2. Precautions for Use

1. Precautions before use
 1) Ensure that the skin area where the patch will be attached is clean and dry. Avoid attaching the patch to areas with skin irritation or wounds.
 2) Before use, ensure that the device is functioning properly and that the battery is fully charged.
 3) Check for possible interference with other electronic devices, especially medical equipment, and consult with medical personnel if necessary.
 4) Attach the patch in the correct position to obtain accurate data. Follow the guidance of medical staff for the placement of the patch.
 5) Avoid exposure to strong magnetic fields or electromagnetic waves, as they may affect the device's performance.
 6) Ensure the device's data storage capacity and communication status are adequate for proper data recording and transmission. In areas where wireless communication may be disrupted (e.g., locations with metal structures, many electronic devices, or basements), communication errors can occur, making accurate measurements difficult.
 7) Use a KC-certified charger (12 Vdc, 1.5A) and connect it to the cradle provided by the manufacturer.
 8) If any cybersecurity incidents or threats occur during the use of the device, immediately contact the manufacturer's emergency number (Medifarmsoft Co., Ltd., 02-6215-1190) and wait for instructions from an administrator before proceeding.
 9) Be cautious to avoid moving, dropping, or impacting the device.

2. Precautions during use
 1) Maintain your usual daily activities as much as possible, but avoid excessive physical activity or stress, as this may affect the device's recording accuracy.
 2) Protect the device from external impacts, and ensure it does not get wet. Avoid bathing, showering, or swimming, and keep the area around the device dry.
 3) Wear comfortable clothing that does not put excessive pressure on the area where the device is attached, as tight clothing may interfere with the device's contact.
 4) Keep a distance from devices that generate strong magnetic fields or electromagnetic waves (e.g., microwaves, electric blankets), as these can interfere with the device's operation.
 5) Regularly check that the patch is securely attached; if it becomes loose or detached, reattach it according to medical instructions.
 6) Avoid pressing buttons or changing settings on the device arbitrarily. Follow medical guidance if any setting adjustments are needed.
 7) If you experience discomfort, chest pain, dizziness, or similar symptoms during use, record them and notify medical personnel as soon as possible. Recording the time and context of symptoms may also be helpful.
 8) Regularly check the battery status for extended use, and contact hospital staff if the battery is low.
 9) Follow all instructions from medical staff accurately, and contact them immediately if any issues

arise or if you have questions.

10) In real-time monitoring mode, maintain connection with the smartphone application and workstation monitor. If the connection is lost, data cannot be transmitted in real time.

11) Clean the attachment area and dry it thoroughly before reattaching, as measurement can be difficult depending on skin condition.

12) In the event of a malfunction during use, repair services must be performed by designated professional technicians.

13) If battery leakage is detected during use, stop using the device immediately and contact the manufacturer.

14) Frequently check for any abnormalities in the device's operation, and contact the manufacturer if any issues are detected.

15) Normal operation may be challenging in areas with many WiFi or Bluetooth devices.

3. Precautions after use

1) After use, clean the device thoroughly and return it to medical personnel. Dispose of the electrode patch as it is for single use only.

2) Ensure the recorded ECG data is transferred to medical staff for analysis. If data transmission is needed, follow the instructions in the device or application for proper transfer.

3) Check the skin at the patch attachment site, and if any rash or irritation occurs, treat it appropriately. Applying aloe vera gel or moisturizer may help alleviate skin irritation.

4) Inspect the device's battery and operational status, and report any issues immediately. If the device did not function properly, inform medical personnel for potential further examination.

5) Schedule any follow-up examinations or additional appointments as instructed by medical staff. Further diagnostics or treatment plans may be necessary based on the analysis results.

6) Retain any recorded symptoms or event logs during use, and share with medical staff if needed, as this can provide valuable information for diagnosis and treatment.

7) Consult with medical staff if additional training or guidance on device usage is required. This can help address any questions on device usage or result interpretation.

8) Receive counseling regarding the device usage results to understand the findings and any necessary actions. This information can be important for future health management.

9) For reusable devices, manage and store the device according to the specified procedures after use to ensure it remains in good condition for future use.

(1) If the device will not be used for an extended period, turn it off and store it disconnected from the USB cable.

(2) Avoid moisture, high temperatures, dust, salt, and sulfur substances, and store it in a well-ventilated area, away from direct sunlight.

(3) Avoid vibration or mechanical shocks.

4. Warning

1) If severe symptoms such as chest pain, dizziness, shortness of breath, or palpitations occur during use, seek medical attention immediately or call emergency services.

2) Handle the device carefully to avoid dropping or getting it wet, as damage may affect measurement accuracy.

3) Do not use the device near strong electromagnetic fields (e.g., MRI, CT scans), as this can impact device performance.

4) Check the battery level regularly and replace if necessary, as the device may stop working if the battery is discharged.

5) Consult medical staff before using this device alongside other medical equipment, as interference may occur.

6) If you experience an allergic reaction to the patch or electrode, discontinue use immediately and consult medical staff.

7) Do not modify or change device settings without instructions from medical staff, as incorrect settings may affect data accuracy.

8) Avoid activities that produce excessive sweat, and do not shower or swim while wearing the device, as moisture may reduce adhesion or cause device malfunction.

9) Regularly check the connection with the smartphone app or workstation during real-time monitoring, as data transmission errors may occur.

10) After use, clean the device and return it to medical staff according to established procedures for post-use inspection and data analysis.

11) Do not open the cover, disassemble, or modify the device. Only authorized personnel may service or repair the device, and there are no user-serviceable parts.

12) Protect the device from excessive moisture to prevent malfunctions. If liquid enters the device, it may cause malfunction.
 - Do not expose the device to liquid directly or use it in the shower.
 - Do not spray or pour liquid (e.g., water, cleaning solutions) on any part of the device; if liquid spills, wipe immediately and contact the manufacturer.

13) Only use components provided or recommended by the manufacturer, and follow the user manual for correct usage.

14) Manage and use components according to the manufacturer's guidelines or hospital regulations.

15) Electromagnetic emissions from the environment may affect the device and the patient.

16) To ensure patient safety, the device electrodes should not come into contact with any conductive parts, including grounding.

17) When using an AC/DC adapter for charging, use only KC-certified products to prevent electrical shock or fire.

18) Do not use or store the device near flammable gases or anesthetics, as there is a risk of explosion.

19) Immediately disconnect the charging cable from the device if any of the following occur, as continued use may result in electrical shock or fire:
 - Smoke or unusual smells from the charger.
 - The device has been dropped or impacted.
 - Liquid or foreign objects have entered the charger.
 - Malfunction has occurred.

20) Follow these steps if an issue arises:
 - Disconnect the charging cable from the AC/DC adapter.
 - Attach a sign with "Malfunction (Do Not Use)" on the device and refrain from using it.

21) Do not use the device on infants or individuals unable to communicate.

22) If any abnormalities are detected in the device or patient, ensure the patient's safety, halt device operation, and take appropriate action.

5. Precautions for Use Environment

1) Keep this product out of reach of infants and children when charging or storing it.

2) ECG measurement performance may be affected by the patient's physiological conditions, excessive movement, tremors, and other medical technologies like electromyography (EMG). If the product's measurements are deemed inaccurate, always use other verified methods to assess the patient's condition.

6. Adverse Reactions to Medical Device

1) Consult a doctor before use in the following cases:
 - Individuals with trauma or pain at the electrode contact site.
 - Individuals with delicate or sensitive skin who may be at risk of injury from electrode contact.
 - Skin irritation, such as redness, itching, or rash, may occur at the patch or electrode attachment site.

7. General Precautions

1) To ensure patient safety, users must thoroughly understand the instructions before using the device. Operating or storing the device outside the specified environmental conditions, or subjecting it to excessive impact or dropping, may cause it to malfunction.

2) If the product is damaged, unintentionally modified, or suspected of foreign substance infiltration, it is recommended not to use the device and to contact the local distributor or the headquarters department.

3) If the product is stored without use for an extended period, the battery may discharge. In cases of low or critically low battery, the device may suddenly shut down or fail to power on during use. Users should charge the battery before initial use after receiving the product.

4) Only use the AC/DC adapter recommended by the manufacturer.

5) If there is a problem with the battery, place it in a safe location and contact the manufacturer's representative immediately.

6) Do not disassemble or replace the battery arbitrarily, as using an improper battery can pose an explosion risk.

7) Users should carefully manage their personal accounts to prevent any external exposure.

8) The web server is provided exclusively for medical staff.

8. Prohibitions

1) Do not use the device in conjunction with radiation-based examinations or treatments, such as MRI or X-rays, as these may interfere with the device's proper operation and lead to inaccurate results.

2) Do not use the device with a defibrillator.

3) Disassembly of the device by the user or operator is prohibited.

4) Do not use organic solvents when cleaning the device.

9. Precautions for Using the Web Server
 1) Precautions Before Use
  - The web server can only be accessed by logging in with an approved user's email and password.
  - Only designated medical staff are permitted to use the web server.
  - The web server can only be used in locations with a connected TCP/IP network.
 2) Precautions During Use
  - Users must comply with relevant laws, such as the Medical Services Act and the Personal Information Protection Act.
  - If you log out without clicking "Save," recorded diagnostic findings will not be saved. Always click the "Save" button before logging out.

3. Information on Device Usage

1. Storage and Transport Environmental Conditions
(1) Temperature: -10 ℃ to 50 ℃
(2) Humidity: 10 %R.H to 95 %R.H
(3) Atmospheric Pressure: 80 kPa to 106 kPa
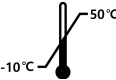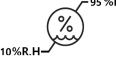
2. Operating Environmental Conditions
(1) Temperature: 10 ℃ to 45 ℃
(2) Humidity: 10 %R.H to 95 %R.H
(3) Atmospheric Pressure: 80 kPa to 106 kPa
(4) Altitude: Up to 2,000 m

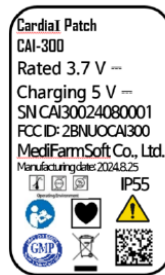3. Symbols and Safety Signs

No.	Symbol	Description	location
1	SN	Product serial number	Product label Charging cable label Packaging box label
2		Date of manufacture	Packaging box label
3		Legal Manufacturer/Manufacture	Product label Unit box label Charging cable label Packaging box label
4		Type BF applied part	Product label
5		class Ⅱ equipment	Charging cable label
6	IP	Waterproof and dustproof rating	Product label
7		Follow instructions	Product label Charging cable label Internal battery label User manual
8		General warning, caution sign	Internal battery label Unit box label User manual

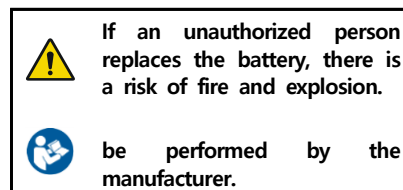| No.	Symbol	Description	location
9		General prohibition sign	User manual
10		Direct current	Product label Packaging box label
11		Keep dry	Packaging box label
12		Storage, transport temperature conditions	Packaging box label
13		Storage, transport humidity conditions	Packaging box label
14		Storage, transport atmospheric pressure conditions	Packaging box label
15		Keep away from sunlight	Packaging box label
16		Discard in the specified manner	Packaging box label
17		DC Voltage	Product Label Packaging box label
18		Bistable Switch	Exterior of the device

4. Label

1) Device Label


```
Cardial Patch
CAI-300
Rated 3.7 V ⎓
Charging 5 V ⎓
SN CAI30024080001
FCC ID: 2BNUOCAI300
MediFarmSoft Co., Ltd.
Manufacturing date: 2024.8.25
[i] [☑] [☒]              IP55
[😊]      [♥]      [⚠]
[GMP]  [🗑]  [▯]
```

2) Power Switch Label

2) Internal Battery Label

⚠	**If an unauthorized person replaces the battery, there is a risk of fire and explosion.**
[👤]	**be performed by the manufacturer.**

4. Instructions For Use

1. Preparations Before Use
  1) Register the Test on the Web Viewer
   (1) Create a Web Viewer Account
     - Access the web server address via an internet browser.
     - Server address: https://admin.medifarmsoft.com
   (2) Create a New Test
     - Register the patient's information and create the patient's account.
     - Create a new test and match it with the patient and patch information.
  2) Install the Cardial Patch Application on the Patient's Phone
  3) Log in with the Patient's Assigned ID and Password
     - Ensure consent to personal data usage and verify smartphone access permissions.
  4) Prepare the Patient's Skin
   (1) If there is hair on the chest area, shave the area accordingly.
   (2) Clean the area with soap and water or an alcohol wipe.
   (3) Make sure the skin is completely dry.
   (4) Do not apply lotion, oil, or any other substance on the skin.
   (5) Identify the patch attachment area on the patient's chest.
   (6) Check for unhealed wounds, lesions, infections, or inflammation.
   (7) Ensure the patient has no skin allergies or adhesive sensitivities.
   (8) Prepare the patient to remain calm and ensure proper positioning for accurate measurement.
  5) Check the Operating Environmental Conditions
  - Temperature: 10 ℃ to 45 ℃
  - Humidity: 10 %R.H to 95 %R.H
  - Atmospheric Pressure: 80 kPa to 106 kPa
  - Altitude: Up to 2,000 m

2. Instructions for Use and Operation Sequence
  1) Prepare the Device
  (1) Fully charge the main body.
  (2) Attach the main body to the patch.
  (3) Remove the release liner from the bottom of the patch and attach it to the patient's chest.

  2) Power ON and Check Communication Connection Standby Status
  (1) Press and release the power button located at the center of the device for 0.5–1 second. The LED light above the power button will briefly illuminate, then turn off, entering a blinking state. In this state, the device can be connected to the dedicated smartphone application.

(2) In the smartphone settings, enable Bluetooth, GPS, and Wi-Fi or mobile data according to Android OS and iOS policies to verify the smartphone's network status.

(3) Once the smartphone and Cardial Patch automatically pair, proceed with the automatic patch test.

   - During the test, you can check if the battery is charged and the device is powered on correctly.

3) Create a Web Viewer Account (Web Viewer Registration)
  - Access the web server address through an internet browser.
  - Server address: https://admin.medifarmsoft.com

  - Click the [Sign Up] button.
  - On the sign-up screen, enter your name, email address, and password.
  - Enter your nationality (country), affiliated hospital (institution), and phone number.
  - After checking the boxes for the Terms of Service and the Privacy Policy, click the [Confirm] button to create your account.

Cardial 웹 뷰어 서비스

의료인 회원가입

* 이름   중간 이름 (선택)   * 성

* 이메일

인증코드 전송

* 비밀번호 (영문+숫자 10~20자 이내)   * 비밀번호 확인

* 국가   * 의료기관 선택 의료기관 등록 요청   * 연락처 (하이픈(-)을 제외하고 입력해주십시오.)
-선택-

* 서비스 이용 약관에 동의합니다.   보기
* 개인정보 처리 방침에 동의합니다.   보기

확인   취소

4) Create a Patient Mobile Application Account

- Set a password when registering the patient. You can use the auto-generate password feature.

- The assigned patient number (ID) and password are used for logging in to the patient's mobile application.

* 환자 성명   * 환자 ID   * 환자 번호

* 생년월일   * 나이   * 성별
2024-07-08   0   ● 남성 ○ 여성

* 비밀번호
자동 생성

* 주치의   진료과목   의료기관
지현 강   2차 의료기관 등록 테스트

취소   확인

5) Launch Mobile Application and Log In

- Click on the Cardial Patch mobile app installed on the mobile device (smartphone, tablet) to launch the Cardial Patch application.

[Mobile App]
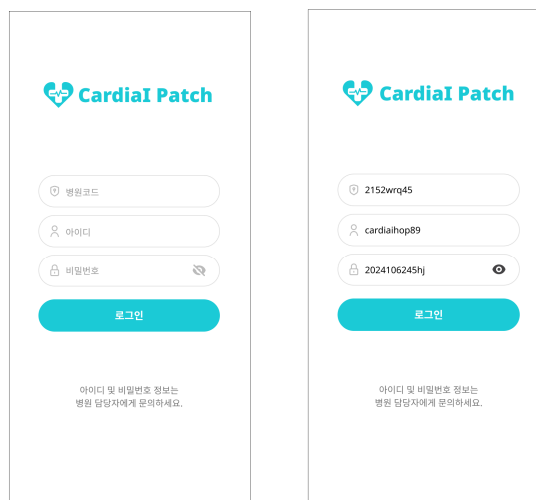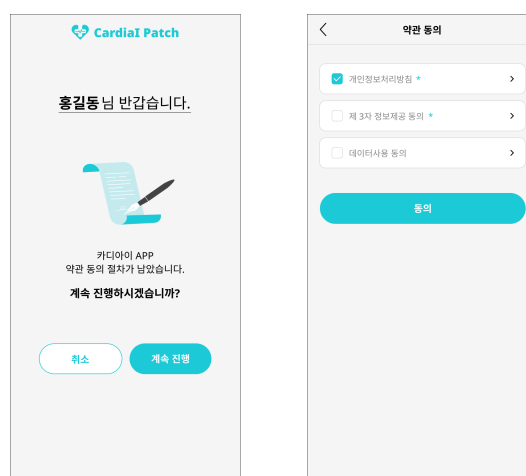
- On the mobile app login screen of the mobile device, enter the hospital code, ID (patient number), and password, then select the "Login" button.
- After logging in, automatic login is enabled, so re-login is not required.
- Select the the allows the entered characters to be visible, so you can verify the input without masking.

<Mobile App Login Screen>

<Mobile App Terms and Conditions Agreement>

- After logging in, proceed with the terms and conditions agreement. You cannot continue

without agreeing to the terms.

6) ECG Test (Connecting Holter ECG with Mobile App)

(1) Prepare the Device
- Press and hold the power button located at the center of the Cardial Patch for 3 seconds, then release it. The LED light above the power button will illuminate briefly, then turn off and enter a blinking state. In this state, the device is ready to connect with the dedicated smartphone application.
- In the smartphone settings, enable Bluetooth, GPS, and Wi-Fi or mobile data according to Android OS and iOS policies.

(2) Bluetooth Connection Before Measurement
- If the Cardial Patch is powered on, it will automatically be scanned via Bluetooth.
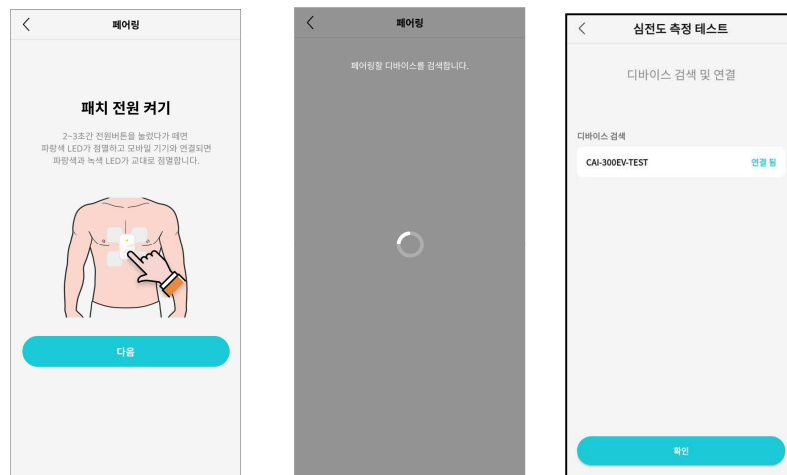
(3) Measurement Test Screen
- When the measurement test begins, the device's LED lights up in bright blue.
- Remain in a stable position and wait until the measurement test is complete (approximately 10 seconds).
- Once the measurement test is complete, press the "Start Test" button to begin the test.

(4) Start Test
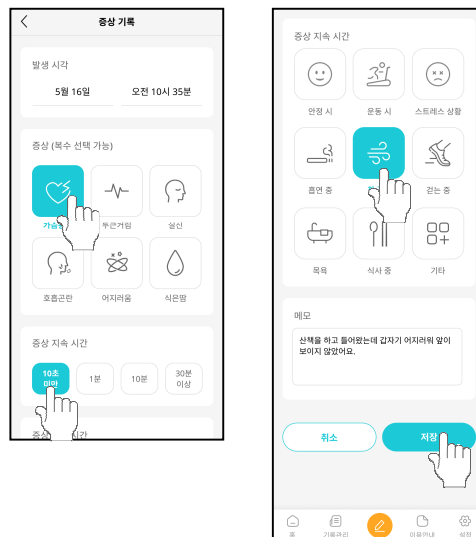   - Navigate to the main page of the mobile app.

<Real-Time Mode>   <Storage Mode>
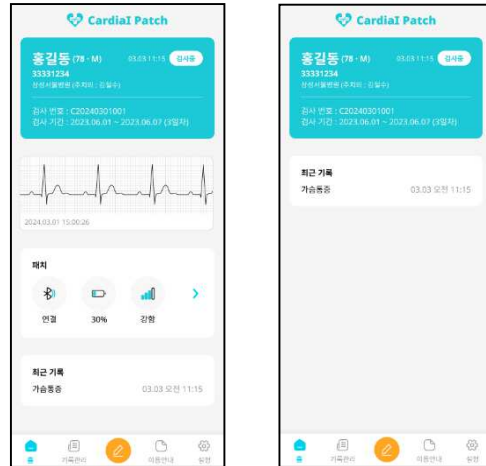
7) Conduct Test
   - During the test period, carefully record any symptoms in the mobile application as they occur.

<Symptom Record>

(1) Completion of Test
   - When the test is complete, a notification message will appear.
   - You can end the measurement by sending a signal from the mobile application.
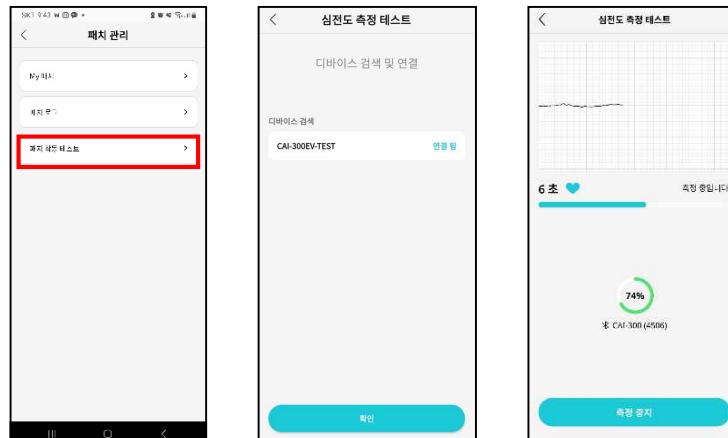
8) Record Management
   View the list of symptom records logged up to the present time.

<Record Management>

9) Reattach the Cardial Patch
- Attach the Cardial Patch and power it on.
- Launch the mobile application, then go to Settings > Patch Management > Patch Operation Test in sequence.
- Once the test is complete, press "Start Test" to begin the test.

10) Check Patch Log
- You can view the patch log by navigating to Settings > Patch Management > Patch Log.

11) Generate Report via Web Server
(1) Access Web Server
- Access the web server through an internet browser.
- Address: https://admin.medifarmsoft.com

(2) Log In
- On the login screen, enter your email address and password, then select the "Log In"

button.
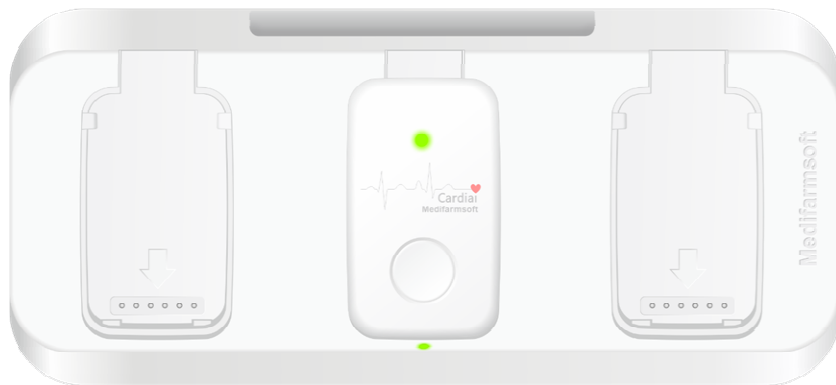

(3) Test List
   - Access it via [Menu] - [Test Management] on the left sidebar.
   - You can view patient information, test start/end dates, data storage mode, test status, and diagnostic report information.

a) ECG Data Upload
  - When the test is complete, attach the Cardial Patch to the dedicated cradle to download the data to the computer.

상태

검사 중

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검사 중

⬆ 검사 종료

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  - Select the File Upload button for the relevant test. Choose the downloaded file from your computer and upload it to save the ECG data on the cloud analysis server.
  - Once all data is uploaded to the server, data analysis will begin automatically. When the analysis is complete, you can view the report.

b) View Diagnostic Report
  Click "View" on the far right of the diagnostic report in the list.

<Test Management List Screen>

ECG 보고서 　📥 다운로드

날짜 2024-06-21 15:05:10

검사 번호	MAC Address	환자 번호	이름	의료기관 명	주치의	시작 일자	종료 일자
CL240621DCB	20:24:05:17:30:01 (jhk202405173001)	en123	김암호	2차 의료기관 등록 테스트	강 지현	2024-06-21 07:17:37	2024-06-25 07:17:37

기간
4 일

Day 1
　이상 징후: PVC(27 %) PVC(40 %) PAC(44 %)
　패치 신호 이벤트: 7
　수동 신호 이벤트: 9
Day 2
　이상 징후: PAC(46 %) PAC(44 %)
　패치 신호 이벤트: 9
　수동 신호 이벤트: 6

전문의 의견

뒤로　확인　　　　　　　　　접기

<Top of ECG Report>

<Bottom of ECG Report>

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

Additional table columns: Pause row values align as Too low | – | 0.97%; 1 | – | 3; 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	105 bpm	-	78 bpm	-	-	-

<Daily Report Detail Screen>

	Description	Symptoms	Precautions
Sinus Rhythm (SR)	Refers to the normal rhythm of the heart.	None	
Atrial Fibrillation	Atrial fibrillation is an arrhythmia in which the atria of the heart contract abnormally and rapidly.	Palpitations, fatigue, shortness of breath, dizziness, chest pain, fainting.	Quit smoking and limit alcohol consumption, reduce caffeine intake, manage stress.
Atrial Flutter	Atrial flutter is an arrhythmia where the	Palpitations,	Quit

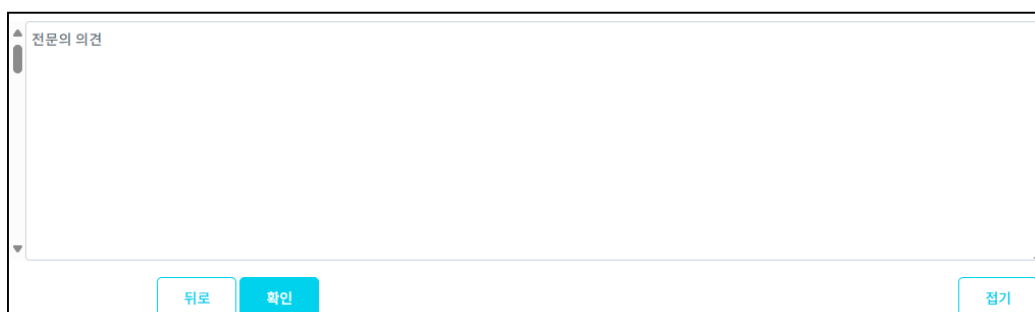|			smoking and limit alcohol consumption, reduce caffeine intake, and manage stress.
	atria contract at a very rapid and regular rate. It is similar to atrial fibrillation but is characterized by a more regular rhythm.	fatigue, shortness of breath, dizziness, chest pain, fainting.	
Premature Ventricular Contractions (PVCs)	Premature ventricular contractions (PVCs) are irregular ventricular contractions that occur between normal heartbeats due to abnormal early electrical signals originating in the ventricles.	Asymptomatic, palpitations, chest discomfort.	Quit smoking and limit alcohol consumption, reduce caffeine intake, and manage stress.
Premature Atrial Contractions (PACs)	Premature atrial contractions (PACs) are early atrial contractions that occur before the normal heart rhythm due to abnormally rapid electrical signals originating in the atria.	Asymptomatic, palpitations, chest discomfort.	Quit smoking and limit alcohol consumption, reduce caffeine intake, and manage stress.
Ventricular Tachycardia	Ventricular tachycardia is an abnormally fast heart rhythm originating in the ventricles of the heart.	Palpitations, dizziness, fainting, chest pain, shortness of breath, fatigue.	Quit smoking and limit alcohol consumption, reduce caffeine intake, and manage stress.
Supraventricular Tachycardia	Supraventricular tachycardia is a rapid heart rhythm originating above the ventricles, specifically in the atria or atrioventricular (AV) node. It tends to	Palpitations, dizziness, shortness of breath, chest	Quit smoking and limit alcohol

			consumption, reduce caffeine intake, and manage stress.
	start and end suddenly. (Includes AVNRT, AVRT, AT)	pain.	
ST elevation	ST elevation refers to the condition where the ST segment is higher than the baseline. It typically indicates acute damage to the heart muscle and is most commonly associated with acute myocardial infarction (heart attack).	Chest pain, radiating pain, shortness of breath, cold sweat, nausea, vomiting.	If the above symptoms occur, visit the hospital immediately for medication, procedures, or surgery.
ST depression	ST depression refers to the condition where the ST segment is lower than the baseline. This may indicate myocardial ischemia and can be associated with various heart conditions.	Chest pain, shortness of breath, cold sweat, dizziness.	Regular treatment, maintaining heart health, managing stress.

- You can download the full report as a PDF file for viewing.

c) Specialist Opinion Entry

In the ECG report, enter your opinion on the ECG data in the specialist opinion section at the top. Click the [Confirm] button to save your opinion.

<Specialist Opinion Entry Screen>

12) Patient Registration

- After logging in, navigate to the patient registration page via the [Menu] - [Patient Management] link on the left sidebar.

환자 관리

환자 등록

| 키워드 | 환자 번호, 환자 ID, 환자 성명 | 검색 |

환자 번호	환자 ID	환자 성명	생년월일	나이	성별	측정 횟수	주치의	생성일자
GOAT413	GOOD413	▓▓▓	1995-04-13	29	여성		▓▓▓	
▓▓▓	▓▓▓	▓▓▓	1995-05-24	29	여성		▓▓▓	2024-05-30 17:37:56
▓▓▓	▓▓▓	▓▓▓	1997-02-10	27	여성		▓▓▓	2024-06-19 14:25:27
▓▓▓	▓▓▓	▓▓▓	2022-06-18	2	여성		▓▓▓	2024-06-18 16:57:48
▓▓▓	▓▓▓	▓▓▓	2024-05-29	0	여성		▓▓▓	
▓▓▓	▓▓▓	▓▓▓	2024-05-30	0	남성		▓▓▓	

◄ 1 ►

- Click the [Register Patient] button, enter the account name to be registered as a patient, and then click the [Confirm] button.

* 환자 성명

* 환자 ID

* 환자 번호

* 생년월일
2024-07-09

* 나이
0

* 성별
○ 남성   ○ 여성

* 비밀번호
자동 생성

* 주치의
지현 강

진료과목

의료기관
2차 의료기관 등록 테스트

취소   확인

<Patient Registration Screen>
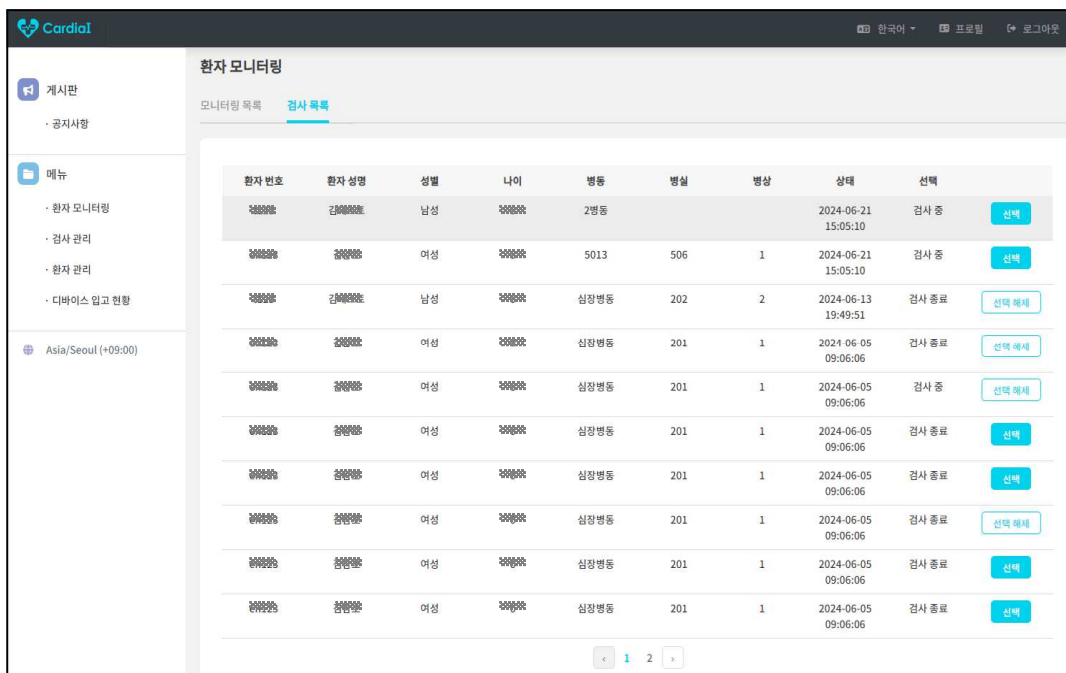
13) Patient Monitoring Screen
- Displays the real-time ECG status of in-hospital patients. Shows patient information, bed information, real-time heart rate, and the highest/lowest heart rate of the day.
- The patient's ECG status is indicated by color: green for normal and red for critical.

<Patient Monitoring Screen>

- The list of monitored patients can be selected from the test list. Clicking "Select" adds the patient to the monitoring list, and clicking "Deselect" removes them from the list.
- Click the icon next to the bed information to view the real-time ECG graph.

<Patient Monitoring Test List>

3. Storage and Maintenance After Use
    1) Store used equipment in a clean, room-temperature environment.
    2) Avoid subjecting the equipment to severe impacts during transport and handling.
    3) Do not use solvents on the external surface of the equipment.
    4) Charge the battery periodically to prevent it from fully discharging.

5. Performance

1. Main Body

  1) Battery Specifications: Rechargeable Lithium-ion Polymer battery, DC 3.7 V, 500 mAh

  2) Device-App Communication Performance

     - Communication Technology: Bluetooth Low Energy (BLE) communication

     - Communication Range: 10 m

  3) Waterproof/Dustproof Rating: IP55

2. Cradle

  1) Power Input Specifications: 12.0V ⎓ 1.5A, 18W

  2) USB Interface Specifications: USB 2.0, 480Mbps

3. ECG Measurement

  1) Number of ECG Channels: 2 channels (6 Leads)

  2) Linearity and Dynamic Range: Within amplitude variation ± 10% or 50 µV at 10 mVp-p, ± 300 mV DC offset

  3) Input Impedance Range: 10 MΩ or higher

  4) CMRR: 60 dB or higher

  5) Gain Accuracy: Within ± 10%

  6) Gain Setting: Adjustable gain of 10 mm/mV

  7) System Noise: 50 µV p-p or lower

  8) Frequency Response: 70% to 140% in the range of 0.67 Hz to 40 Hz

  9) Heart Rate Accuracy: Within ± 3 BPM or ± 5%, whichever is greater, in the range of 30 BPM to 250 BPM

  10) Sampling Rate: 250 samples/s ± 3%

  11) Data Size per Sample: 24 bits (Signed)

4. Mobile App

  1) ECG Measurement Test: Displays ECG data

  2) Login Function: Only registered patients can log in

  3) ECG Device-App (Mobile Platform) Communication Method: Bluetooth Low Energy (BLE) communication

  4) Mobile App (Mobile Platform)-Cloud (Web Server) Communication Method: WiFi / LTE

5. Web Software

  1) Web Access URL: https://admin.medifarmsoft.com/

  2) Cloud: Amazon Wev Services

  3) Communication Protocol: HTTP

  4) Security Protocol: TLS 1.2 (Transport Layer Security)

     - 256 bit AES (Advanced Encryption Standard)

  5) Log Storage: Assigns unique IDs to each user, doctor, and measured ECG, and stores logs based on a UID (Unique Identifier) system

6) Display of Arrhythmia Detection Results

7) Record Measurement Date Function: Displays the date of data measurement (year/month/day/hour/minute/second) in the ECG Report

6. Maintenance

1. Storage and Maintenance After Use

 1) After using the device, wipe it with an alcohol-dampened cloth before storing it.

 2) If not in use for an extended period, turn off the device, disconnect it from the USB cable, and store it separately.

 3) Storage location should follow these precautions:

  (1) Store in a place where it is not exposed to water.

  (2) Ensure it is protected from adverse effects of pressure, temperature, humidity, ventilation, sunlight, dust, salt, and ions.

  (3) Store in a secure place with no risk of tilting, vibration, or impact.

  (4) Avoid storing near chemical containers or gas-emitting areas.

  (5) Keep accessories and cords clean and free of foreign substances.

  (6) Maintain the product in a clean state to avoid interference during the next use.

 4) Cleaning Method: Gently wipe the device surface with a dry cloth, taking care to prevent any water or liquid from entering the device.

 5) Inspection and Maintenance

  (1) When using a device that has not been used for a long period, ensure it operates correctly.

  (2) Do not use corrosive cleaners or disinfectants.

  (3) For additional information, refer to the user manual for handling or repairs.

 6) Storage and Transportation Conditions

  (1) Temperature: -10 to 50 ℃

  (2) Humidity: 10 to 95 %R.H.

  (3) Atmospheric Pressure: 80 kPa to 106 kPa

2. Battery Replacement Method

 1) Battery replacement can only be performed by the manufacturer or an authorized service provider.

 2) Specifications for the replacement battery:

  - Manufacturer: ATL(Amperex Technology Co., Ltd.)

  - Type: Recharge Lituim-ion Polymer battery

  - Model name: BAT500-562129

  - Rating: 3.7 Vdc

  - Capacity: 500mAh

 3) Remove the screws from the device, and detach the upper and lower cases.

 4) Disconnect the connector of the battery to be replaced.

 5) Verify the specifications of the new battery, connect the connector to the new battery, and reassemble the case.

 6) After replacing the battery, confirm that the device powers on correctly.

 7) Dispose of the replaced battery according to designated disposal procedures.

3. Disposal of Product and Components

 1) The main unit and components can be disposed of according to electronic device disposal

guidelines or returned to the manufacturer.

2) The charging adapter and cradle should be disposed of according to the method provided by the supplier.

7. Product Warranty Policy

- This product has been manufactured by Medifarmsoft Co., Ltd. under rigorous quality control, inspection, and production processes.

- The criteria for compensation regarding product repair and replacement follow the "Consumer Injury Compensation Rules."

- Medifarmsoft Co., Ltd. assures that proper care has been taken in the design and manufacture of this product. This warranty replaces or excludes all other warranties, whether implied or stated by law or other means, including (but not limited to) implied warranties of merchantability or fitness for a particular purpose.

- The handling, storage, and cleaning of this product, as well as factors related to the patient, diagnosis, and other issues beyond Medifarmsoft Co., Ltd.'s control, may directly affect the product's outcomes and use.

- Medifarmsoft Co., Ltd.'s obligations under this warranty are limited to the repair or replacement of this product. Medifarmsoft is not liable for any incidental or unavoidable losses, damages, or expenses arising directly or indirectly from the use of this product.

- Medifarmsoft Co., Ltd. has no authority to assume any other person's incidental liability or obligations related to this product.

- Medifarmsoft Co., Ltd. does not take responsibility for products that have been reused, reprocessed, or otherwise altered, and makes no express or implied warranties, including but not limited to those related to commercial use or intended purpose.

- Service requests for product and cybersecurity incidents can be made through the following contact:

Manufacturer: Medifarmsoft Co., Ltd., Phone: 02-6215-1190

Address: 25, Beobwon-ro 11-gil, B-dong 906, 907, Songpa-gu, Seoul (Munjeong-dong, H Business Park)