

ADVOCATE DUO™

TD-3223 A/B

**Blood Glucose plus Blood
Pressure Monitoring System**



OWNER'S MANUAL

47-3223A-001

Versión 1.0 Noviembre 2006



Advocate Duo™ TD-3223A/B Blood Glucose plus Blood Pressure Monitoring System

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

For other questions regarding this system, please contact Diabetic Supply of Suncoast, Inc. For all non system health related questions you should contact your health care professional for assistance.

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. Do not use the device near a mobile phone or microwave oven, or it may cause inaccurate results.

KEEP THESE INSTRUCTIONS

BEFORE YOU START	04
Warnings and Precautions	04
Health Information	05
ABOUT THIS SYSTEM	07
Intended Use	07
Principle of Measurement	07
Major Features	07
Alternative Site Testing	08
Contents of the System	10
Appearance and Key Function of the Monitor	11
LCD Display	12
Appearance of the Test Strip	13
PREPARATIONS BEFORE USE	14
Battery Installation and Replacement	14
Setting the Monitor	16
BLOOD GLUCOSE MEASUREMENT	18
Important Information	18
Possible Interferences	18
Calibration	19
Checking with Advocate™ Control Solution	21
Important Control Solution Information	22
Do a Control Solution Test	23
Testing Your Blood Glucose	25
Reading Your Result	29

Comparing Monitor and Laboratory Results	30
BLOOD PRESSURE MEASUREMENT	32
Suggestions Before Measuring	32
Correct Application of the Pressure Cuff	32
Testing Your Blood Pressure	33
Reading Your Result	35
MONITOR MEMORY	36
Viewing Results on the Monitor	36
Viewing Results on a Personal Computer	38
TAKE CARE OF YOUR MONITOR & STRIP	39
Cleaning	39
Storage	39
PROBLEM-SOLVING GUIDE	42
Error Message	43
Problem in Operation	44
SPECIFICATIONS	47
SYMBOL INFORMATION	48
WHEN/WHAT DO YOU HEAR	49
Blood Glucose Measurement	49
Blood Pressure Measurement	50
SUMMARY OF OPERATION	51
Warranty/Customer Care	51

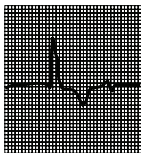
● Warnings and Precautions



- ▶ The Advocate Duo™ TD-3223A/B System is designed for use on individuals **age 16 and above**. It shall **NOT** be used:
 - To diagnose newborns with diabetes.
 - On infants or persons who cannot communicate.



- ▶ This device does **NOT** serve as a cure of any symptoms or diseases. 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 near a mobile phone or microwave oven or it may cause inaccurate results.



- ▶ Do **NOT** use the device for purposes other than measuring blood glucose and blood pressure for human beings.



- ▶ Do **NOT** apply the cuff to body areas other than the wrist.

● 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 Advocate Duo™ TD-3223A/B system can help you and your healthcare professional monitor and adjust your treatment plan to gain better control of your diabetes.

Time of day	Glucose range for people without diabetes (mg/dL)/(mmol/L)	Your target range (mg/dL)/(mmol/L)
Before breakfast	(70–105)/(3.9–5.8)	_____ (mg/dL)/(mmol/L)
Before lunch or dinner	(70–110)/(3.9–6.1)	_____ (mg/dL)/(mmol/L)
1 hour after meals	Less than (160)/(8.9)	_____ (mg/dL)/(mmol/L)
2 hour after meals	Less than (120)/(6.7)	_____ (mg/dL)/(mmol/L)
Between 2 and 4 A.M.	Greater than (70)/(3.9)	_____ (mg/dL)/(mmol/L)

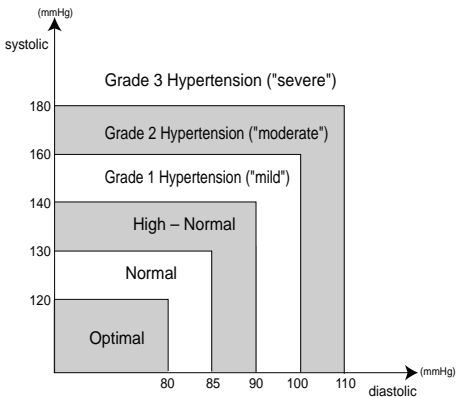
Source: Krall, L.P., and Beaser, R.S.: Joslin Diabetes Manual.

Philadelphia: Lea and Febiger (1989), 138.

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

Blood Pressure

Clinical studies show that the adult diabetes is often accompanied by elevating 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 Dis-ease Link Surveying Attitudes, Knowledge and Risk (2002).

● Intended Use

The **Advocate Duo™ TD-3223A/B** system is a 2 in 1 system designed to measure blood glucose outside of human body, and to measure blood pressure non-invasively. It is intended for use in the home and in clinical settings. It shall not be used for the diagnosis of diabetes and hypertension, or for testing of newborns.



● Principle of Measurement

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

Blood pressure is measured non-invasively at the 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 its **speaking function** (with a talking symbol  on the monitor), which is an acoustic aid for users especially with visual disability. Please note that this function is optional. If the monitor does not have , it will not provide speaking function.

Another unique feature is its **internal established code**. Not only does it simplify the glucose test, but it also provides you and your doctor with more precise and accurate test results.

● Alternative Site Testing (AST)

Important: There are limitations for doing AST.

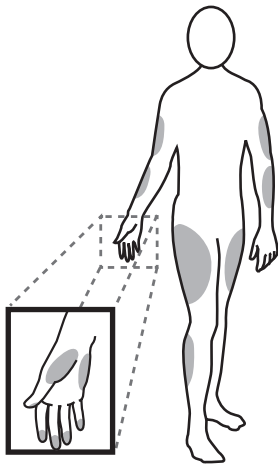
Please consult your healthcare professional before you do AST.

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 to do AST **ONLY** in the following intervals:

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

Do NOT use AST if:

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

If you would like to obtain blood from sites other than the finger, replace the lancet device cap with the clear cap. The clear cap for AST is an optional accessory, please contact your local customer service.

NOTE: We suggest that before getting a drop of blood rub the picture site about 20 seconds before penetration.

● Contents of the System

A blood glucose plus blood pressure monitor



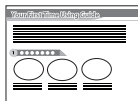
Owner's manual



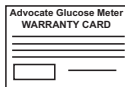
Sporty carrying bag



First time using guide



Warranty Card



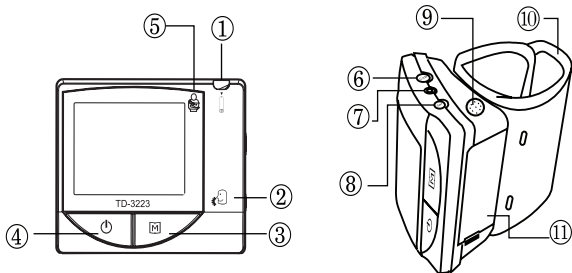
The above products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. Use only Advocate Duo™ TD-3223 test strips and Advocate™ control solution with your Advocate Duo™ TD-3223A/B Monitor.

NOTE !

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.

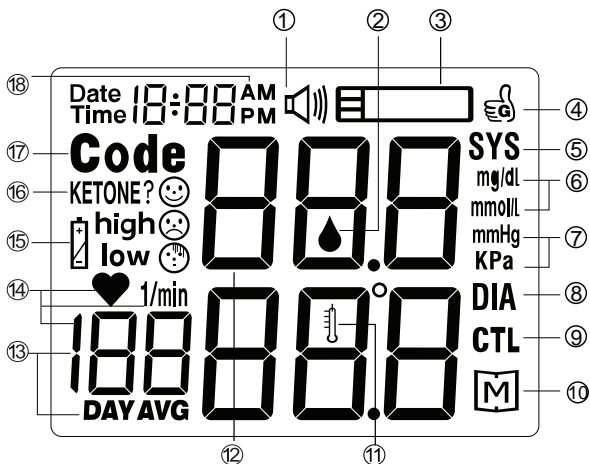
ABOUT THIS SYSTEM

● Appearance and Key Function of the Monitor



- ① **Test Slot** is where you insert the test strip.
- ② **Talking Symbol** indicates that the monitor has speaking function.
- ③ **M Button** is used to enter the memory and to assist setting.
- ④ **Button** is a power button for blood pressure measurement.
- ⑤ **Position Symbol** reminds you to put the device at the same level as your heart when measuring blood pressure.
- ⑥ **Code Button** is for code selection when calibrating.
- ⑦ **Data Port** is for cable connection.
- ⑧ **Set Button** is used to set up the monitor.
- ⑨ **Speaker** is where voice comes from.
- ⑩ **Wrist Cuff** is used to wrap around your wrist when measuring blood pressure.
- ⑪ **Battery Compartment.**

● LCD Display



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

ABOUT THIS SYSTEM

● 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 cell where the reaction takes place.

The test strip consists of the following parts:

Contact Bars

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

Test Strip Handle

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

Confirmation Window

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

Absorbent Hole

Apply a drop of blood here, the blood will be sucked automatically. The minimum required blood volume is 0.7 microliter.

See pages 25~28, Testing Your Blood Glucose, for complete instructions.

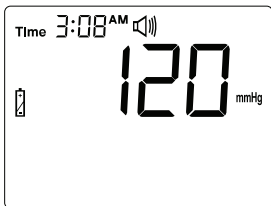



PREPARATIONS BEFORE USE

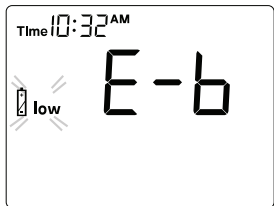
● Battery Installation and Replacement


Use ONLY 1.5V AAA size alkaline batteries for best performance and longest life.

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

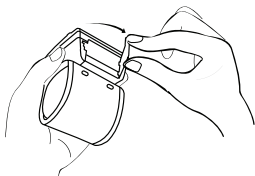


1. Battery Symbol  appears with your test result. This means it is about time to change the batteries although still 30 more measurements can be made.

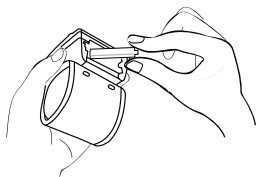


2. Error message "E-b" shows together with flashing "  " and "low". This means you must change the batteries before making any measurements.

Make sure the monitor is off when replacing the batteries.




Step 1 Press the buckle on battery cover and lift up to remove cover.



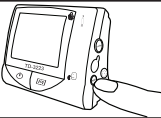



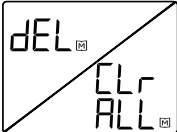
Step 2 Replace with two new 1.5V AAA alkaline batteries and close the cover.

Please remember:

- ▶ When “” appears, the monitor cannot speak but beeps instead.
- ▶ Do not use different type/brand name or used batteries together. Use only the new ones in required size and type.
- ▶ Replacing the batteries does not affect previously stored test results. But the settings may need to be updated again.
- ▶ Batteries might leak chemicals if not used for a long time. Remove the batteries if you are not going to use the device for an extended period (i.e., 3 months or more).
- ▶ As with all small batteries, the batteries should be kept away from small children who still put things in their mouths. If they are swallowed, promptly see a doctor for help.
- ▶ Discard batteries according to your local regulations.

● Setting the Monitor

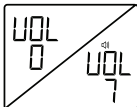
Time, date, units, memory deletion, speaking function (optional) can be set in the monitor. Two keys are involved: **Set** button and **M** button.

<p>Step 1 Press the Set button to start setting.</p> 	<p>Step 2 Year flashes first.</p> 
<p>Step 3 Press the M button to make changes. Press the Set button to next.</p> 	<p>Step 4 Date flashes. Follow Step 3 for changes.</p> <p>Date 10-08</p>
<p>Step 5 Time flashes. Follow Step 3 for changes.</p> <p>Time 10 08 PM</p>	<p>Step 6 Unit of glucose concentration*³ flashes. Follow Step 3 for changes.</p> <p>mg/dl mmol/L</p>
<p>Step 7 Unit of blood pressure flashes. Follow Step 3 for changes.</p> <p>mmHg KPa</p>	<p>Step 8 Unit of temperature flashes. Follow Step 3 for changes.</p> 
<p>Step 9 [M] (Memory) flashes.</p> <ul style="list-style-type: none"> ▶ If you'd like to skip this step, press Set button to next. ▶ If you'd like to delete memory, press M button again so that "dEL" and [M] will both flash. Press M button again to delete ALL memory. "CLr/ALL" appears and then the monitor automatically goes to next step. 	

**Step10 Speak-
ing volume**

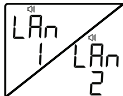
number flashes.

Follow **Step3** for
changes.




**Step11 Lan-
guage** flashes.

Follow **Step3** for
changes.



Please remember:

- ▶ Number can be advanced faster by holding down the **M** button.
- ▶ While setting speaking volume, number 0 indicates that the speaking function is off, where “

17

BLOOD GLUCOSE MEASUREMENT

● Important Information

1. Do not use expired test strips and control solutions for test. Failure to do so will lead to error reading.
2. Test results below $60\text{mg/dL}^* \text{ }^4$ (3.3mmol/L) indicates hypoglycemia, which means abnormally low glucose level. If higher than 240^*mg/dL (13.3mmol/L), symptoms of hyperglycemia might occur. Consult your physician when a result above occurs.
3. Apply **only capillary whole blood sample** to the absorbent hole. Applying other substances to the absorbent hole will cause inaccurate results.
4. If you have symptoms that are not consistent with your blood glucose or pressure level **AND** you have followed all instructions described in the owner's manual, contact your healthcare professional.

● Possible Interferences

1. Severe dehydration and excessive water loss may cause false low results.
2. A red blood cell percentage (hematocrit) that is extremely high (above 60%) or low (less than 20%) may cause false results.
3. Elevated blood triglyceride, reducing substances such as uric acid and ascorbic acid at normal blood concentration, or acetaminophen, dopa, methyl dopa, L-dopa, and tolbutamide at normal blood concentrations do not significantly affect the test results.

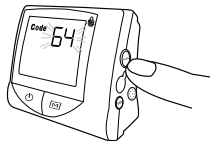
*4: Kahn, R., and Weir, G.: Joslin's Diabetes Mellitus, 13th ed. Philadelphia: Lea and Febiger (1994), 489.

*5: Krall, L.P., and Beaser, R.S.: Joslin Diabetes Manual. Philadelphia: Lea and Febiger (1989), 261-263.

● Calibration

When using the system for the first time, or before using a new vial of test strips, you will need calibration, which can be easily done by selecting the code number from the monitor. Code selection can be approached when the monitor is off, or when the monitor has a test strip inserted. **Only test blood glucose when the codes are identical, so the test results will be accurate.**

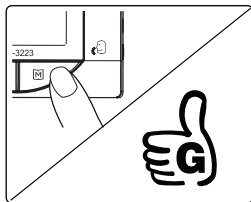
Selecting code when the monitor is off



Step 1 Directly press the Code button.

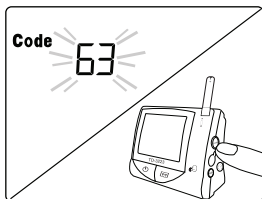
"Code" and "SEL" appear first. Next, a flashing code number shows.

Step 2 While the code number is flashing, press the Code button to advance one number until the correct code appears.



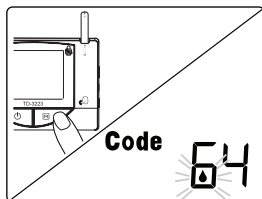
Step 3 Press the M button to set the code or wait 5 seconds for auto-save. "👍" appears, which indicates that calibration is complete. The monitor will automatically turn off after showing "OFF".

Selecting code when the monitor has a test strip inserted



Step 1 Insert the test strip and wait until the code number flashes.

Step 2 Press the Code button to select code number while the number is flashing.



Step 3 Press the M button to set the code or wait 5 seconds for auto-save. Then blood drop symbol  flashes. You can apply test sample now.

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 inaccurate results.

● **Checking with Advocate™ Control Solutions**

Advocate™ 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.
- ▶ To routinely check the monitor and test strips, perform a single test for each level of control solution supplied at least once a week.

When should the control solution test be performed?

- ▶ When you first get your Monitor.
- ▶ When you begin using a new vial of test strips.
- ▶ Whenever you suspect that the monitor or test strips are not working properly.
- ▶ When your blood glucose test results are 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 **TAKE CARE OF YOUR MONITOR & STRIP** section of this manual).
- ▶ When you want to practice running the test.
- ▶ If you drop the monitor.

● Important Control Solution Information

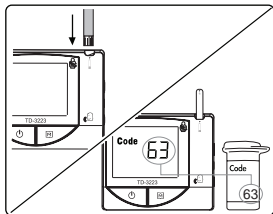
- ▶ Use only Advocate™ control solutions.
- ▶ Check the expiration date on the control solution vial. Do not use if expired.
- ▶ Control solution, monitor, and test strips should come to room temperature (20-25°C/68-77°F) before testing.
- ▶ Shake the vial, discard the first drop of control solution, 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 30°C (86°F). Do not refrigerate.

PLEASE NOTE

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

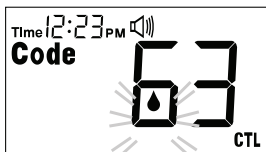
● Do a Control Solution Test

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



Step 1 Insert Test Strip and Check the Code Number

Be sure the code number on the display matches the code number on the test strip vial. If the code numbers do not match, please refer to “page 19–20” for the correct code selection.

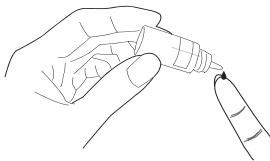


Step 2 Press the M button

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

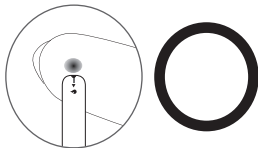
WARNING!

- ▶ Contact bars must be inserted all the way into the monitor 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.



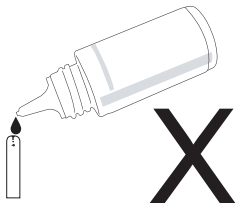
Step 3 Obtain Control Solution

Shake the control solution vial well before squeezing. Discard the first drop, wipe off the dispenser tip and squeeze the second one into a fingertip.

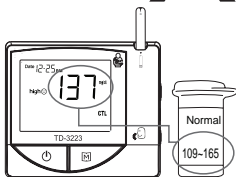


Step 4 Apply Control Solution

Move your finger (with control solution on it) close to the absorbent hole. The drop is auto-drawn into the test strip. The monitor begins to count down.



To avoid contamination, **please do not directly apply** the control solution into the test strip.



Step 5 Read and Compare the Result

Compare the result with the range printed on the test strip vial. The result should fall within this range.

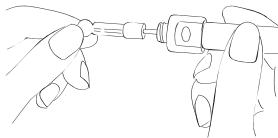
Out-of-range results

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. Contact your local customer service for help.

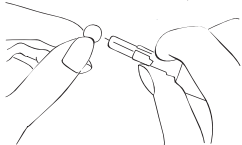
● Testing Your Blood Glucose

Wash and dry your hands first before starting. To test your blood glucose, you will need: the monitor, test strips, the lancing device, and lancets.

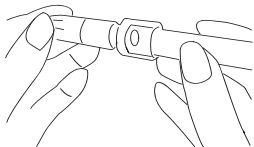
Step 1 Set the lancing device



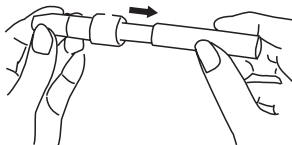
Remove the cap of the lancing device. Insert a lancet into the lancet holder and push down firmly until it is fully seated.



Twist the protective disk until it separates from the lancet.



Replace and screw the lancing device cap until it is snug but not too tight. Adjust depth of penetration: 1-2 for soft or thin skin, 3 for average skin, 4-5 for thick or calloused skin. **For AST, use clear cap instead of lancing device cap to get a drop of blood easily.**



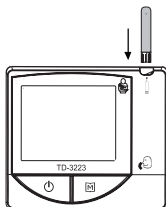
Slide the ejection/cocking control back until it clicks. If it does not click, the lancing device may have been cocked when the lancet was inserted.

Warning!

To reduce the chance of infection:

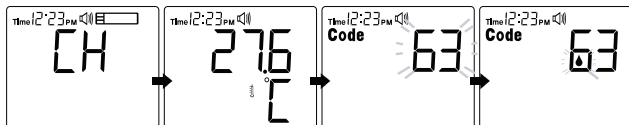
- ▶ Never share a lancet or the lancing device with anyone.
- ▶ Always use a new, sterile lancet. Lancets are for single use only.
- ▶ Avoid getting hand lotion, oils, dirt, or debris in or on the lancets and the lancing device.

Step 2 Insert the test strip and check the code number

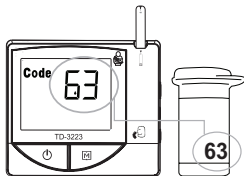


Take a test strip out with clean and dry hands first.

Insert a test strip with contact bars end first and the “▲” side of the test strip facing up into the test slot. The monitor turns on automatically. The sequences of LCD display are shown below.



The code number and flashing ▲ will be kept for 3 minutes until the drop of blood is applied.



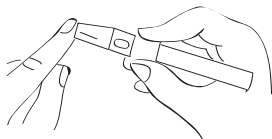
Be sure the code number on the display matches the code number on the test strip vial. If the code numbers are different, please refer to section of “**Calibration**”, for the procedure of coding.

Please remember:

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

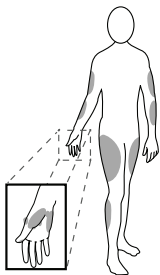
Step 3 Get a drop of blood

Select the puncture site either in finger or limbs. Clean the puncture site with 70% alcohol cotton and **let it air dry**.



► Fingertip

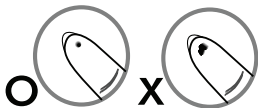
Hold the lancing device firmly against the side of your finger. Press the release button. You will hear a click, indicating that the puncture is complete.



► Site other than Fingertip

Follow the section of “Alternative Site Testing” to obtain blood.

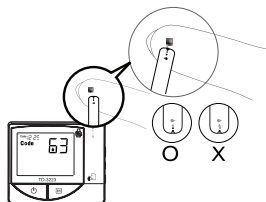
After penetration, gently massage the punctured area to obtain blood. But pay attention **NOT to smear the blood sample**. It is recommended to discard the first drop of blood with a clean tissue paper or cotton and use the second drop of blood for testing. Since the first drop of blood usually contains tissue fluid and serum, which may affect the test result.



Warning!

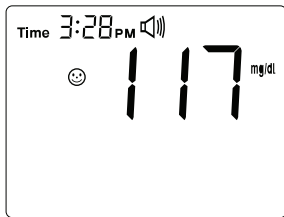
- Choose a different spot each time you test. Repeated punctures in the same spot may cause soreness and calluses.
- Before you decide to do AST, please consult your health professional first.

Step 4 Apply blood into the test strip



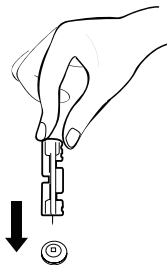
When ● flashes on the display, hold and touch the absorbent hole of test strip to the drop of blood until the confirmation window is completely filled.

Step 5 Read a result



Your test result appears after the monitor counts to 0. This blood glucose result displays along with Date/Time and is automatically stored in the monitor memory. Turn the monitor off by removing the test strip. Discard the used test strip carefully to avoid contamination.

Step 6 Discard lancet



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







Warning!



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

● Reading Your Result

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

Message	What it means
	Lo appears when your result is below measurement limit, which is less than 20 mg/dL (1.1 mmol/L).
	low ☹️ flashes when your result is between 20 and 69 mg/dL (1.1 to 3.8 mmol/L). It indicates that the result is below reference range.
	☺️ appears when your result is at reference range from 70 and 120 mg/dL (3.9 to 6.6 mmol/L).
<p>“Lo” or “low ☹️” symbol indicates hypoglycemia (low blood glucose). You should immediately treat hypoglycemia as recommended by your health-care professional.</p>	
	high ☹️ flashes when your result is between 121 and 239 mg/dL (6.7 to 13.3 mmol/L). It indicates that the result is higher than reference range.
	KETONE? flashes together with high ☹️ when your result is equal or higher than 240 mg/dL (13.3 mmol/L). This indicates there is a possibility of ketone accumulation if you are Type 1 diabetes. Please seek immediate medical assistance.
	Hi appears when your result is above measurement limit, which is higher than 600 mg/dL (33.3 mmol/L).

● Comparing Monitor and Laboratory Results

Test results from the monitor and laboratory are both expressed in plasma-equivalent units. However, the result you obtain from your monitor may differ somewhat from your laboratory result due to normal variation. Monitor results can be affected by factors and conditions that do not affect laboratory results in the same way. (See test strip package insert for typical accuracy and precision data, and for important information on limitations.) To make an accurate comparison between meter and laboratory results, follow the guide-lines 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. 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.

Therefore, it is best to fast for eight hours before doing comparison tests. Factors such as the amount of red blood cells in the blood (a high or low hematocrit) or the loss of body fluid (severe dehydration) may also cause a meter result to be different from a laboratory result.

References

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

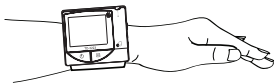
*7: Sacks, D.B.: "Carbohydrates." Burtis, C.A., and Ashwood, E.R. (ed.), Tietz Textbook of Clinical Chemistry. Philadelphia: W.B. Saunders Company (1994), 959

● Suggestions Before Measuring

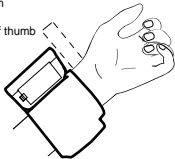
1. Avoid caffeine, tea, alcohol, and cigarettes at least 30 minutes before measurement.
2. Wait 30 minutes after exercising or bathing before measurement.
3. Sit down for at least 10 minutes before measuring.
4. Do not measure when feeling anxious or tense.
5. Take a 5-10 minute break between measurements.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

● Correct Application of the Pressure Cuff

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



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

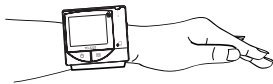


The top margin of the monitor should be about 0.6 cm to 1.3 cm (1/4 to 1/2 inch) below the ball of thumb. When the cuff is positioned correctly, fold the loose end back and secure it in place by pressing the pile material firmly against the hook material.

Warning!

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

● Testing Your Blood Pressure



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

Step 2 Apply the wrist cuff according to page 32.



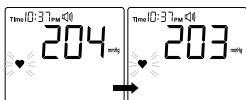
Step 3 Press the \odot button and place your arm in front of your chest. Relax and make sure **the device is at the same height as your heart.** Holding your left elbow with your right hand helps you hold still during measurement. Remain still and do not talk or move during the measurement.

Step 4 Measurement is in progress.

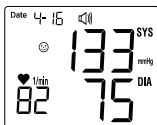
After power on, all symbols in the display will appear with a long “beeping” sound.




Then the cuff begins to inflate automatically. You will see number increasing in the display.




After the cuff pressure is reached, the cuff begins to deflate. You will see number decreasing and ♥ flashing in the display.



Step 5 Read a result.


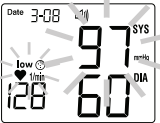
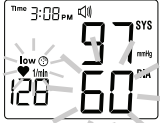

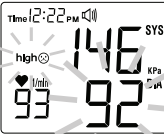
The monitor displays the systolic pressure, diastolic pressure, and heart rate along with Date/Time. **Press**  **button to switch off**. Or it will switch off automatically after 3 minutes.

Please remember:

- ▶ It is extremely important that you put the device at the same level of the heart. If the device is put relatively lower (higher) than the heart, your measurement will be higher (lower) than the actual value.
- ▶ If a higher pressure value is needed, the monitor will stop deflation and inflate again.
- ▶ If you press the  button during the measurement, the monitor will turn off immediately.

● Reading Your Result

Your blood pressure result comes with indicators that transfer special messages for your reference.

Message	What it means
	<p>😊 appears when your result is at reference range: systolic pressure between 100 and 140 mmHg; diastolic pressure between 70 and 90 mmHg.</p>
 	<p>low 😞 and the “abnormal” result both flash when your result is below reference range: systolic pressure less than 100 mmHg; diastolic pressure less than 70 mmHg.</p>
 	<p>high 😞 and the “abnormal” result both flash when your result is higher than reference range: systolic pressure over 140 mmHg; diastolic pressure over 90 mmHg.</p>

Your monitor stores the most recent 450 test results, and also provides the average of the blood glucose test results currently stored. Please follow the steps listed below to review those results.

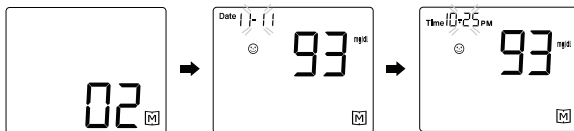
View Results on the Monitor

Recall the Stored Test Results:

Step 1 When the monitor is “off”, press and release the M button. “01” appears first, followed by the latest result of blood glucose/blood pressure along with date and time.



Step2 Press the M button once by once to recall the rest results stored in the monitor consecutively.



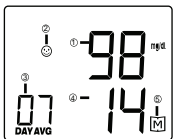
Step3 After viewing the oldest test result , push down the M button again to resume to the latest test result.

Read the Average of Blood Glucose Results:

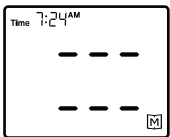
Step 1 When the monitor is off, keep pressing the **M** button for **3 seconds**. The 7-day average of blood glucose results will be shown first.

Step 2 Press the **M** button **once by once** to review the 14-, 21-, 28-, 60- and 90- day average in order.

Step 3 After viewing the **90-day average**, push down the **M** button again to resume to the 7-day average.



- ① The **average** of glucose tests.
- ② Result indicator.
- ③ The average was calculated from the test results of the **last 7 days**.
- ④ **14 glucose tests** have been performed in the last 7 days.
- ⑤ Memory Symbol Interpretation: The average of 14 glucose tests performed in the last 7 days is 98 mg/dL.



When using the monitor for the first time, “---” appears, showing that there is not any test result stored in memory.

Please remember:

1. The control solution results are **NOT** stored in the memory (please also go to page 23 **WARNING** for information).
2. If you'd like to exit from the memory, press the \odot button to turn off the monitor or wait without pressing for 3 minutes for auto-shut down.

● View Results on a Personal Computer

Results in memory can be transmitted to the personal computer. Health Care System Software and an Interface Cable are required before installation. The software can be downloaded from: www.dsosi.com. The interface cable is an optional accessory. Please contact your local customer service for purchasing.

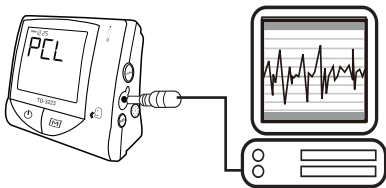
Step1 Install Software

Install Health Care System Software on your Computer by following the instructions provided on Advocate's website: www.dsosi.com.

Step2 Connect to Personal Computer

Connect the interface cable to a serial port on the back of your computer. With the monitor turned off, connect the Interface Cable to the Data Port located at the side of the monitor. Then "PCL" and time will appear in the display, indicating that the monitor is ready to transmit data.

Step3 Transmit Data



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

Please remember:

While the monitor is connected to the PC, it is unable to perform a blood glucose or blood pressure test.

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

● **Cleaning**

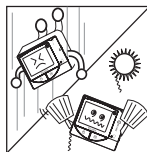
1. To clean the monitor exterior, wipe with a cloth moistened with tap water or a mild cleaning agent, then dry the device with a soft and dry cloth. Do not flush with water.
2. Do not use organic solvents to clean the monitor and cuff.
3. The cuff can be cleaned by wiping with a moistened cloth and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

● **Storage**

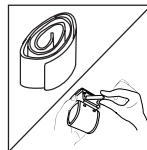
1. Monitor Storage



- ▶ Storage condition: -20°C – 50°C , below 95% relative humidity.
- ▶ Always store or transport the monitor in its original bag.

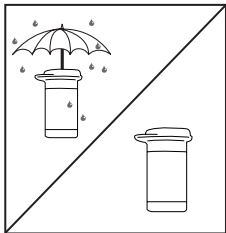


- ▶ Avoid dropping and strong impact.
- ▶ Avoid direct sunlight and humidity.
- ▶ Do not disassemble, modify or try to repair the monitor or wrist cuff by your self.



- ▶ Do not over-wrap 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.

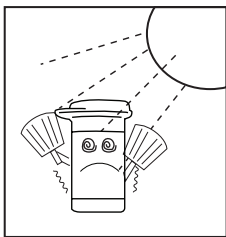
2. Strip Storage



► Storage condition: 4°C-40°C, (39°F/104°F) below 85% relative humidity.

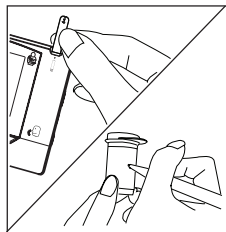
Do NOT refrigerate.

► Store your test strips in the 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.

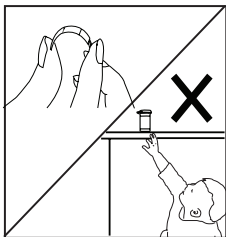
► After removing a test strip from the vial, immediately replace the vial cap and close it tightly.



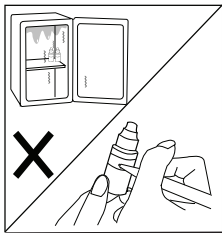
► Touch the test strip with clean and dry hands.

► 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 temperatures below 30°C(86°F). **Do NOT refrigerate.**
- ▶ Record the discard date (date opened plus 90 days) on the control solution vial. Discard after 90 days.

PROBLEM-SOLVING GUIDE

Following is a summary of some display messages and symbols. 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 or a symbol.




In the event of a problem, refer to the information under TROUBLESHOOTING.

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.

TROUBLESHOOTING

If you follow the action recommended but the problem is still existed, or error messages other than the ones below appear, please call your local customer service. Do not try to repair by yourself.

● Error Message

Message	Cause	What to Do
 E-b	Batteries are dead.	Replace the batteries immediately.
low E-t <small>strip</small>	Appears when environmental temperature is below system operation range : 10°C	System operation range is 10~40°C (50~104°F). Repeat the test after the monitor and test strip have reached the above temperature.
high E-t <small>strip</small>	Appears when environmental temperature is above system operation range : 40°C	
E r r 02	Unable to detect systolic pressure	Refit cuff tightly and correctly. Relax and repeat measurement.
E r r 04	Unable to detect diastolic pressure	
E r r 09	Cuff pressure is not enough.	
Time: 12:25 PM   E-U	Used strip insertion.	Repeat the test with a new strip.
Lo <small>mmol</small>	Blood glucose value is under measurement range : 20mg/dL	Repeat and Seek immediate medical assistance.
Hi <small>mg/dl</small>	Blood glucose value is over measurement range : 600mg/dL	

1. Blood Glucose Measurement



What happened?

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

POSSIBLE CAUSE	WHAT TO DO
Batteries exhausted	Replace the batteries.
Batteries incorrectly installed or absent .	Check 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.	Contact local customer service

What happened?

The test does not start after applying the sample.

POSSIBLE CAUSE	WHAT TO DO
Insufficient blood sample.	Repeat the test with a new test strip and a larger sample.
Defective test strip.	Repeat the test with a new test strip.
Sample was applied when flashing blood Symbol  was not displayed .	Repeat the test with a new test strip. Apply sample only when  flashing appears on the display .
Defective monitor.	Contact local customer service

What happened?

If you turned off the monitor but it makes a beeping sound.

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

What happened?

If the control solution test result is out of range.

POSSIBLE CAUSE	WHAT TO DO
Error in performing the test	Read the instruction thoroughly and repeat the test again.
Improper code number	Check if the code number on the display matches the code number on the test strip vial
Do not shake the control solution vial very well.	Shake the control solution vigorously and repeat the test again.
Expired or contaminated control solution.	Check the expire date or the discarded date of the control solution.
Control solution that is too warm or too cold.	Control solution, monitor, and test strips should come to room temperature (20-25°C/68-77°F) before testing.
Test strip deterioration	Repeat the test with a new test strip.
Monitor malfunction.	Contact local customer service

2. Blood Pressure Measurement

What happened?

No display after pushing the  button.

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

What happened?

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

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

What happened?

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

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

What happened?

Cuff inflates again during measuring.

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

SPECIFICATIONS

Model number: TD-3223 A/B

Power source: Two 1.5V AAA size alkaline batteries

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

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

Memory: 450 measurement results with date & time

Power saving: Automatic power off if idle for 3 minutes

System operating condition: -20°C a 60°C , (4°F – 140°F) , below 85% R.H.

Monitor storage condition: 4°C to 40°C (39°F to 104°F), below 95% R.H.

Strip storage condition: 4°C to 40°C , (39°F to 104°F) below 85% R.H.

KETONE? warning: glucose value over 240 mg/dL

Measurement unit: mg/dL or mmol/L

Linear range: 20-600 mg/dL (1.1 -33.3 mmol/L)

Precision: $\pm 5\%$ (CV)

Accuracy: $\pm 15\text{mg/dL}$ when glucose $< 75\text{mg/dL}$;

$\pm 20\%$ when glucose $\geq 75\text{mg/dL}$

Pressure Range: 0-300 mmHg

Heart Rate Range: 40-199 beat per minute














Measurement unit: mmHg or KPa

Accuracy of Pressure: $\pm 3\text{mmHg}$ or $\pm 2\%$ of reading

Accuracy of Heart rate: $\pm 4\%$ of reading


Maximum inflation pressure: 300 mmHg

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 61010-2-101, EN 60601-1-2, EN 61326.

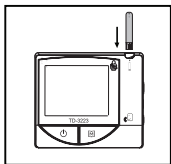
Symbol	Referent
	In vitro diagnostic medical device
	Do not re-use
	Consult instructions for use
	Keep away from sunlight
	Keep dry
	Temperature limitation
	Use by
	Date of manufacture
	Batch code
	Manufacturer
	Serial number
	Caution, consult accompanying documents
	Biological risks

WHEN/WHAT DO YOU HEAR

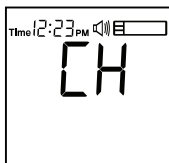
(Special for the monitor with speaking function)

When a talking symbol  is on the monitor, it means that the monitor provides speaking function. The following pictures tell you when and what the monitor "speaks".

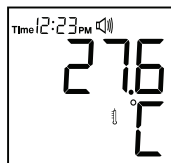
● Blood Glucose Measurement



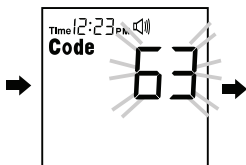
Insert a test strip to begin.



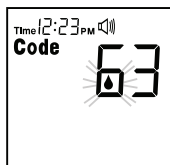
ⓘ Welcome music.
Thank you for using this product.
Please relax during measurement.



ⓘ The room temperature is
27.6 degree Celsius.



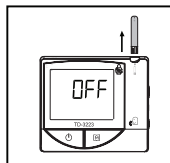
ⓘ The code number is 63.



ⓘ Please apply blood into the
strip.

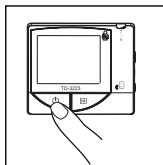


ⓘ The blood glucose is 117 mil -
ligram per deciliter.

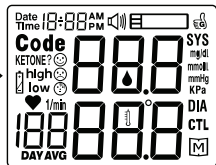


ⓘ Ending music

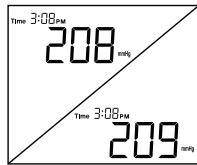
● Blood Pressure Measurement



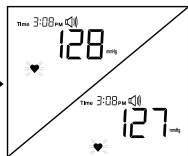
Press to start.



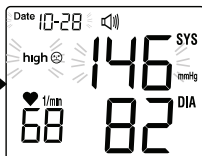
🔊 Welcome music.
Thank you for using this product.
Please relax during measurement.



The device is in inflation.



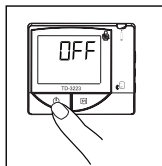
The device is in deflation with flashing ♥ symbol.



🔊 The systolic blood pressure is 146 millimeters of mercury.



🔊 The diastolic blood pressure is 82 millimeters of mercury.
The heart rate is 68 beats per minute.



🔊 Ending music

Advocate Duo Warranty Registration Information

Customer Care

Call us with Questions or Comments about your Advocate Blood Glucose Monitor. We are here to help. 9am - 5pm EST., Mon - Fri.

Toll Free 1-866-373-2824 www.dsosi.com

Important

Before using these products carefully read the owner's manual. For in vitro diagnostic use only. Store at room temperature below 86°F (30°C). Keep out of direct sunlight and humidity.

Warranty

The Advocate Duo is warranted to be free of defects in material and workmanship for the period of one (1) year from the date of purchase. The warranty is not transferable. This warranty does not apply to the performance of an Advocate Meter that has been damaged by accident or has been altered, misused, tampered with, or abused in any way.

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