

Hemonitor H1

Hemoglobin Testing System



English

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Symbols
















	Manufacturer		Symbol for "KEEP DRY"
	Date of manufacture: To indicate the date of manufacture for this analyzer		To indicate that the product is fragile and you need to handle it with care
	Serial number for this analyzer		Crossed out wheeled bin: To discard it separately from other household waste
	Consult instructions for use		Direct current
	Caution, consult accompanying documents		In vitro diagnostic medical device
	Do not use if package is damaged		Temperature limitation
	Be careful as there is a biological cross-infection		Catalog number
	Unique device identifier		

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1. Warning and Precaution for Safety

1.1. Warnings and Precaution for Safety

- 1.1.1. For safe use of the instrument, please be sure to read the User Manual thoroughly.
- 1.1.2. This user manual only contains exterior cleaning method and does not contain information about factory calibration, repairing or maintenance. In the event of a problem with the instrument, please contact your Dealer or GenBody Inc. for service.
- 1.1.3. Do not disassemble, repair or modify the instrument.
- 1.1.4. GenBody Inc. shall not be liable for any malfunction or damage to the product caused by improper operation not covered in this manual.

1.2. Precautions for Installation of the Product

- 1.2.1. Do not install in an unsafe place (for Indoor use).
- 1.2.2. Do not install the instrument near flammable materials or contaminated areas.
- 1.2.3. Do not install the instrument near moist or direct sunlight, near heating appliances, or near magnets.
- 1.2.4. When moving the instrument, do not drop or shock the instrument.

1.3. Precautions before using the Product

- 1.3.1. This instrument is only for human In Vitro Diagnostics use.
- 1.3.2. This instrument should be used by medical professionals, such as doctors, medical laboratory scientists and trained healthcare professionals.
- 1.3.3. Only Micro-cuvette provided by the manufacturer can be used.
- 1.3.4. Read this manual and the Micro-cuvette manual thoroughly before using the system.
- 1.3.5. Check the instrument regularly for damage or contaminants.
- 1.3.6. Use in a well-ventilated and dry place.
- 1.3.7. Check if the battery is sufficient before use, if insufficient, replace before use.

1. Warning and Precaution for Safety

1.4. Precautions while using the Product

- 1.4.1. Do not shock or move during use.
- 1.4.2. When loading the Micro-cuvette into the tray, close the tray while resting it completely on the supporting surface.
- 1.4.3. Do not press the buttons too hard or operate with wet hands.
- 1.4.4. Do not remove the ID Chip or open the tray during analysis.
- 1.4.5. If the product is affected by electromagnetic waves, it will reboot. This is normal operation, please try again.

1.5. Precautions for Storing and Managing the System after Use

- 1.5.1. Used Micro-cuvettes should be treated in accordance with the Medical Waste Disposal Act
- 1.5.2. Do not store the instrument in a place affected by temperature, humidity, or wind or other abnormal environmental conditions.
- 1.5.3. Store the instrument on a flat surface and avoid shock or vibration.
- 1.5.4. Do not place any objects on the Hemonitor H1.

2. Product Introduction

2.1. Intended Use

This product is a medical device for in vitro diagnostics targeting the human body. It calculates quantitative data by numerically analyzing the hemoglobin concentration of human capillary or venous blood in point-of-care, hospital, and medical laboratory environments.

2.2. Principle of Analysis

A sample of human capillary or venous blood is added to a Micro-cuvette. The Micro-cuvette with sample is added to the open measure tray and inserted into the instrument. The measure tray is then closed, and the instrument automatically starts the analysis.

The optical module inside the analyzer measures the degree of light absorption and converts it into a digital signal through mathematical calculation. The converted digital signal is displayed to the user for numerical confirmation.

2.3. Product Components



Hemonitor H1



Manual



USB Cable



REF HMAC050

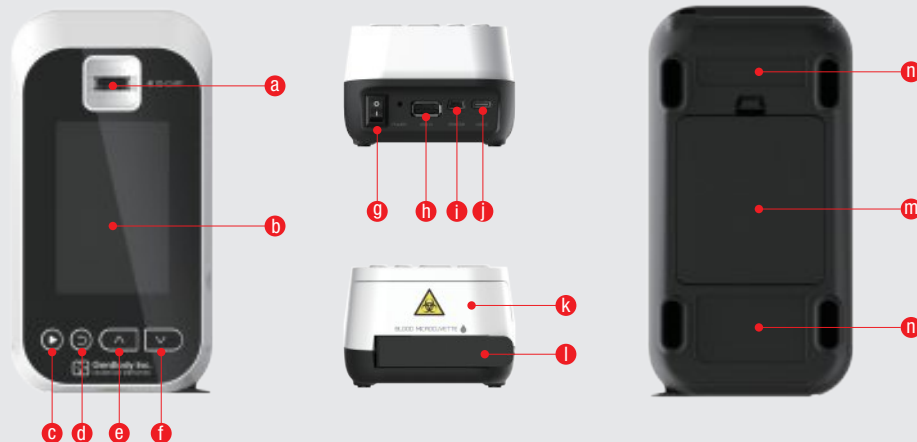
Micro-cuvette
(marketed separately)
* Not provided



Battery x 4
LR6(AA-Alkaline)
* Not provided

2. Product Introduction

2.4. Parts Description



Instrument Top

- a. ID Chip Slot
- b. LCD Display
- c. Select Button
- d. Back Button
- e. Up Button
- f. Down Button

Instrument Back

- g. Power Switch
- h. USB-A Port (F/W Update[admin])
- i. USB-Mini-B port (Ext. Printer)
- j. USB-C Port (Power)

Instrument Front

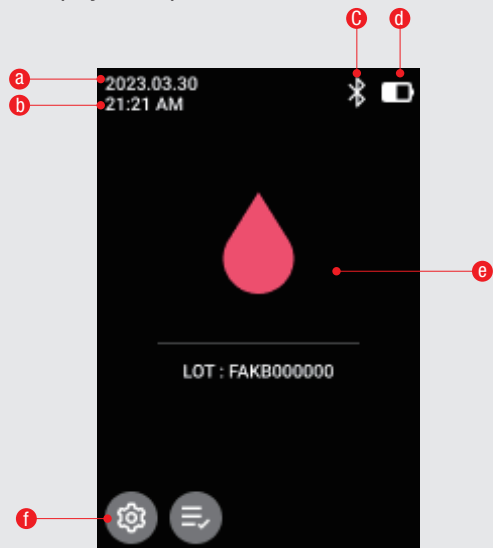
- k. Cleaning Cover
- l. Measure Tray

Instrument Underside

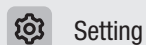
- m. Battery Cover
- n. Label

2. Product Introduction

2.5. Display Description



- a. Date
- b. Time
- c. Bluetooth
- d. Power type & Battery level
- e. Analysis Display
- f. Button icon



Setting



Result list



Select



Back



Up



Down



Print



Number down



Number up



Number down



Date setting



Date notation style




Delete

3. Installation and Start

3.1. Powering on the System



3.1.1. Powering with battery

- ① Remove the battery cover from the bottom of the device.
- ② Insert four AA type (refer to 9. Technical specifications) batteries in the correct direction.
- ③ Turn on the power switch [] on the back of the device.



2. Product Introduction


3.1.2. Powering with USB Cable

- ① Apply power of 4.0 to 5.5 VDC using a USB cable to the USB-C port on the back of the device.
 - ② Turn on the power switch[] on the back of the device.
 - ③ Press the select button[].
- ⚠ Be careful as the equipment may break down when applying power exceeding the standard voltage.



3. Installation and Start



3.2. Reading ID-Chip

- When the device is powered on and an ID-Chip is inserted into the ID-Chip Slot, LOT information is displayed.
- If the ID chip is not inserted, the message "Please insert the ID chip" will be displayed.
- Insert the ID chip and press the down button [] to display LOT information.

⚠ Be sure to insert the ID chip in the correct direction.



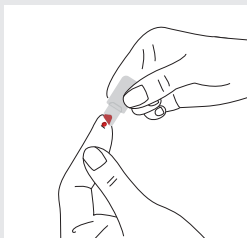
3.3. Powering off the system

- If you turn off the power switch [] on the back of the device, the device turns off.
- When operating on battery, the device automatically turns off when the set Power Off Time (5min or 10min) is reached.
(Press the select button[] to turn the device on)

4. Test Procedure

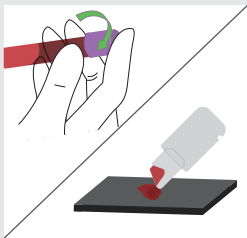
4.1. Collect the sample into a microcuvette.

- ⚠ Be careful of infection when testing, always wear protective gloves.
- ⚠ After collecting the specimen in the microcuvette, measure it within 40 seconds.
(Over time, the specimen may clot, leading to inaccurate results)
- ⚠ Be sure to use a microcuvette of the same lot as the lot number of the ID chip.
(Lot number is indicated on the microcuvette Bottle Label)



4.1.1. When using the capillary blood in finger, Fill the microcuvette with enough capillary blood by contacting the edge of the microcuvette with the capillary blood sample.

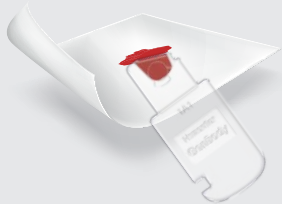
- ⚠ Disinfect before collecting the specimen and be cautious of other potential infections.
- ⚠ When collecting capillary blood from a finger, wipe off the first 2-3 drops before using the capillary blood.



4.1.2. When using pre-collected venous blood, place a drop of venous blood (10 μ L or more) on a clean hydrophobic surface and fill the microcuvette with enough venous blood by contacting the edge of the microcuvette with the venous blood sample

- ⚠ Use freshly stored venous blood (2~8°C).
- ⚠ If the sample is refrigerated, reach operating temperature before mixing.
- ⚠ Mix thoroughly on a mixer for at least 1 minutes or mix thoroughly by hand.
- ⚠ Only one microcuvette is used per drop of sample.

4. Test Procedure



4.2. Use a low-lint wiper or soft gauze to wipe off any specimen on the exterior of the microcuvette.

⚠ Be careful not to let the specimen spill out of the microcuvette.



Correct case



Incorrect case

4.3. Visually check the microcuvette.

⚠ If specimen is not completely filled or if there are air bubbles or foreign substances, the results may be inaccurate (Discard and use a new microcuvette).

4. Test Procedure



4.4. Open the measure tray and place the microcuvette from which specimen was collected.

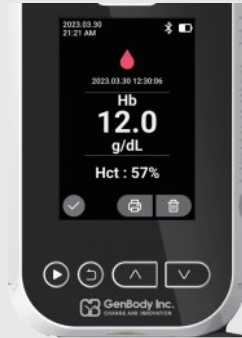
- ⚠ Check the engraved direction of the tray and position it accurately.
- ⚠ Position the microcuvette accurately to prevent it from floating.



4.5. When the measure tray is completely closed, a measurement tone sounds, and the measurement starts.

- ⚠ If the measurement does not proceed, open the tray and close it again.
- ⚠ Do not open the tray or remove the ID chip during measurement.

4. Test Procedure



4.6. When the test is complete, a buzzer will sound, and the results will be displayed within seconds.

- The results display the hemoglobin concentration in the set units.
- The calculated HCT value is displayed ($Hct: Hb \times 3\%$).
- Results are automatically stored in memory. (Up to 5,000 results)

4.6.1. Press the select button[] to move to the main screen.

4.6.2. Press the up button[] to print the result.

4.6.3. Press the down button[] to deletes the results and moves to the main screen.



4.7. Open the measure tray to remove and discard the measured microcuvette.

- ⚠ Never reuse a used microcuvette.
- ⚠ Follow local safety procedures for disposal of used microcuvettes.

5. Result Management

5.1. If you press the back button on the main screen, you can check the saved result list.

- To check the result list, enter the 4-digit password you set.

(for password settings, refer to 6.9 Info section)

- When you press the Select button[▶] the password will be selected, proceed to the next step.

- When you press the up button[▲] the number goes up, and when you press the down button[▼] the number goes down.




- Once you enter all 4-digits, you will be taken to the results list screen.

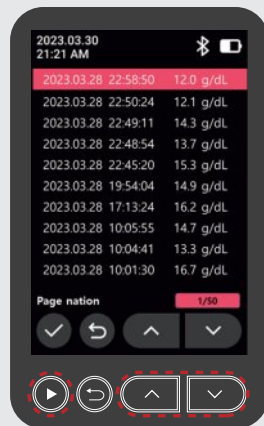
- When you press the back button[↶] will take you to the main screen.




5. Result Management

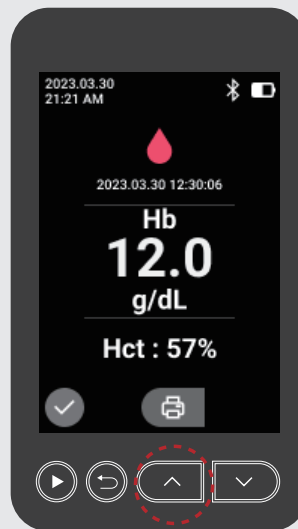
5.2. You can manage saved results in the results list.

- Test results are automatically saved.
- You can move with the up button[] and down buttons[].
- Press the select button[] will select the results.
- Maximum number of stored results is 5,000.
- If more than 4900 results are saved, a warning message “Memory is almost full” will be displayed on the results screen.
(Manage the results by referring to section 6.3 Data Management).



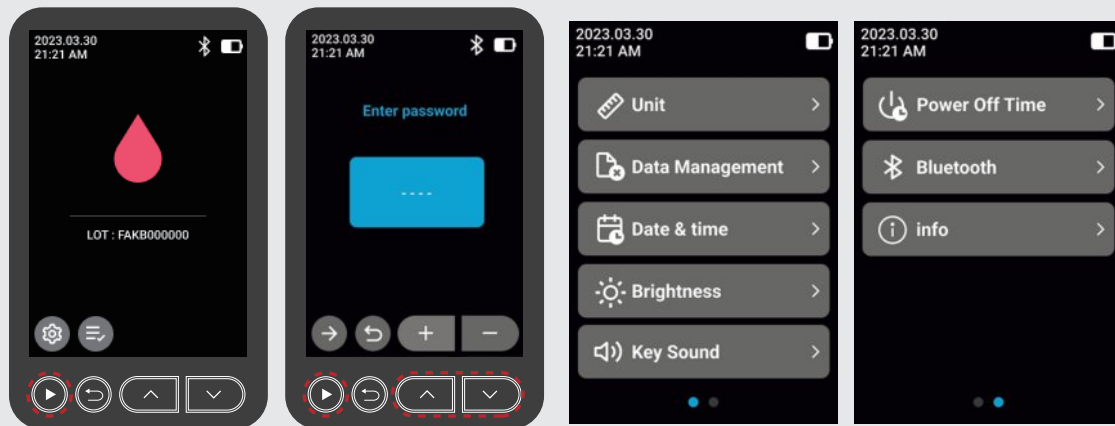
5.3. Select a result to display the measured value.

- Press the up button[] to print the result
(For printer connection, see Section 9).



6. Setting

- Press the select button[▶] on the main screen to change the device settings.
- To enter the setting screen, enter the 4-digit password you set.



6. Setting

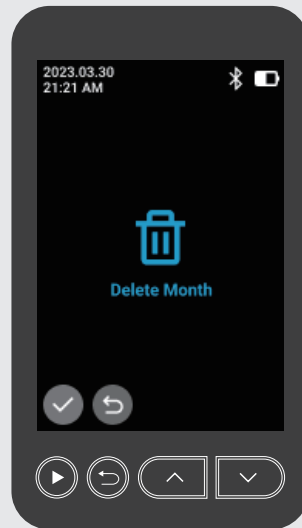
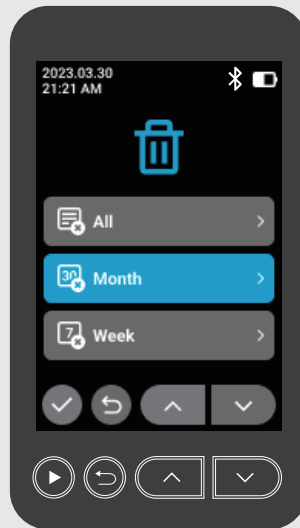
6.1. Unit

- Three units of hemoglobin concentration are available:
g/L, g/dL, mmol/dL








6.2. Data Management

- Delete saved results by All, Month, Week units.



6. Setting

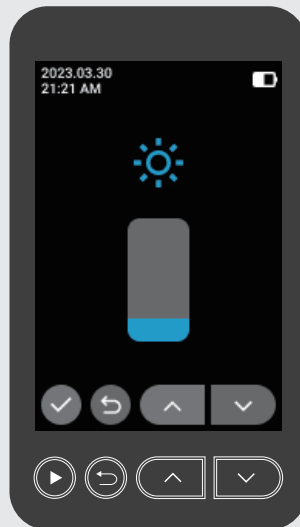
6.3. Date & Time

- To change the date and time on the first screen, press the select button[].
- After Moving to an item, you can set it using the up button[] and down button[].
- Save with the back button[].
- Change the date format by press the up button[] on the first screen.



6.4. Brightness

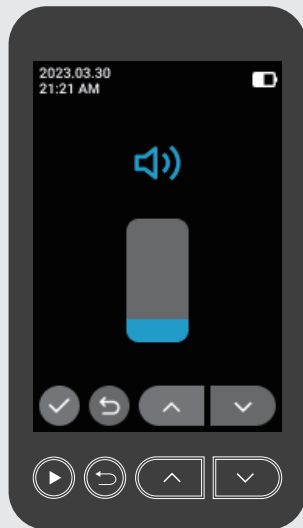
- Set the brightness of the screen.



6. Setting

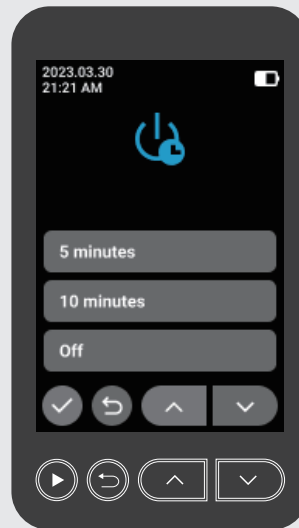
6.5. Key Sound

- Set the volume of the device.



6.6. Power Off Time

- Set the Power Off time when not in use.
(Only when operating in battery mode)



6. Setting

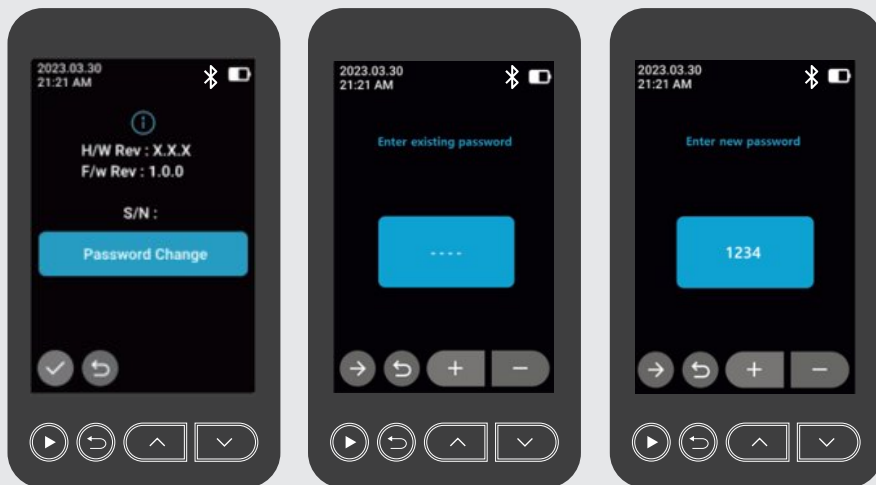

6.7. Bluetooth (Option)

- Turn on/off the Bluetooth function.
- For printer connection, see section 8.2



6. Setting

6.8. Info

- Displays H/W, F/W and S/N of Hemonitor H1.
- Change the 4-digit password(The initial password is “0000”)
- Change password by pressing the Select button[

The image displays three sequential smartphone screens for the Hemonitor H1 device. Each screen shows the date and time as '2023.03.30 21:21 AM' and has Bluetooth and battery status icons at the top right. The bottom of each screen features a navigation bar with four icons: a circle with a right arrow, a circle with a left arrow, a circle with an up arrow, and a circle with a down arrow.

 - Screen 1 (Left):** Displays device information: 'H/W Rev : X.X.X', 'F/w Rev : 1.0.0', and 'S/N :'. A large blue button labeled 'Password Change' is centered. At the bottom left of the screen area are two small circular icons: a checkmark and a refresh symbol.
 - Screen 2 (Middle):** Displays 'Enter existing password'. It features a blue rectangular input field with four dashes '----'.
 - Screen 3 (Right):** Displays 'Enter new password'. It features a blue rectangular input field with the number '1234'.

7. Maintenance

7.1. Product cleaning

- You can clean the product's Measure Tray and measurement interior.
- After daily use, it is recommended to clean the measurement tray and the interior of the measurement unit.
- Turn off the power before cleaning.

7.1.1. Open measure tray.



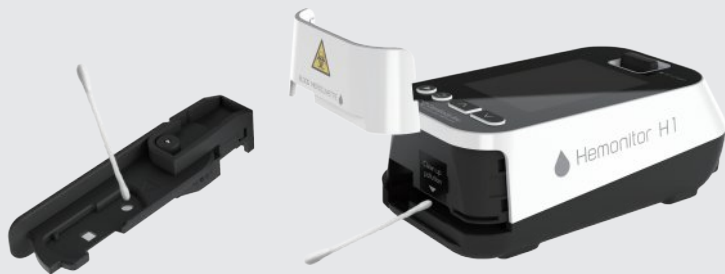
7.1.2. Remove the cleaning cover ① and pull out the measure tray ② to detach it .



7. Maintenance

7.1.3. Lightly moisten a cotton swab with detergent and clean the Measure Tray and the inside of the measurement (Cleanser: alcohol or mild detergent).

- ⚠ Let the detergent dry sufficiently for at least 15 minutes.
- ⚠ Do not use contaminated cotton swabs.
- ⚠ Be careful not to apply too much detergent.



7.1.4. Insert the measure tray① and assemble the cleaning cover②.




8. Printer Connection

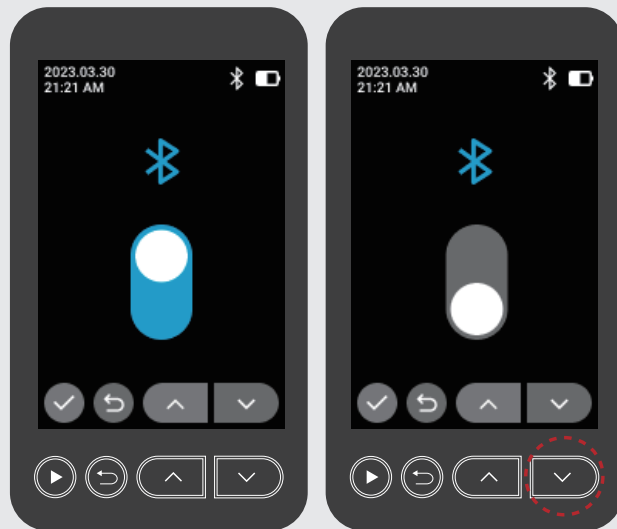
8.1. USB Connection

8.1.1. Connect USB cable(MINI B Type) to the printer port on the back of the Hemonitor H1 and the printer COM port.



- ⚠ Use a USB cable that meets the specifications (MINI B Type).
- ⚠ Connect the USB cable to the correct location on the device.

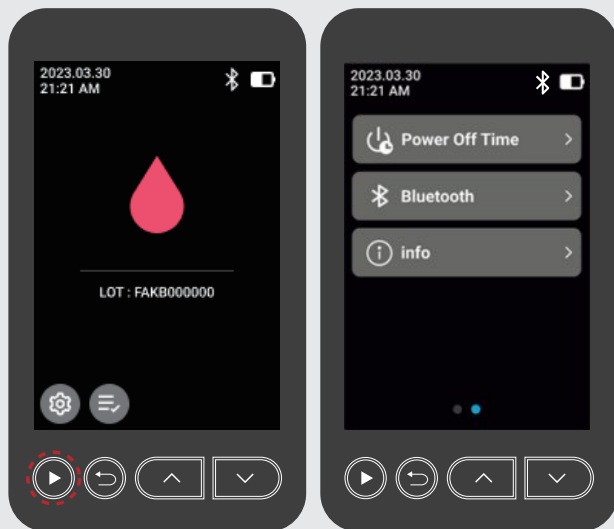
8.1.2. If the bluetooth function is activated, press the down button [] in the settings screen to deactivate the bluetooth function.





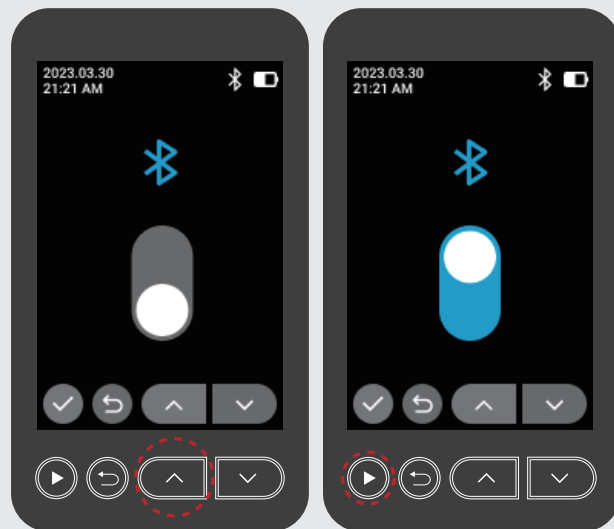
8. Printer Connection

8.2. Bluetooth connection

8.2.1. Go to the Bluetooth settings window in the setup menu.



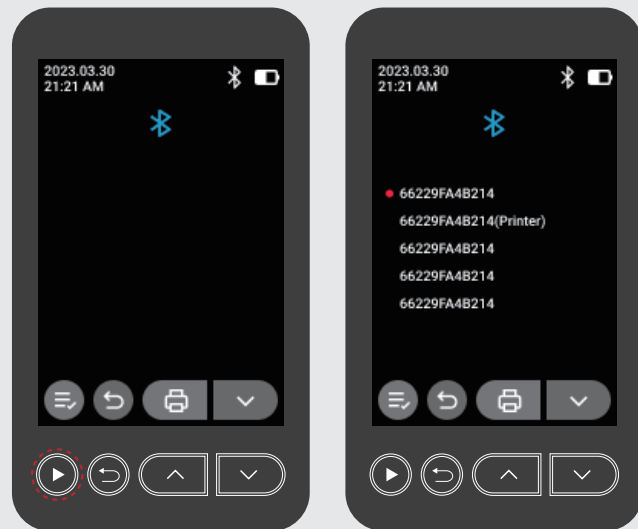
8.2.2. Press the  button to activate the Bluetooth function.
Press the  button for more than 3 seconds to move to the Bluetooth device search screen.



8. Printer Connection

8.2.3. Press the select button[▶] to search for Bluetooth devices.

Check the number of the printer to connect and re-search if there is no printer to connect to.

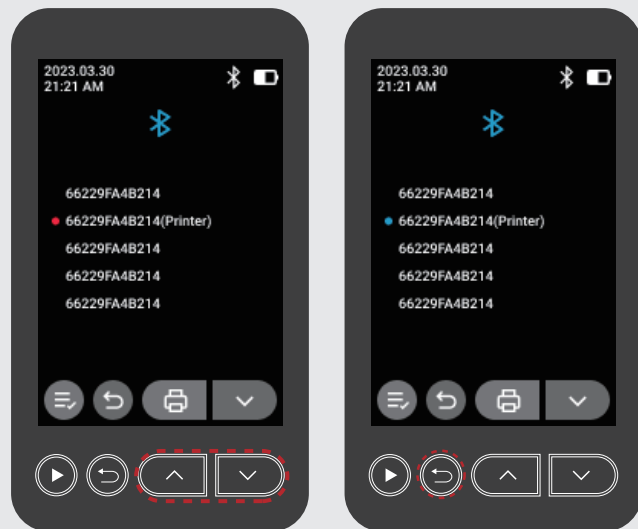


8.2.4. Press the down button[▼] to move to the device to connect.

Press the up button[▲] to select your device.

When a device is selected, it will appear in blue.

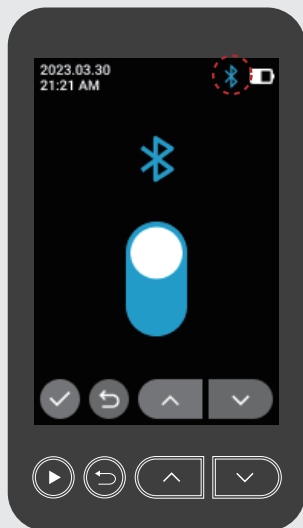
Press the back button[↶] to move to the Bluetooth settings screen.



8. Printer Connection

8.2.5. When the printer is connected, the Bluetooth symbol in the top display will appear in blue.

Once the printer is connected, you must reboot the device.



Caution

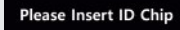

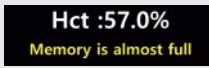
- Use only the designated printer
- Only one device Bluetooth printer.
- When using Bluetooth, turn on the printer device first.
- Check that the Bluetooth symbol on the top display is displayed in blue.
- Once connected, the device will remain connected, but if the printer's battery is disconnected or discharged, the connection will be lost and must be reconnected.

9. Technical Specifications

Sample	Capillary or venous whole blood
Sample volume	8~10 μ L
Measurement range	0 ~ 27 g/dL (refer to User manual 9. Technical specifications measuring range)
Measurement time	< 3 Seconds
Operating time	More than 5,000 continuous measurements when battery is full
Stand-by time	More than 60 days
Data Storage	5,000 Results
Rating	Battery: 6VDC(AA 1.5V Alkaline battery X 4ea) / 0.2A USB-C: 5VDC(4.0~5.5V) / 0.2A
Dimension	160(L) x 84(W) X 60(H) mm
Weight	Under 320g(w/o Battery)
Operating Condition	Temperature: 5 ~ 40°C, Humidity: Under 80 % R.H
Shipping & Storage Condition	Temperature: 0 ~ 50°C, Humidity: Under 80 % R.H
Altitude	up to 2000 m
Print	External Bluetooth printer (optional)
BT Frequency Range	2.402 to 2.480 GHz
BT Number of channel	0-39

10. Product Service

10.1. Trouble shooting

What you see	What it mean	What to do
Device won't turn on	<ul style="list-style-type: none"> - No battery - Battery power is low - Battery orientation does not match - USB-C Cable is not connected - Adapter power is incorrect 	<ul style="list-style-type: none"> - Insert the battery - Replace with a new battery - Check battery orientation - Connect the USB-C cable correctly - Use an adapter that that meets the specifications
Please insert ID Chip 	<ul style="list-style-type: none"> - No ID Chip - ID chip defective 	<ul style="list-style-type: none"> - Insert the ID Chip - Replace with a new ID Chip
Check the Microcuvette 	<ul style="list-style-type: none"> - No micro-cuvette 	<ul style="list-style-type: none"> - Place the micro-cuvette and start measuring
Not measured	<ul style="list-style-type: none"> - Sensor malfunction - Measure Tray does not close completely 	<ul style="list-style-type: none"> - Open and close the measurement tray again to start measuring - Make sure the Measure Tray is completely closed
Memory is almost full 	<ul style="list-style-type: none"> - More than 4900 results stored 	<ul style="list-style-type: none"> - Delete the results from Data Management in Settings

10. Product Service

10.2. Compliance

FCC Part 15.19

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.

FCC Part 15.21

Any changes or modifications (including the antennas) to this device that are not expressly approved by the manufacturer may void the user's authority to operate the equipment.

FCC RF Radiation Exposure Statement

This equipment complies with FCC RF Radiation exposure limits set forth for an uncontrolled environment. This device and its antenna must not be co-located or operating in conjunction with any other antenna or transmitter.

FCC Part 15B

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

10. Product Service

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

- (1) This device may not cause interference.
- (2) This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

- (1) L'appareil ne doit pas produire de brouillage;
- (2) L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

ISED RF Radiation Exposure Statement

This equipment complies with IC RF Radiation exposure limits set forth for an uncontrolled environment.

This device and its antenna must not be co-located or operating in conjunction with any other antenna or transmitter.

RF du ISED d'exposition aux radiations

Cet équipement est conforme à l'exposition de la IC rayonnements RF limites établies pour un environnement non contrôlé.

L'antenne pour ce transmetteur ne doit pas être même endroit avec d'autres émetteur sauf conformément à la IC procédures de produits Multi-émetteur.

10. Product Service

10.3. Guarantee

- This product has been produced through strict quality control and inspection processes and GenBody guarantees that there are no defects in the quality and manufacturing of the product.
- This warranty applies only to purchasing customers, and the warranty period is valid for 24 months from the date of purchase.
- Maintenance and repair costs incurred after the warranty expiration date will be repaired at a cost.
- In the following cases, repairs will be made at a cost even within the warranty period.
 - Use for purposes other than those recommended
 - If the product is arbitrarily disassembled, repaired, or parts are replaced
 - Defects caused by fire, pollution, earthquake or natural disaster
 - Damage caused by user negligence

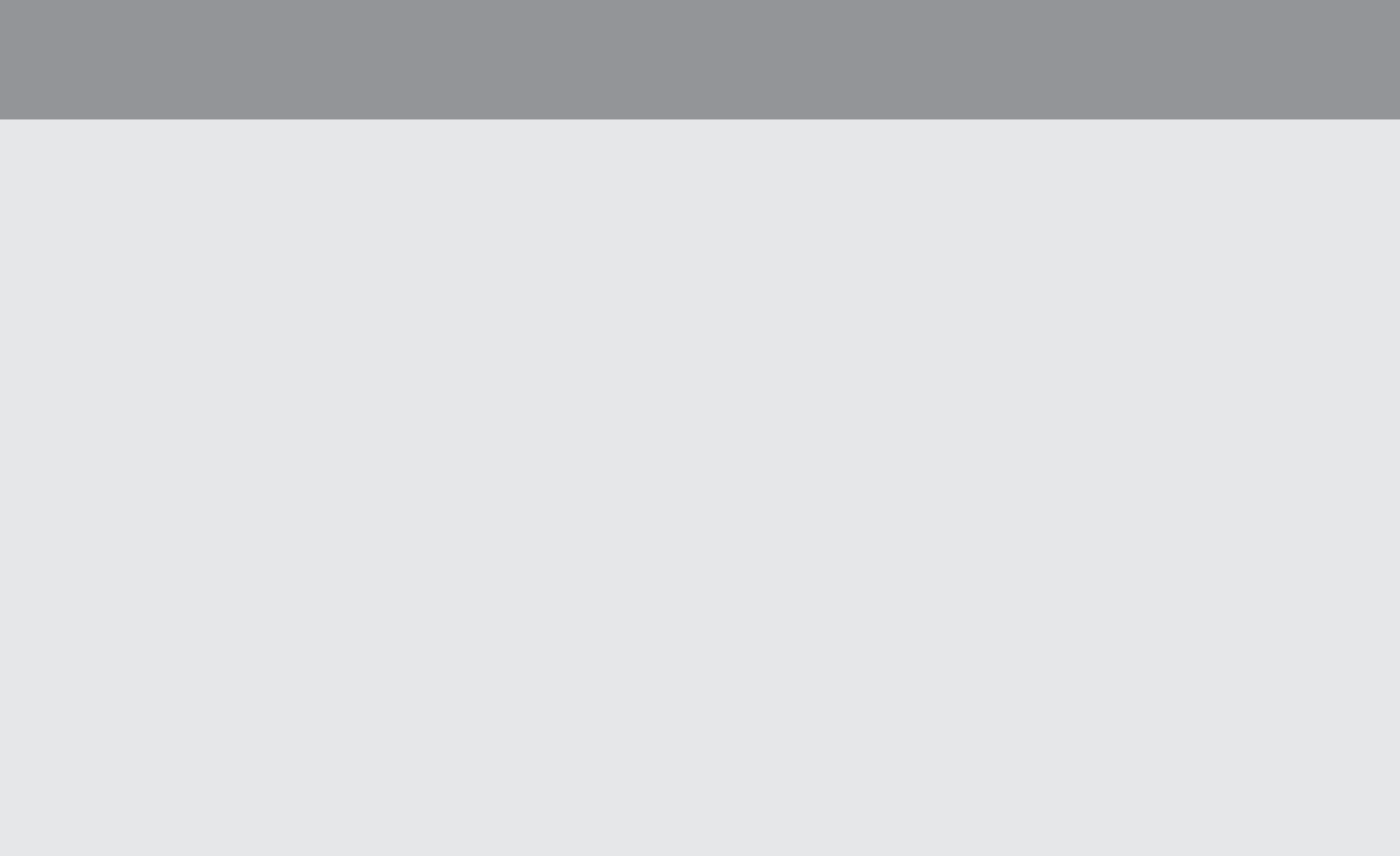


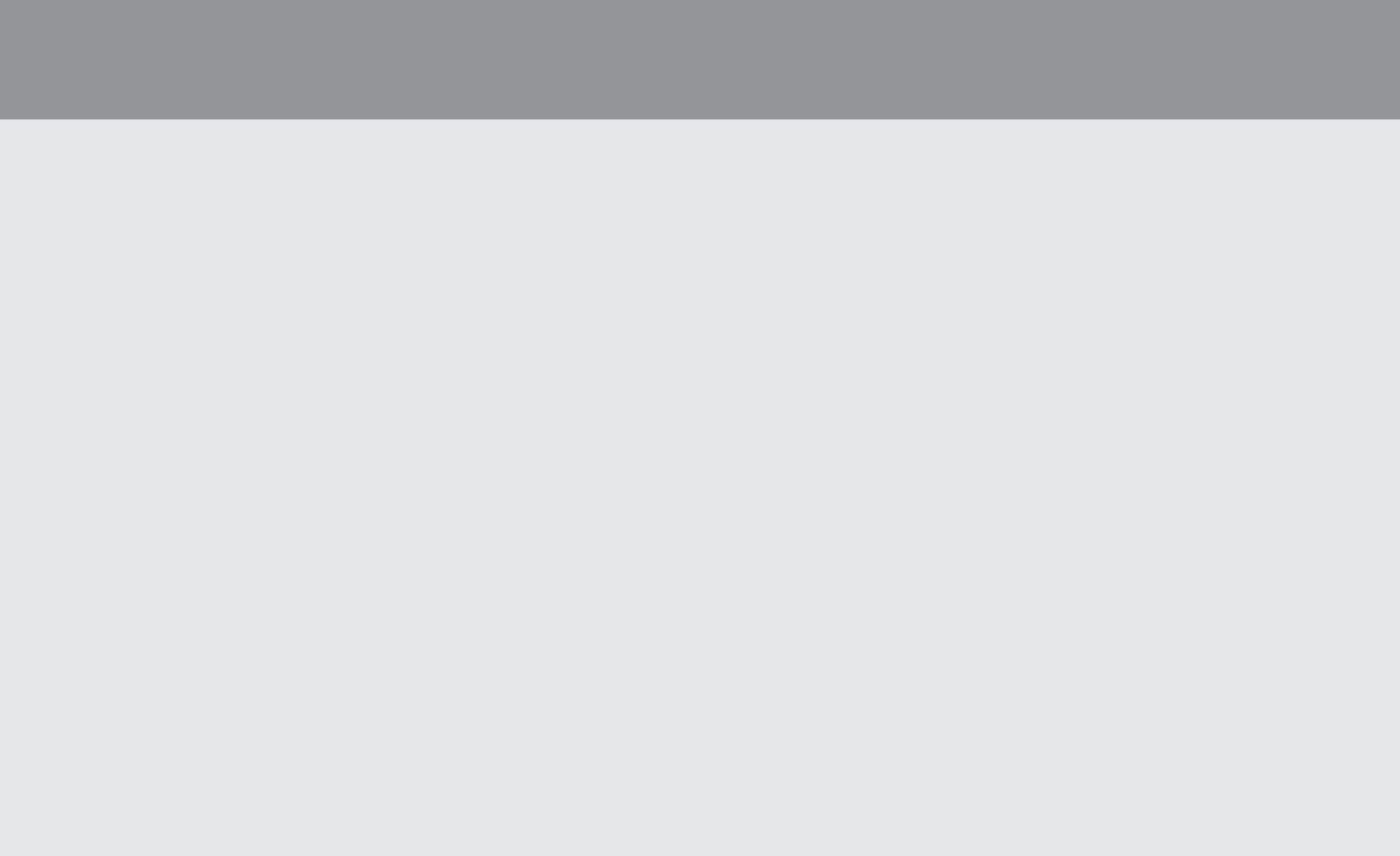
GenBody Inc.

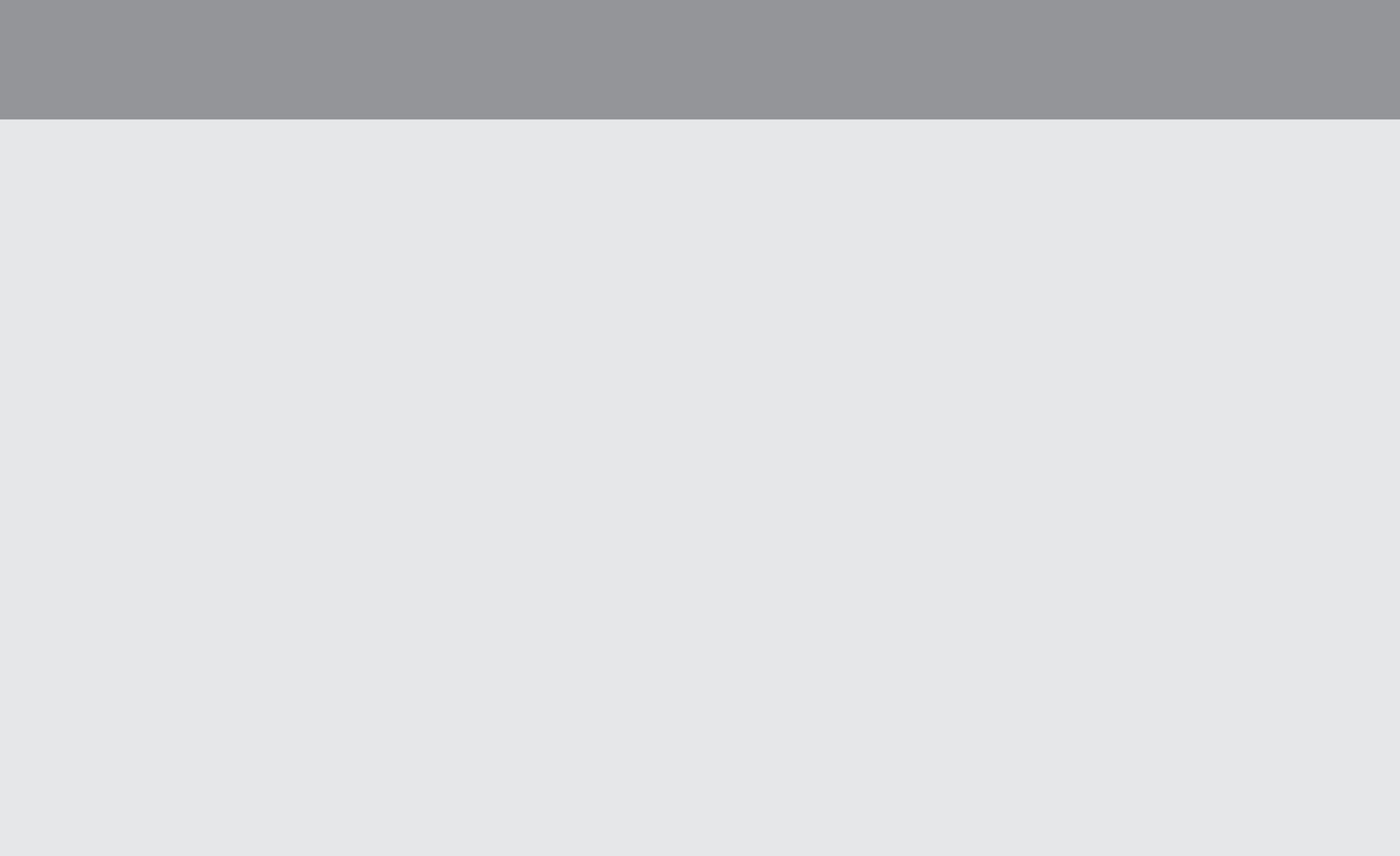
3-18, Eopseong 2-gil, Seobuk-gu, Cheonan-si,

Chungcheongnam-do, Republic of Korea

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Hemonitor H1

Hemoglobin Testing System