User Manual for

Kardia™ by AliveCor®

and

OMRON Connect™*

*OMRON Connect application is powered by AliveCor

AliveCor®

Contents

1. INTRODUCTION

Kardia is AliveCor's family of mobile, clinical-quality electrocardiogram (EKG or ECG) recorders, mobile applications, and EKG data processing analytics. This User Manual contains instructions for the following products:

- KardiaMobile System
- KardiaMobile (Patient Version)
- KardiaStation (Clinical Version)
- KardiaBand System

Unless specifically mentioned by name, this manual will refer to Kardia phone app and OMRON Connect smartphone applications as the "Kardia app" and the Apple Watch applications as the "Watch app"; any instructions in this document regarding the Kardia app or Watch app apply to OMRON Connect Phone and Watch applications as well. KardiaStation app is the clinical model of the Kardia app that is specifically for use in a healthcare setting under the supervision of a healthcare professional.

Users may use the Kardia app to record and display EKGs using KardiaMobile Hardware with their smartphone or tablet, or the Watch app in their Apple Watch with the KardiaBand Hardware. These applications also provide instant analysis of the recorded EKG to evaluate whether the heart rhythm is normal or if atrial fibrillation is detected.

The default duration of an EKG recording is 30 seconds. Users may extend KardiaMobile recording duration on the Kardia app to a maximum time of 5 minutes. Kardia family of products allows users to take an unlimited number of EKG recordings and send each to themselves or their physicians for review. In addition, Kardia products can store and allow access to your entire EKG history in the cloud (Premium feature).

Patients with known or suspected heart conditions as well as health conscious individuals can use KardiaMobile System or KardiaBand System to record an EKG daily or whenever they are feeling symptoms and to share their recordings with their physician. Medical professionals can quickly assess rate and rhythm, screen for arrhythmias, and remotely engage with patients who use Kardia.

The KardiaMobile System is used with a user-supplied compatible smartphone or tablet. The KardiaMobile product consists of:

1. KardiaMobile Hardware– a device that has electrodes to sense and transmit EKG rhythms to the smartphone or tablet and that can optionally attach to your compatible smartphone with the provided phone clip;
2. Phone Clip – an optional accessory to attach to the back of your smartphone that your KardiaMobile device can slide in and out of;
3. Kardia app – used to collect, view, and save (Premium feature) EKG recordings and to wirelessly transmit to the AliveCor server.

The KardiaBand System is paired with a user-supplied compatible iOS iPhone and a user-supplied compatible Apple Watch to form the KardiaBand System, which consists of:

4. KardiaBand – Apple Watch watchband with embedded electrodes that sense and transmit EKG rhythms to the Apple Watch;

5. Watch app (a companion to the Kardia app) – used to collect, view, and save (Premium feature) recordings on the Apple Watch, and wirelessly transmit recordings to the Kardia app.

6. Kardia app – used to collect, view, and save EKG recordings and to wirelessly transmit to the AliveCor server (Premium feature).

NOTE: The KardiaMobile System and KardiaBand System products have the ability for users to connect to their physicians (who view the data on Kardia Pro) with a referral code. When connected, the user's EKG recordings are available to be viewed by their physicians. Users without a referral code may send their EKG recordings to their physician by emailing the PDF from the Kardia app on the smartphone.

The KardiaMobile System and KardiaBand System products enable users to:

● Collect and store single-channel EKG recordings.

● Record voice memos that are automatically transcribed to notes.

● Edit user data associated with recordings.

● Wirelessly transmit EKG recordings to the AliveCor server.

● Access past EKG recordings stored on the AliveCor server. (Premium feature).

● Print or save EKG recordings in PDF format.

● Request professional clinical interpretation and analysis of EKG recordings.

● Track events that may impact your heart health, such as symptoms, activities, diet, etc. (Premium feature).

After a user has created an account on the Kardia app and received an EKG analysis, users can:

● View EKG recordings in real-time and after the recording.

● View the output of the Atrial Fibrillation, Normal, and Unreadable detectors.

● Email EKG recordings to their physician or other recipients of their choice.

1.1. Medical Device Products Indications for Use – U.S.

KardiaMobile System:

The KardiaMobile System is intended to record, store and transfer single-channel electrocardiogram (EKG) rhythms. The KardiaMobile System also displays EKG rhythms and output of EKG analysis from AliveCor's KardiaAI platform including detecting the presence of normal sinus rhythm, atrial fibrillation, bradycardia, tachycardia, and others (when prescribed or used under the care of a healthcare professional). The

KardiaMobile System is intended for use by healthcare professionals, patients with known or suspected heart conditions and health conscious individuals. The device has not been tested and is not intended for pediatric use.

KardiaBand System:

The KardiaBand System is intended to record, store and transfer single-channel electrocardiogram (EKG) rhythms. The KardiaBand System also displays EKG 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 healthcare professionals, adult patients with known or suspected heart conditions and health conscious individuals.

Indications for Use – Canada

Kardia Mobile:

The Kardia Mobile product is intended to record, store and transfer single-channel

electrocardiogram (EKG) rhythms. The Kardia app (also known as the Omron Connect app) also displays EKG rhythms and detects the presence of atrial fibrillation, bradycardia, tachycardia, and normal sinus rhythm (when prescribed or used under the care of a physician). The Kardia Mobile product is intended for use by healthcare professionals, patients with known or suspected heart conditions and health conscious individuals. The product has not been tested and it is not intended for pediatric use.

1.2. Clinical Validation and Research

The KardiaMobile System and KardiaBand System have been extensively validated in clinical studies at several leading institutions. All Kardia devices have been favorably compared to Lead I recordings of a standard FDA-cleared 12-lead device. Clinical equivalence of recordings from the Kardia devices and the 12-lead EKG device were also validated by board-certified Cardiac Electrophysiologists. See https://www.alivecor.com/research/ for details.

1.3. Contraindications

There are no known contraindications for the KardiaMobile or KardiaBand System products, although care should be taken when considering using the device according to the warnings and precautions in this manual.

AliveCor®

2. CAUTIONS

General:

- DO NOT use with a cardiac pacemaker, ICDs, or other implanted electronic devices.
- DO NOT use to self-diagnose heart related conditions. Consult with your physician before making any medical decision, including altering your use of any drug or treatment.
- DO NOT store in extremely hot, cold, humid, wet, or bright conditions.
- DO NOT expose to strong electromagnetic fields.
- DO NOT expose the device to a magnetic resonance (MR) environment.
- DO NOT wear during cautery and external defibrillation procedures.
- DO NOT take recordings in close vicinity to other equipment emitting ultrasonic acoustics.
- DO NOT take a recording while driving or during physical activity.
- DO NOT use KardiaMobile while charging your phone. DO NOT use KardiaBand while charging your watch.
- DO NOT take a recording if the electrodes are dirty. Clean them first.
- 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 a portion of the body with too much body fat, body hair or very dry skin, as a successful recording may not be possible.
- DO NOT continue use until further instructed by a physician if your skin is irritated or inflamed around the sensor or band.
- 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.DO NOT drop or bump device.DO NOT use in the presence of flammable anesthetics, drugs or pressurized oxygen.
- After EKG analysis, the app may incorrectly identify ventricular flutter, ventricular bigeminy, and ventricular trigeminy heart conditions as unreadable. Please consult with your physician.
- AliveCor does not guarantee that you are not experiencing an arrhythmia or other health conditions when labeling an EKG as normal. You should notify your physician for possible changes in your health.

AliveCor®

3. SET UP YOUR KARDIAMOBILE OR KARDIABAND SYSTEM AND RECORD YOUR FIRST EKG

3.1. Compatibility

For help deciding which smartphone, smartwatch, or tablet to use, refer to:

KardiaMobile Compatibility:

KardiaMobile requires a compatible Apple iPhone, iPad, or Android device.

Please consult the list of compatible devices on AliveCor's website at the address: https://www.alivecor.com/compatibility.

KardiaBand Compatibility:

KardiaBand requires a paired set of compatible iPhone and Apple Watch.

Please consult the list of compatible devices on AliveCor's website at the address: https://www.alivecor.com/compatibility

3.2. Unpack KardiaMobile (KardiaMobile Users)

1. Remove KardiaMobile from the box.

    1. Choose KardiaMobile placement.
        a. For KardiaMobile phone cases (sold separately), insert the KardiaMobile device into the phone case and snap it on your phone as you would any standard phone case.
        b. The KardiaMobile can be attached to the smartphone or to its case of your choosing with the included phone clip (the surface should be smooth and flat).

            - AC-001 - AC-007: With the AliveCor logo right side up, the top of the smartphone or tablet should be on the right.

            - AC-009 devices with an Alivecor logo should be positioned with the top of the Alivecor logo pointing towards the top of the smartphone.

            - AC-009 devices with the Kardia logo should have the 'K' of the Kardia logo closest to the top of the smartphone or tablet.

        c. You may choose to carry the KardiaMobile loose, in a pocket or bag. When ready to take a recording, rest the KardiaMobile in both hands or place on a flat surface with the device within 1 foot of your smartphone or tablet.

    NOTE: Do not use the phone clip with your tablet. Instead, rest KardiaMobile in both hands or place it on a flat surface less than one foot away from the iPad to record EKGs.

3.3. Unpack KardiaBand (KardiaBand System Users)

1. Remove KardiaBand from the box. The KardiaBand consists of 2 straps – one strap with a buckle and another strap that houses the electrode module.
2. Remove existing watchband from the Apple Watch – consult the Watch user manual if necessary.
3. Attach both sides of the KardiaBand to the Apple Watch – consult the watch user manual if necessary. Ensure that you attach the strap that houses the electrode module to the 6 o'clock side of the watch body and the strap with the buckle to the 12 o'clock side of the watch body.

For more information on how to attach the bands to the watch, refer to a video at https://www.youtube.com/watch?v=p7ZnT_ubEFY.

NOTE: Wrist hair may affect the performance of the device. We recommend removing excess hair from your wrist below KardiaBand's sensor.

3.4. Download the Kardia app

Note: if you already use OMRON Connect, you can update to the latest version of the OMRON Connect App instead of downloading the Kardia app. The OMRON Connect app offers the same functionality as the Kardia app.

1. Using your smartphone or tablet, search for Kardia in the App Store or Google Play store.
2. Download and install the Kardia app.

NOTE: The Apple Watch only works with compatible Apple iPhones – consult the KardiaBand compatibility, if necessary.

3.5. Add Watch app to Apple Watch (KardiaBand System Users)

1. After installing the Kardia app (see above), open the Watch app on your iPhone.
2. Scroll down to Kardia (or OMRON Connect) and tap on "Install". Installation may take a short amount of time.
3. To adjust your watch's Wake Screen to ensure that it stays on while recording an EKG, follow Steps 3-5.
4. In the Watch app on your iPhone, scroll to and tap on "General".
5. Scroll down and tap on "Wake Screen".
6. In the "On Tap" section, select the "Wake for 70 seconds" option.

3.6. Set up your Account

You will use your account to access, print, and save your EKG recordings stored on the Kardia app and the AliveCor server. Follow the instructions presented when you open

the Kardia app and tap "Create Account". You can go back later and edit your information if necessary.

NOTE: KardiaBand users and KardiaMobile users alike should use the Kardia app to setup their account and go through onboarding.

3.7. Free Trial of Premium Features

Once an account has been created, you have access to Premium features for 30 days. At the end of the free trial, your access to those features ends. If you wish to continue to access the Premium features, follow the onscreen instructions for purchasing a subscription.

3.8. Security

Add a passcode (personal identification number [PIN]), or Touch ID (fingerprint) to your smart device to add a layer of security. It is important to secure the smart device since you will be storing personal health information. Review the manual of the smart device for information on how to add a layer of security.

4. RECORDING AN EKG

NOTE: You will not be able to view your recordings or utilize any of Kardia's detectors until you set up your free account. To gain access to the app's features, you must create an account on the Kardia app. Follow instructions on the Kardia app to take a first recording as part of setting up the device.

USA CUSTOMERS ONLY: AliveCor will send your first EKG to a board-certified cardiologist for analysis as part of the purchase price. Due to federal regulations, this analysis must be completed before you are able to view your EKG. The analysis can take up to 24 hours, but typically less, and will include a report detailing the findings. Once the analysis is complete, you will have access to your EKG data and will be able to take and view future recordings.

4.1. To take an EKG recording with KardiaMobile with your smartphone or tablet, follow the instructions below.

Before taking each recording:

- Disconnect headphones, charger cables, or any other connected devices.
- If you wear hearing aids, please turn off.
- Clean the two electrodes with alcohol-based sanitizer.
- Using your smartphone or tablet, launch the Kardia app.

1. From the Kardia app home screen, select "Record your EKG", or alternatively "Add Resting HR". The standard recording is recommended for taking an EKG at any time, e.g.

when you are feeling symptomatic. The resting heart rate option is recommended to establish your resting heart rate baseline. We recommend taking resting heart rate EKGs when you first rise in the morning; the time of day when the body is most rested.

NOTE: The Kardia app is setup for your personal use. If you wish to have another person use the KardiaMobile device, have them set up the Kardia app on their smartphone/tablet or log out of your account on the Kardia app so that they can log in to their account on the Kardia app. The KardiaMobile device can be used with more than one Kardia account and/or smart device.

NOTE: The Kardia app builds a personalized model of your EKGs and will detect if someone accidently uses your smart device to record an EKG. To build this model, the app will sometimes ask if you or someone else took the EKG after completion of a recording.

2. Rest two or more fingers (it doesn't matter which fingers) on KardiaMobile, with your right hand on one electrode and your left hand on the other. Recording of a Lead I EKG on the Kardia app will begin automatically when you make good contact with the KardiaMobile electrodes.

3. While recording your EKG, you may speak your symptoms (e.g. "I'm feeling palpitations. Maybe due to anxiety") into the smartphone. Any voice memo recorded will be transcribed to text and added to the Notes section for that EKG recording.

    You may also choose from two other placements:
    - For a Lead II EKG, the left knee should contact one electrode and the right hand should contact the other electrode.
    - For an Anterior Precordial Lead, the device can be placed on the lower left side of the chest, just below the pectoral muscle.

4.2. To take an EKG recording with the KardiaBand System, follow the instructions below.

NOTE: For the sake of clarity, the instructions below 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.

1. Tap the Kardia or OMRON Connect watch app on the Apple Watch to open the application.
2. Follow any stated directions to complete login or setup activities displayed on the Watch.
3. Tap the "Record EKG" button. A "waiting for signal" indicator will be displayed.
4. With your right hand, grasp your left hand. Rest your right thumb on the outer electrode on the KardiaBand EKG. Press 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. This is a Lead I EKG.

5. While recording your EKG, you may speak your symptoms (e.g. "I'm feeling palpitations") to the smartwatch. Any voice recording taken will be transcribed to text, which will be found in the Notes section for that EKG recording in the Kardia app.
6. The recording takes 30 seconds.

NOTES:

- The KardiaMobile and KardiaBand System do not require a Wi-Fi or mobile data connection to record an EKG and save it to the device's local memory; however, they do require a connection to sync automatically with the AliveCor server, email, or print directly from the Kardia app. If you do not have a Wi-Fi or mobile data connection at the time of the EKG recording, you may email or print the data later when you have such a connection and the sync will happen automatically at that time.
- KardiaMobile may be used up to a distance of 30 cm (1 ft.) from the smartphone or tablet. Using KardiaMobile at a distance greater than 30 cm (1 ft.) may lead to communication issues between the devices and your recording may not be successful.
- KardiaBand must be attached to the Apple Watch. Using KardiaBand at a greater distance may lead to communication issues between the devices and your recording may not be successful.
- On the paired iPhone, Bluetooth must be turned on to transfer data from the Apple Watch.
-
- To reduce muscle noise, rest your arms on a flat surface to increase stability while you are recording.
- The recording must be at least 30 seconds to complete, and to be analyzed by the detectors.
- If you are in a noisy area (e.g. train station, coffee shop, etc.), the voice recording with the KardiaBand may pick up other conversations and will be found in the Notes for that EKG. You may edit the Notes to remove any unwanted text in the Kardia app.

5. **ONCE THE EKG RECORDING IS FINISHED**

5.1. **For KardiaMobile users:**
- On the Kardia app, immediately after recording, you will be shown an analysis of your EKG if there was a successful 30-second recording.
- After a recording, you are also prompted to add tags such as symptoms, activities, diet, etc. to the Data Entry screen. You may also enter personalized tags or notes and edit the transcribed voice memo. After making your choices, tap "Save" to continue.

- You may review the EKG in the History screen, or go to Insights and view the trending of your EKGs, heart rate, symptoms, activities, etc. You may also tap the EKG on the History screen for a larger view of the EKG on the EKG Review screen. EKGs can be starred, emailed, shared, or sent for analysis from the History screen, or on the EKG Review screen.
- Additionally, you may add notes or tags to the recording. Tags include symptoms, activities, diet, etc. that are relevant to heart health. You may go to the History screen and tap the dropdown arrow to the right of the EKG recording, then tap Edit. This will also take you to the Data Entry screen where you may add or edit notes and tags.

5.2. For KardiaBand users:

- If an EKG was successfully recorded on your Watch app, an analysis result – if available - for your EKG appears.
- To view the full EKG, use the digital crown or swipe right to left on the result screen. These actions both will scroll through the EKG.
- Return to the home screen from an EKG by tapping "Close" in the upper left corner.
- On the home screen in the Watch app, tap the "Record EKG" button to take another EKG recording. Past EKG recordings are marked by a circular dot that is color-coded based on the analysis result. To view a past EKG, tap on the dot (Premium Feature).
- Additionally, you may add notes or tags to the recording in the Kardia app (Premium Feature). Tags include symptoms, activities, diet, etc. that are relevant to heart health. You may go to the History screen and tap the dropdown arrow to the right of the EKG recording, then tap Edit. This will also take you to the Data Entry screen where you may add or edit notes and tags.

NOTE: The Watch app will store all unsynced recordings until the Apple Watch has connected and synced to the Kardia app.

NOTE: Due to the limited size of the Apple Watch screen, you may view the EKG on your phone, tablet, or computer for interpretation or analysis.

6. ENTER AN EVENT WITHOUT AN EKG (KARDIA APP ONLY)

You may enter a tag or note without an EKG at any time. This may help you track your symptoms, activities, diet, etc. either before or after an EKG:

- Tap the EKG History button, then tap the green "Plus" icon at the top left.
- In the Data Entry screen, you may enter notes, or select tags such as symptoms, activities, diet, etc., or create personalized tags.

- In the Data Entry screen, you may also select a different date/time for the event you are logging, for example alcohol from the previous evening, or a meal from a couple days ago.
- All of your events will appear in the History screen in chronological order and may be edited anytime by selecting the dropdown arrow to the right of the event on the History screen.

7. SETTINGS AND ADJUSTMENTS

7.1. Kardia app Settings and Adjustments

7.1.1. Recording Review Adjustments

- **Enhanced Filter.** The Enhanced Filter suppresses noise in the EKG. The filter may be toggled on a particular EKG from the EKG Review screen. To enable or disable the Enhanced Filter, tap "MORE" at the bottom of the EKG Review screen, and then tap the "ENHANCED" switch to toggle the filter ON or OFF.
- **Invert the EKG Recording.** In the event that KardiaMobile was oriented improperly when the EKG was recorded, it may appear inverted. The orientation may be toggled on a particular EKG from the EKG Review screen. Tap "MORE" at the bottom of the EKG Review screen, and then tap the "INVERT" switch to toggle it ON or OFF.

7.1.2. Adjustable Settings

To access the Settings, tap the Menu icon at the upper left and then tap "Settings".

- **Duration**. Recording Duration is the maximum length of time the Kardia app will record a single EKG recording. For example, if the recording duration is set to 30 seconds, the Kardia app will automatically stop recording after 30 seconds of data has been collected.
- **Audio Recording**. While recording your EKG, with audio recording turned on, you are able to say out loud the symptoms you are experiencing and have the audio recording saved with your EKG. The audio recording will also be transcribed as a text memo that is saved with the EKG.
- **Mains Filter**. The Mains Filter removes any mains interference from the EKG; it should be set to match the frequency of the alternating current (AC) used in your location. For the United States, Canada and Mexico, this is 60 Hz; in most other countries, it is 50 Hz.
- **Paper Size**. Paper Size of the PDF report can be changed to accommodate Letter and A4 paper sizes.
- **Reminders**. Reminders allow the EKG analysis reminder to be turned on or off. It also allows you to turn on or off the EKG reminder, and to set the frequency and time for the reminder. You can also modify your medication reminders.

7.2. Watch App Settings

To access the Watch app settings, force touch on the Watch app home screen and tap "Settings."

- **Voice Recording.** While recording your EKG, with voice recording turned on, you are able to say out loud the symptoms you are experiencing and have the voice recording saved with your EKG. The voice recording will also be transcribed as a text memo that is saved with the EKG.

8. EMAIL, PRINT, OR DELETE RECORDINGS

To email a recording from the Kardia app:

1. Tap the envelope icon next to the EKG you would like to email/print on the History screen. Alternatively, you may tap the EKG, then tap the envelope icon on the EKG Review screen.
2. Tap Email. The PDF version of the EKG recording will then be attached to a new email in whatever email account you have set up on your smartphone or tablet.

Note: To email a recording from the Kardia app, you must have an email account set up on your smartphone or tablet. If you need assistance setting up an email account or troubleshooting your email account, contact your smartphone or tablet provider for assistance.

To print a recording from the Kardia app:

1. Tap the envelope icon next to the EKG that you would like to email/print on the History screen. Alternatively, you may tap the EKG, then tap the envelope icon on the EKG Review screen
2. Tap Print.
3. Select the appropriate printer to send the EKG to print.

Note: To print a recording from the Kardia app on Apple iPhones, you must have an AirPrint compatible printer set up on your smartphone or tablet. If you need assistance setting up an AirPrint compatible printer or troubleshooting your AirPrint compatible printer, contact your smartphone or tablet provider for assistance.

To delete a recording:

1. Go to the History screen.
2. Tap the dropdown icon to the right of the EKG that you want to delete.
3. Tap "Delete".

9. HISTORY (KARDIA APP ONLY)

History is where your previously recorded EKG recordings are displayed. To access it, tap the "History" icon.

- Launch the Kardia app.
- Tap History at the top of the screen to see a list of all EKG recordings on your smartphone or tablet (excluding any previously deleted).
- Tap the EKG recording you wish to view.

NOTE: You may listen to the voice memo associated with the EKG by tapping the Play button.

9.1. Search or filter recordings (KARDIA APP ONLY)

You may search or filter the events in the History screen by using the search icon on the top right of the screen.

To filter:

1. Tap the search icon on the top right.
2. Select one of the existing filters. The filters allow you to choose one of the following: Custom Search…, Starred, Atrial Fibrillation, Analysis Reports, My EKGs, and Guest EKGs.
3. Your History screen will show you EKGs that meet the filter criteria until you disable the filter.
4. You may disable the filter by tapping the "x" icon next to the filter name at the upper right of the History screen.

To search:

1. Tap the search icon at the top right.
2. Tap "Custom Search" at the top of the search menu.
3. Type in the term you are searching for in your events using the keyboard. For example, you may be looking for "Caffeine" or "Walked the dog" in your tags and notes.
4. Tap outside of the keyboard area if you would like to remove the keyboard for better scrolling through your records.
5. You may disable the search view by tapping "Cancel" on the top right of the screen or edit your search term by tapping in the search bar and entering another term.

10. CLINICIAN REVIEW (KARDIA APP ONLY)

The Kardia app includes the ability to request professional clinical interpretation and analysis of your EKG recordings. Due to telemedicine restrictions, your location may restrict your ability to use this service. AliveCor does not know your location; it is your responsibility to ensure this service is legal according to your local telemedicine laws. This service is not intended to replace medical advice, please seek professional medical assistance if you are suffering from any medical problem.

NOTE: Some users with a referral code to a cardiac monitoring service do not have access to this feature. EKGs from such users are automatically sent to that monitoring service. Users may additionally use the email an EKG or print an EKG feature to share information with their physician.

To request a Clinician Review:

1. Tap History and find the EKG you would like to send for analysis. Tap the envelope icon to the right of the recording, then "Clinician Review". Alternatively, you may tap the EKG, and then tap the envelope icon at the top right of the EKG Review screen.

2. Select one of the listed options.

3. If you haven't already entered your name, date of birth and gender, you will be prompted to enter these details. Enter the required details and tap "Next".

4. Select or enter your credit card information. Enter your card details and tap "Next".

5. Confirm that the purchase order is correct and tap "Purchase" to place the order.

Your order is then processed, and you will be sent an email confirmation. Another email will be sent when the report is available.

NOTE: The "Clinician Review" option is only visible if the analysis service is available in your country.

To view an EKG Analysis Report:

1. Tap "History".

2. Tap the desired report below the EKG.

Alternatively, you may access EKG Analysis Reports from the EKG Review screen by tapping "Analysis".

NOTE: To view PDF reports on your smartphone or tablet you must have a PDF reader, such as Adobe Reader, built-in or installed on your Android smartphone or tablet. Support for printing depends on the built-in printing options on your Android smartphone or tablet, or you may need to install a printer app from the Google Play Store. PDF functionality is built in to iOS devices.

11. KARDIASTATION (CLINICAL MODEL)

KardiaStation is a version of the KardiaMobile that is specifically for use in a healthcare environment (i.e. under the care of a healthcare professional). KardiaStation uses the KardiaMobile hardware and has its own KardiaStation app. The KardiaStation app uses the

KardiaMobile hardware and is used to record EKGs from patients in a healthcare clinic including clinician office, hospital, pharmacy or other healthcare setting.

11.1. Download the KardiaStation app:

Contact AliveCor sales to create your healthcare professional account. AliveCor verifies the healthcare professional credentials before creating the account. AliveCor will also set up the kind of patient ID the healthcare clinic will require for their identification. You may decide whether EKG analysis should be shown to each patient upon completion of recording.

1. Using your smartphone or tablet, search for KardiaStation in the App Store
2. Download and install the KardiaStation app.

Note: A pre-configured Mobile Computing Platform (phone, tablet, etc.) with the KardiaStation app may also be requested from AliveCor sales.

11.2. Recording EKG (for patients):

As a patient, please use the following sequence to record an EKG:

- Provide a patient identification number, typically a medical record number (MRN);
- Rest two or more fingers (it doesn't matter which fingers) on KardiaMobile's electrodes, with your right hand on one electrode and your left hand on the other. As soon as you place your fingers from each hand on the electrodes and make good contact, the EKG recording will begin automatically. You will observe your EKG trace on the screen;
- Keep your fingers on the electrodes and follow the on-screen timer till it goes to zero;
- Once the recording is complete, notify your healthcare professional that the recording is complete and you can remove your fingers from the electrode.

Note: Depending on the healthcare clinic you are at, you may see automatic EKG analysis after completion of recording. Ask your healthcare professional to explain the results if the KardiaStation app provides you with an instant analysis. These analysis options are described further in Section 13.

12. DETECTORS (ATRIAL FIBRILLATION, NORMAL, UNREADABLE, BRADYCARDIA[1], TACHYCARDIA[1])

NOTE: Your EKG must be at least 30 seconds long to use the detectors. If an EKG is recorded that is less than 30 seconds, the detectors will not display a result. The detectors only analyze the first 30 seconds of your EKG recording, regardless of recording duration.

Atrial Fibrillation Detector

The Atrial Fibrillation (AF) detector detects atrial fibrillation in an EKG tracing. After you take an EKG, if atrial fibrillation is detected you will be notified within the app. This finding is not a diagnosis, it is only a potential finding for the recorded EKG. You should contact your physician to review any EKG recording in which atrial fibrillation was detected or send it for clinician review (see section 10). If you are experiencing any symptoms or concerns contact a medical professional.

Caution: If the Kardia app detects AF in an EKG, please consult with your physician before making any medical decision, including altering your use of any drug or treatment.

Caution: The AF detector evaluates for atrial fibrillation (AF) only. It will not detect other potentially life-threatening arrhythmias, and it is possible that other cardiac arrhythmias may be present.

Caution: The AF detector only evaluates for AF after you have taken an EKG recording. It does NOT continuously monitor your heart and therefore cannot alert you if AF happens at any other time.

Bradycardia and Tachycardia are available for the KardiaMobile System only

Normal Detector

The Normal detector notifies you when a recording is "normal". This means that the heart rate is between 50 and 100 beats per minute, there are no or very few abnormal beats, and the shape, timing and duration of each beat is considered normal sinus rhythm. It is important to remember that there is a wide range of normal variability among different individuals. Changes in the shape or timing of an EKG might be normal for a single individual, but since the apps are used by a large and diverse population, the Normal detector has been designed to be conservative with what it detects as normal.

If you have been diagnosed with a condition that affects the shape of your EKG (e.g., intraventricular conduction delay, left or right bundle branch block, Wolff-Parkinson-White Syndrome, etc.), experience a large number of premature ventricular or atrial contractions (PVC and PAC), are experiencing an arrhythmia, or took a poor-quality recording it is unlikely that you will be notified that your EKG is normal.

It is also important to note that the Normal detector looks at the entire signal before determining if it can be declared to be normal. If you experience a small number of PACs or PVCs in a recording of otherwise normal beats in normal rhythm, the Normal detector will likely declare that EKG recording to be normal.

The Normal detector will not declare an EKG outside the heart beat rate of 50-100 beats per minute as normal, even if the EKG has normal sinus rhythm. As a result, if you typically get "Normal" results but take an EKG immediately after any physical activity that raises your heart rate above 100 beats per minute, you may not get a "Normal" result.

Bradycardia and Tachycardia (For KardiaMobile System Only):

If your Normal detector detects normal rhythm and the heart rate is outside 50-100 beats per minute, you may get one of these results below:

a. Heart rate between 40-50 bpm: The Normal Algorithm declares the EKG as "**Bradycardia**" for EKGs with this heart rate range.

b. Heart rate between 100-140 bpm: The Normal Algorithm declares the EKG as "**Tachycardia**" for EKGs with this heart rate range.

c. Unclassified: The Normal Algorithm declares the EKG as "Unclassified" for EKGs that have a heart rate below 40 or above 140 bpm.

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

Unreadable Detector

The Unreadable detector determines whether a recording can be accurately interpreted or not. After you take an EKG, if interference is detected you will be notified within the app that your recording has "No analysis" and given some suggestions for acquiring good quality EKG recording. You subsequently have the option to Save the recording or Try Again. If the recording can be analyzed, the AF and Normal detectors will run on the EKG and inform you as described above.

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

12.1. What is Atrial Fibrillation?

The most common type of non-sinus tachyarrhythmia is atrial fibrillation. In atrial fibrillation, disorganized electrical impulses that originate in the atria and pulmonary veins initiate the electrical activity in the conduction system of the heart. This causes what are commonly termed as "irregularly irregular" heart beats.

When a heart is in atrial fibrillation, its two upper chambers, the right and left atria, essentially quiver instead of beating efficiently. This does not allow for complete emptying of the atria and thus blood may become stagnant and create blood clots. This can lead to major health problems, including strokes, transient ischemic attacks (TIAs), and pulmonary emboli (PEs); depending which chamber of the heart has the blood clot in it.

Approximately 15 percent of strokes occur in people with atrial fibrillation. As age increases in a population, so too does the incidence of atrial fibrillation, which peaks at about 3-5% in people over the age of 65.

The most common presenting symptoms of atrial fibrillation are palpitations, dizziness, fast pulse rate, irregularly irregular rhythm, an abnormal heart sound (S1),

chest pain, chronic shortness of breath, abnormal jugular venous pressure, fatigue, and impaired exercise tolerance. Other symptoms related to TIAs and strokes may be the initial symptoms of atrial fibrillation.

Some of the most common causes of atrial fibrillation are long-standing hypertension, congestive heart disease, cardiac valvular lesions, myocardial infarctions, history of coronary artery bypass grafts, hyperthyroidism, alcohol abuse, smoking, diabetes mellitus, and electrolyte imbalances.

12.2. AFib, Normal, Bradycardia[1], Tachycardia[1], Unreadable, and Unclassified Recordings in EKG review screen and History

All EKG recordings analyzed as positive for atrial fibrillation, normal, bradycardia1, tachycardia1 or unreadable will have a tag for future review. The Kardia app and Watch app may display the "Unclassified" message for an EKG recording that was not detected as Normal, Bradycardia1, Tachycardia1, nor as AFib, and not as Unreadable. If you consistently get "Unclassified" recordings, you may want to review these EKGs with your physician or alternatively send these EKGs for Clinician Review from the Kardia app. These tags will be visible in the History screen, Data Entry screen, and the EKG review screen.

12.3. Detector Usage

KardiaMobile allows users to record EKGs as Lead II or Anterior Precordial Lead. The detectors have been trained and tested on Lead I recordings only. Due to the difference in the waveform from Lead II or Anterior Precordial Lead recordings, detector analysis messages (e.g. "Normal", "Unreadable", etc.) of these recordings may be incorrect and you should not use the results of the detector. Please consult your physician or perform a Clinical Review if you wish to get an analysis of the recorded non-Lead-I EKG.

13. MEDICATIONS (KARDIA APP)

You may track your medications with the Kardia app. To access and edit the medications:

- Open the Kardia app and scroll down to Medication; tap "Get started". You may edit your medications or select those taken that day.
- Tap on "Edit your medications" to go to your Medications List. Here you may add new medications or delete existing medications.
- On the Medication Logging page, you may mark a medication as taken by tapping on the medication and then hitting "Save" in the upper right corner.
- Alternatively, tap the medication push notification that is sent to you by default at 9:00am every day. You may then edit your medications or select those taken that day.

- You may select a medication more than once per day by tapping "Log medication" on the home screen and tapping the specific medication again. The number to the right of the medication will update.
- To add or edit medication reminders go to Menu > Settings from the home screen and scroll down to "Medication Reminders".

14. INSIGHTS (KARDIA APP ONLY)

 (Premium Feature) This app screen displays and graphs your data over time. The graphed data includes your EKGs, EKG results, heart rate, symptoms and medications. To access it, tap the labeled button at the bottom of the home screen.

15. HEALTH APP AND GOOGLE FIT INTEGRATION

The Kardia app is integrated with the Apple Health and Google Fit apps. Additionally, information about your activities and vitals helps us provide you with a monthly Personal Report (Premium). You have the option of turning off the integration within the Apple Health and Google Fit apps; however, doing so will limit the information available in your Personal Report. The Kardia app shares the following information with the Apple Health and Google Fit app:

- Heart Rate
- Height
- Weight
- Blood Pressure

The Kardia app collects the following pieces of information from the Apple Health and Google Fit apps:

- Active Energy
- Blood Glucose
- Diastolic Blood Pressure
- Flights Climbed
- Heart Rate
- Height
- Oxygen Saturation
- Resting Energy
- Sleep Analysis
- Steps
- Systolic Blood Pressure
- Walking + Running Distance
- Weight

- Workouts

16. REFERRAL CODE

If you were prescribed Kardia by your doctor or through a cardiac monitoring service, you should have received a 12-character referral code. The code may be entered during account creation or may be entered by tapping the shield icon located at the top right of the Home screen on the Kardia app. Once a valid code has been entered, EKGs taken by you will be shared with the cardiac monitoring service. To see if you are sharing EKGs with a cardiac monitoring service, tap the shield icon located at the top right of the Home screen.

NOTE: Some users with a referral code to a cardiac monitoring service do not have access to the Clinician Review feature described in section 11 on page.

17. BLOOD PRESSURE

AliveCor has a partnership with Omron that allows you to upload blood pressure readings directly into the Kardia app.

Pair your Omron blood pressure monitor* to the Kardia app:

1. From the Home screen, scroll to Blood Pressure and tap "Get started".
2. Turn on the blood pressure monitor.
3. On the blood pressure monitor, press and hold the Transfer or Clock button until you see a flashing "P" or "o".
4. Tap the Pair now button in the Kardia app to begin pairing.

NOTE: If you experience an error, repeat the above steps

Upload your blood pressure readings into the Kardia app:

1. From the Home screen, tap Blood Pressure.
2. After taking a recording, with the results displayed on the monitor's screen, tap the Transfer recording button in the Kardia app.

Connect to Google Fit (Android Only)

1. From the Home screen, tap Blood Pressure.
2. Tap the Learn more button and tap Next on the next screen.
3. Tap the Connect to Google Fit button.

Manual entry

1. From the Home screen, tap Blood Pressure.

2. By default, the systolic value is set at 120 and the diastolic value is set at 80. Tap the + and – buttons to change the values.

3. Tap the Submit button to record the blood pressure measurements.

18. WEIGHT

You may track your weight over time in the Kardia app. You have the option to enter your weight manually or the Kardia app or to enable the Kardia app to pull your weight data from the Apple Health or Google Fit apps.

To connect to Apple Health or Google Fit:

1. From the Home screen, tap Weight.

2. Tap the Learn more button and tap Next on the next screen.

3. Tap the Connect to Google Fit or Connect to Health button.

To enter manually:

1. From the Home screen, tap Weight.

2. Scroll the scale gradations to the left or right to set the correct weight. Use the + or – buttons to add or subtract 0.1 lbs.

3. Tap the Submit button to record the weight.

The Body Mass Index (BMI) value is calculated using a person's weight and height. Although BMI does not measure body fat directly, research has shown that BMI is moderately correlated with other body fat measurement techniques. The BMI categories are derived from the BMI value (see the CDC website at https://www.cdc.gov/healthyweight/assessing/bmi/index.html). To view the weight and BMI results, go to the History screen and tap Weight.

19. PERSONAL REPORT

The Personal Report (Premium feature) is a monthly report that displays associations between your Kardia data and your activity data. The Personal Report provides you with analysis and insights to help you care for your heart. The report becomes more illustrative as you share more of your activity data through the Apple Health app.

20. ACCESSING HELP

Learn more about using your KardiaMobile by tapping the Menu icon at the top left of the Home screen. Tap "Support" to see all the options available.

AliveCor®

- **Tutorials.** Review these tutorials to learn about to navigate all the features of the app.
    - o   Recording an EKG
    - o   Alternate Recording Positions
- **Reference.** Access the user manual and provide feedback.
    - o   User Manual
    - o   Feedback

Learn more about using your KardiaBand by tapping the information icon accessed through the menu in the Watch app (force touch on the Watch app home screen). Instructions for accessing the user manual will appear.

21. EDITING USER PROFILE (KARDIA APP ONLY)
- Launch the Kardia app.
- Tap the Menu icon at the top left of the Home screen.
- Tap "Your Profile".
- User details can be edited.

22. ACCESSING EDUCATION (KARDIA APP ONLY)
- Launch the Kardia app.
- Tap Menu icon at the top left of the Home screen.
- Tap "Heart Education". Users have the ability to learn about:
    - o   Cardiac Anatomy
    - o   What is an EKG
    - o   Arrhythmia Library
    - o   External Resources

NOTE: The information contained within this section is for educational purposes only. This information has been written and verified by medical professionals.

Do not attempt to use this information to interpret your own EKG. This information is not intended to replace medical advice, please seek professional medical assistance if you are suffering from any medical problem.

AliveCor®

23. TROUBLESHOOTING

Problem	Solution

My KardiaMobile is not working.	Ensure that the Kardia app has access to the smartphone's microphone. On an Android phone, go into "App Settings". On an iPhone:
	
	1. Tap on iPhone "Settings"
	2. Tap on "Privacy"
	3. Tap on "Microphone"
	4. Ensure that "Kardia" is turned on (the background of the slider is green)
	
	Change the battery
	1. Expose the battery door at the back of KardiaMobile:
	   a. Remove the case from the smartphone or tablet by pushing the iPhone through the camera cutout, while peeling back KardiaMobile from this corner.
	   OR
	   b. Remove KardiaMobile from the phone clip:
	     • AC-001 - AC-007: Place your thumbs on the electrodes and press down firmly. Turn counterclockwise about 45 degrees to "unlock" KardiaMobile. Once it's "unlocked", KardiaMobile can then be lifted out of the plate.
	     • AC-009: Use your thumbs to slide KardiaMobile toward the open end of the plate.
	2. Remove the battery door:
	   a. AC-001 - AC-007: Use a 1.6mm Phillips screwdriver, press down firmly and turn counterclockwise to remove the screw in the battery door.
	   b. AC-009: Insert a pen, pencil or other similarly shaped object into the cutout next to the battery door to pop the battery door off.
	3. Remove the used battery and replace it with a new 3V coin cell battery matched to your model.
	4. Orient the battery with the positive terminal up, so that you can see the writing. Remove the protective sticker from the battery, as applicable. AC-009: Ensure that the battery slides **under** the two battery tabs.

My KardiaBand is not working.	Ensure that the Watch app has access to the watch's microphone:

	1. On the iOS smartphone, tap the "Settings" app. 2. Scroll down the screen until you see Kardia and tap it. 3. Tap the "Microphone" toggle. 4. Ensure that "Kardia" is turned on (the background of the slider is green). Check for obstructions Ensure that the watch microphone is unobstructed. In the event an obstruction exists, consult your watch user manual. Change the battery 1. Gently pull the watchband and gently push the KardiaBand sensor from the groove of the watchband. 2. Remove the battery door. Use a Torx T3 screwdriver, press down firmly and turn counterclockwise to remove the screw in the battery door. Repeat for the remaining screws. 3. Remove the used battery and replace it with a new 3V CR1620 coin cell battery. 4. Orient the battery with the positive terminal up, so that you can see the writing. Remove the protective sticker from the battery, as applicable. 5. Replace the battery door; note that the battery door only fits in one orientation and you may need to rotate the door to achieve the correct fit. 6. Replace the four screws and hand-tighten with the Torx T3 screwdriver.
My Apple Watch face goes black when recording an EKG with my KardiaBand System.	Ensure that the Apple Watch wake screen is set to 70 seconds. 1. In the Watch app on your iPhone, scroll to and tap on "General". 2. Scroll down and tap on "Wake Screen". 3. In the "On Tap" section, select the "Wake for 70 seconds" option.
I have a lot of artifact, noise, interference, or see "No EKG" in my recording	Try the following tips for acquiring the best quality EKG recording: • Ensure that the "Enhanced Filter" is on. • Clean the electrodes on KardiaMobile with an alcohol-based sanitizer. • If hands are very dry, use a water-based lotion before recording.

	• When recording from the hands, relax the arms and hands to reduce muscle noise. Rest the forearms and hands on a flat surface and let KardiaMobile rest on the hands. Do not squeeze KardiaMobile. • Ensure that your smartphone or tablet is not charging/syncing and you are not using headphones with your smartphone or tablet during the recording. • Make sure that both the smartphone or tablet and the user remain still during EKG recordings. Movement during recordings will cause noise in the tracing. • Make sure Mains Filter is set appropriately for your geographical location. This can be adjusted under the Kardia app Settings.
The EKG rhythms appear upside down	To invert a recording on your smartphone or tablet, see "Invert the EKG recording" under "Recording Adjustments" in Section 8.1.1.
I forgot my password and I'm unable to reset it	If you forget your password, tap on the "Forgot Password" link in the Kardia app login screen. We'll send a link and further instructions to the email address that you used to set up and access Kardia. Follow the reset instructions in the email. Note, the reset link contained in the email is only active for a short while.
My personal information (name, DOB, etc.) disappears when I'm trying to create an account	If you navigate backwards when creating your account, the personal information you entered on the previous page is deleted and will have to be re-entered.
I see large spikes at the start of my recording	Large amounts of noise/artifact can be seen for the first few milliseconds of a recording when the Enhanced Filter is looking for your heartbeat. This is very rare and only lasts until your first heartbeat is seen in the app; this doesn't affect the rest of your recording.
I can't see my age in the PDF report	If your first and last names are longer than 35 characters combined, your age may be covered due to size restrictions in the PDF report. Please consider using initials for your first or last name in order to ensure your age is visible.
My credit card isn't being accepted	In rare occasions, the error message indicating that your credit card is incorrect or invalid is automatically cleared by rotating the phone from portrait to landscape or vice versa. Please ensure that your credit card information is valid before processing payments.
I need a printed version of the manual	Contact support@alivecor.com for a printed copy of this manual.

Is the manual available in another language?	This manual is available in English, Dutch, French, German, Italian, Spanish and Norwegian.

AliveCor®

24. KARDIA DEVICE SPECIFICATIONS

Performance Characteristics

EKG Channel	Single Channel
Input Dynamic Range	10mV Peak-to-Peak
Memory length	Practically Unlimited
Recording Format	Continuous
Shelf Life	Estimated 2 years

Circuitry

Frequency Response	0.5 Hz to 40 Hz
CMRR	76 dB
Input Impedance	> 100 MOhm
Differential Range	+/- 5 mV
A/D Sampling Rate	300 samples/second
Resolution	16 bit
DC Offset Correction	+/- 300 mV

Output

Modulation	Frequency Modulated Ultrasonic Audio Tone
Center Frequency	19 kHz
Frequency Deviation	200 Hz/mV

Power Requirements

Battery Type (AC-001)	CR2016
Battery Type (AC-003)	CR2025
Battery Type (AC-004 & AC-007)	CR2032
Battery Type (AC-009)	CR2016
Battery Type (AC-011)	CR1620
Battery life (KardiaMobile)	min. 200 Hours Operational Time, 12 months typical use
Battery life (KardiaBand)	min. 90 Hours Operational Time, 2 years typical use

Physical Characteristics

AC-001 (for iPhone 4/4s)	40 grams, 118 x 62 x 15 mm 9 cm^2 Electrode
AC-003 (for iPhone 5/5s)	41 grams, 128 x 62 x 15 mm 9 cm^2 Electrode
AC-004 & AC-007-I5-A (for iPhone 5/5s)	33 grams, 126 x 62 x 11 mm 10cm^2 Electrode
AC-004 & AC-007-UA-A (w/Phone Clip)	28 grams, 89 x 48 x 9 mm 10cm^2 Electrode
AC-009	15 grams, 82 x 32 x 4 mm 9 cm^2 Electrode
AC-009-UA-DI	15 grams, 82 x 32 x 4 mm 9 cm^2 Electrode
AC-011 (sensor only)	30.6 grams, 2.1 x 2.0 x 0.8 cm 3 cm^2 Electrode

Environmental Specifications

Operational Temperature	+10 to +45 degrees C

Operational Humidity	10% to 95% (non-condensing)
Operational Altitude	based on your smartphone, smartwatch, or tablet specification
Storage Temperature	0 to +40 degrees C
Storage Humidity	10% to 95% (non-condensing)

Ingress Protection Marking

KardiaBand is IP64 rated, meaning that it is splash resistant but that submerging it in water is not recommended. KardiaBand is compliant with standard IEC60601-1-11:2015.

Expected Service Life

The expected service life is 2 years for KardiaBand.

Warm up time

Warm up time is not required for KardiaMobile or for KardiaBand for their intended uses.

User Interface

Two stainless-steel electrodes are exposed on the back of KardiaMobile. These electrodes make contact with the user's skin. For the KardiaBand, two stainless-steel electrodes are exposed on the front and back of the KardiaBand. These electrodes make contact with the user's skin.

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

AliveCor®

25. EUROPEAN AUTHORIZED REPRESENTATIVE

Obelis SA
BD General Wahis 53
1030, Brussels
Belgium
Tel: +(32) 2. 732.59.54
Fax: +(32) 2.732.60.03
E-Mail: mail@obelis.net

26. ALIVECOR (MANUFACTURER) CONTACT INFORMATION

AliveCor, Inc.
444 Castro Street, Suite 600
Mountain View, CA 94041
United States
www.alivecor.com

AliveCor, Ltd.
Herschel House
58 Herschel Street
Slough
SL1 1PG
United Kingdom

27. ELECTRICAL SAFETY

27.1. KARDIAMOBILE ELECTRICAL SAFETY

Guidance and manufacturer's declaration - electromagnetic emissions		
KardiaMobile is intended for use in the electromagnetic environment specified below. The customer or the user of KardiaMobile should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	KardiaMobile uses RF energy only for its internal function. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	KardiaMobile is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

AliveCor®

Guidance and manufacturer's declaration—electromagnetic immunity			
KardiaMobile is intended for use in the electromagnetic environment specified below. The customer or the user of KardiaMobile should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of KardiaMobile requires continued operation during power mains interruptions, it is recommended that the KardiaMobile be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE— U_T is the a.c. mains voltage prior to application of the test level.			

AliveCor®

Guidance and manufacturer's declaration—electromagnetic immunity			
KardiaMobile is intended for use in the electromagnetic environment specified below. The customer or the user of KardiaMobile should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of KardiaMobile, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\dfrac{3.5}{V_1}]\sqrt{P}$ $d = [\dfrac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\dfrac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: $((\cdot))$
NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which KardiaMobile is used exceeds the applicable RF compliance level above, KardiaMobile should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating KardiaMobile. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between

portable and mobile RF communications equipment and KardiaMobile

KardiaMobile is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of KardiaMobile can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and KardiaMobile as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = [\dfrac{3.5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\dfrac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.5 GHz $d = [\dfrac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1—At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

27.2. KARDIABAND ELECTRICAL SAFETY

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

Guidance and manufacturer's declaration - electromagnetic emissions		
KardiaBand is intended for use in the electromagnetic environment specified below. The customer or the user of KardiaBand should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	KardiaBand uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	KardiaBand is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

AliveCor®

Guidance and manufacturer's declaration—electromagnetic immunity			
KardiaBand is intended for use in the electromagnetic environment specified below. The customer or the user of KardiaBand should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

AliveCor®

Guidance and manufacturer's declaration—electromagnetic immunity			
KardiaBand is intended for use in the electromagnetic environment specified below. The customer or the user of KardiaBand should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	N/A	N/A	Portable and mobile RF communications equipment should be used no closer to any part of KardiaBand, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $$d = [\frac{3.5}{E_1}]\sqrt{P}$$ 80 MHz to 800 MHz $$d = [\frac{7}{E_1}]\sqrt{P}$$ 800 MHz to 2.7 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	10 V/m	
NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which KardiaBand is used exceeds the applicable RF compliance level above, KardiaBand should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating KardiaBand. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.			

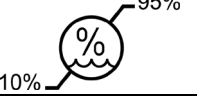| Recommended separation distances between portable and mobile RF communications equipment and KardiaBand			
KardiaBand is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of KardiaBand can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and KardiaBand as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3.5}{E_1}]\sqrt{P}$	**800 MHz to 2.7 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.035	0.035	0.070
0.1	0.11	0.11	0.22
1	0.35	0.35	0.70
10	1.1	1.1	2.2
100	3.5	3.5	7.0
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1—At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

AliveCor®

28. SYMBOLS USED SYSTEM OR PACKAGE LABELING

Symbol	Description
	Type BF Applied Part (KardiaBand)
	Type CF Applied Part (KardiaMobile)
CE 0123	European Conformity Mark
	Do not dispose with household waste
	Read instructions before use
	Manufacturer
45°C / 10°C	Temperature range
95% / 10%	Humidity range
QTY	Quantity of device included in the package
REF	Model number
SN	Serial number