English

Dear FORA D40 Pro System Owner:

Thank you for purchasing the FORA D40 Pro Blood Pressure plus Blood Glucose Monitoring System. This manual provides important information which helps you to operate this system smoothly. Before using this product, please read this manual thoroughly to ensure safe and accurate use.

If you have other questions regarding this product, please contact the place of purchase or the local customer service for assistance.

Version 2.0 2011/07 311-3261500-001

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SAFETY INFORMATION

The information in this manual is a comprehensive guide to the operation of the monitor. For safety reasons, please read this manual thoroughly before using the monitor.

General Warnings

- Only the healthcare professionals who have trained for this system should operate.
- Use this device only for the intended use described in this manual.
- Do not use accessories which are not specified by the manufacturer.
- Do not use the device if it is not working properly or damaged.
- Do not use the equipment where aerosol sprays are being used or where oxygen is being administered.
- Do not use under any circumstances on newborns or infants.
- Keep the equipment and its flexible cord away from hot surfaces.
- Use this device in a dry environment. Avoid high humidity and high temperature.
- Do not use this device in close proximity to sources of strong electromagnetic radiation, as these may interfere with the correct operation.
- Do not disassemble or modify this device.
- Do not touch the AC adapter with wet hands.
- Do not share an electric outlet with other device or electric appliance.
- Unplug the AC adapter from the electric outlet if this device is unused for an extended period of time.

- Unplug the AC adapter from the electric outlet when installing, removing, or cleaning the device.
- After cleaning this unit, dry it well before plugging the AC adapter in the electric outlet.
- If this device fails to perform as indicated, stop the measurement immediately and turn off the unit, unplug the AC adapter from the electric outlet, contact customer service for assistance.
- Do not use an AC adapter or battery pack not specified for this device.
- Turn off the device and unplug the AC adapter from the electric outlet before moving the device.
- Check the device operation on a regular basis when using this monitor for the first time or after a long period. If the device has not been used for more than three months, be sure to check if the device operates normally and safely before use.
- Do not install or store this device where it may come into contact with water or liquid medication.
- Read the instruction manual of the other devices to be used at the same time with this unit, to understand and be aware of the interaction between the devices.
- Do not autoclave.
- Do not install or store this unit in the places where has the storage of chemicals or the gas may be generated.
- Do not use this unit in a vehicle.
- Do not use any cuff other than the models exclusive for this device.
- Before using this device to test blood glucose, read all instructions thoroughly and practice the test. Do all quality control checks as directed.
- Keep the device and testing supplies away from young children. Small items such as the battery cover, batteries, test strips, lancets and vial caps are choking hazards.

BEFORE YOU BEGIN

Intended Use

This system is a 2 in 1 system designed to measure blood glucose outside the human body (in vitro diagnostic use) and to measure blood pressure non-invasively.

It shall not be used for the diagnosis of diabetes and hypertension, or for the testing of neonates.

Test Principle

This system measures the amount of sugar (glucose) in whole blood. The glucose testing is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the strip. The monitor measures the current, calculates the blood glucose level, and displays the result. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

The blood pressure is measured non-invasively at the upper arm based on the oscillometric and the Korotkoff method.

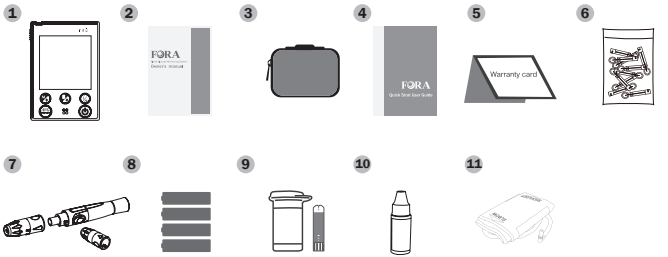
This device is NOT able to take measurements in the presence of common arrhythmia, such as arterial or ventricular premature beats or arterial fibrillation. It may produce reading error.

In auscultatory mode using the Korotkoff method you may take measurements in the presence of arrhythmia.

In single and average mode, this device inflates the cuff to the ideal level with each use. No adjustments are required by the operator to select an inflation level. In auscultatory mode you can any time adjust the inflation pressure, stop the inflation and start deflation if necessary.

Contents of System

The FORA D40 Pro system kit includes:

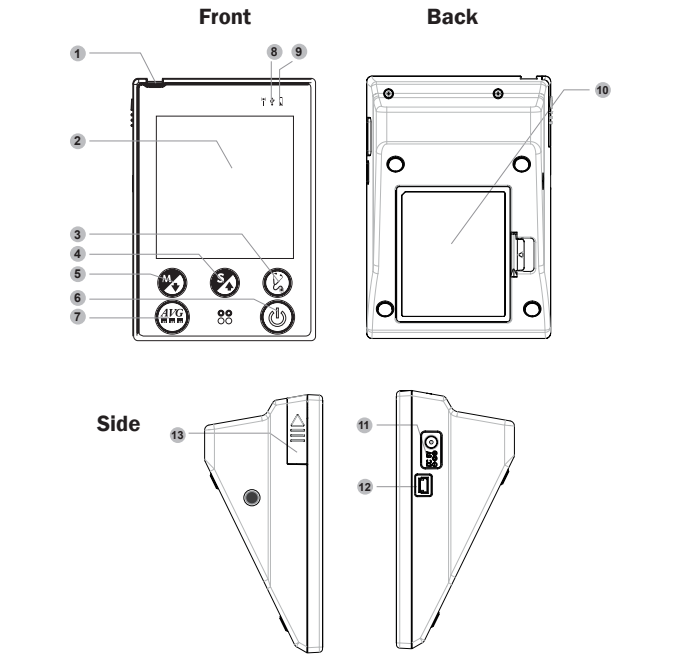


1. Monitor
2. Owner's Manual
3. Protective Wallet
4. Quick Start User Guide
5. Warranty Card
6. Sterile Lancets
7. Lancing Device with One Clear Cap
8. Batteries
9. Test Strips
10. Control Solution
11. Pressure Cuff (M and L size: upper arm type)

NOTE

All items can be purchased separately and some accessories may not be included in the kit. If you wish to purchase any accessories, please contact our local customer service.

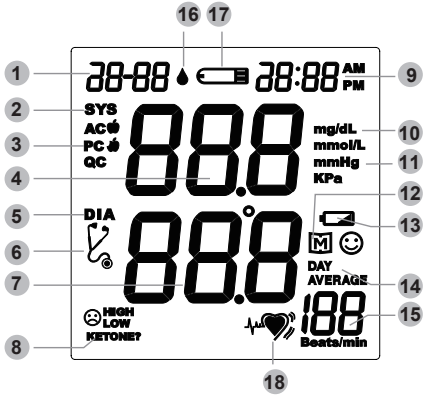
Monitor Overview



Pressure Cuff

1. **TEST SLOT**
   Insert test strip here to turn the monitor on for testing.
2. **DISPLAY SCREEN**
3. **AUSCULTATION BUTTON**
   Assist you with auscultatory mode.
4. **S BUTTON**
   Enter and confirm the monitor settings.
5. **M BUTTON**
   Enter the monitor memory.
6. **ON/OFF BUTTON**
   To start a single NIBP (non-invasively blood pressure) measurement
7. **AVERAGE BUTTON**
   Assist you with blood pressure average mode.
8. **USB INDICATOR**
   Indicate a data transmission via USB.
9. **POWER INDICATOR**
   Appear when battery is low.
10. **BATTERY COMPARTMENT**
11. **DC ADAPTER PORT**
    Connect to a power supply.
12. **USB LINK PORT**
    Download test results with a cable connection.
13. **STRIP EJECTOR**
    Eject the used strip by pushing up this button.
14. **AIR JACK**
15. **PRESSURE CUFF**
16. **AIR TUBE**
17. **AIR PLUG**
    Connect to air jack.

Screen Display



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

Test Strip

1 **Absorbent Hole**

Apply a drop of blood here.
The blood will be automatically absorbed.

2 **Confirmation Window**

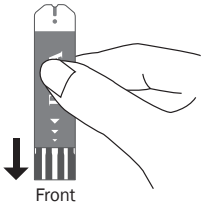
This is where you confirm if enough blood has been applied to the absorbent hole in the strip.

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:

The front side of test strip with FORA Logo should face up when inserting test strip.

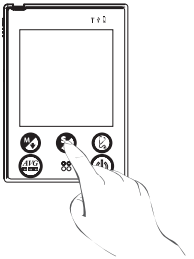
Test results might be wrong if the contact bar is not **fully** inserted into the test slot.

NOTE

The **FORA D40 Pro** monitor should only be used with **FORA D40 Pro** Test Strips. Using other test strips with this meter may produce inaccurate results.

SETTING THE MONITOR

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



► Entering the setting mode

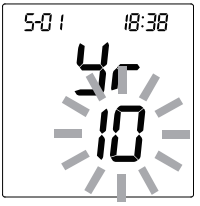
Start with the monitor off (no test strip inserted).

Press S for 3 seconds until the monitor turns on.

Step 1

Setting the date

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



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

With the month flashing, press M/+ until the correct day appears. Press S/- .

Step 2

Setting the time

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

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

Step 3

Setting the time format

Press M/+ to select the desired time format — 12h or 24h. Press S/- .

Step 4

Deleting the memory

While “dEL” and a blinking “ M ” symbol appear on the display, if you do not wish to delete the saved results, press ⏻ to skip this step.

If you wish to delete ALL the results, press ⏻ twice.

The device turns off automatically after the settings are completed.

NOTE

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

TESTING BLOOD PRESSURE

This monitor provides you three different ways to measure the blood pressure. Select from the options below:

- Single measurement
  Perform a single blood pressure measurement.

- Average measurement
  Automatically perform three (3) consecutive blood pressure measurements and display the final average result.

- Auscultatory measurement:
  Only trained health-care professionals may use this mode to measure blood pressure manually with a stethoscope by listening to the Korotkoff sound.

WARNING

- Do NOT apply the cuff to areas other than the place directed.
- If cuff inflation does not stop, remove the cuff or pull out the air tube from the device.
- Do not wrap the cuff over an arm to which intravenous injection or transfusion is being conducted, or when otherwise contraindicated.
- Do not connect the air tube or the cuff to other equipment which is connected to an intracorporeal organ. Air embolisms may result.
- Confirm readings with a stethoscope when an irregular pulse wave is displayed or when the measured value is questionable.
- When using the device:
  - Do not inflate the cuff without being wrapped over the arm.
  - Do not use a damaged cuff.

Before Measurement

- Make sure that your patient avoids caffeine, tea, alcohol, tobacco, exercising or bathing at least 30 minutes before measurement.
- Ask your patient to relax (sit or lie down) for at least 10 minutes before measurement.
- Do not measure when your patient feeling anxious or tense.
- Take a 5-10 minute break between measurements. This break can be longer if necessary, depending on the patient physical condition.
- Blood pressure may vary between each arm. Always measure blood pressure on the same patient's arm.
- To take a blood pressure measurement after performing a blood glucose test, make sure that the test strip has been removed from the monitor.

Selecting the Correct Cuff

Two different cuff sizes are provided with this blood pressure monitoring system: Medium and Large. Select the cuff size that best matches the circumference of the patient's upper arm.

Arm circumference:

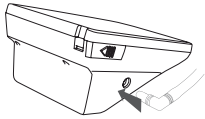
M (Medium size)
25-35 cm (9.8"-13.8")

L (Large size)
32-44 cm (12.7"-17.3")

► Fitting the Cuff Correctly

Step 1

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

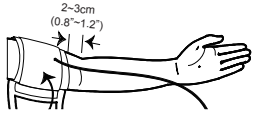


Step 2

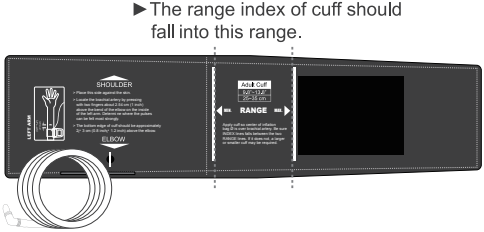
ake out the cuff as shown on the right. The smooth surface should be inside the cuff.

Step 3

Stretch patient's left (or right) arm in front of you with the palm facing up. Align the artery mark over the brachial artery.



Wrap and fasten the cuff securely. The red margin on the lower edge of the cuff should be approximately **2 to 3 cm (0.8" to 1.2")** above the elbow.



Step 4

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

Step 5

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

► Proper Measurement Position

Step 1

Patient's elbow should be placed on a flat surface; hand should be relaxed with the palm facing up.

Step 2

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

Step 3

Measurement is in progress.

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

► Taking Measurements

To take a single measurement	Single Mode	Press ⏻ to start.
To measure 3 times automatically and consecutively	AVG Mode	Press AVG to start.
To measure with a stethoscope	Auscultatory Mode	Press to start.

Taking a Single Measurement

Always apply the pressure cuff before turning on the monitor.

Step 1

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

Step 2

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

Step 3

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

Step 4

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

NOTE

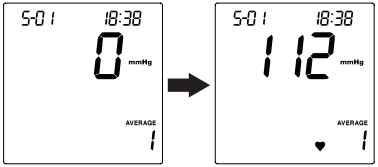
- If you press ⏻ during measurement, the monitor will be turned off.
- If the pulse rate symbol is shown as " ♥ " instead of " ♥ ", this indicates that the monitor has detected an irregular heart beat.

Measurement Average Mode

Always apply the pressure cuff before turning on the monitor.

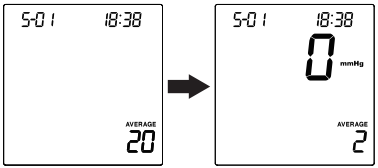
Step 1

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

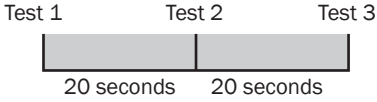


Step 2

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



The testing order would be:



Step 3

After taken three measurements, the results are averaged to produce the blood pressure measurement. Press ⏻ to turn off the monitor.

Auscultatory Mode

Only trained health care professionals are able to operate manually.

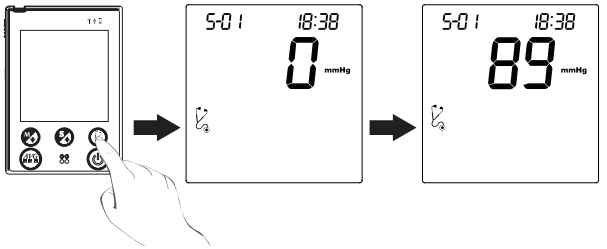
The manual operation method involves applying a stethoscope and listening to the pulse during deflation while the air is slowly let out.

Step 1

Place a stethoscope on the patient's arm where there is a pulse. Wrap the cuff around the patient's upper arm and hold in place with Velcro.

Step 2

Press . A stethoscope symbol will appear on the display with a beep. Then cuff begins to inflate automatically.



Step 3

The operator can adjust the inflation pressure if necessary. During the measurement, press at any time to stop the inflation and start deflation, or press to inflate again. After reaching the cuff pressure, the deflation begins.

Step 4

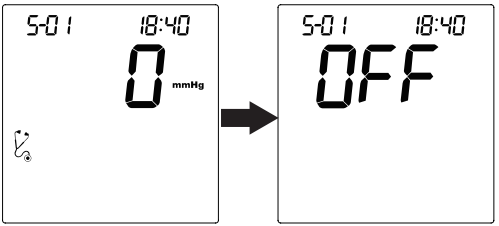
The systolic pressure is the maximum pressure in an artery at the moment when the heart is beating and pumping blood through the body. The systolic pressure is measured when the operator first hears the pulse. Take the reading according to the value on the display. This reading indicates the patient's systolic pressure. You have to mark the reading due to the result will not be stored in the memory.

Step 5

The diastolic pressure is the lowest pressure in an artery in the moments between beats when the heart is resting. The diastolic pressure is measured from the moment the operator is unable to hear the sound of the pulse. Take the reading according to the value on the display. This reading indicates the patient's diastolic pressure. You have to mark the reading due to the result will not be stored in the memory.

Step 6

The monitor will return to the screen of 0 mmHg after the measurement is completed. To start the next measurement, press  again. To turn off the monitor, press  .



TESTING BLOOD GLUCOSE

► **Important Information**

- Severe dehydration and excessive water loss may cause readings which are lower than actual values.

- If the patient's blood glucose results are lower or higher than usual, and he/she does not have symptoms of illness, first repeat the test. If he/she has symptoms or continue to get results higher or lower than usual, please check the patient's state carefully and act accordingly.

- Use only fresh capillary whole blood sample to test the blood glucose.

- We do not recommend using this product on severely hypotensive individuals or patients in shock. Readings which are lower than actual values may occur for individuals experiencing a hyperglycaemic-hyperosmolar state, with or without ketosis.

The Four Measuring Modes

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

Modes	Use when
Gen (not displayed)	any time of day without regard to time since last meal
AC	no food intake for at least 8 hours
PC	2 hours after a meal
QC	testing with the control solution

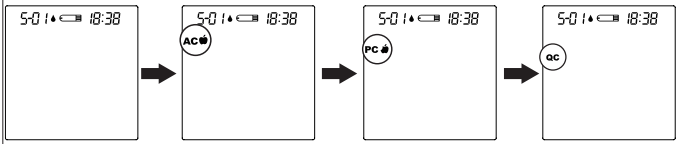
You can switch between each mode by:

Step 1

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

Step 2

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



CONTROL SOLUTION TESTING

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

- Control solution tests are performed regularly, or in specific time intervals, or with the number of patient test results.
- Only use the control solutions for FORA D40 Pro Test Strips.
- Use control solutions by the expiry date printed on the bottle and the box.
- When using a new bottle of control solution, write the opening date on the bottle label. Each bottle of control solution bottle is stable for use within 3 months after first opening (replace cap tightly after use each time). Discard all remaining solutions after opened more than 3 months.
- Shake the control solution bottle up side down for several times before use.

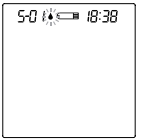
Performing a Control Solution Test

Always wear gloves and follow your facility's biohazard control policy and procedures.

Step 1

Insert the test strip to turn on the monitor

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



Step 2

Press M to mark this test as a control solution test

With “QC” displays, the monitor will not store the test result in memory. If press M again, the “QC” will disappear and this test is no longer a control solution test.

WARNING:

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

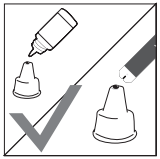
Step 3

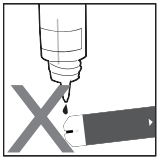
Apply Control Solution

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

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

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

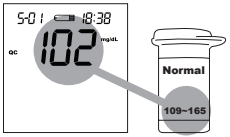




Step 4

Read and Compare the Result

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



Out-of-range results

If you continue to have test results fall outside the range printed on the test strip vial, the monitor and strips may not be working properly. Do NOT test any blood. Contact the local customer service or place of purchase for help.

NOTE:

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

TESTING WITH BLOOD SAMPLE

NOTE

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.

Preparing the Lancing Device for Blood Testing

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

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.

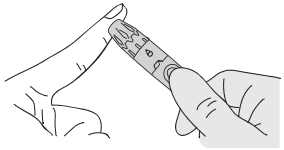
Blood from a site that has not been rubbed exhibits a measurably different glucose concentration than blood from the finger. When the puncture site is rubbed before blood extraction, the difference is significantly reduced.

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

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

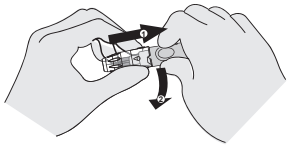
► Fingertip testing

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



► Blood from sites other than the fingertip

Replace the lancing device cap with the clear cap for AST. Pull the cocking control back until it clicks. When lancing the forearm, upper arm, hand, thigh, or calf, avoid lancing the areas with obvious veins to avoid excessive bleeding.

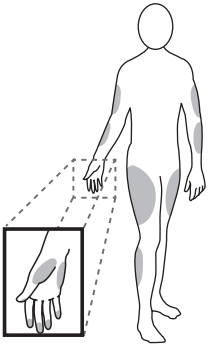


NOTE

- Repeated punctures at 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.

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

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



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

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

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

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

Do **NOT** use AST if:

- You think the patient's blood glucose is low.
- The patient is unaware of hypoglycaemia
- The patient is testing for hyperglycaemia
- The AST results do not match the way the patient feel.
- The patient's routine glucose results are often fluctuating.

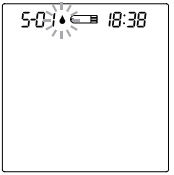
Performing a Blood Glucose Test

- **Always wear gloves and follow your facility's biohazard control policy and procedures when performing tests involving patient blood samples.**
- Test strips should be used before their expiry date.
- Do not use wet, bent, scratched or damaged test strips.
- After the blood is applied to the test strip and the count down begins, do not remove the test strip.
- Use a new test strip for a new test.
- Read instructions before using test strips. Please refer to the strip manual included in the kit.

Step 1

Insert the test strip to turn on the monitor

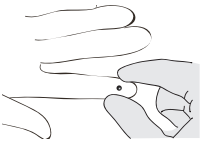
Wait for the monitor to display the test strip and blood drop symbol.



Step 2

Obtaining a blood sample

Use the pre-set lancing device to puncture desired site. After penetration, discard the first drop of blood with a clean tissue or cotton. Gently squeeze the punctured area to obtain another drop of blood.

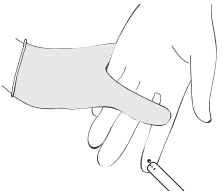


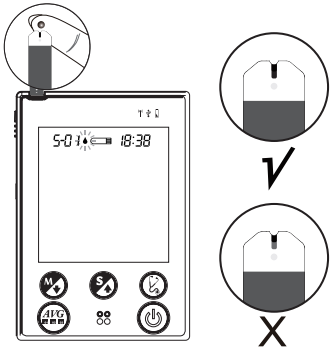
The volume of blood sample must be at least 0.5 microlitre of volume.
(∘ actual size).

Step 3

Apply the Sample

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





NOTE

- Do not press the puncture site against the test strip or try to smear the blood.
- If no blood sample is applied to the test strip within 3 minutes, the monitor will automatically turn off. You must remove and reinsert the test strip to start a new test.
- The confirmation window should be filled with blood before the monitor begins to count down. NEVER try to add more blood to the test strip after the drop of blood has moved away. Discard the used test strip and retest with a new one.

Step 4

Read the Result

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

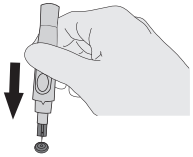
Step 5

Eject the used test strip and remove the lancet

To eject the test strip, point the strip at a disposal container for sharp objects. The monitor will switch itself off automatically after the test strip is ejected.

Always use caution when removing the lancet.

Remove the lancet by pulling the cap off first. Safely dispose of the used lancet by placing the protective disk on a hard surface, and push the exposed tip into the disk.



Slide the ejector forward to remove the used lancet.

WARNING

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

MONITOR MEMORY

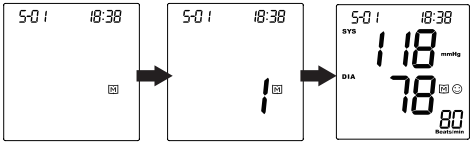
This monitor stores the 864 most recent results along with respective dates and times in the monitor memory. To recall the memory, **start with the monitor off.**

Reviewing Test Results

Step 1

Press and release .

" M "will appear on the display.



Step 2

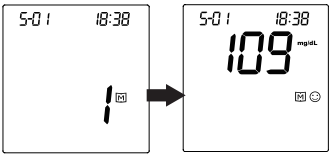
Press .

Review all test results stored in the monitor.

Step 3

Press .

Switch to review your blood pressure test results.



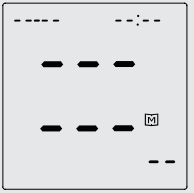
Step 4

Exit the memory.

Press and the monitor will turn off.

NOTE

- Any time you wish to exit the memory, press ⏻ or leave it without any action for 3 minutes. The monitor will turn off automatically.
- If using the monitor for the first time, "---" displays when you recall the test results or review the average result. It indicates that there is no test result in memory.



DOWNLOADING RESULTS ONTO A COMPUTER

► Data transmission via cable

Results in memory may be transmitted to a personal computer. Health Care Software System and a USB cable are required before installation. To learn more about Health Care Software System or to obtain a USB cable separately, please contact the place of purchase.

Step 1

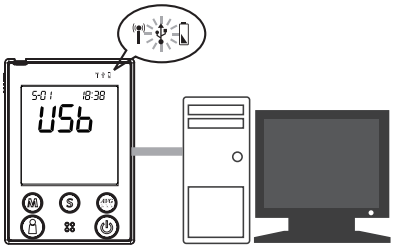
Install Software

Download Health Care System Software and instruction manual provided on Fora Care Suisse AG website: www.foracare.ch to a computer. Follow the instructions to install the software on the computer.

Step 2

Connect the USB cable to a data port on PC

With the monitor turned off, connect the 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 3

Transmit Data

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

MAINTENANCE

Battery

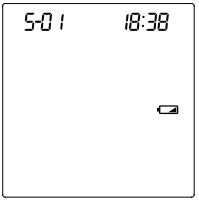
The monitor comes with four 1.5V AA size alkaline batteries.

► Low Battery Signal

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

Step 1

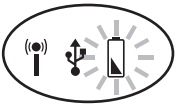
The " ▭ " symbol appears along with display messages:
The monitor is functional and the result remains accurate, but it is time to change the batteries.



If the power is not enough to do a test, the ▭ symbol starts blinking. You must change the batteries immediately.

Step 2

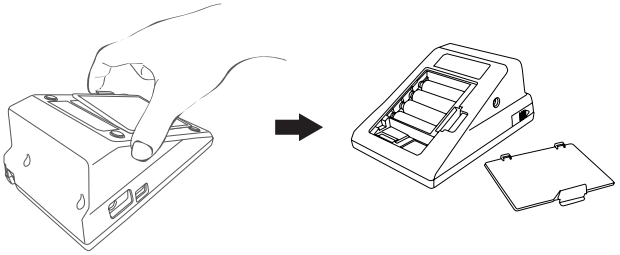
The power indicator lights up in red.



► **Replacing the Battery**

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

1. Press the edge of the battery cover and lift it up to remove.
2. Remove the old batteries and replace with four 1.5V AA size alkaline batteries.
3. Close the battery cover. If the batteries are inserted correctly, you will hear a "beep" afterwards.



NOTE

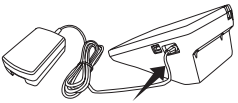
- Replacing the batteries does not affect the test results stored in memory.
- As with all small batteries, these batteries should be kept away from small children. If swallowed, promptly seek medical assistance.
- Batteries might leak chemicals if unused for a long time. Remove the batteries if you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

Using AC Adapter

► Connect AC adapter to the monitor.

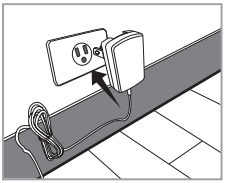
Step 1

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



Step 2

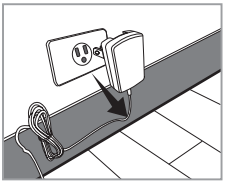
Plug AC adapter power plug into an electrical outlet. The monitor is ready for use.



► Remove AC adapter from the monitor.

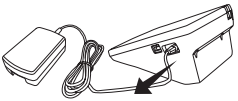
Step 1

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



Step 2

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



NOTE

- Do NOT use the AC adapter to recharge the batteries, or it may damage the monitor.

Caring for Your Monitor

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

► Cleaning

- To clean the monitor exterior, wipe it with a cloth moistened with tap water or a mild cleaning agent, then dry the device with a soft dry cloth. Do NOT flush with water.
- Do NOT use organic solvents to clean the monitor.
- Do NOT wash the pressure cuff.
- Do NOT iron the pressure cuff.

► Monitor 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 or heavy impact.
- Avoid direct sunlight and high humidity.

Caring for the Test Strips

- Storage condition: 10 °C to 40 °C (50 °F to 104 °F), below 85% relative humidity. Do not freeze.
- Store the test strips in their original vial only. Do not transfer to other container.
- Store test strip packages in a cool and dry place. Keep away from direct sunlight and heat.
- After removing a test strip from the vial, immediately close the vial cap tightly.
- Touch the test strip with clean and dry hands.
- Use each test strip immediately after removing it from the vial.
- Write the date on strip vial label when you first open it. Discard any test strips after 3 months.
- Do not use test strips beyond the expiry date. This may cause inaccurate results.
- Do not bend, cut, or alter a test strip in any way.
- Keep the strip vial away from children since the cap and the test strip may be a choking hazard. If swallowed, promptly see a doctor for help.

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

Important Control Solution Information

- Use only FORA control solutions with the monitor.
- Do not use the control solution beyond the expiry date or 3 months after first opening. Write the opening date on the control solution vial and discard the remaining solution after 3 months.
- It is recommended that the control solution test should be done at room temperature (20°C to 25°C / 68°F to 77°F). Make sure your control solution, monitor, and test strips are at this specified temperature range before testing.
- Shake the vial before use, discard the first drop of control solution, and wipe off the dispenser tip to ensure a pure sample and an accurate result.
- Store the control solution tightly closed at temperatures between 2°C and 30°C (36°F and 86°F). Do NOT freeze.

SYSTEM TROUBLESHOOTING

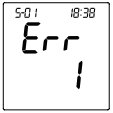
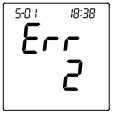
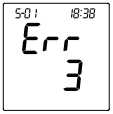
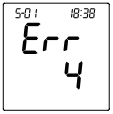
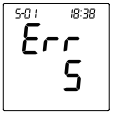
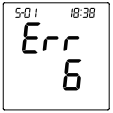
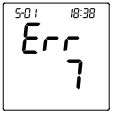
If you follow the recommended action but the problem persists, or error messages other than the ones below appear, please call your local customer service. Do not attempt to repair by yourself and never try to disassemble the monitor under any circumstances.

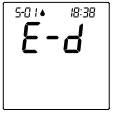
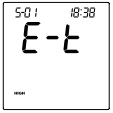
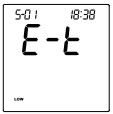
Result Readings

MESSAGE	WHAT IT MEANS
BLOOD PRESSURE	
	Appears when the systolic pressure is below 140mmHg and the diastolic pressure is below 90mmHg.
	Appears when the systolic pressure is equal to or higher than 140mmHg or the diastolic pressure is equal to or higher than 90mmHg.
BLOOD GLUCOSE	
	Appears when the result is below measurement limit, which is less than 20 mg/dL (1.1 mmol/L).
	Appears when the result is between 20 to 69 mg/dL (1.1 to 3.8 mmol/L). It indicates the result is below reference range.
These symbols indicate hypoglycaemia (low blood glucose). Please check the patient's state carefully and act accordingly.	

MESSAGE	WHAT IT MEANS
	Appears when the result is in the reference range from 70 to 119 mg/dL (3.9 to 6.6 mmol/L).
	Appears when the result is equal to or greater than 120 mg/dL (6.6 mmol/L). It indicates the result is higher than reference range.
	Appears when the result is equal to or higher than 240 mg/dL (13.3 mmol/L). This indicates the possibility of ketone accumulation. Please check the patient's state carefully and act accordingly.
	Appears when your systolic pressure is below 140mmHg and your diastolic pressure is below 90mmHg.

Error Messages

MESSAGE	CAUSE	WHAT TO DO
	Inflation or pressure error.	Please contact local customer service for help.
	Pressure error.	Refit cuff tightly and correctly. Repeat the measurement. If error still remains, please contact local customer service for help.
	Cuff pressure is too high.	
	No pulse rate detected or the pulse rate is too low.	
		
	Systolic pressure is outside the system measurement range.	System measurement range is 55 mmHg – 255 mmHg. Review the instructions and repeat the test. If error still remains, please contact a healthcare professional for help.
		

MESSAGE	CAUSE	WHAT TO DO
	Strip has been used.	Repeat the test with a new strip.
	Problem in operation.	Review the instructions and repeat the test with a new strip.
	Environmental temperature is outside the system operational range.	System operational range is 10°C to 40°C (50°F to 104°F). Repeat the test after the monitor and test strip have reached the above temperature.
		

Troubleshooting

1. Blood Pressure Measurement

► If no display after pressing ⏻:

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

► If the heart rate is higher/lower than user's average:

POSSIBLE CAUSE	WHAT TO DO
Movement during measurement.	Repeat measurement.
Measurement taken just after exercise.	Repeat measurement in 30 minutes.

► If the result is higher/lower than user's average measurement:

POSSIBLE CAUSE	WHAT TO DO
Incorrect patient's position while measuring.	Adjust to the correct position and repeat measurement.
Blood pressure naturally varies from time to time.	Keep in mind for the next measurement.

2. Blood Glucose Measurement

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

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

► If the test does not start after applying the sample:

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

► If the control solution testing result is out of range:

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

DETAILED INFORMATION

Reference Values

Blood Pressure

Human blood pressure naturally increases after reaching middle age. This symptom is a result of continuous ageing of the blood vessels. Further causes include diabetes, obesity, lack of exercise and cholesterol (LDL) adhering to the blood vessels. Rising blood pressure accelerates hardening of the arteries, and the body becomes more susceptible to apoplexy and coronary infarction.

Definitions and Classification of blood pressure levels according to 2007 ESH-ESC Practice Guidelines for the Management of Arterial Hypertension:

Category	Systolic (mmHg)		Diastolic (mmHg)
Optimal	< 120	and	< 80
Normal	120–129	and/or	80–84
High normal	130–139	and/or	85–89
Grade 1 hypertension	140–159	and/or	90– 99
Grade 2 hypertension	160–179	and/or	100–109
Grade 3 hypertension	≥ 180	and/or	≥ 110
Isolated systolic hypertension	≥ 140	and	< 90

Isolated systolic hypertension should be graded (1, 2, 3) according to systolic blood pressure values in the ranges indicated, provided that diastolic values are < 90mmHg.

Source: The European Society of Hypertension and European Society of Cardiology Task Force Members. 2007 ESH-ESC Practice Guidelines for the Management of Arterial Hypertension. *J Hypertens* 2007; 25: 1751-1762.

Blood Glucose

Blood glucose monitoring plays an important role in diabetes control. A long-term study showed that maintaining blood glucose levels close to normal can reduce the risk of diabetes complications by up to 60%*[1]. The results provided by this system can help healthcare professionals monitor and adjust the treatment plan to gain better control of patient's 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 (2008). Clinical Practice Recommendations. Diabetes Care, 31 (Supplement 1): S1-108.

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

Comparing Monitor and Laboratory Results

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

Before going to the lab:

Perform a control solution test to make sure that the monitor is working properly.

- Fast for at least eight hours before doing comparison tests, if possible.
- Take the monitor with you to the lab.

While staying at the lab:

Make sure that the samples for both tests 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 have a variation from the monitor and laboratory results because of your patient blood glucose levels can change significantly over short periods of time, especially if they have recently eaten , exercised, taken medication, or experienced stress*[2]. In addition, if the patient has eaten recently, the blood glucose level from a finger prick can be up to 70 mg/dL (3.9 mmol/L) higher than blood drawn from a vein (venous sample) used for a lab test*[3]. Therefore, it is best to fast for eight hours before doing comparison tests. Factors such as the amount of red blood cells in the blood (a high or low hematocrit) or the loss of body fluid (dehydration) may also cause a monitor result to be different from a laboratory result.

References:

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

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

SYMBOL INFORMATION

Symbol	Referent
	For in vitro diagnostic use
	Do not reuse
	Read instructions before use
	Keep away from sunlight
	Keep dry
	Temperature limitation
	Use by/ Expiry date
	Use within three months after first opening
	Batch code
	Manufacturer
	Serial number
	Caution, consult accompanying documents
	Sterilized using irradiation
	Do not use if package is damaged
	CE Mark

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:	Maximum 864 memory records
Power saving:	Automatic power off if system idle for 3 minutes
System operating condition:	10°C to 40°C (50°F to 104°F), below 85% RH
Monitor storage condition:	-20°C to 60°C (-4°F to 140°F), 5 - 95% RH
Power Supply Input:	DC +6V / 1A (max) via Power Plug

Blood glucose measurement performance	
Measurement unit:	mg/dL
Linear range:	20 to 600mg/dL (1.1 to 33.3mmol/L)
Precision:	±5 % (CV)
Accuracy:	±15 mg/dL (0.83 mmol/L) when glucose < 75mg/dL (4.2 mmol/L)
	±20% when glucose ≥ 75mg/dL (4.2 mmol/L)
Ketone warning:	glucose value is over 240 mg/dL (13.3 mmol/L)

Blood pressure measurement performance	
Pressure range:	0 - 300 mmHg
Heart rate range:	40 -199 beat per minute
Measurement unit:	mmHg
Systolic Measurement Range:	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

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

Reference to Standards:

- EN 1060-1 / EN 1060-3, NIBP-requirements
- IEC 60601-1 General requirement for safety
- IEC 60601-1-2 Requirements for EMC
- EN 1060-4, NIBP clinical investigation
- ANSI/AAMI SP10, NIBP requirements

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