KardiaBand System
by AliveCor®

Instructions For Use

INDICATIONS FOR USE

The KardiaBand System is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The KardiaBand System 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 KardiaBand System is intended for use by health-care professionals, adult patients with known or suspected heart conditions and health conscious individuals.

USING KARDIABAND

1. Assembly
- Remove KardiaBand from the box.
- Remove existing watchband from your Apple Watch.
- Attach both KardiaBand pieces to the watch – the electrode piece attaches to the 6 o'clock side of the watch body. Choose the band that ensures a tight fit so that the sensor contacts the skin.

band

electrodes (sensor)
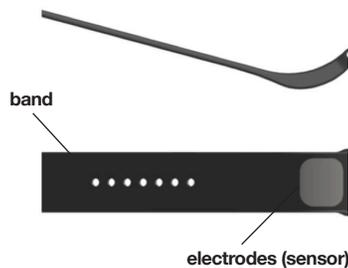
2. App set up
- On your iPhone, download the Kardia app from the App Store.
- Open the Apple Watch app on your iPhone and tap the My Watch tab.
- Scroll to find the Kardia watch app and tap it.
- Tap the "Show app on Apple Watch" toggle to turn on each feature.
- On your iPhone, tap the Kardia app and follow the on-screen instructions.

3. 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.
- In the in-app tutorial, swipe the screen right to left to view the instructions.
- With your right hand, grasp your left hand. Rest your right thumb on the outer electrode on the KardiaBand. Push your right thumb with enough force to ensure that the inner electrode is in contact with the skin of your left wrist for the entire duration of the recording. Remain still while recording – your watch, forearm, and hands should not move while recording.

Close
Relax and rest arms on stable surface.
Hold thumb on sensor.
● ● ●
Waiting for signal

Need help?
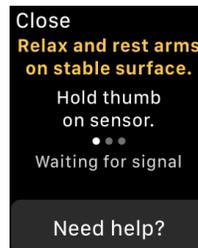
- Do not use KardiaBand while charging your watch.
- Do not take a recording while driving or physical activity.
- Do not take a recording if the electrodes are dirty. Clean them first.
- Wrist hair may affect the performance of the device. We recommend removing excess hair from your wrist.
- Tap the "Record" button. Ensure that your hands and fingers are in the proper position.
- The recording takes 30 sec.
- After 30 sec, you have the option to Save or Cancel the recording.

Free medical interpretation of your first ECG reading in 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.

4. 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 description of the result.

- To view the ECG, use the digital crown or swipe the screen right to left.
- 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.

CLINICAL TESTING

KardiaBand was extensively tested in clinical studies. Overall, 41 volunteers over 18 years old participated in the KardiaBand studies, where Lead I recordings were compared between KardiaBand and an FDA-cleared 12-lead device. Clinical equivalence of the recordings from the two devices was verified by two Board Certified Cardiac Electrophysiologists.

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:	Solution:
My KardiaBand is not working.	**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. **Option 3:** Check and change the battery. Use a Torx T3 screwdriver for the sensor battery door.
I have a lot of artifact, noise, or interference in my recording, or "No EKG recorded" message displays.	**Option 1:** Ensure that your watch, arms, and hands remain still during recordings. **Option 2:** Clean the electrodes on the KardiaBand 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.
The ECG rhythms appear upside down.	**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 KardiaBand 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.

KardiaBand:
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 expose the device to a magnetic resonance (MR) environment.

DO NOT wear during 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.

KARDIABAND SPECIFICATIONS

Battery: CR1620 Coin Cell

Storage Conditions: Original package under normal room temperature and humidity

The KardiaBand sensor may be removed and inserted a maximum of 50 times without performance degradation.

ELECTROMAGNETIC & OTHER INTERFERENCES

The KardiaBand has been tested and deemed in conformance with the relevant requirements in IEC60601-1-2:2014 Class BF for Electromagnetic Compatibility (EMC).

INGRESS PROTECTION MARKING

KardiaBand is IP64 rated. KardiaBand is protected against insertion of fingers and is not affected by vertically dripping water. KardiaBand has been tested with relevant requirement standard IEC60601-1-11:2015.

EQUIPMENT SYMBOLS

Symbol	Description
SN	Serial number
REF	Model number
EC REP	European Authorized Representative
(Manufacturer symbol)	Manufacturer
(Read instructions symbol)	Read instructions before use
(Type BF symbol)	Type BF applied part
10°C–45°C	Temperature range
10%–95%	Humidity range
(Crossed-out bin symbol)	Do not dispose with household waste

ADDITIONAL INFORMATION

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