Dear SD CodeFree™ System Owner;

Thank you for choosing the SD CodeFree™ Blood Glucose Monitoring System. Your new SD CodeFree™ Blood Glucose Monitoring System is an important tool that can help you better manage your diabetes. 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
webside : www.sdbiosensor.com

We offer assistance 24 hours a day, 365 days a year in many languages. You can also visit www.sdbiosensor.com for diabetes management tools and product demonstrations.

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

⚠️ CAUTION	Identifies conditions or practices that could result in damage to the equipment or other property.	📝 NOTE	Provides additional useful information.

📝 **NOTE**

Before using this product to test your blood glucose, read all instructions and practice the test. Perform all quality control checks as directed and consult with a diabetes health care professional. These recommendations apply to all blood glucose monitoring systems and are supported by the American Association of Diabetes Educators, the American Diabetes Association, the U.S. Food and Drug Administration, and the Advanced Medical Technology Association.

TABLE OF CONTENTS

TABLE OF CONTENTS

3

CHAPTER 1 :
Understanding Your New System

The SD CodeFree™ Blood Glucose Monitoring System

1. Before You Start Testing

About the meter and test strips

- **It is very important to carefully read and follow the instructions in order to prevent an incorrect result or improper treatment. It is advisable to read all the pages before using the meter. The detailed instructions commence with "Inserting the Battery" on page 17.**
- 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 SD CodeFree™ test strips. Other test strips will give inaccurate results.
- Do not use the SD CodeFree™ 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 the SD Biosensor Customer Care Service Center. Damaged test strips can cause inaccurate results, which could lead to improper treatment.

About your new meter
- You will be first setting the beep, date, time, hypo warning and alarm on your meter before you begin testing.
- You will also be able to set the Pre-meal and Post-meal mark on your meter, if you want to do so.
- This meter has a pre-set unit, mg/dL or mmol/L, for your Country. It cannot be changed.
- The SD CodeFree™ 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 swallow or inject control solutions, or use control solutions for any purpose other than testing the SD CodeFree™ system.

Important Information
- **Dehydration:** Severe dehydration resulting from excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.
- **Low glucose results:** If your test result is lower than 70 mg/dL (3.9 mmol/L) or is shown

Understanding Your New System

5

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 than180 mg/dL (10 mmol/L) 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 (10 mmol/L) or if you have symptoms.

- **Repeated unexpected results:** If you continue to get unexpected results, follow the instructions on PAGE 60 "Performing an SD Check Strip Test". If this shows no errors you should have the unit checked by your medical professional who can use a Control Solution to check the veracity of the results given(See pages 31-37). If you are experiencing symptoms that are not consistent with your blood glucose results and you have followed all instructions in this User Instruction Guide, call your healthcare professional. Never ignore symptoms or make significant changes to your diabetes control program without speaking to your healthcare professional.

- 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. Special Information for Healthcare Providers and Carers

• Do not use this device to measure blood glucose in people who are experiencing cardiovascular collapse (severe shock) or decreased peripheral blood flow.

• **Hematocrit:** A hematocrit (percentage of your blood that is red blood cells) that is either very high (above 60%) or very low (below 20%) can cause false results.

3. Indications for use (Purpose of the device)

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

Your SD CodeFree™ blood glucose monitoring system is designed to measure the level of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm or upper arm. Your SD CodeFree™ meter must only be used with SD CodeFree™ blood glucose test strips. Testing is done outside the body (*in-vitro* diagnostic use). This system is indicated for home use (OTC or over-the-counter) by those with diabetes, or in a clinical setting, 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 newborn babies. 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

Understanding Your New System

in how you manage your diabetes every day. Discussing your results with your doctors and following their advice about medicine, exercise and diet can help you better control your diabetes.

The SD CodeFree™ blood glucose monitoring system is suitable for self-testing.

4. Product Description and the Principle of use

The SD CodeFree™ test strip is designed with an electrode that measures glucose levels. Glucose in the blood sample mixes with reagent on the test strip that causes a small electric current. The amount of current that is created depends on how much glucose is in the blood.

SD CodeFree™ 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 the SD CodeFree™ test strip, the strip's reaction chamber automatically draws the blood into the strip through capillary action. When the chamber is full, the SD CodeFree™ meter starts to measure the blood glucose level. It is a simple and practical system for the daily monitoring of your blood glucose level.

## 5. The Complete SD CodeFree™ Blood Glucose Monitoring System

The system includes:

- SD CodeFree™ Meter
- SD CodeFree™ Test strips
- SD Check strip
- 3V battery type CR2032
- User Instruction Guide
- Quick Guide
- Self-test Diary
- Test Strip Package Insert
- Carrying Case
- Lancing device (with a white cap for fingertip testing and a clear cap for Alternative Site Testing)
- Lancets

<Option>

- SD Control Solution
- Control solution package insert

Understanding Your New System

6. The SD CodeFree™ Meter
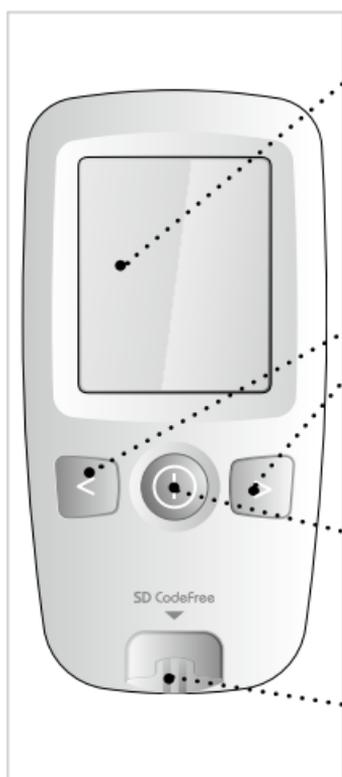
Display
Shows blood glucose result, messages and glucose result stored in memory.
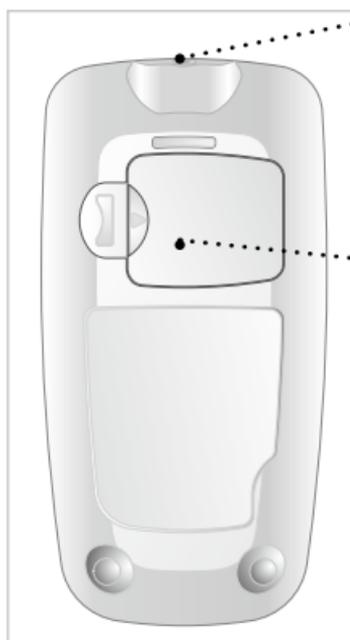
Arrow Buttons
Used for meter setup and review of the results held in memory.

ON/OFF Button
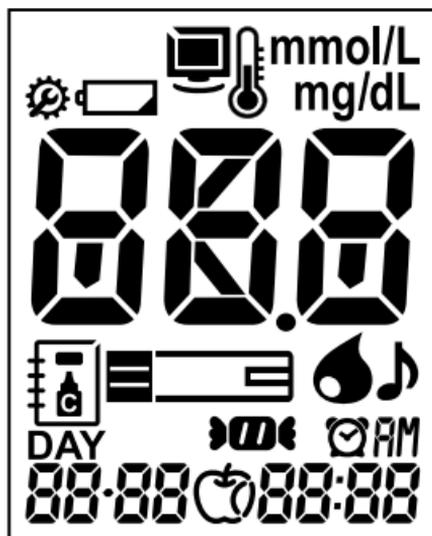Press to turn meter ON or OFF.

Test Strip Slot
Insert test strip here.

Data port
Download test results to a personal computer.(If you have software)

**Battery Cover**
Remove cover to change battery.

Understanding Your New System

Display

🕗88:88 AM	Indicates Measurement time	⚙	Displayed when in setup mode
♪	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

Understanding Your New System

11

|			
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	Ċ	Indicates a control solution test result
⏰	Indicates alarm setting	›📟‹	Indicates hypo warning
🖥	indicates S/W communication		

1) Strip Stand-by Display

After turning on the meter, the image below will be displayed automatically showing a flashing test strip icon. In this Strip Stand-by Display, you are able to enter the setup mode (e.g. time, date, alarms) of the meter or search previous test results.
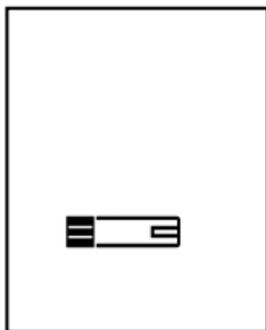

2) Blood Stand-by Display

If a test strip is inserted into the meter when the unit is switched off or when the test srtip icon is flashing the image below will be displayed. This indicates the unit is ready to have the blood sample added to the inserted test strip. If you remove the test strip the unit will revert to the flashing test strip icon. When the blood drop icon is flashing with the test strip inserted the On/Off button will not function although the unit will switch itself off if no blood is added within 3 minutes.

Understanding Your New System

13
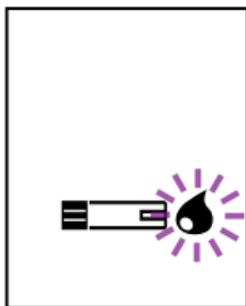
If you press the right arrow once when the Add Blood icon is flashing the Pre-meal icon will be displayed. This will indicate the glucose level being measured will be a Pre-meal reading.

Pressing the right arrow a second time will show the Post-meal icon. Pressing the right arrow a third time will revert the display to just the flashing blood drop icon. At any time removing the test strip will return the display to the flashing test strip icon.
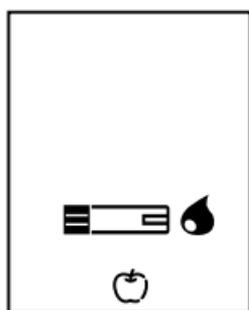
[Pre-meal]
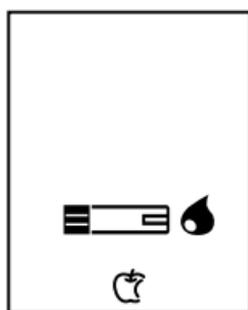
[Post-meal]

NOTE

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 display when you test within the following time period:- from 30 to 130 minutes after your Pre-meal test.

7.   The SD CodeFree™ Test Strip

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

Yellow Window (Top Edge)
Apply a drop of blood here.

-Before Applying Blood-
This window should be completely yellow.
-After Applying Blood-
This window should be completely filled with the blood drop.

Electrodes
Insert strip with gold-coloured bars up and toward the meter.

Understanding Your New System

15

8. **SD CodeFree™ Accessories**

Lancet   **SD Check strip**

                                    ········ Electrode
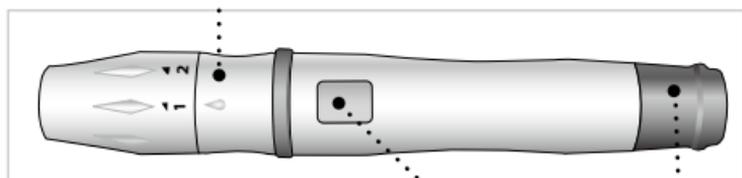
                                    ········ Hold
                                              Here

Lancing Device
Cap & Comfort dial with puncture depth
selection

AST Cap   Release   Arming
                              Button   Knob

Cap & Comfort
dial with puncture
depth selection

**SD Control Solution** (available to order)
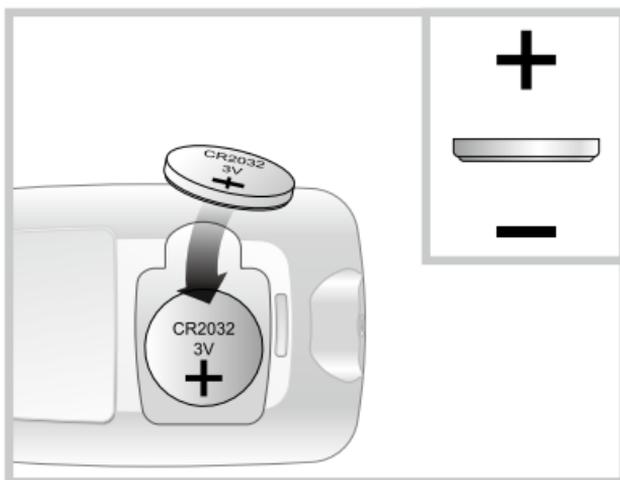
9. Inserting the Battery
Inserting and replacing the Battery

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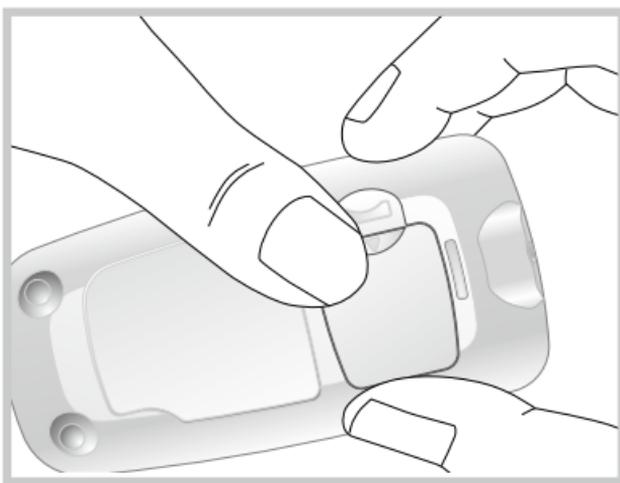
STEP-1: Push the recessed plastic tab of the battery compartment forward to flip and open the battery door.

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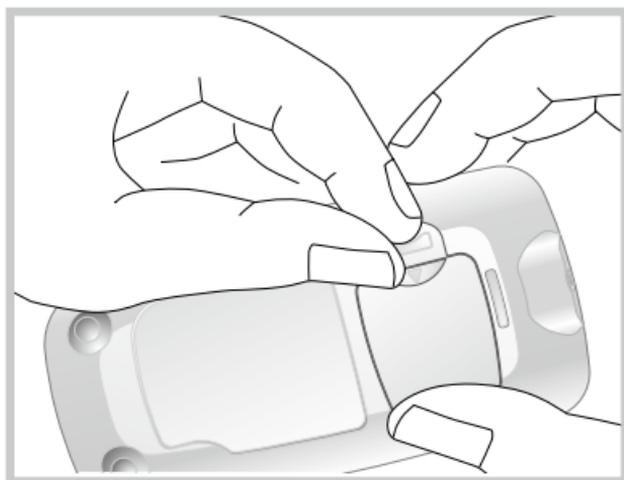
STEP-2: Insert the 3V battery (type CR2032) into the compartment with "+" side facing you.

STEP-3: Clip battery cover back in place.

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

> 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 "10 Meter Setup" on the next page.
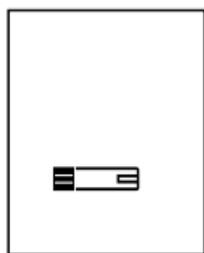
NOTE

10. Meter Set up
STEP-1 : Setting the Audible Beep
1. In Strip Stand-by Display, press the ON/OFF button for 3 seconds and the display for setting the audible beep will be visible. The spanner symbol is always shown when in Setup mode.

[Press and hold]
for 3 seconds

2. Set the audible beep 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.

[Left or right button]   [ON/OFF button]

Understanding Your New System

19

STEP-2: Setting the Hypo warning

1. After setting the beep, the display shown below will appear. At the base of the display will be the hypo warning symbol (candy wrapper).

2. Pressing the left or right arrow button will switch the hypo warning from OFF to 60,70,80 mg/dL or to 3.3, 3.9, 4.4 mmol/L. Select your preferred option and press the ON/OFF button to confirm the preferred option.

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 the selected hypo result, the candy symbol will appear on the display with a 'beep' sound. It is very important to manage your hypoglycemia.

Understanding Your New System
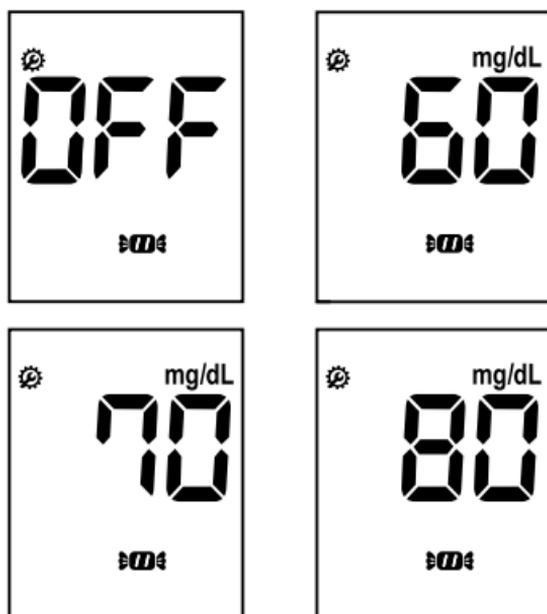
STEP-3: Setting the date and time

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.

[Date Setting]
1. After setting the hypo warning, the next setting will show the Year - press the right or left arrows to select the year and then press the ON/OFF switch to confirm your selection.

Understanding Your New System

21
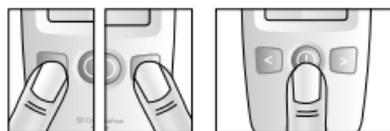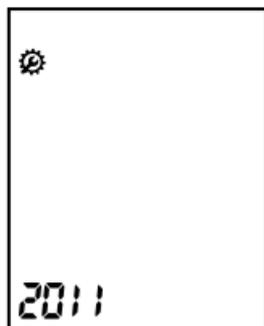
[Left or right button] [ON/OFF button]

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 confirm by pressing the ON/OFF button.
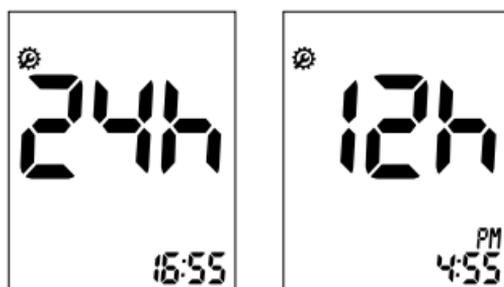

3. Set the correct month or day on the display by pressing either the left or the right button and confirm by pressing the ON/OFF button.

Understanding Your New System

[Time Setting]

1. Next will appear the display for setting the 12 or 24 Hour clock format. 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 confirm by pressing the ON/OFF button.
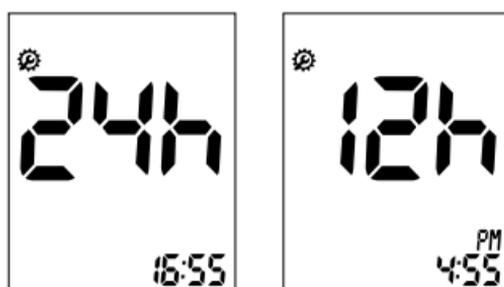

[Left or right button]   [ON/OFF button]

2. Next will appear the setting display for time format. 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.

Understanding Your New System

23

STEP-4: Post-meal alarm

The next setup option to appear will be the meter's post-meal alarm function to remind you to test your blood glucose 2 hours after a meal.

1. The display will show a flashing OFF symbol and a half eaten apple. Pressing the right or left arrow will switch between alarm 'off' and on.

2. Once you have selected if you want the post meal alarm confirm your selection by pressing the ON/OFF button.

[Left or right button]   [ON/OFF button]

NOTE

- If you select the post-meal alarm '2h' feature and subsequently, at any time, test your blood glucose level using the pre-meal mark, the 'clock symbol' will appear on the result display and the monitor will 'beep' 2 hours later continuously for 1 minute to remind you to test your blood glucose level.
- If you perform the pre-meal test while the post-meal alarm setting is on, then the post-meal mark will appear automatically on the display when you test within the following period: from 30 to 130 minutes 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.
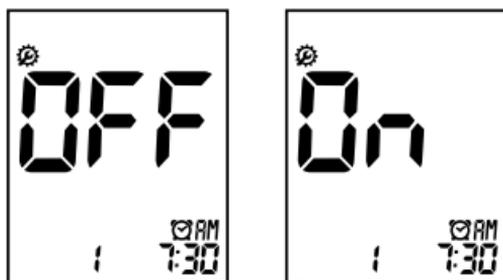
STEP-5: Setting the alarm
You can use the meter's alarm function to remind you to test your blood glucose level.

1. After the Post-meal alarm setting the display for setting the alarm will appear on

the display

2. Set the first alarm on or off by pressing either the left or the right button and then confirm you want to set the alarm by pressing the ON/OFF button.

[Left or right button] [ON/OFF button]

> **NOTE**
> - If you select the alarm off feature, the Strip Stand-by Display will appear next.
> - 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 confirm the preferred feature by pressing the ON/OFF button.
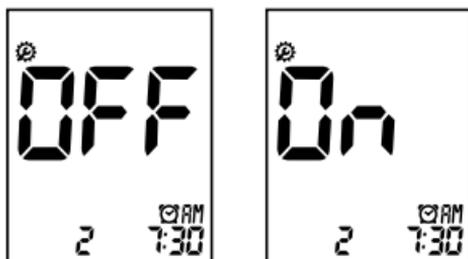

[Left or right button]   [ON/OFF button]

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

**Understanding Your New System**

27

4. Once you have finished setting the first alarm, the second alarm setting mode will be displayed. Set the alarm the same way as in 2 and 3 above.

5. You can set the third and fourth alarm in the same way as in 2 and 3 above.
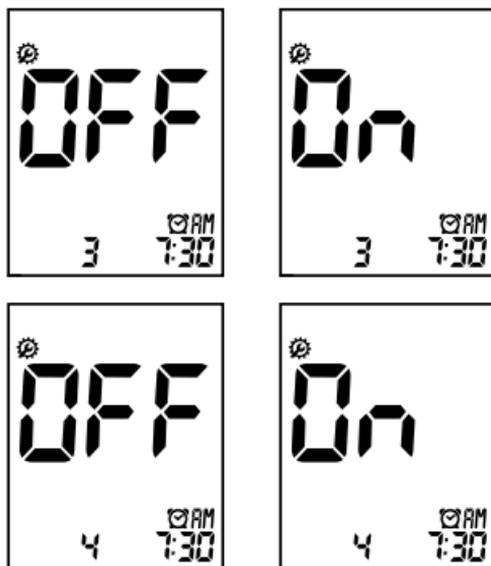
6. When you have finished setting the last alarm the display will revert to the Strip Stand-by Display.

Understanding Your New System
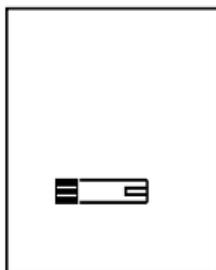
11. Using SD CodeFree™ Test Strips
[Important Test Strip Information]

- Only use SD CodeFree™ test strips. Using other test strips with this meter can cause inaccurate results or even damage the meter.
- 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 test 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.
- Only store test strips in their original container to avoid damage or contamination. Do not transfer test strips to any other storage device and do not store the test strips outside of their original container.
- Do not use test strips from any container that is damaged or has been left open to the air.
- Write the opening date on the container label when you first open it. Discard remaining SD CodeFree™ Test Strips after the discard date. (3 months after first opening the container).

Understanding Your New System

- Do not use test strips beyond the expiration date (printed on package) or discard date, whichever comes first, because this may cause inaccurate results.
- SD CodeFree™ 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 a SD CodeFree™ Test Strip in any way.
- Apply only SD Control Solution or a blood sample to the test strip.
- Refer to additional information in the SD CodeFree™ Test Strip package insert.
- Not following these precautions can lead to inaccurate results.

CAUTION

Do not swallow test strips. The test strip container may contain drying agents that are harmful if inhaled or swallowed and may cause skin or eye irritation.

CHAPTER 2 :
Control Solution Test

CAUTION

If you believe the meter is giving inaccurate or inconsistent results and you have carried out the SD Check Strip test(See Chapter 5 - Maintenance and Troubleshooting) then the SD Control Solution should be used to check the meter is working correctly. This section is for medical professional use or for those purchasing the SD Control Solution. Never ignore symptoms or make significant changes to your diabetes conrtol program without speaking to your healthcare professional.

Why you should do a control solution test ;
- SD Control Solution is used to check that the meter and the test strips are working together as a system and that the meter is giving accurate results.
- This check should be carried out by your medical professional or the official distributor when your meter is giving unexpected and/or inconsistent results. The SD Control Solution is available from your distributor.

When you should do a control solution test ;
- The meter does not appear to be working accurately.
- You wish to check that the test strips are giving accurate results or you think the test

Control Solution Test

31

strips have been damaged.
•   The meter has been dropped or damaged.

Before you begin ;
•   Use only SD 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 control solution - it is not for human consumption.
•   Do not apply control solution to the skin or eyes as it may cause irritation.

Control Solution Test

32

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 medical professional or the distributor. Your meter is designed to recognize the difference between the SD Control solution and blood. The meter automatically stores the test results using a control solution, letting you review them. The meter does not include them in averages.

For more information on how to obtain SD Control Solution, contact your distributor or call +82-31-300-0400

STEP-1:

1) Remove a new test strip from its storage container. Be sure to tightly replace container cap after removing the test strip.

2) Insert a test strip (with gold coloured bars facing upwards and arrow pointing towards the meter) into the 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.
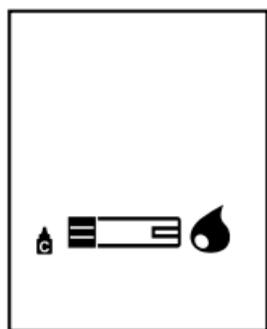

[Left button]

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 seconds on the display. Tightly replace the cap on the control solution.

3) The control solution result appears on the display in just 5 seconds.

4) Compare the 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.
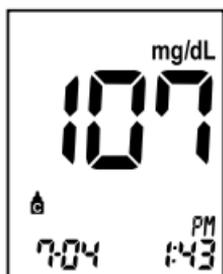
NOTE

The control solution range printed on the test strip container is for SD 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 test strip used with the control solution from the meter and discard it.

35

2. Troubleshooting Control Solution

Check	Action
Did you carry out the test in control solution mode? Did you see the"control solution container icon" on the screen with the result?	If not, do the test again. Insert a test strip; Press the left button for 3 seconds in Blood Stand-by Display to display a control solution container icon.
Have the test strips and/or control solution expired?	Make sure that test strips and control solutions are not past expiration date. This date is shown on the container/bottle. Make sure containers have not been open for more than 3 months.
Were control solutions at room temperature (18-30℃, 64-86°F) when used?	If not, warm up/cool down bottle to room temperature (18-30℃, 64-86°F) or retest with a new bottle of control solution.

Control Solution Test

36

| Check	Action
Did you insert test strip firmly into the meter?	Make sure the test strip is inserted into the test strip slot until it will go no further.
Did you follow the procedure correctly?	Read again "Chapter 2: Control Solution Test" (pages 31-37) and retest.
Were the test strips stored correctly (between 2-32°C, 36-90°F)?Was the bottle cap replaced immediately after removing a test strip?	If not, retest with a new container of test strips.
Is the meter damaged? Does it show an error code?	If yes, contact your distributor or SD Biosensor Customer Care Service Center at Tel : +82-31-300-0400
Is the control result outside the acceptable range (printed on your test strip container)?	Repeat the test. If you get the same results, do not use your meter and test strip until you solve the problem. If you still have problem, call the SD Biosensor Customer care service center Tel:+82-31-300-0400

Control Solution Test

37

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 the 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.
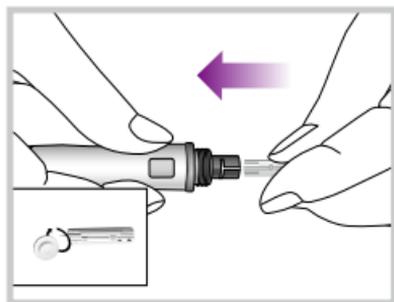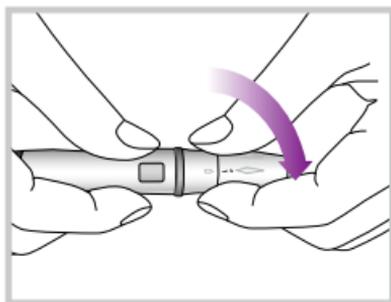

3) Replace the cap and turn it clockwise, until it is snug. Adjust the puncture depth setting by turning the comfort dial. The dial has 1 to 5 steps, and the higher the step number, the stronger the blood sampling pressure on the puncture site.
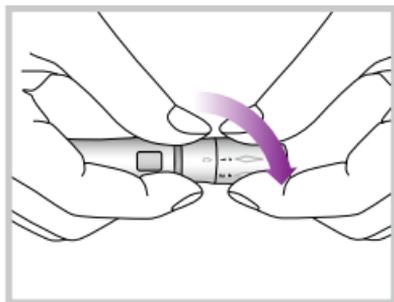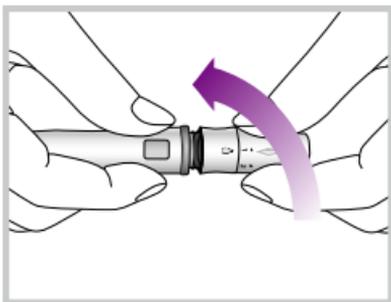
The comfort tip offers 5 different levels of skin penetration.
- 1-2 : for soft or thin skin
- 3 : for average skin
- 4-5 : for thick or callused skin

4) Prime the lancing device as shown below by pulling the top of the device. Hold the lancing device firmly against the side of finger and then press the release button.
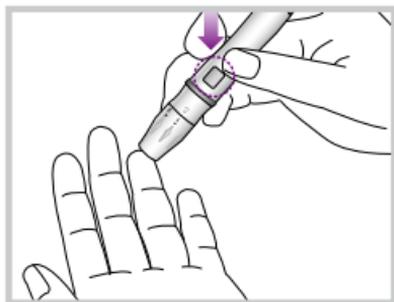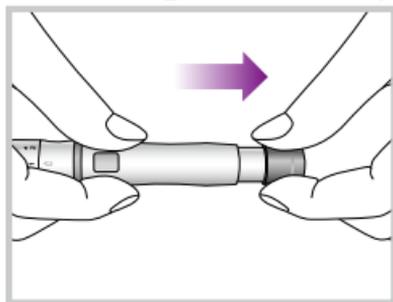
CAUTION

- 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.

Testing Your Blood Sugar

2. Performing a Blood Glucose Test

NOTE

Always wash hands with warm, soapy water. Rinse and dry them before testing.

1) Remove a new test strip from the container. Be sure to tightly replace the container cap after removing test strip.

2) The meter turns on by two ways.
   The first method is to press the ON/OFF button. The second method is to just insert the test strip into the test strip slot in power off mode, the meter turns on automatically. Just inserting the test strip this way means you don't need to press the ON/OFF button.

3) When the blood drop symbol flashes (Blood Stand-by Display), you are ready to perform a test.
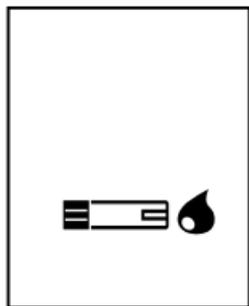
4) Before you perform a test, you can display the symbols that indicate post-meal or pre-meal mark by pressing the right button one or two times.
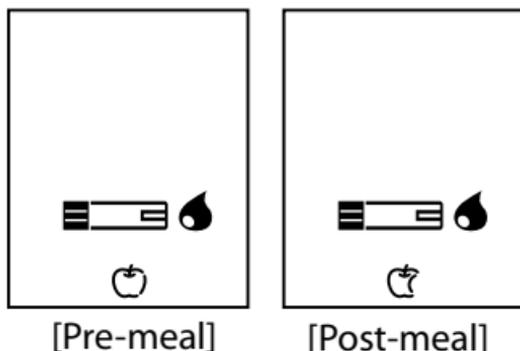
[Pre-meal]   [Post-meal]

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 30 to 130 minutes 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. The drop size shown is ideal.

●
―――――
0.9µl
[actual size]

Testing Your Blood Sugar

41
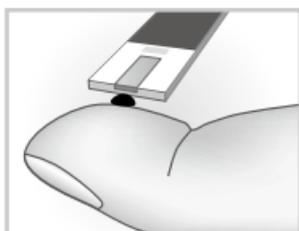
8) The blood will be drawn into the strip automatically. If the beeper is turned on the meter will beep to let you know the test is beginning.

9) When blood is applied to the strip, the display counts down from 5 to 1 seconds and your result appears on the display in just 5 seconds.
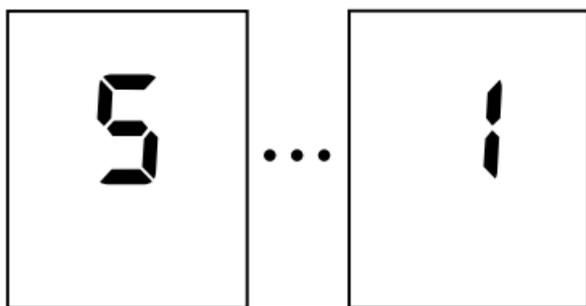

10) The blood glucose result is displayed in mg/dL or mmol/L.

11) When the test is complete, pull out the used test strip. The meter will shut off automatically 5 seconds after you remove the test strip.

NOTE

- Dispose of all used test strips in accordance with your local guidelines.
- Remove the inserted lancet from the lancing device and dispose of the used lancet according to local guidelines.
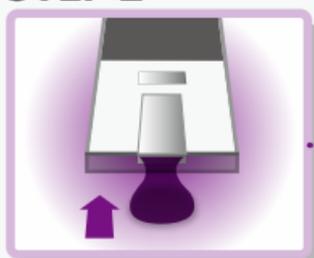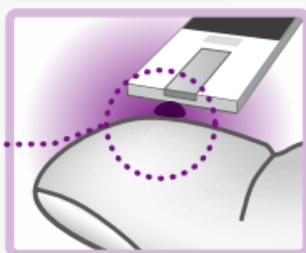- Always use fresh capillary whole blood on meter tests.

Testing Your Blood Sugar

STEP 1
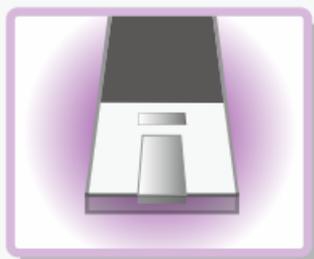
Line up the blood drop with the yellow window channel on the test strip.

STEP 2

Narrow Channel

NOTE

Gently touch test strip to the blood drop.

Do not press or shake test strip too firmly aginst the finger.

STEP 3

Correct test strip appearance.

Testing Your Blood Sugar

43

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. These changes show up 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, a fingertip test is usually the preferred method of testing in these circumstances.

If bruising using AST, 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, hair and away from bone.
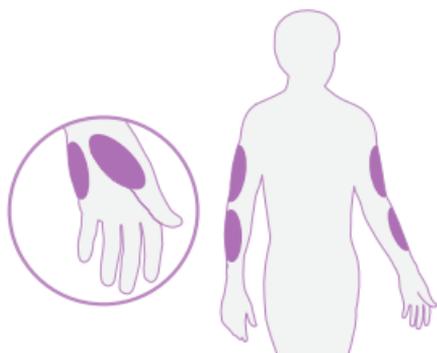

Prepare Your Lancing Device

We recommend using the SD Lancing device with the clear end cap when testing from alternative sites other than the fingertip. You will find this item included with your kit.

Testing Your Blood Sugar

Performing a Blood Glucose Test From an Alternative Site

STEP-1

Remove the standard cap, insert the lancet, replace the standard cap with the AST clear cap (supplied) and prime the lancet device. Adjust the comfort level.
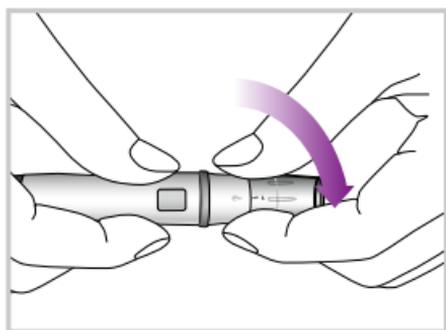
STEP-2

The meter turns on in two ways. The first way is to press the ON/OFF button and the second way is to just insert the test strip into the test strip slot in power off mode, the meter turns on automatically. Just inserting the test strip this way means you don't need to press the ON/OFF button.


Testing Your Blood Sugar

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.
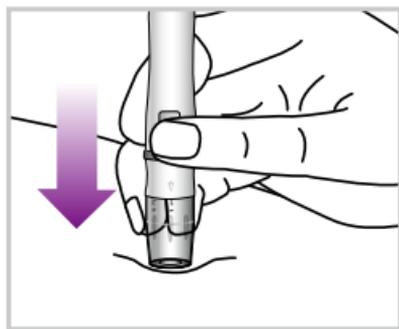
4. Press the release button on the lancing device to lance the skin. Continue to hold the lancing device firmly against the skin until a blood drop forms.
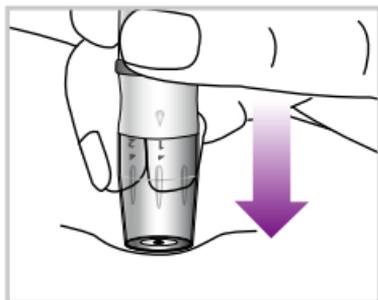
5. Once a large enough drop of blood has formed, remove the lancing device.
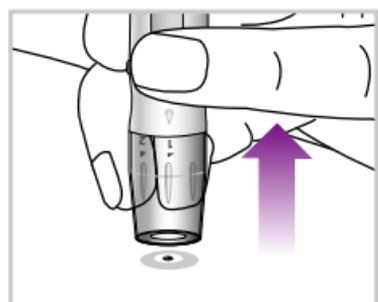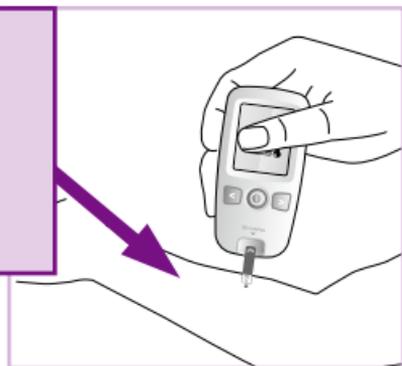

STEP-4
Pick up the meter and touch the end of the test strip to the blood sample until the reaction site is full. Immediately remove the meter and test strip from the blood drop.

IMPORTANT:
Insert strip vertically into the blood sample; not at an angle.

Testing Your Blood Sugar

STEP-5

The meter will count down and display the result after 5 seconds.

Consider your result. and then repeat the Alternative Site Test if...

- The blood sample appeared to be diluted with clear fluid
- You did not vigorously rub the test site.
- The blood drop was not large enough to fill the reaction site.
- The test was accidentally marked as a "Control" result.
- Your result was not consistent with how you feel.
- More than 20 seconds elapsed from sample collection to measurement commencement. (evaporation of the blood sample can cause a test result that is higher than the correct level).

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 healthcare professional. The meter shuts off automatically when the test strip is removed.

4. Understanding Test Results

Your test results

1. After the 5 seconds testing time has elapsed from applying blood onto the strip, you will receive a result, The result will be in the range of 10mg/dL to 600mg/dL (0.55mmol/L to 33mmol/L).

2. If your blood glucose is above the maximum recordable level of 600 mg/dL (33mmol/mL), you will receive a "HI" warning and if it is below 10 mg/dL (0.55mmol/L), you will receive a"Lo" warning. In these cases, repeat the test with a new test strip. If the same warning is repeated, contact your healthcare professional immediately.

Testing Your Blood Sugar

51
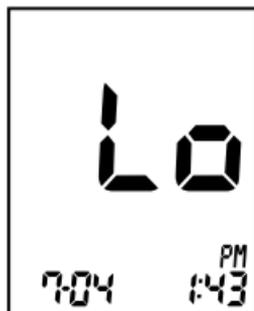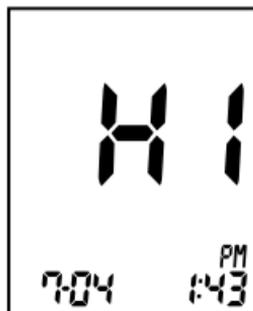
3. If you set the pre-meal mark before testing, you will receive a result with pre-meal mark. (🍎)

4. If you set the post-meal mark before testing, 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 the following period: from 30 to 130 minutes 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(4.1 - 5.8mmol/L).[1]

Two hours after meals, the blood glucose range for an adult without diabetes is less than 140 mg/dL (7.7 mmol/L).[2]

- Fasting: 74 to 106 mg/dL or
  4.07 - 5.83 mmol/L
- 2 hours after meals : <140 mg/dL or
  < (7.7 mmol/L).

What This Means For You

Frequent blood glucose testing is the best means to track how you are managing your diabetes. Regular testing 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.

Testing Your Blood Sugar

CHAPTER 4 :
Using the Meter Memory

The meter automatically stores about 500 glucose results, letting you 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 automatically.

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. 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.
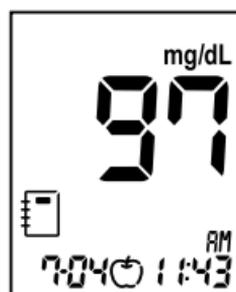
1. Searching Test Results

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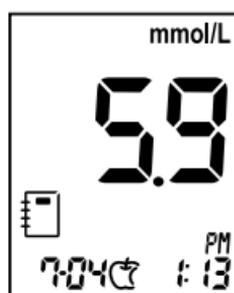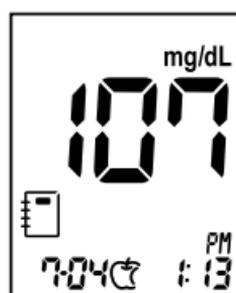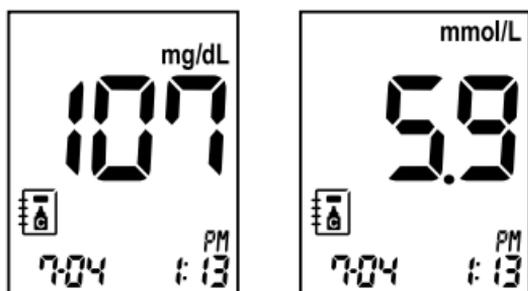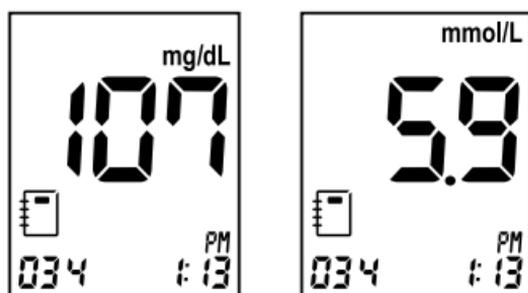

[Left button]
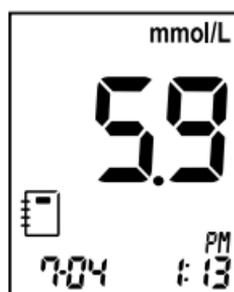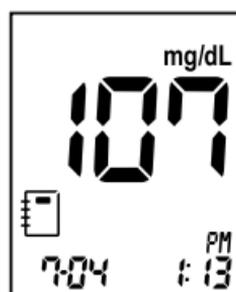
[Normal result]

[Pre-meal result]
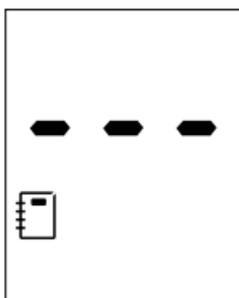

[Post-meal result]

Using the Meter Memory

55

[Control Solution result]

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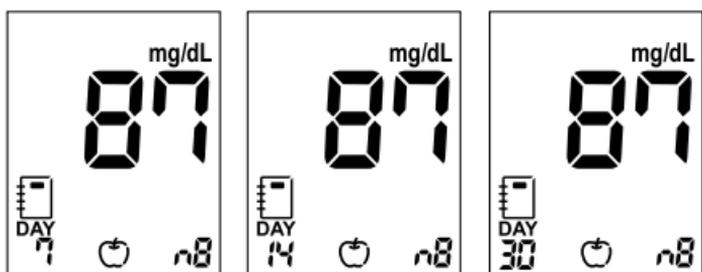

3) If there are no stored test results, the following display will appear for 1 second. The meter will the display the Strip Stand-by Display automatically.

4) In Strip Stand-by Display, press the right arrow button to review three kinds of 7,14 and 30 day averages of the 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 will appear again.
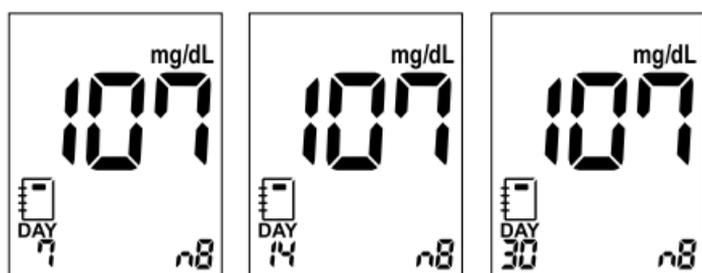
[Normal average]

[Pre-meal average]

[Post-meal average]

Using the Meter Memory

57
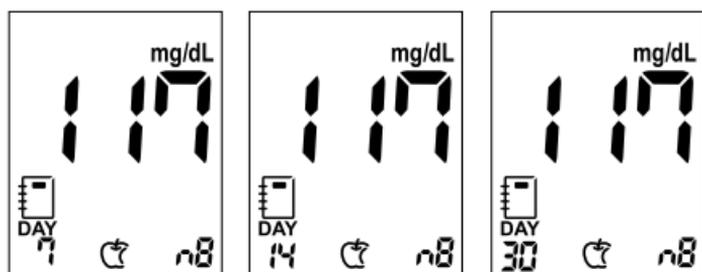
5) If there are no stored 7, 14 and 30-day average of test results, the following display will appear on the LCD.

Using the Meter Memory

2. Downloading results to a computer

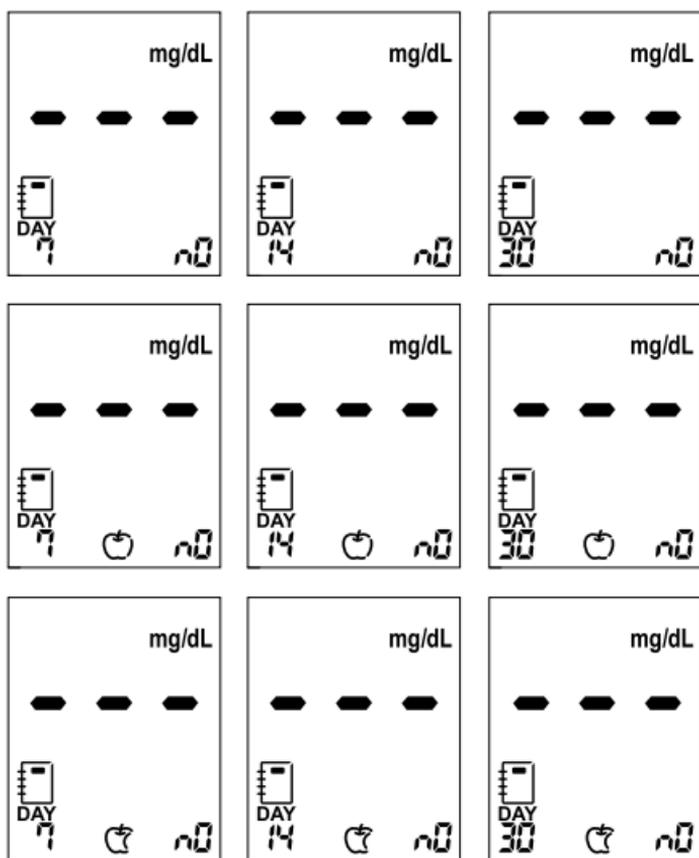You can use your meter with the SD Diabetes Management Software to store your records and to help you spot patterns for planning meals, exercise, and medication. The SD Diabetes Management Software puts information downloaded from the meter into charts, diagrams and graphs.

1) Obtain the SD Diabetes Management Software (see below) and the SD SW Interface Cable. These are both available from your healthecare professional or from the place you purchased this meter.

2) Install the software on a personal computer. Please refer to Software Product Manual.

NOTE

- When the meter is connected to the PC, it is not possible to perform a blood glucose test.
- To download the SD Diabetes Management Software and manual (both are free of charge), please visit www.sdbiosensor.com
- Select English at top right of the screen, then select "software" or SD DMS manual.
- For further information, please refer to the Software Product Manual.
- SD Diabetes Management Software is intended for both professional and home use.

Using the Meter Memory

59

CHAPTER 5 :
Maintenance and Troubleshooting

1. Performing an SD Check strip Test
When should I check my meter using the SD Glucose Check strip?

- 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 how you feel
- If you have repeated a test and the blood glucose result is still lower or higher than expected.
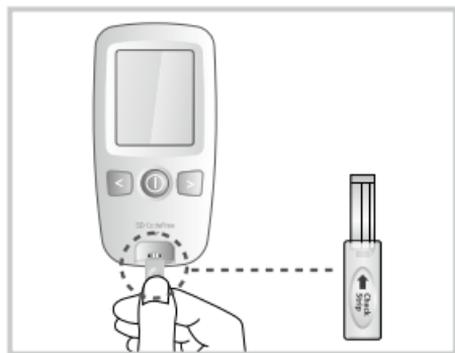
<table>
<tr><td>⚠
CAUTION</td><td>• The SD Check strip test does not replace an SD Control Solution test.</td></tr>
</table>

How to Use the SD Check strip

1. Insert the SD Check Strip, face up, into the test strip slot ('check strip' is printed on the check strip). The meter will turn on automatically.
2. If the SD Check Strip is inserted properly, the meter will start the check.

3. The check result will appear on the display in 5 seconds. If the meter is working properly the 'OK' message will be displayed. Otherwise, if there is a problem with the meter, the 'EEE' error message will be displayed.

['OK' Message]

['EEE' Error Message]

2. Cleaning the meter

Caring for the SD CodeFree™ meter is easy. To prevent malfunction of the meter, keep the meter and especially the test strip port free of blood, moisture, dirt or dust. If you need to clean the meter follow these guidelines carefully to help you get the best performance possible.

Use a lint-free cloth dampened with water to clean the meter. Thoroughly wring out the colth before use. Do not use an abrasive cloth or antiseptic solution, as these may damage the display screen.

Maintenance and Troubleshooting

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 haven't expired, then run a "check strip" test. If you are still getting unexpected results carry out the "Control solution" check to ensure the meter is working correctly -see Chapter 2, Control Solution Test.

Precautions for Maintenance, Testing and Transportation

1) Meter

- Keep the test strip slot free of dust.
- Protect the internal meter from getting wet or from places of high humidity e.g. a shower room.
- The carrying case is designed to let you store a variety of supplies you may need and helps to protect your meter.
- The temperature and humidity of the meter during transport and storage are -20-60°C (-4-140°F) and 15%-95% RH, non-condensing.
- If you keep the meter with the battery inserted, then keep it in a low humidity environment.

2) Test strip

- The test strip is sensitive to humidity, keep

it in a dry and cool environment - do not store in direct sunlight.

- After taking out the test strip from its container, close the container cap of the test strip immediately.
- The test strip container closes tightly and can protect the test strips, so you should keep unused test strips in the container in which they came.

3) Lancet and Lancing device

- The needle of lancet is sharp, so keep the lancet away from children.
- Keep the lancet and lancing device dry and do not store in direct sunlight, or locations with high heat or humidity.
- A lancet should not be used for any other intended use except sampling blood.
- A lancet is for single use only. Do not reuse.
- The lancets provided with the SD CodeFree™ Blood glucose meter should only be used with the lancing device manufactured by SD Biosensor, Inc.
- Before use, check the packaging condition. If there is any problem, you should not use the lancing device or the lancets.
- If a lancet protective disk is loose or the needle of a lancet is exposed, you should not use that lancet.
- To reduce any possibility of infection from used lancets, dispose carefully in

Maintenance and Troubleshooting

63

accordance with local guidelines.

4) Control solution

If you are a medical professional or have the control solution in your possession please note the following.

- Keep the SD Control Solution in a cool dry environment 8-30°C (46-86°F) .
- Do not refrigerate or freeze.
- Do not use SD Control Solution that has passed its expiration date.
- The SD Control Solution can be used for 3 months after opening the container. Do not use after this time. Write the opened date on the SD Control Solution container when first opened.
- No reconstitution or dilution is necessary.
- Wipe the container tip clean and reseal the container tightly after each use.

4. Cleaning the Lancing Device

Clean the outside of the SD 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 removable comfort cap after cleaning by placing it in 70% rubbing alcohol for 10 minutes. Allow the cap to air-dry after disinfecting.
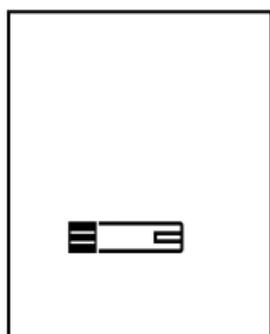
5. Screen Messages and Troubleshooting
Message Description
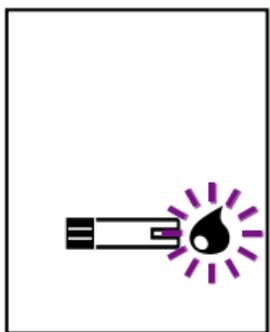
• The meter turns on normally.
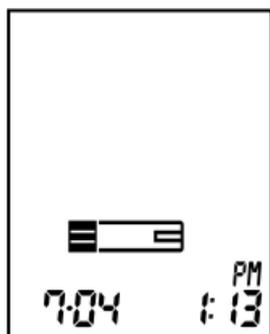
[Strip Stand-by Display]

• The meter is ready for you to insert a test strip.

[Blood Stand-by Display]

• The meter is ready for a drop of blood.

• The meter is ready for a drop of blood with pre-meal mark.

Maintenance and Troubleshooting

65
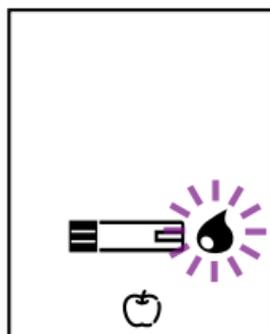
- The meter is ready for a drop of blood with post-meal mark.
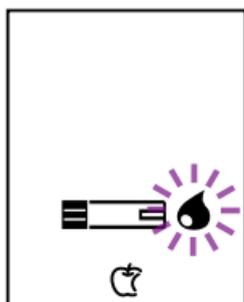
- The meter shows the result of blood glucose strip test.

- The meter shows three kinds of average results.

[Normal Results Average]

[Pre-meal Results Average]

Maintenance and Troubleshooting
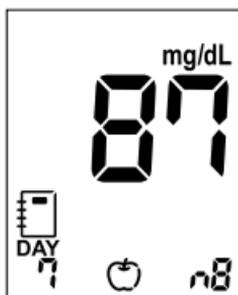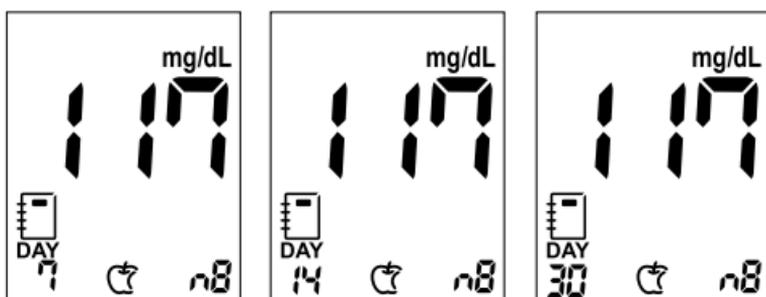
[Post-meal Results Average]

• The meter shows the saved results of blood glucose levels.
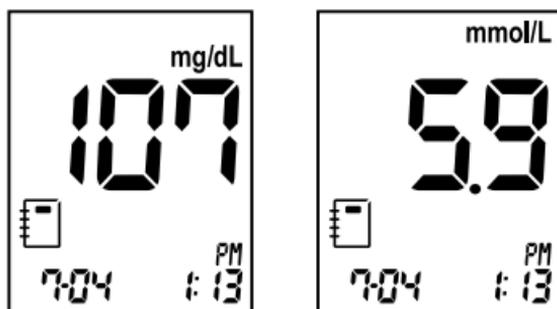
• The meter is ready for a drop of control solution.
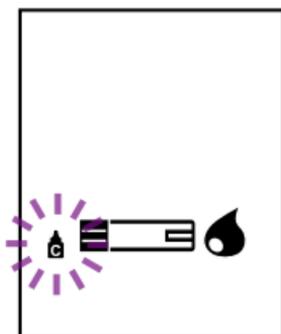
[Low battery]
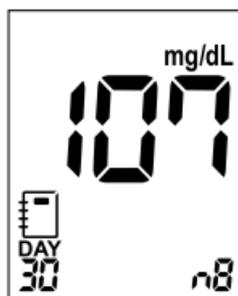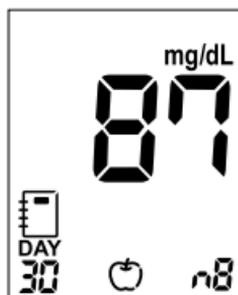When the battery is getting low the meter will show the low battery icon but you will still be able to carry out about 50 more tests. Replace the battery soon. See Chapter 1, "9. Inserting the Battery"
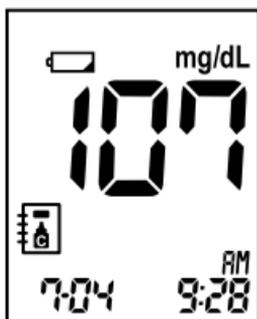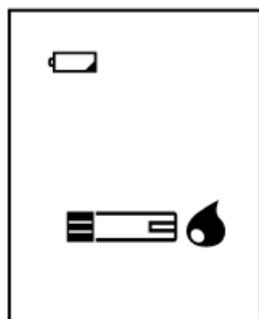
[Replace battery]
• When the low battery icon flashes you must replace the battery immediately. See Chapter 9. "Inserting the Battery" If you press the ON/OFF button after the battery is discharged, the battery icon will flash and the meter will turn off automatically after ten seconds.
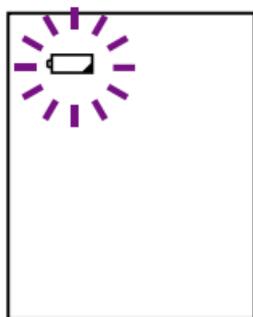
[HI message]
• Blood glucose may be higher than the measuring range of the meter. See chapter 3 "4. Understanding Test Results"
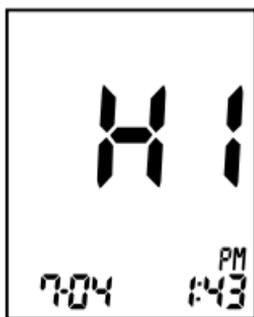
[Lo message]

• Blood glucose may be lower than the measuring range of the meter. See chapter 3 "4. Understanding Test Results"

[Internal Error Message for a meter]

• Turn off the meter. Then turn on the meter again. If the error message persists, please contact SD Biosensor, Inc. TEL: +82-31-300-0400 or the place from where the unit was purchased.

[Strip Error]

• The test strip is defective, damaged or inserted incorrectly. Discard this test strip and test again using new test strip. See Chapter 3 "2.Performing a Blood Glucose Test"

Maintenance and Troubleshooting
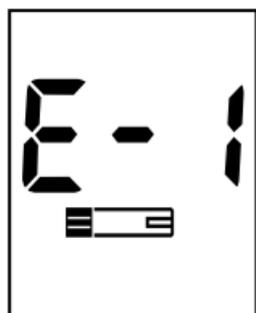
[Blood Sample Error]

• An insufficient amount of blood was applied. Discard this test strip and test again using a new test strip and a larger sample, making sure blood is placed to the narrow channel in the top edge of the test strip. See Chapter 3 "2.Performing a Blood Glucose Test"
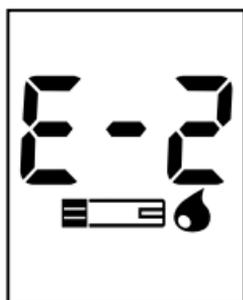
[Temperature Error]

• If the environmental temperature is above or below the operating range of the meter, a thermometer icon will appear on the display. Move to a location between 10-45°C (50-113°F), wait 30 minutes, and then carry out the test. Do not artificially heat or cool the meter. See Chapter 6. "Product Technical Information"
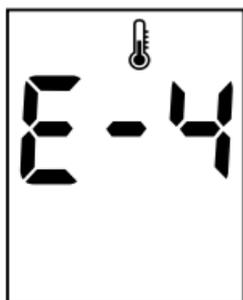
[Communication Error]

• The communication between the meter and the computer has failed. Re-connect the cable between the meter and your PC.
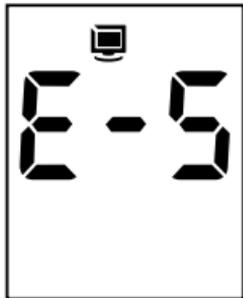
6. Warnings, Precautions and Limitations

- 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.
- 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 blood glucose results obtained.

Maintenance and Troubleshooting

- Interferences : Elevated levels, as indicated in the table below, of of ascorbic acid, uric acid, acetaminophen, total bilirubin and triglycerides may affect results.

Compound	Limitation
Ascorbic acid	> 4 mg/dL
Uric acid	> 9 mg/dL
Acetaminophen	> 6 mg/dL
Total bilirubin	> 40 mg/dL
Triglycerides	> 1026 mg/dL

- Externally taked drugs L-dopa, dopamine, methyl-dopa, acetaminophen, and ibuprofen will not interfere with SD CodeFree™ blood glucose results when taken at therapeutic concentrations.
- The SD CodeFree™ 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 the SD CodeFree™ 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

1. System Specifications

Result Range	10 - 600 mg/dL, (0.6 - 33.3 mmol/L)
Calibration	Plasma-equivalent
Sample	Fresh capillary whole blood
Sample Size	Minimum 0.9 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	47 mm × 95 mm × 17.5mm
Weight	47.5g (with battery)
Automatic Shutoff	• 1 minute after last user action if no test strip is inserted in the meter • 3 minutes after the last user action if a test strip is inserted in the meter

Product Technical Information

Memory	500 blood glucose tests

Function	- Hypo warning : 60, 70, 80 mg/dL(3.3, 3.9, 4.4 mmol/L)
	- Pre-meal and post-meal mark
	- Alarm setting (up to 4 times)
	- Post-meal Alarm
	- 7-, 14- and 30-day Averages of the following results
	  1)Normal Results
	  2)Pre-meal Results
	  3)Post-meal Results
	- Automatic shutoff

- Meter

Operation	
Temperature	10℃ - 45℃ (50°F - 113°F)
Humidity	15% RH – 90% RH
Hematocrit	20% - 60%
Altitude	Up to 12,388 feet. (3,776 meters)
Transport and Storage (in shipping container)	
Temperature	-20℃ to 60℃ (-4°F to 140°F)
Humidity	15% RH – 90% RH

- Test strip

Storage	
Temperature	2℃ – 32℃ (36°F – 90°F)

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, the meter meets the electro-magnetic emissions requirements as per EN 61326. Electromagnetic emission from the meter is thus low. Interference from other electrically driven equipment is unlikely.

Annex 1 : Information for Healthcare Professionals

Healthcare professionals :Please follow the infection control procedures appropriate for your location.

Decisions about whether to recommend alternative site testing (AST) should take into account the motivation and knowledge level of the patient and his or her ability to understand the considerations relative to diabetes and AST. If you are considering recommending AST for your patients, you need to understand that there is a potential for a significant difference between fingertip and alternative site blood glucose test results. The difference in capillary bed concentration and blood perfusion throughout the body can lead to sample site-to-site differences in glucose results. These physiological effects vary between individuals and can vary within a single individual based upon his or her behavior and relative physical condition. Our studies involving AST of adults with diabetes show that most persons will find their glucose level changes more quickly in the fingers' blood than the alternative sites' blood.

This is especially important when glucose levels are falling or rising rapidly. If your patient is used to making treatment decisions based upon fingertip readings, he or she should consider the delay or lag-time, affecting the reading obtained from an alternative site.

Annex 2 : Symbol

The following list describes all symbols used on the SD CodeFree™ Blood glucose monitoring (BGM) system.

1. Label Symbols for the meter

Symbol	Description
⚠	Caution, consult accompanying documents
(+CR2032 3V)	Battery type used in this meter
🗑	Crossed out wheeled bin: To discard the item separately from other household waste
📖i	Consult instructions for use
IVD	**IN VITRO DIAGNOSTIC MEDICAL DEVICE:** This system is intended for use outside the body (in vitro diagnostic use).
SN	Serial number for this meter.
�	DATE OF MANUFACTURE: To indicate the date of manufacture for this meter

Product Technical Information

2. Package Symbols for the BGM system

Symbol	Description
📖	Consult instructions for use
IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE: This system is intended for use outside the body (in vitro diagnostic use).
LOT	BATCH CODE: To indicate the lot number for this system.
🏭	DATE OF MANUFACTURE: To indicate the date of manufacture for this system.
⧗	USE BY: This item should be used by the given date.
🌡	To indicate the temperature limitations in which the transport package has to be kept and handled.
REF	CATALOGUE NUMBER: To indicate the catalogue number for this system.
🏭	To indicate the manufacturer.
$\boxed{\Sigma}$	Contains Sufficient for <n> Tests.
3M	Use for a maximum of 3 months after first opening the container.

3. Label Symbols for the test strip container

Symbol	Description
IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE: This item is intended for use outside the body (in vitro diagnostic use).
📖i	Consult instructions for use.
⧗	USE BY: This item should be used by the given date.
🌡	To indicate the temperature limitations in which the transport package has to be kept and handled.
LOT	BATCH CODE: To indicate the lot number for this item.
REF	CATALOGUE NUMBER: To indicate the catalogue number for this item.
⊘	DO NOT REUSE: To warn the user of a piece of equipment that it is for single use only and that it must not therefore be used more than once.
∑	Contains Sufficient for <n> Tests.
🔓3M	Use for a maximum of 3 months after first opening the container.

Product Technical Information

Annex 3 : 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

Annex 4 : Supplies and Accessories

The following supplies and accessories are available from SD Biosensor, Inc. or the distributor.

ITEM	Cat No.
System	01GC110
	SD CodeFree™ Blood Glucose meter / SD CodeFree™ Blood Glucose test strip (10T x 1vial) / Lancet(10ea) / Lancing device
	01GC111
	SD CodeFree™ Blood Glucose meter / SD CodeFree™ Blood Glucose test strip (10T x 1vial) / Lancet(10ea) / Lancing device/ SD Control Solution (Level M x 1vial)
	01GC112
	SD CodeFree™ Blood Glucose meter / Lancet(10ea) / Lancing device
	01GC113
	SD CodeFree™ Blood Glucose meter / Lancing device

ITEM	Cat No.
Meter	01GM11
	SD CodeFree™ Blood Glucose meter
Strip	01GS11
	SD CodeFree™ Blood Glucose test strip (25T x 2vial)
	01GS11B
	SD CodeFree™ Blood Glucose test strip (25T x 1vial)
Control Solution	01GCS10
	SD Control Solution (2 vial : Level M and Level H)
Lancet	01GL10
	Lancets (100ea x 1 box)
Software	01SCC10
	SD Communication Cable

NOTE

SD Communication Cable is intended for both home and professional use.

Return
You must contact the medical professional or Company you purchased this meter from to obtain authorisation before returning your meter. Returned meters without this authorization will not be accepted.

Manufactured by ───────────
SD BIOSENSOR, Inc.

C-4th&5th Floor Digital Empire Building 980-3,
Yeongtong-dong, Yeongtong-gu, Suwon-si,
Kyonggi-do, Korea

EC-Representative───────────

| EC | REP |

Authorized Representative ───────────
MT Promedt Consulting GmbH
Altenhofstrasse 80 D-66386 St. Ingbert Germany
Phone : +49 6894 581020, Fax : +49 6894 581021

MEMO

MEMO

For further information on

CodeFree™

please contact your

SD BIOSENSOR, Inc.

Representative

BLOOD GLUCOSE MONITORING SYSTEM

SD CodeFree™

User Instruction Guide

No Coding

SD CodeFree

SD BIOSENSOR, INC.