

Everbeat Ring System User Manual

Version 1.4.3

March 27, 2025

Table of Contents

| | |
|--|-----------|
| 1. INSTRUCTIONS FOR USE PROVIDED IN ELECTRONIC FORM | 1 |
| 2. PRODUCT DESCRIPTION | 1 |
| 3. INTENDED USE AND INDICATIONS FOR USE | 2 |
| 4. CONTRAINDICATIONS | 3 |
| 5.  WARNINGS AND PRECAUTIONS | 3 |
| 6. IMPORTANT USAGE NOTES | 5 |
| 7. DIRECTIONS FOR USE | 5 |
| 8. UNDERSTANDING THE ECG ASSESSMENT | 9 |
| 9. Sharing or Printing ECG | 11 |
| 10. DELETING AN ECG | 12 |
| 11. ECG RECORDING TIPS | 13 |
| 12. SAFETY AND PERFORMANCE | 13 |
| 13. CLEANING, CARE AND MAINTENANCE | 13 |
| 14. HELP | 14 |
| 15. EDITING YOUR PROFILE | 14 |
| 16. TROUBLESHOOTING | 14 |
| 17. HEALTH AND GENERAL WELLNESS METRICS | 15 |
| 18. ELECTROMAGNETIC & OTHER INTERFERENCES | 16 |
| 19. INGRESS PROTECTION MARKING | 16 |
| 20. WARRANTY | 16 |
| 21. SPECIFICATIONS | 16 |
| 22. DISPOSAL | 18 |
| 23. CYBERSECURITY | 18 |
| 24. USER ASSISTANCE INFORMATION | 18 |
| 25. FCC COMPLIANCE AND EMC TABLES | 19 |
| 26. SYMBOLS USED ON DEVICE OR PACKAGE LABELING | 20 |

1. INSTRUCTIONS FOR USE PROVIDED IN ELECTRONIC FORM

The Instructions for Use for the everbeat Ring System are available in electronic form. You can find instructions in the everbeat Application or on the company website at <https://everbeat.net/usermanual.pdf>. If you prefer a paper copy, you can print them from www.everbeat.net, or request a printed copy by calling Everbeat Customer Support at (301) 276-5955.

2. PRODUCT DESCRIPTION

The everbeat Ring System is a medical-grade EKG/ECG (electrocardiogram) recorder. It lets you record your heart's electrical activity using your smartphone. Users with known or suspected heart conditions, as well as those who are health-conscious, can use the Ring System's ECG features if they have a prescription. Healthcare professionals can use the information from the Ring System to check your heart rate and rhythm, look for arrhythmias (irregular heartbeats), and monitor and manage patients remotely.

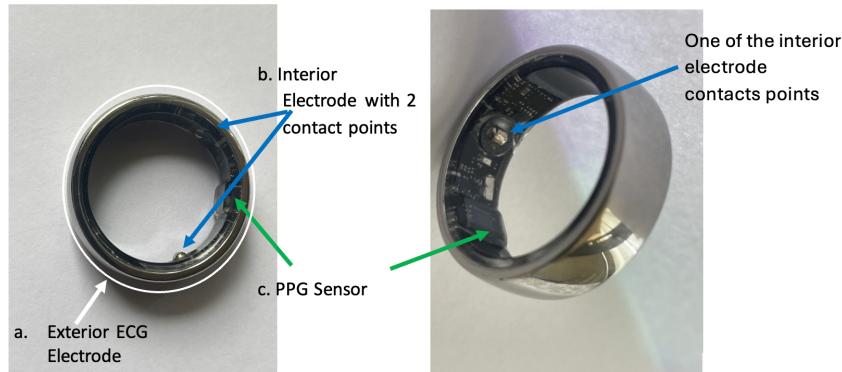
The everbeat System consists of:

- **Ring:** A custom wearable ring with an ECG sensor (electrodes) for detailed heart rhythm assessment. The Ring has two electrodes, one on the outside of the Ring and the other on the inside of the Ring with two electrodes contacting the user's finger. The Ring utilizes a proprietary algorithm to provide your ECG rhythm classification. ***The rhythm classification can provide an indication of possible atrial fibrillation (Atrial Fibrillation Detected) but is not a medical diagnosis.*** This is a custom ring that you can wear on your finger. It has two sensors, one on the outside and one on the inside, to check your heart's rhythm. The ring uses a proprietary program to tell if your heart rhythm looks normal or if there might be a problem, like atrial fibrillation. This is not a medical diagnosis—it just gives you an idea of your heart's rhythm.
- **Charging Dock:** . The charging dock and USB Type C connector need to be plugged into a power source that provides at least 1 Amp of power. Each dock must match the size of the Ring.
- **Mobile App:** The everbeat Ring System mobile App, installed on your cell phone (iPhone or Android), , connects you to the Ring. It collects your ECG data and sends it to the everbeat Cloud.
- **Cloud:** The everbeat Cloud stores and displays your health data which includes ECGs, sleep, steps, heart rate variability (HRV), heart rate, respiration rate, finger temperature and other health data. This information can also be shared.

The everbeat Ring System also requires a USB power source of at least 1 Amp that is not supplied with the Ring System.

The length of the ECG recording is 30 seconds.

Figure 1: everbeat Ring, side and slanted views



⚠ CAUTION: The everbeat Ring System has ECG features that are exclusively accessible to users only when unlocked with a prescription.

The everbeat Ring System allows you to:

- Record single-channel ECGs on demand.
- Print or save the ECG recordings in PDF format to provide to your physician.
- Track health and wellness (non-medical) variables that may impact your heart health, such as activities, steps, sleep, HRV, etc.

After an everbeat account is setup and a prescription obtained, the ECG feature will be unlocked. In addition to recording an ECG using the everbeat App, you can also:

- See the output of rhythm classifications in the everbeat App (Atrial Fibrillation Detected, Normal Sinus Rhythm, Tachycardia, Bradycardia, Inconclusive Rhythms or Unreadable)
- Provide a PDF of the ECG recording and analysis to your physician or seek virtual care.

3. INTENDED USE AND INDICATIONS FOR USE

The everbeat Ring System is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The everbeat Ring System also displays ECG rhythms and detects the presence of Atrial Fibrillation, Normal Sinus Rhythm, Bradycardia, Tachycardia, Unreadable, and Inconclusive (when prescribed or used under the care of a physician). The everbeat Ring System is intended for use by healthcare professionals for patients with known or suspected heart conditions and health-conscious individuals. The everbeat Ring system has not been tested and is not intended for pediatric use in individuals under the age of 18 years.

4. CONTRAINDICATIONS

No known contraindications have been identified for the everbeat Ring System. The results of the everbeat ring system will not be valid if you have a pacemaker or defibrillator, but use will not harm your device. It is important to exercise caution and adhere to the warnings and precautions outlined in this manual before using the device.

5. WARNINGS AND PRECAUTIONS

- **At any time, if you are feeling any concerning symptoms, please contact your healthcare provider or dial 911.**
- Regardless of your ECG results, including a normal sinus rhythm, Everbeat does not guarantee that you are free from arrhythmias or other health issues. You should contact your doctor if you notice any changes in your health.
- Do not use everbeat to diagnose heart-related conditions. The device is intended to be used to only record heart rate and heart rhythm assessment.
- Do not diagnose yourself or change your medication based solely on device readings without involvement of your physician. Consult with your physician before making any medical decisions, including altering your use of any drug or treatment.
- The Everbeat does not continuously monitor for Atrial Fibrillation and will only give readings after recordings have been successfully completed.
- The everbeat Ring System can classify detection of Atrial Fibrillation, Bradycardia, and Tachycardia and cannot detect other cardiac conditions like heart attacks.
- The everbeat Ring System does not detect arrhythmias other than Atrial Fibrillation, Bradycardia, and Tachycardia.
- The everbeat Ring System may not detect all instances of Atrial Fibrillation.
- Everbeat cannot guarantee ECG analysis results. Consult a doctor immediately for symptoms indicating a change in health, regardless of device interpretations.
- Interpretations made by this device are preliminary; consult a medical professional for clinical decision-making.
- Obtain approval from your doctor before starting any new medication, adjusting or stopping any existing medication. Consult a doctor immediately for symptoms indicating a change in health, regardless of device interpretations.
- Everbeat makes no warranty for any data or information that is collected erroneously by the device, or misuse or malfunction because of abuse, accidents, alteration, neglect, or failure to maintain the product 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.
- Proper ring size selection is crucial to the performance of the everbeat Ring device. Improper ring size selection may result in unreadable or inconclusive device assessments. If none of the ring sizes fit your finger, please contact your physician.
- The everbeat Ring system has not been tested and is not intended for pediatric use in individuals under the age of 18 years and is not intended for infants under 22 lbs.

- Although everbeat will not damage or interfere with the implanted device, do not use everbeat if you have a cardiac pacemaker, implantable cardioverter-defibrillator, (ICD), or other implanted electronic device that generates electricity or magnetic field, including neural stimulators. Everbeat readings may be not accurate if used with an implanted device.
- Do not wear while undergoing or near MRI scan equipment, electrocautery, or external defibrillation procedures.
- Do not store the everbeat ring outside of the recommended conditions or in extreme conditions (hot, cold, humid, wet, or bright conditions). Do not leave the Ring in high-temperature environments such as vehicles or direct sunlight. (See Section 20, Environmental Specifications.)
- Take recordings only within the temperature and humidity ranges outlined in the user manual. (See Section 20, Environmental Specifications.)
- Do not use the Ring if the electrodes are dirty. Clean the Ring according to the instructions as needed.
- Do not take recordings during physical activity or while driving.
- Do Not place electrodes in contact with other conductive parts including earth.
- Keep away from strong electromagnetic fields (e.g., MRI or X-ray equipment).
- Handle with care to prevent damage from dropping or excessive force.
- Do not use excessive force to push the ring or sizer onto your finger as it may become difficult to remove.
- Avoid catching the Ring on fixed structures or heavy objects.
- Do not wear everbeat during strength training, heavy tool usage, or carrying heavy items made of metal, ceramics, or stone.
- Do not wear the Ring alongside other metal, ceramic, stone, or diamond rings to prevent scratching or damage.
- Seek medical care in cases of emergency or discomfort if unable to remove the Ring.
- Do not puncture the Ring or attempt to take it apart.
- Keep components out of children's reach. Contents may be harmful if swallowed.
- The charger is not water-resistant and is intended for indoor use; avoid humid environments like bathrooms.
- Modifications to the Everbeat system are prohibited. Use only specified accessories.
- Ensure the finger used for ECG recording is uncovered and free of injuries or breaks in the skin.
- Remove the Ring if skin irritation occurs and consult a doctor if symptoms persist beyond 2-3 days.
- You should keep your mobile device operating system (OS) up to date in a standard fashion. Additionally, keep your everbeat ring App version and your everbeat ring firmware up to date to protect against any cyber vulnerabilities.
- Cyber-attacks can compromise personal information and or provide incorrect ECG assessment results. Everbeat encrypts your data during transmission.
- If you have been notified or believe your everbeat system has in any way been compromised, you should contact everbeat: support@everbeat.net for recommended actions and discontinue the use of the everbeat ring system.

6. IMPORTANT USAGE NOTES

- The everbeat Ring and charging dock is designed for use only with UL(R) listed chargers.
- The everbeat System has been tested for biocompatibility & electrical safety. Maintain a distance of 3+ feet from other wireless devices to avoid potential interference.
- If the everbeat Ring System is not functioning normally, please contact everbeat support (help@everbeat.net) for assistance in diagnosing the problem. In some cases the device may possibly need to be reset-or replaced.
- Obtain periodic updates of the everbeat software from the App Store or Play Store as appropriate for your operating system. These updates may contain important security improvements and new features.
- The everbeat Ring will no longer be usable if any of the following conditions are met:
 - the Ring has been physically damaged from shock or vibration.
 - the ECG sensor no longer captures a successful rhythm strip.
 - the Ring battery is no longer able to provide adequate power.
- If the everbeat Ring is no longer usable, it should be disposed of as electronic waste in accordance with applicable local laws and regulations. The Ring should not be disposed of in standard trash or landfill.
- When traveling with your everbeat device, please refer to the Transportation Security Administration's guidance for passengers with disabilities and / or medical conditions.

7. DIRECTIONS FOR USE

Step 1: Unbox the Ring Package

Remove the everbeat Ring System contents from the retail box. Check for the following contents and ensure there is no damage:

- everbeat Ring
- everbeat Charging Dock
- USB-C charging cable
- Everbeat QuickStart Guide

Note: If there is missing contents or damaged contents, please contact Everbeat Customer Support provided in Section 24-User Assistance.

Step 2. Charge the Ring

Connect the everbeat Ring charging dock via USB-C cable into the USB power source/charging adapter of at least 1 -Amp (USB power source is not supplied). Then place the everbeat Ring inside the charging dock, align the sensor bumps with the indents in the Ring dock and gently drop it into place. When correctly positioned, the white charging light will start pulsing. When the everbeat Ring is fully charged the charging light will stay solid (charging time from empty is approximately 90 minutes, and the charge will last for approximately 5 days).

Figure 2: everbeat Charging Dock

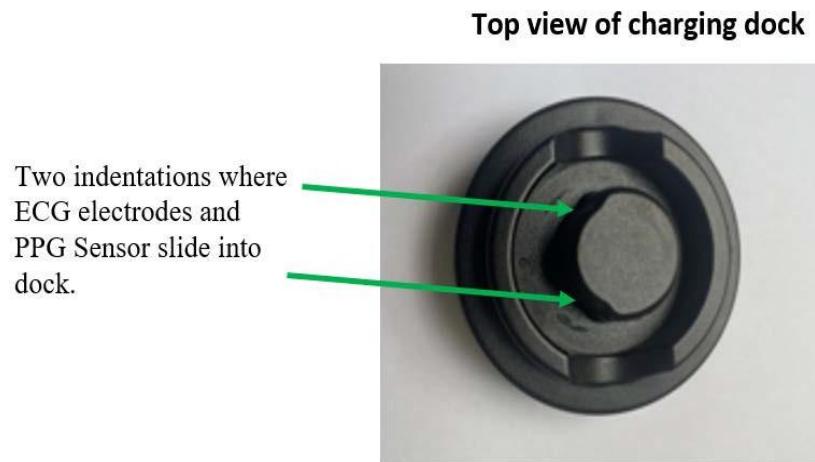
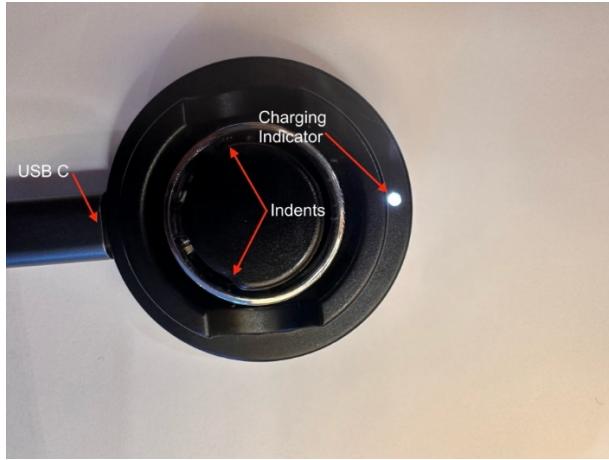


Figure 3: everbeat Charging Dock with Ring charging



NOTE: The everbeat Ring charging dock is designed for use only with UL listed chargers with 5 volts DC, and greater than 1.0-amp output through a standard USB-C connection.

Step 3. Download the everbeat App

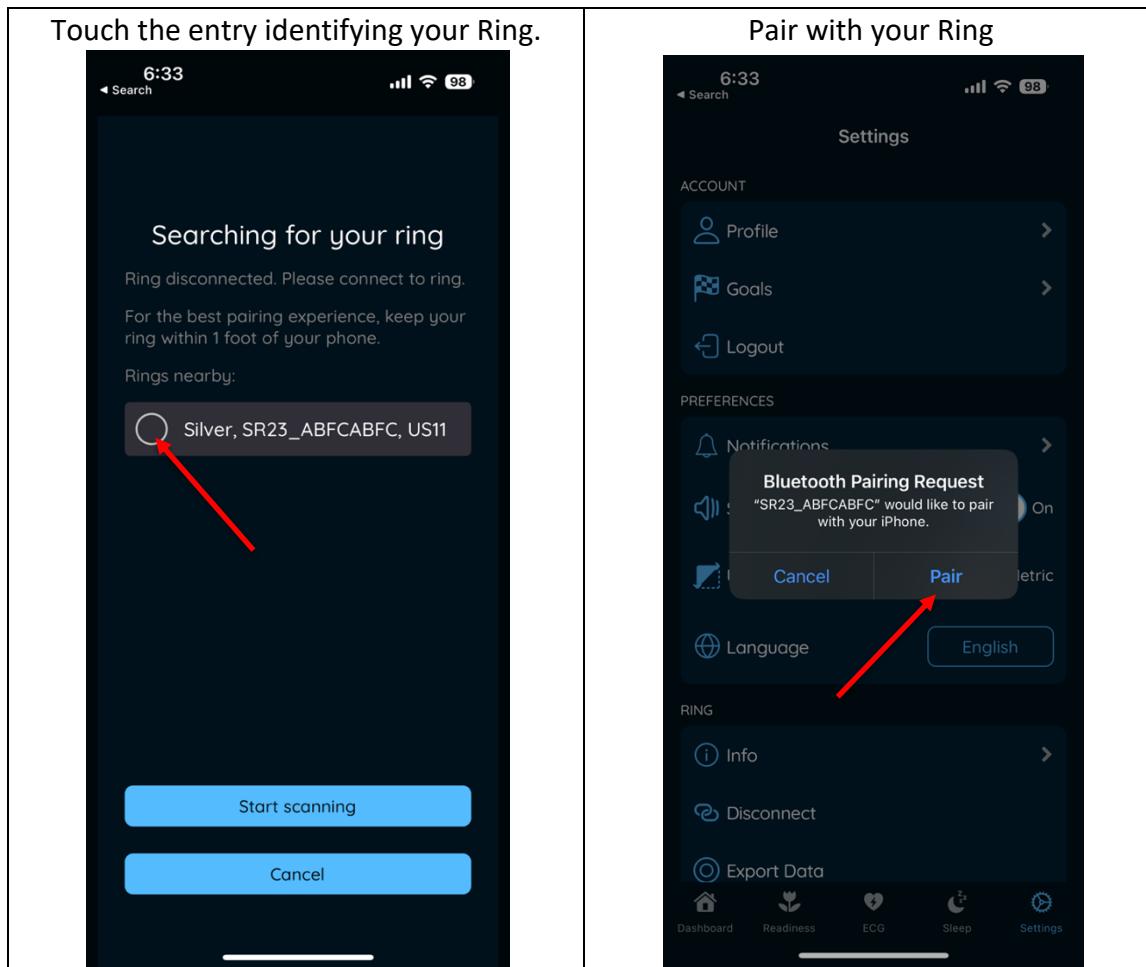
1. Download and install the “everbeat ring” App from the Apple App Store or the Google Play Store.
2. You must have the following to download the everbeat App
 - Apple: iPhone or iPad running iOS 16 or greater.
 - Android: Android phone or tablet running Android 10 or greater.

Step 4. Create your everbeat account

1. Run the everbeat App and create a new patient account by connecting to an existing email (i.e., Gmail or Apple Account) and follow the onscreen instructions to create a new user account.
2. Return to the everbeat App and log in using the code that was emailed to you. Once you log in, you will remain logged in for a month or until you log out.

Step 5. Pair the Ring

1. Open the everbeat App (log in if necessary).
2. You will be navigated directly to the pairing screen. (The everbeat App will also walk through the pairing process.)
3. Place your Ring in the charging dock. It is recommended to charge the Ring for 90 minutes prior to the first use.
4. If your everbeat Ring is not listed for pairing, try turning your handheld device Bluetooth off and on, then refresh the list and make sure that your Ring has charged for at least 5 minutes. You must be within 10 feet of the ring to initiate pairing.
5. Pair your Ring:



6. Once you have completed these steps you are connected to your everbeat Ring.

IMPORTANT: If your Ring and phone are ever out of Bluetooth range, they will disconnect. They will automatically reconnect when they are within range (approximately 10 feet). You may have to wait 5-10 seconds for the ring to reconnect. If the reconnect does not occur, restart the everbeat App by force quitting the App and launching it again. If the ring still does not pair, turn your device Bluetooth off, wait 10 seconds, and turn it on again, or restart your phone (turn it off then on again).

Step 6. Record your ECG

Recording an ECG:

1. Confirm that your Ring is snug on your finger and that it fits securely and comfortably around your right index finger's base.
2. With the everbeat App open, touch on the ECG menu at the bottom of the screen.
3. Open the ECG Details by touching the *ECG* tab.
4. Create a new ECG by touching + icon on the bottom right of the ECG screen.
5. View the instructional ECG recording video if desired which can be accessed through the *Help* button.
6. Sit comfortably in a relaxed position with both arms supported.
7. Make sure the Ring sensor bumps are directly under the section of the Ring that your left finger is touching.
8. Touch the *Start* button and the App will show it is calibrating for 5 seconds.
9. Firmly touch the electrode on the top of the Ring with your left fingertip as shown below.



Alternatively, the Ring sensor bumps may be placed on the palm side of your right index finger with your left thumb touching the outside of the Ring directly over the sensor bumps. (Figure not shown but demonstrated in the ECG tutorial on the Record ECG screen.)

10. Hold still during recording. The everbeat App will present a countdown timer showing the remaining seconds and a progress bar that shows how much time has elapsed and how much time remains. The total recording time is 30 seconds.
11. During recording, your ECG recording will display on the screen with your heart rate.
12. If you receive a low-quality signal warning or the ECG recording does not complete successfully, follow the ECG Recording Tips in Section 11 and restart the recording.

IMPORTANT: If after four (4) more attempts you do not achieve a successful recording, call or email everbeat support for further assistance.

Step 7. Unlock and view the ECGs and Assessments

You will not be able to view your ECG recording or rhythm classification until you have unlocked the ECG feature.

1. To unlock the ECG feature, you will need to submit an ECG recording for review and validation by a cardiologist who will unlock the ECG feature.
2. To do this, touch the *Request Unlock* button, and the ECG recording will be automatically submitted for review.
3. After approval you will receive an email and/or push notification with either:
 - ECG feature has been unlocked
 - Or the recording was not successful, and you should try again (repeat Step 6 ECG Recording and Step 7 Unlock and View the ECG Assessment).

Important: *If you have not received your email notification after one day, please email support@everbeat.net or call the everbeat helpline.*

4. Once the ECG feature has been unlocked, you will be able to view your ECG recordings with rhythm assessments.

8. UNDERSTANDING THE ECG ASSESSMENT

Once you have unlocked the ECG feature, one of the following assessments will be displayed immediately after each recording:



CAUTION: assessments made by this device are potential findings. All assessments should be reviewed by a medical professional for clinical decisions.

1. Normal Sinus Rhythm

These ECG rhythm assessment results mean that the everbeat Ring System has not detected any irregular rhythms.



CAUTION: A result of “Normal Sinus Rhythm” result does not ensure that you are not experiencing an arrhythmia or other health condition. **If you are feeling any concerning symptoms, please contact your healthcare provider or 911.**

2. Atrial Fibrillation Detected

This means your ECG shows signs of an irregular rhythm, Atrial Fibrillation. Atrial Fibrillation happens when the two upper chambers of the heart move in a random

fashion instead of pumping regularly. This does not allow for complete emptying of the heart chambers which may result in the blood being stagnant and the generation of blood clots. If you get this result, you should retake your ECG to confirm the reading and then contact a health care professional for further instructions and to show him/her your ECG recording.

 **CAUTION:** If you are feeling any concerning symptoms, please contact your healthcare provider or 911.

 **CAUTION:** The everbeat Ring System CAN NOT detect all instances of Atrial Fibrillation.

 **CAUTION:** everbeat Ring does not continuously monitor your ECG for Atrial Fibrillation. It will only provide you with detected results after taking an ECG recording with the Ring.

3. Bradycardia or Tachycardia

If the everbeat Ring System ECG rhythm assessment screen shows you have an abnormally low or high heart rate in the absence of Atrial Fibrillation (AFib), you may get one of these results below:

- **Bradycardia** results mean the everbeat system detects that your heart rate is below 50 bpm, but it is not because of a condition called atrial fibrillation (AFib.) This assessment is not to be used as a diagnosis, and you should talk to your doctor if this is an unanticipated result.

A low heart rate can be normal, such as in well-trained athletes. It can also be caused by certain medications or conditions associated with abnormal heart rhythm. You should talk to your doctor if this is an unanticipated result.

 **CAUTION:** If you are feeling any concerning symptoms, please contact your healthcare provider or 911.

 **CAUTION:** A Sinus Bradycardia result does not guarantee that you are not experiencing an arrhythmia or other health condition.

- **Tachycardia** ECG results mean the everbeat system detects your heart is beating above 100 bpm. In this instance, the rapid heartbeat is caused by factors other than Afib. This assessment is not to be used as a diagnosis, and you should talk to your doctor if this is an unanticipated result.

A high heart rate can be normal, such as during exercise or emotional stress. It can also be a response to dehydration, fever, infection or other conditions including atrial fibrillation or another arrhythmia. You should talk to your doctor if your heart rate is over 150 at rest and this is an unexpected result.



CAUTION: If you are feeling any concerning symptoms, please contact your healthcare provider or 911.



CAUTION: A Sinus Tachycardia result does not guarantee that you are not experiencing an arrhythmia or other health condition.

4. Unreadable: Arrhythmic examination not completed

This is an *unreadable* result and may also display:

- The amplitude of the electrocardiogram is very low, please make sure the contact surface is clean and try again
- There is obvious noise in the electrocardiogram signal, please make sure the device is not held too tightly and try again
- The electrocardiogram signal is unstable, please keep still and try again
- There is not enough data, please make sure you keep still and try again

In this case review the ECG Recording Tips in Section 11 and re-record your ECG.

5. Inconclusive: Abnormalities Detected. However, bradycardia, atrial fibrillation, or tachycardia cannot be confirmed

This is an inconclusive reading and the recording falls outside the classification boundaries for AFib, Bradycardia and Tachycardia.

It is recommended these results are reviewed by a medical professional.



CAUTION: An Inconclusive result does not guarantee that you are not experiencing an arrhythmia or other health condition. If you are feeling any concerning symptoms, please contact your healthcare provider or 911.

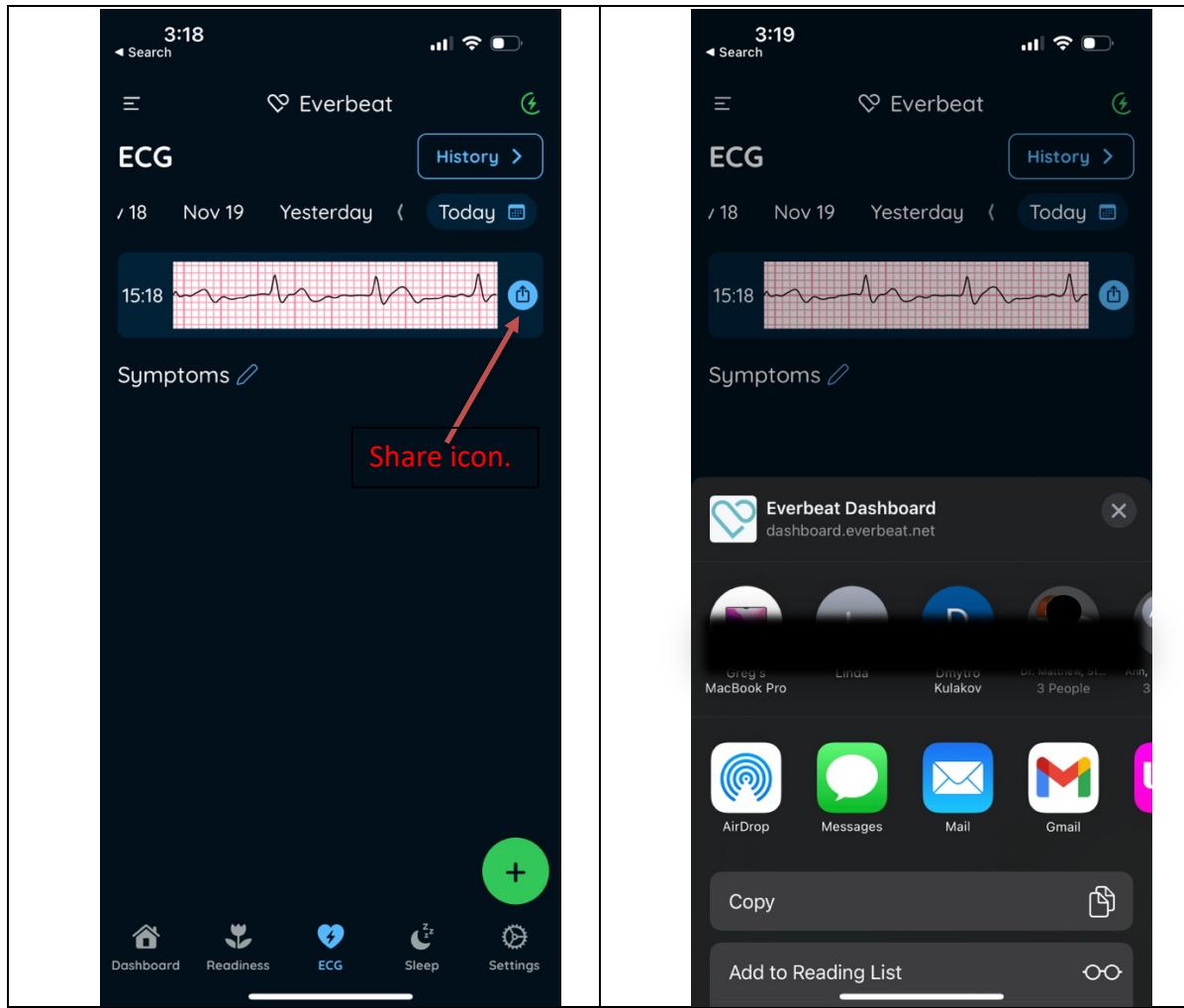
IMPORTANT: If the reading is *Inconclusive*, you can restart the recording and try an ECG recording again. If you regularly get these recordings, consider reviewing these ECGs with your doctor or send these ECGs for Clinician Review by the everbeat Virtual Cardiology Service from the everbeat App as instructed in the Section 9 below.

9. Sharing or Printing ECG

ECGs can be emailed, shared, or submitted for analysis via the everbeat App.

1. From the everbeat App's dashboard, touch the *ECG* tab.

| | |
|--|---|
| Next to the desired ECG recording tap the share icon | Select a contact, share option (like mail, messaging or WhatsApp), or printer |
|--|---|



10. DELETING AN ECG

1. Touch the *ECG* tab in the dashboard to open the list of ECGs you recorded.
2. Swipe left on the specific image of the recording and then select delete to remove it.

11. ECG RECORDING TIPS

- If the Ring isn't tight on your finger, try sliding it up or down on your finger until it is snug. If it does not fit, *email support@everbeat.net or call the everbeat support line.*
- Verify that sensor bumps are directly under the section of Ring that you press with your left hand, move to the proper placement if not.
- You can rotate the ring to locate one of the two metal contacts inside the ring to press directly against the opposite side if the signal is unclear. Ensure the inner electrodes are pressed against your index finger.
- If pushing down with a finger from your left and onto the top of the ring on your right hand does not work, you can try placing the contacts on the bottom of your right index finger and pushing up with your left thumb into the finger. You can see this technique on the tutorial video available before you start the ECG recording.
- Support both hands on your lap or a table so that there is no tension on either arm or hand and that you are relaxed. Muscle contraction can make a recording appear noisy.
- To reduce noise on the ECG, relax, take deep slow breaths, and try not to talk or move during your ECG.
- If the reading is *unreadable*, restart the reading and try again.
- The everbeat Ring and App will still operate normally offline (when not connected to the internet or phone network). However, your physician will not be able to review your health data (including your ECG recording) until you are online.
- The ECG recording must be 30 seconds long for the ECG analysis to provide a result.

12. SAFETY AND PERFORMANCE

Everbeat conducted a clinical validation study with 231 subjects. The protocol was designed to compare the simultaneous recording of an everbeat ring single lead ECG with that of an FDA cleared Holter Monitor. The study had two goals – the first was to compare the rhythm assessments of the holter monitor by two cardiologists and the assessment from the FDA approved algorithm installed on the ring. The ring was able to show a XX% sensitivity and a XX% specificity. The second goal of the study was to show that the ECG waveforms and measurements were the same between the holter and the everbeat ring. The study was able to show a strong correlation in XX% of the subjects.

13. CLEANING, CARE AND MAINTENANCE

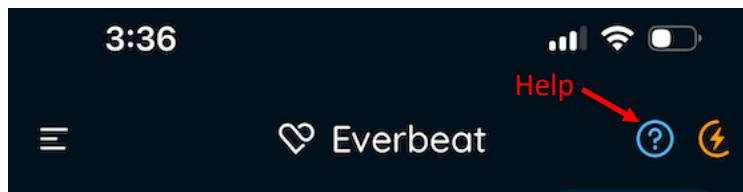
- The Ring may be hand cleaned with a soft cloth, mild soap and water. Make sure that the Ring is completely dry.
- As your finger size can change slightly during the day, sometimes it might be difficult to remove the Ring from your finger. If the Ring gets stuck, you can:
 - Use water and a mild liquid soap to moisten your finger and try to gently twist the Ring to remove it.

- Hold your hand up above your heart until the venous system drains a bit of blood and fluid from your finger, and then try to remove it

 **CAUTION:** In cases of emergency and/or discomfort, if you cannot remove the Ring, seek medical care.

14. HELP

Learn more about using your everbeat Ring System by tapping the ? icon at the top left header of the everbeat App.



- **Tutorial Video:** In the instructional video, you will find a helpful demonstration of the system.
- **References:** The References section provides additional information about your heart, ECGs, and general wellness suggestions.

15. EDITING YOUR PROFILE

- Tap the *Settings* icon at bottom right of the screen.
- Tap the *Profile* option.
- Tap the pencil icon to edit the relevant information.
- Scroll to the bottom and touch the *Save* button.

 **CAUTION:** Do not attempt to use everbeat ECG assessments to interpret your own ECG. This information is not intended to replace medical advice, please seek professional medical assistance if you are suffering from any medical problem.

16. TROUBLESHOOTING

If you are having issues with your everbeat Ring that cannot be resolved and/or unrelated to those provided below, please call the everbeat helpline.

| Issue | Troubleshooting Recommendation |
|---|--|
| 1. Cannot pair Ring to your cell phone/App. | <ul style="list-style-type: none"> ● Try turning Bluetooth off and on. ● Make sure the everbeat Ring has power and is in the charging dock. ● Make sure that no other phone or App is paired with your everbeat Ring. |

| | |
|---|--|
| 2. Poor ECG signal | The ECG signal is flat or very noisy: <ul style="list-style-type: none"> Verify ring fit and orientation (inside metal contact(s) directly underneath your left-hand finger). Press firmly with your left-hand finger. Adjust your hands to be fully supported. |
| 3. Health Monitoring in Progress | <ul style="list-style-type: none"> Wait 10 seconds or until the health monitoring green light goes out and press Start again |
| 4. Weak or Poor ECG signal | If there is a noisy signal, or no signal being displayed on the graph: <ul style="list-style-type: none"> Follow the ECG Recording Tips in Section 11 to improve your results. |
| 5. Low charge on Ring | <ul style="list-style-type: none"> If the charge level on the Ring is below 25% it is recommended that you charge the Ring. The everbeat Ring only takes about 90 minutes to fully charge, and the charge will last for approximately 5 days. |

17. HEALTH AND GENERAL WELLNESS METRICS

In addition to a medical grade ECG, the everbeat Ring System contains sensors to record steps, sleep and heart rate. These additional biometrics provide outputs related to health and wellness for maintaining or encouraging a general state of health or a healthy activity. The everbeat device collects the following information:

- Steps
- Sleep Session Details
- Heart Rate
- Heart Rate Variability (HRV)
- Finger Temperature
- Respiration Rate while sleeping
- Sp02, when sleeping

You can see these health metrics on the App dashboard. Touching on each one will show you more details.



CAUTION: These health and wellness metrics are not medical measurements and do not involve the provision of medical advice by Everbeat. The everbeat Ring health and wellness measurements are recordings of physical parameters from your body and **do not** produce any interpretation of these measurements. Health and wellness metrics are not any kind of diagnosis or medical advice.

18. ELECTROMAGNETIC & OTHER INTERFERENCES

The everbeat Ring has been tested and deemed in conformance with the relevant requirements in IEC 60601-1-2:2007 Class B for Electromagnetic Compatibility (EMC). Further information may be found in Appendix 1, EMC Tables.

19. INGRESS PROTECTION MARKING

Everbeat Ring System is IP68 rated, meaning that it is resistant to being submerged in 1.5 meters of water for up to 30 minutes. Everbeat Ring System is compliant with standard IEC 60529 : 2013

20. WARRANTY

The everbeat ring is warranted for 1 year from purchase. If the ring hardware ceases to operate correctly under normal operating circumstances, contact support@everbeat.net to arrange for a replacement.

21. SPECIFICATIONS

The everbeat Ring is available in US ring sizes 6 to 13.

Technical and Performance Specifications

ECG Channel: Single Channel

ECG Sensor: Two electrodes, one on the outside of the Ring and the other on the inside of the Ring contacting the user's finger or other contact point.

ECG Sensor Service Life: 10,000 operations.

The ECG was tested and conforms to meet the requirements of IEC 60601-2-47:2012 including clause 201.12.4.4.110 for timing accuracy

PPG Sensor: Green LED wavelength: 522 - 542 nm, typical 530 nm

Red LED wavelength: 652 - 658 nm, typical 655 nm

InfraRed LED wavelength: 930 - 950 nm, typical 940 nm

ST-LIS2DS12 Accelerometer

Display: App on Apple or Android phone or tablets

Charger input connector and voltage USB Type-C connector.

USB nominal 5V at 1 amp

Internal Battery Service life expectancy: 500 charging cycles.

Charging Time: typically 90 minutes for a full charge

1. Method of calculating heart rate

The everbeat ring uses the FDA cleared B-Secur algorithm that detects R peaks and uses consecutive R peak intervals to calculate heart rate.

2. Safety type

1) Classification: Class II

2) Power source: Internally powered

- 3) Degree protection against electrical shock: Type BF
- 4) Degree of dust & water resistance: Charge: IP22. Ring: IP68

Expected Service Life

The expected service life for the everbeat Ring is 3 years with typical use.

Environmental Specifications

Ring

Water resistant to 50 meters for 30 minutes
Operational Temperature: 5 - 45 deg C
Operational Humidity: 10 - 95%, non-condensing(non-condensing)
Operational Pressure: 700-1060 hPa
Storage Altitude: max. 3000 m
Storage Temperature: -20°C to +60°C
Storage Humidity: 5 - 95%, non-condensing(non-condensing))

Charger

Not water resistant and is intended for indoor use only.
It is not advised to use in humid environments like bathrooms.
Charging in room temperature recommended.

Materials Specifications

Ring Outer surface material: A physical vapor deposition (PVD) coating of stainless steel.

Ring Inner surface materials: Non-allergenic, non-metallic seamless inner molding.

Battery Specifications

Power Source: Non-replaceable Battery, Lithium Ion 15mAh to 22mAh, based on different size of the Ring
Full Battery Charge: Lasts 4-6 days typically on a full charge (with an ECG recording per day).
Battery Life: At least 3 years, depending on the frequency and degree of charging

Wireless Specifications

The wireless communication of the everbeat is supported by a BLE communication. This communication is established between the everbeat Ring and the everbeat App. The maximum power output for the everbeat Ring is: 5.3 mA peak current in TX (0dBm). Bluetooth LE frequency hops between (2.402 – 2.481 GHz). The maximum range is approximately 30 feet. The communication between the Ring and the App is encrypted using AES128. The communication latency between the Ring and the App is inferior to 10 seconds.

| | |
|-----------------------------|------------------|
| Wireless Technology | Bluetooth BLE |
| Version | Supported BTS.1 |
| Operation Frequency | 2402MHz- 2480MHz |
| Transmission power | +4.5dBm (max) |
| Modulation | GFSK |
| Receiver sensitivity | -96dBm |

22. DISPOSAL

Dispose of the Ring (and internal lithium-ion battery) in accordance with applicable local laws and regulations. Special handling may be required. The charger is an electronic device and local legislation for electronics recycling should be followed. Before deleting the App from your phone, you should delete your account if you want to eliminate any personal information in the everbeat ecosystem.

23. CYBERSECURITY

For security reasons, always pair everbeat Ring in a private (home-based) setting. It is NOT recommended that pairing be done in a public space. You should be at least 30 feet from any unknown people or devices. Everbeat advises that you have a non-trivial passcode for your phone for security since you will be storing personal health information and will receive update notifications for the everbeat System through the everbeat App.

As with all networked systems, unauthorized access, loss, corruption, or misuse of data due to cybersecurity threats cannot be eliminated.

The everbeat ring system contains multiple open-source packages and software. A complete Software Bill of Material information is available to users on a continuous basis at <https://www.everbeat.net/cyber>

It is highly recommended that you keep the authentication email address account that you used to create your everbeat account secure by choosing a complex password and updating it on a regular basis.

All users will be notified of breaches or potential breaches of security to the everbeat system. These notifications will be sent to the user email used to create the everbeat account and will include the scope of the breach, the risk of the breach and recommended corrective actions if required.

24. USER ASSISTANCE INFORMATION

General Assistance Email: support@everbeat.net

Virtual Cardiology Service (EVCS): ecg@everbeat.net

Call: **(301)276-5955**

Website: www.everbeat.net

25. FCC COMPLIANCE AND EMC TABLES

FCC Caution:

Part 15.21

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

Part 15.19

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.

FCC RF Radiation Exposure Statement:

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment.
3. The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

26. SYMBOLS USED ON DEVICE OR PACKAGE LABELING

| Symbol | Description | Symbol | Description |
|--------|--------------------------------------|--------|----------------------------------|
| | BF type applied part | | Attention – refer to User Manual |
| | Wireless Device | | Class II Medical Device |
| | Follow WEEE regulations for disposal | | Serial Number |
| | FCC Mark | | Model Number |
| | Caution or Warning | | Consult Accompanying Document |

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everbeat ring