

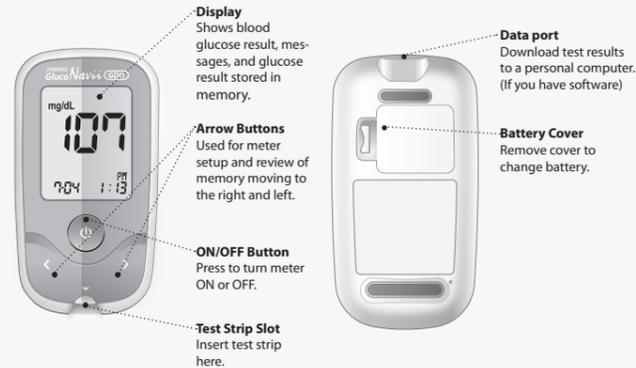
1. Product Structure

List of the system

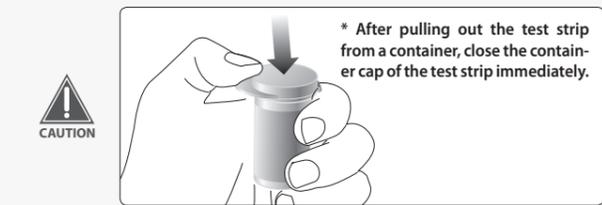


- <Option>**
- STANDARD GlucoNavii GDH Blood Glucose Test Strips
 - Lancing Device (with a white cap for fingertip testing and a clear cap for Alternative Site Testing)
 - Lancet
 - STANDARD GlucoNavii Control Solution

STANDARD GlucoNavii GDH Blood Glucose Meter

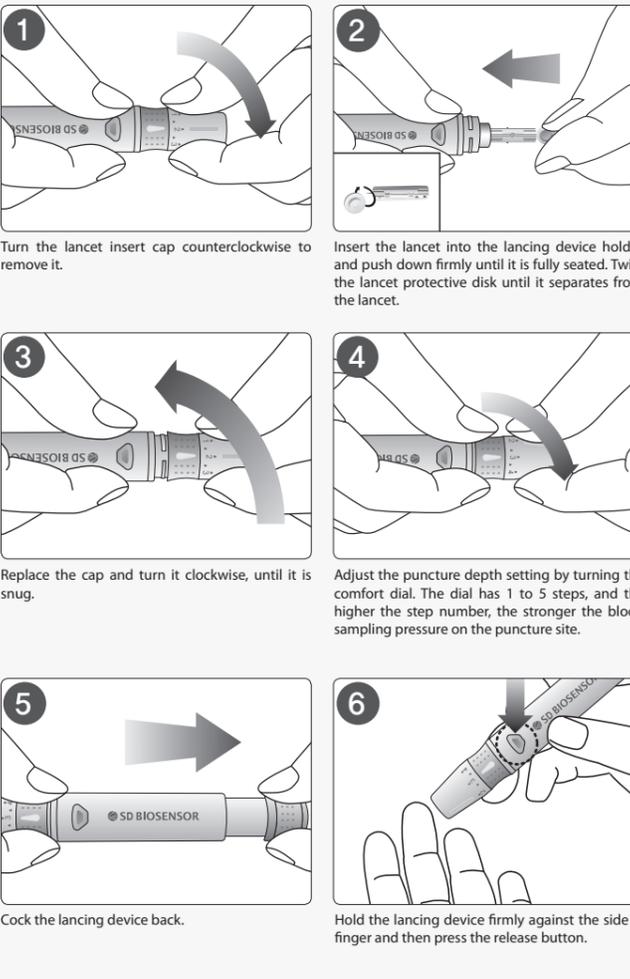
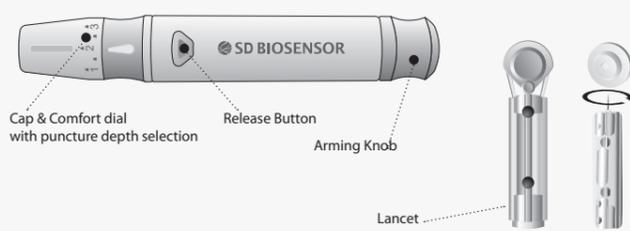


STANDARD GlucoNavii GDH Blood Glucose Test Strips

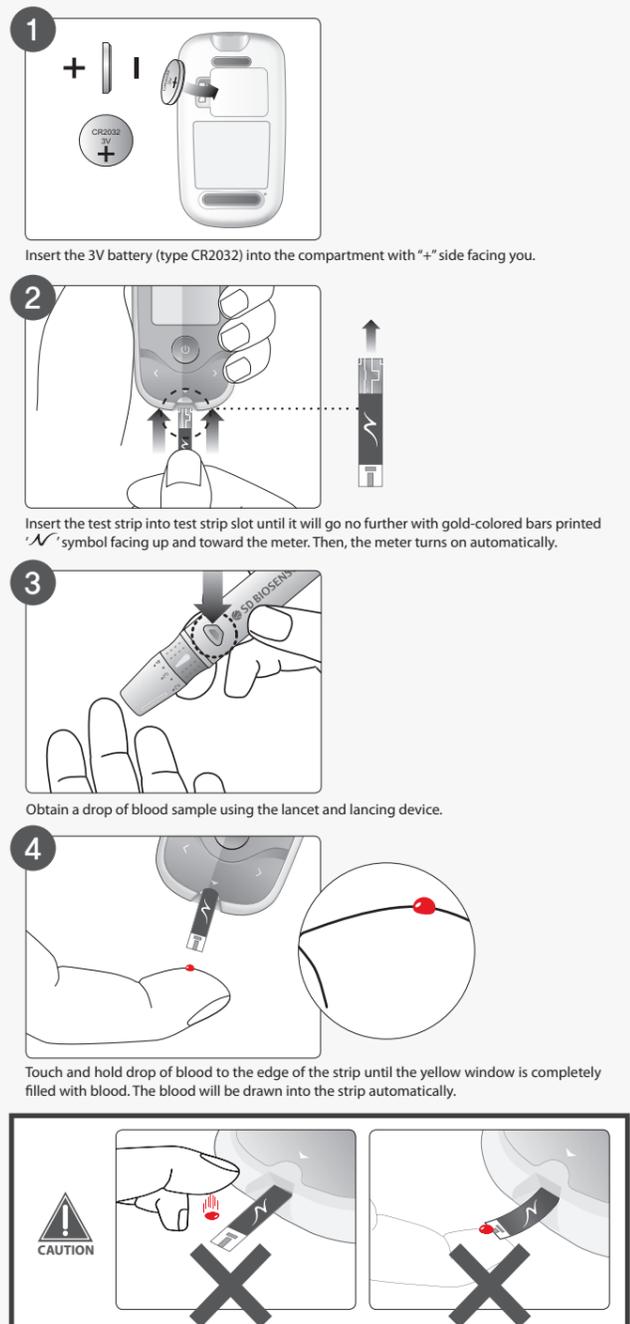


2. Blood Collection

Lancing Device / Lancet



3. Test Procedure



STANDARD GlucoNavii[®] GDH

BLOOD GLUCOSE MONITORING SYSTEM

Important steps for using this 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.

CHAPTER 1: Understanding Your New System

1. Intended Use

Your new STANDARD GlucoNavii GDH Blood Glucose Meter and accessories work together to measure the amount of glucose (sugar) in your blood. Your STANDARD GlucoNavii GDH Blood Glucose Monitoring System is indicated for monitoring glucose in fresh capillary whole blood or fresh venous blood or arterial blood. STANDARD GlucoNavii GDH Blood Glucose Monitoring System is suitable for self-testing and testing is done outside the body. (*in vitro* diagnostic use) This system is indicated for home (over-the-counter or OTC) by person with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control. This system should not be used for the diagnosis of diabetes or for testing neonates for self-testing use. The measurement using the venous, arterial and neonatal blood should be done by healthcare professionals.

2. Product Description and the Principle of the use

STANDARD GlucoNavii GDH Blood Glucose Test Strip is designed with an electrode that measures glucose levels. Glucose in the blood sample mixes with reagent on the test strip that cause a small electric current. The amount of current that is created depends on how much glucose is in the blood.

STANDARD GlucoNavii GDH Blood Glucose Meter measures the current that is created and converts the measurement to the amount of glucose that is in the blood. The blood glucose result is displayed on the meter's LCD display. By touching a drop of blood to the tip of the test strip, the strip's reaction chamber automatically draws the blood into the strip through capillary action. When the chamber is full, the meter start to measure the blood glucose level. It is a simple and practical system for the daily monitoring of your blood glucose level.

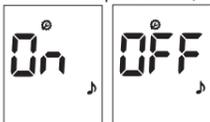
3. Reagent Composition: Active Ingredient (per 100 strips)

Glucose dehydrogenase (GDH) 39.2 units
Potassium ferricyanide (mediator) 1.9 mg

4. Meter Set up

STEP-1 : Setting the Audible Beep

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

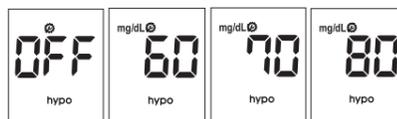


STEP-2: Setting the Hypo warning



- 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 hypo icon will appear on LCD with a 'beep' sound. It is very important to manage your hypoglycemia.

- After beep setting, the display for setting the hypo warning will appear, the second of setting mode.
- 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.



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.

STEP-3: Setting the date and time

[Date Setting]

- 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.
- 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.

[Time Setting]

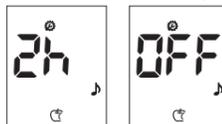
- Next will appear the display for setting the 12 or 24 Hour clock format. The meter can display the time in either the 12h format or the 24h format. Set the preferred format on the display by pressing either the left or the right button and select by pressing the ON/OFF button.
- Next will appear the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



STEP-4: Post-meal alarm

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

- After day and time setting, the display for setting the post-meal alarm will appear, the fourth of setting mode.
- 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.



- 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.

STEP-5: Setting the alarm

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

- After Post-meal alarm setting the display for setting the alarm will appear, the fifth of setting mode.
- 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.



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

- 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.

- 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]
- You can set the third and fourth alarm mode with the same way as above. [2, 3]
- If you finish setting the last alarm, next appear at the strip-stand by display.

5. Precaution and Warning

- STANDARD GlucoNavii GDH Blood Glucose Monitoring 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 STANDARD GlucoNavii GDH Blood Glucose Monitoring System to test neonates for self-testing use. Only professional can use this system for neonatal use.
- Never make significant changes to your diabetes control program or ignore physical symptom without consulting with your healthcare professional.
- Do not use this device to measure blood glucose in people who are experiencing cardiovascular collapse (severe shock) or decreased peripheral blood flow.

[Meter]

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

[Test Strip]

- Only use STANDARD GlucoNavii GDH Blood Glucose Test Strips. Using other test strips with this meter can cause inaccurate results or E-1 error message.
- After removing a test strip from the container, replace the container cap immediately and close it tightly.
- 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. After pulling out the test strip from its container, close a container cap of the test strip immediately.
- 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 test strips after the discard date. (6 months after first opening from the container)
- Do Not use test strips beyond the expiration (printed on package) or discard date, whichever comes first, because they may cause inaccurate results.
- The test strips are for single use only. Never reuse a test strip that has had either blood or control solution applied to it.
- Avoid getting dirt, food or liquids on the test strip. With clean, dry hands, you may touch the test strip anywhere on its surface.
- Do Not bend, cut, or alter a test strip in any way.
- Use only fresh capillary whole blood and venous whole blood and arterial blood. Do not use serum, plasma.
- Not following these precautions can lead to inaccurate results.
- 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.
- Interferences: The following compounds, elevated levels of ascorbic acid, uric acid, acetaminophen, total bilirubin and triglycerides may affect results.

Material	Limitation
Acetaminophen	> 6mg/dL
Ascorbic Acid	> 4mg/dL
Bilirubin	> 40mg/dL
Total cholesterol	> 240mg/dL
Creatinine	> 30mg/dL
Dopamine	> 5mg/dL
EDTA	> 0.1mg/dL
Galactose	> 60mg/dL
Gentisic Acid	> 1.8mg/dL
Glutathione	> 9.2mg/dL
Hemoglobin	> 200mg/dL
Pralidoxime Iodide	> 1.3mg/dL
Heparin	> 3,000U/L
Ibuprofen	> 50mg/dL
Levodopa	> 4mg/dL
Maltose	> 60mg/dL
Methyl-Dopa	> 2mg/dL
Sodium Salicylate	> 20mg/dL
Tolazamide	> 9mg/dL
Tolbutamide	> 4mg/dL
Triglycerides	> 1,800mg/dL
Uric Acid	> 9mg/dL
Xylose	> 60mg/dL
Icodextrin	> 750mg/dL

- Peritoneal dialysis solution: Icodextrin does not interfere with STANDARD GlucoNavii GDH test strip.
- Preservatives: when using the venous blood for 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.

[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 STANDARD GlucoNavii GDH 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.

[Control solution]

- Keep STANDARD GlucoNavii Control Solution in 8-30°C (46-86°F) environment.
- Do not refrigerate or freeze.
- Do not use STANDARD GlucoNavii Control Solution that has passed the expiration date.
- STANDARD 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.

6. Understanding your testing result

[Normal blood glucose result]

Expected blood glucose values for non-diabetic adults are as follows¹

- Before meals < 100 mg/dL (5.55 mmol/L)
- After meals < 140 mg/dL (7.8 mmol/L)



Consult with your healthcare professional for the blood glucose range that is appropriate for you.

[Test Result Range]

The meter reads blood glucose results at 10-600 mg/dL.

- If 'Hi' is displayed, your blood glucose result may be higher than 600 mg/dL. You may have high blood glucose.
- If 'Lo' is displayed, your blood glucose result may be lower than 10 mg/dL. You may have low blood glucose.



High or low blood glucose results can indicate potentially serious medical conditions. In case of an unexpected result, you should repeat the test immediately using a new test strip. If your reading is still unexpected or the reading is not consistent with how you feel, you should treat as prescribed by your healthcare professional and/or contact your healthcare professional immediately.

CHAPTER 2: Control Material

Why you do control solution / Check strip test;

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

When you do a quality control 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.
- 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.

Before you begin;

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



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

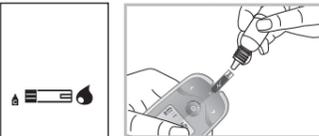
1. Performing a Control Solution Test

You need the meter, a test strip, and control solution level 2 or 3. The acceptable range of each level is printed on the test strip label.

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



- Press the left button for 3 seconds to check the testing system using a control solution in Blood Stand-by Display. If you don't want a control solution check, press the left button again.
- 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.



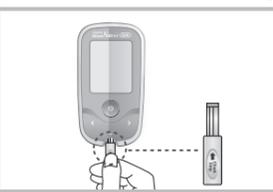
- The control solution result appears on the display in just 5 seconds.
- Compare control solution result to the range printed on the test strip container. If the results are not within the control range printed on the test strip container, then the meter and strips may not be working properly. Repeat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



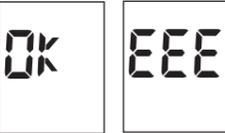
- Remove the used test strip for control solution from the meter and discard it.

2. Performing Check Strip Test

- Insert a Check Strip (facing up 'check strip' printed in arming knob) into test strip slot. The meter turns on automatically.

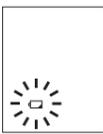


- If the Check Strip is inserted properly, the meter will start the check.
- The check result appears on the screen in just 5 seconds. If there isn't any problem for the meter, 'OK' message appears on the screen. Otherwise, there is some problem for the meter, 'EEE' error message appears on the screen.



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

CHAPTER 3: Maintenance and Troubleshooting



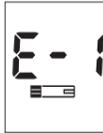
[Replace battery]

Battery power is low. Replace the battery immediately. If you press the ON/OFF button after discharging of the battery, the battery icon will flash and then after ten seconds the meter will turn off automatically.



[Internal Error Message for a meter]

Turn off a meter. Then turn on the meter again.



[Strip Error]

Defective test strip or the test strip is damaged or inserted improperly. Discard this test strip and test again using new test strip.



[Blood Sample Error]

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



[Temperature Error]

If the environmental temperature is above or below the operating range of a meter, a thermometer icon will appear on the display. Move to an area between 8-45°C (46-113°F), wait for 30minutes, and perform a test. Do not artificially heat or cool the meter.



[Communication Error]

The communication between meter and computer is failed. Connect again between meter and PC.

CHAPTER 4: Product Technical Information

Result Range	10 - 600 mg/dL (0.6 - 33.3 mmol/L)
Calibration	Plasma-equivalent
Sample	Fresh capillary or Venous whole blood or Arterial blood
Sample Size	0.5 microliter
Test Time	5 seconds
Assay Method	Glucose Dehydrogenase Biosensor
ON/OFF Source	One replaceable 3 V Lithium Battery type CR2032
Battery Life	Around 1,000 tests
Glucose Unit	mg/dL, mmol/L
Display	LCD (Customized)
Controls	3 Buttons
Size	48 mm x 90 mm x 15mm

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
Memory	500 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"> Normal Results Pre-meal Results Post-meal Results Automatic shutoff
Operation Temperature	8°C - 45°C (46°F - 113°F)
Hematocrit	0 - 70%
Operation Altitude	Up to 11,549 feet. (3,520 meters)
Test Strip Storage Temperature	2°C - 32°C (36°F - 90°F)
Meter Storage & Transport Condition	-20°C - 50°C (-4°F - 122°F) and 10% - 93% RH

CHAPTER 5: Performance Characteristic

Performance characteristic of STANDARD GlucoNavii GDH shall be evaluated with a series of measurements within a short interval of time in accordance with EN ISO 15197:2015.

Precision

The acceptable criteria are within standard deviation(STD) 4mg/dL at the below 100mg/dL (5.55mmol/L), and coefficient of variation(CV) 5% at the above 100mg/dL(5.55mmol/L).

1. Repeatability

Mean Glucose Level (mg/dL)	STD (mg/dL) / CV (%)
48.3	1.8mg/dL
81.1	2.1mg/dL
135.7	3.6%
209.6	4.2%
313.8	4.0%

2. Intermediate Precision

Below 100mg/dL (5.55mmol/L)	Above 100mg/dL (5.55mmol/L)	
Level 1	Level 2	Level 3
STD (mg/dL)	CV (%)	CV (%)
2.2mg/dL	4.1%	3.9%

System Accuracy

The accuracy of STANDARD GlucoNavii GDH blood glucose monitoring system was assessed by comparing blood glucose results obtained by patients with results by using YSI Model 2300/2700 STAT Plus glucose analyzer(reference), a laboratory instrument. The acceptable criteria for system accuracy is following;

95% of the measured glucose values shall fall within either $\pm 15\text{mg/dL}(\pm 0.83\text{mmol/L})$ of the average measured values of the reference measurement procedure at glucose concentrations $< 100\text{mg/dL}(5.55\text{mmol/L})$ or within $\pm 15\%$ at glucose concentrations $\geq 100\text{mg/dL}(\geq 5.55\text{mmol/L})$.

1. Capillary Blood

1) Below 100mg/dL(5.55mmol/L)

Within $\pm 5\text{mg/dL}$ (within $\pm 0.28\text{mmol/L}$)	Within $\pm 10\text{mg/dL}$ (within $\pm 0.56\text{mmol/L}$)	Within $\pm 15\text{mg/dL}$ (within $\pm 0.83\text{mmol/L}$)
49.5%(104/210)	88.6%(186/210)	98.6%(207/210)

2) Above 100mg/dL(5.55mmol/L)

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
70.8%(276/390)	93.3%(364/390)	98.5%(384/390)

3) Between 24mg/dL and 481mg/dL

Within $\pm 15\text{mg/dL}$ or $\pm 15\%$
98.5% (591/600)

2. Arterial Blood

1) Below 100mg/dL(5.55mmol/L)

Within $\pm 5\text{mg/dL}$ (within $\pm 0.28\text{mmol/L}$)	Within $\pm 10\text{mg/dL}$ (within $\pm 0.56\text{mmol/L}$)	Within $\pm 15\text{mg/dL}$ (within $\pm 0.83\text{mmol/L}$)
65.4% (102/156)	98.1% (153/156)	100% (156/156)

2) Above 100mg/dL(5.55mmol/L)

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
50.9% (226/444)	87.4% (388/444)	97.8% (434/444)

3) Between 27.7mg/dL and 500.1mg/dL

Within $\pm 15\text{mg/dL}$ or $\pm 15\%$
98.3% (590/600)

3. Capillary Blood (Neonate)

1) Below 100mg/dL(5.55mmol/L)

Within $\pm 5\text{mg/dL}$ (within $\pm 0.28\text{mmol/L}$)	Within $\pm 10\text{mg/dL}$ (within $\pm 0.56\text{mmol/L}$)	Within $\pm 15\text{mg/dL}$ (within $\pm 0.83\text{mmol/L}$)
36.7% (220/600)	83.8% (503/600)	99.5% (597/600)

2) Between 13.8mg/dL and 80.2mg/dL

Within $\pm 15\text{mg/dL}$
99.5% (597/600)

User Performance

This study is for evaluating glucose values from fingertip capillary blood samples obtained by 165 lay persons showed the following results;

"100% within $\pm 15\text{mg/dL}(0.83\text{mmol/L})$ of the medical laboratory values at glucose concentrations below $100\text{mg/dL}(5.55\text{mmol/L})$, and 100% within $\pm 15\%$ of the medical laboratory values at glucose concentrations at or above $100\text{mg/dL}(5.55\text{mmol/L})$."

Electromagnetic Compatibility

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

References

American Diabetes Association: Standards of Medical Care in Diabetes – 2017. Diabetes Care, January 2017, vol. 40, Supplement 1, S11-S24

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.

Ankk Cares
Delivering Better Healthcare

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