Sky Labs ROK1 CART-I Smart Ring User Manual

USER MANUAL

Sky Labs ROK1 Smart Ring
Model: CART-I

Thank you for choosing CART-I. Please read this Instruction for use, including all Precautionary information and instructions, before using your device.

Failure to follow the instructions below could result in device damage err malfun.cn, or even injury.

The issue date for IF-01(revisnm 1) is December 2019. If more than three years have elapsed since this date, contact Sky Labs Inc. to determine if addibonal device informabon updates are available.

If you have any questions about using your device or mobile app, plea. contact Sky Labs Inc.

CHAPTER 1. Device description & Intended use

CART-I consists of devices, including CART-Ring and CART-Cradle, CART-App(Mobile Application) for general users, and CART-Web(website) for doctors. CART-I provides photoplethysmography (PPG) signals to measure heart rate(HR) and to identify Atrial Fibrillation or its burden, and electrocardiogram(ECG) signals to offer supplementary information to doctors. A part of CART-I, CART-Ring is a ring-type wearable device, which collects(or records), stores, and transfers not only PPG signals but also single-channel ECG signals. CART-Ring operates continuously to collect only PPG signals

- referred to as "Background-Chede within this submission – without user intervention, while collecting both PPG and ECG signals

- referred to as "Self-Check" within this submission – by users' intention. Inside of CART-Ring, a Lithium Polymer battery can be recharged using CART-Cradle, operating based on the wireless charging technique.

CART-I utilizes an iOS-based CART-App, which is installed on an Phone, to obtain PPG and ECG signals from CART-Ring. After obtaining both signals,
CART-App transmits those signals to a cloud server to get results, such as an estimation of HR and an analysis of Atrial Fibrillation or not.
CART-App offers the statistics, including the number of checks, the analyzed results, and etc., with graphs and lists to users; Data offered to users are synchronized to their own account. After connecting to users, doctors get more detailed information from a cloud server for their connected users than those for general users using CART-Web.

Chapter 2. Packages

CART-Ring

CART-Cradle

USB Cable

User manual(IFU)

NOT including the mobile phone to install the application, CART-app and adapter.
You'll additionally need the followings to operate the device of Sky Labs Inc.

✓ mobile phone : >iPhone 6, >i0S10.0, BLE(BT 5.0)
✓ CART-App is available in the Apple App Store.

CHAPTER 3. Device specification

1. **Product name : Heart Monitor**
2. **Trade name / Model name : CART-I**
3. **Model Number**

Model number of full packages(set)
AOKI.
AOK2
AOK3
AOK4
AOK5
AOK6
AOK7
AOK8

Model number of CART-Ring
ROK1
ROK2
ROK3
ROK4
ROK5
ROK6
ROK7
ROK8

Model number of CART-Cradle
COK1
COK2
COK3
COK4
COK5
COK6
COK7
COK8

4. Intended use

CART-I is indicated for self-testing by patients who have been diagnosed with, or are susceptible to developing, atrial fibrillation or its burden and who would like to monitor and record their heart rhythms and heart rates on an intermittent or continuous basis. CART-I is intended to be used in the home-healthcare environment.

5. General information.

Part	Feature	
CART-Ring	Rated Power	Internally Powered, Lithium polymer battery, 3.7 Vd.c.
	Max power(R0K1)	-4 dBm *(Burst Average power)*
	BT frequency	Charging frequency : 205kHz Operating frequency : 2402-2480MHz
	IP Grade	IP58
	Temperature	-20°C ~ 50°C
	Mode of operation	Continuous
	Protection against electric shock	Grade II / Internally Powered, BF type applied part, Body-worn
	RF specification	Bluetooth Low Energy, Bluetooth *5.0*, distance: <2m
	Firmware	*Ver.1.0.0*
CART-Cradle	Rated Power	5Vd.c.
	Rated Power Consumption	50mW~5W
	Charging method	Wireless Charging / Operating Frequency < 205kHz / Magnetic Inductive / using USB cable
CART-App	Ver. 1.0.0 Language : English	

6. Applied part

Inner Metal, Sensor and Outer of CART-Ring

7. Product Life Time

CART-I is Guaranteed to last for a minimum 2 years.

CHAPTER 4. Environment Specifications

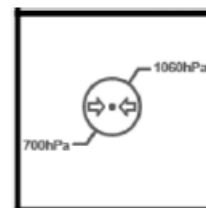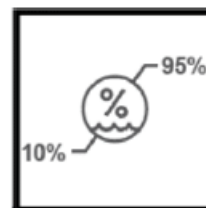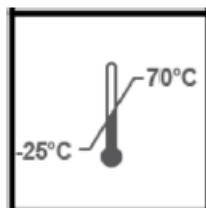| Item	Description
Operating & Charging Temperature	5°C~45°C
Operating & Charging Humidity	10%~95%
Storage/Transport Temperature	-25°C to 70°C
Storage/Transport Humidity	10%~95%
Operating & Storage/Transport Atmospheric Pressure	700hPa to 1060hPa

CHAPTER 5. Symbols

1. Box symbols

Fragile, handle with   Keep dry   Limitation for Transport and storage

2. Device Symbols

Symbol	Description	Symbol	Description
	Manufacturer information	CE 0068	CE marking of conformity
SN	Serial number		Temperature limitation
Type BF	Type BF	%	Humidity limitation
	Date of manufacture		Atmospheric pressure limitation
	Refer to the Instruction for use	EC REP	Manufacturer's EU Representative information

3. IFU Symbols

Warning : Indicates a potentially hazardous situation which, if not avoided, could result in property damage

CHAPTER 6. Safety Precautions

Warning : Failure to follow these safety precaution could result in fire, electric shock, injury, or damage to CART-I or other property. Read all the safety information below before using the device.

Safety information

- This device has been designed by Harmonized standard of medical devices "IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, MDD 93/42/EEC".
- The patient is an intended operator(user).

Limitation of use

- This device is intended only for adults.
- Users should wear the CART-Ring only on their fingers. (not on toes)

General safety/cautions

- Do not leave your device on the place can be reached by children or pet.
- Do not adjust, repair, open, disassemble, or modify this device. Injury or device damage could occur.
- Do not use damaged cables.
- Do not use damaged devices.
- In case of operating difficulties, do not continue using the device.
- Do not use your device if it becomes uncomfortably warm during use.

- If you experience redness or skin irritation on your finger around the sensor due to your device, remove it immediately. If symptoms persist longer than 2-3 days of not using your device, please contact a dermatologist.
- If you don't wear a CART-Ring of inappropriate size, it cannot be guaranteed of the accuracy of the heart rate and it can cause injury or interfere with blood circulation.
- The battery in the CART-Ring cannot be replaced, but it is specified to have 80% of capacity left after 2 years.
- *This device is IP58. It means, the device is protected from limited dust ingress and protected from long term immersion up to a specified pressure. This device is waterproof. But it should be kept dry.*
- *Keep your child safe from usb cable that could choke, suffocate, or strangle.*

Affects your heart rate reading

- Skin perfusion (or how much blood flows through your skin) is one factor. If you're exercising in the cold, for example, the skin perfusion in your wrist might be too low for the heart rate sensor to get a reading.
- Permanent or temporary changes to your skin, such as some tattoos, can also impact heart rate sensor performance.
- Motion is another factor that can affect the heart rate sensor.

Cleaning

- Do not autoclave or submerge the device in any cleaning solution. This will seriously damage the device.
- Clean the surface of the CART-Ring with a soft cloth before you put it on your finger.
- Clean CART-Ring once a day before wearing on

Radio frequency / Electromagnetic / Environment

- Do not expose to strong electromagnetic fields.
- Do not use the device together with MRI, CT or X-ray equipment.
- This device contains components and radios that emit electromagnetic fields.
- Do not store in extremely hot, cold, humid, wet, or bright conditions.
- Do not use or store this device near an open flame.
- Do not wear CART-Ring in the sauna or steam room.
- Use this device within the environment condition being described.
- Do not swallow CART-Ring or any small parts of the device.
- Do not use unauthorized power adapter and power cable.

Intended use

- Use this device to measure heart rate and to analyze the heart rhythm to detect atrial fibrillation.
- Do not use this device for any other purpose than intended use being described.
- Do not use to diagnose heart related conditions.
- This device is an aid to the medical professional to monitor heart rate and atrial fibrillation.
- SKY Labs Inc. makes no warranty for any data or information that is collected erroneously by the device, or misuse or malfunction as a result of abuse, accidents, alteration, misuse, neglect, or failure to maintain the devices as instructed. Interpretations made by this device are potential findings, not a complete diagnosis of

cardiac conditions. Doctors should make diagnosis in conjunction with clinical manifestation and symptoms.

- This device can be operated in at least one Member State without infringing applicable requirements on the use of radio spectrum.

CHAPTER 7. Contraindications

There are no known contraindications for CART-I, although care should be taken when considering using the device according to the safety precautions.
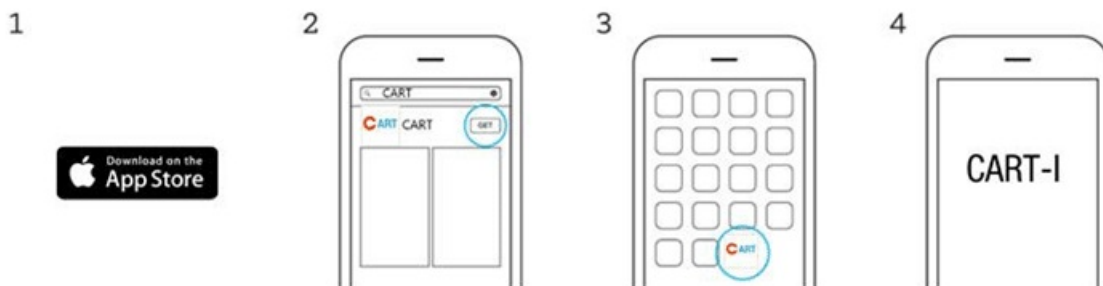
CHAPTER 8. Disposal

CART-Ring and/or battery should not be disposed of with household waste. Dispose of the device and/or battery in accordance with local environmental laws and guidelines.

CHAPTER 9. Warranty

This device will come with 1years warranty from the date you receive it. You can also return the device for an exchange or refund up to 30 days after it ships.

CHAPTER 10. Installation & Charging

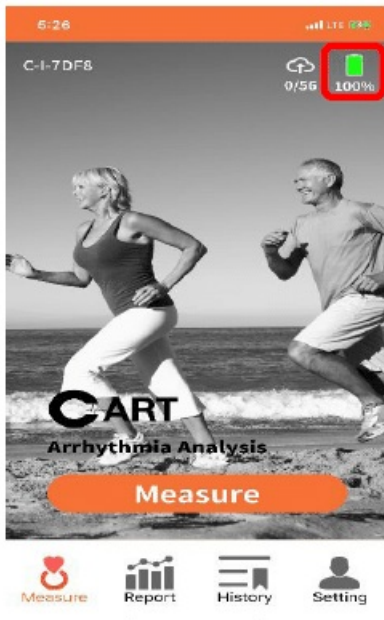### Installation (Download the application) (ONLY FOR iOS)

On your compatible iPhone, download the CART-App from the App store. Please search "CART" in the search box.Open the CART-App and follow the onscreen instructions to use the device.

Charging the CART-Ring

Check the remaining charge of your CART-Ring using CART-App (mobile application).

If battery is low, put CART-Ring down on CART-Cradle(charger).

When charging, LED on the CART-Cradle keeps the red light on. When the battery is fully charged, LED keeps the green light on.
You can use CART-Ring for 48hours continuously and you need to charge it for 2 hours.

Note : Recommend using 1~2A's adaptor of rated power, e.g. adaptor used for mobile phone. If not, any errors on charging can occur or more time can be needed until fully charged.

Note : If LED is on the CART-ring or blinks on CART-Cradle, battery is not charging. Please put CART-Ring down on CART-Cradle appropriately.

LED Indicator

- *When power is connected : A Green LED on the CART-Cradle will blink one time.*
- *When CART-Ring is charging : A Red LED on the CART-Cradle will flash.*
- *When charging is completed : A Green LED on the CART-Cradle will flash.*
- *Some errors occurred while charging : Red LED on the CART-Cradle will be blink continuously*
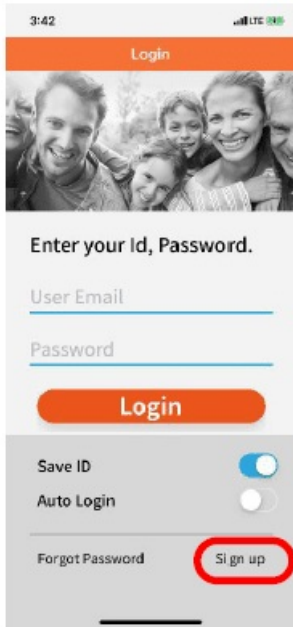
CHAPTER 11. Operation(CART-App)

A. Getting started

1. Download CART-App from iPhone's App Store.
2. Click on CART icon and go through the Login or Sign up process.
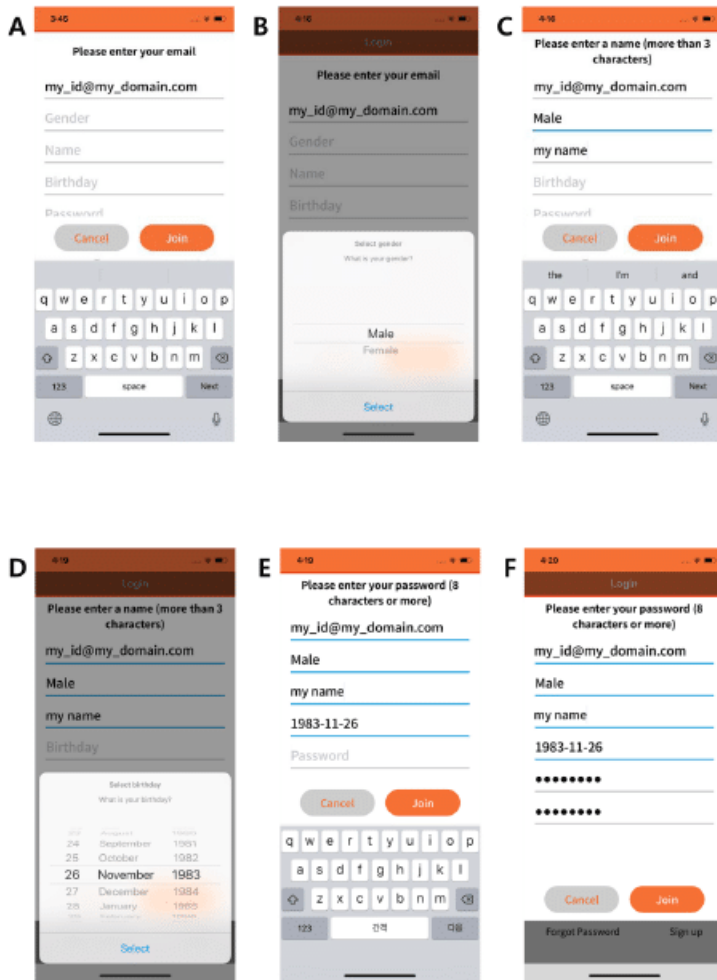
B. Login & Sign up

Creating a new account

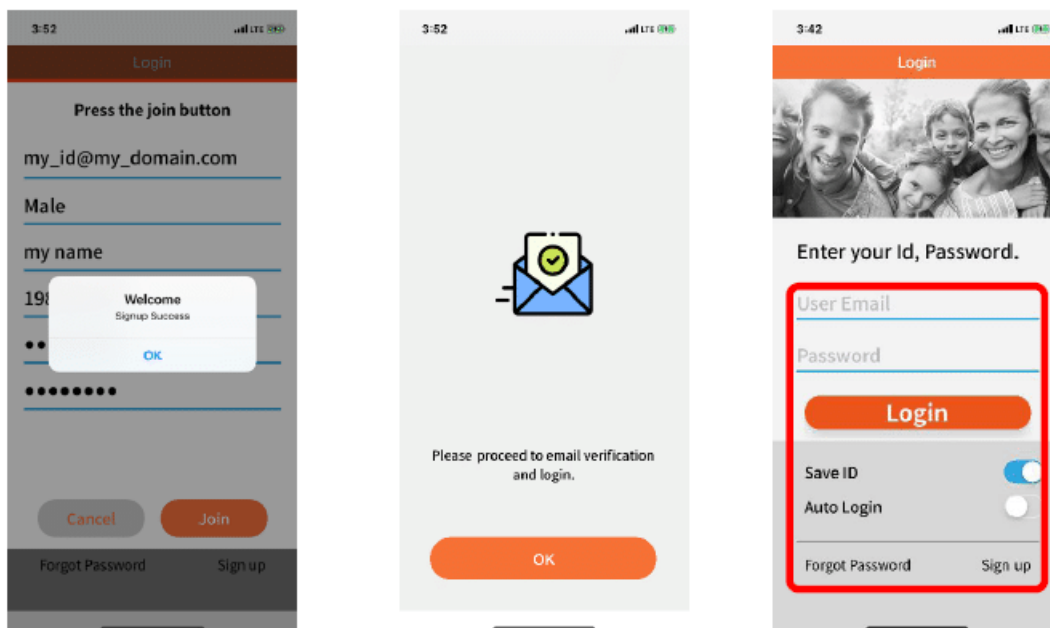1. Click on 'Sign up' to create a new account if you don't have an account.

2. Fill out the form.

A. Click the 'E-mail' and enter your e-mail address

B. Click the 'Gender' and choose your gender by scrolling up and down.

C. Click the 'Name' and enter your name.

D. Click the 'Birthday' and specify your birthday by scrolling up and down with the days, months, and years.

E. Click the 'Password' and set a password. Choose a strong password to protect your information and account. Then, click the 'Password check' and retype your password.

F. After completing, click the 'Join' button. Then, a verification email will be sent to the email address you entered.

3. Click the hyperlink in the email you received to complete the sign-up process.

Note : If the email address you entered is already registered, a verification message will not be sent.
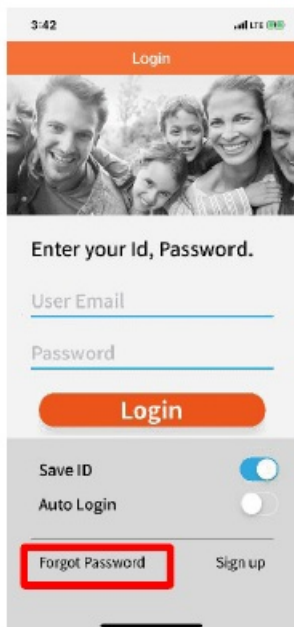

Login to your account

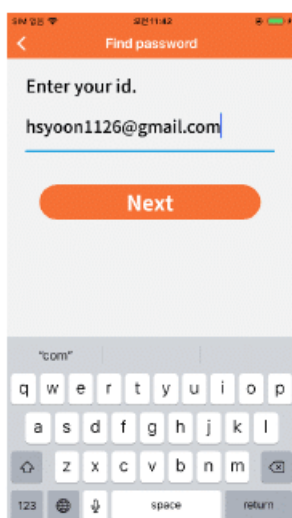1. Enter the email address and password you created previously.

2. If you want to save the ID, swipe 'save ID' to the right to activate it.

3. To activate auto login, swipe 'Auto Login' to the right.

4. Click the 'Login' button.

Forgot Password

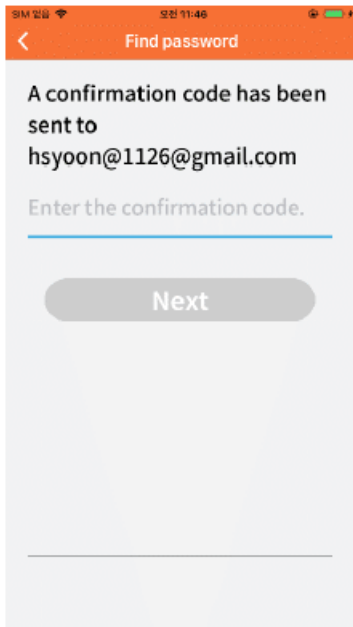1)   If you forgot your password, click the 'Forgot Password' button.

2) Enter the email you used to sign up and click the 'return' button on the keyboard. A password change guide will be sent to the email address you entered. And a confirmation code will be sent to the email.
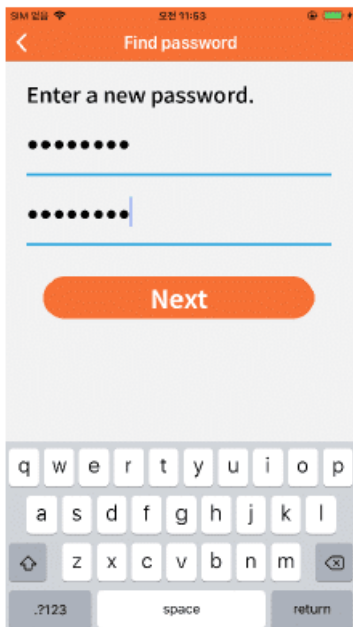

3)   Check the code on the email you registered and put its code on the App.

4) Enter a new password in CART-App.

5) Try to login with the changed password in CART-App.

C. Device Registration

If there is no CART-Ring registered for the ID after login completion, the Device registration page appears.
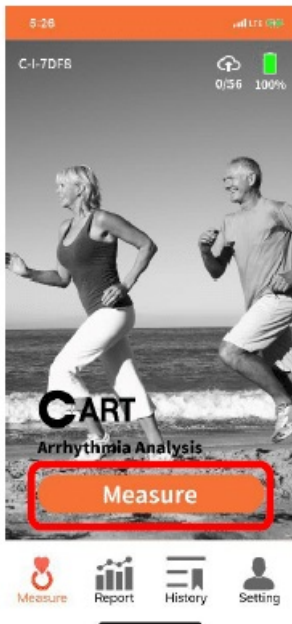
1. Turn on the Bluetooth of the mobile phone.
2. Scan QR code inside the package.
3. After scanning the QR code, you can set the name of CART-ring as your own device

Note : When register, please ensure CART-Ring near to your mobile phone.

D. Measuring Heart rhythm

Self check

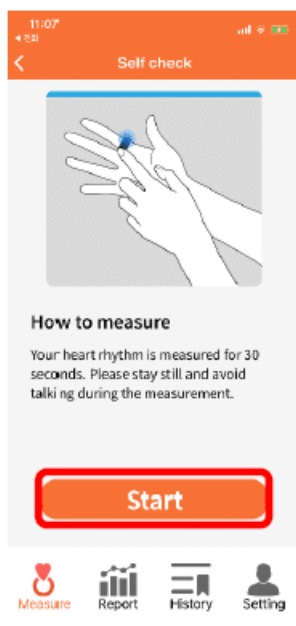1. Click the 'Measure' button on the Main page to move to 'Self check' page

2) Press the 'Start' button when a user is ready to check. The measurement proceeds for about 30 .

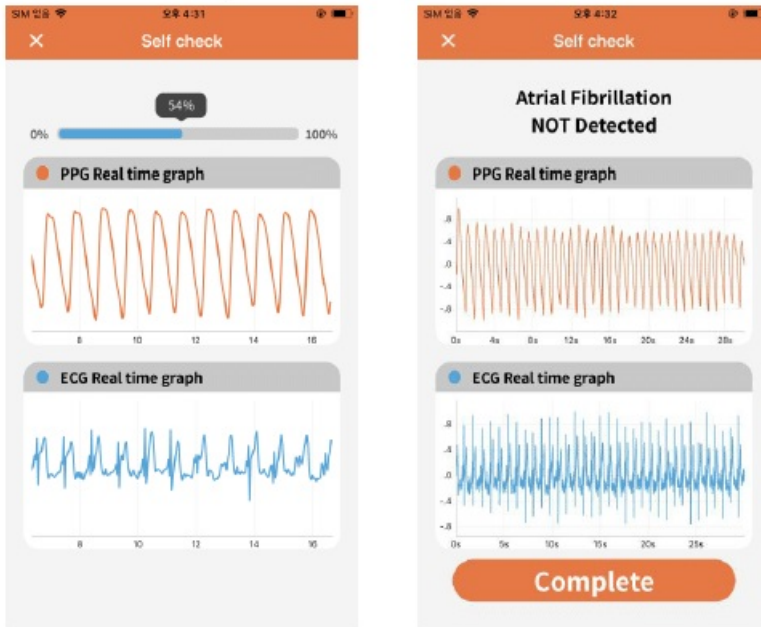**Note :** Top cover of CART-Ring should be facing upwards.
Note : Wear a CART-Ring on the finger of one hand and touch the finger of the other hand on the CART-Ring.
Note : Ensure CART-Ring is fit to your finger. If not, Heart rate and AF symptoms cannot be measured with accuracy.
Note : For more accurate measurement, when using check, stop doing something and hold posture for 30 seconds.

3) The progress of 'Self check' is displayed at the top of the page. Hold your posture until progress is 100%.
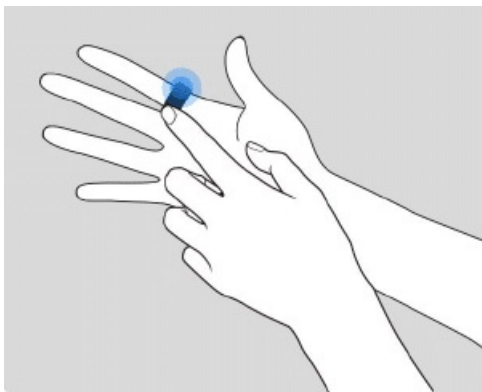
4. After measuring, a result is displayed on the page. The detection of AF symptoms is displayed at the top of the page. Click on the 'Complete' button to return to the main page.

Note : The self check result can be checked again in the 'History' tab.

Tap check

1. Tapping CART-Ring twice when a user wants to check without running CART-pp.
2. Take the same posture as Self check and hold for 30 seconds

3) The results can be checked in the 'History' tab when CART-App and CART-Ring are synchronized

Note : Synchronization between CART-App and CART-Ring is done automatically.

Note : If you cannot check the results in the 'History' tab, check the Bluetooth connection.

Background check

1. CART-Ring periodically measures a user's heart rhythm every 10 seconds without running CART-App.
2. The results can be checked in the 'History' tab when CART-App and CART-Ring are synchronized.

Note : The background check is measured only by the hand wearing the CART-Ring.

Note : Synchronization between CART-App and CART-Ring is done automatically.

Note : If you cannot check the results in the 'History' tab, check the Bluetooth connection.

E. **Report –** statistics data by period

Press 'Report' tab to check the statistics data by period.

Monthly Report

Press 'Month' buttons at the bottom of the page.
The bar graph shows how many times a week was measured during the month.
The count without AF symptoms is indicated in blue, and the count with AF symptoms is indicated in red.

Weekly Report
Press 'Week' buttons at the bottom of the page.
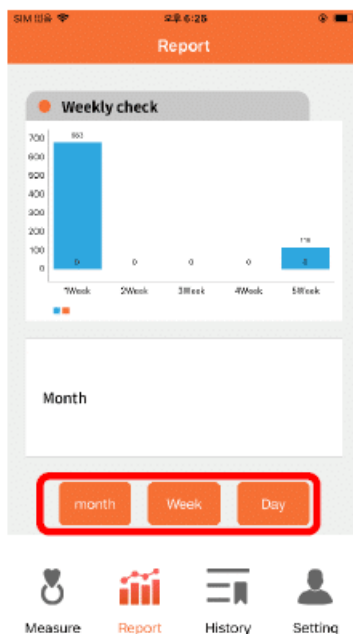The bar graph shows how many times a day was measured during the week.
The count without AF symptoms is indicated in blue, and the count with AF symptoms is indicated in red.

Daily Report
Press 'Day' buttons at the bottom of the page.
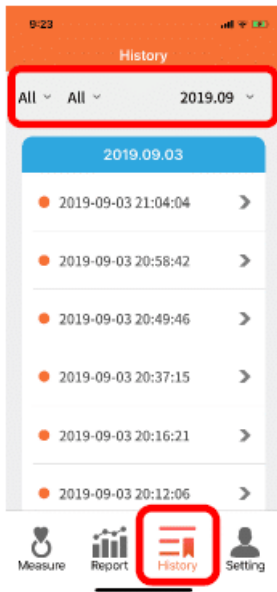The bar graph shows how many times an hour was measured during the day.
The count without AF symptoms is indicated in blue, and the count with AF symptoms is indicated in red.

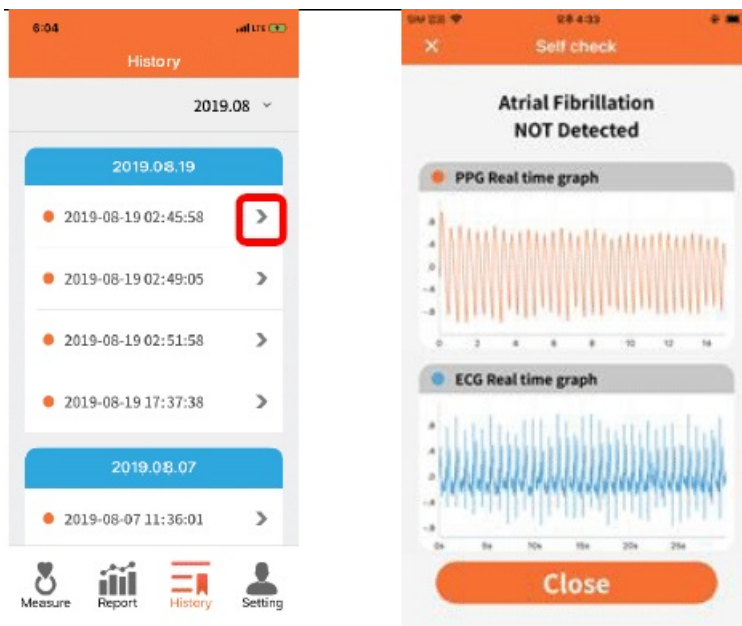F. **History –** previously measured data

1. Click the 'History' tab at the bottom of the main page to view the previously measured history.

2. Can be only reviewed relevant data as choosing "Check Mode"

3. (Self check, Tap check, background check, All)

4. Can be reviewed relevant data as choosing the AF symptom of AF or Non AF. (AF, Non AF, All)

5. Can be reviewed relevant data during the measured period as choosing the date.

5) Check detailed result as choosing a certain item from the list

Note : You can check ECG and PPG graphs in self check and tap check data, and only PPG graph in background check data.

G. Setting

User info

Click the 'User info' button in 'Setting' to manage your logged-in account.

1) Edit

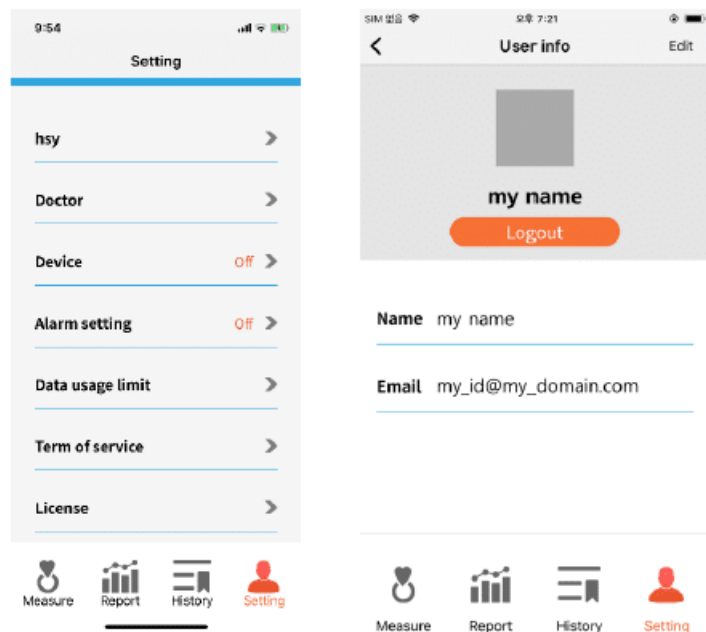A. Click the 'Edit' button in the upper right corner of the page.

B. Tap the item you want to modify and edit the information.

C. Click the 'Confirm' button on the upper right side of the page to save.

2) Login to another account

A. Click on the 'Logout' button under your name.

B. Login by entering Email and Password of the account to register.

Doctor info

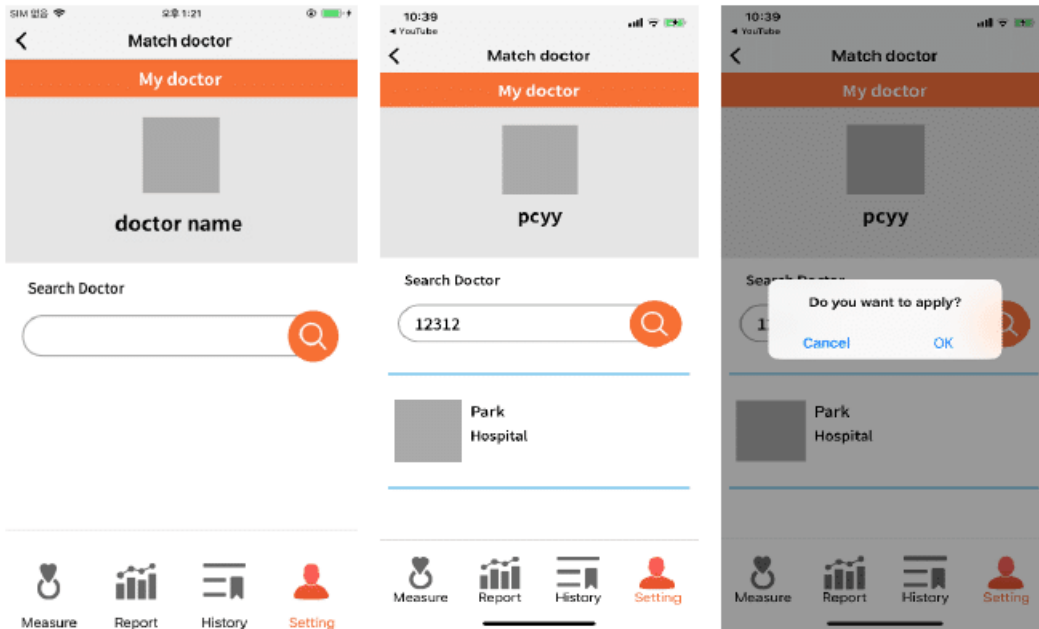Click the 'Doctor' button in 'Setting' to manage your doctor.

1. Register

A. Click the input box under 'Search Doctor' and enter your doctor's number.

B. Click the button.

C. Select the searched item.

'D. Do you want to apply? Select 'OK' to the query

Device info

Click the 'device' button in 'Setting' to manage your devices. At the top of the page, recently connected device is displayed. In the list, a blue dot is displayed next to the connected CART-Ring number.

1. Add

A. Press the 'Add Device' button at the bottom.

B. Scan QR code inside the package.(CART-App connects automatically with the device you add.)

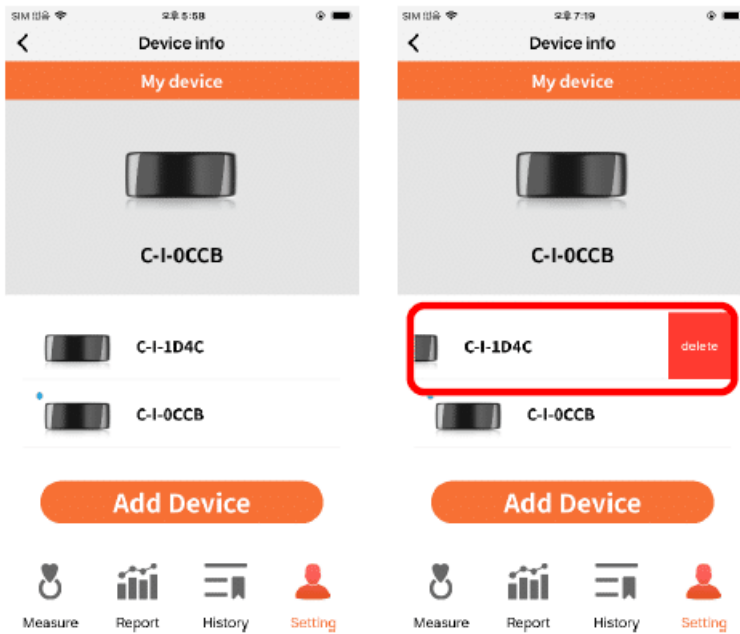**Note :** When register, please ensure CART-Ring near to your mobile phone.

2) Delete
A. Swipe the CART-Ring number you want to delete to the left.
B. Press the 'Delete' button when it is active.

4) Connect to another device
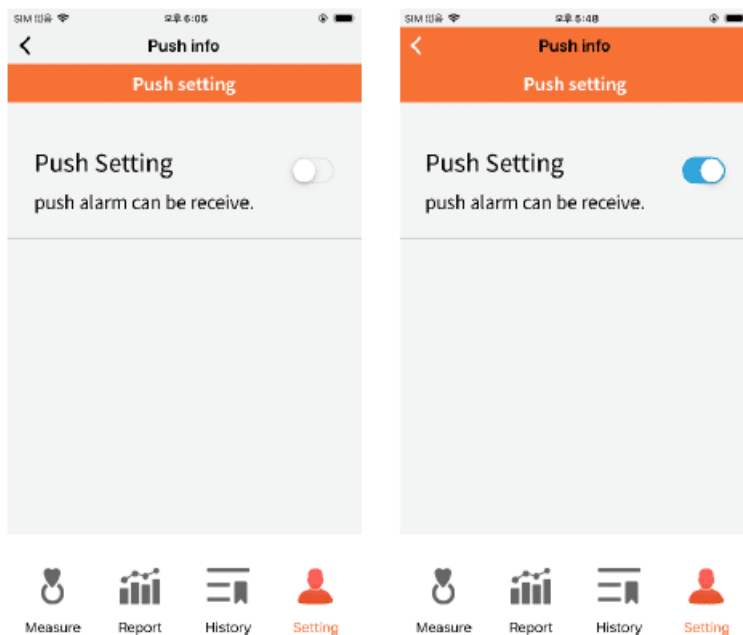A. Press the CART-Ring number you want to connect.
B. Check the blue dot next to the CART-Ring number you want to connect.

Push info

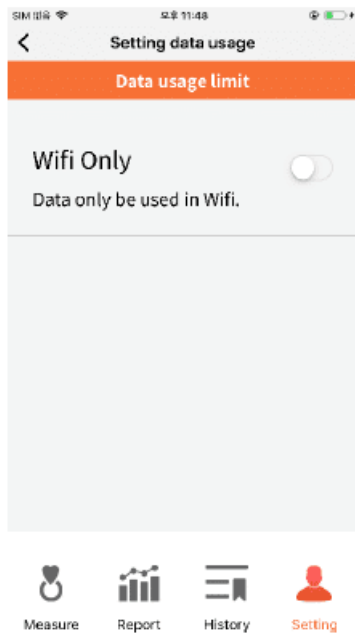Press the 'Push info' button in 'Setting' to set whether to receive a notification.

To receive the notification, swipe the button for 'Push Setting' to the right.

Setting data usage
Set the data usage limit.
If you want to use only data traffic via Wi-Fi, please be active 'WiFi Only' by Swiping.

Term of service & License

Term of service and open framework information for using CART-App.

Sky-Labs-ROK1-CART-I-Smart-Ring-User-Manual

Download

Questions about your Manual? Post in the comments!