

SD GlucoNavii

Mentor **NFC**
Blood Glucose *Mobile* Monitoring System



User Instruction Guide

SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM

Dear SD GlucoNavii® Mentor NFC System Owner;

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



To identify conditions or practices that could result in damage to equipment or other property.



To provide an additional useful information.



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® Mentor 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 Glucose 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 Glucose 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).
- Only use SD GlucoNavii® Mentor test strips. Other test strips will give inaccurate results or E-1 error message.
- Do not use the SD GlucoNavii® Mentor 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 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® Mentor NFC system has been found to be accurate at altitudes up to 12,388 feet. (3,776 meters)

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- 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 Glucose 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. 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

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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 over 60% or below 20% can cause false results.

3. Indication for use (Purpose of the devices)

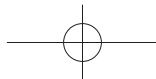
Your new SD GlucoNavii® Mentor NFC meter and accessories work together to measure the amount of glucose (sugar) in your blood.

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

4. Product Description and the Principle of the use

SD GlucoNavii® Mentor test strip is designed with an electrode that measures glucose levels. Glucose in the blood sample mixes with reagent on the test strip that cause a small electric current. The amount of current that



SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM

is created depends on how much glucose is in the blood. SD GlucoNavii® Mentor 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® Mentor test strip, the strip's reaction chamber automatically draws the blood into the strip through capillary action. When the chamber is full, SD GlucoNavii® Mentor 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:

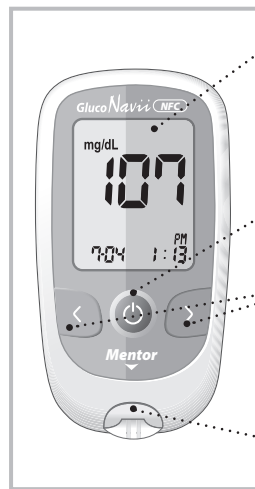
- SD GlucoNavii® Mentor NFC Meter
- SD Glucose Check strip
- 3V battery type CR2032
- User Instruction Guide
- Quick Guide
- Carrying Case
- Lancing device
- Lancing device
- Lancing device

<Option>

- SD GlucoNavii® Mentor Test strips
- SD GlucoNavii® Mentor Package Insert
- SD Glucose Control Solution
- SD Glucose Control Solution Package Insert
- Self-test Diary
- GlucoNavii Application for Android phone
- GlucoNavii DMS for PC
- NFC Reader/Writer

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6. SD GlucoNavii® Mentor NFC Meter



Display

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

ON/OFF Button

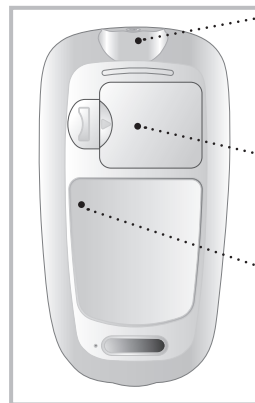
Press to turn meter ON or OFF.

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

Communicate test results with a personal computer. (If you have software)

Battery Cover

Remove cover to change battery.

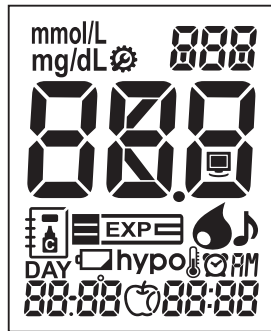
Location of NFC function








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

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Display



 08:08	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
08.08	Testing date		Indicates a test result stored in memory
mmol/L mg/dL	Unit of test result	000	Test result and nfc message

Understanding Your New System

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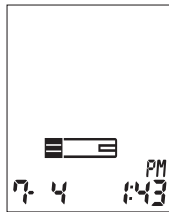
DAY	Indicates the average result		Test strip
	Tell you when to apply the sample and indicates if you select whole blood for blood reference type		Indicates a control solution test result
	Indicates alarm setting	hypo	Indicates hypo warning
	Indicates S/W communication		

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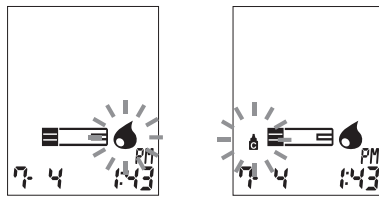
1) Strip Stand-by Display

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.

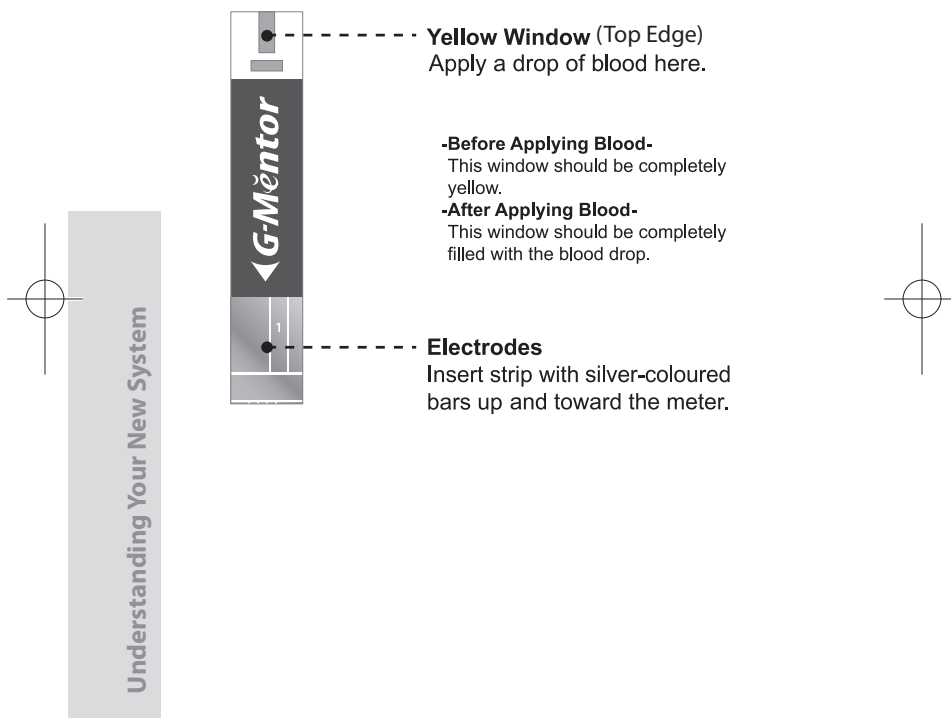


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7. SD GlucoNavii® Mentor Test Strip

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

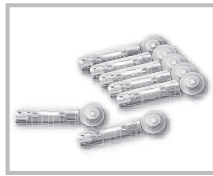


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8. SD GlucoNavii® Mentor NFC Accessories

Lancet

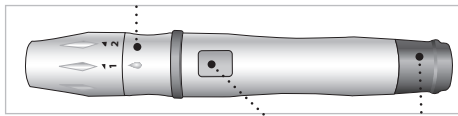
SD Glucose check strip



Electrode
Arming Knob

Lancing Device

Cap & Comfort dial with puncture depth selection



Release Button
Arming Knob

SD GlucoNavii® control solution



NFC Reader/Writer



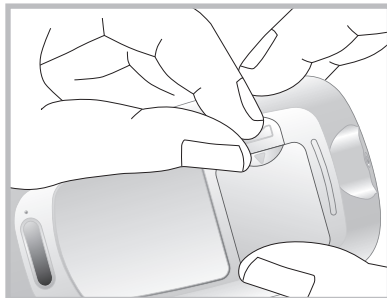
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9. Changing the Battery

Inserting and replacing the Battery

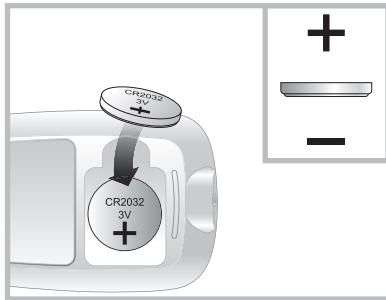
Your meter is shipped with one 3V battery type CR2032 that needs to be inserted before testing. The battery that comes with your meter can be found in the mesh pocket of your carrying case. Battery life will vary depending on usage, so always keep a spare on hand. The meter saves battery power by automatically 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.

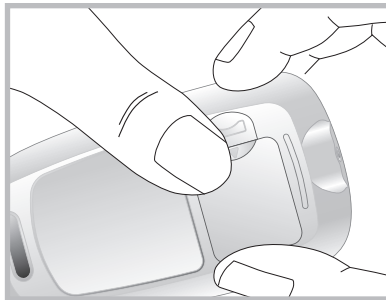


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STEP-2: Insert the 3V battery (type CR2032) into the compartment with “+” side facing you.



STEP-3: Snap battery cover back in place.



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

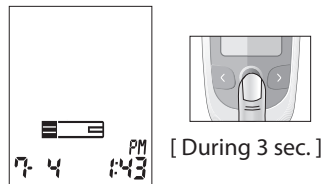


After inserting or replacing the battery, confirm that the time and date are set correctly. If they are not, use the ON/OFF and left/right buttons to reset the meter before testing. See the “10. Meter Set up”.

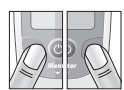
10. Meter Set up

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.



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



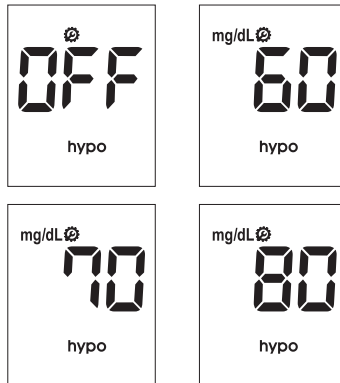
- You can set the meter to let you know when your result indicates a possible low blood glucose (hypoglycemia). You can also select what blood glucose level you want this indicator to have 60, 70, 80 mg/dL(3.3, 3.9, 4.4 mmol/L).
- If your results are lower than selected hypo result, the candy symbol 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

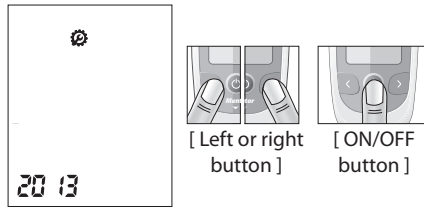
Your new meter comes with a preset time and date. You may need to change the time to your time zone. Having the right time and date in your meter is important if you use the meter memory. It also helps your healthcare team interpret your results.

STEP-3: Setting the date and time

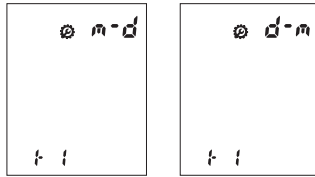
[Date Setting]

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.

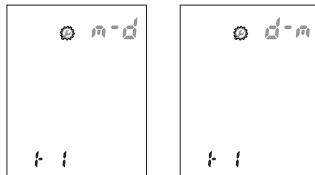
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2. Next will appear the setting display for month and day format. The meter can display the month and day in either a Month-Day (m-d) format or a Day-Month (d-m) format. Set the preferred format on the display by pressing either the left or the right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



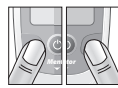
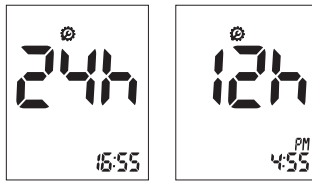
3. Set the correct month or day on the display by pressing either the left or the right button and select by pressing the ON/OFF button.



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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.

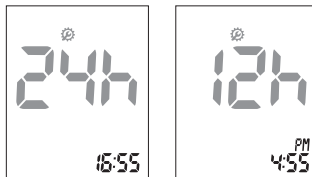


[Left or right button]



[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.



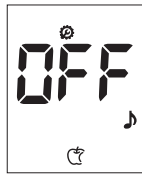
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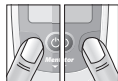
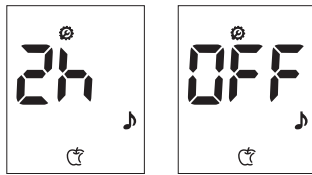
STEP-4: Post-meal alarm

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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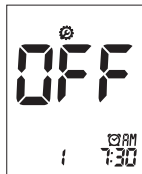
- If you select the post-meal alarm '2h' feature and test with pre-meal mark, the 'clock symbol' will appear on result display and the 'beep' sound will be made in 2 hours to remind you to test your blood glucose after meal for 1 minute.
- If you perform the pre-meal test while the post-meal alarm setting 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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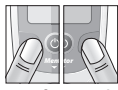
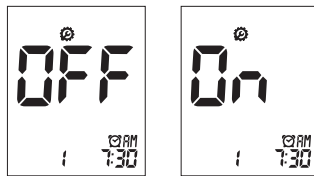
STEP-5: Setting the alarm

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 button]



[ON/OFF button]



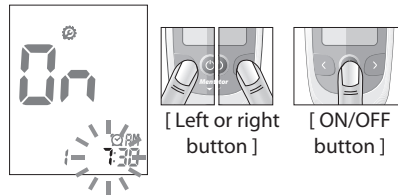
NOTE

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

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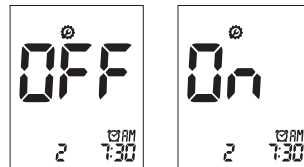
SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM

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.



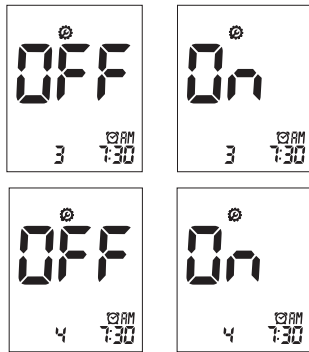
If you select the alarm off feature in first (also second, third and fourth) alarm mode, next will appear the Strip Stand-by Display.

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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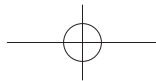


If you finish alarm setting, next appear at the strip-stand by display.

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11. Using SD GlucoNavii® Mentor NFC Test Strips [Important Test Strip Information]

- SD GlucoNavii® Mentor NFC blood glucose test strip should be used with SD GlucoNavii® Mentor 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® Mentor Test Strips after the discard date. (6 months after first opening from the container.)
- SD GlucoNavii® Mentor Test Strips are for single use only. Never reuse a test strip that has had either blood or control solution applied to it.



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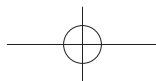
- Avoid getting dirt, food or liquids on the test strip. With clean, dry hands, you may touch the test strip anywhere on its surface.
- Do not bend, cut, or alter SD GlucoNavii® Mentor Test Strip in any way.



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



CHAPTER 2 : Control Solution Test

Why you do control solution test ;

- SD Glucose control solution is used to check that the meter and the test strips are working together as a system and that you are performing the test correctly.
- It is very important that you do this simple check routinely to make sure you get an accurate result.

When you 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 Glucose control solution.
- Check the expiration date on the control solution container. Record the opening date on the container label. Do Not use after expiration or discard date (date opened plus three months), whichever comes first.
- Control solution, meter and test strips should be at room temperature 18-30°C (64-86°F) before testing with control solution.

SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM

- 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 Glucose control solution tightly closed at temperatures between 8-30°C (46-86°F). Do Not refrigerate.



- Do not swallow SD Glucose control solution; it is not for human consumption.
- Do not apply SD Glucose 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 Glucose control solution, call at +82-31-300-0400.



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 Control Solution and blood. The meter automatically stores the test results using a control solution, letting you review them. But the meter does not include them in averages.

Control Solution Test

SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM

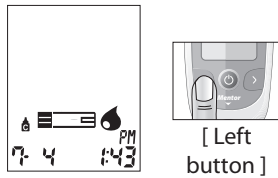
STEP-1:

- 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 'Mentor' 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.



- 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.

SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM

- 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.]

Control Solution Test

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°C, 64-86°F) when used?	If not, retest with new bottle of control solution, or warm up/cool down to room temperature. (18-30°C, 64-86°F)

Control Solution Test

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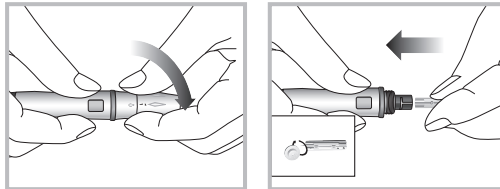
Check	Action
Did you insert test strip firmly into meter?	Make sure test strip is inserted into the test strip slot until it will go on further.
Did you follow the procedure correctly?	Read again "Chapter 2 : Control Solution Test" (pages 28-33) and retest.
Were test strips stored correctly? (at 2-32°C, 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 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

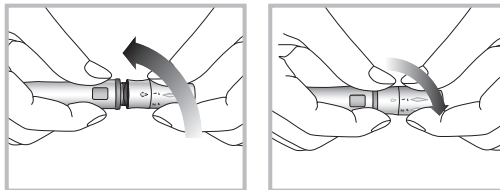
CHAPTER 3 : Testing Your Blood Glucose

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.

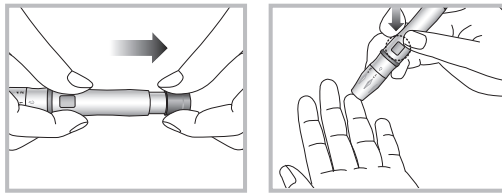


- 3) Replace the cap and turn it clockwise, until it is snug. Adjust the puncture depth setting by turning the comfort dial. The dial has 1 to 5 steps, and the higher the step number, the stronger the blood sampling pressure on the puncture site. The comport tip offers 5 different levels of skin penetration.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



SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM

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



- 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.

2. Performing a Blood Glucose Test

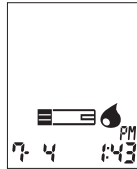


Always wash hands with warm, soapy water. Rinse and dry them before testing.

- 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.



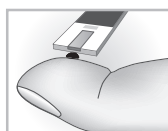
- 3) When the blood drop symbol flashes (Blood Stand-by Display), you are ready to perform a test.



- 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.

Testing Your Blood Sugar

SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM



- 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.
- 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) After applying the blood, the test result will appear for 5 seconds.
- 11) 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 .

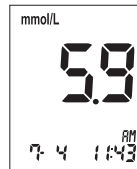
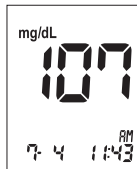
Testing Your Blood Sugar

SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM

3. Understanding Test Results

Your test results

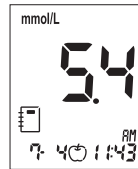
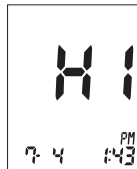
1. After 5 seconds testing time from applying a blood into strip, you will receive a normal result, 10mg/dL to 600mg/dL.



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.



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.



Testing Your Blood Sugar

SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM

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

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 proximity.

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

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

2. Information on Caution for NFC

- Check your smartphone or PC OS version. For PC, It is available for Windows XP, Windows VISTA, Windows 7 and need to 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 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 NFC Reader/Writer) is far(about over 2cm/0.06ft), NFC function is not operated.

SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM

3. Using NFC function

- 1) Check the location of NFC at your smartphone.
- 2) If you tap SD GlucoNavii® Mentor NFC to your smartphone, two kinds of action are happened. First, start GlucoNavii App., seconds, upload the glucose results stored in SD GlucoNavii® Mentor NFC meter to smartphone.



- 3) After finishing the communication, check that the test



NOTE

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

results are transferred well in your smartphone or PC.

Using NFC function

4. How to use GlucoNavii App

1) Download & Install

- Search 'GlucoNavii' in Google Play at your smartphone. You can search other keyword that are 'SD Biosensor'.
- Install GlucoNavii App. in your smartphone.



NFC enabled smartphone 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 smartphone. If it is the 'Off' setting, turn NFC function 'On'.
- 2) Communicate with SD GlucoNavii® Mentor NFC meter
- If you tap SD GlucoNavii® Mentor NFC meter 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.



Please remember the points of contact for both devices.

3) Utilize GlucoNavii App

- (1) Start App.
- (2) If you need to upload new data, just tap SD GlucoNavii NFC meter to your smartphone.

Using NFC function

5. How to use GlucoNavii DMS 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 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.



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

If you have any question or queries about GlucoNavii App.or GlucoNavii DMS for PC, please email to (SD_Dev@sdbiosensor.com).

European Union Directive Conformance Statement



Hereby, SD Biosensor declares that SD GlucoNavii® Mentor 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.



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

SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM

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.



NOTE

Using NFC function

CHAPTER 5 : Using the Meter Memory

The meter automatically stores about 300 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.

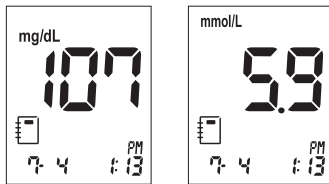
SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM

1. Searching Test Results

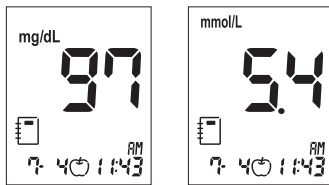
- 1) In Strip Stand-by Display, press the left arrow button to review in sequence from the most recent test result to the last test results stored in memory.



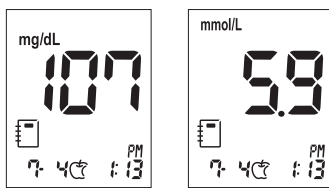
[Left button]



[Normal result]



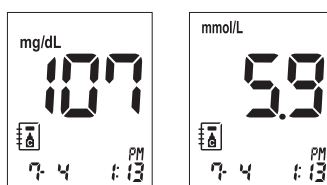
[Pre-meal result]



[Post-meal result]

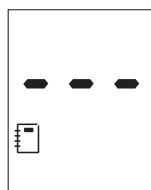
Using the Meter Memory

SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM



[Control Solution result]

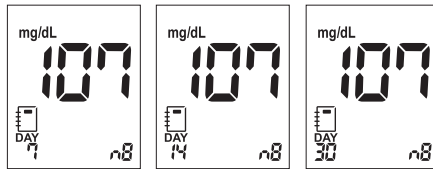
- 2) If there aren't the stored test results, the following display appears for 1 second, and then the meter will display Strip Stand-by Display automatically.



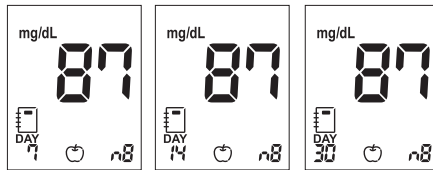
SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM

- 3) 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.

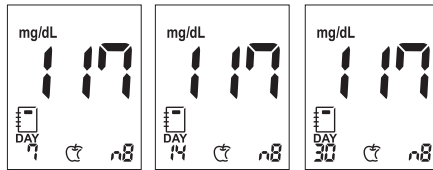
Using the Meter Memory



[Normal average]



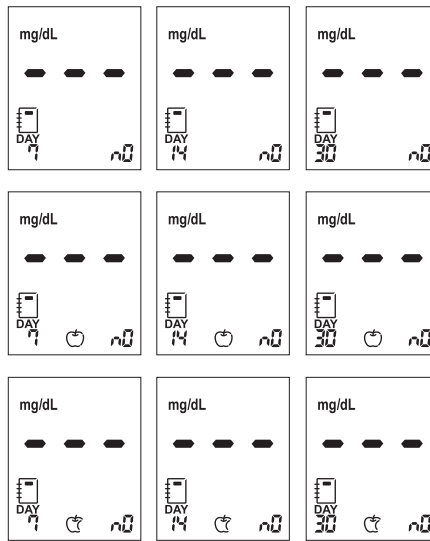
[Pre-meal average]



[Post-meal average]

SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM

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



NOTE

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

Using the Meter Memory

2. Downloading results to a computer

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

GlucoNavii DMS puts information downloaded from the meter into charts, diagrams and graphs.

- 1) Obtain the GlucoNavii DMS and NFC Reader/Writer.
- 2) Install the software on a personal computer. Please refer to Software Product Manual.

- While the meter is connected to the PC, it is unable to perform a blood glucose test.
- For downloading GlucoNavii DMS and Software Product manual(both are free of charge), please visit www.sdbiosensor.com.
- For ordering 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



CHAPTER 6 : Maintenance and Troubleshooting

1. Performing Check strip Test

When you do the check strip test?

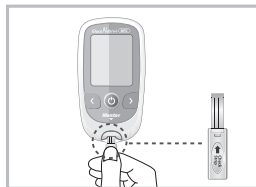
- When you want to easily check the performance of the meter.
- Before using your meter for the first time.
- Whenever your result does not agree with the level you feel.
- If you have repeated a test and the blood glucose result is still lower or higher than expected.



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.



SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM

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'
Message]



['EEE'
Message]

2. Cleaning the meter

Caring for SD GlucoNavii® Mentor 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.

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 remodeling 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.

SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM

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® Mentor 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 Glucose control solution in 8-30°C (46-86°F) environment.
- Do not refrigerate or freeze.
- Do not use SD Glucose control solution that has passed the expiration date.
- SD Glucose 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.

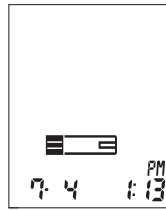
4. Cleaning the Lancing Device

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.

5. Screen Messages and Troubleshooting

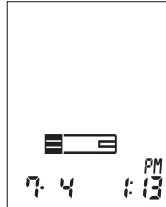
Message Description

- The meter turns on normally.



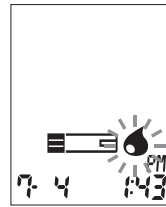
[Strip Stand-by Display]

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



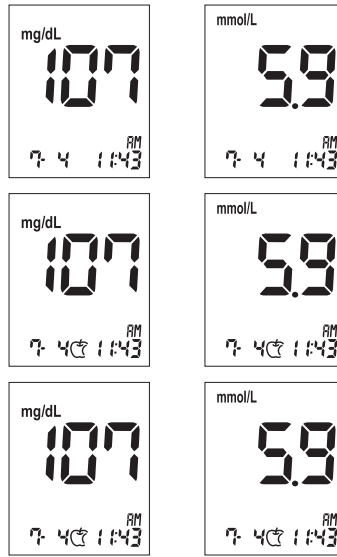
[Blood Stand-by Display]

- The meter is ready for a drop of blood.



SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM

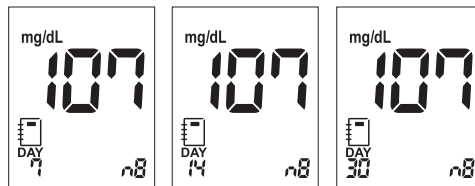
- The meter shows the test result.



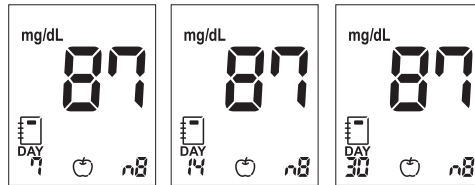
Maintenance and Troubleshooting

SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM

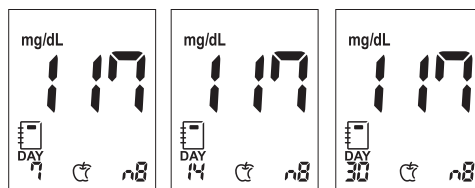
- The meter shows three kinds of average of results.



[Normal Results Average]



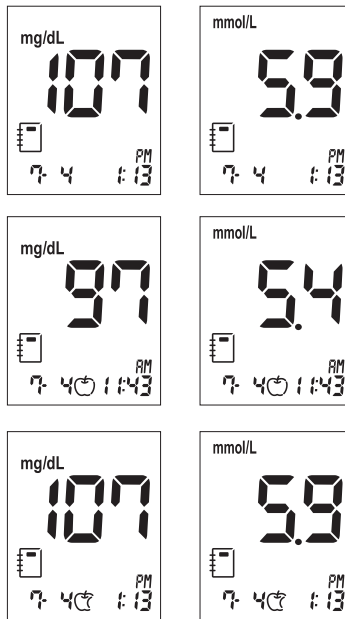
[Pre-meal Results Average]



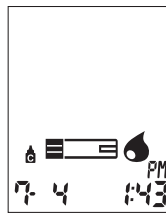
[Post-meal Results Average]

SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM

- The meter shows the saved results of blood glucose.



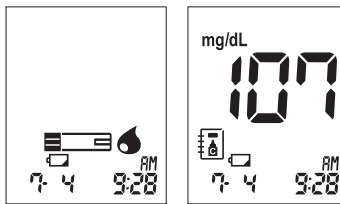
- The meter is ready for a drop of control solution.



SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM

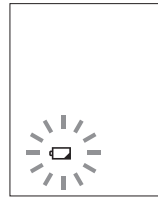
[Low battery]

- 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".



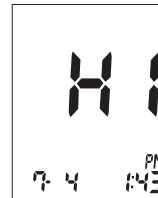
[Replace battery]

- 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".



SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM**[Lo message]**

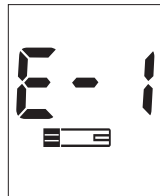
- Blood glucose may be lower than the measuring range of the system. See chapter 3 "4. Understanding Test Results".

**[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]**

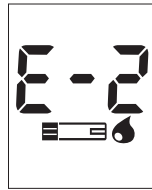
- Defective test strip or the test strip is damaged or inserted improperly. Discard this test strip and test again using new test strip. See Chapter 3 "2. Performing a Blood Glucose Test".



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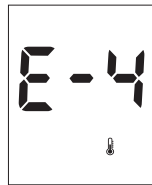
[Blood Sample Error]

- 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".



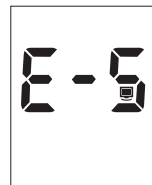
[Temperature Error]

- 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.

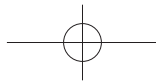


6. Warnings, Precautions and Limitations

- 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 less than 20% may cause falsely high readings. Hematocrit levels greater than 60% may cause falsely low readings.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.
- Normal endogenous (within body) natural levels of uric acid, ascorbic acid (vitamin C), bilirubin, triglycerides, and hemoglobin do not interfere with your blood glucose results obtained.
- 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	> 1026 mg/dL

Maintenance and Troubleshooting

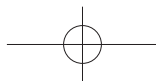


SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM

- Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference.
- SD GlucoNavii® Mentor 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® Mentor NFC meter to test neonates. It has not been validated for neonatal use.



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 whole blood
Sample Size	0.3 microliter
Test Time	5 seconds
Assay Method	Glucose Oxidase Biosensor
ON/OFF Source	Battery type CR2032
Battery Life	Around 1,000 tests
Glucose Unit	mg/dL , mmol/L
Display	LCD (Customized)
Controls	3 Buttons
Size	50mm ×93 mm ×18 mm
Weight	50g (with battery)
Automatic Shutoff	<ul style="list-style-type: none"> • 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

SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM

Memory	300 blood glucose tests
Function	<ul style="list-style-type: none"> - 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 <ol style="list-style-type: none"> 1)Normal Results 2)Pre-meal Results 3)Post-meal Results - Automatic shutoff

- System

Operation	
Temperature	10 - 45°C (48 - 113°F)
Hematocrit	20~60%
Altitude	Up to 12,388 feet. (3,776 meters)

- Test strip

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

Product Technical Information

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.

SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM









Annex 2 : Symbol

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

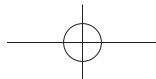
Symbol	Description
	Caution, consult accompanying documents
	Battery type used in this meter
	Crossed out wheeled bin: To discard it separately from other household waste
	Consult instructions for use
	In-vitro diagnostic medical device: This system is intended to use outside the body (in vitro diagnostic use).
	Serial number for this meter.
	Date of manufacture : To indicate the date of manufacture for this meter

Product Technical Information

SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM

Symbol	Description
	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
	Catalogue number: To indicate the catalogue number for this system
	To indicate the manufacturer
	Contains Sufficient for <n> Tests
	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

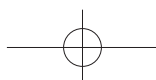
Product Technical Information

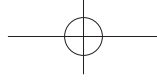


SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM

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



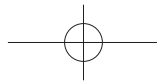


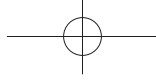
SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM

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.





SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM

Manufactured by _____
SD BIOSENSOR, Inc.

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

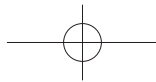
EC-Representative _____

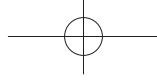


Authorized Representative
MT Promedt Consulting GmbH
Altenhofstrasse 80 D-66386 St. Ingbert Germany
Phone : +49 6894 581020, Fax : +49 6894 581021



Product Technical Information

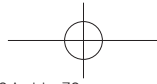




SD GlucoNavii® Mentor NFC BLOOD GLUCOSE MONITORING SYSTEM

MEMO

Product Technical Information



REF 01GM24/01GC24 series

CE0168
0123

FCC ID: RRU01GM24
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