



LBDG02



Blood Glucose Monitoring System User Guide

IVD	For <i>In vitro</i> diagnostic use		Temperature limitation / Store at
	Please consult instructions for use		Use by /Expiry date
	Do not reuse		Manufacturer
LOT	Lot number	ECIREP	EU representative
	Caution, consult accompanying document	CE 0120	This product fulfils the requirements of Directive 98/79/EC <i>In vitro</i> diagnostic medical device.

Applied standards: EN ISO 13485:2003, EN ISO 14971:2009, EN ISO 15197:2003, EN 980:2008, EN ISO 18113-1:2009, EN ISO 18113-4:2009, EN ISO 18113-5:2009, IEC/EN60601-1, IEC/EN60601-1-2, EN61010-1, EN61010-2-101:2002, EN 61326-1, ISO 17511:2003, EN ISO 9001, and EN61326-2-6.

Performance Characteristics:  
**ACCURACY:** More than ninety-five percent (95 %) of the individual glucose results fell within  $\pm 0.83$  mmol/L (15 mg/dL) of the results of the glucose analyzer YSI 2300 measurement procedure at glucose concentrations < 4.2 mmol/L (< 75 mg/dL) and within  $\pm 20$  % at glucose concentrations  $\geq 4.2$  mmol/L ( $\geq 75$  mg/dL).  
**PRECISION:** CVs (%) of intermediate precision and repeatability were less than 5%.



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**PRINCIPLE OF MEASUREMENT**

Blood glucose is measured by an electrical current that is produced when a blood sample mixes with the reagent (special chemicals) of the test strip. The electrical current changes with the amount of glucose in the blood sample. The L'Docile LBDG02 meter measures the strength of the electrical current, calculates your blood glucose level and then displays your result in either milligrams of glucose per deciliter (mg/dL) or millimoles of glucose per liter (mmol/L).

**CAUTION**

1. *Venous and arterial tests are for professional use only. Do not try them at home!*
2. The user should not take any decision of medical relevance without first consulting his or her medical practitioner.
3. Call your doctor immediately if you experience symptoms that are not consistent with your blood glucose test results.
4. High altitudes above than 3,402 meter (11,161 ft) may affect the test results.
5. Temperatures outside the range of 10°C to 40°C (50°F to 104°F) may affect the test results. Do not test beyond of temperature range.

**IMPORTANT HEALTH-RELATED INFORMATION**

1. Apply whole blood sample to test your blood glucose. Applying other substances or plasma, serum will cause wrong results.
2. Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.
3. Test results below 60 mg/dL (3.3 mmol/L)\*1 indicates low blood glucose (hypoglycemia). Test results greater than 240 mg/dL (13.3 mmol/L)\*2 indicates high blood glucose (hyperglycemia). If your results are below 60 mg/dL (3.3 mmol/L) or above 240 mg/dL (13.3 mmol/L), repeat the test, and if the results are still below 60 mg/dL (3.3 mmol/L) or above 240 mg/dL (13.3 mmol/L), consult your healthcare professional immediately.

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4. 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 meters.
5. Abnormal red blood cell counts (hematocrit level below 20% or above 60%) may cause false results. Please consult your healthcare professional if you do not know your hematocrit level.
6. Interference: Reducing substances occurring in the blood naturally (uric acid, bilirubin) or from therapeutic treatments (ascorbic acid, acetaminophen) will not significantly affect L'Docile LBDG02 test results. However, elevated concentrations of these substances may affect test results. The compounds listed in the tables were found to have no affect at the concentration indicated.

Compounds	Lowest concentrations tested at which no interference occurred	Compounds	Lowest concentrations tested at which no interference occurred
Acetaminophen	$\leq 8.0$ mg/dL (0.53 mmol/L)	Gentisic Acid	$\leq 5.0$ mg/dL (0.32 mmol/L)
Ascorbic Acid	$\leq 5.0$ mg/dL (0.28 mmol/L)	Hydroxyurea	$\leq 3.0$ mg/dL (0.39 mmol/L)
Aspirin	$\leq 60$ mg/dL (3.33 mmol/L)	L-dopa	$\leq 10$ mg/dL (0.51 mmol/L)
Bilirubin	$\leq 90$ mg/dL (1.54 mmol/L)	Maltose	$\leq 900$ mg/dL (26.3 mmol/L)
Cholesterol	$\leq 500$ mg/dL (12.9 mmol/L)	Methyldopa	$\leq 3.0$ mg/dL (0.13 mmol/L)
Creatinine	$\leq 5.0$ mg/dL (0.44 mmol/L)	Tolbutamide	$\leq 400$ mg/dL (14.8 mmol/L)
Dopamine	$\leq 2.0$ mg/dL (0.11 mmol/L)	Triglycerides	$\leq 2,000$ mg/dL (22.6 mmol/L)
Galactose	$\leq 900$ mg/dL (50 mmol/L)	Uric Acid	$\leq 8.0$ mg/dL (0.48 mmol/L)

**REFERENCE:**

\* 1: Kahn, R. and Weir, G.: Joslin's Diabetes Mellitus, 13th ed Philadelphia: Lea and Febiger (1994), 489.  
 \* 2: Krall, L.P. and Beaser, R. S.: Joslin Diabetes Manual, Philadelphia: Lea and Febiger (1989), 261-263.

**Before You Begin**

**PLEASE 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 User Guide.
  3. Do not use test strips 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.
  6. Do not use this meter in a dry environment, especially if synthetic materials are present. Synthetic clothes, carpets, etc., may cause damaging static discharges in a dry environment.
  7. Do not use this meter near cellular or cordless telephones, walkie talkies, garage door openers, radio transmitters, or other electrical or electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.
  8. KEEP THIS USER GUIDE WITH YOU.

**INTENDED USE**

**IVD** The system is intended for use outside the body (*in vitro* diagnostic use only). It should be used only for testing blood glucose (blood sugar) with fresh capillary, venous, or artery blood samples. The system is intended for use in the home and in clinical settings. It should not be used for the diagnosis of diabetes or for the testing of newborns.

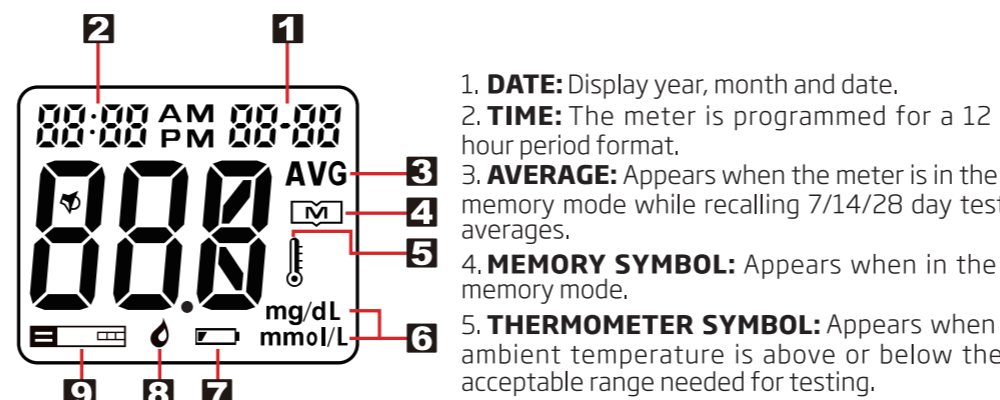
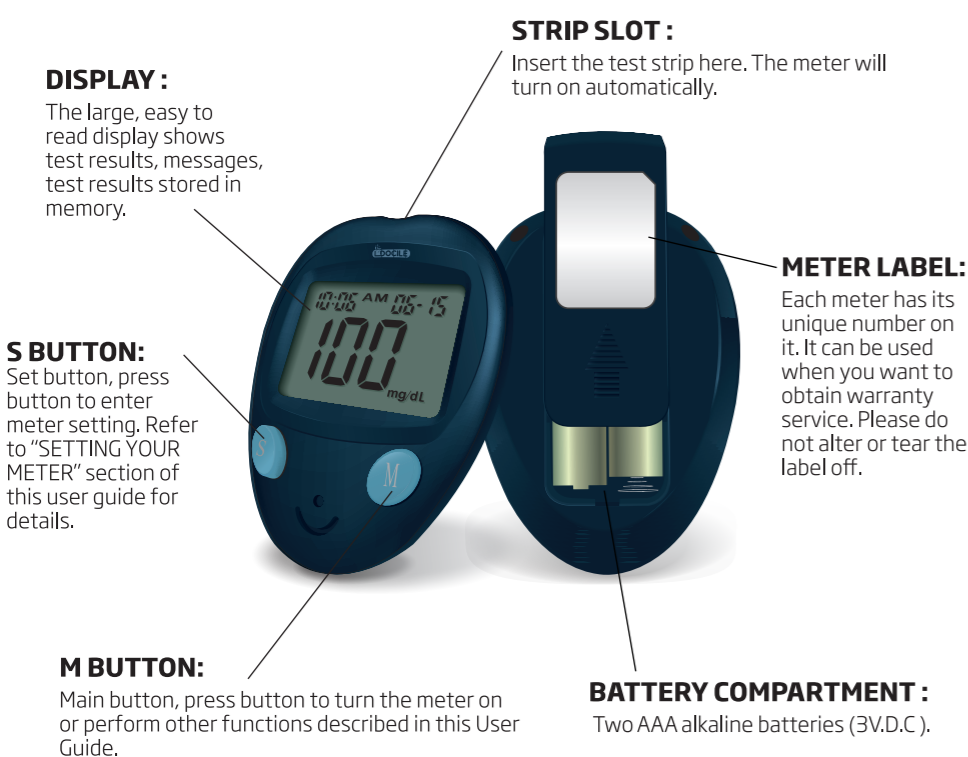
**1. Getting To Know Your System**

**THE L'DOCILE LBDG02 BLOOD GLUCOSE MONITORING SYSTEM.**

The L'Docile system uses the latest technology to provide you with easy and comfortable testing. The system requires only a 0.7  $\mu$ L of blood sample to complete the testing in only 5 seconds.

**The L'Docile system consists of**

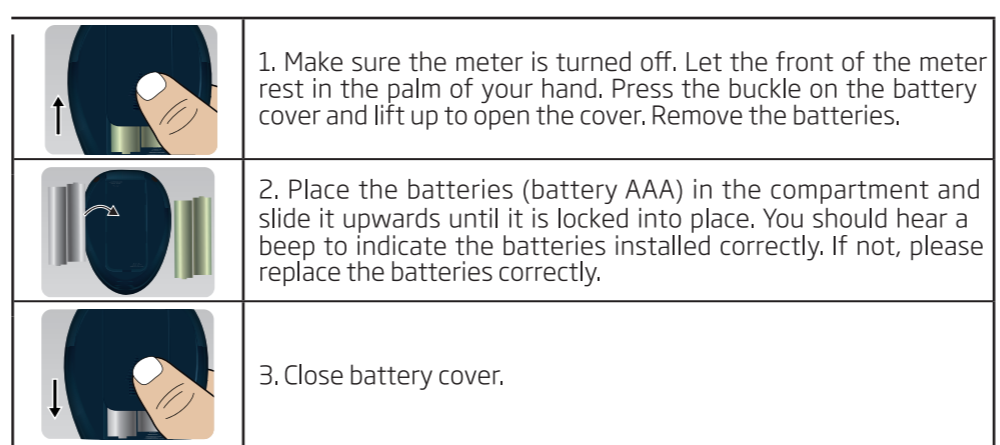
1. L'Docile LBDG02 Blood Glucose Meter
2. L'Docile LBDG02 Blood Glucose Test Strips



**REPLACING THE BATTERY**

1. The meter comes with Two AAA alkaline batteries (3V.D.C.).
2. Battery life will vary depending on usage, so always keep spare batteries on hand. The batteries should last about 1000 tests or 12 months when testing 3 times a day.
3. When the battery symbol appears on the meter display, battery is getting low. You will still be able to test with low battery, but you should replace them as soon as possible.
4. When battery symbol appears together with E-b on the display, the meter will no longer give results and you must replace the batteries immediately. Please always have spare batteries with you to ensure that you can replace the battery anytime.

**HOW TO REPLACE THE BATTERY**



**NOTE:**

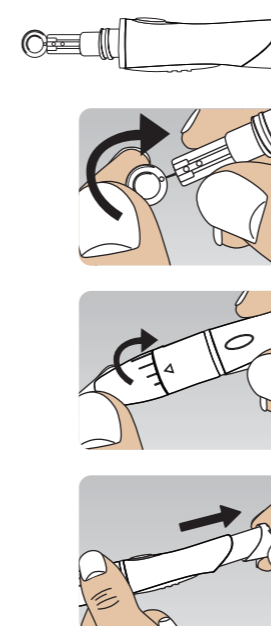
1. Replacing the batteries does not affect the test result stored in memory. However the time and date may need to re-set.
2. As with all small objects, the batteries should be kept away from small children as a safety precaution. If a battery is swallowed, see medical assistance immediately.
3. Batteries might leak chemicals if not used for a long time. Remove the batteries if you are not going to use the device for 3 months or more.
4. Please discard the product or the batteries properly according to the regulations of your country.

**IMPORTANT LANCING DEVICE AND LANCETS INFORMATION**

1. Lancet is for single use only.
2. Keep lancing device and lancets clean.
3. Use caution when removing the used lancet from the device and when disposing the used lancet.
4. The lancing device and lancets are in conformity with MDD 93/42/EEC. Refer to product labels for contact information of manufacturer and CE marking.

**IMPORTANT:** • The meter and lancing device are for single patient use.

- Do NOT share them with anyone including other family members!
- Do NOT use on multiple patients!



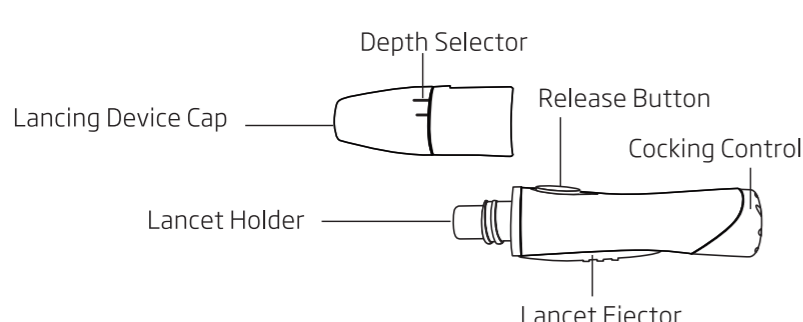
**SETTING YOUR LANCING DEVICE**

1. Screw off the cap of lancing device. Insert a lancet into the lancet holder and push down until it is fully seated.
2. Twist off the protective cap until it separates from the lancet.
3. Replace the lancing device cap and set the puncture depth to the desired number.  
**NOTE: THE DEPTH SELECTOR OFFERS 5 LEVELS OF SKIN**  
 1-2: FOR SOFT OR THIN SKIN    3: FOR AVERAGE SKIN    4-5: FOR THICK OR CALLOUSED SKIN
4. Pull back the cocking control until it makes a click, and then release. If it does not click, the device may have been cocked when the lancet was inserted.

**2. Prepare For Blood Sampling**

**ADJUSTABLE LANCING DEVICE**

Your lancing device and lancets are used for obtaining blood samples from the puncture site.

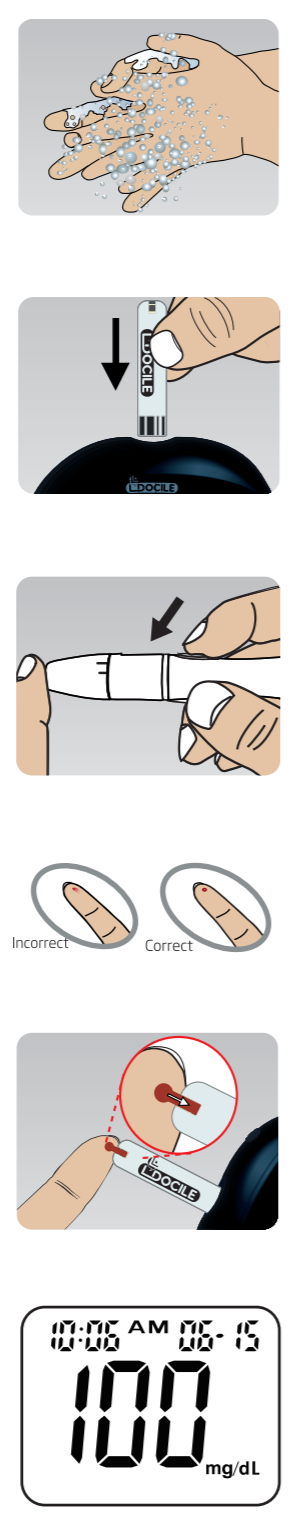


**LANCET**



### 3. Performing Blood Test

- Wash Your Hands and the Puncture Site:** Wash your hands in warm, soapy water. Rinse and dry completely. Warm your fingers to increase blood flow.
- Insert Test Strip:** Remove a new test strip from vial. Be sure to tightly replace vial cap after removing test strips. Insert test strip immediately into strip slot as illustrated. The meter turns on automatically. When the blood symbol blinking, you are ready to perform a test.
- Select and Lance a Puncture Site:** Hold the prepared lancing device firmly against the puncture site. Press release button.
- Obtain a Blood Sample:** Gently massage your finger or puncture site to obtain the required blood volume. To perform the test, you need only 0.7 µL of blood sample. Do not smear the blood sample. To obtain best accurate result, wipe off the first drop of blood and gently squeeze another drop of blood.
- Apply Blood Sample:** Apply the blood sample to the opening of absorbent channel of test strip until the confirmation window is fully covered with blood. Then the meter begins to count down.
- Read Your Result:** The meter will display your blood glucose value after 5 seconds.



- Remove Strip to Turn Meter Off:** Your blood glucose result is automatically stored in the meter memory. Turn the meter off by removing the test strip.
- Secure the Used Lancet:** Twist off the lancing device cap, and push the exposed tip of the lancet into its protective cap.
- Discard the Used Lancet:** Slide the lancet ejector forward and dispose the lancet. Discard the lancet and test strip according to your safety regulations. \*Do not reuse lancets.

### 4. Understanding Your Test Result

The normal blood glucose range is 70 to 105 mg/dL (3.9 to 5.8 mmol/L) for a fasting, non-diabetic adult, but less than 140 mg/dL (7.8 mmol/L) two hours after meals. Consult your healthcare professional to find out your target blood glucose value.

If your blood glucose result seems unusually high or low, or inconsistent with your previous results, check the following:

- Was the blood sample applied immediately to the test strip after removing it from the vial?
- Was the volume of the blood sample sufficient?
- Was the test strip vial cap tightly sealed?
- Was the test strip used before the expiration date?
- Were the test strips stored away from extreme temperatures in very cold or hot weather or from areas of high humidity?

If your blood glucose value is still inconsistent with your previous results, glucose trend, or how you feel, contact your doctor immediately for help.

### 6. Caring For Your Meter And Test Strip

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

**CLEANING**  
Your meter does not require special maintenance. As long as no blood or control solution comes in direct contact with the meter, there is no special cleaning required. To clean the meter 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 meter. Your meter is a precision instrument. Please handle it with care.

**STORAGE**  
**1. Meter Storage**  
\* Storage condition: -20°C~50°C (-4°F~122°F), below 90% relative humidity  
\* Avoid dropping and strong impact.  
\* Avoid direct sunlight and humidity.  
**2. Strip Storage**  
\* Storage condition: 4°C~40°C (39°F~104°F), and 10~85% 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.  
\* You may touch the test strip anywhere with clean, dry hands when removing it from the vial or inserting it into the meter.  
\* Use each test strip immediately after removing it from the vial.  
\* 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 can be a potential choking hazard. If swallowed, please seek medical assistance immediately.

### 7. System Specifications

Model Name	LDBG02
Assay Method	Electrochemical biosensor
Test Sample	Capillary, venous, and artery whole blood
Test Result	Referenced to plasma glucose value
Alternative Site Testing	YES (palm, forearm, upper arm, calf, and thigh)
Sample Size	0.7 µL
Measuring Time	5 seconds
Measuring Range	20 - 600 mg/dL (1.1 - 33.3 mmol/L)
Acceptable Hematocrit Range	20~60%
Operating Condition	10°C~40°C(50°F~104°F), between 10-85% R. H.
Storage/Transportation Condition	4°C~40°C(39°F~104°F), between 10-85% R. H.
Memory Capacity	450 test results with time and date
Average Calculation	7, 14, and 28 days
Power Supply	Two AAA alkaline batteries (3V.D.C)
Battery Life	Approximately 1,000 tests
Automatic shut-off	In 1 minute
Dimensions	80 mm(L)x 58 mm(W) x 23 mm(H)
Weight	58 g

### 5. Memory Recall

The L'Docile LDBG02 automatically stores 450 test results, letting you review them in order from the most recent to the oldest. The meter also calculates and displays 7, 14 and 28-day averages. You can review the individual or average test result by entering the memory mode.

	<b>STEP 1. Enter the Memory Mode</b> While the meter is turned off, press M BUTTON to turn on the meter. When the strip symbol blinks in the display, press M BUTTON again to enter memory mode.
	<b>STEP 2. Recalling Average Test Results</b> When entering the memory mode, the 7-day average will appear. If you continue to press the M BUTTON, the 14-day and 28-day averages will appear in order.
	<b>STEP 3. Recalling Individual Test Results</b> After 28-day average, the most recent test result with date and time will be shown. Press M BUTTON once and the next most recent test result will appear. Each time you press and release the M BUTTON, the meter will recall up to your last 450 test results in order. When the memory is full, the oldest result is dropped as the newest is added. After reaching the last set of result, the meter will turn off automatically.
	<b>STEP 4. Exit the Memory Mode</b> If you want to exit the memory mode before reaching the last result, press and hold M BUTTON for three (3) seconds to turn off the meter.

**NOTE:**

- The list of past results and the result average are for blood glucose results only.
- When using the meter for the first time, "----" is displayed. When you recall the test results or review the average result, it means that there is no test result in memory.
- The averages are calculated from your latest result obtained during the last 7, 14 and 28 days.
- Anytime in memory mode, you can press M BUTTON for three (3) seconds to exit and turn off the meter.
- While in the memory mode, if you leave the meter alone without any action for one (1) minute, the meter will turn off automatically.

### 9. About Alternative Site Testing (Ast)

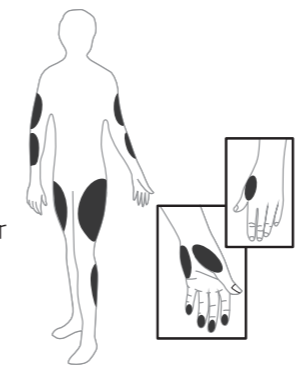
There are important limitations for doing AST. Please consult your healthcare professional before you perform AST.

**WHAT IS AST?**  
Alternative Site Testing (AST) means you can use parts of the body other than your fingertips to check your blood glucose levels. The system allows you to test from the palm, forearm, upper arm, calf or thigh, with equivalent results to fingertip testing.

**WHAT IS THE ADVANTAGE?**  
Fingertips feel pain more readily because they are full of nerve endings (receptors). At other body sites, nerve endings are not so numerous and you will not feel as much pain as you will experience 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, if you are testing blood glucose level during or immediately after meal, physical exercise or stressful event, take the blood sample from your fingertip only.

- USE AST ONLY:**
- 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.
  - During steady state blood glucose conditions. Do NOT use AST if:
    - You have reason to believe you have hypoglycemia or 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 fingertip. When the puncture site was rubbed prior to blood extraction, the difference was significantly reduced.
- IMPORTANT:** To increase the accuracy when using AST, rub the puncture site more than 20 seconds before extracting blood.



### 8. Display Messages And Problem-solving Guide

The 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. In the event of a problem, refer to information under "action to take"

DISPLAY	DESCRIPTION	ACTION TO TAKE
	Display check.	If some parts of the display are not working. Contact your local distributor for help.
	Moving Strip.	The meter is waiting for test strip to be inserted.
	Blinking Blood.	The meter is ready for blood applying into test strip.
	Deleting memory.	Deleting is complete.
	Test result is higher than 600 mg/dL (33.3 mmol/L).	Repeat blood test, if the display still appears, please call medical assistance immediately.
	Test result is lower than 20 mg/dL (1.1 mmol/L).	Repeat blood test, if the display still appears, please call medical assistance immediately.
	Battery is weak.	Replace battery soon.
	Battery is dead.	Replace battery now.
	Maybe: 1. Used strip or moistened strip. 2. defective meter.	You have to: 1. Repeat test with a new test strip. 2. Contact your local distributor for help.
	Temperature is out of the operating range.	The meter is not working. Move to an area with temperature between 10°C to 40°C (50°F - 104°F) and wait at least 30 minutes. Do not artificially heat or cool the meter.
<b>No responses when strip is inserted into the meter</b>	Maybe: 1. Battery is dead. 2. Wrong strip be inserted. 3. Meter is defective.	You have to: 1. Replace battery. 2. Insert the test strip correctly. 3. Contact your local distributor for help.
<b>No responses when blood sample is applied to the strip</b>	Maybe: 1. Blood sample is not sufficient. 2. Meter is defective.	You have to: 1. Repeat test with sufficient sample. 2. Contact your local distributor for help.