

CARDINOVA ECG Recorder

User's Manual

Model Number: EC-100

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Important Warnings

- Read this manual thoroughly before using this product. For your safety, follow the operating instructions and all safety measures, including warnings and cautions listed in this manual, to ensure the safe and reliable performance of the system.
- The electrode patch on the market, which can be used with the CARDINOVA ECG Recorder, is for one-time use only. Do not reuse it. To prevent the spread of infection or disease, dispose of the electrode patch properly after each use.
- To have the best user experience, update the CARDINOVA ECG RECORDER App to the latest version.
- Fully charge the CARDINOVA ECG Recorder.
- Install the App exclusively designed for the ECG recorder to the smartphone: "CARDINOVA ECG RECORDER App."
- Turn on the Bluetooth function on the smartphone.
- Procedures, screenshots, and illustrations in the user manual may be modified without any further reminder.

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Introduction

1.1 Description of CARDINOVA ECG Recorder

The CARDINOVA ECG Recorder can act as a single-lead electrocardiogram (ECG) in hospitals care facilities, and home settings. The sensor acquires ECG signals from users and transmits data to the exclusive App via wireless technology. Doctors can access users' health status based on the data displayed on the smartphone.

1.2 Intended Use

The CARDINOVA ECG Recorder is a wireless recording system intended for use by healthcare professionals for record and display of physiological data within healthcare settings or at home. This includes electrocardiogram (ECG), R-R interval and heart rate. Data is transmitted wirelessly to a separate location (such as a mobile phone) for storage and display. The CARDINOVA ECG Recorder can be configured by authorized persons to modify, merge or ignore any of the operational alerts, but not to set new alerts related to physiological data.

The device is not intended to be used on critical care patients and is intended to supplement vital signs recording for later viewing by healthcare professionals, not to replace current standards of care. The device is an ambulatory, continuous recording system intended for use on general care patients and on patients who are 21 years of age or older.

1.3 Contraindications

Not suitable for users with sensitive skin to hydrogel and patch gel.

Do not use this sensor when there is a wound or inflammation on the sticking part of the skin.

1.4 Side Effect and Complication

N.A.

1.5 Equipment Requirements of CARDINOVA ECG Recorder

Smartphones with Bluetooth function (Android 11 or higher/iOS 13.0 or higher).

CARDINOVA ECG RECORDER App*

Note: The item marked with an * are not included in this product.

1.6 Approaches to Calculate Heart Rates

While continuously measuring the ECG signal, the sensor analyzes the signal quality of the signal segments collected from the previous to the present. If the signal quality is not good, the returned heart rate value is the one calculated last time. If the signal quality is standard, the R wave detection is performed for this ECG to obtain the RR interval (RRI). Outliers are

filtered. The heart rate value is calculated based on the reserved RRI.

1.7 Statements

Conductive components of ELECTRODES and associated connectors for TYPE BF or CF APPLIED PARTS, including NEUTRAL ELECTRODE, cannot contact other conductive components, including earth.

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1.8 Caution and Important Information

Caution

- The CARDINOVA ECG Recorder is only for adults over 21 years old but not for pregnant women.
- The CARDINOVA ECG Recorder is designed for clinical evaluation and reference only. It does not have diagnostic functions.
- Do not use this device if the patients have had symptomatic episodes, which could result in immediate health danger to the patients.
- Do not use this device on patients who have a known history of life-threatening arrhythmias.
- Not suitable for people with very sensitive skin, skin allergies, and hydrogel allergies.
- Remember not to use the CARDINOVA ECG Recorder in environment with electromagnetic interference, such as surgical equipment, electrosurgery, ultrasound, radiology equipment, automated external defibrillator (AED), computed tomography (CT), magnetic resonance imaging (MRI), wireless signal transmitters, pacemakers, and other electronic devices which may generate electromagnetic interference.

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Important Information

- Use the manufacturer-approved CARDINOVA electrode patch for the ECG measurement. Other approaches may cause abnormal ECG signals.
- The electrode patch must be discarded immediately after use and cannot be reused. Repeated use may cause skin allergies or other adverse reactions.
- Users must use the exclusive docking to charge the battery of the sensor.
- The CARDINOVA ECG Recorder works only with its app developed by the manufacturer. The app is available on Google Play Store and Apple App Store.
- Without the manufacturer's authorization, modification of the CARDINOVA ECG Recorder is not allowed.
- Do not disassemble the device or alter any component. For technical assistance, please get in touch with the official manufacturer.
- Remember to charge the CARDINOVA ECG Recorder if you use it for the first time.
- Prolonged use of the electrode patch may cause allergic reactions or skin irritation. Contact your doctor if you have an allergic reaction or skin irritation persists.
- When connecting the CARDINOVA ECG Recorder with the mobile device, follow the manual to ensure that all steps are completed properly.
- When using the recorder, the user must keep still to obtain qualified ECG signals for clinical references.
- The electrode patch can be attached for 24 hours to facilitate a long-term examination.
- When the power of the CARDINOVA ECG Recorder is low, the measurement will be stopped automatically. Please charge the recorder as soon as possible.
- Do not take a bath or swim when the recorder is attached to the body. You can take a shower, but do not rinse the recorder directly with water.
- Do not use caustic or abrasive cleanser to clean or wipe the CARDINOVA ECG Recorder.
- Charge the recorder at least once every three months to preserve battery life.

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Cardinova ECG Recorder

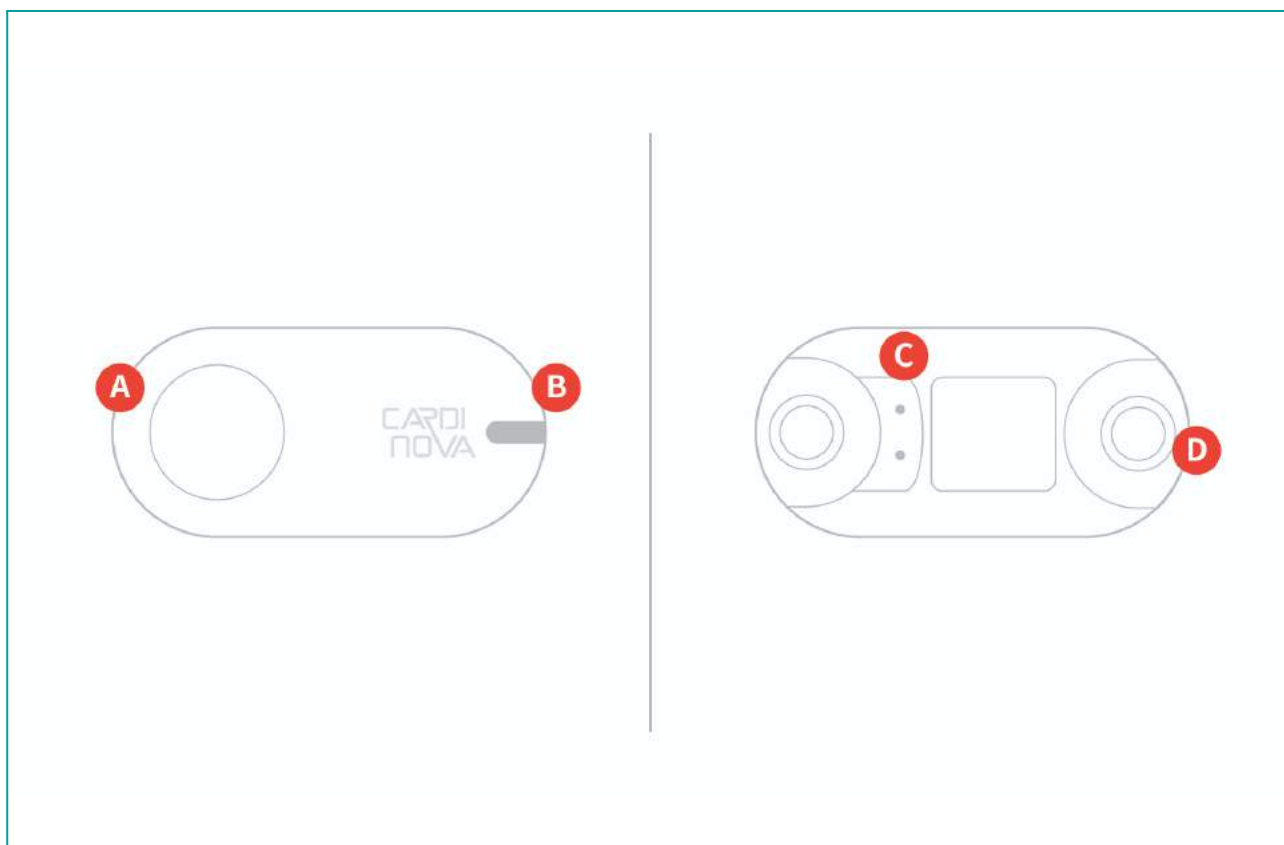
2.1 Package Contents

- A. ECG Recorder (EC-100)
- B. Docking for the ECG recorder (CG-200)
- C. User manual
- D. USB charging cable



2.2 Product Profile

- A. Power Switch Button
- B. RGB LED indicator
- C. Electrode for charging
- D. Electrode connector



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Product Specifications

Model Name	EC-100
Sizes ECG Recorder	58.5 x 28.5 x 9.9±0.2 (mm)
Docking	71.5 x 32.3 x 16.3±0.2 (mm)
Materials	PC+ABS
Weights	ECG Recorder: 15 ± 0.5 g (0.53 oz)
Docking	12 ± 0.5 g (0.44 oz)
Operating Life	3 years
Channel	Single channel
Sampling Rate (Hz)	250 Hz
Heart Rate	30~240 bpm (±1% or ±1 bpm)
R-R Interval	250~2000 (±10%) ms
Operating Temperature	5°C~45°C (41°F~113°F)
Operating Humidity	10%~95%RH (non-condensing)
Storing Temperature	-25°C to 70°C (13°F to 158°F)
Storing Humidity	10% ~ 95%RH (non-condensing)
Atmospheric Pressure	700 to 1060 hPa
Ingress Protection Rating	IP47
Communication	Wireless 2.4GHz
Transmission Range	Up to 3 meters (Up to 10 feet, open space without any obstacle)
Data Storage	In the App
Battery	Li-ion polymer (3.8V/160 mAh)
Charging Time	3 hours (0 ~ 100%)
Charging Temperature	0°C~45°C (32°F~133°F)
Button Function	On/Off
Indicators	RGB LED Motor vibrator
Charger (CG-200)	Rate input: 5V = 0.5A

Product Specifications (Continued)

Frequency Response	0.67~40 Hz
Dynamic Input Range	± 5 mV
Input Impedance	> 10M Ohm
Common-mode Rejection Ratio	> 66 dB

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2.3 Wearing the Recorder and Patch

Figure 1

Place the CARDINOVA ECG Recorder on the electrodes of the patch, and press it until you hear a "CLICK." This sound means that the sensor is inserted into the patch successfully.

Figure 2

Use an alcohol pad to wipe the left chest for exfoliation (wipe for the alcohol to dry after wiping), then tear off the sticker from the back of the electrode patch.

Note: if there is chest hair where the user attaches the electrode patch, please remove the hair first.

Figure 3

Attach the electrode patch which carries the CARDINOVA ECG Recorder below the clavicle (with the power switch button facing up), and the other end is inclined at 45°~60°.

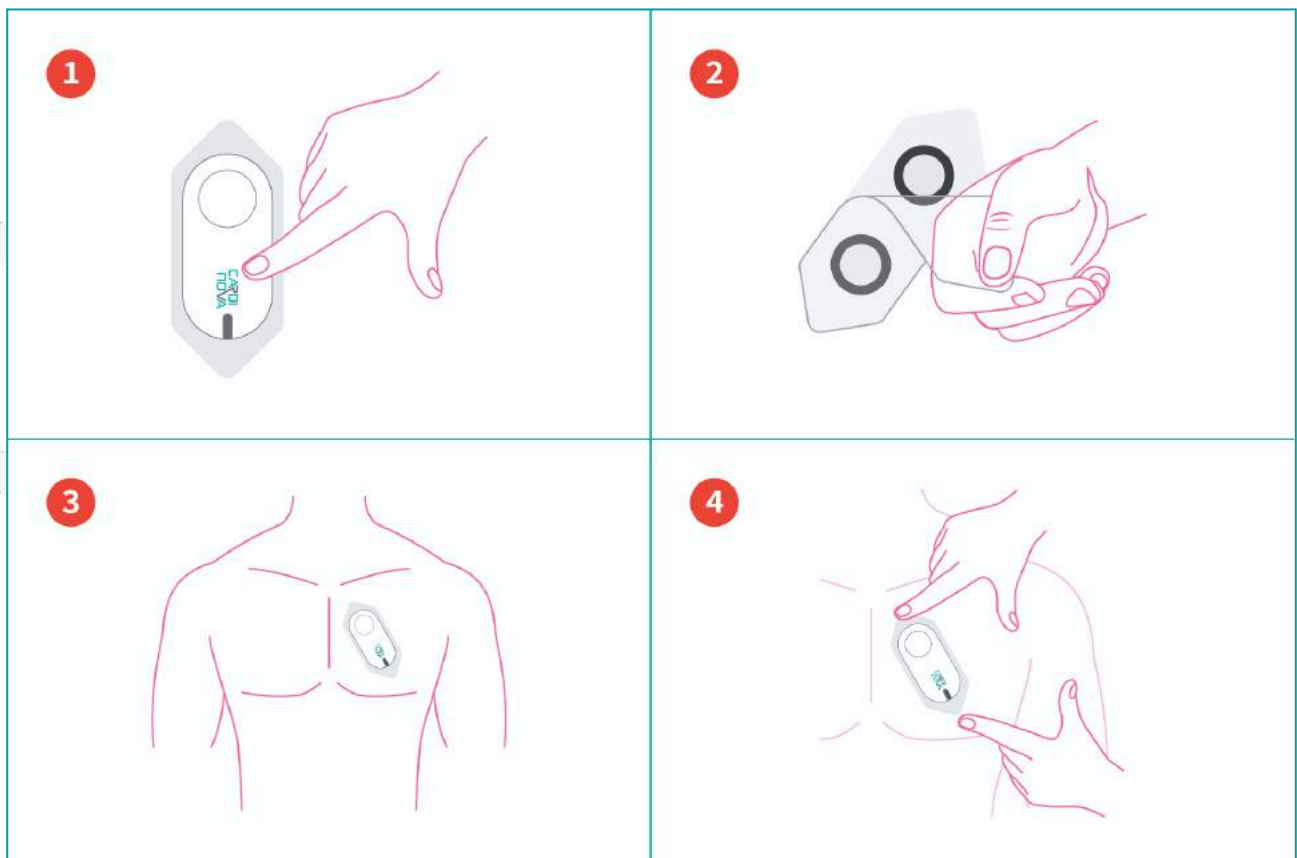
Figure 4

To ensure that the electrode patch is adhered to the body completely, press the electrode patch with both hands for 30 seconds to confirm that it is properly adhered.

Notes.

If the electrode patch is not sticky enough to adhere to the body, please replace the electrode patch with a new one.

If you experience a rash, blisters, inflammation, or other discomforts where the electrode patch adheres to your skin, consult a doctor/physician immediately.



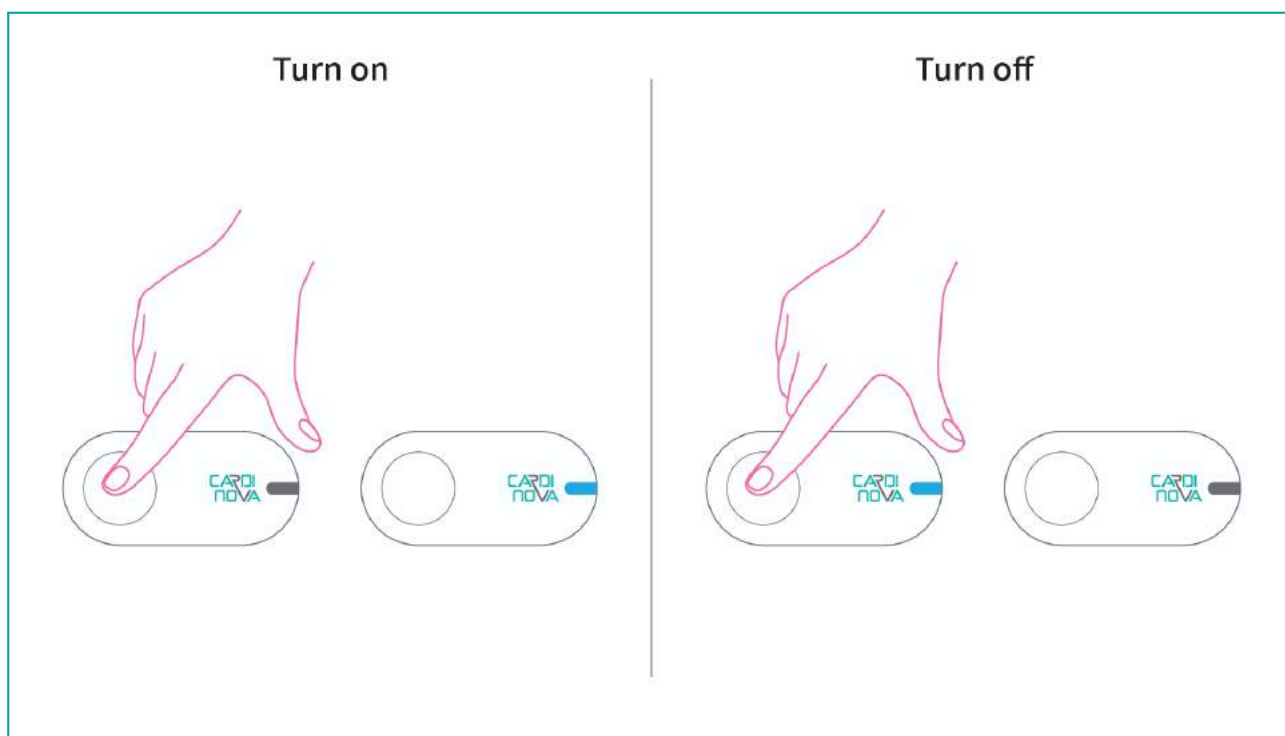
2.4 Turn on/off the CARDINOVA ECG Recorder

Turn on.

Press the button to turn on the CARDINOVA ECG Recorder. The blue LED indicator will flash and vibrate three times. The blue light means the power is on.

Turn off.

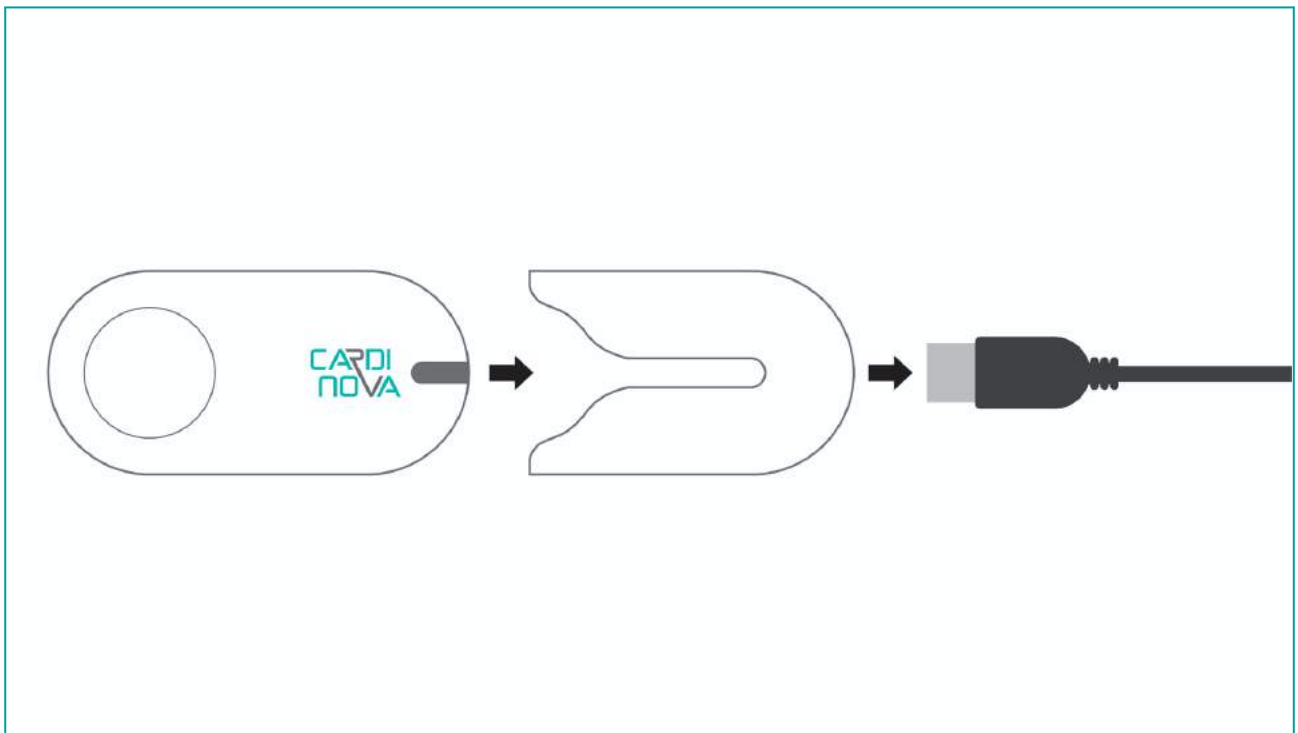
When the LED indicator of the CARDINOVA ECG Recorder is flashing blue, press the button and the LED will turn off and vibrate three times to indicate the power is off.



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2.5 Charging the CARDINOVA ECG Recorder

- A. Place the CARDINOVA ECG Recorder in the dock. The power switch button must be outside of the dock.
- B. Connect the dock to the USB cable.
- C. Connect the USB cable to a USB charger or a PC USB.
- D. The flashing red light indicates that charging is in progress.
- E. The green light indicates that charging has been completed.



2.6 Approaches to Clean the ECG Recorder

Please use a clean, soft cloth to clean the CARDINOVA ECG Recorder. Do not use benzene, gasoline, or corrosive or volatile detergents to clean.

2.7 Approaches to Remove the Patch and the ECG Recorder

To remove the patch, slowly and carefully peel off the patch with one hand to avoid skin damage caused by peeling the patch too quickly.

Cardinova Application

3.1 Download and install the app.

Android Devices.

Scan the QR code and download the App to your device. You can also search "CARDINOVA ECG RECORDER" in Google Play Store and download the App.



Apple Devices.

Scan the QR code and download the App to your device. You can also search "CARDINOVA ECG RECORDER" in the Apple App Store and download the App.

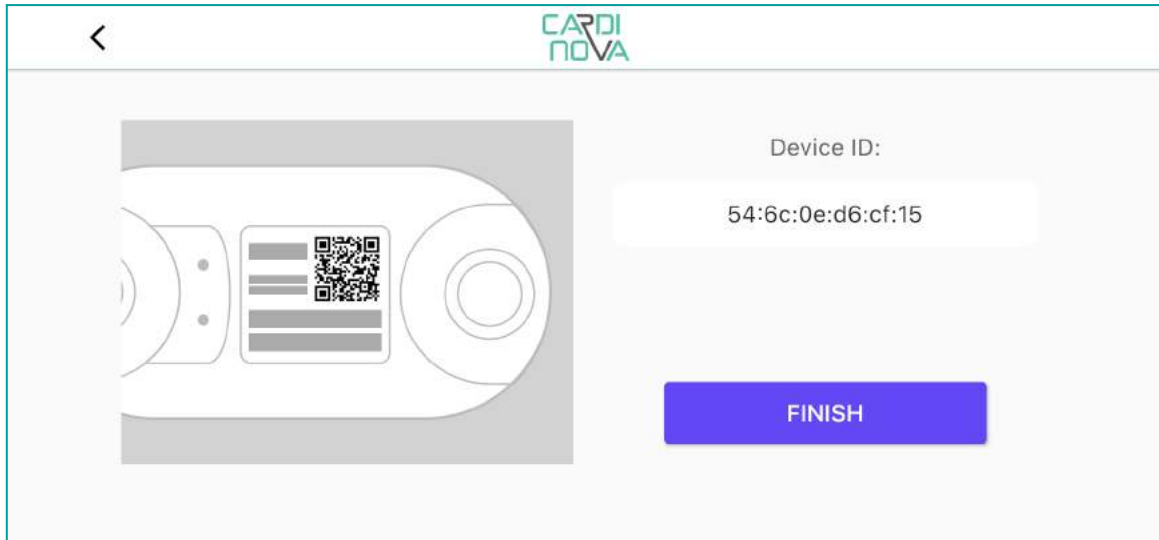


3.2 Launch the App and Login

- A. Tap the CARDINOVA ECG RECORDER app icon to launch the app. If this is the first time you have used this App, tap the login button.
- B. Enter your name and password, and press “Next.”
- C. Create your user profile and fill in all the blanks.

3.3 Pair the App with the CARDINOVA ECG Recorder.

After completing the profile, your need to pair the recorder with the App. Please scan the small QR code under the CARDINOVA ECG Recorder.



3.4 CARDINOVA App Homepage.

The homepage allows the user to connect the app with the CARDINOVA ECG Recorder, perform ECG tests, and select test time. Users can use the ECG History Section to review, comment, and download ECG tests.

Main Screen (I).

- A. Test Duration: Select the test duration (30 seconds or 3 minutes).
- B. User Profile: Review users' information.
- C. History Section: Review all completed tests and export them as PDF files.
- D. Connection/Disconnection with the Recorder, and battery percentage left of the Recorder.
- E. Start the test.



Main Screen (II).

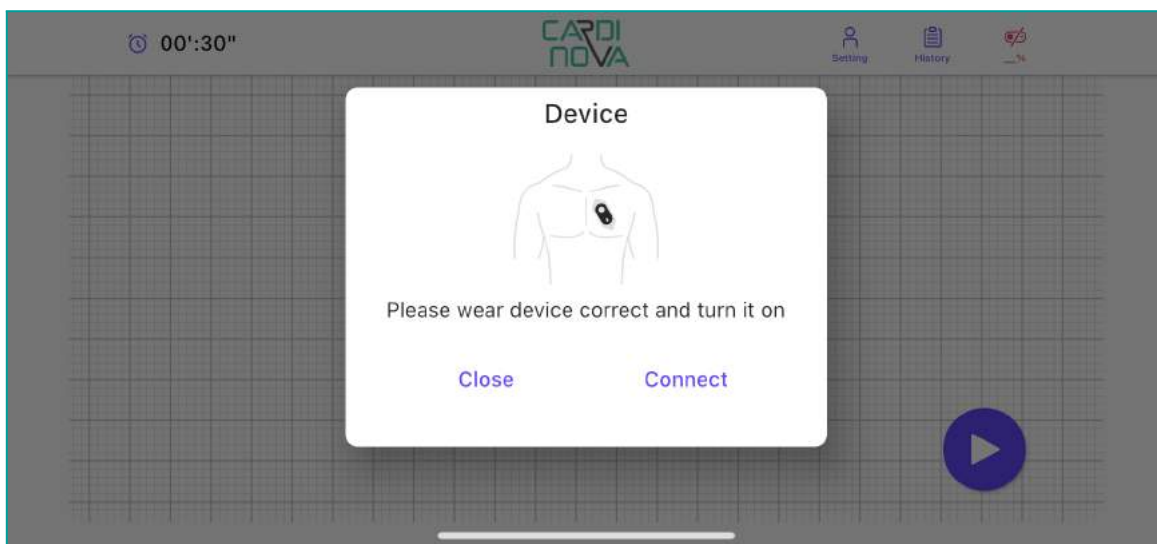
- A. Heartbeat monitoring.
- B. Add comments.
- C. ECG monitoring.



3.5 Approaches to Connect with the Mobile Device.

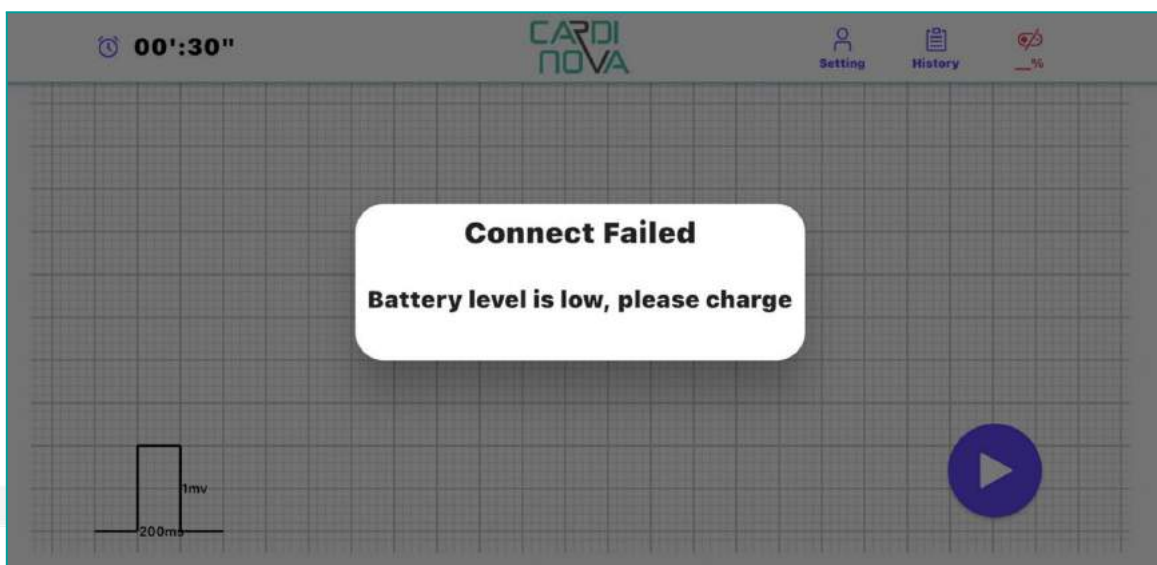
- A. Wear and turn on your CARDINOVA ECG Recorder.
- B. On the homepage, find the start icon and then tap it.
- C. A pop-up menu will remind you to wear the device correctly and turn on the recorder.
- D. Click "connect."
- E. When the icon becomes blue, the app connects to the mobile device, and you can start your tests.





3.6 Battery Low Display.

If the window "Battery level is too low, please charge" is displayed, please do not use the ECG recorder and charge it fully before testing.

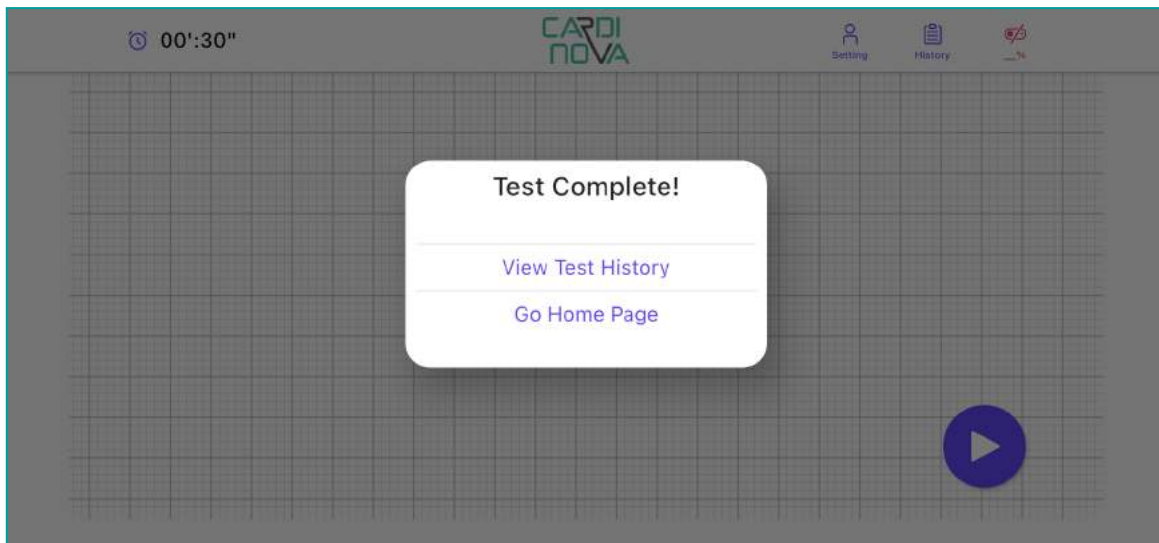


3.7 Perform ECG Tests.

- A. Tap the purple button to start the test.
- B. During the test, you can see your heartbeats here.
- C. During the test, you can add a comment by tapping the red button.
- D. During the test, the App displays a real-time ECG graph (refresh rates: 10 seconds).



If the test is completed, a pop-up menu will let the user choose to view the test history immediately, or go to the homepage and perform a new test.



3.8 Approaches to Add Comments.

During the test, users can add comments (an empty comment at this stage) whenever they feel uncomfortable or for any other reason.

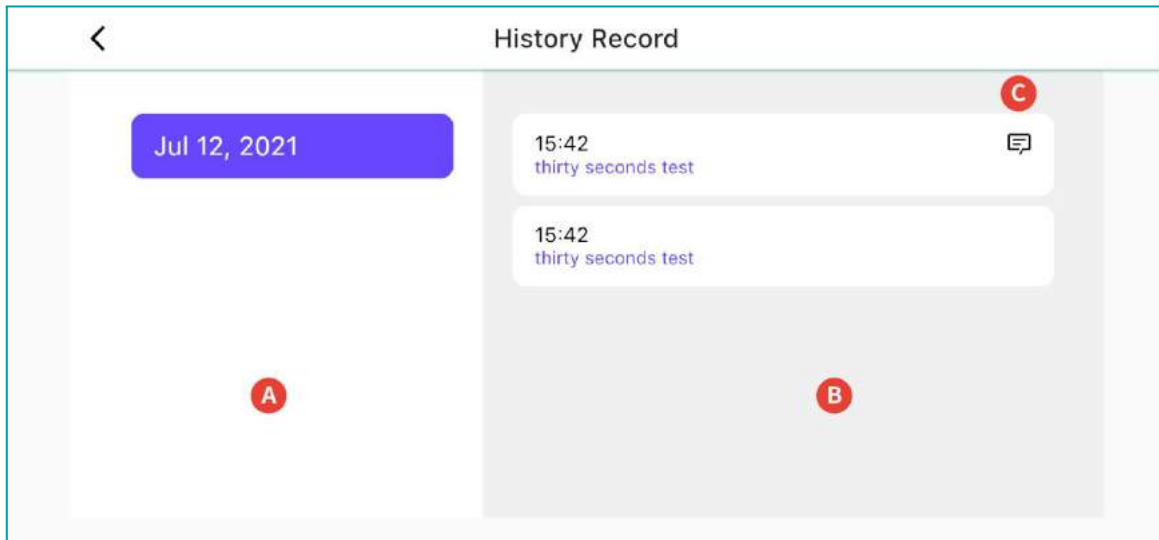
- A. Tap the comment button to add the comment.
- B. An empty comment will be added. Users can add the content later in the History Section.



3.9 History Section.

In this section, it is possible to view all recorded ECG tests and select one of them to review. Interface.

- A. The dates of recorded tests are displayed here (by day).
- B. All the tests completed on the selected date are displayed here.
- C. An icon will be presented if the recorded ECG has comments.



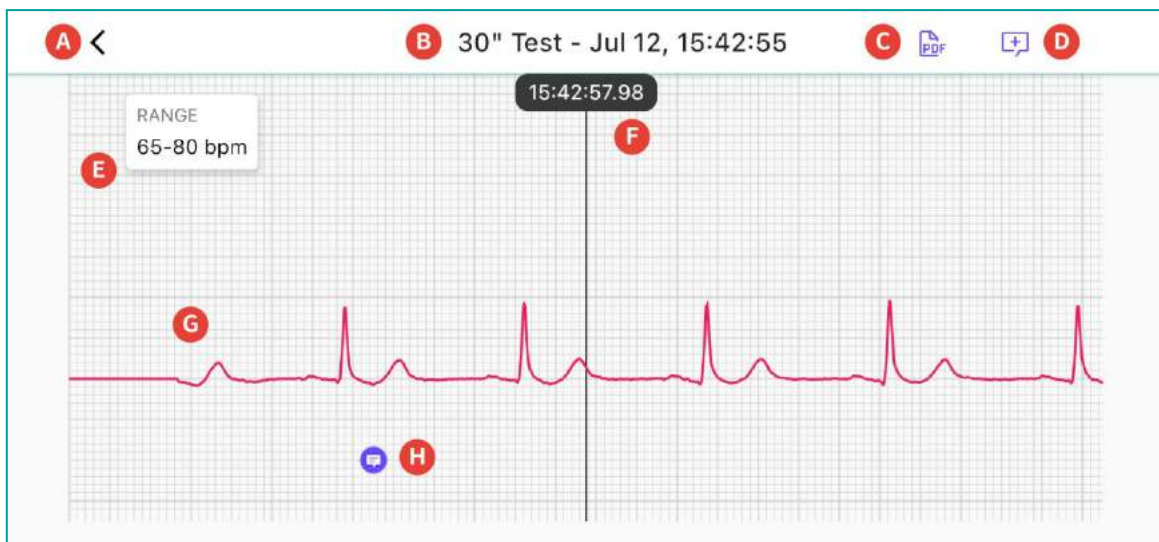
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3.10 ECG Interface (History).

Once you select one of the recorded ECG tests, you can access the recorded ECG to review your heart activities and all the comments you added. It is also possible to navigate the ECG through swiping right/left and share and save the PDF report.

Interface

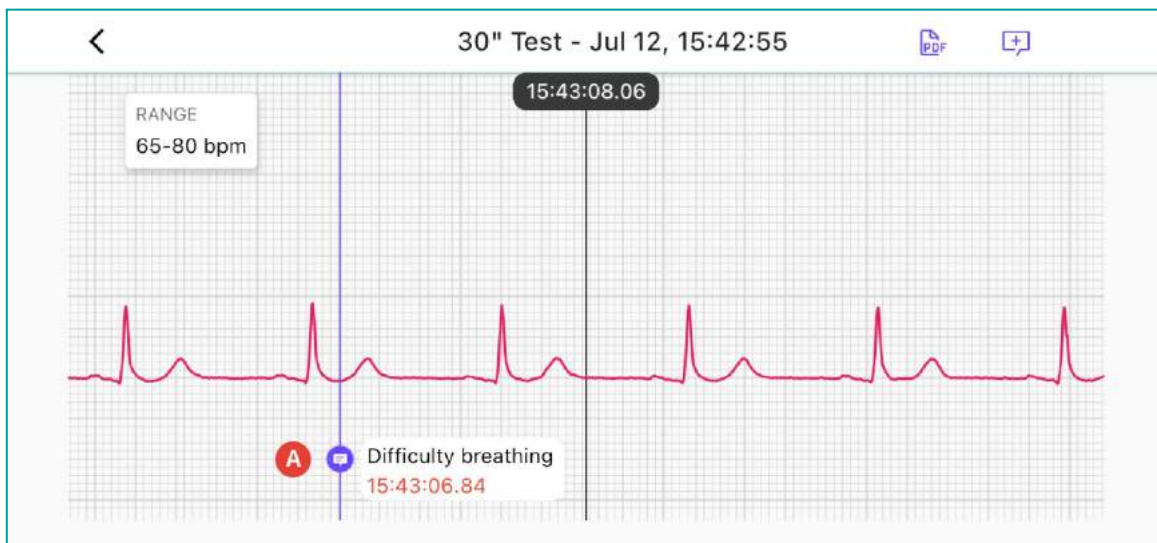
- A. Close and return to the History page.
- B. Test name (date, hour: minute: second).
- C. View and export a PDF report.
- D. Add a comment.
- E. Heart rate monitoring.
- F. Test time monitoring.
- G. ECG monitoring.
- H. Icon of comment.



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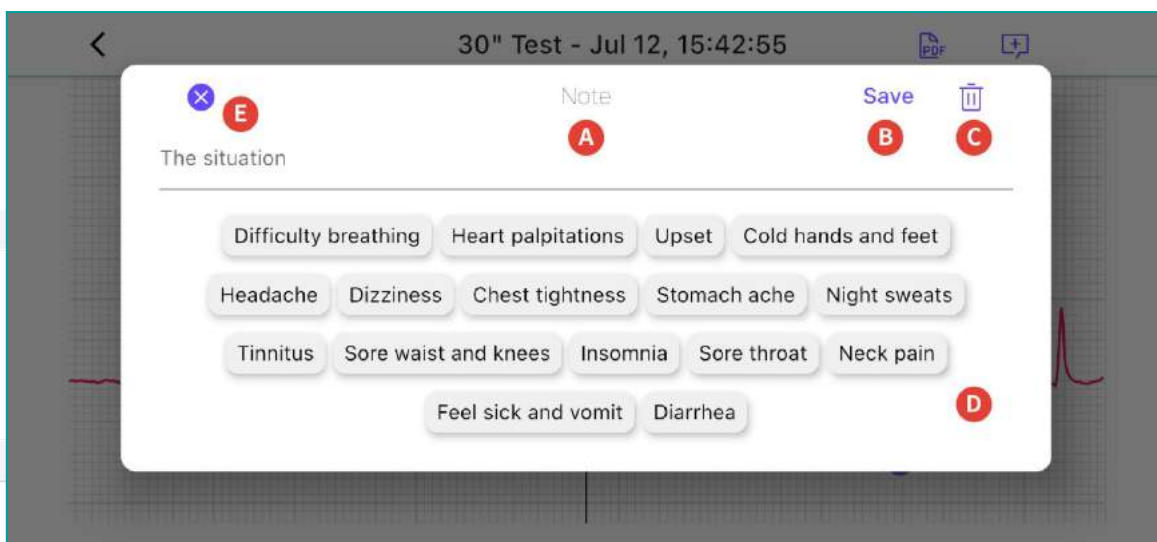
3.11 Review and Add Comments.

In the recorded ECG interface, select a comment by tapping the purple icon.



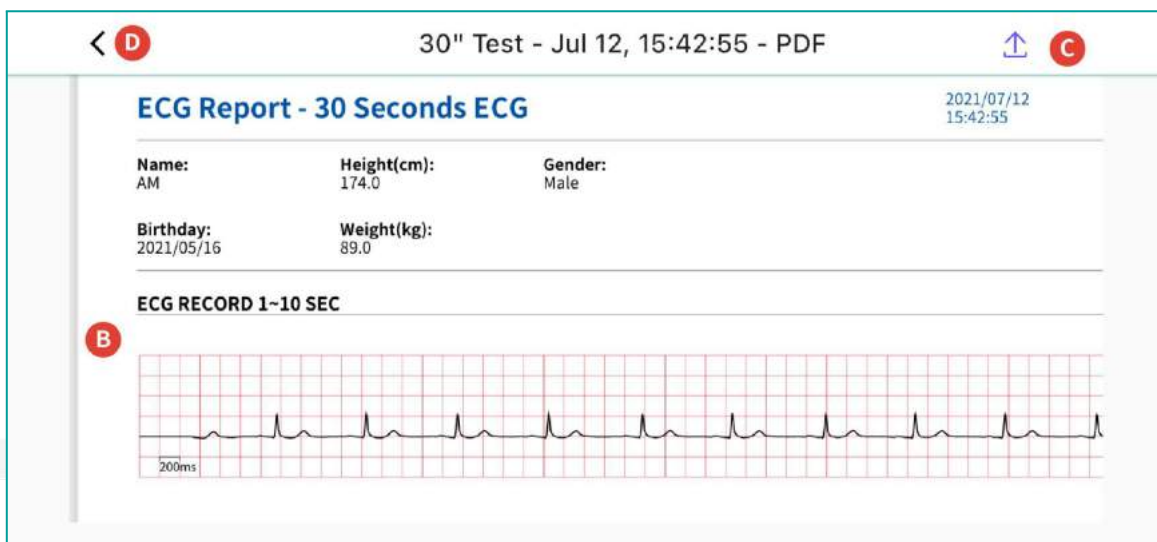
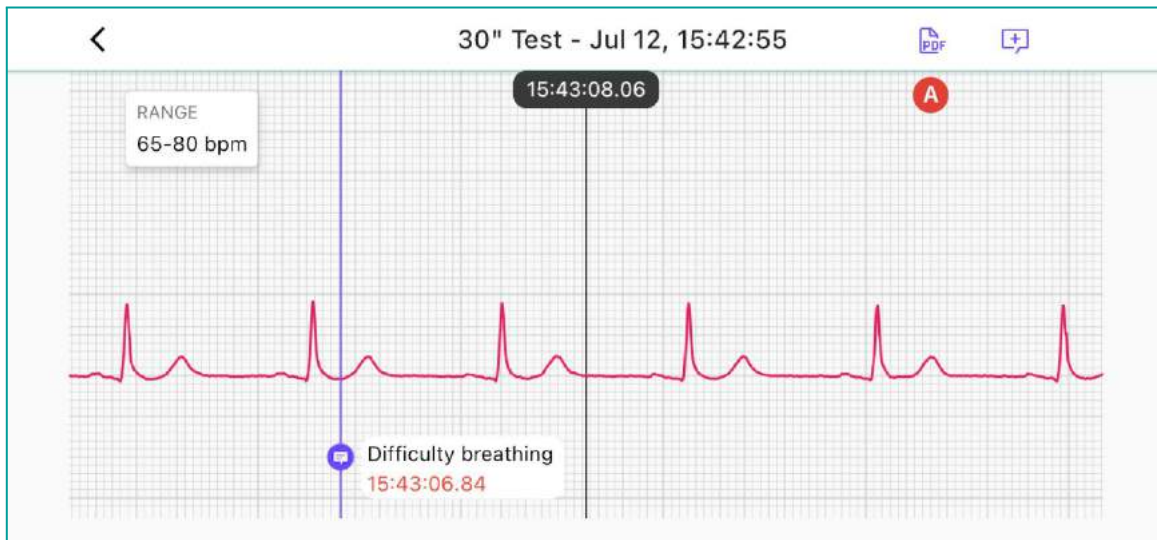
The second tap will open a menu where:

- A. it is possible to write a comment;
- B. users can choose to add an existing tag;
- C. it is possible to save the comment;
- D. it is possible to delete the comment by tapping the icon of trash;
- E. close the menu.



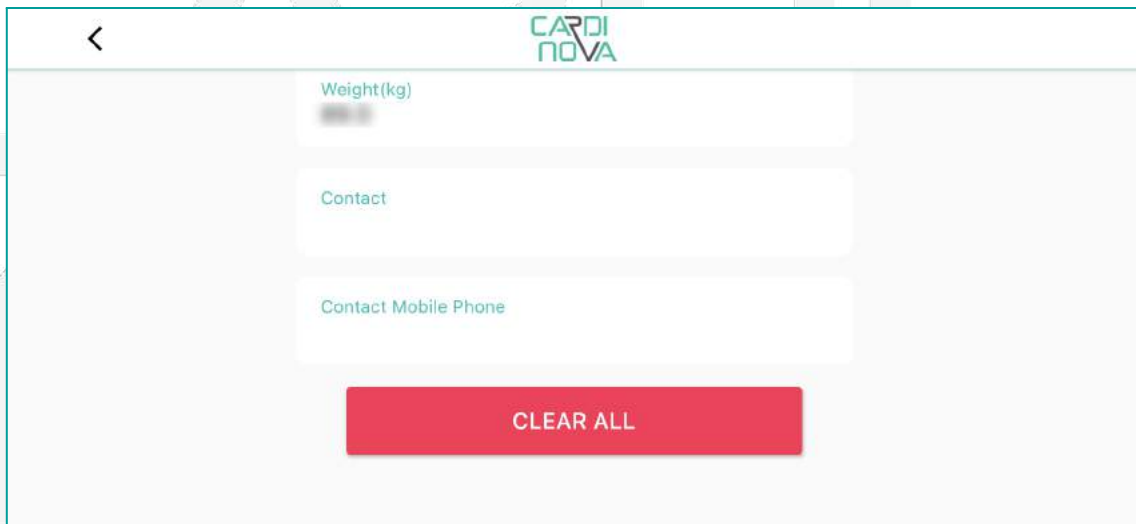
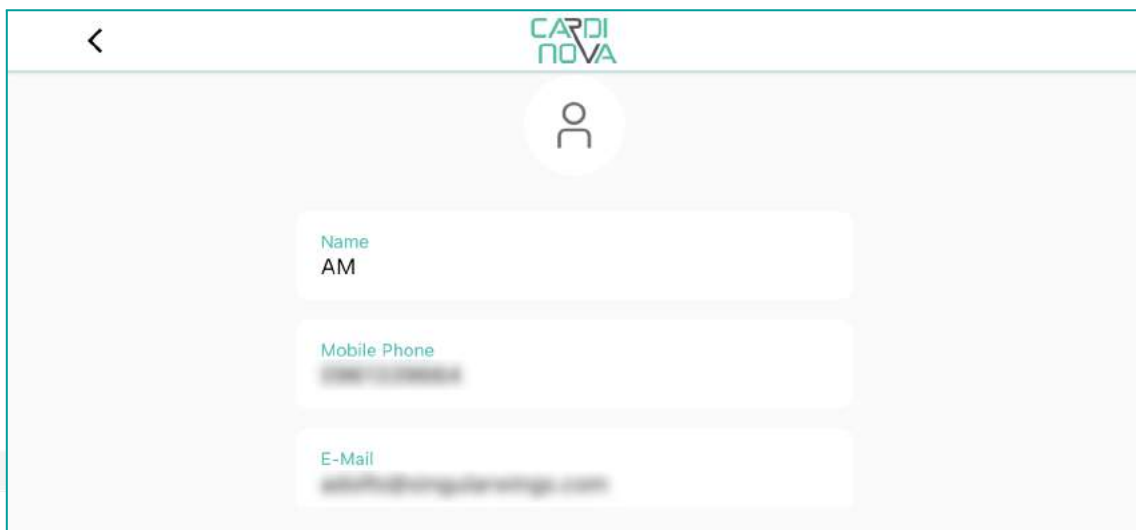
3.12 Read and Export PDF Reports.

- A. In the recorded ECG interface, select the PDF icon.
- B. The app will load the PDF. You can read it here.
- C. Reports can be shared and exported by tapping the share icon.
- D. Tapping this icon will close the PDF and return to the previous screen.



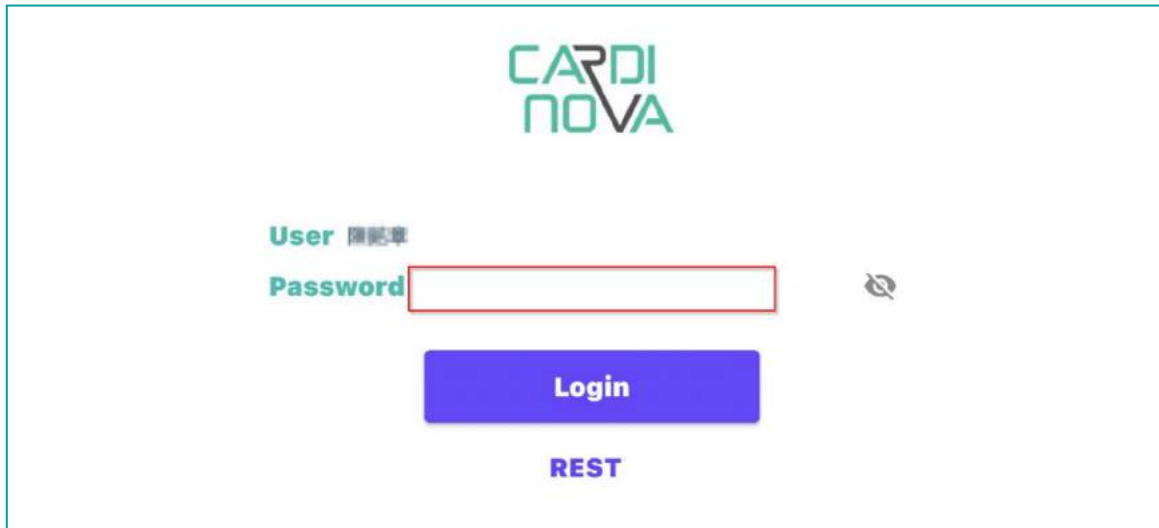
3.13 User Profile.

- A. From the homepage, tap the icon to view users' information.
- B. The User Profile page shows the information which is added (by the users).
- C. Scroll all the way down; there is a red button. The user can reset the app and his/her data by tapping the button.



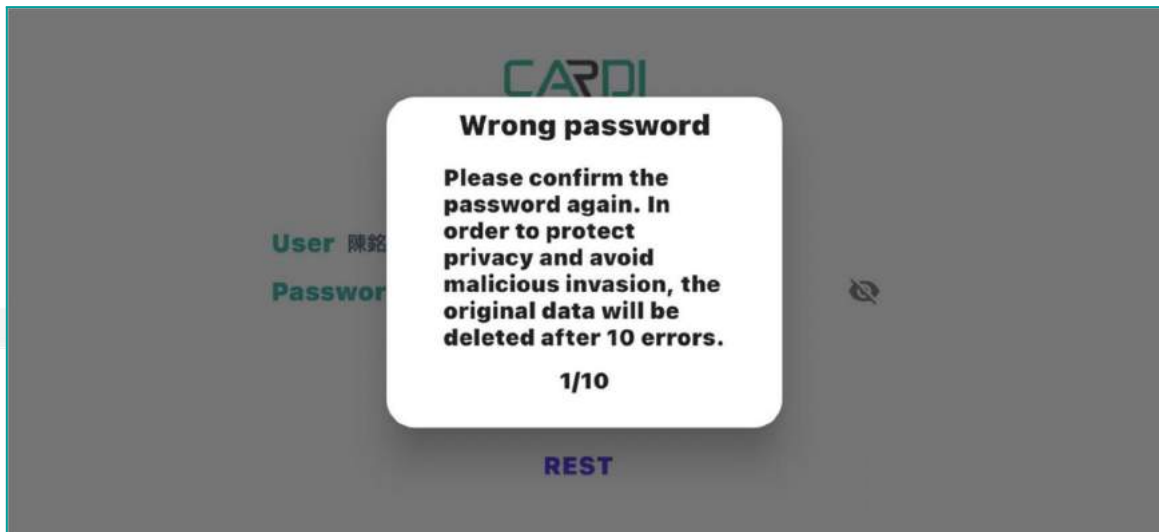
3.14 Information Security.

If you have not logged to the CARDINOVA ECG RECORDER App for a long time, you will be required to fill in your “password” again.



The screenshot shows the login interface of the CARDINOVA ECG RECORDER App. At the top center is the CARDINOVA logo. Below it, the text "User 陳銘章" is displayed. Underneath, the label "Password" is followed by a red-outlined input field. To the right of the input field is a small eye icon. Below the input field is a blue "Login" button. At the bottom center, the word "REST" is written in blue.

If you enter the wrong password ten times, the original information will be deleted, and the user profile must be re-entered.



The screenshot shows the same login interface as before, but with a white warning dialog box in the center. The dialog box has the title "Wrong password" and the text: "Please confirm the password again. In order to protect privacy and avoid malicious invasion, the original data will be deleted after 10 errors." Below this text, it says "1/10". The background is dimmed, showing the "User 陳銘章", "Password" input field, "Login" button, and "REST" text.















4.0 The LED Indicator of the CARDINOVA ECG Recorder.







The following table describes the meanings of the colors the LED indicator flashes.

Events	Actions	Indexes
Turn On	Press the button	The LED indicator flashes blue and vibrates three times.
Turn Off	Press the button	The LED indicator extinguishes and vibrates three times.
Testing	N.A.	The LED indicator flashes green once every 5 seconds.
Charge	Place the recorder in the docking	The LED indicator flashes blue.
Fully charged	Place the recorder in the docking	The LED indicator flashes green.

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5.0 Explanations of icons and symbols.

	Cardinova logo		Serial number
	FCC: This product is certified by the Federal Communication Commission		Non Sterile
	NCC: This product is certified by the National Communication Commission		Do not use if the package is damaged
	Recyclable product		Keep dry. Keep from rain drops
	Please recycle according to local official or dealer recycling recommendations		Temperature limitation
	Type BF equipment		International Protection Marking. First Digit – SOLIDS (4): Protected from tools and small wires greater than 1.0 millimeter. Second Digit – WATER (7): Protected from immersion between 15 centimeters and 1.0 meter in depth. Immersion for 30 minutes at a depth of 1 meter
	Refer to instruction manual / booklet		Humidity limitation

	Manufacturer		Direct current
	Date of manufacture		Expiration date
	Caution		Prescription only



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