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CART BP User Manual

Sky Labs Inc.

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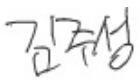
Signature				
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No.	Date	Description	Remarks
00	23 / 07 / 11	- Initial publication	
01	23 / 08 / 23	- Product name change (CART-I BP -> CART BP) - Add model name (SL-MRD1G06 to SL-MRD1G13)	
02	23 / 10 / 26	- Repurposing - Edit an announcement - Modifying the battery warranty - Deleting the Sizing Kit	
03	23 / 11 / 15	- Changing precautions for use	
04	24 / 05 / 10	- Change the observation period to less than 24 or 48 hours	

Table of Contents

1. device description and purpose 6
- **1.1. Purpose of use 6**
- **1.2. How it works 6**
- **1.3. Product accuracy and calculation method 6**

2. components 7

3. product specifications 8
- **3.1. Product information 8**
- **3.2. Product Specifications 9**

4. environmental conditions 10

5. label symbols (symbols) 11
- **5.1. Symbols on the shipping carton 11**
- **5.2. Product Symbols 11**

6. safety warnings 12
- **6.1. Safety-related information 12**
- **6.2. Limitations of Use 12**
- **6.3. General safety/warning notes 12**
- **6.4. Blood Pressure (BP) Measurement Cautions/Warnings 13**
- **6.5. Managing products 13**
- **6.6. Battery and Charging 13**
- **6.7. Radio Frequency/Electromagnetic/Environment 13**
- **6.8. dust and water resistant 14**
- **6.9. Cybersecurity 14**
- **6.10. FCC compliance information 14**

7. Product usage restrictions 15

8. How to dispose of the product 15

9. Warranty and Limited Warranty 15

10. Preparation before use 16

11. How to use CART BP 16
- **11.1. Medical staff 16**
- **11.2. Patients 16**

12. How to use CART-Ring 17
- **12.1. Charging the CART-Ring 17**
- **12.2. Combined appearance of CART-Ring and CART-Cradle 17**
- **12.3. LED indicators in CART-Cradle 18**
- **12.4. How to wear the CART-Ring 18**

12.5. Storage and care after use 18
13. How to use the CART BP App (for hospitals) **19**
13.1. Install (download the application) 19
13.2. Sign in 19
13.3. Change your password 20
13.4. Main screen 21
13.5. Storage and care after use 26
14. How to use the CART BP App (for patients) **27**
14.1. Install (download the application) 27
14.2. Log in 27
14.3. Main screen 28
14.4. Storage and care after use 29
14. How to use CART BP Web **30**
14.1. Sign in 30
14.2. Change your password 31
14.3. Main page 32
14.4. Connect your device 33
14.5. Calibrating 35
14.6. Transferring data 39
14.7. Update your device 41
14.8. Storage and care after use 43
15. electromagnetic information **44**
15.1. Instructions and Manufacturer's Declaration - Electromagnetic Emissions 44
15.2. Instructions and Manufacturer's Declaration - Electromagnetic Immunity 44

Notice

SKYLABS CART BP

Thank you for using CART BP. To ensure safe and correct use of the product, please read this user manual before using the product.

Failure to follow the contents of the user manual may result in damage or malfunction of the product, or even personal injury. If the User Manual is more than three months old, please download the latest User Manual from the SKYLABS website (www.skylabs.io) or contact SKYLABS for additional information. If you have any questions about using the Product or Software, please contact SKYLABS.

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MADE IN KOREA

1. device description and purpose

1.1. Purpose of use

A device worn by the subject for an extended period of time that provides a non-invasive measurement of systolic and diastolic blood pressure and pulse rate.

1.2. How it works

This product is a blood pressure monitor that collects PPG signals by wearing a ring-shaped device and transmits, stores, and analyses the collected signals via wireless communication (Bluetooth) to display systolic and diastolic blood pressure (BP), average BP, and pulse rate. The collected PPG signals are analysed by a programmed algorithm.

Used for indirect (non-coronary) measurement of blood pressure, photoplethysmography (PPG) uses the optical properties of the skin to measure the amount of blood flowing through the blood vessels. The principle of photoplethysmography is that when the volume of blood vessels changes due to the heartbeat, a light source is shone on the body, and biological tissue reflects and transmits some of the light, and a light sensor detects the change in light sensitivity as the volume of blood vessels changes. The photoplethysmographic pulse wave consists of an LED that emits light and a photosensor that detects the emitted light and can be measured in reflection mode. The shape and appearance of the pulse wave is similar to that of the arterial blood pressure (ABP) waveform, and the changes in the waveform due to changes in blood pressure are also very similar. Therefore, the blood pressure can be estimated by tracking the changes in the shape of the pulse wave based on a convolution neural network (CNN) to estimate the change in blood pressure compared to the calibration.

1.3. Product accuracy and calculation method

Item	Separation	Measurement range and accuracy
Blood pressure	Blood pressure measurement range	70 to 180 mmHg (systolic)
		40 to 120 mmHg (diastolic)
	Blood pressure accuracy	The average of the difference is ±5 mmHg or less, Standard deviation of the difference 8 mmHg

2. components

CART-Ring

CART-Cradle

USB-Cable

User manual(IFU)

The PC and mobile device for installing the CART BP's software are not included in the components.

Sky Labs Inc. products require a few additional things to work.

- Mobile device: ≥iPhone 7, ≥iOS 10.0, ≥Android 6.0 (& ≥BT 4.1)
- The CART BP App is available for installation from the Apple App Store and Google Play.

[Name of component according to the broadcasting equipment conformity assessment system].

- CART-Ring: Specific small power radio (radio for radio data communication systems)
  KC Certificate Number: R-C-15i-CART1R
- CART-Cradle: Low Field Strength Wireless Device
  KC Certificate Number: R-R-15i-CART1C

3. product specifications

3.1. Product information

Separation	Description	
Item name	Blood pressure monitor	
Item number	A23035.01(2)	
Product name	CART BP	
Type and degree of protection against electric shock	Internally powered instrument, BF type mounting	
Mounting	Inside the exterior of the CART-Ring (PPG sensor)	
Model Name	1. There are 16 types of CART BP models. 2. The difference between each model is the dimension. 3. The difference between the SL-MRD1Kxx and SL-MRD1Gxx models is the colour.	**Model Reference**
		SL-MRD1K06
		SL-MRD1K07
		SL-MRD1K08
		SL-MRD1K09
		SL-MRD1K10
		SL-MRD1K11
		SL-MRD1K12
		SL-MRD1K13

3.2. Product Specifications

Separation	Description		
CART-Ring	Rated power		Internal power, lithium-polymer battery, 3.7 Vd.c.
	RF Frequency		(RX) Solid state charging frequency: 205kHz Frequency during operation: 2402~2480MHz
	IP grade		IP58
	RF test temperature		-20℃ to 50
	Driving Modes		Continuous mode
	Protection from electric shock		Internally powered devices, BF mounting
	RF specifications		Bluetooth Low Energy (BLE), BT 5.0, distance: <2m
	PPG LED Specification	Red	660nm (IF=10mA), Optical power: Max 0.35mW
		IR	940nm (IF=10 mA), Optical power: Max 0.35mW
		Green	525nm (IF=10 mA), Optical power: Max 1.00mW
CART-Cradle	Rated power		5 Vd.c.
	Power consumption		50mW to 1W
	How to charge		(TX)Wireless charging / Magnetic induction / USB cable
	RF frequency		(TX) Solid state charging frequency: 205 kHz (TX) Operating frequency: 175.3 kHz
CART-App	Language: English Version: Available on the main screen of the mobile application > About me		
Date of manufacture	YYYY-MM		
Country of manufacture	Republic of Korea		
Manufacturer	SkyLabs Corporation		
Product Availability	The product (including batteries) is warranted for one year free of charge. However, we are not responsible for user negligence or intentional damage.		

4. environmental conditions

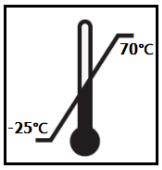
Separation	Description
Temperature requirements for operation & charging	5℃ to 40
Humidity conditions for operation & charging	10% to 95
Temperature conditions for storage & transport	-25℃ to 70
Humidity conditions for storage & transport	10% to 95
Atmospheric pressure conditions for operation & storage & transport	700 hPa to 1060 hPa

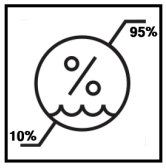
5. label symbols (symbols)

5.1. Symbols on the shipping carton

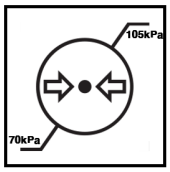
Handling with care

Beware of moisture





Temperature, humidity, and atmospheric pressure conditions during storage and transport



5.2. Product Symbols

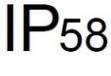
Manufacturer

Date of manufacture

Manufacturing unit

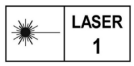
Type BF Mounting

User Guide References



Dustproof/Waterproof Rating

Direct current



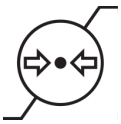
CLASS 1 Laser

No household waste disposal

Caveats

Temperature Limitations

Humidity Limitations



Atmospheric pressure Limitations

6. safety warnings

Warning: Failure to observe the safety warnings mentioned in the manual can result in fire, electric shock, personal injury, or damage to the product. Please read all cautions/warnings for safety before using the product.

6.1. Safety-related information

- This product is designed and manufactured to meet the international standards "IEC 60601-1, IEC 60601-1-2" applicable to medical devices.
- You must comply with applicable laws, including healthcare and privacy laws, when using this product.

6.2. Limitations of Use

- This product can be used by youth or adults weighing 30kg or more. However, you must be able to wear the device correctly and in accordance with the CART-Ring's wearing instructions.
- The CART-Ring can only be worn on the fingers; do not wear it on any other part of the body.
- This product is not intended to diagnose any medical condition without the assistance of a medical professional.
- Do not use this product for any purpose other than those described.
- Sky Labs Inc. makes no warranty with respect to information resulting from abuse, accident, alteration, misuse, neglect, or malfunction of the device caused by failure to maintain the device in accordance with the manual.
- Interpretation by this product is a potential outcome, not a complete diagnosis. Your doctor should make a diagnosis based on clinical signs and symptoms.

6.3. General safety/warning notes

- Do not leave this product where children or pets are present.
- Do not attempt to adjust, repair, disassemble, or modify this product. Personal injury or damage to the product may result.
- Do not use a damaged cable.
- Do not use a damaged product.
- If you have difficulty operating the product, do not continue to use the product.
- If you experience a fever while using the product, do not use the device.
- If wearing the product causes redness or skin irritation on your fingers in the area of the CART-Ring sensor, stop wearing the product immediately. If symptoms persist after more than 2-3 days of non-wearing, contact a dermatologist.
- If the CART-Ring is not selected according to the size of your finger, the accuracy of the data collected cannot be guaranteed and may result in injury or impaired circulation.
- USB cables can be a choking and strangulation hazard for children.
- If this product has been stored at a minimum or maximum temperature, please allow it to come to room temperature for at least 1 hour before use.
- Use of controls or procedures for operation and maintenance other than those specified herein may result in exposure to hazardous radiation.

Note:
- Wear it on a hand that you don't use as often as possible, and don't wear it with other rings.

6.4. Blood Pressure (BP) Measurement Cautions/Warnings

- Do not change your dosing regimen or dosage based on the results of this product. Always consult your doctor.
- The Product is not suitable for continuous measurement of a patient's blood pressure during surgical procedures or other emergency situations.
- Follow the instructions on the product to take measurements in a stable position.
- Blood pressure values can vary throughout the day due to weather, emotions, exercise, and more.
- This product calibrates and measures blood pressure based on the blood pressure value of the arm wearing the cuff. If there is a significant difference (more than 10 mmHg) between the two arms, you should consult a healthcare professional.
- Do not measure with a product that has been calibrated by someone else.

6.5. Managing products

- Do not hot wash or immerse the Product in cleaning solutions. This may cause serious damage to the product.
- Before wearing, wipe the CART-Ring with a soft cloth on the inside and outside of the surface.
- Once a day, wipe the surface of your CART-Ring before wearing it.

6.6. Battery and Charging

- The product (including batteries) is warranted for one year free of charge. However, we are not responsible for user negligence or intentional damage.
- The CART-Ring takes approximately 2 hours to fully charge and provides approximately 48 hours of continuous use.
- To protect the battery life of this product, always place the CART-Ring on the CART-Cradle when not in use to keep it charged.
- If this product is stored without use for long periods of time, the battery's performance may deteriorate. Fully charge the CART-Ring at least once every three months.
- This product is not compatible with ultra-fast chargers (USB-PD) used for mobile devices or laptops, etc. Please check the type of charger before use.

6.7. Radio Frequency/Electromagnetic/Environment

- Do not expose this product to strong electromagnetic fields
- Do not use this product with MRI, CT, or X-ray equipment.
- This product contains components that emit electromagnetic fields and radio frequencies.
- Do not store the product in hot, cold, damp, wet, or direct sunlight.
- Do not use or store this product near an open flame.
- Do not wear the CART-Ring in baths and saunas.
- Use this product only in the environmental conditions described.
- The CART-Ring is a battery-containing product. Be careful not to leave it in the car for long periods of time.
- Do not put the CART-Ring or any part of the device in your mouth or swallow it.
- Do not use unauthorised adapters and cables.
- Due to the possibility of radio interference, this wireless facility cannot provide services related to life safety.
- This device can be operated in at least one Member State without infringing applicable requirements on the

use of radio spectrum

6.8. dust and water resistant

- Do not allow the CART-Ring to come into contact with water under high water pressure.
- Do not wear the CART-Ring when swimming, diving, snorkelling, and other water sports with high currents.
- If the CART-Ring is wet or your hands are wet, dry it thoroughly before using it.
- If the CART-Ring gets wet with clean water, wipe it with a soft, clean cloth and make sure it is completely dry before using it.
- If your CART-Ring has been exposed to liquids other than clean water (salt water, pool water, soapy water, oils, perfumes, chemicals such as sunscreen, hand sanitiser, cosmetics, etc. Failure to do so may cause problems with the performance or appearance of the product.
- Be careful if the CART-Ring is dropped or impacted, as this can damage its water or dust resistance.
- The CART-Ring is not intended to be disassembled. Do not attempt to disassemble it yourself as this may damage the water and dust resistance.
- Do not expose the CART-Ring to sudden changes in air and water temperature.
- Do not use a heating device such as a hair dryer to dry the CART-Ring.
- Do not wear the CART-Ring in environments such as saunas and steam rooms as the water resistance may be compromised.

Note:
- The CART-Ring has been tested in a controlled environment (IEC60529) and has a dust/water resistance rating of IP58. Please observe the above to ensure normal dust and water resistant behaviour. Failure to observe the above may result in damage to the product.

6.9. Cybersecurity

- In the event of an incident related to the cybersecurity of this product, contact the manufacturer and wait for an administrator to take action.

6.10. FCC compliance information

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.

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 try to correct the interference by one or more 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 that to which the receiver is connected.

Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with RF exposure requirement.

For CART-CRADLE, it should be installed and operated with minimum 20 cm between the radiator and your body.

7. Product usage restrictions

There are no measurement restrictions for this product.

8. How to dispose of the product

This product and its battery cannot be disposed of with household waste. Dispose of the device and battery in accordance with local environmental laws and regulations.

9. Warranty and Limited Warranty

This product is warranted for 1 year after purchase and can be exchanged or refunded up to 30 days after delivery if the product is faulty.

10. Preparation before use

To ensure safe and correct use of the product, please read these instructions before using the product.

Your personal information can only be shared with your consent and cannot be used for telemedicine purposes.

11. How to use CART BP

11.1. Medical staff

1) Before using the product, fully charge the CART-Ring with the CART-Cradle.
2) Healthcare staff should complete their membership of the CART BP App (for hospitals) and CART BP Web.
3) After completing the registration, please use the CART-BP App to enter the patient number and complete the registration of the CART-Ring device.
4) Once the device registration is complete, the Bluetooth (BLE) connection between CART-Ring and the CART BP App (for hospitals) is automatically established.
5) Once the Bluetooth connection is established, place the CART-Ring on your finger to calibrate your blood pressure. Blood pressure calibration is performed twice.
6) If the patient or connected device changes, be sure to recalibrate the blood pressure.
7) Once the device registration and blood pressure calibration are complete, text the patient a link so they can sign up for membership.
8) When the patient returns to the clinic after the observation period (blood pressure measurement period) (within 24 or 48 hours), please use the CART BP App to send the remaining data in the ring to the server.
9) Once the data transfer is complete, please use CART BP Web to print the report.

11.2. Patients

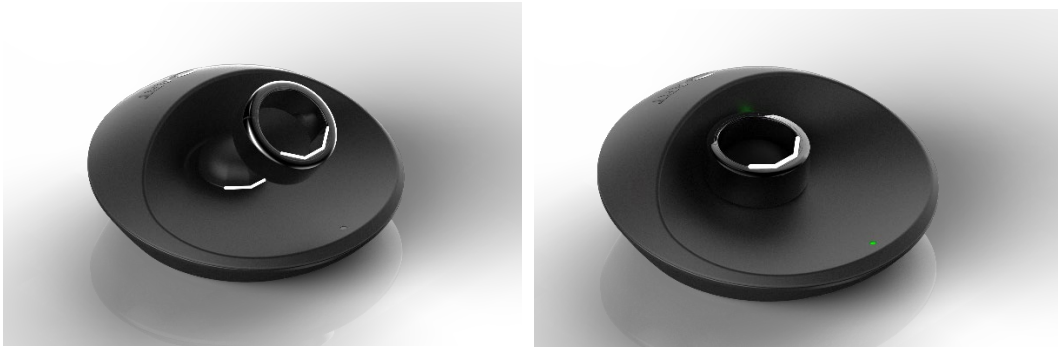
1) Install the CART BP App (for patients) using the link text sent by your healthcare provider.
2) After installation, if the patient's information and the information on the CART-Ring are correct, a Bluetooth (BLE) connection between the CART BP App (for the patient) and the CART-Ring will be established automatically, and the patient's blood pressure will be automatically measured while wearing the ring. Please wear the ring for the observation period (blood pressure measurement period) (within 24 or 48 hours) to measure your blood pressure.
3) During the observation period (blood pressure measurement period) (within 24 or 48 hours), you can check your measurement results using the CART BP App (for patients).
4) At the end of the observation period (blood pressure measurement period) (within 24 or 48 hours), please return to the clinic to check your blood pressure monitoring results.

12. How to use CART-Ring

12.1. Charging the CART-Ring

Number	Name	Description
1	USB C Type Port	You can connect power to the USB port using a USB cable.
2	CART-Ring retaining wick	You can charge your device by securing the CART-Ring to the CART-Ring retaining wick.
3	LED indicators	While charging is in progress, the LED on the CART-Cradle will light up red, and when fully charged, the LED will change to green. The CART-Ring takes approximately 2 hours to fully charge and provides approximately 48 hours of continuous use.

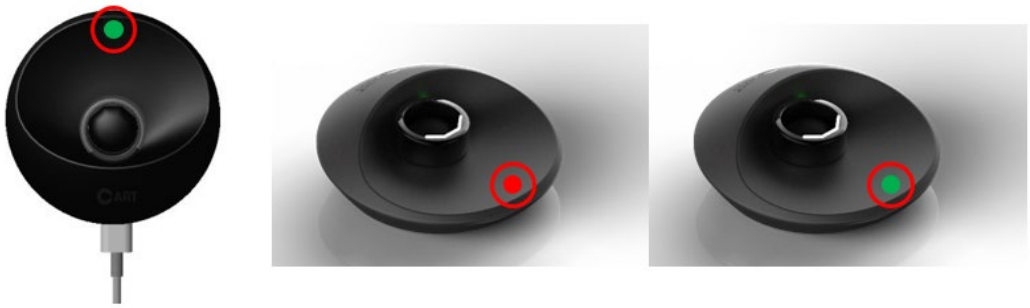
12.2. Combined appearance of CART-Ring and CART-Cradle



Note

- Use an adapter with a voltage rating of 1 to 2 amps (such as a mobile charging adapter), otherwise you may experience errors during charging or need more time to fully charge.
- If the LED on the CART-Ring or CART-Cradle is flashing, the battery is not charging. Double-check the charging direction and recharge.

12.3. LED indicators in CART-Cradle



Number	Name	Description
1	When plugged in	When powered up with a USB cable, the LED indicator will flash green for 1 second.
2	Charging	The LED indicator lights up red when charging begins.
3	Charging complete	When charging is complete, the LED indicator lights up green.
4	In case of charging error	If a charging error occurs, the LED indicator flashes red.

12.4. How to wear the CART-Ring

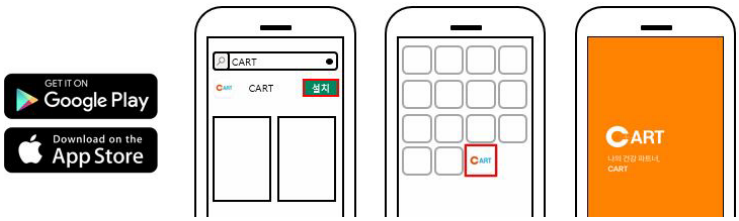
Number	Name	Description
1	Top	The CART-Ring should be worn so that the top of the CART-Ring is on the top of the finger.
2	Sensor	The CART-Ring should be worn so that the sensor is positioned on the underside of the finger.

12.5. Storage and care after use

Keep the CART-Ring, CART-Cradle, and USB Cable disconnected when not in use for extended periods of time.

13. How to use the CART BP App (for hospitals)

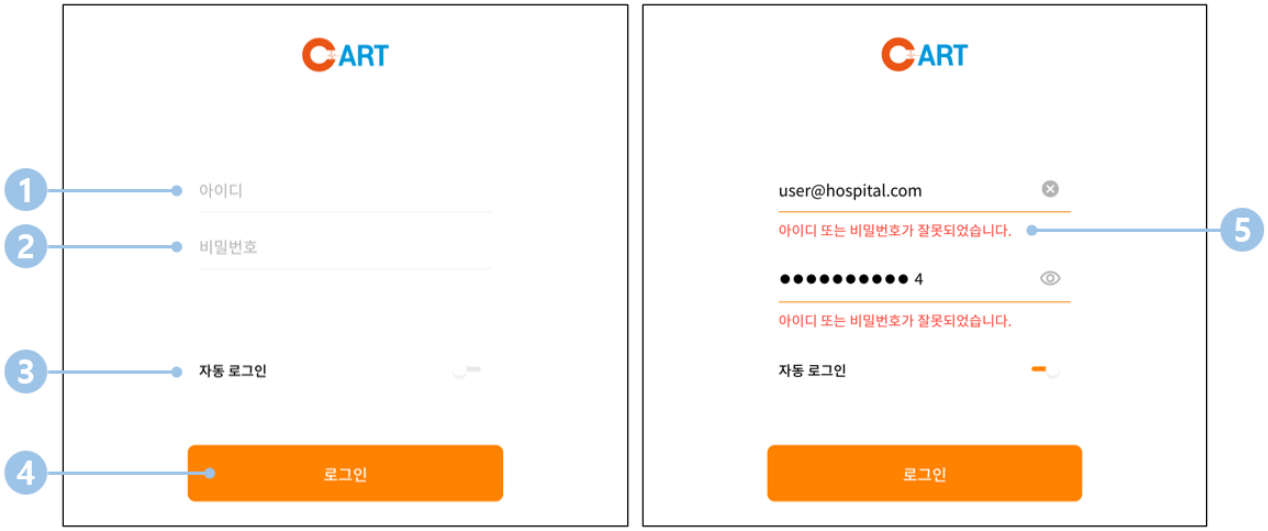
13.1. Install (download the application)



Download the CART BP App from the App Store or Google Play on your mobile. Be sure to install the application for your hospital.

13.2. Sign in

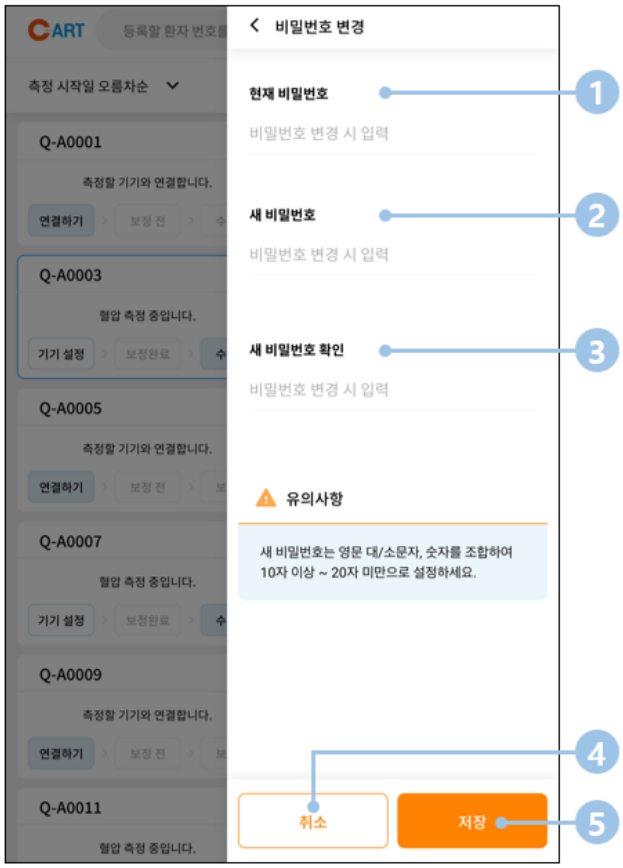
1) Sign in with the username and password provided by the manufacturer.
2) The password you receive initially is a temporary password. Make sure that you change it before you use the CART BP App. If you don't change your password, then you won't be able to use the CART BP App.
3) If you forget your password, there is no way for you to change it - please contact the manufacturer.



Number	Name	Description
1	Id.	Touch the "Username" field and enter your username.
2	Password	Touch the "Password" field, and enter your password.
3	Automatic sign-in	To enable the auto-login feature, swipe right on "Auto-login" to enable it.
4	Login button	Tap the "Login" button to log in to the application.
5	Error messages	If the username or password is incorrect, an error message is exposed.

13.3. Change your password

1) Please log in with the temporary password you were initially sent and change your password. If you do not change your password, you will not be able to use the product.
2) After you've finished changing your password, please log back in with the changed password.

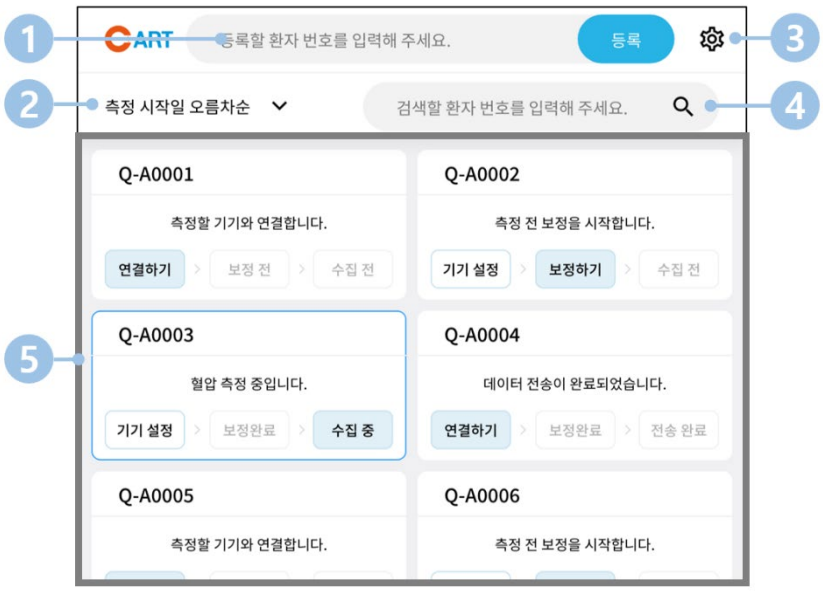


Number	Name	Description
1	Current password	Tap the "Current password" field and enter the current password you received from the manufacturer.
2	New password	Tap the "New password" field and set a new password for your account. Set a strong password to protect your privacy.
3	Confirm your new password	To confirm your password, touch the "Confirm password" field and re-enter your newly set password.
4	取消	Selecting the "Min" button will end the password change and take you to the login screen.
5	Save	Select the "Confirm" button to complete the password change.

Note

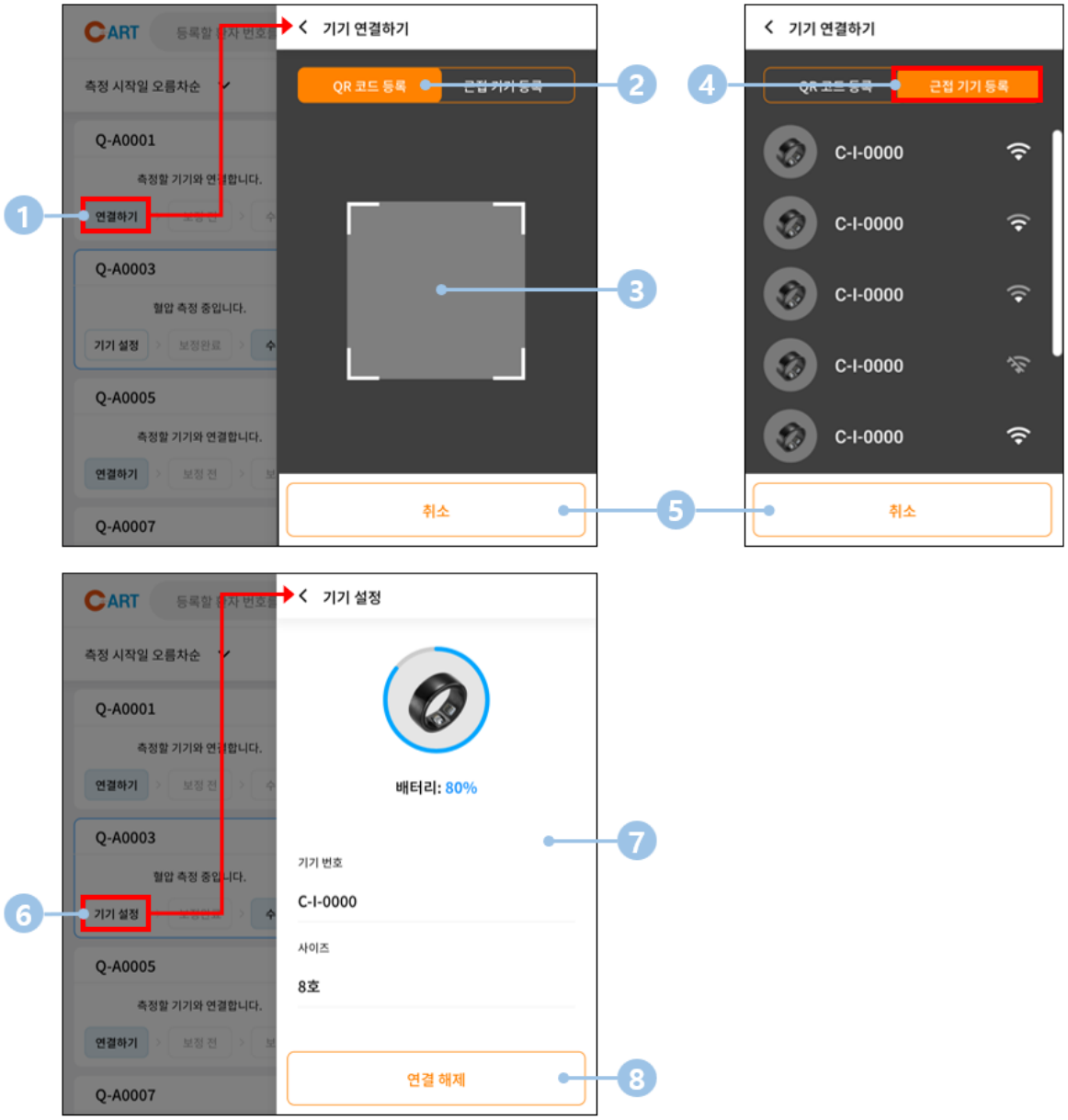
- For security purposes, your password should be at least 10 and no more than 20 characters, including "uppercase, lowercase, and numbers".
- If you don't change your password, you won't be able to use the service.

13.4. Main screen



Number	Name	Description
1	Patient Registration	Enter the patient number in the patient registration field and tap the "Register" button to register the patient.
2	Sorting patients	Tap the "Sort" field to sort the patient list in any way you like.
3	Settings	Tap the "Settings" button to go to the settings screen.
4	Patient Search	You can search for a specific patient by tapping on the "Search Patient" field.

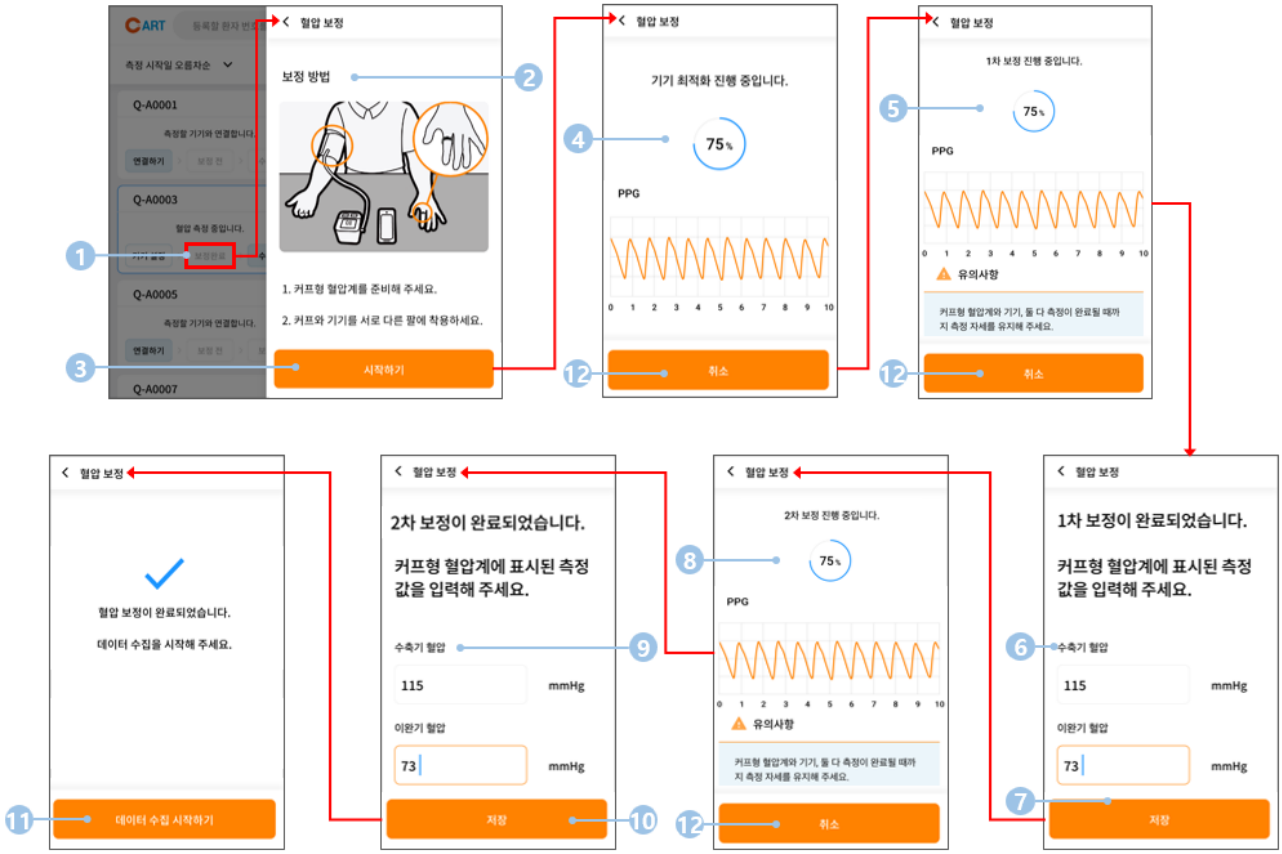
13.3.1. Connecting and setting up your device



Number	Name	Description	
1	Connecting	Connecting	Tap the "Connect" button to go to the Connect your device screen.
2		QR code registration	Tap the "Register QR Code" button to go to the QR Code registration screen.
3		Scan QR code	You can register your device by scanning the QR code.
4		Registering proximity devices	Tap the "Register Proximity Device" button to go to the Proximity Device Registration screen and tap the found device to register the device.
5		取消	You can cancel device registration by tapping the "Cancel" button.
6	Device	Device settings	Tap the "Device Settings" button to go to the Device Settings screen.

7	settings	Device information	You can view your device information on the Device settings screen.
8		Disconnect	You can disconnect your device by tapping the "Disconnect" button.

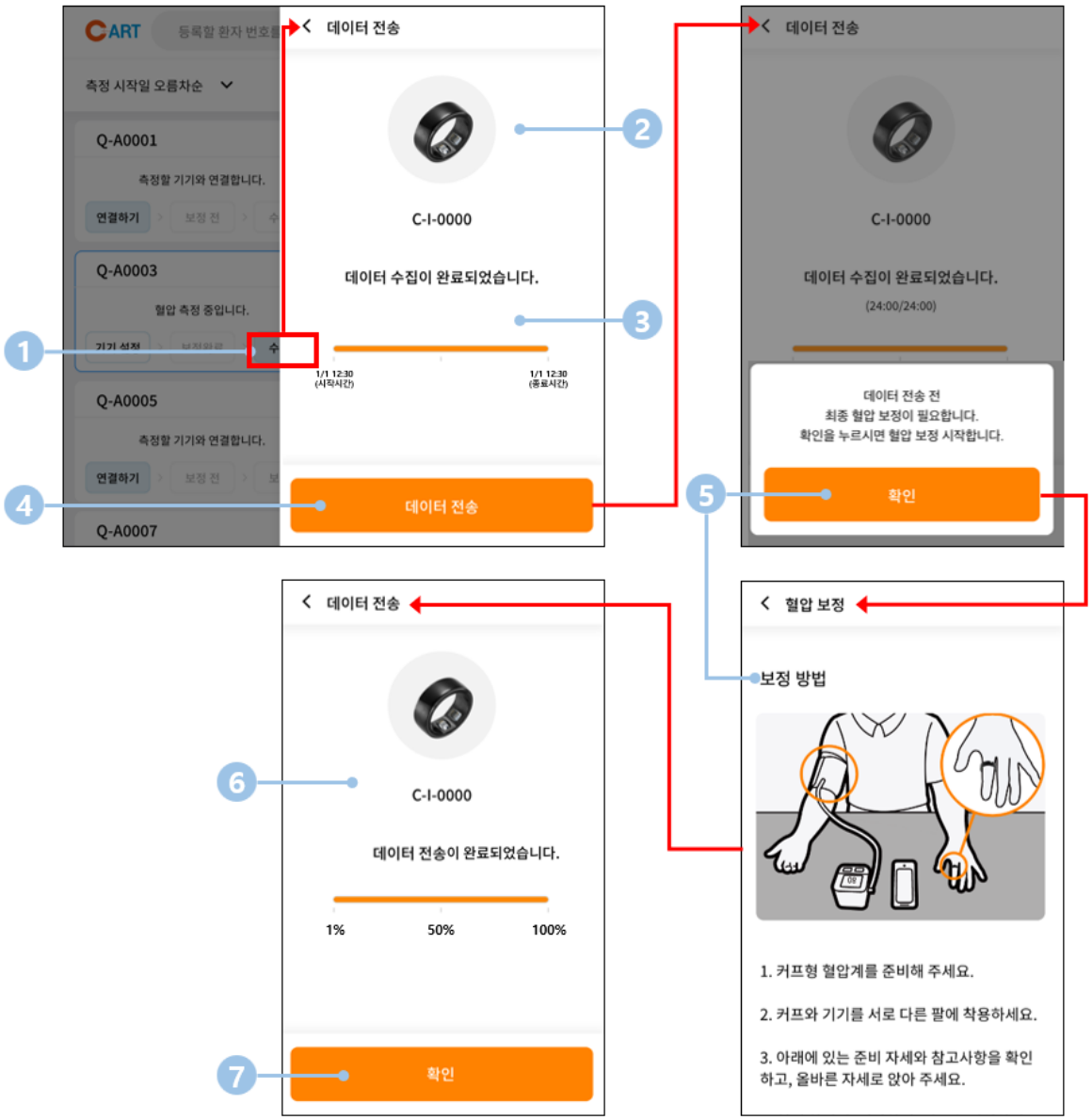
13.3.2. Calibrate (Blood Pressure Calibration)



Number	Name	Description
1	Blood pressure correction	Tap the "Calibrate Blood Pressure" button to go to the "Calibrate Blood Pressure" screen.
2	Blood pressure calibration guide	Check out our guide to calibrating your blood pressure.
3	Getting started	Tap the "Start" button to start calibrating your blood pressure.
4	Device optimisation	Proceed with device optimisation.
5	Primary blood pressure correction	Proceed with the primary blood pressure calibration.
6	Primary blood pressure correction Enter results	Enter the results of the first blood pressure calibration (systolic, diastolic).
7	Save primary blood pressure calibration results	Tap the "Save" button to save the primary blood pressure calibration results.
8	Secondary blood pressure correction	Proceed with secondary blood pressure calibration.

9	Secondary blood pressure correction Enter results	Enter the results of the secondary blood pressure correction (systolic, diastolic).
10	Saving secondary blood pressure calibration results	Tap the "Save" button to save the secondary BP calibration results and the BP calibration is complete.
11	Start collecting data	After completing the blood pressure calibration, tap the "Start Data Collection" button to start measuring your blood pressure.
12	取消	Touch the "Cancel" button to cancel the blood pressure correction.

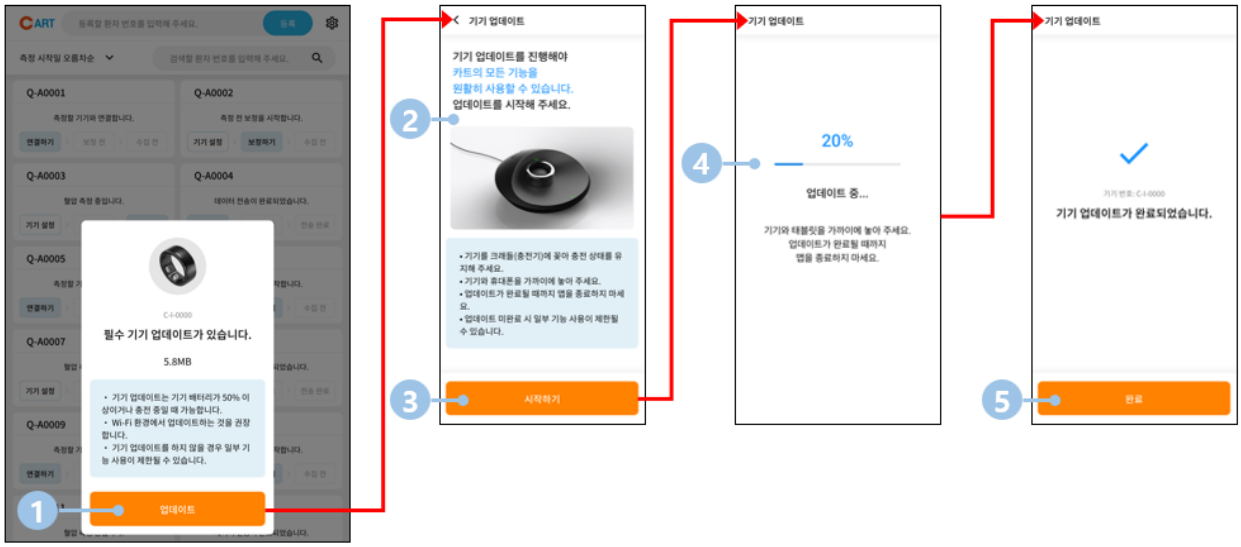
13.3.3. Data transfer



Number	Name	Description

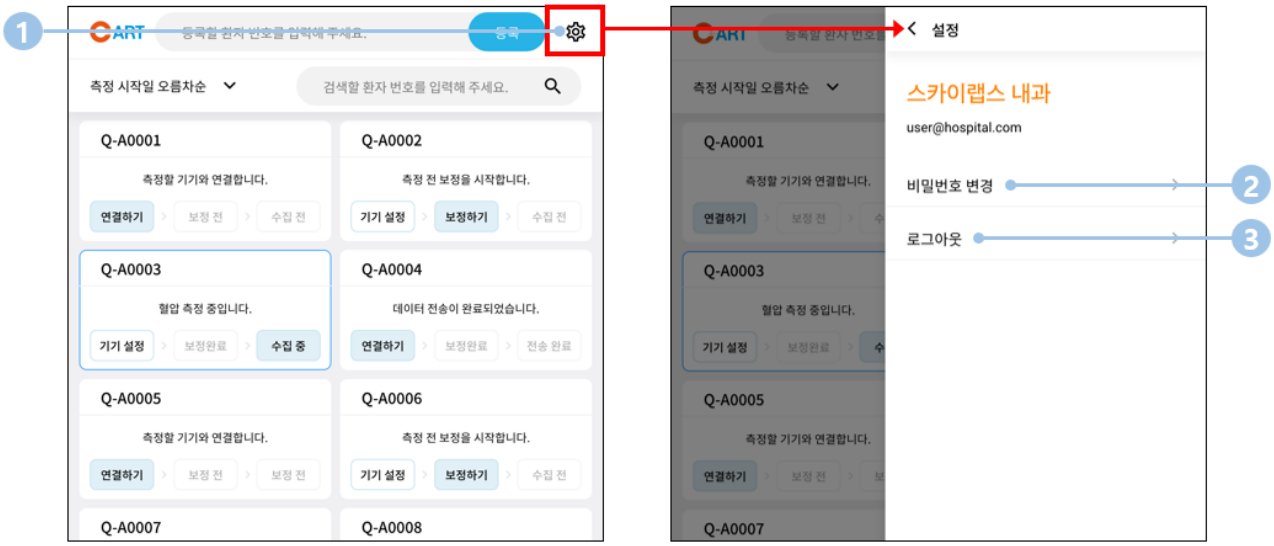
1	Collecting data	Tap the "Collecting" button to go to the data transfer screen.
2	Device information	You can see information about the device you're using.
3	Data collection status	You can see the start and end time of data collection and the progress.
4	Transferring data	Tap the "Transfer Data" button to transfer the remaining data stored in the CART-Ring.
5	Blood pressure correction	If additional blood pressure calibration is required prior to data transfer, repeat the blood pressure calibration in 4.3.2.
6	Data transfer status	Once the blood pressure calibration is complete, it will send the data and you can check the status of the data transfer.
7	Confirm	Tap the "OK" button to complete the data transfer.

13.3.4. Updating the firmware



Number	Name	Description
1	Update	Tap the "Update" button to go to the device update screen.
2	Device update guide	Check your device update guide.
3	Getting started	Tap the "Start" button to start updating your device.
4	Device update screen	You'll see the progress while your device is updating.
5	Device update complete	Tap the "Done" button to complete the device update.

a



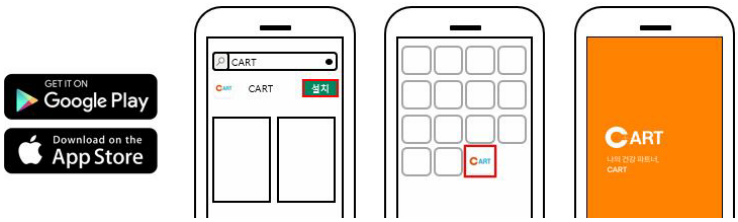
Number	Name	Description
1	Settings	Tap the "Settings" icon to go to the Settings screen.
2	Change your password	You can change the current password.
3	退出	You can log out of the mobile application.

13.5. Storage and care after use

Remember to stay logged out when not using the CART BP App (for hospitals).

14. How to use the CART BP App (for patients)

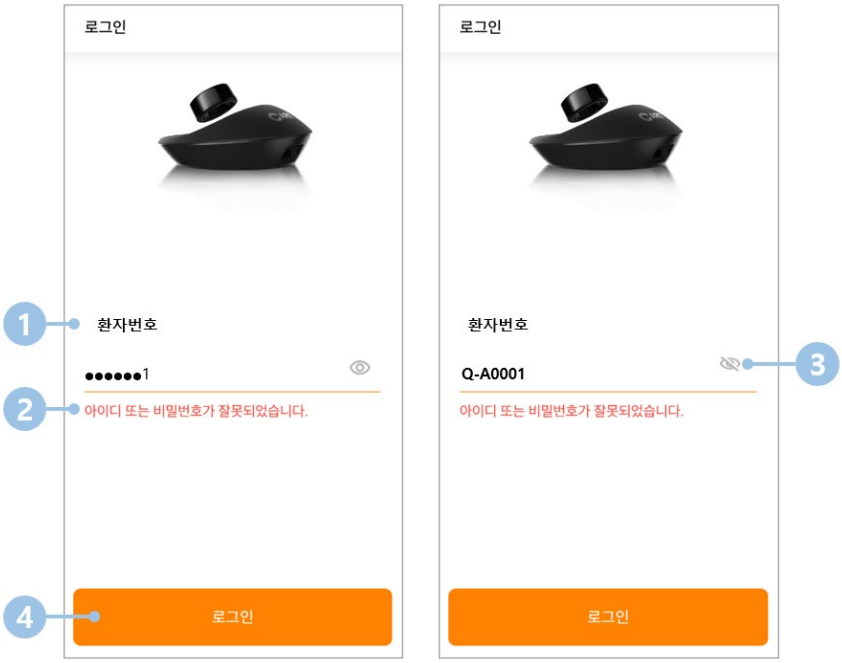
14.1. Install (download the application)



Install the CART BP App (for patients) using the link sent to your mobile device. Be sure to install the patient application.

14.2. Log in

1) Enter your patient number and you will be automatically logged into the CART BP App (for patients)
2) If the patient number and the information in CART-Ring do not match, you will not be able to use the product. If you cannot log in, please check that the patient number and device connection information in CART BP APP (for hospitals) match.
3) If the two match and you still can't sign in, please contact the manufacturer.



Number	Name	Description
1	Patient number	Tap the "Patient number" field and enter the patient number given to you by your healthcare provider.
2	Error messages	If the patient number does not match the information in CART-Ring, an error message is displayed.
3	Protecting patient numbers	Your patient number is protected in the form of "●●●●●●". To view your patient number, tap the icon.

4	登录	Tap the "Login" button to log in.

14.3. Main screen

Number	Name	Description
1	Displaying data status	You can check the status of data collection or transmission.
2	Battery status	You can check the charge status of your battery.
3	Date	You can see today's date.
4	Blood pressure	Displays the most recently measured blood pressure and pulse rate.
5	Today's average	Shows today's average blood pressure and today's average pulse rate in graphs and numbers.
6	Refresh	Update the data shown on the main screen to the latest.

14.4. Storage and care after use

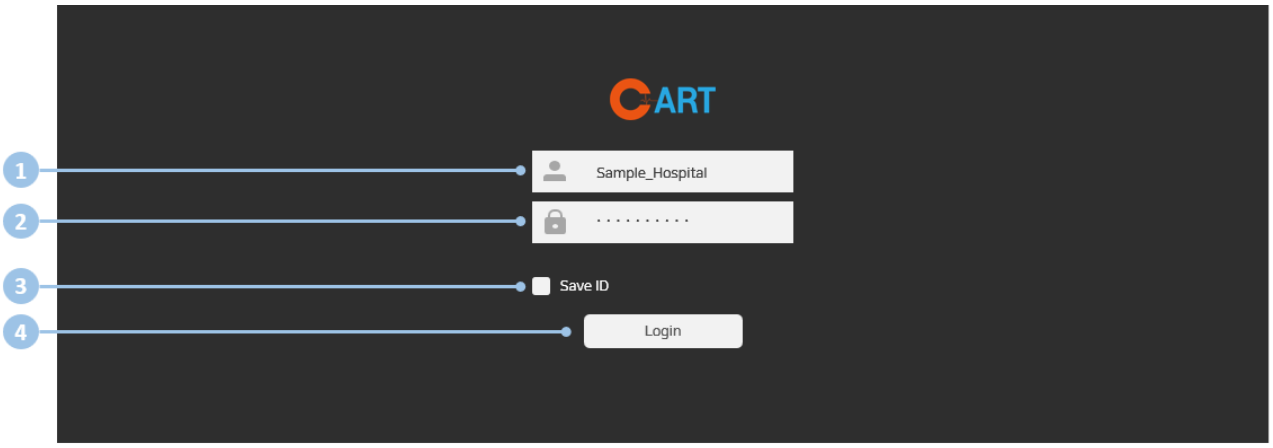
Be sure to stay logged out when not using the CART BP App (for patients).

14. How to use CART BP Web

14.1. Sign in

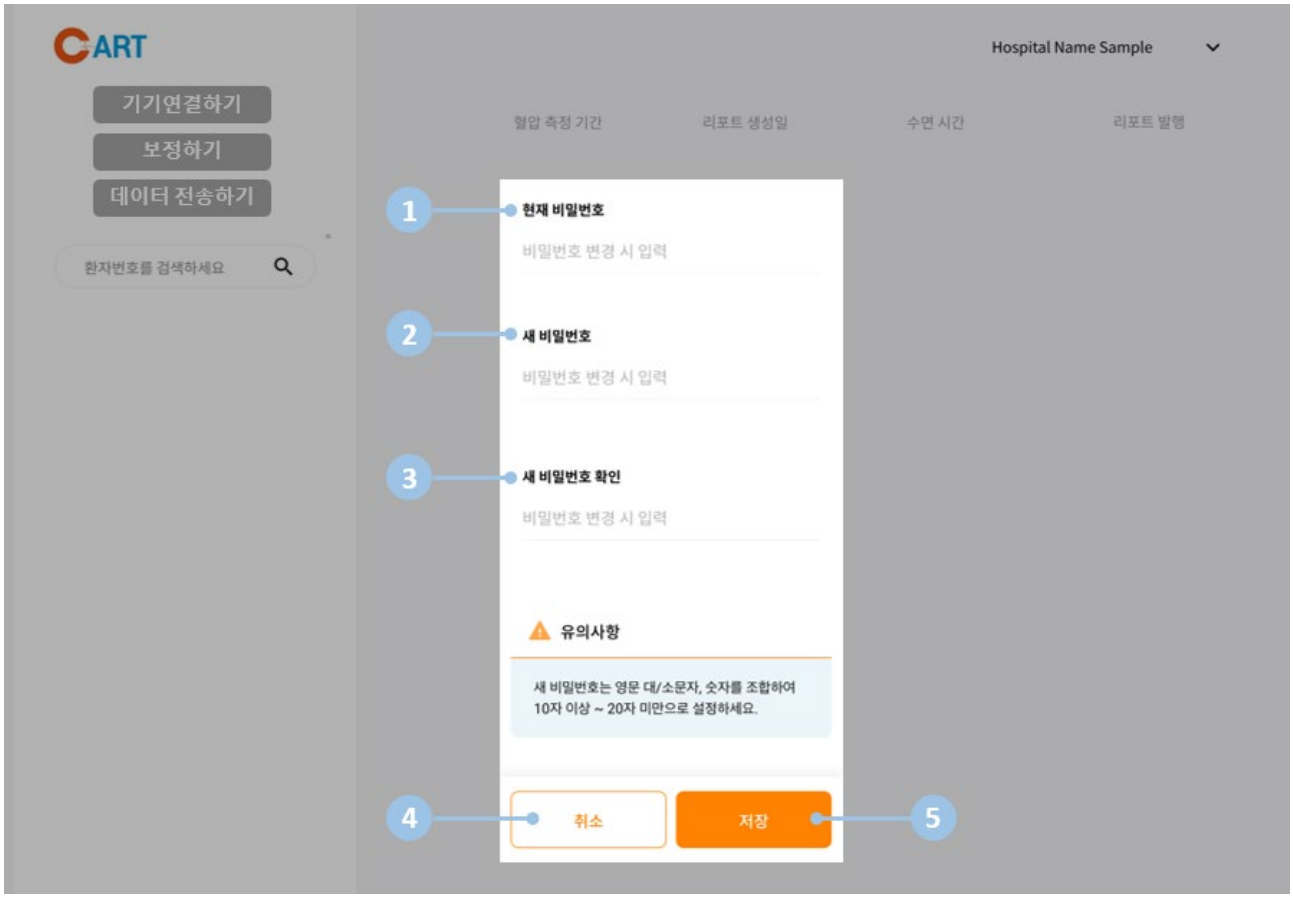
1) Please log in with the temporary password you were initially sent and change your password. If you do not change your password, you will not be able to use the product.

2) After you've finished changing your password, please log back in with the changed password.



Number	Name	Description
1	Id.	Touch the "Username" field and enter your username.
2	Password	Touch the "Password" field, and enter your password.
3	Save your ID	Tick the box for "Save ID" to remember your ID.
4	登录	Tap the "Login" button to log in to CART BP Web.

14.2. Change your password

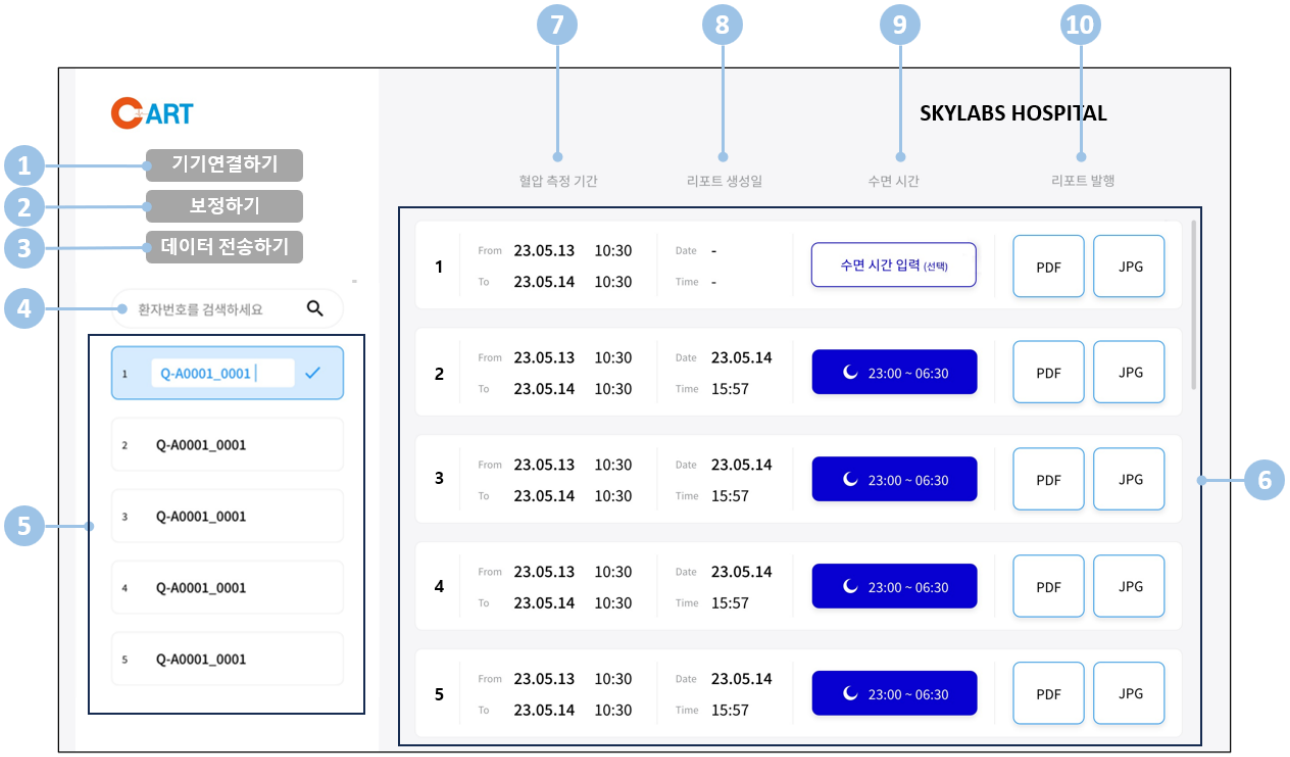


Number	Name	Description
1	Current password	Click the "Current password" field and enter the current password you received from the manufacturer.
2	New password	Click the "New password" field and set a new password for your account. Set a strong password to protect your privacy.
3	Confirm your new password	To confirm your password, click the "Confirm password" field and re-enter your newly set password.
4	取消	Selecting the "Min" button will end the password change and take you to the login screen.
5	Save	Select the "Confirm" button to complete the password change.

Note

- For security purposes, your password should be at least 10 and no more than 20 characters, including "uppercase, lowercase, and numbers".
- If you don't change your password, you won't be able to use the service.

14.3. Main page



Number	Name	Description
1	Connect your device	Click the "Connect your device" button to go to the Connect your device page.
2	Calibrate	Click the "Calibrate" button to go to the Calibrate Blood Pressure page.
3	Transferring data	Click the "Transfer data" button to go to the Transfer data page.
4	Patient Search	Search for a patient by entering the patient number in the Search for patient number field.
5	Patient list	A list of registered patients is displayed.
6	Patient detail list	The details of the registered patients are displayed in a list.
7	Blood pressure measurement period	The time period over which the patient's blood pressure was observed is displayed.
8	Report Generation Date	The date the patient's report was created by the provider is displayed.
9	Sleep duration	Enter the number of hours the patient slept during the observation period (blood pressure measurement period) (within 24 or 48 hours).
10	Publishing reports	Generate a report based on the data collected during the observation period (blood pressure measurement period) (within 24 or 48 hours).

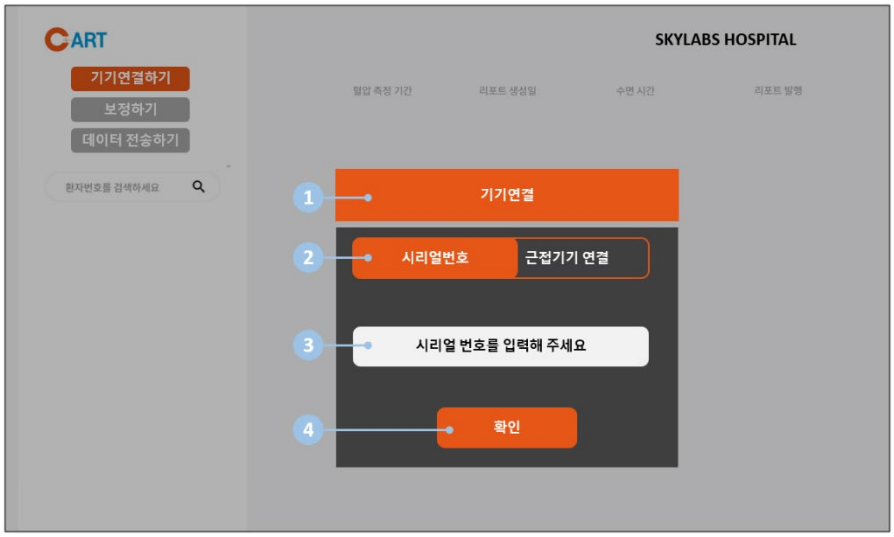
14.4. Connect your device

14.4.1. Enter patient number

Number	Name	Description
1	Connect your device	Click the "Connect device" button on the main screen to connect your device.
2	Patient Registration	A screen appears where you can register the patient.
3	Enter patient number	Please register the patient by entering the patient number in the Patient number field.
4	Confirm	Click the OK button to complete the patient registration.

14.4.1. Enter patient number

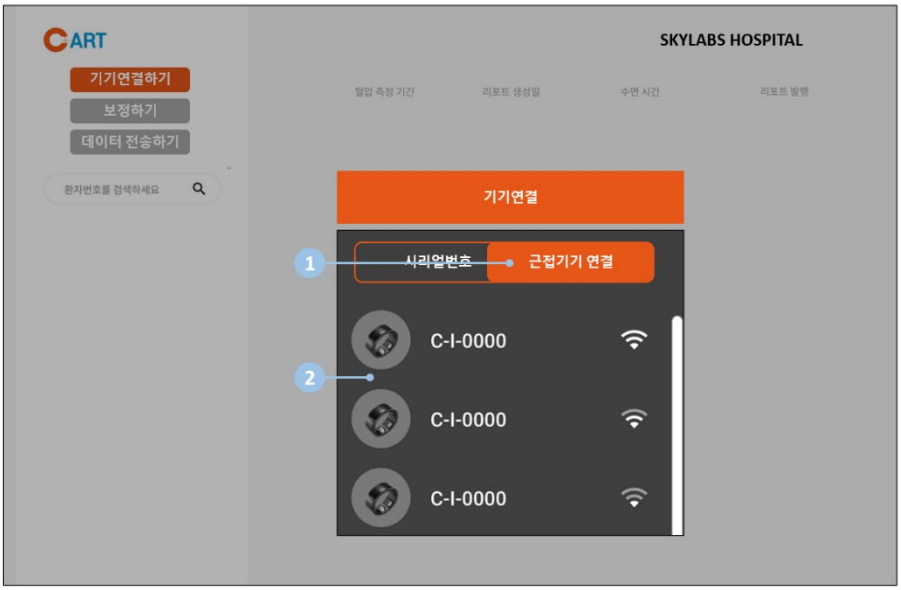
1) Serial number connection



Number	Name	Description
1	Connecting devices	Once patient registration is complete, you will be taken to the Connect Device screen.

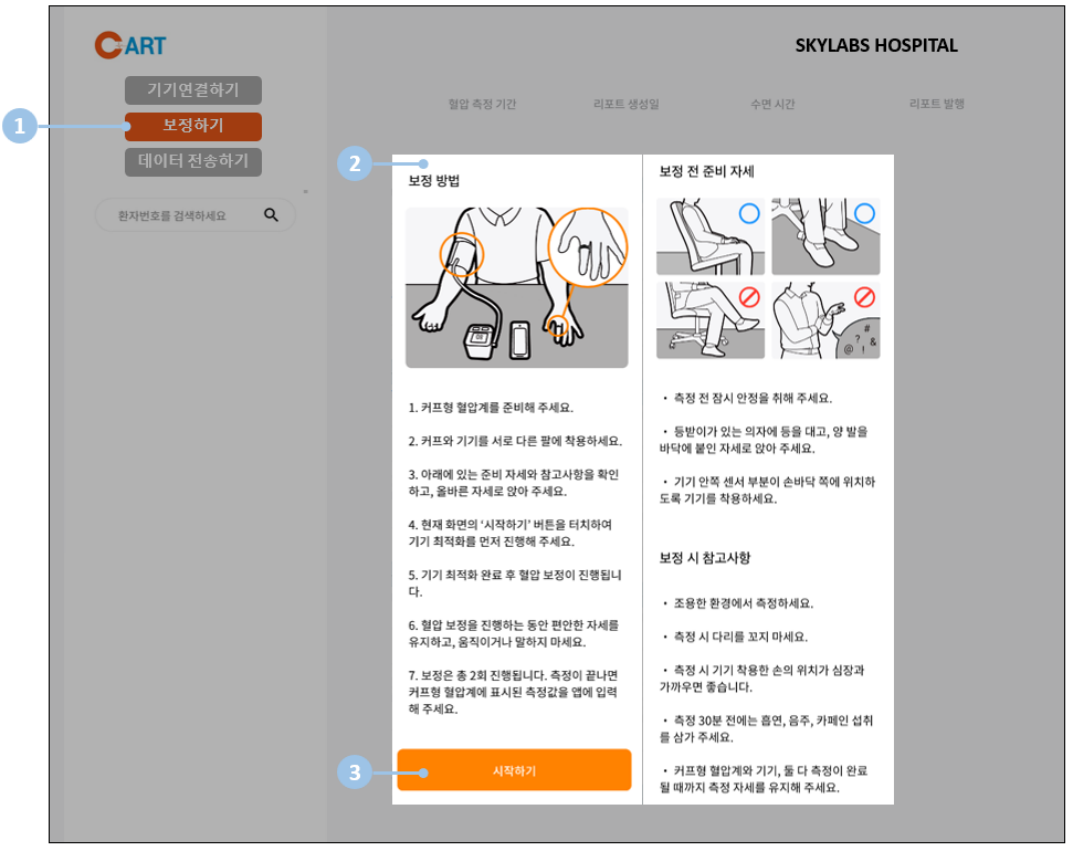
2	Choose a device connection method	Select the serial number from the device connection methods.
3	Serial number	Enter the serial number in the Enter serial number field to connect your device.
4	Confirm	Click the OK button to complete the device connection.

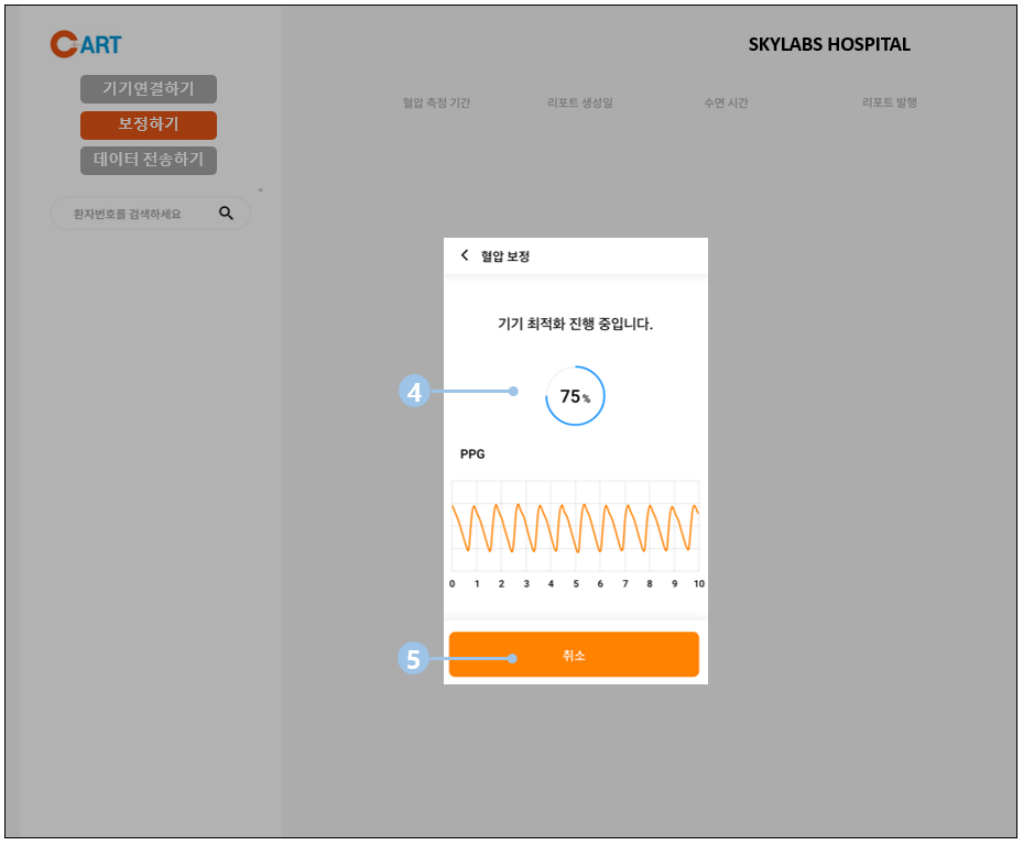
2) Connecting proximity devices

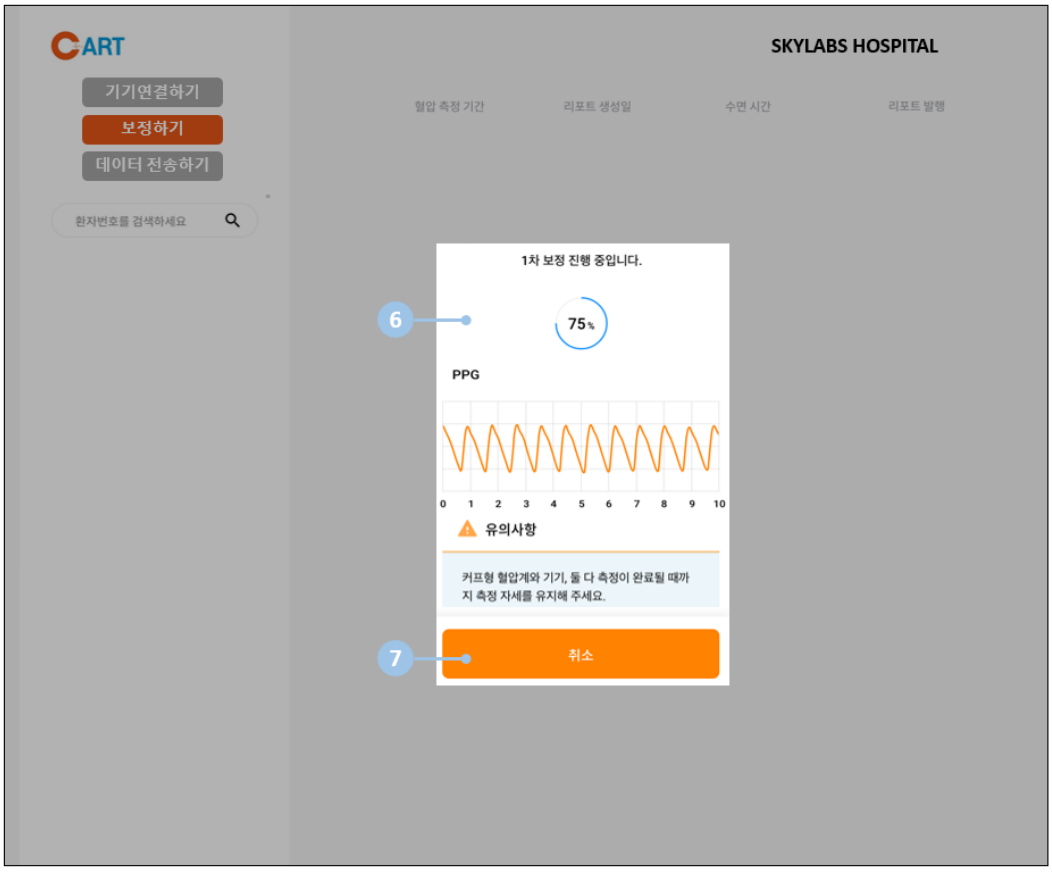


Number	Name	Description
1	Choose a device connection method	Under Device Connection Method, select Connect to Proximity.
2	Connecting proximity devices	Connect a device from the list of proximity devices to be used by the registered patient.

14.5. Calibrating






CART
기기연결하기
보정하기
데이터 전송하기
환자번호를 검색하세요
SKYLABS HOSPITAL
혈압 측정 기간
리포트 생성일
수면 시간
리포트 발행
1차 보정 진행 중입니다.
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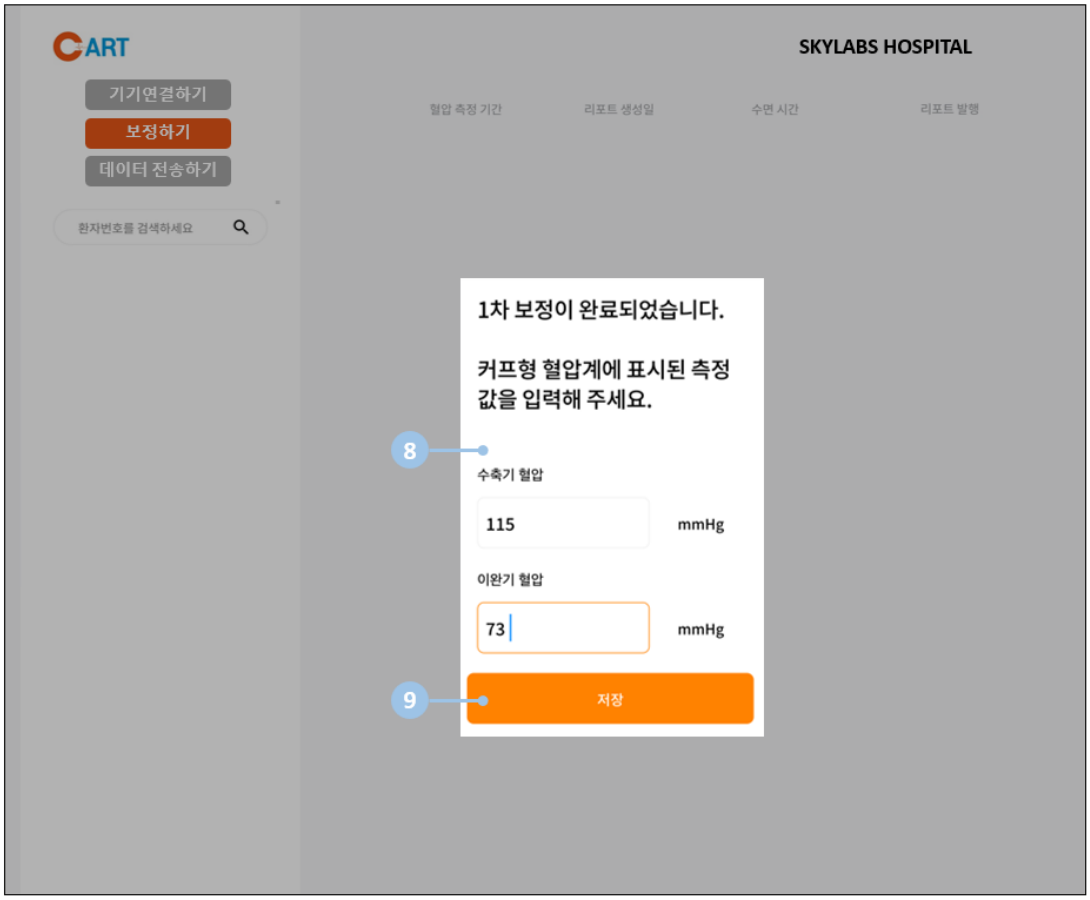
커프형 혈압계와 기기, 둘 다 측정이 완료될 때까지 측정 자세를 유지해 주세요.
7
취소


CART
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보정하기
데이터 전송하기
환자번호를 검색하세요
SKYLABS HOSPITAL
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리포트 발행
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커프형 혈압계에 표시된 측정 값을 입력해 주세요.
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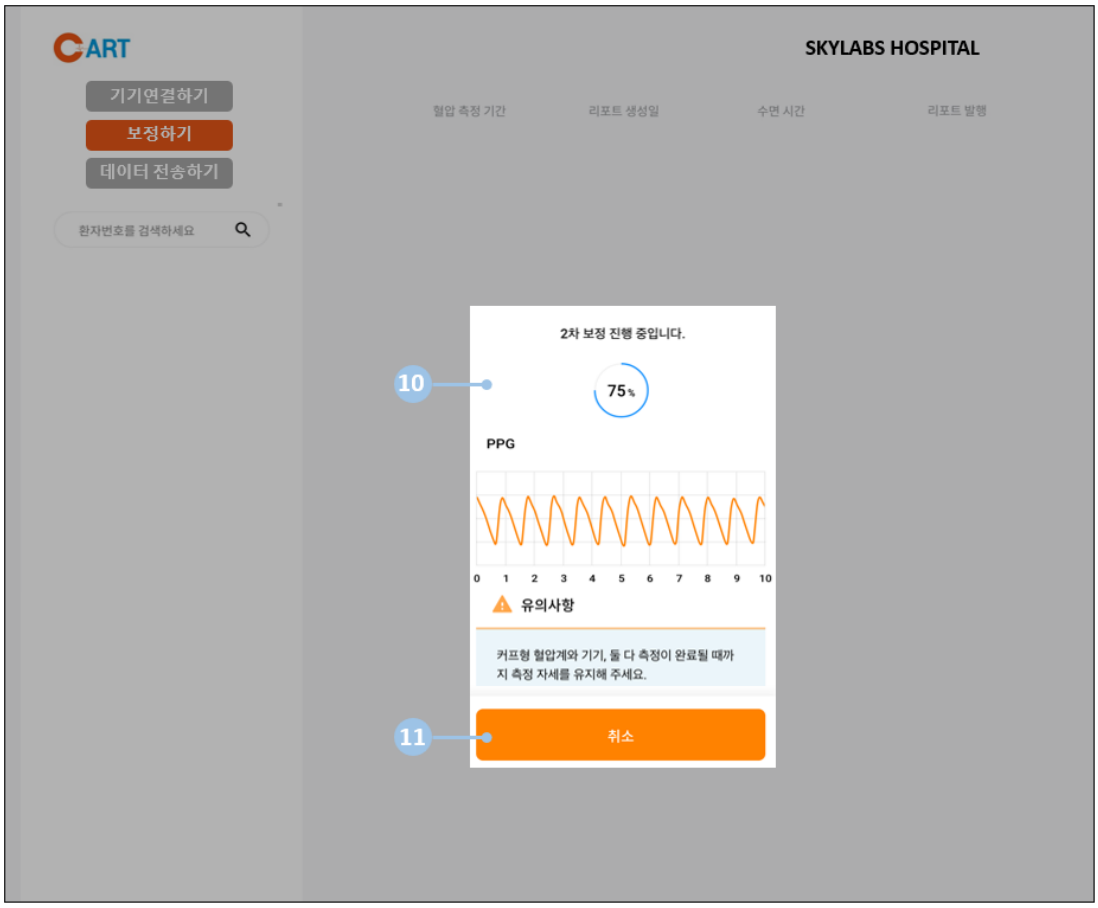
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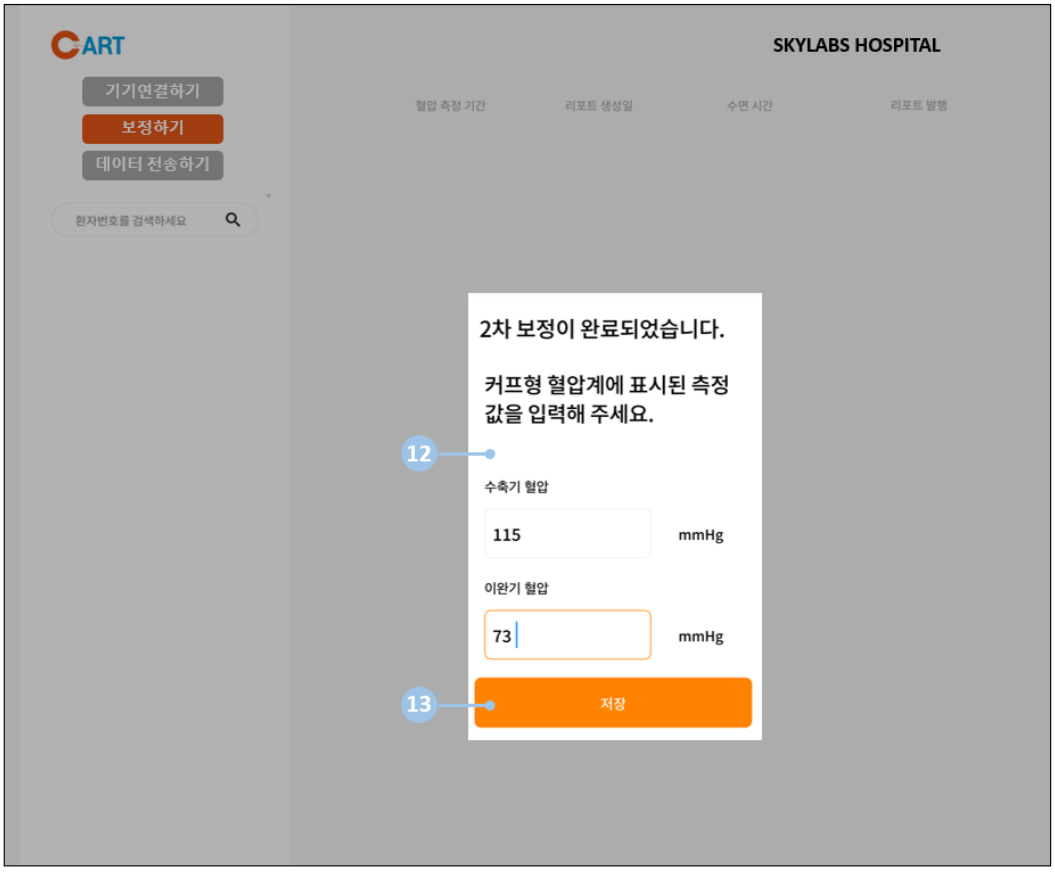
11
취소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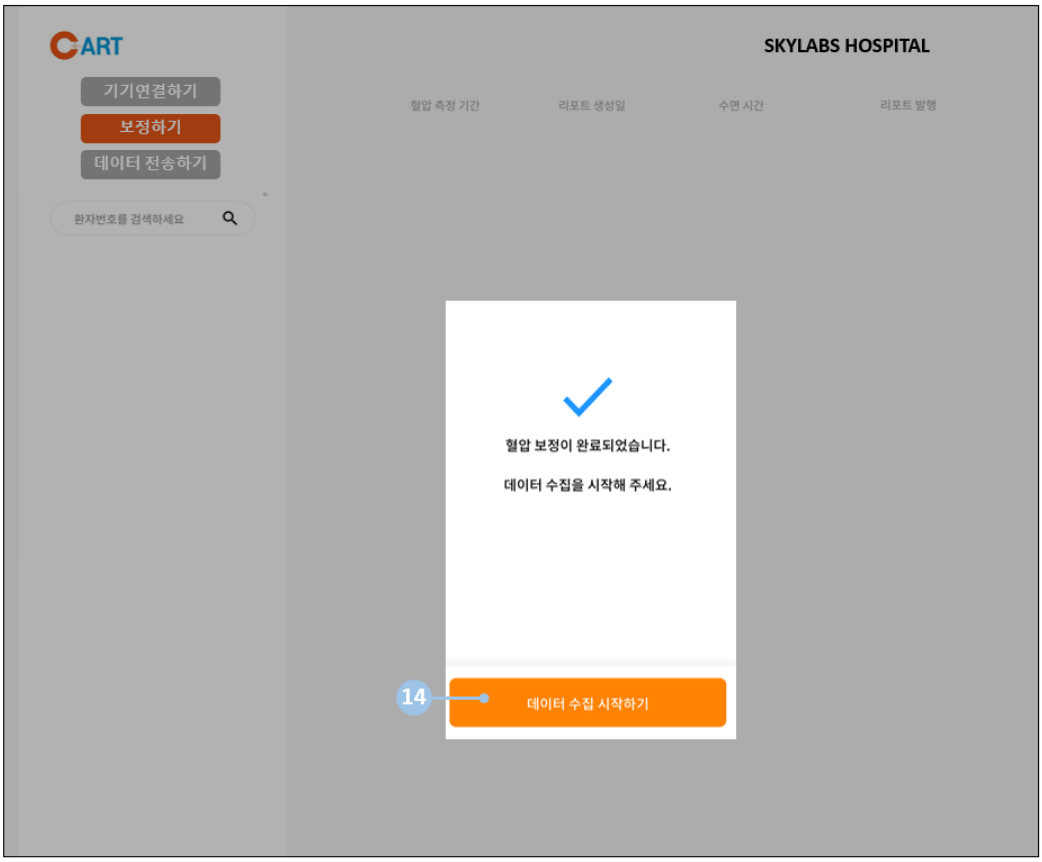
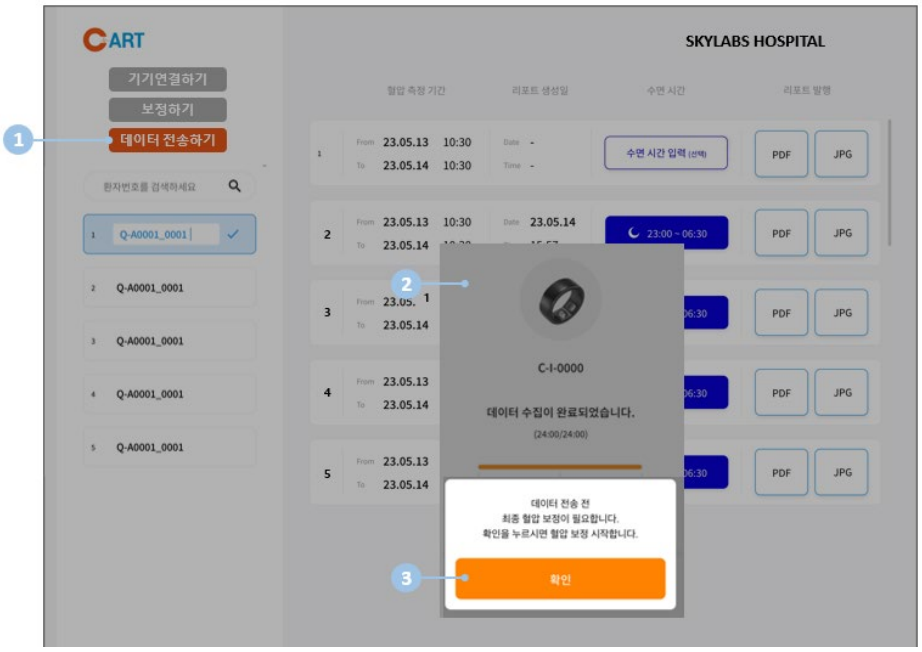
저장

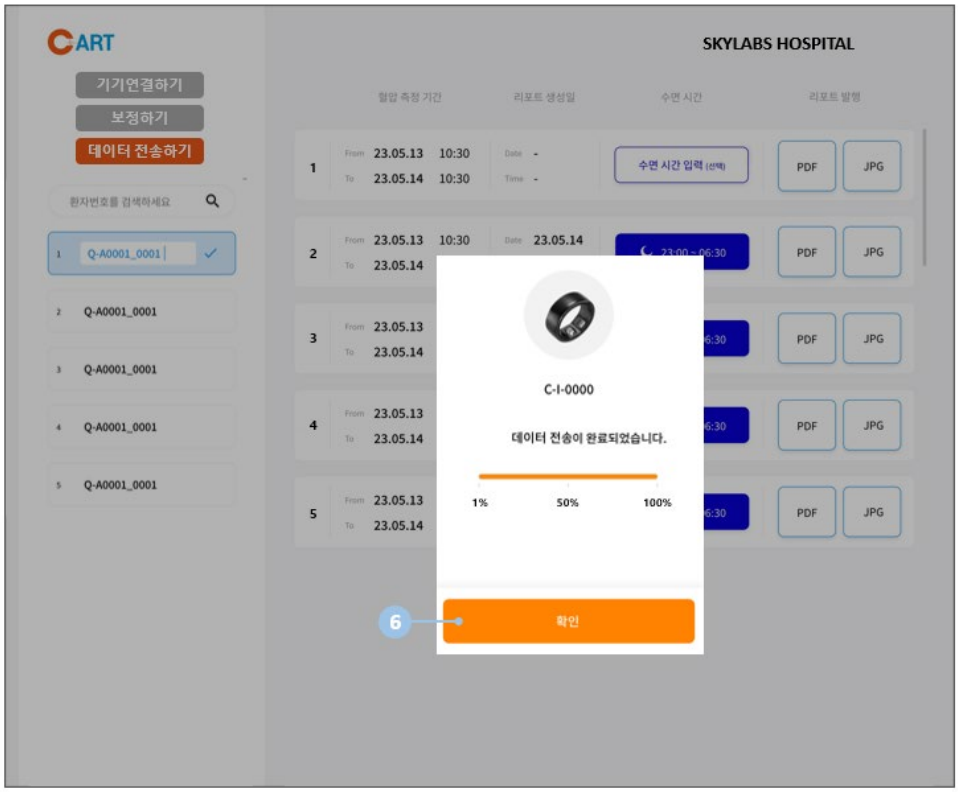


Number	Name	Description
1	Calibrate	Clicking the Calibrate button will take you to the Blood Pressure Calibration screen.
2	Blood pressure calibration guide	The Blood Pressure Calibration Guide is exposed.
3	Getting started	Click the "Start" button to start the blood pressure calibration. The blood pressure calibration will be performed twice.
4	Device optimisation screen	Displays the progress and PPG waveform while the device optimisation is in progress.
5	取消	Click the Cancel button to cancel the device optimisation.
6	Primary Calibration Screen	Displays the progress and PPG waveform while the primary blood pressure calibration is in progress.
7	取消	Click the Cancel button to cancel the primary blood pressure correction.
8	Enter primary calibration results	Enter the results of the first blood pressure calibration (systolic, diastolic).
9	Save the first calibration result	Click the "Save" button to save the primary blood pressure calibration results.
10	Secondary Calibration Screen	Displays the progress and PPG waveform while secondary blood pressure correction is in progress.
11	取消	Click the Cancel button to cancel the secondary blood pressure correction.
12	Enter secondary calibration results	Enter the results of the secondary blood pressure correction (systolic, diastolic).

13	Saving secondary calibration results	Click the "Save" button to save the secondary blood pressure calibration results.
14	Start collecting data	After calibrating your blood pressure, click the "Start Data Collection" button to start measuring your blood pressure.

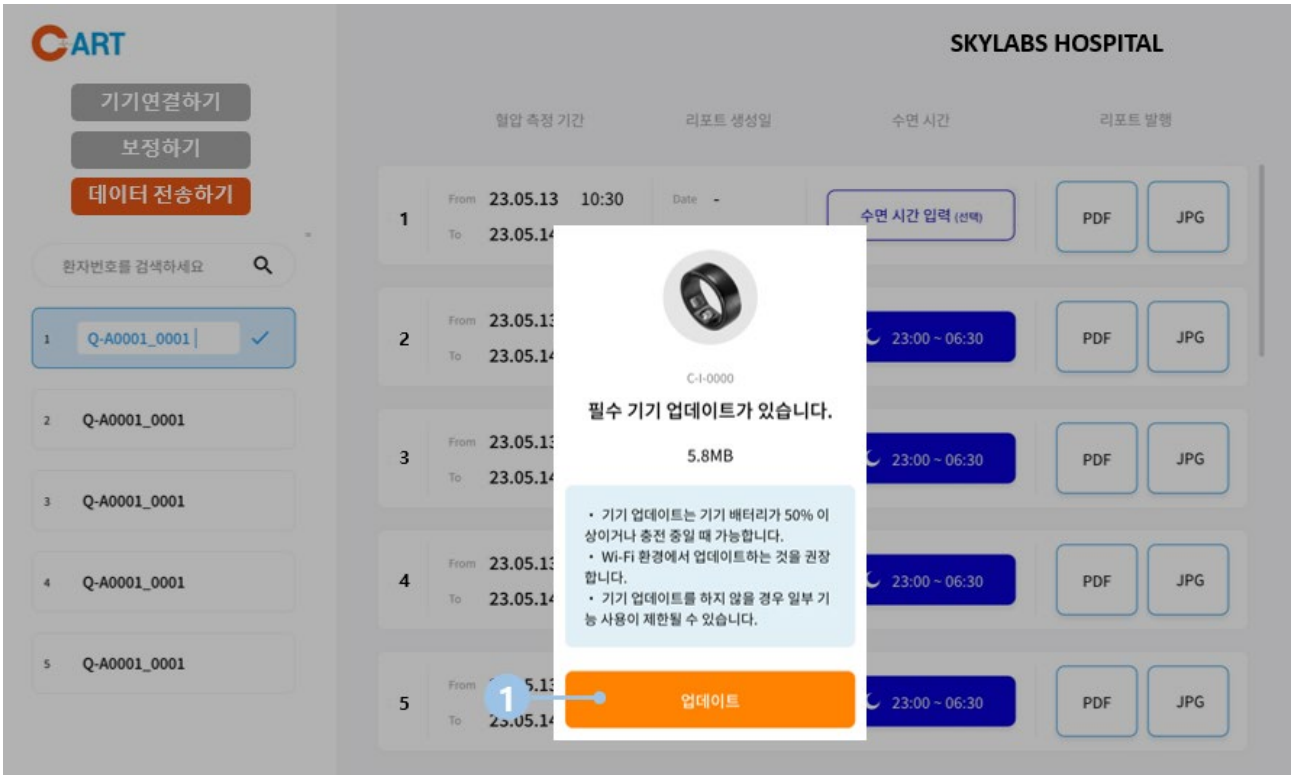
14.6. Transferring data

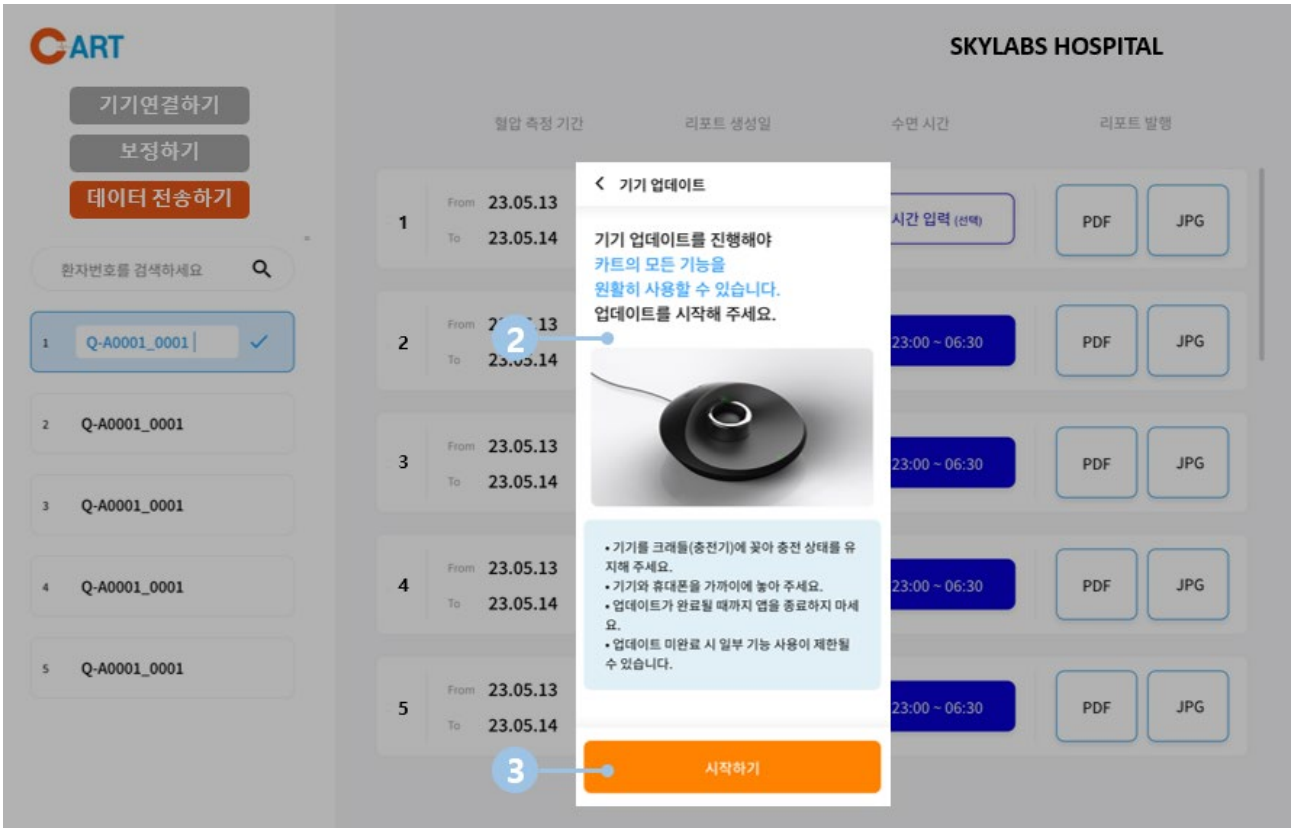


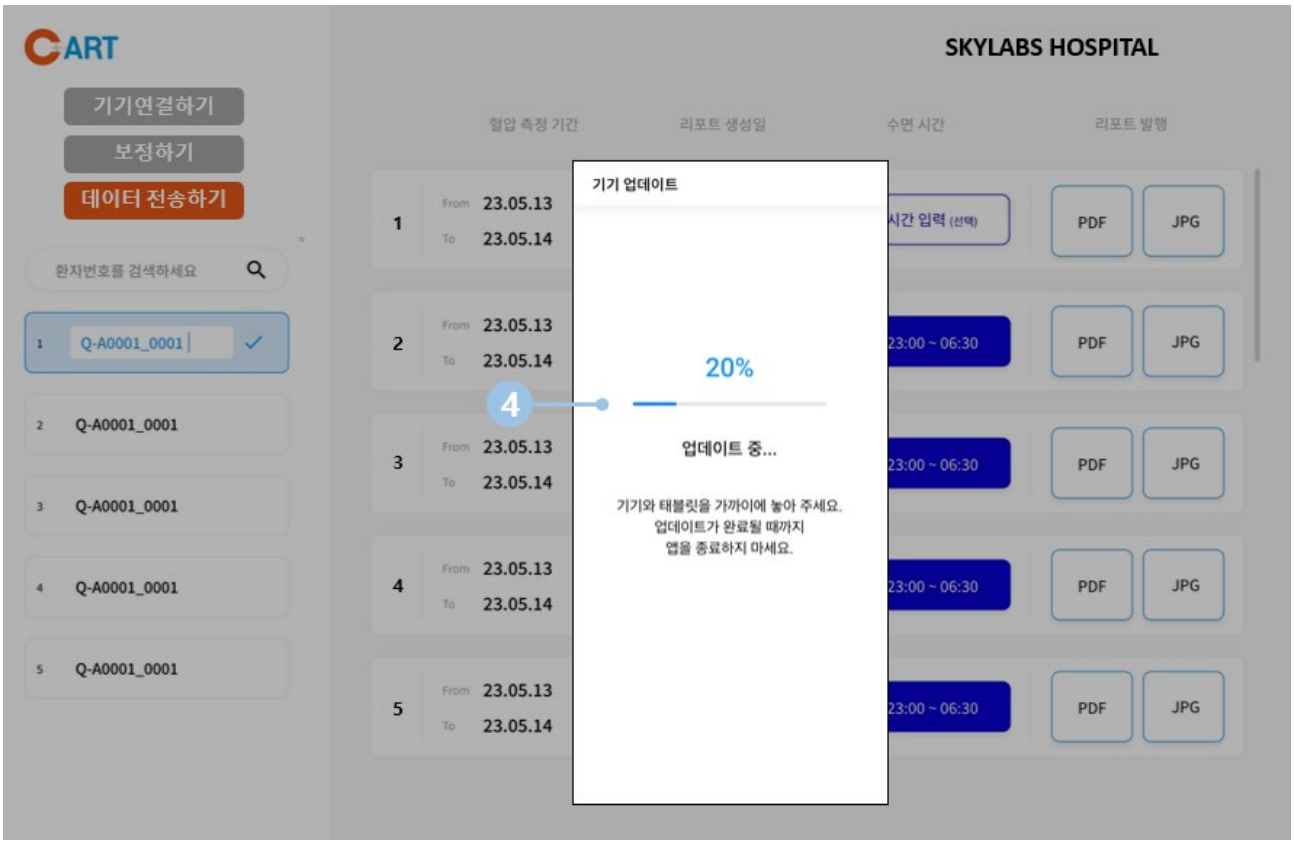


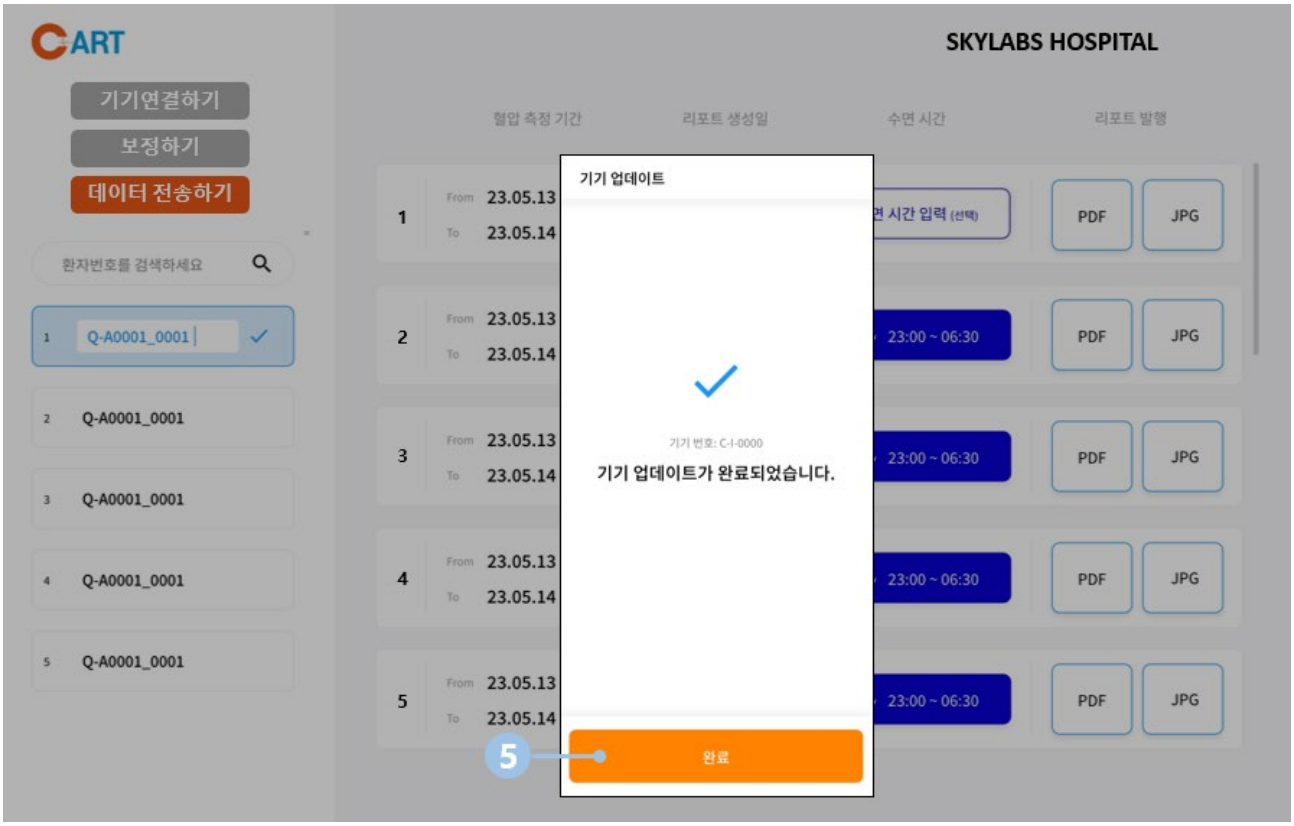
Number	Name	Description
1	Transferring data	Click the "Transfer data" button to go to the Transfer data screen.
2	Confirm	If additional blood pressure calibration is required before data transfer, a prompt window will be displayed and you will be taken to the blood pressure calibration screen by clicking the "OK" button.
3	Blood pressure correction	Proceed again with the blood pressure calibration in 6.5.
4	Getting started	Click the "Start" button to proceed with blood pressure calibration.
5	Transferring data	When the blood pressure calibration is complete, the residual data stored in the CART-Ring is sent.
6	Confirm	Click the "OK" button to complete the data transfer.

14.7. Update your device









Number	Name	Description

1	Update	Tap the "Update" button to go to the device update screen.
2	Device update guide	Check your device update guide.
3	Getting started	Tap the "Start" button to start updating your device.
4	Device update screen	You'll see the progress while your device is updating.
5	Device update complete	Tap the "Done" button to complete the device update.

14.8. Storage and care after use

Remember to stay logged out when you're not using CART BP Web.

15. electromagnetic information

15.1. Instructions and Manufacturer's Declaration - Electromagnetic Emissions

This product is intended for use in the electromagnetic environment specified below. In addition, you must use this product in the following environments

Emission test	Conformance	Electromagnetic Environment - Guidelines
RF emissions CISPR 11	Group 1	This product uses RF energy only for internal functions, so RF emissions are very low and will not cause interference to nearby electronic equipment.
RF emissions CISPR 11	Class B	The product is suitable for use in all installations, including domestic installations and those directly connected to the low voltage power supply networks that supply domestic buildings.
High frequency emissions IEC 61000-3-2	A	
Voltage fluctuations IEC 61000-3-3	Complies	

15.2. Instructions and Manufacturer's Declaration - Electromagnetic Immunity

This product is intended for use in the electromagnetic environment specified below. You must use this product in the environment specified below.

Tolerance testing	IEC 60601 Test Level	Conformance levels	Electromagnetic Environment - Guidelines
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV Contact ±2kV, ±4kV, ±8kV, ±15kV air	±8kV contact ±15kV air	The floor must be wood, concrete, or ceramic tile. If the flooring is synthetic, the relative humidity must be at least 30%.
Electrical fast transient/burst IEC61000-4-4	±2kV 100kHz repetition frequency	±2kV 100kHz repetition frequency	The mains power must be of the quality of a normal commercial or hospital environment.
Surge Line-to-line IEC 61000-4-5	±0.5kV, ±1kV	±1kV	The mains power must be of the quality of a normal commercial or hospital environment.
Surge Line-to-ground IEC 61000-4-5	±0.5kV, ±1kV, ±2kV	±2kV	
Voltage dips IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	The mains power must be of the quality of a normal commercial or hospital environment. If users need to continue using the device during an outage, we recommend powering it from the device's uninterruptible power supply or batteries.
Voltage interruptions IEC 61000-4-11	0 % UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0°	0 % UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0°	
Power frequency (50/60 Hz) Magnetic Fields IEC 61000-4-8	30A/m	30A/m	The power frequency magnetic field should have the typical location level characteristics of a typical commercial or hospital environment.
Conductive RF IEC 61000-4-6	3V 0.15 MHz - 80 MHz 6V in ISM bands between 0.15 MHz and 80MHz 80% AM at 1kHz	3V 0.15 MHz - 80 MHz 6V in ISM bands Between 0.15 MHz and 80MHz 80%AM at 1 kHz	Portable and mobile RF communications equipment must not be used closer to any part of this product, including cables, than the recommended separation distance calculated from the equation for the transmitter frequency.

Radioactive RF IEC 61000-4-3	3 V/m 80MHz - 2,7GHz 80% AM at 1kHz	3 V/m 80MHz - 2,7GHz 80%AM at 1kHz	$d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.7 GHz Where P is the maximum power rating of the transmitter (W) according to the transmitter manufacturer, and d is the recommended separation distance (M). The field strength of fixed RF transmitters, as determined by the electromagnetic site survey, must be less than the compliance level for each frequency range. Interference may occur near equipment marked with the following symbols

USER’s MANUAL

March / 2024 / Revision.0

Sky Labs Inc.

◆ Contents

1. label and symbols 5

1.1. Symbols on the shipping carton 5

1.2. Symbols 5

2. Safety Warnings 6

2.1. Safety-related information 6

2.2. Limitations on the use 6

2.3. General safety 6

2.4. Product maintenance 6

2.5. Radio frequency / electromagnetism / environmental requirements 6

2.6. Waterproof 7

2.7. Cyber security 7

3. Product Description 9

3.1. Intended Use 9

3.2. Principles of operation 9

3.3. Product Accuracy and Calculations 9

4. Product configuration 10

4.1. CART-RING 10

4.2. CART BP APP 10

4.3. Accessories 11

4.4. Sizing Kit 12

5. How to use for CART-RING 13

5.1. Preparation before use 13

5.2. Charging the CART-RING 13

5.3. Wearing the CART-RING 14

5.4. Bluetooth (BLE) Connection 14

5.5. PPG Measurement 14

6. How to use for CART BP APP 16

6.1. Preparation before use 16

6.2. Install CART BP APP (Download the application) 16

6.3. Sign up & Login 16
6.4. Find ID and Find Password 19
6.5. Device registration 21
6.6. BP Calibration 22
6.7. Update device 23
6.8. Main 24
6.9. Blood Pressure Calendar 25
6.10. My Information 26
7. Performance Characteristics **28**
7.1. Product Specifications 28
7.2. IT-Network 28
8. Operating and Storage conditions **30**
9. Disposal **31**
10. Warranty and Limited Warranty **32**
8.1. Manufacturer's Limited Warranty 32
10.2. 30-day return policy 32
10.3. Damage and Issues 32
10.4. Exceptions/non-returnable items 32
10.5. Exchange 32
11. Storage and maintenance **33**
11.1. Storage 33
11.2. Maintenance 33
11.3. Cleaning and disinfection 33
12. Electromagnetic Compatibility **34**
12.1. Guidelines and manufacturer's declaration – Electromagnetic emission 34
12.2. Guidelines and manufacturer's declaration – Electromagnetic susceptibility 34
13. Troubleshooting **36**

NOTICE

Sky Labs Inc. CART BP

Thank you for using CART BP. To ensure safe and proper use of the product, please read this user's manual before using the product.

Failure to follow the contents of the user manual may result in damage or malfunction of the product, or even personal injury. If the User's Manual is more than three months old, please download the latest USER's MANUAL from the Sky Labs website (www.skylabs.io) or contact Sky Labs to see if there is additional information you need. If you have any questions about using the product or software, please contact Sky Labs.

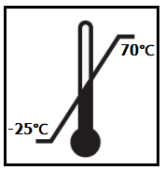
Manufacturer	Sky Labs Inc.
Address	702, 703, 58, Pangyo-ro 255 beon-gil, Bundang-gu, Seongnam-si, Gyeonggi-do, Republic of Korea
Web site	http://www.skylabs.io
E-Mail	info@skylabs.io
Tel	+82-1599-3402
Country	Made in KOREA

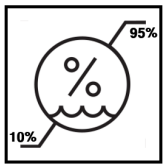
1. label and symbols

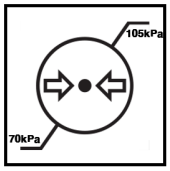
1.1. Symbols on the shipping carton

Handling with care

Guard against Damp







Storage and transport temperature, humidity and atmospheric pressure

1.2. Symbols

Manufacturer

Date of manufacture

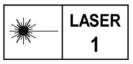
Lot Number

Type BF Applied part

See the User's manual

IP Grade

DC



CLASS 1 Laser

Do not dispose as household waste

Temperature limits

Humidity limits

Atmospheric pressure limits

No alarm

Warning

Note

2. Safety Warnings

Warning: Failure to follow safety warnings specified in the user manual may result in fire, electric shock, injury or product damage. Make sure to check all safety precautions and warnings before using the product.

2.1. Safety-related information

This product is designed and made to meet “IEC 60601-1, IEC 60601-1-2” which is international standards applicable to medical equipment.

When using this product, make sure to follow the Medical Device Regulation Act, General Data Protection Regulation Act and other applicable laws and regulations.

2.2. Limitations on the use

This product can be used by adults only. Ensure that the CART-RING is put on properly, using the correct method to wear it.

The CART-RING can be put on a finger only. Ensure that it is not put on a body part that is not a finger.

This product cannot be used to diagnose any disease without assistance by a medical professional.

Sky Labs Inc. does not guarantee any data resulting from malfunction of the device caused by abuse, misuse, modification or negligence of the product, an accident, or failure to perform maintenance as instructed in the user manual.

2.3. General safety

Due to its technical nature, this product cannot be repaired. If there are any problems, please contact the manufacturer.

Do not modify, repair, dismantle or alter this product. Injury or product damage may occur.

The CART-RING has an ingress protection rating of IP58, which is daily life waterproof. Nevertheless, if your hand or the CART-RING is wet, use a soft cloth to wipe the moisture away, to increase the quality of collected data.

If this product has been stored at a minimum or maximum temperature, keep it at a room temperature for at least one hour before use.

If you use procedures or control actions for a maneuver or maintenance that is not specified herein, this may cause exposure to hazardous radiation.

Do not leave this product in a location where there are children or pets.

The CART-RING contains a lithium-polymer battery that can be a choking hazard and may cause severe tissue injury if ingested. Never swallow.

2.4. Product maintenance

Do not clean this product with hot water or immerse it in a cleansing solution. The product may become seriously damaged.

Before wearing the CART-RING, use a soft cloth to wipe the inner and outer surfaces.

Once a day, wipe the surfaces of the CART-RING before putting it on.

2.5. Radio frequency / electromagnetism / environmental requirements

Do not expose this product to a strong electromagnetic field.

Do not use this product together with MRI, CT or X-ray equipment.

This product contains electromagnetic field-emitting components and uses radio frequencies.

LED sensor of CART-RING is a device that emits Class I laser. For safe use, do not look or look directly at the light from a close location.

	Do not store the product in a location that is exposed to extremely high or low temperature, humidity, moisture, or direct sunlight.
	Use this product under the specified environmental conditions only.
	The CART-RING comes with an embedded battery. Do not leave it inside an automobile for a prolonged period of time.
	Do not put the CART-RING or other component in your mouth or swallow it.
	Do not use an uncertified adapter or cable.
	If you move your body excessively during measurement, correct measurement may not be obtained. Do not exercise or engage in strenuous movements.
	This device can be operated in at least one Member State without infringing applicable requirements on the use of radio spectrum.

2.6. Waterproof

	Be careful and ensure that the CART-RING does not come into contact with high-pressure water.
	Do not wear the CART-RING when playing a water sport in fast-flowing water, diving or snorkeling.
	If the CART-RING or your hand is wet, thoroughly dry it before using the Ring.
	If the CART-RING is wet in clean water, use a clean, soft cloth to wipe the moisture away.
	If the CART-RING has been exposed to liquid that is not clean water (e.g., salted water, swimming pool water, soapy water, oil, or chemicals such as perfume, sunblock, hand sanitizer or cosmetics), rinse it with clean water and then use a clean, soft cloth to wipe and thoroughly dry it before use. If you use it without drying it, the performance or the exterior may become affected.
	Be careful and ensure that the CART-RING is not dropped or impacted. The waterproof or dustproof performance may be affected.
	The CART-RING cannot be dismantled. Do not dismantle it. The water/dust-proof (ingress protection) performance may be affected.
	Do not expose the CART-RING to extreme air or water temperature fluctuations.
	Do not dry the CART-RING using a heat generating device, such as a hair dryer.
	Do not wear the CART-RING in a sauna or steam bath. The waterproof performance may be affected.
	The CART-RING was tested under controlled environmental conditions (IEC60529) and has an ingress protection rating of IP58. For the ingress protection to work properly, follow the instructions specified above. Failure to follow the instructions above may damage the product.

2.7. Cyber security

- Bluetooth 5.0 LE (Low Energy) communication of CART-RING uses AES-256 encryption algorithm to safely protect user's sensitive information.
- Firmware update of CART-RING can only be done with CART BP APP to block unauthorized access. After logging in to CART BP APP, update the firmware of CART-RING.
- CART-RING can be used only when the authenticity of the device is verified for security. Complete device activation using CART BP APP.
- Security Add a passcode (personal identification number [PIN]), or Touch ID (fingerprint), or Face ID recognition (if your phone supports this) to your smartphone to add a layer of security. It is important to secure your smartphone since you will be storing personal health information. Review your smartphone for information on how to add a layer of security.
- If the user's account is not used for one year, it will be converted to a dormant account for security.
- In principle, CART-RING does not store data in the device and transmits it to CART BP APP. However, untransmitted data can be stored in the flash memory to prevent data omission in the actual use environment.

Stored data is transmitted immediately when Bluetooth communication between CART-RING and CART BP APP is connected, and the storage capacity of memory is 8 M bits.

- CART-RING is shipped with the latest version of firmware to protect against malware. If there is a firmware update, the user must log in to CART BP APP to update. To protect your device from malware, pay attention to the following:
  - Always keep CART-RING's firmware and mobile device's OS up to date.
  - Do not trust pop-up windows asking you to download software on your mobile device.
  - Use the antivirus program required by your mobile device.
- If a problem relating to cyber security for this product occurs, report it to the manufacturer and wait for the administrator to fix the problem.

If a problem relating to cyber security for this product occurs, report it to the manufacturer and wait for the administrator to fix the problem.

2.8. FCC compliance information

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.

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 try to correct the interference by one or more 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 that to which the receiver is connected.

Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with RF exposure requirement.

For CART-CRADLE, it should be installed and operated with minimum 20 cm between the radiator and your body.

3. Product Description

3.1. Intended Use

CART BP is a device that subjects wear for extended periods of time to noninvasively measure and display systolic and diastolic blood pressure and pulse rate.

3.2. Principles of operation

This product is a blood pressure monitoring device that collects PPG signals by wearing a ring-shaped device and transmits, stores, and analyzes the collected signals through wireless communication (Bluetooth) to display systolic and diastolic blood pressure (BP), average blood pressure, and pulse rate. The collected PPG signals are analyzed by a programmed algorithm.

Used for indirect (non-coronary) measurement of blood pressure, photoplethysmography (PPG) uses the optical properties of the skin to measure blood flow through blood vessels. The principle of photoplethysmography is that when the volume of blood vessels changes due to the heartbeat, a light source is shone on the body, and biological tissue reflects and transmits some of the light, and a light sensor detects the change in light sensitivity as the volume of blood vessels changes. Photoplethysmography consists of an LED that emits light and a photosensor that detects the emitted light and can be measured in reflection mode. The shape of the pulse wave is similar to that of the arterial blood pressure (ABP) waveform, and the changes in the waveform due to changes in blood pressure are also very similar. Therefore, the blood pressure can be estimated by tracking the changes in the shape of the pulse wave based on a convolution neural network (CNN) to estimate the change in blood pressure compared to the calibration.

3.3. Product Accuracy and Calculations

<table>
<tr><th colspan="3">Contents</th><th colspan="2">Measuring range and accuracy</th></tr>
<tr><td colspan="3">Pulse rate</td><td colspan="2">40bpm~240bpm(± 2bpm)
The number of pulses during the measurement period.</td></tr>
<tr><td rowspan="6">Blood Pressure</td><td rowspan="2">BP measuring range</td><td>Systolic blood pressure</td><td colspan="2">70 to 180 mmHg</td></tr>
<tr><td>Diastolic blood pressure</td><td colspan="2">40 to 120 mmHg</td></tr>
<tr><td rowspan="4">Accuracy of BP
(In case of calibration)</td><td rowspan="2">Systolic blood pressure</td><td>Mean difference</td><td>±5 mmHg</td></tr>
<tr><td>Standard deviation</td><td>8 mmHg</td></tr>
<tr><td rowspan="2">Diastolic blood pressure</td><td>Mean difference</td><td>±5 mmHg</td></tr>
<tr><td>Standard deviation</td><td>8 mmHg</td></tr>
</table>

Blood pressure readings can vary throughout the day due to weather, emotions, and exercise.

Do not change the medication method or dosage based on the measurement results of this product. Be sure to consult your doctor.

This product is not suitable for continuously measuring a patient's blood pressure during surgery or other emergency situations.

This product corrects and measures the blood pressure based on the blood pressure value of the cuffed arm. If there is a large difference in blood pressure between the arms (more than 10 mmHg), be sure to consult a specialist.

Electrodes are applied parts. Operational temperature of the device is +10°C to +40°C. If ambient temperature exceeds +41°C, Applied Parts can exceed +41°C.

4. Product configuration

4.1. CART-RING

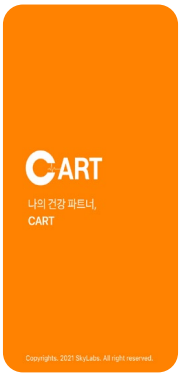
Device name	VITAL SIGNS MONITORING INSTRUMENTS
Model name	CART BP
Classification	Class IIa
Model Reference	SL-MRE1K06
	SL-MRE1K07
	SL-MRE1K08
	SL-MRE1K09
	SL-MRE1K10
	SL-MRE1K11
	SL-MRE1K12
	SL-MRE1K13

A mobile device to install the CART BP APP (mobile application) used with CART-RING is not provided by the manufacturer.

Bluetooth communication of CART-RING supports BLE 5.0 (Version) or higher. Check the Bluetooth version of the mobile device to be used in conjunction with the device.

CART-RING has 8 model references. Make sure to purchase after checking the size with the SIZING KIT provided by the manufacturer.

4.2. CART BP APP



A few more things are required to make the CART BP APP work.

- Mobile devices: ≥iPhone 7, ≥iOS 10.0, ≥Android 6.0 (& ≥BT 4.1)
- The CART BP APP is available for installation from the Apple App Store and Google Play.

The mobile device for installing the CART BP's software is not included in the components.

4.3. Accessories

1) CART-CRADLE

Model name	CART-CRADLE
Model Reference	SL-MCA1K06
	SL-MCA1K07
	SL-MCA1K08
	SL-MCA1K09
	SL-MCA1K10
	SL-MCA1K11
	SL-MCA1K12
	SL-MCA1K13

If it is not properly combined with the CART-RING, charging will not work. Please charge after checking the direction of CART-RING and CART-CRADLE.

The manufacturer does not provide a separate adapter for charging. Be sure to use an internationally certified adapter.

2) USB C-Type Cable

3) User's Manual

4.4. Sizing Kit

How to find the perfect size		
Step 1		- Video You can find the video through QR code and YouTube about "How to find the perfect size"
Step 2		- Finger Any finger except thumb and little finger.
Step 3		- Size Choose comfortable size which is too tight but not spinning.
Step 4	24 h	- Test Wear it at least 24 hours to test in avarious situations.
Step 5	6	- Confirm Confirm your size at Sizing page-www.skylabs.io
Step 6		- Delivery We will ship your CART BP right away.

The sizing kit is not included with this product. Once you have determined the size of your CART-RING, be sure to send the sizing kit back to Sky Labs Inc.

5. How to use for CART-RING

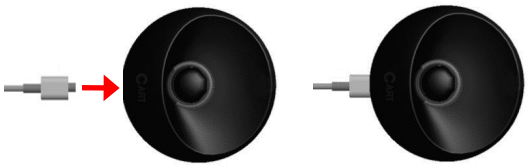
5.1. Preparation before use

1) In order to use the CART-RING safely and correctly, be sure to read this user manual before using the product.
2) CART-RING must be used in conjunction with CART BP APP (mobile application). Be sure to read the user manual of CART BP APP before use.
3) Before using the CART-RING, fully charge it using the CART-I Cradle.
4) Before wearing the CART-RING on your finger, wipe the product with a soft cloth before wearing it.

CART-RING cannot be used alone and must be used in conjunction with CART BP APP.

5.2. Charging the CART-RING

1) Connect power to the USB port of the CART-CRADLE using the USB C-Type cable.



Be sure to use a verified device that has received international certification for the charging adapter.

This product is not compatible with super-fast chargers (USB-PD) used for mobile devices or laptops. Be sure to check the type of charger before use.

Do not use a damaged cable.

Keep your child safe from CART-RING and USB cable that could choke, suffocate, or strangle.

2) Charge by fixing the CART-RING to the fixture of the CART-CRADLE.

If the LED on the CART-RING or CART-CRADLE blinks, the battery is not being charged. Check and confirm that the charging orientation is correct and charge the device.

It takes about 2 hours to fully charge the CART-RING. A fully charged Ring can be used continuously for about 48 hours.

Use an adapter with a rated voltage of 1 to 2 A. (It is best to use a mobile device charging adapter.) Otherwise, an error may occur while charging or it may take longer to fully charge the device.

The battery embedded in the CART-RING is not replaceable. The guaranteed battery life is 2 years. After 2 years of use, the battery performance becomes approximately 80%.

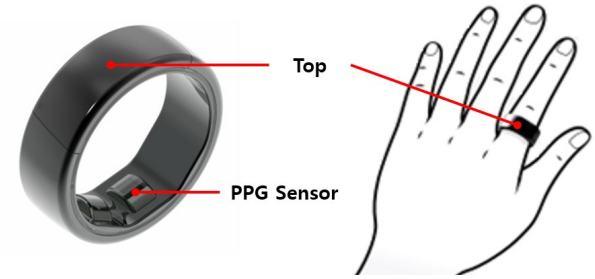
CART-RING can only be charged with CART-CRADLE. Do not use other devices to charge the CART-RING.

3) LED indicator
   - During charging, the CART-Cradle's LED lights up in red.
   - When fully charged, the LED will turn green.
   - When a charging error occurs, the LED indicator will blink red.

5.3. Wearing the CART-RING

1) Wear the CART-RING with the top placed on the back of the finger.

2) Wear the CART-RING with the sensor placed on the belly of the finger.



To choose an appropriate CART-RING size for your finger, it is recommended to use the sizing kit provided by the manufacturer. It is best to put on the Ring on a finger on the less frequently used hand, that is not the thumb or little finger. Do not wear the Ring together with other finger rings.

If you do not choose a CART-RING that fits your finger size, the accuracy of collected data cannot be guaranteed, which may result in injury or a blood-flow disorder.

If the product temperature increases during use, stop using it.

If the finger area around the CART-RING sensor turns red or skin irritation is experienced in that area, immediately remove the Ring. If the symptom persists for more than a couple of days after removing the Ring, consult a dermatologist.

3) LED indicator

- In case of malfunction, the LED of the PPG sensor of the CART-RING does not turn off and remains red.

5.4. Bluetooth (BLE) Connection

1) Connect CART-RING and Bluetooth of CART BP APP to measure.

2) For smooth communication, the distance between the CART-RING and the mobile device must be kept within 2m.

.

The maximum BLE communication distance between CART-RING and mobile device is 2m. For smooth use, keep the CART-RING close to your mobile device.

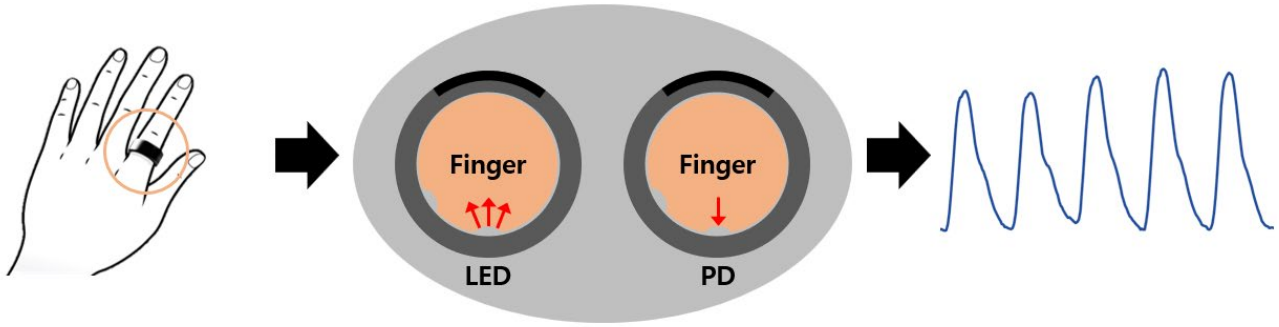
5.5. PPG Measurement

1) The PPG signal is collected using the PPG sensor of CART-RING.

2) During Self-Check, the patient collects PPG signals intermittently by manipulating the mobile application.

3) During Periodic Spot Measurement, PPG signals are automatically collected without patient intervention.

4) CART-RING collects PPG signals and can measure Pulse Rate and Blood Pressure.



PPG signals are also collected during sleep. Wear your CART-RING even when you sleep for healthcare while you sleep.

Factors affecting the accuracy are as follows. Do not use the product in the applicable environment.

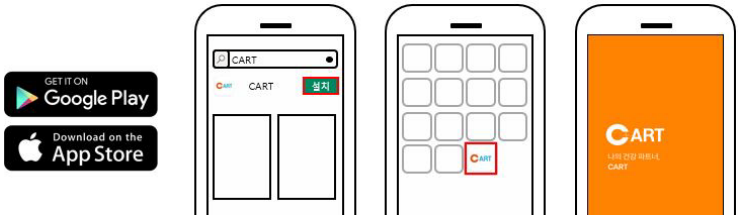
- Exposure to excessive ambient light
- Low skin perfusion (the amount of blood passing through the blood vessels is small)
- Use of blood vessel dye, such as indocyanine or methylene blue
- A permanent or temporary change to the skin, such as a tattoo
- Moving the body during measurement
- High level of difunctional hemoglobin, such as carboxy hemoglobin or methemoglobin
- High bilirubin level
- Use of the product together with a high-frequency electric device
- Connection of a blood pressure cuff or catheter to the arm on which the CART-RING is worn
- Severe hypotension, severe vasoconstriction, severe anemia, severe hypothermia, or heart attack shock
- Artery occlusion in the area where the CART-RING is put on
- Venous congestion or venous pulse

6. How to use for CART BP APP

6.1. Preparation before use

To ensure safe and correct use of the product, please read this user guide before using the product.

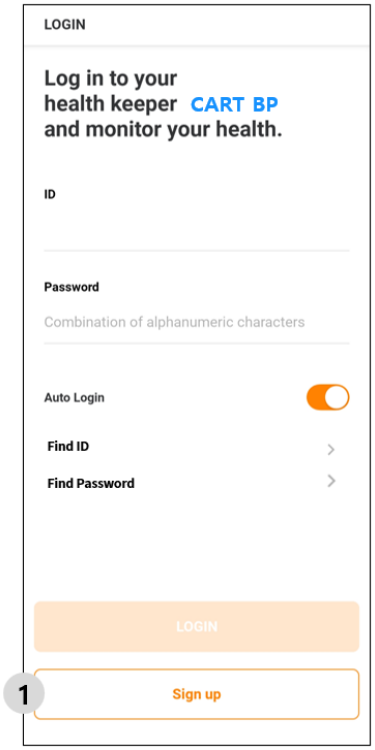
6.2. Install CART BP APP (Download the application)



1) Download the application CART BP APP from the App Store or Google Play on your mobile.
2) Tap the icon of the installed CART BP APP and proceed to login or sign up.

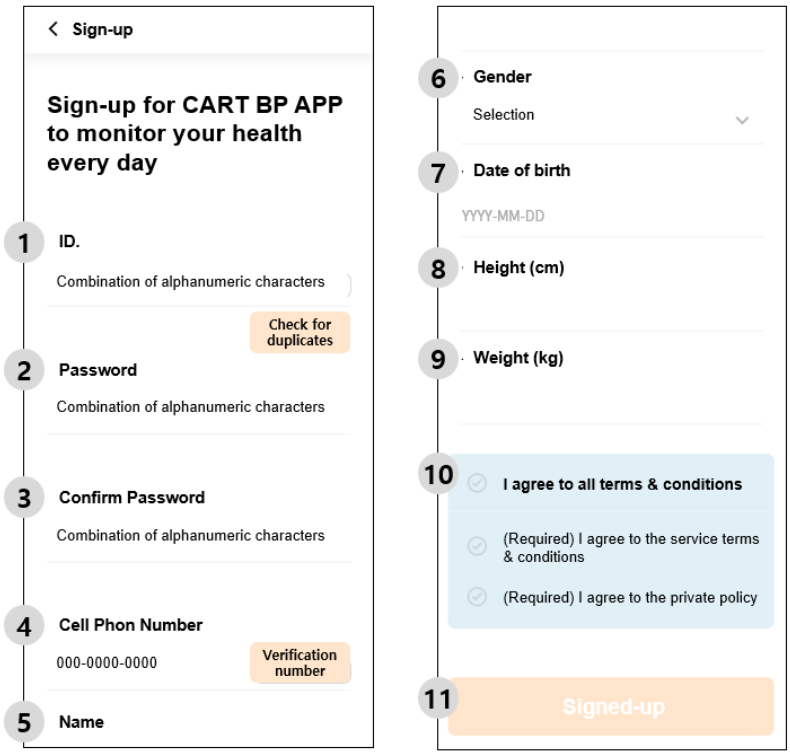
6.3. Sign up & Login

6.3.1. Sign up



No.	Name	Description.
1	Sign up	If you don't have an account, click the "Sign up" button to sign up.

6.3.2. Fill out the sign-up form



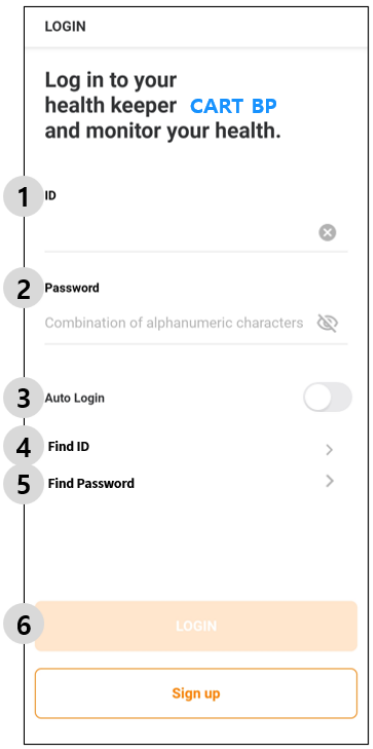
No.	Name		Description.
1	ID	ID	Tap the "ID" field, and enter your own email address to use
		Check for duplicates	Tap the "Check for duplicates" button to check for duplicate IDs
2	Password		Tap the "Password" field, and enter the password you want to use
3	Confirm password		Tap the "Confirm password" field, and re-enter the password you set
4	Cell phones Number	Cell phone number	Tap the "Mobile number" field, and enter your mobile number
		Verification number	Tap the "Get verification number" button to verify your identity using the verification number sent to your phone.
5	Name		Tap the "Name" field, and enter your name
6	Gender		Tap the "Gender" field, and select your gender
7	Date of birth		Tap the "Date of Birth" field, and select your birth date
8	Height		Tap the "Height" field and enter your height in centimeters
9	Weight		Tap the "Weight" field and enter your weight in kilograms
10	Accept Terms		Check the "Terms of Service" and "Privacy Policy" boxes in the Accept Terms layout
11	Signed up		Tap the "Sign up" button, and complete your registration

Users of this product must comply with applicable laws, including healthcare and privacy laws, in their use.

Users who have not verified their identity will not be able to sign up. Complete your identity verification with cell phone verification.

Set the password to at least 10 characters and no more than 20 characters, including "uppercase, lowercase, and numbers" for security.

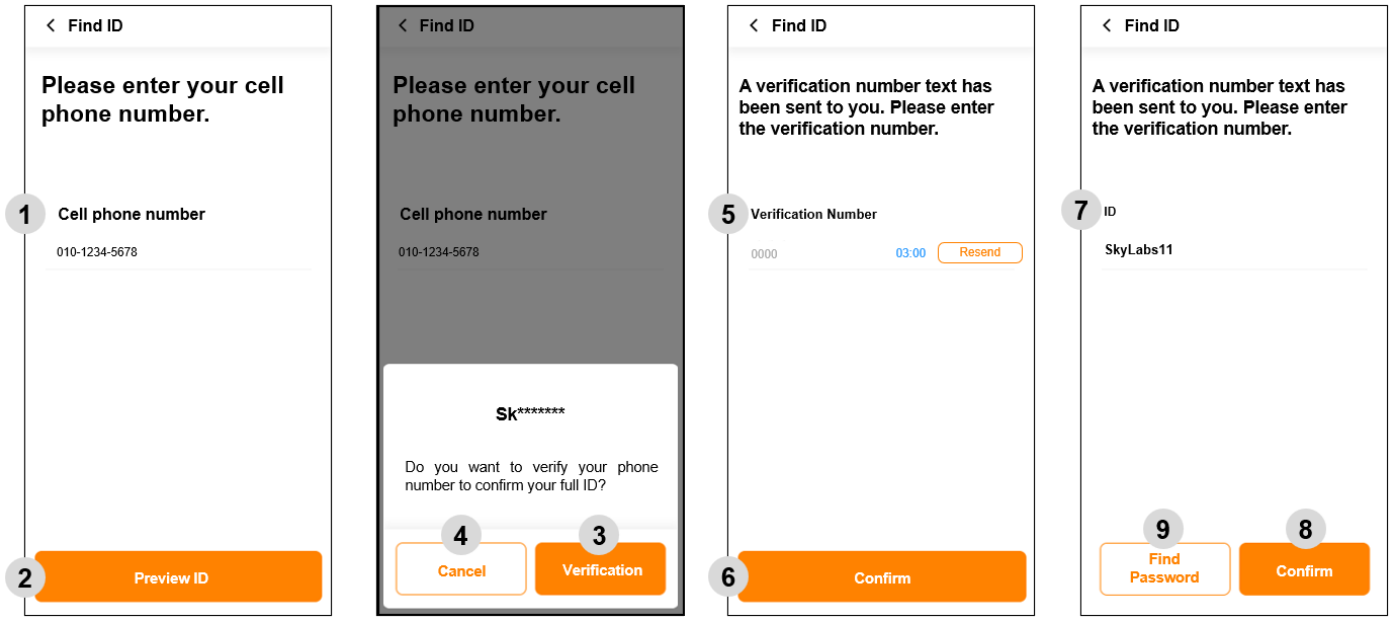
6.3.3. LOGIN



No.	Name	Description.
1	ID	Tap the "ID" field and enter the email ID of the registered user
2	Password	Tap the "Password" field, and enter the password of the subscribed user
3	Automatic login	Slide the "Auto sign in" button to the right to enable it
4	Find ID	Tap the "Find ID" button and follow the steps to check your registered ID
5	Find password	Tap the "Find password" button and follow the steps to set a new password
6	LOGIN	Tap the “LOGIN” button, and login to the application

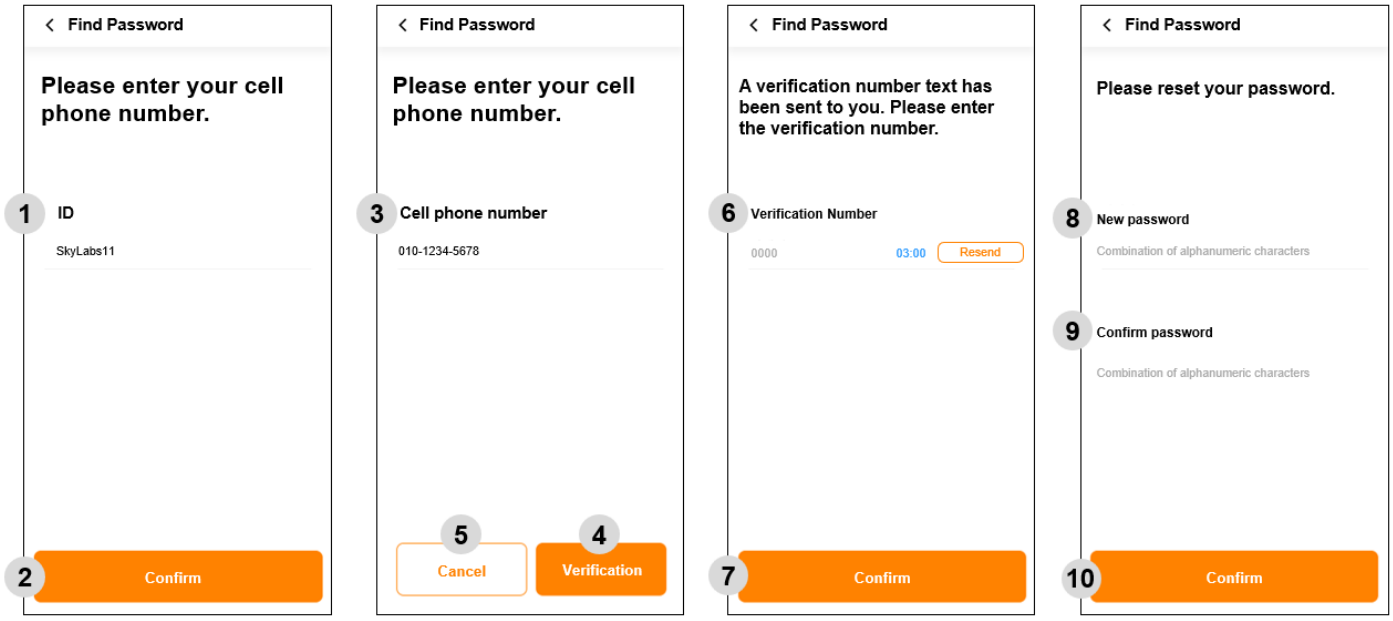
6.4. Find ID and Find Password

6.4.1. Find ID



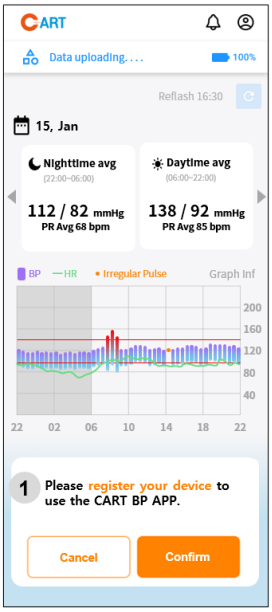
No.	Name		Description.
1	Cell phone number		Tap the "Cell phone number" field, and enter the subscribed user's cell phone number
2	Preview ID		Tap the "Preview ID" button to see some of the ID of registered users
3	Verification number		Tap the "Verification number" button to receive a verification number on your phone to verify your identity.
4	Cancel		Tap the "Cancel" button to cancel Find ID
5	Authentication	Verification number	Tap the "Verification number" field and enter the verification number sent to your phone
		Resend	If the verification number is invalid, tap the "Resend" button and receive the verification number again.
6	Confirm		Tap the "Confirm" button to complete verification
7	ID		The username of the login user appears on the screen
8	Confirm		Tap the "Confirm" button to finish finding your ID
9	Find password		Tap the "Find password" button to go to the forgot password screen

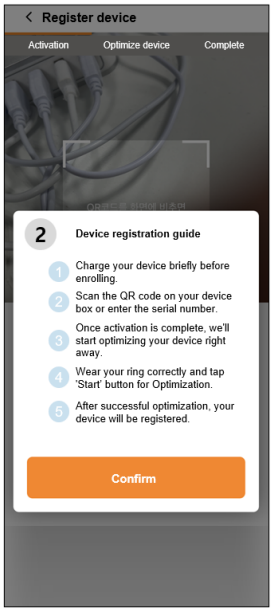
6.4.2. Find Password

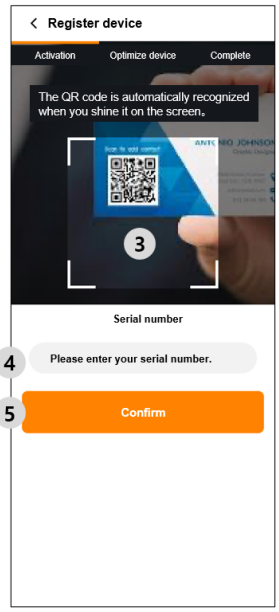


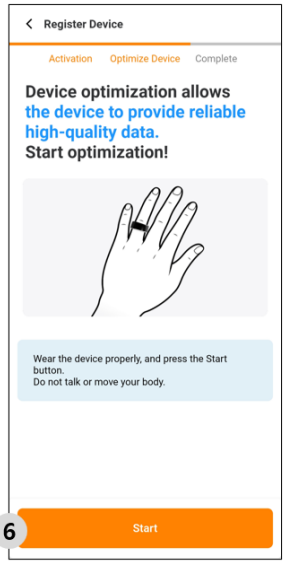
No.	Name		Description.
1	ID		Tap the "ID" field and enter the username of the registered user
2	Confirm		Tap the "Confirm" button to move to the next step
3	Cell phone number		Tap the "Mobile phone number" field, and enter the subscribed user's cell phone number
4	Verification		Tap the "Verification" button to receive a verification number on your cell phone to verify your identity.
5	Cancel		Tap the "Cancel" button to cancel Find ID
6	Authentication	Verification number	Tap the "Verification number" field and enter the verification number sent to your phone
		Resend	If the verification number is invalid, tap the "Resend" button and receive the verification number again.
7	Confirm		Tap the "Confirm" button to move to the next step
8	New password		Tap the "New password" field and enter a new password
9	Confirm password		Tap the "Confirm password" field, and enter the password you set again
10	Confirm		Tap the "Confirm" button to complete the password change

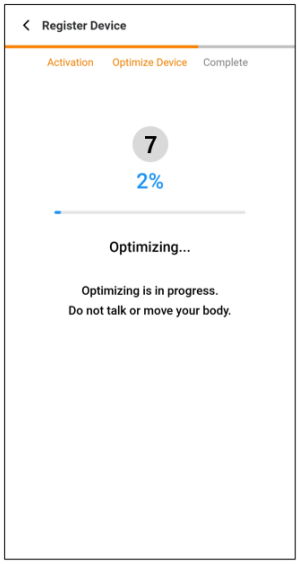
6.5. Device registration

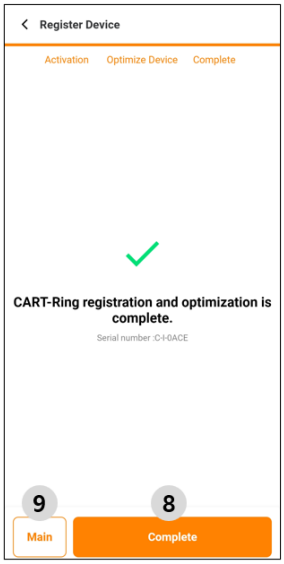






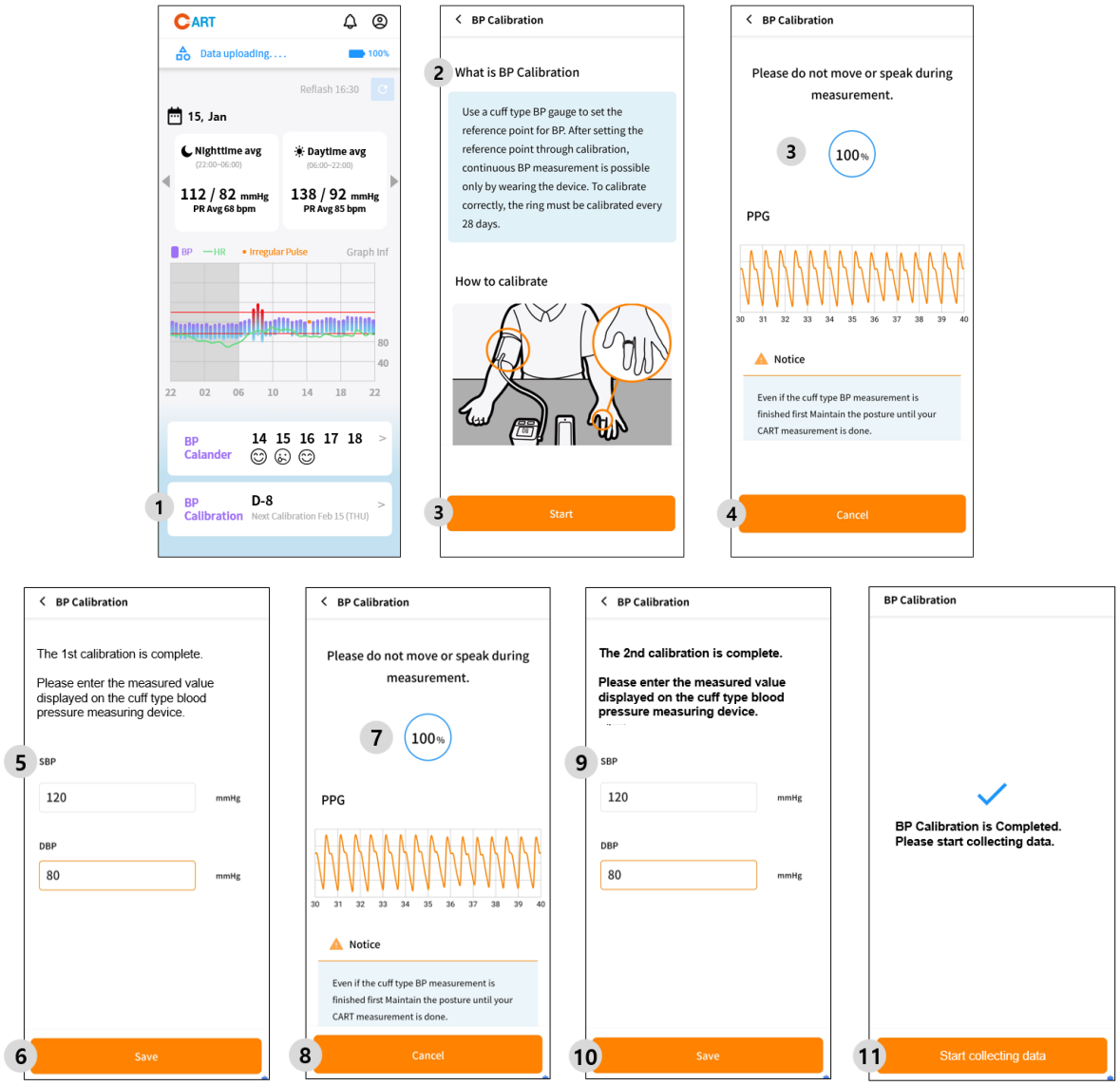






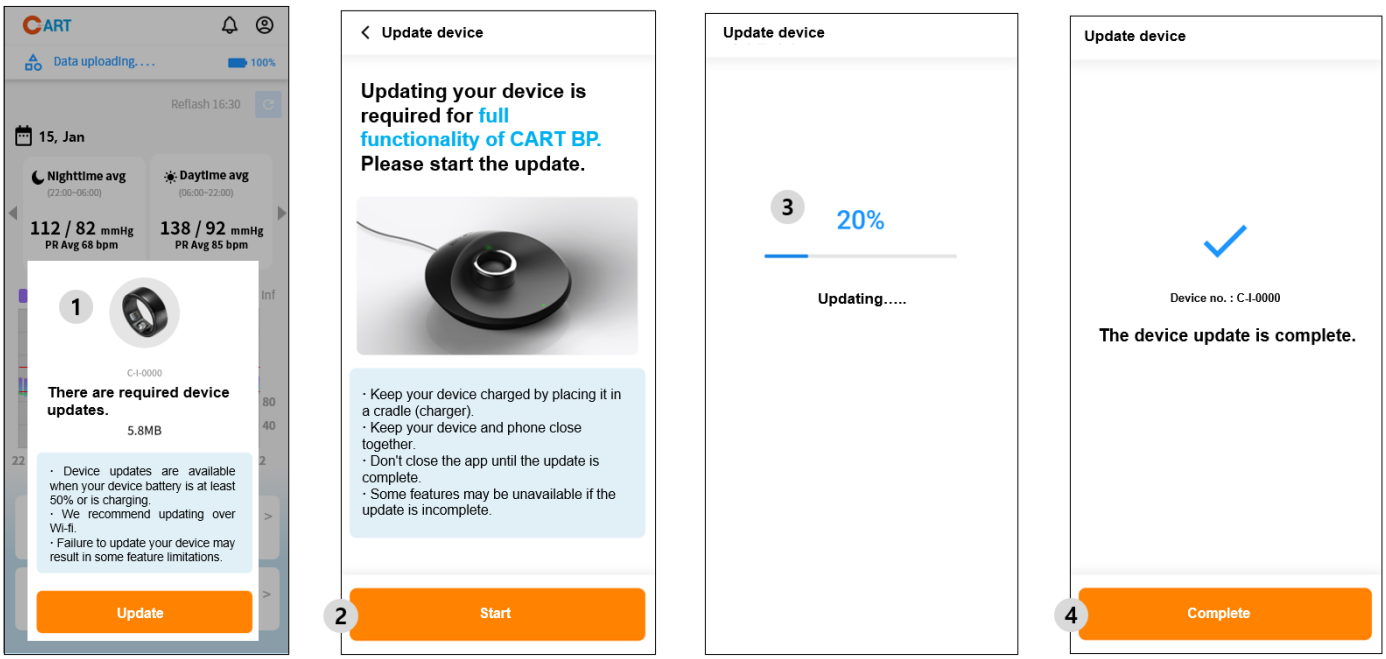
No.	Name		Description.
1	Device Activation	Confirm	Tap the "Confirm" button to move to the next step
		Cancel	Tap the "Cancel" button to unregister your device
2		Device Registration Guides	Check the device registration guide and tap the "Confirm" button to move to the next step
3		QR Code	Scan the "QR Code" to register your device
4		Serial number	Enter "serial number" to register your device
5		Confirm	Tap the "Confirm" button to move to the next step
6	Devices Optimize	Start	Tap the " Start" button to proceed with device optimization
7		Device optimization	Follow the instructions to optimize your device
8		Complete	Tap the "complete" button to complete device optimization
9		Main	Tap the "Main" button to go to the main screen after device optimization is complete

6.6. BP Calibration



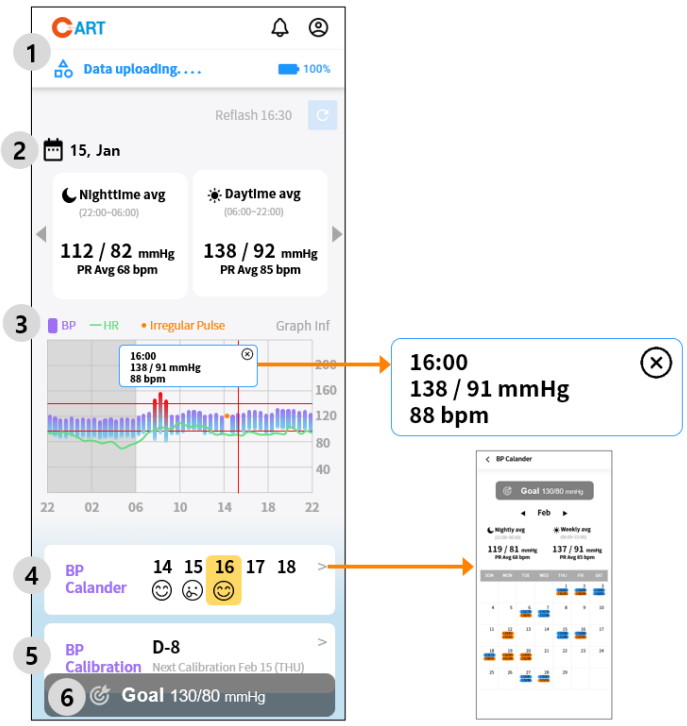
No.	Name		Description.
1	BP calibration	>	Tap the " Go " button to move to the next step
2	Blood pressure calibration guide		After reading the blood pressure calibration guide, tap the "Start" button to begin calibrating your blood pressure.
3	Primary Blood pressure calibration	Calibration screen	Check your primary blood pressure calibration progress with the Blood Pressure Calibration screen
4		Cancel	Tap the "Cancel" button to cancel blood pressure calibration
5		Enter the results	Enter the measured systolic/diastolic blood pressure values after the primary blood pressure calibration is complete.
6		Save	Tap the "Save" button to save the primary blood pressure calibration value and start the secondary calibration
7	Secondary Blood pressure calibration	Calibration screen	Check the progress of secondary blood pressure calibration with the Blood Pressure Calibration screen
8		Cancel	Tap the "Cancel" button to cancel blood pressure calibration
9		Enter the result	Enter the measured systolic/diastolic blood pressure values after the primary blood pressure calibration is complete.
10		Save	Tap the "Save" button to save the secondary blood pressure correction value
11	Started collecting data		Tap the "Start collecting data" button to collect blood pressure data

6.7. Update device



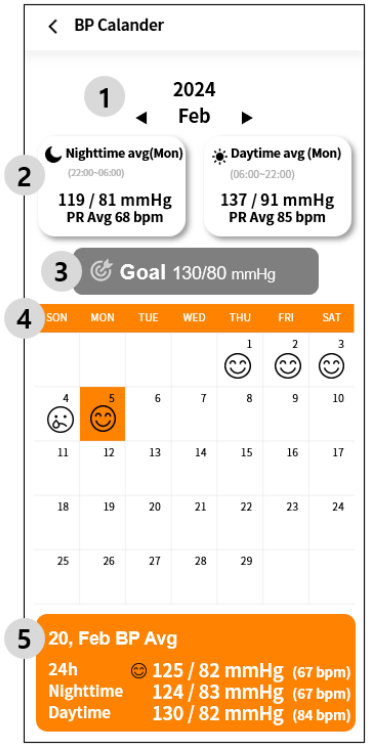
No.	Name	Description.
1	Device update popup	Tap the "Update" button and start updating your device
2	Device update guide	Check the device update guide and tap the "Start" button to proceed with the device update
3	Update device	Check progress with the Device update screen
4	Done	Tap the "Done" button and complete the device update

6.8. Main



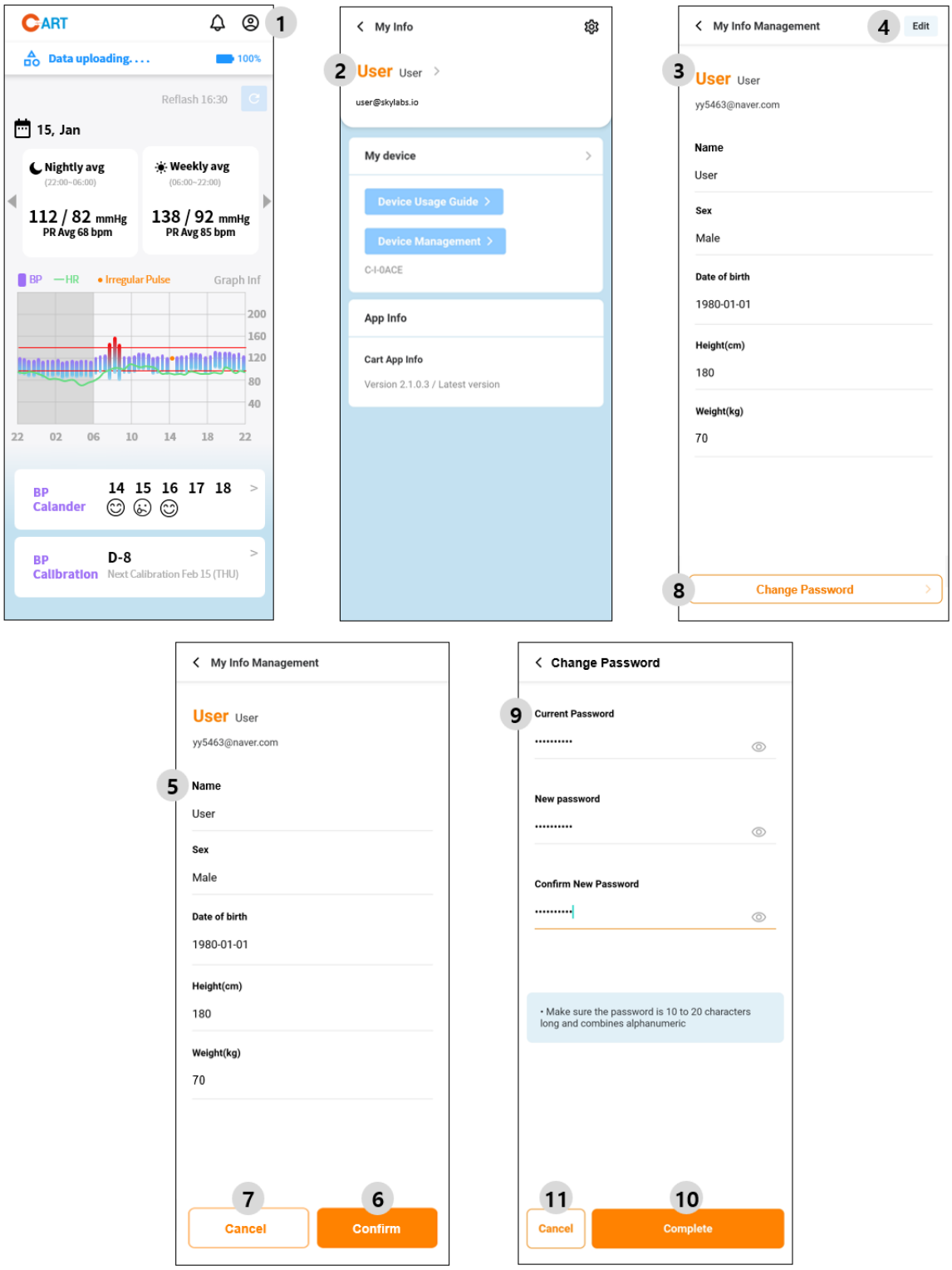
No.	Name		Description.
1			Tap the announcements icon and go to the announcements list
			Tap the My Inf icon and go to the My Inf screen
	Data uploading. . . .		Data transfer status information
	100%		Battery level display
			Tap the reflash icon and update the main screen information to the latest
2	Blood pressure by date		Tap the calendar icon and select a date
			Tap the Move button and move the date
		Nighttime average (22:00~06:00)	Show nighttime averages for selected days or time periods. (Average of systolic/diastolic blood pressure and pulse rate)
		Daytime Average (06:00~22:00)	Show daytime averages for selected days or time periods. (Average of systolic/diastolic blood pressure and pulse rate)
3	Statistical charts	BP	Chart blood pressure information for selected days or time periods
		HR	Chart pulse rate information for a selected date or time period
		Irregular Pulse	Chart irregular pulse wave information that occurred on a selected date or time period
4	Blood pressure calendar		Show if blood pressure statistics for the day are in the normal range
			Shows if the day's blood pressure statistics are outside the normal range
		>	Tap the Go button and go to the Blood Pressure Calendar screen
5	Blood pressure	Blood pressure calibration	Tap the Go button and go to the Blood Pressure Calibration screen
		>	Chart blood pressure information for selected days or time periods
6	Target blood pressure		Shows the target blood pressure set by the user

6.9. Blood Pressure Calendar



No.	Name		Description.
1	Select a date	Date	Tap Date and select the date you want to check as the year/month
		◀ ▶	Tap the Move button and move the date
2	Blood pressure by date	Nighttime average (22:00~06:00)	Show nighttime averages for the selected month (Average of systolic/diastolic blood pressure and pulse rate)
		Daytime Average (06:00~22:00)	Show daytime averages for the selected month (Average of systolic/diastolic blood pressure and pulse rate)
3	Target blood pressure		Shows the target blood pressure set by the user
4	Blood pressure calendar	☺	Blood pressure calendar shows if the day's blood pressure statistics are in the normal range
		☹	Blood pressure calendar shows if the day's blood pressure statistics are out of normal range
5	Daily blood pressure		Display blood pressure information for the selected day in the blood pressure calendar as day/night (Average of systolic/diastolic blood pressure and pulse rate)

6.10. My Information



No.	Name		Description.
1			Tap the My Inf icon and go to the My Inf screen
2	My Inf	Username	Display the names of signed-in users
		>	Tap the Go button and go to the My Inf management screen
3	User information		Show details of signed up users
4	User information	Edit	Tap the "Edit" button and edit the subscription information for your use

5	Modify	Modify	Tap each subscription and edit the user's subscription information
6		Conform	Tap the "Done" button and finish editing your membership information
7		Cancel	Tap the "Cancel" button and cancel editing your membership information
8	Change Password	Change Password	Tap the "Change password" button and edit your password
9		Current passwords	Tap the "Current password" field and enter your current password
		New password	Tap the "New password" field and enter the password you want to change
		Confirm your new password	Tap the "Confirm new password" field and re-enter the password you want to change
10		Conform	Tap the "Done" button and complete the password change
11		Cancel	Tap the "Cancel" button and cancel the password change

7. Performance Characteristics

7.1. Product Specifications

Device	Specifications		
CART-RING	Rated power		Internal power supply, lithium-polymer battery, 3.7 Vd.c.
	Radio frequency (RF)		(RX) Non-contact charging frequency: 205 kHz Frequency during operation: 2402-2480 MHz
	Ingress protection (IP) rating		IP58
	RF test temperature		-20℃ to 50℃
	Operation mode		Continuous mode
	Protection against electric shock		Internally powered equipment, BF applied part
	RF spec.		Bluetooth Low Energy (BLE), BT 5.0, distance: <2m
	PPG LED Specification	Red	660nm (IF=10mA), Optical power: Max 0.35mW
		IR	940nm (IF=10 mA), Optical power: Max 0.35mW
		Green	525nm (IF=10 mA), Optical power: Max 1.00mW
CART-CRADLE	Rated power		5 Vd.c.
	Power consumption		50 mW to 1 W
	Charging method		(TX) wireless charging / magnetic induction type / using a USB cable
	Radio frequency (RF)		(TX) non-contact charging frequency: 205 kHz (TX) operating frequency: 175.3 kHz

7.2. IT-Network

1) Privacy Policy

   Sky Labs is committed to your peace of mind—in our products and services and in how we treat your data. We comply with all laws where applicable to our handling of data, including GDPR (General Data Protection Regulation). We are committed to using your data only for the purpose of improving your health and life.

   Our privacy policy can be found at the link below.

   Privacy Policy: https://skylabs.io/privacy-policy/, https://skylabs.io/privacy-policy/cart-web/

   Terms of Service: https://skylabs.io/terms-of-service/

2) CART-RING works with mobile devices using Bluetooth 5.0 LE (Low Energy) communication.
3) CART-RING uses AES-256 encryption algorithm to safely protect user's sensitive information.
4) Firmware update of CART-RING can only be done with CART BP APP to block unauthorized access. After logging in to CART BP APP, update the firmware of CART-RING.
5) CART-RING can be used only when the authenticity of the device is verified for security. Complete device activation using CART BP APP.
6) Security Add a passcode (personal identification number [PIN]), or Touch ID (fingerprint), or Face ID recognition (if your phone supports this) to your smartphone to add a layer of security. It is important to secure your smartphone since you will be storing personal health information. Review your smartphone for information on how to add a layer of security.

7) In principle, CART-RING does not store data in the device and transmits it to CART BP APP. However, untransmitted data can be stored in the flash memory to prevent data omission in the actual use environment. Stored data is transmitted immediately when Bluetooth communication between CART-RING and CART BP APP is connected, and the storage capacity of memory is 8 M bits.

8. Operating and Storage conditions

Operating and charging temperature	5℃ to 40℃
Operating and charging humidity	10%-95%
Storage and transport temperature	-25℃ to 70℃
Storage and transport humidity	10%-95%
Operating, storage and transport atmospheric pressure	700 to 1060 hPa

When storing an opened product, do not store in extremely hot, cold, humid, wet or bright conditions.

Before using a product that has been stored for a long time, expose it to room temperature(About 20℃) for at least 1 hour before using it.

9. Disposal

This product is compliant with Directive 2012/19/ EU. Please dispose used electrical and electronic equipment (WEEE) according to national laws and regulations with electrical waste. It should not be mixed with general household waste.

10. Warranty and Limited Warranty

8.1. Manufacturer's Limited Warranty

Sky Labs warrants to you that the Product will substantially conform to its published specifications and will be free from defects in material and workmanship under normal use, for a period of one (1) year from the date of shipment or the period required by applicable consumer regulations in the country of purchase, whichever is greater.

10.2. 30-day return policy

Customers are covered by our 30-day return policy, which allows you to request a return within 30 days of receiving the item. To return an item, it must be in the same condition as when you received it, unworn or unused, and in its original packaging with tags attached. You'll also need a receipt or proof of purchase.

If you return a Product to Sky Labs in accordance with this Returns Policy, Sky Labs will refund the full purchase price and applicable taxes paid for the Product, minus shipping and handling charges, to the account used to make the original purchase. You are responsible for and must prepay all return shipping charges and assume all risk of loss or damage to the Product while in transit to Sky Labs.

To initiate a return, contact happycustomer@skylabs.io. Once your return is accepted, we'll provide you with a return shipping label and instructions on how and where to send the package. Items sent back to us without first requesting a return will not be accepted for return.

After we receive and inspect your return, we'll let you know whether or not we've authorized a refund. If your refund is approved, then you'll be automatically refunded to your original payment method. Remember that it can take some time for your bank or credit card company to process and post your refund.

If you have any questions about refunds, please feel free to contact happycustomer@skylabs.io.

10.3. Damage and Issues

Please inspect your order upon receipt and if you receive defective, damaged, or incorrect merchandise, please contact us immediately so we can assess and rectify the issue.

10.4. Exceptions/non-returnable items

This limited warranty is void if

- You have used the Product in a manner inconsistent with the intended purpose or design of the Product as described in the documentation published by Sky Labs for the Product.
- Your product has changed in any way.
- You use or maintain the Product in a manner inconsistent with Sky Labs' instructions or warnings included with the Product.
- The product has been subjected to other misuse, abuse, neglect, accident, or external forces.

10.5. Exchange

If a Product is found to be defective during the warranty period, Sky Labs will replace the Product with the same or equivalent Product you purchased. The replacement Product will be warranted for the remaining warranty period of the original Product or 30 days from the date of replacement, whichever is longer. Sky Labs reserves the right to replace discontinued Products with new Products of equivalent value and functionality.

11. Storage and maintenance

11.1. Storage

1) Keep the CART-RING, CART-CRADLE, and USB CABLE separate from each other if the product will not be used for an extended period of time.
2) Fully charge it once every three months to protect the battery if you don't use it for an extended period of time.

11.2. Maintenance

1) The product must not be repaired by any means other than the maintenance listed in this chapter.
2) It is important to keep the electrodes clean by spraying with an alcohol-based disinfectant and wiping with a soft cloth as needed.
3) External visual inspection, inspect the electrodes for warping, surface damage, or corrosion.
4) Check for other forms of corruption.

Use a clean, lint-free cloth.

Don't use abrasive cleaners or materials.

Do not immerse device in water or expose it to excessive liquid.

11.3. Cleaning and disinfection

1) If the product needs to be cleaned and disinfected, clean and disinfect the exterior of the CART-RING by rubbing it with a soft cloth moderately moistened with ethyl alcohol or isopropyl alcohol (70-90%) for at least 1 minute.
2) Carefully clean and sanitize angled areas of the CART-RING, such as around the PPG sensor cap.
3) After cleaning and disinfecting, allow to dry until completely dry before using.
4) Clean the surface of your CART-RING with a soft cloth at least once a day before use.

12. Electromagnetic Compatibility

12.1. Guidelines and manufacturer's declaration – Electromagnetic emission

This product is intended to be used in specified electromagnetic conditions, as detailed below. The user must use this product in an environment that meets the following conditions.

Emission testing	Compatibility	Electromagnetic environment – Guidelines
RF emission CISPR 11	Group 1	This product uses RF energy for its internal features only. It has very low RF emissions and does not interfere with ambient electronic equipment.
RF emission CISPR 11	Class B	This product is suitable for use in any facility, including facilities connected to a low-voltage power supply network which supplies power to household facilities or household buildings.
Harmonics emission IEC 61000-3-2	A	
Voltage fluctuation IEC 61000-3-3	Complies	

12.2. Guidelines and manufacturer's declaration – Electromagnetic susceptibility

This product is intended to be used in specified electromagnetic conditions, as detailed below. The user must use this product in an environment that meets the following conditions.

Susceptibility testing	IEC 60601 Test level	Compatibility level	Electromagnetic environment – Guidelines
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV Contact ±2kV, ±4kV, ±8kV, ±15kV air	±8kV contact ±15kV air	Make sure the floor is made of wood, concrete or ceramic tiles. If the floor is made of composite material, make sure the relative humidity is at least 30%.
Electrical fast transient/burst IEC61000-4-4	±2kV 100kHz repetition frequency	±2kV 100kHz repetition frequency	The main power's quality must be similar to a typical commercial or hospital environment.
Surge Line-to-line IEC 61000-4-5	±0.5kV, ±1kV	±1kV	The main power's quality must be similar to a typical commercial or hospital environment.
Surge Line-to-ground IEC 61000-4-5	±0.5kV, ±1kV, ±2kV	±2kV	
Voltage dips IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	The main power's quality must be similar to a typical commercial or hospital environment. If the product should be used continuously even during a power failure, it is recommended to use an uninterrupted power supply, such as a battery.
Voltage interruptions IEC 61000-4-11	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	
Magnetic field IEC 61000-4-8	30A/m	30A/m	The power-frequency magnetic field must have the general position level characteristics of the typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3V 0.15 MHz – 80MHz 6V in ISM bands between 0.15 MHz and 80MHz 80% AM at 1kHz	3V 0.15 MHz – 80MHz 6V in ISM bands Between 0.15 MHz and 80MHz 80%AM at 1 kHz	Portable or mobile RF communication equipment, including relevant cables, must not be used at a distance less than the recommended separation distance, calculated using the transmitter frequency equation, from any part of the product. $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m 80MHz – 2.7GHz 80% AM at 1kHz	3V/m 80MHz – 2.7GHz 80%AM at 1kHz	$d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.7 GHz

			where P is the transmitter's maximum power rating (W), which depends on the transmitter manufacturer, and d is the recommended separation distance (M). The fixed RF transmitter's field strength, decided from a survey by the relevant electromagnetic compatibility website, must be smaller than the compatibility level for each frequency range. Interference may occur in areas around equipment that is marked with the following symbol:

13. Troubleshooting

Error	Cause	Measures to take
CART-RING does not work.	Product non-operation due to shipping mode	The product is shipped in shipping mode. Please charge using CART-CRADLE. When charging starts, shipping mode is released. If the problem is not resolved, contact the manufacturer.
The PPG sensor LED on the CART-RING does not turn off and remains red.	Device defect of CART-RING	Please recharge after leaving the CART-RING for 3 days. If the problem is not resolved, contact the manufacturer.
The LED indicator of the CART-CRADLE blinks in red.	Poor charging of CART-RING	Fixing the CART-RING to the CART-CRADLE correctly as in Section 5.2. If the problem is not resolved, contact the manufacturer.
Authentication of CART-RING does not work.	The product is not genuine from the manufacturer	If you have purchased a counterfeit product, immediately contact the place of purchase or the manufacturer.
Bluetooth connection between CART-RING and CART BP APP is not possible.	When the Bluetooth communication distance between devices is more than 2m	Keep the distance between the CART-RING and the mobile device within 2m. If the problem is not resolved, contact the manufacturer.
CART-RING's firmware cannot be updated.		

- If any of the problems above occurs persistently, please contact Sky Labs Inc. for assistance.
- Main phone number: 1599-3402
- Customer Service Center service hours: 09:00-18:00 (lunch break: 12:00-13:00)
- Website: www.skylabs.io