

FORA[®] D40 Pro

BLOOD GLUCOSE PLUS BLOOD PRESSURE
MONITORING SYSTEM



Operations & Procedures Manual

Long-Term Care

Thank you for purchasing the **FORA D40 Pro** Blood Glucose Plus Blood Pressure Monitoring System. This manual provides important information to help you 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 1-888-307-8188.

The **FORA D40 Pro** is intended for multi-patient use in a long-term care or home health 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 and Home Health Care Manual and administering blood glucose and blood pressure tests.

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IMPORTANT SAFETY PRECAUTIONS

READ BEFORE USE

Users should 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 bloodborne 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 system 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 may 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 newborns or infants.
5. This device does **NOT** serve as a cure for any symptoms or diseases. The data measured is for reference only.
6. Before using this device to test blood glucose, read all instructions thoroughly and practice the test. Carry out all the quality control checks as directed.
7. Keep the device and testing equipment away from young children. Small items such as the battery cover, batteries, test strips, lancets and vial caps are choking hazards.
8. Keep the device and its flexible cord away from hot surfaces.
9. **DO NOT** apply the cuff to areas other than the place directed.
10. Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets, etc.) may cause damaging static discharges that may cause erroneous results.
11. **DO NOT** use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with the accurate operation.
12. Proper maintenance and periodic control solution tests are essential to the longevity of your device. If you are concerned about your accuracy of measurement, please contact customer service or place of purchase for help.

Interfering Substances

Interfering substances depend on concentration. The interfering substances listed below will have no effect up to the limiting concentration level 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
Dopamine	1.25	0.03
Levodopa	1.4	0.02 - 0.28
Methyldopa	1.25	0.1 - 0.5
Tolazamide	12.5	1.6
Galactose	250	< 5
Mannose	250	1.15
Glutathione Reduced	23	47 - 100 (Intracellular)
Hemoglobin (Hemolysis Method)	100	2.5
Pralidoxime Iodide	5	~ 10 (IV Dose 500 mg)

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 does not have any symptoms of illness, first repeat the test. If the patient has symptoms or continues to get results which are higher or lower than usual, follow the treatment advice of a 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 a 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 hyperglycemic-hyperosmolar state, with or without ketosis. Please consult a healthcare professional before use.
- Critically ill patients should not be tested with a blood glucose monitoring system.

INTENDED USE

The **FORA D40 Pro** Blood Glucose Plus Blood Pressure Monitoring System is intended for use in the quantitative measurement of glucose in

fresh capillary whole blood from the finger and the following alternative sites: palm, forearm or upperarm. This system is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control. This system is only used with single-use auto-disabling lancing devices.

The system should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing such as the palm, forearm, and upper arm should be done only during steady state times (when glucose is not changing rapidly).

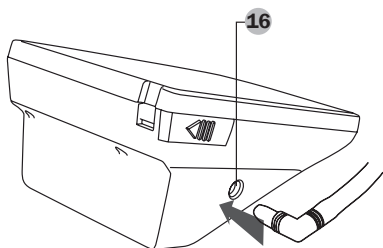
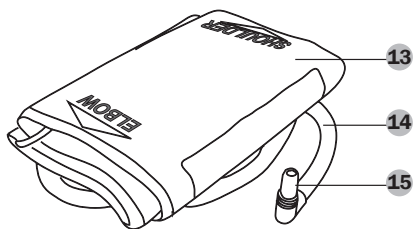
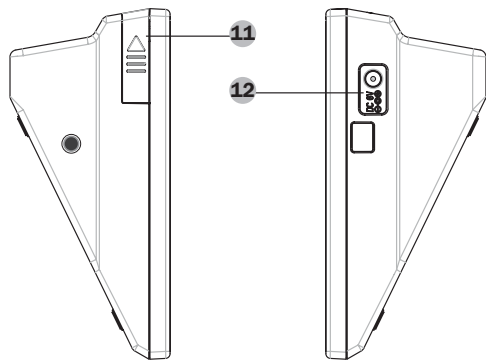
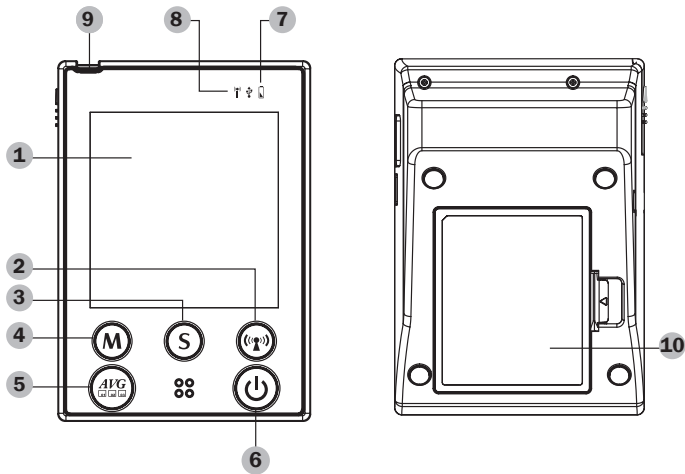
This system is also intended to be used to non-invasively measure the systolic and diastolic blood pressure and pulse rate of an adult individual. The blood pressure is measured by using an inflatable cuff wrapped around the arm.

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.

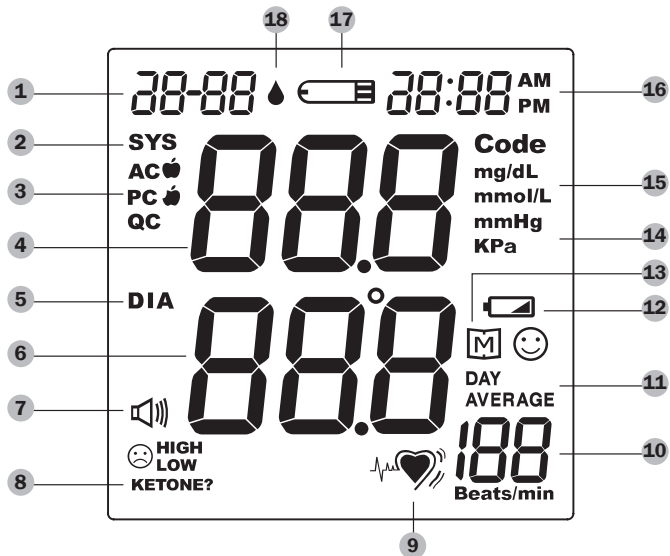
The blood pressure is measured non-invasively at the arm based on the Oscillometric method. This device is **NOT** able to take measurements in the presence of common arrhythmia, such as atrial or ventricular premature beats or atrial fibrillation; it may produce reading errors.

METER OVERVIEW



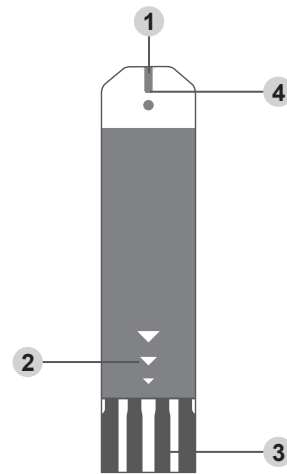
- 1 Display Screen**
- 2 RF Button**
Assists you with wireless data transmission.
- 3 S Button**
Enter and confirm the meter settings.
- 4 M Button**
Enter the meter memory.
- 5 AVERAGE Button**
Assists you with blood pressure average mode.
- 6 ON/OFF Button**
Starts a single non-invasive blood pressure measurement.
- 7 Power Indicator**
Indicates the power status of the device.
- 8 RF Indicator**
Indicates a wireless data transmission.
- 9 Test Slot**
Insert test strip here to turn the meter on for testing.
- 10 Battery Compartment**
- 11 Strip Ejector**
Eject the used strip by pushing this button up.
- 12 AC/DC Adapter Port**
Connects to a power supply.
- 13 Pressure Cuff**
- 14 Air Tube**
- 15 Air Plug**
Connects to air jack.
- 16 Air Jack**

Display Screen



- 1 Date
- 2 Systolic Pressure Symbol
- 3 Measuring Mode
- 4 Systolic Pressure Value
- 5 Diastolic Pressure Symbol
- 6 Diastolic Pressure Value
- 7 Volume Symbol
- 8 Ketone Warning
- 9 Heart Symbol for IHB Detection (Irregular Heart Beat)
- 10 Pulse Rate
- 11 Day Average Result
- 12 Battery Symbol
- 13 Memory Mode Symbol
- 14 Unit for Blood Pressure
- 15 Unit for Blood Glucose
- 16 Time
- 17 Test Strip Symbol
- 18 Blood Drop Symbol

Test Strip



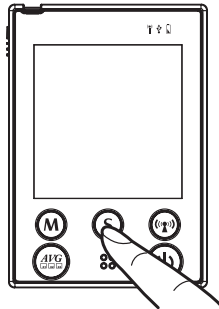
- 1 **Absorbent Hole**
Touch a drop of blood here, blood will be automatically drawn in.
- 2 **Test Strip Handle**
Hold this part to insert the test strip into the slot.
- 3 **Contact Bars**
Insert this end of the test strip into the meter. Push it in firmly until it will go no further.
- 4 **Confirmation Window**
This is where you confirm if enough blood has been applied to the absorbent hole in the strip.

ATTENTION:
The front side of the test strip should face up when inserting test strip.
Test results might be wrong if the contact bar is not fully inserted into the test slot.

NOTE:
The FORA D40 Pro meter should only be used with FORA D40 Pro Test Strips. Using other test strips with this meter can produce inaccurate results.

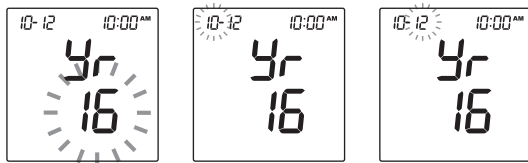
Setting the Meter

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



Entering the Setting Mode

Start with the meter off (no test strip inserted). Hold **S**.

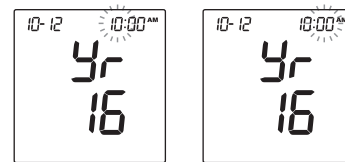


1. Setting the date

With the year flashing, press **M** until the correct year appears. Press **S**.

With the month flashing, press **M** until the correct month appears. Press **S**.

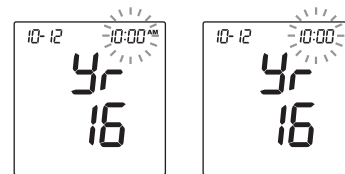
With the day flashing, press **M** until the correct day appears. Press **S**.



2. Setting the time

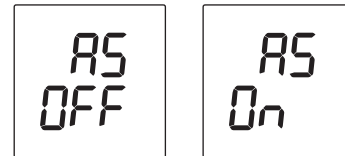
With the hour flashing, press **M** until the correct hour appears. Press **S**.

With the minute flashing, press **M** until the correct minute appears. Press **S**.



3. Setting the time format

Press **M** to select the desired time format – 12h (AM/PM) or 24h. Press **S**.




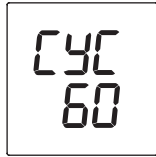
4. Setting the auto-send

Press **M** to select the auto-send “On” or “OFF”. Press **S**. This function is for the Bluetooth transmission. If “On” is selected, your results will be transmitted right after each test.



5. Deleting the memory

If you wish to delete ALL the results, press **M** twice when you see “dEL” and a flashing “” on the display. If you do not wish to delete the saved results, press **S** to skip this step.



6. Setting the cycle mode

Press **M** to choose the desired blood pressure cycle mode from the following time interval selections: OFF, 5, 10, 15, 20, 30, 40 or 60 minutes. Press **S** to turn off the meter.

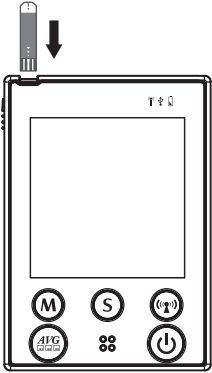
Congratulations!
You have completed all settings!

THE FOUR MEASURING MODES

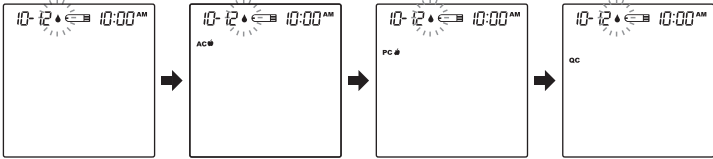
The meter provides you with four modes for measuring: General, AC, PC and QC.

MODES	WHEN TO USE
General Tests (GEN)	Any time of day without regard to time since last meal
AC	No food intake for at least 8 hours
PC	2 hours after a meal
QC	Testing with the control solution

You can switch between each mode.



1. Start with the meter switched off. Insert a test strip to turn on the meter.



2. Press **M** to switch between General, AC, PC and QC mode.

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 switch off automatically.

BEFORE TESTING

Control Solution Testing

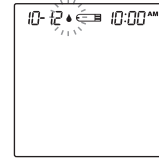
Our control solution contains a known amount of glucose that reacts with test strips and is used to ensure your meter and test strips are working together correctly.

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



Do a control solution test when:

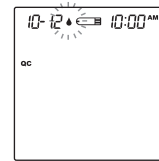
- You first receive the meter (optional)
- Occasionally, once a week is sufficient, to check the meter and test strips for in-range readings
- Every time you open a new container of test strips
- If you drop the meter
- Whenever you get unusual results (high or low)
- **Control solution is NOT used for calibration of the meter.**

Performing a Control Solution Test





1. Insert the test strip to turn on the meter

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

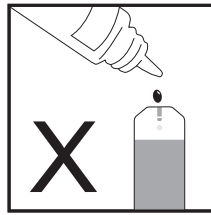
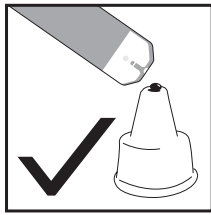
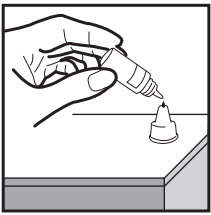


2. Press M to mark this test as a control solution test

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

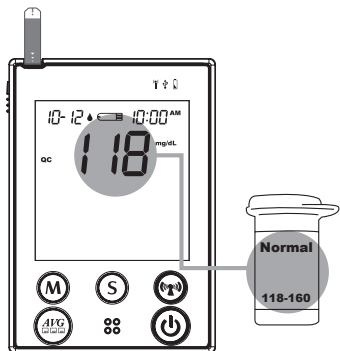
WARNING:

When doing the control solution test, you have to mark it so that the test result will **NOT** mix with the blood glucose **TEST RESULTS** stored in the memory. Failure to do so will mix up the blood glucose test results with the control solution test results in memory.



3. Apply control solution

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



4. Read and compare the results

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

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. Go to www.foracare.com or call customer service for help.

NOTE:

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

BLOOD GLUCOSE TESTING

WARNING: Potential Biohazard!

Healthcare professionals using this system on multiple patients should follow the infection control procedure approved by their facility. All products or objects which come in contact with human blood, even after cleaning, should be handled as if capable of transmitting viral diseases.

Only auto-disabling, single-use lancing devices may be used with this device. To reduce the chance of infection:

- Always wear gloves and follow your facility's biohazard control policy and procedures when performing tests involving patient blood samples.
- Wear a new pair of clean gloves before testing each patient. Change gloves between patients.
- Wear protective glasses and/or other protective clothing if necessary.
- Never share a lancet or the lancing device.
- Avoid getting hand lotion, oils, dirt, or debris in or on the lancets and the lancing device.

We recommend you perform disinfection procedures between each patient. Please refer to the section **MAINTENANCE** for complete instructions. After disinfection, used gloves should be removed and hands washed before proceeding to the next patient.

Please refer to the following practice guidelines for more information about the correct procedure:

- Biosafety in Microbiological and Biomedical Laboratories (BMBL) found at <http://www.cdc.gov/biosafety/publications/bmbl5/>
- "Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline-Third Edition" Clinical and Laboratory Standards Institute (CLSI) M29-A3.

Preparing the Puncture Site

Rubbing the puncture site before blood extraction has a significant influence on the accuracy of your test results.

Blood from an alternate site that has not been rubbed exhibits a measurably different glucose concentration than blood from the finger.

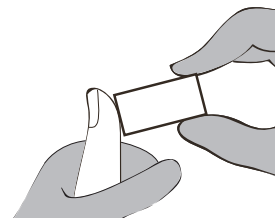
When the puncture site was rubbed prior to blood extraction, the test result will be more precise.

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

- **Wash and dry your hands before starting.**
- Select the puncture site either at fingertips or another body part (please see section "Alternative Site Testing" (AST) on how to select the appropriate site).
- Rub the puncture site for about 20 seconds before penetration.
- Clean the puncture site using cotton moistened with 70% alcohol and **let it air dry.**

• **Fingertip Testing**

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



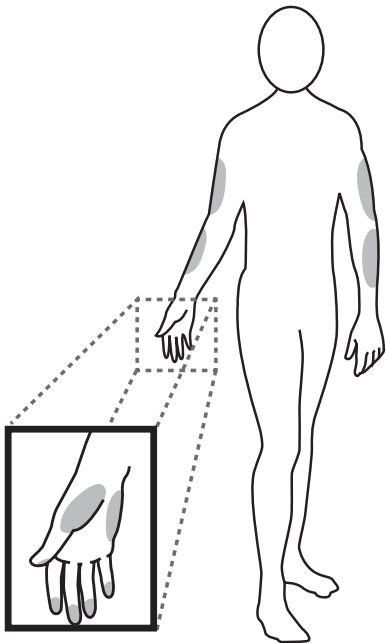
NOTE:

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

Alternative Site Testing

Important: There are limitations with AST (Alternative Site Testing).

- **AST results should not be used for CGM calibration.**
- **AST results should not be used for insulin dosing calculations. Please consult your health care professional before you perform AST.**



What is AST?

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

What is the advantage?

Fingertips feel pain more readily because they are full of nerve endings (receptors). At other body sites, since nerve endings are not so condensed, you will not feel as much pain as on the fingertips.

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. Thus, when testing blood glucose during or immediately after a meal, physical exercise, or any other event, **take a blood sample from your finger only.**

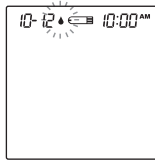
We strongly recommend that you perform AST **ONLY** at the following times:

- 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:

- You think your blood glucose is low.
- You often do not notice when your blood glucose is low.
- You think your blood glucose is high.
- Your AST results do not match the way you feel.
- Your routine glucose results often fluctuate.

Performing a Blood Glucose Test



1. Insert the test strip to turn on the meter


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

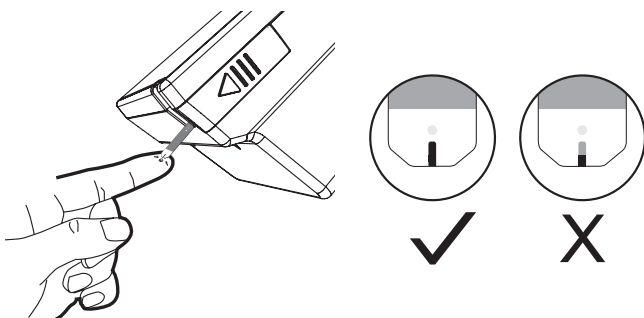
2. Select the appropriate measuring mode by pressing the M button

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



3. Obtaining a blood sample

Use the pre-set lancing device to puncture the desired site. Wipe off the first appeared drop of blood with a clean cotton swab. The size of the drop should be at least as big as () actual size, which is 0.5 microliter (μL) of volume. Gently squeeze the punctured area to obtain another drop of blood. Be careful **NOT** to smear the blood sample.

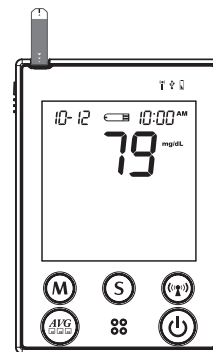


4. Bring strip to sample

While holding the meter at an angled position with the strip facing down, gently bring the strip to the sample so that the absorbent hole can sip in the blood. Confirmation window should be completely filled if enough blood has been applied. Do **NOT** remove the finger until you hear a beep sound.

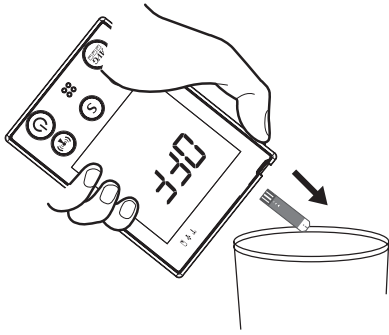
NOTE:

- Do not press the punctured site against the test strip or try to smear the blood.
- If you do not apply a blood sample 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 your health-care professional or local customer service for assistance.



5. Read the result

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



6. Eject the used test strip

Eject the test strip by pushing the eject button on the side. Use a sharps container to dispose of the used test strips. The meter will switch itself off automatically.

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

TESTING THE BLOOD PRESSURE

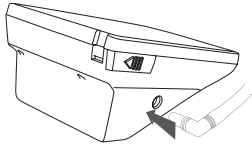
Before Measurement

- Avoid caffeine, tea, alcohol and tobacco at least 30 minutes before measurement.
- Wait 30 minutes after exercising or bathing before measurement.
- Sit or lie down for at least 10 minutes before measurement.
- Do not measure when feeling anxious or tense.
- Take a 5-10 minute break between measurements. This break can be longer if necessary, depending on your patient's physical conditions.
- Keep the records for the patient's doctor as reference.
- Blood pressure varies between each arm. Always measure your patient's blood pressure on the same arm.
- To take a blood pressure measurement after performing a blood glucose test, make sure that the test strip has been removed from the meter.

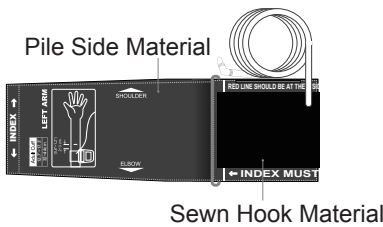
WARNING:

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

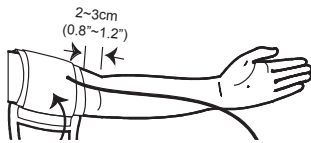
Fitting the Cuff Correctly



1. Connect the air plug of the tubing to the air jack of the meter.



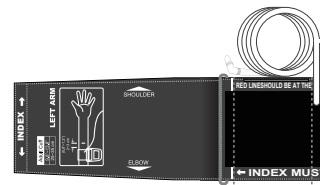
2. Assemble the cuff as shown. The smooth surface should be inside the cuff loop and the metal D-ring should not touch the patient's skin.



3. Stretch the left or right arm in front of your patient with the palm facing up. Slide and place the cuff onto the arm with the air tube and artery mark region (in red) toward the lower arm.

Wrap and tighten the cuff above the elbow. The red line on the edge of the cuff should be approximately **0.8 to 1.2 inches (2 to 3 cm)** above the elbow. Align the tube over the main arteries on the inside.

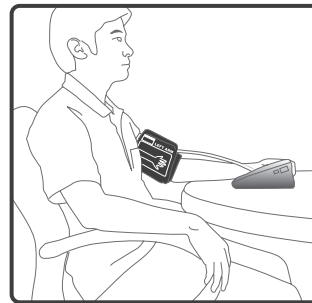
4. Leave a little free space between the arm and the cuff; you should be able to fit 2 fingers between them. Clothing must not restrict the arm. Remove all clothing covering or constricting the measurement arm.



► The range index of cuff should fall into this range.

5. Press the hook material firmly against the pile material. The top and bottom edges of the cuff should be tightened evenly around the upper arm.

Proper Measurement Position



1. Sit down for at least 10 minutes before measuring.

2. Place the elbow on a flat surface. Relax the hand with the palm facing up.

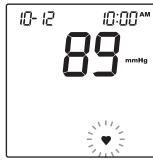
3. **Make sure the cuff is about the same height as the location of the patient's heart.** Remain still and do not talk or move during the measurement.

Taking Measurements

This meter provides three different ways to measure the blood pressure.

• Single Measurement Mode

Always apply the pressure cuff before turning on the meter.



1. Press . All the LCD symbols will appear. The cuff will begin to inflate automatically.

2. The heart symbol “♥” will flash when a pulse is detected during the inflation.



3. After the measurement, the meter displays the systolic pressure, diastolic pressure and pulse rate.

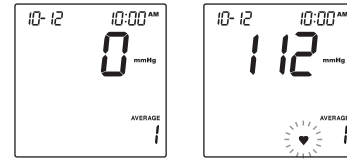
4. Press to switch off. Or it will switch off automatically after left idle for 3 minutes.

NOTE:

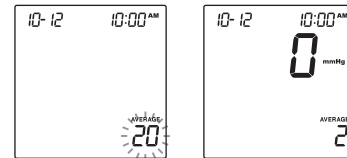
- If you press during measurement, the meter will be turned off.
- If the pulse rate symbol is shown as “” instead of “♥”, the symbol means that the measured heart beat is 25% over the average heart beat.

• Measurement Average Mode

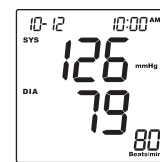
Always apply the pressure cuff before turning on the meter.



1. Press . The meter will turn on and enter the averaging mode. The cuff will begin to inflate automatically.



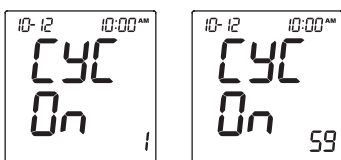
2. After the first measurement is complete, the meter will start counting down before the second measurement begins. The number on the right represents the remaining countdown between each measurement. The meter will take three (3) measurements consecutively with an interval of 20 seconds.



3. After taking three measurements, the results are averaged to produce the blood pressure measurement. Press to turn off the meter.

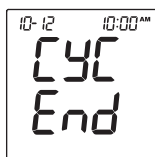
• Auto Cycle Mode

Always apply the pressure cuff before turning on the meter.



1. Hold **S** to enter cycle mode. The meter will automatically take blood pressure measurement within 1-2 minutes for first measurement. The **CYC On** will show on the display and stay on until the remaining time is at 1 minute. The number on the right represents the remaining seconds countdown from 59 between each measurement.

2. The cuff will begin to inflate automatically. After the first measurement is complete, the meter will take measurements consecutively in the selected time intervals for up to 5 hours.



3. After completion of the cycle mode for 5 hours, the meter will display **CYC End** and press any key to turn off the meter.

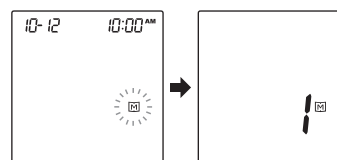
NOTE:

To discontinue the cycle mode measurement during the time intervals, press **S** and hold for 3 seconds to enter setting mode and select cycle mode OFF. Press **S** again to turn off the meter.

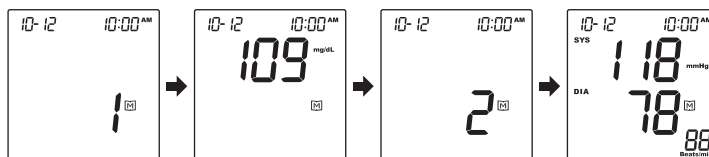
METER MEMORY

Your meter stores the 864 most recent blood glucose and blood pressure test results with date and time in its memory. To enter the meter memory, **start with the meter switched off.**

Reviewing Test Results



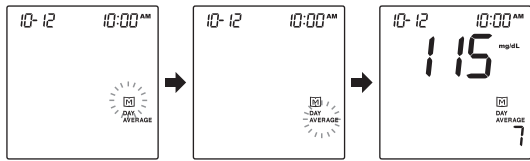
1. **Press and release M.** “**M**” will appear on the display.



2. **Press M.** Review all test results stored in the meter. Results display according to the time of measurement taken. The latest measurement displays first. Press **M** to view older results, and press **S** to view newer results.

3. **Exit the memory.** Press **⏻** and the meter will turn off.

Reviewing Day Average Results



1. Press and hold M.

When “**M**” appears on the display, keep pressing **M** for 3 seconds until the flashing “**DAY AVERAGE**” 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 blood glucose results stored in each measuring mode.

3. Press **S** to review 7-, 14-, 21-, 28-, 60- and 90- day average blood pressure results stored in each measuring mode.

4. Exit the meter memory. Press **⏻** and the meter will turn off.

NOTE:

- Any time you wish to exit the memory, press **⏻** or leave the meter idle for 3 minutes. The meter will turn off automatically.
- Control solution results are **NOT** included in the day average.
- If there are no records in memory, “---” displays when you recall the test results or review the average results. This indicates that there is no test result in the memory.
- The blood glucose test results of **Lo** and **Hi** will **NOT** be calculated in the day average results.

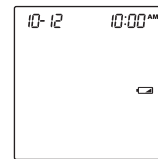
MAINTENANCE

Battery

Your meter comes with one 3.7V lithium-ion rechargeable battery.

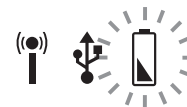
Low Battery Signal

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



1. The “**🔋**” appears along with display messages: The meter is functional and the result remains accurate, but it is time to charge the battery.

If the power is not enough to do a test, the symbol starts blinking. Please charge the battery immediately.



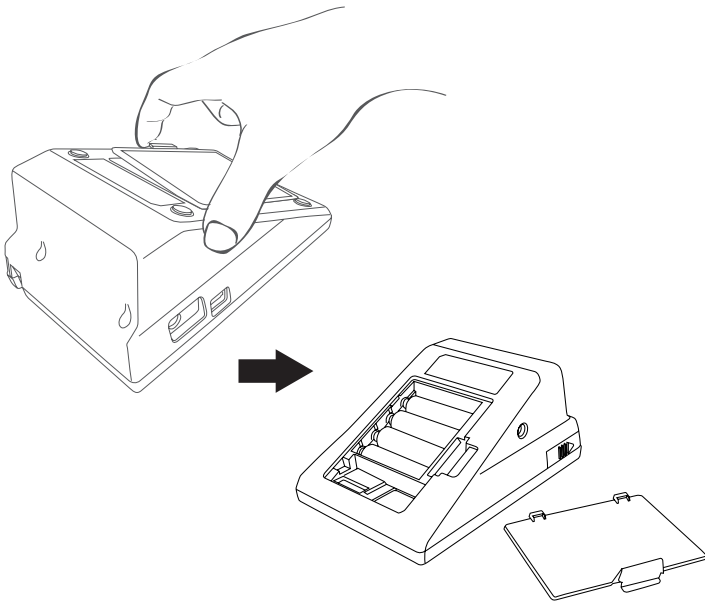
2. The power indicator lights up in red.

Replacing the Battery

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

WARNING:

- FORA D40 Pro uses one Li-ion rechargeable battery **ONLY** (battery pack no. S14500 1S4P).
- Wrong types of batteries may cause an explosion.
- Do not use other types of batteries, mix old and new or different brands of batteries. Use only new batteries of the specified size and type.



1. Press the edge of the battery cover and lift it up to remove.
2. Remove the old battery and replace it with one 3.7V rechargeable Li-ion battery.
3. Close the battery cover. If the battery is inserted correctly, you will hear a “beep” afterwards.

CAUTION:

Risk of explosion if battery is replaced by an incorrect type. Dispose of used batteries according to the instructions.

The Li-ion battery is about the same shape and size as the four alkaline batteries, thus the location of Li-ion battery is the same as that for inserting alkaline batteries. If you are installing a Li-ion battery, make sure the battery is correctly inserted in the compartment.

NOTE:

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

Recharging the Battery

The power adapter can be used as the battery charger when you need to recharge Li-ion battery. To recharge the 3.7V Li-ion battery, connect AC adapter to the meter and a power source.



The power indicator will light up in green, which indicates the battery is undergoing a recharge. It should take approximately 5 hours to be fully charged.

If the power indicator is blinking in red when connecting AC adapter to a power source, this indicates the meter is in a pre-charging stage. If the power indicator starts blinking in green, this indicates the recharge is nearly finished. The power indicator will diminish when the recharge completes.

CAUTION:

The Li-ion battery must be recharged with the **FORA D40 Pro** meter by connecting AC adapter to an electrical outlet. Only this 3.7V rechargeable Li-ion battery (battery pack no. S14500 1S4P) can be recharged by **FORA D40 Pro** with the connection of AC adapter. Any other kind of rechargeable battery is not allowed or it may damage the meter.

CLEANING AND DISINFECTING PROCEDURES

Caring for Your Meter

Wash and dry your hands thoroughly before use or handling of the meter and strips.

► **What is Cleaning and Disinfecting?**

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

► **When to clean and disinfect the meter?**

Clean the meter when you see any dirt on it. Disinfect the meter between each patient to prevent infection.

► **How to clean and disinfect the meter?**

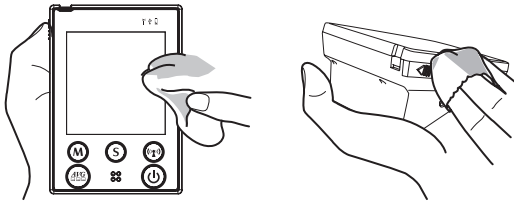
The meter must be cleaned prior to the disinfection. Use one disinfecting wipe to clean exposed surfaces of the meter thoroughly and remove any visible dirt or blood or any other body fluid with the wipe. Use a second wipe to disinfect the meter. Do **NOT** use organic solvents to clean the meter.

We recommend for meter cleaning and disinfection you should use the disinfecting wipes/towelettes from below. The following product has been shown to be safe for use with the **FORA D40 Pro** Blood Glucose Monitoring System.

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

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

Disinfecting Procedures



1. Put on non-sterile gloves.
2. Take out one disinfecting wipe from the package and squeeze out any excess liquid in order to prevent damage to the meter.
3. Wipe all meter's exterior surface display and buttons. Hold the meter with the test strip slot pointing down and wipe the area around the test slot but be careful not to allow excess liquid to get inside. Keep the meter surface wet with disinfection solution for a minimum of 2 minutes for Micro-Kill+™ wipes. Follow the instructions on the package label of disinfecting wipes. **Do not use the wipe to clean or disinfect the pressure cuff.**
4. Remove the wipe. Allow the meter surface to dry completely.
5. Discard the used wipes and never reuse them.
6. Remove and discard gloves in appropriate receptacles and wash hands.

Wash your hands thoroughly with soap and water after handling the blood glucose monitoring system, lancing device and test strips to avoid contamination.

Each cleaning and disinfection cycle includes a pre-cleaning step with one wipe and a disinfection step with a second wipe. Improper system cleaning and disinfection may result in meter malfunction. If you have a question, please contact customer service at 1-888-307-8188 for assistance.

This device has been validated to withstand 10,000 cleaning and disinfection cycles using the recommended disinfecting wipe/towelette. The tested number of cycles is estimated by 5 cleaning and disinfection cycle per meter per week for 3 years, the expected life of the device.

The meter should be replaced after the validated number of disinfection cycles or the warranty period has been met, whichever comes first.

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

- meter cannot be turned on,
- LCD display cracks or becomes cloudy,
- buttons no longer function,
- meter outer casing cracks,
- data can not be transmitted to PC,
- color or paint/printing on housing is abnormal, or
- scratches or abrasions on meter are higher than acceptable.

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

NOTE:

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

For more information of how to perform disinfection procedures for the meter between patients, please refer to:

“FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication” (2010)
<https://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm234889.htm>

“CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens” (2010)
<http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>

Cleaning

- Do **NOT** flush your monitor with water.
- Do **NOT** wash the pressure cuff.
- Do **NOT** iron the pressure cuff.

Meter Storage

- Storage conditions: -4°F to 140°F (-2°C to 60°C), below 95% relative humidity.
- Always store or transport the meter in its original storage case.
- Avoid dropping and heavy impact.
- Avoid direct sunlight and high humidity.

Important Test Strip Information

- Storage conditions: 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 dry place. Keep away from direct sunlight and heat.
- After removing a test strip from the vial, immediately close the vial cap tightly.
- Touch the test strip with clean and dry hands.
- Use each test strip immediately after removing it from the vial.
- Write the opening date on the vial label when you first opened it.
- Discard remaining test strips after 3 months.
- Do not use test strips beyond the expiration date. This may cause inaccurate results.
- Do not bend, cut, or alter a test strip in any way.
- Keep the strip vial away from children since the cap and the test strip may be a choking hazard. If swallowed, promptly see a doctor for help.

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

Important Control Solution Information

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


SYSTEM TROUBLESHOOTING

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

Result Readings

MESSAGE	WHAT IT MEANS
Lo	Appears when your blood glucose test result is below the lower measurement limit, which is less than 20 mg/dL (1.1 mmol/L).
KETONE?	Appears when your 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. Please seek medical assistance immediately.
Hi	Appears when your result is higher than the limit of measurement, which is higher than 600 mg/dL (33.3 mmol/L).

Error Messages

MESSAGE	WHAT IT MEANS	WHAT TO DO
Err 1 Err 2	Inflation or pressure error.	Refit cuff tightly and correctly. Relax and repeat the measurement. If the error still remains, please contact customer service for help.
Err 3	Cuff pressure is too high.	
Err 4 Err 5	No pulse rate detected or the pulse rate is too low.	
Err 6	Systolic pressure is outside the system's measurement range.	System measurement range is 60 mmHg – 250 mmHg. Review the instructions and repeat the test. If the error still remains, please contact your healthcare professional for help.
Err 8	Forced to stop the blood pressure measurement after re-pump for 2 times.	Turn off the device and start over. Follow the instructions and try again.
	Appears when the batteries cannot provide enough power for a test.	Replace or recharge the batteries immediately.
E-U	Strip has been used.	Repeat the test with a new test strip. If the meter still does not work, please contact the customer service for assistance.
E-t HIGH E-t LOW	Environmental temperature is outside the system's operational range.	System operational range is 50°F to 104°F (10°C to 40°C). Repeat the test after the meter and test strip have reached the above temperature.


Troubleshooting

• Blood Glucose Measurement

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

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

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

POSSIBLE CAUSE	WHAT TO DO
Defective test strip.	Repeat the test with a new test strip.
Sample applied after automatic switch-off (3 minutes after last user action).	Repeat the test with a new test strip. Apply sample only when flashing “  ” appears on the display.
Defective meter.	Please contact customer service.

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

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

• Blood Pressure Measurement

1. If there is no display after pressing :

POSSIBLE CAUSE	WHAT TO DO
Batteries incorrectly installed or absent.	Check that the batteries are correctly installed.

2. If the heart rate is higher or lower than user's average:

POSSIBLE CAUSE	WHAT TO DO
Movement during measurement.	Repeat measurement.
Measurement taken just after exercise.	Rest at least 30 minutes before repeating measurement.

3. If the result is higher or lower than user's average measurement:

POSSIBLE CAUSE	WHAT TO DO
May not be in correct position while measuring.	Read instructions thoroughly and repeat the test again.
Blood pressure naturally varies from time to time.	Keep in mind for next measurement.

SPECIFICATIONS

• System Performance

Power Source:

One 3.7V lithium-ion rechargeable battery (battery pack no. S14500 1S4P)

Size of Meter without Cuff:

147 mm (L) x 105 mm (W) x 80 mm (H), around 500 g with battery

Memory: Maximum 864 memory records

Power Saving:

Automatic power off if system is idle for 3 minutes (normal mode) or 5 minutes (RF mode)

System Operating Condition:

50°F to 104°F (10°C to 40°C), 10 - 85% RH

Meter Storage Condition:

-4°F to 140°F (-20°C to 60°C), 10 - 95% RH

Strip Storage Condition:

39.2°F to 104°F (4°C to 40°C), below 85% RH

Power Supply Input:

DC +6V / 1A (max) via Power Plug

Expected Service Life: 3 years

• Blood Glucose Measurement Performance

Measurement Unit: mg/dL

Measurement Range:

20 to 600 mg/dL (1.1 to 33.3 mmol/L)

Precision: $\pm 5\%$ (CV)

Accuracy:

± 15 mg/dL (0.83 mmol/L) when glucose < 75mg/dL (4.16 mmol/L)

$\pm 20\%$ when glucose ≥ 75 mg/dL (4.16 mmol/L)

Ketone Warning: ≥ 240 mg/dL (13.3 mmol/L)

• Blood Pressure Measurement Performance

Pressure Range: 0 to 300 mmHg

Measurement Unit: mmHg

Systolic Measurement Range: 60 to 250 mmHg

Diastolic Measurement Range: 30 to 180 mmHg

Pulse Rate Measurement Range:

40 to 199 beats / minute

Maximum Inflation Pressure: 280 mmHg

Accuracy of Pressure:

± 3 mmHg or $\pm 2\%$ of reading

Accuracy of Pulse Rate: $\pm 4\%$ of reading

This device has been tested to meet the electrical and safety requirements of: IEC/ EN 60601-1, IEC/EN 60601-1-2, IEC/ EN 61010-1, IEC/EN 61010-2-101, IEC/EN 61326-2-6.

Reference to Standards:

- IEC 60601-1 General requirement for safety
- IEC 60601-1-2 Requirements for EMC
- AAMI/ANSI /IEC 80601-2-30, ANSI/AAMI/ISO 81060-2, NIBP requirements

TRAINING TOOLS

Attachment 1: FORA D40 Pro Blood Glucose Plus Blood Pressure 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 D40 Pro meter.	
	Understands different test types - finger, quality control, preferred sample type and sample volume.	
	Principles of quality testing and QC materials.	
	Only uses FORA D40 Pro test strips and FORA control solution with the FORA D40 Pro meter.	
	Understands the important features, benefits and limitations of the FORA D40 Pro system.	
	Knows the proper method of disposing 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 D40 Pro system.	
	Locates the serial number, test strip port, test strip ejector, M 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	Knows how to properly place the blood pressure cuff on the patient's arm.	
	Demonstrates proper safety lancet technique when collecting a blood sample.	
	Demonstrates the correct blood testing procedures using the FORA D40 Pro 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 D40 Pro 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 D40 Pro Blood Glucose plus Blood Pressure Monitoring System** before performing glucose and blood pressure testing on residents.

Attachment 2: FORA D40 Pro Blood Glucose and Blood Pressure Monitoring System Training Quiz

Complete the following questions to assess your understanding about using the FORA D40 Pro Blood Glucose plus Blood Pressure Monitoring System to perform blood glucose and blood pressure tests on residents.

NO.	QUESTIONS	ANSWER
1	The FORA D40 Pro Blood Glucose Monitoring System uses: a) GOD (glucose oxidase) enzyme b) GDH (glucose dehydrogenase) enzyme	
2	The FORA D40 Pro 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 D40 Pro Blood Glucose Monitoring System requires a blood volume of: a) 0.3 µL b) 0.7 µL c) 0.5 µL	
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	
8	If you saw the following message (no message) on the meter's display, what action should you take?  a) Replace the battery b) Retest with a new strip c) Repeat the test when the room temperature is within 50°F to 104°F	
9	The test strips should be stored: a) At 39.2°F to 104°F (4°C to 40°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	
10	The blood pressure cuff should be placed on the arm closest to the patient's: a) Heart b) Shoulder c) Wrist	

Training Completed by:

Name of Trainee	Date	SCORE

Answers:

1.(a) 2.(d) 3.(c) 4.(d) 5.(b)
6.(d) 7.(a) 8.(a) 9.(b) 10.(a)

FORA[®] D40 Pro

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