



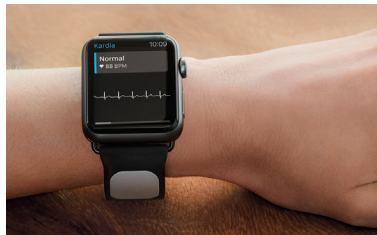
Kardia™ Band by AliveCor®

Instructions For Use

 AliveCor, Inc.
444 Castro Street, 6th Floor
Mountain View, CA 94041
United States
www.alivecor.com
Tell: 650-396-8650

INTENDED USE

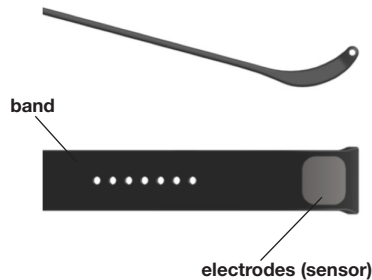
The Kardia Band is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The Kardia Band also displays ECG rhythms and detects the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician). The Kardia Band is intended for use by healthcare professionals, patients with known or suspected heart conditions and health conscious individuals.



USING KARDIA BAND

A. Assembly

- Remove Kardia Band from the box.
- Remove existing watchband from your Apple Watch.
- Attach both Kardia Band pieces to the watch – the electrode piece attaches to the 6 o'clock side of the watch body.



B. App set up

- On your iPhone, download the Kardia app from the App Store.
- Open the Apple Watch app on your iPhone and tap the My Watch tab.
- Scroll to find the Kardia watch app and tap it.
- Tap the “Show app on Apple Watch” and “Show in Glances” toggles to turn on each feature.
- On your iPhone, tap the Kardia app and follow the onscreen instructions.



C. Recording an ECG

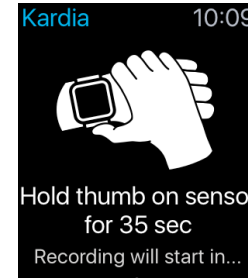
NOTE: These instructions are specific for those who wear their Apple Watch on their left wrist. If you wear your watch on your right wrist, follow the instructions by swapping left and right.

- Tap the Kardia watch app on the Apple Watch to open the application.
- With your right hand, grasp your left hand. Rest your right thumb on the outer electrode on the Kardia Band. The inner electrode should be in contact with the skin of your left wrist. Remain still while recording – your watch, forearm, and hands should not move while recording.



- Do not use Kardia Band while charging your watch.
- Do not take a recording while driving or physical activity.

- Do not take a recording if the electrodes are dirty. Clean them first.
- Tap the “Record” button. Ensure that your hands and fingers are in the proper position.



- The recording takes 35 sec.
- After 35 sec, you have the option to Save or Cancel the recording.



Free medical interpretation of your first ECG reading

For the United States only.

A U.S. board-certified cardiologist will automatically review your first recording for free and will provide a medical interpretation of your ECG within 24 hours. Due to FDA regulations, the heart rhythm for your first recording will not be visible on your mobile device screen and you will not be able to record any additional ECGs while the cardiologist is preparing your report. After you receive your report notification email, you will be able to record and view as many ECGs as you like.

D. ECG Analysis

Subsequent recordings:

- After an ECG recording is complete, the ECG is analyzed to determine if it is at least 30 seconds long, if

it is Normal, Unclassified, if Atrial Fibrillation is present, or if it is too noisy to interpret.

- Tapping the analysis result displays a detailed display of the result.
- Presence of Atrial Fibrillation (AF) in your ECG results may present only potential findings. If you are experiencing any symptoms or have concerns, contact your physician.
- Normal results mean your heart rate is between 50 and 100 beats per minute, and shape, timing and duration of each beat is considered normal.

CAUTION: AliveCor does not guarantee that you are not experiencing an arrhythmia or other health conditions when labeling an ECG as normal. You should notify your physician for possible changes in your health.

- Unreadable ECG results determines that you didn't have proper ECG recording for analysis. You might try to re-record your ECG.
- ECG reports viewed at any magnification other than 100% may appear distorted and could lead to misdiagnosis.
- All ECGs are synced to the Kardia phone app. You may use the phone app to send your ECGs for physician analysis.

SAFETY AND PERFORMANCE

Kardia Band was extensively tested in clinical studies. Overall, 23 volunteers over 18 years old participated in the Kardia Band studies representing 46 recordings. During these clinical studies, no adverse events were observed.

 Obelis SA
BD General Wahis 53
1030, Brussels
Belgium



Made in USA

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TROUBLE SHOOTING

If you experience difficulties in operating your AliveCor products, refer to the troubleshooting guide below or contact technical support at support@alivecor.com.

Problem:

My Kardia Band is not working.

Solution

Option 1: Ensure that the Kardia watch app has access to the watch's microphone. On the iPhone, go to Settings and tap the Kardia app. Tap the microphone toggle.

Option 2: Ensure that the watch microphone is unobstructed. Consult the watch user manual if it is obstructed.

Problem:

I have a lot of artifact, noise, or interference in my recording, or "No EKG recorded" message displays.

Solution

Option 1: Ensure that your watch, arms, and hands remain still during recordings.

Option 2: Clean the electrodes on the Kardia Band with an alcohol-based sanitizer.

Option 3: If your hands are very dry, use a water-based lotion before recording.

Option 4: When recording, relax your arms and hands to reduce muscle noise. Rest the forearms and hands on a flat surface.

Problem:

The ECG rhythms appear upside down.

Solution

Option 1: The watch orientation may be set to the wrong wrist. On your iPhone, go to the Watch app. Tap My Watch > General > Watch Orientation.

Option 2: The Kardia Band pieces may be attached to the watch in the wrong orientation. Review "Assembly" instructions.

CAUTIONS:

General:

DO NOT store in extremely hot, cold, humid, wet, or bright conditions.

DO NOT expose to strong electro-magnetic fields.

DO NOT take recordings in close vicinity to other equipment emitting ultrasonic acoustics.

DO keep components out of reach of children.

DO use this device to record heart rate and heart rhythm only.

DO not use the sensor on portion of the body with too much body fat, body hair or very dry skin, a successful recording may not be possible.

AliveCor 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.

Kardia Band

DO NOT use with a cardiac pacemaker, ICDs, or other implanted electronic devices.

DO NOT continue use until further instructed by a physician if your skin is irritated or inflamed around the sensor or band.

DO NOT drop or bump with excessive force.

DO NOT use to diagnose heart-related conditions.

DO NOT wear during magnetic resonance imaging (MRI), cautery and external defibrillation procedures.

After ECG analysis, the app may incorrectly identify ventricular flutter, ventricular bigeminy, and ventricular trigeminy heart conditions as unreadable. Please consult with your physician.

CAUTION: AliveCor does not guarantee that you are not experiencing an arrhythmia or other health conditions when labeling an ECG as normal. You should notify your physician for possible changes in your health.

KARDIA BAND SPECIFICATIONS

Battery _____ Coin Cell
Storage Conditions _____
Original package under normal room temperature and humidity

ELECTROMAGNETIC & OTHER INTERFERENCES

The Kardia Band has been tested and deemed in conformance with the relevant requirements in EN60601-1-2:2007 Class BF for Electromagnetic Compatibility (EMC).

EQUIPMENT SYMBOLS

SN Serial number


REF Model number

 European Authorized Representative

 Manufacturer


 Read instructions before use

 Type BF applied part

 Emits radio waves

 Temperature range

 Humidity range

 Do not dispose with household waste

ADDITIONAL INFORMATION

For more detailed troubleshooting and technical information, please visit: <https://www.alivecor.com/support/#user-manual>