HeartBeam AIMIGo Patient User Manual

Document Revision 6

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Warnings/Cautions/Definitions

The terms **WARNING, CAUTION**, and **NOTE** are used throughout this manual to point out hazards, and to designate a degree or level of seriousness. Familiarize yourself with their definitions and significance.

⚠ **WARNING:** *indicates a potential hazard or unsafe practice which, if not avoided, could result in death or serious injury.*

CAUTION: *indicates a potential hazard or unsafe practice which, if not avoided, could result in minor personal injury or product/property damage.*

NOTE: *provides application tips or other useful information to assure that you get the most from your equipment.*

Additional safety messages that provide appropriate safe operation information may be found throughout this manual.

Warnings

⚠ **WARNING:** For medical emergencies, call 911 or seek emergency medical care. Do NOT rely on the HeartBeam AIMIGo System to alert or notify medical service personnel of an emergency.

⚠ **WARNING:** No medical action should be taken based on the device output without consultation of a qualified healthcare professional.

⚠ **WARNING:** The device is available only by prescription.

⚠ **WARNING:** The device should not be shared with anyone besides the prescribed patient.

⚠ **WARNING:** The device has not been tested for and is not intended for pediatric use.

⚠ **WARNING:** MR-Unsafe: The HeartBeam AIMIGo system is MR Unsafe. Do not use in a MR environment. The device may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnet core.

⚠ **WARNING:** The device is not intended for users who have implanted devices such as a pacemaker or defibrillator. This device has not been tested for use with cardiac implanted devices (e.g., pacemakers, defibrillators).

⚠ **WARNING:** Contains ECG sensors, which can damage skin if used improperly. Apply sensors to intact, clean skin only. Do not apply over an open wound, lesion, infected or inflamed skin.

Cautions

- This device may experience temporary signal disturbance or Bluetooth connection issues when exposed to electromagnetic interference. To ensure accurate recordings do not use nearby**:**
    - MRI Machines
    - Diathermy and electrocautery machines
    - Security systems (electromagnetic anti-theft systems (EAS) and metal detectors)
    - RFID security gates (store entrances, libraries); RFID tags (including Access control systems)
    - NFC-enabled devices (including smartphones, electronic payment terminals and card readers)
    - Wireless-power-transfer (WPT), (including wireless charging pads and stations)
    - 5G wireless devices
- Use of this equipment may disrupt the operation of nearby equipment or may cause radio interference. Mitigation measures, such as re-orienting the device or shielding the location may be necessary.
- The device should not be used near diathermy, and electrocautery machines. Additionally, avoid use near security systems (e.g., electromagnetic anti-theft systems (EAS), and metal detectors).

- The device Bluetooth communication may be susceptible to electromagnetic interference from Wireless-power-transfer (WPT) and 5G wireless signals. If a device communication malfunction is observed, move away from potential interference sources, or move to a different environment.
- Filters applied may impact the ECG signal morphology, including significant attenuation of low-level atrial activity (P-waves / Flutter-waves), which may result in inability to discriminate certain types of arrhythmias (e.g., Atrial Fibrillation/Atrial Flutter).
- The ECG report produced by HeartBeam AIMIGo is not intended for analysis of the T-wave or other morphological ECG evaluation.
- The device is not intended for patients with tremors and/or those unable to place and maintain the device in the correct position for the duration of the recording.
- Poor contact of the ECG sensors on the HeartBeam AIMIGo Device with the chest can negatively affect the monitoring performance. Ensure that device is held firmly against the chest to improve skin contact.
- Ensure proper back and posture support is used while taking any ECG recordings with the AIMIGo Device.
- The HeartBeam AIMIGo Device should only be used and charged when the device is clean and dry. Do not use the device when wet, and particularly when the contacts of the sensors are wet. The sensors should be dried by gently wiping them with a dry cloth.
- Use only as directed. Tampering with the HeartBeam AIMIGo Device may render it unusable and will void any warranty.
- Only use the supplied wall adapter, cable, and charging dock to charge the AIMIGo Device. See Technical Information section of this manual for wall adapter specifications.
- Use of accessories or cables other than those specified or supplied by the equipment manufacturer could result in increased electromagnetic emissions or decreased electromagnetic immunity and could result in improper operation.
- Conductive parts of electrodes and associated connectors, including neutral electrode, should not contact other conductive parts including earth.

See Technical Information section for specific standards testing and conformity of the AIMIGo Device.

Introduction

HeartBeam AIMIGo System Indications for Use

The HeartBeam AIMIGo™ System is a portable, non-invasive recorder intended to record, store, and transfer a patient's 3-Lead (in three-directions) electrocardiogram (ECG) acquired from 5 electrodes. The device is intended to be used by adult patients in either a clinical setting or at home. The device does not conduct cardiac analysis and can be used with an ECG Viewer software system for manual interpretation of non-life-threatening arrhythmias by a physician or healthcare professional.

HeartBeam 12-Lead ECG Synthesis Software Indications for Use

The HeartBeam 12-L ECG Synthesis Software synthesizes a 12-L ECG from the HeartBeam AIMIGo 3-Leads (in three-directions) recording device, producing a visual 12-L ECG representation that is similar, but not identical, to the same leads of a standard diagnostic 12-L ECG.

The synthesized 12-L ECG output is solely intended for manual assessment of normal sinus rhythm and the following non-life-threatening arrhythmias: sinus arrhythmia, sinus tachycardia, sinus bradycardia, atrial premature complexes, atrial fibrillation, and ventricular premature complex. The synthesized 12-L ECG output is not intended for the assessment of any other arrhythmia or conditions (including but not limited to: other atrial arrhythmias, ventricular arrhythmias, hypertrophy, conduction disorders, myocardial infarction or ischemia, pacemaker functions, localization of arrhythmia foci, ECG wave abnormalities, and/or any other disorder). The software does not conduct cardiac analysis and is not intended to replace a standard 12-L ECG. The 12-L ECG Synthesis Software is intended for adult use only.

General Description of the AIMIGo Device

When a patient initiates a recording session on their mobile device, they are instructed to place the HeartBeam AIMIGo Device against their chest over the heart. The Patient App on the mobile device interacts with the AIMIGo Device (via Bluetooth) to begin the recording, capture the ECG signal, end the recording, and then send the recording to the Clinician Portal for analysis by a Healthcare Professional.

Using the HeartBeam AIMIGo Device the patient will be able to:

- Complete patient onboarding upon initial use of the system, including taking three (3) ECG recordings (see Patient Onboarding).
- Take ECG recordings on-demand at home or in a clinical setting to be sent to clinician for review and analysis (See Recording ECGs at Home).
- Record and log general symptoms associated with a recording session (See *Home Recording Step 2b: Choose Routine or Symptomatic Recording*).

By reading and reviewing these instructions for use, the user will be properly trained to use the HeartBeam AIMIGo System.

System Usage Requirements & Information

Mobile Phone

The system requires that the patient have a modern mobile device, either an Android Phone or an iPhone. Contact HeartBeam for full list of compatible devices and operating systems. The mobile device must support Bluetooth 5.0 and have data connectivity (either by cellular connection, Wi-Fi, or both).

HeartBeam AIMIGo Patient Application

During onboarding, the clinician will prescribe and register the patient within the HeartBeam Clinician Portal. During this process a QR code will be generated on the screen and may be scanned to easily access and download the HeartBeam AIMIGo Patient App from the App Store or Google Play Store. The app can also be found by searching in the App Store (for iOS devices) or Google Play Store (for Android devices) for "**MyHeartBeam**".

NOTE: Updates to the application may be made available from HeartBeam from time to time. The latest application will be available for download from the respective App Store. The HeartBeam App will notify the patient when a new version is available, at which time, they should proceed to download and install to ensure the optimal performance of the system.

HeartBeam AIMIGo Device Software ("Firmware")

The AIMIGo Device software is installed during manufacturing. If there are updates to the device software, they will be managed by the Patient App. The Patient App will automatically check the device software each time the device is connected to ensure the latest available version is installed. If an update is required, the Patient App will attempt to update the AIMIGo Device and notify the user once complete.

AIMIGo Bluetooth Connection

The HeartBeam AIMIGo Device connects to the patient's mobile device using Bluetooth wireless communication. Keep the AIMIGo within arm's length, approximately 2-3 feet, of the mobile device when connecting (e.g. during recording sessions).

The AIMIGo Device Bluetooth operates on the 2.4Ghz RF spectrum (see Technical Information section for more information). The communication method via Bluetooth LE 5.0 between the mobile device and HeartBeam AIMIGo Device is fully encrypted using AES 128.

NOTE: The Patient App indicates connection status of the AIMIGo Device during use, see AIMIGo Patient Application – Home Screen.

AIMIGo System USB Connection(s)

The AIMIGo Device does not have any USB ports. The Charging Dock has a USB-C port which is only used to supply power from the wall power adapter. No data is transferred between the AIMIGo Device and the Charging Dock.

The USB-C port on the Charging Dock does not have access to data on the AIMIGo Device. These ports are discussed in this manual in the context of their intended uses for charging the respective components. There are no cybersecurity risks associated with these ports that would compromise the functionality or security of the AIMIGo Device or its acquired signals.

Mobile Device Data (Cellular, Wi-Fi) Connection

Use of this system requires that the patient's mobile device have internet ("data") access. The mobile device must be connected to an active cellular connection or to a Wi-Fi network with internet access. The wireless data transmission between the mobile device and patient mobile application, and HeartBeam cloud-based services are fully encrypted using TLS 1.2.

NOTE: The system is designed to be used with minimum data bandwidth of 2Mbps download speeds and 2Mbps upload speeds. Use of the system with a data connection that does not meet these recommendations may result in data upload failure. The mobile application will notify the patient if an ECG recording fails to upload due to a poor connection (see Troubleshooting for more details) and will store the recording until a data connection is re-established. The data connection speeds may be tested using commercially available applications or websites by searching for "Internet Speed Test". Contact your mobile device manufacturer and/or your internet provider for additional support if you encounter data connectivity issues.

AIMIGo Battery

The AIMIGo Device is equipped with a rechargeable (non-replaceable) battery for power. When not being charged, the device will automatically enter a low-power "standby" mode. A fully charged device is expected to allow for up to 30 days of standby time with daily recordings. The device should be charged between uses when the charge level becomes low or should be kept in the charging dock between uses for convenience (see Charging the AIMIGo Device section for further instructions).

Security Requirements

Following cybersecurity best practices is strongly recommended. Including:

- Using strong passwords; create unique, strong passwords for all your accounts
- Implement user authentication such as biometric ID
- Regularly update your phone operating system as recommended by the manufacturer
- Only connect to trusted Wi-Fi networks that provide a stable data connection
- Beware of Phishing Scams
- Be mindful of granting permissions or installing unknown applications

CAUTION: If you suspect that your Mobile Device is compromised or encounter any suspicious activity while using the system, promptly discontinue use and inform the HeartBeam support team.

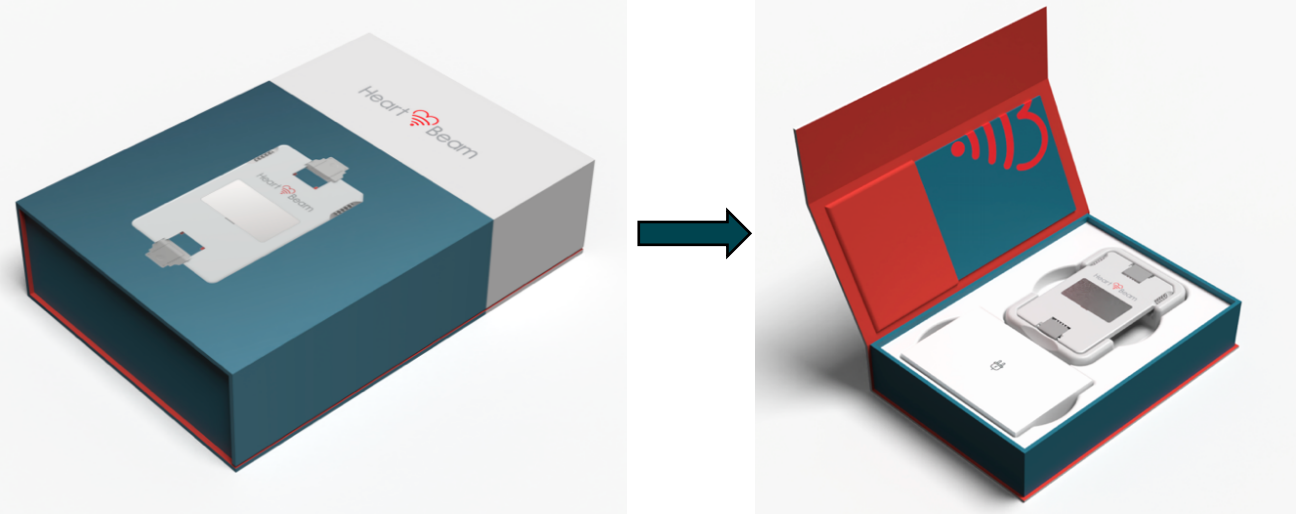
NOTE: In the event HeartBeam has detected cybersecurity threat within the HeartBeam Device, App, and/or Server, users will be informed via e-mail address (and/or phone number) on file during registration. HeartBeam will provide details about the detected threat, steps taken to mitigate the threat, and additional actions required from the user (if applicable). Detailed remedial instructions will be provided in the event of a cybersecurity incident.

Getting to Know Your AIMIGo System

HeartBeam AIMIGo System Box & Contents

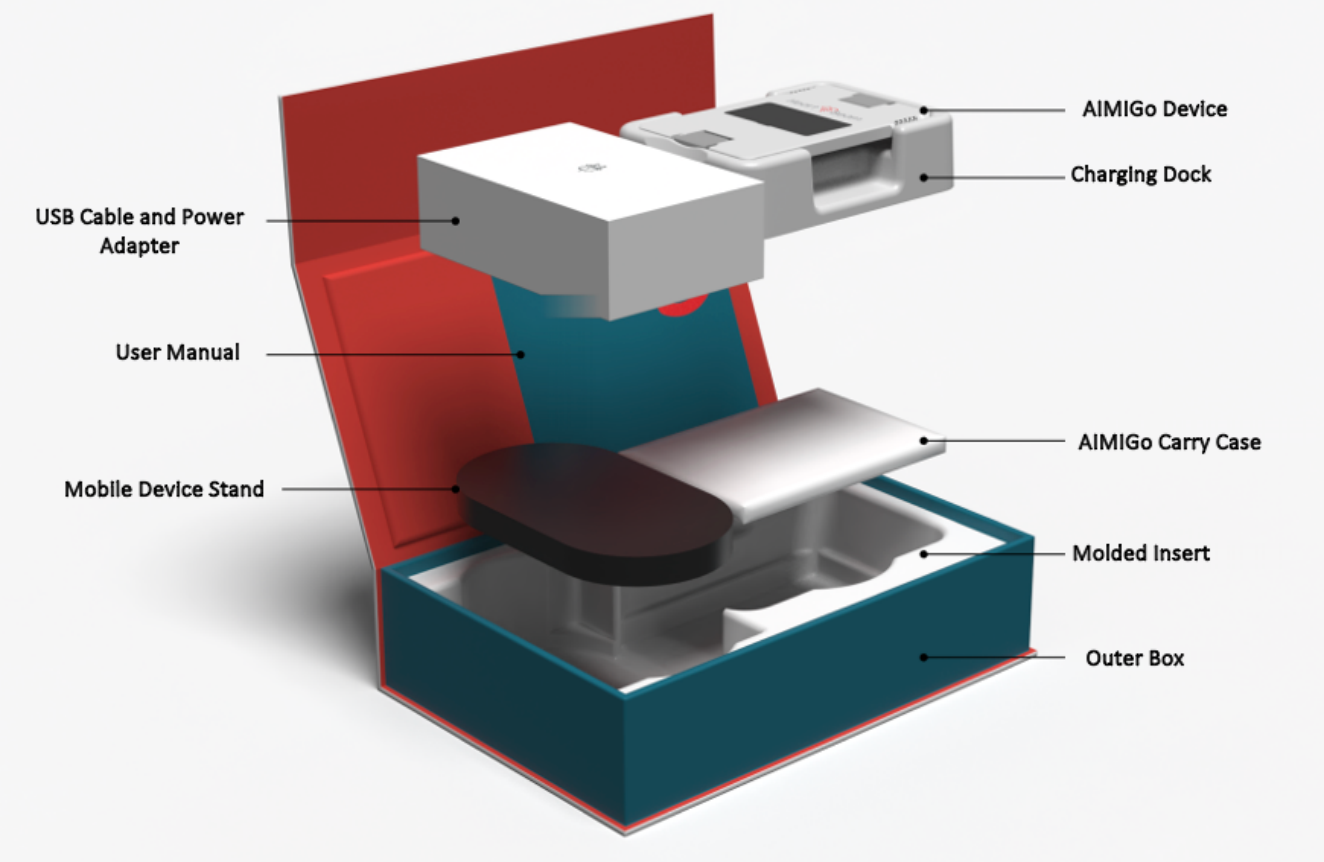
Opening the Box

To open the AIMIGo packaging begin by lifting from the side panel. The top cover will hinge open as seen below.

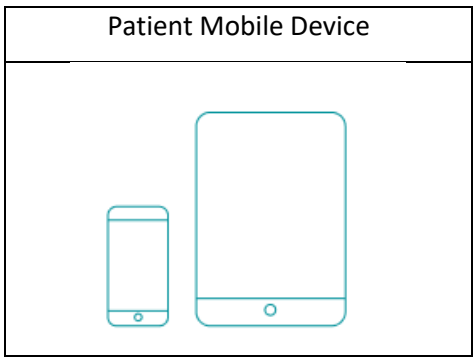


Box Contents

- AIMIGo Device
- Charging Dock
- USB Cable and Power Adapter
- User Manual
- Mobile Device (Phone) Stand
- AIMIGo Carry Case



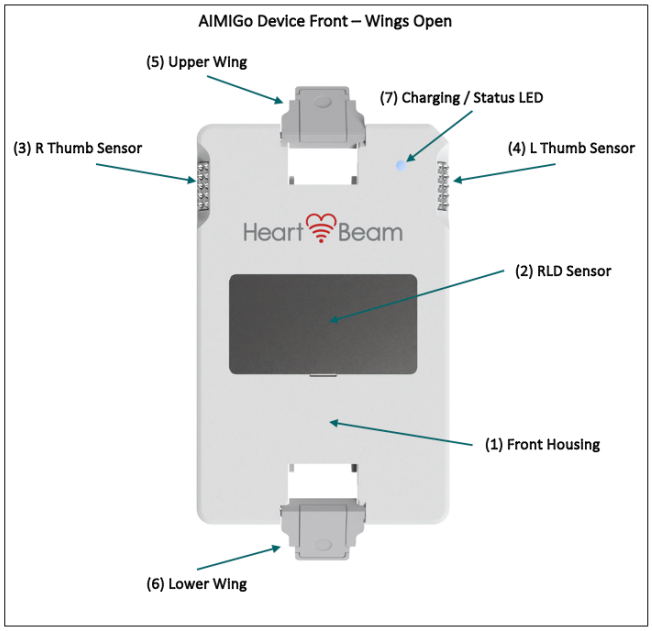
Not included: To use your AIMIGo Device you will need a compatible Android Phone or iPhone (“mobile device”) and to download the HeartBeam AIMIGo Application from the Google Play Store, or Apple App Store, respectively. See System Usage Requirements for phone compatibility information.

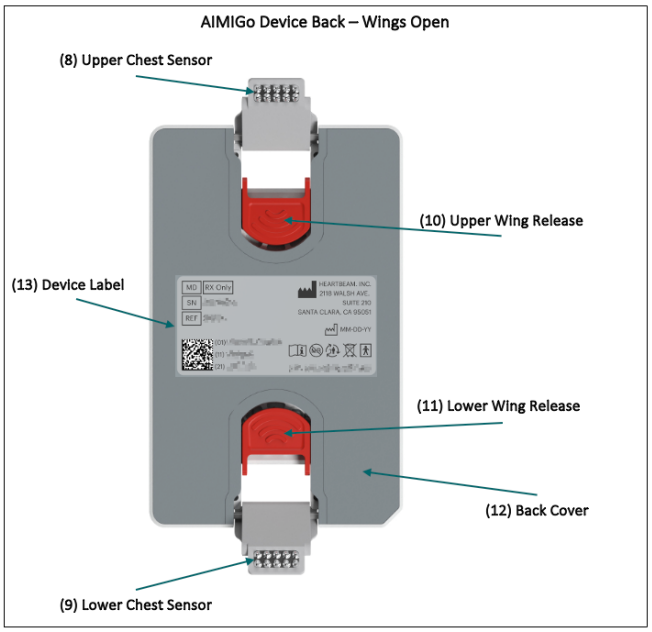


HeartBeam AIMIGo Information & Features

AIMIGo Device Parts Description

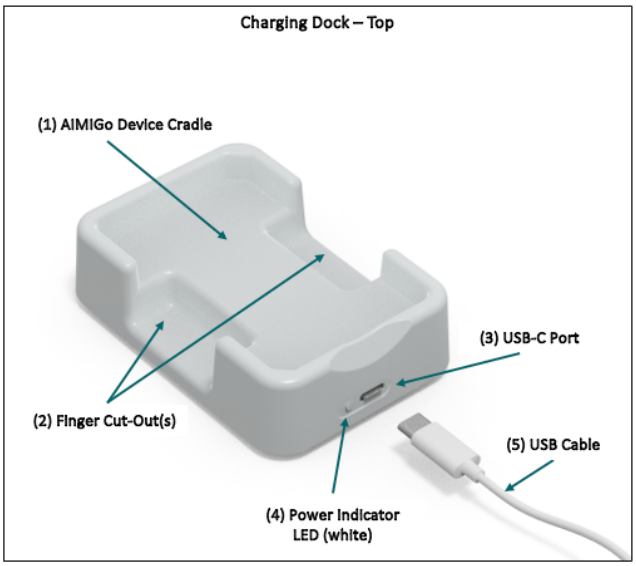
AIMIGo Parts		
Part #	**Part Name**	**Description**
1	Device Front Housing	*White Housing – faces out during recording*
2	Front Electrode / RLD (“Sensor”)	*Front Facing Sensor, rest/gently press fingertips during recording*
3	R Thumb Electrode (“Sensor”)	*Patient Right Thumb Sensor*
4	L Thumb Electrode (“Sensor”)	*Patient Left Thumb Sensor*
5	Upper / Top Wing	*Upper Wing – towards patient head during recording*
6	Lower / Bottom Wing	*Lower Wing – towards patient feet during recording*
7	Charging / Status LED	*LED illuminates Blue during charging, Green during connection to the mobile device, Yellow during connection to mobile device when battery is low and charging is recommended*
8	Upper / Top Chest Electrode (“Sensor”)	*Upper Chest Sensor – towards patient head during recording*
9	Lower / Bottom Chest Electrode (“Sensor”)	*Lower Chest Sensor – towards patient feet during recording*
10	Upper Wing Release	*Red latch used to release Upper Wing*
11	Lower Wing Release	*Red latch used to release Lower Wing*
12	Back Cover	*Gray Cover – faces chest during recording*
13	Device Label	*Device REF, SN, Manufacturing Info, etc.*

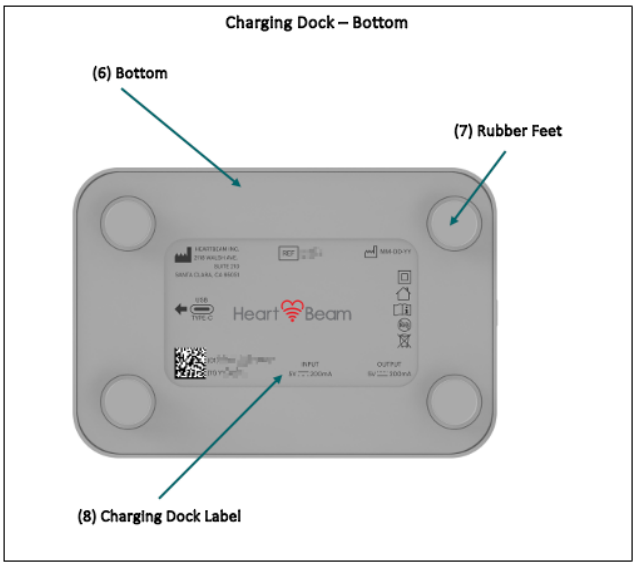


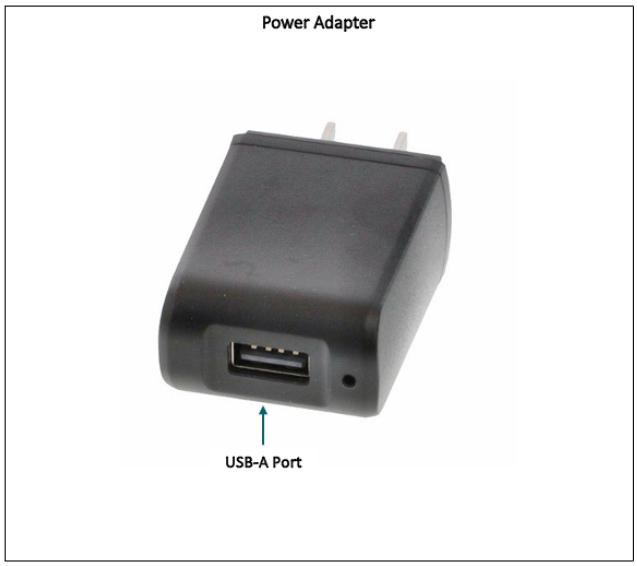


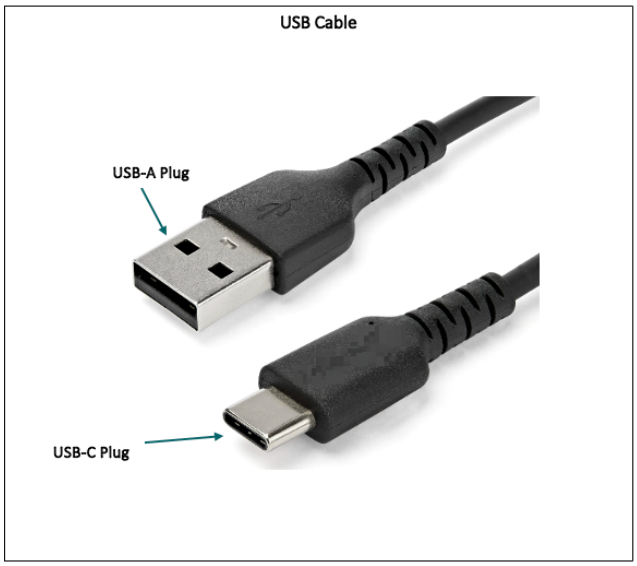
AIMIGo Charging Dock Parts Description

AIMIGo Charging Dock Parts		
Part #	**Part Name**	**Description**
1	AIMIGo Device Cradle	*AIMIGo should be set here to charge*
2	Finger Cut-Out(s)	*Access to remove the AIMIGo from the Charging Dock*
3	USB-C Port	*Plug the USB-C cable here for power*
4	Power Indicator LED	*Illuminates when connected to power*
5	USB Cable	*Plug USB-C end into Charging Dock*
6	Bottom	*Bottom of device, facing down when in-use*
7	Rubber Feet	*Feet should be placed down on a hard surface*
8	Charging Dock Label	*Device REF, SN, Manufacturing Info, etc.*
9	Power Adapter – USB-A Port	*Insert USB-A Plug here*
10	Wall Prongs	*Insert into Wall Outlet*
11	USB Cable – USB-A Plug	*Insert into Power Adapter*
12	USB Cable – USB-C Plug	*Insert into Charging Dock*





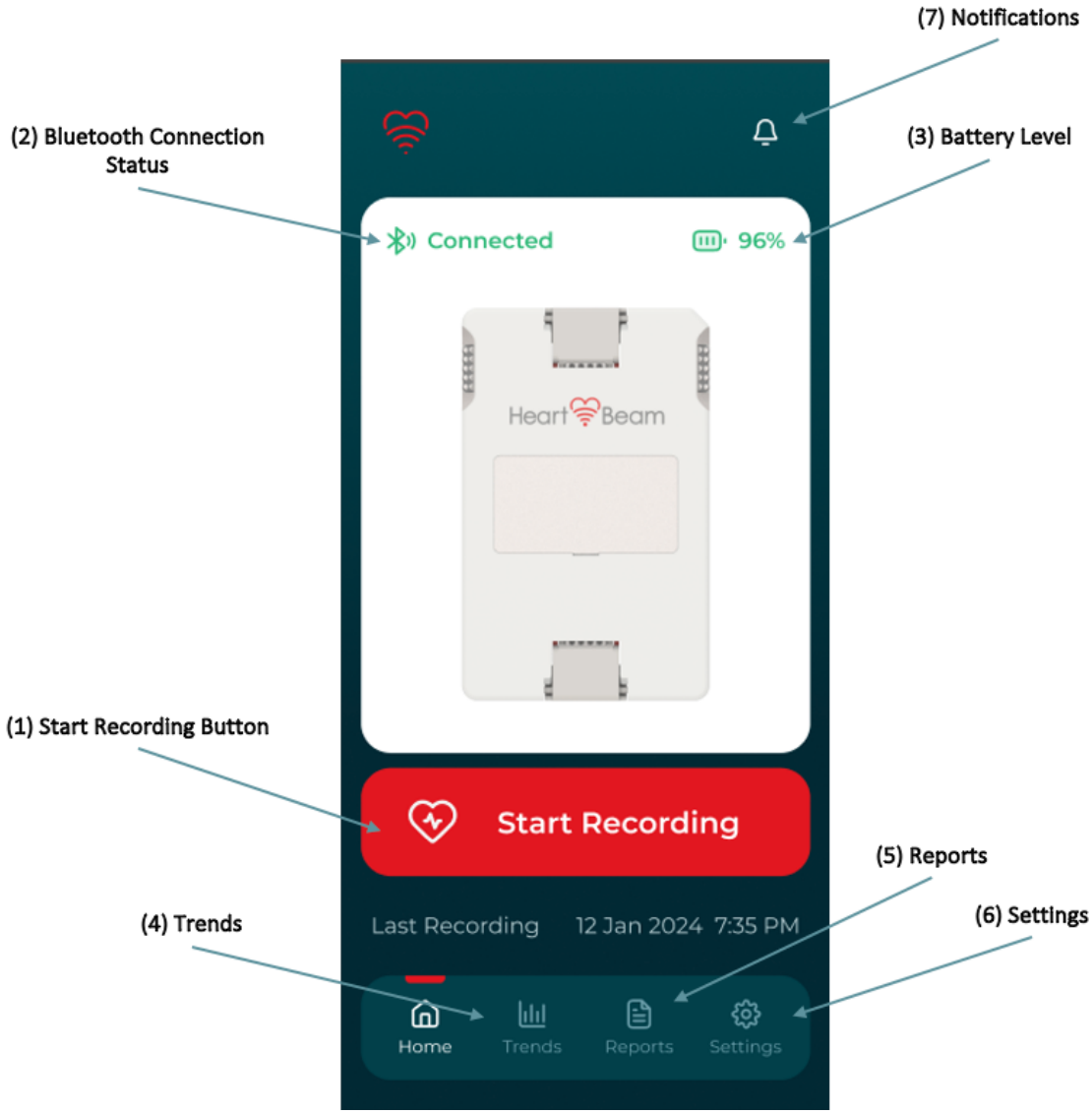




NOTE: The Power Adapter and USB Cable included with your AIMIGo Device may be black or white.

AIMIGo Patient Application – Home Screen

Patient Application Features		
Part #	**Part Name**	**Description**
1	Start Recording Button	*Tap to begin a Routine or Symptomatic Recording*
2	AIMIGo Device Bluetooth Connection Status	*Shows if the device is Connected or Not connected*
3	AIMIGo Device Battery Level	*Displays Battery Level as a Percentage*
4	Trends	*Open to View Trends, such as Recording History*
5	Reports	*Open to Access ECG Reports to share with your Clinician*
6	Settings	*Access Settings, such as device info, FAQ, profile information*
7	Notifications	*Access Notifications from your care team or app information*

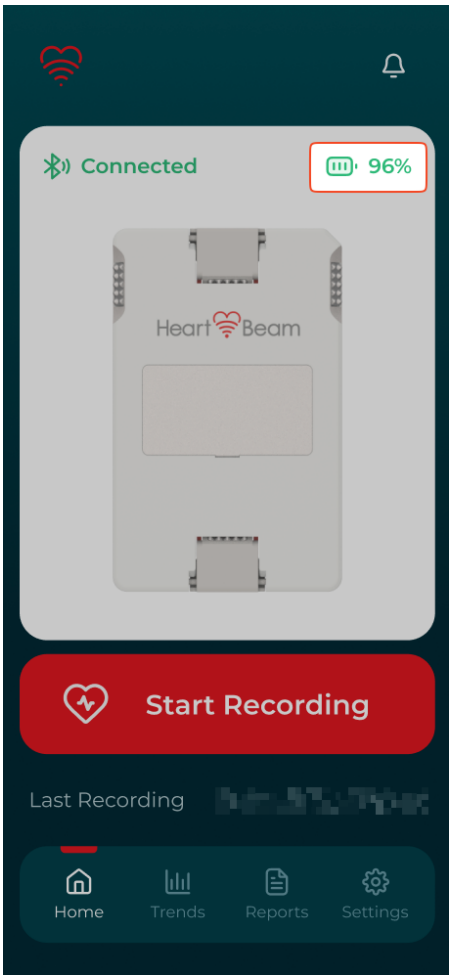


HeartBeam AIMIGo Device – Charging Process

The AIMIGo Charging Dock conveniently uses wireless power transfer (WPT) technology to charge the AIMIGo Device while placed into the dock cradle. There are no connectors or fasteners needed to charge the device.

Monitoring Battery Level

The battery level on the device is monitored through the AIMIGo Patient App. When the device is connected, the battery level is displayed in the top right corner as shown below.



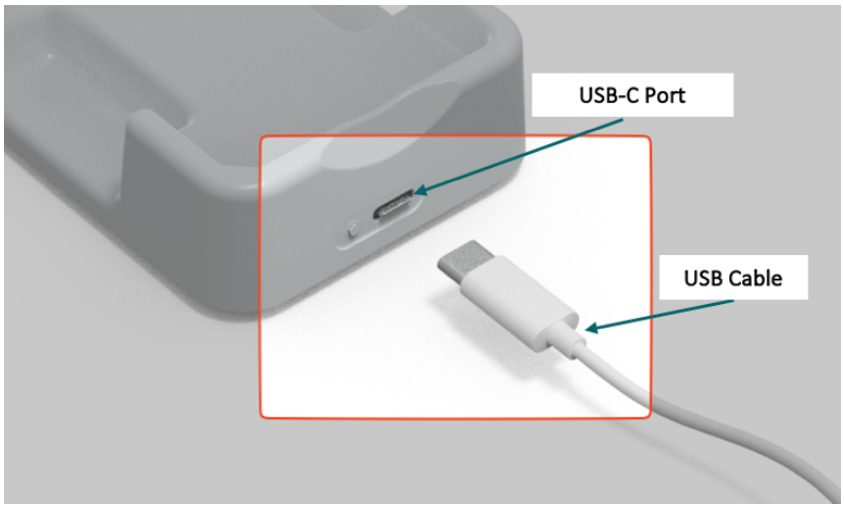
Your AIMIGo Device is equipped with a rechargeable battery. This battery is not replaceable, and the device must be charged using the included Charging Dock.

When not being charged, the device will automatically enter a low-power “standby” mode. A fully charged device is expected to allow for up to 30 days of standby time with daily recordings. The device should be charged between uses when the charge level becomes low. The AIMIGO device may also be kept in the charging dock between uses for convenience.

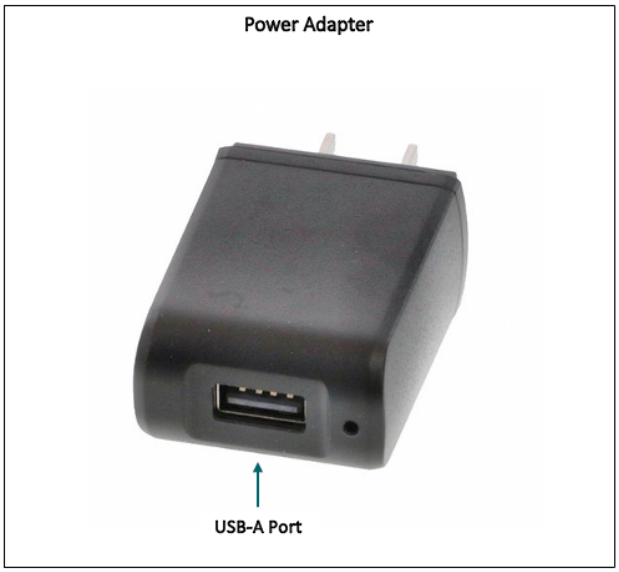
NOTE: The device will indicate a low battery by blinking yellow while connected to the patient application.

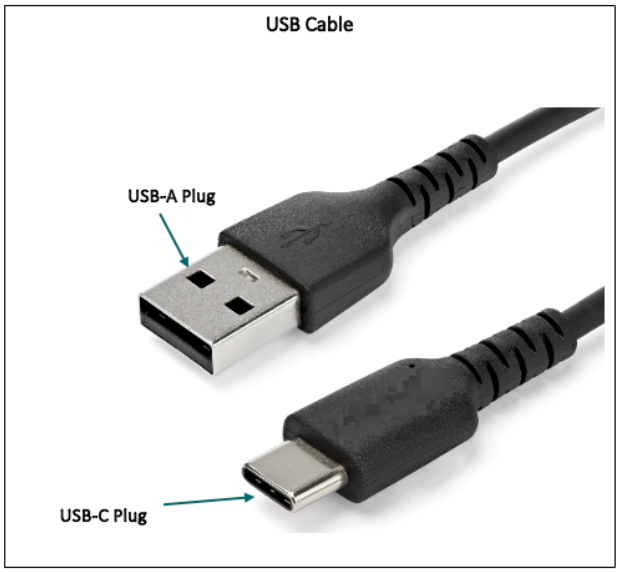
Powering the Charging Dock

Remove the included USB cable and Power Adapter from the packaging. Plug the smaller oval (USB-C) end into the Charging Dock (see below).

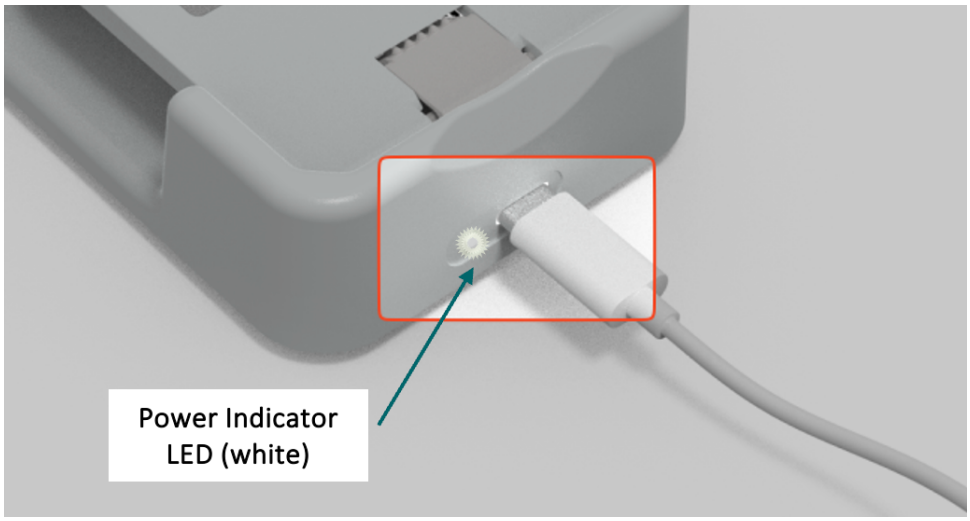


Plug the USB-A end of the cable into the Power Adapter and the Power Adapter into a Power Outlet.





NOTE: The Power Adapter and USB Cable included with your AIMIGo Device may be black or white.
The White LED on the Charging Dock will illuminate to indicate it is ready for use (see below).



- ⚠ **WARNING**: Charging cables may represent a strangulation hazard. Ensure that the AIMIGo charging cable is secured from children and pets.
- ⚠ **WARNING**: Do not plug the USB end of the cable directly into the wall outlet as this will result in electric shock. Only plug the Wall Adapter prongs into the wall outlet.

CAUTION: Only use the supplied Power Adapter and Charging Dock to charge the AIMIGo Device.

NOTE: The Wall Outlet should remain accessible so that the Power Adapter can be unplugged if needed.

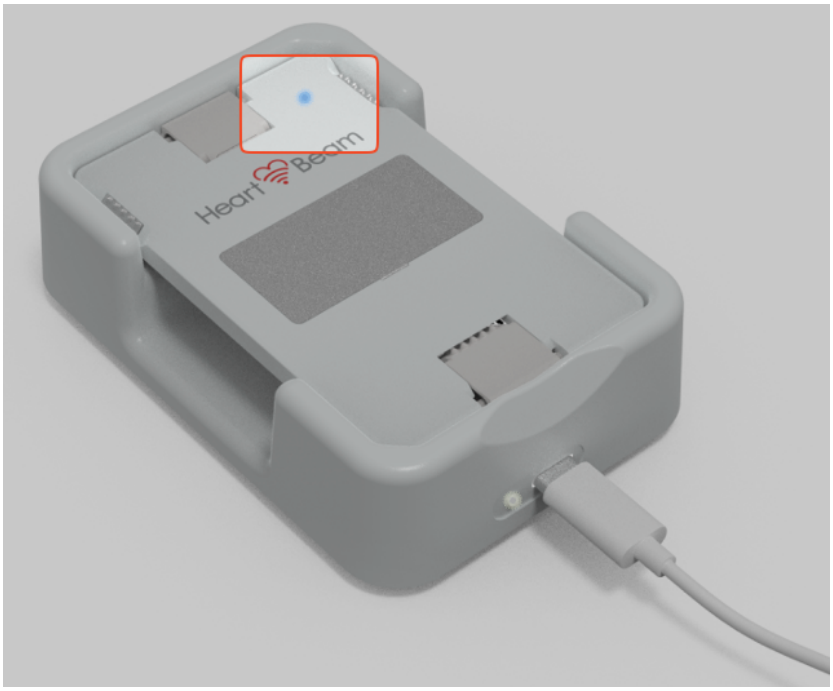
NOTE: The AIMIGo Device and charging dock should be used indoors and out of direct sunlight, see Operating Conditions for full details.

Charging the AIMIGo Device

To begin Charging your AIMIGo Device, place it into the Charging Dock with the Front (White side with HeartBeam Logo) facing up. The LED indicator on the device will blink blue quickly when initializing the wireless charging then will blink blue slowly to indicate the charging has begun. Once the device is fully charged the LED indicator will turn solid blue. See Below.

NOTE: Ensure the Charging Dock has power as indicated by the white LED (see Powering the Charging Dock)

NOTE: It is recommended to store the AIMIGo Device in the Charging Dock when not in use. For example, the device may be charged at night. This will ensure a full battery when you choose to make a recording and helps preserve battery health.



AIMIGo Device LED Behavior	Indication
Fast Blinking (when first placed in dock) Blue	*Wireless Charging is Initializing*
Slow Steady Blinking Blue	*Charging In Progress*
Solid Blue	*Device Fully Charged*
Off	*Device Not Charging (see Troubleshooting section if needed)*

Remove the AIMIGo Device from the Charging Dock

The AIMIGo Device can be removed from the Charging Dock by lifting it from the sides of the device.

Using Your HeartBeam AIMIGo System

To use the AIMIGo Device for recording your ECGs at home you will need to complete Patient Onboarding. Once onboarding is complete, the system is ready to use on-demand.

Complete Patient Onboarding

⚠ **WARNING**: Do not complete Patient Onboarding if you are feeling unwell or are experiencing any cardiac related symptoms (such as heart palpitations, dizziness, light headedness, etc.).

NOTE: The HeartBeam AIMIGo Device is prescribed by a clinician who will complete the initial registration steps on the Clinician Portal (See HeartBeam AIMIGo Clinician User Manual for full details). This includes confirming your patient information such as Name, Date of Birth, and Contact Information. You will have an AIMIGo Device registered to your account and the Clinician will also upload your Reference Standard 12-Lead ECG to the patient profile.

Once the Patient Registration process is completed by the Clinician, you will be required to complete Onboarding:

Onboarding Step 1: Download and install the AIMIGo Mobile Application

The HeartBeam AIMIGo Patient Application is available for Android based Phones and Apple iPhones through the Google Play Store and Apple App Store, respectively (See System Usage Requirements for compatibility).

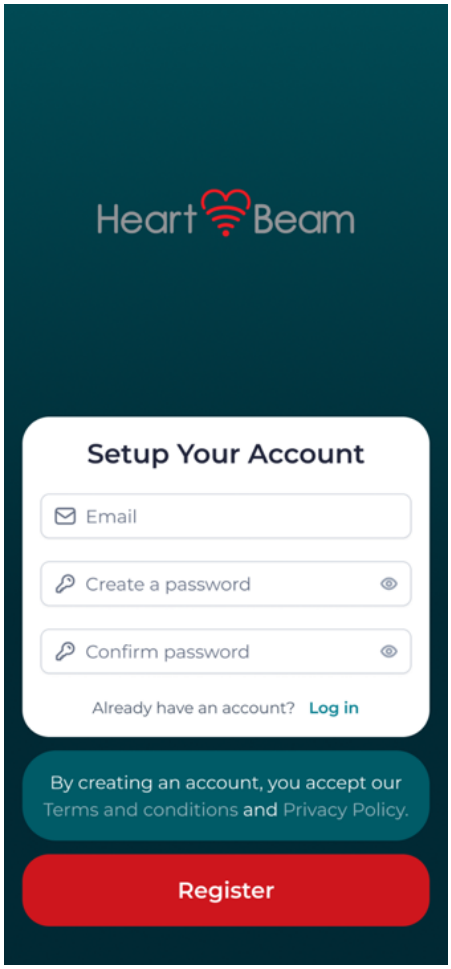
The app can be found the App Stores by searching for "**MyHeartBeam**".

Onboarding Step 2: Launch the Application

Once the application has been installed on your mobile device, tap the icon from your phone home screen to launch the application.

Onboarding Step 3a: Setup your Account

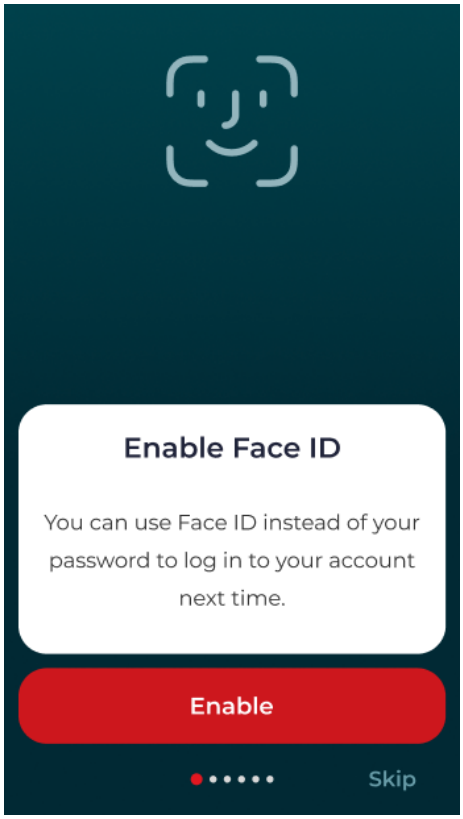
Upon launching the Patient App, you will see an account setup window. If not already pre-filled, please enter the email address provided by your HCP at the time of registration or where you received an email to download the HeartBeam AIMIGo app. Create and confirm a password to authenticate your account and register. Please remember your email address and password for future log-ins.

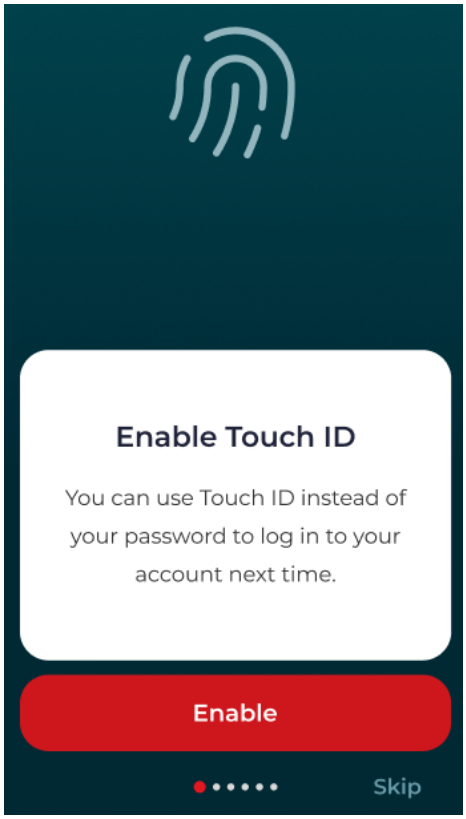


(Optional) Onboarding Step 3b: Enable Face ID) or Biometric ID

Once you have successfully registered and logged into the app for the first time, you may enable Face ID or TouchID. Doing so will allow you to use these methods of log-in in lieu of entering your username and password. Tap **Enable Face ID** or **Enable Touch ID**.

Alternatively, if you would not like to enable Face ID or Biometric ID, you may tap the **Skip** button to proceed.



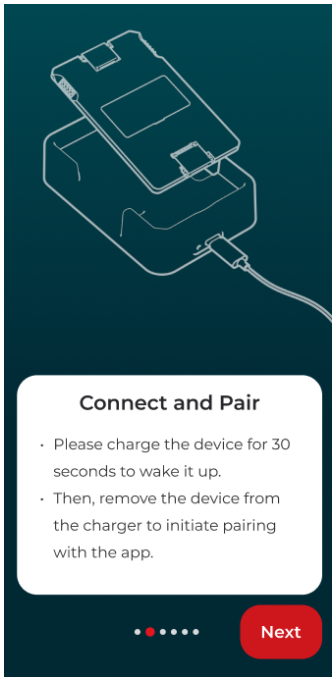


Onboarding Step 4a: Connect and Pair the AIMIGo Device to Patient Mobile Device

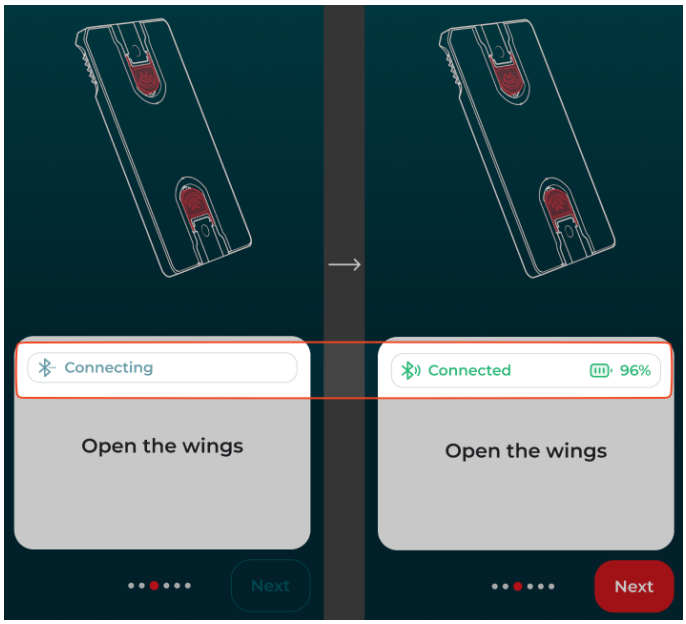
To connect and pair the AIMIGo Device with your mobile device, charge the AIMIGo Device for 30 seconds to wake the device for first use (See HeartBeam AIMIGo Device – Charging Process for full detail).

Remove the device from the Charging Dock. Bring it within 2-3 feet of your mobile device and tap **Next**.

NOTE: Your mobile device may request Bluetooth permission to connect to the AIMIGo Device, if so, please tap **Pair** (iPhone) or **OK** (Android).



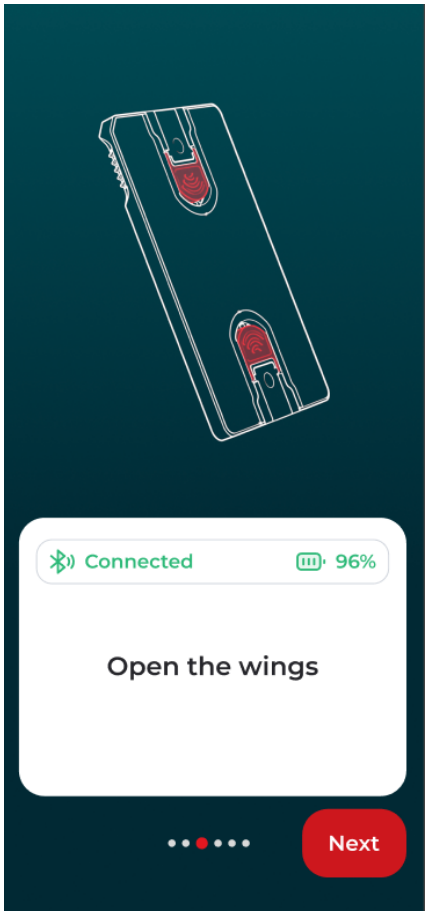
The Patient app will attempt to connect ("Connecting") to the AIMIGo Device and will display "Connected" once it has successfully paired. See the Troubleshooting section if you are unable to connect.



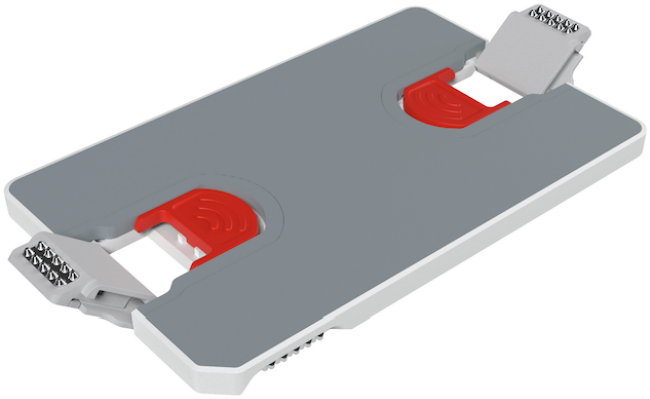
Onboarding Step 4b: Open the Wings

While the Patient App is connecting to the AIMIGo Device you may also begin to prepare the device for a recording session by opening the wings.

The App provides an animation of how to slide the red Upper and Lower Wing Release latches. The latches should slide towards each other and release the wings to the open position (also reference AIMIGo Device Parts Description).



Confirm the wings are in the open position as displayed below. Tap **Next** on the Patient App to continue.



Onboarding Step 5: Positioning the AIMIGo Device

NOTE: Before placing the HeartBeam AIMIGo Device on your body, make sure that any clothing or jewelry is removed from the chest as the device **must be placed directly on the skin**.

⚠ **WARNING**: Do not place the device directly over an open wound, lesion, infected, or inflamed skin. Doing so may present risk of infection.

Proper Device Placement:

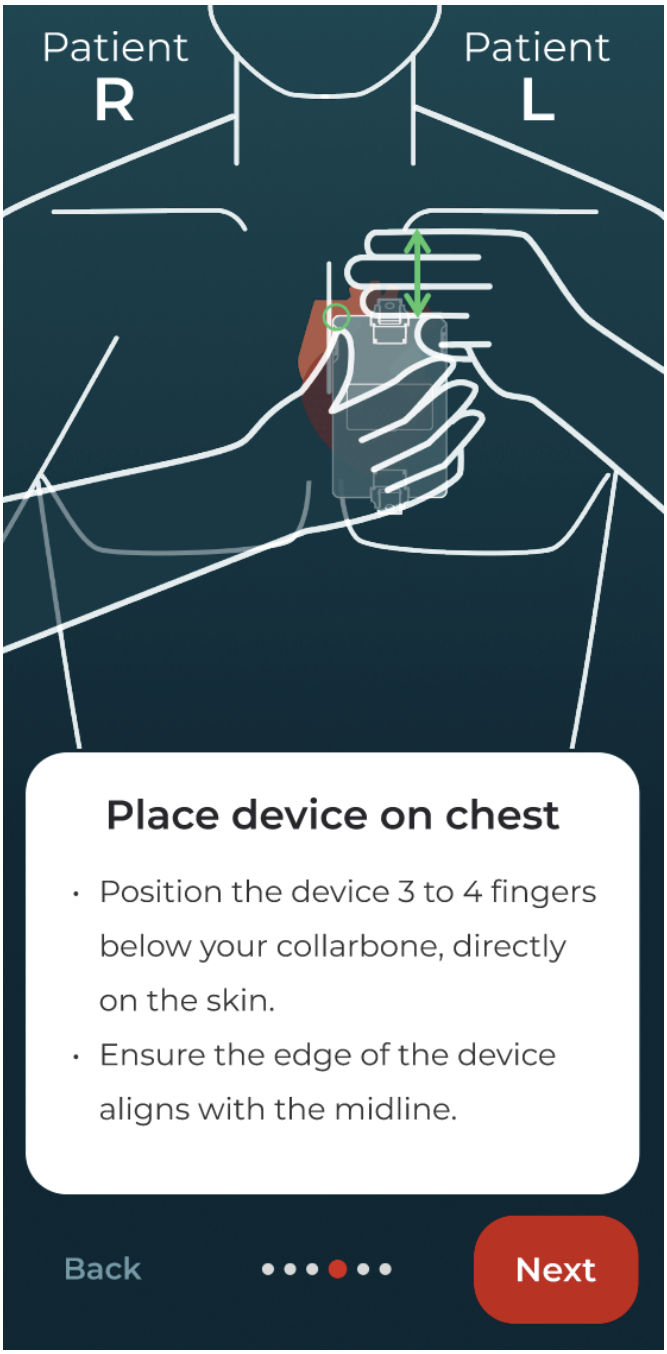
- Place the device directly on the **left side of your chest, over your heart**. Notice Patient Left (L) and Patient Right (R) as indicated on the screen.
- The device should be 3 to 4 finger widths below the collarbone (clavicle bone) and the edge of the device should touch the midline (sternum), on your left chest.

NOTE: Ensure that both the Upper and Lower Chest Sensors contact bare skin. You may need to make minor positioning changes based on the shape of your chest to ensure proper contact. Do not allow the wings to fold to the closed position.

NOTE: The chest sensors should not be placed over your breastbone (sternum) in the middle of your chest.

NOTE: It is important to place the device in a similar position **each time** you record an ECG.

Tap **Next** to continue.



Onboarding Step 6: Prepare Your Body

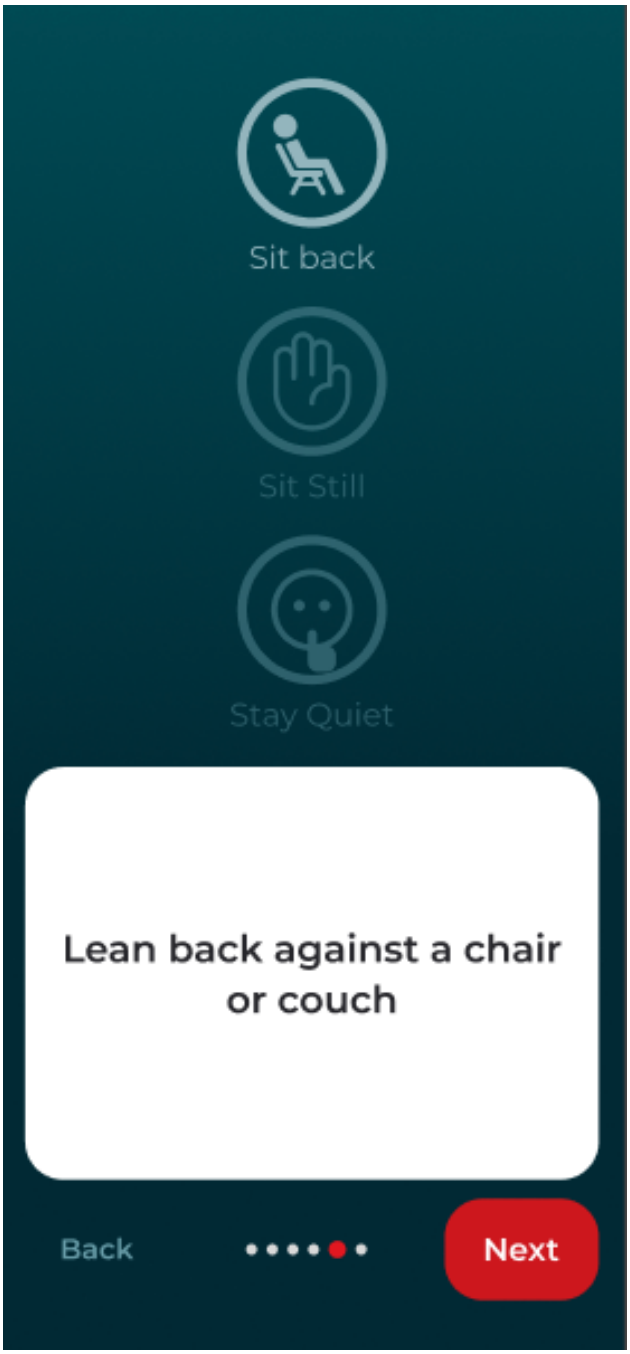
The AIMIGo Device records the best quality signals when you are relaxed, holding still, and quiet.

Recommended Seating:

- **Sit Back**
  Recline comfortably in a chair or couch
- **Sit Still**
  Try not to move while the recording is in progress
- **Stay Quiet / No Talking**
  Remain quiet during the recording

CAUTION: Make sure that your back is comfortably supported to prevent injury.

Tap **Next** to continue.

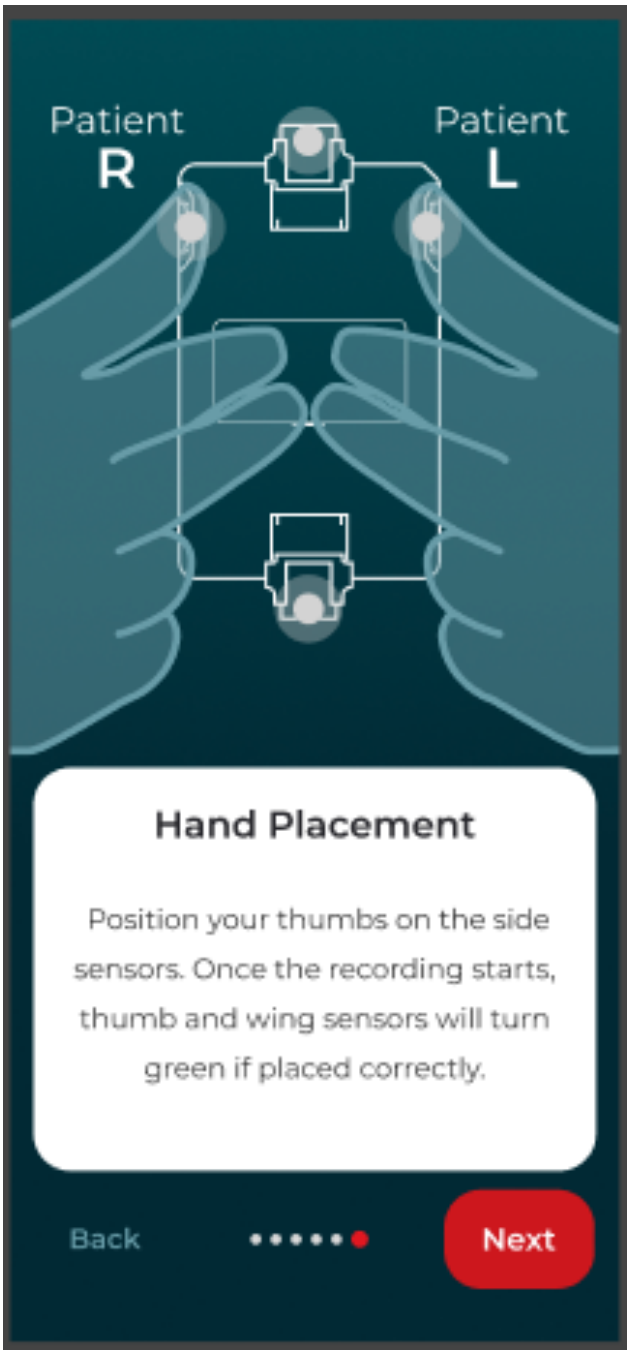


Onboarding Step 7: Hand and Finger Placement

After you have properly positioned the AIMIGo Device on to your chest and relaxed in a comfortable, reclined position, review these steps for proper hand and finger placement.

Proper Hand & Finger Placement:

- Your left and right Thumbs should rest on the Left and Right Thumb Sensors
- The Pointer and Middle fingers should rest comfortably on the Front Sensor
- User your Pointer and Middle fingers to apply gentle pressure towards your chest to hold the AIMIGo Device in place.

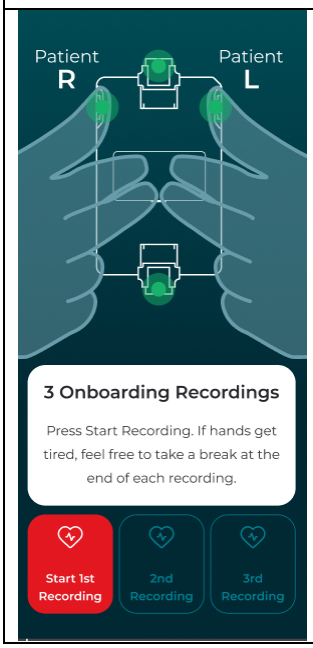
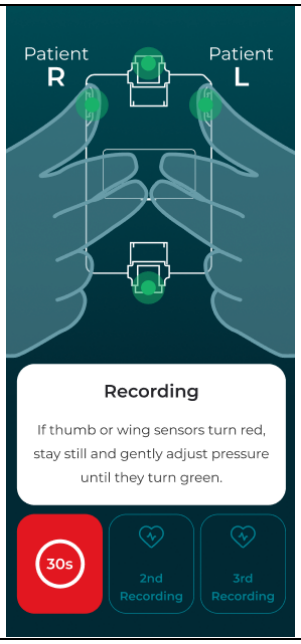
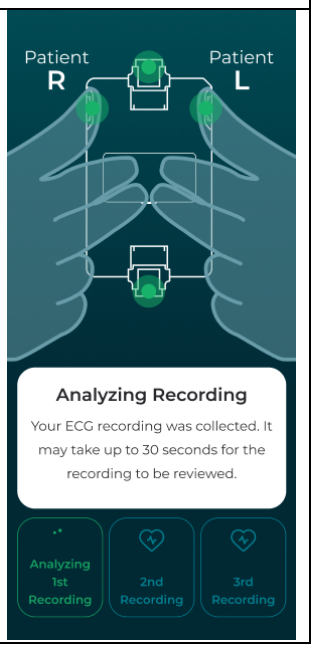


Tap **Next** to continue.

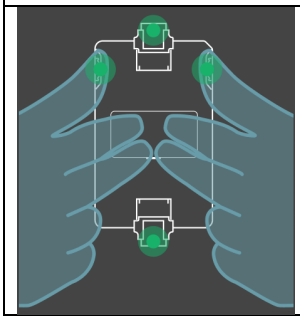
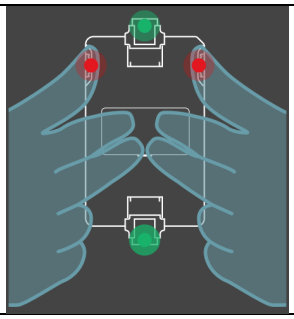
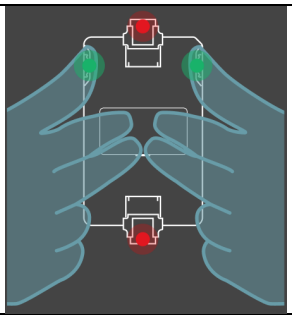
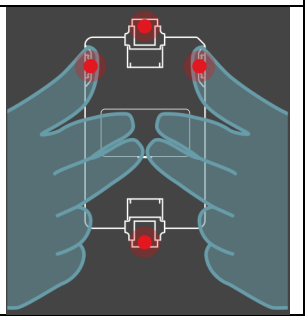
Onboarding Step 8a: Begin Onboarding Recording #1

After you have properly positioned the AIMIGo Device on to your chest, relaxed in a comfortable reclined position, and reviewed proper finger placement, you are ready to begin the first onboarding recording. Tap **Start 1st Recording** to begin (see A below).

The screen will display "Starting 1st Recording" (see B below) then begin a 30-second countdown timer (see C below). Hold still until the recording is complete. Once the timer ends, the recording will be analyzed (see D below).

(A) Start 1st Recording	(B) Recording Starting	(C) Recording in Progress / 30 second timer	(D) Analyzing
			

NOTE: During the recording session, the sensor indicators will turn green when proper contact is achieved. The sensor indicators may turn red if there is excessive motion or movement during the recording, see below. Try to remain steady and relaxed to complete the recording.

Proper Sensor Contact	Poor Finger Sensor Contact	Poor Chest Sensor Contact	Poor Finger and Chest Sensor Contact
			

Onboarding Step 8b: Complete Onboarding #1

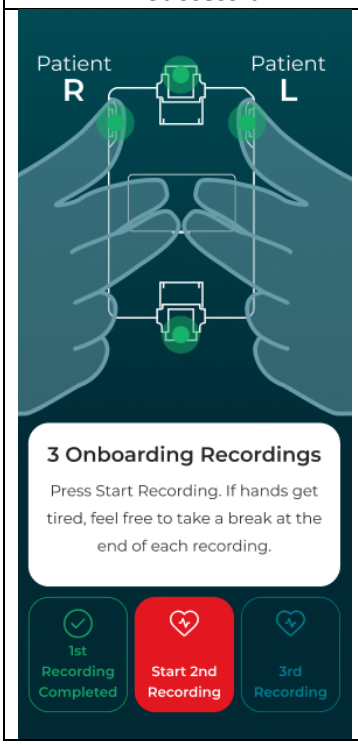
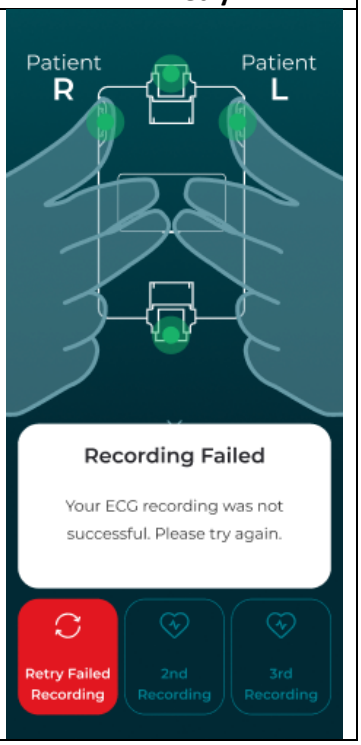
After your 1st recording has completed, it will be analyzed for signal quality:

- If the recording was successful you will see "1st Recording Completed" and the "Start 2nd Recording" button will turn red (see E below). Tap to proceed to Recording #2.

OR

- If the recording was unsuccessful you will see "Recording Failed", and the "Retry Failed Recording" button will turn red (see F below). Tap to retry Onboarding Recording #1.

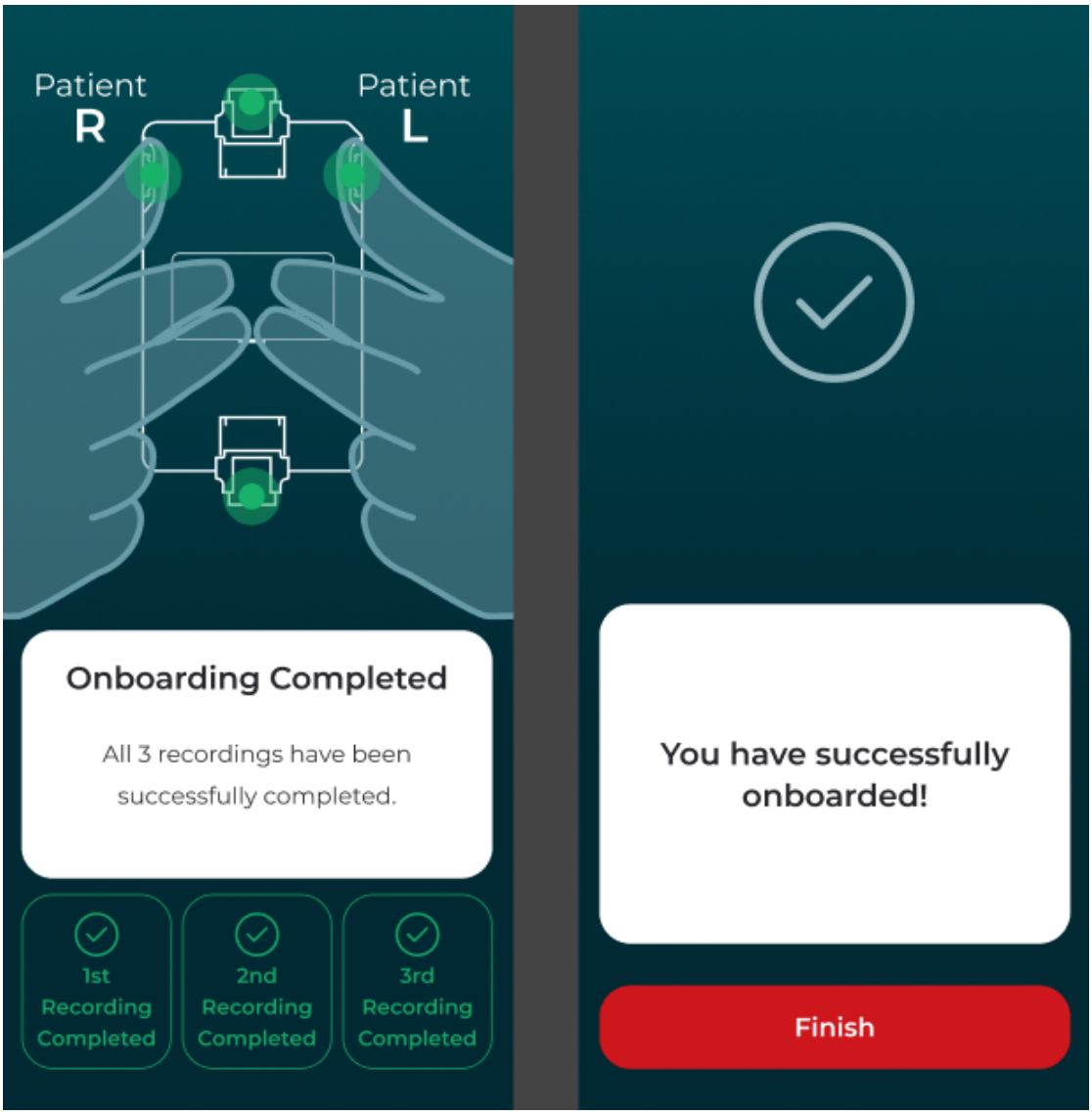
NOTE: If the recording was unsuccessful, review Onboarding Steps 5-7 to ensure proper device positioning, posture, and finger placement.

(E) 1st Recording Successful	**(F) 1st Recording Failed, Retry**
	

Onboarding Step 8c: Repeat to Complete Onboarding #2 and #3

Repeat the recording steps to complete Onboarding Recording #2 and #3. Once all three Onboarding Recordings have been completed, the App will display “You have Successfully Onboarded!”.

Tap **Finish** to continue to the Home Screen.



Recording ECGs at Home

After successful Onboarding you may use the AIMIGo Device to make routine or symptomatic recordings at home, on-demand.

> ⚠ **WARNING:** For medical emergencies, call 911 or seek emergency care. Do NOT rely on the HeartBeam AIMIGo System to alert or notify medical service personnel of an emergency.

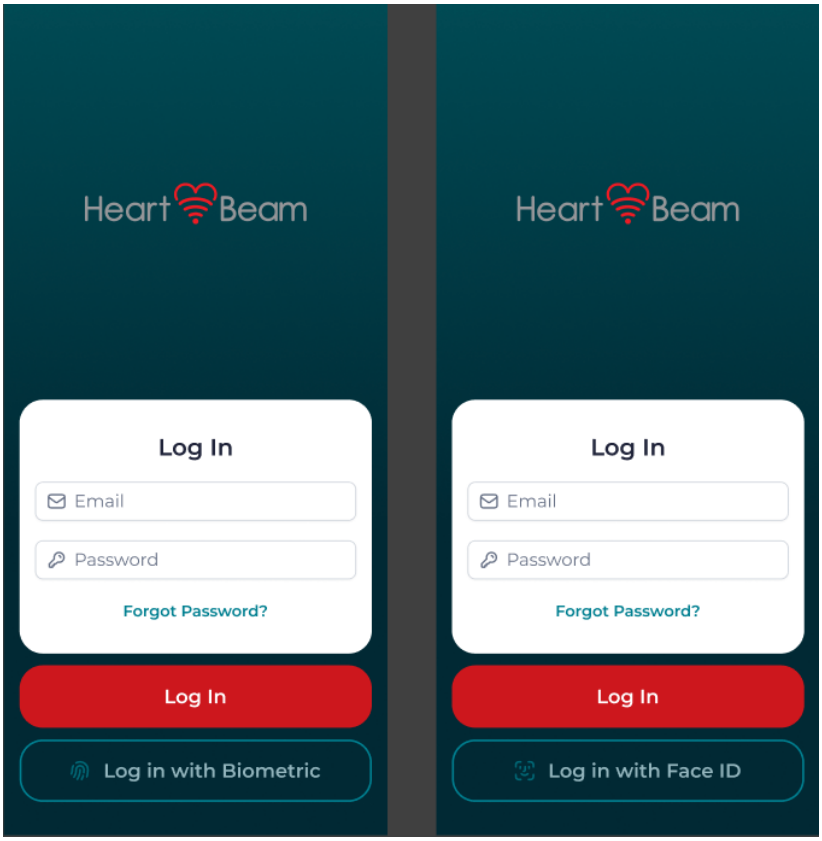
CAUTION: The HeartBeam AIMIGo Device should only be used when the device is clean and dry.

NOTE: The synthesized 12-Lead ECG (including PDF reports) is not intended to replace traditional methods of diagnosis or standard of care and no medical action(s) should be taken based on the device output without consultation of a qualified healthcare professional.

Home Recording Step 1: Launch the Application and Log-in

Tap the icon from your phone home screen to launch the application.

Upon launching the application, you will see a log-in window. Enter your username and password, then tap **Log In** to proceed. If you have enabled biometric login, you may select Log in with Biometric (Android) or log in

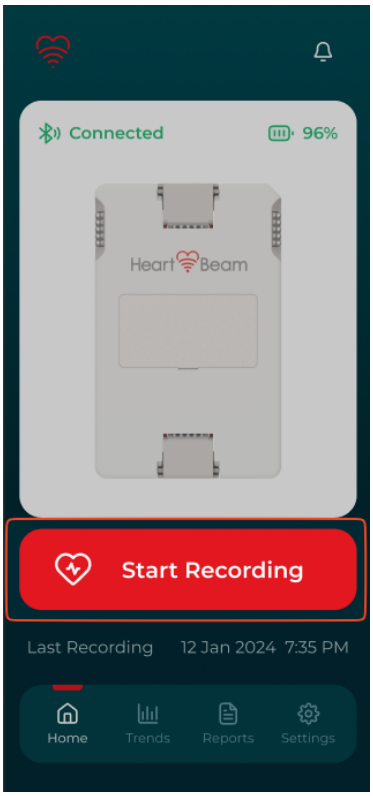


with Face ID (iPhone). See below.

NOTE: For password reset select **Forgot Password**; see Troubleshooting for more details.

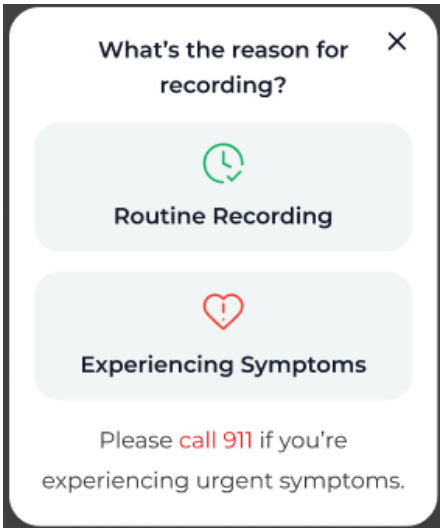
Home Recording Step 2a: Start a Recording Session

From the Home Screen tap Start Recording to begin a new Recording Session



Home Recording Step 2b: Choose Routine or Symptomatic Recording

After you've initiated a new Recording Session you may choose to log a Routine Recording or a Symptomatic Recording.



Choose a **Routine Recording** when you are not symptomatic and are making a recording as part of your scheduled routine determined with your care provider.

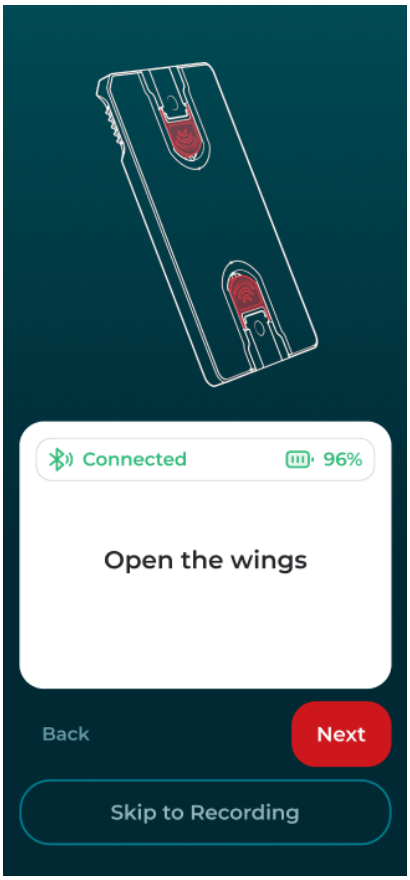
Choose a **Symptomatic Recording** if you are feeling mild or unexpected symptoms and you'd like to capture an ECG recording for your care provider.

⚠ **WARNING:** If you are experiencing severe or urgent symptoms, you should call 911 or seek emergency care immediately.

Home Recording Step 4: Open the Wings

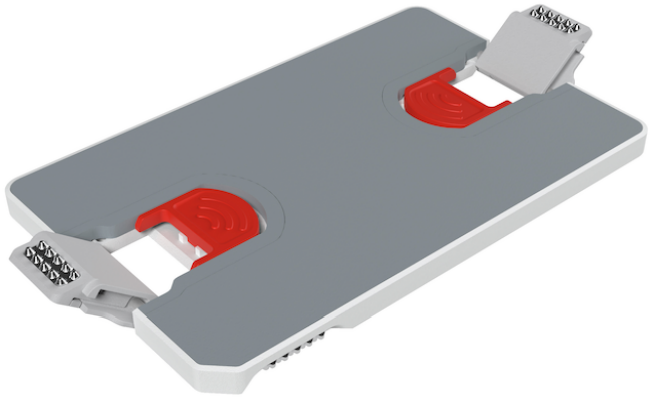
While the Patient App is connecting to the AIMIGo Device you may also begin to prepare the device for a recording session by opening the wings.

The App provides an animation of how to slide the red Upper and Lower Wing Release latches. The latches should slide towards each other and release the wings to the open position (you may also reference the AIMIGo Device Parts Description).



Confirm the wings are in the open position as displayed below. Tap **Next** to continue.

NOTE: Experienced users may tap Skip to Recording to immediately begin the recording.



Home Recording Step 5: Positioning the AIMIGo Device and Placing Fingers on the Sensors

NOTE: Before placing the HeartBeam AIMIGo Device on your body, make sure that any clothing or jewelry is removed from the chest as the device **must be placed directly on the skin**.

⚠ **WARNING**: Do not place the device directly over an open wound, lesion, infected, or inflamed skin. Doing so may present risk of infection.

Proper Device Placement:

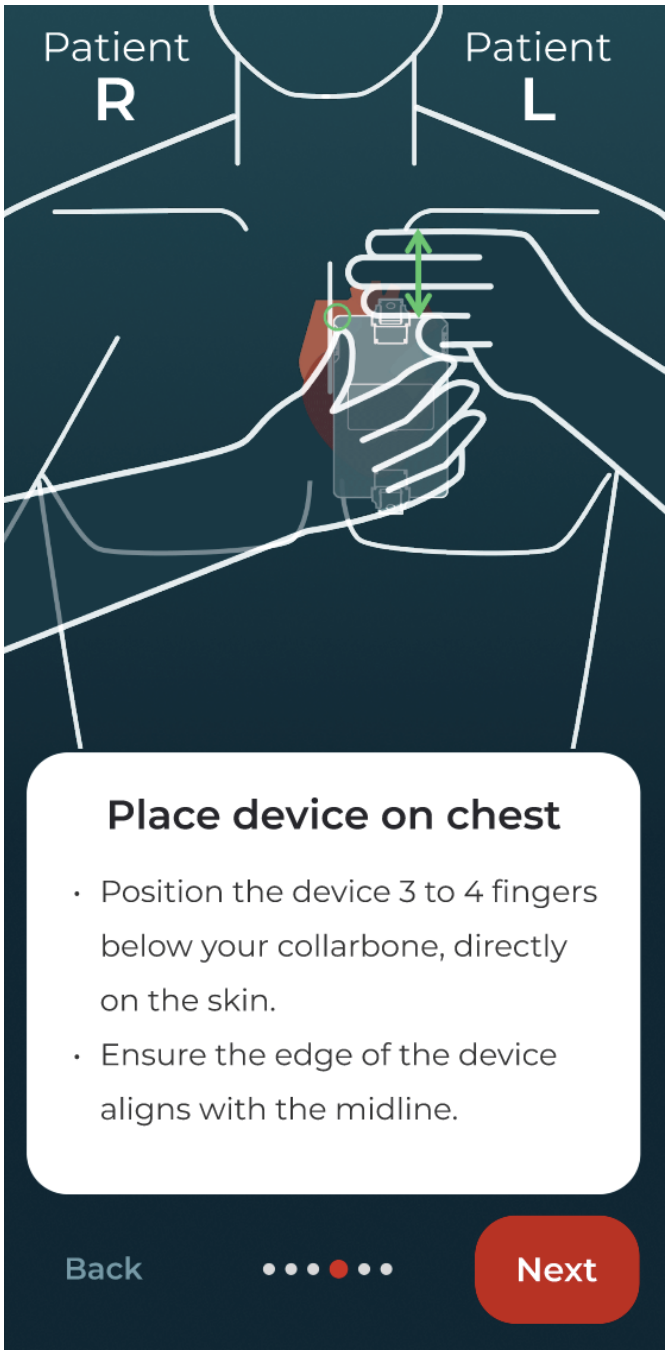
- Place the device directly on the **left side of your chest, over your heart**. Notice Patient L and Patient R as indicated on the screen.
- The device should be 3 to 4 finger widths below the collarbone (clavicle bone), and the edge of the device should touch the midline (sternum).

NOTE: Ensure that both the Upper and Lower Chest Sensors contact bare skin. You may need to make minor positioning changes based on the shape of your chest to ensure proper contact. Do not allow the wings to fold to the closed position.

NOTE: The chest sensors should not be placed over your breastbone (sternum) in the middle of your chest.

NOTE: It is important to place the device in a similar position **each time** you record an ECG.

Tap **Next** to continue.



Home Recording Step 6: Prepare Your Body

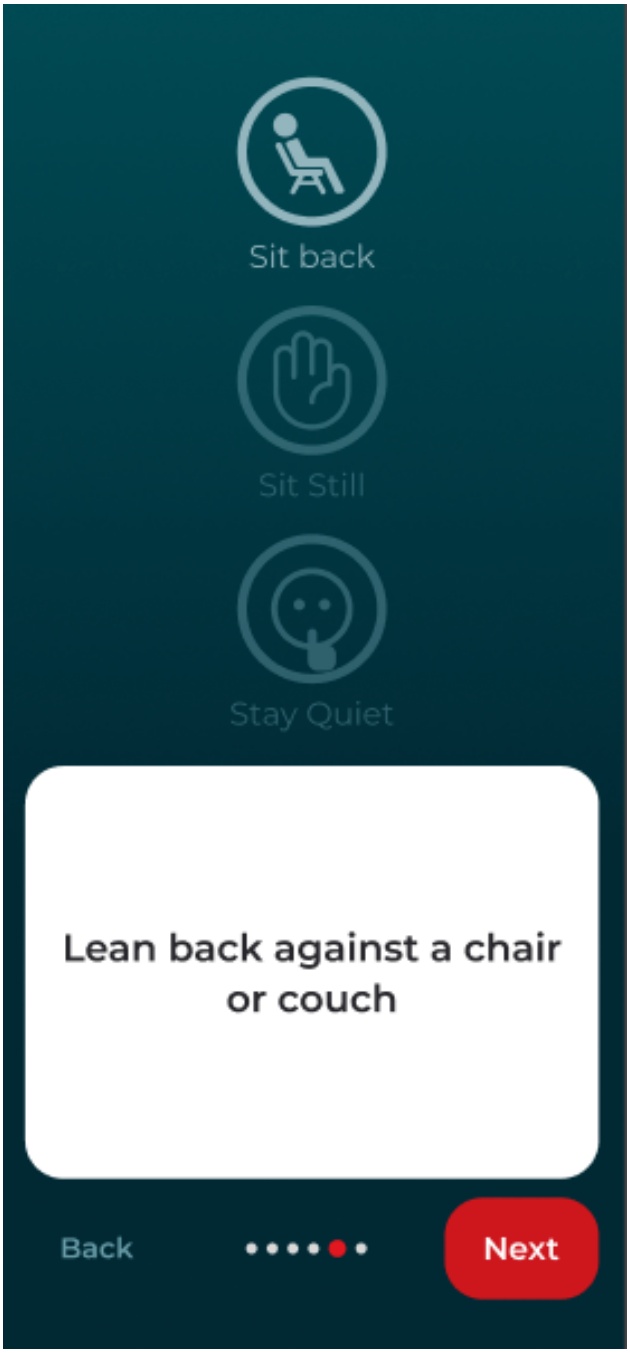
The AIMIGo Device records the best quality signals when you are relaxed, holding still, and quiet.

Recommended Seating:

- **Sit Back**
  Recline comfortably in a chair or couch
- **Sit Still**
  Try not to move while the recording is in progress
- **Stay Quiet / No Talking**
  Remain quiet during the recording

CAUTION: Make sure that your back and posture is comfortably supported to prevent injury.

Tap **Next** to continue.



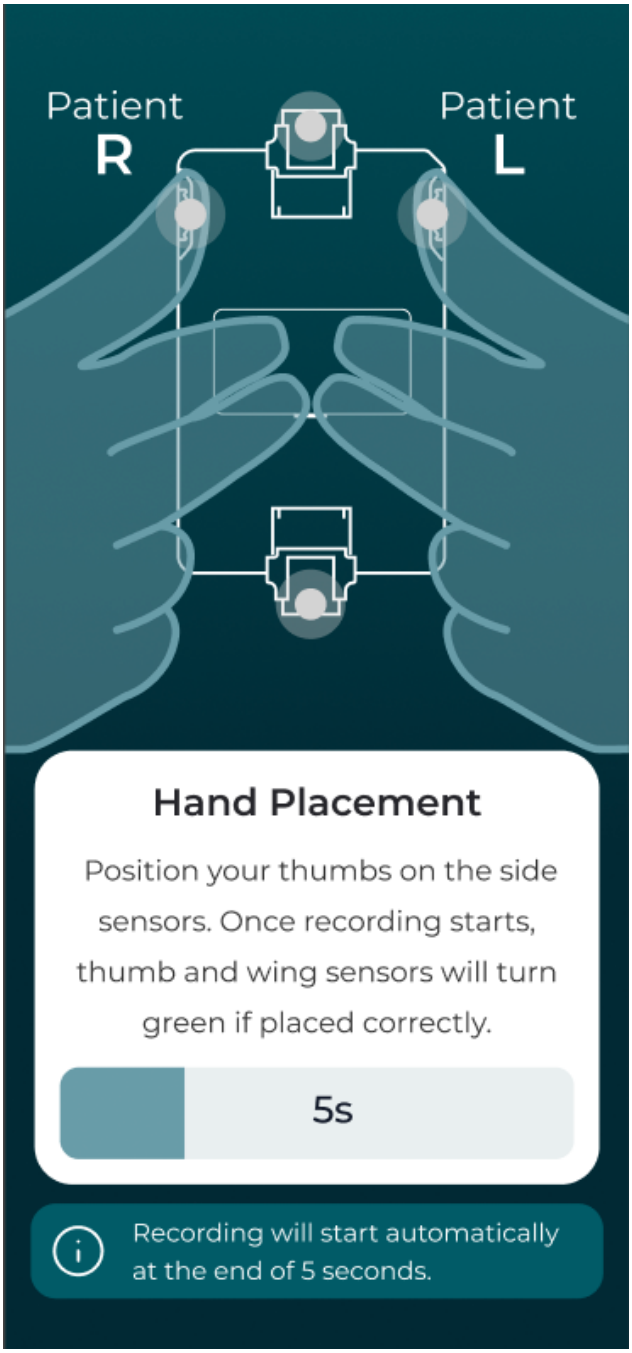
Home Recording Step 7: Hand and Finger Placement

After you have properly positioned the AIMIGo Device on to your chest and relaxed in a comfortable reclined position review these steps for proper hand and finger placement.

Proper Hand & Finger Placement:

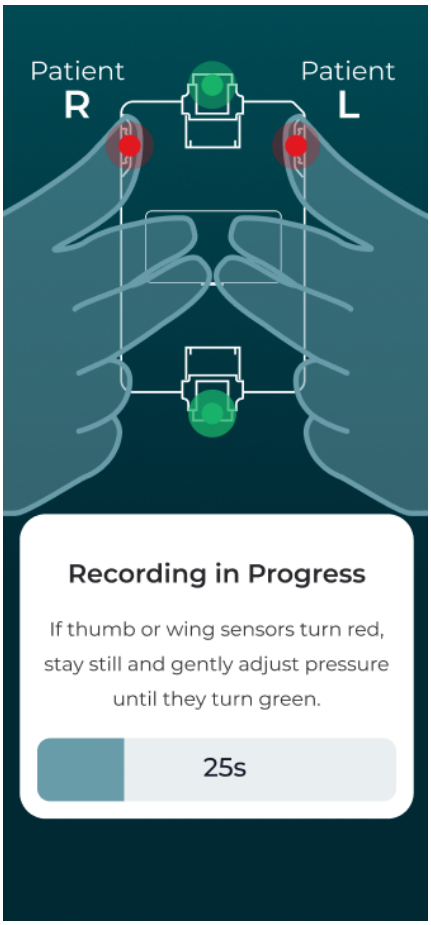
- Your left and right Thumbs should rest on the Left and Right Thumb Sensors
- The Pointer and Middle fingers should rest comfortably on the Front Sensor
- User your Pointer and Middle fingers to apply gentle pressure towards your chest to hold the AIMIGo Device in place.

The recording will start automatically after a 5-second countdown.

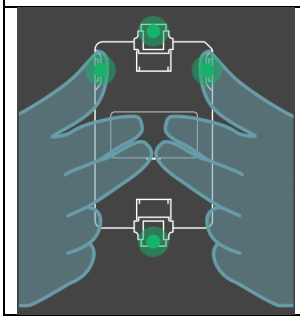
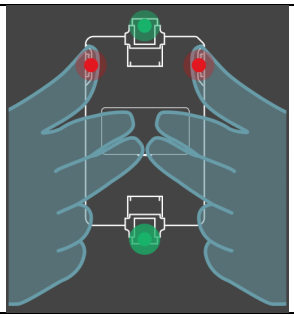
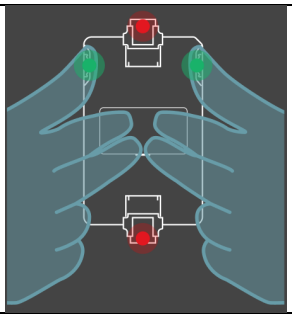
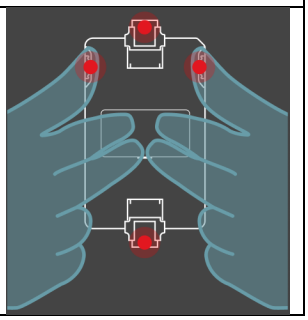


Home Recording Step 8: Complete Your ECG Recording Session

After the 5-second countdown the App will display **Recording in Progress** with a 30-second countdown timer. Remain relaxed with the device and fingers properly positioned until the recording is complete.

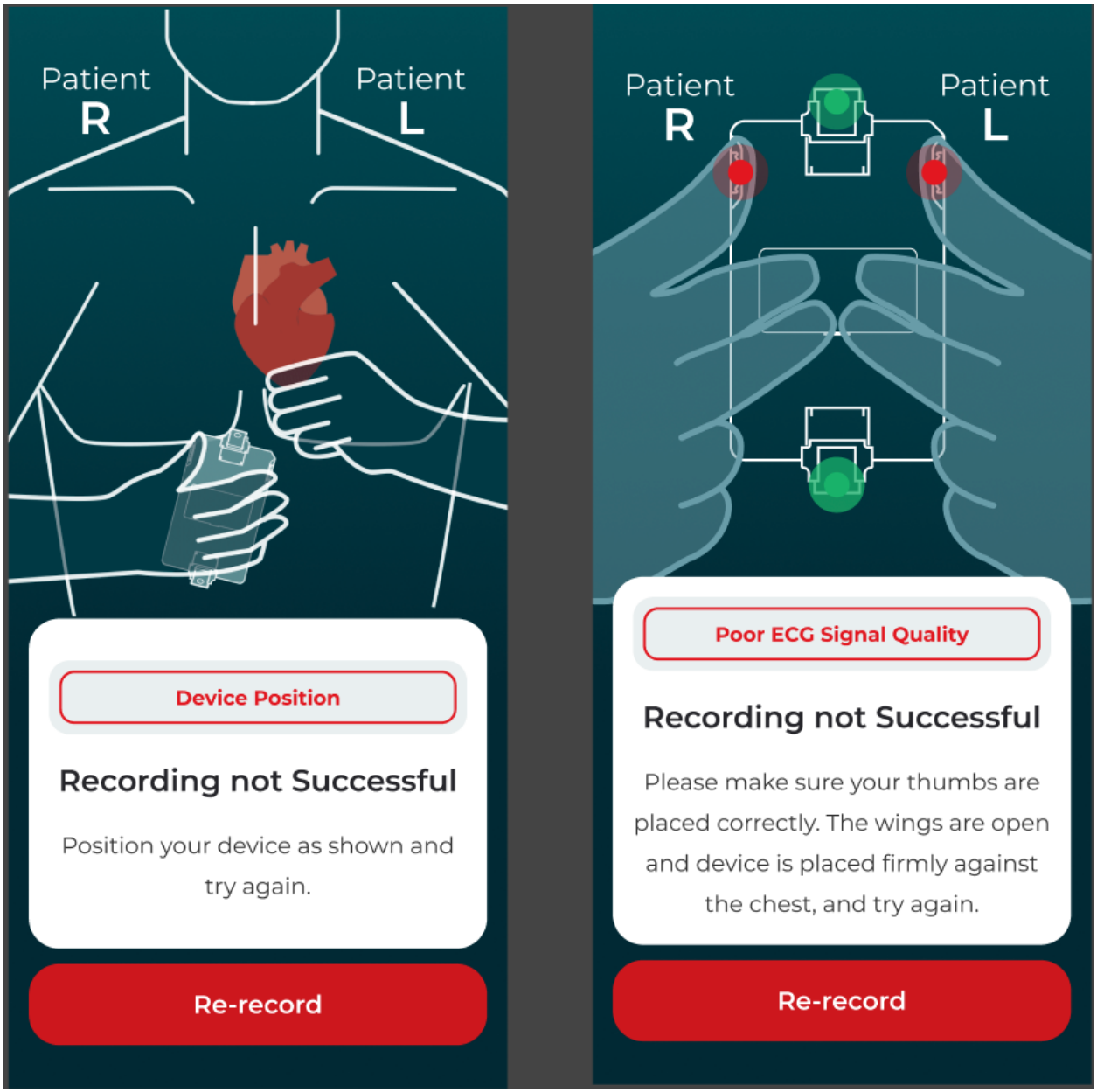


NOTE: During the Recording session the sensor indicators will turn green when proper contact is achieved. The sensor indicators may turn red if there is excessive motion or movement during the recording, see below. Try to remain steady and relaxed to complete the recording.

Proper Sensor Contact	Poor Finger Sensor Contact	Poor Chest Sensor Contact	Poor Finger and Chest Sensor Contact
			

Home Recording Step 8: Complete Your ECG Recording Session (continued)

If the recording is not successful due to positioning or signal quality, you may tap Re-record to try again.

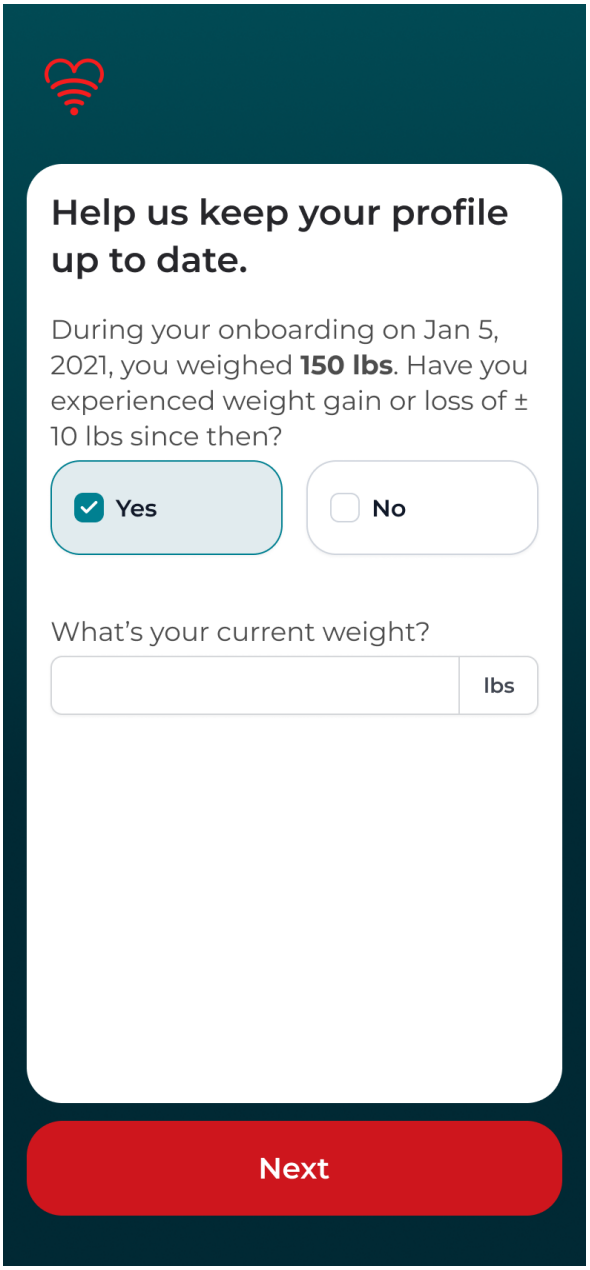


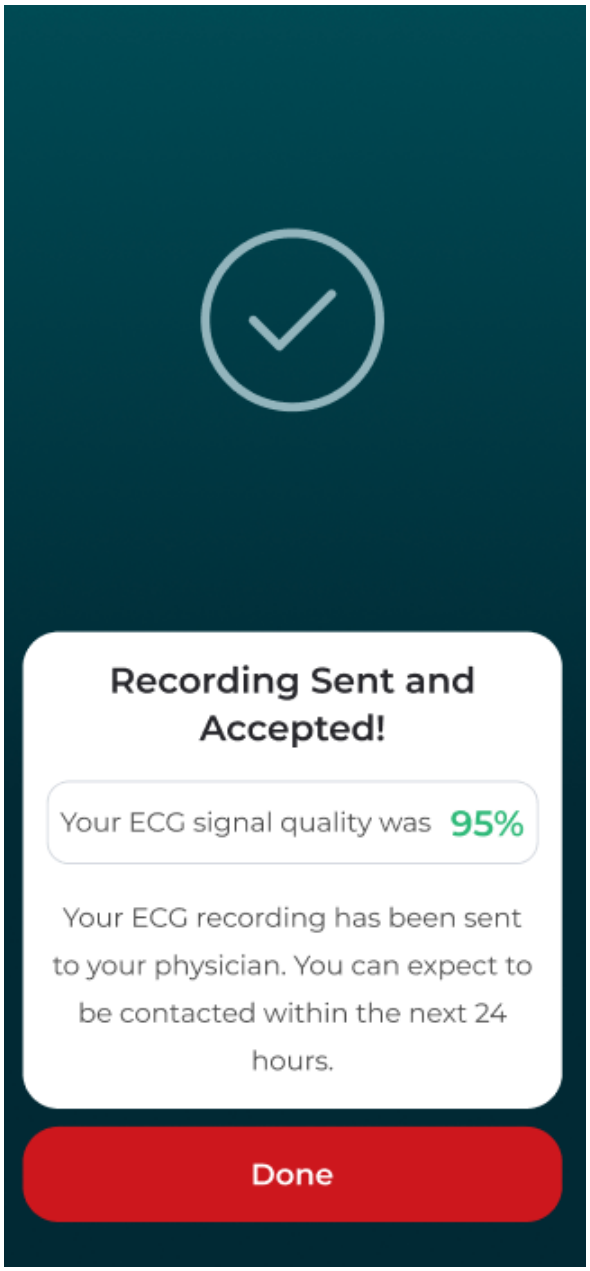
Home Recording Step 9a: For Routine Recording – Update Your Profile with Weight Gain / Loss

After the recording session has completed, you may update your patient profile to indicate if you've experienced a weight gain or loss of more than **10 pounds** since your onboarding.

NOTE: It is important to keep your patient profile up to date. This information is used by your clinician to assess if a new onboarding may be needed.

The application will display your weight as of your onboarding date. Tap **Yes** to indicate a weight gain or loss greater than 10 pounds and enter your current weight. Otherwise, tap **No**. Then tap **Next** to continue. After the recording has been analyzed for signal quality the App will display 'Recording Sent and Accepted' and the Signal Quality. Tap **Return to Home** to end the recording session and return to the Home Screen.

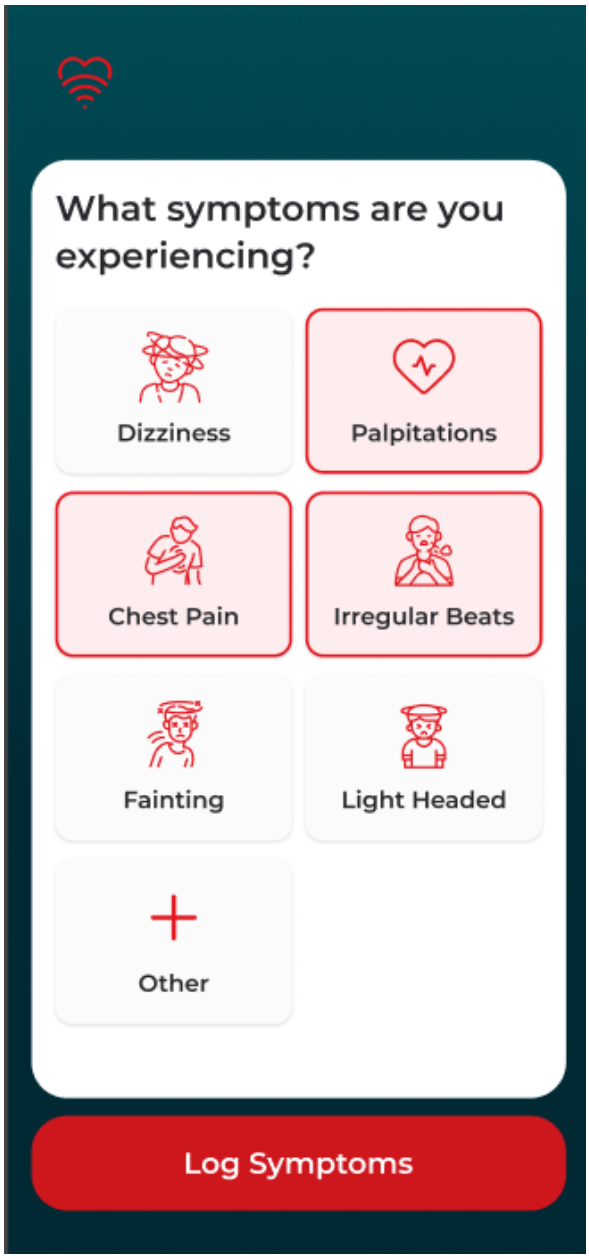


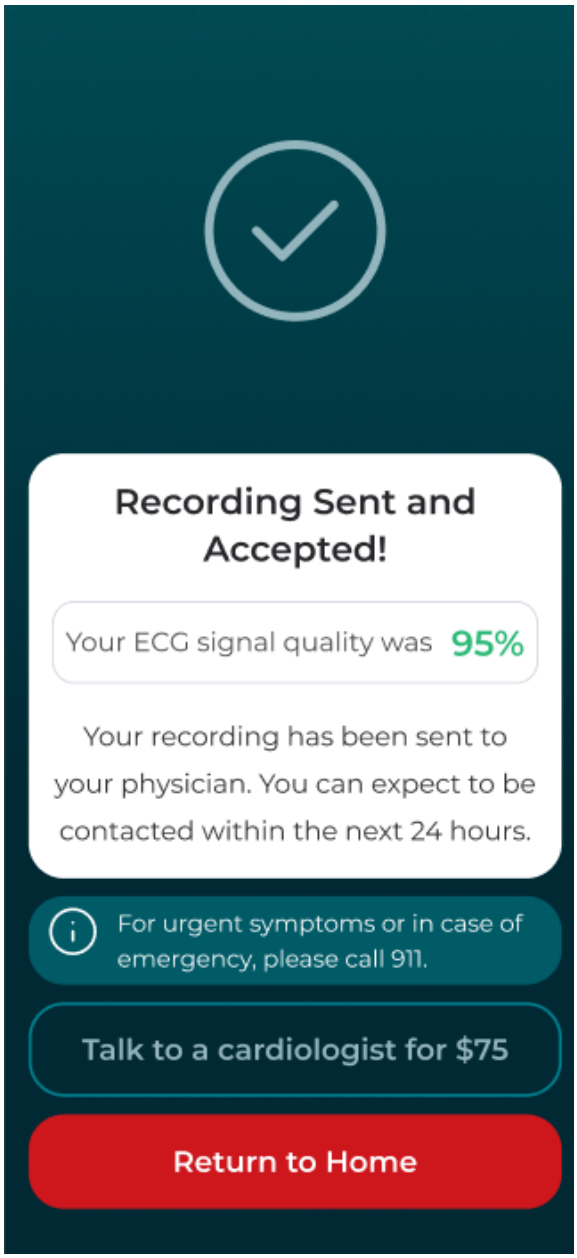


Home Recording Step 9b: For Symptomatic Recording – Select Symptoms

After the symptomatic recording session has completed, you may choose to log any of the symptoms you are experiencing, such as Dizziness, Palpitations, Chest Pain, Irregular Beats, Feeling Faint, Lightheaded, or add Other symptoms. Tap each option as needed.

Tap **Log Symptoms** to continue. After the recording has been analyzed for signal quality the App will display Recording Sent and Accepted and the Signal Quality. Tap **Return to Home** to end the recording session and return to the Home Screen.

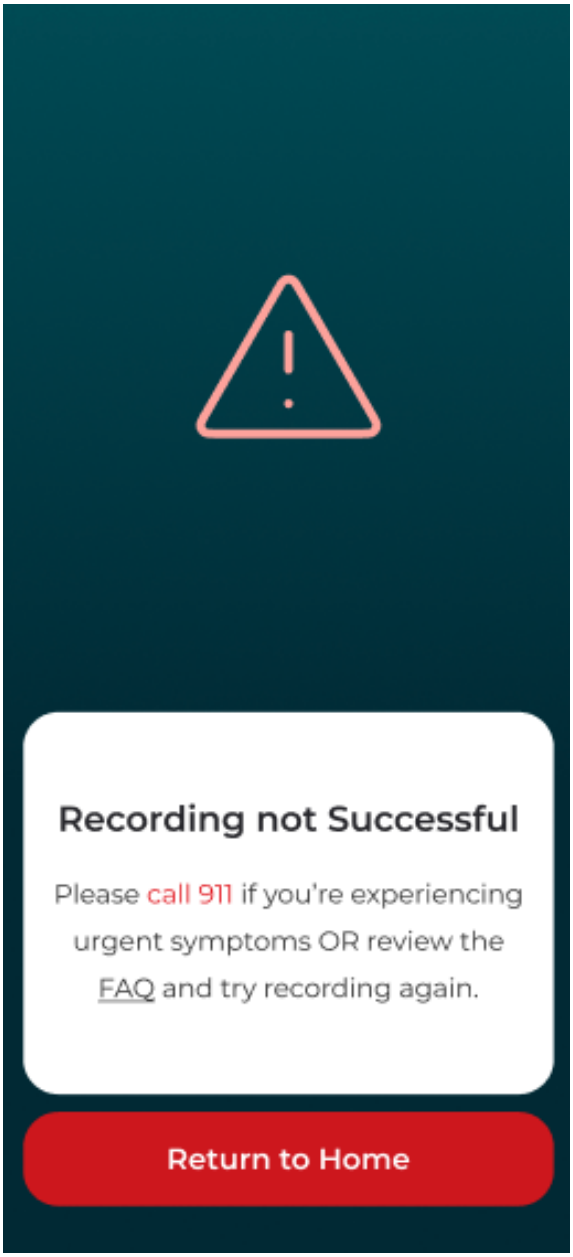




Home Recording Step 9b: For Symptomatic Recording – Select Symptoms (continued)

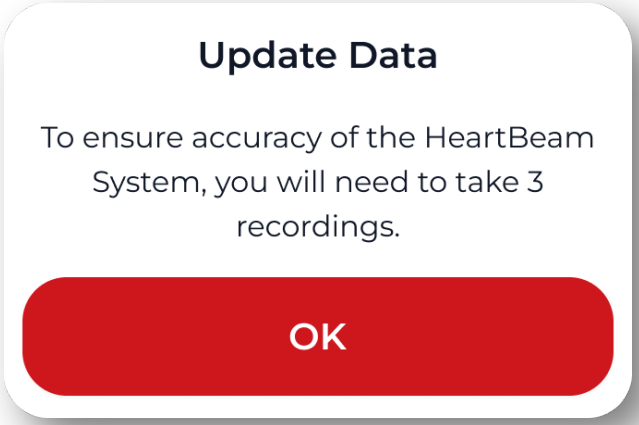
If the symptomatic recording was not successful, the App will display Recording Not Successful. Tap **Return to Home** to retry the recording session.

⚠ **WARNING:** If you are experiencing severe or urgent symptoms, you should call 911 or seek emergency care immediately.



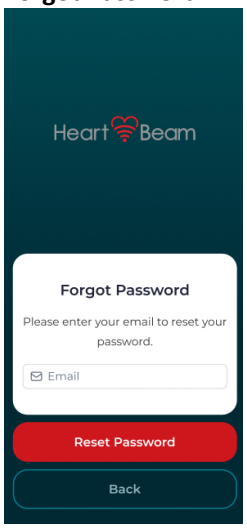
Updating Your Onboarding (Clinician Driven)

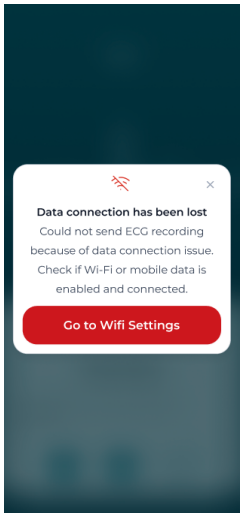
Over time there may be changes in your medical history that your clinician may determine require a new onboarding session. These changes could include weight gain or weight loss, certain medical procedures, or new diagnosis. If your clinician determines that a new onboarding session is required, you will be asked to visit the hospital or clinic to repeat onboarding. In these visits your patient application will prompt you to update your data.

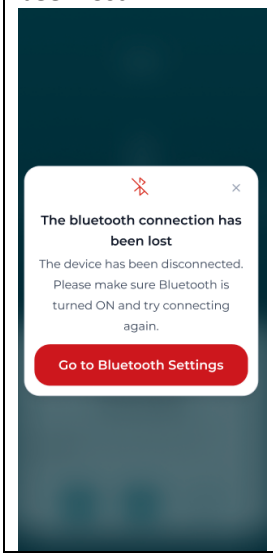
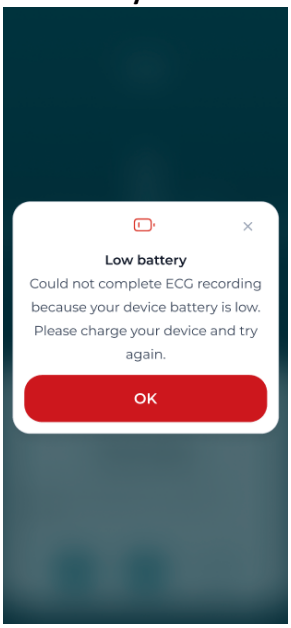


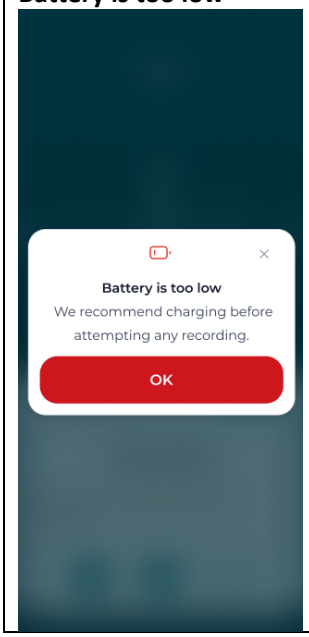
See **Onboarding Step 8a: Begin Onboarding Recording #1** for full instructions and follow the prompts on the application. After completing three onboarding recordings you may resume normal use of the system to take Assessment Recordings at home.

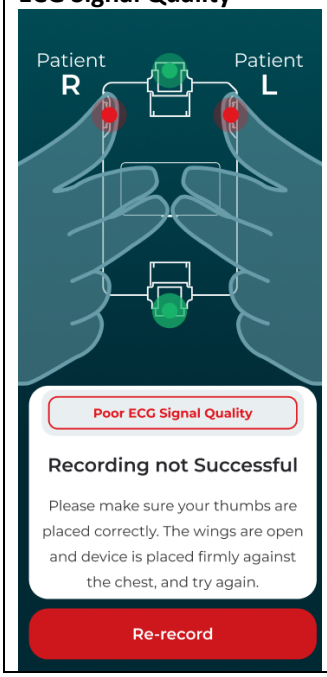
Troubleshooting

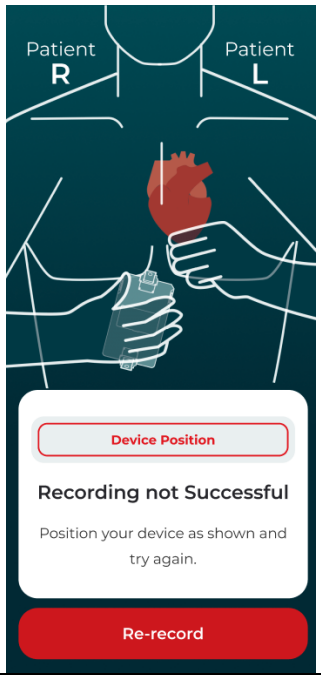
Issue	Solution
Forgot Password 	• Select Forgot Password from the Login Screen, enter your e-mail address and reset instructions will be sent.

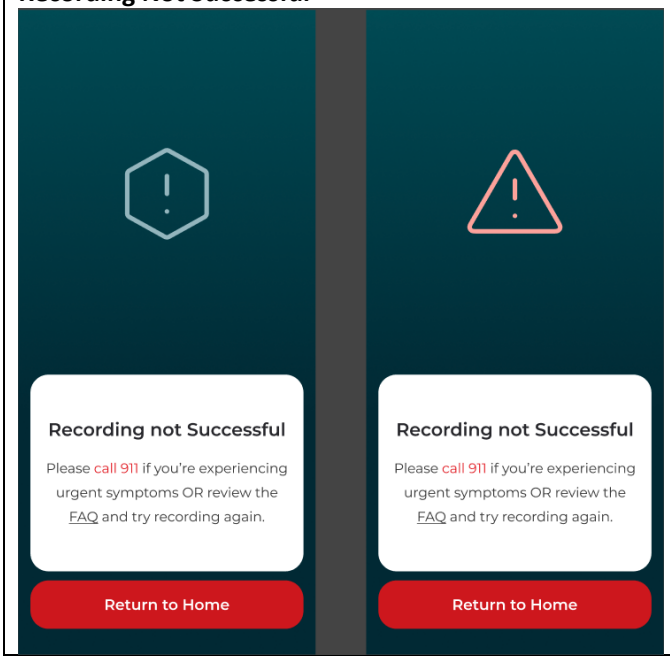
Issue	• Solution
Data connection has been lost 	• Ensure the mobile device cellular and Wi-Fi settings are enabled. • Ensure that Airplane Mode is not enabled on the mobile device. • Ensure mobile device is connected to an active data connection, either via Cellular or Wi-Fi. • Restarting the router or modem may help re-establish internet connection. • Ensure the mobile device is within range of the Wi-Fi network. • If connected to a cellular network, ensure the mobile device has a good connection as indicated in the signal strength icon on the mobile device. Alternatively, connect the mobile device to a personal Wi-Fi. • Test the connection using commercially available internet speed tools (apps or websites). • If the issue persists, contact HeartBeam customer support.

The Bluetooth connection has been lost 	• Ensure that Bluetooth on the mobile device is turned on and try bringing the AIMIGo Device close (within 2-3 feet) to the mobile device to attempt pairing/connecting again. • Make sure the AIMIGo Device has been charged. • Reset the AIMIGo Device: charge the device for 5 seconds and re-try the connection. • Ensure clothing is not covering or blocking the AIMIGo Device. • Make sure patient's mobile device is within 2-3 feet (approximately an arm's length) during device use. • Restart the mobile device and re-launch the Patient App. • Ensure the AIMIGo and patient's mobile device are sufficiently distanced from RF emitters. See RF Communications Equipment Recommended Separation Distances section. • If attempting to make a recording with the AIMIGo in an environment where strong RF emitters may be present, you may need to leave the environment. • If issue persists, contact HeartBeam customer support.
Low Battery 	• Charge the device before attempting recording again (See HeartBeam AIMIGo Device – Charging Process). • If the issue persists, contact HeartBeam customer support.

Battery is too low 	• Charge the device before attempting recording again (See HeartBeam AIMIGo Device – Charging Process). • If the issue persists, contact HeartBeam customer support.

Recording not Successful - Poor ECG Signal Quality
 
	• Press Re-record on the Patient App screen, and ensure that fingers and sensors are placed correctly:
	  ○ The wings on the AIMIGo Device are open and chest sensors are placed firmly against the skin.
	  ○ Confirm Right and Left Thumbs are held against the respective Thumb Sensors.
	  ○ Rest your fingertips on the Front Sensor on the front of the device.
	• Take a deep breath before recording to relax.
	• Remove all clothing and jewelry from upper chest that may interfere with device or sensor placement.
	• Lean back comfortably with proper back support.
	• Allow the AIMIGo Device and hands to move with your chest as you breathe and remain as relaxed as possible.
	• Do not talk or move during the recording.
	• If attempting to make a recording with the AIMIGo in an environment where strong RF emitters may be present, you may need to leave the environment.

Issue	Solution
Recording not Successful - Device Positioning 	• Press Re-Record on the Patient App screen, and ensure the AIMIGo Device is positioned on the chest correctly: ○ Place the device directly on the chest, ○ on the left side of the chest over the heart, ○ 3 to 4 fingers below collarbone, ○ and its edge is aligned with the midline.

Recording Not Successful	
	• ⚠ **WARNING:** Call 911 or seek emergency medical attention if you are experiencing urgent symptoms. • An ECG recording is deemed to have poor quality after two tries and the app will display this warning message. See Home Recordings steps 4-7 for guidance on Device Positioning, Body Positioning, and Finger Placement. • If attempting to make a recording with the AIMIGo in an environment where strong RF emitters may be present, you may need to leave the environment.

Technical Information

Operating Conditions

The HeartBeam AIMIGo Device should only be used and charged when the device is clean and dry.

CAUTION: Do not use the device when wet, and particularly when the contacts of the sensors are wet. The sensors should be dried by gently wiping them with a dry cloth.

Operating Conditions (charging and recording)	
Temperature	+10 °C to +40 °C
Humidity	15 %–93 % RH (non-condensing)
Atmospheric Pressure	700 hPa to 1060 hPa

Storage

The HeartBeam AIMIGo Device and Charging Dock should be stored between uses in a clean and dry environment.

Storage Conditions	
Temperature	-10 °C to +40 °C
Humidity	10 %–95 % RH (non-condensing)
Atmospheric Pressure	500 hPa to 1060 hPa

Cleaning

External surfaces of the AIMIGo Device can be gently wiped with a slightly dampened cloth.

- Alcohol in water (up to 70% ethyl or 70% isopropyl), common household spray cleaners without bleach, or mild detergents with water may be applied to the cloth.
- Do not spray the HeartBeam AIMIGo Device directly with water or any cleaning solutions.

CAUTION: If the Charging Dock or Power Adapter require cleaning, they should be unplugged from the wall first. After unplugging the power adapter from the wall, proceed with the same cleaning procedure and cleaning materials as above.

NOTE: Visually inspect the AIMIGo Device following cleaning for any remaining residue or soiled surfaces. If needed, repeat cleaning with a dampened cloth and reinspect. If the AIMIGo Device remains soiled after repeated cleaning, contact customer support or see Safe Disposal Guidance section.

Device Useful Life

The HeartBeam AIMIGo Device and Charging Dock have an expected useful life of two (2) years under normal use. It is recommended that the system be monitored for any unusual wear or performance degradation.

- The AIMIGo Device should be visually inspected periodically for any form of corrosion or discoloration to the electrodes, any damage to the housing or wings that prevents smooth articulation, and any general damage. If any damage is identified after cleaning, you may contact HeartBeam support for guidance or see Safe Disposal Guidance section. Attempted use beyond this life may result in reduced effectiveness or malfunction.
- The AIMIGo rechargeable battery has an expected useful life of two (2) years, however the life of the device may vary based on use and recharge cycles of the device. Use of the device should be

discontinued when the battery will no longer maintain a charge during use. Attempted use beyond this life may result in reduced effectiveness or malfunction. See Safe Disposal Guidance section for details regarding safe disposal of the AIMIGo.

- The AIMIGo charging dock should be visually inspected periodically for any form of damage to the housing and charging cables. If any damage is identified, you may contact HeartBeam support for guidance or see Safe Disposal Guidance section. Attempted use beyond this life may result in reduced effectiveness or malfunction.
- The declared useful life is separate from the product warranty terms defined in the purchase or subscription agreement.
- You may also contact customer support for any questions about your device, troubleshooting help, and options to return the device to HeartBeam.

Safe Disposal Guidance

CAUTION: The HeartBeam AIMIGo Device and Charging Dock should be disposed of in a safe manner:

- Do Not Dispose in Household Waste: To prevent environmental harm and comply with regulations, do not dispose of this device in household waste bins or dumpsters.
- Recycling Options: Consider recycling this device through authorized electronic waste recycling programs. Many communities offer drop-off locations or collection events for electronic devices.
- Local regulations: Please check with your local waste management authorities for guidelines on the disposal of electronic devices. Different regions may have specific procedures for handling electronic waste.
- Contact Manufacturer: If you have any questions regarding the disposal of this device or need assistance with data erasure, please contact the HeartBeam customer support.
- Data Security: The AIMIGo Device does not store any recording data.

CAUTION: Do not dismantle, disassemble, or tamper with the device or attempt to repair it yourself, as this may cause harm or damage. Keep this device out of reach of children and pets to prevent accidental ingestion or injury.

AIMIGo Device Model Numbers

- AIMIGo Device Hardware REF: **2002A**
- Charging Dock REF: **3002A**

Standards Testing

The HeartBeam AIMIGo Device has been tested to the following standards:

- IEC 60601-1:2020
- IEC 60601-1-2:2014 + A1 (2020)
- IEC 60601-1-11:2015 + A1 (2021)
- 60601-2-47 (for signal acquisition)

Charger Specifications

Wall power adapter specification

- 60601-1 Certified
- Class II (two prong)
- Limited Power Source (LPS)
- DC5V @2A <15W

Device Materials

The Applied Parts (Type BF) of the device are listed in AIMIGo Parts Table below. Also see 'HeartBeam AIMIGo Device Information & Features' section for layout of these parts. These materials comply with FDA guidance for biocompatibility: Use of International Standard ISO 10993-1, published September 8, 2023.

AIMIGo Materials Table	
Part Name	**Material**
RLD Electrode/Sensor, "RLD", "Metal Plate"	304 Stainless Steel
Ridge Side – "Thumb Electrode/Sensor"	Silver-Silver Chloride coated ABS plastic
Top Chest Electrode/Sensor	Silver-Silver Chloride coated ABS plastic
Bottom Chest Electrode/Sensor	Silver-Silver Chloride coated ABS plastic
Housing	Polycarbonate (PC) Plastic
Wing(s) – Top/Upper and Bottom/Lower	Polyetheretherketone (PEEK) Plastic

NOTE: These applied parts should not contact other conductive parts of the device, including earth.

FCC Compliance Statement – ECG Device

The HeartBeam ECG Device complies with applicable FCC Part 15.
FCC ID: **2BQ5Z-HBM2002A**

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.

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

NOTE: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

FCC Compliance Statement – Charging Dock

The HeartBeam ECG Device Wireless Charging Dock complies with FCC Part 18 rules for Industrial, Scientific, and Medical (ISM) equipment. It has been tested and found to comply with the limits for ISM equipment under FCC Part 18.

Operation is subject to the following conditions:

- This equipment may not cause harmful interference.
- This equipment must accept any interference received, including interference that may cause undesired operation.

NOTE: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

FCC RF Exposure Statement

This equipment complies with the FCC radiation exposure limits set forth for an uncontrolled environment. This device has been evaluated and found compliant with the FCC Specific Absorption Rate (SAR) requirements for portable devices. The device is designed to operate with no minimum separation distance between the radiator and the user's body, consistent with the exposure conditions tested.

Electromagnetic Compatibility

CAUTION: The device has been tested for use in a professional healthcare and home healthcare environment per IEC 60601-1-2:2020 for radiated and conducted radio frequency immunity. The device is not intended for use outside of professional healthcare and home environments.

Medical electrical equipment can be affected by mobile communications equipment. Walkie-talkies and emergency service radios are known to generate very strong signals which may cause interference. Interference can result in disruptions in the tracing. Strong electrostatic discharge may result in a disturbance in the displayed tracing without interruption of the recording. This is the expected performance.

Although there are no known reports of mobile (cellular) phone interference, phone technology is continually evolving with varying standards by country so there is the possibility of interference when analyzing ambulatory ECG data.

Because of the potential for interference, it is important to use the accessories provided with your HeartBeam AIMIGo Device to ensure that the device performs as intended. Use of HeartBeam AIMIGo accessories ensures compliance with EMC standard EN60601-1-2:2020. Increased emissions or decreased immunity may result from the use of other accessories.

Electromagnetic Emissions Guidance

The HeartBeam AIMIGo Device is intended for use in the electromagnetic environment specified below. Healthcare professionals and patients should ensure use in the specified environment.

Emissions test	**Compliance**	**Electromagnetic environment recommendation**
RF emissions CISPR 11	Group 1	HeartBeam AIMIGo RF emissions are considered very low and not likely to result in interference in nearby electronic equipment.
RF emissions CISPR 11	Group 1, class B	HeartBeam AIMIGo can be used in all establishments, including domestic locations as well as those directly connected to public low-voltage networks that supply domestic buildings.
Harmonic emissions – IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions – IEC 61000-3-2	Not applicable	

Electromagnetic Immunity Guidance

The HeartBeam AIMIGo device is intended for use in electromagnetic environments typical of home healthcare and professional healthcare facilities. The device maintains essential performance after exposure:

- Recording and transmission of ECG data
- No change to operating mode or specified set up
- No failure, damage, or safety hazard

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment**
Electrostatic discharge IEC 61000-4-2 (Normal Operating Mode & Charging Mode)	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4 (Charging Mode Only)	AC Mains: ±0.5kV, ±1kV, ±2kV Pulse repetition frequency 100kHz	AC Mains: ±0.5kV, ±1kV, ±2kV Pulse repetition frequency 100kHz	The mains power quality should be that of a typical commercial, hospital or home environment.
Surge IEC 61000-4-5 (Charging Mode Only)	AC Mains: Line (L) to Neutral (N): ±0.5kV, ±1kV	AC Mains: Line (L) to Neutral (N): ±0.5kV, ±1kV	The mains power quality should be that of a typical commercial, hospital or home environment.
Voltage dips, short interruptions, voltage variations on power supply input lines IEC 61000-4-11 (Charging Mode Only)	AC Mains: Immunity Test Condition: • 100VAC/50Hz, 120VAC/60Hz, 240VAC/60Hz Voltage Dips • 0% UT:0.5 cycle @ 0, 45, 90. 135, 180, 225, 270 and 315° • 0% UT: 1.0 cycle • 70%, UT25/ 30 cycle Voltage Interruptions: 0% UT: 250/300 cycle	AC Mains: Immunity Test Condition: • 100VAC/50Hz, 120VAC/60Hz, 240VAC/60Hz Voltage Dips • 0% UT:0.5 cycle @ 0, 45, 90. 135, 180, 225, 270 and 315° • 0% UT: 1.0 cycle • 70%, UT25/ 30 cycle Voltage Interruptions: 0% UT: 250/300 cycle	The mains power quality should be that of a typical commercial, hospital or home environment.
Power frequency (50/60 Hz)	30 A/m at 50/60 Hz	30 A/m at 50/60 Hz	Power frequency magnetic

magnetic field IEC 61000-4-8 (Normal Operating Mode & Charging Mode)			fields should be at levels consistent with a typical hospital or home environment.

Electromagnetic Radiofrequency (RF) Immunity Guidance

The HeartBeam AIMIGo device is intended for use in electromagnetic (RF) environments typical of home healthcare and professional healthcare facilities. The device maintains essential performance during and after exposure, subject to the precautions below.

- Recording and transmission of ECG data
- No change to operating mode or specified set up
- No failure, damage, or safety hazard

CAUTION: This device may experience temporary signal disturbance or Bluetooth connection issues when exposed to electromagnetic interference. To ensure accurate recordings:

DO NOT USE nearby:

- MRI equipment
- Diathermy and electrocautery machines
- Security systems (electromagnetic anti-theft systems (EAS) and metal detectors)
- RFID security gates (store entrances, libraries); RFID tags (including Access control systems)
- NFC-enabled devices (including smartphones, electronic payment terminals and card readers)
- Wireless-power-transfer (WPT), (including wireless charging pads and stations)
- 5G wireless devices

CAUTION: While brief exposure to interference sources will not damage the device and normal operation will resume once moved away from the interference source, repeated exposure should be avoided.

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment**
Conducted RF IEC 61000-4-6 (Charging Mode Only)	3 V/m 150 kHz – 80 MHz 6 V (ISM and amateur radio)	3 V 1 kHz 80% AM 6 V (ISM and amateur radio)	Professional and home healthcare environments, including 6 V disturbances in Industry, Scientific and Medical (ISM) bands and amateur radio bands.
Radiated RF IEC 61000-4-3 (Normal Operating Mode & Charging Mode)	10 V/m 80 MHz – 2.7 GHz	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the HeartBeam AIMIGo Device than the recommended separation distance calculated from the equation applicable at the frequency of the transmitter: $d = 0.7\sqrt{P}$ P = maximum output power of transmitter in watts (W) according to the transmitter manufacturer d = recommended separation distance Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[1], should be less than the compliance level in each frequency range. Interference may occur in the

			vicinity of equipment marked with the following symbol: 
Radiated Fields in Close Proximity IEC 61000-4-39 (Normal Operating Mode & Charging Mode)	30kHz @8A/m, CW 134.2 kHz @ 65A/m, 2.1kHz PM 50% DC 13.56 MHz @ 7.5A/m, 50kHz PM 50% DC	8A/m 65A/m 7.5A/m	Check recommended separation distance from table below to ensure safe operation without interference, based on the decay rate of electromagnetic fields at the frequency of operation.

[S1]Fixed transmitters, such as radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM/FM radio broadcast and TV broadcast field strengths cannot be predicted with 100% accuracy. An electromagnet site survey should be considered to assess electromagnetic environment due to fix RF transmitters. If the measured field strength exceeds the applicable RF compliance level listed above, device use should be observed to verify normal operation. If abnormal performance occurs, additional measures may be required including reorienting or relocating the device.

RF Communications Equipment Recommended Separation Distances

The HeartBeam AIMIGo Device is intended for use in professional healthcare and home environments in which radiated RF disturbances are controlled. Electromagnetic interference can be prevented during the expected use life by maintaining a minimum distance between the device and portable and mobile RF communications equipment (i.e., transmitters) as recommended below, according to the maximum output power of the communications equipment. Use of the AIMIGo System outside of these recommendations may result in Bluetooth interference.

CAUTION: The HeartBeam AIMIGo Device should not be used near diathermy, and electrocautery machines. Additionally, avoid use near security systems (e.g., electromagnetic anti-theft systems (EAS), and metal detectors).

CAUTION: The HeartBeam AIMIGo Device Bluetooth communication may be susceptible to electromagnetic interference from Wireless-power-transfer (WPT) and 5G wireless signals. If a device communication malfunction is observed, move away from potential interference sources, or move to a different environment. See Troubleshooting section for more information.

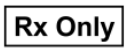
Rated max power of transmitter (P)	**Separation – based on transmitter frequency (m)**		
	(Conducted Immunity) 150 kHz to 80 MHz $d = 1.17\sqrt{P}$ **coex E= 3 Vrms 6Vrms**	**(Radiated immunity) 80 MHz to 800 MHz** $d = 0.35\sqrt{P}$ **E=10 V/m (3 m)**	**(Radiated immunity) 800 MHz to 2.5 GHz** $d = 0.7\sqrt{P}$ **E=10 V/m (1.5 m) or 20 V/m**
0.01w	0.12m	0.04m	0.07m
0.1w	0.36m	0.11m	0.22m
1w	1.17m	0.35m	0.7m
10w	3.74m	1.12m	2.24m
100w	11.7m	3.5m	7m

Where *P* is the maximum power in W, *d* is the minimum separation distance in m, and *E* is the IMMUNITY TEST LEVEL in V/m.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Symbols & Definitions

Symbol	Description	Notes
	**Warning:** Consult Accompanying Documents	
	Consult instructions for use	
	Manufacturer	HeartBeam, Inc.
	Type BF Applied Part	
IP52	Ingress Protection Rating	Device protected against limited dust ingress and dripping water up to 15° from vertical
	Keep Dry	Device packaging should be kept dry
	For Prescription Use Only (U.S.)	
	**Warning:** MR-Unsafe. Do not use the equipment near an MRI machine / MRI scan room.	
	Date of Manufacturer	e.g. MM-DD-YYYY; 01-01-2025
	Lot / Batch Number	e.g. LOT XXXX
	Medical Device	
	Unique Device Identifier (UDI)	Both human and machine readable
	Serial Number	e.g. A000001
REF	Catalog or Model Number	e.g. 2002A

	Non-Sterile	
	Single Patient Multiple Use	
	Storage Temperature Limit	
	Do not use if package is damaged	
	Do Not dispose with household waste	

Customer Support Contact Information

For assistance in setting up, using, or maintaining the AIMIGo Device, or to report any unexpected operating events, contact Customer Service:

Customer Support Toll-free number: ***1-(844)- 4-HEARTB*** 1-(844)-443-2782
Customer Support E-mail: **Support@heartbeam.com**
Mail to: **HeartBeam Inc., 2118 Walsh Ave., Ste 210, Santa Clara, CA 95050**

Manufacturer

HeartBeam, Inc.
2118 Walsh Ave. Ste 210
Santa Clara, CA 95050
www.heartbeam.com