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STANDARD™ Mentor
BLOOD GLUCOSE MONITORING SYSTEM

# STANDARD™ Mentor
## BLOOD GLUCOSE MONITORING SYSTEM

Important steps for using the System are inside this guide. Please read it carefully.

If you have questions, we are here to help. Please contact SD Biosensor, Inc.
Tel : +82-31-300-0400 Fax : +82-31-300-0499 website : www.sdbiosensor.com

Please refer to the instructions with following symbols in this User Instruction Guide.

| | | | |
|---|---|---|---|
| CAUTION | To identify conditions or practices that could result in damage to equipment or other property. | NOTE | To provide an additional useful information. |

## CHAPTER 1 : Understanding Your New System

### 1. Before You Start Testing

About the meter and test strips

- Carefully read and follow the instructions in the User Instruction Guide and Package Inserts for the test strips and control solutions. It is very important to follow the instructions in order to prevent an incorrect result or improper treatment.
- The meter, test strips, and control solutions are only for use outside the body (in vitro).
- Your new meter is designed for testing fresh capillary whole blood samples (for example, blood from your fingertip, palm, upper arm, or forearm). Only use STANDARD™ Mentor test strips. Other test strips will give inaccurate results.
- Do not use STANDARD™ Mentor blood glucose monitoring system for testing of serum or plasma or arterial, venous whole blood.
- Inspect the container of test strips before using them for the first time. If you see any damage to the container cap or if anything prevents the cap from closing properly, do not use the test strips. Contact SD Biosensor Customer Care Service Center. Damaged test strips can cause inaccurate results, which could lead to improper treatment.
- Set the beep, date, time, hypo warning, post-meal alarm and alarm on your meter before you begin testing.
- Set the Pre-meal and Post-meal mark on your meter, if you want to display it.
- STANDARD™ Mentor blood glucose monitoring system has been found to be accurate at altitudes up to 12,388 feet. (3,776 meters)

CAUTION

- Keep the meter and testing supplies away from small children.
- The battery door, test strips, lancets, protective disks, and control solution cap are choking hazards.
- Do not eat the test strips.
- Do not swallow or inject control solutions, or use control solutions for any purpose other than testing STANDARD™ Mentor system.

Important Information

- **Low glucose results:** If your test result is lower than 70 mg/dL or is shown as LO, it may mean hypoglycemia(low blood glucose). This may require immediate treatment according to your healthcare professional's recommendations. Although this result could be due to a test error, it is safer to treat first, and then repeat the test.
- **High glucose results:** If your test result is greater than 180 mg/dL or is shown as HI, it may mean hyperglycemia (high blood glucose). If you do not have symptoms, first repeat the test. Your healthcare professional can work with you to decide what actions, if any, you should take if you continue to get results higher than 180 mg/dL or if you have symptoms.
- Consult your physician to determine if it is appropriate for your child to be taught how to use the meter system or any other medical products.

### 2. Intended Use

Your new STANDARD™ Mentor meter and accessories work together to measure the amount of glucose (sugar) in your blood.

Your STANDARD™ Mentor blood glucose monitoring system is indicated for monitoring glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm or upper arm. Your STANDARD™ Mentor meter must be used with only STANDARD™ Mentor blood glucose test strip. Testing is done outside the body(*in vitro* diagnostic use). This system is indicated for home (over-the-counter or OTC) by person with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control. This system should not be used for the diagnosis of diabetes or for testing newborns. When you put a drop of blood onto the test strip, the meter displays a blood glucose result in five seconds. Testing your blood glucose regularly can make a big difference in how you manage your diabetes every day. Discussing your results with your doctors and following their advice about medicine, exercise, and food plans can help you better control your diabetes.
The STANDARD™ Mentor blood glucose monitoring system is suitable for self-testing.

### 3. Product Description and the Principle of the use

STANDARD™ Mentor Blood Glucose test strip is designed with an electrode that measures glucose levels. Glucose in the blood sample mixes with reagent on the test strip that cause a small electric current. The amount of current that is created depends on how much glucose is in the blood.
STANDARD™ Mentor Blood Glucose meter measures the current that is created and converts the measurement to the amount of glucose that is in the blood.
The blood glucose result is displayed on the meter's LCD display.
By touching a drop of blood to the tip of STANDARD™ Mentor Blood Glucose test strip, the strip's reaction chamber automatically draws the blood into the strip through capillary action. When the chamber is full, STANDARD™ Mentor Blood Glucose meter start to measure the blood glucose level. It is a simple and practical system for the daily monitoring of your blood glucose level.

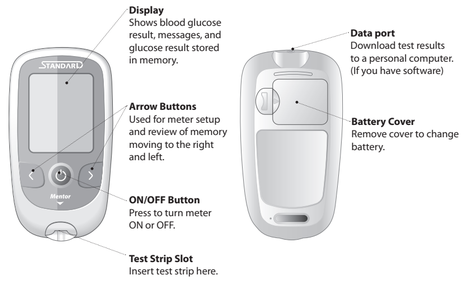
### 4. List of the system

- STANDARD™ Mentor Meter
- STANDARD™ Glucose Check Strip
- 3V battery type CR2032

**<Option>**

- STANDARD™ Mentor Test Strips
- Lancing Device (with a white cap for fingertip testing and a clear cap for Alternative Site Testing)
- Lancet
- STANDARD™ Glucose Control Solution

### 5. STANDARD™ Mentor Meter

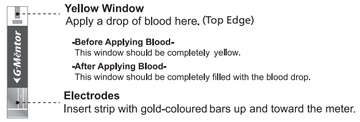



**Display**

| | | | |
|---|---|---|---|
| AM 88:88 | Indicates Measurement time | | Indicates during the meter setting |
| | Indicates beep setting | | Warns when the battery is low or must be replaced |
| | Indicates if environmental temperature is exceeded during testing | | Indicates post-meal or pre-meal |
| 88:88 | Testing date | | Indicates a test result stored in memory |
| mmol/L mg/dL | Unit of test result | 888 | Test result |
| DAY | Indicates the average result | | Test strip |
| | Tells you when to apply the sample and indicates if you select whole blood for blood reference type | C | Indicates a control solution test result |
| | Indicates alarm setting | hypo | Indicates hypo warning |
| | Indicates S/W communication | | |

### 6. STANDARD™ Mentor Test Strip

STANDARD™ Mentor Blood Glucose Monitoring System measures the amount of glucose in whole blood. Blood is applied in the Yellow Window (TOP EDGE) of the STANDARD™ Mentor Test Strip and is automatically drawn into the reaction cell where the reaction takes place.

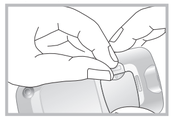



### 7. Changing the Battery

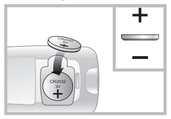
Inserting and replacing the Battery

Your meter is shipped with one 3V battery type CR2032 that needs to be inserted before testing. The battery that comes with your meter can be found in the mesh pocket of your carrying case. Battery life will vary depending on usage, so always keep a spare on hand. The meter saves battery power by automatically turning off after 1 minute without inserting a test strip or 3 minutes with a test strip, from non-use. If the meter does automatically shut off, all tests in memory are saved.

**STEP-1:** Push the recessed plastic tab of the battery compartment forward to flip and open the battery door.



**STEP-2:** Insert the 3V battery (type CR2032) into the compartment with "+" side facing you.



**STEP-3:** Snap battery cover back in place.

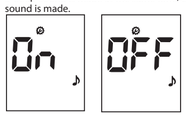
**STEP-4:** Push the ON/OFF button or insert a strip to start testing.

NOTE After inserting or replacing the battery, confirm that the time and date are set correctly. If they are not, use the ON/OFF and left/right buttons to reset the meter before testing. See the "8. Meter Set up".

### 8. Meter Set up

**STEP-1: Setting the Audible Beep**

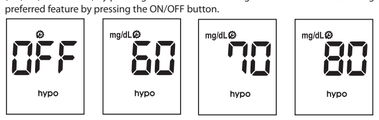
1. In Strip Stand-by Display, if you press the ON/OFF button during 3 seconds, the display for setting the beep will appear, the first step of the setting mode.
2. Set the beep mode on or off by pressing either the left or the right button and then selecting the preferred feature by pressing the ON/OFF button. If you select the beep on feature, a 'beep' sound is made at the same time; otherwise, if you select the beep off feature, no sound is made.



**STEP-2: Setting the Hypo warning**

NOTE
- You can set the meter to let you know when your result indicates a possible low blood glucose (hypoglycemia). You can also select what blood glucose level you want this indicator to have 60, 70, 80 mg/dL(3.3, 3.9, 4.4 mmol/L).
- If your results are lower than selected hypo result, the candy symbol will appear on LCD with a 'beep' sound. It is very important to manage your hypoglycemia.

1. After beep setting, the display for setting the hypo warning will appear, the second of setting mode.
2. Set the hypo warning mode 'off' or the result you want to select among 60, 70, 80 mg/dL (3.3, 3.9, 4.4 mmol/L) by pressing either the left or the right button and then selecting the preferred feature by pressing the ON/OFF button.

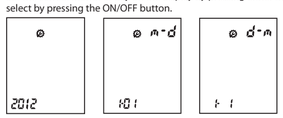


NOTE Your new meter comes with a preset time and date. You may need to change the time to your time zone. Having the right time and date in your meter is important if you use the meter memory. It also helps your healthcare team interpret your results.

**STEP-3: Setting the date and time**

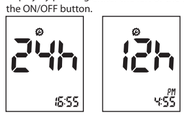
**[ Date Setting ]**

1. The third step of setting mode is the Date & Time setting. After setting the hypo warning, the display for setting Date & Time will appear, the third step of the setting mode. Set the correct year by pressing either the left or the right button and then select the correct year by pressing the ON/OFF button.
2. Next will appear the setting display for month and day format. The meter can display the month and day in either a Month-Day (m-d) format or a Day-Month (d-m) format. Set the preferred format on the display by pressing either the left or the right button and select by pressing the ON/OFF button.
3. Set the correct month or day on the display by pressing either the left or the right button and select by pressing the ON/OFF button.



**[ Time Setting ]**

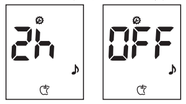
1. Next, the display for setting the 12 or 24 Hour clock format will appear. The meter can display the time in either the 12h format or the 24h format. Set the preferred format on the display by pressing either the left or the right button and select by pressing the ON/OFF button.
2. Next, the setting display for time format will appear. Set the correct hour and minute on the display by pressing either the left or the right button and select the correct time by pressing the ON/OFF button.



**STEP-4: Post-meal alarm**

You can use the meter's post-meal alarm function to remind you to test your blood glucose after meal.

1. After day and time setting, the display for setting the post-meal alarm will appear, the fourth of setting mode.
2. Set the post-meal alarm mode '2h' or 'off' by pressing either the left or the right button and then select the preferred feature by pressing the ON/OFF button.



NOTE
- If you select the post-meal alarm '2h' feature and test with pre-meal mark, the 'clock symbol' will appear on result display and the 'beep' sound will be made in 2 hours to remind you to test your blood glucose after meal for 1minute.
- If you perform the pre-meal test while the post-meal alarm setting is on, then the post-meal mark will appear automatically on your LCD when you test within following period: from 30min to 130min after your pre-meal test.
- If you mark the new test result with a pre-meal mark, the old alarm setting will be ignored and only the new setting will sound in 2 hours.

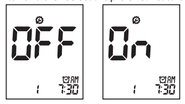
**STEP-5: Setting the alarm**

You can use the meter's alarm function to remind you to test your blood glucose.

1. After Post-meal alarm setting the display for setting the alarm will appear, the fifth of setting mode.
2. Set the first alarm on or off by pressing either the left or the right button and then select the preferred feature by pressing the ON/OFF button.

NOTE
- If you select the alarm off feature, next will appear the Strip Stand-by Display.
- If you select the alarm on feature, you can set the alarm up to four times a day at any time you want.

3. If you select the alarm on feature in first alarm mode, the clock will blink. Set the correct time and minute you want to set an alarm on the display by pressing either the left or the right button and then select the preferred feature by pressing the ON/OFF button.



NOTE If you select the alarm off feature in first (also second, third and fourth) alarm mode, next will appear the Strip Stand-by Display.

4. If you finish setting the first alarm, the second alarm setting mode will appear. Set the alarm with the same way as above. [2, 3]
5. You can set the third and fourth alarm mode with the same way as above. [2, 3]
6. If you finish setting the last alarm, the Strip Stand-by Display, will appear.

### 9. Precaution

**[Meter]**

- Keep the test strip slot free of dust.
- Protect the internal meter from humidity.
- The carrying case is designed to let you store a variety of supplies you may need and helps to protect your meter.
- If you keep the meter with the battery inserted, then keep it in a low humidity environment.

**[ Test Strip ]**

- STANDARD™ Mentor blood glucose test strip should be used with STANDARD™ Mentor meter. Using other glucose test strip can cause inaccurate the result.
- After removing a test strip from the container, replace the container cap immediately and close it tightly.
- Use the test strip within three minutes after you take it out of the container.
- Store test strip containers in a cool, dry place at 2-32°C(36-90°F). Keep away from direct sunlight and heat. Do Not refrigerate test strips.
- Do not expose strips to heat, moisture or humidity. Temperatures outside the required range, as well as moisture and humidity (e.g. bathroom, kitchen, laundry room, car, or garage) can damage your test strips and lead to inaccurate results.
- Store test strips in their original container only to avoid damage or contamination. Do Not transfer test strips to any other storage device, and do not store outside of their original container.
- Do not use test strips from any container that is damaged or left open to air.
- Write the opening date on the container label when you first open it. Discard remaining STANDARD™ Mentor Test Strips after the discard date (6 months after first opening from the container).
- Do not use test strips beyond the expiration (printed on package) or discard date, whichever comes first, because they may cause inaccurate results.
- STANDARD™ Mentor Test Strips are for single use only. Never reuse a test strip that has had either blood or control solution applied to it.
- Avoid getting dirt, food or liquids on the test strip. With clean, dry hands, you may touch the test strip anywhere on its surface.
- Do not bend, cut, or alter STANDARD™ Mentor Test Strip in any way.
- Refer to additional information in STANDARD™ Mentor Test Strip package insert.
- Not following these precautions can lead to inaccurate results.
- After pulling out the test strip from its container, close a container cap of the test strip immediately.
- The test strip container closes tightly and can protect the test strips, so you should keep the unused test strips in the container in which they came.

**[ Lancet and Lancing device]**

- The needle of lancet is sharp, keep the lancet away from children.
- Keep the lancet and lancing device dry and do not store in direct sunlight, or high heat and humidity locations.
- A lancet should not use for the other intended use except sampling blood.
- A lancet is for single use only. Do not reuse.
- Before using, check a packaging condition, if there is any problem, you should not use it.
- If a lancet protective disk is loosed or needle of a lancet is exposed, you should not use it.
- To reduce the chance of infection for the used lancet, discard it.

**[Control solution]**

- Keep STANDARD™ Glucose control solution in 8-30°C (46-86°F) environment.
- Do not refrigerate or freeze.
- Do not use STANDARD™ Glucose control solution that has passed the expiration date.
- STANDARD™ Glucose control solution can be used for 3 months after opening the container. Write the opened date on STANDARD™ Glucose control solution container when you first opened.
- No reconstitution or dilution is necessary.
- Wipe the container tip clean and reseal the container tightly after each use.

## CHAPTER 2 : Control Solution Test

**Why you do control solution test ;**

- STANDARD™ Glucose Control Solution is used to check that the meter 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 an accurate result.

**When you use Control solution ;**

- You open a new box test strips.
- You left the test strip container open or you think your test strips have been damaged.
- Your test strips were stored in extreme temperatures and/or humidity.
- You want to check the meter and test strips.
- You dropped the meter.
- Your test result does not agree with how you feel.
- You want to check if you are testing correctly.

**Before you begin ;**

- Use only STANDARD™ Glucose Control Solution.
- Check the expiration date on the control solution container. Record the opening date on the container label. Do Not use after expiration or discard date (date opened plus three months), whichever comes first.
- Control solution, meter, and test strips should be at room temperature 18-30°C (64-86°F) before testing with control solution.
- Shake the container, discard the first drop of control solution, and wipe off the tip to ensure a proper sample and an accurate result.
- Store control solution tightly closed at temperatures between 8-30°C (46-86°F). Do Not refrigerate.

CAUTION
- Do not swallow STANDARD™ Glucose control solution; it is not for human consumption.
- Do not apply STANDARD™ Glucose control solution to the skin or eyes as it may cause irritation.

### 1. Performing a Control Solution Test

You need the meter, a test strip, and control solution Level M or Level H. The control level is printed on the test strip label.

NOTE A set of Level M and H control solutions is available for purchase. To order control solutions, talk to your pharmacist or medical surgical supply dealers. Your meter is designed to recognize the difference between the STANDARD™ Glucose Control Solution and blood. The meter automatically stores the test results using a control solution, letting your review them. But the meter does not included them in averages.

For more information how to obtain STANDARD™ Glucose Control Solution, call at +82-31-300-0400.

**STEP-1:**

1) Remove a new test strip from container. Be sure to tightly replace container cap after removing test strip.
2) Insert a test strip (yellow window printed arrow symbol facing up) into test strip slot. The meter turns on automatically.

**STEP-2:**

1) Press the left button for 3 seconds to check the testing system using a control solution in Blood Stand-by Display. If you don't want a control solution check, press the left button again.
2) Shake the control solution container and discard the first drop of solution. Gently squeeze the container to form one small drop. Bring the drop to the edge of the strip, and allow the strip to automatically draw the control solution into the yellow window. When control solution is applied to the test strip, the meter counts down from 5 to 1 second on the display. Tightly replace the cap on control solution.

3) The control solution result appears on the display in just 5 seconds.
4) Compare control solution result to the range printed on the test strip container. If the results are not within the control range printed on the test strip container, then the meter and strips may not be working properly. Repeat the control solution test.

The control solution range printed on the test strip container is for STANDARD™ Glucose Control Solution only. It is not a recommended range for your blood glucose level.

[Example]

| Control Range | |
|---|---|
| Level M | Level H |
| 90-140 mg/dL | 170-240 mg/dL |
| 5.0-7.8 mmol/L | 9.4-13.3 mmol/L |

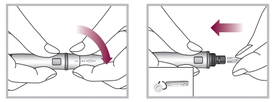
[This is an example. Refer to the ranges on your test strip container.]

5) Remove the used test strip for control solution from the meter and discard it.

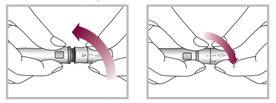
## CHAPTER 3 : Testing Your Blood Glucose

### 1. Getting a Drop of Blood

1) Wash your hands in warm, soapy water. Rinse well and dry completely. Warming fingers can increase blood flow.
2) Turn the lancet insert cap counterclockwise to remove it, insert the lancet into the lancing device holder and push down firmly until it is fully seated. Twist the lancet protective disk until it separates from the lancet.



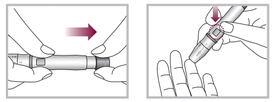
3) Replace the cap and turn it clockwise, until it is snug. Adjust the puncture depth setting by turning the comfort dial. The dial has 1 to 5 steps, and the higher the step number, the stronger the blood sampling pressure on the puncture site.



The comport tip offers 5 different levels of skin penetration.

- 1-2 : for soft or thin skin
- 3 : for average skin
- 4-5 : for thick or callused skin

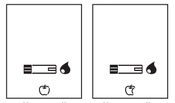
4) After cocking the lancing device back, hold the lancing device firmly against the side of finger and then press the release button.



CAUTION
- A lancet should only be used once. DO NOT share used lancets with another person. To prevent possible infection, a used lancet should not be touched by another person.
- Dispose of used lancets in accordance with local regulatory guidelines and in a safe manner, so as not to cause accidental injury.

### 2. Performing Blood Glucose Test

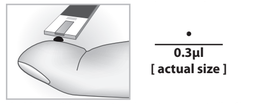
1) Remove a new test strip from container. Be sure to tightly replace container cap after removing test strip.
2) The meter turns on by two methods. First method is that press the ON/OFF button and second method is that insert the test strip into test strip slot in power off state, the meter turns on automatically. In second case, you don't need to press the ON/OFF button of the meter to turn it on.
3) When the blood drop symbol flashes (Blood Stand-by Display), you are ready to perform a test.
4) Before you perform a test, you can display the symbols that indicate post-meal or pre-meal mark by pressing the right button one or two times.


[Pre-meal]


[Post-meal]

CAUTION If you perform the pre-meal test while the post-meal alarm setting is on, then the Post-meal mark will appear automatically on your LCD when you test within following period: from 30min to 130min after your Pre-meal test.

5) Let your arm hang down at your side to allow blood to flow to your fingertips. Grasp your finger just below the joint closest to the fingertip.
6) Obtain a drop of blood sample using the lancet and lancing device.
7) Hold your finger to the tip of the strip until the yellow window is completely filled with blood. Do not place the blood drop on top of the strip.



0.3µl
[ actual size ]

8) The blood will be drawn into the strip automatically. If beeper is turned on, meter will beep to let you know the test is beginning.
9) When blood is applied to the strip, the display counts down from 5 to 1 second and your result appears on the display in just 5 seconds.
10) The blood glucose result is displayed in mg/dL or mmol/L.
11) When the test is done, pull out the used test strip. The meter shuts off automatically in 5 seconds after you remove the test strip.

NOTE
- Dispose the used test strip as per your local guidelines.
- Remove the inserted lancet from the lancing device and dispose the used lancet according to local guidelines.
- Always use fresh capillary whole blood on meter tests.

### 3. Alternative Site Testing (AST)

**Important Information About AST**

Sites other than your fingertip may have fewer nerve endings so obtaining a blood sample from these sites may be less painful. The technique for Alternative site testing is different from fingertip testing. Blood glucose results from sites other than your fingertip could be significantly different due to blood glucose levels changing rapidly after a meal, insulin, or exercise.

Consult with your diabetes healthcare professional prior to testing from a site other than your fingertips.

Results obtained from sites other than the fingertip may differ significantly as is the case with all blood glucose monitoring systems. Rapidly changing results are likely to occur after eating. Insulin dosing and physical activity are shown in the fingertip more quickly than in Alternative sites.

**Consider Alternative Site Testing When ;**

- Testing before a meal
- You are in a fasting state
- Two hours have passed since a meal
- Two hours have passed since insulin dosing
- Two hours have passed since physical activity

**Use Fingertip Testing ;**

- Within two hours after a meal
- Within two hours after insulin dosing
- Within two hours after physical activity
- If you have a history of hypoglycemia, are experiencing low blood glucose, or suffer from hypoglycemic unawareness (you cannot tell when you have low blood glucose)
- During times of stress or illness

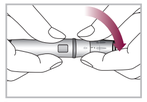
Ask your diabetes healthcare professional about recommended testing procedures. When operating machinery or driving a car, as fingertip test is usually the preferred method of testing under these circumstances. If bruising occurs, you may choose to lance a fingertip instead.

**Preparing to Test Your Blood Glucose From an Alternative Site**

**Choose a Site**
Select a soft, fleshy area on the palm, forearm, or upper arm that is free of visible veins, moles, and hair and away from bone.

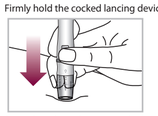
**Prepare Your Lancing Device**
We recommend using the STANDARD™ Lancing device with the clear end cap when testing from alternative sites other than the fingertip. To order an AST lancing kits containing the lancing device, lancets and instruction, please call +82-31-300-0400.

**Performing a Blood Glucose Test From an Alternative Site**
**STEP-1**
Put the AST cap on the top of lancing device. And then insert lancet and cock lancing device.

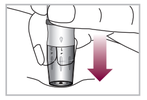


**STEP-2**
The meter turns on by two methods.
First method is that press the ON/OFF button and second method is that insert the test strip into test strip slot in power off state, the meter turns on automatically. In second case, you don't need to press the ON/OFF button of the meter to turn it on.

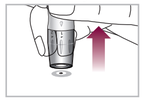
**STEP-3**
1. Press and vigorously rub the selected area for 10 seconds until it starts to feel warm to the touch.
2. Wash the area with warm, soapy water. Rinse and dry completely. If you use alcohol wipes to cleanse the site, make sure that the area is dry before lancing the site.
3. Firmly hold the cocked lancing device against the clean skin for 5-10 seconds.



4. Press the release button on the lancing device to lance the skin. Continue to hold the lancing device firmly against the skin until a blood drop forms.



5. Once a large enough drop of blood has formed, remove the lancing device.



**STEP-4**
Pick up the meter and touch the end of the test strip to the blood sample until the reaction site is full. Immediately remove the meter and test strip from the blood drop.

**IMPORTANT :** Insert strip vertically into blood sample, not at an angle.

**STEP-5**
The meter will count down and display result in 5 seconds.

**Consider your result. Repeat Alternative site test ;**
- If the blood sample appeared to be diluted with clear fluid.
- If you did not vigorously rub the test site.
- If the blood drop was not large enough to fill the reaction site.
- If the test was accidentally marked as a "Control" result.
- If your result was not consistent with how you feel.
- If more than 20 seconds elapsed from sample collection to measurement. (evaporation of the blood sample may cause a test result that is higher than the accurate value.)

Any of the above situations can lead to an inaccurate test result.
If the repeated Alternative site result is still not consistent with how you feel, confirm your blood glucose level with fingertip testing.

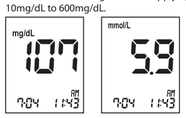
**STEP-6**
Always record your results in your self-test diary along with other information such as insulin dosage, diet, and exercise. The result is automatically stored in memory with the time and date.

**STEP-7**
Remove the test strip and dispose of it in accordance with local guidelines or as directed by your health-care professional. The meter shuts off automatically when the test strip is removed.

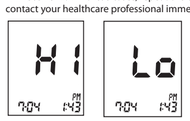
### 4. Understanding Test Results

**Your test results**

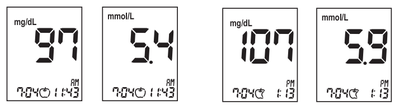
1. After 5 seconds testing time from applying a blood into strip, you will receive a normal result, 10mg/dL to 600mg/dL.




2. If your blood glucose is above 600 mg/dL, you will receive a "HI" and is below 10 mg/dL, you will receive "Lo". In these cases, repeat the test with new test strip. If this massage show again, contact your healthcare professional immediately.




3. If you set the pre-meal mark before test, you will receive a result with pre-meal mark. ( )
4. If you set the post-meal mark before test, you will receive a result with post-meal mark. ( )




**CAUTION** If you perform the pre-meal test while the post-meal alarm setting is on, then the post-meal mark will appear automatically on your LCD when you test within following period: from 30min to 130min after your Pre-meal test.

**Normal Blood Glucose Readings**
The normal fasting blood glucose range for an adult without diabetes is 74 - 106 mg/dL.[2]
Two hours after meals, the blood glucose range for an adult without diabetes is less than 140 mg/dL.[1]

**What This Means For You**
Frequent blood glucose testing is the best means to track how well you are doing with your diabetes management. It helps you track the effects of medications, diet, exercise, and stress management. Blood glucose test results can also tell you if your diabetes is changing. This may alert you to adjust your treatment plan. Always consult your healthcare professional before making any adjustments.

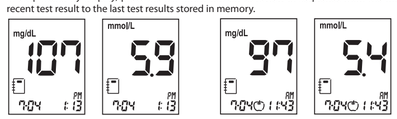
**Frequency of Testing**
Work with your healthcare professional to decide when and how often to test. This will depend on such things as age, type of diabetes, and medications. It is important to make testing part of your daily routine.

## CHAPTER 4 : Using the Meter Memory

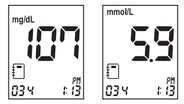
The meter automatically stores about 500 glucose results, letting your review them in order from the most recent to the oldest. If you have set the time/ date feature, the time and date of the results are also displayed. If the memory is full and a new result is added, the meter deletes the oldest result.
The meter also calculates three kinds of 7, 14 and 30-day averages of test results stored in memory, 1)normal, 2)pre-meal and 3)post-meal state averages. You do not need to set the time and date for the meter to give you average calculations. HI/Lo result (results outside of the meter's reading range) and results with control solution symbol are not included in averages.

### 1. Searching Test Results

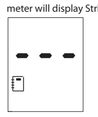
1) In Strip Stand-by Display, press the left arrow button to review in sequence from the most recent test result to the last test results stored in memory.



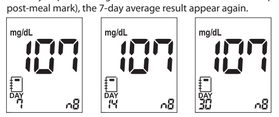

2) After the result with date and time display for 1 second, the date will change into the appropriate memory number automatically.



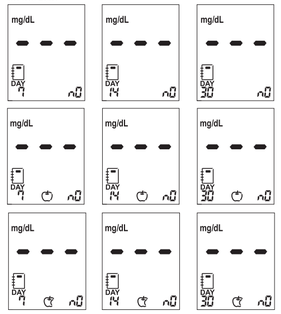

3) If there aren't the stored test results, the following display appears for 1 sec., and then the meter will display Strip Stand-by Display automatically.



4) In Strip Stand-by Display, press the right arrow button to review three kinds of 7,14 and 30 day averages of test result stored in memory in sequence. (normal, pre-meal and post-meal state) You can also review the number of results at each average in the right bottom of the LCD window. If you press the right arrow button once more after displaying the 30 day average(with post-meal mark), the 7-day average result appear again.




5) If there aren't any stored 7, 14 and 30-day average of test results, following display will appear on the LCD.




**NOTE** You cannot search the stored test results and average of results in the meter, if a test strip is inserted in the meter, Blood Stand-by Display. After removing the test strip from the meter, you can search the test results and average of results stored in memory by pressing the left or the right button.

### 2. Downloading results to a computer

You can use your meter with STANDARD™ Diabetes Management Software to store your records and to help you spot patterns for planning meals, exercise, and medication. STANDARD™ Diabetes Management Software puts information downloaded from the meter into charts, diagrams and graphs.

1) Obtain the STANDARD™ Diabetes Management Software and STANDARD™ Communication Cable.
2) Install the software on a personal computer. Please refer to Software Product Manual.

**NOTE**
- While the meter is connected to the PC, it is unable to perform a blood glucose test.
- For downloading STANDARD™ Diabetes Management Software and Software Product manual(both are free of charge), please visit www.sdbiosensor.com.
- For ordering Software Communication Cable, please contact our representative.
- For more information, please refer to Software Product Manual. If the cable port got ESD while downloading data, time delay, a few seconds, may be happened. After a while, the meter retransmit data automatically.
- STANDARD™ Diabetes Management Software is intended for professional use only.

## CHAPTER 5 : Maintenance and Troubleshooting

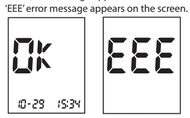
### 1. Performing the Check Strip Test

**When you use a check Strip for checking your meter?**
- When you want to easily check the performance of the meter.
- Before using your meter for the first time.
- Whenever your result does not agree with the level you feel
- If you have repeated a test and the blood glucose result is still lower or higher than expected.

**CAUTION**
- The Check Strip test does not replace the Control Solution test.

**How to Use STANDARD™ Glucose Check strip**
1. Insert a Check Strip (facing up 'check strip' printed in arming knob) into test strip slot. The meter turns on automatically.
2. If the Check Strip is inserted properly, the meter will start the check.

3. The check result appears on the screen in just 5 seconds. If there isn't any problem for the meter, 'OK' message appears on the screen. Otherwise, there is some problem for the meter, 'EEE' error message appears on the screen.




[ 'OK' Message ] [ 'EEE' Error Message ]

### 2. Cleaning the meter

Caring for the STANDARD™ Mentor meter is easy. Just keep it free of dust. If you need to clean it, follow these guideline carefully to help you get the best performance possible;

To prevent malfunction of the meter, keep the test strip port free of blood, moisture, dirt, or dust. Use a lint-free cloth dampened with water to clean meter. Thoroughly wring out cloth before use. Do not use an abrasive cloth or antiseptic solution, as these may damage the display screen.

### 3. Maintenance, Testing and Transportation

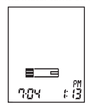
The meter needs little or no maintenance with normal use. It automatically tests its own systems every time you turn it on and lets you know if something is wrong. If you drop the meter or think it is not giving accurate results, make sure that your test strips and control solution haven't expired, and then run a control test.

### 4. Cleaning the Lancing Device

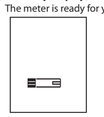
Clean the outside of the STANDARD™ lancing device regularly with 70% isopropyl (rubbing) alcohol. Do not place the entire device under water. Do not use bleach. At least once a week, disinfect the cap after cleaning by placing it in 70% rubbing alcohol for 10 minutes. Allow the cap to air-dry after disinfecting.

### 5. Screen Messages and Troubleshooting Message Description

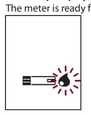
- The meter turns on normally.



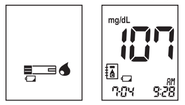
**[Strip Stand-by Display]**
- The meter is ready for you to insert a test strip.



**[Blood Stand-by Display]**
- The meter is ready for a drop of blood.



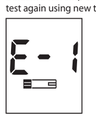
**[Low battery]**
- At this time, battery is getting low but you can still perform about 50 tests. Replace the battery soon. See Chapter 1 "7. Changing the Battery".



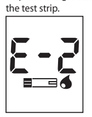

**[Replace battery]**
- Battery power is low. Replace the battery immediately. See Chapter 1 "7. Changing the Battery" If you press the ON/OFF button after discharging of the battery, the battery icon will flash and then after ten seconds the meter will turn off automatically.

**[Internal Error Message for a meter]**
- Turn off a meter. Then turn on the meter again. If there is still error massage, please contact SD Biosensor, Inc. TEL: +82-31-300-0400.


**[Strip Error]**
- Defective test strip or the test strip is damaged or inserted improperly. Discard this test strip and test again using new test strip.




**[Blood Sample Error]**
- An insufficient amount of blood was applied. Discard this test strip and test again using new test strip and a larger sample, making sure blood is placed to the narrow channel in the top edge of the test strip.




**[Temperature Error]**
- If the environmental temperature is above or below the operating range of a meter, a thermometer icon will appear on the display. Move to an area between 10-45°C (50-113°F), wait for 30 minutes, and perform a test. Do not artificially heat or cool the meter.


**[Communication Error]**
- The communication between meter and computer is failed. Connect again between meter and PC.


### 6. Warning and Limitation

- Never make significant changes to your diabetes control program or ignore physical symptom without consulting with your healthcare professional.
- Severe dehydration (excessive water loss) may cause false low results. If you believe you are suffering from dehydration, consult your healthcare professional right away.
- Do not use this device to measure blood glucose in people who are experiencing cardiovascular collapse (severe shock) or decreased peripheral blood flow.
- Extremes in hematocrit may affect test results. Hematocrit levels less than 20% may cause falsely high readings. Hematocrit levels greater than 60% may cause falsely low readings.
- 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.
- Normal endogenous (within body) natural levels of uric acid, ascorbic acid (vitamin C), bilirubin, triglycerides, and hemoglobin do not interfere with your blood glucose results obtained.
- Externally taked drugs L-dopa, dopamine, methyl-dopa, acetaminophen, and ibuprofen will not interfere with STANDARD™ Mentor blood glucose results when taken at therapeutic concentrations.
- Interferences : The following compounds, elevated levels of ascorbic acid, uric acid, acetaminophen, total bilirubin and triglycerides may affect results.

| Material | Limitation |
|---|---|
| Acetaminophen | > 6mg/dL |
| Ascorbic Acid | > 4mg/dL |
| Bilirubin | > 40mg/dL |
| Total cholesterol | > 506mg/dL |
| Creatinine | > 30mg/dL |
| Dopamine | > 5mg/dL |
| EDTA | > 0.1mg/dL |
| Galactose | > 60mg/dL |
| Gentisic Acid | > 1.8mg/dL |
| Glutatione | > 0.46mg/dL |
| Hemoglobin | > 200mg/dL |
| Pralidoxime Iodide | > 1.3mg/dL |
| Heparin | > 3,000U/L |
| Ibuprofen | > 50mg/dL |
| Levodopa | > 4mg/dL |
| Maltose | > 60mg/dL |
| Methyl-Dopa | > 2mg/dL |
| Sodium Salicylate | > 20mg/dL |
| Tolazamide | > 8.4mg/dL |
| Tolbutamide | > 4mg/dL |
| Triglycerides | > 1,026mg/dL |
| Uric Acid | > 9mg/dL |
| Xylose | > 60mg/dL |

- STANDARD™ Mentor System is not designed to be a substitute for pathology laboratory equipment and should not be used for the diagnosis of diabetes.
- Use only fresh capillary blood. Do not use serum or plasma or venous whole blood.
- Do not use STANDARD™ Mentor meter to test neonates. It has not been validated for neonatal use.
- Always insert the test strip into the meter first, and then prick the finger.

## CHAPTER 6 : Product Technical Information

| | |
|---|---|
| **Result Range** | 10 - 600 mg/dL (0.6 - 33.3 mmol/L) |
| **Calibration** | Plasma-equivalent |
| **Sample** | Fresh capillary whole blood |
| **Sample Size** | 0.3 microliter |
| **Test Time** | 5 seconds |
| **Assay Method** | Glucose Oxidase Biosensor |
| **ON/OFF Source** | One replaceable 3 V Lithium Battery type CR2032 |
| **Battery Life** | Around 1,000 tests |
| **Glucose Unit** | mg/dL , mmol/L |
| **Display** | LCD (Customized) |
| **Controls** | 3 Buttons |
| **Size** | 50 mm × 93 mm × 18 mm |
| **Weight** | 50g (with battery) |
| **Automatic Shutoff** | • 1 minutes after last user action without inserting test strip into the meter<br>• 3 minutes after last user action when inserting test strip into the meter |
| **Memory** | 500 blood glucose tests |
| **Function** | - Hypo warning : 60, 70, 80 mg/dL (3.3, 3.9, 4.4 mmol/L)<br>- Pre-meal and post-meal mark<br>- Alarm setting (up to 4 times)<br>- Post-meal Alarm<br>- 7-, 14- and 30-day Averages of the following results<br>1)Normal Results<br>2)Pre-meal Results<br>3)Post-meal Results<br>- Automatic shutoff |
| **Operation Temperature** | 10°C - 45°C (50°F - 113°F) |
| **Operation Altitude** | Up to 12,388 feet. (3,776 meters) |
| **Test Strip Storage Temperature** | 2°C – 32°C (36°F – 90°F) |
| **Meter Storage & Transport Condition** | -20°C - 50°C (-4°F - 122°F) and 10% - 93% RH |

**Electromagnetic Compatibility**
This meter meets the electromagnetic immunity requirements as per EN ISO 15197 Annex A. The chosen basis for electrostatic discharge immunity testing was basic standard IEC 61000-4-2. In addition, it meets the electro -magnetic emissions requirements as per EN 61326. Its electromagnetic emission is thus low. Interference from other electrically driven equipment is not to be anticipated.


**Annex 1 : References**
1. American Diabetes Association, Clinical Practice Recommendation Guidelines 2003, Diabetes care, Vol. 26, Supplement 1. p.22
2. Stedman, TL, Stedman's Medical Dictionary, 27th Edition, 1999, p. 2082
3. Ellen T. Chen, James H. Nichols, Show-Hong Duh, Glen Hortin, MD: Diabetes Technology & Therapeutics, Performance Evaluation of Blood Glucose Monitoring Devices, Oct 2003, Vol. 5, No. 5 : 749 -768


**Return**
You must contact SD Biosensor Customer Service at +82-31-300-0400 before returning your meter. You will be instructed how to return the meter to SD Biosensor, Inc. Returned meters without this authorization will not be accepted.



REF - Catalogue number (Reference number) | IVD - In vitro diagnostic medical device | Consult instructions for Use | Caution | Temperature limit | CE 0123 - This product fulfills the requirements of Directive 98/79/EC on in vitro Diagnostic medical device | Use-by date | LOT - Batch code | Manufacturer | Date of manufacture | Disposal of Waste Electrical and Electronic Equipment | EC REP - Authorized representative in the European Community | CR 2032 battry (3V)