User Manual

CAI-300

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MediFarmSoft Co., Ltd.
B-906,907 25, Beobwon-ro 11-gil, Songpa-gu,
Seoul, Republic of Korea

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.

1. Product introduction

1. General Information

Manufacturer	MediFarmSoft Co., Ltd
Manufacturer Address	B-906,907 25, Beobwon-ro 11-gil, Songpa-gu, Seoul, Republic of Korea
Product name.	Cardial patch
Model name.	CAI-300
Device Classification	Holter ECG, Class IIa
Electric rating	3.7 Vd.c, 500 mAh ※ Rated during charging: 12 Vd.c, 1.5 A
Protection rating against electric shock	In use: Internally powered devices Charging: Class II
Degree of protection against electric shock	Type CF applied part (All of device body)
Protection against harmful ingress of water or particulate matter	IP55
Expected service period	3 years from date of manufacture

Harmonized Standards	
IEC 60601-1:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: usability
IEC 60601-1-11:2020	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance Collateral standard: Requirement for medical electrical equipment and medical electrical system used in the Home healthcare environment
IEC 60601-2-47:2012	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
IEC 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
ISO 10993 series	Biological evaluation of medical devices

2. Intended Use

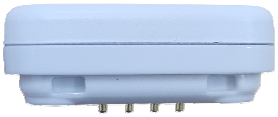
The Cardial Patch is a 6-lead, patch-type Holter ECG device designed to be attached to the chest to detect ECG signals, which it records in the device's memory. This device can continuously log heart activity for over 10 days in storage mode or, alternatively, monitor heart activity in real time for up to 48 hours in both clinical and everyday settings via a smartphone application and workstation monitor.

3. Appearance Picture

3.1 Main Body

[Front view]

[Rear view]



[Top view]

[Bottom view]

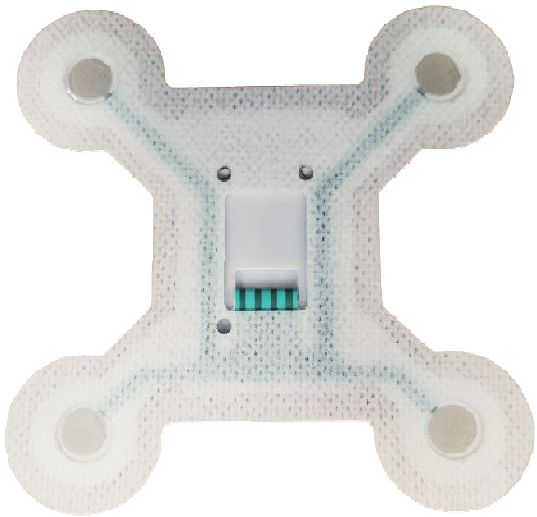
[Side view]

[Diagonal view]

3.2 Patch

[Front view]

[Front view]



[Rear view]

[Diagonal view]

[Diagonal view]

3.3 Cradle

[Front view]

[Rear view]

[Top view]

[Bottom view]

[Side view]

[Diagonal view]

4. Appearance Description

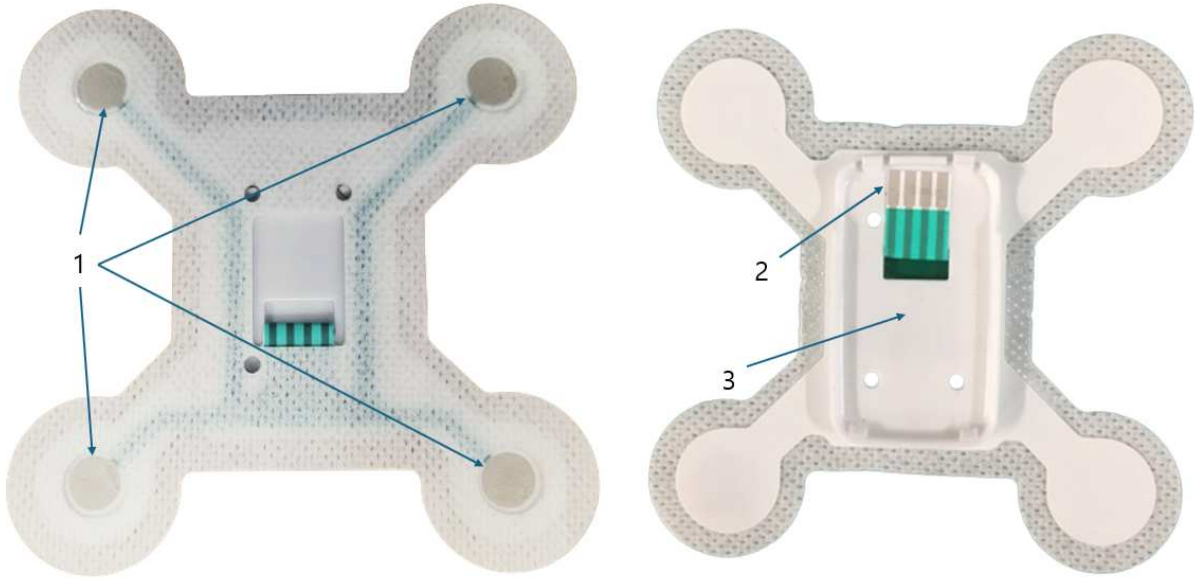
4.1 Main Body

<table>
<tr><th>No.</th><th>Name</th><th>Description</th></tr>
<tr><td>1</td><td>Status Indicator LED</td><td>
<table>
<tr><th>Operation Mode</th><th>LED Operation</th><th>Time Out</th></tr>
<tr><td>Power On</td><td>The green LED lights up and then blinks or turns off depending on the operation status.</td><td>It blinks within 1 second after powering on (advertising mode), and if no connection is established within 180 seconds, it turns off.

When connected to the charging cradle, the yellow LED lights up while charging, and the blue LED lights up when charging is complete.</td></tr>
<tr><td>Advertising Mode</td><td>The green LED blinks at 1-second intervals.</td><td>If no connection request is received within 180 seconds, the power turns off.</td></tr>
<tr><td>Connection Mode</td><td>The green LED blinks 10 times at 0.3-second intervals, then the blue LED lights up.</td><td>If no command packets are received within 180 seconds, the power turns off.</td></tr>
<tr><td>Measurement Mode</td><td>The green LED blinks every 5 seconds (0.3 seconds on, 4.7 seconds off) for 10 minutes.</td><td>If no button or command packets are received within 10 minutes, the LED turns off.</td></tr>
<tr><td>Charging</td><td>The yellow LED lights up.</td><td>Once fully charged, it transitions to the charging complete mode.</td></tr>
<tr><td>Charging Complete</td><td>The green LED lights up.</td><td>It turns off within 3 seconds after the charging cradle is disconnected.</td></tr>
<tr><td>Cradle Connected</td><td>The green LED lights up when fully charged, and the yellow LED lights up while charging.</td><td>Power is on.</td></tr>
<tr><td>Cradle Disconnected</td><td>All LEDs turn off.</td><td>Within 3 seconds after disconnection, the LEDs turn off, and the power turns off.</td></tr>
</table>
</td></tr>
</table>

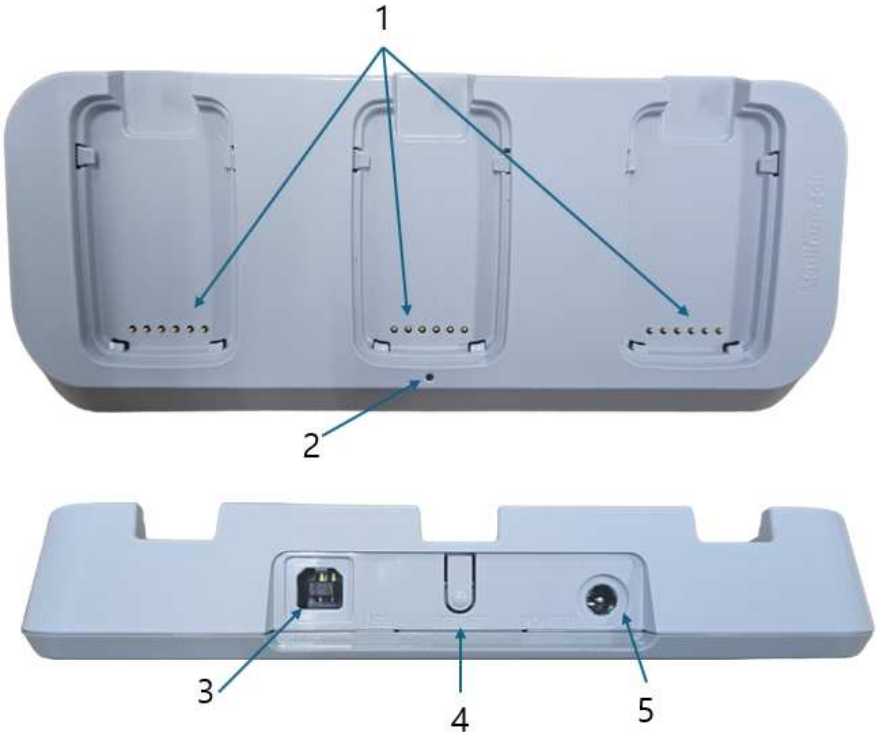
		<table><tr><td>Download</td><td>The blue LED blinks at 1-second intervals.</td><td>When complete, the charging status is displayed: green for fully charged, yellow while charging.</td></tr><tr><td>Power Off</td><td>The green LED blinks three times and then turns off.</td><td>-</td></tr><tr><td>OTA Mode</td><td>The white LED blinks at 1-second intervals.</td><td>It turns off when complete.</td></tr></table>
2	Power Button	A power button to turn the device ON/OFF.
3	Patch Electrode Contact	Contact point for receiving the user's ECG when connected with the patch.
4	Charging & USB Interface Contactr	Contact point for battery charging and extracting user ECG data when connected to the cradle.

4.2 Patch



No.	Name	Description
1	Electrode	Area that attaches to the user's skin surface.
2	Main Body Electrode Contact	Contact point for transmitting the user's ECG to the main body when connected.
3	Main Body Holder	Mechanism for securing the main body in place.

4.3 Cradle



No.	Name	Description
1	Main Body Interface Contact	Contact point for receiving the user's ECG data stored in the main body and for charging the main body's battery.
2	LED	Indicates whether the cradle's 12V power input is active.
3	USB Interface Connector	Connector for transmitting the main body's ECG data to a host PC.
4	RESET Button	Reset button for the cradle.
5	Power Input	Input port for the cradle's 12V power supply.

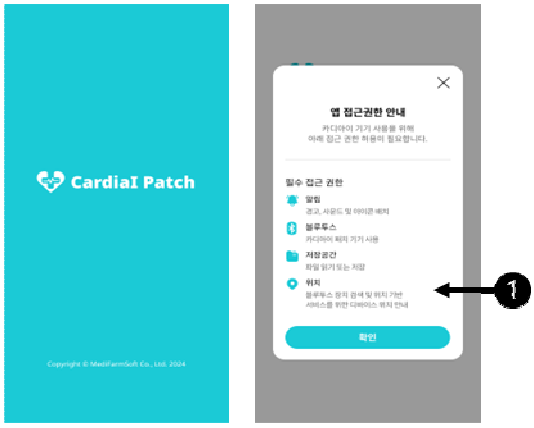
The CAI-300 can be charged with a dedicated cradle.

5. Mobile App

1) Dedicated App Icon

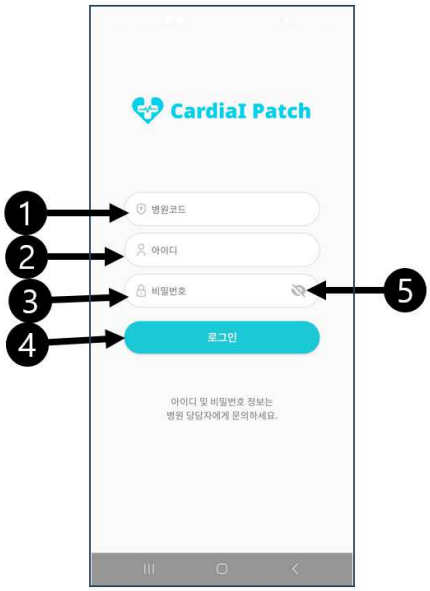
2) Initial Screen

(1) Splash & App Permissions Screen



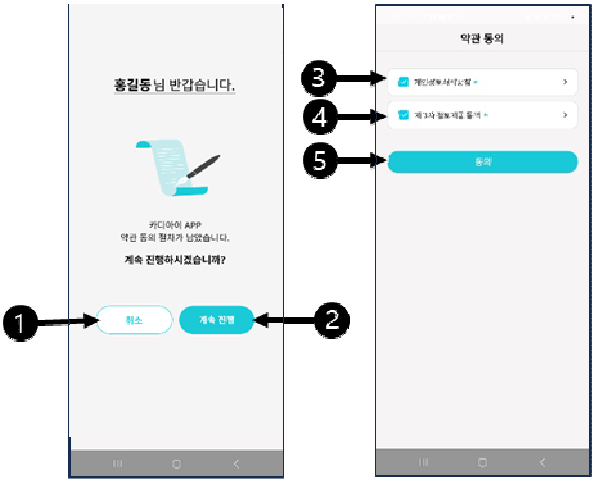
No.	Name	Description
1	App Permissions Notification Popup	Notifications, Bluetooth, Storage, and Location permissions are required.

(2) Login Screen



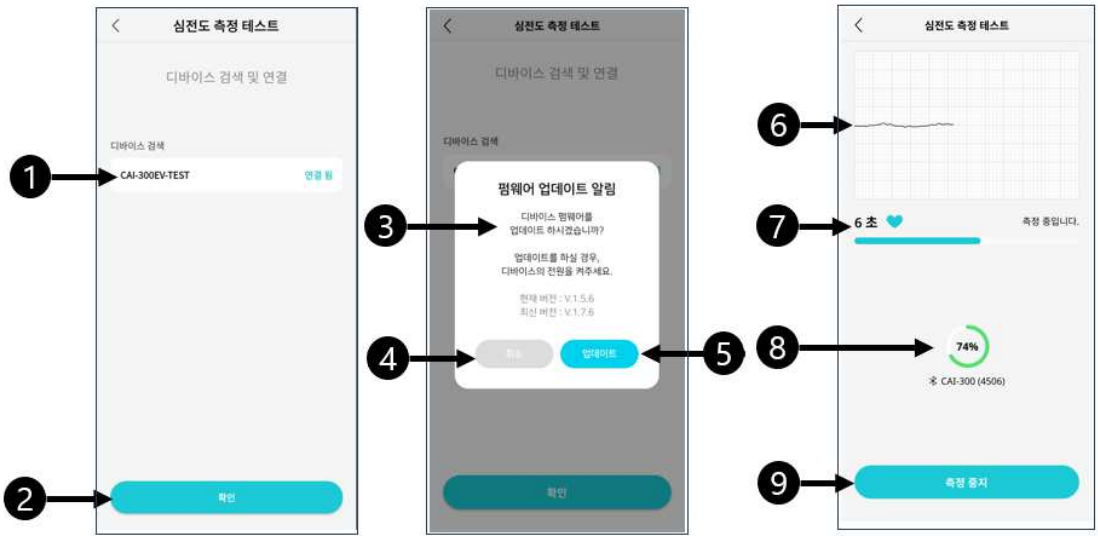
No.	Name	Description
1	Hospital Code	Enter the hospital code associated with the device.
2	ID	ID provided through the medical staff web viewer.
3	Password	Password provided through the medical staff web viewer.
4	Login	After logging in, automatic login is enabled.
5	Password Viewer Function	Displays the password without masking during entry.

(3) Terms and Conditions Agreement (One-time Initial Process)



No.	Name	Description
1	Cancel Button	Closes the app.
2	Continue Button	Moves to the Terms and Conditions Agreement page.
3	Privacy Policy	View the full privacy policy for the Cardial Patch app.
4	Third-Party Information Sharing Consent	View the full third-party information sharing consent for the Cardial Patch app.
5	Agree Button	Confirms agreement to the terms and conditions.

(4) Cardial Patch Connection Test (When Connecting Device with Mobile App)

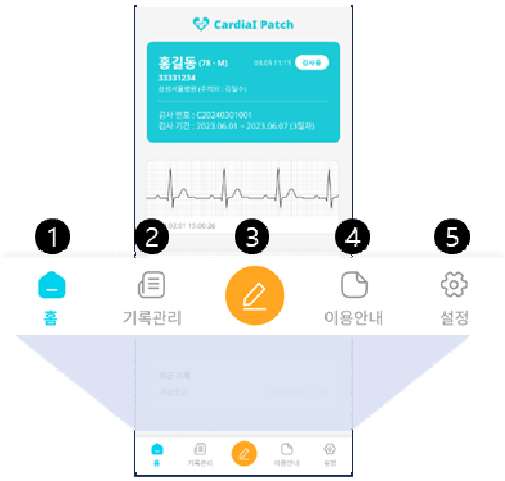


No.	Name	Description
1	Device Search	Automatically searches for the Cardial Patch assigned to the patient.
2	Confirm Button	Navigate to the ECG Measurement Test Page.
3	Device Firmware Update Popup	Checks the firmware version of the scanned device; if it is not the latest version, a popup appears.
4	Cancel Button	Closes the popup without proceeding with the firmware update.
5	Update	Proceeds with the firmware update on the current scre.
6	ECG Graph	Displays the real-time measured ECG.
7	Measurement Progress Bar	Displays a 10-second measurement progress bar.
8	Battery Level Indicator	Shows the battery level of the CAI-300.
9	Measurement Stop Button	Stops the ongoing ECG measurement test and enables the re-measurement button.

(5) Main Screen (Real-Time Mode vs. Storage Mode)

No.	Name	Description
1	Patient Information	(Common) Provides patient information and affiliated hospital details.
2	Test Information	(Common) Displays test number and test duration information.
3	Real-Time ECG	(Real-Time Mode) Displays real-time ECG graph.
4	Real-Time Patch Information	(Real-Time Mode) Displays patch connection status, battery level, and network signal strength.
5	Recent Record	Displays the most recent record logged by the patient.

(6) Menu Bar



No.	Name	Description
1	Home	Default home screen.
2	Record Management	Lists records logged by the patient in order of newest to oldest.
3	Log Record	Records a new symptom entry.
4	User Guide	FAQ on using the Cardial Patch and the app.
5	Settings	Includes patient information, patch management, and general settings.

(7) Record Management

No.	Name	Description
1	Number of Entries	Displays the total number of symptom records, sorted by date in descending order.
2	Symptom Record Card	Displays the symptom details logged by the patient.
3	Edit Button	Edits the recorded symptom entry.
4	Delete Button	Deletes the recorded symptom entry.

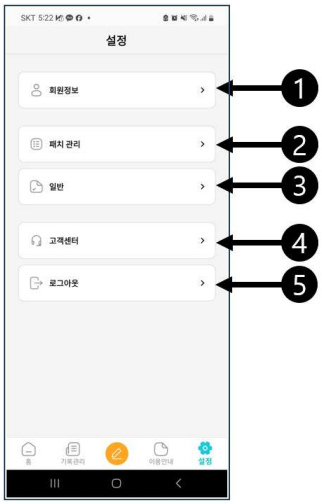
(8) Symptom Record

No.	Name	Description
1	Occurrence Time	Allows setting of occurrence time; defaults to the current time.
2	Symptom	Multiple selections allowed: Chest pain (radiating pain), palpitations, syncope, shortness of breath, dizziness, cold sweat.
3	Symptom Duration	Choose one: Less than 5 minutes, 5–15 minutes, 15–30 minutes, or more than 30 minutes.
4	Activity	Choose one of nine activities, such as resting, exercising, or stressful situations.
5	Memo	Free entry up to 1,000 characters.
6	Cancel	Clears the entered information.
7	Save	Saves the entered information.

(9) User Guide

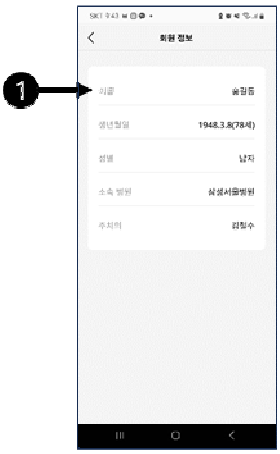
No.	Name	Description
1	User Guide	Introduction to the Cardial Patch, instructions for using the Cardial Patch, app usage guidelines, and precautions for the Cardial Patch.

(10) Settings



No.	Name	Description
1	Patient Information	Provides patient's name, date of birth, gender, affiliated hospital, and primary doctor's information.
2	Patch Management	Includes My Patch information, patch log, and device connection test menu.
3	General	Contains app version information, privacy policy agreement, and third-party information sharing consent.
4	Customer Service	Button to connect to Medifarmsoft customer service.
5	Logout	Logout function.

(11) Settings > Patient Information

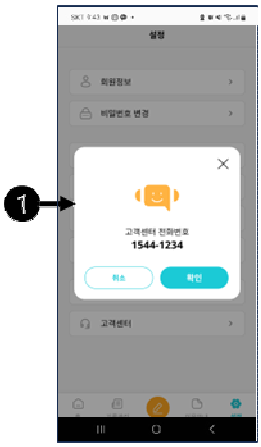


No.	Name	Description
1	Patient Information	Provides the patient's name, date of birth, gender, affiliated hospital, and primary doctor's information.

(12) Settings > Patch Management

No.	Name	Description
1	My Patch	Navigates to the My Patch information page.
2	Patch Log	Navigates to the detailed Patch Log page.
3	Patch Operation Test	Navigates to the Patch Operation Test page.
1-1	My Patch Information	Displays the Cardial Patch serial number and MAC information.
2-1	Patch Log	Displays event occurrence date and time, Cardial Patch MAC, and event details.
2-2	More	Allows viewing of additional logs, 5 logs at a time.
7	ECG Measurement Test	Allows ECG measurement test after reattaching and restarting the Cardial Patch.

(13) Settings > Customer Service



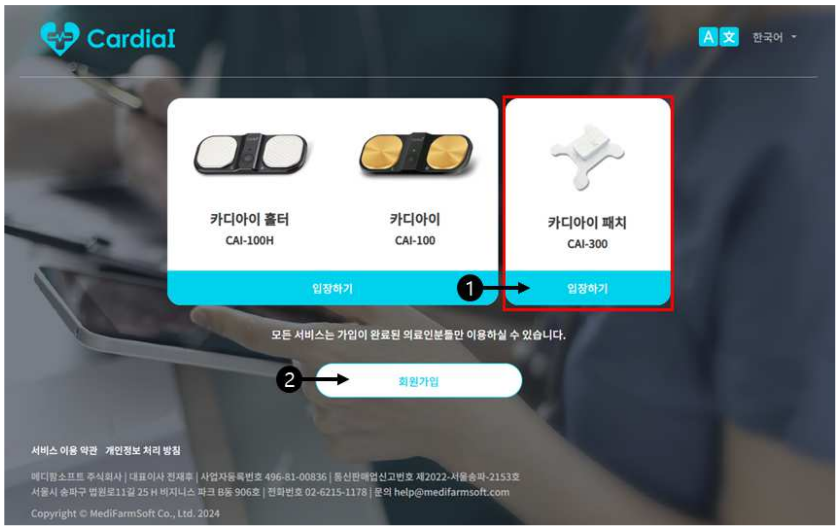
No.	Name	Description
1	Customer Service	Enables calling when selecting "Confirm."

(14) Settings > Logout

No.	Name	Description
1	Logout	App logout

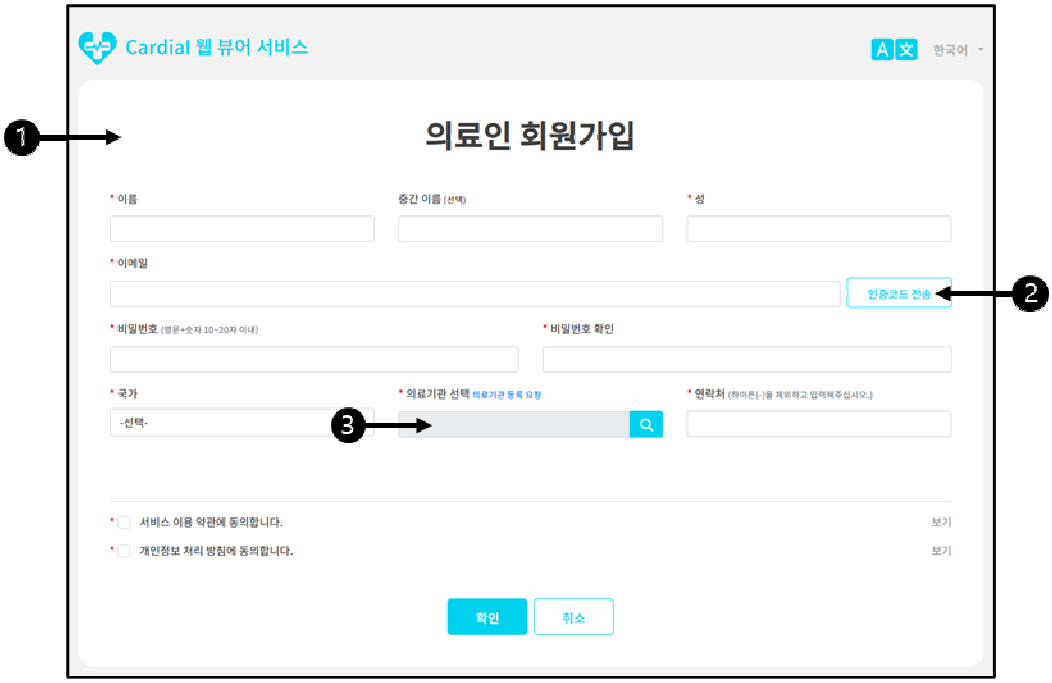
6. Web Software

1) Login Screen



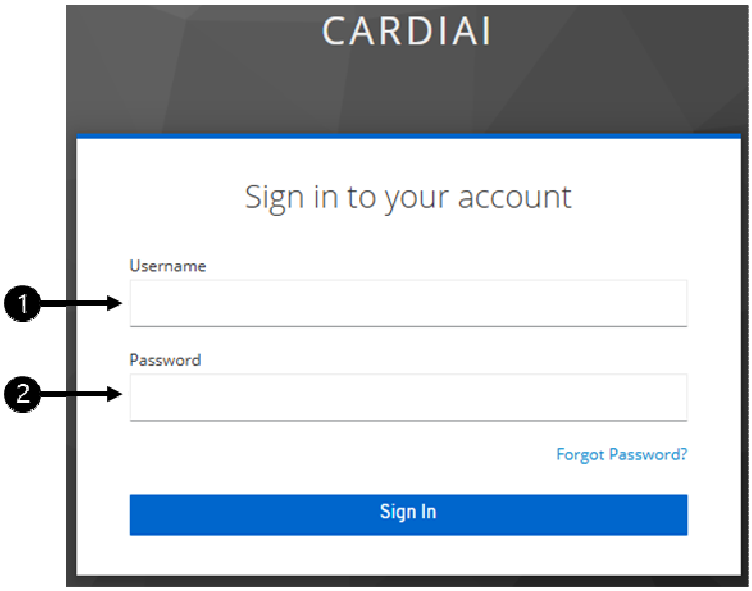
No.	Name	Description
1	Login Button	Navigates to the web viewer login screen.
2	Sign Up Button	Navigates to the doctor registration page.

2) Doctor Registration Screen



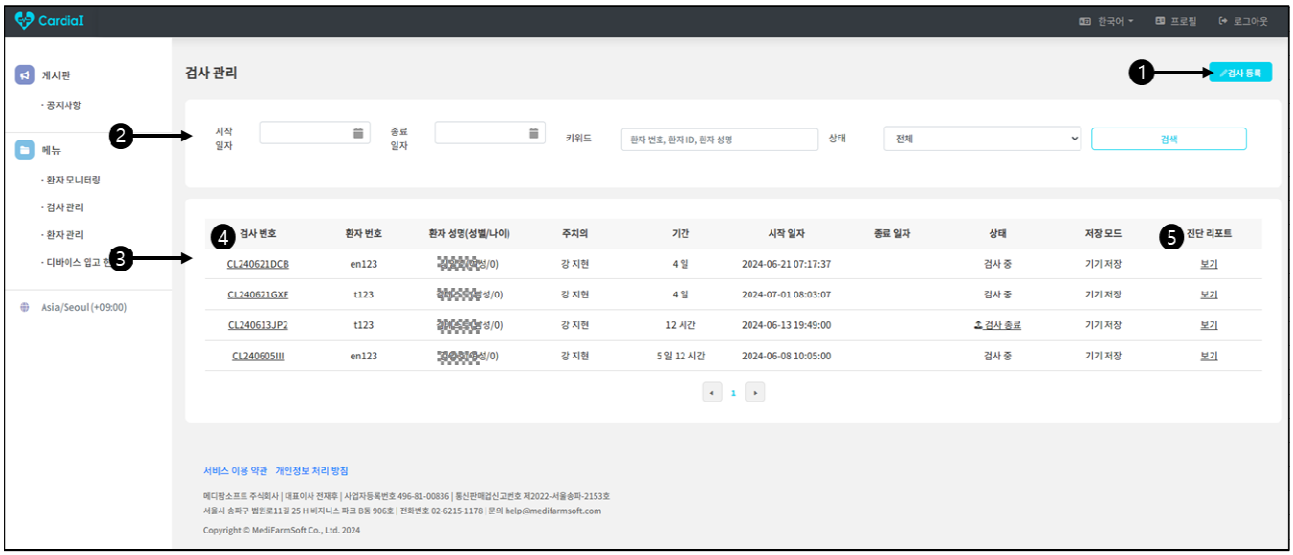
No.	Name	Description
1	Registration Form	Enter first name, last name, email address, password, and contact information, and select country and medical institution.
2	Send Verification Code	Requires a one-time email verification.
3	Select Medical Institution	Choose a medical institution from the list or register a new one if it is not listed.

3) Login Screen (Doctor)



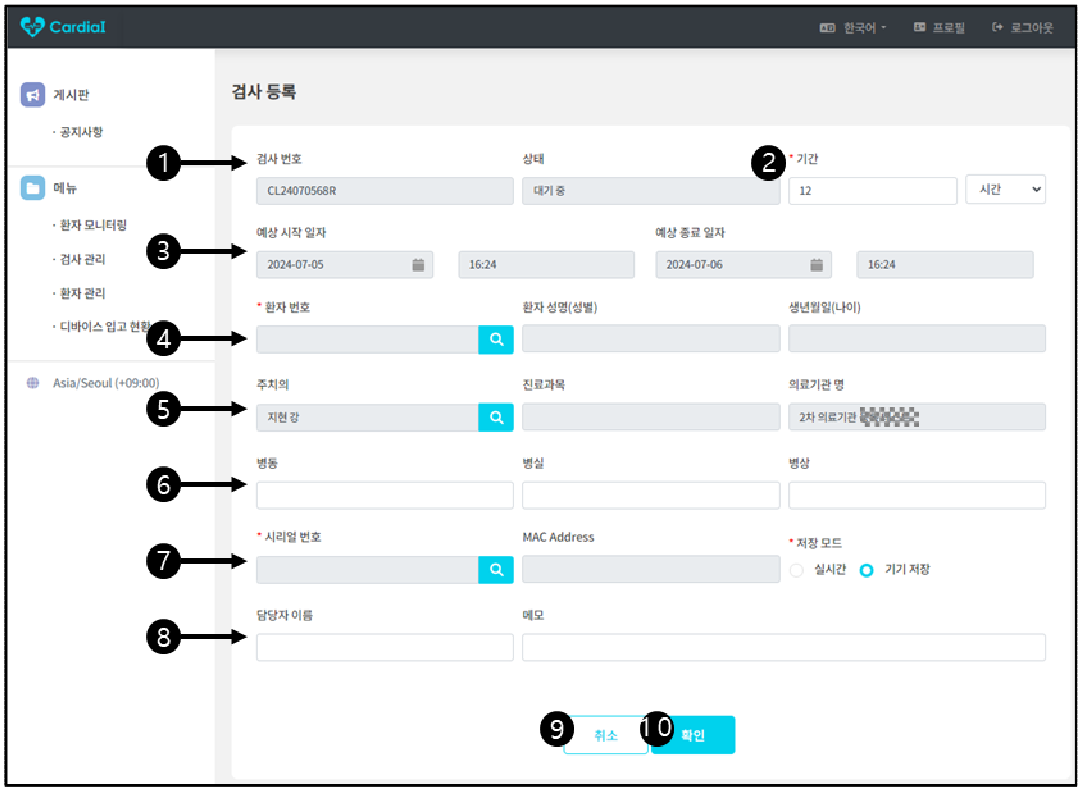
No.	Name	Description
1	Login ID	Enter login ID.
2	Login PW	Enter login password.

4) Test Management Screen



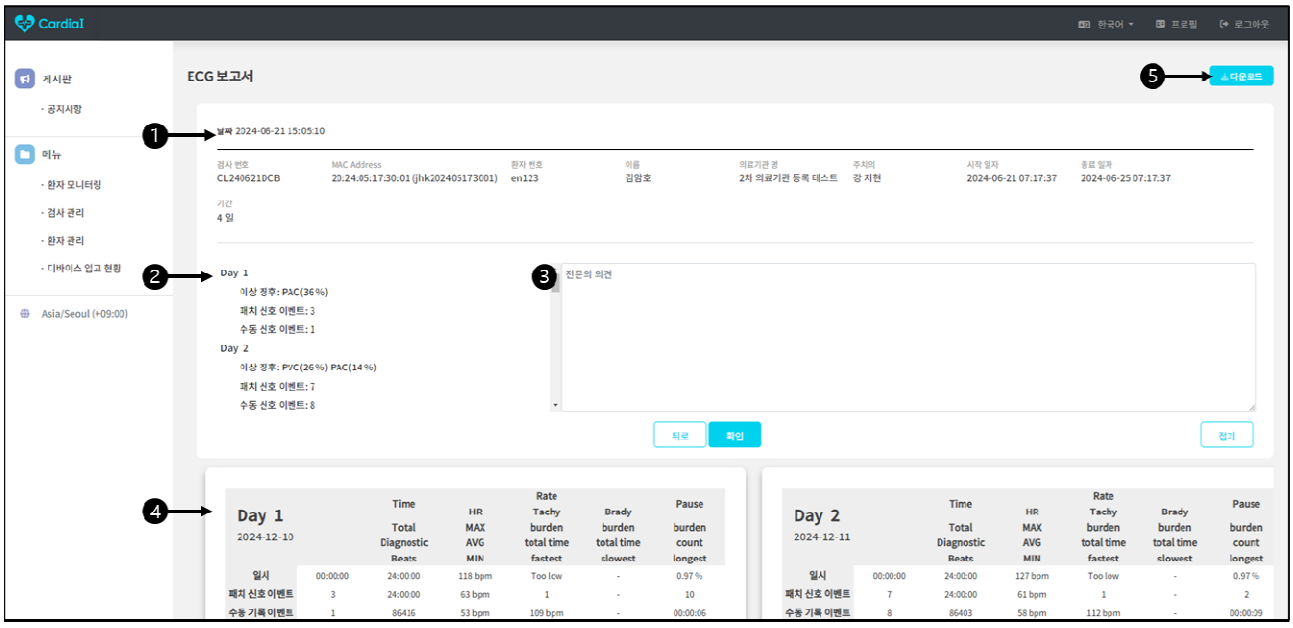
No.	Name	Description
1	Register Test	Navigates to the test registration page.
2	Search Items	Search options include start date, end date, patient number, patient name, and status.
3	Test List	Fields include test number, patient number, patient name, gender, age, primary doctor, test period, start date, end date, status, data storage mode, and diagnostic report.
4	Test Number	Navigates to the test details page.
5	Diagnostic Report	Navigates to the detailed diagnostic report page.
6	Upload	Upload button appears when the test is completed.
7	Upload Popup	Uploads data to the cloud server.

5) Test Registration Screen



No.	Name	Description
1	Test Number, Status	Automatically assigned.
2	Period	Can be selected in hours or days.
3	Expected Start/End Date	Can select date and time
4	Patient Information	Includes patient number, name, gender, and age.
5	Medical Staff Information	Includes primary doctor's name, specialty, medical institution name, and staff member name.
6	Bed Information	Includes ward, room, and bed number.
7	Patch Information	Includes serial number, MAC address, and storage mode (real-time or storage).
8	Memo	Text input field.
9	Cancel	Closes the test registration screen when clicked.
10	Confirm	Saves the test when clicked.

6) ECG Report Screen



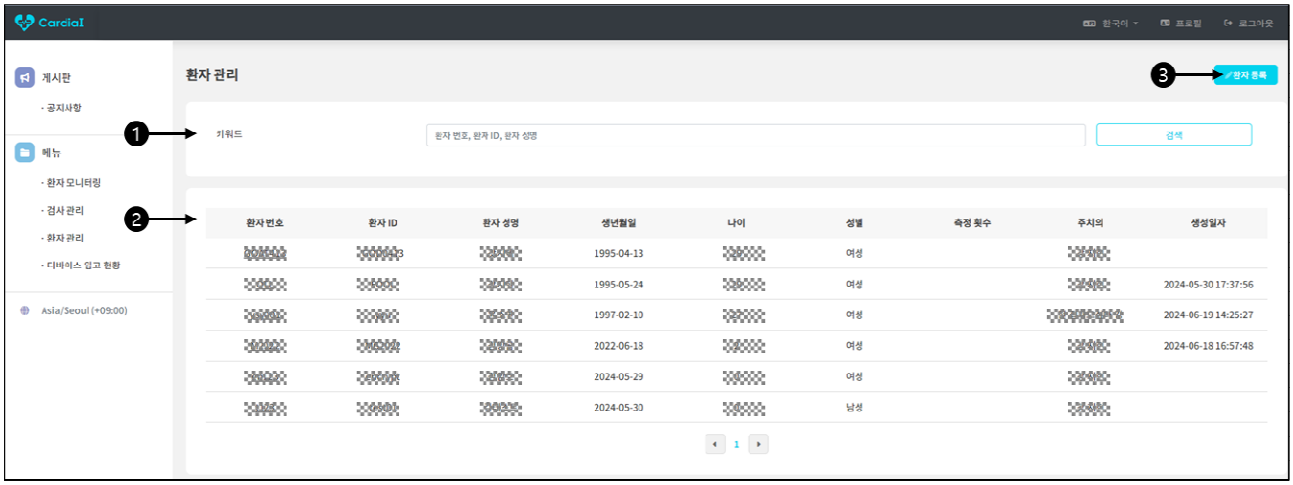
6

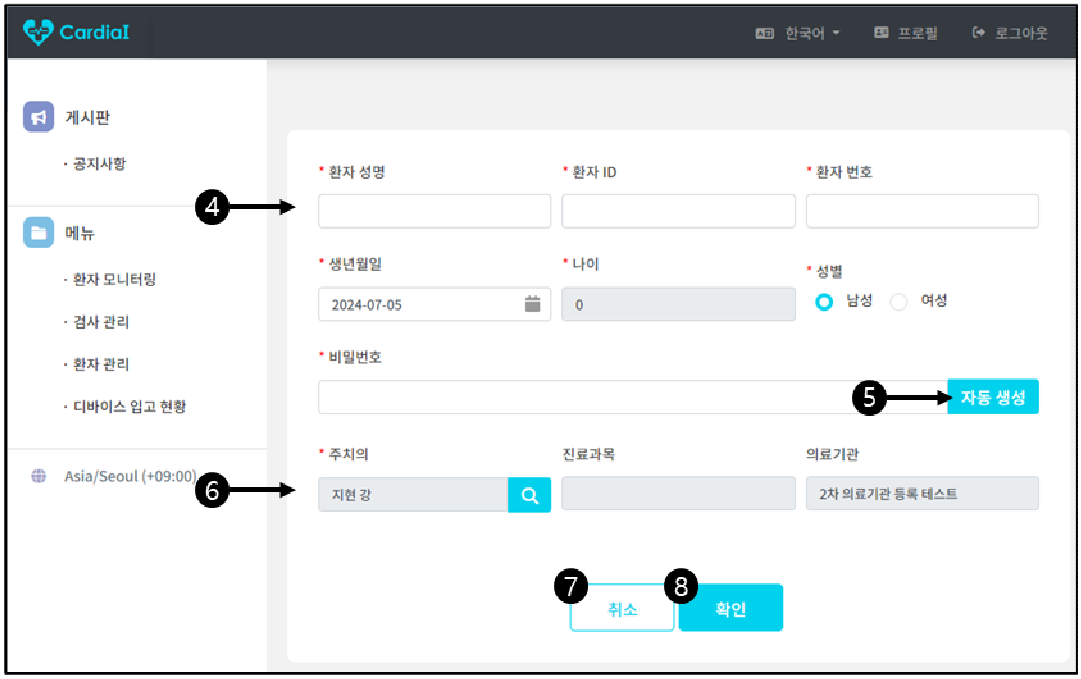
Day 1 2024-12-10		Time Total Diagnostic Beats	HR MAX AVG MIN	Rate Tachy burden total time fastest	Brady burden total time slowest	Pause burden count longest
일시	00:00:00	24:00:00	124 bpm	Too low	-	0.97 %
패치 신호 이벤트	6	24:00:00	67 bpm	1	-	3
수동 기록 이벤트	8	86425	56 bpm	109 bpm	-	00:00:02

		Ventricular			Supraventricular		
		Day (6~14)	Evening (14~22)	Night (22~6)	Day (6~14)	Evening (14~22)	Night (22~6)
Total	Burden	0.51 %	-	0.38 %	0.51 %	-	0.38 %
	Beats	2	-	7	9	-	1
		PAC			PVC		
Single	Burden	-	-	1.0 %	1.0 %	-	1.0 %
	Beats	-	-	2	2	-	-
Couplet	Burden	1.89 %	-	2.73 %	0.36 %	-	0.27 %
	Beats	1	-	4	6	-	-
	Episodes	1	-	4	6	-	-
		Short-Duration SVT(AT, AVNRT, AVRT)			NSVT		
less then 30 sec	Burden	1.35 %	-	1.95 %	2.55 %	-	1.9 %
	Episodes	4	-	3	-	-	7
	Longest	00:00:00	00:00:00	00:00:00	6 beats @Avg 166 bpm	-	-
	MAX	164 bpm	-	144 bpm	154 bpm	-	191 bpm
	AVG	128 bpm	-	165 bpm	101 bpm	-	68 bpm
	MIN	114 bpm	-	110 bpm	-	-	-
		SVT(AT, AVNRT, AVRT)			Sustained VT		
more then 30 sec	Burden	1.35 %	-	1.95 %	2.55 %	-	1.9 %
	Episodes	-	-	2	6	-	4
	Longest	00:05:19	00:00:00	00:07:04	6 beats @Avg 156 bpm	-	-
	MAX	101 bpm	-	110 bpm	161 bpm	-	183 bpm
	AVG	90 bpm	-	130 bpm	130 bpm	-	92 bpm
	MIN	110 bpm	-	43 bpm	137 bpm	-	114 bpm
ST elevation		95.0 %	-	61.0 %	-	-	-
ST depression		93.0 %	-	48.0 %	-	-	-
Afib/AFL	Burden	-	-	-	발견 징후		
	Episodes	-	-	-	1. PAC(6 %)	-	-
	MAX	146 bpm	-	185 bpm	-	-	-
	AVG	134 bpm	-	97 bpm	-	-	-
	MIN	106 bpm	-	78 bpm	-	-	-

No.	Name	Description
1	Test Information	Includes test number, patch MAC, patient number, name, medical institution name, primary doctor, start/end date, and duration.
2	Daily Summary	Displays abnormal signs, patch signal events, and manual signal events.
3	Specialist's Opinion	Text area for entering specialist's opinions.
4	Detailed Report	Provides daily reports by test date.
5	Download	Allows downloading of the full report.
6	Report Details	Detailed view of the daily report.

7) Patient Management Screen



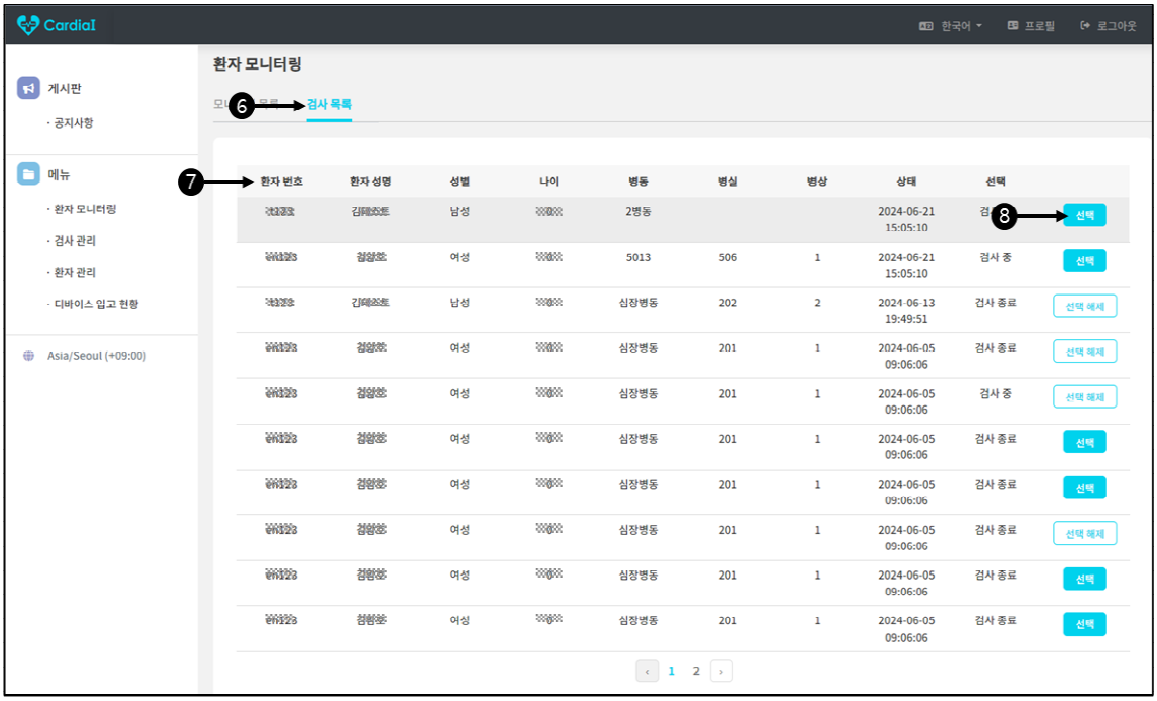


No.	Name	Description
1	Search Items	Search by patient information or patient name.
2	Patient List	Displays patient number, patient ID, patient name, date of birth, age, gender, primary doctor, and creation date.
3	Register Patient	Navigates to the patient registration screen.
4	Patient Information	Includes patient name, patient number, date of birth, age, gender, and password (set).
5	Generate Password	Automatically generates a password.
6	Medical Staff Information	Enter primary doctor's name, specialty, and medical institution.
7	Cancel	Closes the patient registration screen.
8	Confirm	Saves the patient information.

8) Device Inventory Status

No.	Name	Description
1	Search Items	Search by serial number or MAC address.
2	Patch List	Automatically updates with serial number, MAC address, arrival date, supplier, and quantity.

9) Real-Time Patient Monitoring



No.	Name	Description
1	Monitoring List	List of patients under monitoring.
2	Patient Bed Information	Displays bed information registered in the patient's information.
3	View ECG	Allows viewing of the real-time ECG graph upon clicking.
4	Real-Time Heart Rate	Displays the real-time heart rate.
5	Patient Information	Displays patient name, gender, age, and primary doctor information.
6	Test List	Full list of patients registered in the web viewer.
7	List Items	Displays patient number, patient name, gender, age, ward, room, bed, and status.
8	Select/Deselect	Toggle button to add or remove a patient from the monitoring list.

7. Dimensions

1) Main Body

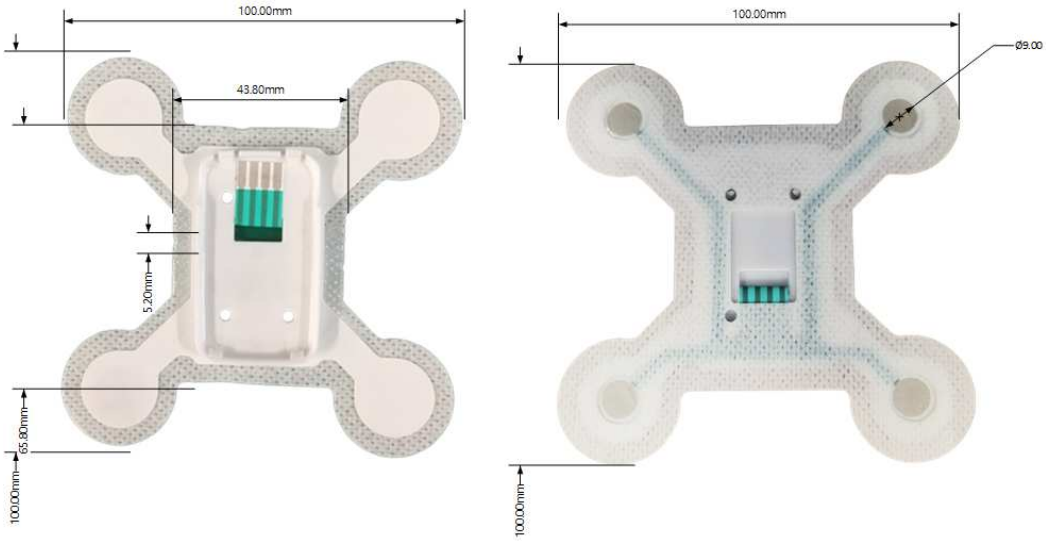
(1) Dimensions: 53.80(W) x 31.00(D) x 10.90(H) mm (± 0.5 mm)

(2) Weight: 20.1g ± 0.5g

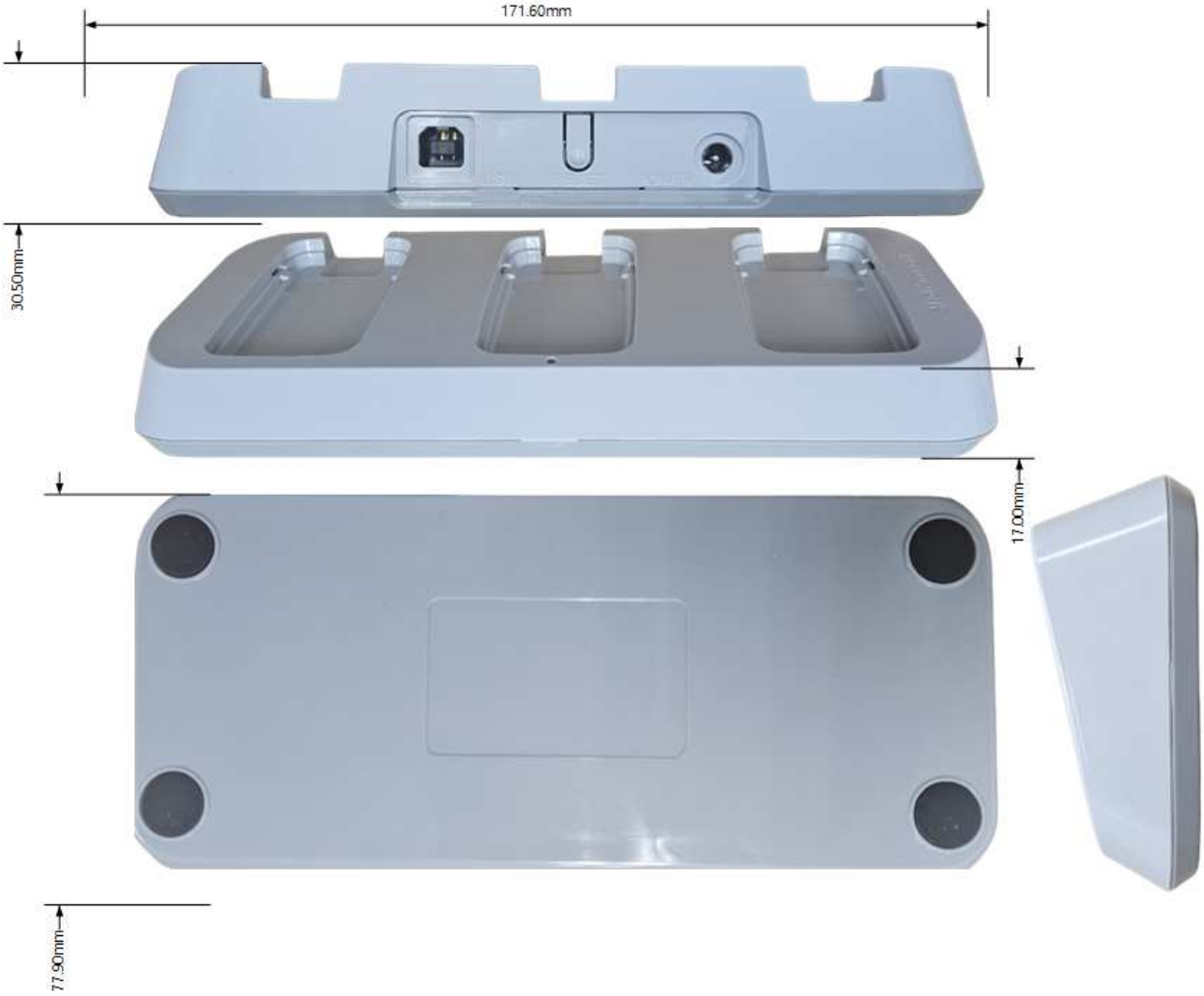
2) Patch

(1) Dimensions: 100.00(W) x 100.00(D) x 5.20(H) mm (± 0.5 mm)

(2) Weight: 7.5g ± 0.5g



3) Cradle

(1) Dimensions: 171.60(W) x 77.90(D) x 30.50(H) mm (± 0.5 mm)

(2) Weight: 133.7g ± 0.5g