

User Manual

Ambulatory ECG Monitor

Trade/Device Name: MEMO Patch T

Model Name: MPT-E14C-UNC01

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1.0 DEVICE OVERVIEW

1.1 Instruction

This user manual is intended for Ambulatory ECG Monitor (MEMO Patch T). The manual includes information about components, instructions for use and safety precautions of Ambulatory ECG Monitor. 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, 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

This product is a patch-type 1-channel or 3-channel electrocardiogram (ECG) and respiration signal recording device. It detects potential differences on the body surface caused by the electrical activity of the myocardium through electrodes to record ECG signals. The device is designed to continuously measure and store ECG and impedance-based respiration signals by attaching electrodes to designated positions on the body. The respiration signal provided by this product is intended as supplementary reference information for ECG analysis and is not meant for independent respiration measurement or the diagnosis of respiratory diseases.

When using the 1-channel ECG configuration, this product can continuously record for up to 14 days. By automatically recording data during the examination period without requiring continuous patient intervention, it aims to enhance user convenience and improve patient compliance. If symptoms occur during the examination, the patient can press the event button on the device to mark the onset time. This event information is then used to identify the correlation between the ECG rhythm and the symptoms in the final analysis report.

Medical professionals can check the attachment status of the patch and activate the examination using MEMO Launcher (iOS/Android), a dedicated medical application. Once the examination is completed, the patient removes the Holter monitor and returns it to the medical staff. The recorded ECG and respiration signals are transmitted and stored in a cloud or on-premise server database via wireless communication or wired data download, based on which arrhythmia analysis is performed. Medical professionals can review the ECG data and analysis results through a web-based user interface. This product

is designed for use in both hospital and out-of-hospital healthcare environments, and it can transmit the respiration signals estimated by impedance measurement and the ECG signals to a separate gateway (such as a mobile app) using wireless communication technology (Bluetooth).

1.3.2 Indications for use

This product is a Holter ECG system designed for long-term electrocardiogram (ECG) recording. It is engineered to continuously record, playback, and analyze ECG signals while worn by the subject during their daily activities. Depending on the configuration, this product can record ECG signals, impedance-based estimated respiration-related signals, symptom events marked by the patient, and pacemaker pulse detection flags. The recorded data can be verified and reviewed by healthcare professionals through a web-based user interface and is used to support the diagnosis of arrhythmia through ECG analysis. This product is intended for the purpose of recording and reviewing ECG data and is used to assist the clinical judgment of healthcare professionals.

1.3.3 User

Patients and healthcare professionals (including physicians, nurses, and clinical laboratory technologists)

1.3.4 Indication for Use: Arrhythmia

This product is a prescription-only, continuous-recording ECG monitor that can be worn for up to 14 days. This product is recommended for use in asymptomatic patients or patients who may experience transient symptoms such as palpitations, shortness of breath, dizziness, lightheadedness, presyncope, syncope, fatigue, or anxiety.

1.3.5 Intended Patient Population

- ◆ Age: adult
- ◆ Weight: All body types can use this product, including individuals who are underweight, overweight, or obese. There are no body-weight limitations for proper device performance.
- ◆ 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: Healthcare professional and patient
- ◆ Intended Operator for ECG dataloader viewer and cradle: Healthcare professional

1.4 Marks and symbols

Symbol	Definition	Symbol	Definition
	Serial Number		Prescription only
	Date of Manufacture		Manufacturer

	Read instructions		Medical Device
	Refer to User Manual		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. Do not use the device if the patient has a current symptom or history of skin cancer, rashes, skin diseases, keloids, or skin injuries.
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. The lithium battery included in this product must be used in accordance with the battery manufacturer's instructions. Failure to do so may result in fire, explosion, or leakage. HUINNO is not liable for any accidents such as fire, explosion, or leakage caused by the battery unit itself.
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 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.
11. Cybersecurity Vulnerabilities: Limited automatic updates due to low OS specifications may leave the device vulnerable to known cybersecurity threats. If possible, upgrade to a device that meets the latest OS specifications.
12. The device is not intended to be used during intense physical activity.
13. This product is a prescription-only measurement/recording device and must not be used for specific purposes without the guidance of medical personnel.

2.3 Precautions & Cautions

- If a cybersecurity threat occurs at any stage of using the device, contact the manufacturer's emergency number immediately to address it and wait until the administrator takes action.
- To comply with FCC's RF exposure limits for general population / uncontrolled exposure, the antenna(s) used for this transmitter must be installed to provide a separation distance of at least 20cm from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter.
- If any abnormality is detected in the device or the patient, appropriate measures must be taken, such as ensuring the patient's safety and stopping the operation of the device.
- Use only the provided cables to protect the ME (Medical Electrical) equipment against the effects of defibrillator discharge.
- In a charging environment, the product adapter plug serves as the disconnecting means. When using the charging cradle, the adapter plug must not be positioned in a location where it is difficult to disconnect it from the power source.
- Avoid using the device in locations where wireless communication connectivity issues may occur (e.g., areas with a high density of metallic objects or electronic equipment).
- The device and its packaging materials must be kept out of reach of children. Caution must be exercised as swallowing the components of the product can cause serious harm.
- Excessive or strenuous exercise may affect data measurement, so please use with caution.
- Do not repair, disassemble, or modify this device. This device does not require calibration during its expected life cycle.
- Auxiliary equipment connected to the data interface section of the MEMO Patch T must comply with IEC 60950 (Data Processing Equipment) or IEC 60601-1 (Medical Electrical Equipment). All connected systems, including auxiliary equipment, must satisfy the IEC 60601-1 (Medical Electrical Equipment) and IEC 60601-1-2 (Electromagnetic Compatibility) standards. If you are uncertain, consult the HUIINNO Customer Center before use.
- This device must not be used by individuals who are unable to express their intentions or consent.
- When collecting and using the patient's (data subject's) personal information, the Personal Information Protection Act must be complied with, such as obtaining prior consent to protect the patient's personal information.
- Users falling under the following categories should consult a physician before use:
 - ◆ Patients with sensitive or allergic skin
 - ◆ Patients with wounds on the skin that comes into contact with the device
 - ◆ Patients with artificial cardiac pacemakers or other implantable electrical devices
 - ◆ Pregnant women, breastfeeding women, and children

2.4 Precautions for Using the ECG Patch Device

2.4.1 Pre-use Precautions

- ◆ Only disposable ECG electrodes specified by the manufacturer must be used.
- ◆ The device's battery must be charged before prescribing it to a new patient.
- ◆ When attaching the device, ensure there are no foreign substances between the electrodes and the skin.
- ◆ The recommended disposable electrodes can be used for up to 24 hours. When replacing the electrode, detach only the device from the electrode and replace it with a new one, without needing to turn off the device or unpair it from the app.
- ◆ This product must be attached only to the designated chest area of the body and must not be attached to or used on any other body parts.

2.4.2 Precautions During Use

- ◆ Do not subject the device to strong shocks or vibrations while in use.
- ◆ If an electrode detaches from the skin during use, contact the hospital.
- ◆ If a malfunction occurs during use, you must contact the hospital or the manufacturer.
- ◆ Avoid excessive contact of the device with water (e.g., prolonged exposure to water such as bathing or swimming).
- ◆ Ensure that the electrodes of the device do not come into contact with other conductive parts.

2.4.3 Post-use Precautions

- ◆ After using the device, disinfect the product using isopropyl alcohol of 60% or higher or an alcohol swab (ensure that organic chemical substances do not come into contact with the device).
- ◆ Electrodes are for single use only and must be disposed of by the hospital after use (Do Not Reuse).
- ◆ When disposing of the device and rechargeable batteries, local waste disposal regulations must be followed. Failure to follow waste disposal regulations may cause environmental pollution.

2.5 Precautions for App and Software Use

2.5.1 Pre-use Precautions

- Prior to use, the manual must be thoroughly understood, and the system must only be used by individuals with medical knowledge regarding the proper use of the device.
- Implement access control functions within the software to ensure that only authorized users can use this product.
- Since information is provided through a web service platform, it can only be used in hospitals connected to a TCP/IP network.
- As PCs used within the hospital can be infected with malware, install firewalls and anti-virus software.

2.5.2 Precautions During Use

- If any abnormality in the operational status is identified while using the program, contact the manufacturer.
- Regular virus scans and security precautions are required for the PC you are using.

2.5.3 Post-use Precautions

- Log out of the program to protect patient information and safeguard against security threats such as data tampering or forgery.

2.5.4 Others

- Precautions must be taken against leaks, tampering, and forgery when transmitting and storing medical information.
- To prevent leaks, tampering, and forgery, medical information is transmitted using the HTTPS communication protocol via the TLS security protocol.
- If MEMO Patch T information is leaked, an unauthorized person may disconnect the link between the MEMO Patch T and its interlocking gateway (including the mobile app). Periodically check the communication status of the MEMO Patch T. If a security threat is detected, stop use immediately and contact your distributor or the Huinno Customer Center.
- Manufacturer CS Contact: +82-2-3443-3160

2.6 IT Network

The 'MEMO Patch T' device can connect to a mobile phone or gateway device via Bluetooth, and this mobile phone or gateway device can communicate with the server via Wi-Fi or LTE.

- MEMO Launcher: Allows verification of ECG data, device activation, and connection via the app.
- MEMO for Desktop: Allows verification of ECG data, device activation, and connection via the app.
- ◆ Hospitals and medical institutions (the responsible organization) using this product by connecting it to an IT network must recognize that subsequent changes to the IT network may introduce new risks to the system, requiring additional analysis and measures. Hospitals and medical institutions must perform additional risk management to newly identify, evaluate, and control associated risks when the following changes to the IT network occur:
 - Changes in the IT network configuration (topology)
 - Connection of additional items (devices, etc.) to the IT network
 - Disconnection of items (devices, etc.) from the IT network
 - Updates to devices and systems connected to the network
 - Upgrades to devices and systems connected to the network

2.7 Environmental Protection

- ◆ Responsible non-professional organizations should consult local authorities to determine the proper disposal method for components and accessories that pose biological hazards. Follow local, state, and national guidelines regarding disposal or recycling.
- ◆  Non-specialized organizations with responsibility should contact local authorities to determine the proper disposal methods for components and accessories that pose biological hazards.
- ◆  Battery recycling must meet local requirements.

2.8 FCC Statement and Caution

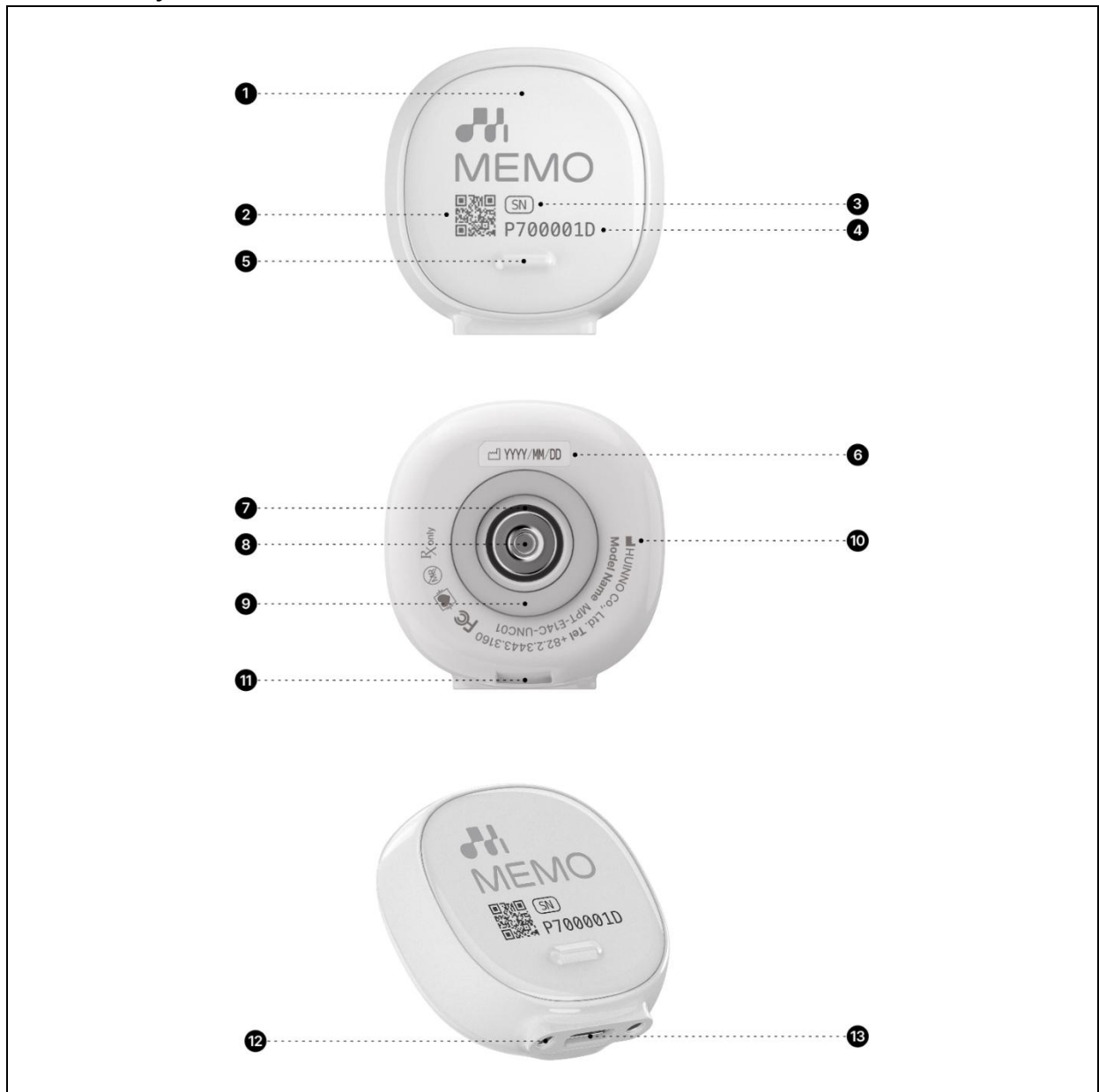
- **FCC Compliance Statement**
- This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- **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 (section 3.1)
- 1 Paper type user manual
- Option
 - 1 Single-Lead Cable (section 3.2)
 - 1 Multi-Lead Cable (section 3.3)
 - 1 Charging Cradle (5-Port) (section 3.4)
 - 1 Dedicated Cable (section 3.5)
- ◆ **NOTE:** It is recommended to use approved products with proven safety. **We recommend using 3M red dot (model name: 2560)**

3.1 Main body



No.	Name	Description
1	Status Indicator	An LED that displays the power-on status, patient events, and Bluetooth connectivity status.
2	Front QR Code	A two-dimensional code scanned for device identification.
3	Serial Number Mark	An identification mark indicating where the device's serial number (SN) is located.
4	Front Serial Number	A unique identification number assigned to each individual patch body.
5	Power / Event Marker Button	Used to turn the device power ON and to record patient symptoms.
6	Manufacturing Date Label	A label containing information about the date the product was manufactured.
7	Waterproof Silicone Ring	A silicone ring that prevents moisture or foreign substances from entering the inside of the device.
8	Electrode Connector	A metal contact portion that electrically connects the device with disposable electrodes.
9	Electrode Retention Pad	A pad designed to support disposable electrodes so they adhere stably to the device.
10	Product Information	A section displaying the key specifications and identification data of the device, including the model name and manufacturer.
11	Lead Secure Groove	A groove designed to securely fix the combined cable lead, preventing it from shaking or detaching.
12	Charging Contacts	Contact terminals designed to mate with the pogo pins of the charging cradle to charge the battery.
13	Multi-function USB Port	A Type-C port utilized for battery charging, lead cable connection, and wired transmission of biometric data to a PC.

3.2 Single-Lead Cable

		
번호	명칭	설명
1	Lead Cable Connector	A mating interface that couples with the cable connector of the main body to transmit signals.
2	Device Attachment	A structural portion where the single-lead cable physically couples with the patch body.
3	Cable	A flexible conducting wire that transfers biometric signals measured from disposable electrodes at the electrode interface to the main body.
4	Electrode Interface	The section that couples the disposable electrode with the cable.
5	Lead Secure Clip	A clip designed to secure the main body and the lead cable connector to prevent signal noise caused by cable movement during measurement.
6	Rear QR Code	A two-dimensional code scanned for device identification of the lead cable.
7	Rear Serial Number	A unique identification number assigned to the single-lead cable.
8	Electrode Retention Pad	A supporting structure designed to press the electrode so it adheres closely to the patient's skin without lifting.
9	Electrode Connector	A metal terminal portion that directly connects with the pin of a disposable electrode.

3.3 Multi-Lead Cable

No.	Name	Description
1	Lead Cable Connector	A mating interface that couples with the cable connector of the main body to transmit signals.
2	Device Attachment	A connector utilized to couple the entire multi-lead cable to the patch body.
3	Cable Stopper	A device that prevents the split lead wires from opening excessively or tangling.
4	Lead Secure Clip	A clip designed to secure the main body and the lead cable connector to prevent signal noise caused by cable movement during measurement.
5	Rear QR Code	A two-dimensional code scanned for device identification of the lead cable.
6	Rear Serial Number	A unique identification number assigned to the multi-lead cable.

7	Lead ID	A unique identification number assigned to the multi-lead cable.
8	Cable	Multi-core conducting wires that transfer ECG signals measured from the electrodes of each site to the main body.
9	Cable Holder	A component designed to neatly gather and organize long, extended lead wires.
10	Electrode Connector (RL)	A green terminal that connects to the disposable electrode attached to the lower right abdomen (Right Leg).
11	Electrode Connector (LL)	A red terminal that connects to the disposable electrode attached to the lower left abdomen (Left Leg).
12	Electrode Connector (LA)	A black terminal that connects to the disposable electrode attached below the left clavicle (Left Arm).
13	Electrode Connector (V)	A brown terminal that connects to the disposable electrode attached to the right side of the sternum (Chest).
14	Individual Lead ID	Color and text markings that help ensure each electrode terminal is attached to the correct anatomical position.

3.4 Charging Cradle (5-port)





No.	Name	Description
1	Power Indicator	A green LED that illuminates when power is connected to indicate the operational status.
2	Charging Pogo Pins	Pins designed to mate with the charging contacts of the main body to supply electrical power.
3	USB-C Port	A USB Type-C input port used to connect with the power adapter.
4	Side Label	A label containing information such as the input voltage parameters of the charging cradle.
5	Anti-slip Rubber Pad	A rubber pad attached to prevent the cradle from slipping or sliding on surfaces.
6	Bottom Label	A label indicating the serial number and primary technical specifications of the device.
7	Charging Cradle Power Adapter	A device that converts AC power into the appropriate DC voltage to supply the cradle.
8	Charging Cradle Power Cable	A cable utilized to connect the power adapter to the charging cradle.

3.5 Dedicated Cable

Cable for uploading biosignal data from the device to the PC



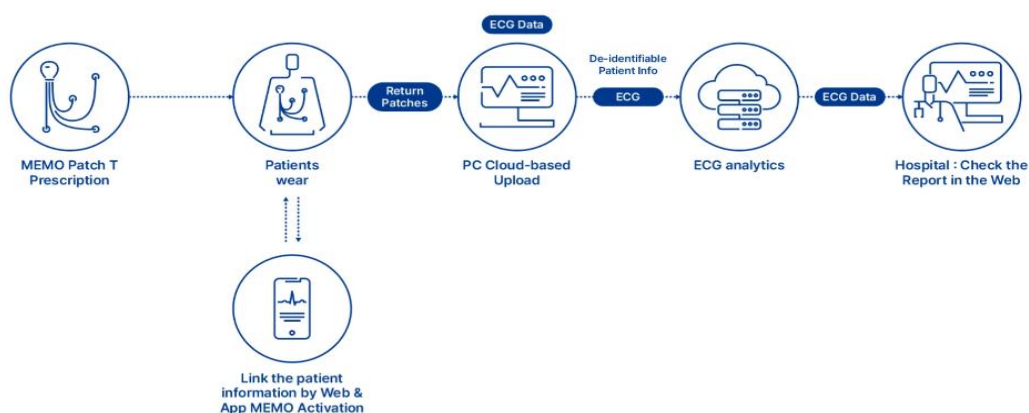
3.6 Service Architecture & Workflow

3.6.1 Service Architecture



- ◆ **Web Server:** A web-based test management software utilized for patient registration and retrieving analysis results.
- ◆ **'MEMO Launcher' App (Android/iOS):** A mobile application used to pair the 'MEMO Patch T' device with a patient and verify whether the device has been correctly attached.
- ◆ **'MEMO for Desktop' (Windows):** An integrated PC application designed to provide a more streamlined service operating environment. It enables web access to the web server, activates the MEMO Patch T device to start tests, and supports extracting ECG data and uploading it to the cloud. Additionally, Bluetooth-enabled desktops and laptops can utilize Bluetooth to activate the patch's measurement features via the MEMO for Desktop software.
- ◆ **'MEMO Patch ECG Dataloader' (Windows):** A PC software that supports extracting ECG data from the measurement device and uploading it to the web server.

3.6.2 Service Workflow



> This guide provides instructions for using the MEMO Patch T.

> For detailed information on using a web server, please refer to the User Manual for web server.

4.0 PREPARATION BEFORE USE [HCP, DESKTOP APP, WEB]

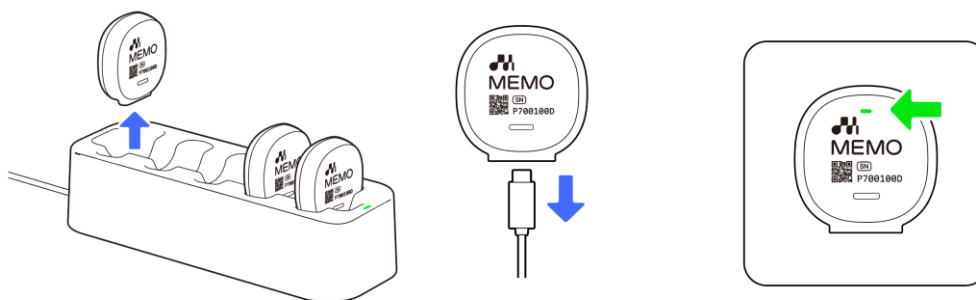
*Healthcare Professional: HCP

4.1 Service Login for Patient Registration

- Log in to the designated webpage (www.memopatch.care) using the email ID and password issued by Huinno, then register the patient test.
- The web server functions in the same manner.

4.2 Preparing the MEMO T Device

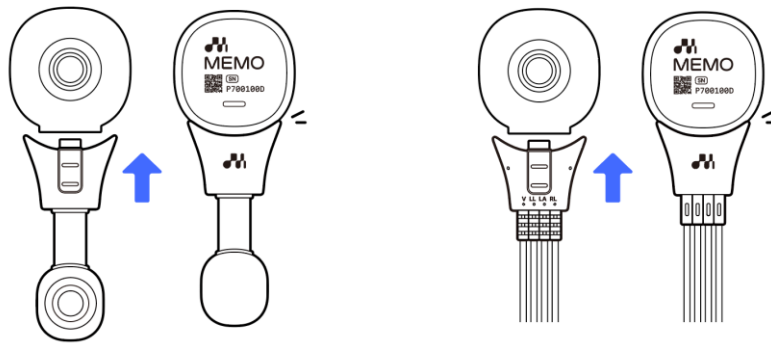
- Check the charging status via the status indicator on the MEMO T Device, then disconnect the fully charged device from the Charging Cradle or Dedicated Cable.
 - Charging Status Guide
 - Charging: Green
 - Fully Charged: Blue
 - Charging Error: Orange



5.0 STARTING THE TEST [HCP, MOBILE APP, DESKTOP APP]

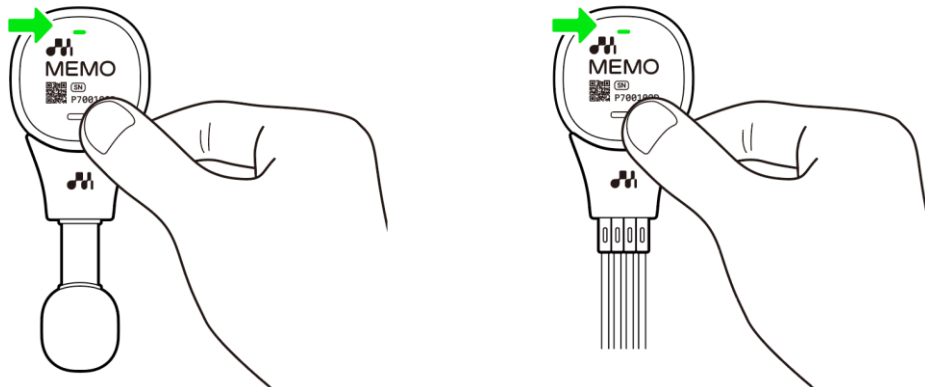
5.1 Connecting the Lead Cable and MEMO T Device

- Connect either the Single-Lead Cable or Multi-Lead Cable depending on the test type.
- Snap it into place until you hear a 'click' from the Lead Secure Clip located on the rear of the lead cable.
 - Snap it into place until you hear a 'click' from the Lead Secure Clip located on the rear of the lead cable.



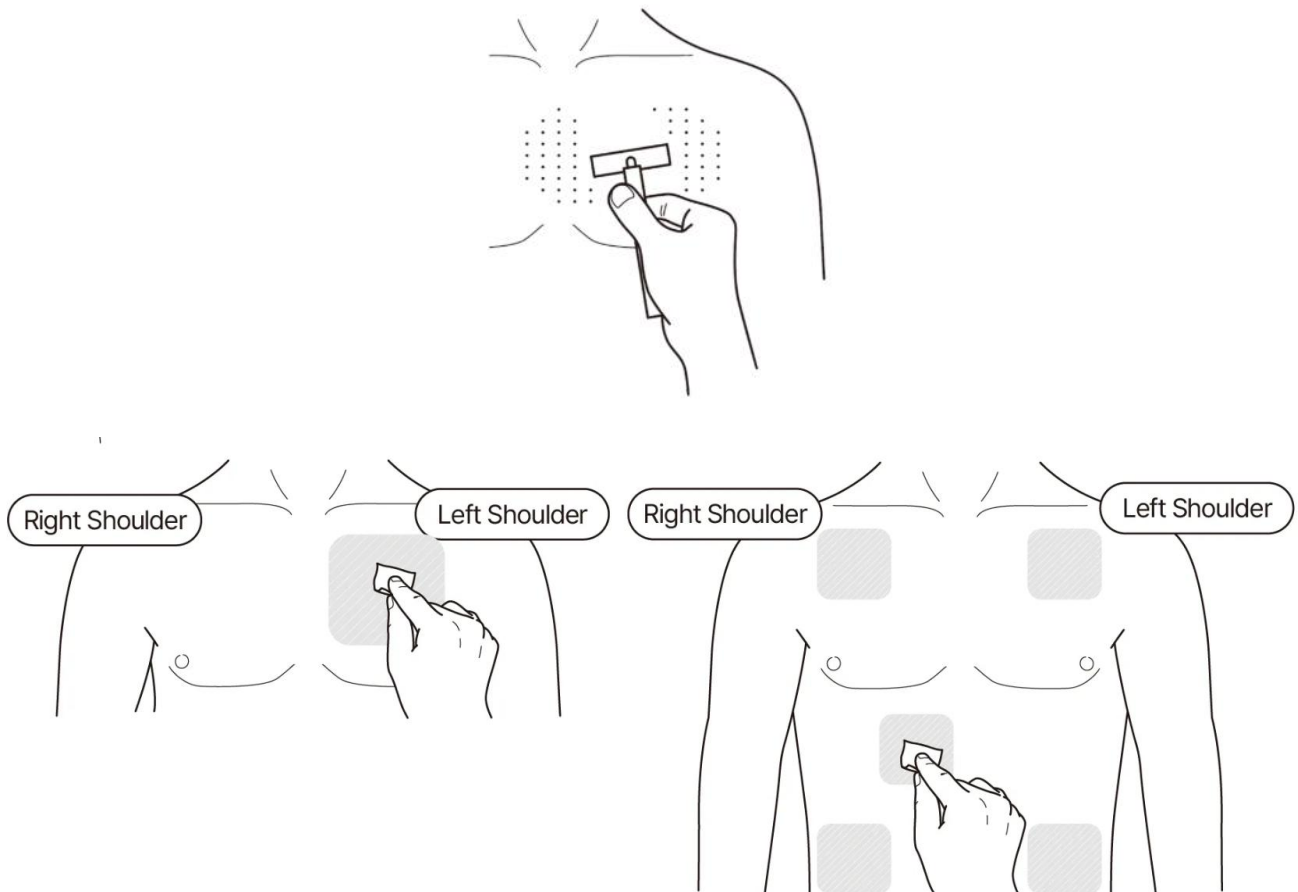
5.2 Checking Battery Status

- This step is required to check the battery status; however, if skipped, it can safely be performed during the patch connection step after attachment.



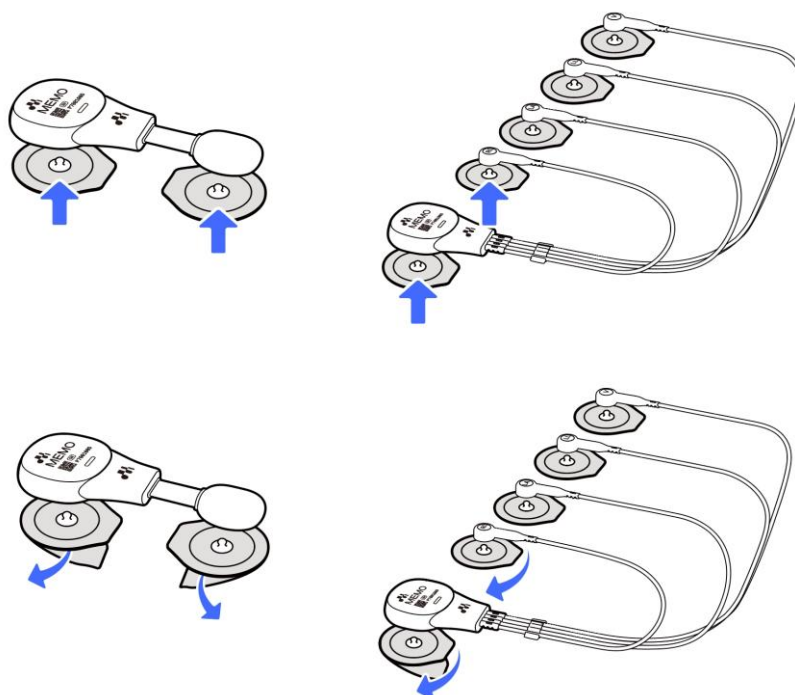
5.3 Checking the Attachment Site

- Shave the patient's attachment site, then sanitize it with alcohol.
 - If body hair prevents the device from adhering closely to the skin, it may interfere with signal measurement.



5.4 Connecting Disposable Electrodes

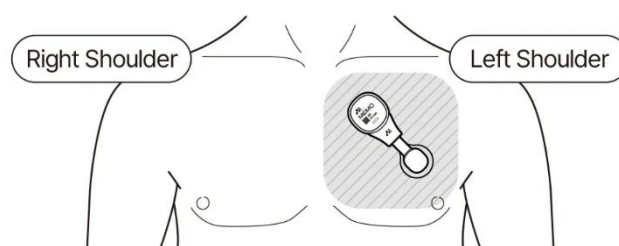
- Connect the disposable medical electrodes to the assembled MEMO T Device and lead cable.
- Remove the transparent protective film from the bottom of the connected electrodes.



5.5 Attachment

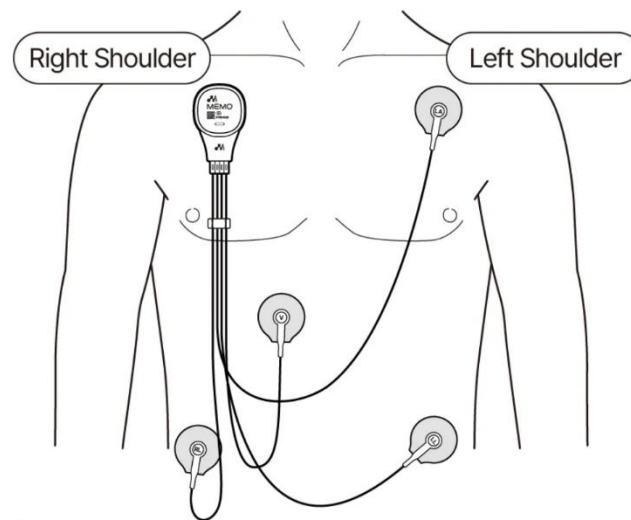
5.5.1 Single-Lead Cable

- Attach the Single-Lead Cable (already connected to the device) to the patient's chest between the left clavicle and the nipple at a 45-degree angle, then press firmly across the entire surface to ensure close adhesion to the skin.



5.5.2 Multi-Lead Cable

- Position the device's RA electrode on the upper right chest below the clavicle. Attach the LA electrode to the upper left chest below the clavicle, the RL electrode to the lower abdomen or a neutral position on the right chest, the LL electrode to the lower left abdomen or below the intercostal space, and the V electrode to the right 4th intercostal space next to the sternum (V1). Once positioned, press firmly across the entire surface of each to ensure close adhesion to the skin.
 - The V electrode can be attached to any position from V1 to V6 depending on the user's preference.



5.6 Connecting the Device

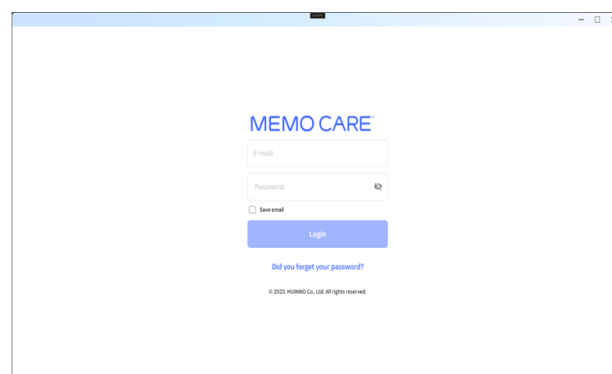
5.6.1 Desktop App (MFD)

5.6.1.1 Installing and Running the App

- Download and install the [Desktop App (MFD)] from the designated webpage. (www.memopatch.care)

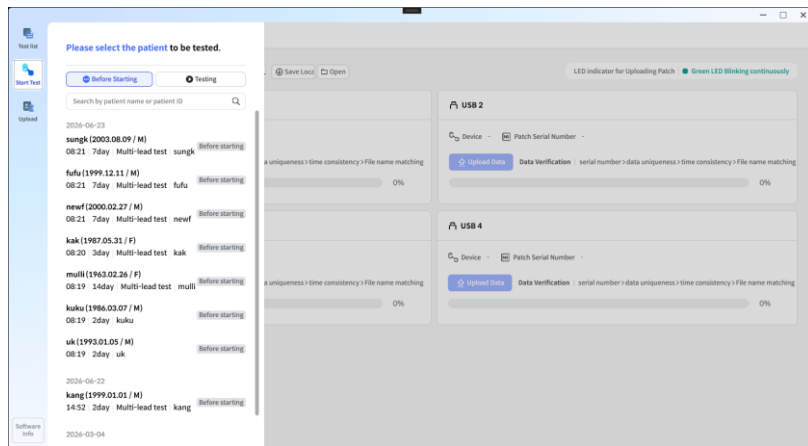
5.6.1.2 Logging in to MFD

- After installation, launch the program and log in using the same credentials as the Web version.



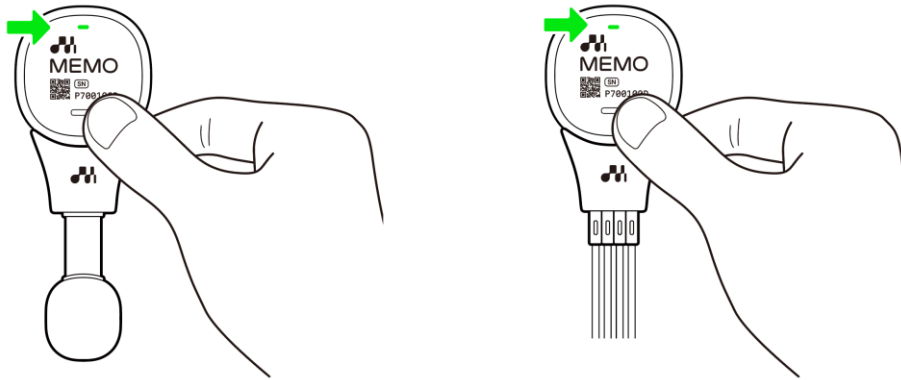
5.6.1.3 Selecting a Patient in the "Start Test" Tab

- Click the [Start Test] menu on the left panel to go to the patient selection page.
- Select the patient to begin the test.
- Depending on the hospital account, a patient consent screen may appear next.



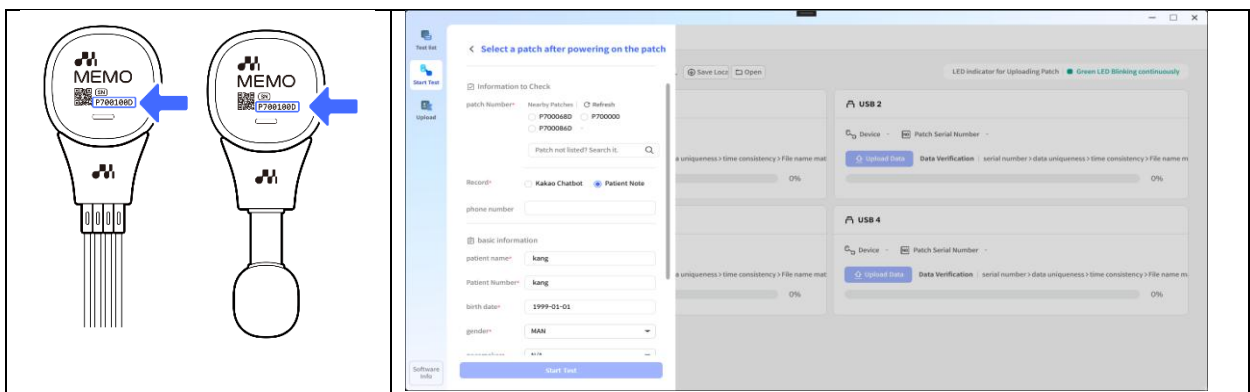
5.6.1.4 Activating the Device

- Press and hold the power button on the attached MEMO T Device for 3 seconds to activate it..



5.6.1.5 Selecting the Device

- In the patient information confirmation window within the program, select the item that matches the device's serial number (SN).
- Verify the information entered during patient registration, update any changes, and then click the [Start Test] button to begin.
- If you need to modify the initially created patient information on this screen where the device selection and patient data are displayed, make the necessary edits on this page.



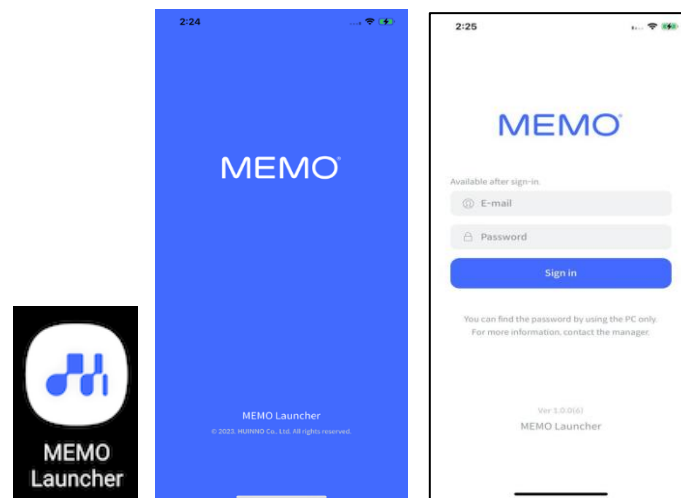
5.6.2 Mobile App (MSA)

5.6.2.1 Installing and Running the App

- Download [MEMO Launcher] from the Google Play Store or Apple App Store.

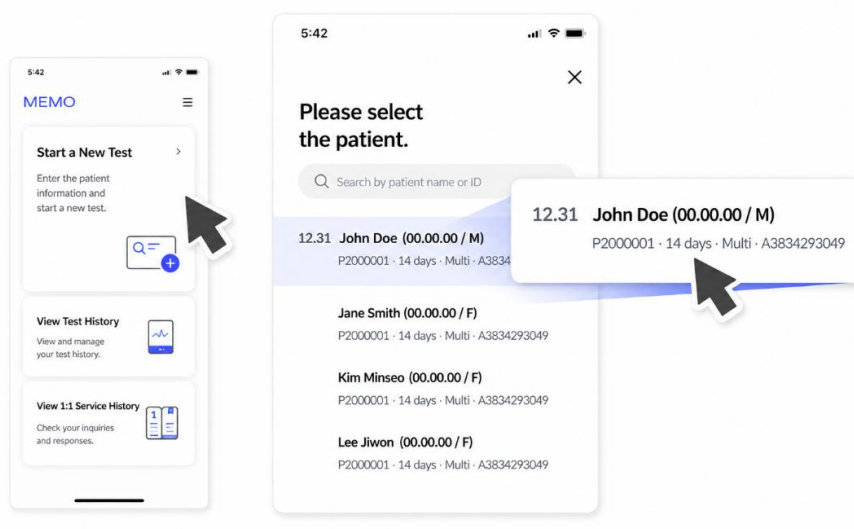
5.6.2.2 Starting the Test

- Access the app and log in using the same credentials as your Web or Desktop account.



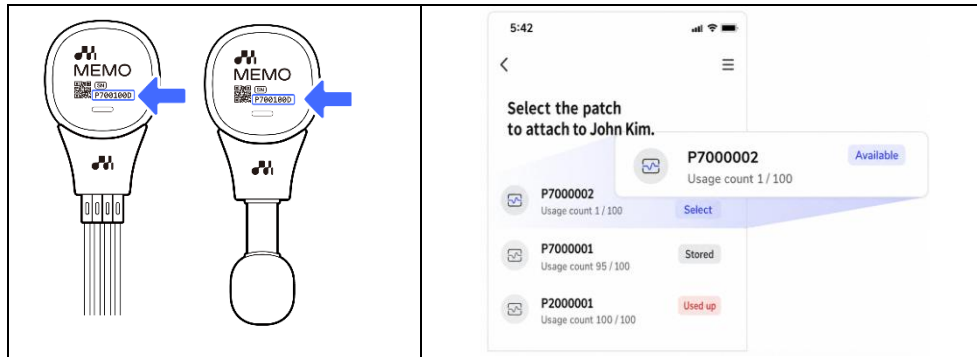
5.6.2.3 Selecting a Patient

- Tap the [Start New Test] button, then select the patient to be tested.
- Depending on the hospital account, a patient consent screen may appear next.



5.6.2.4 Selecting the Device

- Activate the device and select it from the list of discovered devices.
- Verify the serial number printed on the front of the MEMO T Device.



5.7 Signal Verification

5.7.1 Desktop App (MFD)

5.7.1.1 Checking the Signals

- Check the status of the 3 leads output based on the 5 attached electrodes.



5.7.2 Mobile App (MSA)

5.7.2.1 Verifying ECG Signals within the MEMO App for HCP

- If the P-wave and QRS-complex are not clearly visible, re-adhere the device to find the optimal placement based on the observed waveform. Please note that it may take some time for the signal to stabilize after each repositioning.

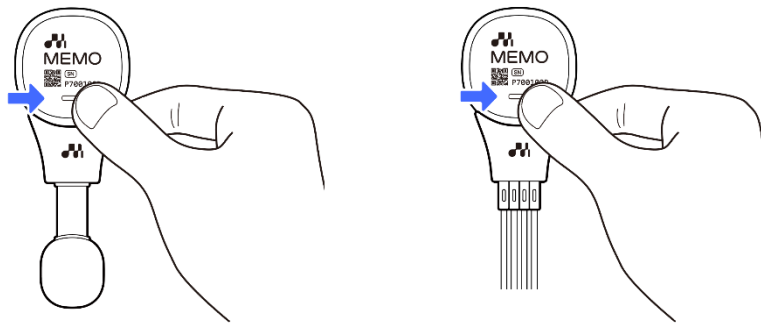


6.0 TEST

6.1 Symptom Logging

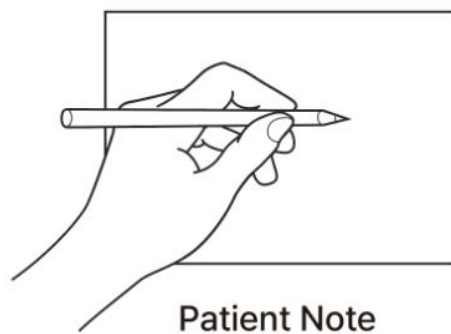
6.1.1 Saving Logs to the Device

- Press and hold the symptom logging button for about 1 second to save the record.
 - Even if symptoms persist, press the button only once.



6.1.2 Writing in the Patient Note

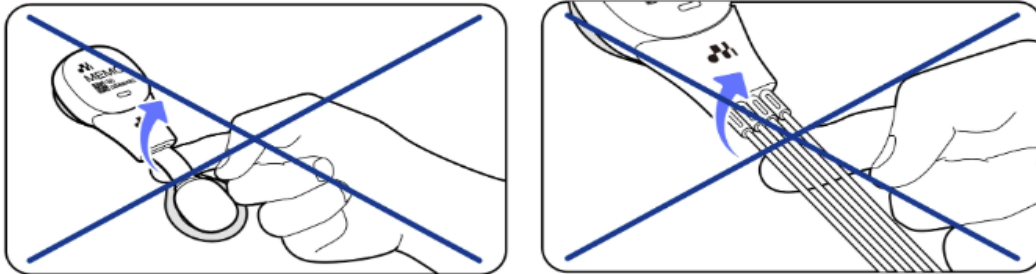
- In case of intermittent sleep, please use the patient note to log your symptoms.



6.2 Detaching the Device and Replacing Electrodes

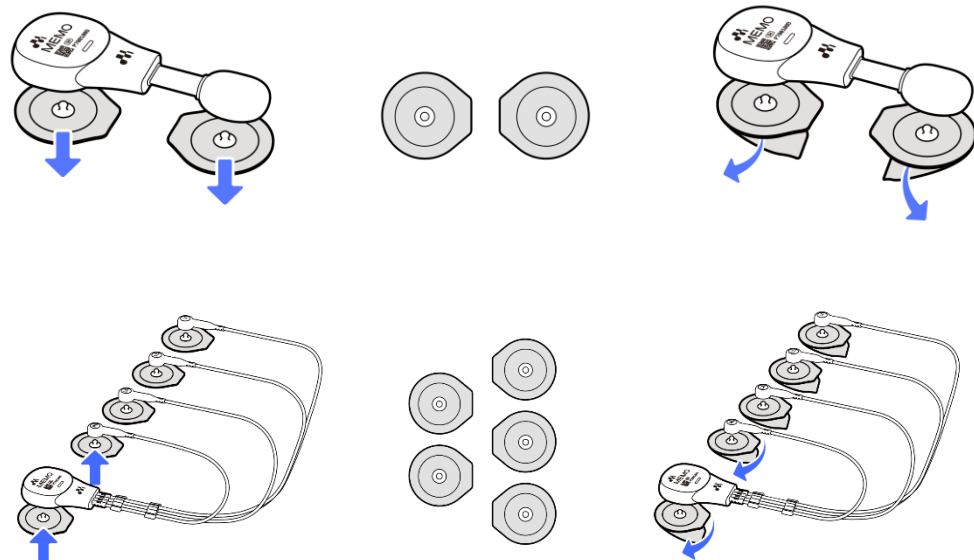
6.2.1 Detaching the Device

- Caution: Attempting to detach the device by pulling or applying force directly to the cable may damage it, which can cause device malfunction.
- If the cable is damaged, data may fail to save, or previously stored data may be lost.



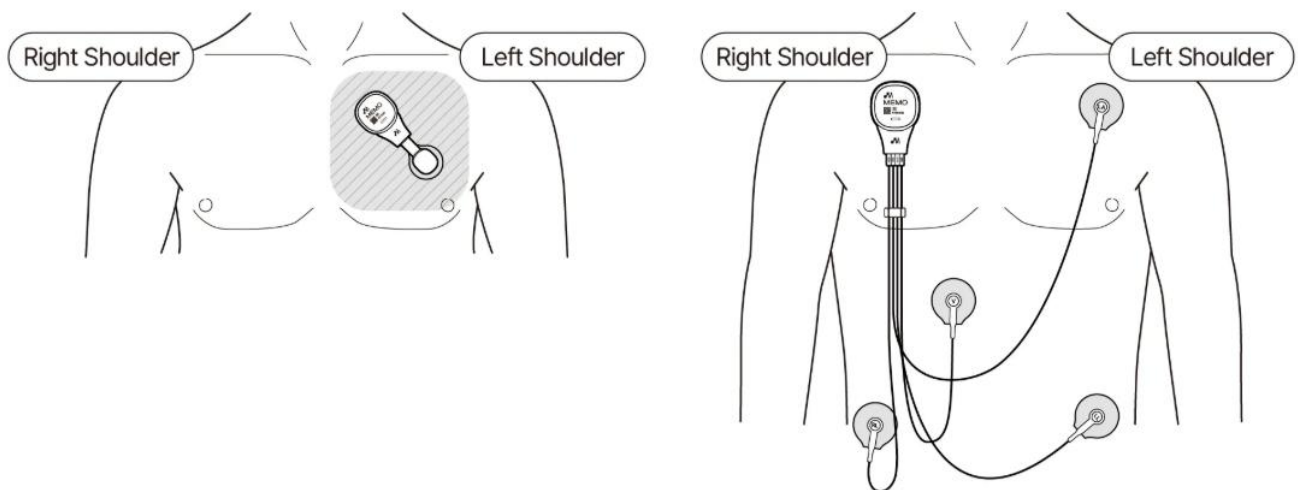
6.2.2 Replacing Electrodes

- 6.2.2.1 Separate the used disposable electrodes from the detached device. Please discard the used electrodes.
- 6.2.2.2 Prepare new medical-grade electrodes.
- 6.2.2.3 Connect the device to the new electrodes, then peel off the protective film from the electrodes.



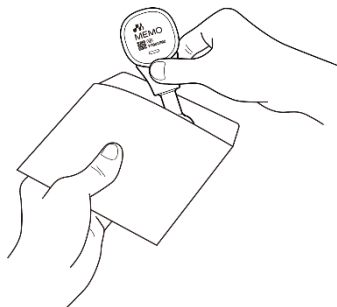
6.2.3 Attaching the Device

- Attach the device combined with the patch and new electrodes to the chest between the left clavicle and the nipple. Once positioned, press firmly across the entire surface to ensure close adhesion to the skin.



6.2.4 Returning the Device

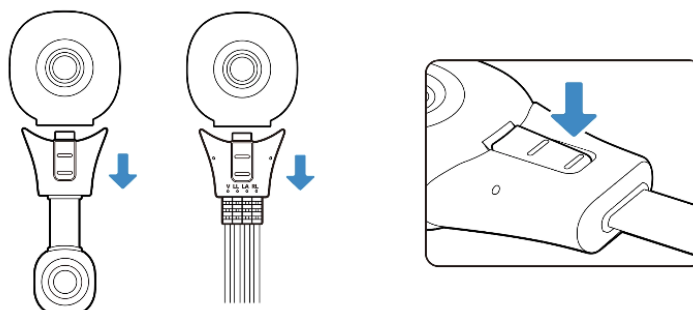
- Place the used device (the patch and lead cable) into the return envelope and return it.



7.0 TEST COMPLETION

7.1 Disconnecting the Device

- Disconnect the MEMO T Device from the lead cable currently in use.
 - Press and hold the Lead Secure Clip located on the back of the lead cable while pulling it apart.

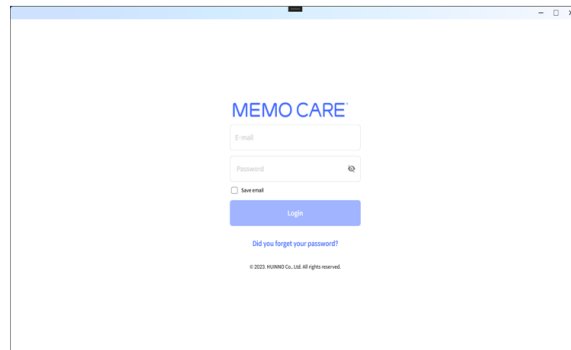


7.2 Data Upload

7.2.1 Desktop App (MFD)

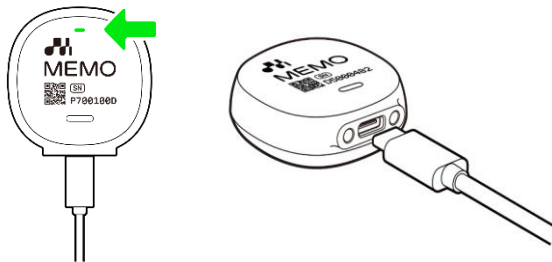
7.2.1.1 Launching the Desktop Application

- Launch the MEMO for Desktop app and log in.



7.2.1.2 Connecting the Device

- Connect the Dedicated Cable to the MEMO Patch T Device.

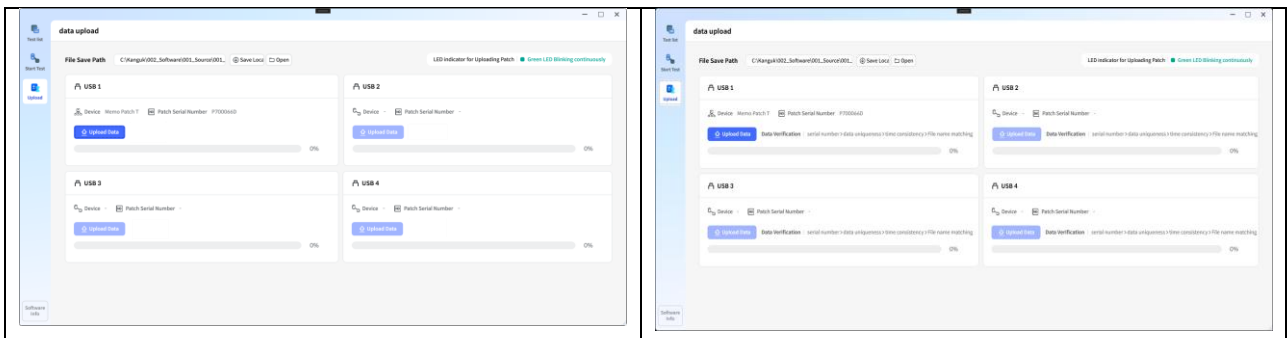


7.2.1.3 Navigating to the Upload Tab in the Desktop App

- Click the [Upload] menu on the left panel to go to the upload page.
- Verify the device connected to the USB port, then click the [Upload Data] button to begin the upload.
- Depending on the account type, a different UI layout may be displayed.

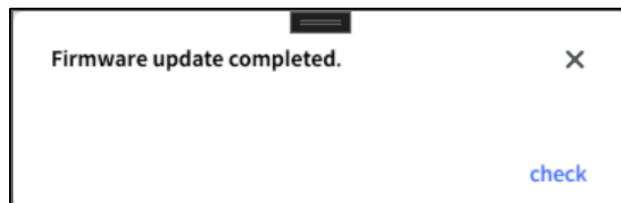
Logging in with a Standard Account

Logging in with a Specific Account (Depending on the account type, a different UI layout may be displayed.)



7.2.1.4 Firmware update

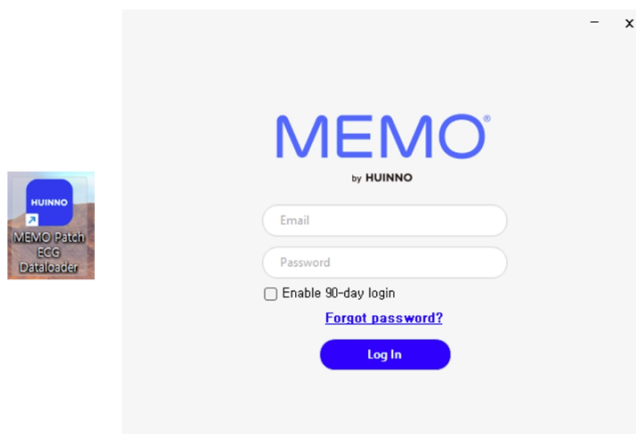
- The firmware update will proceed, and a confirmation message will appear once it is complete.



7.2.2 Dataloader

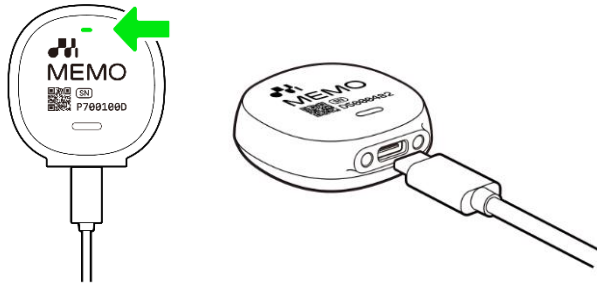
7.2.2.1 Running the Data Loader

- Launch the MEMO Patch ECG Dataloader app and log in.



7.2.2.2 Connecting the MEMO Patch

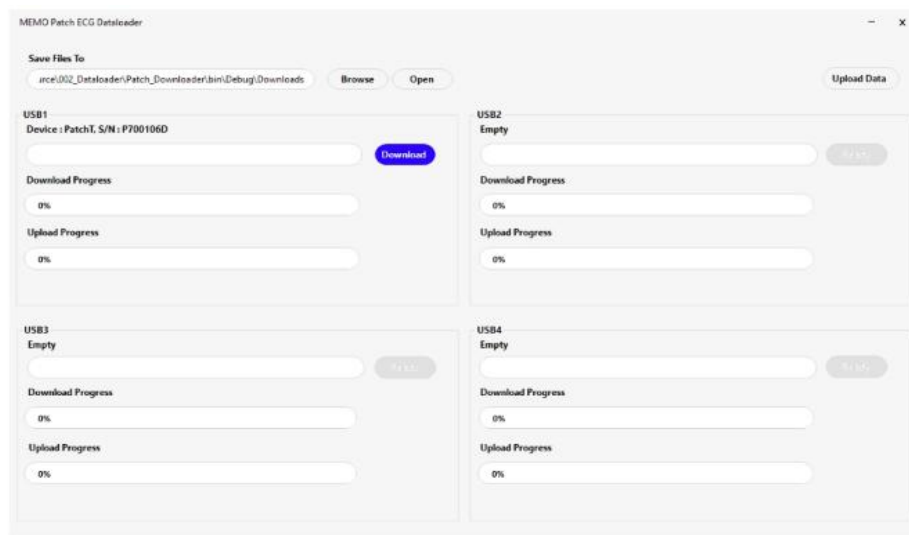
- Connect the Dedicated Cable to the MEMO Patch T device.



7.2.2.3 Data Download / Upload

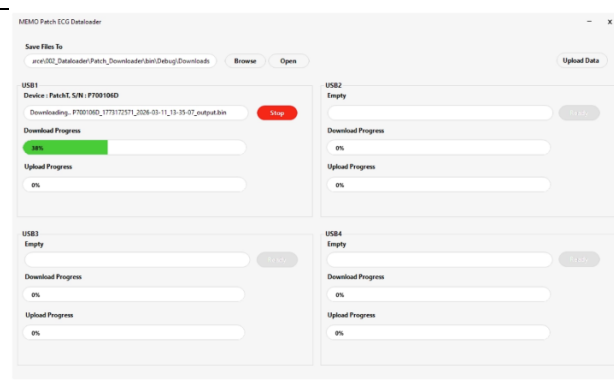
- Once the device is connected, verify that its serial number is displayed, and click the [Download] button to start the download and upload process.

7.2.2.3.1 Connection

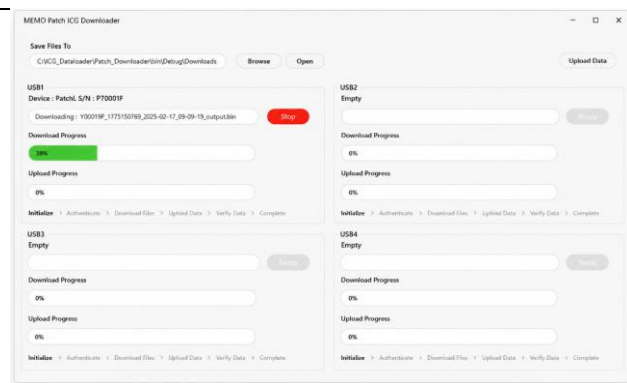


7.2.2.3.2 Starting the Download

Logging in with a Standard Account



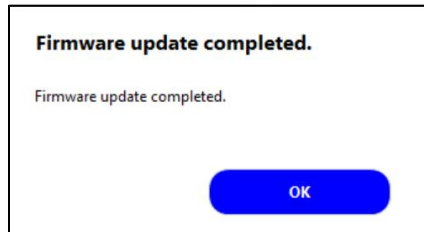
Logging in with a Specific Account (Depending on the account type, a different UI layout may be displayed.)



- Once the download is complete, the upload will start automatically.

7.2.2.3.3 Firmware Update

- The firmware may update automatically from time to time, and you may see the message below.



7.3 Device Shutdown Procedure

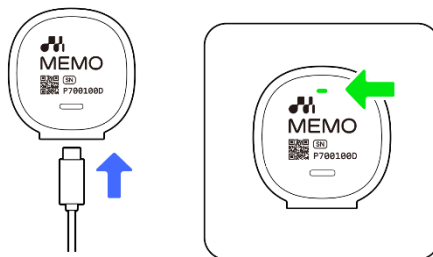
- 7.3.1 There is no physical power button on the device.
- 7.3.2 For the software, please log out of your account after use.

7.4 Post-Use Storage and Maintenance

7.4.1 Charging the MEMO Patch T Device

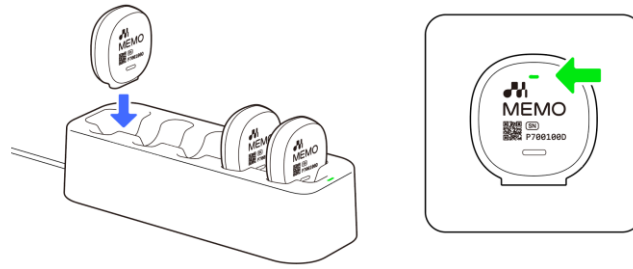
7.4.1.1 Single Charging

- Connect the Dedicated Cable to charge the device.
 - Charging Status Indicator Guide
 - Charging: Green
 - Fully Charged: Blue
 - Charging Error: Orange



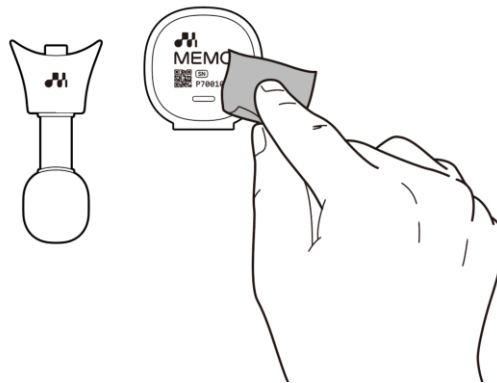
7.4.1.2 Multi-Charging

- Connect the Charging Cradle to charge multiple devices.
 - Charging Status Indicator Guide (MEMO Patch T Device)
 - Charging: Green
 - Fully Charged: Blue
 - Charging Error: Orange
 - Power Indicator Guide (Charging Cradle)
 - Power ON: Green



7.4.1.3 Cleaning and Disinfecting

- Check the exterior of the disconnected MEMO T Device and lead cable for any signs of damage, then disinfect them with alcohol.



8.0 STATEMENTS AND TABLES FOR EMC



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 HUINNO Co., Ltd. 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 to any part of the MEMO Patch T, including cables specified by HUINNO Co., Ltd.

8.1 Electromagnetic Emissions

Table 1- MEMO Patch T(MPT-E14C-UNC01) Electromagnetic Compatibility Information

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The MPT-E14C-UNC01 is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.		
Emissions Test / Method	Compliance	Electromagnetic Environment – Guidance
RF Emissions / CISPR 11 IEC/EN 55011	Group 1, Class B	The MPT-E14C-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 IEC/EN 55011	Group1, Class B	The MPT-E14C-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: This equipment or system is intended for use by healthcare professionals only. This equipment or system 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 MPT-E14C-UNC01 or shielding the location.
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8.2 Electromagnetic Immunity

Table 2 - Electromagnetic Immunity for MEMO Patch T (MPT-E14C-UNC01)

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The MPT-E14C-UNC01 is designed for use in the electromagnetic environment specified below. The customer or the user of the MPT-E14C-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) IEC 61000-4-2	±8 kV contact ±2, ±4, ±8, ±15 kV air	±8 kV contact ±2, ±4, ±8, ±15 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 Electromagnetic Fields IEC 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	The MPT-E14C-UNC01 is suitable for use in a home healthcare environment. RF communications equipment should be used no closer than 30 cm to any part of the MPT-E14C-UNC01, including cables specified by HUINNO Co., Ltd.
Immunity to Proximity Fields from RF Wireless Communications Equipment IEC 61000-4-3	Max 28 V/m according to 385–5785 MHz of Table 9 in IEC 60601-1-2	Max 28 V/m according to 385–5785 MHz of Table 9 in IEC 60601-1-2	
Electrical Fast Transient/Burst IEC 61000-4-4	100 kHz repetition Power supply lines: ±2 kV Input/output lines: ±1 kV	Power supply lines: ±2 kV Input/output lines: ±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Line-to-line: ±0.5 kV, ±1 kV Line-to-ground: ±0.5 kV, ±1 kV, ±2 kV	Line-to-line: ±0.5 kV, ±1 kV Line-to-ground: ±0.5 kV, ±1 kV, ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.

Conducted Disturbances Induced by RF Fields IEC 61000-4-6	3V 0.15MHz ~ 80MHz 0.15MHz~80MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz at 1 kHz 80% AM	3V 0.15MHz ~ 80MHz 0.15MHz~80MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz at 1 kHz 80% AM	In the frequency range above 150 kHz – 80 MHz, the strength of the RF field is less than 3 V.
Power Frequency Magnetic Field Immunity (50/60 Hz) 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	w 0% UT: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° w 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° w 0 % UT; 250/300 cycles	w 0% UT: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° w 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° w 0 % UT; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MPT-E14C-UNC01 requires continued operation during power mains interruptions, it is recommended that the MPT-E14C-UNC01 be powered from an uninterruptible power supply (UPS) or a battery.
Proximity Magnetic Fields IEC 61000-4-39	Max 65A/m 30 kHz to 13.56 MHz according to Table 11 of IEC 60601-1-2	Max 65A/m 30 kHz to 13.56 MHz according to Table 11 of IEC 60601-1-2	The MPT-E14C-UNC01 is suitable for use in the home healthcare environment. Portable radio frequency (RF, RFID) communications equipment can affect medical devices.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Recommended separation distances between portable and mobile RF communications equipment and the MPT-E14C-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-E14C-UNC01, including cables specified by the manufacturer.

If the separation distance is less than 30 cm (12 inches), the performance of the MPT-E14C-UNC01 could be degraded.

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.

9.0 TROUBLESHOOTING GUIDE

9.1 Troubleshooting

MEMO Launcher App	
Problem	Solution
The email or password you entered does not match. Please check your account information and try again.	If you need help retrieving your account, please email us at sales@huinno.com for assistance.
Your account is dormant. Your account has been deactivated because you have not used the service for more than a year. You can use it again after applying to reactivate it from your PC.	To continue using the service, please log in to http://memopatch.care and reactivate your dormant account.
A new version is available. Please update the app to the latest version to continue.	Please update the app to the latest version.
You have been automatically logged out. You were automatically logged out due to inactivity for 24 hours.	You will be automatically logged out if there is no service activity for more than 24 hours. Please log in to continue using the service.
Can't see the patch in the list? Please make sure the MEMO Patch is powered on and within search range.	Press and hold the button for more than 3 seconds; the green LED will blink and the power will turn on.
Bluetooth is turned off. The connection failed because the mobile device's Bluetooth feature is turned off. Please turn on Bluetooth and try again.	Turn on Bluetooth on your mobile device and check the connection again.
Failed to start the test. An error occurred while initializing the MEMO Patch (ECG Patch). Please re-initialize the MEMO Patch or switch to another device and try again.	Replace the patch device or restart the PC Web Viewer program.
There is no patient list to start the test.	Please verify the patient and restart the test.
No search results found for the patient.	Please check the patient's name or phone number.

Logged in from another mobile device. After logging in with the same ID on another mobile device, you were automatically logged out from the previously logged-in device.		To continue using the service, please log in on the mobile device you wish to use.
The network is unavailable. Please check your mobile device's network connection and try again.		Check your network connection and access the app again.
Dataloader ('MEMO Patch ECG Dataloader')		
Login	Unable to log in.	The email and password entered do not match our records. Please check your account again.
	Unable to connect.	An issue occurred while communicating with the server. Please try again later.
	System Error	Restart the program to resolve the unexpected error.
	Update Required	It is now ready to install the latest version.
	Unable to update.	An issue occurred while communicating with the server. Please try again later.
	Cannot connect to the Internet.	Please check your internet connection status.
Data Download	A device error has occurred. Please try again.	Check the patch for communication errors.
	Invalid device information. Please check the device again.	Check the saved patch information.
	Invalid serial number. Please check the device again.	Check the serial number of the patch.
	A system error has occurred on the device. Please try again.	This is an undefined error. For inquiries, please contact sales@huinno.com.

	Download failed. The device is pending activation.	This device has not started the test yet. For inquiries, please contact sales@huinno.com.
Data Upload	An issue occurred while communicating with the server. Please try again later.	This is an undefined error. For inquiries, please contact sales@huinno.com.
	Please check your internet connection status.	Please check your internet connection status.
	This device has not been returned.	Please check the status of the returned device.
	The response timed out. Please check your internet connection status.	Check your internet connection and log in again.
	The file to upload cannot be found.	Please check the upload file.
	Your login session has expired. Please log in again.	Please log in to continue using the service.
Desktop App (MEMO for Desktop)		
Errors Occurring During Program Execution	Failed to download the file.	Please restart the program and try again.
	Unable to open the installed file.	Please restart the program and try again. If the same problem persists, please install it manually. · <i>Latest Version</i> : Download from the web server. · WebView Driver: https://go.microsoft.com/fwlink/p/?LinkId=2124703
	Edge WebView Driver installation is required.	Click the Update button to proceed with the installation.
	An update to the latest version is required.	Click the Update button to proceed with the installation.
	The program must be deleted before updating to the latest version.	Go to Control Panel → Add/Remove Programs → Delete 'MEMO for Desktop', then click the Update button to install the latest version.
	The email or password does not match.	Please check your login credentials and try again.

Errors Occurring During Login	Please try again from an authorized IP network. (Error Code: E10002)	The IP of the PC attempting to log in must be registered on the server. Please contact the HUINNO Customer Center (02-3443-3160).
	The account has transitioned to dormant status because the service has not been used for over a year.	Click the Go button to reactivate your account on the website, then log in again.
	The password has not been changed for 3 months.	Click the Go button to change your password on the website, then log in again.
	If an incorrect password is entered 5 times, the account will be locked for security purposes.	Please check your login credentials and try again after 10 minutes.
	The account has been locked. Please reset your password or try again after 10 minutes.	Reset your password or check your login credentials again and retry after 10 minutes.
	Invalid email format.	Please enter it in the format of ID@emailaddress.com and try again. (e.g., example@huinno.com)
	No account is registered with the email address entered.	Please check if the entered account is registered on the server.
Errors Occurring When Starting a Test	Failed to start the test because a patch that is already measuring was selected.	Connect another patch to start the test, or unassign the test from the existing patch and try again.
	The network connection is unstable.	Please check your PC's internet status. If it is blocked by a security program, please register it as an exception.
	An issue has occurred on the server. Please try again in a moment.	Please try again in a moment. If the problem persists, please contact the customer center.
	The information entered (mobile phone number, patient number, processing period, etc.) is incorrect.	Please verify the entered information and try again.
	This is not a registered device. Please contact the customer center.	Check the patch number in use and consult the administrator regarding server registration status.
	Cannot start the test due to a communication issue with the connected patch.	Reconnect the patch to the PC and try again. If the same problem recurs, proceed with another patch.
	Failed to connect to the Bluetooth patch.	Please ensure the patch is turned on and within range.
	A code indicating a required device inspection has been found. (Including CS codes)	This device cannot be used; please replace it with another device. Contact the customer

		center (02-3443-3160) to inquire about the CS code.
Bluetooth Errors	The Bluetooth driver is not installed.	Check the connection status of the Bluetooth dongle, install the driver, and try again.
	Bluetooth is disabled.	Enable Bluetooth settings on your PC and try again.
Device Connection / Download / Upload / Errors	Connection failed due to an incorrect serial number. Please reconnect the patch.	Please reconnect the patch. If the same problem occurs even after rebooting the PC, replace it with another patch. Wipe the contact parts clean and try again.
	This account has been logged in from another computer.	Check if you are logged in from a web browser or another PC, terminate that session, and try again.
	Upload failed. Please check your network connection status.	Check your internet connection status and try again.
	There are no files to upload.	Please try downloading again.
	The session has expired. Please log in again and try.	Please log in again and try again.
	Download failed. Please reconnect the patch or reboot your computer and try again.	Please reconnect the patch or reboot your computer and try again.
	Upload failed. Please disconnect the cradle and reconnect it.	Disconnect the cradle, reconnect it, and try again.
	Upload failed due to a network issue.	Check your internet connection status and try again.
	Download failed. The device is pending activation.	If the test was started incorrectly, connect the patch to unassign the test and try again.
	Please secure storage space and try again.	Free up at least 2 GB of storage space on the drive set as the download path, then try again.
Configuration Error	C:\W cannot be used as a storage path.	Please change the data download storage path to a path other than C:.
Signal Comparison Error	A file matching the TID does not exist in the PC storage path.	Check if the file exists in the download storage path and whether the file name is identical to the name at the time of download.
	Failed to load the file from the server.	Please try again in a moment. If the problem persists, please check the internal logs.

Other Errors	Webview Failed to initialize WebView. Please restart the program.	Please restart the program. If the problem persists, check if WebView Runtime is installed correctly, reinstall it, and try again.
	Failed to output WebView. Please click the Refresh button and try again.	Click the Refresh button to try again. If the problem persists, please check the internal logs.
	Cannot navigate to 'Start Test' while a data upload is in progress.	Please move after the download is complete.
	The network connection is unstable.	Check your network connection status and try again.
	An issue has occurred on the server. Please try again in a moment.	Please try again in a moment. If the problem persists, please contact the customer center.

9.2 FAQs

Ambulatory ECG Monitor	- How do I turn off the power? This product cannot be turned off. - How can I check if the device is operating correctly? Press and release the button for 1 second. Depending on the status of the MEMO Patch, the green or orange LED will blink once. - How can I check if the connection is secure? If the connection is unstable, the orange LED will blink at 3-second intervals. Additionally, if you press and release the button for 1 second, the orange LED will blink once. - Patch Firmware Software Update Since updates to the firmware software version of the patch body may only be available to authorized personnel, please contact the customer center (02-3443-3160).
MEMO Launcher App	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	- 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.. - 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	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	- How can a patient wearing the ECG Patch check if the device is working properly during use? Press and release the power button on the patch for at least 1 second; the green LED will blink. A blinking green LED indicates that the device is operating properly. If the green LED does not blink, please contact the HUINNO Customer Center (02-3443-3160). - What should I do if symptoms occur while wearing the ECG Patch device? If symptoms occur, you must press the symptom recording (Power) button on the ECG Patch. Pressing the button for about 1 second or longer and seeing the green LED blink indicates that the symptom has been recorded. If it is difficult to press the symptom recording button, you can also record your symptoms in the Patient Note. - What should I do if I forget to record a symptom? If you forget to record a symptom, write down the approximate time the symptom occurred and the symptom itself in the Patient Note. - What should I do if I accidentally press the symptom recording button multiple times, or if I press it by mistake when there are no symptoms?

	The symptom recording button is used to compare whether the palpitations felt by the patient occurred simultaneously in the patient's heart. Therefore, pressing the button multiple times or by mistake will not affect the examination results. 5. What should I do if the ECG Patch detaches from the body? Contact your attending medical staff and follow their instructions. 6. Can I use an electric blanket or an electric bed while wearing the ECG Patch? Do not use an electric blanket or an electric bed connected to a power cord. Electric devices can interfere with the patient's bio-signals, affecting the accuracy of the test results. * <i>Note:</i> However, it is fine to use them after unplugging the power cord. * <i>Note:</i> You may use electric cars, microwaves, and induction cooktops as they do not affect the ECG Patch. 7. Can I exercise while wearing the ECG Patch? It is recommended to avoid strenuous exercise, as it can affect the measurement of ECG signals. In particular, be careful as sweating may cause the device to fall off. 8. Can I shower, bathe, or swim while wearing the ECG Patch? Although the ECG Patch is waterproof, the device must be removed during showering, bathing, or swimming. 9. Can I reattach the ECG Patch to a position different from the original attachment site? Yes. You can reattach the patch to a slightly different position, but it is recommended to consult with your medical staff. 10. What should I do if skin irritation or itching occurs?
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	Some patients may experience mild skin irritation or itching. If irritation or itching occurs or worsens, please contact the hospital where it was prescribed. 11. What activities should be avoided during the test? Please avoid strenuous exercise that may cause excessive sweating during the test. Sweating can cause the electrodes attached to the body to fall off. 12. Is it okay to travel while wearing the patch? Generally, traveling during the test is fine, but it is best to avoid excessive physical activity that could cause the patch to fall off. 13. Can I board an airplane while wearing the patch? Are there any issues with airport security checks? No, there are no issues. There may be slight additional noise in the signals or changes in the ECG waveform that do not affect the analysis results. However, an alert sound may be heard while passing through airport security checkpoints. 14. How do I return the patch after the test is completed? You can place the patch in the storage bag (pouch) and return it to the medical staff at the hospital where you received the prescription. 15. Who should I contact if I have questions during the test? Please call the HUINNO Customer Center. Depending on the nature of the question, you may need to contact the hospital directly.
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- 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).

10.0 DEVICE SPECIFICATION

10.1 Performance Characteristics

ECG Channel	1 Channel or 3 Channels
Internal Storage Capacity	4 Gbit (Up to 14 days)
Recording Type	Continuous
Service Life	Up to 14 days
Useful Life	2 years
Signal Processing / Annotation	Pacemaker pulse detection flag (IC level, non-diagnostic annotation)
	Respiration measurement signal calculated by analyzing thoracic impedance variations

10.2 Electrical Characteristics

Protection Against Electric Shock	Defibrillation-proof type CF applied part
	Internally powered medical device
ECG Frequency Response Range	0.05Hz to 40Hz
ECG Input Impedance	$\geq 10 \text{ M}\Omega$
ECG A/D Sampling Rate	250 Hz
ECG Resolution	12bit
ACC A/D Sampling Rate	12.5 Hz, 50 Hz
ACC Resolution	8bit
Defibrillation Recovery Time	Within 5 seconds

10.3 Power Characteristics

Battery Type	Li-ion Polymer (Lithium-ion Polymer)
Battery Life	Up to 500 cycles (Charge/Discharge)
Battery Capacity	3.7V / 310mAh Cell size: 4.4 mm x 26.5 mm x 26.5 mm Pack size: 4.4 mm x 26.5 mm x 28.5 mm

5-Port Charging Cradle [ACC-C05P-C1]	DC IN: 9V, 2.22A, DC OUT: 5.5V, 0.45A
Adapter Rating	Input: 100-240V~50/60Hz 0.6A Output: USB-C1:5.0VDC 3.0A, 9.0VDC 2.22A, 12.0VDC 1.67A

10.4 Physical Characteristics

Main Body Dimensions & Weight	42.55mm(W) X 43.8mm(L) X 14.85mm(H), 25.5g (including battery)
5-Port Charging Cradle Dimensions & Weight	174.1mm(W) X 64mm(L) X 44mm(H), 342g
Multi-Lead Cable Dimensions & Weight	36mm X 741mm $\pm$ 3.0 X 12mm, 4-Port Cable, 33.5g
Single-Lead Cable Dimensions & Weight	36mm X 80mm X 12mm, 12.7g

10.5 Wireless Communication Characteristics

Transmission Frequency, Number of Channels & Frequency Band	wireless transceiver, Number of channels: 40 (2402-2480MHz)
Supported Physical Layer (PHY)	1M, 2M
Antenna & Chipset	SDBTPTR3015, NRF52840
Modulation Scheme	GFSK(Gaussian Frequency Shift Keying) Modulation
Effective Radiated Power (ERP)	Less than 2.5 mW (4 dBm)
Wireless Communication Method	BLE 5.1

10.6 Compatible Devices

Disposable ECG Electrodes	3M red dot, model name: 2560, K970796), applied part
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10.7 Environmental Characteristics

Operational temperature	10°C - 45°C
Operational altitude	0 to 3,000 m

Operational & Storage Humidity	10% to 95% (non-condensing)
Operational, Transport & Storage Atmospheric Pressure	700hPa – 1060hPa
Transport & Storage Temperature	-20°C - 60°C
Device Body (Patch) Enclosure Protection Rating	IP25
* Note: Do not expose to severe vibration, rain, direct sunlight, and high humidity during transport.	

10.8 Minimum System Requirements for Computer and Mobile Devices

Category	Data Dataloader	MEMO for Desktop	MEMO Launcher
OS	Windows 11 or higher	Windows 11 or higher	- Android OS 13 or higher - iOS 18 or higher
Memory	8 GB or higher	8 GB or higher	4GB or higher
HDD	128GB or higher	128GB or higher	64GB or higher
Screen Resolution	1920 x 1080 (Full HD) 이상	1920 x 1080 (Full HD) 이상	iOS: 2340 x 1080 or higher Android: 2400 x 1080 or higher
External Port	USB 2.0 or higher	USB 2.0 or higher	-
Network	Wi-Fi or Ethernet	- Wired/Wireless communication - Bluetooth (Optional): 4.2 or higher (on available desktops and laptops)	Bluetooth 5.0 or higher

10.9 Device Operation Scenarios

Status	MEMO Patch T
Power ON	Press and hold the power button normally (for 3 seconds or longer).

Device Before Test Start	Automatically enters Discovery Mode. If pairing is not completed within 5 minutes, it powers OFF (If any pairing activity occurs within 5 minutes, the timer is extended for another 5 minutes from the completion of the pairing activity).
Symptom Occurrence After Test Start	- Mark the event by briefly pressing or holding the button. - Transmit the timestamp data to the mobile app.
When BLE Disconnected	- Measurement continues. - Notification for disconnection is triggered: > Blue LED blinks twice. > During real-time monitoring: Buzzer sounds 20 times.
Low Battery During Use	- Low-Battery Threshold : SOC 7% - Auto power-off : Automatically powers down within approximately 5 minutes after displaying 0%.
Power OFF	N/A

10.10 Button Scenarios

Press Duration	MEMO Patch T
Short Press (< 2.5 seconds)	- Power OFF state: N/A - Power ON state: Symptom Marking
Long Press (≥ 2.5 seconds)	- Power OFF state: Power ON - Power ON state: Symptom Marking

10.11 Operation Scenarios

Status	MEMO Patch T	Description
Power ON	Green LED blinks once	Indicates power turned on
Discovery Mode After Power ON	- Before test start: Green LED blinks slowly repeatedly (every 5 seconds for 5 minutes) - After test start: None	Verifies the waiting state to start the test
Button Pressed Before Test Start	Orange LED blinks quickly once	Confirms that the power is on
Test Start	Green LED blinks quickly 4 times	Indicates the start of the test

BLE Connection (Pairing)	Blue LED blinks quickly 3 times	Confirms BLE connection
BLE Disconnection	Blue LED blinks quickly 2 times	Confirms BLE disconnection
Symptom Marking (After Test Start)	Green LED blinks once	Confirms that the patient event has been saved
Lead Off	Orange LED blinks quickly once repeatedly (every 3 seconds)	Indicates Lead Off status
Button Pressed During Lead Off	Orange LED blinks quickly once	Confirms Lead Off status
Low Battery	Orange LED blinks twice repeatedly (every 6 seconds)	Indicates low battery status
Device Reset Occurs	- Reset occurs due to a device anomaly - White LED On -> Reset -> Power On Green LED blinks once	Indicates a device error
Power OFF	Orange LED blinks quickly 3 times	Indicates power turned off
Download	Green LED blinks	Data downloading
Charging	Green LED remains solid ON	Battery is charging
Charging Complete	Blue LED remains solid ON	Battery charging complete
Charging Error	Orange LED remains solid ON	Error during battery charging (e.g., overheating)

10.12 Heart Rate Calculation

Episode Heart Rates	Max	Maximum episode heart rate (e.g., the maximum value of all instantaneous heart rates within the episode)
	Min	Minimum episode heart rate (e.g., the minimum value of all instantaneous heart rates within the episode)
	Ave	Average episode heart rate (e.g., the average value of all instantaneous heart rates within the episode)

Overall, Rhythm Heart Rates	Max	Maximum overall heart rate (e.g., the maximum value among the maximum heart rates of all rhythm episodes within the recording)
	Min	Minimum overall heart rate (e.g., the minimum value among the minimum heart rates of all rhythm episodes, excluding pauses, within the recording)
	Ave	Average overall heart rate (e.g., the duration-weighted average of all rhythm episode heart rates within the recording)

- ♦ Heart Rate Calculation Method

Detect the R peak from the ECG waveform, then calculate the heart rate according to the following formula: $\text{current_HR} = (60 \times \text{sample_rate}) / (\text{current_R_peak_index} - \text{prev_R_peak_index})$

10.13 Pause Determination

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

11.0 PRODUCT WARRANTY

11.1 Warranty Claims

If the issue is not resolved after reviewing the user manual, please contact HUINNO Customer Service.

11.2 Scope and Period of Warranty

- ♦ The warranty period for this device is one (1) year, and the warranty period for accessories and consumables is three (3) months.
- ♦ This warranty covers functional and performance defects that occur under normal use in accordance with the user manual of this device.
- ♦ The warranty period refers to the period during which HUINNO Co., Ltd. or the seller is obligated to replace the product free of charge for quality, performance, and functional defects arising from normal use.
- ♦ The warranty takes effect from the date of purchase. Please retain the product warranty card or proof of purchase. In the absence of such proof of purchase, the warranty will begin 90 days after the date of manufacture according to HUINNO Co., Ltd.'s records.
- ♦ The warranty applies only to the original purchaser who bought the product from an authorized distributor.
- ♦ The warranty does not apply to second-hand goods or products purchased from unauthorized retailers. HUINNO Co., Ltd. is not liable for any damages resulting from the replacement of or service to such products.
- ♦ The warranty for products supplied under a separate contract with HUINNO Co., Ltd. shall be governed by the terms of that contract.

11.3 Warranty Exclusions

The warranty does not apply, and service fees may be charged regardless of the warranty period, in the following cases:

- ♦ The warranty period has expired, or the warranty period cannot be verified.
- ♦ Failure or damage caused by the user's careless handling, negligence, or improper operation of the device.
- ♦ Failure caused by using the device in a manner not in accordance with the user manual.
- ♦ Failure or damage caused by using electricity with an unauthorized voltage.
- ♦ Failure caused by using parts, accessories, or consumables not approved by the manufacturer.
- ♦ Any unauthorized removal, modification, or tampering with the product or its parts.
- ♦ Products serviced and/or disassembled by unauthorized personnel not designated by the manufacturer.
- ♦ Service unrelated to product defects (e.g., product education, inspection, Bluetooth connection issues in external environments, defects caused by the use of third-party products and/or software).

11.4 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

12.0 REVISION HISTORY

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