

FORA



GD20

BLOOD GLUCOSE
MONITORING SYSTEM

Operations & Procedures Manual

Long Term Care



Thank you for purchasing the ForaCare GD20 Blood Glucose Monitoring System. This manual provides important information to help you to use the system properly. Before using this product, please read the following contents thoroughly and carefully.

If you have other questions regarding this product, please contact the place of purchase or call Customer Service at (888) 425-1149.

The FORA GD20 is intended for multi-patient use in a long term care setting. Please note that the following Procedures are provided only as a model to help your facility establish its own policy and procedures. Your own policy may differ depending upon the existing procedures. Please consult with the Director of Nursing for further guidance.

CAUTION: Please carefully read the User's Manual and all product instructions before using this Long Term Care Manual and administering blood glucose tests.

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IMPORTANT SAFETY PRECAUTIONS

READ BEFORE USE

Users need to adhere to Standard Precautions when handling or using this device. All parts of the glucose monitoring system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals. For more information, refer to “Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007”, <http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html> .

- The meter should be disinfected after use on each patient. This Blood Glucose Monitoring System may only be used for testing multiple patients when Standard Precautions and the manufacturer’s disinfection procedures are followed.
 - Only auto-disabling, single use lancing devices should be used with this device.
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 neonates 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, 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.

Interfering Substances

Interfering substances depend on the concentration. The interfering substances listed below may produce elevated glucose test results (up to test concentration levels noted).

| Substance | Limiting Concentration (mg/dL) | Therapeutic / Physiological Concentration Range (or Upper Limit) (mg/dL) |
|--------------------------|--------------------------------|--|
| Acetaminophen | 6.25 | 0.45 - 3 |
| Ascorbic Acid | 5 | 2 |
| Bilirubin (Unconjugated) | 20 | 0 - 2 |
| Dopamine | 1.25 | 0.03 |
| Levo - Dopa | 0.7 | 0.02 - 0.28 |
| Methyl - Dopa | 1.875 | 0.1 - 0.5 |
| Glutathione Reduced | 23 | 47 - 100 (intracellular) |
| Pralidoxime Iodide | 5 | ~10 (IV Dose 500mg) |
| Tolazamide | 12.5 | 1.6 |
| Uric Acid | 10 | .2 - 8 |
| Mannitol | 5000 | 0.0128 |
| Mannose | 125 | 1.15 |
| Xylose | 3.125 | N/A |
| *Na-Fluoride/K-Oxalate | <250 | 250 |

* The NaF/Koxalate concentration is the standard concentration in a blood collection tube.

Regulatory Requirements

The Clinical Laboratory Improvement Amendments (CLIA) has classified tests of blood glucose as tests that are waived. For all entities that conduct one or more tests, including waived tests on materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of human beings, CLIA has stated that the entity conducting the tests shall meet certain Federal requirements. If any entity conducts tests for the aforementioned purposes, then the entity, under CLIA, is considered to be a laboratory and thus must register with the CLIA Program.

**KEEP THESE INSTRUCTIONS
IN A SAFE PLACE**

BEFORE YOU BEGIN

Severe dehydration and excessive water loss may cause readings which are lower than actual values. If the patient is suffering from severe dehydration, consult a healthcare professional immediately.

- If the patient's blood glucose results are lower or higher than usual, and do not have any symptoms of illness, first repeat the test. If the patient has symptoms or continue to get results which are higher or lower than usual, follow the treatment advice of the healthcare professional.
- Use only fresh whole blood samples to test patient's blood glucose. Using other substances will lead to incorrect results.
- If the patient has symptoms that are inconsistent with the blood glucose test results and you have followed all the instructions given in this owner's manual, contact the healthcare professional.
- We do not recommend using this product on severely hypotensive individuals or patients in shock. Readings which are lower than actual values may occur for individuals experiencing a hyperglycaemic-hyperosmolar state, with or without ketosis. Please consult the healthcare professional before use.

INTENDED USE

This system is intended to be used for the quantitative measurement of glucose (sugar) in fresh whole blood samples (from the finger, palm, forearm and upper arm). This system is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control.

It should not be used for the diagnosis of diabetes, or testing on neonates. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

TEST PRINCIPLE

Your system measures the amount of sugar (glucose) in whole blood. The glucose testing 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, calculates the blood glucose level, and displays the result. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

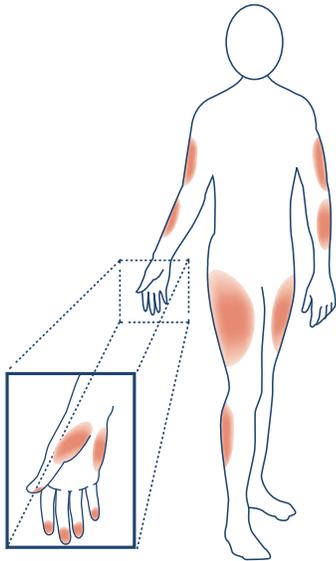
This system uses enzyme of FAD-dependent glucose dehydrogenase.

ALTERNATIVE SITE TESTING

IMPORTANT:

There are limitations with AST (Alternative Site Testing). The alternative site testing of the system can be used in only during steady-state blood glucose conditions. Please consult the doctor before you perform AST on the patient.

Measurements from alternative site testing should never be used to calibrate a continuous glucose monitoring systems (CGMs) or entered into insulin dose calculators for insulin dosing recommendations.



What is AST?

Alternative site testing (AST) means that people use parts of the body other than fingertips to check their blood glucose levels. This system provides you to test on the palm, the forearm, the upper arm, and with the equivalent results to fingertip testing.

What's the advantage?

Fingertips feel pain more readily because they are full of nerve endings (receptors).

At other body sites, since nerve endings were not

so condensed, patients will not feel as much pain as at the fingertip.

When to use AST?

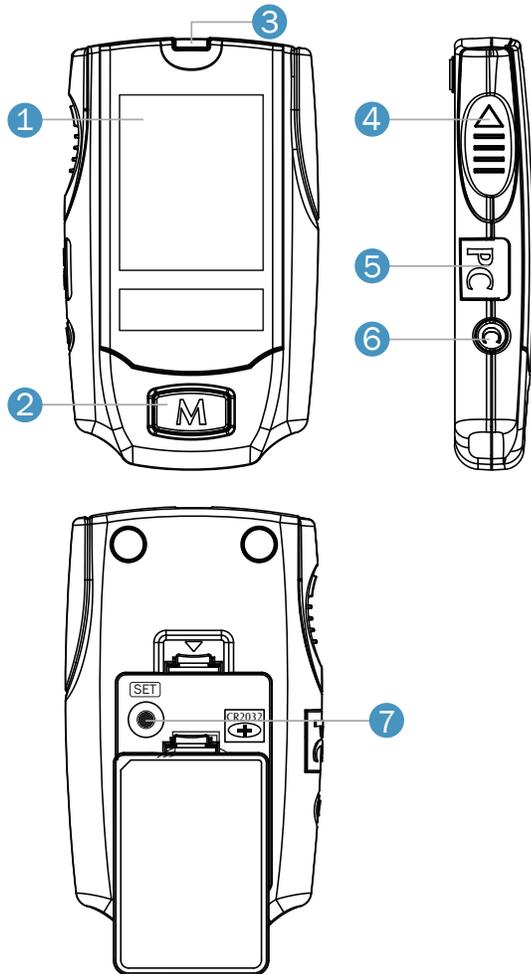
Food, medication, illness, stress and exercise can affect blood glucose levels. Capillary blood at fingertip reflects these changes faster than capillary blood at other sites. Therefore when testing blood glucose during or immediately after meal, physical exercise, or any other event, **take blood sample from finger only**. We strongly recommend that you perform AST **ONLY** at the following times:

- 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:

- Your patient has frequent low blood glucose.
- The AST results do not match the way the patient feels.
- You are testing for hyperglycemia.
- You are testing for hypoglycemia.
- The patient's routine glucose results are often fluctuating.

METER OVERVIEW



1 Display Screen

2 M Button

Enter the meter memory and silence a reminder alarm.

3 Test Slot

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

4 Test Strip Ejector

Eject the used strip by pushing up this button.

5 Data Port

Download test results with a cable connection.

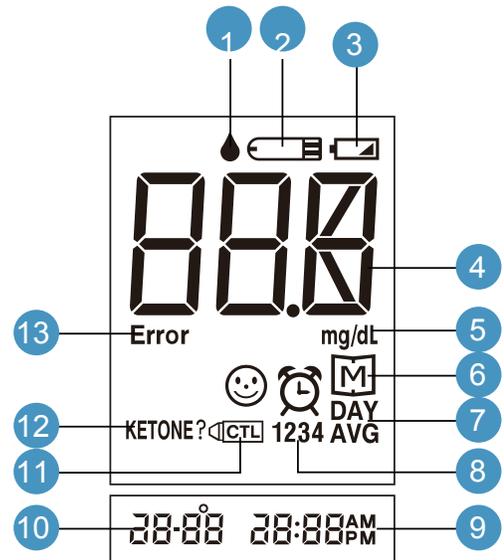
6 C Button

Marks a control solution test.

7 SET Button

Enter and confirm the meter settings.

Display Screen



1 Blood sample symbol

2 Test strip symbol

3 Low battery symbol

4 Test result

5 Measurement unit

6 Memory symbol

7 Day average

8 Reminder alarm

9 Time

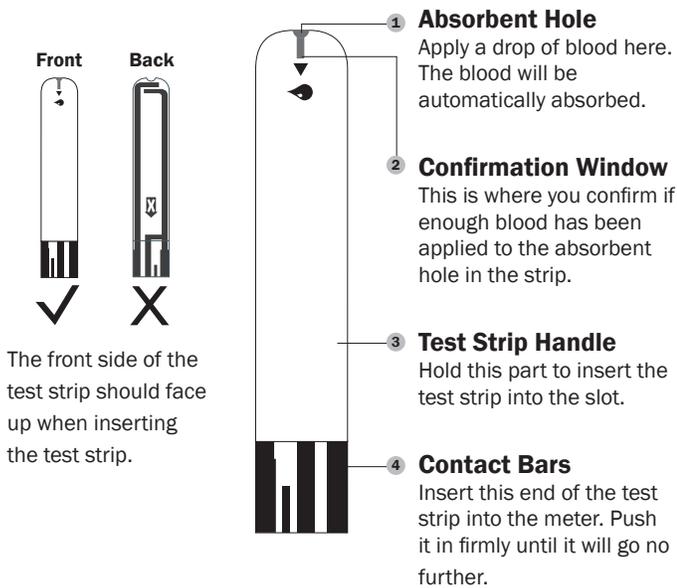
10 Date

11 Control solution mode

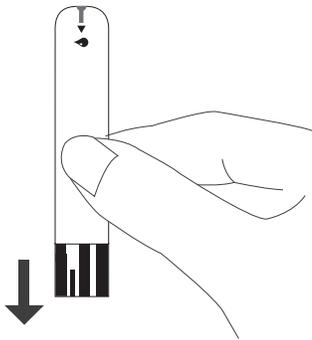
12 Ketone warning

13 Error

Test Strip



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



ATTENTION:

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

NOTE

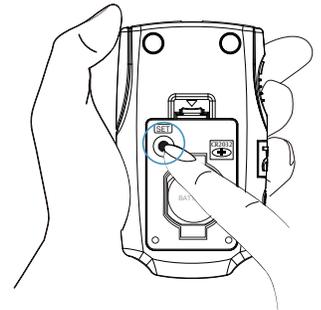
- This system uses enzyme of glucose dehydrogenase (GDH).
- The FORA GD20 meter should only be used with FORA GD20 Test Strips. Using other test strips with this meter will produce inaccurate results.

Setting the Meter

Before using the 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 **SET** to turn on the meter.



1. Setting the date

With the year flashing, press **M** to select the correct year. Press **SET**.

With the month flashing, press **M** to select the correct month. Press **SET**.

With the day flashing, press **M** to select the correct day. Press **SET**.

2. Setting the time format

Press and release **M** to select the desired time format --- 12h or 24h. Press **SET** to confirm.

3. Setting the time

With the hour flashing, press **M** to select the correct hour. Press **SET** to confirm.

With the minute flashing, press **M** to select the correct minute. Press **SET** to confirm.

4. Deleting the memory

With "dEL" and a flashing "M" symbol on the

display, press **M** and select “No” to keep the results in memory then press **SET** to skip.

To delete all the results, press **M** to select “Yes”. Then press **SET** to delete All results. “OK” is displayed in the meter, which means that all data stored is deleted.

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 **M** to turn on or turn off to set the first reminder alarm.

Press **M** to select “On”, then press **SET** to set the hour. When the hour is flashing, press **M** to add an hour. Press **SET** to confirm. Now adjust the minutes. Press **M** to add one minute. Hold **M** 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 **M** to change from “ON” to “OFF”. At the time of your alarm, the meter will beep and automatically turn on.

You can press **M** to silence the alarm and insert a test strip to begin testing. If you do not press **M**, the meter will beep for 2 minutes then switch off. If you do not want to test at this time, press **M** to switch off the meter.

NOTE

- These parameters can **ONLY be changed** in the setting mode.
- If the meter is idle for 3 minutes during the setting mode, it will automatically switch off.

QUALITY CONTROL TESTING

Quality control testing using the FORA Control Solution is required to check the performance of the FORA GD20 Blood Glucose Monitoring System. The FORA Control Solution checks if the meter and test strips are working correctly as a system and if the system is being utilized correctly.

This section explains how to take a control solution test in order to verify the performance of FORA GD20 Blood Glucose Monitoring System.

You Should Perform a Control Solution Test

- Before testing with the FORA GD20 Blood Glucose Monitoring System for the first time.
- When you open a new vial of test strips.
- Whenever you suspect the meter or test strips may not be functioning properly.
- If test results appear to be unusually high or low or are inconsistent with clinical symptoms.
- To check your technique.
- When the FORA GD20 meter has been dropped or you think you may have damaged the meter.

IMPORTANT:

Depending on different state regulations, control solution testing may be required on a daily basis. Refer to your facility procedures for further details.

NOTE

- Only use the control solutions for FORA GD20 test strips.
- When using a new bottle of control solution, write the opening date on the bottle label. Each bottle of control solution is stable for use within 90 days after first opening (replace cap tightly after each use). Discard all remaining open solutions after 90 days.
- Shake the control solution bottle several times before use, discard the first drop of control solution and wipe off the dispenser tip to ensure a pure sample and an accurate result.

Equipment Needed:

1. FORA GD20 Blood Glucose Meter
2. FORA GD20 (GDH) Control Solutions
3. FORA GD20 Test Strips
4. FORA GD20 Meter Record Sheet

Performing a Control Solution Test

1. Insert the test strip to turn on the meter

Insert the test strip into the meter. Wait for the meter to display the test strip and blood drop symbols.

2. Press C to mark this test as a control solution test

With “CTL” displayed, the meter will not store your test result in memory. If you press the C button again, the “CTL” will disappear and this test is no longer a control solution test.

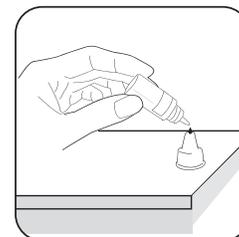
WARNING:

When doing a control solution test, you need to Press C to mark it so the test result will not be stored in the memory. Failure to do so will mix up the control solution test with a blood glucose test result in the memory.

3. Apply control solution

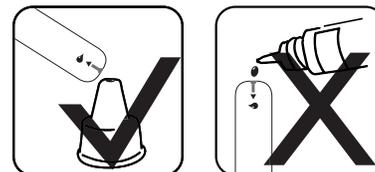
Shake the control solution vial thoroughly before use.

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 sample area 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.



4. Read and compare the result

After counting down to 0, the control solution test result will appear on the display. Compare this result with the range printed on the test strip vial. It should fall within this range. If not, please read the instructions again and repeat the control solution test.



5. Record the results.

Record the control solution test results in the System Quality Control Results Record sheet or as instructed by your facility.

Out-of-range results

If you continue to have test results fall outside the range printed on the test strip vial, the meter and/or strips may not be working properly.

Please check the Troubleshooting section for possible causes and actions. If a problem still persists, contact Customer Service at (888) 425-1149 for assistance.

BLOOD GLUCOSE TESTING

- If a single meter is used to test multiple patients, the meter must be cleaned and disinfected using the instructions as specified in this manual after each use, whether or not blood contamination is suspected.

Equipment Needed:

1. FORA GD20 Blood Glucose Meter
2. FORA GD20 Test Strips
3. Safety lancet
4. Gloves
5. Alcohol wipe or swab

Only auto-disabling, single use lancing devices should be used with this device.

Preparing the Puncture Site

Stimulating blood perfusion by rubbing the puncture site before blood extraction has a significant influence on the glucose value obtained.

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

Wash and dry your hands before starting.

1. Put on a new pair of gloves.
2. Select the puncture site.
3. Clean the puncture site using cotton moistened with 70% alcohol and **let it air dry.**
4. Rub the puncture site for about 20 seconds before penetration.

► Fingertip testing

Press the lancing device's tip firmly against the lower side of patient's fingertip.

► Blood from sites other than the fingertip

When lancing the palm, forearm and upper arm avoid lancing the areas with obvious veins because of excessive bleeding.

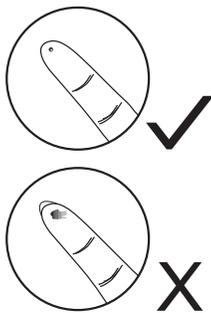
NOTE

- 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.
- When cleaning the puncture site, make sure alcohol is thoroughly dry before puncture site is lanced. Testing with alcohol remaining on skin can cause higher results.

Performing a Blood Glucose Test

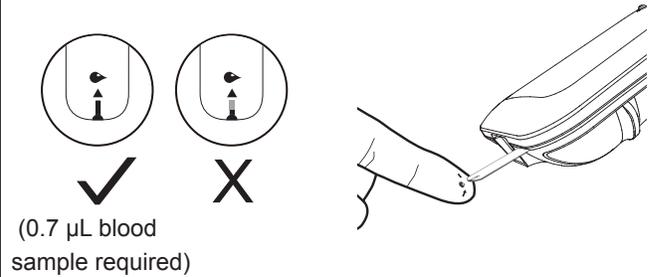
Consult manufacturer's instructions for additional information regarding the use of the FORA GD20 Blood Glucose Meter.

1. Verify physician's order.
2. Identify the patient.
3. Explain procedure.
4. Provide privacy.
5. Wash hands.
6. Put on non-sterile gloves.
7. Ensure that the meter and test strips are at room temperature. If there is a temperature change, the meter and test strips should sit at room temperature for 10 to 12 minutes.
8. Verify that the vial of test strips has not expired and/or that the vial has not been opened for longer than 90 days. Discard the vial of test strips if it has expired and/or has been opened for more than 90 days.
9. Cleanse area that is to be punctured with an alcohol swab. Allow area to dry.
10. Insert a test strip in the meter.
11. Lightly hold lancet device against the skin and lance the area. Obtain a blood sample (a hanging drop of blood).



12. Make contact with the blood sample to the sample area of the test strip. Blood will be

wicked and after the confirmation window is filled, the meter will begin counting down.



13. Read the result.



14. Eject the used test strip.
15. Clean and/or disinfect the meter following the cleaning and disinfecting procedures in this manual.
16. Remove gloves and wash hands.

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 to the test strip within 3 minutes, the meter will automatically turn off. You must remove and reinsert the test strip 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 blood sample has moved away. **Discard the used test strip and retest with a new one.**
- If you have trouble filling the confirmation window, please contact Customer Service at (888) 425-1149.

CLEANING AND DISINFECTION PROCEDURES

Cleaning & Disinfecting the FORA GD20 Blood Glucose Meter

It is Links Medical Product's policy to advise health care professionals to clean and disinfect blood glucose meters between each resident test in order to avoid cross-contamination issues. Whether your facility uses an alcohol based solution or a bleach based solution should depend upon your individual resident requirements and your facility's disinfection protocol.

Links Medical Product's cleaning and disinfecting guidelines are as follows:

FORA GD20 Cleaning Guidelines: Use a lint free cloth dampened with soapy water or isopropyl (70% - 80%) to clean the outside of the blood glucose meter.

NOTE: Lint free cloth should not be dripping wet when cleaning the meter.

FORA GD20 Disinfecting Guidelines: To disinfect the meter, dilute 1 mL of household bleach (5% - 6% sodium hypochlorite solution) in 9 mL of water to achieve a 1:10 dilution (final concentration of 0.5% - 0.6% sodium hypochlorite). The solution can then be used to dampen a paper towel (do not saturate the towel). Then use the dampened towel to thoroughly wipe down the meter.

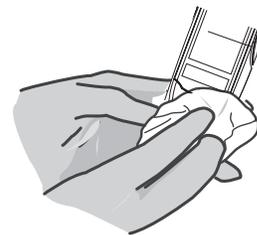
Please note that there are commercially available 1:10 quaternary/alcohol wipes and bleach wipes from a variety of manufacturers. Professional Disposables Inc (PDI) is an example of a manufacturer that offers both of these options.

Their product offerings include:

- Super Sani-Cloth™ Germicidal Wipe - ideal disinfection for most residents and hard surfaces.
- Sani-Cloth™ Bleach Germicidal Disposable Wipe - ideal disinfection for residents with C-Diff.

Both germicidal wipes mentioned above are EPA registered wipes that are compliant with the CDC guideline for disinfection and sterilization in healthcare facilities and are readily available through major medical distributors. When using any disinfection wipe, take extreme care not to get liquid in the test strip dock or key code parts of the meter. With all recommended glucose meter cleaning methods, it is crucial that the FORA GD20 meter be completely dry before testing a resident's glucose level. Please follow the disinfectant product label instructions to ensure proper drying time.

While there are many other options for disinfecting blood glucose meters, Links Medical Products has not tested the effectiveness of these products on the FORA GD20 meter. If you use a product or method other than those that we've recommend above, you should document accordingly in your cleaning protocol.



METER MEMORY

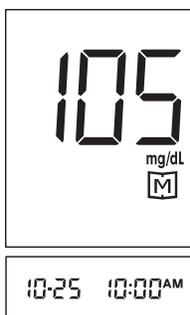
The meter stores the 448 most recent blood glucose test results along with respective dates and times in its memory. To enter the meter memory, **start with the meter switched off.**

Reviewing Test Results

1. Press and release **M**.

M will appear on the display.

Press **M** again, and the first reading you see is the last blood glucose result along with date and time.



2. Press **M** repeatedly to recall the test results stored in the meter.

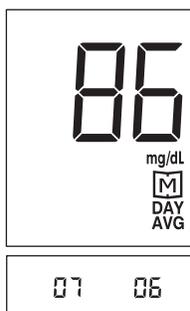
3. Exit the meter memory.

After the last test results, press **M** again and the meter will be turned off.

Reviewing Blood Glucose Day Average Results

1. Press and release **M**.

When **M** appears on the display, keep pressing **M** for 3 seconds until the flashing “**DAY**” **AVG**” appears. Release **M** and then your 7-day average result measured in general mode will appear on the display.



2. Press **M** to review 14-, 21-, 28-, 60- and 90- day average results stored in memory.

3. Exit the meter memory.

Keep pressing **M** and the meter will turn off after displaying the last test result.

DOWNLOADING RESULTS ONTO A COMPUTER

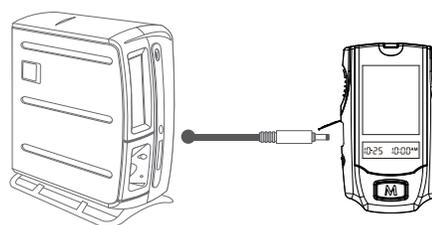
You can use the meter with an interface cable and the Health Care Software System to view test results on your personal computer. To learn more about the Health Care Software System or to obtain an interface cable separately, please visit www.foracare.com or call (888) 425-1149 for assistance.

1. Obtaining the required cable and installing the software

To download the Health Care Software System, please visit the FORA Care Inc. website at www.foracare.com.

2. Connecting to a personal computer

Connect the cable to an interface port on your computer. With the meter switched off, connect the other end of the interface cable to the meter data port. “PC” 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.

WARNING:

While the meter is connecting to the PC, it will be unable to perform a blood glucose test.

MAINTENANCE

Battery

Your meter comes with one 3V CR2032 lithium battery.

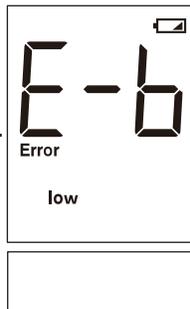
► Low Battery Signal

The meter will display one of the messages below to alert you when the meter's power is getting low.

1. The  symbol appears along with a display message: The meter is functional and the results remain accurate, but it is time to change the battery.

2. The meter displays E-b:

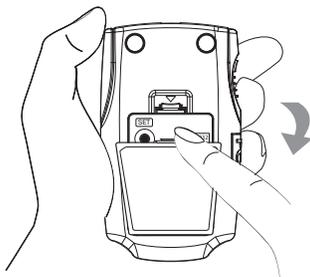
There is not enough power for a test. Please change the battery immediately.



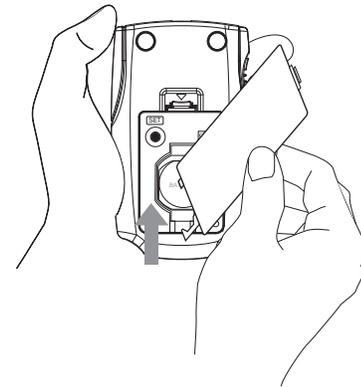
Replacing the Battery

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

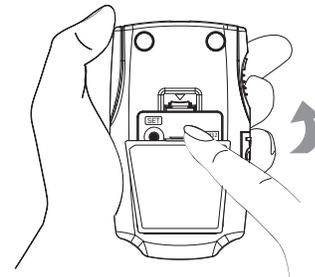
1. Press the edge of the battery clip and lift it up to remove.



2. Remove the old battery and replace with a new 3V CR2032 lithium battery.



3. Close the battery cover. If the battery is inserted correctly, you will hear a "beep" confirming the battery has been properly inserted.



NOTE

- Replacing the battery does not affect the test results stored in the memory.
- Battery might leak chemicals if unused for a long period of time. Remove the battery if you are not planning to use the device for an extended period (i.e., 3 months or more).
- Properly dispose of the battery according to your local environmental regulations.

Meter Storage

- Storage conditions: -4°F to 140°F (-2°C to 6°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.

Important Test Strip Information

- Storage conditions: 35.6°F to 89.6°F (2°C to 32°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 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 open it. Discard remaining test strips after 3 months (90 days).
- 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. The cap and the test strip may be a choking hazard. If swallowed, promptly seek medical attention.

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.
- Store the control solution tightly closed at temperatures between 36°F and 86°F (2°C and 30°C). DO NOT FREEZE.

SYSTEM TROUBLESHOOTING

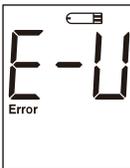
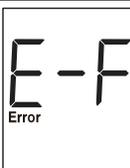
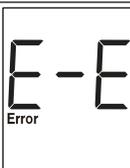
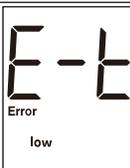
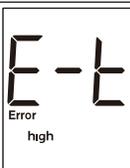
If you follow the recommended action but the problem persists, or error messages other than the ones below appear, please call (888) 425-1149 for assistance. Do not attempt to repair yourself and never try to disassemble the meter under any circumstances.

Result Readings

| MESSAGE | WHAT IT MEANS |
|---|--|
|  <p>10-25 10:00AM</p> | Appears when the result is below the measurement limit of 20 mg/dL (1.1 mmol/L). |
|  <p>10-25 10:00AM</p> | Appears when the result is equal to or higher than 240 mg/dL (13.3 mmol/L). This indicates the possibility of ketone accumulation for type 1 diabetes. |
|  <p>10-25 10:00AM</p> | Appears when the result is above the measurement limit of 600 mg/dL (33.3 mmol/L). |

Error Messages

| MESSAGE | WHAT IT MEANS | WHAT TO DO |
|--|---|----------------------------------|
|  | Appears when the battery can not provide enough power for a test. | Replace the battery immediately. |

| | | |
|---|---|--|
|  | Appears when inserting a used test strip. | Re-test using a new test strip. |
|  | Test strip was removed after applying a blood sample prior to glucose test completion. | Re-test using a new test strip. |
|  | Problem with the meter. | Review the instructions and re-test with a new test strip. If the above steps do not work, please contact Customer Service. |
|  | Appears when the environmental temperature is below system operation range: 50°F (10°C). | System operation range is 50°F to 104°F (10°C to 40°C). Repeat the test after the meter and test strip have reached the appropriate temperature. |
|  | Appears when the environmental temperature is above system operation range: 104°F (40°C). | |

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 incorrectly. | Insert the test strip correctly with the contact bars end first and facing up. |
| Defective meter. | Please contact Customer Service at (888) 425-1149. |

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

| POSSIBLE CAUSE | WHAT TO DO |
|---|---|
| Insufficient blood sample. | Re-test using a new test strip with larger volume of blood. |
| Defective test strip. | Re-test with a new test strip. |
| Sample applied after automatic switch-off (3 minutes after last user action). | Re-test with a new test strip. Apply sample only when "▲" appears on the display. |
| Defective meter. | Please contact Customer Service at (888) 425-1149. |

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

| POSSIBLE CAUSE | WHAT TO DO |
|--|--|
| Error in performing the test. | Read the instructions thoroughly and repeat the test again. |
| Control solution vial was poorly shaken. | Shake the control solution vial and repeat the test again. |
| Expired or contaminated control solution. | Check the expiration date or the discard date of the control solution. |
| Control solution that is too warm or too cold. | Control solution, meter, and test strips should come to room temperature (68°F to 77°F (20°C to 25°C)) before testing. |
| Defective test strip. | Re-test with a new test strip. |
| Meter malfunction. | Please contact Customer Service at (888) 425-1149. |

SPECIFICATIONS

Model No.: TD-4251

Dimension & Weight: 86.9mm(L) x 51mm(W) x 15.8mm(H), 42.2g

Power Source: one CR2032 lithium battery

Display: LCD

Memory: 448 measurement results with respective date and time

External output: RS232 PC interface

Auto electrode insertion detection

Auto sample loading detection

Auto reaction time count-down

Auto switch-off after 3 minutes without action

Temperature warning

Operating Condition: 50°F to 104°F (10°C to 40°C), below 85% R.H. (non-condensing)

Storage/Transportation Conditions:

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

Test strip: 35.6°F to 89.6°F (2°C to 32°C), below 85% R.H. Do not freeze.

Measurement Units: mg/dL

Measurement Range: 20 to 600mg/dL (1.1 to 33.3mmol/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, IEC/EN 61326-2-2.

Distributed by:

Manufactured by:



ForaCare Inc.
893 Patriot Dr., Suite D,
Moorpark, CA 93021

Links Medical Products Inc.®

9247 Research Drive · Irvine, CA

Toll Free: (888) 425-1149

(8:00am-5:00pm PST, Mon.-Fri.)

www.linksmed.com

Attachment 1:

FORA GD20 Blood Glucose Monitoring System Training Checklist

Use the following checklist to assess the trainee's understanding and knowledge of the following areas:

| | Task | (√) |
|------------------|--|-----|
| Area | Clinical Use of Device | |
| Knowledge | Knows key features of FORA GD20 meter. | |
| | Understands different test types - finger, AST, quality control, preferred sample type and sample volume. | |
| | Principles of quality testing and QC materials. | |
| | Only uses FORA GD20 test strips and FORA control solution with the FORA GD20 meter. | |
| | Understands the important features, benefits and limitations of the FORA GD20 system. | |
| | Knows the proper method of disposing of used test strips, lancet and gloves according to facility procedures. | |
| | Understands the displayed error messages and corresponding actions to take. | |
| | Understands the appropriate steps to take for troubleshooting. | |
| | Knows the actions to be taken when the results are abnormally high or low. | |
| | Understands the information required to be documented by law and by institution. | |
| Equipment | Identify the essential equipment used with the FORA GD20 system. | |
| | Locates the serial number, test strip port, test strip ejector, M, C and SET buttons on the meter. | |
| | Locates the expiration date, first opening date, lot number and control solution ranges on the test strip vial. Locates sample area, confirmation window, contact bars and test strip handle on the test strips. | |
| | Locates the expiration date, first opening date and lot number on the control solution bottle. | |
| | Knows the proper storage conditions of the meter, test strips and control solutions. | |
| | Knows how to maintain the meter. | |
| Practical | Demonstrates proper safety lancet technique when collecting a blood sample. | |
| | Demonstrates the correct blood testing procedures using the FORA GD20 Blood Glucose Monitoring System. | |
| | Demonstrates the correct test strip insertion technique. | |
| | Performs quality control tests at specific times and determines if the results are acceptable. Takes appropriate action if there is a problem. | |
| | Demonstrates the proper cleaning and disinfecting techniques for the FORA GD20 meter. | |
| | Performs meter set up, memory retrieval and data transmission operations. | |
| | Demonstrates the proper actions to take for inaccurate results. | |

Training Completed by:

| | |
|--------------------|-------------------------|
| Name of Trainee | Date |
| | |
| Name of Instructor | Signature of Instructor |
| | |

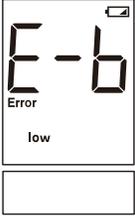
The trainee must complete the training of the FORA GD20 Blood Glucose Monitoring System before performing glucose testing on residents.

Attachment 2:

FORA GD20 Blood Glucose Monitoring System Training Quiz

Complete the following questions to assess your understanding about using the FORA GD20 Blood Glucose Monitoring System to perform blood glucose tests on residents.

| No. | Questions | Answer |
|-----|---|--------|
| 1. | The FORA GD20 Blood Glucose Monitoring System uses: a). GOD (glucose oxidase) enzyme b). GDH (glucose dehydrogenase) enzyme | |
| 2. | The FORA GD20 Blood Glucose Monitoring System can test samples from: a). Finger b). AST (Alternative Sites Testing) c). Control solutions d). All of the above | |
| 3. | The FORA GD20 Blood Glucose Monitoring System requires a blood volume of: a). 0.3 μ L b). 0.7 μ L d). 1.0 μ L | |
| 4. | You should perform a control solution test when: a). You think the meter or test strip may be working incorrectly b). You drop the meter c). You have repeated a test and the test result is still lower or higher than expected d). All of the above | |
| 5. | After the control solution and test strip vials have been opened, when do you discard the remaining materials? a). 30 days b). 90 days c). 6 months d). 1 year | |
| 6. | When performing a quality control test, how do you apply the control solution onto the test strip? a). Place a drop directly onto the test strip b). Place a drop on a clean surface and then contact the drop with the test strip c). Place a drop on your finger and then contact the drop with the test strip d). Shake the control solution vial and squeeze out a drop onto the tip of the vial cap, then touch test strip to drop | |
| 7. | When do you clean and disinfect the meter? a). After each use b). Daily c). Weekly d). Monthly | |

| | | |
|------------------|--|--|
| <p>8.</p> | <p>If you saw the following message on the meter's display, what action should you take?</p>  <p>a). Replace the battery b). Re-test with a new strip c). Repeat the test when the room temperature is within 50°F to 104°F</p> | |
| <p>9.</p> | <p>The test strips should be stored:</p> <p>a). At 35.6°F to 89.6°F (2°C to 32°C), below 85% humidity b). At -4°F to 140°F (-20°C to 60°C), below 95% humidity c). In the freezer d). In a different container than the original vial</p> | |

Quiz Completed by:

| Name of Trainee | Date | Score |
|-----------------|------|-------|
| | | |

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