User Manual

Ambulatory ECG Monitor

Brand Name: MEMO Patch-One

Model Number: MPT-E14D-UNA02

Document Number: UM-B-999

Revision Number: 0

Revision Date: January 26, 2023

1.0 PRODUCT WARRENTY

1.1 Warranty Claim

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

1.2 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.

1.3 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.

1.4 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.

1.5 Warranty Card

<Warranty Card>

Product Name:

Model Number:

Serial Number:

Date of Purchase:

Place of Purchase:

Warranty Period: 1 year from date of purchase

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

Content of Tables

2.0 INSTRUCTION

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

3.0 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

4.0 DEVICE OVERVIEW

4.1 Product Description

The Ambulatory ECG Monitor is a single patient use ECG monitor that provides a continuous, single channel recording for up to 14 days. The Ambulatory ECG Monitor records ECG without patient interaction, with the goal of improving patient compliance via simplicity of operation. Patients have the option of pressing a convenient event marking button which marks the time of symptom. The patient is encouraged to fill out a log to document symptomatic events, which will support symptom rhythm correlation in the Final Report.

At the conclusion of the wear period (up to 14 days), the patient removes the Ambulatory ECG Monitor and returns it by mail or directly to the doctor.

4.2 Intended Use

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

It is indicated for use on patients 18 years or older who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety and patients who are asymptomatic. Indication for Use

Arrhythmia

4.3 Intended Environment of Use

Ambulatory ECG Monitor is intended for use in a clinical environment. The product cannot be used in hospital emergency rooms or ambulances, but it is possible for patients to use the product at home during the monitoring period. In addition, the product can be used in places other than the patient's home.

NOTE: Ambulatory ECG Monitor ECG Data Cradle can be only used in hospitals.

4.4 Intended Patient Population

Age: More than 18 years old

Weight: Irrelevant

Health: The person who can recognize and record the symptoms that occur while using the product.

Nationality: Irrelevant

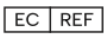
Intended Operator: Patient & Physician

4.5 Patient Contacting Components

ECG electrodes

5 MARKS AND SYMBOLS

Symbol	Definition	Applicable products	Label Placement
	Serial Number	Ambulatory ECG Monitor	Gift Box
	Date of Manufacture	Ambulatory ECG Monitor	Device, Gift Box
	Manufacturer	Ambulatory ECG Monitor, ECG Data transferred cradle	Device, Gift Box
	BF Type	Ambulatory ECG Monitor	Device, Gift Box
IP24	IP Classification	Ambulatory ECG Monitor	Device, Gift Box
	Refer to User Manual	Commonly applicable products	Device, Gift Box
	Caution	Commonly applicable products	User Manual
	Prohibitions	Commonly applicable products	User Manual

	Handle with care	Commonly applicable products	Carton Box
	This way up	Commonly applicable products	Carton Box
	Fragile	Commonly applicable products	Carton Box
	Keep dry	Commonly applicable products	Carton Box
	Temperature Limit	Ambulatory ECG Monitor	Gift Box
	Humidity Limit	Ambulatory ECG Monitor	Gift Box
	Atmospheric Pressure Limitation	Ambulatory ECG Monitor	Gift Box
	MR, Magnetic Resonance Unsafe	Ambulatory ECG Monitor	Device, Gift Box
	Medical Device	Ambulatory ECG Monitor	Device, Gift Box
	Authorized representative in the European community/European Union	Ambulatory ECG Monitor	Gift Box
	Rx only	Ambulatory ECG Monitor	Device, Gift Box
	CE Mark	Ambulatory ECG Monitor, ECG Data transferred cradle	Device, Gift Box
	FCC Mark	Ambulatory ECG Monitor	Gift Box
	UKCA-UK Mark	Ambulatory ECG Monitor	Gift Box
	C-Tick Mark	Ambulatory ECG Monitor	Gift Box
	Keep away from direct sunlight	Commonly applicable products	Gift Box

	Keep Dry	Commonly applicable products	Gift Box
	Do not re-use	Ambulatory ECG Monitor	Gift Box
	Unique Device Identification	Ambulatory ECG Monitor, ECG Data transferred cradle	Gift Box
	Non-ionizing electromagnetic radiation	Ambulatory ECG Monitor	Device
	Class II equipment	ECG Data transferred cradle	User Manual
	Direct Current	ECG Data transferred cradle	Device

6 SAFETY REQUIREMENTS

6.1 Contraindications

1. Please do not examine or treat using radiation such as ultrasound, CT, MRI, and X-ray it interfere with the regular operation of the product and lead to inaccurate results of use.
2. Please do not use it at the same time as a defibrillator.
3. Please do not disassemble the device by the user or operator.
4. 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.
5. Device is not intended for infants under 10kg.
6. Do not use the Patch for patients with symptomatic episodes where instance variant in cardiac performance could result in immediate danger to the patient.
7. Do not use the Patch for patients with known history of life-threatening arrhythmias.
8. Do not use the Patch in combination with external cardiac defibrillators or high frequency surgical equipment near strong magnetic fields or devices such as MRI.
9. Do not use the Patch on patients who do not have the competency to wear the device for the prescribed monitoring period.

6.2 Warnings

1. Do not use the Patch on patients with known allergic reaction to adhesives or hydrogels or with family history of adhesive skin allergies. Patients may experience skin irritation.
2. Do not reuse the Patch on multiple patients. It is a single use device.
3. Infants or people who cannot express themselves must not use the device.
4. Without the manufacturer's permission, you must not modify the device.

5. Please be aware of the risk of strangulation for infants and children due to cables and hoses.
6. Please be careful as children may swallow small parts such as batteries.
7. 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.
8. If skin irritation such as severe redness, itching or allergic symptoms develops, remove the Patch from the patient's chest. Call HUINNO Customer Service at +82-2-3443-3160. If you feel the need for immediate medical care at any time, call emergency.
9. * CAUTION: Federal (USA) law restricts the sale of this device to or on the order of a physician.

6.3 Precautions

1. Read all instructions and labels including this manual before starting to use the device system.
2. Do not attach or detach any device components while the device is on to prevent any damage to the system or components.
3. Do not use acetone or any other cleaning solvents to clean the device.
4. The Ambulatory ECG Monitor includes temperature and humidity limitations If it is used beyond these limitations, the adhesive performance may be reduced and the device may slip or fall off during the patient's wearing period.
5. The Ambulatory ECG Monitor has a shelf-life data. Use of expired device may cause a degradation of ECG signal quality and/or low battery condition.
6. Keep the device and packaging away from young children. Contents may be harmful if swallowed. The Patch contains button cell batteries that are not accessible during normal use but, if exposed to the children, they have choking hazards and may cause severe tissue injury if ingested.
7. The battery life of the device may be shortened if the device is used frequently and/or for a prolonged period.
8. The battery life and capacity may decrease when the device is stored in a high-temperature environment.
9. The battery may self-discharge when the device is in storage.
10. Do not immerse the device into any liquid.
11. Do not expose the device to direct sunlight, heat source of thermal radiation, moisture, vibration, mechanical shock, excessive dust, or humidity.
12. The warranty will be void if the device is opened, disassembled, or altered by any unauthorized personnel.
13. Do not use caustic or abrasive cleaning agents to clean the device.
14. Do not excessively pull or overstress the device as it may break the device.
15. Do not sit or place a heavy object on the device.
16. Do not use the Patch if the package is damaged. Devices may not perform as intended.

17. Safety and effectiveness of the Patch on pediatric patients (younger than 18 years old) ~~has~~ have not been established.
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. Device is not intended for infants under 10kg.
20. 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.
21. When the abnormality is found during the examination, keep the patient in safe status and stop the examination.
22. 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 the manufacturer immediately.
23. Allergic reactions may occur to the tape on the electrodes used in the product.
24. Ensure that the electrodes and conductive portions of the BF type mounting part, including the neutral electrode, do not come into contact with other conductive parts that include grounding.

6.4 IT Network

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

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

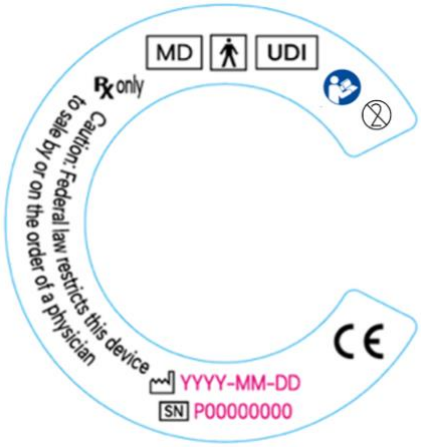
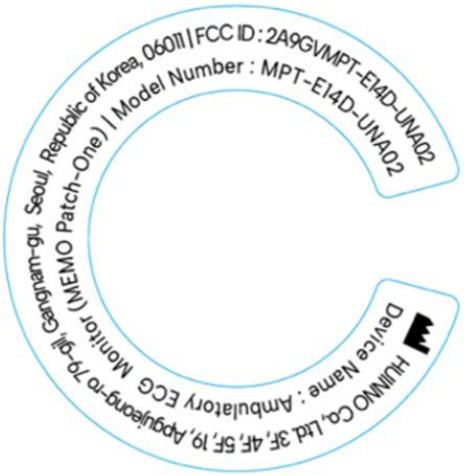
6.5 Environmental Protection

Non-specialized organizations with responsibility should contact local authorities to determine the proper disposal methods for components and accessories that pose biological hazards.

7. LABELING AND PACKAGING

7.1 Device Label

	Device	Device Label

Main Body **Bottom**		 

7.2 Package (Gift Box) Label

Device	MEMO Patch **Product Name** Ambulatory ECG Monitor (MEMO Patch-One) **Model Number** MPT-E14D-UNA02 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 ℞ only CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed physician **Rating** 3.0VDC, 300mAh (CR2430) SN P0000000 **IP24** UDI (01)08800126500062 (11)YYMMDD HUINNO MR MD EC REP XXXXX Month-2023

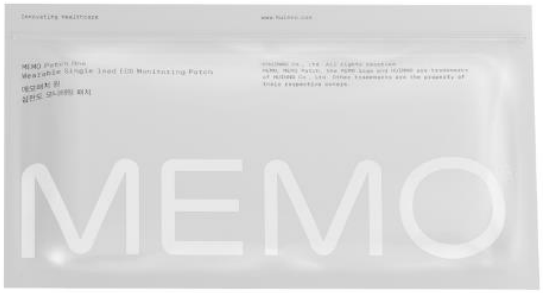
7.3 Accessory Label

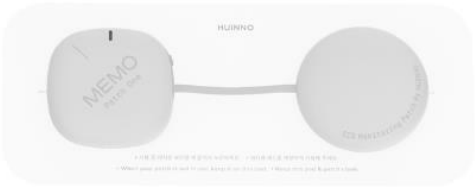
ECG Data transferred Cradle	**Data Transferred Cradle** **Model Number** ACC-C01P-02 **Serial Number** C0000000 **Country of Manufacture** Republic of Korea **Rating** 5V⎓ , 0.5A (01)08800126500017 (11)000000

7.4 Accessory Package (Gift Box) Label

ECG Data transferred Cradle	**Data Transferred Cradle** **Model Number** ACC-C01P-02 **Serial Number** C0000000 **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

7.5 Package Components





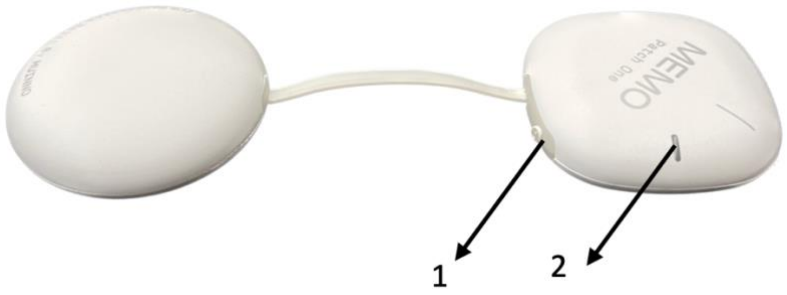
- ❿ Ambulatory ECG Monitor (MEMO Patch One)
- ❿ Quick Guide
- ❿ Accessory: ECG Data transferred Cradle and Cable

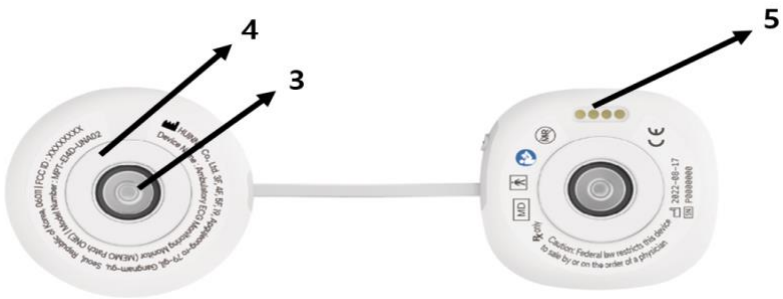
7.6 Package Components

- ❿ Ambulatory ECG Monitor (MEMO Patch One)
- ❿ Software

8. DEVICE COMPONENTS

8.1 Ambulatory ECG Monitor





No.	Term	Description
1	Power LED	The LED that allows checking the status of the product.
2	Power Button	This is used to turn on the power of the device.
3	Electrode connection pin	This is the part used to connect the electrodes to the device.
4	Electrode fixation double-sided tape	This is a double-sided adhesive tape used to secure the electrodes to the device.
5	Data upload port	This is the port used to transfer ECG data to a PC. It is used in conjunction with a cradle and a USB cable.

8.2 ECG Data Transferred Cradle

No.	Term	Description
1	USB port	This is the port where the USB cable connecting to the PC is connected.
2	Data upload pin	This is the pin that connects to the device's data upload port.

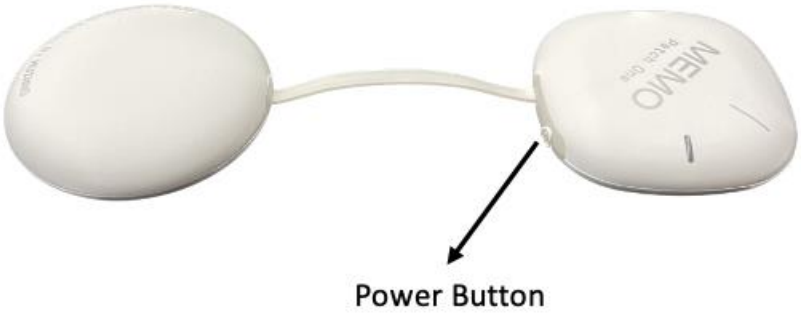
9. SERVICE CONFIGURATION AND FLOW

9.1 Attaching the 'Ambulatory ECG Monitor'

Prepare the device and ECG electrodes. ECG electrode is not provided to the user.

NOTE: It is recommended to use approved products with proven safety. We recommend using 3M red dot (model name: 2560)

The device is for one-time use only and should be disposed of after use. Reuse is strictly prohibited. For electrode, follow the instruction of the product.

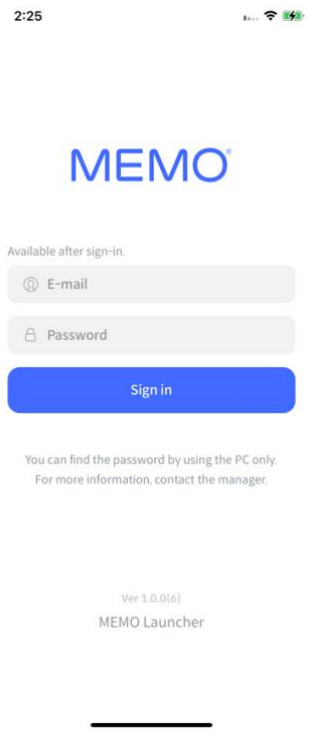


Press and hold the power button for about 3 seconds to turn on the device.

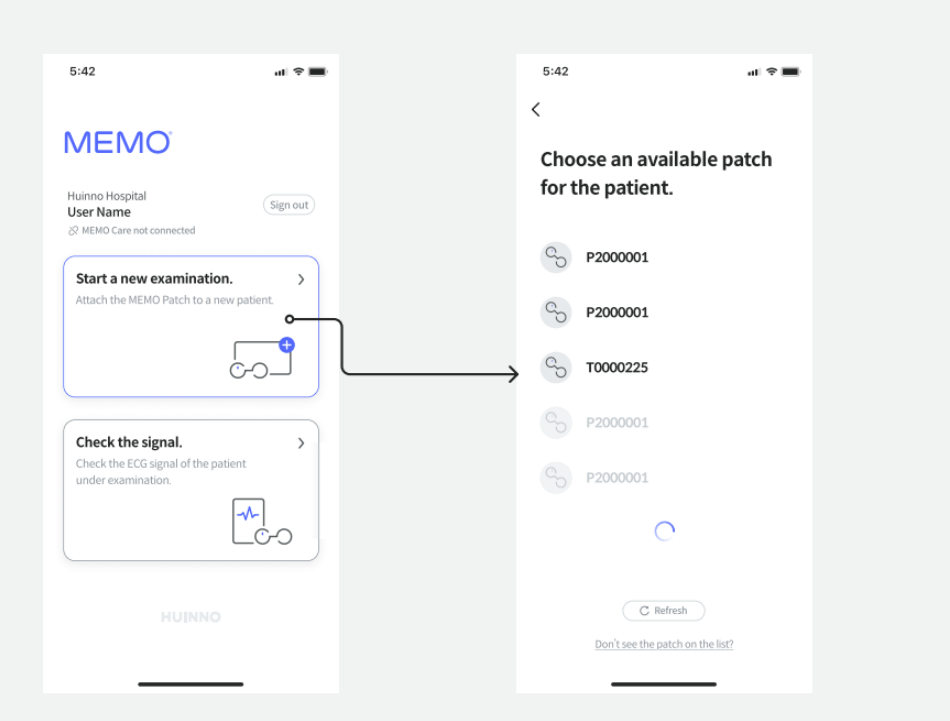
When you turn on the power, the LED indicator will flash.

NOTE: If the device is not paired with the 'MEMO Launcher' App within 5 minutes before the start of examination, the device will be automatically power off.

9.2 Applying the Ambulatory ECG Monitor: Step-by-step guide.



Launch the 'MEMO Launcher' app and log in with the same credentials provided by HUINNO.



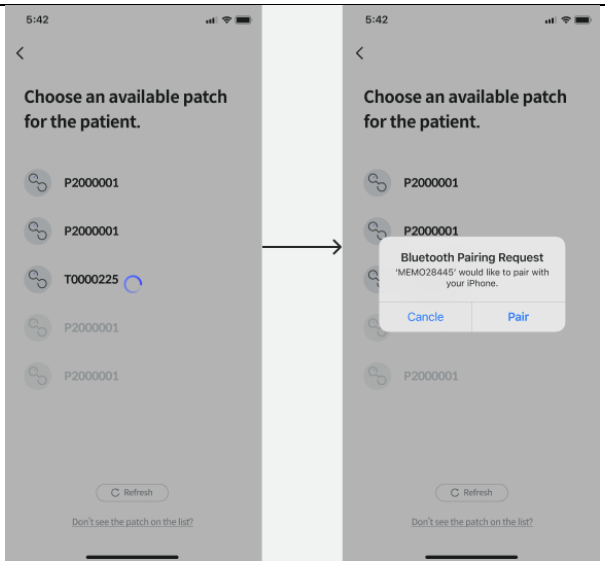
Click on **'Start a new examination'** and select the available patch serial for the patient.

NOTE: If a patient is not displayed in the list, please check if the Bluetooth function of your mobile phone is activated.

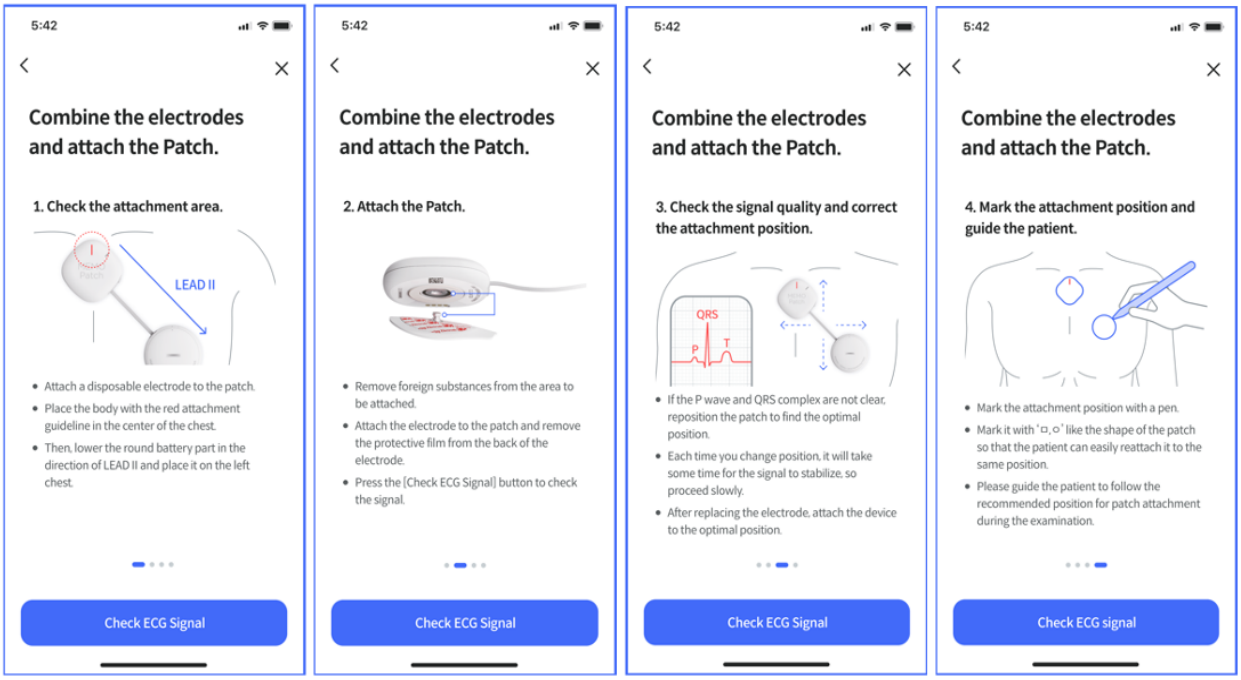
Check the serial number of the device to be attached to the patient.

The serial number is written under the device label.

NOTE: The serial number is a combination of an English letter "P" and numbers and can be found on the front of the device.



Select the serial number of the patch to be attached to the patient from the list and pair it.



After completing the pairing process, please check the attachment guide that appears.

Note: Disinfect the attachment site with alcohol before attachment or 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 to body hair, it may interfere with the signal measurement.

1. Place the device in the middle of the clavicle and attach the electrode 45 degrees to the right (Right-handed side of the Medical Doctor). 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.

2. Check if the ECG signal appears well in the 'MEMO Launcher' App.

→ If the P wave and QRS complex are not clear, move the patch position slightly to find the optimal position

→ It may take some time for the signal to stabilize after each location change.

3. Click the button 'patch attachment completion' in the 'MEMO Launcher' App as well.

NOTE: The signal is for verification purposes and may differ from the actual electrocardiogram data that is being saved.

4. To stop the display of real time ECG from the App, click the button 'pause'. If the signal does not come in, check the attachment status again.

NOTE: The recommended interval for replacing the electrode is one day (24 hours).

Since the patient may remove the patch after returning home, instructions should be given on how to reattach the patch at the location where it was originally applied in the hospital.

9.3 Check the quality of the ECG signal and finalize the examination.

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- After checking the quality of the ECG signal, press the 'Start examination' button.

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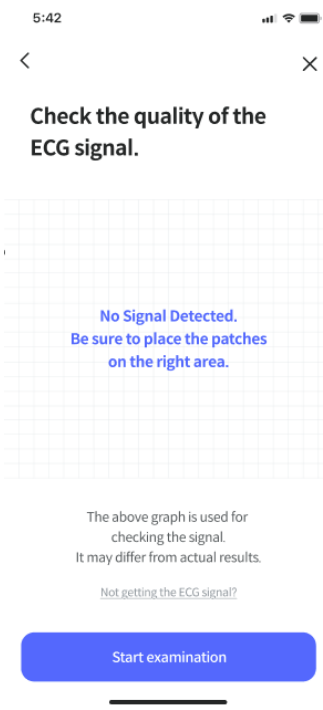
<td> 
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- After pressing the 'Done' button, finish the process.

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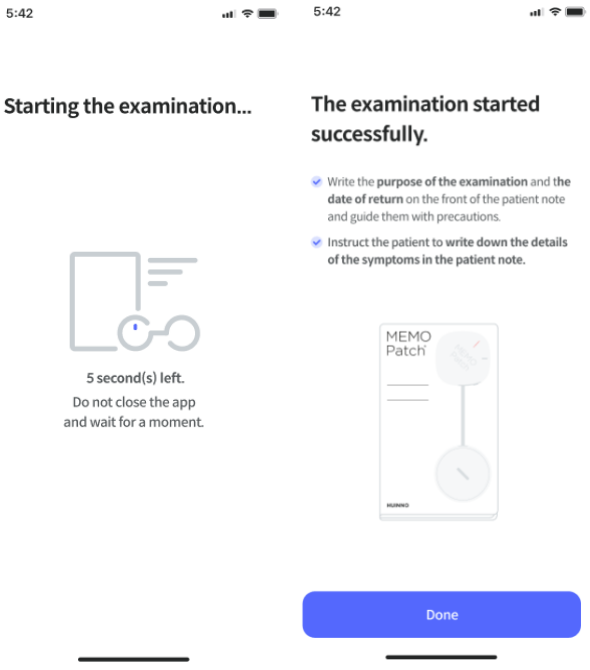
<td> 
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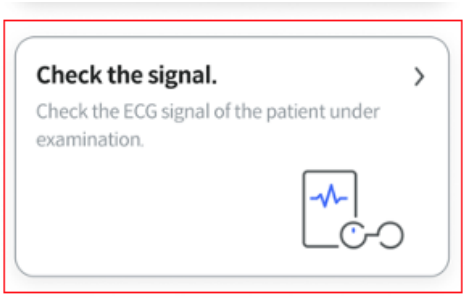
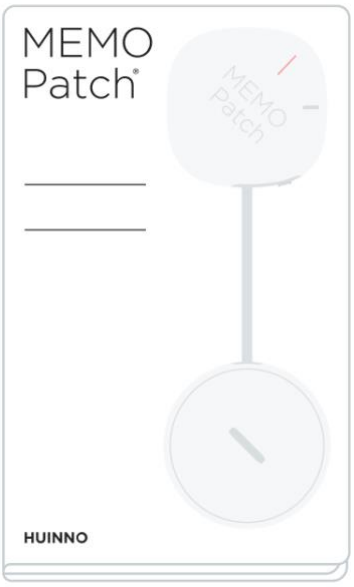
</table>

If you want to check the signal after starting the examination, log in to the app and select 'Check the signal' on the first screen.

You can check the signal by clicking on the patient's name in the list. However, since the patch and app are connected via Bluetooth, they may not be available if the patch is out of range or if the signal is weak.



9.4 Delivery of instructions and supplies to patients.

• After completing the examination, provide the patient with the following items: • Patients note: Record sleep time and symptoms. • Ambulatory ECG Monitor 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.	 <Patient notes & Ambulatory ECG Monitor storage package>

10. INSTRUCTION TO FOLLOW DURING MONITORING

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. 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.

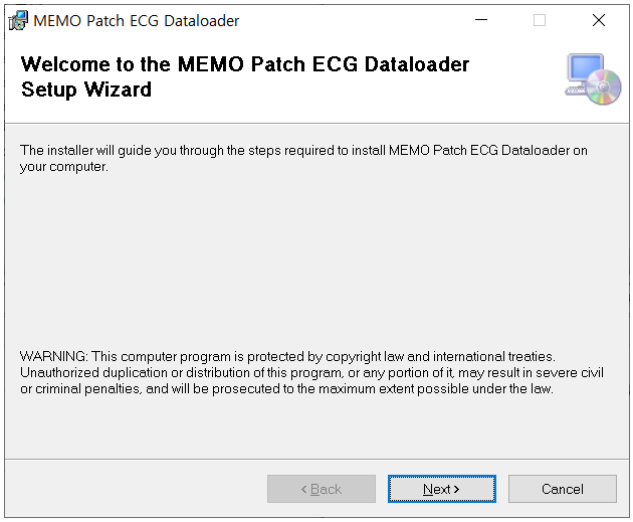
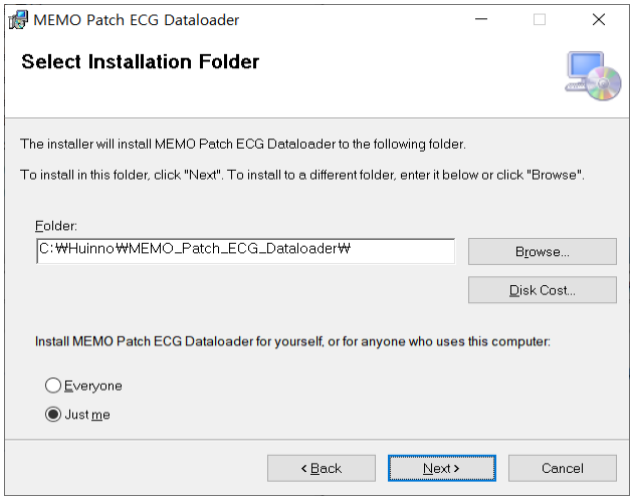
When undergoing X-ray, CT, or MRI tests, do not wear the device. However, do not turn off the power of the device when you are not wearing it. For more details, please refer to the safety requirements.

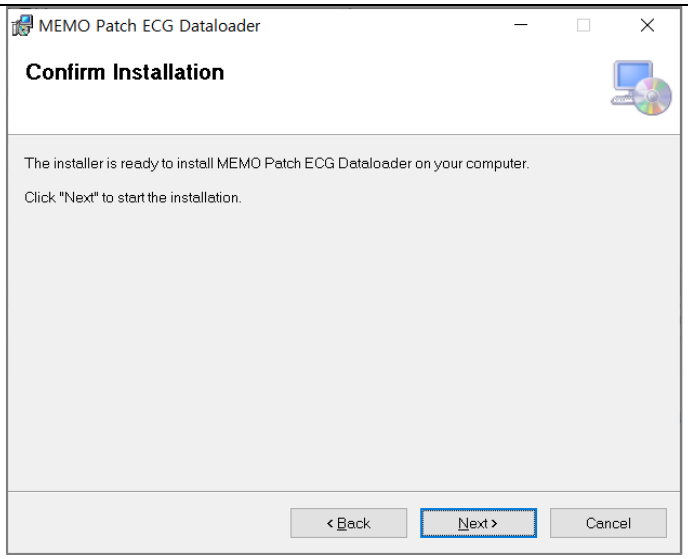
11. PROCEDURES AFTER COMPLETING THE TEST

11.1 Patient: Detaching and Returning the ‘Ambulatory ECG Monitor’

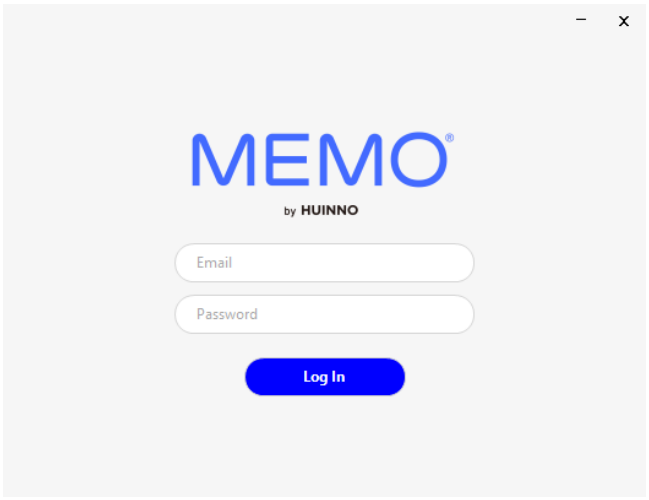
• 1 After the test is completed, the patient removes the patch. •	

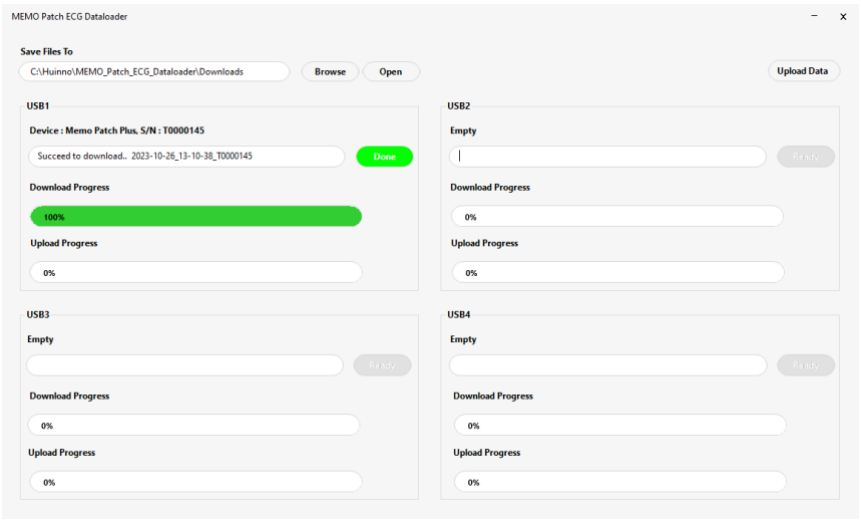
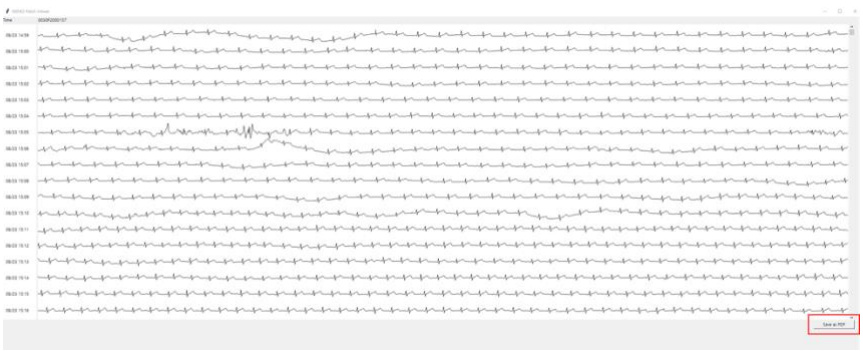
11.2 Checking the ‘Ambulatory ECG Monitor’, processing returns, and uploading data

• 1 To check the ECG data saved in the device, use the Dataloader program in the Windows PC. • 2 Run MEMO Patch ECG Dataloader.	 



- 3 After running the Ambulatory ECG Monitor ECG Dataloader, login with the same email and password provided by HUINNO.
- 4 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 Ambulatory ECG Monitor will be displayed. Then, click the download button.



• 5 When the download is successfully completed, a 'Done' message will appear.	
• 6 Click the 'Done' button, and raw ECG data will be displayed on the viewer. • 7 To export the data to a PDF file, click 'Save as PDF', and it will be saved in a PDF file.	

12 PRODUCT OPERATING ENVIRONMENT

MEMO Launcher (APP)		
	iOS	**Android**
OS	- Model: iPhone 8 or above - OS: iOS 13 or above	- OS: Android OS 9(Pie) or above
Screen	- Resolution: 1344 x 750 or higher - Optimized for portrait mode for iPhone	- Resolution: 720 x 1280 or higher - Optimized for portrait mode
Network	- Wireless Internet connection - Bluetooth 5.0 or later	- Wireless Internet connection - Bluetooth 5.0 or later

MEMO Patch ECG Dataloader	
Operating environment	
Above Window 10	
Hardware requirement	
Memory	Above 512MB
HDD	Above 128GB
Screen resolution	Above 1024 x 768
External port	Above USB 2.0, 1 port
Network	Wi-Fi or Ethernet

13 TROUBLE SHOOTING GUIDE

13.1Trouble 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.
	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.

13.2FAQs

Ambulatory ECG Monitor	1. How do I turn off the power? After the examination, it is impossible to power off the device. Even in an emergency, it is impossible to power off the device. In an emergency, please remove the device from the patient and immediately call HUINNO customer service.
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 Ambulatory ECG Monitor to the cradle and then to the PC, but the patch is not showing a green light. What should I do? The cable provided with the cradle must be used to function properly.
Product Storage	1. How should Patch be stored? ⑩ After the patient returns the device and the data upload is complete, please follow the appropriate local, state, and national regulations and recycling instructions for the disposal or recycling of the device and its components.
Patient Questions	1. As a patient wearing a Patch, 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 3 seconds, and the power will turn off after 5 minutes. 2. What should I do if I experience symptoms while wearing the Patch? If you experience symptoms, you should press the symptom record button on the Patch. The symptom record button is located on the power unit of the Patch. Press the button for about 0.5 seconds, 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.) If you find it difficult to press the symptom record button, you can also record your symptoms in the patient note. 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 Patch 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 Patch. If the Patch 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 Patch?
   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 Patch and are okay to use.

7. Can I exercise while wearing the Patch?
   Strenuous exercise can affect the electrocardiogram signal measurement, so it is recommended to avoid it. If sweating, the device can fall off, so we don't recommend to workout. Please be careful.

8. Can I take a shower, bath, or swim while wearing the Patch?

	➓ The Patch is waterproof, and you may use during shower, but it is recommended to remove the device before bathing, or swimming. 9. Can I reattach the Patch to a slightly different location from the original attachment site? ➓ Yes, you can reattach the Patch to a slightly different location. 10. What should I do if I experience skin irritation or itching? ➓ 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? ➓ 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? ➓ 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? ➓ No, there is no problem. However, there may be added noise to the signal or changes in the ECG waveform which does not affect the analysis result. 14. How do I return the patch after the test is finished? ➓ 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?

	⑩ You can call HUINNO customer service at +82-2-3443-3160. Depending on the question, you may also need to contact the hospital directly.

- To receive support for installation, use, or maintenance of the device, or to report unexpected behavior or events, please contact HUINNO's customer service at +82-2-3443-3160.

⑩ We operate from 09:00 to 18:00 on weekdays, with a one-hour lunch break from 12:00 to 13:00, and we are closed on holidays and weekends.

14 DEVICE SPECIFICATION

14.1Performance Characteristics

ECG Channels	1 channel
Memory capacity	14 days
Recording Format	HUINNO's internally defined format. (Encrypted by AES128 algorithm)
Service Life	Up to 14 days
Shelf Life	2 years
Out-of-Pouch Shelf life	Use upon opening

14.2Electrical Characteristics

Protection Against Electrical Shock	Type BF Applied Part (Electrode)
	Internally powered ME equipment
ECG Frequency Band	0.5Hz to 125Hz
ECG Input Impedance	≥10 MΩ
ECG Differential Range	±6.3 mV
ECG A/D Sampling Rate	250 Hz
ECG Resolution	12bit
Bandwidth width of the receiving section	1M

Each transmission frequency or frequency band.	2.4 GHz ISM Bang (2.402-2.480GHz)
Modulation Type and Frequency Characteristics	GFSK (Gaussian Frequency Shift Keying) modulation & 1Mbps
Effective Radiated Power (ERP)	2.5mW (4dB) or less.

14.3Power Characteristics

Patch Battery Type	CR2430, 300mAh
Battery Life	14 days

14.4Physical Characteristics

Patch Dimensions	142mm(W) X 48mm(D) X 12.8mm(H)
Patch Weight	35g (with battery)
Data transferred cradle Dimensions	54mm(W) x 53.95mm(D) x 14.5mm(H)
Data transferred cradle Weight	22g

14.5Environmental Characteristics

Operational Temperature	10℃ - 45℃
Operational Altitude	0 to 9,882 ft
Operational & Storage Humidity	10% to 95% (non-condensing)
Operational Atmospheric Pressure	700hPa – 1060hPa
Transport or Storage Pressure	700hPa – 1060hPa
Shipping (Short-term Storage) Temperature	-40℃ - 70℃
Storage Altitude	0 to 9,882 ft
Patch IP Classification	IP24
IP24) Protected from water spray from any direction.	

14.6 Product Maintenance, Storage and Disposal Summary

Cleaning and Maintenance	The device is for single use only. No Cleaning or maintenance is required.
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: -40°C to 70°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	Follow local, state, and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components.

1.0 Cleaning and Maintenance

The device is for single use only. No Cleaning or maintenance is required.

2.0 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: -40°C to 70°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.

3.0 Disposal (Accessory)

Follow local, state, and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components.

15 DEVICE LED SCENARIO

Power ON	Green LED, Fast flashing Once
Discover mode after Power ON	Before Operation: Green LED Slow flashing Continuously (Every 3 seconds for 5 minutes)

	After Operation: N/A
Before starting examination Button	Green LED, Fast flashing Once
Start examination	Green LED, Fast flashing Four times
Connection of BLE	Green LED, Fast flashing Three times
Disconnection of BLE	N/A
Event Marking	Green LED, Fast flashing Once
Low Battery	N/A

16 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)

17 PAUSE DETERMINATION

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

18 ELECTRICAL SAFETY AND COMPATIBILITY

Ambulatory ECG Monitor (MPT-E14D-UNA02) & ECG Data transferred cradle.

WARNING: 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.

WARNING: 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.

WARNING: 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-E14D-UNA02, including cables specified by the HUINNO.

18.1Table1 – ELECTROMAGNETIC EMISSIONS for Ambulatory ECG Monitor (MPT-E14D-UNA02)

Guidance and manufacturer's declaration – electromagnetic emissions		
MPT-E14D-UNA02 is intended for use in the electromagnetic environment specified below. The customer or the user of the MPT-E14D-UNA02 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The MPT-E14D-UNA02 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	Class B	The MPT-E14D-UNA02 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

18.2Table2 – Electromagnetic IMMUNITY for Ambulatory ECG Monitor (MPT-E14D-UNA02)

Guidance and manufacturer's declaration – electromagnetic immunity			
The MPT-E14D-UNA02 is intended for use in the electromagnetic environment specified below. The customer or the user of the MPT-E14D-UNA02 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 %.
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	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines EN 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MPT-E14D-UNA02 requires continued operation during power mains interruptions, it is recommended that the MPT-E14D-UNA02 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

18.3Table3 – Electromagnetic IMMUNITY for Ambulatory ECG Monitor (MPT-E14D-UNA02) that are not LIFE-SUPPORTING

<table>
<tr><td colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</td></tr>
<tr><td colspan="4">The MPT-E14D-UNA02 is intended for use in the electromagnetic environment specified below. The customer or the user of the MPT-E14D-UNA02 should assure that it is used in such an environment.</td></tr>
<tr><td>IMMUNITY test</td><td>IEC 60601 TEST LEVEL</td><td>Compliance level</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td>Conducted RF
EN 61000-4-6

Radiated RF
EN 61000-4-3</td><td>3 Vrms
150 kHz to 80 MHz

3 V/m
80 MHz to 2,5 GHz</td><td>3 Vrms

3 V/m</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the MPT-E14D-UNA02, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$\sqrt{P}$
d = 1.17
$\sqrt{P}$
d = 1.17 80 MHz to 800 MHz
$\sqrt{P}$
d = 2.33 80 MHz to 800 MHz
where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer and d is the recommended separation distance in meters(m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ~~a~~ should be less than the compliance level in each frequency range.
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</td></tr>
</table>

a Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MPT-E14D-UNA02 is used exceeds the applicable RF compliance level above, the MPT-E14D-UNA02 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MPT-E14D-UNA02.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

18.4Table4 – Recommended separation distances between portable and mobile RF communication equipment and the ME EQUIPMENT or ME SYSTEM – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the MPT-E14D-UNA02

The MPT-E14D-UNA02 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MPT-E14D-UNA02 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MPT-E14D-UNA02 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter. W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $\sqrt{P}$ d = 1.17	80 MHz to 800 MHz $\sqrt{P}$ d = 1.17	800 MHz to 2,5 GHz $\sqrt{P}$ d = 2.33
0.01	0.117	0.117	0.233
0.1	0.370	0.370	0.736
1	1.17	1.17	2.33
10	3.70	3.70	7.36
100	11.7	11.7	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

18.5Table5 – Electromagnetic Compatibility Information for 'Ambulatory ECG Monitor (MPT-E14D-UNA02) & ECG Data transferred cradle

Phenomenon	Basic EMC standard or test method	Test level /Requirement
Mains terminal disturbance voltage	CISPR 11 EN 55011	Group1, Class B
Radiated disturbance	CISPR 11 EN 55011	Group1, Class B
Harmonic Current Emission	IEC 61000-3-2 EN 61000-3-2	Class A
Voltage change, Voltage fluctuations and Flicker Emission	IEC 61000-3-3 EN 61000-3-3	Pst: 1 Plt: 0.65 Tmax:0.5 dmax: 4% dc: 3.3%
Electrostatic Discharge Immunity	IEC 61000-4-2 EN 61000-4-2	± 8 kV/Contact ± 2, ± 4, ± 8, ± 15 kV/Air
Radiated RF Electromagnetic Field Immunity	IEC 61000-4-3 EN 61000-4-3	10 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz
Immunity to Proximity Fields from RF wireless Communications Equipment	IEC 61000-4-3 EN 61000-4-3	Table 9 in IEC 60601-1-2: 2014 +A1:2020
Immunity to proximity magnetic fields in the frequency range 9 kHz to 13.56 MHz	IEC 61000-4-39 EN 61000-4-39	30 kHz: 8 A/m, CW 134.2 kHz: 65 A/m, PM 2.1 kHz

		13.56 MHz: 7.5 A/m, PM 50 kHz
Electrical Fast Transient/Burst Immunity	IEC 61000-4-4 EN 61000-4-4	± 2 kV, 100 kHz repetition frequency
Surge Immunity	IEC 61000-4-5 EN 61000-4-5	Line to Line ± 0.5 kV, ± 1 kV
Immunity to Conducted Disturbances Induced by RF fields	IEC 61000-4-6 EN 61000-4-6	3 V 0.15 MHz - 80 MHz 6 V in ISM and Amateur radio band between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Power Frequency Magnetic Field Immunity	IEC 61000-4-8 EN 61000-4-8	30 A/m 50 Hz and 60 Hz
Voltage dips	IEC 61000-4-11 EN 61000-4-11	0 % U_T: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11 EN 61000-4-11	0 % U_T; 250/300 cycle

19 BUG LIST

Defect free software

20 CUSTOMER SERVICE

If you encounter any issues during the inspection, please contact our customer center.

Our hours of operation are weekdays from 9am to 6pm (Closed for lunch from 12pm to 1pm, and closed on weekends and holidays)

TEL: +82-2-3443-3160

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

E-Mail: sales@huinno.com

NOTE: Manufacturers have an obligation to disclose data on essential product performance to users whenever they request it.

21 REVISION HISTORY

Rev. No.	Rev. Date	Page(s) Affected	Revision Description
0	January 26, 2023	All	Newly Established

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.