CardioTag™

Instructions For Use

Caution: Federal law restricts this device to sale by or on the order of a physician.

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www.cardiosense.com

Indication For Use

The CardioTag device is a tool that can be used to record, display and transfer vibrational waveforms produced by the heart contractions and transmitted to the chest as well as single-channel electrocardiogram (ECG) rhythms and heart rate. It also measures pulse waveform and pulse rate by photoplethysmograph (PPG). The CardioTag may be used as a tool to measure the timing of the aortic valve opening and closing in the cardiac cycle. The CardioTag is intended for spot-checking of adult patients in clinics or at home under the care of a physician. The data from the CardioTag is intended for use by healthcare professionals as an aid to diagnosis and treatment.

Description

The CardioTag device consists of a rechargeable wearable that is responsible for collecting raw cardiac signals from a single patient, and produces a spot-check report of a patient's electrocardiogram (ECG), photoplethysmogram (PPG), and seismocardiogram (SCG) signals and heart rate. To generate the report, the user places the wearable on the sternum and starts a 2 minute recording session for waveform output and heart rate /pulse rate calculation. The wearable contains electrodes to measure single-lead ECG, light sources and optical sensor arrays to measure PPG, and an accelerometer to measure vibrational waveforms from the heart's contractions transferred to the chest wall (SCG). Sensor data is then transferred for storage and processing (e.g. to a cloud-based backend). The backend uses the recording to calculate heart rate and pulse rate and then visualizes the waveforms and heart rate in the format of a downloadable PDF report for the clinician. The SCG signal is intended to be used for manual interpretation by the clinician in conjunction with other information from the device. The device may be used as a tool to measure the timing of the aortic valve opening and closing in the cardiac cycle.

Getting To Know The Device

Figure 1 below shows the CardioTag device that is included:

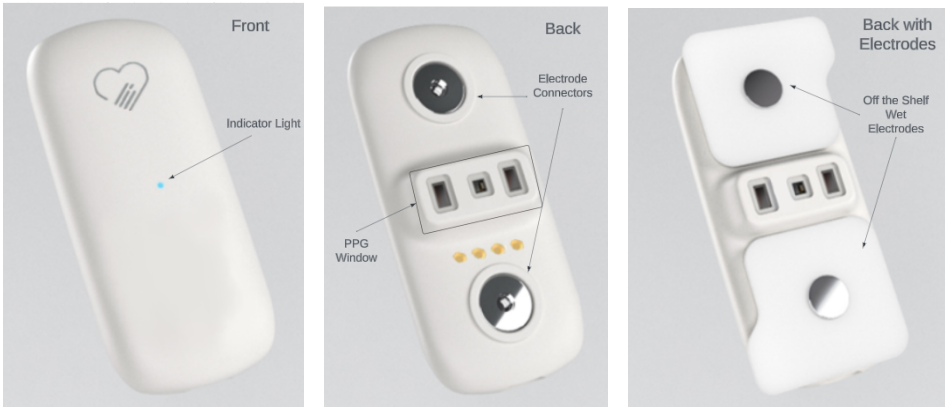

Figure 1. CardioTag wearable device showing front (left), back (middle), and back with electrodes connected to the snaps (right) views. (*note: actual colors may vary)

The CardioTag is for indoor use only. With the CardioTag device, the following should also be found with the device:

- Disposable Electrodes. Legally marketed off-the-shelf wet electrodes sufficient for cardiac monitoring can be used on the CardioTag device and can be purchased on most medical supply sites (ex. 3M™ Red Dot™ Repositionable Monitoring Electrode, 2600 Series | 3M United States). Please contact Cardiosense customer service if more help is needed or there are questions.
- Disposable Alcohol Wipes
- Charging Station:

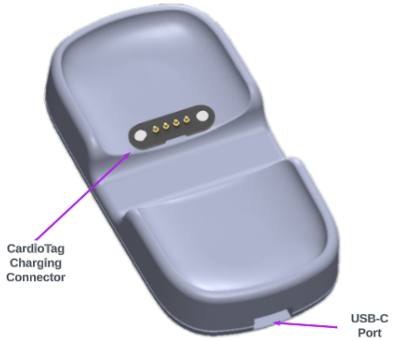

Figure 2: CardioTag charging station (*note: actual color may vary)

- USB Charging Cable

Additionally, the following items will also be needed:

- Tools for prepping or shaving chest area, as needed
- USB-A certified wall adapter
- PC or mobile device with internet access and a compatible web browser (Google Chrome v120.x or later is supported using a WPA2-Personal wireless network)

Note: Check that the CardioTag device setup page can be accessed at Cardiosense's device setup web page (https://cardiotagsetup.cardiosense.com) via a web browser. This is where the CardioTag device can be configured to a local Wi-Fi network during device setup. If there is visible damage to the CardioTag device or if any of the other components are missing or damaged, or the device setup web page cannot be reached, Cardiosense customer support should be contacted for assistance at support@cardiosense.com.

Caution:

- DO NOT store in conditions outside of those specified in the Product Storage section.
- DO NOT use the device if the patient has known allergies to wet electrodes, or sensitive areas (e.g. healing surgical sites or wounds).
- DO NOT use the electrodes on the body when wet, as a successful recording may not be possible.
- DO NOT use the CardioTag device during an MRI scan, or around high frequency surgical devices.
- DO NOT use the CardioTag during the application of external defibrillation.
- DO NOT use the CardioTag if it appears to be damaged.
- DO NOT get the CardioTag device wet or expose to excessive moisture.
- DO NOT drop or bump with excessive force.
- DO NOT use the CardioTag on patients under 21 years of age.
- Seismocardiography should not be performed as an independent diagnostic test.
- DO NOT rely on CardioTag ECG Heart Rate readings in the presence of arrhythmias, such as atrial fibrillation (AFib).
- Pacemaker spikes are not rejected by the CardioTag device. Do not rely on CardioTag ECG Heart Rate readings for patients with a pacemaker.

Note: If you experience any skin irritation, redness, itching, or a rash, contact support@cardiosense.com.

Portable RF communications equipment should be used no closer than 30 cm (12 inches) to any part of the CardioTag during data transmission.

Cardiosense makes no warranty for any data or information that is collected erroneously by the device, or misuse or malfunction as a result of abuse, accidents, alteration, misuse, neglect, or failure to maintain the products as instructed. Interpretations made by this device are potential findings, not a complete diagnosis of cardiac conditions. All interpretations should be reviewed by a medical professional for clinical decision making.

For Clinician Use Only: The following section is for Healthcare Providers

If you have any questions on setting up CardioTag(s) or interpretation of the PDF report(s), please contact Cardiosense at support@cardiosense.com. Cardiosense will provide detailed instructions to individual Healthcare Providers to assist with the following:

- Obtaining and tracking CardioTag devices for use in your practice.

- Obtaining the PDF Report after the CardioTag device is used by your patient(s).

Check with the patient if they have any known allergies that may prevent them from using the device.

When interpreting report results, note that **Heart Rate** is derived from the ECG waveform, whereas **Pulse Rate** is derived from the PPG waveform. If the displayed calculated values differ, use your clinical interpretation of the corresponding waveforms to make a clinical decision.

Using the CardioTag Device

Charging The CardioTag Device

All CardioTags should be charged before initial use and in between every use.

- To charge the CardioTag, remove the CardioTag, charging station, and cables from the package.
- Place the CardioTag in its charging station.
- Connect the smaller end of the provided USB cable (the USB-C side) to the Charging Station. Connect the larger end (the USB-A side) of the cable to a wall charging adapter. Plug the adapter into the wall.
- Charge until the device's LED is solid white, indicating it is ready for use.

Note: Ensure that the charging station is on a flat surface away from children, pets, water sources, or any moving objects. Charging can only start when the charging station is properly and carefully connected to the USB power adapter using a USB-C cable.

Setting Up The CardioTag

- Carefully connect the larger end of the provided USB cable (i.e. the USB-A side) of the cable to a PC. If not already connected, plug the smaller end of the USB cable (i.e. the USB-C side) into the Charging Station.
- Navigate to Cardiosense's device setup web page (https://cardiotagsetup.cardiosense.com).
- Select "Connect to USB Device", as shown in Figure 3. Select your "CardioTag" device, and then select "Configure" to connect, as shown in Figure 4. Follow the subsequent onscreen instructions to connect the device to a local Wi-Fi network.

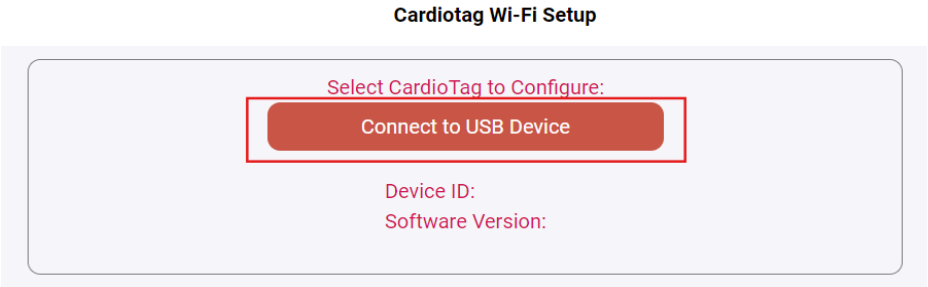

Figure 3: Wi-Fi Setup, “Connect to USB Device” option

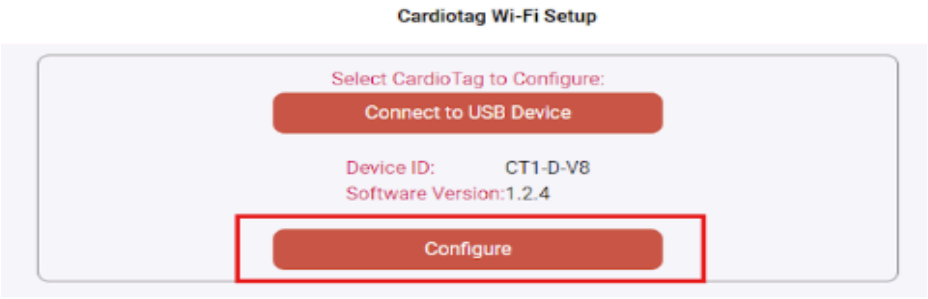

Figure 4: Wi-Fi Setup, “Configure” option

- When setup is complete, unplug the charging station from the PC and plug the charging station into the power adapter until the CardioTag’s LED is solid white.

Recording the first measurement session

A. Preparing the patient’s skin

- If body hair is present on the patient’s sternum, shave the hair on the sternum completely (see Figure 7 for anatomical location).
- Use a 70% isopropyl alcohol wipe to clean the CardioTag placement site area on the patient’s skin (Figure 8). Allow the area to dry completely. Do not apply lotions, oils, or perfumes.

B. Attaching the CardioTag and Recording Data

- Remove the CardioTag from the charging station.
- Attach one wet electrode on each of the metal snaps on the back of the CardioTag. Rotate the electrodes if they cover the windows on the back side of the CardioTag, as shown in (A) of Figure 5:

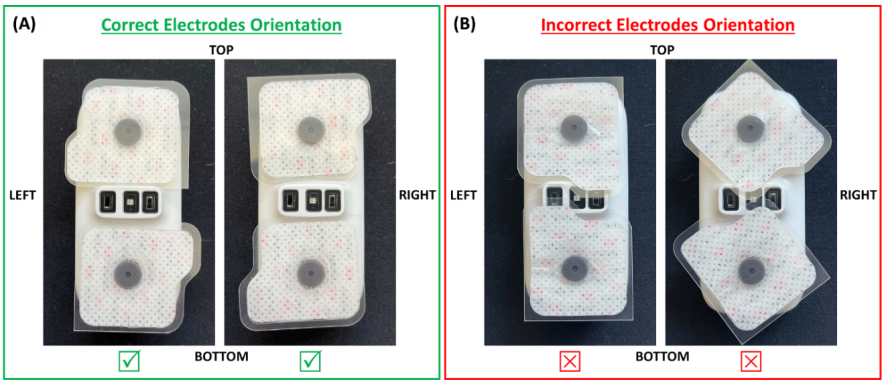

Figure 5: (A) Correct and (B) Incorrect CardioTag Electrodes Orientation

- Remove the clear plastic backing of the two (2) electrodes that are attached to the back of CardioTag to expose the adhesive surface.
- Patients should lie down in a flat position on their back with their legs straight in front of them (i.e. in a supine position) on a comfortable surface, as shown in Figure 6 below.

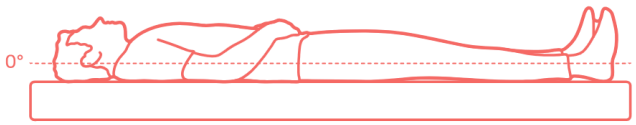

Figure 6: Patient Position during CardioTag data collection

- Using Figure 7 as an anatomical reference, place the CardioTag device perpendicular on the center of the patient's sternum with the upper edge of the top electrode two finger widths below the bottom of the suprasternal notch, as shown in Figure 8. Make sure the heart logo is upright. Press the CardioTag firmly on the sternum to make sure it is attached.
- Confirm that the CardioTag's LED is flashing green, which will confirm that the data measurement session has started.
- Have the patient remain still for two (2) minutes, or 120 seconds, while the CardioTag is recording. Once the measurement session has completed, the device LED will turn solid green.

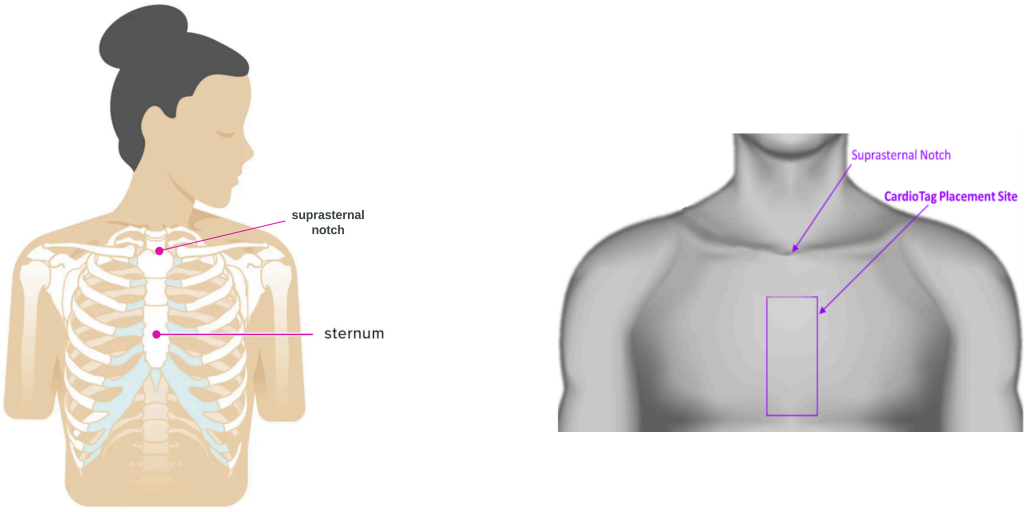

Figure 7: Suprasternal notch and sternum, anatomy view

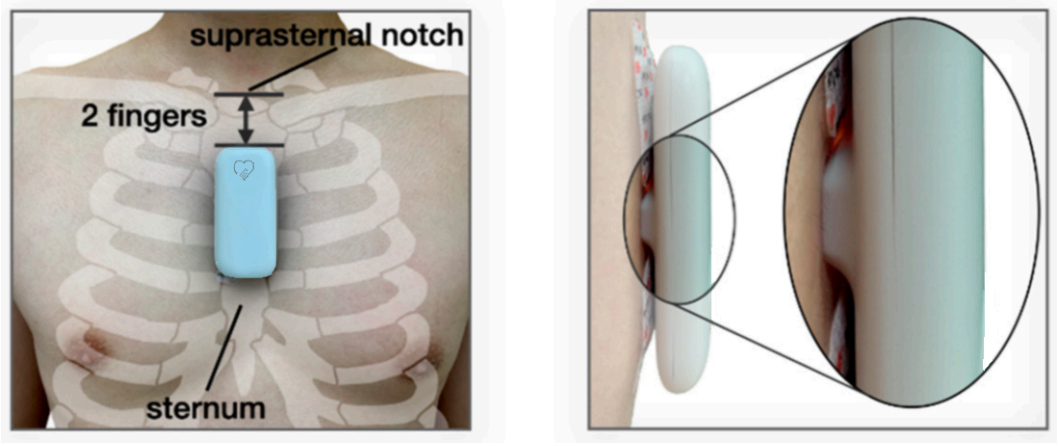

Figure 8: Estimate of CardioTag Placement Site, and correct Placement of the CardioTag on the chest via electrodes

Note: Be sure to snap on the two electrodes to the CardioTag's two Electrode Connectors before placing the CardioTag on the patient's chest. If the CardioTag must be reapplied for any reason, the two (2) electrodes attached to the back of the CardioTag must be replaced with new electrodes to ensure a good connection.

C. Removing the CardioTag, cleaning, and transmitting session data

- After the CardioTag's LED turns green, with your fingers, hold the electrode pads down and with the other hand gently snap the CardioTag off the electrode. Repeat for the second electrode to detach the CardioTag.
- Once the CardioTag is completely detached, remove and dispose of the used electrodes from the patient's chest.
- Use a 70% isopropyl alcohol wipe to clean all surfaces of the CardioTag, ensuring that all surfaces of the device are thoroughly wiped.

- Allow the CardioTag to air dry for a few minutes, or until all residual alcohol has evaporated from the surface.
- Place the CardioTag back on the charging station.

Note: If the CardioTag's LED is red or there is no color on the LED, indicating that the device has run out of battery prior to the end of the data recording session, remove the CardioTag using the steps above and charge the device.

D. Disposing of the CardioTag device

- Repeat sections A-C to record for as many two minute sessions as needed during the prescribed monitoring period. The CardioTag should be removed from the body after each 2-minute session and placed on the charging station in order to generate a report. After each use, the disposable electrodes should be replaced.
- When the CardioTag is no longer needed or becomes inoperable, dispose of it as electronic waste according to local regulations. Do not dispose of it in the normal trash.

CardioTag Indicator Light Patterns

Use the following table to interpret the CardioTag's status via its LED Indicator Light. For actions or statuses indicating an error, refer to the Troubleshooting section for suggestions on next steps.

Action/State	Indicator Light Pattern	CardioTag Status
CardioTag is on its charging station. The charging station is plugged either into a PC (for device wireless setup) or to the wall outlet via the wall adapter for charging.	None	Battery = 0%
	1 White Flash (every ~2 sec)	CardioTag's battery is is charging, do not remove from charging station
	1 White Flash (every ~0.5 sec)	CardioTag is transmitting data files from completed session, do not remove from charging station
	Solid White	CardioTag ready for use (i.e. battery > 25%, data files uploaded successfully, etc.)
	1 Yellow Flash (every ~2 sec)	CardioTag unable to connect to WiFi . Troubleshoot and/or (re)complete device setup
CardioTag (Undocked, electrodes are either on or off of device, not placed on chest)	None	CardioTag is idle OR Battery = 0%
	1 Red Flash (every ~1 sec)	Low battery/Return CardioTag to Docking Station
CardioTag (with electrodes attached) is placed on chest	Flashing Green (every ~5 sec)	Recording is in progress (2 min). Keep device on chest
	Solid Green	Recording is complete. Device can be removed from the chest
	1 Red Flash (every ~1 sec)	Low battery/Return CardioTag to charging station
	None	Battery = 0%
An error has occurred in any of the above scenarios	Solid Red	CardioTag has encountered an error. Refer to the troubleshooting section.

Troubleshooting

If difficulties in operating the CardioTag product are experienced, refer to the quick troubleshooting guide below or, for further assistance, contact technical support at support@cardiosense.com

Problem: The CardioTag was received severely damaged or has missing components	**Solution** Contact customer support to receive replacements for the damaged components. Do not attempt to use the damaged components
Problem: The CardioTag's LED is not blinking white when it is charging while on the charging station, or the LED is red while it is on the charging station	**Solution** Option 1: Ensure that the USB cable and charging station are properly connected Option 2: Ensure that the USB cable and wall adapter are properly connected Option 3: Remove the CardioTag from the charging station and place it back on
Problem: The CardioTag's LED is red during the device set up process while the device is on the charging station and the charging station is plugged into the PC	**Solution** Option 1: Ensure that the USB cable and charging station are properly connected Option 2: Ensure that the USB cable is properly connected to the PC Option 3: The WiFi credentials could not be set for the device. Follow the onscreen instructions on PC web browser to retry again
Problem: The CardioTag doesn't stay adhered to my chest properly	**Solution** Option 1: Check that the attached electrodes are connected properly to the CardioTag Option 2: Ensure that the device placement site on the chest is properly cleaned and shaved and there is no perspiration Option 3: Remove the CardioTag, dispose of the current electrodes, and replace the device with new electrodes
Problem: The CardioTag LED turns red during a recording session, or I do not see the CardioTag's LED blink green during an active recording session	**Solution** Option 1: Remove the CardioTag AND electrodes off of the patient's chest, dispose of the current electrodes, and replace the device with new electrodes to restart the session Option 2: While the recording is in progress, ensure the patient has their arms and hands relaxed or rested on a flat surface. Ensure that the CardioTag is not accidentally knocked out of place
Problem: The CardioTag's LED turns red or is blinking red when it is removed from the charging station, before it has been placed on the patient's chest	**Solution** Option 1: Ensure that the Wi-Fi connection is stable. Place the CardioTag back onto the charging station, ensure that the LED is solid white when the device is "ready to use", and re-remove it from the charging station when the LED is solid white.
Problem:	**Solution** Remove the CardioTag and its electrodes from the patient's

The CardioTag's LED started blinking red in the middle of the current recording session, before it has indicated the end of the two minute measurement period	chest, dispose of the electrodes, clean the CardioTag device, and place it on the charging station to charge. When charging is complete, repeat the test.
Problem: The CardioTag's LED does not show a solid (i.e. non-flashing) green light after a completed measurement session, and more than 2 minutes has passed	**Solution** Remove the CardioTag and electrodes from the patient's chest, dispose of the electrodes, and replace the CardioTag with new electrodes to try again
Problem: The CardioTag's LED turns red when it is placed in the charging station, right after a two minute measurement session is recorded.	**Solution** Remove the CardioTag from the charging station and re-dock it. Check the LED status. Re-record another measurement session at the healthcare provider's discretion
Problem: The CardioTag's LED is not solid (i.e. non-flashing) white to show that it is fully charged or is ready for use, and it has been on the charging station for longer than 2 hours	**Solution** Remove the CardioTag from the charging station and re-dock it. Check the LED status after ~5 minutes
Problem (HCPs Only): The recorded measurements show a lot of artifact, noise, or interference in the report	**Solution** Option 1: Advise the patient to keep their arms and hands still and relaxed during the 2 minute recording period Option 2: Advise the patient to make sure their chest and CardioTag is properly cleaned using the provided disposable wipes in between uses Option 3: Ensure that the patient has properly identified their suprasternal notch and the placement on the sternum is per these instructions Option 4: If feasible, advise the patient to have a healthcare professional guide the device placement on them, either in a clinic, via telehealth session, or at their home

Performance

ECG Heart Rate Accuracy: ±5 bpm or 10% of the actual heart rate, whichever is greater

PPG Pulse Rate Accuracy: ±2 bpm

The PPG waveform is intended for determining the adequacy of the signal quality.

Technical Specifications

ECG Heart Rate Range: 30–230 bpm

PPG Pulse Rate Range: 30–230 bpm

Max T-wave Amplitude: 2.1 mV

The average heart rate will be displayed in beats per minute. Heart rate is calculated as the time interval between consecutive heart beats. Specifically, the inverse of the time interval between successive R waves in the QRS complex. The average heart rate is the average of this inverse calculation over 80 seconds.

Battery: 1.5 hour charging

Communications

Communication Technology: WiFi
Quality of Service (QoS) needed: Not Required. (If transmission is not successful, the device will attempt to transmit until successful.)
Operating frequency: 2450 MHz
Transmission power: maximum 18.3 dBm
Security: WPA2-Personal wireless network
Operating Range (docked CardioTag to router): Up to 150 ft
When docked after a read, the CardioTag will transmit data to the cloud over WiFi. If the connection is lost during transmission, the transmission will begin again once WiFi has been reestablished.

Product Storage and Operating Conditions

Storage:

- Temperature: 0 – 40 °C/32 – 104 °F
- Humidity: 10 – 90% RH

Operating:

- Temperature: 5 – 40 °C/41 – 104 °F
- Humidity: 15 – 90% RH
- Atmospheric Pressure: 70 – 106 kPa
- Ingress Protection Rating: IP22

Electromagnetic, Immunity, and Other Interferences

- Test Standard(s): IEC 60601-1-2:2020 and 60601-4-2:2018
- Emissions Class/Group: Class B/Group 1
- Immunity Test Level: 3 V/m & 10 V/m

Symbols

The following symbols apply to the the CardioTag device:


Read instructions before use


Manufacturer

MR Unsafe


Type CF Applied Part

Temperature Range (Operating)

Humidity Range (Operating)

Atmospheric Pressure Range (Operating)

Model Number

 Do not dispose with household waste

SN Serial Number

Rx Only By Prescription Use Only

Contact Information

For additional support not specified in this document, contact Cardiosense support: support@cardiosense.com

LEGAL

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Getting To Know The Device

Figure 1 below shows the CardioTag device that is included:

Figure 1. CardioTag wearable device showing front (left), back (middle), and back with electrodes connected to the snaps (right) views. (*note: actual colors may vary)

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- Disposable Alcohol Wipes
- Charging Station:

Figure 2: CardioTag charging station (*note: actual color may vary)

- USB Charging Cable

Additionally, the following items will also be needed:

- Tools for prepping or shaving chest area, as needed
- USB-A certified wall adapter
- PC or mobile device with internet access and a compatible web browser (Google Chrome v120.x or later is supported using a WPA2-Personal wireless network)

Note: Check that the CardioTag device setup page can be accessed at Cardiosense's device setup web page (https://cardiotagsetup.cardiosense.com) via a web browser. This is where the CardioTag device can be configured to a local Wi-Fi network during device setup. If there is visible damage to the CardioTag device or if any of the other components are missing or damaged, or the device setup web page cannot be reached, Cardiosense customer support should be contacted for assistance at support@cardiosense.com.

For Clinician Use Only: The following section is for Healthcare Providers

Prior to using the CardioTag device or distributing to patients for home-use, please contact Cardiosense at support@cardiosense.com. Cardiosense will provide detailed instructions to individual Healthcare Providers to assist with the following:

- Obtaining and tracking CardioTag devices for use in your practice.
- Obtaining the PDF Report after the CardioTag device is used by your patient(s).

Check with the patient if they have any known allergies that may prevent them from using the device.

Using the CardioTag Device

Charging The CardioTag Device

All CardioTags should be charged before initial use and in between every use.

- To charge the CardioTag, remove the CardioTag, charging station, and cables from the package.
- Place the CardioTag in its charging station.
- Connect the smaller end of the provided USB cable (the USB-C side) to the Charging Station. Connect the larger end (the USB-A side) of the cable to a wall charging adapter. Plug the adapter into the wall.
- Charge until the device's LED is solid white, indicating it is ready for use.

Note: Ensure that the charging station is on a flat surface away from children, pets, water sources, or any moving objects. Charging can only start when the charging station is properly and carefully connected to the USB power adapter using a USB-C cable.

Setting Up The CardioTag

- Carefully connect the larger end of the provided USB cable (i.e. the USB-A side) of the cable to a PC. If not already connected, plug the smaller end of the USB cable (i.e. the USB-C side) into the Charging Station.
- Navigate to Cardiosense's device setup web page (https://cardiotagsetup.cardiosense.com).
- Select "Connect to USB Device", as shown in Figure 3. Select your "CardioTag" device, and then select "Configure" to connect, as shown in Figure 4. Follow the subsequent onscreen instructions to connect the device to a local Wi-Fi network.

Figure 3: Wi-Fi Setup, "Connect to USB Device" option

Figure 4: Wi-Fi Setup, "Configure" option

- When setup is complete, unplug the charging station from the PC and plug the charging station into the power adapter until the CardioTag's LED is solid white.

Recording the first measurement session

A. Preparing the patient's skin

- If body hair is present on the patient's sternum, shave the hair on the sternum completely (see Figure 7 for anatomical location).
- Use a 70% isopropyl alcohol wipe to clean the CardioTag placement site area on the patient's skin (Figure 8). Allow the area to dry completely. Do not apply lotions, oils, or perfumes.

B. Attaching the CardioTag and Recording Data

- Remove the CardioTag from the charging station.
- Attach one wet electrode on each of the metal snaps on the back of the CardioTag. Rotate the electrodes if they cover the windows on the back side of the CardioTag, as shown in (A) of Figure 5:

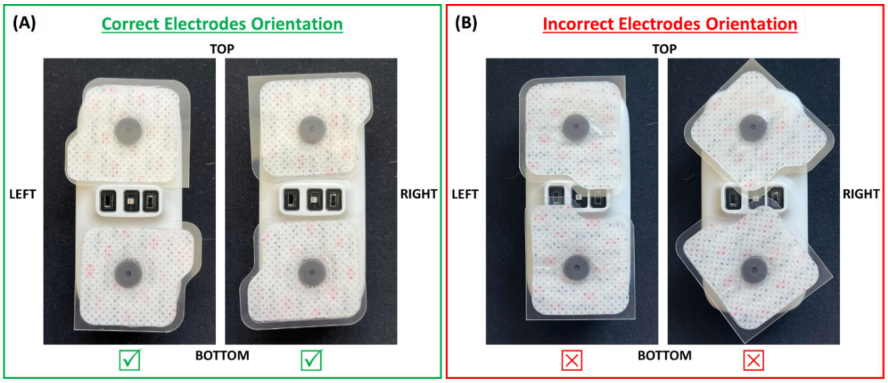

Figure 5: (A) Correct and (B) Incorrect CardioTag Electrodes Orientation

- Remove the clear plastic backing of the two (2) electrodes that are attached to the back of CardioTag to expose the adhesive surface.
- Patients should lie down in a flat position on their back with their legs straight in front of them (i.e. in a supine position) on a comfortable surface, as shown in Figure 6 below.

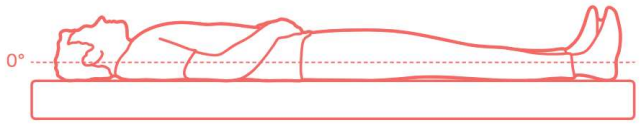

Figure 6: Patient Position during CardioTag data collection

Note: Cardiosense recommends the above position for patients; however, if not possible, patients can also sit in a comfortable chair at a 90 degree angle.

- Using Figure 7 as an anatomical reference, place the CardioTag device perpendicular on the center of the patient's sternum with the upper edge of the top electrode two finger widths below the bottom of the suprasternal notch, as shown in Figure 8. Make sure the heart logo is upright. Press the CardioTag firmly on the sternum to make sure it is attached.
- Confirm that the CardioTag's LED is flashing green, which will confirm that the data measurement session has started.
- Have the patient remain still for two (2) minutes, or 120 seconds, while the CardioTag is recording. Once the measurement session has completed, the device LED will turn solid green.

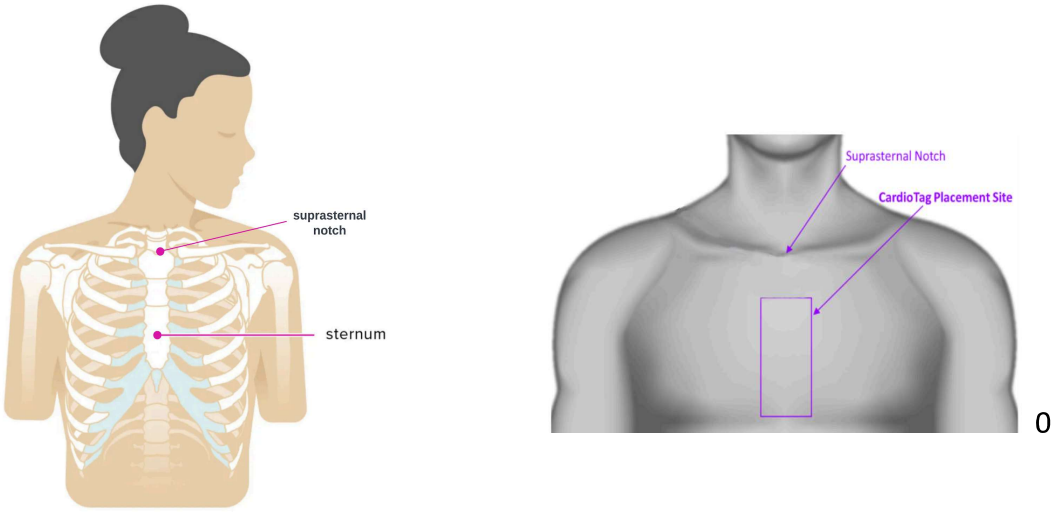

Figure 7: Suprasternal notch and sternum, anatomy view

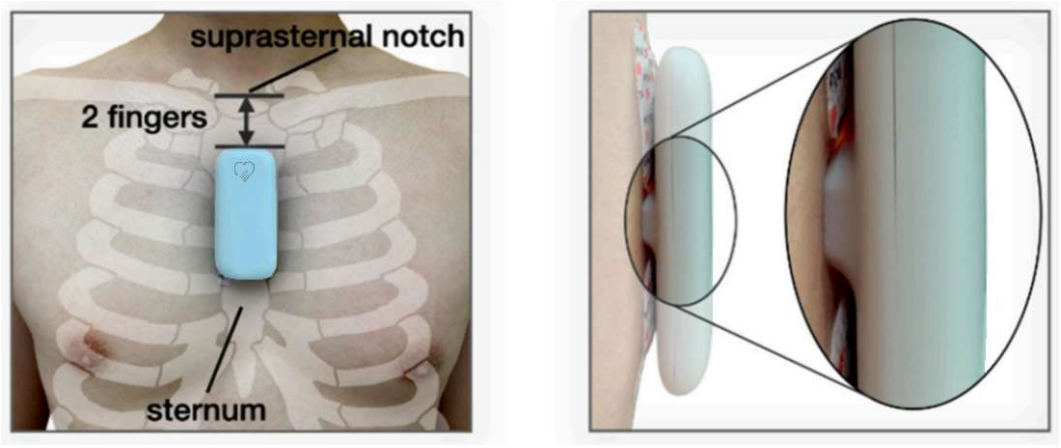

Figure 8: Estimate of CardioTag Placement Site, and correct Placement of the CardioTag on the chest via electrodes

Note: Be sure to snap on the two electrodes to the CardioTag's two Electrode Connectors before placing the CardioTag on the patient's chest. If the CardioTag must be reapplied for any reason, the two (2) electrodes attached to the back of the CardioTag must be replaced with new electrodes to ensure a good connection.

c. **Removing the CardioTag, cleaning, and transmitting session data**

- After the CardioTag's LED turns green, with your fingers, hold the electrode pads down and with the other hand gently snap the CardioTag off the electrode. Repeat for the second electrode to detach the CardioTag.
- Once the CardioTag is completely detached, remove and dispose of the used electrodes from the patient's chest.
- Use a 70% isopropyl alcohol wipe to clean all surfaces of the CardioTag, ensuring that all surfaces of the device are thoroughly wiped.

- Allow the CardioTag to air dry for a few minutes, or until all residual alcohol has evaporated from the surface.
- Place the CardioTag back on the charging station.

Note: If the CardioTag's LED is red or there is no color on the LED, indicating that the device has run out of battery prior to the end of the data recording session, remove the CardioTag using the steps above and charge the device.

D. Disposing of the CardioTag device

- Repeat sections A-C to record for as many two minute sessions as needed during the prescribed monitoring period.
- When the CardioTag is no longer needed, dispose of it as electronic waste.

CardioTag Indicator Light Patterns

Use the following table to interpret the CardioTag's status via its LED Indicator Light. For actions or statuses indicating an error, refer to the Troubleshooting section for suggestions on next steps.

Action/State	Indicator Light Pattern	CardioTag Status
CardioTag is on its charging station. The charging station is plugged either into a PC (for device wireless setup) or to the wall outlet via the wall adapter for charging.	None	Battery = 0%
	1 White Flash (every ~2 sec)	CardioTag's battery is is charging, do not remove from charging station
	1 White Flash (every ~0.5 sec)	CardioTag is transmitting data files from completed session, do not remove from charging station
	Solid White	CardioTag ready for use (i.e. battery > 25%, data files uploaded successfully, etc.)
	1 Yellow Flash (every ~2 sec)	CardioTag unable to connect to WiFi . Troubleshoot and/or (re)complete device setup
CardioTag (Undocked, electrodes are either on or off of device, not placed on chest)	None	CardioTag is idle OR Battery = 0%
	1 Red Flash (every ~1 sec)	Low battery/Return CardioTag to Docking Station
CardioTag (with electrodes attached) is placed on chest	Flashing Green (every ~5 sec)	Recording is in progress (2 min). Keep device on chest
	Solid Green	Recording is complete. Device can be removed from the chest
	1 Red Flash (every ~1 sec)	Low battery/Return CardioTag to charging station
	None	Battery = 0%
An error has occurred in any of the above scenarios	Solid Red	CardioTag has encountered an error. Refer to the troubleshooting section.

Troubleshooting

If difficulties in operating the CardioTag product are experienced, refer to the quick troubleshooting guide below or, for further assistance, contact technical support at support@cardiosense.com

Problem: The CardioTag was received severely damaged or has missing components	**Solution** Contact customer support to receive replacements for the damaged components. Do not attempt to use the damaged components
Problem: The CardioTag's LED is not blinking white when it is charging while on the charging station, or the LED is red while it is on the charging station	**Solution** Option 1: Ensure that the USB cable and charging station are properly connected Option 2: Ensure that the USB cable and wall adapter are properly connected Option 3: Remove the CardioTag from the charging station and place it back on
Problem: The CardioTag's LED is red during the device set up process while the device is on the charging station and the charging station is plugged into the PC	**Solution** Option 1: Ensure that the USB cable and charging station are properly connected Option 2: Ensure that the USB cable is properly connected to the PC Option 3: The WiFi credentials could not be set for the device. Follow the onscreen instructions on PC web browser to retry again
Problem: The CardioTag doesn't stay adhered to my chest properly	**Solution** Option 1: Check that the attached electrodes are connected properly to the CardioTag Option 2: Ensure that the device placement site on the chest is properly cleaned and shaved and there is no perspiration Option 3: Remove the CardioTag, dispose of the current electrodes, and replace the device with new electrodes
Problem: The CardioTag LED turns red during a recording session, or I do not see the CardioTag's LED blink green during an active recording session	**Solution** Option 1: Remove the CardioTag AND electrodes off of the patient's chest, dispose of the current electrodes, and replace the device with new electrodes to restart the session Option 2: While the recording is in progress, ensure the patient has their arms and hands relaxed or rested on a flat surface. Ensure that the CardioTag is not accidentally knocked out of place
Problem:	**Solution** Option 1: Ensure that the Wi-Fi connection is stable. Place the CardioTag back onto the charging station, ensure that the LED

The CardioTag's LED turns red or is blinking red when it is removed from the charging station, before it has been placed on the patient's chest	is solid white when the device is "ready to use", and re-remove it from the charging station when the LED is solid white.
Problem: The CardioTag's LED started blinking red in the middle of the current recording session, before it has indicated the end of the two minute measurement period	**Solution** Remove the CardioTag and its electrodes from the patient's chest, dispose of the electrodes, clean the CardioTag device, and place it on the charging station to charge. When charging is complete, repeat the test.
Problem: The CardioTag's LED does not show a solid (i.e. non-flashing) green light after a completed measurement session, and more than 2 minutes has passed	**Solution** Remove the CardioTag and electrodes from the patient's chest, dispose of the electrodes, and replace the CardioTag with new electrodes to try again
Problem: The CardioTag's LED turns red when it is placed in the charging station, right after a two minute measurement session is recorded.	**Solution** Remove the CardioTag from the charging station and re-dock it. Check the LED status. Re-record another measurement session at the healthcare provider's discretion
Problem: The CardioTag's LED is not solid (i.e. non-flashing) white to show that it is fully charged or is ready for use, and it has been on the charging station for longer than 2 hours	**Solution** Remove the CardioTag from the charging station and re-dock it. Check the LED status after ~5 minutes
Problem (HCPs Only): The recorded measurements show a lot of artifact, noise, or interference in the report	**Solution** Option 1: Advise the patient to keep their arms and hands still and relaxed during the 2 minute recording period Option 2: Advise the patient to make sure their chest and CardioTag is properly cleaned using the provided disposable wipes in between uses Option 3: Ensure that the patient has properly identified their suprasternal notch and the placement on the sternum is per these instructions Option 4: If feasible, advise the patient to have a healthcare professional guide the device placement on them, either in a clinic, via telehealth session, or at their home

Caution:

- DO NOT store in conditions outside of those specified in the Product Storage section.
- DO NOT use the device if the patient has known allergies to wet electrodes, or sensitive areas (e.g. healing surgical sites or wounds).
- DO NOT use the electrodes on the body when wet, as a successful recording may not be possible.
- DO NOT use the CardioTag device during an MRI scan.
- DO NOT use the CardioTag during the application of external defibrillation.
- DO NOT use the CardioTag if it appears to be damaged.
- DO NOT submerge the CardioTag device in water.
- DO NOT drop or bump with excessive force.

Note: If you experience any skin irritation, redness, itching, or a rash, contact support@cardiosense.com.

Cardiosense makes no warranty for any data or information that is collected erroneously by the device, or misuse or malfunction as a result of abuse, accidents, alteration, misuse, neglect, or failure to maintain the products as instructed. Interpretations made by this device are potential findings, not a complete diagnosis of cardiac conditions. All interpretations should be reviewed by a medical professional for clinical decision making.

Product Storage and Operating Conditions

Store the CardioTag device in its original packaging under the following recommended storage temperature and humidity ranges:

- Temperature: 0 – 40 °C/32 – 104 °F
- Humidity: 10 – 90% RH

Operate the CardioTag device under the following recommended operating ranges:

- Temperature: 5 – 40 °C/41 – 104 °F
- Humidity: 15 – 90% RH
- Atmospheric Pressure: 70 – 106 kPa

Electromagnetic and Other Interferences

The CardioTag has been tested and deemed in conformance to the relevant requirements in IEC 60601-1-2:2020 and IEC 60601-4-2:2018 for Electromagnetic Compatibility (EMC).

Symbols

The following symbols apply to the the CardioTag device:

	Read instructions before use		Temperature Range (Operating)
	Manufacturer		Humidity Range (Operating)
	MR Unsafe		Atmospheric Pressure Range (Operating)
	Type BF Applied Part		Model Number
	Do not dispose with household waste		Serial Number
Rx Only	By Prescription Use Only		

Contact Information

For additional support not specified in this document, contact Cardiosense support:
support@cardiosense.com

Legal

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