Fora Comfort 2 in 1 Blood Glucose plus Blood Pressure Monitoring System

Version 1.0
2007/09/03
01

IMPORTANT SAFETY INSTRUCTIONS

READ THIS BEFORE USING

The following basic safety precautions should always be taken.

1. Close supervision is necessary when the device is used by, on, or near children, handicapped persons or invalids.

2. Use the device only for the intended use described in this manual.

3. Do not use strips and control solutions which are not supplied by the manufacturer.

4. Do not use the device if it is not working properly, or if it has suffered any damage.

5. Before using any 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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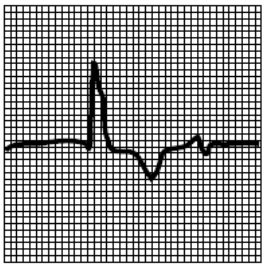
BEFORE YOU START

◉ Warnings and Precautions

■ The Fora comfort 2 in 1 blood glucose plus blood pressure monitoring system is designed for use on individuals **age 16 and above**. It shall NOT be used:
1. To diagnose newborns with diabetes.
2. On infants or persons who cannot communicate.

■ This device does NOT serve as a cure of any symptoms or disease. The data measured are only for reference. Always consult your physician to have the results interpreted.



■ This device is **NOT** able to measure 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** wrap the pressure cuff on anything besides 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 get with the Fora comfort 2 in 1 blood glucose plus blood pressure monitoring system can help you and your healthcare professional monitor and adjust your treatment plan to gain better control of your diabetes.

Time of day	Plasma glucose range (mg/dL) for people without diabetes	Your target range (mg/dL)
Fasting and before meal[*1a]	70-110 mg/dL (3.9 – 6.1 mmol/L)	
2 hours after meals[*1b]	Less than 140 mg/dL (7.8 mmol/L)	

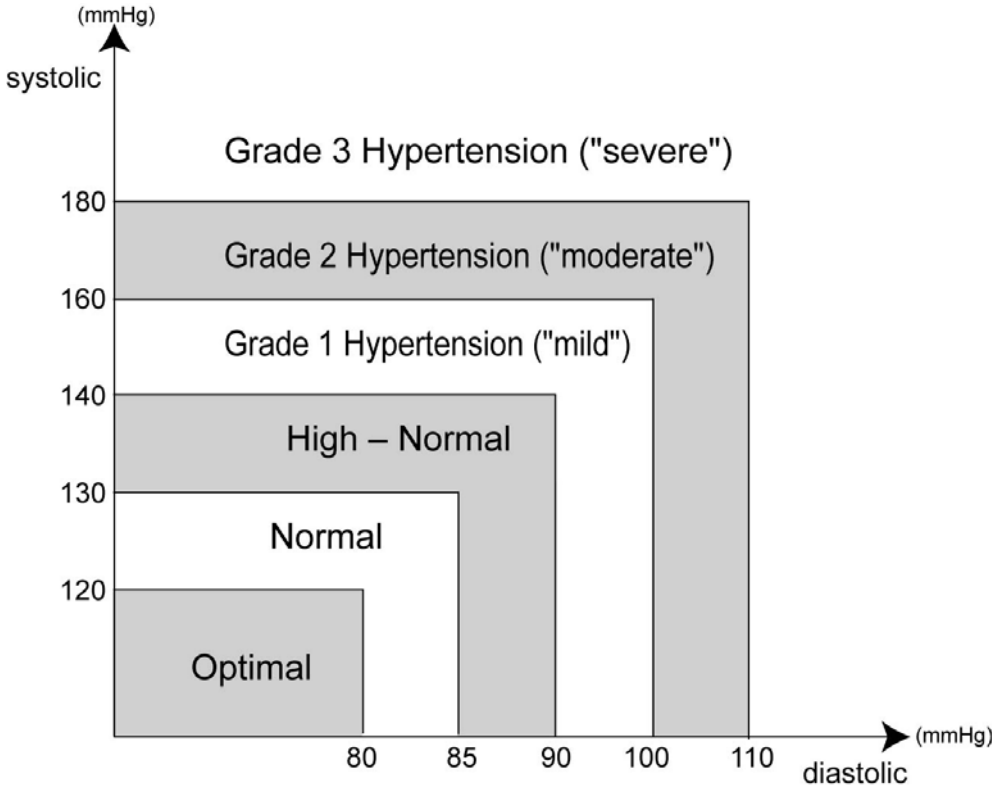
*1a: Sacks, DB in “Carbohydrates”, Burtis, CA, Ashwood, ER (ed), Tietz Textbook of Clinical Chemistry, Philadelphia, WB Saunders Company, 1999.

*1b: ADA Clinical Practice Recommendations 2003

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

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*[2]. Knowing your routine blood pressure trend tells whether your body is in good condition or not.
Human blood pressure naturally increases after reaching middle age.
This symptom is a result of continuous 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 WHO (world health organization) published the guideline of blood pressure range:



Source: 1999 WHO/ISH guidelines for the management of hypertension
*2: American Diabetes Association: The Diabetes-Heart Disease Link Surveying Attitudes, Knowledge and Risk (2002)

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ABOUT THIS SYSTEM

⦿ Intended Use

The Fora Comfort TD-3260 2 in 1 Blood Glucose plus Blood Pressure Monitoring System is indicated for the quantitative measurement of glucose in fresh whole blood (capillary blood from the finger, the palm, the forearm, the upper-arm, the calf and the thigh) for self testing by persons with diabetes in the home or by healthcare professionals in healthcare facilities. The system is also intended to be used to measure non-invasively the systolic and diastolic blood pressure and pulse rate of an adult individual, over age 16, at home.

⦿ Principle of Measurement

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

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

Both functions work separately (one measurement either blood glucose or blood pressure at a time) to avoid any interference problems.

⦿ Major Features

The greatest feature of this system is that you can view results on the PC through wireless connection using Zigbee Gateway technology. It provides a simply way to transmit data into your PC.

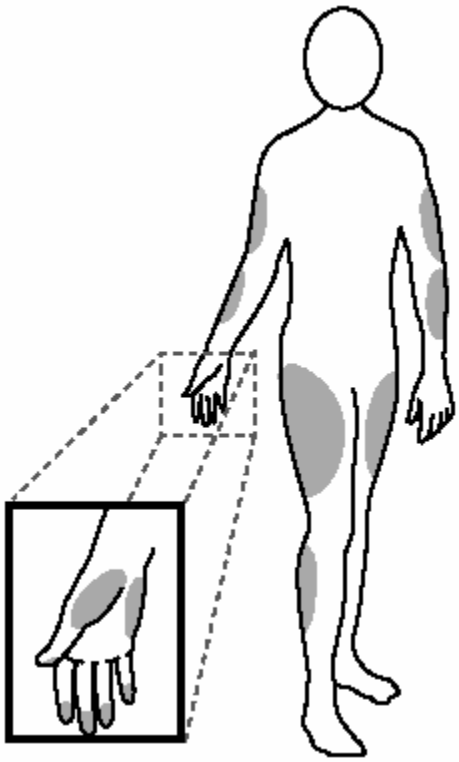
⊙ Alternative Site Testing (AST)

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 the 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 were not so condensed, you will not 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 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.

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Do **NOT** use AST if:

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

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.

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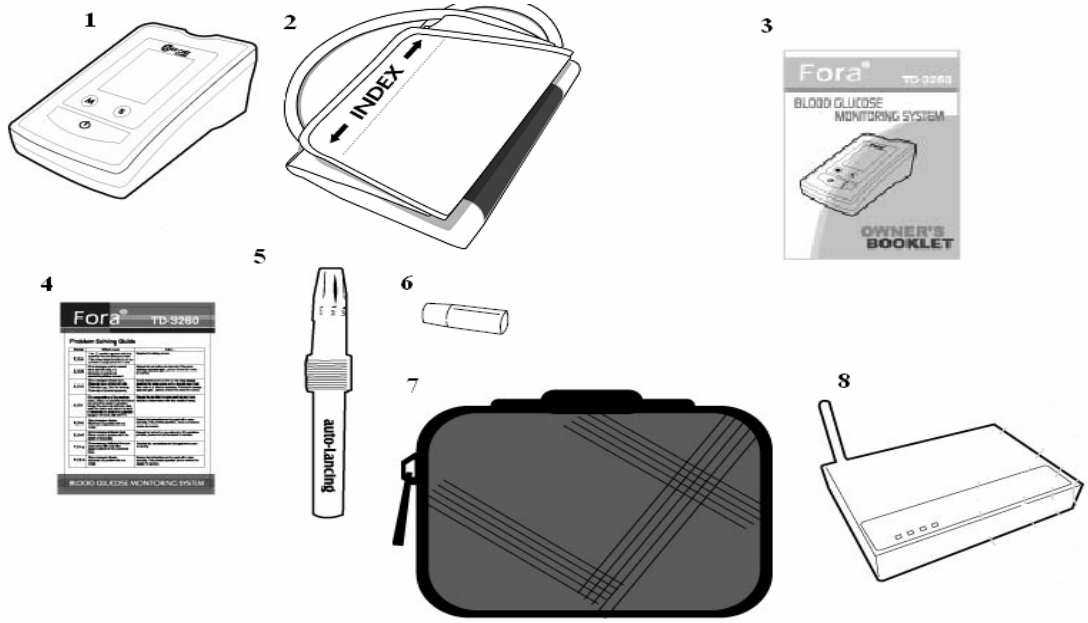
◉ Content of the System

These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. Use only the same brand-name test strips and a control solution with the blood glucose and blood pressure monitor.

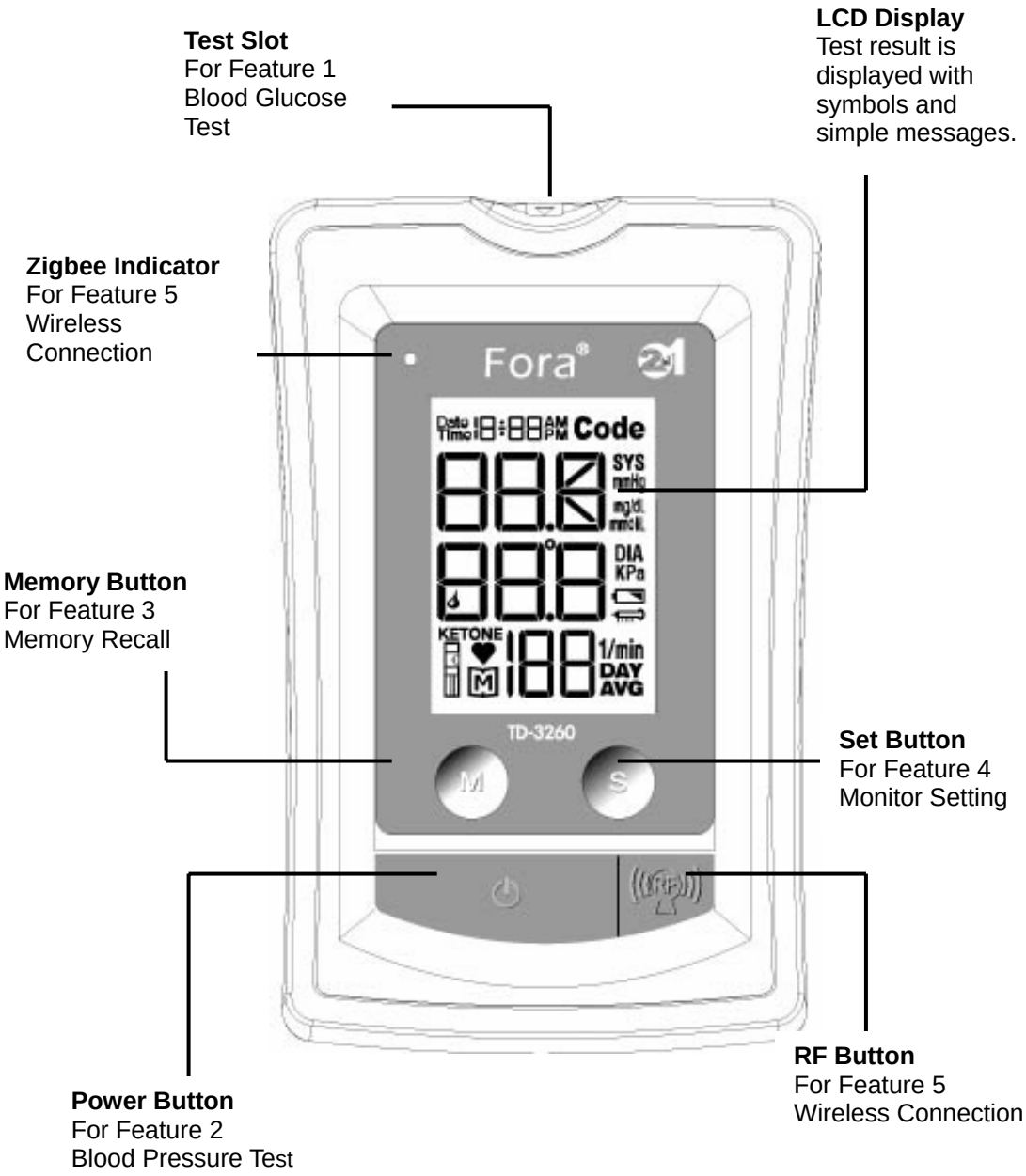
1. Blood glucose and blood pressure monitor	x1	6. A clear cap	X1
2. Pressure cuff	x1	7. Carry bag	X1
3. Owner's manual	X1	8. Zigbee gateway adaptor	X1
4.Quick using card	X1		
5. Lancing device	x1		



CAUTION

- Check your system to be sure that it is unopened prior to use and that it contains all parts listed above. If either of these conditions occurred, please return your system to the place of purchase.
- Please note that Fora comfort test strips, lancets, TaiDoc control solution are optional and are not included in the standard kit. Please ask your local agent for help.

◉ Appearance and Key Function of the Monitor



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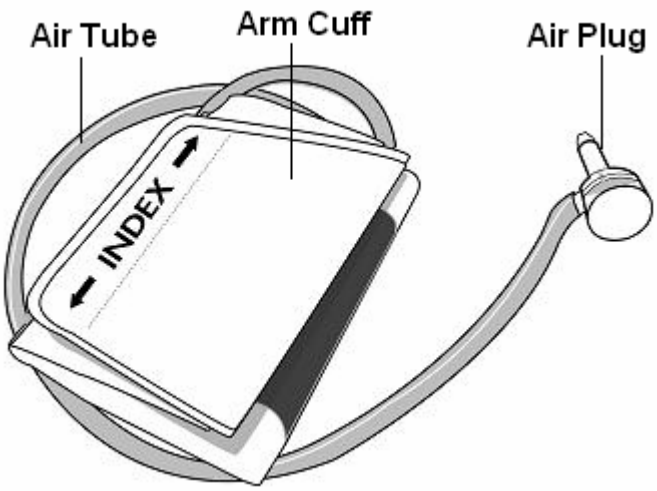
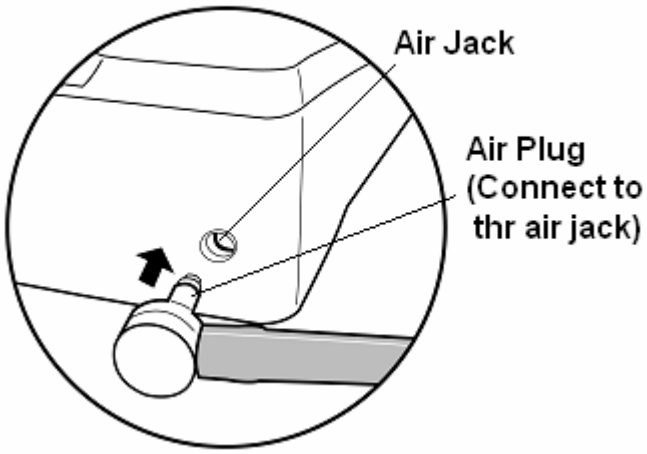

Air Tube
Arm Cuff
Air Plug
INDEX


Air Jack
Air Plug
(Connect to
thr air jack)

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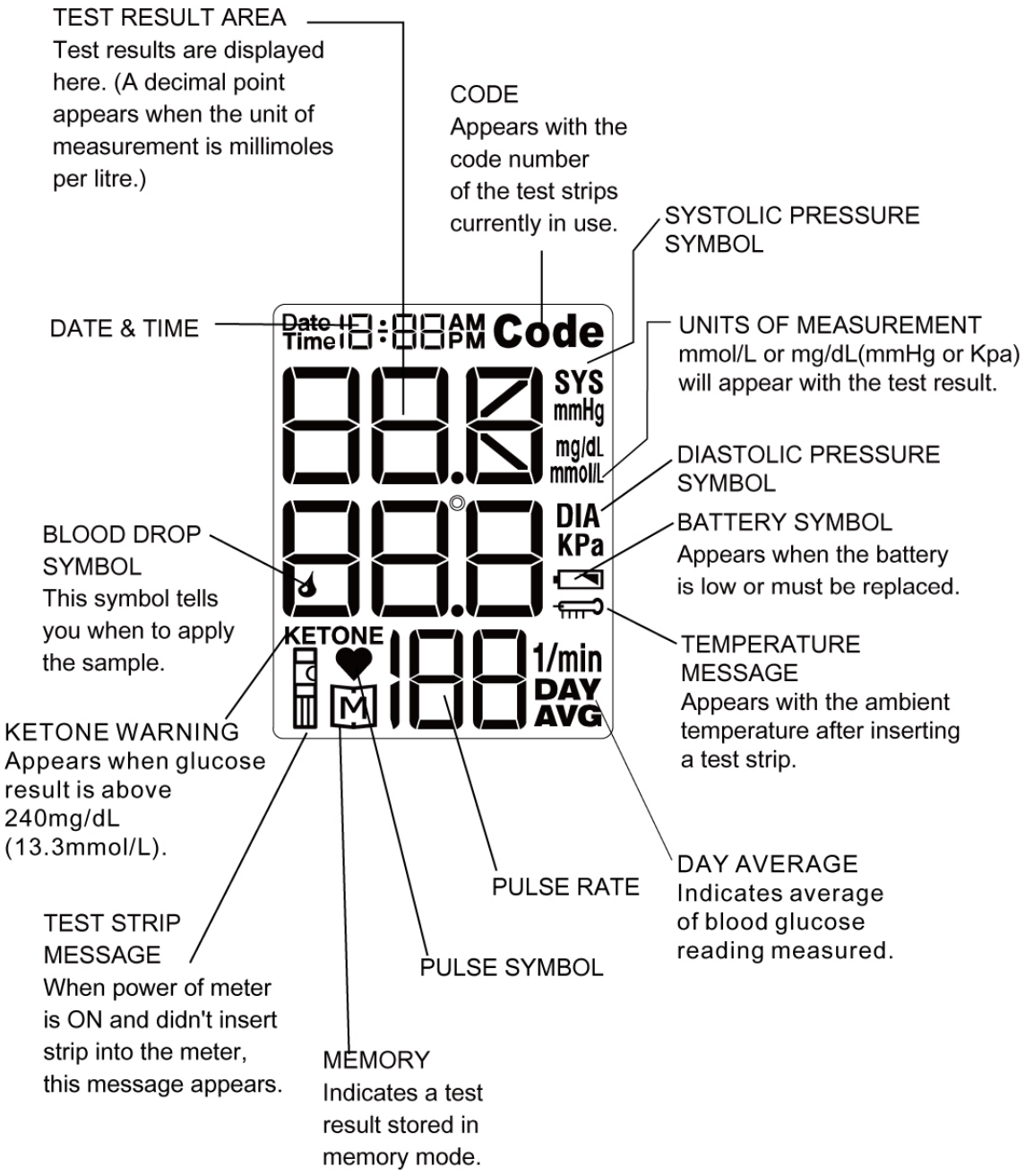
◉ LCD Display



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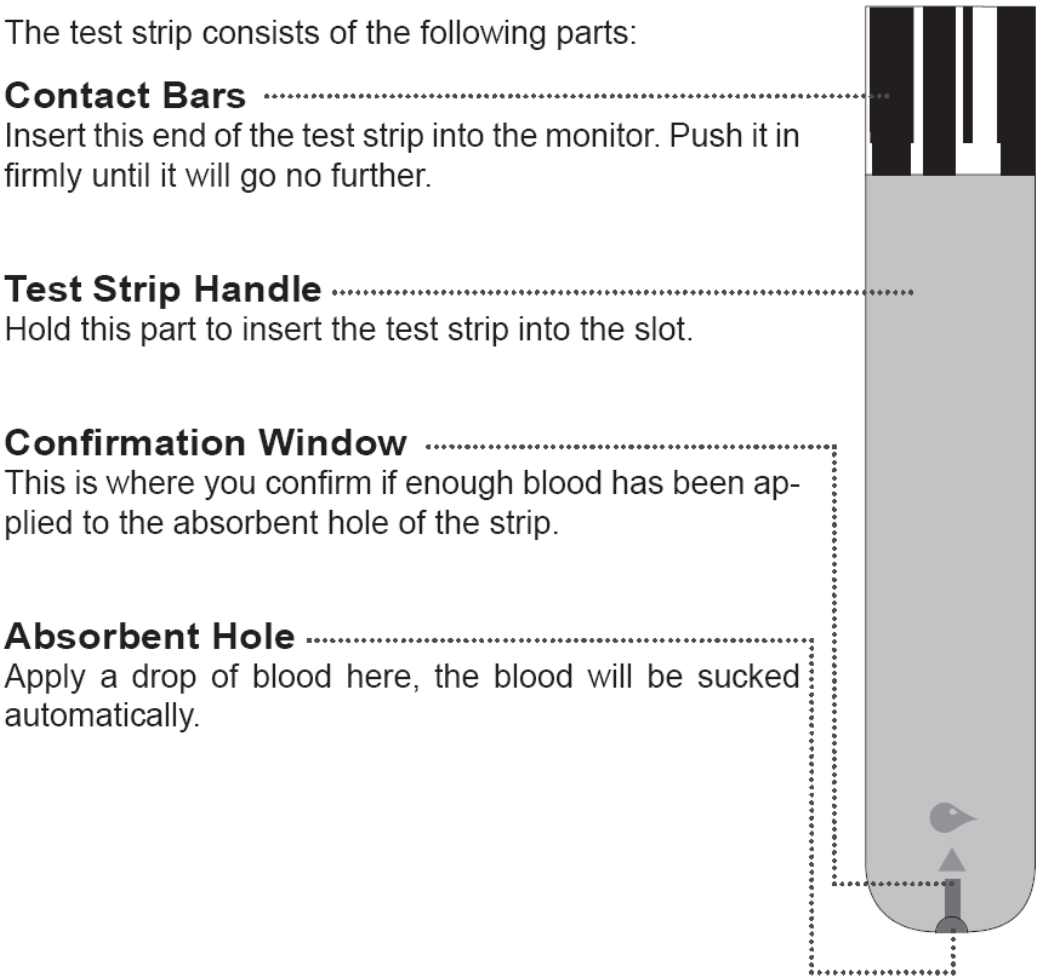
◉ Appearance of the Test Strip

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 chamber where the reaction takes place.



See pages 21-36, How to measure blood glucose, for complete instructions.

NOTE

We recommend that you should hold the test strip by the Test Strip Handle only when you perform blood glucose test. Do not hold the Absorbent Hole in order to avoid contamination.

PREPARATIONS BEFORE USE

◉ Battery Installation and Replacement

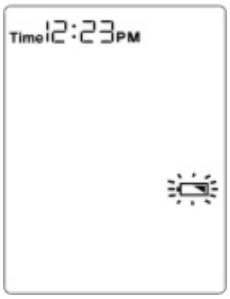
Your monitor comes with batteries already installed. When replacing, use ONLY 1.5V AA size alkaline batteries for best performance and longest life.

Low Power Signal

The monitor will remind you when the power is getting low by displaying two different messages:

(Fig. 1)

1. Battery Symbol appears while you perform tests (Fig. 1).This means it is about time to change the batteries although still 30 more measurements can be made.



(Fig. 2)

2. Battery Symbol flashes by itself and the monitor cannot perform any measurement (Fig. 2). This means you must change the batteries immediately.

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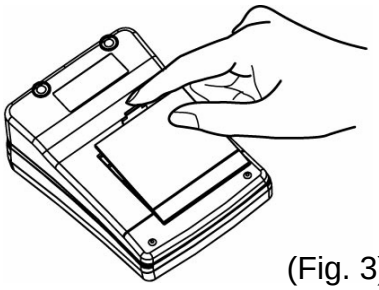
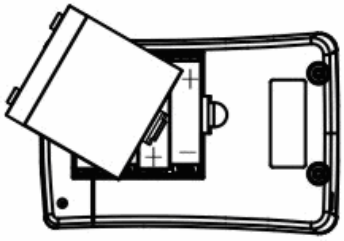
Make sure the monitor is off before replacing the batteries.



(Fig. 3)

STEP 1- Press the edge of the battery cover and pull up (Fig. 3). Lift the battery cover and remove the batteries inside.



(Fig. 4)

STEP 2- Insert four 1.5V AA size alkaline batteries. Make sure the + (positive) and–(negative) marks match as indicated in the battery compartment (Fig. 4). If inserted correctly, you will hear a "beep".

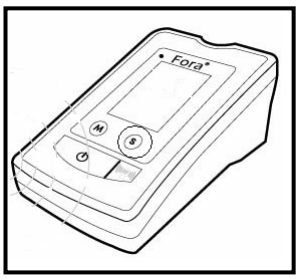
CAUTION

1. Do not use different type, date or brand name batteries together. Use only new batteries of the required size and type.
2. Replacing the batteries does not affect previous test results stored in the monitor. But you may need to update the settings.
3. 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).
4. 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.
5. Discard batteries according to your local regulations.

⊙ Setting the Monitor

Your monitor comes with the time, date, units and ambient temperature preset. These options may be changed any time to fit your needs. They also need to be set again when you change the batteries.

How to set the monitor?

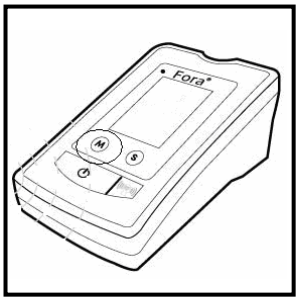


(Fig. 5)

STEP 1- Start with the Monitor Turned Off. Press the S button to enter the Setting Mode. (Fig. 5)

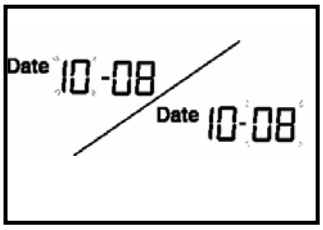
(Fig. 6)

STEP 2- The **year** will appear first.(Fig. 6)



(Fig. 7)

STEP3 - Press the S button to select what you would like to change. The selected one will be flashing. Press the M button to make the change.(Fig 7)



(Fig. 8)

STEP 4- The **date and day** will appear automatically**.** Press the M button to select the changes you made and press the S button move on to next step.(Fig 8)

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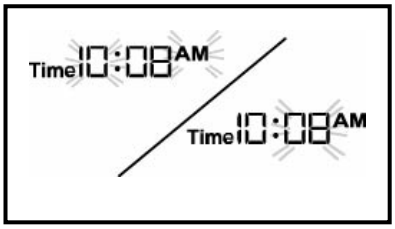
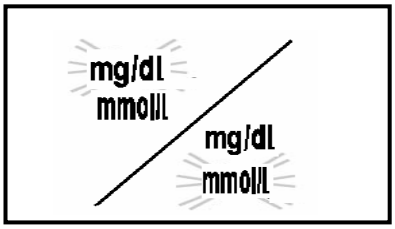


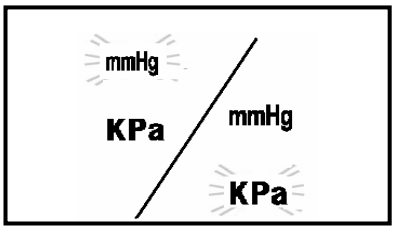
(Fig. 9)

STEP 5- The **hour and minute** will appear automatically**.** Press the M button to select the changes you made and press S button move on to next step.(Fig. 9)



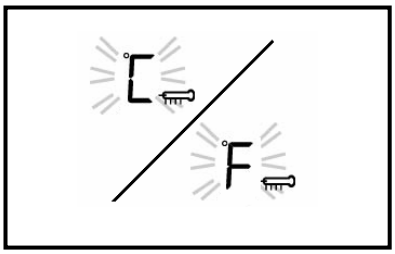
(Fig. 10)

STEP 6- The **blood glucose unit*[3]** will appear automatically**.** Press the M button to select the changes you made and press the S button move on to next step.(Fig. 10)



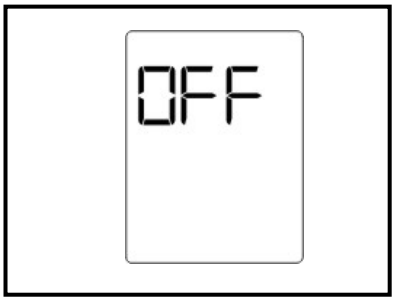
(Fig. 11)

STEP 6- The **blood pressure unit** will appear automatically**.** Press the M button to select the changes you made and press the S button move on to next step.(Fig.11)



(Fig. 12)

STEP 7- The **ambient temperature** will appear automatically**.** Press the M button to select the changes you made and press the S button move on to next step.(Fig 12)



(Fig. 13)

STEP 8- You may also press the ⏻ button any time to turn off the monitor and exit the Setting Mode.(Fig.13)

NOTE

- The time, date, unit of measurement and unit of temperature can **ONLY** be changed in the setting mode. Therefore, when you perform a glucose testing or blood pressure testing, those parameters are not possible to be changed.
- *3: The milligram per deciliter (mg/dL) is the standard unit in the United States. The millimole per liter (mmol/L) is the standard unit in Canada. Use of the wrong unit of measure may cause you to misinterpret your blood glucose level, and may lead to incorrect treatment.
- While the monitor is in the setting mode, if no button is pressed for 3 minutes, the monitor will turn off automatically.
- You may also press the ⏻ button any time to turn off the monitor and exit the Setting Mode.

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HOW TO MEASURE BLOOD GLUCOSE

◉ Important Information and Possible Interferences

- Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.

- Test results below 60 mg/dL[*4] (3.3 mmol/L) mean low blood glucose (hypoglycemia). Test results greater than 240 mg/dL[*5] (13.3 mmol/L) mean high blood glucose (hyperglycemia). If you get results below 60 mg/dL or above 240 mg/dL, and do not have symptoms, first repeat the test. If you have symptoms or continue to get results that fall below 60 mg/dL or above 240 mg/dL, follow the treatment advice of your healthcare professional.

- Apply only capillary whole blood sample to test your blood glucose. Applying other substances will cause wrong results.

- If you are experiencing symptoms that are not consistent with your blood glucose test results and you have followed all instructions described in this owner’s manual, call your healthcare professional.

- Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose plus blood pressure monitor.

- Please refer to your test strip package insert for additional important information.

*4: Kahn, R., and Weir, G.: Joslin’s Diabetes Mellitus, 13th ed. Philadelphia: Lea and Febiger (1994), 489.
*5: Krall, L.P., and Beaser, R.S.: Joslin Diabetes Manual. Philadelphia: Lea and Febiger (1989), 261-263.

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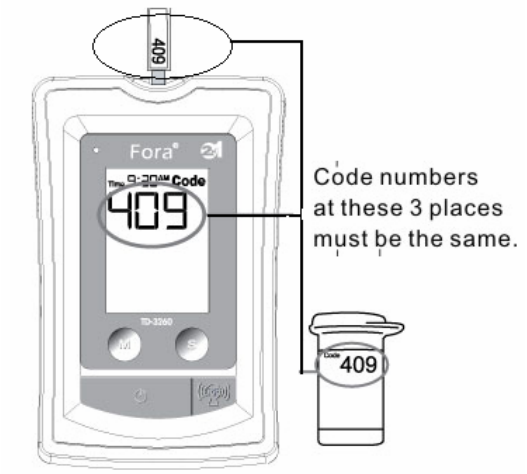
◉ Coding the Monitor

You must code the monitor every time you begin to use a new vial of test strips. Test results may be wrong if the code number displayed on the monitor does not match the number printed on the strip vial.



(Fig. 14)

Step 1- Insert the code strip when the monitor is off. Wait until the code number appears on the LCD display .(Fig.14)

Make sure the code number on LCD display, on the code strip, and on strip vial are identical.

(Fig. 15)

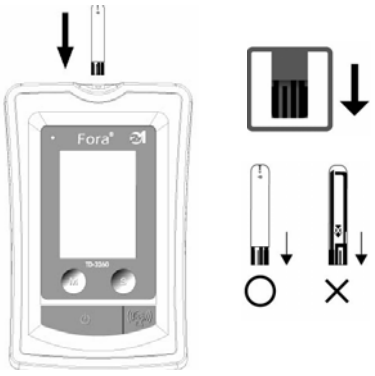
Step 2- Remove the code strip, the LCD display will show “OK”.
This tells you that the monitor has finished coding and is ready for blood glucose testing.(Fig.15)

WARNING

It is important to make sure that the LCD displayed code is the same as the code on the test strip vial before testing. Failure to do so will get wrong results.

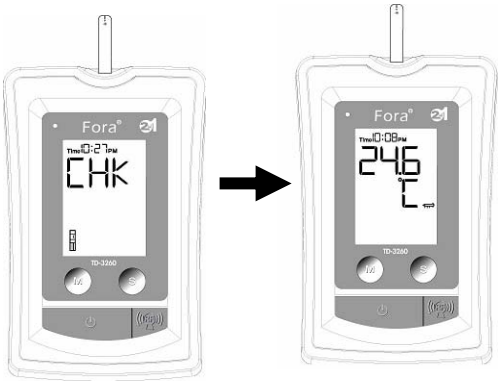
◉ Checking the Code

When you start measuring blood glucose, check the code number first.



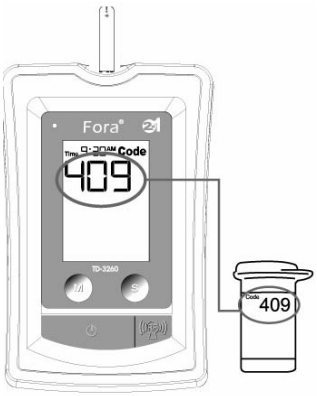
(Fig. 16)

STEP1- With the monitor off, insert a test strip into the Test Slot. Make sure you insert the end with the contact bars first and facing up. Contact bars must be inserted all the way into the monitor for an accurate result (Fig. 16).



(Fig. 17) (Fig. 18)

STEP2- The monitor will display “CHK” and the strip symbol (Fig. 17). Then the ambient temperature will be shown (Fig. 18).



(Fig.19)

STEP3- Then the code number and flashing blood drop appears. Check if the number shown on the monitor matches the number on the test strip vial (Fig. 19). If it matches, you can proceed with your test.

If it does not match, please code the monitor as described in the previous page.

CAUTION

If the code number displayed on the monitor does not match the number printed on the vial, test results will be wrong.

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⦿ Checking the System with Control Solutions

TaiDoc 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.

How often the control solution test should be performed?

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

When the control solution test should 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 not consistent with how you feel, or when you think your results are not accurate.
- When your test strips are exposed to extreme environmental conditions (See Storage section of this manual).
- When you want to practice running the test.
- If you drop the monitor.

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◉ Important Control Solution Information

- Use only TaiDoc control solutions.
- Check the expiry date on the control solution vial. Do not use if expired.
- Control solution, monitor, and test strips should come to room temperature (68-77℉/20-25℃) before testing.
- Shake the vial, discard the first drop of control solution, and wipe off the dispenser tip to ensure a good sample and an accurate result.
- Use only for 90 days after first opening. Record the discard date (date opened plus 90 days) on the control solution vial. Discard after 90 days.
- Store the control solution tightly closed at temperatures below 86℉ (30℃). Do not refrigerate.

NOTE

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

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◉ Doing a Control Solution Test

TAKE A TEST STRIP OUT WITH CLEAN AND DRY HANDS FIRST.

(Fig.20)

STEP1- Insert 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:

"CHK" and " " ➔ambient temperature➔code number and flashing" "(Fig.20)

Be sure the code number on the display is the same as the code number on the test strip vial. If the code numbers are not identical, please see "Coding the Monitor" section of this manual.

(Fig.21)

(Fig.22)

STEP 2- Press the M button

While the " " symbol appears on the display, press the M button (Fig.21) and then "CTL" will appear on the display (Fig.22). With the "CTL" sign on the display, the meter will not store your test result in memory. If you decide not to perform a control solution test, press the M button again, and the "CTL" sign will disappear.

NOTE

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

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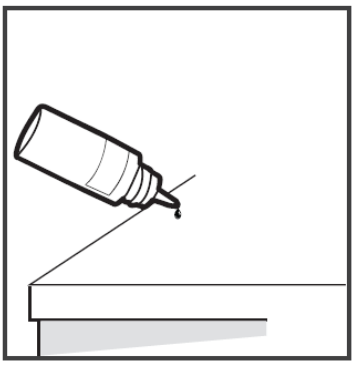
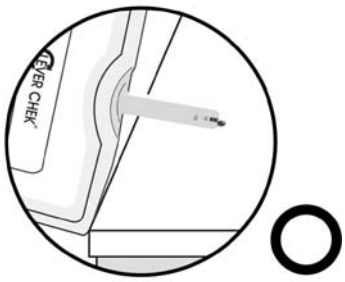


(Fig.23)

STEP 3- Obtain control solution

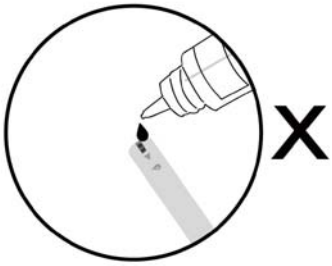
Shake the control solution vial well. Remove the cap. Squeeze the vial, discard the first drop, and wipe off the dispenser tip to prevent contamination. Squeeze the vial again to get another drop and place on a clean surface (Fig. 23).



STEP 4- Apply Control Solution

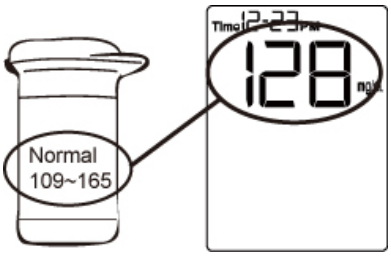
Move the monitor to meet the absorbent hole of the test strip and the drop will be automatically drawn into the test strip (Fig 24).

Remove the monitor until the confirmation window is filled. The monitor begins to count down.



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

(Fig.24)



STEP 5 – Read and Compare the Result

After counting to 0, the test result of control solution is shown on the screen. Compare this result with the range printed on the test strip vial. It should fall within this range (Fig. 25).

(Fig.25)

Out-of-range results

If test results fall outside the range printed on the test strip vial, check the section of “Problem in Operation” in troubleshooting guide and repeat the test. If you continue to get out-of-range results, it means that the system may not be working properly. Do NOT test your blood. Please contact your local agent for help.

⊙ 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:

A. Monitor

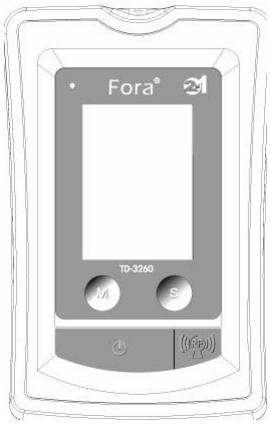
B. Test Strips

C. Lancing Device

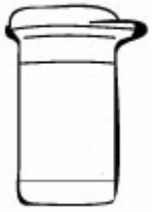
D. Sterile Lancet.

E. Clear Cap

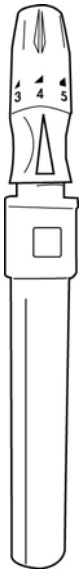
A.



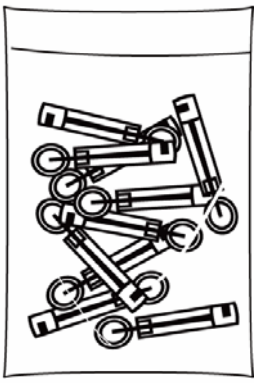
B.



C.



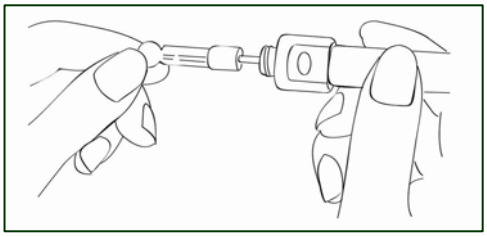
D.



E.

28

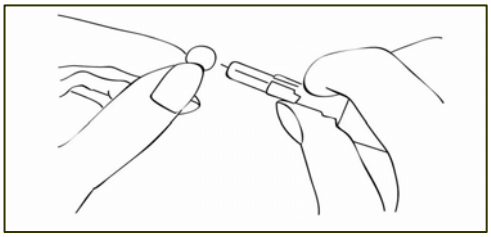
WASH AND DRY YOUR HANDS FIRST BEFORE STARTING.



(Fig.26)

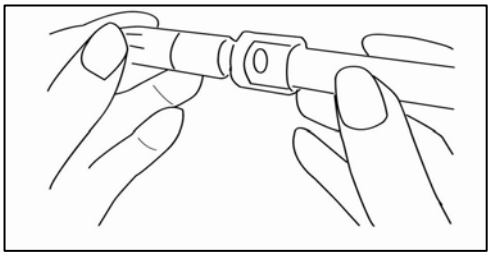
STEP 1- Set the Lancing Device

Remove the cap of lancing device. Insert a lancet into the lancet holder and push down firmly until it is fully seated.(Fig.26)



(Fig. 27)

Remove the protective disk.Replace the lancing Device cap.(Fig. 27)



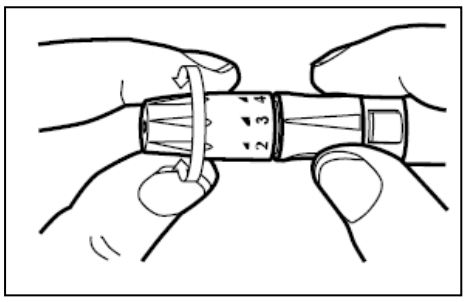
(Fig.28)

Replace the lancet device cap.Turn the cap unit it is snug but not too tight.(Fig.28)

WARNING

To reduce the chance of infection:

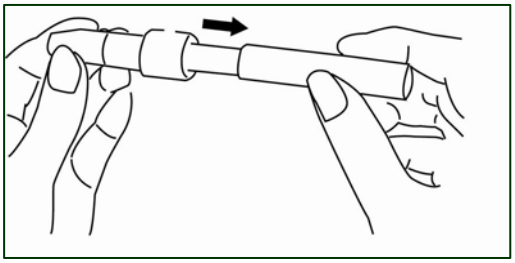
- Never share a lancet with anyone.
- Always use a new, sterile lancet. Lancets are for single use only.
- Avoid getting lotion, oil, dirt, or debris in or on the lancets and the sampler.



(Fig.29)

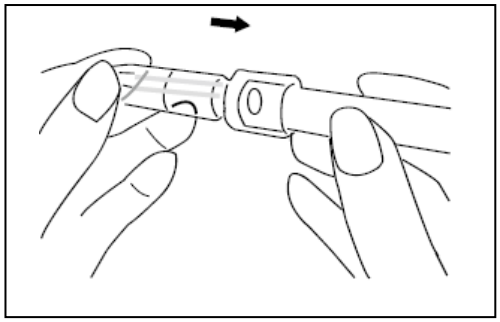
The adjustable tip offers 5 levers of skin penetration. Twist the adjustable tip in either direction until the number lines up with the Arrow:

1-2 for soft or thin skin, 3 for average skin, 4-5 for thick or calloused skin. (Fig. 29)



(Fig.30)

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.(Fig. 30)



(Fig.31)

■ **Blood from sites other than the fingertip**

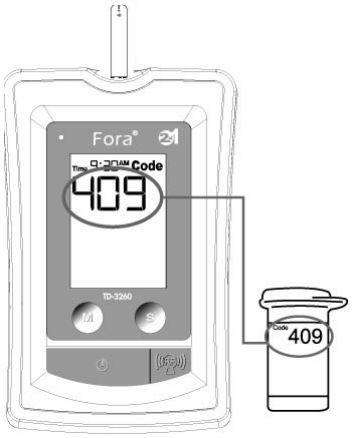
A clear cap, together with the kit, makes it easier to get a drop of blood for AST. When you want to obtain blood from sites other than the finger, **replace the lancet device cap with the clear cap** (Fig.31) Turn the clear cap until it is snug but not too tight.

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

STEP 2- Insert Test Strip

(Fig.32)

Insert a test strip with contact bars end first and facing up, into the test slot(Fig.32). The monitor turns on automatically and displays the followings in sequence:
CHK and" " ➔ ambient temperature ➔ code number and flashing " "



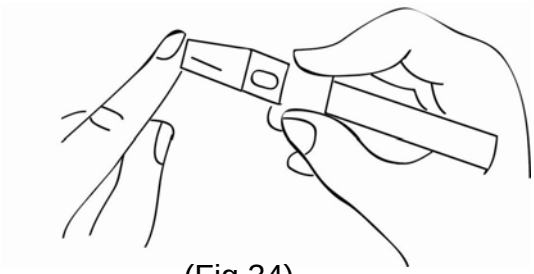
(Fig.33)

Make sure the code number showed on the screen is the same as the code number printed on the test strip vial. If the code numbers are different, please refer to section of "Coding the Monitor", for the procedure of coding(Fig 33).

31

STEP 3- Get a Drop of Blood

Select the puncture site either in finger or in other parts (AST). Clean the puncture site with 70% alcohol cotton and let it air-dry.



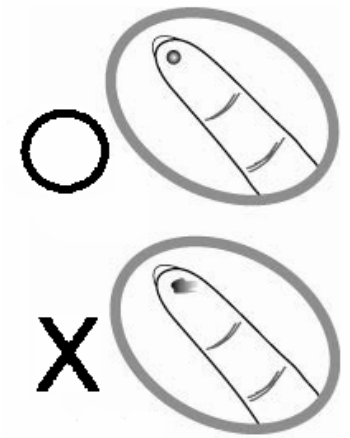
(Fig.34)

■ Fingertip

Hold the Lancing Device firmly against the side of your finger. Press the release button. You will hear a click, indicating that the puncture is complete(Fig. 34).

■ Site other than fingertip

Please refer to the section of" About AST" for available punctured sites.



(Fig.35)

After penetration, discard the first drop of blood with a clean tissue paper or cotton. Then gently squeeze the punctured area to obtain blood. But be attention **NOT** to smear the blood sample. The volume of blood sample must be at least 0.7 microliter(• actual size)(Fig.35).

WARNING

1. Choose a different spot each time you test. Repeated puncture in the same spot may cause soreness and calluses.
2. The first drop of blood usually contains tissue fluid and serum, which may affect the test result. It should be discarded.

32

STEP 4- Apply Blood into the Test Strip

When “ “is flashing on the screen, apply your blood to the absorbent hole of the test strip until the confirmation window is fully covered with blood(Fig. 36). The monitor then begins to count down automatically.

(Fig.36)

STEP 5- Obtain an accurate result in 7 seconds

The result of your blood glucose test is shown after the meter counts to 0. This reading is automatically stored in the monitor (Fig.37).

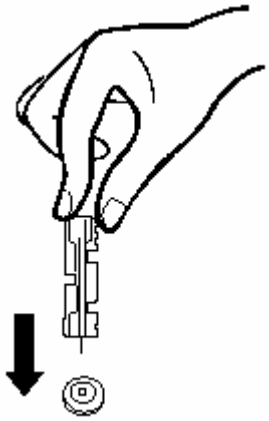
(Fig.37)

PLEASE NOTE

1. Do not push your finger (with blood on it) against the test strip or try to apply a smeared sample on the test strip.
2. If you do not apply blood sample within 3 minutes, or if you accidentally turn off the monitor by pressing the ⏻ 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.
3. The blood should be completely filled the confirmation window before the monitor begins to count down. If you find that the confirmation window is not filled with blood when the monitor is counting, NEVER try to add more blood to the test strip. Discard the test strip and retest with a new one.
4. 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 "HOW TO MEASURE BLOOD PRESSURE".

33

STEP 6- Remove the Lancet



Always use caution when removing the lancet. Take the lancet out carefully. Place the disk on a hard surface and push the exposed tip into the protective disk(Fig. 38).

(Fig. 38)

WARNING
The used lancet and the used test strip may be potentially biohazard. Please discard it carefully according to your local regulations.

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◉ Special Messages

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

⦿ Comparing Monitor and Laboratory 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 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 monitor 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.

HOW TO MEASURE BLOOD PRESSURE

◉ 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.

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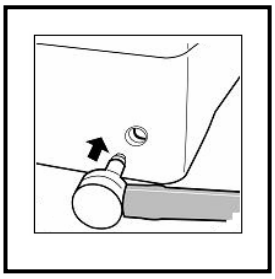
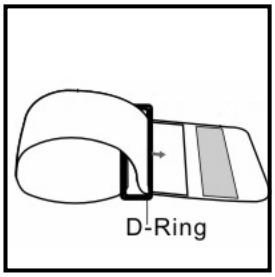
◉ Testing Your Blood Pressure

SETP 1 Please sit and take a rest at least 10 minutes before measuring.



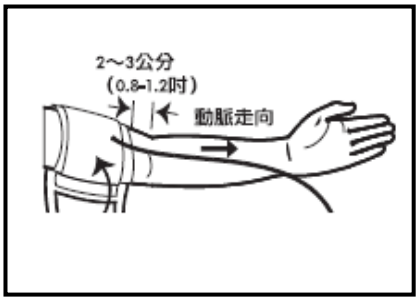
(Fig.39)

STEP 2- Connect the air plug of the tubing to the air jack at the side of the monitor (Fig. 39) .



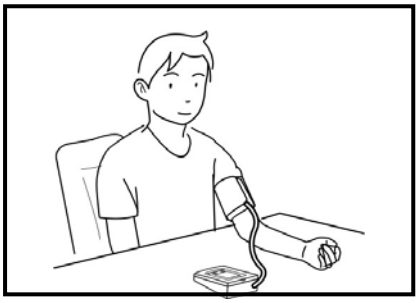
(Fig. 40)

STEP 3- Assemble the cuff as Figure 40. The smooth cloth is on the inside of the cuff loop and the metal D-ring will not touch your skin (Fig. 40) ..



(Fig. 41)

STEP 4- Hold 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 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 (Fig. 41).



(Fig. 42)

STEP 5-Place your elbow on a table or other object.relax your hand with the plam facing up.relax and make sure the cuff is the same height as your heart.press the ⏻ button.remain still and do not talk or move during the measurement (Fig 42).

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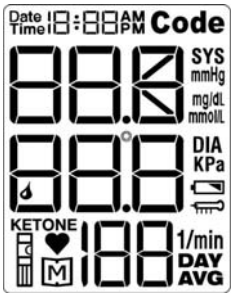
WARINING

It is extremely important that the cuff is at the same level of 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.

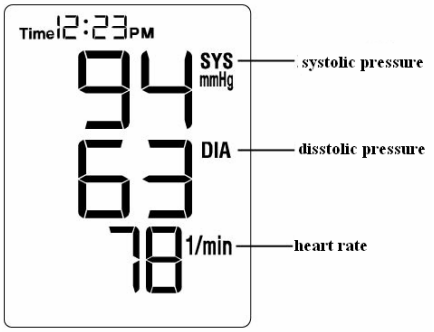


(Fig. 43)

STEP 6- All the LCD display symbols will appear with a long “beep” sound (Fig. 43). Then cuff begins to inflate automatically.

(Fig. 44)

STEP 7- After the cuff pressure is reached, the cuff begins to deflate. When detecting pulse, the Pulse Symbol “♥” will flash, along with a beeping sound during measurement (Fig. 44).



(Fig. 45)

STEP 8- After the measurement, the monitor displays the systolic pressure, diastolic pressure, and heart rate (Fig. 45). Press the ⏻ button to switch off. Or it will switch off automatically after 3 minutes.

NOTE

If you press the ⏻ button during the measurement, the monitor will turn off.

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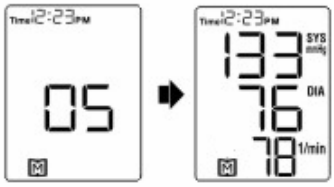
HOW TO USE THE MEMORY FEATURES

◉ Viewing Memory in the Monitor

Your monitor stores the most 352 recent results of blood glucose and blood pressure with date and time in its memory. You can review the test results in memory with these easy steps.

(Fig. 46)

STEP 1- When the monitor is off, press the M Button once. You will see the average of the blood glucose results (Fig. 46).

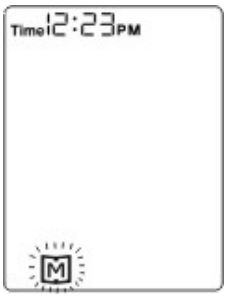


(Fig. 47)

STEP 2- Press the M Button again to recall the readings measured previously. The other results will be displayed in the order of time and date taken. You will see the number of the result stored, followed by the result (Fig. 47). When the memory is full, the oldest results are deleted as new ones are added.

STEP 3- Press the ⏻ button to turn off the monitor and exit the memory mode.

Note



(Fig. 48)

1. When using the monitor for the first time, or when there are no test results in memory, you will only see flashing " M ". This means that there are no test results in memory (Fig. 48).

2. The control solution results are **NOT** stored in the memory (please also go to page 26 NOTE for information). The list of past results are for blood glucose results and blood pressure results and the result average are for blood glucose results.

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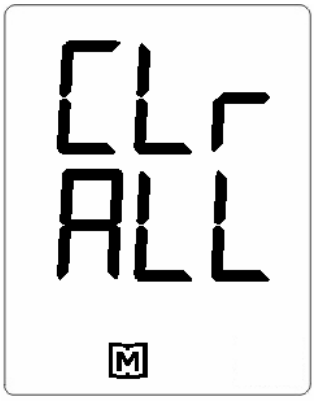
HOW TO USE THE MEMORY FEATURES

◉ Deleting Memory



(Fig. 49)

To clear the memory, with the monitor turned off, press and hold the M Button for 3 seconds. “CLr/ALL” then appears and indicates that ALL the memories stored in the monitor will be cleared (Fig. 49).

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HOW TO TAKE CARE OF YOUR MONITOR

⊙ Cleaning

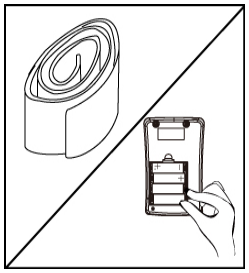
- To clean the monitor exterior, wipe with a cloth moistened with tap water or a mild cleaning agent, then dry the device with a soft and dry cloth. Do not flush with water.
- Do not use organic solvents to clean the monitor and cuff.
- The cuff can be cleaned by wiping with a moistened cloth and soap.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

⊙ Storage

1. Monitor Storage

- Storage conditions: -20℃~60℃, 10%~95% relative humidity.
- Always store or transport the monitor in its original storage case.

- Avoid dropping and strong impact.
- Avoid direct sunlight and humidity.
- Do not disassemble, modify or try to repair the monitor or wrist cuff by yourself.



- Do not over-wring the cuff and turn the cuff inside out.
- If you are not going to use the monitor for an extended period, please remove the batteries

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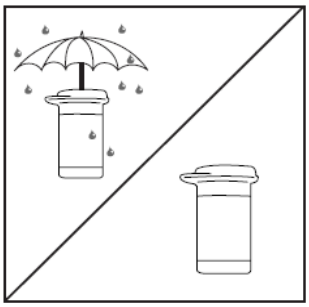
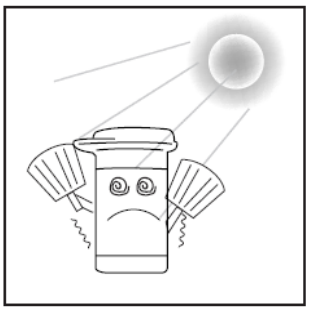
2. Strip Storage



■ Storage condition: 4°C-40°C, below 85% relative humidity. **Do NOT refrigerate**.

■ Store your test strips in their original vial only. Do not transfer to other container.



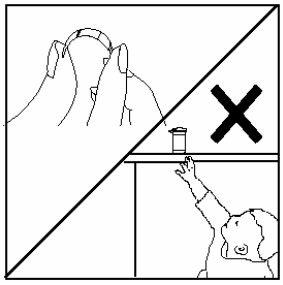
■ Store test strip packages in a cool and dry place. Keep away from direct sunlight and heat.

■ After removing a test strip from the vial, immediately 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.

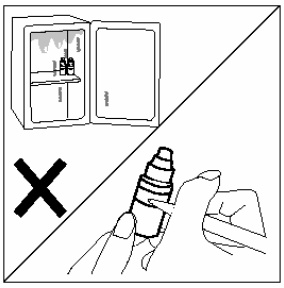
■ Write the discard date (the date opened plus 90 days) on the vial label when you first open it. Discard remaining test strips 90 days after first opening date.



■ 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 condition: Store the control solution tightly closed at temperature below 30℃ (86℉). **Do NOT refrigerate**.

■ Record the discard date (date opened plus 90 days) on the control solution vial. Discard after 90 days.

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PROBLEM-SOLVING GUIDE

Following is a summary of some display messages. These messages help to identify certain problems but do not appear in all cases when a problem has occurred. Improper use may cause an inaccurate result without producing an error message. In the event of a problem, refer to the information under action.

Never try to disassemble the monitor in any circumstances. If you encounter any error messages not listed below or if you have followed the actions recommended below but the problem keeps unsolved, please call the customer service for support.

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⊙ ERROR MESSAGE

<table>
<tr><th>Message</th><th>Cause</th><th>What to Do</th></tr>
<tr><td>Err.00</td><td>Weak pulse.</td><td rowspan="3">Refit cuff tightly, relax, and repeat measurement as shown in "Applying the Pressure Cuff".</td></tr>
<tr><td>Err.02</td><td>Monitor can not figure out systolic pressure.</td></tr>
<tr><td>Err.04</td><td>Monitor can not figure out diastolic pressure or it is out of range.</td></tr>
<tr><td>Err.22</td><td>Invalid coding.</td><td>Insert the code strip and try coding again.</td></tr>
<tr><td>Err.24</td><td>Used strip insertion.</td><td>Use a new strip.</td></tr>
<tr><td>Err.25</td><td>Ambient temperature is below operating temperature.</td><td rowspan="2">Please operate this monitor between 10℃ ~40℃</td></tr>
<tr><td>Err.26</td><td>Ambient temperature is over operating temperature.</td></tr>
<tr><td>Lo</td><td>Blood glucose value lower than 20 mg/dL</td><td rowspan="2">Follow directions in “HOW TO MEASURE BLOOD GLUCOSE” and test again. Please seek immediate medical assistance.</td></tr>
<tr><td>Hi</td><td>Blood glucose value higher than 600 mg/dL</td></tr>
<tr><td>Err.05
Err.06
Err.09
Err.10
Err.11
Err.15
Err.20
Err.28</td><td colspan="2">Those messages indicate internal problems with the monitor. You cannot fix by yourself.
Please contact your local agent for help.</td></tr>
</table>

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⊙ Problem in Operation

Please check the chart below for problems you may encounter during measurement and what to do. If you follow “What to Do” but the problem still exists, please contact Customer Service Line for help.

Blood Glucose Function

■ If no message appears after inserting a test strip:

Possible Cause	What to Do
Batteries exhausted.	Replace the batteries.
Batteries incorrectly installed or absent.	Check that the batteries are correctly installed.
Test strip inserted upside down or not completely inserted.	Insert the test strip correctly With the contact bars end first and facing up.
Defective monitor.	Please contact your local customer service for help.

■ If 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.
Defective monitor.	Please contact your local customer service for help.

■ If you accidentally touch the ⏻ button during glucose measurement, or if you do not apply a drop of blood in 3 minutes, the monitor will turn off with a beeping sound. Please remove the strip from the slot.

■ If you remove the strip form the slot before the monitor finishes count down, the result will not be accurate. Please use a new strip to test again.

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Blood Pressure Function

■ If there is no display after pushing the ⏻ button.

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

What happened?

■ If the 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.

■ If a result is higher/lower than user's average measurement.

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

■ If the cuff inflates again during measuring.

POSSIBLE CAUSE	WHAT TO DO
Cuff is not fastened.	Fasten the cuff again.
Normal action. If user's blood pressure is higher than the previous value, the device would automatically pump to a higher pressure by until it reaches a suitable pressure. Keep relax and wait for the measurement.	

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SPECIFICATIONS

■ System Performance

Power source:	Four 1.5V AA alkaline batteries
Size of monitor w/o cuff:	137mm (L) x 90 mm (W) x 54 mm (H)
Memory:	352 measurement results with date& time
Power saving:	Automatic power off if idle for 3 minutes
System operating condition:	10℃-40℃ (50-104℉), below 85% RH
System storage condition:	4℃ to 40℃ (39-104℉), below 85% RH

■ Blood Glucose Measurement Performance

Measurement unit:	mg/dL or mmol/L
Linear range:	20-600 mg/dL (1.1 -33.3 mmol/L)
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
Heart rate range:	40-199 beat per minute
Measurement unit:	mmHg or KPa
Accuracy of pressure:	±3mmHg or ±2% of reading
Accuracy of heart rate:	±4% of reading
Maximum inflation pressure:	300 mmHg

■ Typ. RF Characteristics

Receive sensitivity:	-90dBm
Max. Transmit power:	0dBm
Transmit power:	3.6V
Maximum input signal:	-10dBm
RSSI range:	-95 to -10dBm
RF Port impedance-SMA Connector:	50 ohm
VSWR (max):	2:1

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

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.

Operation of this equipment is subject to the following two conditions:
(1) This device may not cause harmful interference.
(2) This device must accept any interference received, including interference that may cause undesired operation.

FCC RF Radiation Exposure Statement:
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

NOTE
The changes or modifications not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment.

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Customer Care Line:
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Hours of Operation: 9 am- 4 pm PDT

At all other times, you should contact your health care professional for assistance.

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