

FORA

**FORA D10
BLOOD GLUCOSE
PLUS BLOOD PRESSURE
MONITORING SYSTEM**

English

Thank you for choosing

FORA D10
BLOOD GLUCOSE PLUS
BLOOD PRESSURE
MONITORING SYSTEM

This product can assist you in monitoring your blood glucose level as well as your blood pressure. You can visit our website www.foracare.com/usa to view other updated instructions or product information.

This owner's manual contains important information that you must know about your system. Please read it carefully and keep it for future reference.

For other questions regarding this system, please contact your local customer service. For all other questions, contact your health care professional for assistance.

IMPORTANT SAFETY PRECAUTIONS

READ BEFORE USE

- Users need to adhere to Standard Precautions when handling or using this device. All parts of the glucose monitoring system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals. For more information, refer to “Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007”, <http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html>
- The meter should be disinfected after use on each patient. This Blood Glucose Monitoring System may only be used for testing multiple patients when Standard Precautions and the manufacturer’s disinfection procedures are followed.
- Only auto-disabling, single use lancing devices may be used with this device.

For more information on the risk of blood-borne pathogen transmission from blood glucose meter and lancing devices, please refer to:

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.
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** use the equipment in places where aerosol sprays are being used, or where oxygen is being administered.
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. 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.
9. Do not use this device in close proximity to sources of strong electromagnetic radiation, as these may interfere with the accurate operation.
10. Read all instructions thoroughly and practice the test before using the product to test your blood glucose. Do all quality control checks as directed and consult with a diabetes healthcare professional.

KEEP THESE INSTRUCTIONS IN A SAFE PLACE

TABLE OF CONTENTS

BEFORE YOU START	07
Warnings and Precautions	07
Detailed Information	08
ABOUT THIS SYSTEM	10
Intended Use	10
Principle of Measurement	11
Alternative Site Testing	12
Content of the System	14
Appearance and Key Function of the Monitor	15
LCD Screen	16
Test Strip	17
BEFORE USE	18
Battery Installation and Replacement	18
Setting the Monitor	20
BLOOD GLUCOSE MEASUREMENT	23
Important Information	23
Checking with FORA Control Solution	24
Important Control Solution Information	25
Performing a Control Solution Test	26
Testing Your Blood Glucose	29
Reading Your Result	35
Comparing Monitor and Laboratory Results	36

BLOOD PRESSURE MEASUREMENT	38
Suggestions Before Measuring	38
Correct Application of the Pressure Cuff	39
Testing Your Blood Pressure	40
MONITOR MEMORY	42
Viewing Results on the Monitor	42
Viewing the Average Blood Glucose Results	43
Viewing Results on a Personal Computer	44
TAKING CARE OF YOUR MONITOR & STRIPS	45
Caring for Your Meter	45
Storage	50
TROUBLESHOOTING	52
Error Message	52
Problem in Operation	54
SPECIFICATIONS	59

BEFORE YOU START

Warnings and Precautions

- The FORA D10 system is designed for use on individuals age 16 and above. It shall **NOT** be used under any circumstances on newborns, infants or persons who cannot communicate.
- This device does **NOT** serve as a cure for any symptoms or diseases. The data measured are for reference only. Always consult your physician to have the results interpreted.
- 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 error.
- **Do NOT** use the device for purposes other than measuring blood glucose and blood pressure for human beings.
- **Do NOT** apply the cuff to areas other than your wrist.

Detailed Information

Reference Values

Blood glucose monitoring plays an important role in diabetes control. A long-term study showed that keeping **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). Clinical Practice Recommendations. Diabetes Care, 35 (Supplement 1): S1–S100.

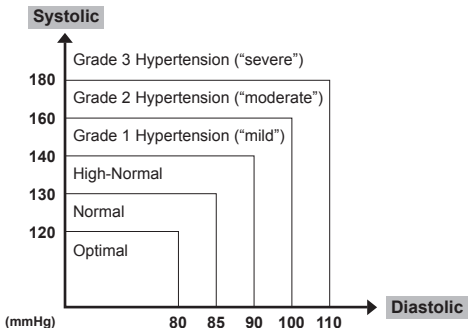
*1: ADA Clinical Practice Recommendations 2003.

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

Blood Pressure

Clinical studies show that the diabetes in adult 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 blood pressure patterns can help determine whether or not your body is in good condition. Human blood pressure naturally increases after reaching middle age. This symptom is a result of continuous aging of the blood vessel.

Other causes include obesity, lack of exercise, and cholesterol (LDL) adhering to the blood vessels. Rising blood pressure accelerates hardening of the arteries, making the body becomes more susceptible to apoplexy and coronary infarction. The WHO (World Health Organization) published the following guidelines for blood pressure range:



Source: 1999 WHO/ISH guidelines for the management of hypertension.

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

ABOUT THIS SYSTEM

Intended Use

The FORA D10 system is a 2 in 1 system designed to measure blood glucose outside of human body and to measure blood pressure non-invasively. It is intended for use in the home and in clinical settings. It shall not be used for the diagnosis of diabetes and hypertension, or for the testing of newborns.

The talking functions on the meter is not intended for use by visually impaired users.

AST of this system can be used only during steady-state blood glucose conditions as described in the section of "Alternative Site Testing (AST)".

Principle of Measurement

Blood glucose is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the strip. The monitor measures the current and displays the corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

Blood pressure is measured non-invasively at the wrist based on the Oscillometric method.

Both functions work separately independent of the other (one measurement either blood glucose or blood pressure at a time) in order to avoid any interference problems.

Alternative Site Testing (AST)

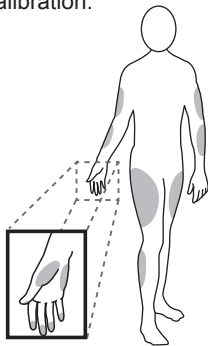
Important: There are limitations for doing AST (Alternative Site Testing).

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

Please consult your healthcare professional before you begin AST.

What is AST?

Alternative site testing (AST) refers to when individuals check their blood glucose levels using areas of the body other than fingertip. This system allows AST at the palm, the forearm, the upper arm, the calf or the thigh with results as reliable as those obtained from fingertip testing.



What's the advantage?

Fingertips feel pain more readily because they are full of nerve endings (receptors). Since nerve endings are not so condensed at other body sites, tests performed there will be less painful.

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. Therefore, when testing blood glucose during or immediately after a meal or physical exercise, results from AST and fingertip may be significantly different.

We strongly recommend you perform AST **ONLY** during the following intervals:

- In a pre-meal (more than 2 hours since the last meal) or fasting state.
- Two or more hours after taking insulin.
- Two or more hours after exercise.

Do NOT use AST if:

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

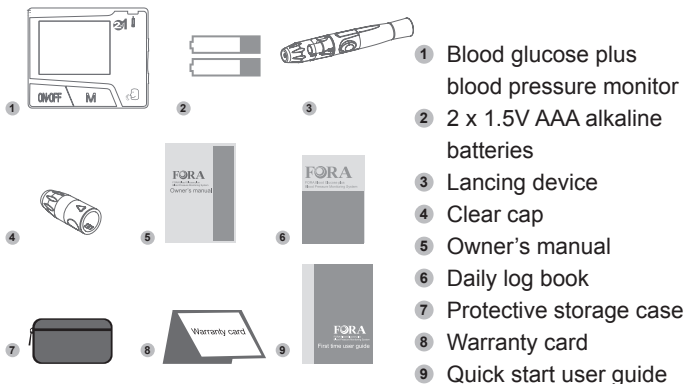
How to increase the accuracy?

Stimulating blood perfusion by rubbing the puncture site prior to blood extraction has a significant influence on the glucose value obtained. Blood from the site without rubbing exhibits a measurably different glucose concentration than blood from the finger. When the puncture site is rubbed prior to blood extraction, the difference is markedly reduced.

Please follow suggestions below before puncturing the skin:

- Rub the puncture site approximately 20 seconds before penetration.
- Use a clear cap (included in the kit) instead while setting the lancing device.

Contents of the System

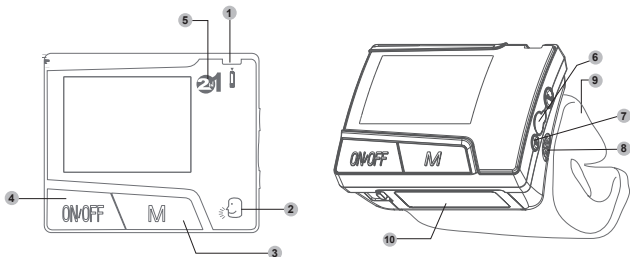


The products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. Use only FORA D10 test strips and FORA control solution with your FORA D10 Monitor.

NOTE

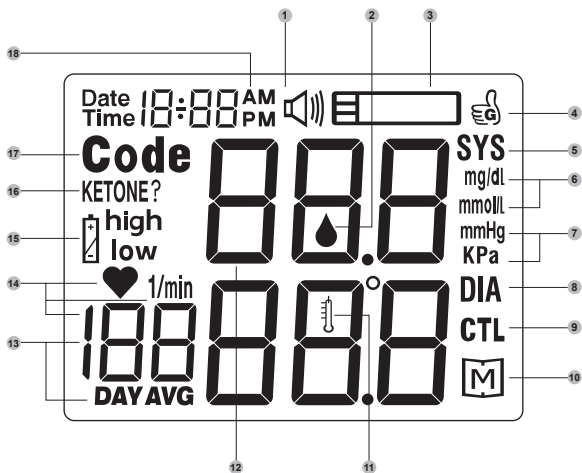
- If your system has been opened prior to use or does not contain all items listed above, please return your system to the place of purchase.
- Please note that strips, control solutions (low, normal and high) and lancets are optional. Those are not included in the standard kit. Please contact the Customer Service at 1-888-307-8188, 1-866-469-2632 or place of purchase for availability.

Appearance and Key Function of the Monitor



- 1 **Test Slot** is where you insert test strip.
- 2 **Talking Symbol** indicates that the monitor has speaking function.
- 3 **M Button** is used to enter memory and assist setting.
- 4 **ON/OFF Button** is a power button for blood pressure measurement.
- 5 **2 in 1 Symbol** is a 2 in 1 system designed to measure blood glucose and blood pressure.
- 6 **Data Port** is for cable connection.
- 7 **Set Button** is used to set up monitor.
- 8 **Speaker** is where voice comes from.
- 9 **Wrist Cuff** is used to wrap around wrist when measuring blood pressure.
- 10 **Battery Compartment.**

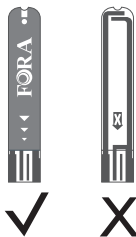
LCD Screen



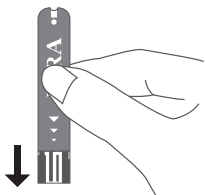
- | | |
|----------------------------|--------------------------------|
| 1 Voice Symbol | 10 Memory Mode Symbol |
| 2 Blood Drop Symbol | 11 Temperature Symbol |
| 3 Test Strip Symbol | 12 Test Result & Error Message |
| 4 Good Symbol | 13 Day Average Result |
| 5 Systolic Pressure | 14 Pulse Rate |
| 6 Units for Blood Glucose | 15 Battery Symbol |
| 7 Units for Blood Pressure | 16 Ketone Indicator |
| 8 Diastolic Pressure | 17 Code |
| 9 Control Mode Symbol | 18 Date & Time |

Test Strip

Front Back



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 **FORA D10** monitor should only be used with **FORA D10** Test Strips. Using other test strips with this meter can produce inaccurate results.


BEFORE USE

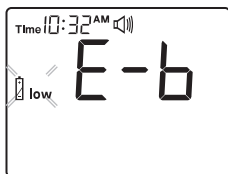
Battery Installation and Replacement


Use ONLY 1.5V AAA size alkaline batteries for best performance and optimal lifespan.

When the power is getting low, the monitor will remind you by displaying two different messages:

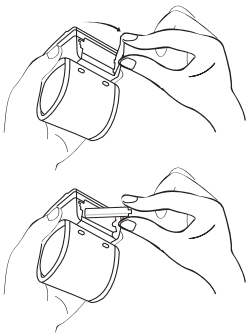


1. Battery Symbol “” appears with your test result to indicate that only 30 more measurements (either glucose tests or blood pressure tests) can be made before power runs out.



2. Error message “E-b” shows together with flashing “” and “low” to indicate that you must change the batteries before making any measurements.

Make sure the monitor is off when replacing the batteries.




Step1

Press the buckle on battery cover and lift up to remove cover.

Step2

Replace with two new 1.5V AAA alkaline batteries. Align the positive and negative terminals of the batteries with the positive (+) and negative (-) signs engraved inside the battery compartment and close the cover.

Please remember:

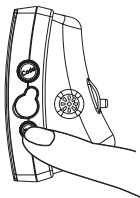
- When “” appears, the monitor will automatically turn down the volume for energy saving.
- Do not replace batteries with used batteries or those of a different type/brand name. Use only new ones in required size and type/brand.
- Replacing the batteries does not affect previously stored test results; however, the settings may need to be updated again.
- Batteries might leak chemicals if unused for a long period of time. Remove the batteries if you are not going to use the device for an extended period (i.e. 3 months or more).
- Batteries should be kept away from small children. If they are swallowed, promptly see a doctor for help.
- Discard batteries according to your local regulations.

Setting the Monitor

Time, date, units, memory deletion and speaking function (optional) can be set in the monitor. Two keys are involved: **Set** button and **M** button.

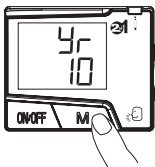
Step1

Press the Set button to start setting.



Step3

Press the M button to make changes. Press the Set button to next.



Step5

Time flashes. Follow Step3 for changes.

Time **10:08** PM

Step2

Year flashes first.

4r
10

Step4

Date flashes. Follow Step3 for changes.

Date **01-08**

Step6

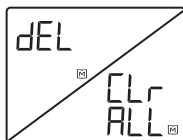
Unit of blood pressure flashes. Follow Step3 for changes.

mmHg
KPa

Step7

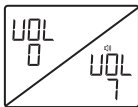
M Memory flashes.

- If you'd like to skip this step, press the **Set button** to next.
- If you'd like to delete memory, press the **M button** again so that "dEL" and **M** will both flash. Press the **M button** again to delete **ALL** memory. "CLr/ALL" appears and the monitor will automatically go to next step.



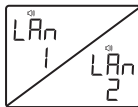
Step8

Voice volume number flashes.
Follow Step3 for changes.





Step9

Lanauage flashes. Follow
Step3 for changes.



Please remember:

- Number can be advanced faster by holding down the **M button**.
- While setting speaking volume, number 0 indicates that the speaking function is off. “” will not display. Numbers 1 to 7 indicate speaking volume from low to high. They will be displayed together with “.
- If the monitor does not contain speaking function, it will automatically shut down after **Step 8**.
- **Step 8** and **Step 9** are only for users who desire to use speaking function.
- The time, date and unit of measurement can **ONLY be changed** in the setting mode. Therefore, these parameters cannot be changed while performing tests.

BLOOD GLUCOSE MEASUREMENT

Important Information

1. Severe dehydration and excessive water loss may cause inaccurate results. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.
2. 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 from your healthcare professional.
3. Apply only capillary whole blood sample to test your blood glucose. Applying other substances will cause inaccurate results.
4. 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.
5. Severely hypotensive individuals, patients in shock and individuals in a hyperglycemic-hyperosmolar state, with or without ketosis, may experience inaccurate results.
6. Please refer to your test strip package insert for important additional information.

Checking with FORA Control Solution

FORA control solution contains a known amount of glucose that reacts with test strips. By comparing your control solution test results with the expected range printed on the test strip vial label, you can ensure that the monitor and the test strips are working together as a system and that you are performing the test correctly. It is very important that you do this simple check routinely to make sure your results are accurate.

How often should the control solution test be performed?

- When you use this system to test your blood for the first time, practice the procedure using control solution. When you can do three tests in a row that are within the expected range, you are ready to test your blood.
- To routinely check the monitor and test strips, perform a single test for each level of control solution at least once a week.

When should the control solution test be performed?

- When you first get your monitor.
- When you begin using a new vial of test strips.
- Whenever you suspect that the monitor or test strips are not working properly.
- When your blood glucose test results are inconsistent with how you feel, or when you think your results are inaccurate.
- When you want to practice running the test.
- If you drop the monitor.

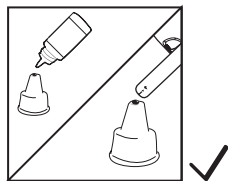
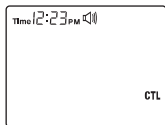
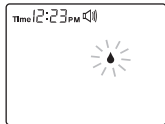
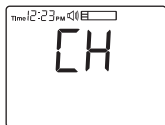
Important Control Solution Information

- Use only **FORA** control solutions.
- Check the expiration date on the control solution vial. Do not use if expired.
- Control solution, monitor, and test strips should come to room temperature (68°F-77°F/20°C-25°C) before testing.
- Shake the vial, discard the first drop of control solution, and wipe off the dispenser tip to ensure a good sample and an accurate result.
- Use for only 3 months after first opening. Record the first opening date on the control solution vial. Discard after 3 months.
- Store the control solution with lid tightly closed at temperatures between 36°F-86°F (2°C-30°C). Do not freeze.

NOTE

The control solution range printed on the test strip vial is for FORA control solution only. It is used to test evaluate monitor and test strip performance. It is not recommended range for your blood glucose level.


Performing a Control Solution Test



Step1

Take a test strip out with clean, dry hands first.

Step2

Insert the Test Strip to Turn On the Meter. Insert the test strip into the meter and wait for the meter to display “CH” and a blood symbol “”.

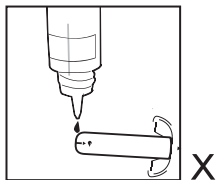
Step3

Press the M button. After blood drop symbol flashes, press the M button. “CTL” will appear on the display. With the “CTL” sign on the display, the monitor will **NOT** store your test result in memory.

Step4

Obtain control solution. Shake the control solution vial well. Remove the cap. Squeeze the vial, discard the first drop, and wipe off the dispenser tip to prevent contamination. Squeeze the vial again to

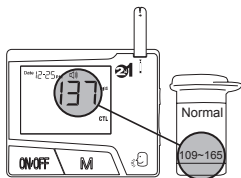
get another drop and place the drop on the top of the cap.



Step5

Apply control solution. While holding the monitor, move the absorbent hole of the test strip to touch the drop of control solution. Then the drop will be automatically drawn into the test strip. Make sure the confirmation window fills completely. The meter begins counting down.

To avoid contaminating the control solution with the content of the test strip, you have to place a drop of control solution on a clean surface. Then touch the test strip to the drop.



Step6

Read and compare the result. Compare the result with the range printed on the test strip vial. The result will fall within this range.

Out-of-range results

If test results fall outside the printed range, check the “Operating Problem” section in troubleshooting guide and repeat the test. If your results continue to be out-of-range, the system may not be working properly. Do NOT test your blood. Please contact the Customer Service at 1-888-307-8188, 1-866-469-2632 for help.

WARNING!

- Contact bars must be inserted all the way into the monitor or your test results may be inaccurate.
- Every time you perform a control solution test, you must enter into the “CTL” test mode so that the test result will not be stored in the monitor memory. Failure to do so will confuse the blood glucose test result with the control solution test result in memory.

Testing Your Blood Glucose

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.

WARNING!

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.
- Only auto-disabling, single use lancing devices may be used with this device.
- Avoid getting hand lotion, oils, dirt, or debris in or on the lancets and the lancing device.

Sharing the lancing device and lancets may increase the risk of contracting infectious diseases. Please follow the infection control procedure of lancing device approved by your facility.

We recommend you perform disinfection procedures between each patient. Please refer to the section Cleaning and Disinfection Procedures 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

Stimulating blood perfusion by rubbing the puncture site prior to 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. Put on a new pair of gloves.**
- Rub the puncture site for about 20 seconds before penetration.
- Select the puncture site either at the fingertips.
- Clean the puncture site using cotton moistened with 70% alcohol and **let it air dry.**

NOTE

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

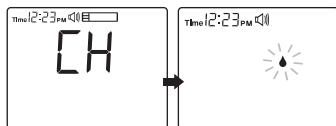
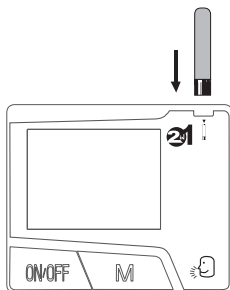
For healthcare professionals:


- Always wear gloves and follow your facility's biohazard control policy and procedures when performing tests involving patient blood samples.
- Use a new pair of gloves when performing a patient test. Change gloves between patients.
- Wear protective glasses and/or other protective clothing if necessary.

Step1 Insert the test strip

Take a test strip out with clean and dry hands.

Insert test strip face up with contact bars end first into the test slot. The monitor will turn on automatically. The LCD screen will display the sequences shown below.



A flashing “” will be displayed for 3 minutes until the drop of blood is applied.

Please remember:

The monitor will be auto-shut down after 3 minutes without action. To restart the test procedure, remove the test strip and insert it back again.

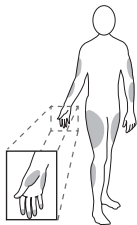
Step2 Get a drop of blood.

Select the puncture site (either the finger or an alternative site). Clean the puncture site with 70% alcohol cotton and **let it air dry**.



► Fingertip testing

Hold the lancing device firmly against the side of your finger. Press the release button. You will hear a click, indicating that the puncture is complete.



► Alternative Site Testing

Follow the section “Alternative Site Testing” on pages 11 and 12.

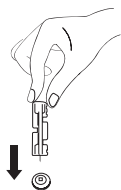
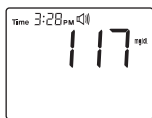
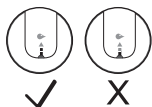
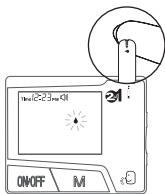
After penetration, gently massage the punctured area to obtain blood. Be careful **NOT to smear the blood sample**.



The first drop of blood usually contains tissue fluid and serum, which may affect the test result. For this reason, discard the first drop of blood with a clean tissue paper or cotton and use the second drop of blood for testing.

WARNING!

- Choose a different spot each time you test. Repetitive punctures in the same spot may cause soreness and calluses.
- Before you decide to begin AST, please consult your health professional.



Step3

Apply blood into the test strip. When “☀” flashes on the display, hold and touch the absorbent hole of test strip to the drop of blood until the confirmation window is completely filled.

Step4

Read a result. Your test result, along with Date/Time, appears after the monitor counts down to 0. It will automatically be stored in the monitor memory. Turn the monitor off by removing the test strip. Discard the used test strip carefully to avoid contamination.

Step5

Discard lancet. Remove the lancing device cap and the lancet. Place the disk on a hard surface and push the exposed needle tip into the protective disk. **Always use caution when removing the lancet.**

WARNING!

The used lancet and test strip may be potentially biohazardous. Please refer to your healthcare provider and discard them carefully. Or contact our local customer service for more information.

Reading Your Result

Your glucose test result comes along with indicators that transfer special messages for your reference.

MESSAGE	WHAT IT MEANS	ACTION
Lo	Appears when your result is below measurement limit, which is less than 20 mg/dL.	This indicates hypoglycemia (low blood glucose.) You should immediately treat hypoglycemia as recommended by your healthcare professional.
Hi	Appears when your result is above measurement limit, which is higher than 600 mg/dL.	This indicates severe hyperglycemia (high blood glucose). You should seek immediate medical assistance.
KETONE ?	KETONE? appears when your result is equal to or higher than 240 mg/dL.	This indicates there is a possibility of ketone accumulation for type 1 diabetes patients. Please seek immediate medical assistance.

Comparing Monitor and Laboratory Results

The meter provides you with whole blood 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. (See test strip package insert for typical accuracy and precision data, and for important information on limitations.) To make an accurate comparison between meter and laboratory results, follow the guidelines below.

Before you go 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.
- Don't forget to take your monitor with you.

While at the lab:

Make sure that the samples for both tests (the monitor test and the lab test) 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 experience variations in the results because blood glucose levels can change significantly over short periods, especially if you have recently eaten, exercised, taken medication or experienced stress^{*4}. For example, if you have just eaten, the blood glu-

ucose level from a finger stick 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.*⁵

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 (severe dehydration) may also cause a meter result to differ from a laboratory result.

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

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

BLOOD PRESSURE MEASUREMENT

Suggestions Before Measuring

1. Avoid caffeine, tea, alcohol, and smoking for at least 30 minutes before measurement.
2. Wait 30 minutes after exercising or bathing before measurement.
3. Sit down for at least 10 minutes before measuring.
4. Do not measure when feeling anxious or tense.
5. Take a 5-10 minute break between measurements. This break can be longer if necessary, depending on your physical conditions.
6. Keep the records for your physician as reference.
7. Blood pressure naturally varies from one hand to the other. Always measure your blood pressure using the same wrist.

Correct Application of the Pressure Cuff



Slide the cuff onto your wrist. Wrap the cuff comfortably around your wrist.

0.6 cm to 1.3 cm
(1/4 to 1/2 inch)
below the ball of thumb



The top margin of the monitor should be about 0.6 cm to 1.3 cm (1/4 to 1/2 inch) below the ball of thumb. When the cuff is positioned correctly, fold the loose end back and secure it in place by pressing the pile material firmly against the hook material.

WARNING!

Always apply the wrist cuff before turning on the device. Failure to do so will damage the device.

Testing Your Blood Pressure



Step1

Sit down for at least 10 minutes before measurement.

Step2

Apply the wrist cuff according to page 37.

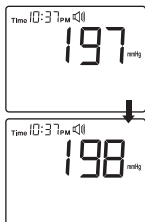
Step3

Press the ON/OFF button and place your arm in front of your chest. Relax and make sure the device is at the same height as your heart. Holding your left elbow with your right hand helps you hold still during measurement. Remain still and do not talk or move during the measurement.

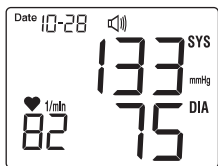


Step4

Measurement is in progress. Once the monitor is on, all symbols on the display will appear, accompanied by a long “beeping” sound.



The cuff will begin to inflate automatically. You will see number increasing on the display.



After reaching the cuff pressure, the cuff will begin to deflate. You will see number decreasing and “♥” flashing on the display.

Step5

Read a result. The monitor displays the systolic pressure, diastolic pressure and heart rate, along with Date/Time. **Press ON/OFF button to turn off.** Otherwise, it will turn off automatically if left idle over 3 minutes.

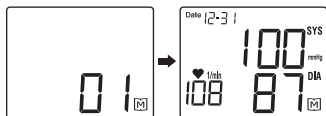
Please remember:

- It is extremely important that you keep the device level with the heart. If the device is lower (higher) than the heart, your measurement will be higher (lower) than the actual value.
- If a higher pressure value is needed, the monitor will stop deflation and inflate again.
- If you press the **ON/OFF** button during the measurement, the monitor will turn off immediately.

MONITOR MEMORY

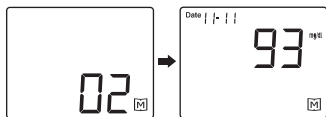
Your monitor stores the 450 most recent results, in addition to calculating their average. Please follow the steps listed below to review these results.

View Results on the Monitor



Step1

When the monitor is off, press and release the M button. "01" appears first, followed by the latest recall of blood glucose/pressure measurements and their respective dates and times.



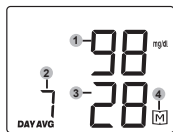
Step2

Press the M button multiple times to recall the stored results one by one.

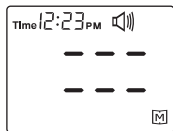
Step3

After viewing the oldest test result, push the M button again to return to the latest test result.

View the Average Blood Glucose Results



- 1 The **average** of glucose tests.
- 2 The average was calculated from the test results over the **last 7 days**.
- 3 **28 glucose tests** have been performed in the last 7 days.
- 4 Memory symbol interpretation: The average of 28 glucose tests in the last 7 days is 98 mg/dL.



When using the monitor for the first time, "----" will appear, indicating that there are no test results in memory.

Please remember:

- The control solution results are **NOT** stored in the memory (please go to **WARNING** on page 28 for more information). The list of past results and the result average are for blood glucose results only.
- To exit from the memory, press the **ON/OFF** button to turn off the monitor or leave it idle for 3 minutes for auto-shutdown.

Step1

When the monitor is off, press the **M** button for **3 seconds**. The 7-day average of blood glucose results appears first.

Step2

Press the **M** button **multiple time** to review the 14-, 21-, 28-, 60- and 90- day averages in order one by one.

Step3

After viewing the **90-day average**, push down the **M** button once more to return to the 7-day average.

Viewing Results on a Personal Computer

Stored results can be transmitted to a personal computer. Health Care System Software and an interface cable are required before installation. This software can be downloaded from the home page of FORA Care. The interface cable is an optional accessory. Please contact the Customer Service at 1-888-307-8188, 1-866-469-2632 for help.

To view results on your personal computer:

Step1

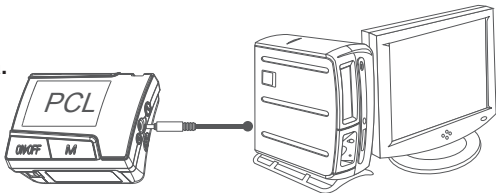
Install Software. Install Health Care System Software on your computer by following the instructions provided on FORA Care's website: <http://www.foracare.com/usa> Users can download the software at FORA's website.

Step2

Connect to Personal Computer. Connect the interface cable to a serial port on the back of your computer. With the monitor turned off, connect the interface cable to the data port located at the side of the monitor. "PCL" will appear in the display, indicating that the monitor is ready for transmitting data.

Step3

Transmit Data.



Follow the instructions provided in the software to transmit data (results along with dates and times). Remove the cable and the monitor will automatically turn off.

Please remember:

The monitor is unable to perform a blood glucose or blood pressure test while connecting to the PC.

TAKING CARE OF YOUR MONITOR & STRIPS

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

Caring for Your Meter

To avoid the meter and test strips attracting dirt, dust or other contaminants, please wash hands thoroughly with soap and water before and after 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, blood, or any other body fluid with the wipe. Use a second wipe to disinfect the meter by following the disinfecting procedure below. Do NOT use organic solvents to clean the meter.

We recommend using the disinfecting wipes/towelettes below for meter cleaning and disinfection because the active ingredients have been tested to be effective against Hepatitis B Virus (HBV) for FORA blood glucose meter.

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. You can also purchase at www.amazon.com.

Disinfecting Procedures

1. Take out one disinfecting wipe from the package and squeeze out any excess liquid in order to prevent damage to the meter.
2. 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 meter wet with disinfection solution contained in the wipe for a minimum of 2 minutes for Micro-Kill+™ wipes.
3. Remove the wipe. Allow the meter surface to dry completely.
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.

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 5 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, whichever 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 at 1-888-307-8188 or 1-866-469-2632 for a replacement meter if any of the signs of deterioration are noticed.

- Improper system cleaning and disinfection may result in meter malfunction. Stop using the meter if you see any signs of malfunction, for example: meter cannot be turned on, meter has error message, reading not consistent with your feeling.

If you have a question, please contact the Customer Service at 1-888-307-8188 or 1-866-469-2632 for assistance.

NOTE

- **Do NOT** clean and disinfect the meter while performing tests.
- Please follow the instructions on the package label of Micro-Kill+™ disinfecting wipe.
- 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.

Storage

1. Monitor Storage

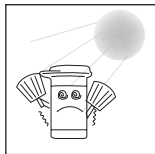


- Storage condition: -4°F to 140°F (-20°C to 60°C), below 95% relative humidity.
- Avoid dropping the monitor.
- Avoid direct sunlight.
- Always store or transport the monitor in its original storage case.
- Do not disassemble, modify or try to repair the monitor or wrist cuff by yourself.
- Do not over-wring the cuff or turn it inside out.
- If you are not going to use the monitor for an extended period, please remove the batteries.

2. Strip Storage



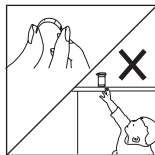
- Storage condition: $39.2-104^{\circ}\text{F}$ ($4-40^{\circ}\text{C}$), below 85% humidity. **Do NOT freeze.**
- Store your test strips in their original vial only. Do not transfer to other container.



- Store test strip packages in a cool, dry place. Keep away from direct sunlight and heat.
- After removing a test strip from the vial, immediately replace the vial cap and close it tightly.

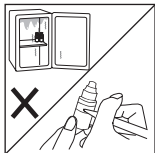


- Touch the test strip with clean, dry hands.
- Use each test strip immediately after removing it from the vial.
- Write the first opening date on the vial label when you first open it. Discard remaining test strips after 3 months.



- Do not bend, cut or alter a test strip in any way.
- Keep the strip vial away from children as the cap and the test strip may be a choking hazard. If swallowed, promptly see a doctor for help.

3. Control solution storage



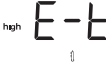


- Storage condition: Store the control solution with lid tightly closed at temperatures below 36-86°F (2-30°C). **Do NOT freeze.**
- Record the first opening date on the control solution vial. Discard after 3 months.

TROUBLESHOOTING

If you follow the action recommended 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.

Error Message

MESSAGE	CAUSE	WHAT TO DO
 E-b Err 33	Batteries are dead.	Replace the batteries immediately.
 E-t ↓	Appears when environmental temperature is below system operation range.	System operation 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.
 E-t ↓	Appears when environmental temperature is above system operation range.	

MESSAGE	CAUSE	WHAT TO DO
Err 02	Unable to detect systolic pressure.	Refit cuff tightly and correctly. Relax and repeat measurement.
Err 04	Unable to detect diastolic pressure.	
Err 09	Cuff pressure is insufficient.	
E-U	Used strip insertion.	Repeat the test with a new strip.
Err 00	Weak pulse.	Refit cuff tightly and correctly, relax and repeat measurement as shown in page 37.
Err 01	Cuff leakage.	
Err 03	Cuff pressure is over 300 mmHg.	
Err 05 Err 06	Deflation error.	
Err 12 Err 23	Problem with calibration.	
		Review instructions and retest with a new strip.

Problem in Operation

1. Blood Glucose Measurement

What happened?

The monitor does not display a message after inserting a test strip.

POSSIBLE CAUSE	WHAT TO DO
Batteries exhausted.	Replace the batteries.
Batteries incorrectly installed or absent.	Check to see if the batteries are correctly installed.
Test strip inserted upside down or not completely inserted.	Insert the test strip correctly with the contact bars end first.
Defective monitor.	Contact the customer service at 1-888-307-8188, 1-866-469-2632 for help.


What happened?

You turned off the monitor but it makes a beeping sound.

POSSIBLE CAUSE	WHAT TO DO
The strip is still inserted.	Remove the strip. If you need to test blood glucose, insert an unused strip.

What happened?

The test does not start after applying the sample.

POSSIBLE CAUSE	WHAT TO DO
Insufficient blood sample.	Repeat the test with a new test strip and a larger sample.
Defective test strip.	Repeat the test with a new test strip.
Sample was applied at a time when “  <p>55</p>	


What happened?

If the control solution test result is out of range.

POSSIBLE CAUSE	WHAT TO DO
Error in performing the test.	Read the instructions thoroughly and repeat the test.
Control solution vial shaken poorly.	Shake the control solution vigorously and repeat the test again.
Expired or contaminated control solution.	Check the expiration and discard dates of the control solution.
Control solution that is too warm or too cold.	Allow control solution, monitor and test strips to come to room temperature (68°F-77°F/20°C-25°C) before testing.
Test strip deterioration.	Repeat the test with a new test strip.
Monitor malfunction.	Contact the customer service at 1-888-307-8188, 1-866-469-2632 for help.

2. Blood Pressure Measurement

What happened?

No display after pushing the “” button.

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

What happened?

Heart rate is higher/lower than user's average.

POSSIBLE CAUSE	WHAT TO DO
Moving during measurement.	Repeat measurement.
Measuring right after exercise.	Rest at least 30 minutes before measurement.

What happened?

A result is higher/lower than user's average measurement.

POSSIBLE CAUSE	WHAT TO DO
May be not 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.

What happened?

Cuff inflates again during measuring.

POSSIBLE CAUSE	WHAT TO DO
Cuff is not fastened.	Fasten the cuff again.
Normal action.	If user's blood pressure is higher than the default value, the device will automatically pump to a higher pressure. Stay relaxed and wait for the measurement.

SPECIFICATIONS

Device name: FORA D10

Power source: Two 1.5V AAA size alkaline batteries

Size of monitor w/o cuff: 6.3(L) x 7.5(W) x 4.0(H) cm

Weight of monitor w/o cuff and batteries: 158g

Memory: 450 measurement results with date& time

Power saving: Automatic power off if idle for 3 minutes

System operating condition:

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

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

Strip storage condition: 39.2°F to 104°F(4°C to 40°C), below 85% R.H.

KETONE warning: glucose value over 240 mg/dL

Measurement unit: mg/dL

Linear range: 20-600 mg/dL

Precision: ±5 %(CV)

Accuracy:

±15mg/dL when glucose < 75mg/dL; ±20% when glucose ≥ 75mg/dL

Pressure Range: 0-300 mmHg

Heart Rate Range: 40-199 beats per minute

Measurement unit: mmHg or KPa

Accuracy of Pressure: ±3mmHg or ±2% of reading

Accuracy of Heart rate: ±4% of reading

Maximum inflation pressure: 300 mmHg

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

Performance characteristics

Accuracy

Within ± 15 mg/dL (0.83 mmol/L) at glucose concentration < 75 mg/dL (4.2 mmol/L) and within $\pm 20\%$ at glucose concentration ≥ 75 mg/dL (4.2 mmol/L).

Precision

CVs (%) of intermediate precision and repeatability are less than 5%.
The product has been tested to meet the requirements of ISO 15197.