User Manual
Ambulatory ECG Monitor

Trade/Device Name: MEMO Patch M

Model Name: MPT-E08R-UNC01

Document Number: UM-M-002

Revision Number: 0

Revision Date: July 15, 2024

Table of Contents

1.0 DEVICE OVERVIEW

1.1 Instruction

This user manual is intended for Ambulatory ECG Monitor. The manual includes information about components, instructions for use and safety precautions of Ambulatory ECG Monitor and web viewer. Please read the user manual before using them. We recommend storing the manual in a safe place near the device.

1.2 Manufacturer Information

HUINNO Co., Ltd.

TEL: +82.2.2051.3161, FAX+82.2.2051.3160

Address: 3F, 4F, 5F, 19, Apgujeong-ro 79-gil, Gangnam-gu, Seoul, Republic of Korea

Webpage: https://www.huinno.com/en

1.3 Product Information

1.3.1 Product Description

The MEMO Patch M is a continuous electrocardiogram (ECG) recording device to record, store, and transfer single channel ECGs and is designed for remote ECG data collection and remote monitoring. The MEMO Patch M has Bluetooth module to verify ECG signals with mobile device and to authenticate the activation of MEMO Patch M. The device is in the form of an ECG patch that records ECG signals. As well the patch connects with a cradle and transmits ECG data via USB communication to PC. A healthcare professionals active the ECG patch, connect the patch with the cradle to the PC, and access raw ECG data on the ECG dataloader viewer. The MEMO Patch M includes a battery powered electronic unit that is used with off-the-shelf (OTS) disposable medical grade gel electrodes for long term monitoring. The adhesive electrodes should be replaced by the user every 24 hours or when it no longer adheres to skin. The MEMO Patch M is a prescription use device and the recorded ECG data is intended to be used with patient-triggered events. The device does not provide any automated ECG analysis.

1.3.2 Intended Use

The Ambulatory ECG Monitor is intended to capture and continuous electrocardiogram information for long-term monitoring. While continuously recording patient ECG, both patient-triggered events are saved at the device.

1.3.3 Indications for Use

The MEMO Patch M is intended to record and store single-channel electrocardiogram (ECG) data which are transferred to PC via USB transmission. As well the monitor is intended for use by healthcare professionals. The ECG data is not intended for automated analysis. The device has not been tested and it is not intended for pediatric use.

1.3.4 Intended Patient Population

- Age: 18 years or older
- Weight: it's irrelevant
- Health: The person who can recognize and record the symptoms that occur while using the Ambulatory ECG Monitor
- Nationality: it's irrelevant
- Intended Operator for Ambulatory ECG Monitor: Physician
- Intended Operator for ECG dataloader viewer and cradle: Physician

1.3.5 Patient Contacting Components

ECG electrodes

1.3.6 Software in Ambulatory ECG Monitor

1.3.6.1 MEMO Launcher (Android/iOS)

- This is the mobile software required for patch registration and checking ECG data by physician.

1.3.6.2 MEMO Patch ECG Dataloader (Window)

- This is the PC software needed to extract the raw patch data with cradle by physician.

1.3.6.3 Web viewer (Web)

- This is the web software to edit and publish the patient data by physician.

1.4 Marks and symbols

Symbol	Definition	Symbol	Definition
SN	Serial Number	Rx only	Prescription only
	Date of Manufacture		Manufacturer
	Read instructions	MD	Medical Device
	Refer to User Manual	FC	FCC Mark
	Warnings		Cautions
	Prohibitions	IP27	Protection Level

	Humidity Limit		Atmospheric Pressure Limitation
	MR, Magnetic Resonance Unsafe		Temperature Limit
	CE Mark		Defibrillation proof type CF Applied Part
	Single-use only for electrodes		Keep away from direct sunlight
	Unique Device Identification		Direct Current
	Recycling		WEEE
	Expiration date		Non-ionizing electromagnetic radiation
	Batch code		Model Number
	Handle with care		This way up
	Fragile		Keep dry

2.0 SAFETY REQUIREMENTS

2.1 Contraindications

1. Please do not examine or treat using radiation such as ultrasound, CT, MRI, and X-ray interfere with the regular operation of the product and lead to inaccurate results of use.
2. Please do not disassemble the device by the user or operator.
3. Please do not lay or cover electrical or magnetic products such as electric blankets, magnetic mats, electric stone beds, and jade mats during the examination.
4. Do not use the device for patients with symptomatic episodes where instance variant in cardiac performance could result in immediate danger to the patient
5. Do not use the device for patients with known history of life-threatening arrhythmias.
6. Do not use the device in combination with high frequency surgical equipment near strong magnetic fields or devices such as MRI.
7. Do not use the device on patients who do not have the competency to wear the device for the prescribed monitoring period.

2.2 Warnings

1. Do not use the device on patients with known allergic reaction to adhesives or hydrogels or with family history of adhesive skin allergies. Patients may experience skin irritation.
2. Infants or people who cannot express themselves must not use the device.
3. Without the manufacturer's permission, you must not modify the device.
4. Please be aware of the risk of strangulation for infants and children due to batteries and battery opener.
5. Please be careful as children may swallow small parts such as batteries.
6. Direct use of electrical products such as electric blankets and heated mats is prohibited during the prescribed period of using the product, as it may affect the performance of the test results.
7. If skin irritation such as severe redness, itching or allergic symptoms develop, remove the device from the patient's chest. Call HUINNO Customer Service at +82.2.3443.3160
8. If a user who is not familiar with the proper usage replaces the battery of the product, there is a risk of battery ignition or explosion.
9. The ECG Monitoring Electrode can be used for up to 8 days, and the disposable electrode using an electrode bracket can be used for up to 24 hours.
10. Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

2.3 Precautions & Cautions

1. Read all instructions and labels including this manual before starting to use the device.

2. Do not use acetone or any other cleaning solvents to clean the device.
3. The device includes temperature and humidity limitations. If exposed, patients may experience degradation of adhesive performance causing the device to slip or fall off during the patient wear duration.
4. The device has a shelf-life data. Use of expired device may cause a degradation of ECG signal quality and/or low battery condition.
5. Keep device and packaging away from young children. Contents may be harmful if swallowed. Device contains button cell batteries that are not accessible during normal use but, if exposed, are known choking hazards and may cause severe tissue injury if ingested.
6. The battery life of the device may be shortened if the device is used frequently and/or for a prolonged period of time.
7. The battery life and capacity may decrease when the device is stored in a high-temperature environment.
8. The battery may self-discharge when the device is in storage.
9. Do not immerse the device into any liquid.
10. Do not expose the device to direct sunlight, heat source of thermal radiation, moisture, vibration, mechanical shock, excessive dust, or humidity.
11. The warranty will be void if the device is opened, disassembled, or altered by any unauthorized personnel.
12. Do not use caustic or abrasive cleaning agents to clean the device.
13. Do not excessively pull or overstress the device as it may break.
14. Do not sit or place a heavy object on the device.
15. Do not use the device if the package is damaged. Devices may not perform as intended.
16. Safety and effectiveness of the device on under 18 years old include pediatric patients has not been established.
17. Keep devices and packaging away from young children. Contents may be harmful if swallowed. The Device contains button cell batteries that are not accessible during normal use but, if exposed, are known choking hazards and may cause severe tissue injury if ingested.
18. Registration errors may result in limited functionality or erroneous ECG reporting. Utmost caution should be applied to ensure that patient registration is accurate and complete.
19. Ensure that the electrodes of the device do not come into contact with other conductive parts. If electrode is not contact well with the skin the performance and accuracy of the ECG test might not accurate.
20. When the abnormality is found during the examination, keep the patient in safe status and stop the examination.

21. Exposure of attachment parts or other accessories of the product for a long period of time may cause skin irritation. If the skin irritation is severe, please contact HUINNO Customer Service at +82.2.3443.3160 immediately.
22. Allergic reactions may occur to the tape on the electrodes used in the product.
23. Ensure that the electrodes and conductive portions of the CF type mounting part, including the neutral electrode, do not come into contact with other conductive parts that include grounding.
24. MEMO report made by a diagnostic aid software uses to assists a physician in making the final diagnosis with a patient's condition.

2.4 IT Network

The Ambulatory ECG Monitor is connected to the mobile device via Bluetooth. Through the mobile device the following can be done:

1. Activate and connect the device with the patient
2. Check the ECG data through 'MEMO Launcher' app

2.5 Environmental Protection

-  Non-specialized organizations with responsibility should contact local authorities to determine the proper disposal methods for components and accessories that pose biol ogical hazards.
-  Battery recycling must meet local requirements.

2.6 FCC Statement and Caution

- **FCC Compliance Statement**
- 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 Interference Statement**
- 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 correct the interference by one of the following measures:

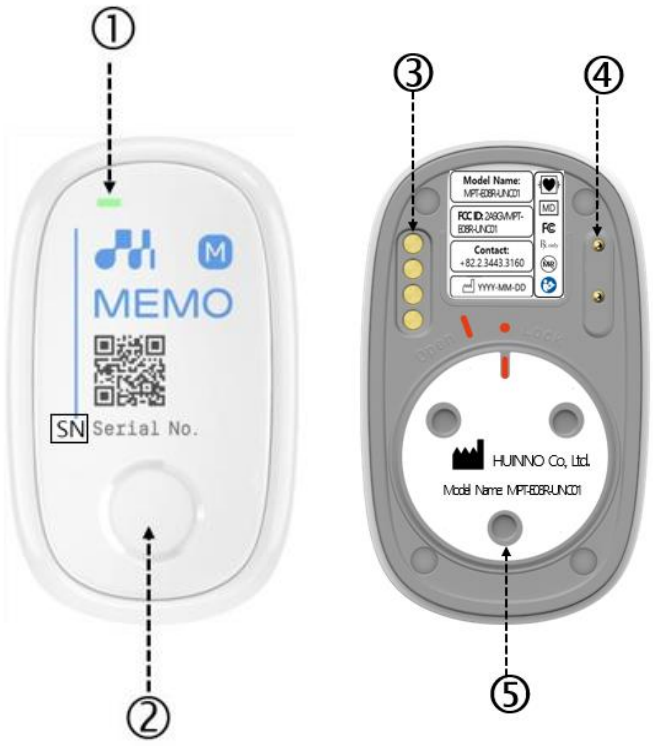
- • Reorient or relocate the receiving antenna.
- • Increase the separation between the equipment and receiver.
- • Connect the equipment into an outlet on a circuit different from which the receiver is connected.
- • Consult the dealer or an experienced radio/TV technician for help.
-
- **FCC Caution**
- Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

- **FCC Radiation Exposure Statement**
- This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 5 mm between the radiator and your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

3.0 PACKAGE COMPONENTS

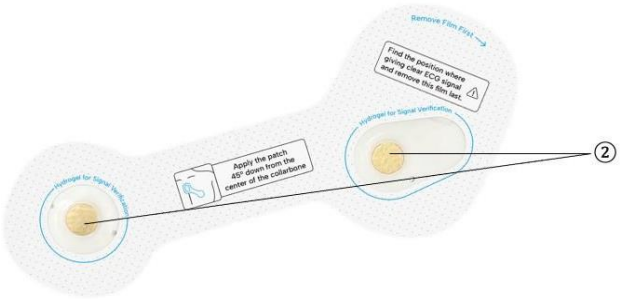
- 1 Ambulatory ECG Monitor
- 1 Paper type user manual
- Option
  - 1 Battery cover opener
  - 1 ECG Data Transferred Cradle
  - Electrode
    - 1 ECG Monitoring Electrodes
    - 1 Electrode bracket (60mm or 100mm)
      - **NOTE:** It is recommended to use approved products with proven safety. **We recommend using 3M red dot (model name: 2560)**
      - **Information for 3M red dot (model name: 2560)**
        - 510(k) Number : K970796(1997.4.9.)
        - Device name: 3M Red Dot™ 2560 Monitoring Electrode with Foam Tape and Sticky Gel
        - Biocompatibility Evaluation Criteria: ISO 10993-1 Part-1

3.1 Ambulatory ECG Monitor



No.	Term	Description
①	Status LED	This is the LED displays status of the power on/off, error, patient event and the status of Bluetooth.
②	Power Button & Event marking button	This is used to turn on the power of the device and mark the event.
③	Pogo terminal	This is the port used to transfer ECG data to a PC. It is used in conjunction with a cradle.
④	Electrode connection pin	This is the part used to connect the electrodes to the device.
⑤	Battery cover	This is the cover that is detached when replacing the battery.

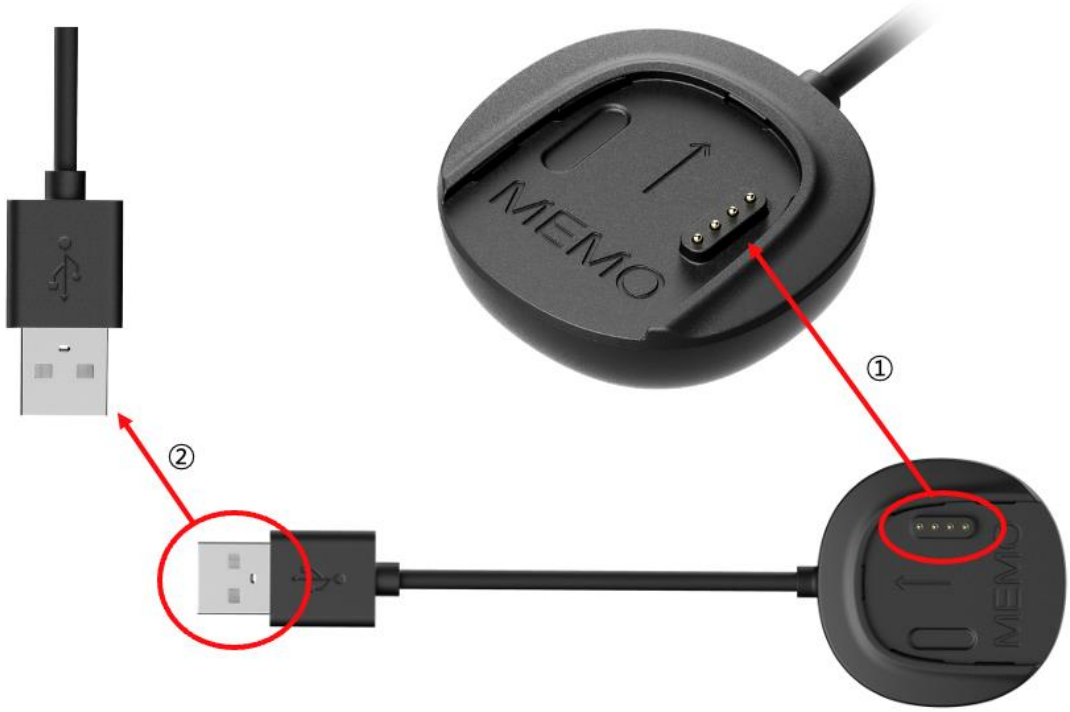
3.2 ECG Monitoring Electrodes



No.	Term	Description
①	Output connector	This is the part that connects the measuring device to transmit the electrocardiogram signal from the electrocardiograph machine and is called the lead.
②	Electrode	This is the part that uses hydrogel and transmits the electrocardiogram signal from the human body.

3.3 ECG Data Transferred Cradle (1port)

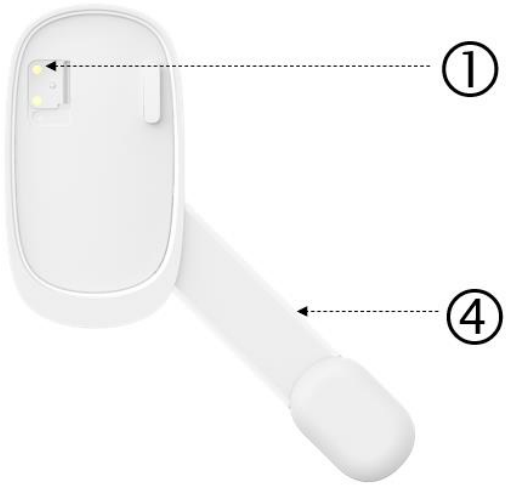
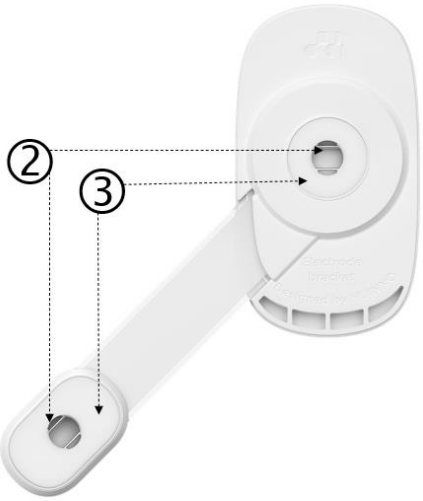
lo



No.	Term	Description

①	Data upload pin	This is the pin that connects to the device's data upload port.
②	USB port	This is the port where the USB cable connecting to the PC is connected.

3.4 Electrode bracket

Front	Back
	

No	Term	Description
①	Mainbody connector	The part connected to the connector of the Ambulatory ECG Monitor
②	Electrode connector	Connectors compatible with electrodes
③	Adhesive tape	Tape to prevent medical electrodes from shaking (white, gray, black)
④	Connecting wire	FPCB wire connecting two compatible electrodes (ex: 3M red dot, model name: 2560)

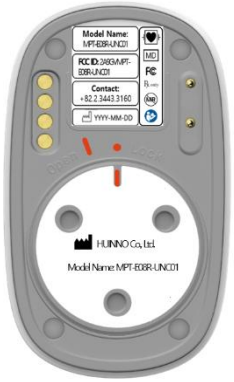
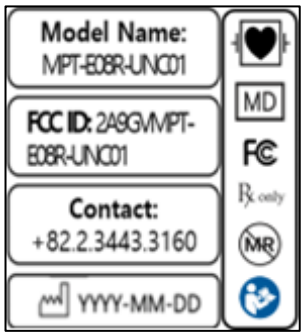
3.5 Battery cover opener

	Tool for opening the battery cover of the Ambulatory ECG Monitor

3.6 Labeling and Packaging

3.6.1 Device Label

Position	Main Body Top	Main Body Bottom

Device		
Device Label	Serial No: PXXXXXXX	 

Position	ECG Data Transferred Cradle Top	ECG Data Transferred Cradle Bottom

Device		
Device Label		

3.6.2 Package (Gift Box) Label

Main body

MEMO Patch

Product Name
Ambulatory ECG Monitor
(MEMO Patch M)

Rating
3.0VDC, 225mAh (CR2032)

Model Number
MPT-E08R-UNC01

SN PXXXXXXX

IP27

HUINNO Co., Ltd.
3F, 4F, 5F, 19, Apgujeong-ro 79-gil, Gangnam-gu,
Seoul, Republic of Korea (06011)

Tel +82-2-3443-3160
Fax +82-2-2051-3160

FCC ID: 2A9GVMPT-E08R-UNC01

Caution: Federal law restricts this device to sale by or on the order of a physician

UDI (01)08800126500185 (11)YYMMDD HUINNO

MR MD

Rx only 2024-11-14

ECG Monitoring Electrodes

Model Number
ACC-E10T-01

Rx only

Caution: Federal law restricts this device to sale by or on the order of a physician

HUINNO

UDI (01)08800126500093 LOT H221207E01

-20°C 60°C 10% 95% 700hPa 1060hPa

YYYY-MM-DD

Month-Year

HUINNO Co., Ltd.
3F, 4F, 5F, 19, Apgujeong-ro 79-gil, Gangnam-gu,
Seoul, Republic of Korea (06011)

Tel +82-2-3443-3160
Fax +82-2-2051-3160

MD Do Not Reuse

ECG Data transferred Cradle

ECG Data Transferred Cradle

Model Number
ACC-C01P-03
Serial Number
CXXXXXXX
Country of Manufacture
Republic of Korea
Rating
5V⎓ , 0.5A

HUINNO

HUINNO Co., Ltd.

Address
3F, 4F, 5F, 19, Apgujeong-ro 79-gil,
Gangnam-gu, Seoul,
Republic of Korea (06011)

(01)08800126500017
(11)000000

Electrode bracket	

4.0 USAGE

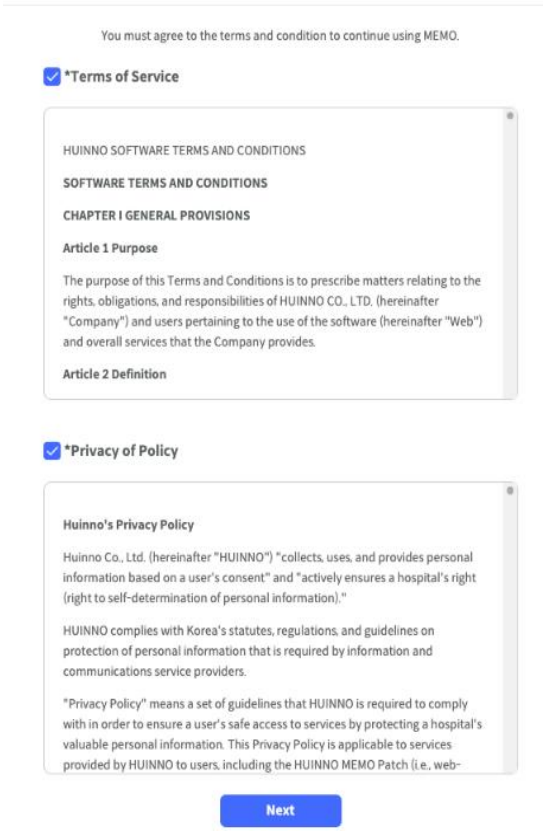
4.1 Creating account and Accessing

4.1.1 Accounting Setting

1. To use the service, the clinic needs to obtain an account from HUINNO. With an account, the clinic can access and operate our system, including 'web viewer', 'MEMO Launcher', and the 'MEMO Patch ECG Dataloader'.

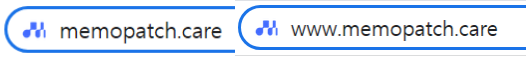
2. For users who are granted a new account and logging in for the first time, they must agree to the "Terms of Service and Privacy Policy" before they can use the service.

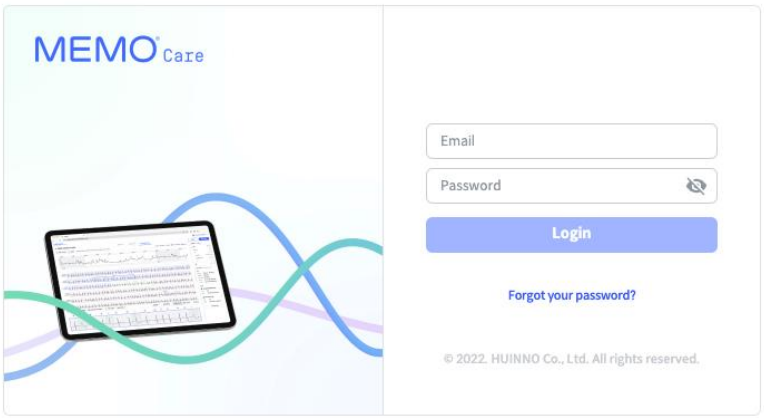
3. If you do not agree to the 'Terms and Conditions', a user will not be able to use the software.



4.1.2 Accessing and Configuring Web viewer

1. To access web viewer, open a web browser and go to www.memopatch.care or memopatch.care.

- 



- To ensure optimal performance, we recommend using web viewer with either (1) Google Chrome or (2) Microsoft Edge web browsers.

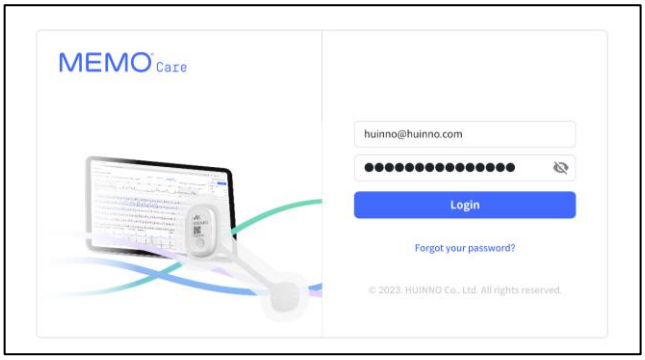
<table>
<tr><td></td><td>

- When logging in for the first time, a link to set your password will be sent to the email address that you used to sign up for the service. Follow the link to set your password, and then log in."

</td></tr>
<tr><td>

2. After entering the login credentials (email address and password) issued by HUINNO, click the login button.

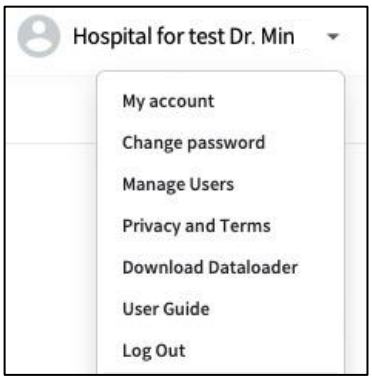
</td><td>

- 

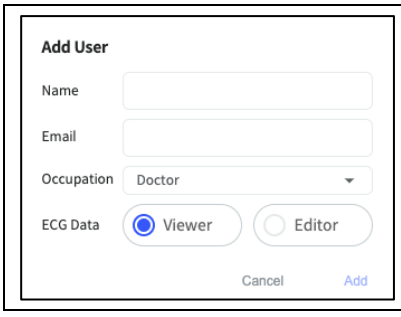
</td></tr>
<tr><td>

3. To manage user settings, click the ▼ button in the top right corner of the web viewer page, then click on 'Manage Users' and 'Add User'.
4. To add a new user, enter the following information in the 'Add User'.
   i. Name
   ii. Email
   iii. Occupation (Doctor, Nurse, Clinical Pathologist, Staff)
   iv. ECG Data (Select between Viewer and Editor)

</td><td>

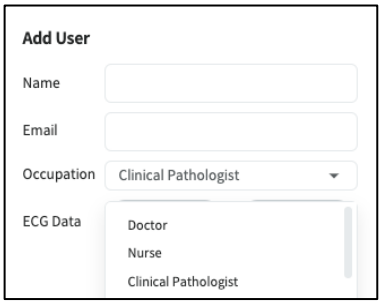
- 

- 



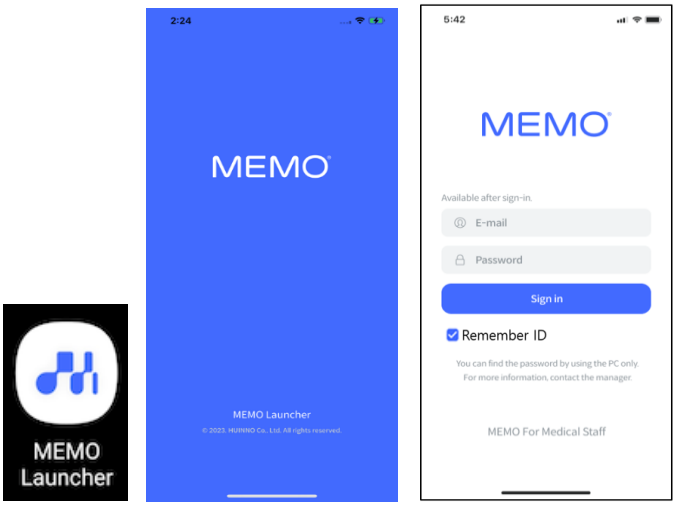
* Viewer: You can only view the ECG analysis report.

* Editor: You can edit the ECG analysis report.

- 

</td></tr>
</table>

4.1.3 Service access of MEMO Launcher App

1 If you are using an Android device, search for 'MEMO Launcher' on the Google Play Store. 2 If you are using for iOS device search on the App store.	
3 After downloading and installing the App, enter the identical account information provided from HUINNO. **Note:** Login information is provided only to hospitals that have contracted with HUINNO services.	

4.2 When visiting a patient

To attach the Ambulatory ECG Monitor, follow the steps blow

4.2.1 Patient registration in web viewer

4.2.2 Preparing for patch attachment

4.2.3 Examination setup and attachment

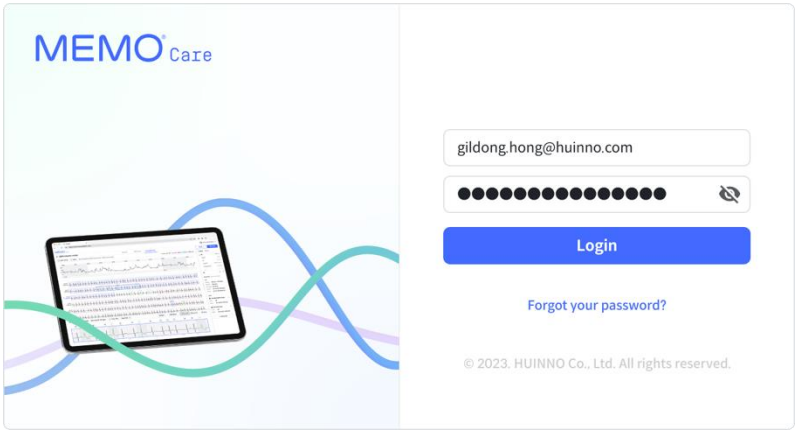
4.2.4 Delivery of instructions and supplies to patients

4.2.5 Instruction to follow during monitoring of Ambulatory ECG Monitor

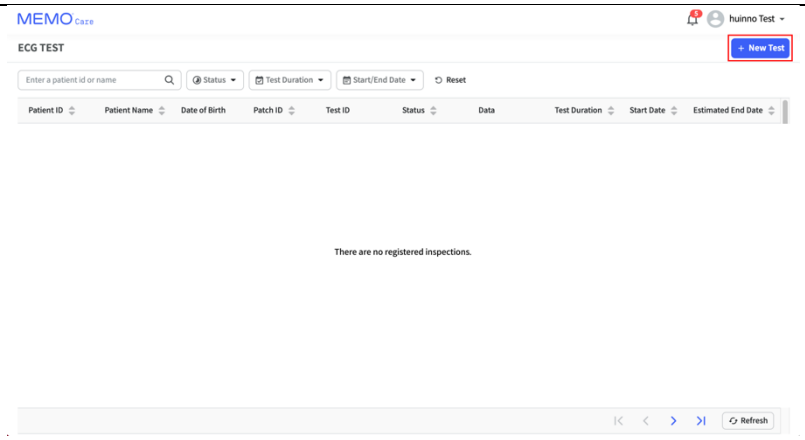
4.2.1 Patient registration in web viewer

1 Access the web viewer, memopatch.care, enter your email address and password, and log in.

* To ensure optimal performance, we recommend using Web viewer with either (1) Google Chrome or (2) Microsoft Edge web browsers.



2 Click the Add Test button o n the top right



3 Enter all of the following inf ormation in the 'New Test' window and then click the 'Add' button.

(1) Patient Name

(2) Patient ID

(3) Gender

(4) Date of Birth

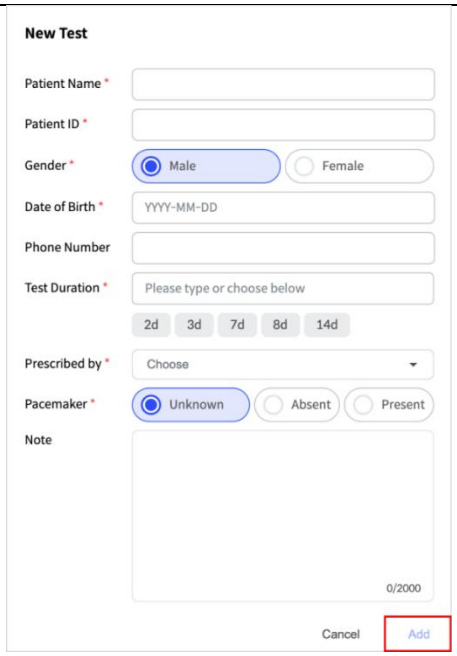
(5) Phone Number

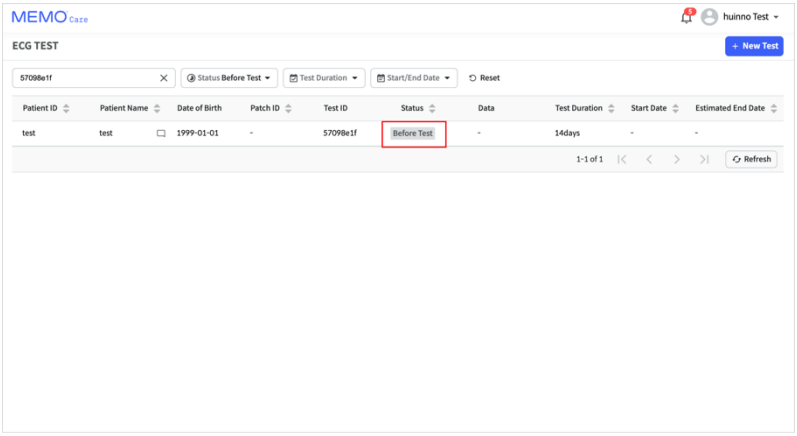
(6) Test Duration

(7) Prescribed by

(8) Pacemaker

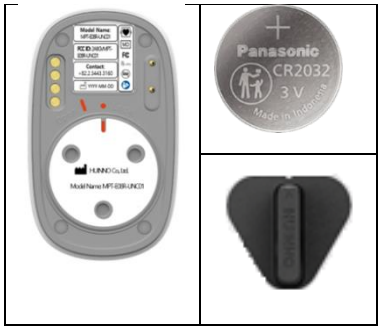
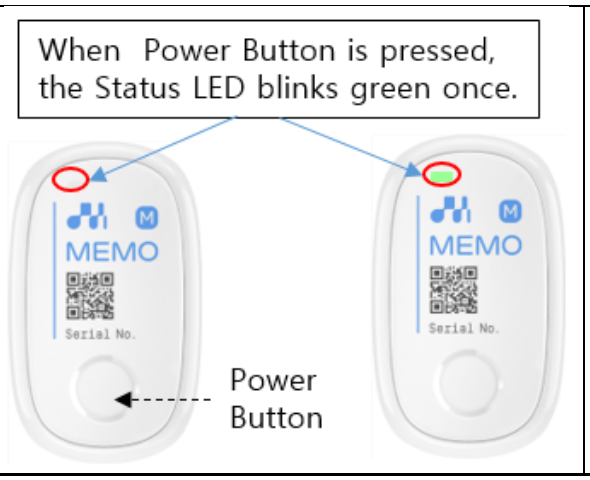
(9) Note



4 A new test is created and it s status will appear as 'Befo re Test'.	

4.2.2 Preparing for patch attachment

1 Prepare Ambulatory ECG Monitor, electrode, new battery and battery cover opener	 ◆ Select and prepare the electrode to attach. ECG Monitoring Electrodes / Electrode bracket and 3M red dot 

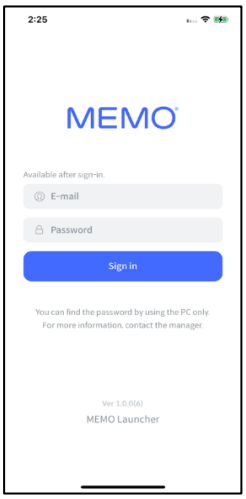
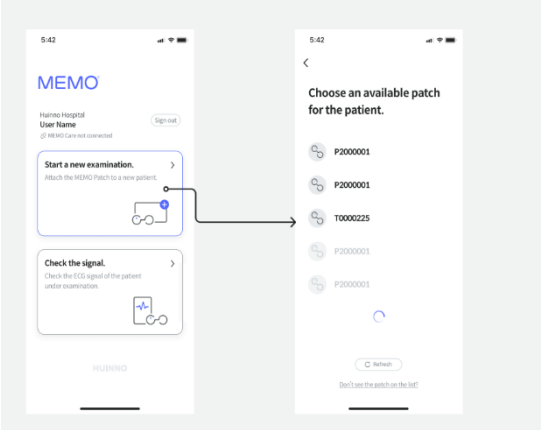
<table>
<tr>
<td>2 Replace with a new battery.</td>
<td>
<table>
<tr>
<td>1</td>
<td> 
</td>
<td>2</td>
<td>  </td>
</tr>
<tr>
<td></td>
<td>Prepare the Ambulatory ECG Monitor, new battery, and Battery cover opener.</td>
<td></td>
<td>Attach the battery cover opener to the battery cover, and prepare to open the battery cover.</td>
</tr>
<tr>
<td>3</td>
<td>  </td>
<td>4</td>
<td> 
</td>
</tr>
<tr>
<td></td>
<td>While pressing the opener attached to the battery cover, turn it 15 degrees to the left.</td>
<td></td>
<td>After replacing with a new battery(CR2032), secure the battery cover in the opposite manner of opening the battery cover.</td>
</tr>
</table>
</td>
</tr>
<tr>
<td>3 The device is turned on by pressing the Power Button for 3 seconds.</td>
<td>


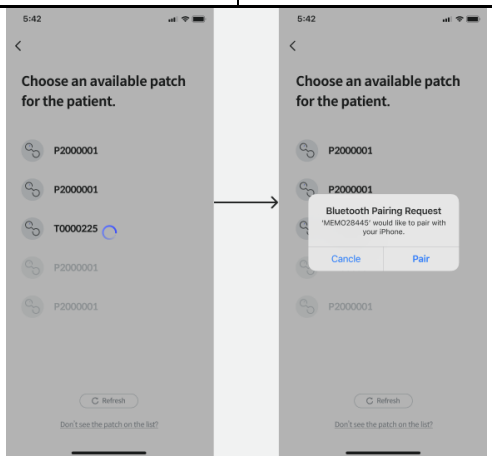
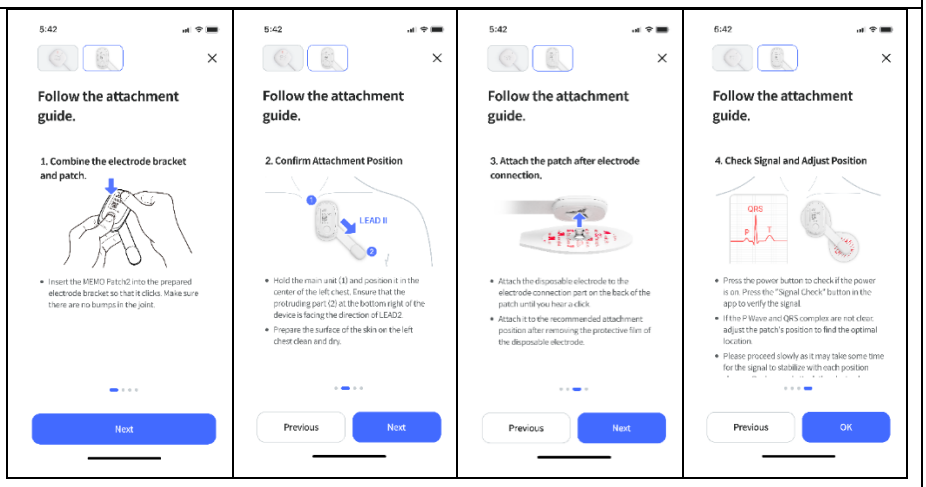
</td>
<td>Note: Ambulatory ECG Monitor automatically turns off if it is not paired through the ‘MEMO Launcher’ App within 5 minutes of turning it on.</td>
</tr>
</table>

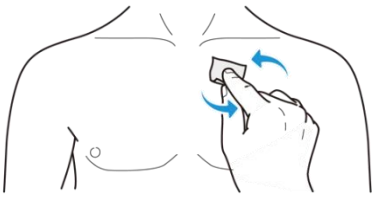
4. Remove the blue protective film on the electrode and connect powered-on patch to the fixing pad (Blue Part) * If you are using an electrode bracket, simply connect powered-on patch in the direction of the electrode bracket.)	 *Using ECG Monitoring Electrodes	 *Using Electrode bracket and 3M red dot

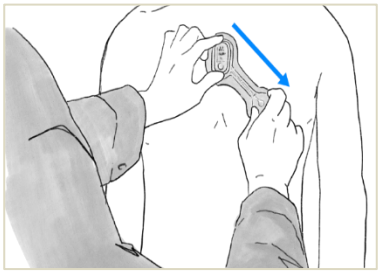
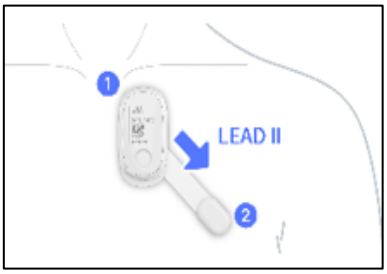
✻ The device will automatically turn off if it is not paired with the 'MEMO Launcher' app within 5 minutes of turning it on.

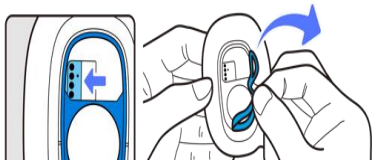
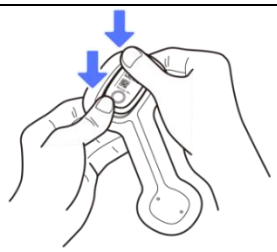
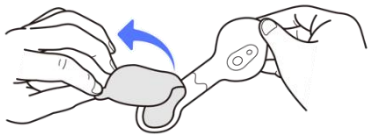
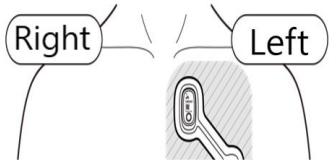
4.2.3 Examination setup and attachment

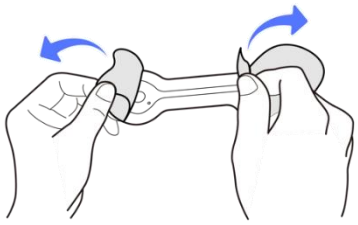
Examination setup and attachment		
1. To run the 'MEMO Launcher' App, log in using the same ID and password as the web viewer.	  	
2. Click 'Start a new examination', then select and click the patient registered for examination on the web viewer.		NOTE: If the patient does not appear in the list, please make sure the Bluetooth function on your mobile device is enabled.

<table>
<tr><td>3. Check the serial number of the 'MEMO Patch M' to be attached to the patient.</td><td><table><tr><td> 
</td><td>NOTE: The serial number is a combination of the English letter ‘P’ and numbers and can be found on the front of Ambulance ECG Monitor.</td></tr></table></td></tr>
<tr><td>4. Select the serial number of the patch to attach to the patient from the list and pair.</td><td> 
</td></tr>
<tr><td>5. User can check the patch attachment guide by clicking User Guide in the App’s draw menu.</td><td> 

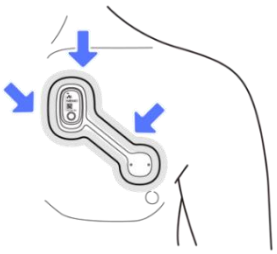
After completing the pairing process, please check the attachment guide that appears.</td></tr>
<tr><td rowspan="2">Note: Disinfect the attachment site with alcohol before attachment.</td><td>After checking for damage to the Ambulatory ECG Monitor, clean the patient’s electrode attaching area.</td><td>  </td></tr>
<tr><td>If there is hair on the attachment site, shave the hair before attaching. If the device is not in close contact with the body due</td><td>  </td></tr>
</table>

	to body hair, it may interfere with the signal measurement.
6. After removing the white sticker on the back of the electrode, place the patch in the center of the clavicle and attach the electrodes at a 45-degree angle to the right.	6. Hold the main unit ①and position it in the center of the left chest. Ensure that the protruding part ② at the bottom right of the device is facing the direction of LEAD II. Attach electrodes at a 45-degree angle.   <u>6-a. Detailed attaching method using ECG Monitoring Electrodes</u>

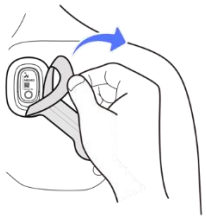
 1) Remove the blue protective film from the electrode connector	 2−1) Connect the Ambulatory ECG Monitor to the electrodes. 2−2) Make sure there are no loose parts in the joined area.
 3) Remove the white protective film on the back of the electrodes.	 4) Check the location with the best signal using a temporary attachment between the clavicle and nipple on the left side of the patient's chest.



5) After removing the protective film, attach it to the patient's adhesive area.



6) To prevent the electrode from falling off, press the entire adhesive area to adhere it to the skin.

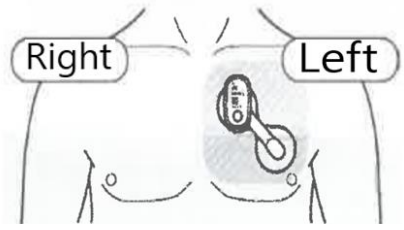


7) Finally, remove the transparent film on the front of the electrode.

6-b. Detailed attaching method using electrode bracket and 3M red dot

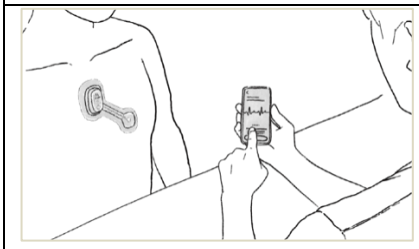
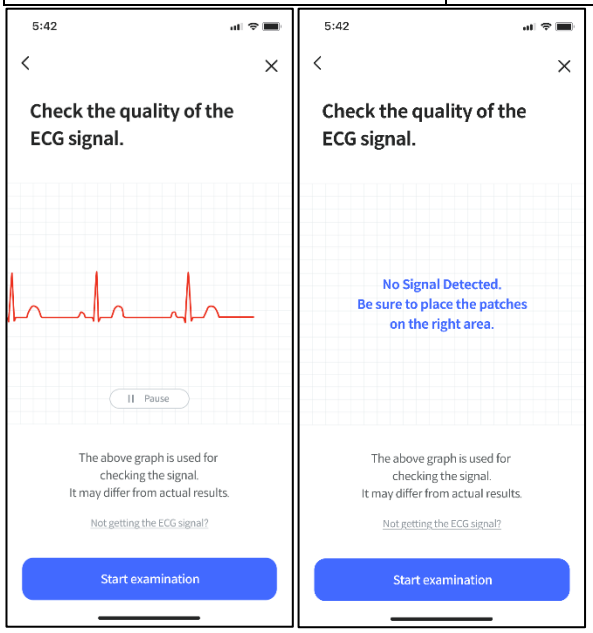
1) Attach the Ambulatory ECG Monitor toward the electrode bracket, and attach the disposable 3M red dot electrode to the bottom of the electrode bracket.

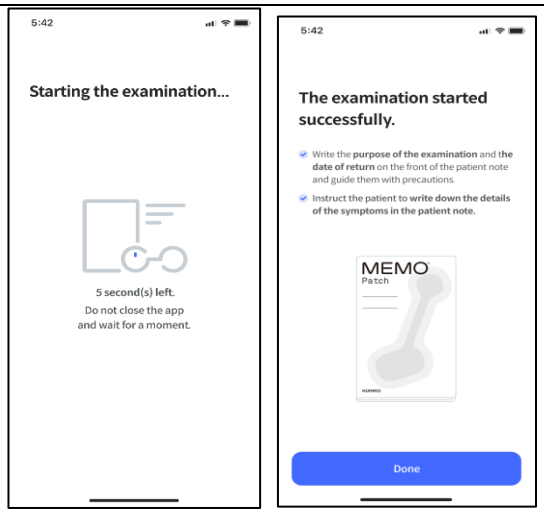
2) Remove the transparent film on the bottom of the combined 3M red dot electrode.

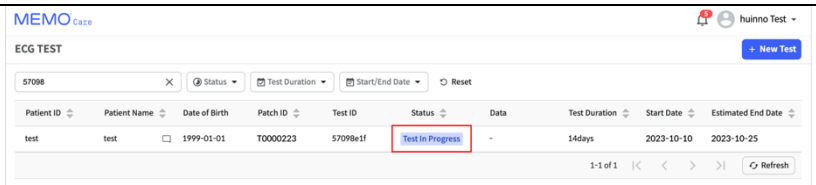


3) Attach the electrode bracket combined with the Ambulatory ECG Monitor to the left side of the patient's chest between the clavicle and nipple.

4) To prevent the electrode from falling off, press the entire adhesive area to adhere it to the skin.

<table>
<tr>
<td>7 Check if the ECG signal appears well in the MEMO Launcher app.
1) If the P wave and QRS complex are not clear, move the patch position slightly to find the optimal position
2) After checking the quality of the ECG signal, press the 'Start examination' button.</td>
<td>
7. Check ECG signal

Note: Since this signal is for verification purposes, it may differ from the actual ECG data being saved.
• It is recommended to attach the patch in the direction of Lead II, and if the P wave is clear, the signal can be considered excellent.


• Pressing the pause button below a signal will stop the signal from playing.
• If the signal does not come in, check the attachment status again. (It is necessary to check whether the tape on the back of the electrode is removed or whether the power is on)
</td>
</tr>
<tr>
<td>8. After pressing the 'Done' button, finish the process.</td>
<td>


</td>
</tr>
<tr>
<td>9. When the examination has started, the status will change to 'Test In progress' on the</td>
<td>


</td>
</tr>
</table>

web viewer interface, and the examination start date and the device return date for the patient will be displayed.	If you want to check the signal after starting the examination, click on the 'Check Signal' menu by clicking on the top drawer menu. You can check the signal by clicking on the patient's name in the list. However, patches and apps are Bluetooth-connected, so they cannot be used if the patch is out of range or if the signal is weak.

4.2.4 Delivery of instructions and supplies to patients

After completing the examination, provide the patient with the following items:

- Patient note: Record sleep time and symptoms.
- MEMO Patch M storage envelope: Used to return the device to the hospital. Please put the detached device into the envelope and return it.
- Patient guidebook: The patient guidebook contains instructions for recording symptoms, reattachment, precautions, and contact information.

4.2.5 Instruction to follow during monitoring of Ambulatory ECG Monitor

During monitoring, the Ambulatory ECG Monitor continuously records ECG information. In addition, to check the frequency and pattern of arrhythmia more accurately, if an arrhythmia symptom occurs, press the symptom record button on the device or record it in the patient note. As well sleep time also should be recorded in the patient notes. If a problem occurs during monitoring, contact the Ambulatory ECG Monitor customer center at +82-2-3443-3160.

Patient: Record symptoms and sleep time

1 If the patient experiences any symptoms during the examination period, they can record it using the following methods:

2 Press and hold the symptom button on the MEMO Patch for about 1 second. When the green LED flashes, the symptom has been recorded.

3 Alternatively, they can record the symptom on their patient note.

	 < Recode the symptom on patient notes > ◆ During the ECG examination period, a patient can sequentially select a bedtime for each period. If a patient had intermittent sleep, please note it in the patient notes.

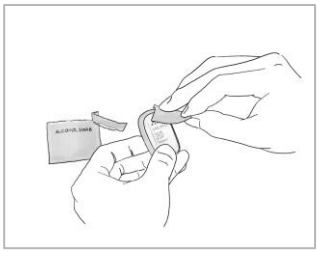
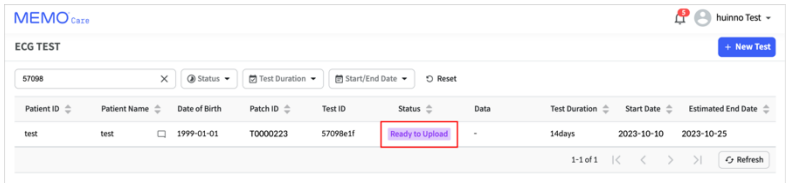
4.3 Procedures after completing the examination

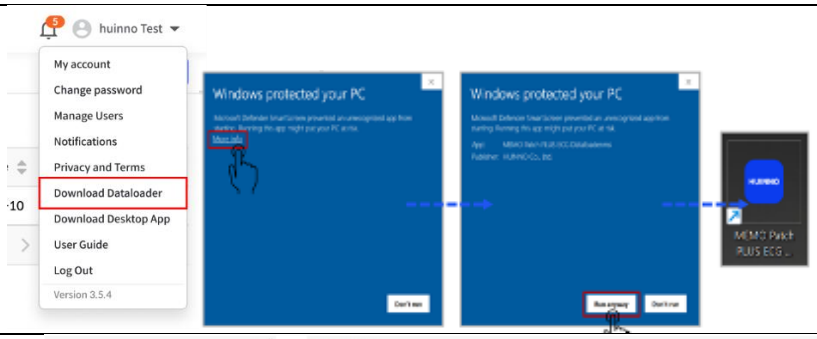
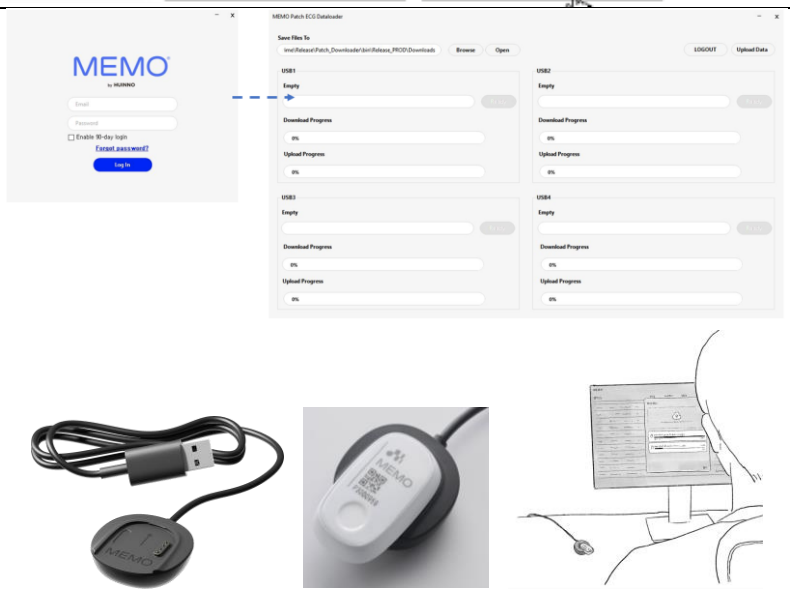
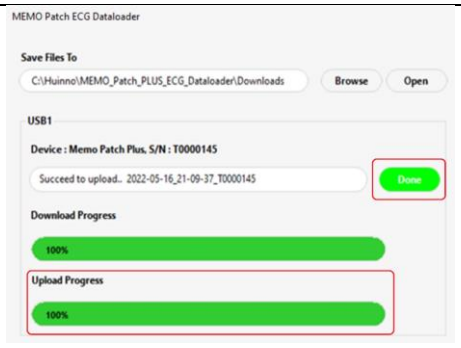
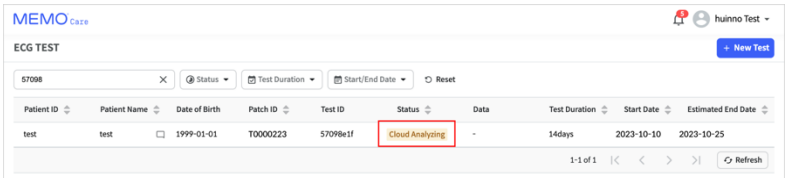
4.3.1 Patient: Detaching and Returning the 'MEMO Patch M'

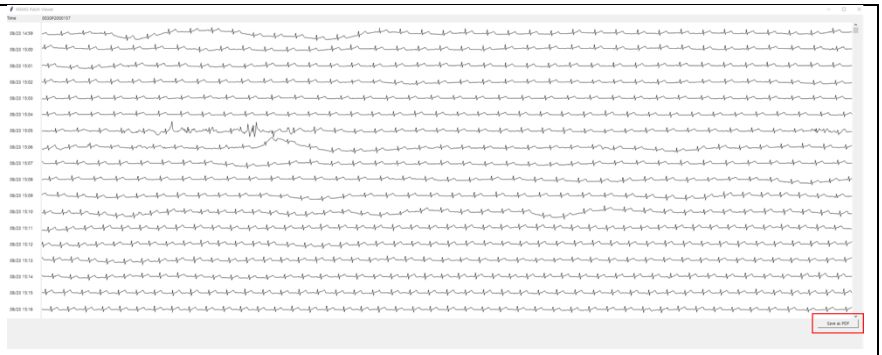
1. After the examination is completed, the patient removes the patch and puts it in the storage bag received from the hospital. 2. Patient notes recording symptoms are also returned. 3. After the ECG analysis is completed, schedule a treatment day and return home.	

4.3.2 Clinic

: Checking the 'MEMO Patch M' device, processing returns, and uploading data

1 After checking the appearance of the device and the electrode bracket for abnormalities, disinfect them with alcohol 2 After measurement, the scan changes to the upload waiting state. The scan of the upload waiting state can proceed with the data upload.	 

3 To upload the ECG data stored in the device to the PC, use the data loader program. The method of installing the Data Loader program is as follows. 4 Click ▼ next to Account in the upper right corner of the web viewer web and click Download Data Loader to install the program.	
5 After running the MEMO Patch ECG Dataloader, login with the same email and password as the web. 6 Combine the device and the cradle, and connect the cradle to the PC using the provided cable. If the connection is successful, the Serial No. of the MEMO Patch M will be displayed. Then, click the download button.	
7 When the download is successfully completed, a 'Done' message will appear. On the memo web, the status changes from waiting for upload to Cloud Analysis.	 

8 Click the 'Done' button, and raw ECG data will be displayed on the dataloader viewer. 9. To export the data to a PDF file, click 'Save as PDF', and it will be saved in a PDF file.	
10 The uploaded ECG data is analyzed by server. A report with the analysis results is generated after a review.	

4.3.3 Cleaning and maintenance

Cleaning and Maintenance	◆ After use of the device, gently wipe with an alcohol swab with an alcohol content of at least 60% and then clean the Ambulatory ECG Monitor and electrode bracket with a soft and dry cloth. ◆ Do not use caustic or abrasive cleaning agents, or any cleaning agent containing ammonium chloride or isopropyl alcohol. ◆ Do not sterilize, autoclave, or immerse this device in liquid. ◆ Do not pour or spray any liquids onto the device. ◆ Do not repair, disassemble and modify this device. ◆ This device does not require calibration during its expected life cycle.
Storage and Transport	◆ When storing the device, avoid exposure to direct sunlight or heat. ◆ The device should be stored under the storage temperature range. If the device will be stored for a long time, the recommended conditions are: ◆ Temperature: -20°C to 60°C ◆ Relative humidity: 10% to 95% (non-condensing) ◆ The device should be stored in the room without acid, alkali, and harmful gas. ◆ Avoid exposure to violent vibration, rain, sunshine, and high humidity during transportation.

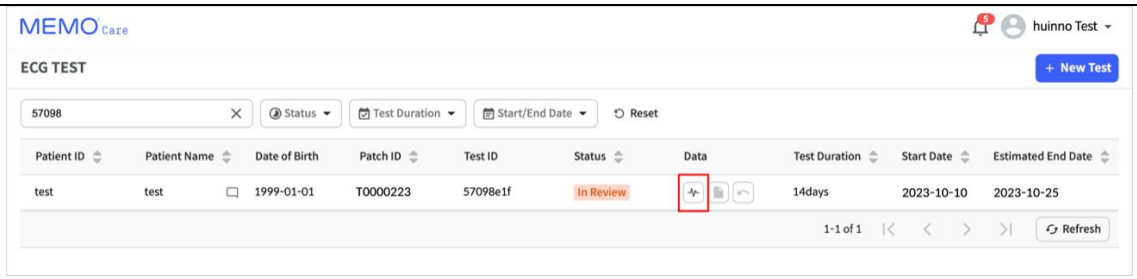
Disposal 	◆ Before prescribing to a new patient, the electrodes must be replaced with new ones before use. Reuse of electrodes is prohibited and discarded after use. ◆ Follow local, state, and national governing ordinances and recycling instructions regarding disposal or recycling of the device components.

4.4 Review with Web viewer

4.4.1 Edit and publish 'Web viewer' reports

4.4.1.1 Editing Reports in 'Web viewer'

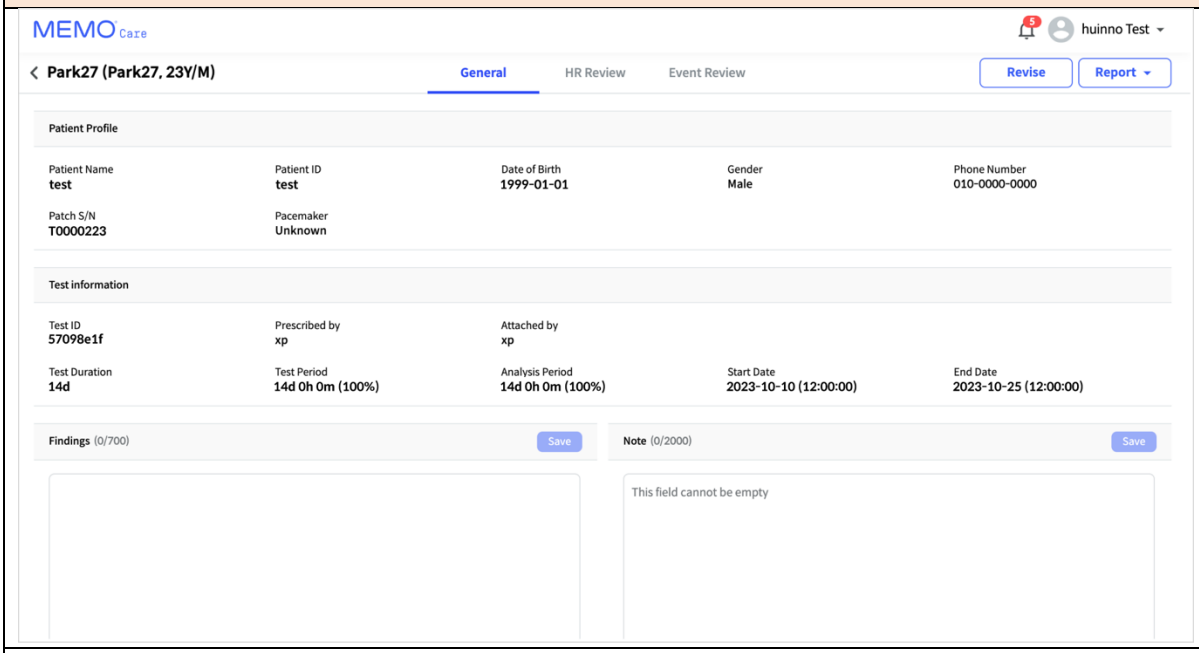
1 Filter the examination of the status under review, and click the View Patient Data button in the list.



2 Clicking on the patient's name will switch the screen to a page with tabs for 'General, HR Review, and Event Review.'

- **General tab:** It displays the patient's basic information, examination information, and summary of the analysis findings.
- **HR Review tab:** It shows the distribution of 10-second biased HR for the entire ECG data, and shows the distribution of the R-R interval.
- **Event Review tab:** It is possible to review and edit the entire ECG in the 'Event Review' tab.

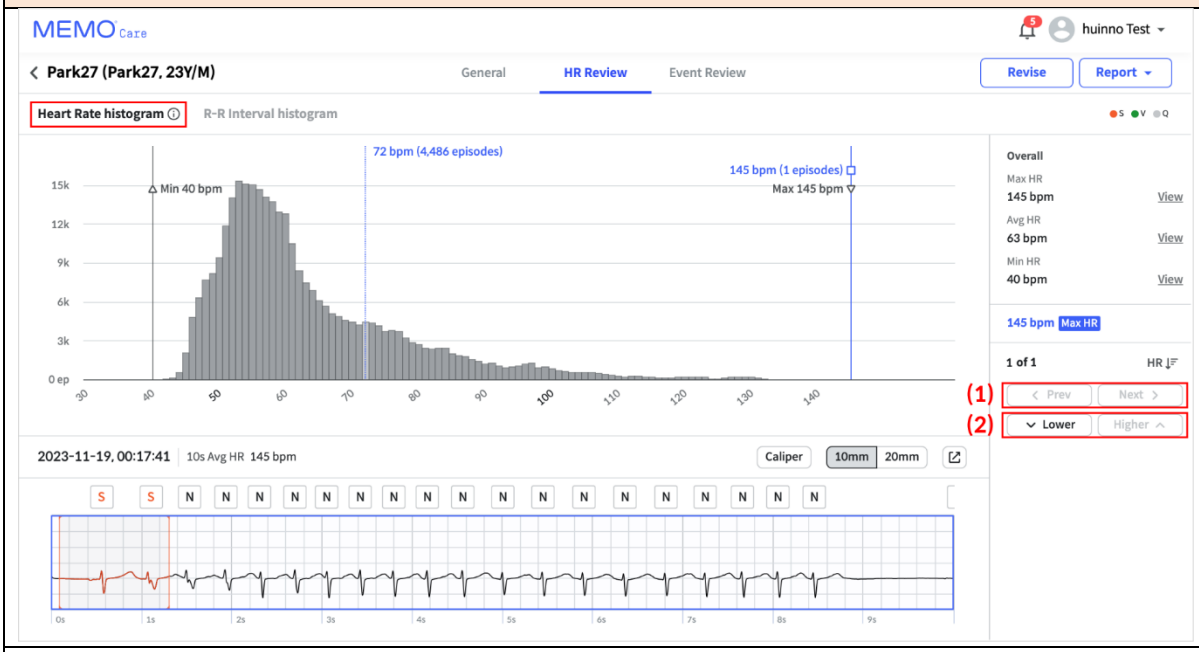
4.4.1.2 General' tab



1 In 'General' tab, there is a page that displays the patient's basic information, examination information, and summary of analysis findings. The components are described as follows:

- Prescribed Date: The period for which the patient was prescribed the examination.
- Examination Period: The duration from when the patient started wearing the 'MEMO Patch M' to just before removal.
- Analysis Period: The period during the examination period that was analyzed, excluding any noise or lead-off periods.
- Start Date, End Date: The dates when the 'MEMO Patch M' was attached and removed.
- Findings: The Physician's opinions on the patient's examination results, which are reflected in the report when written.

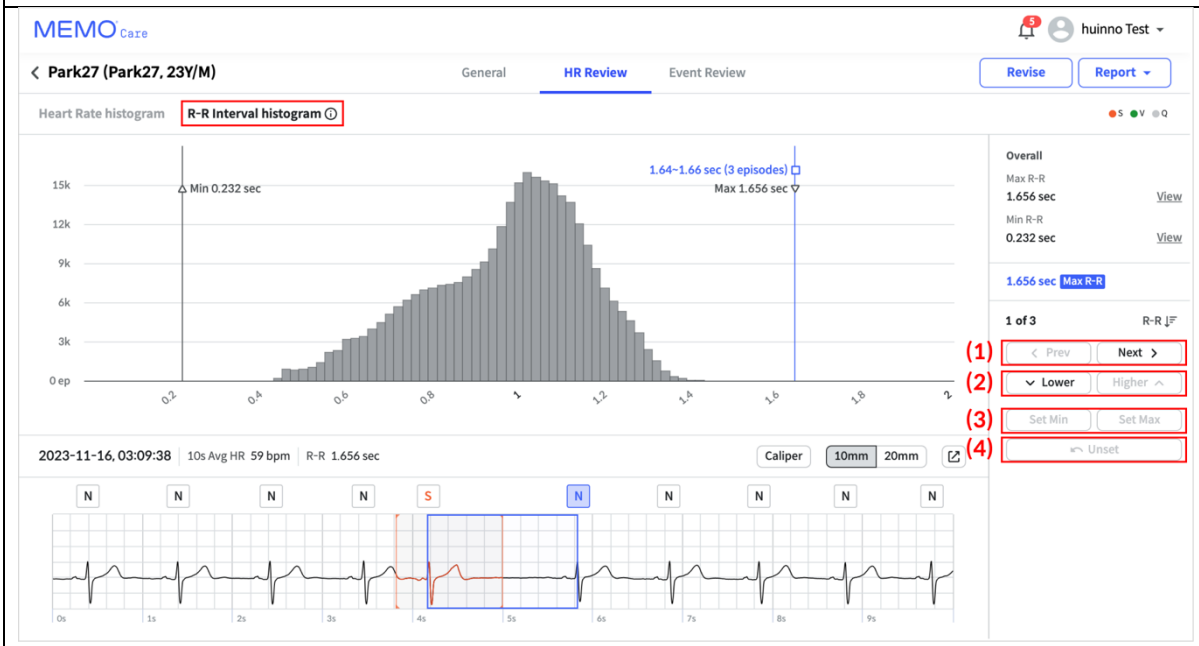
4.4.1.3 'HR Review' tab



1 The HR Histogram menu within the HR Review tab shows the 10-second average HR distribution of all ECG data. You can click on the HR section to see how many beats there are.

(1) Prev/Next Beat: Enables the review of beats within the selected HR ground in chronological order.

(2) Lower/Higher HR: Allows for reviewing HR in lower/higher increments.



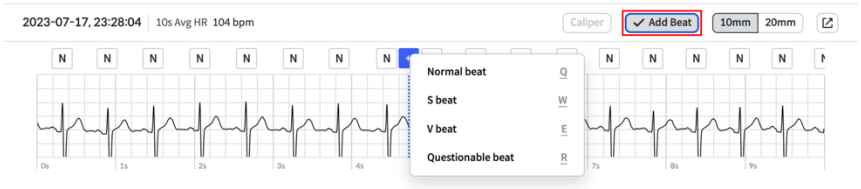
2 The R-R interval histogram menu within the HR Review tab shows the R-R interval distribution of all ECG data.

(1) Prev/Next Beat: Sequentially queries the previous or next episode of the selected R-R interval.

(2) Lower/Higher HR: Allows for reviewing HR in lower/higher increments.

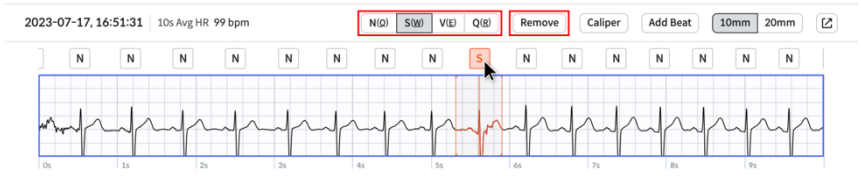
(3) Set Max/Set Min: Sets the maximum or minimum R-R value for the inspection.

(4) Unset: Set Max/Set Min: After functional operation, it can be restored to the Min or Max range before the cha nge.



Add Beat

1. Click Add Beat (Ctrl + A)
2. Click the point at which yo u want to add
3. Select from N/S/V/Q Beat



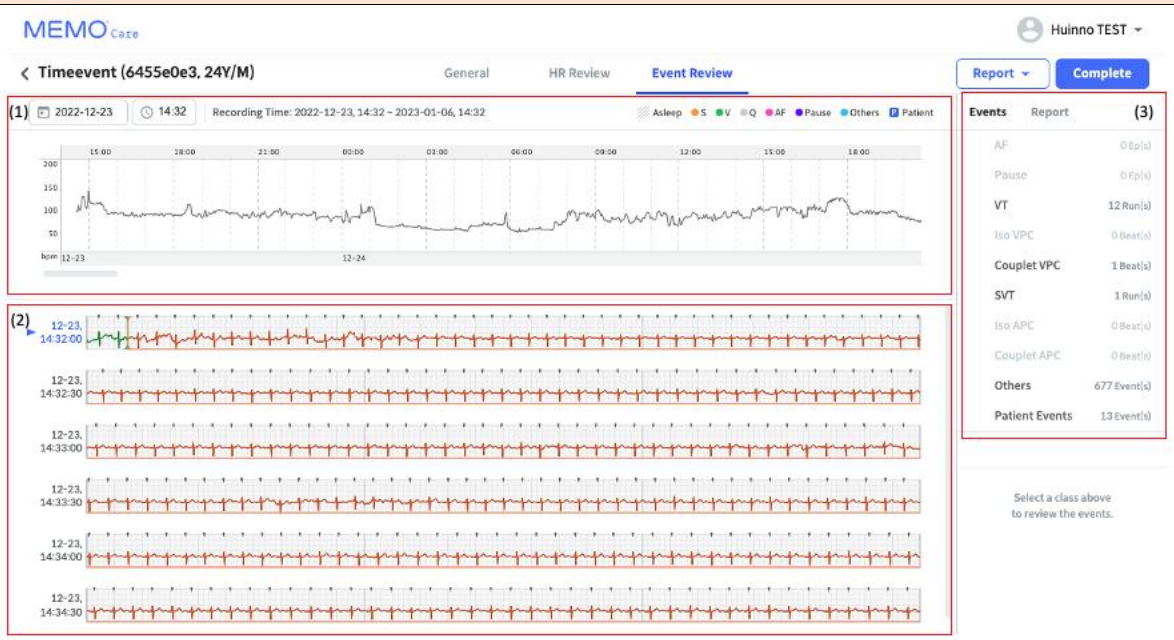
Edit Beat

1. Select Beat Label
2. Select from N/S/V/Q Beat

Delete Beat

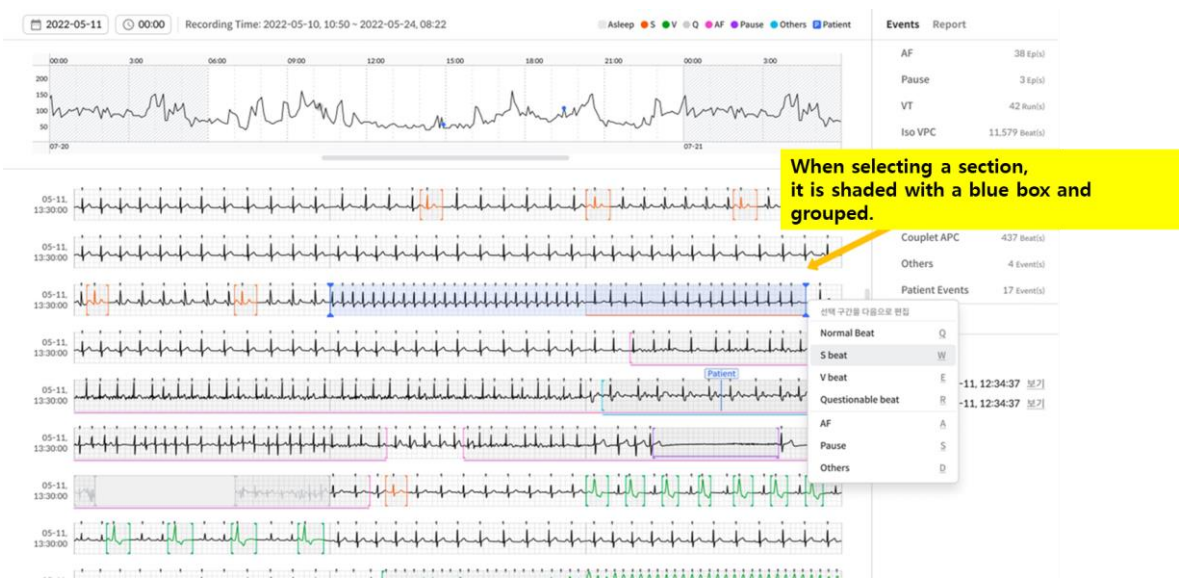
1. Select Beat Label
2. Select Remove Beat (Bac kspace)

4.4.1.4 'Event Review' tab

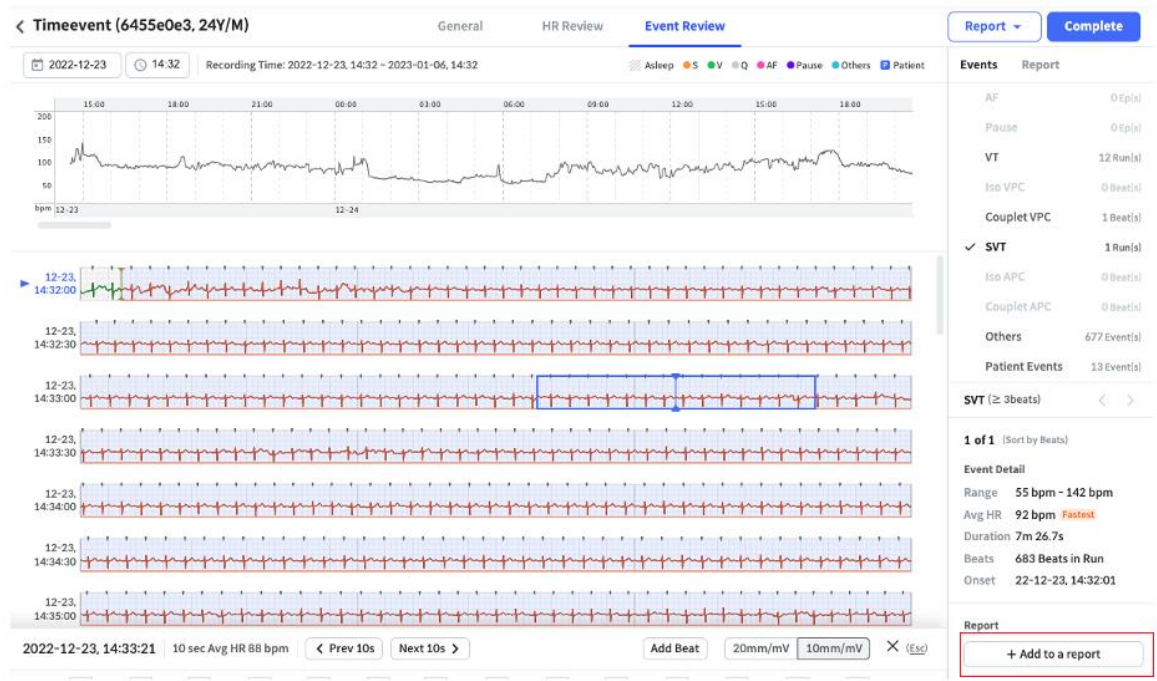


1 The Event Review tab allows you to view and edit the entire ECG.
(1) It shows the HRV graph, and the data point can be queried every 2 minutes. Click to jump to that point in time.
(2) It can be checked by date and time, and graph inquiry movement is done by mouse scroll.
(3) You can check the event occurrence summary. (In the case of episodes, the one with the longest duration comes first.)

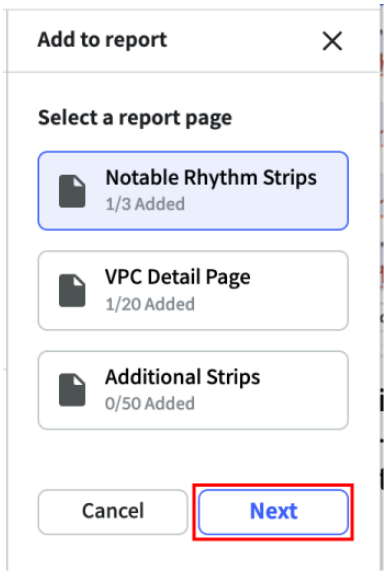
When selecting the section to edit the event, click the starting point, hold down the Shift button, and select the last point. In addition, you can select an event by selecting a beat or selecting an episode.



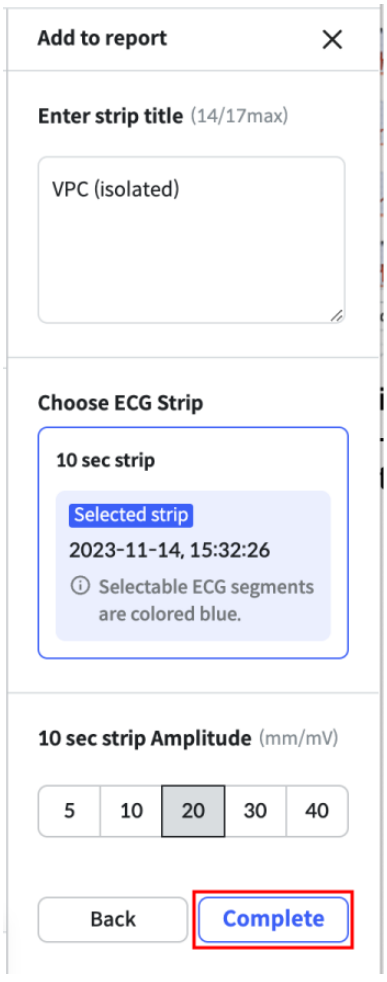
NOTE: To add the strip on the report, follow the process as below



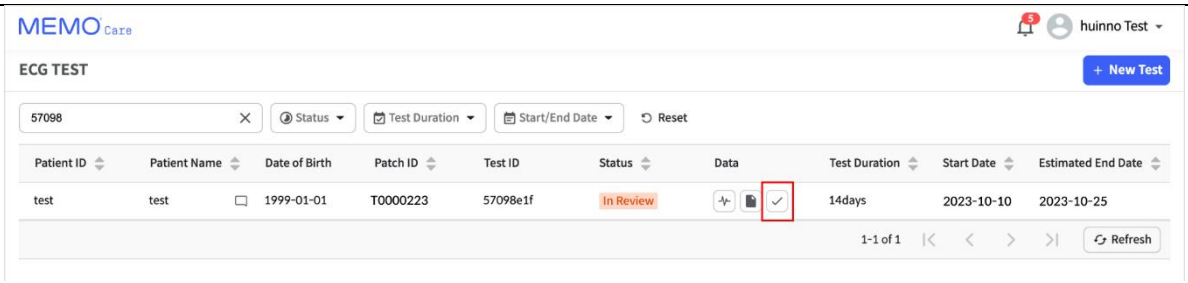
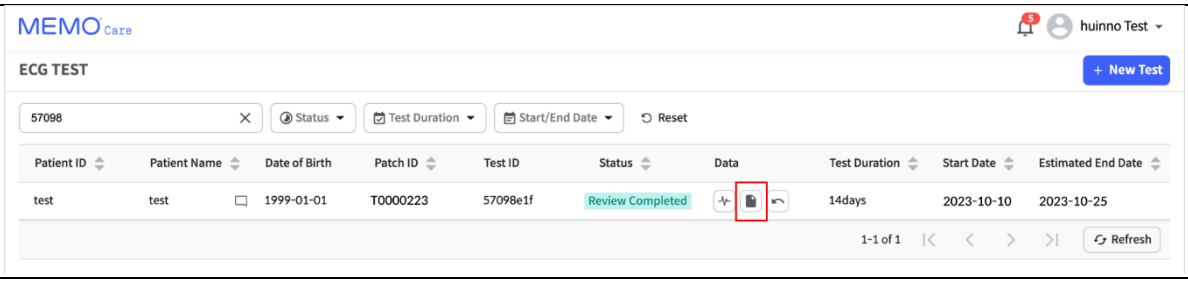
** After selecting the event to include in the report, click the strip and, click '+Add to a report'



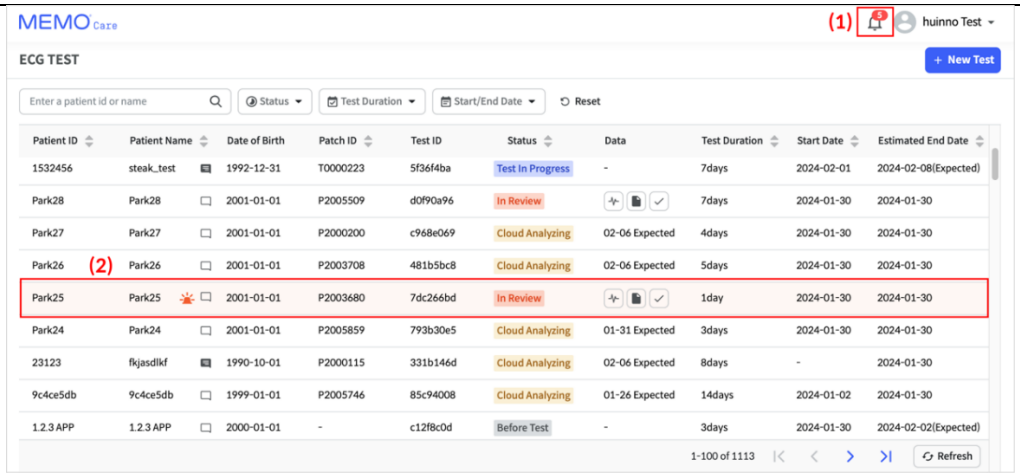
* Select the page to contain in the final report, and click ‘Next’

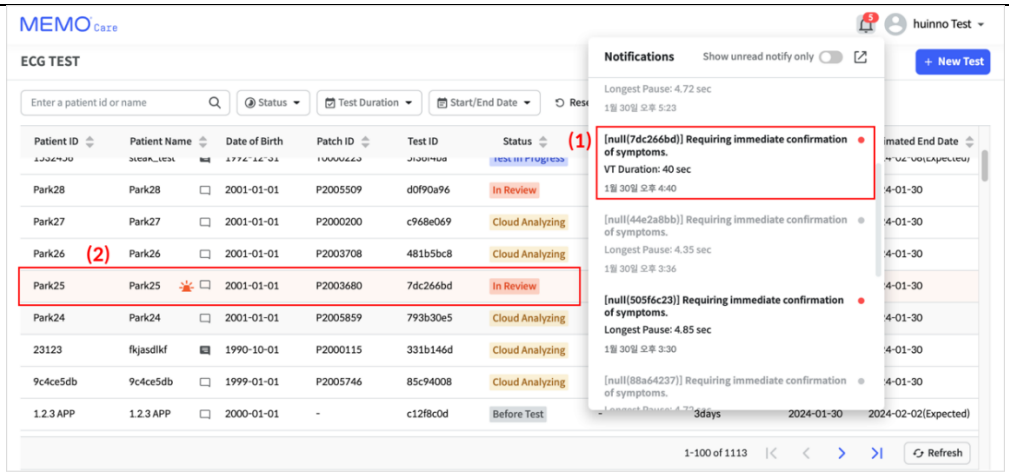


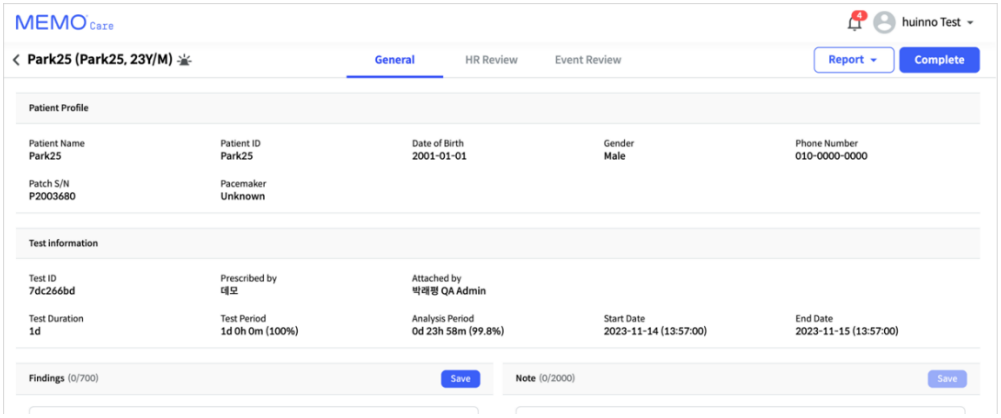
***** Enter the title of the strip, and choose a range of 10 seconds, and click ‘Complete’

4.4.1.5 Publish an ECG Analysis Report
1 The generated report can be found in the View Report button in the list under review. After checking the report, click the Finish Review button

2 A pop-up window to complete the review will appear, and after confirming the information, click 'Complete Revie w'.
3 After the status changes to Reviewed, click the View Report button to confirm.

4 Save the PDF file to the desired location on your computer.

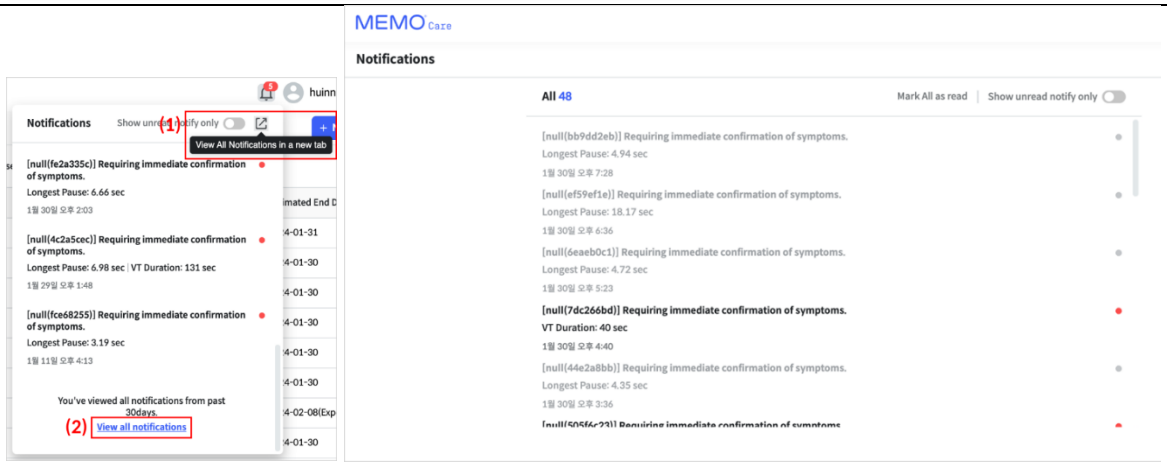
4.4.2 Check Test notification

Check Test notification
1 When the ECG report finds the following abnormalities, you receive a notification. - When the duration of the Longest Pause is more than 3 seconds - When the duration of the Longest VT is greater than 30 seconds

2 The number of notifications that have not been checked in the top notification center icon (1) is displayed. In the check list below, the check that receives notifications is marked with an orange highlight (2), along with the icon.





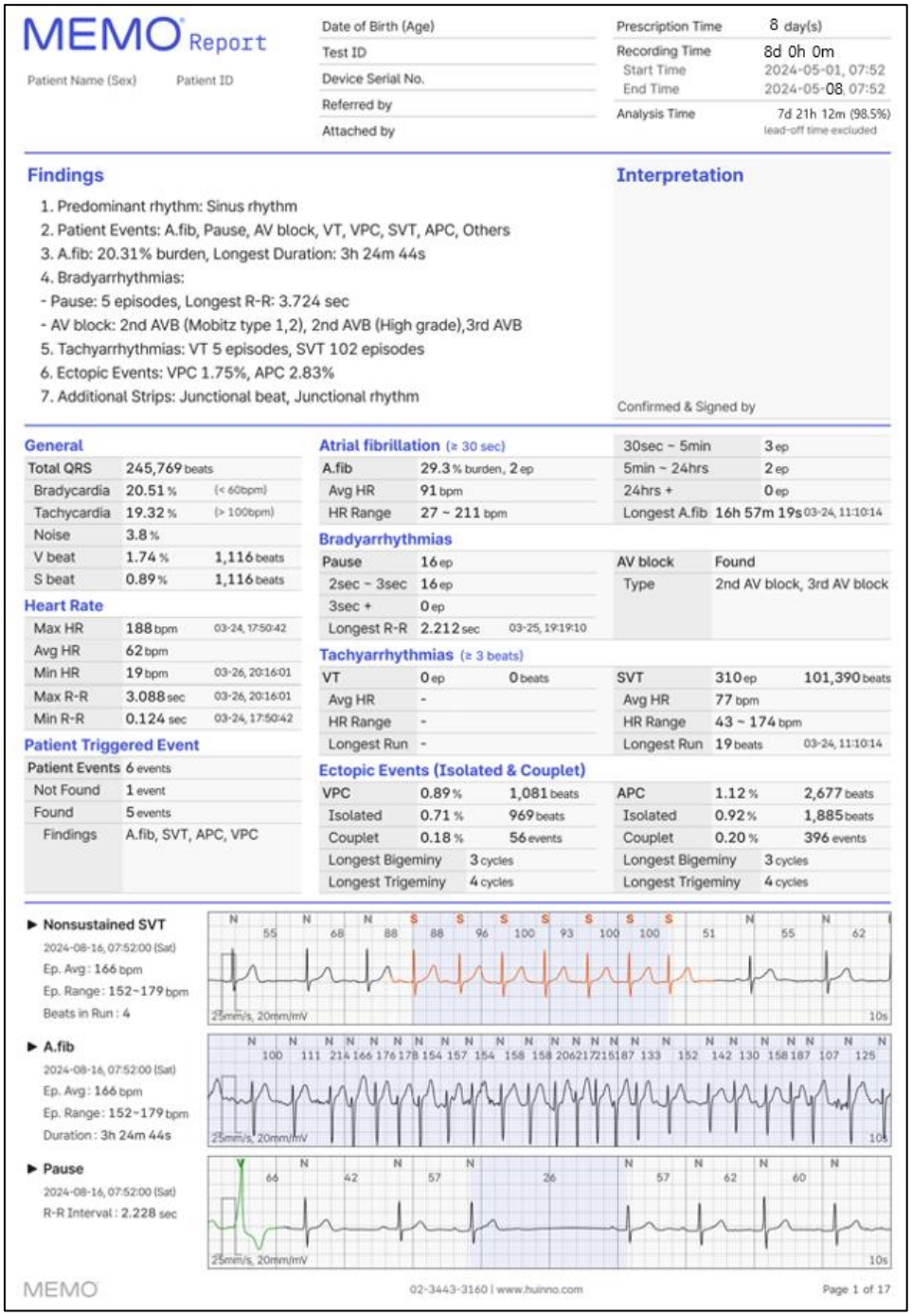
3 To enter the data of the notified inspection, you can enter the details page by (1) clicking the list of notification ce nters or (2) clicking the notified list in the list of notifications.
Go to the Event Review tab or HR Review tab on the detail page to view data for anomalies.



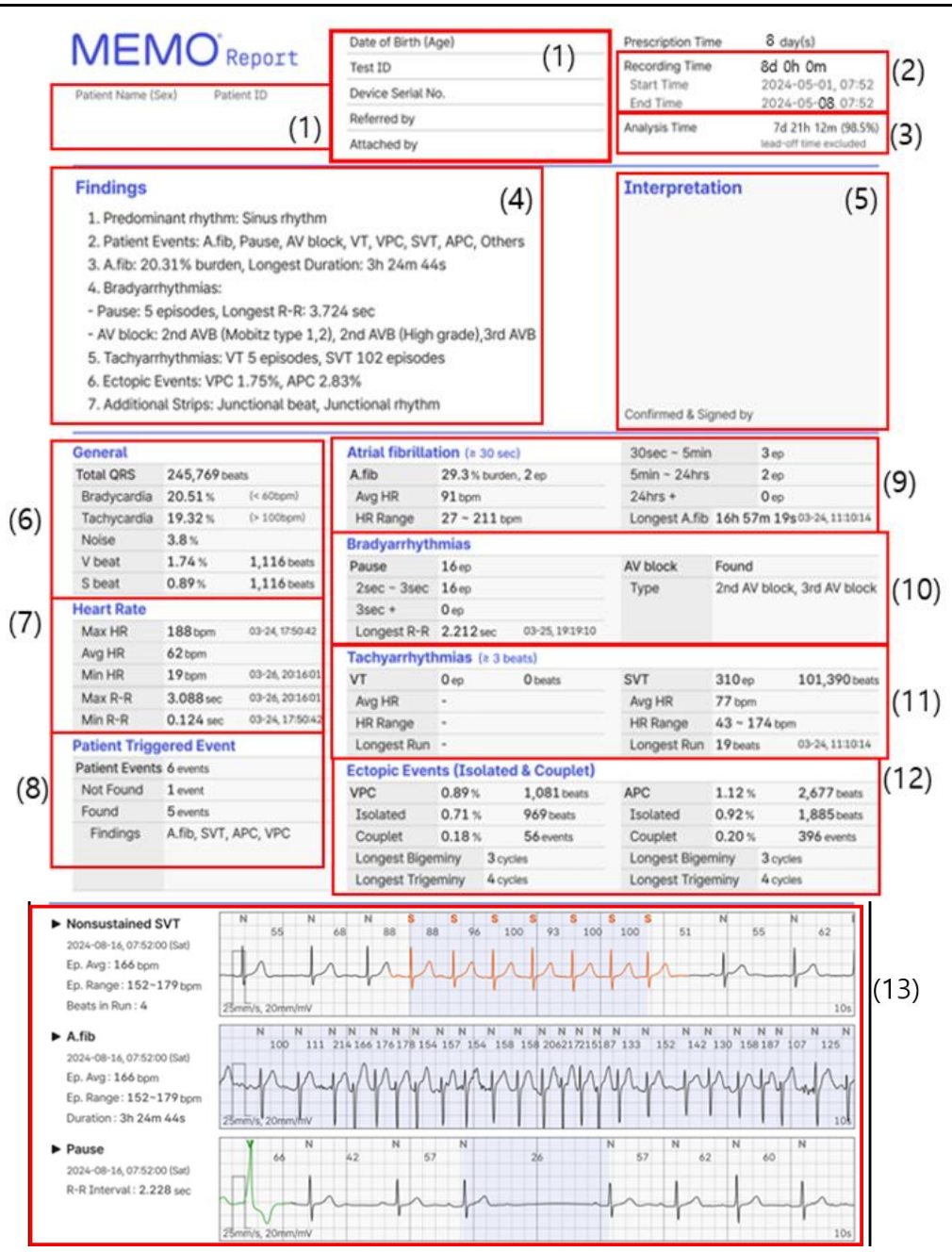
4 Enter the Notification Center and click the (1) View All Notifications button at the top or
(2) View All Notifications at the bottom of the list to go to the Details page where you can view all notifications.

4.4.3 Summary of the Report

The first page of the report is structured as follows and provides a summary of the ECG analysis results.
* NOTE: The data shown is from a sample report and does not represent real patient data



The detailed descriptions for each component are as follows.



No.	Name	Description
(1)	Patient Basic Information	Information of patient gender, ID, age, test ID, device serial no, prescriber, and patch applicator
(2)	Recording Time	from the start time to the end time of the examination
(3)	Analysis Time	Period excluding lead-off time (ratio of analysis time to recording time)
(4)	Findings	● Summary of key information about events found in the test ● Written after Medical Affair Team completes the analysis ● Plays the role of quickly conveying the most essential information during a short treatment time

(5)	Interpretation	● A space where the doctor writes diagnosis information during treatment ● Names of the hospital where the test was performed and of the doctor confirmed
(6)	General	
	Total QRS	Number of beats minus Q beats from total beats recorded during the test period
	Bradycardia	Among the number of beats excluding Q beats, the ratio of beats whose HR converted to R-R of the beat is less than 60bpm
	Tachycardia	Among the number of beats excluding Q beats, the ratio of beats whose heart rate converted to R-R exceeds 100bpm
	Noise	Ratio of the number of Q Beats among the total number of Beats
	V beat	◆ % : Ratio of the number of V Beats to the number of Beats excluding Q Beat ◆ Beat: Total number of V Beats (all V Beats including VT)
	S beat	◆ % : Ratio of the number of S Beats to the number of Beats excluding Q Beat ◆ Beat: Total number of S Beats (all S Beats including SVT)
(7)	Heart Rate	
	Max HR	Highest value among {Average HR of 10-second episodes, 5 seconds before and after Beat}
	Avg HR	Average value of {Average HR of 10-second episodes, 5 seconds before and after the Beat}
	Min HR	Lowest value among {Average HR of 10-second episodes, 5 seconds before and after Beat}
	Max R-R	Highest value in the R-R interval of all beats
	Min R-R	Lowest value in the R-R interval of all beats
(8)	Patient Triggered Event	
	Patient Events	Total number of Patient Triggered Events that occurred during the test
	Not Found	Number of events without findings (arrhythmia) within 90 seconds
	Found	Number of events with Findings (arrhythmia) within 90 seconds
	Findings	Types of Arrhythmias Found in All Patient Triggered Events
(9)	Atrial fibrillation (≥ 30 sec)	
	A.fib	◆ episodes: Number of episodes lasting more than 30 seconds among A.fib episodes ◆ % : Ratio of A.fib time lasting more than 30 seconds during the entire analysis period

	30sec - 5min	Number of A.fib episodes lasting more than 30 seconds but less than 5 minutes
	5min - 24hrs	Number of A.fib episodes lasting more than 5 minutes but less than 24 hours
	24hrs +	Number of A.fib episodes lasting more than 24 hours
	Avg HR	Average HR during the A.fib episode
	HR Range	Minimum HR to maximum HR during the A.fib episode
	Longest Duration	Duration of longest A.fib episode
(10)	Bradyarrhythimias	
	Pause	Total number of Pause episodes
	2sec ~ 3sec	Number of pause episodes with a duration of 2 seconds or more but less than 3 seconds
	3sec +	Number of Pause Episodes with Duration of 3 seconds or more
	Longest R-R	Duration of the episode with the longest Duration among Pause episodes
	AV block	If AV block is present: Found, if not: Not Found
	Type	List of discovered AV block types
(11)	Tachyarrhythmias (≥ 3 beats)	
	VT / SVT	◆ episode: Total number of VT/SVT episodes ◆ Beat: Total number of beats in all VT/SVT episodes
	Avg HR	Average HR of episode duration of VT/SVT
	HR Range	Maximum and minimum HR of episode duration of VT/SVT
	Longest Run	Beat number of the episode with the highest number of beats among VT/SVT episodes
(12)	Ectopic Events (Isolated & Couplet)	
	VPC/APC	• % : Ratio of the number of VPC/APC (Isolated+couplet) Beats to the total number of Beats excluding Q Beats • Beats: Number of VPC/APC (Isolated+couplet) Beats
	Isolated	• % : Ratio of the number of Isolated VPC/APC Beats to the total number of Beats excluding Q Beats

		• Beats: Number of Isolated VPC/APC Beats
	Couplet	• % : Ratio of the number of Couplet VPC/APC Beats to the total number of Beats excluding Q Beats. • Beats: number of Couplet VPC/APC Beat (does not mean number of Events)
	Longest Bigeminy	Cycle number of Bigeminy Cycle, which has the most cycles among VPC/APC Bigeminy
	Longest Trigeminy	Cycle number of Trigeminy Cycle, which has the most cycles among VPC/APC Trigeminy
(13)	Notable Rhythm Strips	• A strip of the most clinically significant arrhythmia event found in the test • Typically displays 3 strips and can display up to 10 strips • Different information is displayed depending on the type of each event.

5.0 STATEMENTS AND TABLES FOR EMC

Ambulatory ECG Monitor (MPT-E08R-UNC01) & ECG Data transferred cradle

 : Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

 : Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

 : Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the MPT-E08R-UNC01, including cables specified by the HUINNO.

5.1 Table1 – ELECTROMAGNETIC EMISSIONS for MEMO Patch M (MPT-E08R-UNC01)

Guidance and manufacturer's declaration – electromagnetic emissions		
Ambulatory ECG Monitor (MPT-E08R-UNC01) is intended for use in the electromagnetic environment specified below. The customer or the user of the MPT-E08R-UNC01 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11 IEC/EN 55011	Group 1, Class B	The MPT-E08R-UNC01 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Group 1, Class B	The MPT-E08R-UNC01 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. **WARNING:** MPT-E08R-UNC01 is intended for use by healthcare professionals only. MPT-E08R-UNC01 may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures,

		such as re-orienting or relocating the device or shielding the location

5.2 Table2 – Electromagnetic IMMUNITY for MEMO Patch M (MPT-E08R-UNC01)

Guidance and manufacturer's declaration – electromagnetic immunity			
The Ambulatory ECG Monitor (MPT-E08R-UNC01) is intended for use in the electromagnetic environment specified below. The customer or the user of the MPT-E08R-UNC01 should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) EN 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Radiated RF EN 61000-4-3	10 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	MPT-E08R-UNC01 is suitable for use in home healthcare environments. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the MPT-E08R-UNC01, including cables specified by the HUINNO.
Radiated, radio-frequency, electromagnetic field IEC 61000-4-3	Up to 28 V/m according to IEC 60601-1-2 Table 9, 385-5785 MH	Up to 28 V/m according to IEC 60601-1-2 Table 9, 385-5785 MH	
Electrical fast transient/burst EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to earth	±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Conducted RF IEC 61000-4-6	3V, 0.15MHz ~ 80MHz 6V, 1kHz, 80% AM in ISM and between 0.15MHz~80MHz	3V, 0.15MHz ~ 80MHz 6V, 1kHz, 80% AM in ISM and between 0.15MHz~80MHz	Over the frequency range 150kHz – 80MHz, field strengths should be less than 3V/m.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m 50 & 60 Hz	3 A/m 50 & 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	◆ 0% UT: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° ◆ 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° ◆ 0 % UT; 250/300 cycles	◆ 0% UT: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° ◆ 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° ◆ 0 % UT; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MPT-E08R-UNC01 requires continued operation during power mains interruptions, it is recommended that the MPT-E08R-UNC01 be powered from an uninterruptible power supply or a battery.
Proximity magnetic fields IEC 61000-4-39	Up to 65A/m 30 kHz - 13.56 MHz according to Table 11 of IEC 60601-1-2	Up to 65A/m 30 kHz - 13.56 MHz according to Table 11 of IEC 60601-1-2	MPT-E08R-UNC01 is suitable for use in home healthcare environments. Portable radio frequency (RF, RFID) communication devices can interfere with medical devices.
NOTE) UT is the a.c. mains voltage prior to application of the test level.			

Recommended separation distances between portable and mobile RF communications equipment and MPT-E08R-UNC01					
Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the MPT-E08R-UNC01, including cables specified by the HUINNO.					
Immunity test	Band a)	Service a)	Modulation	IEC 60601 test level	Compliance level

Proximity fields from RF wireless communications equipment	380-390 MHz	TETRA 400	Pulse modulation 18 Hz	27 V/m	27 V/m
	430–470 MHz	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28 V/m	28 V/m
	704-787 MHz	LTE Band 13, 17	Pulse modulation 217 Hz	9 V/m	9 V/m
	800-960 MHz	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28 V/m	28 V/m
	1700-1990 MHz	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28 V/m	28 V/m
	2400-2570 MHz	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28 V/m	28 V/m
	5100-5800 MHz	WLAN 802.11 a/n	Pulse modulation 217 Hz	9 V/m	9 V/m

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) For some services, only the uplink frequencies are included.

6.0 TROUBLE SHOOTING GUIDE

6.1 Trouble shooting

'MEMO Launcher' app	
Issue	Solution
The e-mail or password you entered does not match. Please check your account information and try again.	To retrieve your account, email sales@huinno.com and we will help you.
Your account is dormant. Your account has been inactive because you haven't used the service for over a year. You can use it again after applying for release from dormancy on your PC.	To continue the service, contact sales@huinno.com to terminate the dormant account.
New version available. Please, update your app to the latest version to continue.	Update to the latest version of the app.
You are automatically signed out. You were automatically signed out because there's no service use for 8hours.	The service will automatically log out when it is out for more than 8 hours. To continue service, log in.
Ambulatory ECG Monitor connection failed. Make sure the Ambulatory ECG Monitor is powered on and within the search range. If Ambulatory ECG Monitor connection continues to fail, please change Ambulatory ECG Monitor and proceed.	It notifies you if the connection fails because the test device is out of range or powered off.
Don't see the patch on the list? Make sure the Ambulatory ECG Monitor is powered on and within the search range. Press and hold the button for 3 seconds to blink the green LED and turn on the power.	Press the power button of Ambulatory ECG Monitor for 3sec.
Bluetooth is turned off. The connection failed because the Bluetooth function of the mobile device was turned off. Turn on Bluetooth and proceed again.	Turn on the Bluetooth and recheck the connection.

Failed to start examination. There was a problem initializing Ambulatory ECG Monitor. Please try to initialize Ambulatory ECG Monitor again or change to another Ambulatory ECG Monitor and proceed.		Replace the patch or restart the program.
There is no examination. Check if there is any patient who has started the examination.		Verify the patient and start the examination again.
There's no search result. Make sure you search it correctly.		Verify the patient's name or number.
You signed into another mobile device. You signed in on another mobile device with the same ID and were automatically signed out of this device.		To continue service, log in.
The network is not available. Please check the network connection status of the mobile device and try again.		Check the network connection and access to the app again.
Ambulatory ECG Monitor is disconnected. Please reconnect Ambulatory ECG Monitor to continue. If Ambulatory ECG Monitor connection continues to fail, please change to another Ambulatory ECG Monitor and proceed.		Turn on the Bluetooth and recheck the connection.
'MEMO Patch ECG Dataloader'		
Login	We couldn't log you in.	The email and password you entered did not match our records. Recheck the account.
	Couldn't connect	There was a problem communicating with the server. Please try again later.
	Import complete	The data is entirely imported.
	System Error	Restart the program to solve the unexpected error.

	Update required	The latest version is ready to install now.
	Couldn't update	There was a problem communicating with the server. Please try again later.
	Not connected Internet	Please check the Internet status.
Data download	An error has occurred on the device. please try again.	Check communication error of patch.
	The device information is incorrect. Please check your device again.	Check the saved information of the patch.
	Serial number is incorrect. Please check your device again.	Check the serial number of the patch.
	CRC Error	Check the CRC data of ECG Data.
	A system error has occurred on the device. please try again.	Undefined error. inquiry email sales@huinno.com
Upload	There was a problem communicating with the server. please try again later.	Undefined error. inquiry email sales@huinno.com
	Please check the Internet status.	Please check the Internet status.
	This device has not been returned.	Check the status of the returned device.
	Response time exceeded. Please check the Internet status.	Check the internet connection and re-log in.
	Unable to find file to upload.	Please check the upload file.
	Your login time has expired. Please log in again…	To continue service, log in.
Web viewer		

Feature	Problem	Options
4.1.1 Creating account and Accessing	Unable to Create Staff Account	1. Confirm admin privileges for account creation. 2. Verify proper navigation to "Manage Users." 3. Report technical issues to support.
4.1.2 Accessing and Configuring Web viewer	Unable to Set Initial Password	1. Request a new invitation email if the link is problematic. 2. Carefully follow steps to access the "Change password" menu. 3. Ensure the new password meets complexity requirements.
4.1.2 Accessing and Configuring Web viewer	Unable to Reset Password	1. Double-check the entered email for accuracy. 2. Check spam folders for the Password Reset Email. 3. Strictly follow the instructions in the Password Reset Email.
4.1.2 Accessing and Configuring Web viewer	Account Automatically Deactivated	1. Log in to reactivate the account. 2. For technical issues, contact support for assistance.
4.4.1 Edit and publish 'Web viewer' reports	Unable to Add a New Test	1. Ensure a stable internet connection and click the "New Test" button again. 2. Double-check and complete all required fields before adding the new test. 3. Refresh the page and attempt to add the new test once more.
4.4.1 Edit and publish 'Web viewer' reports	Unable to Edit Test Information	1. Ensure the correct test row is selected for editing. 2. Carefully follow the steps to access and use the Edit icon.

		3. Wait for a moment and attempt the edit process again.
4.4.1 Edit and publish 'Web viewer' reports	Unable to Delete a Test	1. Verify the correct test row is selected for deletion. 2. Follow the steps accurately to access and use the Delete icon. 3. Retry the deletion process after a brief pause.
4.4.1 Edit and publish 'Web viewer' reports	Test Information Not Visible in the Side Panel	1. Ensure the test row is correctly clicked to open the side panel. 2. Wait for the complete loading of patient and test details. 3. Verify technician permissions for accessing test prescription details.
4.4.1 Edit and publish 'Web viewer' reports	Sorting Test Data Not Functioning Correctly	1. Carefully follow instructions to use the Sort button for alphabetical and numeric ordering. 2. Understand the distinction between sorting options for different data categories. 3. Check for system updates or outages affecting sorting functionality.
4.4.1 Edit and publish 'Web viewer' reports	Unable to Enter Additional Patient Information	1. Ensure the correct test row is clicked to open the side panel. 2. Refresh the page and attempt to enter information in the [Note] section again.
4.4.1 Edit and publish 'Web viewer' reports	Navigation Buttons and Test Count Display Not Working	1. Use a different browser or clear cache to resolve button-related problems. 2. Review user guides to understand the purpose of navigation buttons. 3. Wait for a moment or refresh the page to update the test count.

4.4.1 Edit and publish 'Web viewer' reports	Test Search and Filter Options Ineffective	1. Follow correct search query formats (patient name, ID, Ambulatory ECG Monitor ID, or test ID). 2. Review and understand the meaning of different status filter options. 3. Check for system updates or glitches impacting date-based filters.
4.4.1 Edit and publish 'Web viewer' reports	Inaccurate Patient or Test Information Displayed	1. Review and correct any data entry errors during patient registration. 2. Refresh the page to check for system glitches and update patient or test details. 3. Ensure that modifications to test information trigger an automatic update.
4.4.1 Edit and publish 'Web viewer' reports	HR Review Features Not Functioning Properly	1. Review user guides to understand the correct use of HR Review features. 2. Try accessing HR Review from a different browser or clear browser cache. 3. Contact technical support to address system-related glitches affecting HR Review.
4.4.1 Edit and publish 'Web viewer' reports	Unable to Revert HR Values to Previous Settings	1. Follow instructions to locate and click the Revert button accurately. 2. Allow sufficient time for the system to process the revert action. 3. Ensure HR values are saved before attempting to revert.
4.4.1 Edit and publish 'Web viewer' reports	Difficulty in Navigating ECG Strips in HR Range	1. Review and practice using navigation buttons for ECG strip exploration. 2. Try accessing the feature from a different browser or device. 3. Refresh the page or wait for the system to load ECG strips.

4.4.1 Edit and publish 'Web viewer' reports	Inability to Add, Delete, or Change Beat Type	1. Review and follow the correct steps for adding, deleting, or changing beat types. 2. Refresh the page and attempt beat editing again. 3. Confirm user permissions for beat editing functionality.
4.4.1 Edit and publish 'Web viewer' reports	Unable to Set or Undo HR Range Values	1. Follow precise steps for selecting HR range and using Set Max/Set Min buttons. 2. Allow sufficient time for the system to process HR range actions. 3. Ensure changes are saved before attempting to undo HR range values.
4.4.1 Edit and publish 'Web viewer' reports	Unable to Locate Specific Events or Strips	1. Double-check the accuracy of date and time input during event lookup. 2. Allow sufficient time for the system to process and retrieve specific strips. 3. Refer to user guides for clear instructions on navigating and selecting events.
4.4.1 Edit and publish 'Web viewer' reports	Inaccurate Display of Event Markers	1. Review and correct any data entry errors in marking events. 2. Refresh the page to check for system glitches and update event markers. 3. Ensure modifications to events trigger an automatic update.
4.4.1 Edit and publish 'Web viewer' reports	Difficulty in Accessing Analyzed Test Results	1. Review instructions on HRV graph navigation for a better understanding. 2. Check internet connectivity and reload the page if HRV data does not load completely. 3. Understand the significance of blue dots as indicators of patient-triggered events.

4.4.1 Edit and publish 'Web viewer' reports	Sorting Options Not Functioning as Expected	1. Carefully follow the steps to select and apply the desired sorting option. 2. Allow sufficient time for the system to process the sorting action. 3. Ensure sorting preferences are saved for future reference.
4.4.1 Edit and publish 'Web viewer' reports	Caliper Functionality Not Working	1. Follow the correct steps for using the caliper tool. 2. Try accessing the feature from a different browser or clear browser cache. 3. Contact technical support to address system-related glitches affecting the caliper.
4.4.1 Edit and publish 'Web viewer' reports	Inability to Mark, Change, or Revoke Events	1. Review and follow the correct steps for marking, changing, or revoking events. 2. Refresh the page and attempt event editing again. 3. Confirm user permissions for event editing functionality.
4.4.1 Edit and publish 'Web viewer' reports	Inability to Add, Delete, or Change Beat Type	1. Review and follow the correct steps for adding, deleting, or changing beat types. 2. Refresh the page and attempt beat editing again. 3. Confirm user permissions for beat editing functionality.
4.4.1 Edit and publish 'Web viewer' reports	Unable to View or Download Report	1. Check system and browser compatibility for viewing the report. 2. Ensure a stable internet connection for seamless report download. 3. Verify user permissions to access and download reports.

4.4.1 Edit and publish 'Web viewer' reports	Difficulty Navigating Through Report Pages	1. Review user guides for a better understanding of navigation features. 2. Allow sufficient time for the system to process and load event strips. 3. Refresh the page if event strips do not load completely.
4.4.1 Edit and publish 'Web viewer' reports & 4.4.2 Check Test notification	Errors in Adding or Editing Strips	1. Carefully follow the steps for adding strips, ensuring all required information is accurate. 2. Review entered information for accuracy before completing the strip addition. 3. Refresh the page and attempt the addition or editing process again.
	Inability to Edit Findings	1. Follow the correct steps to navigate to the "General" tab for editing findings. 2. Refresh the page and attempt finding editing again. 3. Confirm user permissions for findings editing functionality.
	Regeneration of Report Fails	1. Allow sufficient time for the system to process and regenerate the report. 2. Ensure a stable internet connection for successful report regeneration. 3. Double-check the selected options and parameters for report regeneration.
	Inability to Finalize Test Review	1. Ensure the "Complete" button is clicked after the review. 2. Refresh the page and attempt the completion process again. 3. Follow the correct sequence of steps for completing the test review.

	Regeneration of Report Fails	1. Allow sufficient time for the system to process and regenerate the report. 2. Ensure a stable internet connection for successful report regeneration. 3. Double-check the selected options and parameters for report regeneration.
	Inability to Finalize Test Review	1. Ensure the "Complete" button is clicked after the review. 2. Refresh the page and attempt the completion process again. 3. Follow the correct sequence of steps for completing the test review.
	Unable to Revert Test Status	1. Confirm the location and click the "Revise" button for activating editing mode. 2. Refresh the page and attempt reverting test status again. 3. Verify user permissions for reverting test status functionality.

6.2 FAQs

Ambulatory ECG Monitor	1. How do I turn off the power? This product cannot be powered off. If an emergency power off is required, use the included battery opener to open the battery cover and remove the built-in battery. When reusing the product, please insert the battery in the correct direction and turn on the product. 2. How can you verify if the device is operating correctly? When you press and release the button for 1 second, the Green LED will flash once. 3. How can you confirm if the connections are secure? If the connections are unstable, the orange LED will blink once every 3 seconds.

MEMO Launcher App	1. I cannot log in to the app, although I had no problem logging in before. What should I do? If you encounter a login error, try logging out and logging back in first. If it still doesn't work, check for an updated version on Google Play Store or Apple App Store and update it. (Android) If you still encounter a login error after the update, try clearing the data by going to Phone Settings > Applications > MEMO Launcher > Storage > Clear data.
Data Upload	1. Can I use a cable other than the provided cradle cable during data upload? You must use the provided cradle cable when performing the data upload process. Uploading may not be completed properly if a cable other than the provided one is used. 2. I connected the memo patch to the cradle and then to the PC, but the patch is not showing a green light. What should I do? The cradle cable must be the provided cable in order to function properly.
Product Storage	1. How should Ambulatory ECG Monitor be stored? Once the patient returns the device and the data upload is complete, it should be wiped down and stored according to the environmental conditions specified by the manufacturer.
Patient Questions	1. As a patient wearing an Ambulatory ECG Monitor, how can I check if the device is functioning properly during use? The Patch has a symptom record button located on the power unit. Pressing the symptom record button for about 0.5 seconds and then releasing it will cause the green LED to flash. If the green LED flashes, it means that the device is functioning properly. If the green LED does not flash, please contact the HUINNO customer service at 02-3443-3160. If the device is not activated, the green LED will flash every 5 seconds, and the power will turn off after 5 minutes. 2. What should I do if I experience symptoms while wearing the Ambulatory ECG Monitor?

If you experience symptoms, you should press the symptom record button on the Ambulatory ECG Monitor. The symptom record button is located on the power unit of the Ambulatory ECG Monitor. Press the button for more about 1 second (Short Press button) and when the green LED flashes, it indicates that the symptom has been recorded. (The symptom record button and the power button are the same button.)

3. What should I do if I forget to record my symptoms?
   If you forget to record your symptoms, write down the approximate time when the symptoms occurred and the symptoms themselves in the patient note.

4. What should I do if I accidentally press the symptom record button multiple times or press it by mistake when no symptoms are present?
   The symptom record button is used to compare whether the palpitation symptoms felt by the patient occurred simultaneously in the heart. Therefore, pressing the button several times or pressing it by mistake will not affect the test results.

5. What should I do if the Ambulatory ECG Monitor falls off my body?
   Check the adhesive on the electrode before reattaching it to the same location as before. If the adhesive is sufficient, reattach the device to the same location. If the adhesive is insufficient, replace both electrodes and then reattach the device. If the skin is moist or sweaty, wipe it dry before reattaching the Ambulatory ECG Monitor. If the Ambulatory ECG Monitor falls off due to hair, shave the area before reattaching.

6. Is it okay to use an electric blanket or electric corded bed while wearing the Ambulatory ECG Monitor?
   Do not use an electric blanket or electric bed with a power cord plugged in. Electrical devices can interfere with the signal and affect the accuracy of the test results.
   *However, it is okay to use the devices after unplugging the power cord.
   **Use of electric cars, microwave ovens, and induction cooktops do not affect the Ambulatory ECG Monitor and are okay to use.

7. Can I exercise while wearing the Ambulatory ECG Monitor?
   Strenuous exercise can affect the electrocardiogram signal measurement, so it is recommended to avoid it. If sweating, the device can fall off, so be careful.

8. Can I take a shower, bath, or swim while wearing the Ambulatory ECG Monitor?
   The Ambulatory ECG Monitor is waterproof, but it is recommended to remove the device before bathing, or swimming.

9. Can I reattach the Ambulatory ECG Monitor to a slightly different location from the original attachment site?
   Yes, you can reattach the Ambulatory ECG Monitor to a slightly different location.

10. What should I do if I experience skin irritation or itching?
    Some patients may experience mild skin irritation or itching. If you experience irritation or itching, or if it becomes severe, please contact the hospital where you received the prescription.

11. What activities should be avoided during the test?
    Please avoid vigorous exercise that can cause excessive sweating during the test. When sweating, the electrodes attached to the body may come off.

12. Is it okay to travel while wearing the patch?
    It is generally okay to travel while undergoing the test, but it is recommended to avoid excessive physical activity that could potentially dislodge the patch.

13. Is it okay to board a plane while wearing the patch? Are there any issues going through airport security?
    No, there is no issue. There might be some additional noise in the signal or alterations in the ECG waveform, which do not impact the analysis

	results. However, you might hear a warning sound while going through security. 14. How do I return the patch after the test is finished? You can either send the patch by mail in a storage bag to the hospital where you received the prescription or visit the hospital in person to return it. 15. If I have any questions during the test, where can I call? Call HUINNO customer service. Depend on the question, you may also need to contact the hospital directly.
Web viewer	**1. What is Web viewer?** • Web viewer is a comprehensive remote patient monitoring solution designed to track and analyze ECG data using wearable Ambulatory ECG Monitor. It helps healthcare providers monitor patients' heart health over an extended period. **2. How does Web viewer work?** • Web viewer utilizes wearable Ambulatory ECG Monitor equipped with ECG sensors to continuously monitor the patient's heart activity. The collected data is then analyzed to provide valuable insights into the patient's cardiac health. **3. What information does Web viewer provide?** • Web viewer offers detailed information on heart rate variability (HRV), ECG data, event markers, and more. It enables healthcare professionals to review and analyze the patient's cardiac performance comprehensively. **4. How can I set up Web viewer for a patient?** • To set up Web viewer for a patient, follow these steps: 1. Attach the Ambulatory ECG Monitor to the patient as instructed. 2. Ensure the Ambulatory ECG Monitor is properly secured. 3. Initiate the monitoring through the Web viewer.

5. Can patients wear Ambulatory ECG Monitor during daily activities?

- Yes, Ambulatory ECG Monitor is designed to be worn during daily activities. It is water-resistant and comfortable for extended use, allowing patients to maintain their regular routines.

6. How long can a patient wear Ambulatory ECG Monitor?

- Ambulatory ECG Monitor is designed for extended wear, typically ranging from several days to weeks, depending on the monitoring requirements. The specific wear duration is determined by the healthcare provider.

7. What do different event marker colors signify?

- Web viewer uses different colors for event markers:
  - Orange: Supraventricular (S) events
  - Green: Ventricular (V) events
  - Gray: Questionable (Q) noise
  - Pink: Atrial fibrillation (AF) events
  - Purple: Pause events
  - Sky Blue: Other abnormalities and events

8. How can I access and interpret HRV graphs?

- HRV graphs in Web viewer illustrate variations in average heart rate over 2-minute intervals. To interpret:
  1. Scroll left and right on the HR Trend graph.
  2. Click on the HRV peaks to explore corresponding ECG data.

9. Can I edit and mark events on the ECG strips?

- Yes, Web viewer allows users to edit and mark events on ECG strips. Users can mark, change, revoke, and modify specific beats and events through the Event Review feature.

10. How do I generate and view reports in Web viewer?

- To view and download reports:

1. Click the "View Report" button.
2. Click the "Download Report" button.

	3. Navigate through the report pages using the left and right arrows. **11. What should I do if there are issues with the Web viewer?** • If you encounter issues: 1. Check your internet connection. 2. Ensure system and browser compatibility. 3. Contact Web viewer support for assistance. **12. How do I revert the test status after completion?** • To revert the test status: 1. Click the "Revise" button to activate Editing mode. 2. Follow the necessary steps to make adjustments.

To receive support for installation, use, or maintenance of the device, or to report unexpected behavior or events, please contact HUINNO's customer service.

Customer service operate from 09:00 to 18:00 on weekdays, with a one-hour lunch break from 12:00 to 13:00, closed on holidays and weekends (KST).

7.0 DEVICE SPECIFICATION

7.1 Performance Characteristics

ECG Channels	1 channel
Memory capacity	8 days
Recording Format	Continuous
Service Life	Up to 8 days
Shelf Life	2 years

7.2 Electrical Characteristics

Protection Against Electrical Shock	Defibrillation proof type CF Applied Part
	Internally powered ME equipment

ECG Frequency Response	0.5Hz to 50Hz
ECG Input Impedance	≥10 MΩ
ECG A/D Sampling Rate	250 Hz
ECG Resolution	12bit
Gain accuracy	Within ±10%
Gain settings	Gain settings of 5mm/mV and 10 mm/mV available
Linearity and operating range	Amplitude change within ±10% or 50 *μV*, whichever is greater, at 10mVp-v, ±300mV DC offset
Measuring range	30 ~ 250 BPM
Accuracy	Within ± 3 bpm or ±5%, whichever is greater
CMRR	Greater than 100 dB

7.3 Power Characteristics

Patch Battery Type	CR2032, 225mAh, 3V, lithium coin battery
Battery Life	8 days

7.4 Physical Characteristics

Patch Dimensions	29.5mm(W) X 48.6mm(D) X 9.85mm(H)
Patch Weight	12g (9g without battery)
Data transferred cradle (1port) Dimensions	41.5mm(W) x 44.8mm(D) x 13.9mm(H), 30g

7.5 Wireless communication characteristics

Frequency, number of channels and the band	- 2.4 GHz radio transceiver - Number of Channels: 40 (2402-2480MHz)
Bandwidth of the receiving section	1M

Antenna and BLE chipset	SDBTPTR3015, NRF52840
Modulation Type and Frequency Characteristics	GFSK(Gaussian Frequency Shift Keying) modulation
Effective Radiated Power (ERP)	2.5mW (4dB) or less.
Wireless communication method	BLE 5.1 between ambulatory ECG Monitor and mobile phone

7.6 Compatible devices

Electrode (applied part)	• ECG Monitoring Electrodes, Model name: ACC-E10D-01 from HUINNO • When using a bracket: disposable ECG electrode (ex: 3M red dot, model name: 2560, K970796)	
ECG data transferred cradle (1port)	• Model name: ACC-C01P-03 • Rating: 5V, 0.5A	
Electrode bracket	• 60mm type • Model name: ACC-B06P-01	• 100mm type • Model name: ACC-B10P-01

7.7 Environmental Characteristics

Operational temperature	10℃ - 45℃
Operational altitude	0 to 3,000 m
Operation, transport and storage Humidity	10% to 95% (non-condensing)
Operation, transport and storage Pressure	700hPa – 1060hPa
Shipping and transporting Temperature	-20℃ - 60℃
IP classification	IP27
*Note: avoid exposure to violent vibration, rain, sunlight and high humidity during transportation.	

7.8 Minimum specification for software

Item	Dataloader	Web viewer	MEMO Launcher
CPU	-	Intel core i7 3.1 GHz	-
OS	Window 10	MS Window 10, Sierra, Apple Mac OS X	◆ Android OS 9(Pie) ◆ iOS 13
Memory	8GB	16GB	4GB
HDD	128GB	256GB	64GB
Screen resolution	1024 x 768	-	-
External port	USB 2.0, 1 port	-	-
Network	Wi-Fi or Ethernet	Wi-Fi or Ethernet	Bluetooth 5.0

7.9 Device LED Scenario

Power ON	• Green LED, flashing Once
Discover mode after Power ON	• Before Operation: Green LED flashing continuously (Every 5 seconds for 5 minutes) • After Operation: N/A
Button before examination,	• Orange LED, flashing Once
Start examination	• Green LED, Fast flashing Four times
Connection of BLE	• Blue LED, Fast flashing Three times
Disconnection of BLE	• Blue LED, Fast flashing Twice
Event Marking (After Examination)	• Green LED, flashing Once
Lead Off Button when Lead Off	• Orange LED, Fast flashing Once every 3 seconds • Orange LED, Fast flashing Once
Low Battery	• Orange LED, flashing Twice every 6 seconds
When Device reset	• Reset due to malfunctioning • White LED On -> Reset-> Power on and Green LED flashing Once

Power OFF	• Orange LED fast flashing Three times
Connecting on cradle	• Green LED On
Execution of Dataloader program	• Green LED On
Download	• Green LED flashing
Download Completed	• LED off

7.10 Heart Rate Calculation

Episode Heart Rates	Max	The maximum episode heart rate (ex. Maximum of all instantaneous heart rates within the episode)
	Min	The minimum episode heart rate (ex. Minimum of all instantaneous heart rates within the episode)
	Ave	The average episode heart rate (ex. Average of all instantaneous heart rates within the episode)
Overall, Rhythm Heart Rates	Max	The maximum overall heart rate (ex. Maximum of all rhythm episode maximum heart rates within the record)
	Min	The minimum overall heart rate (ex. Minimum of all rhythm episode minimum hear rates exclusive of Pause heart rates within the record)
	Ave	The average overall heart rate (ex. Duration-weighted average of all rhythm episode heart rates within the record)

7.11 Pause Determination

Pause is defined as an RR interval greater than 3 seconds.

8.0 PRODUCT WARRENTY

8.1 Warranty Claim

Contact the HUINNO customer service if you are unable to resolve the issue after reviewing the user manual.

8.2 Warranty Coverage

- The warranty provides at no extra cost to the user.
- The device is warranted for a period of 1 year
- The device is warranted for the functional or performance defects arising when used for normal purposes in accordance with the user manual.

8.3 Warranty Exclusion

The warranty is not applicable in any of the following cases:

- Expiry of warranty period and/or inability to check warranty period.
- Failure or damage caused by user's negligent use, neglect, or careless operation of device.
- Failure caused by use of device not in accordance with the user manual.
- Failure or damage caused by using electricity of unauthorized voltage.
- Failure caused by using parts, accessories or consumables that are not approved by the manufacturer.
- Product or its parts arbitrarily removed, altered, modified or damaged.
- Product serviced and/or decomposed by unauthorized personnel that are not designated by the manufacturer.
- Service fee may apply for services irrelevant to product defects (e.g., product training, irregular inspection, Bluetooth connection problem due to external environment, defect due to using third-party products and/or software) regardless of the warranty period.

8.4 Warranty Period

- Warranty period refers to the period in which the manufacturer or authorized seller is obliged to replace the quality, performance, functional defects from normal use for free.
- The warranty becomes effective at the date of purchase. Please retain the product warranty card or the proof of purchase. If you do not have your warranty card or proof of purchase, your warranty will start 90 days after the date of manufacture, according to the manufacturer's records.
- The warranty is confined to the first purchaser of the product at an authorized dealer.
- The warranty is not applicable to second-hand products or products purchased from an unauthorized dealer. The manufacturer will not be responsible for the compensation of damage for the replacement and service of those products.

- The warranty for products delivered under a separate contract with the manufacturer follows the contents of the contract.

8.5 Warranty Card

<Warranty Card>

Product Name:

Model Number:

Serial Number:

Date of Purchase:

Place of Purchase:

Warranty Period: 1 year from date of purchase for device

Client Name:

Organization:

Phone Number:

This is to certify that this device has passed the strict quality control and comprehensive inspection. Replacement and service may be denied in any of the following cases.

1. Unable to perform replace or provide service due to the user's intention and negligence
2. Unable to replace due to discontinuation of parts after the warranty period
3. Damage resulting from a force majeure event such as fire, explosion, storm, flood, earthquake, or other natural disasters
4. Removal, obliteration, or alteration of identification labels (Model Number, Serial Number etc.) of the product

9.0 REVISION HISTORY

Rev.	Rev. Date	Page(s) Affected	Revision Description
0	June 15, 2024	All	Newly Established