English

Dear ForaCare® D20 No-Coding System Owner:

Thank you for purchasing the **ForaCare D20 No-Coding** Blood Glucose plus Blood Pressure Monitoring System. This manual provides important information which helps you to operate this system smoothly. Before using this product, please read the following contents thoroughly and carefully.

According to the clinical studies from American Diabetes Association, elevated blood pressure often accompanies adult diabetes patients. These studies also suggest that diabetes patients could reduce the risk of cardiovascular diseases by managing their blood glucose levels and blood pressure. Therefore, with easy operation of this **ForaCare D20 No-Coding** Blood Glucose plus Blood Pressure Monitoring System, you can easily monitor your blood glucose levels and blood pressure by yourself at any place, any time. In addition, this system can help you and your healthcare professionals to monitor and adjust your treatment plans, and keep your diabetes and blood pressure under control.

If you have other questions regarding this product, please contact the place of purchase.

Version 4.0 2013/01 311-3263100-006

IMPORTANT SAFETY PRECAUTIONS
READ BEFORE USE

- The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

For more information, please visit

1."FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010)
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm

2."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

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 damaged.

4. Do **NOT** use the equipment where aerosol sprays are being used or where oxygen is being administered.

5. Do **NOT** use under any circumstances on newborns or infants.

6. This device does **NOT** serve as a cure for any symptoms or diseases. The data measured is for reference only.

7. Before using this device to test blood glucose, read all instructions thoroughly and practice the test. Do all quality control checks as directed.

8. Keep the device and testing supplies away from young children. Small items such as the battery cover, batteries, test strips, lancets and vial caps are choking hazards.

9. Keep the equipment and its flexible cord away from hot surfaces.

10. Do **NOT** apply the cuff to areas other than the place directed.

11. Use of this device in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging static discharges that may cause erroneous results.

12. Do **NOT** use this device in close proximity to sources of strong electro magnetic radiation, as these may interfere with the correct operation.

13. Proper maintenance and periodically calibration are essential to the longevity of your device. If you are concerned about your accuracy of measurement, please contact local customer service for help.

KEEP THESE INSTRUCTIONS IN A SAFE PLACE

TABLE OF CONTENTS

BEFORE YOU BEGIN

Important Information

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

- If your blood glucose results are lower or higher than usual, and you do not have symptoms of illness, first repeat the test. If you have symptoms or continue to get results higher or lower than usual, follow the treatment advice of your healthcare professional.

- Use only fresh whole blood sample to test your blood glucose. Using other substances will lead to incorrect results.

- If you are experiencing symptoms that are inconsistent with your blood glucose test results and you have followed all instructions described in this owner's manual, call your healthcare professional.

- 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 the healthcare professional before use.

Intended Use

This system is a 2 in 1 system designed to measure blood glucose outside the human body (*in vitro* diagnostic use) and to measure blood pressure non-invasively. It is intended for use at home as an aid to monitoring the effectiveness of diabetes control.

It shall not be used for the diagnosis of diabetes and hypertension, or for the testing of neonates. It is intended to be used by a single person and should not be shared.

Test Principle

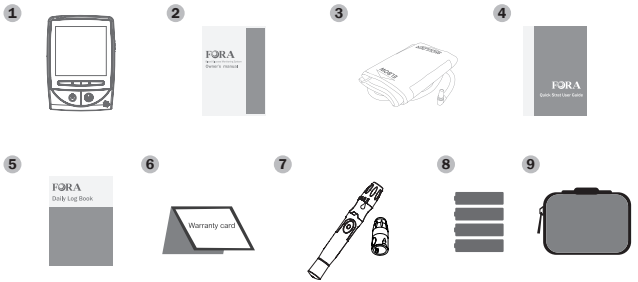
Your system measures the amount of sugar (glucose) in whole blood. The glucose testing is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the strip. Your monitor measures the current, calculates the blood glucose level, and displays the result. 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 arterial or ventricular premature beats or arterial fibrillation. It may produce reading errors.

Contents of System

Your new **ForaCare D20 No-Coding** system kit includes:



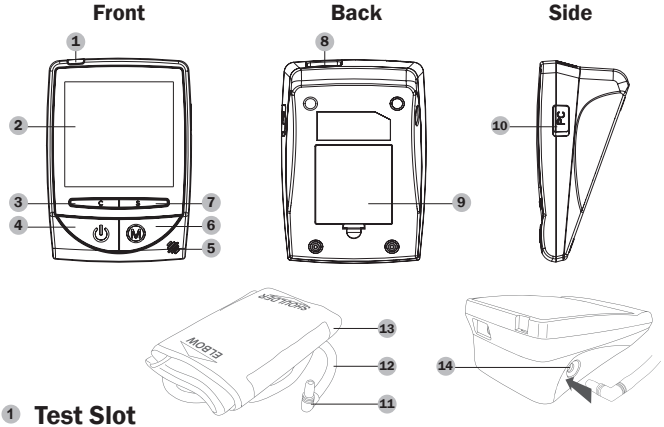
1. Monitor
2. Owner's Manual
3. Pressure Cuff (arm type)
4. Quick Start User Guide
5. Daily Log Book
6. Warranty Card
7. Lancing Device with One Clear Cap (Optional)
8. 4 x 1.5V AA alkaline batteries
9. Protective Storage Case

Test strips, control solutions, lancing device or sterile lancets may not be included in the kit (please check the contents on your product box). They may be purchased separately. Please make sure you have those items needed for a blood glucose test beforehand.

NOTE

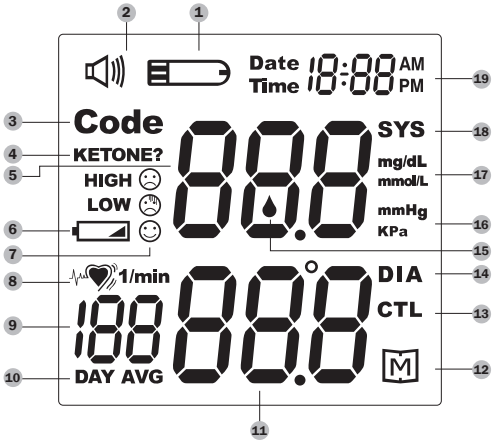
If any items are missing from your kit or opened before use, please contact local customer service or place of purchase for assistance.

Monitor Overview



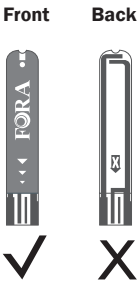
1. **Test Slot**
   Insert test strip here to turn the monitor on for testing.
2. **Display Screen**
3. **C Button**
   Enter control solution test.
4. **On/Off Button**
   To start a single NIBP measurement.
5. **Speaker**
6. **M Button**
   Enter the monitor memory.
7. **S Button**
   Enter and confirm the monitor settings.
8. **AC/DC Adapter Port**
   Connect to a power supply.
9. **Battery Compartment**
10. **USB Link Port**
    Download test results with a cable connection.
11. **Air Plug**
    Connect to air jack.
12. **Air Tube**
13. **Pressure Cuff**
14. **Air jack**

Screen Display

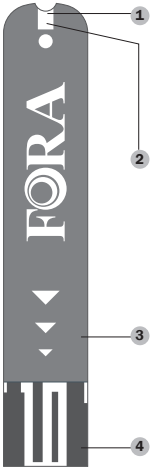


1. Test Strip Symbol
2. Volume Symbol
3. Code Number
4. Special Message
5. Systolic Pressure Value
6. Battery Symbol
7. Indicator Symbol
8. Heart Symbol
9. Pulse Rate
10. Day Average Result
11. Diastolic Pressure Value
12. Memory Mode Symbol
13. Control Mode Symbol
14. Diastolic Pressure Symbol
15. Blood Drop Symbol
16. Unit for Blood Pressure
17. Unit for Blood Glucose
18. Systolic Pressure Symbol
19. Date/Time

Test Strip



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

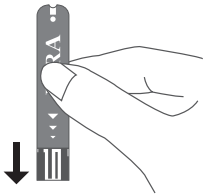


1 **Absorbent Hole**
Apply a drop of blood here. The blood will be automatically absorbed.

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

3 **Test Strip Handle**
Hold this part to insert the test strip into the slot.

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



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

NOTE

The **ForaCare D20 No-Coding** monitor should only be used with **FORA D20** Test Strips. Using other test strips with this meter can produce inaccurate results.

Speaking Function

ForaCare D20 No-Coding “speaks” aloud with step-by-step instructions to guide you through the process of blood glucose testing. The following table tells you when and what the monitor “speaks”.

WHEN does the monitor speak?	**WHAT** does the monitor speak?
When turn on the monitor.	Thank you for using FORA Telehealth product. Please relax during measurement.
When room temperature is outside operating range, which is 50°F to 104°F (10°C to 40°C).	Room temperature out of range, unable to measure.
When the monitor is ready to test the glucose measurement. (symbol appears on display)	Please apply blood into the strip.
When the glucose test is completed (the result appears on display) or when entering the memory mode.	The blood glucose is (number) milligram per deciliter/ millimole per liter.
When the blood pressure test is completed (the result appears on display) or when entering the memory mode.	The systolic blood pressure is (number) millimeter of mercury, the diastolic blood pressure is (number) millimeter of mercury and the heart rate is (number) beats per minute.

WHEN does the monitor speak?	**WHAT** does the monitor speak?
When the glucose test result is outside measurement range, which is 20 to 600 mg/dL (1.1 to 33.3 mmol/L).	The blood glucose out of range, unable to measure.

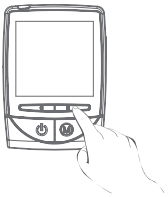
This monitor has some speaking functions but has not been validated for use by visually impaired users.

SETTING THE MONITOR

Before using your monitor for the first time or if you change the meter battery, 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 monitor off (no test strip inserted). Press **S** until the monitor turns on.



Step 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 Ⓜ until the correct day appears. Press Ⓢ .

Step 2

Setting the time.

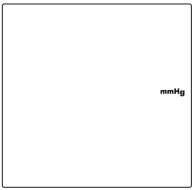
With the hour flashing, press Ⓜ until the correct hour appears. Press Ⓢ .

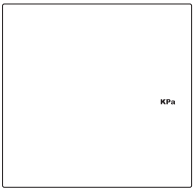
With the minute flashing, press Ⓜ until the correct minute appears. Press Ⓢ .

Step 3

Setting the unit of measurement.

Press Ⓜ to select mmHg or Kpa (the default setting is mmHg). Press Ⓢ .





Step 4

Deleting the memory.

While “dEL” and a flashing “ Ⓜ ” symbol appear on the display along with user numbers, if you do not wish to delete the saved results, press Ⓢ to skip this step. If you wish to delete **ALL** the results, press Ⓜ twice.

Step 5

Setting the speaking volume.

There are seven (7) speaking volume options to let you choose. Press Ⓜ until the desired speaking volume appears. Press Ⓢ .

Volume 0 indicates that the speaking function is turned off, and will not display “ 🔊 ”. Volume 1 to 7 indicates speaking volume from low to high, and “ 🔊 ” will be displayed during testing.

Step 6

Choose a language.

Press Ⓜ to select LAn1 / LAn2. The default language is English (LAn 1). LAn2 is Spanish.

Congratulations! You have completed all settings!

NOTE

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

TESTING YOUR BLOOD GLUCOSE

Control Solution Testing

FORA Control Solution contains a known amount of glucose that reacts with test strips and is used to ensure your monitor and test strips are working together correctly.

Do a control solution test when:

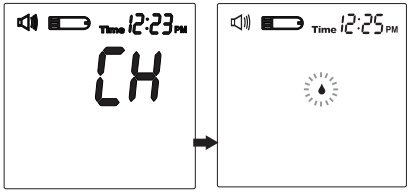
- you first receive the monitor
- at least once a week to routinely check the monitor and test strips
- you begin using a new vial of test strips
- you suspect the monitor or test strips are not working properly
- your blood glucose test results are not consistent with how you feel, or if you think the results are not accurate
- testing process or
- you have dropped or think you may have damaged the monitor.

Performing a Control Solution Test

Step 1

Insert the test strip to turn on the monitor.

Insert the test strip into the monitor. Wait for the monitor to display the test strip and blood drop symbol.



Step 2

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

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

WARNING

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

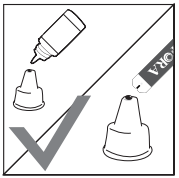
Step 3

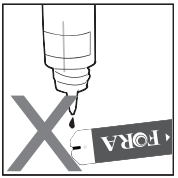
Apply Control Solution.

Shake the control solution vial thoroughly before use. Squeeze out a drop and wipe it off, then squeeze another drop and place it on the tip of the vial cap.

Hold the monitor to move the absorbent hole of test strip to touch the drop. Once the confirmation window fills completely, the monitor will begin counting down.

To avoid contaminating the control solution, do not directly apply control solution onto a strip.

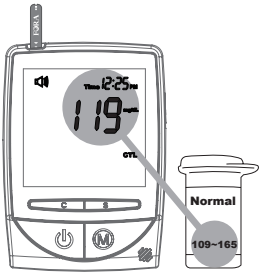




Step 4

Read and Compare the Result.

After counting down to 0, the test result of control solution will appear on the display. Compare this result with the range printed on the test strip vial and it 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 monitor and strips may not be working properly. **Do NOT** test your blood. Contact the local customer service or place of purchase 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.

TESTING WITH BLOOD SAMPLE

Preparing the Lancing Device for Blood Testing

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

WARNING

To reduce the chance of infection:

- Never share a lancet or the lancing device.
- Always use a new, sterile lancet. Lancets are for single use only.
- Avoid getting hand lotion, oils, dirt, or debris in or on the lancets or the lancing device.
- Wash and dry your hands thoroughly before and after handling the meter, lancing device and test strips to prevent infection. For more information, please refer to the “Cleaning and Disinfection” section.
- If the meter is being operated by a person who is providing testing assistance to the user, the meter and lancing device should be decontaminated prior to use by that person.

Sharing the lancing device and lancets may increase the risk of spreading infectious diseases. Lancing device must not be used on more than one person.

Preparing the Puncture Site

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

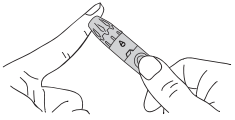
Blood from a site that has not been rubbed exhibits a measurably different glucose concentration than blood from the finger. When the puncture site was rubbed prior to blood extraction, the difference was significantly reduced.

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 parts (please see section “Alternative Site Testing” (AST) on how to select the appropriate sites).
- Clean the puncture site using cotton moistened with 70% alcohol and **let it air dry.**
- Rub the puncture site for about 20 seconds before penetration.
- Use a clear cap (included in the kit) while setting up the lancing device.

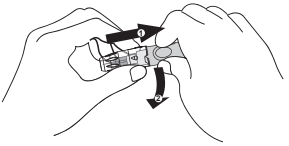
► Fingertip Testing

Press the lancing device's tip firmly against the side of your fingertip. Press the release button to prick your finger, then a click indicates that the puncture is complete.



► Blood from Sites Other Than the Fingertip

Replace the lancing device cap with the clear cap for AST. Pull the cocking control back until it clicks. When lancing the forearm, upper arm, hand, thigh, or calf, 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.
- Please consult your health care professional before you begin AST.
- It is recommended to discard the first drop of blood as it might contain tissue fluid, which may affect the test result.

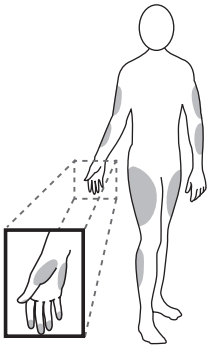
Alternative Site Testing

IMPORTANT: There are limitations with AST (Alternative Site Testing). Please consult your health care professional before you perform AST.

- AST results should not be used for CGM calibration.
- AST results should not be used for insulin dosing calculations

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, the calf or the thigh with the equivalent results 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 at the fingertips.

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. Thus, when testing blood glucose during or immediately after meal, physical exercise, or any other event, **take the 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:

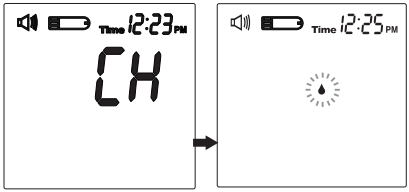
- You think your blood glucose is low.
- You are unaware of hypoglycemia
- You are testing for hyperglycemia
- Your AST results do not match the way you feel.
- Your routine glucose results are often fluctuating.

Performing a Blood Glucose Test

Step 1

Insert the test strip to turn on the monitor.

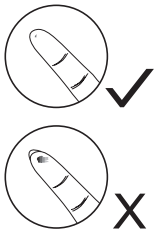
Wait for the monitor to display the test strip and blood drop symbol.



Step 2

Obtaining a blood sample.

Use the pre-set lancing device to puncture your desired site. After penetration, discard the first drop of blood with a clean tissue or cotton. Gently squeeze the punctured area to obtain another drop of blood. Be careful **NOT** to smear the blood sample.

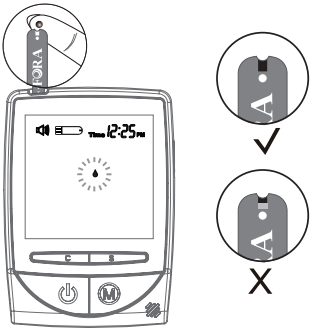


The volume of blood sample must be at least 0.7 microliter (μL) of volume. (◦ actual size).

Step 3

Apply the sample.

Hold the blood drop to touch the absorbent hole of the test strip. Blood will be drawn in and after the confirmation window is completely filled, the monitor begins counting down.



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 monitor 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 monitor begins to count down. **NEVER** try to add more blood to the test strip after your drop of blood 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 the local customer service for assistance.

Step 4

Read your result.

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

Step 5

Remove the used test strip and remove the lancet.

Remove the test strip by hand, throw the strip into a disposal container. The meter will turn itself off automatically after the test strip is removed.

Always follow the instructions in the lancing device insert when removing the lancet.

WARNING

The used lancet and test strip may be biohazards. Please discard them carefully according to your local regulations.

TESTING YOUR BLOOD PRESSURE

This monitor allows you to measure your blood pressure.

- Single measurement
  Perform an individual blood pressure measurement.

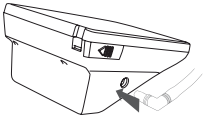
Before Measurement

- 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 physical conditions
- Keep the records for your doctor as reference.
- Blood pressure varies between each arm. Always measure your 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 monitor.

► Fitting the Cuff Correctly

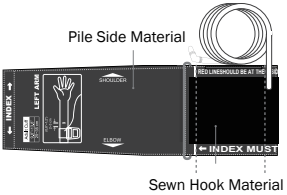
Step 1

Connect the air plug of the tubing to the air jack of the monitor.



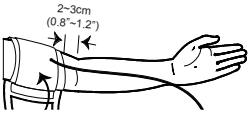
Step 2

Assemble the cuff as shown on the right. The smooth surface should be inside the cuff loop and the metal D-ring should not touch your skin.



Step 3

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



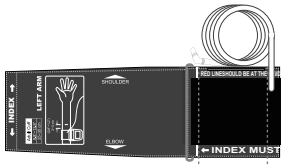
Wrap and tighten the cuff above your elbow. The red line on the edge of the cuff should be approximately 0.8 to 1.2 inches (2 to 3 cm) above your elbow. Align the tube over the main arteries on the inside.

Step 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.

Step 5

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



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

► Proper Measurement Position

Step 1

Sit down for at least 10 minutes before measuring.

Step 2

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

Step 3

Make sure the cuff is about the same height as the location of your heart. Remain still and do not talk or move during the measurement.

Step 4

Measurement is in progress.

After the monitor is turned on, the cuff will begin to inflate automatically.

Taking a Single Measurement

Always apply the pressure cuff before turning on the monitor.

Step 1

Press ⏻ . All the LCD symbols will appear. Then the cuff will begin to inflate automatically.

Step 2

The heart symbol " ♥ " will flash when a pulse is detected during the inflation.

Step 3

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

Step 4

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

NOTE

- If you press ⏻ during measurement, the monitor will be turned off.
- If the pulse rate symbol is shown as "♥" instead of " ♥ ", this indicates that the monitor has detected an irregular heart beat.

MONITOR MEMORY

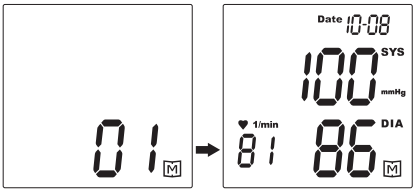
Your monitor stores the 450 most recent test results along with respective dates and times in its memory. To recall the memory, **start with the monitor off.**

Reviewing Test Results

Step 1

Press and release Ⓜ .

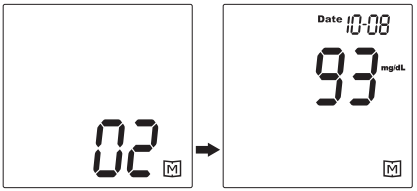
" Ⓜ "will appear on the display.



Step 2

Press Ⓜ .

Review all test results stored in the monitor.



Step 3

Exit the memory.

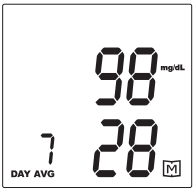
Press ⏻ and the monitor will turn off.

Reviewing Day Average Results

Step 1

Press and hold Ⓜ for 3 seconds.

Release Ⓜ and then your blood glucose 7-day average result will appear on the display.



Step 2

Press Ⓜ .

Review your 14-, 21-, 28-, 60- and 90-day average.

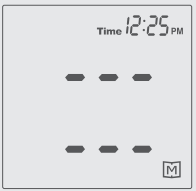
Step 3

Exit the memory.

Press ⏻ and the monitor will turn off.

NOTE

- Any time you wish to exit the memory, press ⏻ or leave it without any action for 3 minutes. The monitor will turn off automatically.
- Control solution results are **NOT** included in the day average.
- If using the monitor for the first time, "---" displays when you recall the test results or review the average result. This indicates that there is no test result in the memory.



- The blood pressure results are **NOT** provided in day averages as the blood glucose results are.

DOWNLOADING RESULTS ONTO A COMPUTER

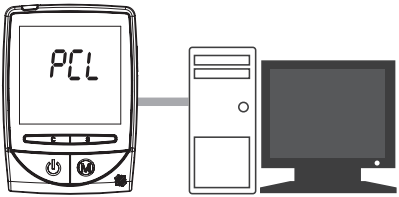
► **Data transmission via cable (For all ForaCare D20 No-Coding)**
Results in memory can be transmitted to the personal computer. Health Care Software System and a RS232 cable are required before installation. To learn more about Health Care Software System or to obtain a USB cable separately, please contact your place of purchase.

Step 1

Installing the Software.
Download Health Care System Software and instruction manual provided on Fora Care website: www.foracare.com to your computer.
Follow the instructions to install the software in your computer.

Step 2

Connecting the USB cable to the data port on PC.
With the monitor turned off, connect the cable to the data port located at the side of the monitor. “PCL” will appear on the display, indicating that the monitor is ready to transmit data.



Step 3

Data transmission.
Follow the instructions provided in the software to transmit data. Data transmitted will include results with date and time. Remove the cable and the monitor will automatically turn off.

MAINTENANCE

Battery

Your monitor comes with four 1.5V AA size alkaline batteries.

► Low Battery Signal

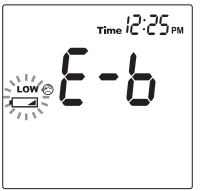
The monitor will display the two messages below to alert you when the monitor power is getting low.

Step 1

The " ▭ " symbol appears along with display messages:
The monitor is functional and the result remains accurate, but it is time to change the batteries.

Step 2

If the power is not enough to do a test, the ▭ symbol starts blinking. Please change or recharge the batteries immediately.



► Replacing the Battery

To replace the batteries, make sure that the monitor is turned off.

Step 1

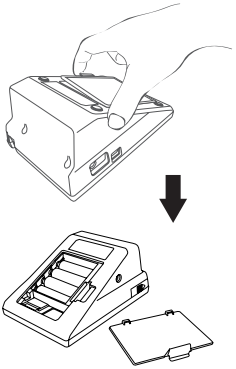
Press the edge of the battery cover and lift it up to remove.

Step 2

Remove the old batteries and replace with four 1.5V AA size alkaline batteries.

Step 3

Close the battery cover. If the batteries are inserted correctly, you will hear a "beep" afterwards.



NOTE

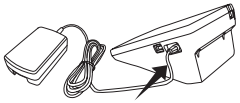
- Replacing the batteries does not affect the test results stored in memory.
- As with all small batteries, these batteries should be kept away from small children. If swallowed, promptly seek medical assistance.
- Batteries may leak chemicals if unused for a long time. Remove the batteries if you are 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.

Using AC Adapter

► Connect AC adapter to the monitor

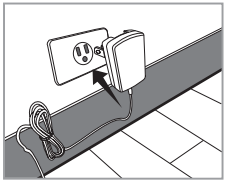
Step 1

Connect AC adapter plug to AC adapter jack of the monitor.



Step 2

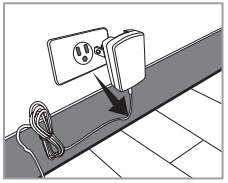
Plug AC adapter power plug into an electrical outlet. The monitor is ready for use.



► Remove AC adapter from the monitor

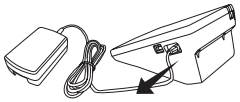
Step 1

When the monitor is off, remove AC adapter power plug from the electrical outlet.



Step 2

Disconnect AC adapter plug from AC adapter jack of the monitor.



Caring for Your Monitor

To avoid the meter and test strips attracting dirt, dust or other contaminants, please wash and dry your hands thoroughly before use.

Why the cleaning and disinfection should be performed?
Cleaning and disinfection are different. Cleaning is the process of removing dirt (e.g. food debris, grease, dust), disinfection 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. You should disinfect the meter at least once a week 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 wipe/towelette from below.

► Micro-Kill+™ (Micro-Kill Plus™) by 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

Step 1

Take out one disinfecting wipe from the package and squeeze out any excess liquid in order to prevent damage to the meter.

Step 2

Wipe all exterior surface of the meter including the 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 moist with disinfection solution contained in the wipe for a minimum of 2 minutes for Micro-Kill+™ wipes. Follow the instructions on the package label of disinfecting wipe. Use two or more wipes if necessary.

Step 3

Remove the wipe. Allow the meter surface to dry completely.

Step 4

Discard the used wipes and never reuse them. Wash your hands thoroughly with soap and water after handling the meter, lancing device and test strips to avoid contamination.

Improper system cleaning and disinfection may result in meter malfunction. If you have a question, please contact local customer service at 1-866-469-2632 for assistance.

This device has been validated to withstand up to 5,000 cleaning and disinfection cycles using the recommended disinfecting wipe/towelette. The tested number of cycles is estimated by 5 cleaning and disinfection cycles per day over 2 years, the expected life of the device. The meter should be replaced after the validated number of cleaning and disinfection cycles or the warranty period, which ever comes first.

Stop using the meter if you see any signs of deterioration, for example, LCD display cracks or becomes cloudy, buttons no longer function, or outer casing cracks. Please contact the customer service or call at 1-866-469-2632 for a replacement meter if any of the signs of deterioration are noticed.

NOTE

- Do **NOT** clean or disinfect the meter while performing a test.
- If the meter is being operated by a second person, the meter and lancing device should be decontaminated prior to handling by an assistant.
- Do **NOT** allow cleaning or 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 the corner of a 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 and damage the electronic components or circuitry.

Monitor Storage

- Storage condition: -4°F to 140°F (-20°C to 60°C), below 95% relative humidity.
- Always store or transport the monitor in its original storage case.
- Avoid dropping and heavy impact.
- Avoid direct sunlight and high humidity.

Caring for Your Test Strips

- Storage condition: 39.2°F to 104°F (4°C to 40°C), below 85% relative humidity. Do not freeze.
- Store your test strips in their original vial only. Do not transfer to other container.
- Store test strip packages in a cool and dry place. Keep away from direct sunlight and heat.
- After removing a test strip from the vial, immediately 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 strip 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 inac curate 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 monitor.
- 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 should be done at room temperature (68°F to 77°F / 20°C to 25°C). Make sure your control solution, monitor, 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 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 your local customer service. Do not attempt to repair by yourself and never try to disassemble the monitor under any circumstances.

Result Readings

MESSAGE	WHAT IT MEANS
BLOOD GLUCOSE	
	Appears when your result is below measurement limit, which is less than 20 mg/dL (1.1 mmol/L).
	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.
	Appears when your result is higher than the limit of measurement, which is higher than 600 mg/dL (33.3mmol/L).

Error Messages

MESSAGE	CAUSE	WHAT TO DO
	Inflation or pressure error.	Refit cuff tightly and correctly. Relax and repeat the measurement. If the error still remains, please contact local customer service for help.
		
		
	Strip has been used.	Repeat the test with a new strip.
	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 monitor and test strip have reached the above temperature.
		

MESSAGE	CAUSE	WHAT TO DO
	Appear when the battery can not provide enough power for a test.	Replace the battery immediately.
	Problem with the meter.	Review the instructions and re-test with a new test strip. If the problem is still unsolved, please contact with local customer service for help.
		

Troubleshooting

► Blood Glucose Measurement

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

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

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

POSSIBLE CAUSE	WHAT TO DO
Insufficient blood sample.	Repeat the test using a new test strip with larger volume of blood sample.
Defective test strip.	Repeat the test with a new test strip.
Sample applied after automatically shutoff (3 minutes after last user action).	Repeat the test with a new test strip. Apply sample only when flashing "💧" appears on the display.
Defective monitor.	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, monitor, 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.
Monitor malfunction.	Please contact customer service.

► **Blood Pressure Measurement**

1. If nothing is displayed 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/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/lower than user's average measurement:

POSSIBLE CAUSE	WHAT TO DO
May not be in correct position while measuring.	Adjust to the correct position to measure.
Blood pressure naturally varies from time to time.	Keep in mind for next measurement.

DETAILED INFORMATION

Reference Values

Blood Glucose

Blood glucose monitoring plays an important role in diabetes control. A long-term study showed that maintaining **blood glucose levels close to normal** can reduce the risk of diabetes complications by up to 60%*1. The results provided by this system can help you and your healthcare professional monitor and adjust your treatment plan to gain better control of your diabetes.

Time of day	Normal plasma glucose range for people **without** diabetes (mg/dL)
Fasting and before meal	Less than 100 mg/dL (5.6 mmol/L)
2 hours after meals	Less than 140 mg/dL (7.8 mmol/L)

Source: American Diabetes Association (2012). Diabetes Care, 35 (Suppl 1): 64-71.

Please consult your doctor to determine a target range that works best for you.

References:

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

Blood Pressure

Clinical studies show that adult diabetes is often accompanied by elevated blood pressure. People with diabetes can reduce their heart risk by managing their blood pressure along with diabetes treatment*2.

Knowing your routine blood pressure trend tells whether your body is in good condition or not. Human blood pressure naturally increases after reaching middle age. This symptom is a result of continuous ageing of the blood vessels. Further causes include obesity, lack of exercise and cholesterol (LDL) adhering to the blood vessels. Rising blood pressure accelerates hardening of the arteries, and the body becomes more susceptible to apoplexy and coronary infarction. The recommended blood pressure range is as below:

Classification	Systolic Pressure (mmHg)	Diastolic Pressure (mmHg)
Hypotension*3	< 90	< 60
Normal*4	< 120	< 80
Pre-hypertension*4	120–139	80–89
Stage 1 Hypertension*4	140–159	90– 99
Stage 2 Hypertension*4	≥ 160	≥ 100

References:

*2: National Heart, Lung, and Blood Institute, Diseases and Conditions.

*3: The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. NIH Publication. 2003. No. 03-5233.

*4: American Diabetes Association: The Diabetes-Heart Disease Link Surveying Attitudes, Knowledge and Risk (2002)

Comparing Monitor and Laboratory Results

The monitor provides you with plasma equivalent results. The result you obtain from your monitor may differ somewhat from your laboratory result due to normal variation. Monitor results can be affected by factors and conditions that do not affect laboratory results in the same way. To make an accurate comparison between monitor and laboratory results, follow the guidelines below.

Before going to the lab:

- Perform a control solution test to make sure that the monitor is working properly.
- Fast for at least eight hours before doing comparison tests, if possible.
- Take your monitor with you to the lab.

While staying at the lab:

Make sure that the samples for both tests are taken and tested within 15 minutes of each other.

- Wash your hands before obtaining a blood sample.
- Never use your monitor with blood that has been collected in a gray-top test tube.
- Use fresh capillary blood only.

You may still have a variation from the result because blood glucose levels can change significantly over short periods of time, especially if you have recently eaten , exercised, taken medication, or experienced stress[*5]. In addition, if you have eaten recently, the blood glucose level from a finger prick can be up to 70 mg/dL (3.9 mmol/L) higher than blood drawn from a vein (venous sample) used for a lab test[*6]. Therefore, it is best to fast for eight hours before doing comparison tests. Factors such as the amount of red blood cells in the blood (a high or low hematocrit) or the loss of body fluid (dehydration) may also cause a monitor result to be different from a laboratory result.

References:

*5: Surwit, R.S., and Feinglos, M.N.: Diabetes Forecast (1988), April, 49-51.

*6: Sacks, D.B.: “Carbohydrates. “ Burtis, C.A., and Ashwood, E.R.(ed.), Tietz Textbook of Clinical Chemistry. Philadelphia: W.B. Saunders Company (1994), 959.

SPECIFICATIONS

SYSTEM PERFORMANCE	
Power Source	Four 1.5V AA alkaline batteries
Size of Monitor w/o Cuff	155 (L) x 110 mm (W) x 69 mm (H), 340g with batteries
Memory	Maximum 450 memory records
Power Saving	Automatic power off if system idle for 3 minutes (normal mode) or 5 minutes (RF mode).
System Operating Condition	50°F to 104°F (10°C to 40°C), below 85% RH
Monitor Storage Condition	-4°F to 140°F (-20°C to 60°C), below 95% RH
Power Supply Input	DC +6V / 1A (max) via Power Plug

BLOOD GLUCOSE MEASUREMENT PERFORMANCE	
Measurement Unit	mg/dL
Linear Range	20 to 600 mg/dL (1.1 to 33.3mmol/L)
Precision	±5 % (CV)
Accuracy	±15 mg/dL (0.83 mmol/L) when glucose < 75mg/dL (4.2 mmol/L)
	±20% when glucose ≥ 75mg/dL (4.2 mmol/L)
Ketone Warning	glucose value is over 240 mg/dL (13.3 mmol/L)

BLOOD PRESSURE MEASUREMENT PERFORMANCE	
Pressure Range	0 - 300 mmHg
Heart Rate Range	40 -199 beat per minute
Measurement Unit	mmHg
Systolic Measurement Range	50 mmHg -250 mmHg
Diastolic Measurement Range	30 mmHg -180 mmHg
Pulse Rate Measurement Range	40 -199 beats / minute
Maximum Inflation Pressure	300 mmHg
Accuracy of Pressure	±3 mmHg or ±2% of reading
Accuracy of Pulse Rate	±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:

- EN 1060-1 / EN 1060-3, NIBP-requirements
- IEC 60601-1 General requirement for safety
- IEC 60601-1-2 Requirements for EMC
- EN 1060-4, NIBP clinical investigation
- AAMI/ANSI /IEC 80601-2-30, ANSI/AAMI/ISO 81060-2, NIBP requirements