

GlucoNavii[®] Elite

TABLE OF CONTENTS

CHAPTER 1	Understanding the Product	
	Intended Use	04
	Precautions	04
	Principles of the Use	04
	Product Details	05
	Separately Purchased Items	06
	Packaging Details	06
	Separately Purchased Items	07
CHAPTER 2	Precautions	
	General Precautions	07
	Cradle	09
	Touch Screen	09
	Camera	09
	Waste Disposal	09
CHAPTER 3	How to Use STANDARD™ GlucoNavii® Elite Blood Glucose Meter	
	Activating Equipment	10
	Blood Glucose Measurement	15
	Understanding the Measurement Results	20

CHAPTER 4	Other Tests and Functions	
	Control Solution Test	21
	A. Why a Control Solution Test is Necessary	21
	B. When to use a Control Solution	21
	C. Precautions in using a Control Solution	21
	D. Measurements	22
	External Quality Control	26
	Linearity Test	29
	Cradle Functions and LED Display	32
	Test Results	33
	Other Settings	37
	A. Elite Manager Communication Settings	37
	B. Elite Manager Settings Information	38
	C. Cradle Settings	39
	D. System Settings	40
	E. Device Information	42
 CHAPTER 5	 Storage and Handling	
	Cleaning the Product	43
	Precautions when Storing	43
 CHAPTER 6	 Error and Corrective Measures	 44
 CHAPTER 7	 Technical Information	
	STANDARD™ GlucoNavii® Elite Meter	45
	STANDARD™ GlucoNavii® Elite Cradle	46
	STANDARD™ GlucoNavii® Elite Test Strip	46
 CHAPTER 8	 References	 47

CHAPTER 1

Understanding the Product

Intended Use

STANDARD™ GlucoNavii® Elite Blood Glucose Meter is an *in vitro* diagnostic medical device for Blood Glucose management. It is a system for monitoring glucose in capillary or venous whole blood. STANDARD™ GlucoNavii® Elite Blood Glucose Meter can be used in conjunction with a designated program to measure blood glucose and transmit and manage data to Electronic Medical Records (EMR) to diagnose glucose metabolism disorders of patients in hospitals.

This product is designed for professionals.

Precautions

For accurate measurement, be familiar with the instructions in this use instructions. Then use the meter.

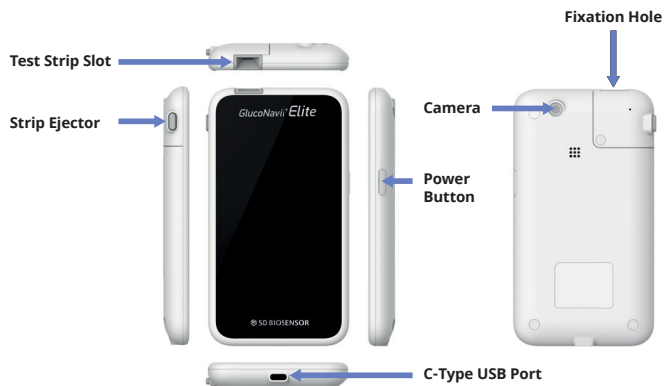
- (1) Use fresh capillary or venous blood. (Incorrect results can be obtained when using contaminated capillary blood.)
- (2) STANDARD™ GlucoNavii® Elite Blood Glucose Meter must be used only with STANDARD™ GlucoNavii® Elite Blood Glucose Test Strip, STANDARD™ GlucoNavii® Control Solution and STANDARD™ GlucoNavii® Linearity Solution.
- (3) When performing a control solution test, the range of the control solution may be different for each test strip Lot, so the user should check the range of the control solution that matches the Lot number of the test strip before proceeding with the test. To see the range of the control solution, please refer to the values in Elite Manager or the test strip bottle. Be sure to check the expiration date and appearance condition before using the test strip. If you use an expired or damaged test strip, inaccurate results may appear.
- (4) Use this product only by a trained professional.

Principles of the Use

STANDARD™ GlucoNavii® Elite 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® Elite 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.

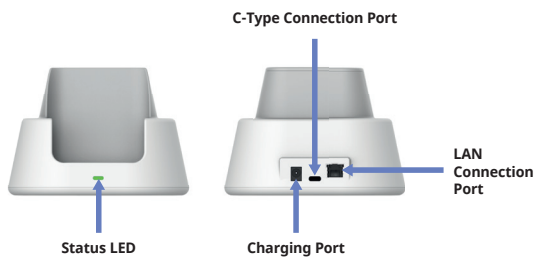
Product Details

(1) STANDARD™ GlucoNavii® Elite Blood Glucose Meter



- Test Strip Slot : Insert test strip.
- Strip Ejector : Use when removing the inserted test strip.
- Fixation Hole : Fixation hole to prevent separation between the instrument and the measuring part
- Power Button : Use the button on the right to turn the product on and off.
- C-type USB Port : Connect a C-Type USB cable to charge the device
- Camera : Used to scan barcodes of a test strip bottle, patients, etc.

(2) Cradle



- Status LED: The device status can be checked via the display LED.
- C-Type Connection Port : BT pairing between the device and cradle to transfer data to PC.
- Charging Port : Connect the charger to the cradle to turn the cradle on, and dock the device to the cradle to charge.
- LAN Connection Port : Connects to the PC to send and receive data

Packing Details

Meter: Meter, Quick manual

Cradle: Cradle

Accessory: Strip, Control Solution, Linearity Solution , USB Cable, Adapter

Separately Purchased Items

The below items are purchased separately from the STANDARD™ GlucoNavii® Elite Blood Glucose Meter.

- STANDARD™ GlucoNavii® Elite Blood Glucose Test Strip
- STANDARD™ GlucoNavii® Control Solution
- STANDARD™ GlucoNavii® Linearity Solution

CHAPTER 2

Precautions

1. General Precautions

- (1) Read the instructions in this user manual before use for an accurate measurement.
- (2) This product is a professional Blood Glucose Monitoring System.
- (3) STANDARD™ GlucoNavii® Elite Blood Glucose Meter should be used only with STANDARD™ GlucoNavii® Elite Blood Glucose Test Strip, STANDARD™ GlucoNavii® Control Solution and STANDARD™ GlucoNavii® Linearity Solution.
- (4) STANDARD™ GlucoNavii® Elite Blood Glucose Meter is available for use only with capillary or venous whole blood (useable anticoagulants: Heparin, EDTA). However, if venous blood is used, it should be done under the guidance of a medical professional.
- (5) Be sure to check the strip bottle before using the test strip for the first time. If there is damage to the bottle cap or the bottle, or if the bottle cap is not closed properly, please stop using the product. If a damaged test strip is used, you may get inaccurate results.
- (6) If the result continuously deviates from normal values, use STANDARD™ GlucoNavii® Control Solution to check the Blood Glucose Meter and Test Strip.
- (7) If all instructions in the user manual were followed properly and the problem persists, contact the person in charge of or the respective distributor.
- (8) The test strip is for single use only. Do not reuse.
- (9) Discard the used test strip carefully.
- (10) If you insert a test strip by a strong power, it is easily to bend. Therefore, insert a test strip in the meter gently until it will go no further.
- (11) The amount of blood sample required for testing is 0.5µl. If the applied blood is insufficient, accurate measurement results cannot be obtained. Discard the test strips applied with insufficient blood.
- (12) Do not apply the blood to other sites except the reaction chamber of the test strip.
- (13) Do not use a test strip that has passed their expiration date or has expired 6 months from opening. Discard the expired test strips.
- (14) The test strip is sensitive to humidity. Therefore, be sure to store the test strip in the designated bottle and immediately close the bottle cap when removing the test strip.
- (15) Keep the test strip in a cool, dry place (2-32°C). Avoid direct sunlight or heat and do not freeze the test strip.
- (16) Do not expose the test strip to heat or moisture. Test Strip stored outside the specified temperature or humidity range (e.g., toilet, kitchen, laundry room, car, garage, etc.) can result in inaccurate results.
- (17) Be careful not to get dust, food, or liquid on all areas of the test strip. Handle the test strip with clean, dry hands.
- (18) Failing to follow the precautions may result in inaccurate results.
- (19) Extreme Hematocrit (HCT) ratio can affect the measurement result. If the Hematocrit ratio is greater than 70%, the result may be lower than its actual value.
- (20) Avoid touching the reaction chamber of the test strip.
- (21) Wash your hands with soap and water then dry it completely before collecting the blood.

(22) To prevent infections, wipe your hand with an alcohol swab and dry it completely before collecting blood.

(23) Interferences: Elevated levels of the following substances may affect measurement results

Interference	Concentration	Interference	Concentration
Acetaminophen	> 6mg/dL	Ibuprofen	> 50mg/dL
Ascorbic acid(Vt.C)	> 4mg/dL	Levodopa	> 4mg/dL
Bilirubin	> 40mg/dL	Maltose	> 60mg/dL
Total Cholesterol	> 250mg/dL	Methyl-DOPA	> 2mg/dL
Creatinine	> 30mg/dL	Salicylate	> 20mg/dL
Dopamine	> 5mg/dL	Tolazamide	> 9mg/dL
EDTA	> 0.1mg/dL	Tolbutamide	> 64mg/dL
Galactose	> 60mg/dL	Triglycerides	> 1800g/dL
Gentisic Acid	> 1.8mg/dL	Uric Acid	> 9mg/dL
Glutathione	> 9.2mg/dL	Xylose	> 60mg/dL
Hemoglobin	> 200mg/dL	Pralidoxime Iodide	> 38mg/dL
Heparin	> 3000U/L	Icodextrin	>1100mg/dL

Precautions when measuring

- Do not shake or move the meter during the measurement process.
- Measurements should be made in an 8~45°C environment.
- Do not use the analyzer near strong electromagnetic radiation sources, as strong electromagnetic fields can damage the function of the meter.
- Store in a flat, dry environment and avoid direct sunlight.
- Extremely strong lights can interfere with the test results. Stay away from strong lights when measuring.
- Do not drop the meter as it may get damaged.
- Do not disassemble the meter.
- Do not put the meter in water or any cleaning solutions.
- If an error message appears repeatedly, stop using the product.

2. Cradle

- Install the cradle out of patient's reach. The cradle is not intended for use in an open space with patients.
- Connect the Cradle to an approved rated 5Vd.c./2A or high current power adapter that complies with LPS requirement with the same connector jack size. Be careful, as there is a possibility of an electric shock.

3. Touch Screen

- When touching a screen, please use your hand to touch. If you touch the screen with a pointed or sharp object (such as a nib), damage to the screen may cause.

4. Camera

- The camera is for scanning barcodes and QR codes. It cannot be used for any other purposes.
- Be careful not to give impact to the camera lens. If the lens is broken or cracked, scanning may not work.

5. Waste Disposal

- STANDARD™ GlucoNavii® Elite Blood Glucose Meter or its accessories must be treated as a potential biological hazardous waste. Removal of contamination (eg. cleaning, disinfection and/or sterilization) is required before reuse, recycling, or disposal. Dispose of the system or its accessories in accordance with local regulations.

6. Electromechanical Safety

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. 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.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. This device complies with RF exposure requirement.

This device complies with RF exposure requirement.

Cradle(FCC ID: RPJ01GMC100-1) should be installed and operated with minimum 20 cm between the radiator and your body.

CHAPTER 3

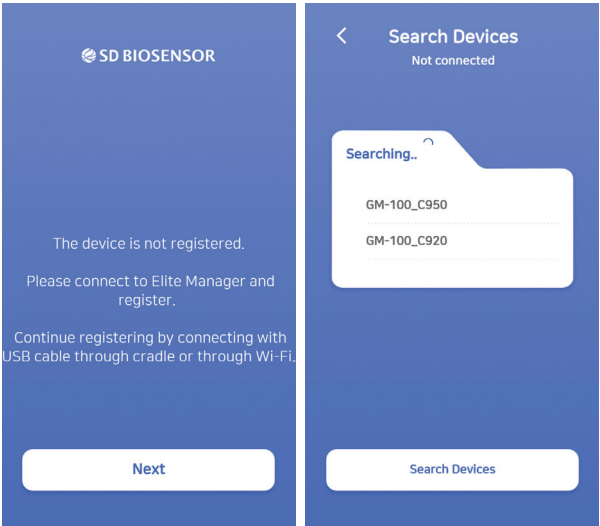
How to Use STANDARD™ GlucoNavii® Elite Blood Glucose Meter

1. Activating Equipment

(1) Press and hold the power button at the right side of the equipment to turn the device on.



(2) Connect cradle and meter through Bluetooth.



- (3) Select the communication method with Elite Manager. You can choose between cradle or Wifi connection. After selecting the option, set the address of Elite Manager to register.
- USB: Connects to the PC through the USB port of the cradle which then connects to the hospital network.
 - DHCP: Connect the router or Internet line through the cradle's LAN port to automatically assign an IP address and connect to the hospital network.
 - IP: Connect the router or Internet line through the LAN port of the cradle, but manually enter IP information to assign an IP and connect to the hospital network.
 - Wifi: Connect the Elite meter to Wifi to connect to the hospital network.

The image displays two screenshots of the 'Elite Manager Communication' setup screen, which allows users to choose between 'Cradle' and 'Wi-Fi' connection methods.

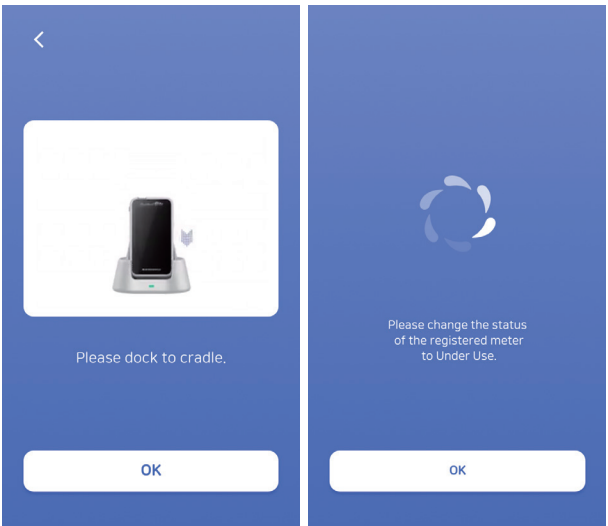
Left Screenshot (Cradle connection):

- Elite Manager Communication** (Cradle / Wi-Fi)
- Connect through Cradle** (Toggle is ON)
- Selection options: ☐ USB, ☐ DHCP, ☐ IP
- Connect through Wi-Fi** (Toggle is OFF)
- Elite Manager IP**: Four input fields for IP address.
- Elite Manager Port**: One input field for port number.
- Register** button.

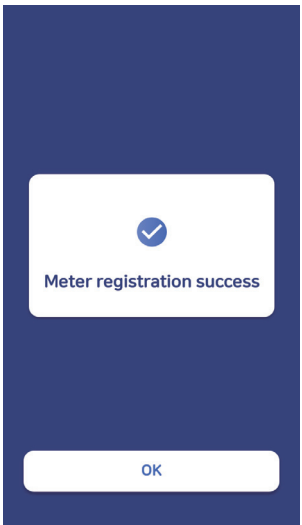
Right Screenshot (Cradle connection with IP selection):

- Elite Manager Communication** (Cradle / Wi-Fi)
- Connect through Cradle** (Toggle is ON)
- Selection options: ☐ USB, ☐ DHCP, ☒ IP
- IP**: Four input fields for IP address.
- S.M**: Four input fields for Subnet Mask.
- G.W**: Four input fields for Gateway.
- DNS**: Four input fields for DNS.
- Connect through Wi-Fi** (Toggle is OFF)
- Elite Manager IP**: Four input fields for IP address.
- Register** button.

(4) When using cradle connection, dock the meter to the cradle. If you use Wi-Fi connection, you do not need to dock the meter to the cradle.



(5) Connect to Elite Manager and change the current registering device to 'Registered' in the Meter Management Settings, then the meter is finally registered and available for use.



1-1. Data Communication

A. BT Communication (Meter → Cradle → Elite Manager server)

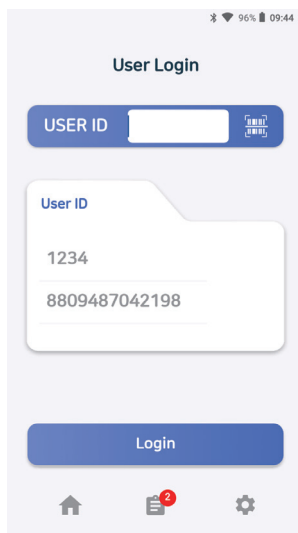
- (1) BT connection between the meter and cradle when registering the device for the first time
- (2) Data transmission when the meter is docked on the cradle (USB, LAN communication)

B. Wi-Fi Communication (Meter → Elite Manager server)

- (1) Connects to Wi-Fi used by the hospital when registering the device for the first time
- (2) Checks data communication by connecting with Elite Manager server
- (3) Data transmission via Wifi upon completion of the data communication check

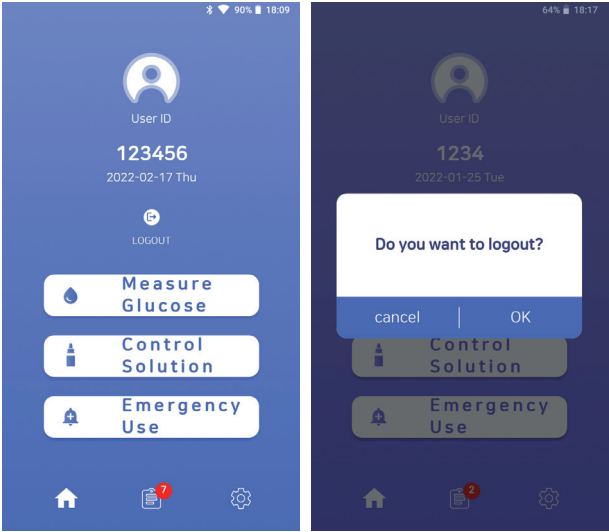
1-2. Login

- (1) In the ID field of the user login screen, manually enter the user number with the on-screen keyboard or press the barcode button and activate the camera to scan the user's barcode.



- (2) Once the barcode scan is complete, the user is logged in to the home screen.

1-3. Home Screen

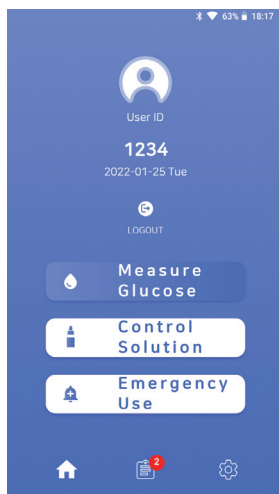


NO.	Function	
1	Logout	Press to log out
2	Measure Glucose	Press to proceed with blood glucose measurement.
3	Control Solution	Press to proceed with control solution test for quality control.
4	Emergency	If you need to measure blood glucose in an emergency situation, you can use this menu to measure glucose without any patient or strip information. However, the result will not be saved.
5	Home	You can move to the home screen.
6	Test Results	Test results can be checked in this menu. Results that were not transmitted are indicated by a number in a red circle.
7	Setting	In this menu, there are other functions such as device settings, external quality control, and linearity test.

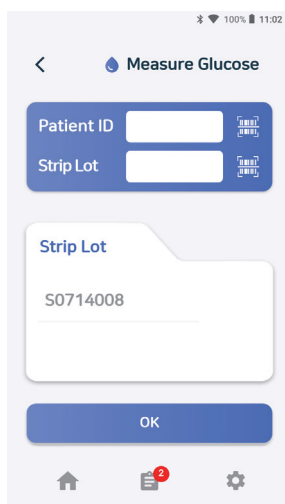
2. Blood Glucose Measurement

2-1. Blood Glucose Measurement

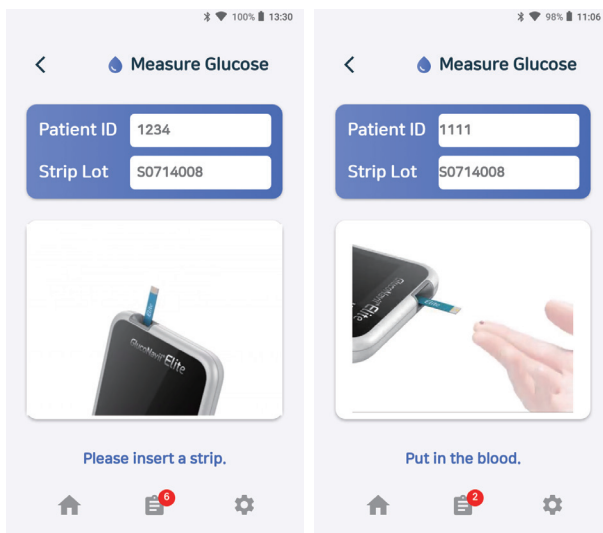
- (1) When logged in, select the **'Measure Glucose'** button on the screen and the screen will move to the Patient ID Scan screen. You may scan the patient's ID or press the **'Enter Manually'** button to enter the information manually.



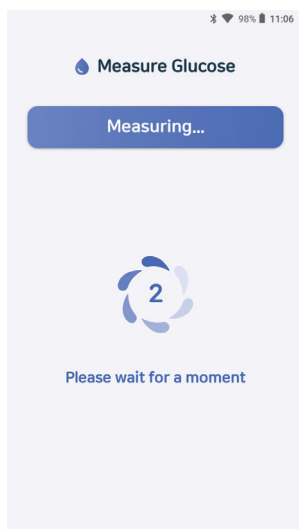
- (2) Enter the patient number in the Patient ID field or select the barcode button to activate the camera and scan the patient barcode.
- (3) Enter the Lot number in the Strip Lot field or select the barcode button to activate the camera and scan the barcode at the side of the test strip bottle. Since the test paper LOT or control LOT used at the time of the previous login is recorded, you can enter the recorded LOT by tapping it.



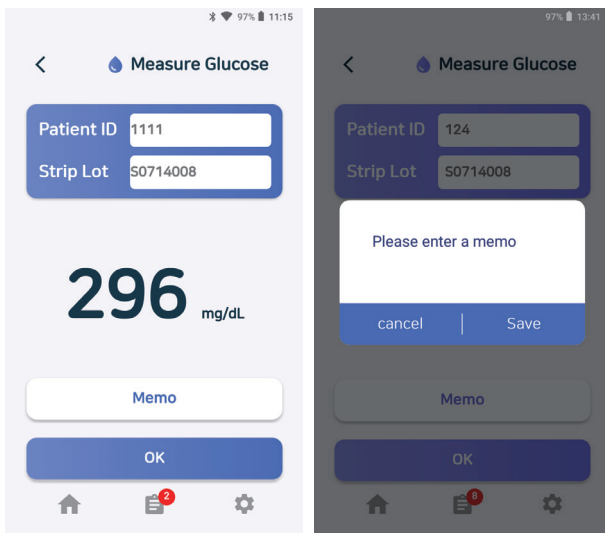
- (4) When the patient ID and test strip Lot number are entered, select the '**Confirm**' button to proceed to the next step.
- (5) Insert the electrode side of the test strip to the meter as shown on the meter's screen, and collect the patient's blood at the edge of the test strip.



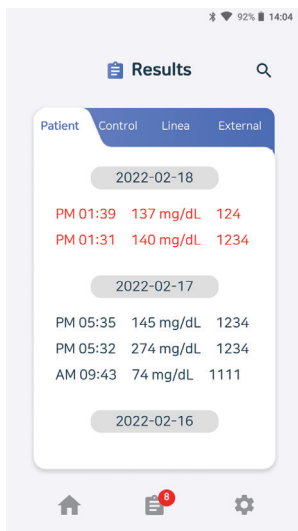
- (6) The result will be displayed in 5 seconds.



- (7) Press the **'Confirm'** button to return to the home screen. If you press the **'Memo'** button, a pop-up is created, where you can enter a memo.



→ Glucose Measurement test results can be checked in the 'Test Results' tab of the menu bar.

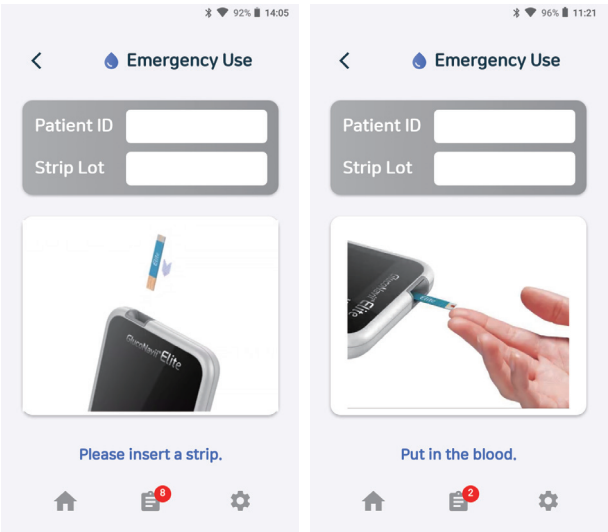


2.2 Emergency Measurement

(1) Select the **'Emergency'** button in the home screen.

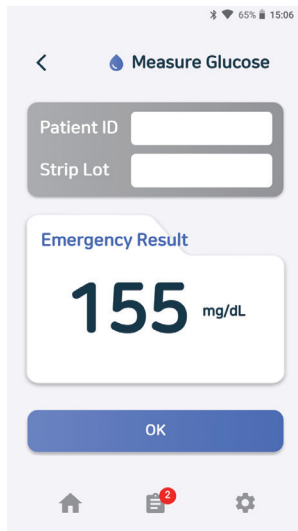


(2) Insert the electrode side of the test strip to the meter as shown on the meter's screen, and collect the patient's blood at the edge of the test strip.



(3) The result will be displayed in 5 seconds.

* When using the Emergency menu, the results will not be saved.



3. Understanding the Measurement Results

Normal Blood Glucose Levels

→ Fasting blood glucose values in adults without diabetes is 70~99mg/dL. Normal blood glucose range two hours after a meal is below 140mg/dL.

When the Measurement Range is out of the Normal Range

1. Was the size of the blood sample sufficient to fill the reaction chamber?
2. Was the test strip bottle cap tightly sealed?
3. Was the test strip used before the expiration date?
4. Were the test strips stored at extreme temperatures such as a car during very cold or hot weather?
5. Were the test strips stored in areas of high humidity such as kitchen or bathroom?

Test Result Range

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

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

CHAPTER 4

Other Tests and Functions

Control Solution Test

A. Why a Control Solution Test is Necessary

- Control solution test allows you to verify that the measurement meter and test strip are functioning correctly, and that the user has measurement in the correct way.
- Periodically checking your equipment using a simple control solution test is critical to getting accurate results.

B. When to Use a Control Solution

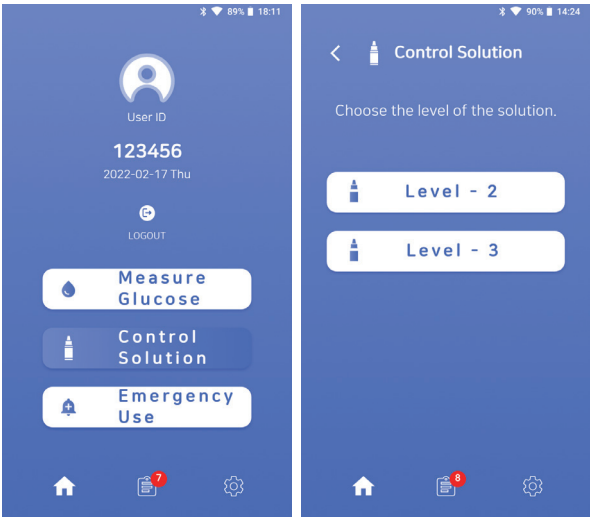
- If you leave the cap off the container of test strips.
- Before using your meter for the first time.
- When you open a new container of test strips.
- If you drop the meter.
- Whenever your result does not agree with the way you feel.
- If you have repeated a test, and the blood glucose result is still lower or higher than expected.
- When you want to check the performance of the meter and test strip.

C. Precautions in Using a Control Solution

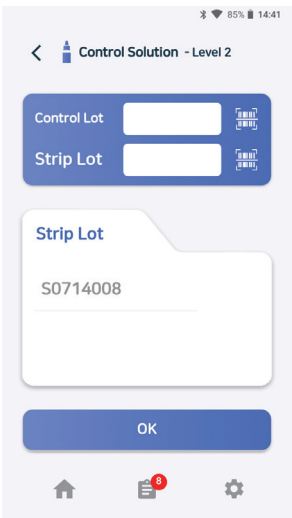
- Only use STANDARD™ GlucoNavii® Control Solution for Quality Control.
- The control solution is for use outside the body (*in vitro* use).
- Test the control solution in an 18–30°C (64–86°F) environment.
- Do not swallow or inject the control solution.
- Do not put the control solution in your eyes.
- Make sure to check the expiration date before use and to write down the date of its first opening. Do not use a control solution that is expired or that has passed 3 months from its opening.
- Keep the control solution away from children.
- Shake the control solution well and discard the first drop before using.

D. Measurements

- (1) Select the **'Control Solution'** button in the home screen and choose the level you wish to proceed with.



- (2) The screen will move to Control Lot Scan screen. You may scan the Control Lot or press the **'Enter Manually'** button to enter the information manually. Enter the Lot number of STANDARD™ GlucoNavii® Control Solution - Level 2 in the Control Lot field or select the barcode button to activate the camera and scan the barcode at the side of STANDARD™ GlucoNavii® Control Solution - Level 2.

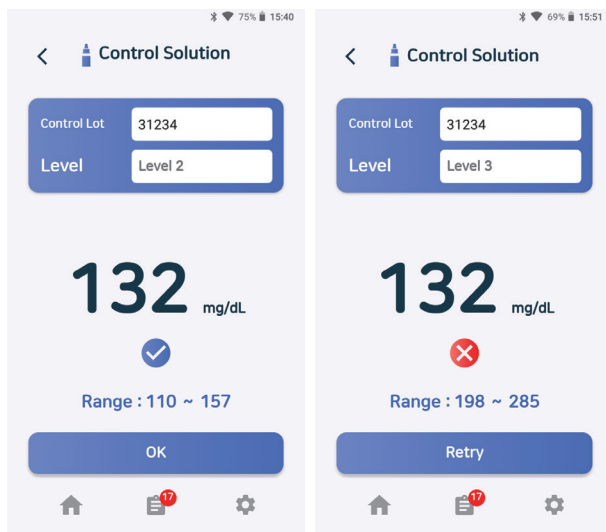


- (3) Enter the test strip Lot number in the Strip Lot field or select the barcode button to activate the camera and scan the barcode at the side of the test strip bottle.
- (4) When the Control Lot and Strip Lot are entered, press the 'Confirm' button to move to the next step.
- (5) Insert the electrode side of the test strip to the meter as shown on the meter's screen. Drop STANDARD™ GlucoNavii® Control Solution - Level 2 to a flat surface and collect the solution by touching the edge of the test strip to the drop.



(6) Check the result in 5 seconds.

(6-1) If the result is within range, select the 'Confirm' button to proceed to the next step. If the result is out of range, select the 'Retry' button and re-test from step (2).



* If the result is continuously out of range, please contact the person in charge in the hospital or the supplier of the product.

(7) For STANDARD™ GlucoNavii® Control Solution - Level 3 test, proceed in the same manner as the above Level 2 test.

→ Control Solution test results can be checked in the 'Test Results' tab of the menu bar.



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



Control Range	
Level 2	Level 3
90-140 mg/dL	170-240 mg/dL

[This is an example. Refer to the ranges on your test strip bottle.]

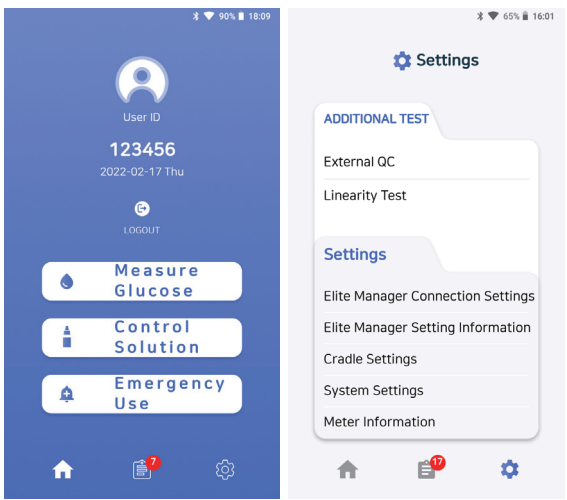
→ QC Lock

If a control solution test is not performed for a specific time or for a certain period of time, there are restrictions on the patient's blood glucose measurement. This setting can be changed in Elite **Manager's Meter Management>Preset Management**. For accurate results, please conduct the control solution tests regularly.

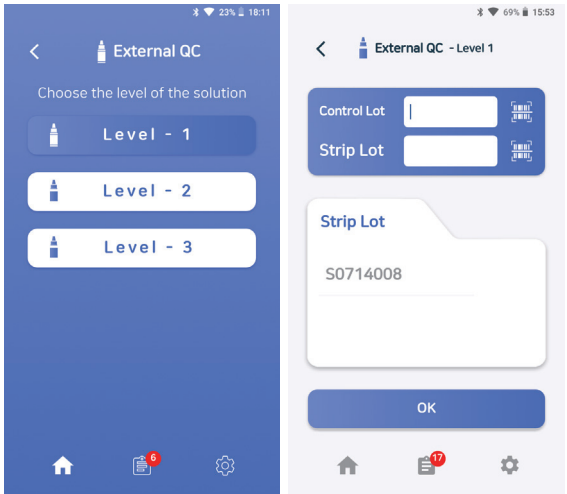
External Quality Control

→ External quality control is a test conducted by an external quality control association, to check the accuracy between hospitals on an external standard by preparing a control sample twice a year on for the registered hospitals.

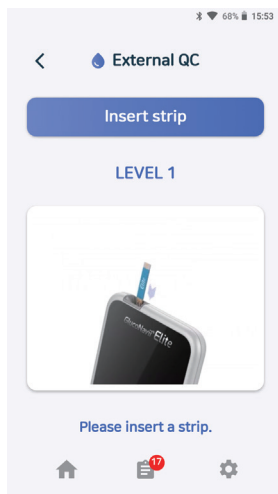
- (1) After user login, select the **'Settings'** tab (cogwheel) on the menu bar of the home screen to enter the settings screen.



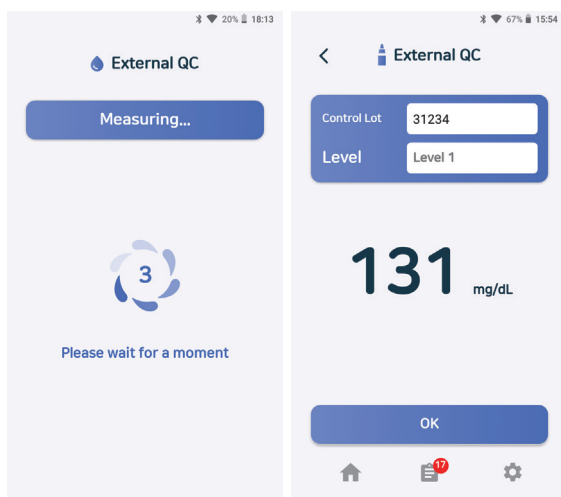
- (2) Select **'External QC'** from the **Settings** menu to enter then select **'Level 1'**.
- (3) Manually enter the Lot number of the Level 1 External Control Solution in the Control Lot field and the test strip Lot number in the Strip Lot field or select the barcode button to activate the camera and scan the barcode.



- (4) When the Control Lot and Strip Lot are entered, press the '**Confirm**' button to move to the next step.
- (5) Insert the electrode side of the test strip to the meter as shown on the meter's screen. Drop the Level 1 Control Solution to a flat surface and collect the solution by touching the edge of the test strip to the drop.



- (6) The result will be displayed in 5 seconds. After checking the result, select the '**Confirm**' button to move to the next step.



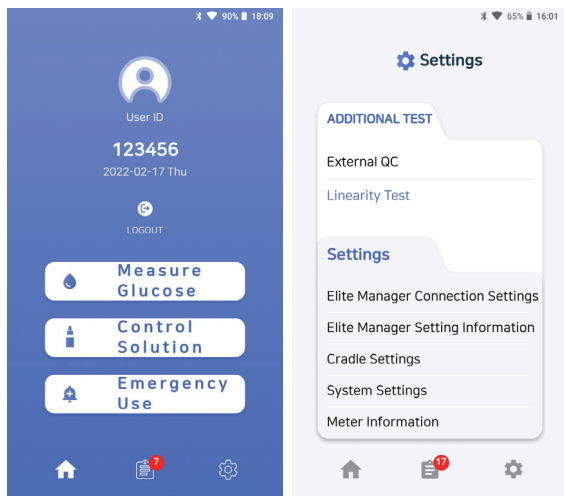
- (7) For Level 2 and Level 3, proceed in the same manner as the above Level 1 test.
- (8) The test is completed when all Level 1, 2, 3 tests are completed.
- External Quality Control test results can be checked in the 'Test Results' tab of the menu bar.



Linearity Test

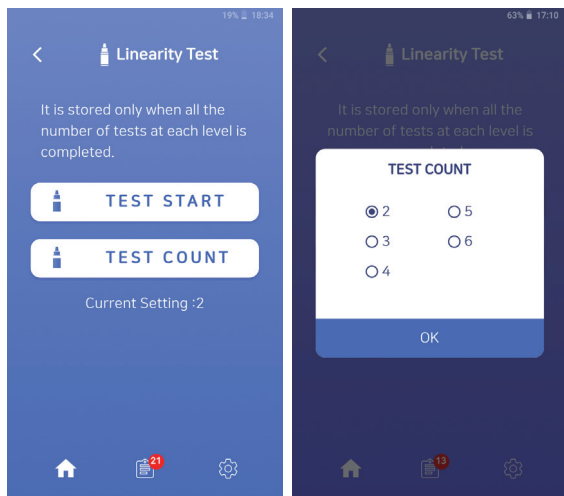
→ Linearity Test is a test to verify the exact performance of the test strip by testing it with a different concentration material. The test method is the same as the control solution test, but the test strip barcode must be scanned first and then repeatedly tested at least 6 substances twice.

- (1) After user login, select the '**Settings**' tab (cogwheel) on the menu bar of the home screen to enter the settings screen. Select the 'Linearity Test' button.

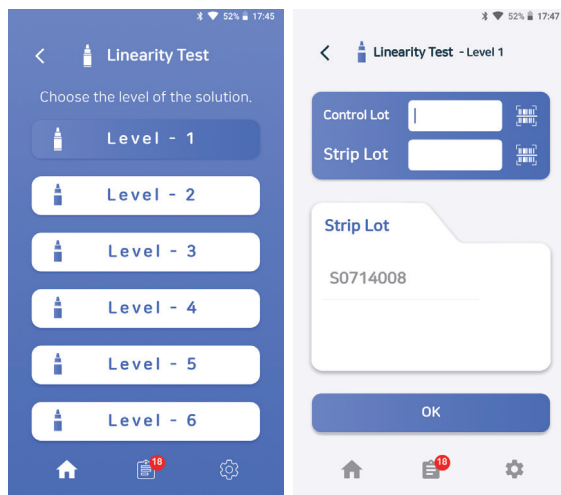


- (2) In the Linearity Test screen, select the '**TEST START**' button.

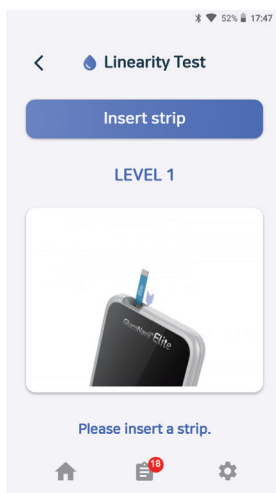
- For linearity tests, at least 2 tests per level should be conducted for the results to be saved. Complete all the tests from Level 1 to Level 6 once the test has begun. Test level and measurement can be changed in the DM of the equipment main server.



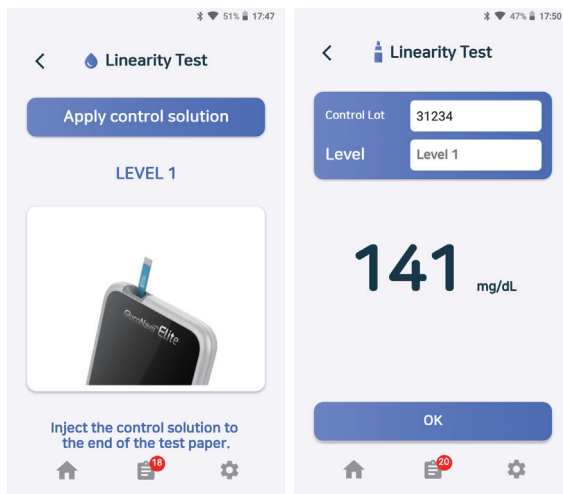
- (3) Select **'Level-1'** to move to the next step.
- (4) Manually enter the Lot number of the Level 1 Linearity Solution in the Control Lot field and the test strip Lot number in the Strip Lot field or select the barcode button to activate the camera and scan the barcode.



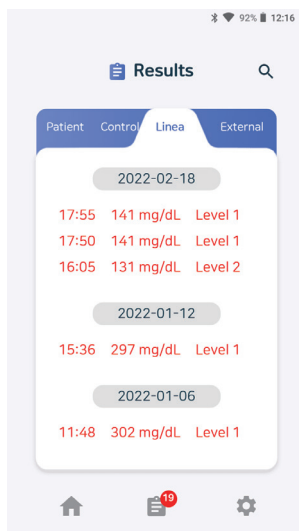
- (5) When the Control Lot and Test Strip Lot are entered, press the 'Confirm' button to move to the next step.
- (6) Insert the electrode side of the test strip to the meter as shown on the meter's screen. Drop the Level 1 Linearity Solution to a flat surface and collect the solution by touching the edge of the test strip to the drop.



- (7) The result will be displayed in 5 seconds. After checking the result, press the '**Confirm**' button and repeat (6) for the set amount of tests.



- (8) After proceeding with (7), select the 'Confirm' button to move to the next step.
 (9) For Level 2 to Level 6, proceed in the same manner as the above Level 1 test.
 (10) The test is completed when all tests from Level 1 to 6 are completed.
 → Linearity test results can be checked in the '**Test Results**' tab of the menu bar.



Cradle Functions and LED display

After connecting the charger to the cradle, dock the measurement meter to the cradle to charge it.

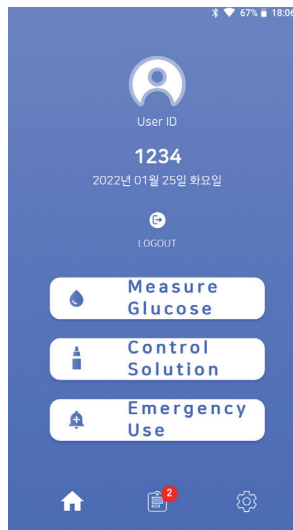


- (1) Connect Charger (Power ON): Green LED blinks 3 times.
- (2) Stand-by Mode: If the meter is not docked on the cradle, it enters a standby mode and there will be no color indication on the LED.
- (3) Charging Mode: A Red LED will light up when charging begins, and a Green LED will light up when charging is complete.
- (4) Cradle-Meter BT pairing: If there are any test results that have not been transmitted to the server, it will start transmitting the data to Elite Manager server. When data transmission is complete, the LED will return to charging mode. Please do not remove the meter from the cradle while data transmission is in process.
 - A. When charging: Red and Orange LED will blink in order until pairing and data transmission are complete.
 - B. When fully charged: Green and Orange LED will blink in order until pairing and data transmission are complete.
- (5) Error : A Red LED will keep blinking if there are any errors or if charging is not working.

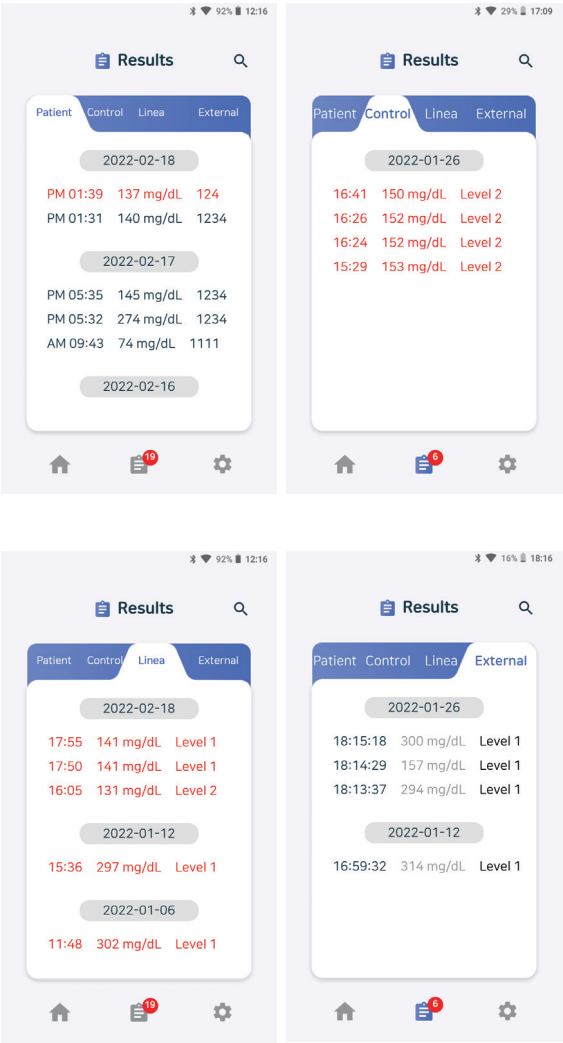
Test Results

(1) Checking the Test Results

A. In the Home Screen, select the '**Test Results**' tab located at the center of the menu bar.

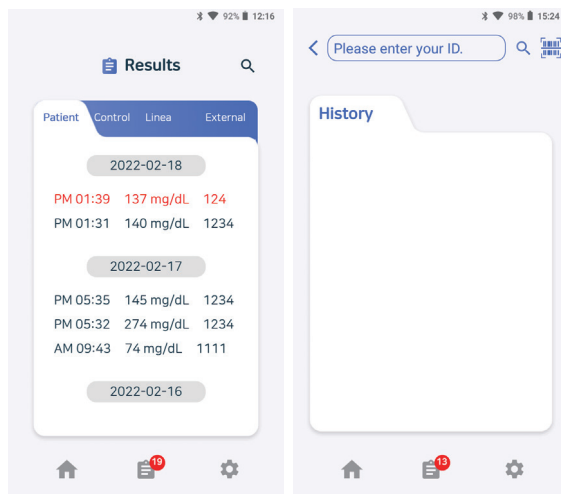


B. You can check patient result, control solution result, external degree management result in the 'result list'. All measurement results measurement with that equipment are recorded, sorted by recent measurement.

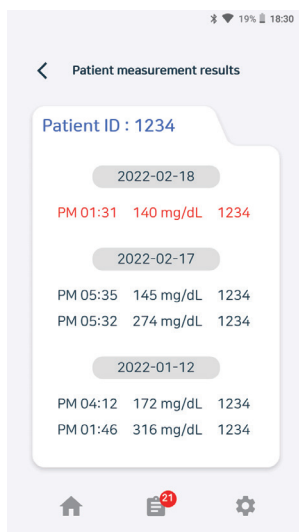


(2) Search : Patient Test Results

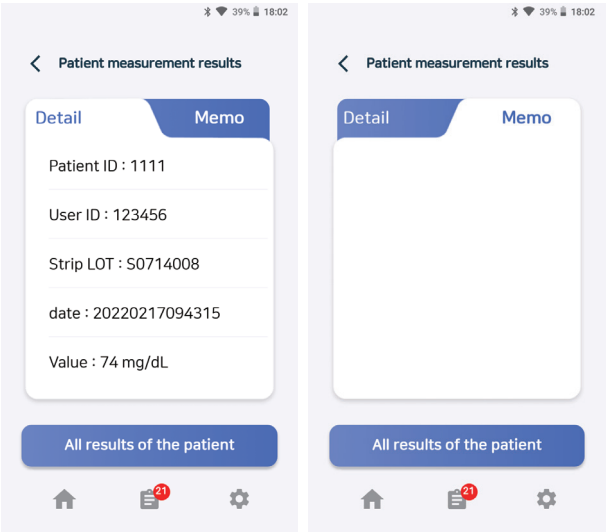
- A. For patient test results, you can search with the patient's ID number using the '**Search Button**' at the upper right corner. In the search bar, you can either manually enter the patient ID or select the barcode button to activate the camera and scan the patient ID.



- B. When a Patient ID is searched, all test results of the patient will be displayed.



C. If you select one of the test results, you can check the details of the test result and any memo that was saved along with the test result.

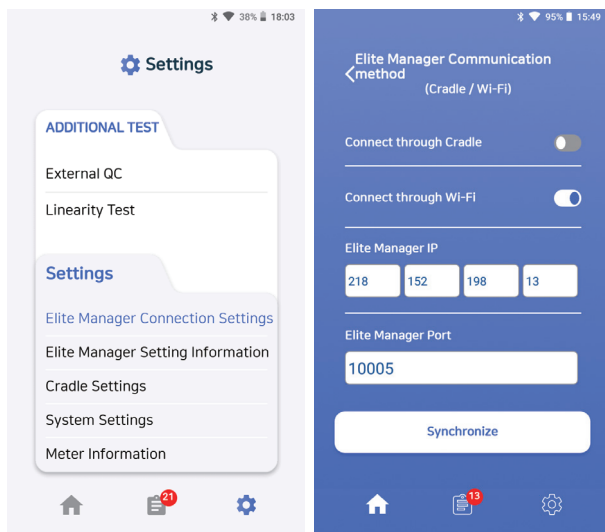


Other Settings

After user login, select the **'Settings'** tab (cogwheel) from the menu bar on the home screen to enter the settings screen. On the Settings screen, you can check Elite Manager communication settings, Elite Manager Settings Information, Cradle Settings, System Settings, and Device Information.

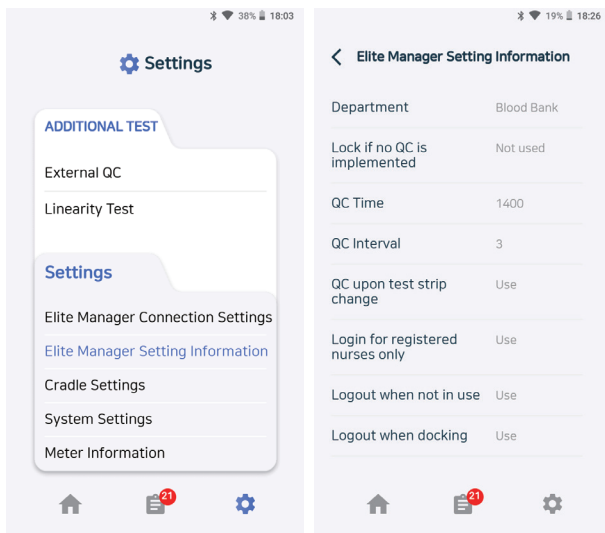
A. Elite Manager Communication Settings

In Elite Manager Communication Settings, you can set the cable or wireless data transmission options for the device. (See Chapter 3, Equipment Activation for details)



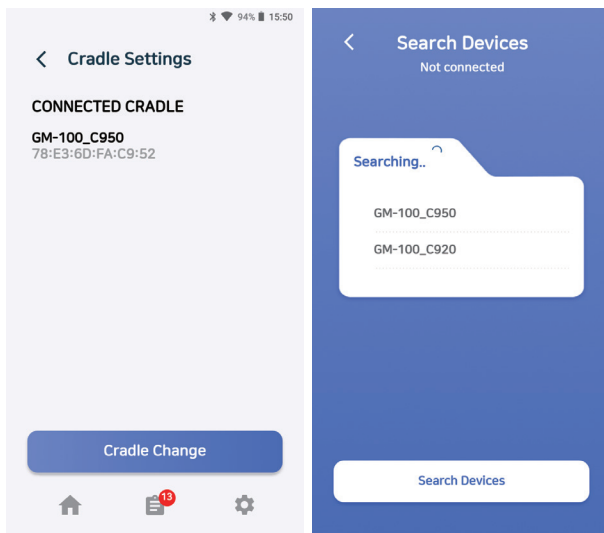
B. Elite Manager Settings Information

- (1) In Elite Manager Settings Information, you can check the information set in Elite Manager. You can check and change the settings in Elite Manager's **Meter Management > Pre-Settings**.
- (2) If **Lock if no QC is implemented** and **QC upon test strip change** is being used, conduct the QC tests in accordance with the settings as glucose tests may be restricted if needed QC tests are not conducted.



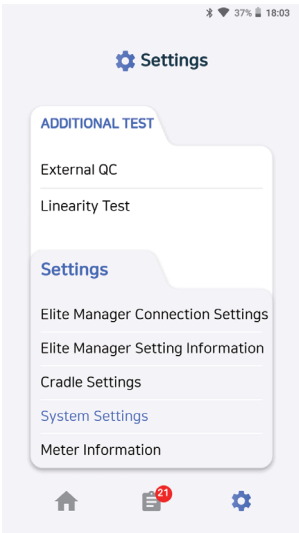
C. Cradle Settings

- (1) In **Cradle Settings** you can check and modify the information of the connected cradle.
- (2) Select the '**Change Cradle**' button and find your device. You can change the connection to a new cradle by pairing it with a cradle from the searched device list.



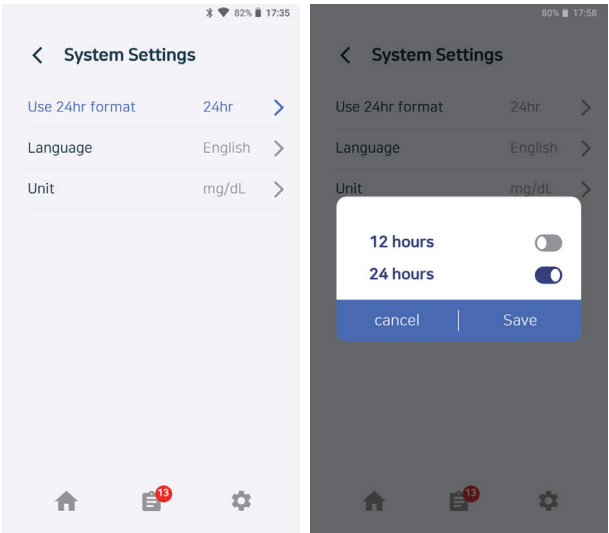
D. System Information

In **System Information**, you can change the time format, language, and measurement unit.



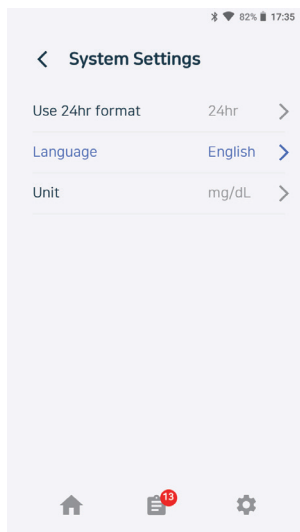
(1) Time Format

In **Time Format**, you can choose to display the time in 12H or 24H format.



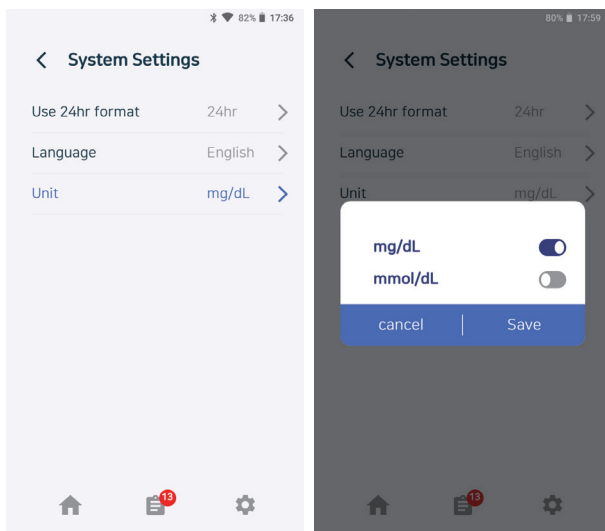
(2) Language

In **Language**, you can choose the system language to be used. You may choose from Korean or English.



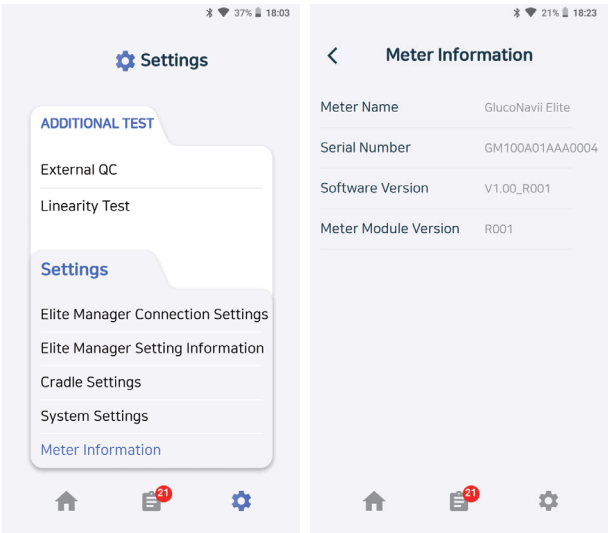
(3) Measurement Unit

In the **Measurement Unit**, you can choose to use mg/dL or mmol/L depending on the measurement units used in your location.



E. Device Information

- (1) In **Device Information**, you can check the basic information of the device being used, such as Device Name, Serial Number, Software Version, Meter Module Version, Cradle Version, etc.



CHAPTER 5

Storage and Handling

Cleaning the Product

- (1) If foreign substances such as blood or dust get into the test strip slot, it may cause malfunction.
- (2) If necessary, wipe the meter with an alcohol swab or soft cloth moistened with water. Use the product once the water or alcohol has been completely dried.
- (3) Do not use any other substances that are not provided or recommended as there is a risk of product damage.
- (4) Maintenance of the device is necessary for accurate measurement and transmission of results. Check the device regularly for any anomalies, and if there is any foreign substance, wipe it off immediately.

Precautions when Storing

- (1) Prevent dust from entering the test strip slot.
- (2) Keep away from the humid environment.
- (3) Keep away from direct sunlight and strong heat.
- (4) Store in a cool and dry place. Do not refrigerate.
- (5) Keep away from the reach of children.
- (6) Check whether the exterior of the test strip is damaged before use, and do not use if there are any damages.
- (7) Always store the test strip in the test strip bottle. Be careful not to leave the bottle cap open when storing. (For further details, refer to the user manual of the test strip.)

CHAPTER 6

Error and Corrective Measures

No.	Error Message	Corrective Measures
1	Unregistered user.	Occurs when logging in with a user number that is not registered. Please contact the management (person in charge) to register the employee number.
2	Insufficient blood(solution) sample.	Insufficient blood(solution) sample was collected. Discard the used test strip and measure again using a new test strip. Apply a sufficient amount of blood(solution) sample into the reaction chamber of the test strip.
3	Invalid test strip.	The test strip inserted is damaged, or an incompatible test strip is used. After confirming that a proper test strip is used, test again using the strip.
4	Unregistered strip.	The barcode of the test strip bottle is not registered. Please check the Lot number of the test strip and try again with another test strip. If the error message continue, contact the management.
5	Test strip has expired.	The test strip has passed its expiration date. Please use a new test strip.
6	Conduct quality control test.	The temperature of the meter is higher or lower than the operating range. Leave the meter between 8~45°C for 30 minutes and let the meter return to its operating temperature. Do not intentionally heat or cool the meter in the process.
7	Conduct quality control test.	The meter has passed its set periodic quality control test period. Please conduct a quality control test to be able to use the glucose measurement function.
8	Control solution has expired.	The control solution used has passed its expiration date. Please use a new control solution
9	Invalid control solution.	The barcode of the control solution is not registered. Please use a new solution. If the error message continues, contact the management.
10	Linearity solution has expired	The linearity solution used has passed its expiration date. Please use a new linearity solution.
11	Device synchronization failed.	The device synchronization was not successful. (1) Cable – Make sure the cradle and device are properly docked. If it is properly docked, check the connection between the LAN or USB cable at the back of the cradle and the PC or router. (2) Wifi – Check the Wi-Fi status of the device. If no problems are found, contact the management.

CHAPTER 7

Technical Information

1. STANDARD™ GlucoNavii® Elite Blood Glucose Meter

Meter Size	80 (W) x 16.2 (D) x 150 (H) mm
LCD Size	62.1 (W) x 110.2 (H) mm
Weight	170g
Measurement Range	10 - 600mg/dL
Correction Method	Plasma correction
Sample Type	Capillaries and venous blood
Sample Volume	Minimum 0.5μl
Measurement Time	5 seconds
Measurement Method	Glucose Dehydrogenase Biosensor
Hematocrit	0~70%
Measurement Unit	mg/dL or mmol/L
Display Screen	LCD
Operation Button	Touch screen
Memory	5000 cases each for patient, control solution, linearity, and external quality control
Capacity	8 GB (Storage capacity of 4 GB)
Communication function	BT / Wifi / LAN / USB
BT Version	Bluetooth 5.0(LE)
RF Range	2402~2480 MHz
Maximum Output Power	-5.55dBm
Storage Conditions	-20°C~50°C / 10%~93% RH
Operating Conditions	8~45°C / 10%~93% RH
Altitude	Max 2000m (80~106 kPa)
Power Consumption	- 5 Vd.c., 1.0 A (for C-type USB cable and Cradle charging) - 3.7 Vd.c., 1700 mAh (for Lithium Polymer battery pack)
Protection against electric shock	- Class II (for Cradle charging) - Internally powered (for Lithium Polymer battery pack)
Degree of protection against electric shock	Not applied parts

2. STANDARD™ GlucoNavii® Elite Cradle

Size	142.8 (W) x 101 (D) x 100.8 (H) mm
Weight	200g
IP Classification	IPX0
Power Supply	C-Type USB or Charging Adapter
Input	5Vdc, 1.5A (for C-Type USB cable and adapter)
Out	5Vdc, 1.0A [wireless charging for meter]

3. STANDARD™ GlucoNavii® Elite Test Strip

PERFORMANCE CHARACTERISTIC

All performance characteristic of STANDARD™ GlucoNavii® Elite BGMS 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 Precision

Range	Number of samples	REF. (mg/dL)	AVG (mg/dL)	STD (mg/dL)	CV (%)
30 - 50 mg/dL	300	42.8	42.6	3.3	7.9
51 - 110 mg/dL	300	100.0	100.4	3.2	3.1
111 - 150 mg/dL	300	138.3	122.9	5.0	4.1
151 - 250 mg/dL	300	237.0	222.9	7.4	3.3
251 - 400 mg/dL	300	343.0	311.3	9.7	3.1

2) Intermediate Precision

	Level 1	Level 2	Level 3
Number of samples	300	300	300
AVG. (mg/dL)	55.9	138.1	222.9
STD	3.3	4.3	8.3
CV (%)	5.9	3.1	3.7

System Accuracy

The accuracy of STANDARD™ GlucoNavii® Elite 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 $\pm 0.83\text{mmol/L}$)
50.6% (91/180)	98.5% (163/180)	100% (180/180)

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

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
43.6% (183/420)	81.0% (340/420)	99.0% (416/420)

3) Between 33.4 mg/dL and 466.7 mg/dL

Within $\pm 15\text{mg/dL}$ or $\pm 15\%$	99.3% (596/600)
---	-----------------

Influence quantities

The acceptable criteria for influence quantities are following;

- Below 100mg/dL(5.55 mmol/L), the average difference between the test sample and the control sample is within 10mg/dL(0.55 mmol/L)
- Over 100mg/dL(5.55 mmol/L), the average difference between the test sample and the control sample is within 10%

1. Packed cell volume: STANDARD™ GlucoNavii® Elite BGMS is performed according to EN ISO 15197:2015, 6.4.3 Packed cell volume evaluation. The suitable for STANDARD™ GlucoNavii® Elite BGMS is 0-70%.

2. Interference testing: STANDARD™ GlucoNavii® Elite BGMS is performed according to EN ISO 15197:2015, 6.4.4 Interference testing. Followings interference materials may affect test results.

Acetaminophen	> 6 mg/dL	Ibuprofen	> 50 mg/dL
Ascorbic acid(Vt.C)	> 4 mg/dL	Levodopa	> 4 mg/dL
Bilirubin	> 40 mg/dL	Maltose	> 300 mg/dL
Total Cholesterol	> 250 mg/dL	Methyl-DOPA	> 2 mg/dL
Creatinine	> 30 mg/dL	Sodium Salicylate	> 20 mg/dL
Dopamine	> 5 mg/dL	Tolazamide	> 9 mg/dL
EDTA	> 0.1 mg/dL	Tolbutamide	> 64 mg/dL
Galactose	> 60 mg/dL	Triglyceride	> 1800 mg/dL
Gentisic Acid	> 1.8 mg/dL	Uric Acid	> 9 mg/dL
Glutathione	> 9.2 mg/dL	Xylose	> 60 mg/dL
Hemoglobin	> 200 mg/dL	Pralidoxime Iodide	> 38 mg/dL
Heparin	> 3000 U/L	Icodextrin	> 1100mg/dL

CHAPTER 8

References

1. American Diabetes Association: Diabetes Care, 2015;38(Suppl. 1): S8-S16
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 meter, Oct 2003, Vol. 5, No. 5: 749 -768

Symbols and Abbreviations

The symbols and abbreviations given below are shown in the user manual, label, and external package.

Symbol	Description
	Manufacturer
	<i>In vitro</i> diagnostic medical device
	Consult instructions for Use
	Reference number
	Date of manufacture
	Serial number (S/N)
	Reference
	The measuring instrument can be easily damaged, so handle it with care.
	Batch code
	It must be disposed of separately from other general waste.
	This product fulfills the requirements of Directive 98/79/EC on <i>in vitro</i> Diagnostic medical device.
	This product complies with part 15 of the FCC Rules.
	The meter should be maintained in a dry condition.
	Precautions
	DC Power



REF 01GM100-1

REF 01GMC100-1

FCC ID: RPJ01GM100-1

FCC ID: RPJ01GMC100-1

SD BIOSENSOR, Inc.

Headoffice

C-4th&5th, 16, Deogyong-daero 1556beon-gil,
Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690,
REPUBLIC OF KOREA
www.sdbiosensor.com



Authorized Representative
MT Promedt Consulting GmbH

Altenhofstrasse 80 66386 St. Ingbert Germany
Phone : +49 6894 581020, Fax : +49 6894 581021

ML21GNEENR1
Issue date : 2023.01