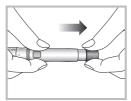


4) After cocking the lancing device back, hold the lancing device firmly against the side of finger and then press the release button.







- 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.

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.



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.
- 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(⑦) or post-meal(⑦) 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.



- 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 42~46.

Your test results

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





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. ()











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.

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® Voice N follows "Felica" standard which include ISO/IEC 18092.

2. Information on Caution for Voice N

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 <u>www.sdbiosensor.com</u>.

Using NFC function

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?

- After testing or you want to test result back-up, turn the meter off.
- 2) Check the location of Voice N at your smartphone.
- 3) If you tap SD GlucoNavii® Voice N 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.



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

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



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® Voice N
 - Please power off SD GlucoNavii® Voice N meter.
 - If you tap SD GlucoNavii® Voice N to your smartphone, 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 GlucoNaviiApp
 - (1) Start App.
 - (2) If you need to upload new data, just tap GlucoNavii® Voice N to your smart-phone.

Using NFC function

5. How to use SD NFC Software for PC

- 1) Download the software at <u>www.sdbiosensor.com</u>. 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.



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).

European Union Directive Conformance Statement



Hereby, SD Biosensor declares that SD GlucoNavii® Voice N 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.

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.

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)premeal 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.





[Normal result]





[Pre-meal result]





[Post-meal result]





[Control Solution result]

 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.









[Normal average]







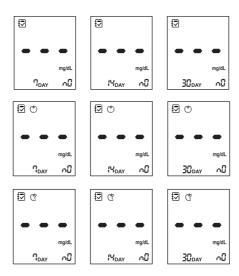
[Pre-meal average]







[Post-meal average]





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

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.
 - 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 <u>www.sdbiosensor.com</u>.



- 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.

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

- 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.



Maintenance and Troubleshooting

SD GlucoNavii® Voice N 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® Voice N 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.

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.

${\bf Precautions} \ {\bf for} \ {\bf Maintenance, Testing} \ {\bf and Transportation}$

1) Meter

- Keep the test strip slot free of dust.
- Protect the internal meter from humidity.

3. Maintenance, Testing and Transportation

- 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.

3) Lancet and Lancing device

- The needle of lancet is sharp, keep the lancet away from
- 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® Voice N 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,
- Before using, check a packaging condition, if there is any problem, you should not use it.
- If a lancet protective disk is loosed or needle of a lancet is exposed, you should not use it.
- To reduce the chance of infection for the used lancet, discard it.

Control solution

- Keep 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.

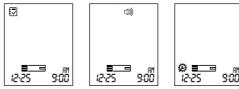
5. Screen Messages and Troubleshooting Message Description

• 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.



SD GlucoNavii® Voice N BLOOD GLUCOSE MONITORING SYSTEM

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]







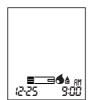
[Post-meal Results Average]

• The meter shows the saved results of blood glucose.





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



[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".



[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

[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 7. "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

SD GlucoNavii® Voice N BLOOD GLUCOSE MONITORING SYSTEM

- Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference.
- SD GlucoNavii® Voice N 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® Voice N 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® Voice N test strip.

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	Two replaceable 1.5V Alkaline Batteries type AAA
Battery Life	Around 1,000 tests
Glucose Unit	mg/dL , mmol/L
Display	LCD (Customized)
Controls	3 Buttons
Size	52 mm x 95 mm x 19 mm
Weight	150g (with batteries)
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

Product Technical Information

SD GlucoNavii® Voice N BLOOD GLUCOSE MONITORING SYSTEM

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 - Voice announce (3 Language)

- Meter

Operation	
Temperature	8 - 45°C (46 - 113°F)
Hematocrit	0 - 70%
Altitude	Up to 11,549 feet. (3,520 meters)

- Test strip

Storage		
Temperature	2 – 32°C (36 – 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.

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

Symbol	Description
\triangle	Caution, consult accompanying documents
$\bigcirc \mathbf{i}$	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.
M	Date of manufacture : To indicate the date of manufacture for this meter

Product Technical Information

SD GlucoNavii° Voice N BLOOD GLUCOSE MONITORING SYSTEM

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
$\overline{\Sigma}$	Contains Sufficient for <n> Tests</n>
6M	To use for 6 months after first opening the container.
②	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

Annex 3: References

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

Return

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

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.

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