SD

Gluco Navii®
NFC

**Blood Glucose
Mobile Monitoring
System**

User Instruction Guide

N
NFC

GDH
FAD
GDH

0.5 µℓ

mg/dL

107

7:04 PM 1:13
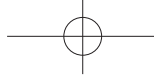
SD BIOSENSOR, INC.
www.sdbiosensor.com

Dear SD GlucoNavii® NFC System Owner;

Thank you for choosing SD GlucoNavii® NFC Blood Glucose Monitoring System. Your new SD GlucoNavii® NFC 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
website : 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.

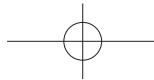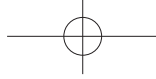| Please refer to the instructions with following symbols in this User Instruction Guide.			
⚠️ **CAUTION**	To identify conditions or practices that could result in damage to equipment or other property.	📖 **NOTE**	To provide an additional useful information.

📖 **NOTE** Before using any product to test your blood glucose, read all instructions and practice the test. Do 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.

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CHAPTER 1 :
Understanding Your New System
The SD GlucoNavii® NFC Blood Glucose Monitoring 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 SD GlucoNavii® control solution. It is very important to follow the instructions in order to prevent an incorrect result or improper treatment.
- The meter, test strips, and SD GlucoNavii® control solution 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) or fresh venous blood.
- Only use SD GlucoNavii® NFC test strips. Other test strips will give inaccurate results or E-1 error message.
- Do not use the SD GlucoNavii® NFC blood glucose monitoring system for testing of serum or plasma or arterial 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 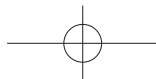strips. Contact SD Biosensor, Inc. Damaged test strips can cause inaccurate results, which could lead to improper treatment.

About your new meter

- Set the beep, date, time, hypo warning, post-meal alarm and alarm on your meter before you begin testing.
- SD GlucoNavii® NFC system has been found to be accurate at altitudes up to 11,549 feet. (3,520 meters)
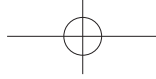
⚠ **CAUTION**

- 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 SD GlucoNavii® control solution, or use control solutions for any purpose.

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 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.

- **Repeated unexpected results:** If you continue to get unexpected results, check your system with control solution. See Checking the System with Control Solution on pages 28 - 33. If you are experiencing symptoms that are not consistent with your blood glucose results and you have followed all instructions in this User Instruction

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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 Caregivers

- 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 higher than 70% can cause false results.

## 3. Indication for use (Purpose of the devices)

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

Your SD GlucoNavii® NFC blood glucose monitoring system is indicated for monitoring glucose in fresh capillary whole blood or fresh venous blood. 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.

The SD GlucoNavii® NFC blood glucose monitoring system is suitable for self-testing.

4. Product Description and the Principle of the use

SD GlucoNavii® NFC test strip is designed with an electrode that measures glucose levels. Glucose in the

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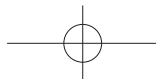
blood sample mixes with reagent on the test strip that cause a small electric current. The amount of current that is created depends on how much glucose is in the blood.

SD GlucoNavii® NFC 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 GlucoNavii® NFC test strip, the strip's reaction chamber automatically draws the blood into the strip through capillary action. When the chamber is full, SD GlucoNavii® NFC meter start 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 GlucoNavii® NFC BGMS
The system includes:
- SD GlucoNavii® NFC Meter
- SD GlucoNavii® NFC Test strips
- SD Glucose Check strip
- 3V battery type CR2032
- User Instruction Guide
- Quick Guide
- Self-test Diary
- Test Strip Package Insert
- Carrying Case
- Lancing device
- Lancet

<Option>
- SD GlucoNavii® control solution
- SD GlucoNavii® control solution insert
- SD GlucoNavii® NFC application for Android phone
- SD NFC Software for PC
- SD NFC Reader/Writer

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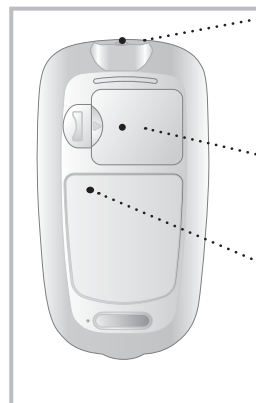
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6. SD GlucoNavii® NFC Meter

Display
Shows blood glucose result, messages, and glucose result stored in memory.

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

Arrow Buttons
Use for meter setup and review of memory moving to the right and left.

Test Strip Slot
Insert test strip here.

Data port
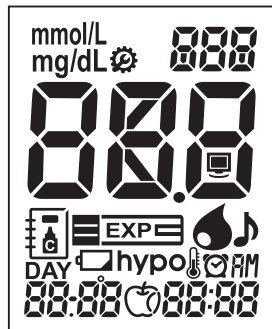Cominucate test results with a personal computer. (If you have software)

Battery Cover
Remove cover to change battery.

Location of NFC function
Tap a smartphone or SD NFC R/W for communication.

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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 and nfc message

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DAY	Indicates the average result	▤▭	Test strip
💧	Tell 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		
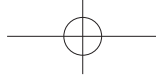
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1) Strip Stand-by Display

After turning on the meter, the below will be displayed automatically to show the test strip icon flashing. In this Strip Stand-by Display, it's able to enter setting mode of the meter or search the test results.
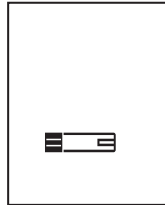
2) Blood Stand-by Display

If a test strip is inserted into the meter in either Strip Stand-by Display or turning off, the below will be displayed automatically to show the appropriate test result after applying blood sample. And if you pull off the test strip, it will return to Strip Stand-by Display. In this Blood Stand-by Display, the ON/OFF button doesn't act. But if you need to check the meter or the test strip, you may use a control solution. Then the control solution icon in the left-side of test strip icon will be displayed by pressing left button during 3 seconds.

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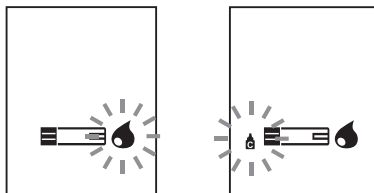
7.   SD GlucoNavii® NFC Test Strip

SD GlucoNavii® NFC System measures the amount of glucose in whole blood. Blood is applied in the Yellow Window (TOP EDGE) of SD GlucoNavii® NFC Test Strip and is automatically drawn into the reaction cell where the reaction takes place.
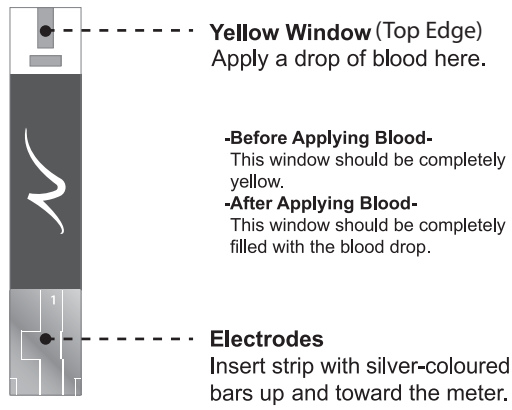
Yellow Window (Top Edge)
Apply a drop of blood here.

-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 silver-coloured bars up and toward the meter.

8. SD GlucoNavii® NFC Accessories

Lancet   SD Glucose check strip
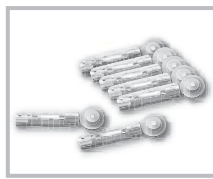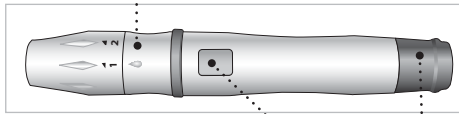

Electrode

Arming
Knob

Lancing Device

Cap & Comfort dial with puncture depth
selection

Release   Arming
Button   Knob

SD GlucoNavii® control solution

SD NFC Reader/Writer

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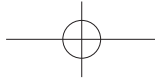
9. Changing the Battery
Inserting and replacing the Battery

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.
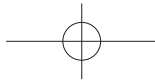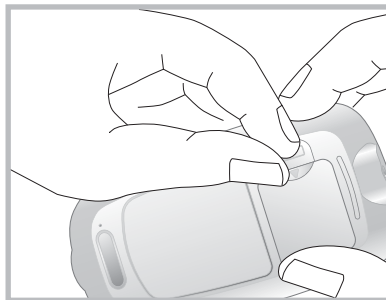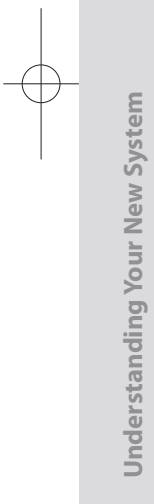
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STEP-2: Insert the 3V battery (type CR2032) into the compartment with "+" side facing you.
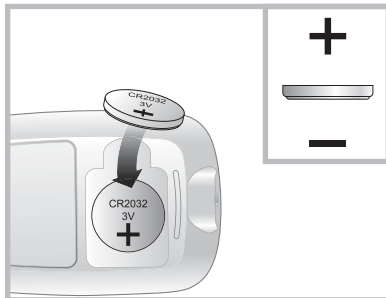
STEP-3: Snap battery cover back in place.
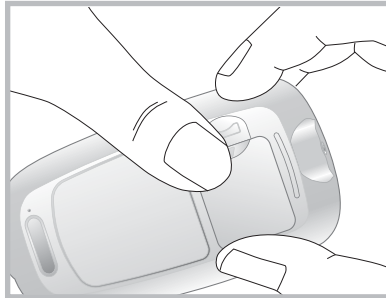
STEP-4: Push the ON/OFF button or insert a strip to start testing.

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 "10 Meter Set up".

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10. 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.

[During 3 sec.]
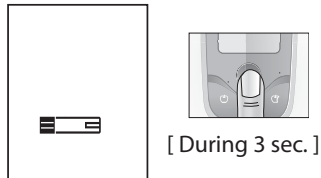
2. Set the beep mode on or off by pressing either the left or the right button and then selecting the preferred feature by pressing the ON/OFF button. If you select the beep on feature, a 'beep' sound is made at the same time; otherwise, if you select the beep off feature, no sound is made.

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

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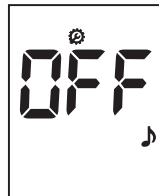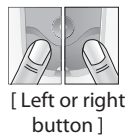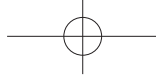
STEP-2: Setting the Hypo warning

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.

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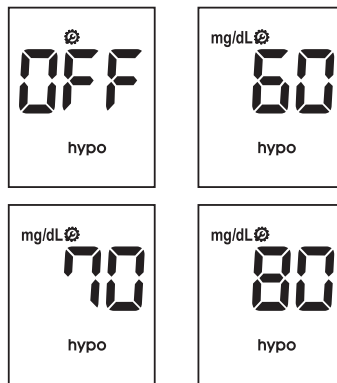
NOTE

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.

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[Left or right button]   [ON/OFF button]
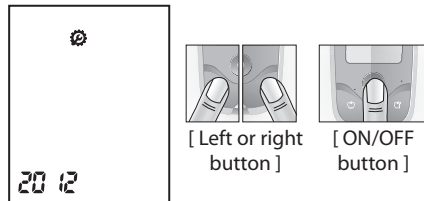
2. Next will appear the setting display for month and day format. The meter can display the month and day in either a Month-Day (m-d) format or a Day-Month (d-m) format. Set the preferred format on the display by pressing either the left or the right button and select by pressing the ON/OFF button.

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.

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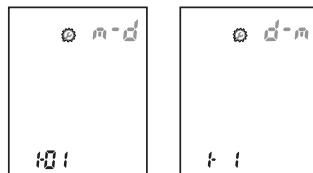
[Time Setting]

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 select 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.
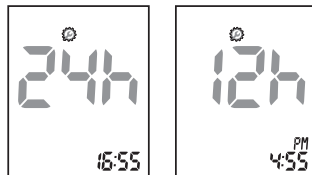
STEP-4: Post-meal alarm
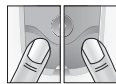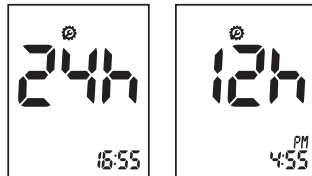
You can use the meter's post-meal alarm function to remind you to test your blood glucose after meal.

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.

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

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NOTE
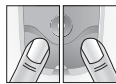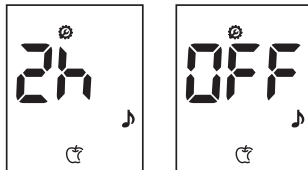
- If you select the post-meal alarm '2h' feature and test with pre-meal mark, the 'clock symbol' will appear on result display and the 'beep' sound will be made in 2 hours to remind you to test your blood glucose after meal for 1mimute.
- If you perform the pre-meal test while the post-meal alarm setting 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.

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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.
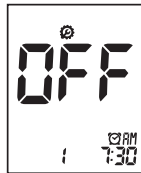
2. Set the first alarm on or off by pressing either the left or the right button and then select the preferred feature by pressing the ON/OFF button.

[Left or right   [ON/OFF
    button]   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.

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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.

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

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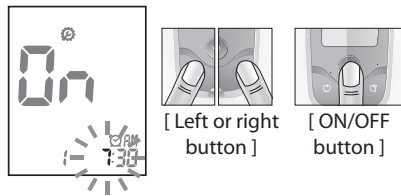
If you select the alarm off feature in first (also second, third and fourth) alarm mode, next will appear the Strip Stand-by Display.

4.   If you finish setting the first alarm, next will appear the second alarm setting mode. Set the alarm with the same way as above. [2, 3]
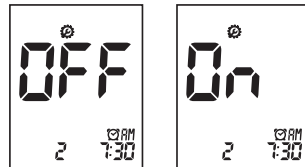
5.   You can set the third and fourth alarm mode with the same way as above. [2, 3]

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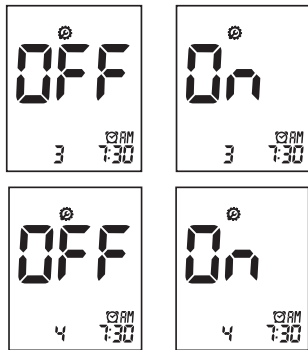
STEP-6: DATA REVIEW SETTING

This function is to review the latest test result when inserting the strip into the meter. You can check your latest test result before testing.

1.   After alarm setting, display the Data review setting mode.

2.   Set the data review function by pressing the left or right button for selecting the preferred feature.

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3.   If you finish data review setting mode, next appear at the strip-stand by display.
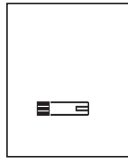
11. Using SD GlucoNavii® NFC Test Strips
[Important Test Strip Information]

- SD GlucoNavii® NFC blood glucose test strip should be used with SD GlucoNavii® NFC meter. Using other glucose test strip can cause inaccurate the result or 'E-1' error message.

- After removing a test strip from the container, replace the container cap immediately and close it tightly.
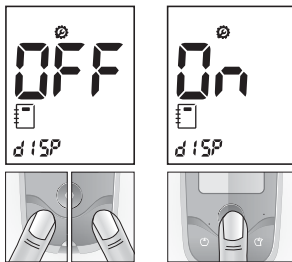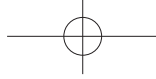
- Use the test strip within three minutes after you take it out of the container.

- 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.
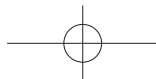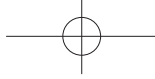
- Write the opening date on the container label when you first open it. Discard remaining SD GlucoNavii® NFC Test Strips after the discard date. (6 months after first opening from the container)

- SD GlucoNavii® NFC 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 SD GlucoNavii® NFC Test Strip in any way.

⚠️ **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.

Understanding Your New System

27
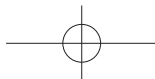
CHAPTER 2 :
Control Solution Test

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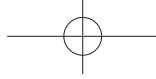
When you do control solution test ;
- You open a new box test strips.
- You left the test strip container open or you think your test strips have been damaged.
- Your test strips were stored in extreme temperatures and/ or humidity.
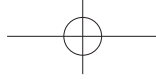- You want to check the meter and test strips.
- You dropped the meter.
- Your test result does not agree with how you feel.
- You want to check if you are testing correctly.

Before you begin ;
- Use only SD GlucoNavii® 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℃ (64-86℉) before testing with control solution.

Control Solution Test

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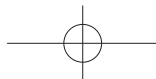
- Shake the container, discard the first drop of control solution, and wipe off the tip to ensure a proper sample and an accurate result.
- Store SD GlucoNavii® control solution tightly closed at temperatures between 8-30°C (46-86°F). Do Not refrigerate.

> **⚠ CAUTION**
> - Do not swallow SD GlucoNavii® control solution; it is not for human consumption.
> - Do not apply SD GlucoNavii® control solution to the skin or eyes as it may cause irritation.

1. Performing Control Solution Test
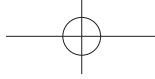
You need the meter, a test strip, and control solution Level M or Level H. The control level is printed on the test strip label.
For more information how to obtain SD GlucoNavii® control solution, call at +82-31-300-0400.

> **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 SD 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 include them in averages.

Control Solution Test
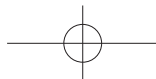
STEP-1:
1) Remove a new test strip from container. Be sure to tightly replace container cap after removing test strip.
2) Insert a test strip (yellow window printed ' ⁄ ' facing up) into test strip slot. The meter turns on automatically.

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 test, press the left button again.
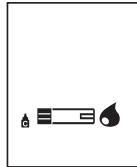
[Left button]

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

Control Solution Test

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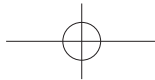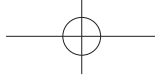
3) The control solution result appears on the screen in just 5 seconds.

4) Compare control solution result with 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.

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

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

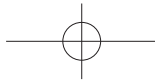[Example]

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.]

NOTE

Control Solution Test

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2. Troubleshooting Control Solution Test

| Check	Action
Did you do the test in control solution mode? Did you see "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 the container/bottle. Make sure the expiration date of both a test strip and a control solution.(test strip : 6 months, control solution : 3months)
Were control solutions at room temperature (18-30℃, 64-86°F) when used?	If not, retest with new bottle of control solution, or warm up/cool down to room temperature. (18-30℃, 64-86°F)

Control Solution Test

Check	Action
Did you insert test strip firmly into meter?	Make sure test strip is inserted into the test strip slot until it will go on further.
Did you follow the procedure correctly?	Read again "Chapter 2 : Control Solution Test" (pages 28-33) and retest.
Were test strips stored correctly? (at 2-32℃, 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 message?	If yes, contact SD Biosensor, Inc. at +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 SD Biosensor, Inc. at +82-31-300-0400.

Control Solution Test

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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.
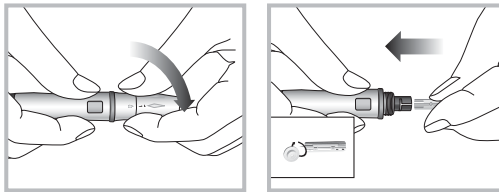

3) Replace the cap and turn it clockwise, until it is snug. Adjust the puncture depth setting by turning the comfort dial. The dial has 1 to 5 steps, and the higher the step number, the stronger the blood sampling pressure on the puncture site.

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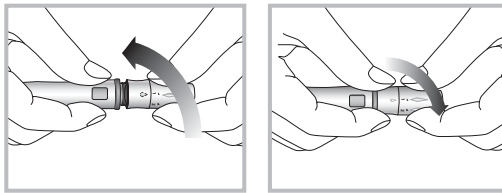
4)   After cocking the lancing device back, hold the lancing device firmly against the side of finger and then press the release button.

⚠ CAUTION
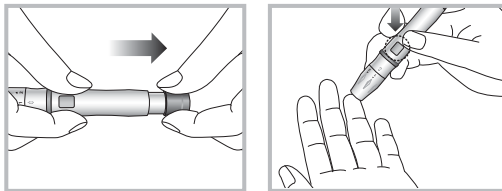
- A lancet should only be used once. Do not share used lancets with another person. To prevent possible infection, a used lancet should not be touched by another person.
- Used lancets in the regular trash can be dangerous. We recommend that you throw out the used lancets in sharps containers or test strip vials. Please be sure to save the cap so that the lancets cannot spill out of the container into the trash.

Testing Your Blood Sugar

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2. Performing a Blood Glucose Test

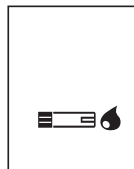 **NOTE** Always wash hands with warm, soapy water. Rinse and dry them before testing.

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

2) Make sure the meter turn off. And then, Insert the test strip into the meter.

3) When the blood drop symbol flashes (Blood Stand-by Display), you are ready to perform a test.

4) 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.

5) Obtain a drop of blood sample using the lancet and lancing device.

6) 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.
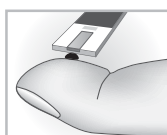
7) The blood will be drawn into the strip automatically. If beeper is turned on, meter will beep to let you know the test is beginning.

8) When blood is applied to the strip, start the test. After 5 seconds, the test result appears on the screen.

9) You can set the pre-meal or post-meal test if you want. The symbol indicating pre-meal( ) or post-meal( ) appears on the screen. Choose what you want by pressing the left or right button. If you press the On/Off button, no select any features.

10) When the test is done, pull out the used test strip and discard it.

NOTE

- Remove the inserted lancet from the lancing device and dispose the used lancet with care.
- Always use fresh capillary or venous whole blood for tests.
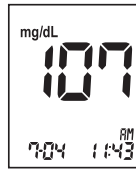- If you want to use NFC function, refer to 'Chapter 4. Using the NFC function' on page 40~44 .

Testing Your Blood Sugar

3. 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.
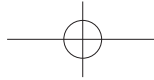

2.   If your blood glucose is above 600 mg/dL, you will receive a "HI" and is below 10 mg/dL, you will receive "Lo". In these cases, repeat the test with new test strip. If this message show again, contact your healthcare professional immediately.

3.   If you set the pre-meal mark after the test, you will receive a result with pre-meal mark. ( )
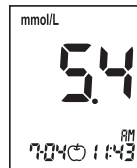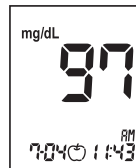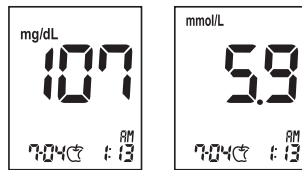
Testing Your Blood Sugar

4. If you set the post-meal mark after the 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]
• Fasting: 74 to 106 mg/dL
• 2 hours after meals : <140 mg/dL

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.

Testing Your Blood Sugar

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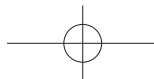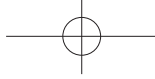
Chapter 4:
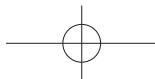## Using NFC function

1. Information on NFC function

NFC(Near field communication) is a set of standards for smartphones and similar devices to establish radio communication with each other by touching them together or bringing them into close proximit.

This function is comfortable for test results back-up at PC or smartphones. So, you can easily monitor your blood glucose results.

SD GlucoNavii® NFC follows "Felica" standard which include ISO/IEC 18092.

2. Information on Caution for NFC

- Check your smatphone or PC OS version.
  For PC, It is available for Windows XP, Windows VISTA, Windows 7 and need to SD NFC reader writer purchased separately.

  For Smartphone, It is available for only smartphones with Android OS v.2.3.1 or higher. Check the list in http://www.nfcworld. com/nfc-data/android/.
- Before using this function, check the meter turn off. If turn the meter on, you cannot use NFC function.
- Check the location of chip for NFC in your smartphone. It is different by manufacturer. For more information, refer to manufacturer website of your smartphone.
- SD NFC software for PC is able to download at www.sdbiosensor.com .
- If the distance between the meter and a smartphone(or

SD NFC reader writer) is far(about over 2cm/0.06ft), NFC function is not operated.

3. Using NFC function?

1) After testing or you want to test result back-up, turn the meter off.
2) Check the location of NFC at your smartphone.
3) If you tap SD GlucoNavii® NFC to your Smart phone, two kinds of action are happened. First, start App. Seconds, Upload Data. (If App. is already running, please, wait a minute.)

4) After finishing the communication, check that the test results are transferred well in your smartphone or PC.

NOTE More information on App or software for PC, refer to each manual.

Using NFC function

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4. How to use GlucoNaviiApp

1) Download & Install
   - Search 'GlucoNavii' in Google Play at your celphone. You can search other keyword that are 'SD Biosensor' or 'NFC glucose meter'.
   - Install GlucoNavii App. in your phone.

NOTE
NFC enabled smart-phone with Android OS v.2.3.1 or higher.
Check the list in http://www.nfcworld.com/nfc-data/android/.

   - Check the NFC function at your smart-phone. If it is the 'Off' setting, turn NFC function 'On'.
2) Communicate with SD GlucoNavii® NFC
   - Please power off SD GlucoNavii® NFC meter.
   - If you tap SD GlucoNavii® NFC to your smart-phone, two kinds of action will be happened. First, if App. is not turning it on, start App. Seconds, if App. is already running, please, wait a minute to upload test results.

NOTE
Please remember the points of contact for both devices.

3) Utilize GlucoNaviiApp
   (1) Start App.
   (2) If you need to upload new data, just tap GlucoNaviiNFC to your Smart Phone.

Using NFC function

5. How to use SD NFC Software for PC

1) Download the software at www.sdbiosensor.com. And then, start the software.
2) Turn the meter off. If not, you cannot start NFC function.
3) Tap the meter with SD NFC reader writer plugged with PC. And then, Start the communication.
4) After finishing the communication, you can look the log book(test results) or graph.

NOTE

More information on App or software for PC, refer to each manual.

If you have any question or queries about SDGlucoNaviiApp, or SD NFC Software for PC ,
please email to (SD_Dev@sdbiosensor.com).

NOTE

European Union Directive Conformance Statement

Hereby, SD Biosensor declares that SD GlucoNavii(R) NFC blood glucose meter is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC.

You can view your product's Declaration of Conformity(DoC) to Derictives 1995/5/EC(R&TTE) Directive at www.sdbiosensor.com.

CAUTION

WARNING: Changes or modifications made to this equipment not expressly approved by SD Biosensor, Inc. for compliance could void the user's authority to operate the equipment.

Using NFC function

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NOTE

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different.
- from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Using NFC function

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CHAPTER 5 :
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.
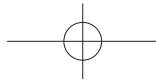
1. Searching Test Results

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.

[Left button]
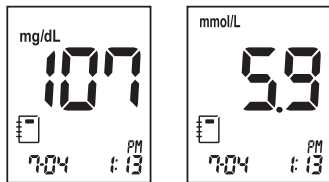
[Normal result]
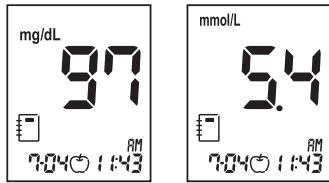
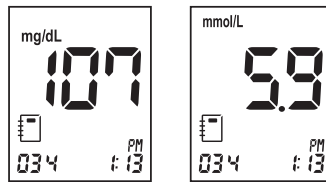[Pre-meal result]
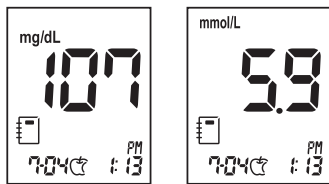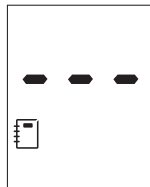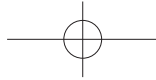

[Post-meal result]

Using the Meter Memory
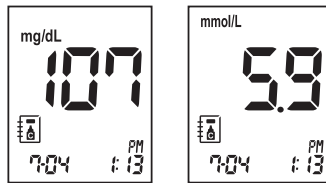
[Control Solution result]

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 second, and then the meter will display Strip Stand-by Display automatically.
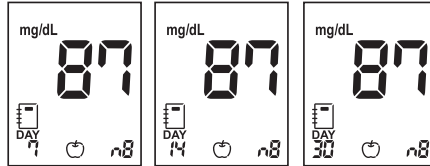

Using the Meter Memory

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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.
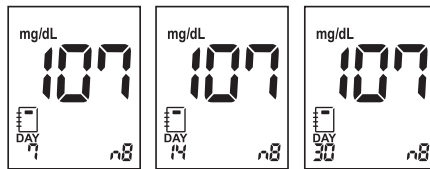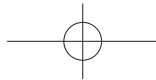

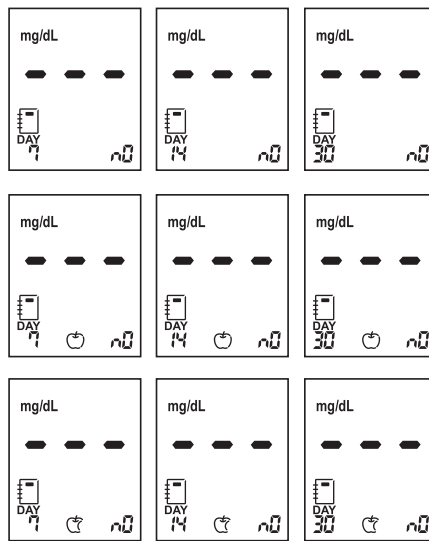[Normal average]

[Pre-meal average]
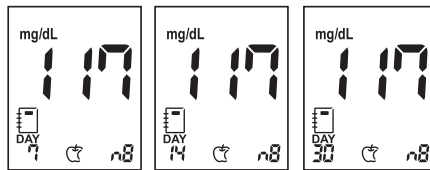
[Post-meal average]

Using the Meter Memory

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

mg/dL	mg/dL	mg/dL
— — —	— — —	— — —
DAY 7 ∽0	DAY 14 ∽0	DAY 30 ∽0

mg/dL	mg/dL	mg/dL
— — —	— — —	— — —
DAY 7 🍎 ∽0	DAY 14 🍎 ∽0	DAY 30 🍎 ∽0

mg/dL	mg/dL	mg/dL
— — —	— — —	— — —
DAY 7 🍎 ∽0	DAY 14 🍎 ∽0	DAY 30 🍎 ∽0

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.

Using the Meter Memory

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2. Downloading results to a computer

You can use your meter with SD NFC Software to store your records and to help you spot patterns for planning meals, exercise, and medication.

SD NFC Management Software puts information downloaded from the meter into charts, diagrams and graphs.

1) Obtain the SD NFC Software and SD NFC R/W.
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 SD NFC Software and Software Product manual(both are free of charge), please visit www.sdbiosensor.com.
- For ordering SD NFC Reader/Writer, 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.

Using the Meter Memory

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CHAPTER 6 :
Maintenance and Troubleshooting

1. Performing Check strip Test
#### When you do the check strip test?
- 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.
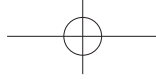- If you have repeated a test and the blood glucose result is still lower or higher than expected.

> ⚠️ **CAUTION** Check Strip test does not replace Control Solution test.

How to Use the check strip
1. Insert SD Glucose 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.

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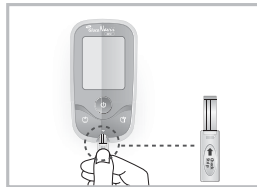
3. The check result appears on the screen in 5 seconds. 'OK' message appears on the screen if there isn't any problem for the meter. If not, 'EEE' message appears on the screen.

OK	EEE
10-29 15:34	
['OK' Message]	['EEE' Message]

2. Cleaning the meter

Caring for SD GlucoNavii® NFC 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.

Maintenance and Troubleshooting
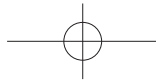
3. Maintenance, Testing and Transportation

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 and control solution haven't expired, and then run a control solution test.

Precautions for Maintenance, Testing and Transportation

1) 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.
- Do not modify the meter, such as resembling or remodeling, NFC function is not operated well. If any function is not perated, please contact SD Biosensor, Inc.

2) Test strip

- The test strip is sensitive to humidity, keep it in a dry and cool environment, and do not store in direct sunlight.
- 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.

Maintenance and Troubleshooting
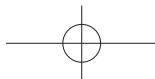
3) Lancet and Lancing device
- The needle of lancet is sharp, keep the lancet away from children.
- Keep the lancet and lancing device dry and do not store in direct sunlight, or high heat and humidity locations.
- A lancet should not use for the other intended use except sampling blood.
- A lancet is for single use only. Do not reuse.
- A lancet provided with SD GlucoNavii® NFC Blood glucose meter is able to use every lancing devices manufactured by other company. But if at all possible, use the lancing device manufactured by SD Biosensor, Inc.
- 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.

4) Control solution
- Keep SD GlucoNavii® control solution in 8-30°C (46-86°F) environment.
- Do not refrigerate or freeze.
- Do not use SD GlucoNavii® control solution that has passed the expiration date.
- SD GlucoNavii® control solution can be used for 3 months after opening the container. Write the opened date on the container when you 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 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 cap after cleaning by placing it in 70% rubbing alcohol for 10 minutes. Allow the cap to air-dry after disinfecting.

Maintenance and Troubleshooting

5. Screen Messages and Troubleshooting

Message Description

- The meter turns on normally.
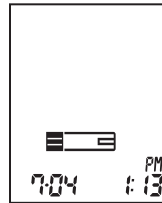
[Strip Stand-by Display]

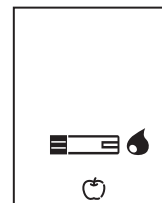- The meter is ready for you to insert a test strip.
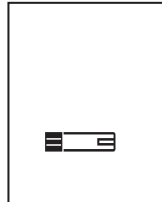
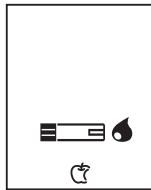### [Blood Stand-by Display]

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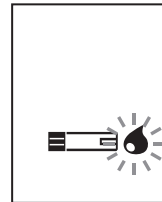
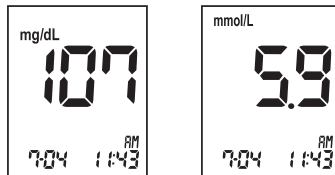- The meter is ready for a drop of blood with pre-meal mark.

Maintenance and Troubleshooting

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

• The meter shows the test result.

• The meter shows three kinds of average of results.
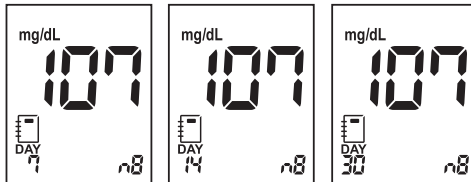
[Normal Results Average]
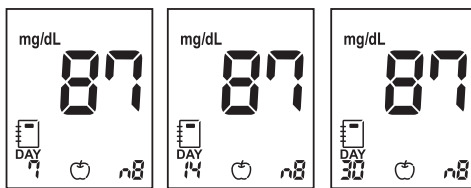
[Pre-meal Results Average]

Maintenance and Troubleshooting
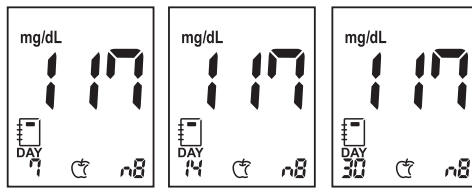
[Post-meal Results Average]

• The meter shows the saved results of blood glucose.
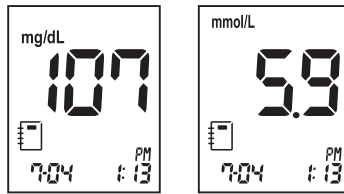
• The meter is ready for a drop of control solution.

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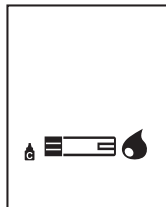
[Low battery]
- At this time, battery is getting low but you can still perform about 50 tests. Replace the battery soon. See Chapter 1 "9. Changing the Battery".
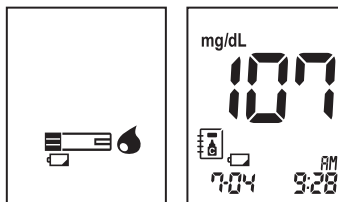
[Replace battery]
- Battery power is low. Replace the battery immediately. See Chapter 1 "9. Changing the Battery". If you press the ON/OFF button after discharging of the battery, the battery icon will flash and then after ten seconds the meter will turn off automatically.
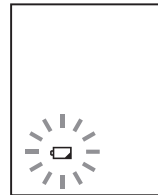
[HI message]
- Blood glucose may be higher than the measuring range of the system. See chapter 3 "4. Understanding Test Results".

Maintenance and Troubleshooting

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[Lo message]
- Blood glucose may be lower than the measuring range of the system. See chapter 3 "4. Understanding Test Results".

[Internal Error Message for a meter]
- Turn off a meter. Then turn on the meter again. If there is still error message, 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. See Chapter 3 "2. Performing a Blood Glucose Test".

Maintenance and Troubleshooting

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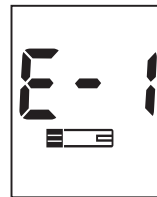
[Blood Sample Error]

- 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. See Chapter 3 "2. Performing a Blood Glucose Test".
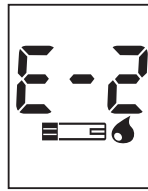
[Temperature Error]

- 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 8-45°C (46-113°F), wait for 30 minutes, and perform a test. Do not artificially heat or cool the meter. See Chapter 6. "Product Technical Information".
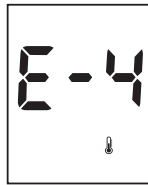
[Communication Error]

- The communication between meter and computer is failed. Connect again between meter and PC.
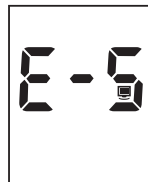
6. Warnings, Precautions and Limitations

- 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 greater than 70% 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.
- Interferences : The following compounds, elevated levels of ascorbic acid, uric acid, acetaminophen, total bilirubin, 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	> 1800 mg/dL

Maintenance and Troubleshooting

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- Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference.
- SD GlucoNavii® NFC System is not designed to be a substitute for pathology laboratory equipment and should not be used for the diagnosis of diabetes.
- Do not use SD GlucoNavii® NFC meter to test neonates. It has not been validated for neonatal use.
- Preservatives: When using the venous blood foe sample, blood may be collected by healthcare professional into test tubes the anticoagulants(EDTA, lithium heparin or sodium heparin). Do not use other anticoagulants or preservatives.
- Peritoneal dialysis solution: Icodextrin does not interfere with SD GlucoNavii® NFC test strip.

Maintenance and Troubleshooting
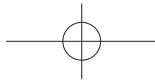
CHAPTER 7 :
Product Technical Information

1. System Specifications

Result Range	10 - 600 mg/dL, (0.6 - 33.3 mmol/L)
Calibration	Plasma-equivalent
Sample	Fresh capillary or venous whole blood
Sample Size	0.5 microliter
Test Time	5 seconds
Assay Method	Glucose Dehydrogenase 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	48 mm × 90 mm × 15 mm
Weight	50g (with battery)
Automatic Shutoff	• 1 minutes after last user action without inserting test strip into the meter • 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)
	- 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	8 - 45℃ (46 - 113°F)
Hematocrit	0 - 70%
Altitude	Up to 11,549 feet. (3,520 meters)

- Test strip

Storage	
Temperature	2℃ – 32℃ (36°F – 90°F)
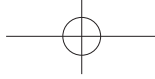
Annex 1 : Information for Healthcare Professionals

Healthcare professionals : Follow the infection control procedures appropriate for your facility

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.

Product Technical Information

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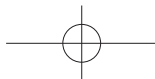
Annex 2 : Symbol

The following list describes all symbols used on SD GlucoNavii® NFC Blood glucose monitoring (BGM) system.

Symbol	Description
⚠	Caution, consult accompanying documents
CR2032	Battery type used in this meter
🗑	Crossed out wheeled bin: To discard it separately from other household waste
📖	Consult instructions for use
IVD	**In-vitro diagnostic medical device:** This system is intended to 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

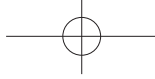| Symbol	Description
LOT	Lot No. or Batch Code To indicate the lot number for this system
	Expiry date: This system should be used by the given date.
	To indicate the temperature limitations in which the transport package has to be kept and handled
REF	Catalogue number: To indicate the catalogue number for this system
	To indicate the manufacturer
Σ	Contains Sufficient for <n> Tests
6M	To use for 6 months after first opening the container.
	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

Product Technical Information

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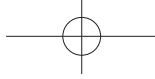
Annex 3 : References

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
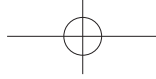
Product Technical Information

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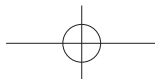
Return

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.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause

harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Product Technical Information

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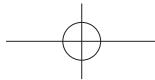
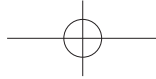**Manufactured by** ──────────

SD BIOSENSOR, Inc.

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

EC-Representative──────────
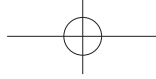
Authorized Representative ──────────

EC	REP

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

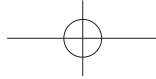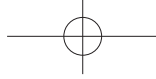**MEMO**

Product Technical Information

MEMO

Product Technical Information
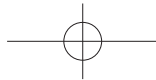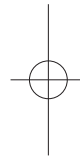
For further information on

SD GlucoNavii® NFC

**please contact your
SD BIOSENSOR, Inc.
Representative**

REF 01GM40/01GC40 series
FCC ID : RPJ01GM40

CE 0168
0123

C-4th&5th Floor Digital Empire Building 980-3,
Yeongtong-dong, Yeongtong-gu, Suwon-si, Kyonggi-do, Korea
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Issue Date: 2013.01

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