

FORA D40
Blood Glucose plus Blood Pressure
Monitoring System

Owner's Manual

09/2009

Version 1.0

Dear FORA D40 System Owner:

Thank you for purchasing the **FORA D40** 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 the compact size and easy operation of this **FORA D40** Blood Glucose plus Blood Pressure Monitoring System, you can easily monitor your blood glucose levels and blood pressure by yourself. 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 or the local customer service.

IMPORTANT SAFETY INSTRUCTIONS

READ THIS BEFORE USE

The following basic safety precautions should always be taken.

1. Use the device only for the intended use described in this manual.
2. Do not use accessories which are not supplied by the manufacturer.
3. Keep the equipment and its flexible cord away from hot surfaces.
4. Do not use the equipment where aerosol sprays are being used, or where oxygen is being administered.
5. Do not use the device if it is not working properly or has been damaged.
6. Before using product to test your blood glucose, read all instructions thoroughly and practice the test. Do all quality control checks as directed and consult with a diabetes healthcare professional.

KEEP THESE INSTRUCTIONS

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BEFORE YOU START

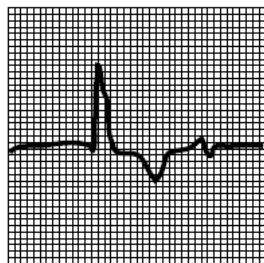
⦿ Warnings and Precautions



- The **FORA D40** 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 arm.

◎ Health Information

Blood Glucose

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 you acquire with the **FORA D40** system can help you and your healthcare professionals monitor and adjust your treatment plan to gain better control of your diabetes.

Time of day	Normal plasma glucose range for people without diabetes
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 (2008). Clinical Practice Recommendations. Diabetes Care, 31 (Supplement 1): S1-108.

Time of day	Plasma glucose range for people with diabetes	Your target range
Fasting and before meal	70 mg/dL -130 mg/dL (3.9 mmol/L -7.2 mmol/L)	
2 hours after meals	Less than 180 mg/dL (10.0 mmol/L)	

Source: American Diabetes Association (2008). Standards of Medical Care in Diabetes. Diabetes Care, 31 (Supplement 1): S12–S54.

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

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

Blood Pressure

Clinical studies show that the 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*⁵.

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 aging of the blood vessel. Further causes include obesity, lack of exercise, and cholesterol (LDL) adhering to the blood vessels. Rising of 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	Less than 90	Less than 60
Normal* ⁴	Less than 120	Less than 80
Prehypertension* ⁴	120 – 139	80 – 89
Stage 1 Hypertension* ⁴	140 – 159	90 – 99
Stage 2 Hypertension* ⁴	160 or more	100 or more

*3 National Heart, Lung, and Blood Institute, Diseases and Conditions

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

*⁵: American Diabetes Association: The Diabetes-Heart Disease Link Surveying Attitudes, Knowledge and Risk (2002)

ABOUT ALTERNATIVE SITE TESTING (AST)

Important: There are limitations for doing AST.

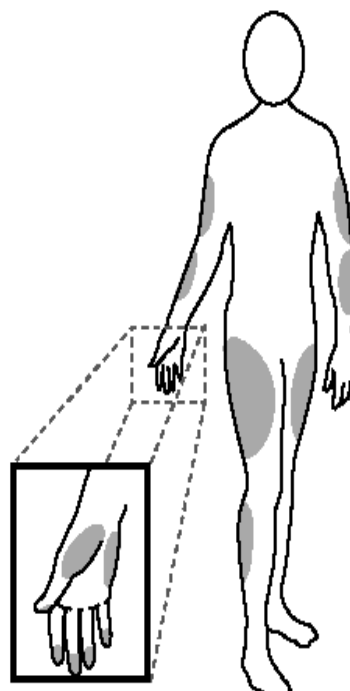
Please consult your healthcare professional before you do AST.

What is AST?

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

What's the advantage?

Fingertips feel pain more readily because they are full of nerve endings (receptors). At other body sites, since nerve endings weren't so condensed, you won't feel as much pain as at the fingertip.



When to use AST?

Food, medication, illness, stress and exercise can affect blood glucose levels. Capillary blood at fingertip reflects these changes faster than capillary blood at other sites. Therefore when testing blood glucose during or immediately after meal, physical exercise, or any other event, **take blood sample from your finger only.**

We strongly recommend that you do AST **ONLY** in the following intervals:

- 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.
- Your AST results do not match 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 was rubbed prior to blood extraction, the difference was significantly reduced.

Please follow suggestions below before getting a drop of blood:

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

ABOUT THIS SYSTEM

☉ Intended Use

The **FORA D40** system is a 2 in 1 system designed to measure blood glucose and to measure blood pressure non-invasively (in vitro diagnostic use.) It is intended for use at home and at clinical settings. It shall not be used for the diagnosis of diabetes or hypertension, or for the testing of newborns.

☉ 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 arm based on the Oscillometric method.

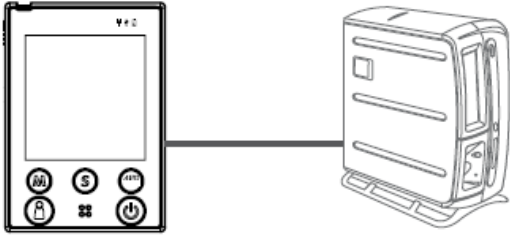
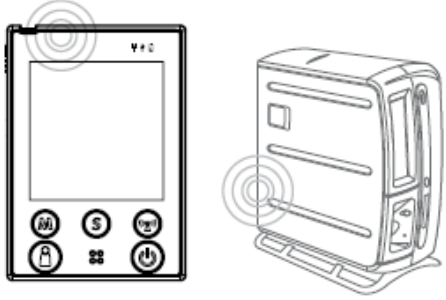
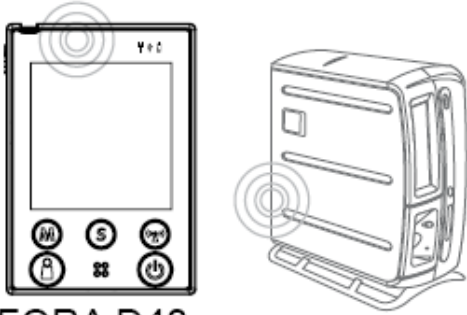
Both functions work independently of each other (one measurement, either blood glucose or blood pressure, at one time) in order to avoid any interference problems.

☉ Major Features

This system has the following distinguishing features and allows you to perform your measurements effectively.

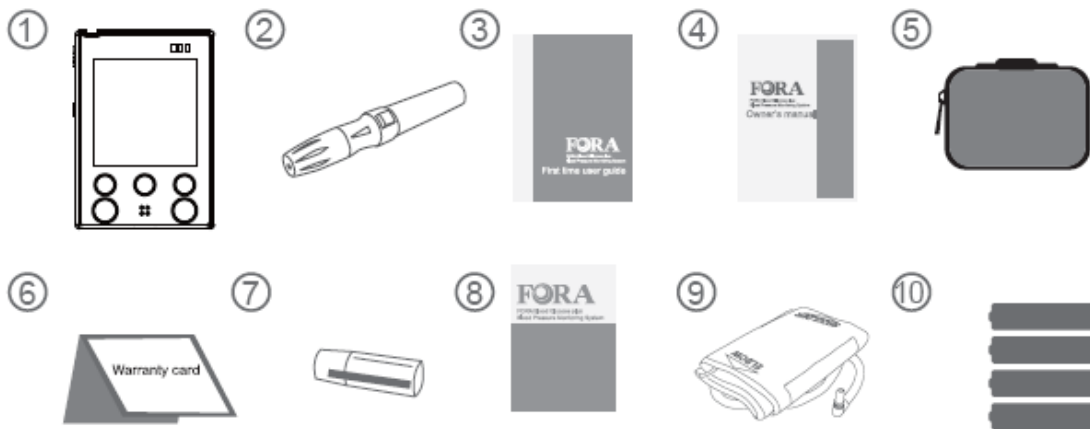
- 1. Talking function** – Instructions will be given throughout the measurement. The settings and test results will be repeated as well.
- 2. No calibration required** – Users do not need to calibrate the monitor.
- 3. AC/PC/QC records** – Glucose AC is the glucose value before meal and PC is the glucose value after meal. QC is the control solution value which users perform to check if the system works effectively.
- 4. Multi-user function** – It provides different users to store their results in the memory individually.
- 5. Data transmission options** – It helps users to manage their test results easily and efficiently.

There are three subtypes of **FORA D40** system available. Each one of them offers a different way to transmit allowing users to choose their own desired ways to manage their test results. The data transmissions are listed below:

Model	Data Transmission Function
 <p>FORA D40a</p>	<p>Test results can be viewed on the PC through the cable connection.</p>
 <p>FORA D40b</p>	<p>Test results can be viewed on the PC through a wireless connection by using Bluetooth technology.</p>
 <p>FORA D40g</p>	<p>Test results can be viewed on the PC through a wireless connection by using GPRS technology.</p>

⦿ CONTENT OF THE SYSTEM

- | | |
|---|------------------|
| ① Blood glucose plus blood pressure monitor | ⑥ Warranty card |
| ② Lancing device | ⑦ A clear cap |
| ③ First time user guide | ⑧ Daily log book |
| ④ Owner's manual | ⑨ An arm cuff |
| ⑤ Sporty bag | ⑩ Batteries |

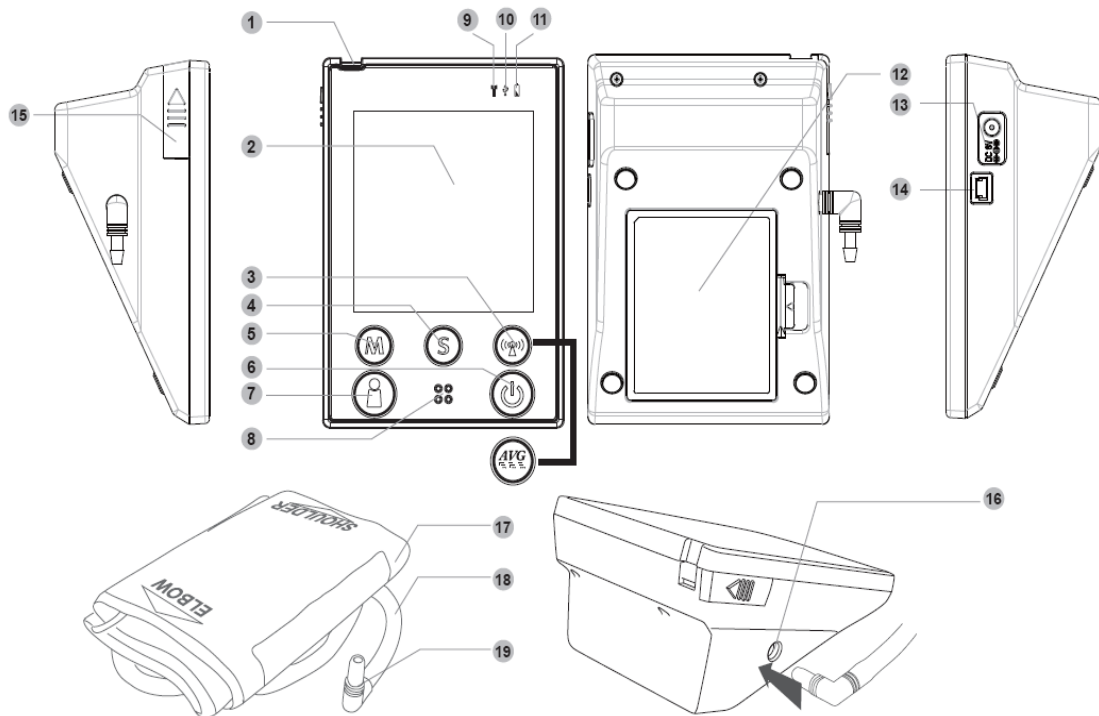


These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. Use only **FORA D40** test strips and control solution with your **FORA D40** monitor.

NOTE

- One 3.7V rechargeable Li-ion battery is included in the kit of FORA D40g instead of alkaline batteries. Use **ONLY** rechargeable Li-ion battery for FORA D40g (battery pack no.S14500 1S4P).
- Make sure your system is properly packaged prior to use and that it includes all components listed above. If not, please return your system to the place of purchase.
- Please note that test strips, control solutions and lancets are not included in the standard kit. Please ask your local agent or the place of purchase for availability.

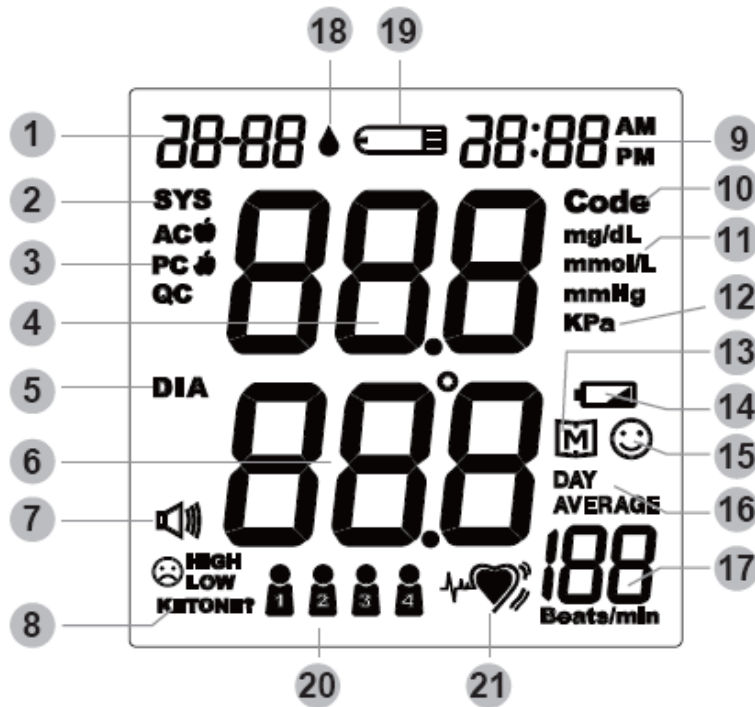
☉ Appearance and Key Functions of the Monitor



1. **TEST SLOT**- is where you insert the test strip.
2. **LCD SCREEN**- guides you through the test using symbols and simple messages.
3. **RF BUTTON**- assists you with wireless data transmission.
- AVERAGE BUTTON**- assists you with blood pressure average mode.
4. **S BUTTON**- is used to set up the monitor.
5. **M BUTTON**- is used to turn on the monitor and enter the memory.
6. **ON/OFF BUTTON**
7. **USER SELECTION BUTTON**- assists you with user number selection.
8. **SPEAKER**
9. **RF INDICATOR**- lights up for data transmission.
10. **USB INDICATOR**- lights up for data transmission.
11. **POWER INDICATOR**
12. **BATTERY COMPARTMENT**
13. **AC ADAPTER PORT**- is for power supply.
14. **USB LINK PORT**- For data transmission.
15. **STRIP-EJECTION BUTTON**- is where the used strip will be automatically ejected after you push up the button.
16. **Air jack**
17. **Arm Cuff**
18. **Air Tube**
19. **Air Plug**- connects to air jack.

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© LCD Screen



1. Date
2. Systolic Pressure Symbol
3. PC Mode
4. & 6. Test Result Area
5. Diastolic Pressure Symbol
7. Voice Volume
8. Ketone Warning
9. Time
10. Code Number
11. Unit of Measurement in Blood Glucose
12. Unit of Measurement in Blood Pressure
13. Memory
14. Battery Symbol
15. Smile Symbol
16. Day Average
17. Pulse Rate
18. Blood Drop Symbol
19. Test Strip Symbol
20. User Number
21. Pulse Symbol

◎ Speaking Function

The monitor “speaks” aloud step-by-step instructions on how to test your blood glucose and blood pressure. The following table tells you when and what the monitor “speaks”.

WHEN does the monitor speak?	WHAT does the monitor speak?
When the monitor is turned on.	Thank you for using this product. The user's number is one, please select the user's number. The user's number is one, please relax during measurement.
When room temperature is outside operating range of 10-40°C.	Room temperature out of range, unable to measure.
When the glucose test is completed (the result appears on display).	The blood glucose is (number) milligram per deciliter/ millimole per liter.
When the monitor is in the setting mode.	You are now in setting mode. The Year is (number).
	The month is (number).
	The day is (number)
	The hour is (number).
	The minute is (number).
	Blood glucose unit is milligrams per deciliter/ millimole per liter.
	Temperature unit is degrees Fahrenheit/ Celsius.
	Voice volume is (number).
	Delete memory record function, press the key the clear all the records.
	Repeat all the setting status.
Have a nice day.	

<p style="text-align: center;">WHEN does the monitor speak?</p>	<p style="text-align: center;">WHAT does the monitor speak?</p>
<p style="text-align: center;">When the test strip is inserted into the monitor.</p>	<p>Thank you for using this product. Test strip is inserted. Today's day is (number), the time is (number), the room temperature is (number), the user's number is one, please apply blood onto the test strip.</p>
	<p>Now testing.</p>
	<p>The user's number is one. Your blood glucose is (number) milligram per deciliter/ millimole per liter.</p>
<p style="text-align: center;">When the glucose test result is outside measurement range of 20-600 mg/dL.</p>	<p>The blood glucose is out of range, unable to measure.</p>
<p style="text-align: center;">When power is insufficient.</p>	<p>Battery is low, please recharge</p>
	<p>Battery is dead, please recharge</p>
<p style="text-align: center;">When the monitor is in blood glucose measurement mode.</p>	<p>You are now in testing mode.</p>
	<p>This is before meal measurement.</p>
	<p>This is after meal measurement.</p>
	<p>You are now in control solution mode.</p>
<p style="text-align: center;">When the blood pressure test is completed (the result appears on display).</p>	<p>Your 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.</p>

<p style="text-align: center;">WHEN</p> <p style="text-align: center;">does the monitor speak?</p>	<p style="text-align: center;">WHAT</p> <p style="text-align: center;">does the monitor speak?</p>
<p>When the monitor is in memory mode.</p>	<p>Thank you for using this product. Today's date is (number), the time is (number), you are now in memory mode, the user's number is one, please select the user's number.</p>
	<p>Memory record for (Time), your blood glucose is (number) milligram per deciliter/ millimole per liter. Your memory record for (Time). Your 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.</p>
<p>When the monitor is in day average memory mode.</p>	<p>Thank you for using this product. You are now in day average mode, the user's number is one, please select the user's number.</p>
	<p>The user's number is (number), the 7-,14-,21-,28-,,60-,90- day blood glucose average is (number)</p>

© Test Strip Description

Your system measures the amount of sugar (glucose) in whole blood. Blood is applied to the absorbent hole of the test strip and is automatically drawn into the reaction cell where the reaction takes place.

The test strip contains the following parts:

Contact Bars

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

Test Strip Handle

Hold this part to insert the test strip into the slot.

Confirmation Window

This is where you confirm if enough blood has been applied to the absorbent hole of the strip.

Absorbent Hole

Apply a drop of blood here and the blood will be absorbed automatically.



See section “Testing Your Blood Glucose” for complete instructions.

PREPARATIONS BEFORE USE


◎ Battery and DC adapter

The monitor is powered by batteries or a DC adapter.

Low Power Signal

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

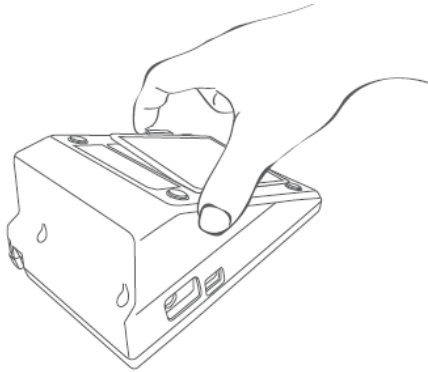


When the flashing “” symbol is displayed on the main screen, this indicates that batteries are dead and it is time to change the batteries.

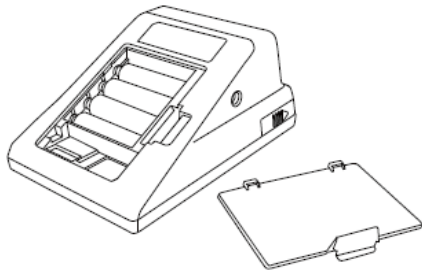
The power indicator located above the main screen would light up in red as well.

⦿ Battery Installation and Replacement

Make sure the monitor is off when replacing the batteries.



STEP 1- Press the edge of the battery cover and pull up. Lift the battery cover and remove the batteries inside.



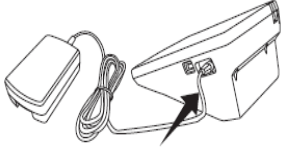
STEP 2 - Insert four 1.5V AA size alkaline batteries or one 3.7V rechargeable Li-ion battery. (Please refer to **CAUTION** for use). Make sure the + (positive) and – (negative) marks match as indicated in the battery compartment.

CAUTION

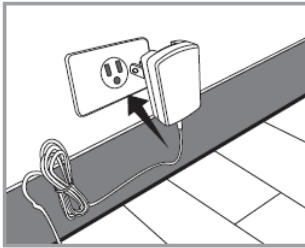
- FORA D40a and FORA D40b can use either four 1.5V AA size alkaline batteries or one 3.7V rechargeable Li-ion battery, whereas FORA D40g can use Li-ion rechargeable battery ONLY (battery pack no.S14500 1S4P.)
- If the battery is replaced by an incorrect type, it may cause risk of explosion.
- Do not use different type, date or brand name batteries together. Use only new batteries of the required size and type.
- Replacing the batteries does not affect previous test results stored in the monitor. But you may need to update the settings.
- Batteries might leak chemicals if not used 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).
- As with all small batteries, the batteries should be kept away from small children who still put things in their mouths. If they are swallowed, promptly see a doctor for help.
- Discard batteries according to your local regulations.

◎ Use the AC Adapter

Connect the AC adapter to the monitor.

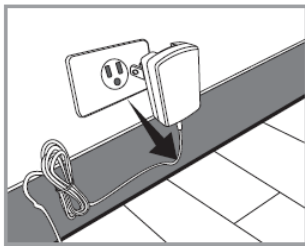


1. Connect the AC adapter plug to the AC adapter jack of the monitor.

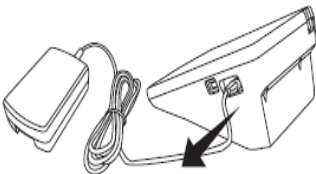


2. Plug the AC adapter power plug into an electrical outlet. You can press the ON/OFF button to start the measurement.

Remove the AC adapter from the monitor.



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



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

NOTE

- FORA D40 with the Li-ion battery must be recharged by connecting the AC adapter to an electrical outlet. Only this 3.7V rechargeable Li-ion battery (battery pack no. S14500 1S4P) can be recharged with FORA D40 by the connection of AC adapter. Any other kind of rechargeable battery is not allowed or it may damage the monitor.
- When alkaline batteries are used for FORA D40a or FORA D40b, these batteries cannot be recharged with the monitor by AC adapter connection. The used alkaline batteries must be replaced by new ones.

◎ Setting the Monitor

Time, date, units of measurement, memory deletion, volume and language can be set in the monitor. Two keys are involved: **S** button and **M** button.

Step 1 Press the **S** button to start setting.



Step 2 Year will flash first.



Step 3 Press **M** button to make changes. Press **S** button to advance to next setting.



Step 4 Date will flash. Follow **Step 3** for changes.



Step 5 Time will flash. Follow **Step 3** for changes.



Step 6 12H/24H mode selection. Follow **Step 3** for changes.



Step 7 Unit of glucose concentration will flash. Follow **Step 3** for changes.



*Please note: The default unit is milligram per deciliter (mg/dL).

Step 8 Unit of blood pressure will flash. Follow **Step 3** for changes.



*Please note: The default unit is mmHg.

Step 9 Unit of temperature will flash. Follow **Step 3** for changes.



Step 10 Voice volume will flash. Follow **Step 3** for changes.



Step 11 Auto send will flash. Follow **Step 3** for changes.





Step 12 "dEL" and flashing "M" will display on the screen for memory deletion.

- If you do not want to delete memory, press **S** button to skip this step.
- If you'd like to delete memory, press **M** button again so that "M" will start flashing. Press **M** button again to delete **ALL** memory. The monitor will repeat all the settings you just finished and then the monitor will turn off.



NOTE

- 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 “.
- The time, date, speaking volume and memory deletion can **ONLY be changed** in the setting mode. Therefore, these parameters cannot be changed while performing tests.
- During the setting mode, you can press **On/Off** button to turn off the monitor.
- While the monitor is in the setting mode, it will turn off automatically if left idle for three minutes.

☉ User Number Selection

This FORA D40 system provides up to four users for both measuring functions, and each user has his/her own individual memory storage.

STEP 1

Press the user selection button to select the desired user number. You can change the user number by pressing the user selection button.



STEP 2

When you have finished the user selection, press **S** button to confirm the setting. The monitor will repeat the user number you just selected and then turn off automatically.



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. Critically ill patients should not be tested with a glucose meter.
6. Please refer to your test strip package insert for important additional information.

☉ Quality Control with FORA Control Solutions

FORA control solutions contain 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, it is able to check 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 you get accurate results.

- 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 your test strips are exposed to extreme environmental conditions (See **TAKING CARE OF YOUR MONITOR & STRIP** section of this manual)
- 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.
- It is recommended to use the control solutions between the temperatures of 20°C and 25°C (68°F and 77°F.)
- 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 only within 3 months after first opening. Record the discard date (date opened plus 90 days) on the control solution vial. Discard on this date.
- Store the control solution tightly closed at temperatures 2°C - 30°C (36°F - 86°F). Do not freeze.

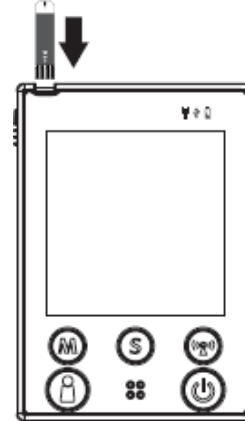
NOTE

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

⦿ Performing a Control Solution Test





STEP 1. Insert a test strip with contact bars end first and facing up, into the test slot. The monitor turns on automatically and displays the followings in sequence:

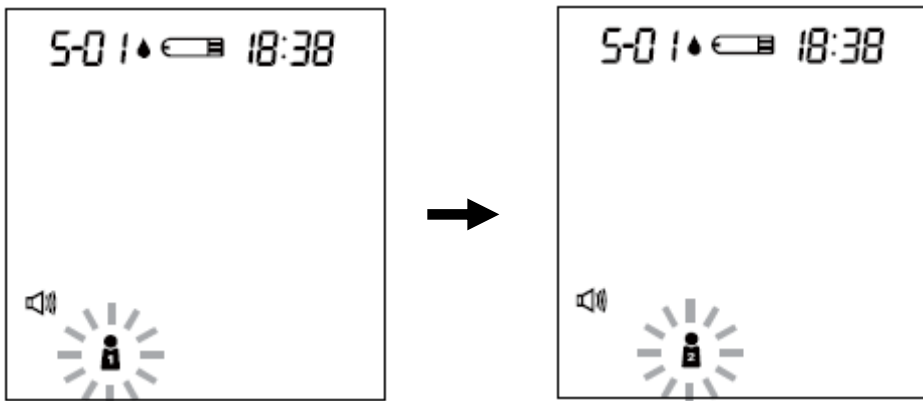
“” and the ambient temperature
→ “” with the user’s number,
and a flashing “.



STEP 2. Select the User Number

After the test strip is fully inserted into the test slot, press the **user selection**

button to select the user     (numbers from 1 to 4) whose test reading will be stored in its memory.



NOTE

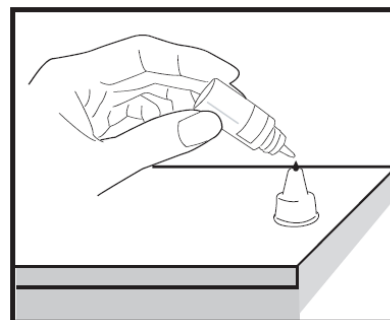
You can also select the user’s number in advance by pressing the user selection button. Please refer to page 25 for detailed information about your user’s number selection.

STEP 3. Press **M** button and select the symbol "**QC.**" When you do this, this reading will be stored as a control solution data.



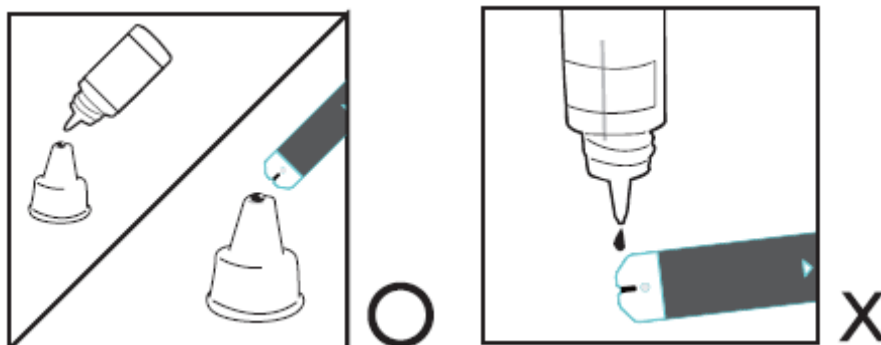
STEP 4. Obtain Control Solution

Shake the control solution vial well. Remove the cap from the control solution bottle. Place cap on flat surface. Squeeze the vial, discard the first drop, and wipe off the dispenser tip to prevent contamination. Squeeze the vial again to produce another drop and **place this drop on the top of cap.**

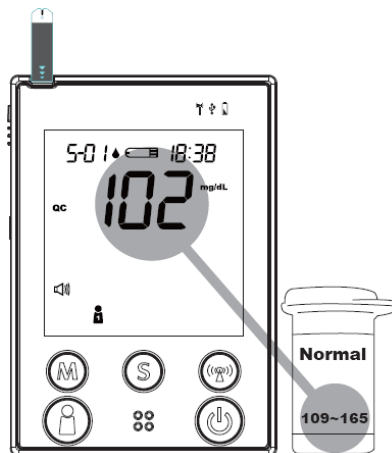


STEP 5. Apply Control Solution.

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.



STEP 6. The monitor will begin countdown. After 5 seconds, the control solution test result will appear. **The result should fall within the range printed on the test strip vial.**



Out-of-range results

If test results fall outside the printed range, check the “Operating Problem” section in the 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 your local customer service 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 “QC” test mode so that the test result with QC symbol will 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.

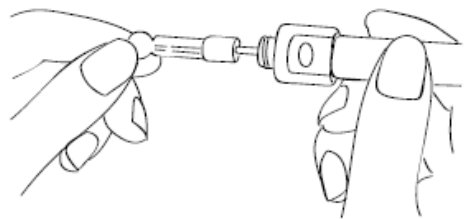
◎ Testing Your Blood Glucose

Be sure to read carefully this section and the test strip package insert found in the test strip box before testing. Make sure you have all items needed to test: the monitor, test strips, lancing device, and sterile lancet.

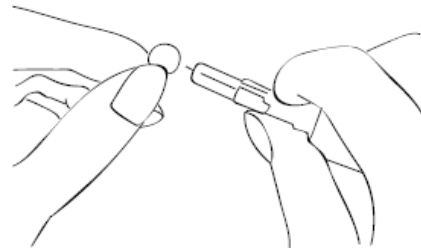
WASH AND DRY YOUR HANDS FIRST BEFORE STARTING.

STEP 1. Set the Lancing Device

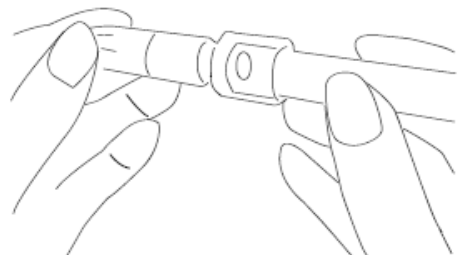
Screw off the cap of the lancing device. Insert a lancet into the lancet holder and push down firmly until it is fully seated.



Twist the protective disk until it separates from the lancet.

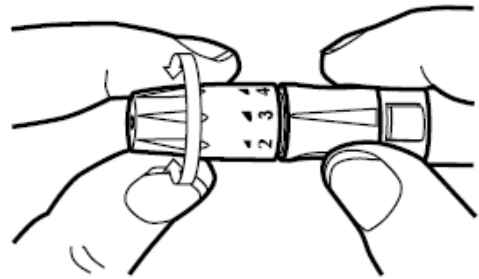


Replace the lancing device cap. Turn the cap until it is snug but not too tight.

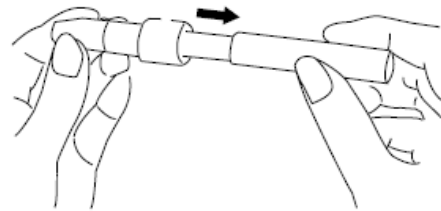


The adjustable tip offers 5 levels of skin penetration. Twist the adjustable tip in either direction until the number lines up with the arrow:

1-2 for soft or thin skin, 3 for average skin, 4-5 for thick or calloused skin.

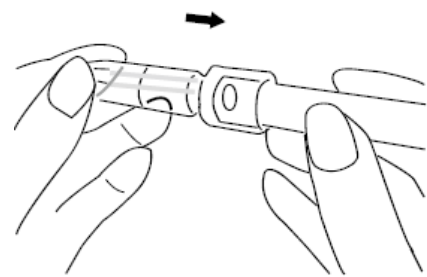


Slide the ejection/cocking control back until it clicks. If it does not click the device may have been cocked when the lancet was inserted.



■ Blood from sites other than the fingertip

A clear cap, together with the kit, make it easier to get a drop of blood for AST. When you want to obtain blood from sites other than the finger, **replace the lancing device cap with the clear cap.** Turn the clear cap until it is snug but not too tight, and then slide the ejection/cocking control back until it clicks.



The lancing device is now ready for use. Set aside for later use.




WARNING

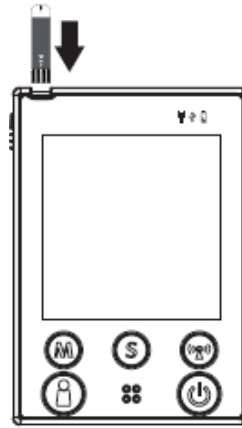
To reduce the chance of infection:

- 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 and the lancing device.

STEP 2. Insert the Test Strip


Insert a test strip with contact bars end first and facing up, into the test slot. The monitor turns on automatically and displays the followings in sequence:

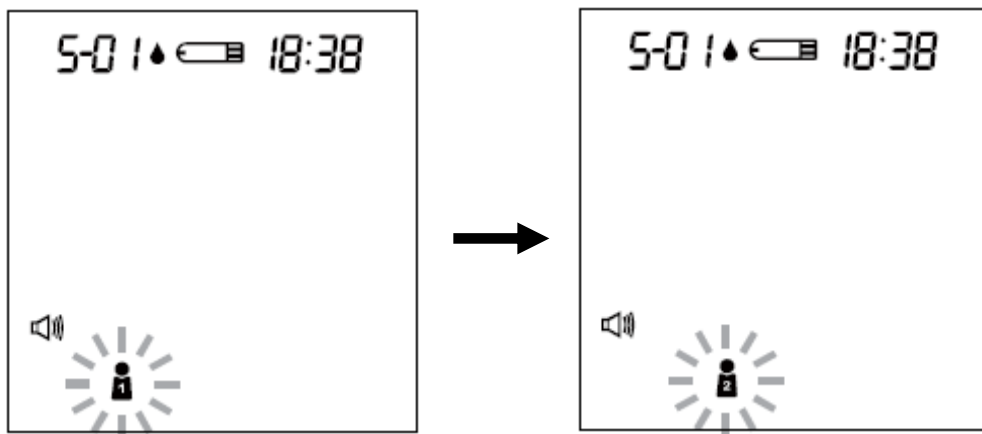
- “” and the ambient temperature
- “” with the code number,
the user’s number and a flashing “”.



STEP 3. Select the User Number

After the test strip is fully inserted into the test slot, press the **user selection**

button to select the user  (numbers from 1 to 4) whose test reading will be stored in its memory.

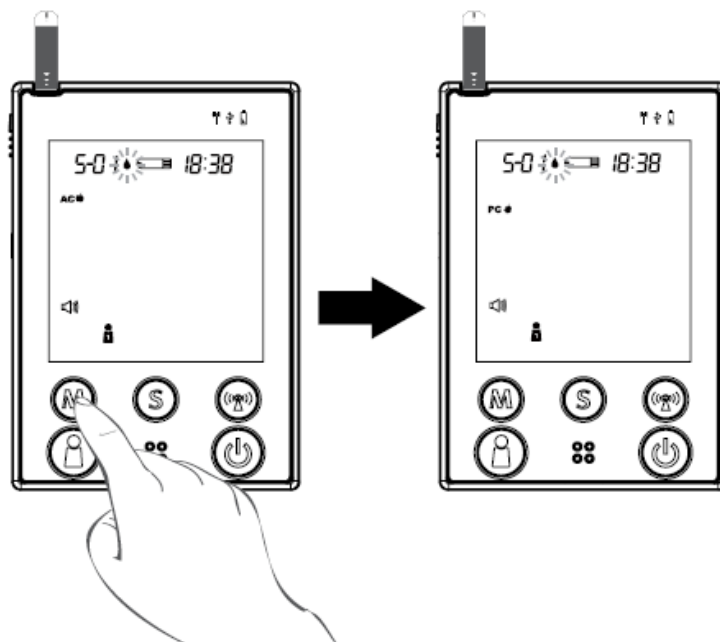


NOTE


You can also select the user’s number in advance by pressing the user selection button. Please refer to page 25 for detailed information about your user’s number selection.

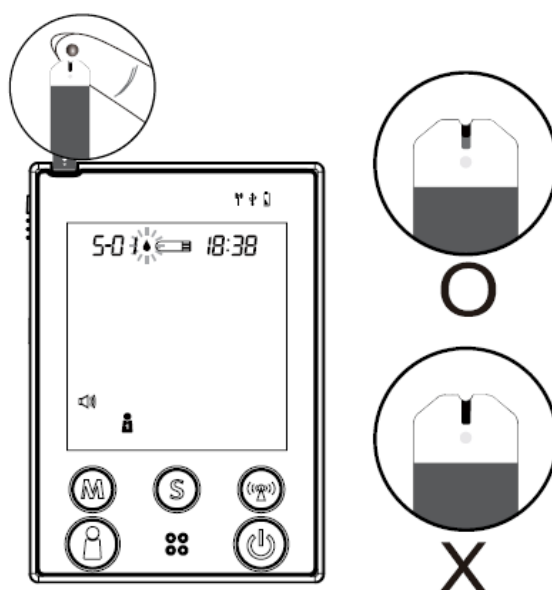
STEP 4. Select AC/PC

Press **M** button to select AC/PC mode, or just perform a general test. Select “**AC**” if performing a blood glucose test before meal, or “**PC**” for performing a test after meal.



STEP 5. Apply Blood into the Test Strip

When the “” symbol is flashing on the LCD display, apply a drop of blood to the absorbent hole of the test strip. Do not push your finger against the test strip or try to apply a smeared sample.



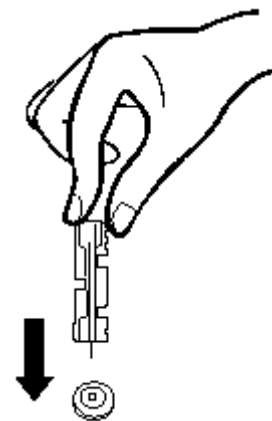
STEP 6. Obtain an Accurate Result in 5 Seconds

Read the test result after 5 seconds. The test result will be automatically stored in the monitor memory. Turn the monitor off by removing the test strip.



STEP 7. Discard the Used Lancet


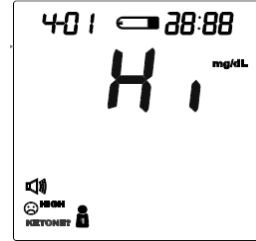

Remove the lancing device cap and the lancet. Place the disk on a hard surface and push the exposed needle tip into the protective disk. **Always use caution when removing the lancet.**



CAUTION

- If you do not apply blood sample within 3 minutes, or if you accidentally turn off the monitor by pressing the **On/Off** button, the monitor will alert you with flashing test strip symbol and continuous beeping. You will need to turn the monitor off by removing the test strip.
- To start a blood pressure test after performing a blood glucose test, make sure that the test strip is removed from the monitor. Then turn the monitor off and refer to "**BLOOD PRESSURE MEASUREMENT**".

◎ Special Message

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

⦿ **Comparing Monitor and Laboratory Results**

The monitor 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 monitor 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.
- It is best to fast for at least eight hours before doing comparison tests.
- Take your monitor with you to the lab.

While being 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 have a variation from the result because blood glucose levels can change significantly over short periods, especially if you have recently eaten, exercised, taken medication, or experienced stress^{*6}. In addition, if you have eaten recently, the blood glucose 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^{*7}. 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 be different from a laboratory result.

References

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

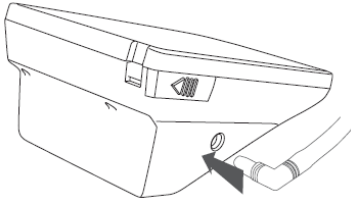
*7: Sacks, D.B.: "Carbohydrates." Burtis, C.A., and Ashwood, E.R. (ed.), Tietz Textbook of Clinical Chemistry. Philadelphia: W.B. Saunders Company (1994), 959.

BLOOD PRESSURE MEASUREMENT

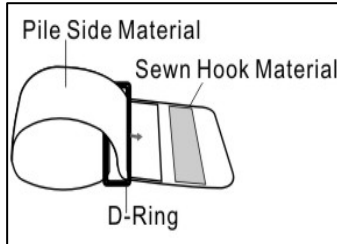
☉ Suggestions before Measuring

- Avoid caffeine, tea, alcohol, and cigarette 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 measuring.
- 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 physician as reference.
- Blood pressure varies from two hands naturally. Always measure your blood pressure on the same arm.

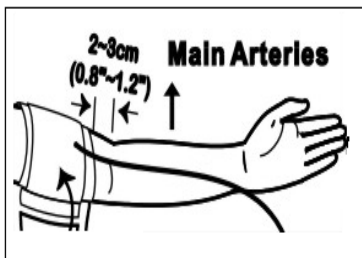
⦿ Applying the Pressure Cuff



STEP 1 Connect the air plug of the tubing to the air jack at the side of the monitor.



STEP 2 Assemble the cuff as the left figure. The smooth surface is on the inside of the cuff loop and the metal D-ring should not touch your skin.



STEP 3 Extend your left arm in front of you with your palm facing up. Slide the cuff onto your left arm, above your elbow. The red line on the edge of the cuff should be approximately **0.8 inch to 1.2 inch (2 cm to 3 cm)** above your elbow. Align the tubing over the main arteries at the inside of your arm.

STEP 4 When the cuff is positioned correctly, pull the end of the cuff to tighten the cuff snugly around your upper arm. You should be able to fit your index finger between the cuff and your 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.

⦿ Proper Measurement Position

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



STEP 2 Place your elbow on a table or other object. Relax your hand with the palm facing up.

STEP 3 Relax and make sure the cuff is at the same height as your heart. Press the **On/Off** button. Then, press the user selection button to select the user's number.

STEP 4 Measurement is in progress.

After the monitor turns on, all the LCD display symbols will appear with a long “beep” sound. Then the cuff will begin to inflate automatically.

Remain still and do not talk or move during the measurement.

WARNING

It is extremely important that the cuff is at the same height as the heart. If the cuff is relatively lower (higher) than the heart, the blood pressure measured will be higher (lower) than the actual value. A 15 cm difference in height may result in an error of 10 mmHg.

NOTE

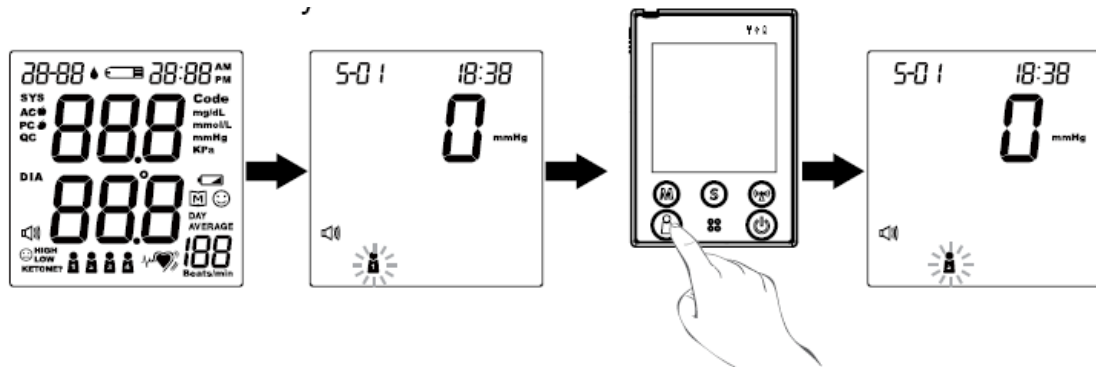
▪ You can either press **On/Off** button to take one measurement, or press and hold the **On/Off** button for 3 seconds to enter measurement average mode.

☉ Take a Reading

Read "**Suggestions before Measuring**" and "**Applying the Pressure Cuff**" before you take a reading. **Always apply the pressure cuff before turning on the monitor.**

STEP 1. Press the **On/Off** button. All the LCD symbols will appear.

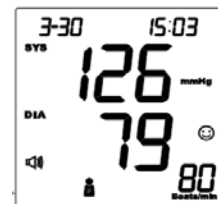
Press the **user selection** button to select user **1 2 3 4** (numbers from 1 to 4) whose test reading will be stored in its memory. Then the cuff will begin to inflate automatically.



STEP 2. After the cuff pressure is reached, the cuff begins deflation. The pulse symbol "♥" will flash when pulse is detected.





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



STEP 4. Press the **On/Off** button to switch off. Or it will switch off automatically after 3 minutes.



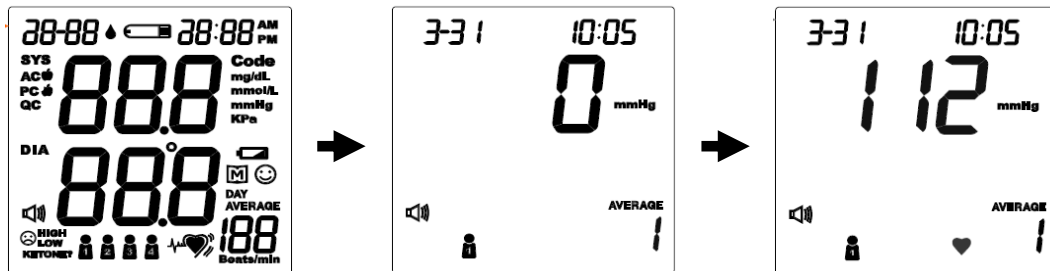
NOTE

- This monitor can record up to 4 users' measurements.
- If you press the **On/Off** button during the measurement, the monitor will turn off.
- If the pulse rate symbol showed as “  ” instead of “  ’, this suggests that the monitor has detected an irregular pulse rate.

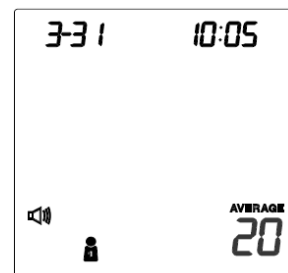
Ⓞ Measurement Average Mode

Always apply the pressure cuff before turning on the monitor.

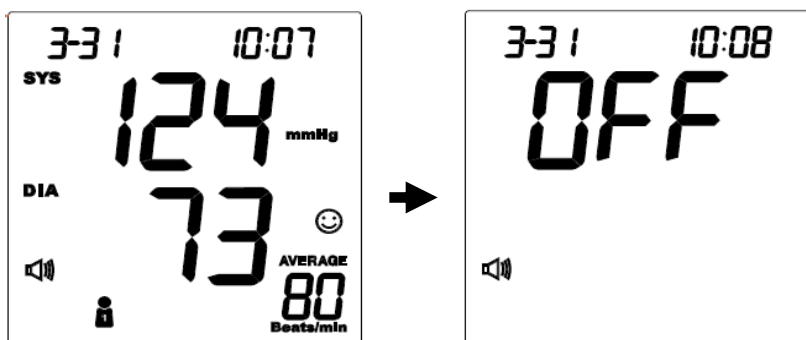
STEP 1. Press and hold the **On/Off** button for three (3) seconds. The monitor will turn on and enter the average mode. Then the cuff will begin to inflate automatically.



STEP 2. The monitor will take three (3) measurements consecutively with an interval of 20 seconds. The number on the right represents the remaining countdown between each measurement.




STEP 3. The monitor will calculate the average of all three measurements and display the average value. Press the **On/Off** button to turn off the monitor.

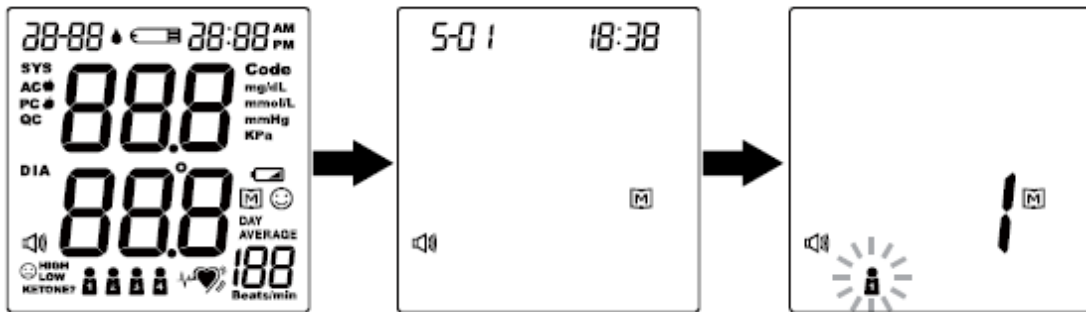


MONITOR MEMORY

Your monitor stores 864 the most recent results, and also provides the average of blood glucose test results. Please follow the steps below to review those results.

☉ Viewing Results on the Monitor:

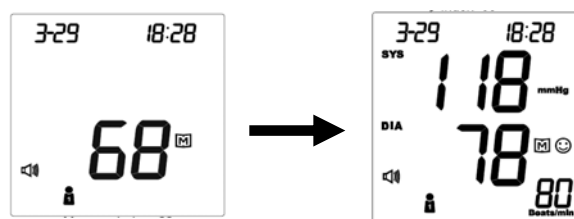
STEP 1. When the monitor is off, press and release the **M** button. The monitor will enter the memory mode. Press the **user selection** button  (numbers from 1 to 4) which you used to store in the memory.



STEP 2. “1” appears first and then the latest blood glucose result or blood pressure result along with date/time showed on the screen. Press the **M** button to review the next result.



STEP 3. Press the **M** button or the **S** button to recall the remaining test results stored in the monitor consecutively. For example, the test result showed below is the sixty-eighth memory record of user number 1.

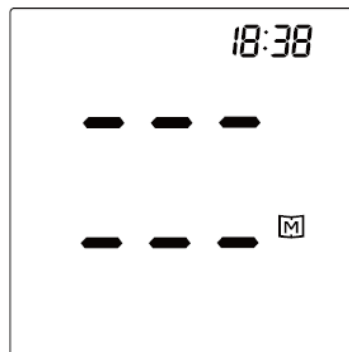


STEP 4. Press the **user selection** button to select another user's number and to view the test results stored in the monitor memory (i.e. user number 2).



NOTE

- If you'd like to exit from the memory, press the **On/Off** button to turn off the monitor or leave it idle for 3 minutes for auto-shut down.
- When using the monitor for the first time, "---" appears, showing that there is no test result stored in memory.



Ⓞ Reading the Day Average of Blood Glucose Results

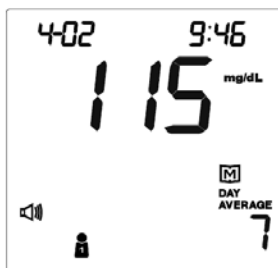
STEP 1 When the monitor is off, keep pressing the M button for 3 seconds to enter the memory mode.

STEP 2 Select the user's number by pressing the user selection button. After the display, press the S button to switch and review blood glucose or blood pressure test results.

STEP 3 Press the M button to review the 14-, 21-, 28-, 60- and 90-day average in order.

STEP 4 After viewing the 90-day average, press the M button again to resume to the 7-day average.

STEP 5 View the day average results of another user's number by pressing the user selection button and selecting another one.



- ① The **day average** of blood glucose tests.
- ② The user's number is 1.
- ③ The average was calculated from the test results of the **last 7 days**.
- ④ Memory symbol interpretation: The average of user number 1's glucose tests in the last 7 days is 115 mg/dL.

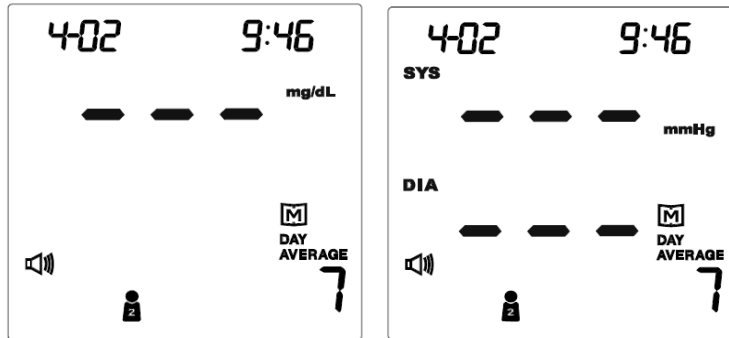


- ① The **day average** of blood pressure tests.
- ② The user's number is 1.
- ③ The average was calculated from the test results of the **last 7 days**.
- ④ Memory symbol interpretation: The last 7 days average of user number 1's systolic pressure is 126 mmHg and diastolic pressure is 76 mmHg.

NOTE

- If you'd like to exit from the memory, press the **On/Off** button to turn off the monitor or wait without pressing for 3 minutes for auto-shut down.

When using the monitor for the first time, “---” appears, showing that there are no test result in memory.



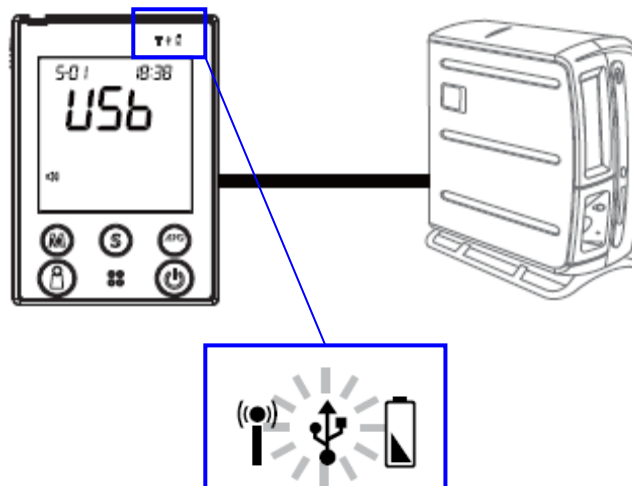
Ⓞ Viewing Results on a Personal Computer

Stored results in memory can be transmitted to a personal computer via either USB cable or wireless connection. An interface cable and the pairing software system will be needed for the data transmission. Please visit our website at <http://www.foracare.ch/products.html> and install the Health Care System Software first. If you have any question about this function, please ask the local customer service for assistance.

Data transmission via cable (For all FORA D40)

STEP 1

Connect the interface cable to a serial port on your computer. With the monitor turned off, connect the interface cable to the data port located at the side of the monitor. "USB" will appear on the display and the USB indicator will light up in green, indicating that the monitor is ready to transmit data.



STEP 2

Follow the instructions provided in the software to transmit data (results and their corresponding dates and times). Remove the cable or press the **On/Off** button and the monitor will turn off.

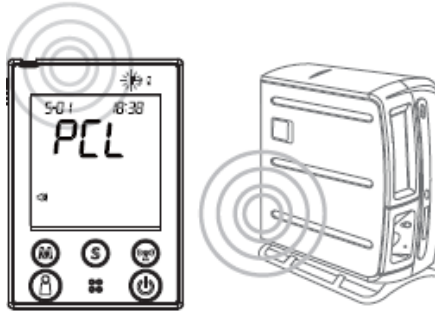
NOTE

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

Data transmission via Bluetooth (For FORA D40b only)

STEP 1

With the monitor turned off, press the **RF button** to initiate the data transmission of the monitor. "PCL" will appear on the display and the RF indicator will light up in blue.



When the RF indicator is blinking fast, indicating the monitor is still searching for pairing. When the RF indicator is blinking slowly, indicating the monitor has found the pairing computer. When the RF indicator is in steady blue light, indicating the monitor is online and ready for data transmission.



STEP 2

Follow the instructions provided in the software to transmit data (results and their corresponding dates and times). Press the **RF button** or the **On/Off** button and the monitor will turn off.

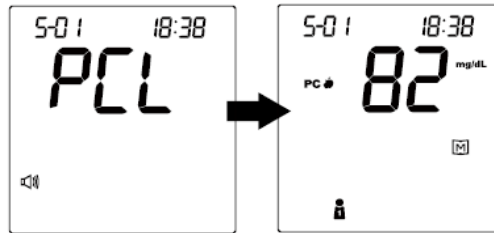
NOTE

- Make sure your PC has Bluetooth before transmitting the data and the monitor is within the receiving range.
- When reviewing the test result by pressing the **M button** (page 45), you can press the **RF button** and just upload one single test result.
- Only one data transmission is allowed at one time. If the **RF button** has been pressed while the USB cable is still connecting the monitor with PC, the monitor can only communicate through USB cable rather than the wireless transmission.

Data transmission via GPRS (For FORA D40g only)

STEP 1

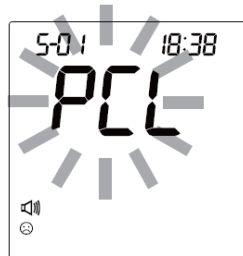
With the monitor turned off, press the **RF button** to initiate the data transmission from the monitor. "PCL" will appear on the display and the RF indicator will light up in blue. Then test results which have not been uploaded will display on the screen and initiate the transmission in sequence of the user's number by GPRS service.



STEP 2

Follow the instructions provided in the software and insert the SIM card at the bottom of the monitor battery compartment to transmit data (results that have not been uploaded and their corresponding dates and times).

If the SIM card is not inserted, the "PCL" will start blinking, as the figure showed below, and the monitor will turn off automatically after blinking for 30 seconds.



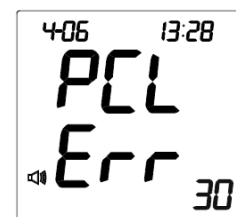
When the RF indicator is blinking in blue light, indicating the data transmission has started. When the RF indicator shows yellow light, indicating the GPRS service is online.

STEP 3

Press the **RF button** or the **On/Off** button and the monitor will turn off.

NOTE

If the monitor displayed a message like one on the right while connecting to the server, please start over and try again. If the problem still persists, please contact the place of purchase for help.



TAKING CARE OF YOUR MONITOR & STRIP

To protect the monitor and test strips from dirt, dust and other contaminants, please wash and dry your hands thoroughly before use.

☉ Cleaning

1. To clean the monitor exterior, wipe with a cloth moistened with tap water or a mild cleaning agent, then dry it with a soft, dry cloth. Do not flush with water.
2. Do not use organic solvents to clean the monitor and cuff.
3. The cuff can be cleaned by wiping with a moistened cloth and soap. Do not immerse in water.

☉ Storage

1. Meter Storage



- Storage condition: -20 °C to 60°C (-4°F to 140°F), below 95% relative humidity.



- Always store or transport the monitor in its original storage case.

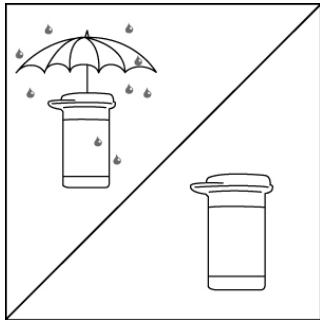


- Avoid dropping and strong impact.

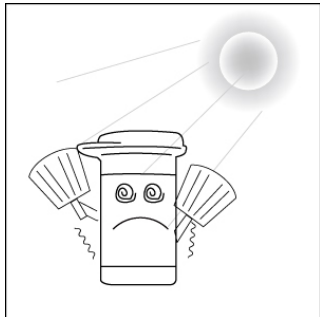


- Avoid direct sunlight and humidity.

2. Strip Storage



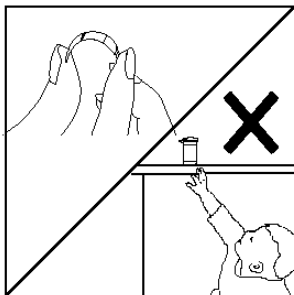
- Storage conditions: 4 °C to 40°C (39.2°F to 104°F), below 85% relative humidity. Do not freeze.
- Store your test strips in their original vial only. Do not transfer to other container.



- Store test strip packages in a cool, 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 and dry hands.

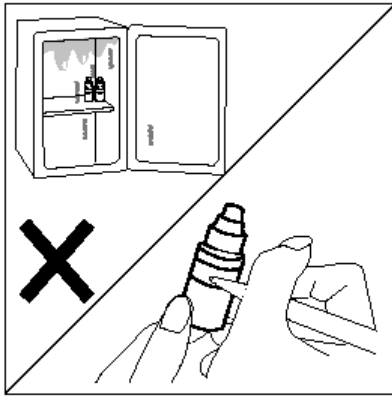


- Use each test strip immediately after removing it from the vial.
- Write the first opening date on the vial label when you first opened it. Discard remaining test strips 3 months after the first opening date.



- 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.

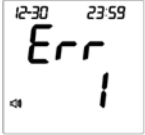

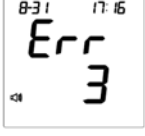
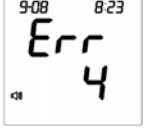
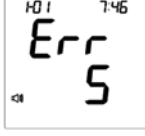
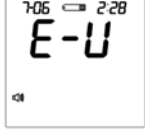
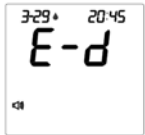
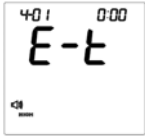
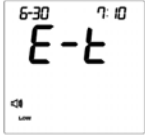
3. Control Solution Storage



- Storage conditions: Store the control solution tightly closed at temperatures 2°C to 30°C (4°F to 86°F). Do not freeze.
- Record the first opening date on the control solution vial. Discard it after 3 months.

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.

MESSAGE	CAUSE	WHAT TO DO
	Inflation or pressure error	Please contact local customer service for help.
	Deflation error	
	Cuff pressure is too high.	Refit cuff tightly and correctly. Relax and the repeat measurement. If error still remains, Please contact local customer service for help.
	No pulse rate detected or the pulse rate is too low.	
		
	Strip has been used.	Repeat the test with a new strip.
	Blood sample insufficient.	Review the instructions and repeat the test with a new strip.
	Environmental temperature is out of the system operational range.	System operational range is 10°C - 40°C (50°F -104°F). Repeat the test after the monitor and test strip have reached the above temperature.
		

⊙ Operating Problem

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 incompletely.	Insert the test strip correctly with the contact bars end first.
Defective monitor.	Please contact your local customer service.

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 “◆” was not flashing on the display.	Repeat the test with a new test strip. Apply sample only when “◆” appears on the display.
Defective monitor.	Please contact your local customer service.

What happened?

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

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

What happened?

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.
Expired or contaminated control solution.	Check the expiration and discard dates of the control solution.
Control solution that is too warm or too cold.	It is recommended to use the control solution between temperatures of 20°C and 25°C (68°F and 77°F).
Test strip deterioration.	Repeat the test with a new test strip.
Monitor malfunction.	Please contact your local customer service.

2. Blood Pressure Measurement

What happened?

No display after pushing the **On/Off** 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 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.

What happened?

Cuff inflates again while measuring.

POSSIBLE CAUSE	WHAT TO DO
Cuff is not fastened.	Fasten the cuff again.

SPECIFICATIONS

■ System performance

Power source:	Four 1.5V AA alkaline batteries
Size of monitor w/o cuff:	147 (L) x 105 mm (W) x 80 mm (H), 500g with batteries.
Memory:	Total 864 memory records
Power saving:	Automatic power off if system idle for 3 minutes (normal mode) or 5 minutes (RF mode).
System operating condition:	10°C - 40°C (50 -104°F), below 85% RH
Meter storage condition:	-20°C - 60°C (-4 -140°F), 5 - 95% RH
Power Supply Input:	DC +6V / 1A (max) via Power Plug

■ Blood glucose measurement performance

Measurement unit:	mg/dL or mmol/L
Linear range:	1.1 mmol/L - 33.3 mmol/L (20 mg/dL - 600 mg/dL)
Precision:	±5 % (CV)
Accuracy:	±15mg/dL when glucose <75mg/dL ±20% when glucose ≥ 75mg/dL
Ketone warning:	glucose value is over 240 mg/dL

■ Blood pressure measurement performance

Pressure range:	0 - 300 mmHg
Pulse rate range:	40 -199 beat per minute
Measurement unit:	mmHg or KPa
Systolic Measurement Range:	55 mmHg -260 mmHg
Diastolic Measurement Range:	25 mmHg -195 mmHg
Pulse Rate Measurement Range:	40 -199 beats / minute
Maximum inflation pressure:	280 mmHg
Accuracy of Pressure:	±3 mmHg or ±2% of reading
Accuracy of Pulse rate:	±4% of reading
Measurement unit:	Either mmHg or KPa

This device has been tested to meet the electrical and safety requirements of: EN 60601-1, EN 61010-1-2, EN 61010-1, EN 61010-2-101, EN 60601-1-2, EN 61326, EN 300 328

Federal Communications Commission (FCC) Statement

15.21

You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

15.105(b)

Federal Communications Commission (FCC) Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
 - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- 1) this device may not cause **harmful** interference and
- 2) this device must accept any interference **received**,, including interference that may cause undesired operation of the device.

FCC RF Radiation Exposure Statement:

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 centimeters between the radiator and your body.

CAUTION

RISK OF EXPLOSION IF BATTERY IS REPLACED

BY AN INCORRECT TYPE.

DISPOSE OF USED BATTERIES ACCORDING TO THE INSTRUCTIONS.