button to select “On”, then press SET to set the hour. When the hour is flashing, press Main button to add an hour. Press SET to confirm and go to minutes, press Main button to add one minute. Hold Main button longer to add faster. Press SET to confirm and go to the next alarm setting.

If you do not want to set an alarm, press SET to skip this step.

If you want to turn off an alarm, find the alarm number by pressing SET in the setting mode, press Main button to change from “ON” to “OFF”.

6. Enter the Bluetooth pairing (for DM30b only)

NOTE:
This step is recommended when the user needs to pair this meter to a Bluetooth receiver for the first time, or when user needs to pair this meter to another new Bluetooth receiver.

With the "no" symbol flashing on the display, press SET to skip the pairing.

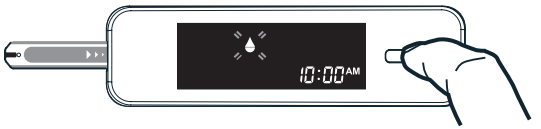
If you wish to enter the pairing mode, press Main button once and the meter will display "yes". Then press SET to confirm and the meter will show "CLr" The meter will then automatically turn off and the Bluetooth indicator will start blinking, which means the meter is in the process of pairing with a Bluetooth receiver.

THE FOUR MEASURING MODES

The meter provides you with four modes for measuring, General, AC, PC and QC.

MODES	USE WHEN
General (displays as “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
QC	testing with the control solution

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 a “ ” .

2. Press Main button to switch between General, AC, PC and QC mode.

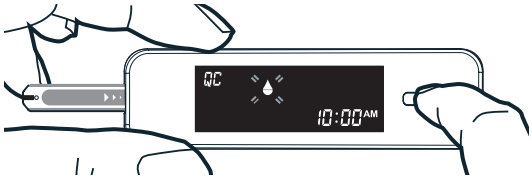
CHECKING THE SYSTEM WITH CONTROL SOLUTIONS

Our control solutions contain a known amount of glucose that reacts with test strips. By comparing the result of your control solution test with the expected range printed on the test strip vial label, you can check 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 perform this simple check routinely to make sure you get accurate results.

HOW TO PERFORM A CONTROL SOLUTION TEST

STEP 1. Insert test strip

Insert a test strip into the test slot 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 turns on automatically and displays the following in sequence:



When the "💧" appears on the display, press the Main button and "QC" will appear on the display. When the "QC" sign is displayed, the meter will not store your test result in the memory. If you decide not to perform a control solution test, press the Main button again and the "QC" sign will disappear.

CAUTION :

Every time you perform a control solution test you must enter "QC" test mode so that the test result will not be stored in the meter memory.

STEP 2. Apply control solution

Shake the control solution vial thoroughly before use. Squeeze out a drop and wipe it off, then squeeze out another drop and place it on the tip of the vial cap. Hold the meter to move the absorbent hole of the test strip to touch 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 a strip.

STEP 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.

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. Contact the local customer service or place of purchase for help.

TESTING YOUR BLOOD

Preparing the Lancing Device for Blood Testing

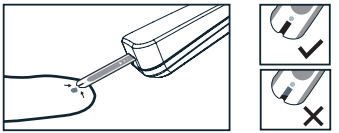
Please follow the instructions in the lancing device insert for collecting a blood sample.

STEP 1. Insert the test strip to turn on the meter

Wait for the meter to display "".

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

For selecting the measurement mode, please refer to the “FOUR MEASURING MODES”.



STEP 3. Apply blood sample

Obtain a drop of blood of at least 0.5 µL using a lancing device. Use the clear cap for sites other than fingers and refer to the strip package insert for more details.

Gently apply the drop of blood to the absorbent hole of the test strip at a titled angle. Confirmation window should be completely filled if enough blood sample has been applied. Do NOT remove your finger until you hear a beep sound.

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.

NOTE :

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

STEP 4. Get result

The result of your blood glucose test will appear after the meter counts down to 0. The blood glucose result will be stored in the memory automatically. (100 mg/dL= 5.6 mmol/L).

Warning:

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

VIEWING THE METER MEMORY

VIEWING RESULTS

Your Meter stores the 450 most recent blood glucose test results with date and time in its memory. You can review the test results with these easy steps.

STEP 1. Enter the memory mode

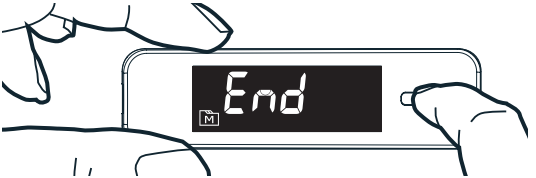
With the meter turned off, press the Main button. The first test result will appear, indicating that you are in the memory mode.

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.

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 450 test results in order. When the memory is full, the oldest result will be deleted when the newest is added.

(200 mg/dL = 11.11 mmol/L ; 300 mg/dL = 16.66 mmol/L).



STEP 3. Exit the memory mode

Press the Main button for three seconds to turn off the meter or after the last result, the display will show "End" and it will turn off automatically.

NOTE :

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

VIEWING DAY AVERAGE RESULTS

1. Press and release Main button.

Keep pressing Main button for 3 seconds until the flashing “AVG” appears. Release Main button and then your 7-day average result measured in general mode will appear on the display.

2. Press Main button to review

14-, 21-, 28-, 60- and 90- day average results stored in each measuring mode in the order of Gen, AC, then PC.

3. Exit the meter memory.

Keep pressing the Main button and the meter will turn off after displaying the last test result.

(100 mg/dL = 5.6 mmol/L).

DOWNLOADING RESULTS ONTO A COMPUTER

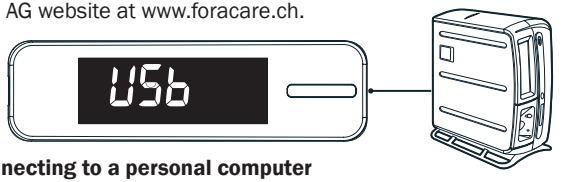
FORA Diamond MINI has 2 types of transmission methods; your meter uses either USB or Bluetooth to transmit the data, please check your meter box for the transmission method of your meter.

DATA TRANSMISSION VIA CABLE (FOR DM30a)

You can use the meter with an USB cable and the Health Care Software System to view your test results on your personal computer. To learn more about the Health Care Software System or to obtain a USB cable separately, please contact local customer services or the place of purchase for assistance.

1. Obtaining the required cable and installing the software

To download the Health Care Software System, please visit ForaCare Suisse AG website at www.foracare.ch.



2. Connecting to a personal computer

Connect the cable to a USB port on your computer. With the meter switched off, connect the other end of the USB cable to the meter data port. "USb" will appear on the meter display, indicating that the meter is in communication mode.

3. Data transmission

To transmit data, follow the instructions provided with the software. Results will be transmitted with date and time. Remove the cable and the meter will automatically switch off.

DATA TRANSMISSION VIA BLUETOOTH (FOR DM30b)

You can use your device with iOS (5.0.1 or higher) or Android system to download data from your meter via Bluetooth. Follow the steps below to transmit data from your meter. Please contact local customer service or place of purchase for assistance.

Please note that you must complete the pairing between meter and Bluetooth receiver before transmitting data.

1. **Make sure your meter is already paired with your device with iOS (5.0.1 or higher) or Android system by following instructions of the setting mode in Step 6.**

2. **Install the software on your device with iOS (5.0.1 or higher) or Android system.**

3. Data transmission

Turn on the Bluetooth on your device with iOS (5.0.1 or higher) or Android system and keep it on, and your meter will be able to connected to the device after measurement. You can view the data on your device.

WARNING :

- While the meter is in transmission mode, it will be unable to perform a blood glucose test.
- Make sure your device with iOS (5.0.1 or higher) or Android system has turned on Bluetooth before transmitting the data and the meter is within the receiving range.
- The USB port of meter DM30b is only for battery recharge. It does not have the function of data transmission.

BATTERY RECHARGE

Your meter comes with a built-in rechargeable Li-polymer battery. If the low battery symbol

"▭"appears on the screen indicating that the battery is low and it is time to recharge the battery.

1. Connect the USB cable to the data port of the meter.
2. Connect the other end of cable to a free USB port on your personal computer.
3. "USb" will appear on the display and the charging indicator will light up in red when battery is recharging. After the battery is fully charged, the red light will turn green.
4. Remove the USB cable and the meter will automatically switch off.

NOTE :

- It should take approximately 2 hours to be fully recharged. Recharging the battery does not affect the test results stored in the memory.
- The USB cable is for battery recharging and data transmission with a computer. If you wish to recharge through a wall outlet, please obtain a USB adapter.

DISPLAY MESSAGES AND PROBLEM-SOLVING GUIDE

The following is a summary of 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.

MESSAGE	WHAT IT MEANS		
Lo	< 20 mg/dL (1.1 mmol/L).		
☹	20 - 69 mg/dL(1.1 – 3.8 mmol/L).		
☺	AC (before meal)	PC (after meal)	**General**
	70 – 129 mg/dL (3.9 – 7.2mmol/L).	70 – 179 mg/dL (3.9 -9.9 mmol/L).	70 – 119 mg/dL (3.9 -6.6 mmol/L).
☹	AC (before meal)	PC (after meal)	**General**
	130 – 239 mg/dL (7.2 - 13.3 mmol/L).	180 – 239 mg/dL (9.9 – 13.3 mmol/L).	120 – 239 mg/dL (6.7 – 13.3 mmol/L).
☹	≥ 240 mg/dL (13.3 mmol/L).		
Hi	> 600 mg/dL(33.3mmol/L).		

MESSAGE	WHAT IT MEANS	ACTION
	The "⚠🔋"symbol appears with this message. This means that the battery does not have enough power remaining for a test.	Replace the battery immediately.
	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.
	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.
	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.
	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.

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

SYMBOL INFORMATION

SYMBOL	REFERENT	SYMBOL	REFERENT
IVD	*In vitro* diagnostic medical device	LOT	Batch code
2	Do not reuse		Manufacturer
i	Consult instructions for use	SN	Serial number
	Keep away from sunlight		Caution, consult accompanying documents
	Keep dry	STERILE R	Sterilized using irradiation
	Temperature limitation		Do not use if package is damaged
	Use by/ Expiry date	CE 0459	CE mark
3M	Use within 3 months after first opening		

SPECIFICATIONS

Model No.: FORA DM30
Dimension: 93.0mm (L) x 26.03 mm (W) x 5.57 mm (H)
Weight: 26.8g (without battery)
Power Source: Li-Polymer battery
Display: LCD
Memory: 450 measurement results with date and time
External Output: USB/ Bluetooth
Automatic detection of electrode insertion
Automatic reaction time count-down
Automatic blood detection
Temperature warning
Operating Conditions:
2°C to 32°C (35.6°F to 89.6°F), below 85% R.H.

Storage/Transportation Conditions:
-20°C to 60°C (-4°F to 140°F), below 95% R.H.

Measurement Units: mg/dL
Measurement Range: 20 to 600 mg/dL (1.1 to 33.3 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, EN 61326-2-6, EN 301 489-17, EN 300 328.

FORA®

Five-Year Warranty Registration Card

Complete this warranty card and mail it promptly

Name

Street Address

APT# City Country

State / Zip Home Telephone

Meter Serial Number
(See label on back of meter)

Date of Purchase
(Month-Day-Year)

☐ I would like to receive special offers and updates from FORA

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PLACE
STAMP
HERE

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Neugasse 55, 9000 St. Gallen, Switzerland

Diamond MINI

Blood Glucose Monitoring System

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For self-testing

CE 0459 IVD