User Manual for Kardia™ by AliveCor®

Contents

1. PRODUCT DESCRIPTION

Kardia™ by AliveCor® is a family of mobile, clinical-quality electrocardiogram (EKG or ECG) recorders. Users may record EKGs using Kardia™ Mobile with their smartphone or tablet, or the Kardia™ Band with their Apple Watch.

The duration of the recording is established by the Kardia phone and Kardia watch apps with a default setting of 30 seconds. The Kardia phone app may extend recordings to a maximum time of 5 minutes. The software application can store thousands of recordings on your smartphone or tablet and these recordings are also accessible to authorized users on AliveCor servers (www.alivecor.com).

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

The Kardia Mobile product consists of:

1. Kardia Mobile attaches to your compatible smartphone or tablet and has electrodes to transmit EKG rhythms to the smartphone or tablet.
2. The Kardia phone app is used to collect, view, save, and wirelessly transmit recordings to the AliveCor server.
3. A user-supplied compatible smartphone or tablet

The Kardia Band product consists of:

1. Kardia Band has electrodes embedded into the watchband that transmit EKG rhythms to the Apple Watch.
2. The Kardia watch app (a companion to the Kardia phone app) is used to collect, view, save, and wirelessly transmit recordings to the AliveCor server.
3. Kardia phone app
4. A user-supplied compatible iOS smartphone or tablet
5. A user-supplied compatible Apple Watch

CAUTION: The Kardia Mobile and Kardia Band products have features that are only available to those users who are under the care of a physician. These features are available to prescription users only.

The Kardia Mobile and Kardia Band products enable users to:

- Collect and store single-channel EKG recordings using the smartphone, smartwatch, or tablet.
- Record voice memos that are automatically transcribed to notes.
- Edit user information data associated with the recording.
- Wirelessly transmit EKG recordings to the AliveCor server.
- Access EKG recordings stored on the AliveCor server.
- Print or save the recording in PDF format.
- Request professional clinical interpretation and analysis of your EKG recordings.

- Track events that may impact your heart health, such as symptoms, activities, diet, etc.

After a user has created an account on the Kardia phone app and received an EKG analysis, the Kardia Mobile and Kardia Band products enable a user to:

- View EKG recordings in real-time and after the recording.
- View the output of the Atrial Fibrillation, Normal, and Unreadable Detectors.

1.1. Indications for Use – U.S.

Kardia Mobile:

The Kardia Mobile product is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The Kardia Mobile product 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 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.

Kardia Band:

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.

1.2. Contraindications

There are no known contraindications for the Kardia Mobile or Kardia Band products, although care should be taken when considering using the device according to the warnings and precautions below.

2. CAUTIONS

General:
- DO NOT store in extremely hot, cold, humid, wet, or bright conditions.
- DO NOT expose to strong electromagnetic fields.
- DO NOT take recordings in close vicinity to other equipment emitting ultrasonic acoustics.
- DO NOT take recordings in a moving vehicle.
- DO NOT use as sole basis for medication treatment decisions. Accuracy is less than 100%. Contact your physician with any questions or concerns regarding medication use.
- DO NOT use Kardia Mobile while charging your phone. DO NOT use Kardia Band 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, 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.
- DO NOT use in the presence of flammable anesthetics, drugs or pressurized oxygen.
- After ECG 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.

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3. SET UP KARDIA MOBILE OR KARDIA BAND AND TAKE THE FIRST EKG RECORDING

3.1. Decide which smartphone, smartwatch, or tablet to use

Your Kardia Mobile or Kardia Band is compatible with all of the smartphones, smartwatches, and tablets listed on AliveCor's website: https://store.alivecor.com/#compatibility, including:

- iPhone 4s, 5/5s, 5c, 6/6 Plus, 6s/6s Plus, 7/7 Plus, and SE
- iPad Air and Air 2
- iPad Mini, Mini 2, and Mini 3
- iPad Pro 9.7-inch
- iPod Touch 5G
- Apple Watch, Series 1 and Series 2, 38mm and 42mm

The Kardia phone app is compatible with iOS versions 5.1 – 10.0.2 and WatchOS 3.0.

- Samsung Note 3 and Note 5
- Samsung Galaxy S3, S4, S5, S6, and S7
- Samsung Galaxy J1
- LG Nexus 5
- HTC One and HTC 10
- Jitterbug Touch 2 and Touch 3

The Kardia phone app is compatible with the Android operating system versions 4.0 – 6.0.1.

Kardia Mobile for iPhone 5/5s and iPhone 6/6s can also be used on all compatible smartphones or tablets by removing Kardia Mobile from its case:

1. If Kardia Mobile is currently attached to an iPhone 5/5s/6/6s, remove it and its case from your iPhone 5/5s/6/6s (press gently on the phone camera through the case cutout and peel back from that corner of Kardia Mobile).
2. Face the electrodes of Kardia Mobile away from you.
3. AC-007: Gently push the left side of Kardia Mobile toward you while at the same time gently pulling the left edge of the case away from the device itself.
4. Kardia Mobile should then "pop out" of its case.

3.2. Unpack Kardia Mobile (Kardia Mobile Users)

1. Remove Kardia Mobile from the box.
2. Choose Kardia Mobile placement.
   a) For Kardia Mobile cases, place Kardia Mobile on your phone as you would any standard phone case.
   b) The Kardia Mobile can be attached directly to the smartphone or tablet or to the case of your choosing (the surface should be smooth and flat).
      a. AC-001 - AC-007: With the AliveCor logo right side up, the top of the smartphone or tablet should be on the right.
      b. AC-009: With the 'K' of the Kardia logo closest to the top of the smartphone or tablet .

c) For use with an iPad, AliveCor does not recommend attaching Kardia Mobile to your iPad. Instead, rest Kardia Mobile in both hands or place it on a flat surface less than one foot away from the iPad to record EKGs.

Note: The Kardia Mobile must be less than 1 foot from the smartphone or tablet to ensure communication between devices.

3.3. Unpack Kardia Band (Kardia Band Users)

1. Remove Kardia Band from the box, which consists of 2 pieces – one band that attaches to the 12 o'clock side of the watch body and the other band that attaches to the 6 o'clock side of the watch body. The band that attaches 6 o'clock side the watch body contains the electrodes.
2. Remove existing watchband from the Apple Watch – consult the watch user manual, if necessary.
3. Attach the Kardia Band EKG to the Apple Watch – consult the watch user manual, if necessary. Ensure that the band with electrode attaches to the 6 o'clock side of the watch body.

3.4. Download the Kardia phone app

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

NOTE: The Apple Watch only works with the Apple iPhone – consult the watch user manual, if necessary.

3.5. Add Kardia watch app to Apple Watch

1. Open the Apple Watch app on your iPhone and tap the My Watch tab.
2. Scroll to find the Kardia watch app and tap it.
3. Tap the "Show App on Apple Watch" and "Show in Glances" toggles to turn on each feature.

NOTE: The toggle will turn to green if turned to the 'on' position.

3.6. Set up an AliveCor Account

You will use your AliveCor account to access, print, and save your EKG recordings stored on the Kardia phone app and the AliveCor server. Follow the instructions presented when you open the Kardia phone app for the first time. You can go back later and change your information if necessary.

NOTE: Kardia Band customers will be directed to the Kardia phone app to setup their account and go through onboarding.

3.7. Set up an AliveCor Account

You will use your AliveCor account to access, print, and save your EKG recordings stored on the Kardia phone app and the AliveCor server. Follow the instructions presented when you open the Kardia phone app for the first time. You can go back later and change your information if necessary.

NOTE: Kardia Band customers will be directed to the Kardia phone app to setup their account and go through onboarding.

3.8. Free Trial for Premium Features

Once an account has been created, you have access to premium features for a period of time. 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.

4. RECORD EKG RHYTHMS

NOTE: You will not be able to view your recordings or utilize any of Kardia's detectors until you are under the care of a physician. To gain access to these features, you must create an account on the Kardia phone app. Your first recording will then be automatically sent for a free analysis by a cardiologist (US customers only). Once you have received the EKG analysis, you will have access to view that recording and subsequent recordings.

4.1. To take an EKG recording with Kardia Mobile, follow the instructions below.

Before taking each recording:

- Disconnect headphones, charger cables, or any other connected devices.
- Clean the two electrodes with alcohol-based sanitizer.
- Using your smartphone or tablet, launch the Kardia phone app.

1. Select an EKG option – Standard EKG, Resting Heart Rate, or Guest EKG. All options will record an EKG. "Standard EKG" is recommended for taking an EKG at any time, e.g. when you are feeling symptomatic. "Resting Heart Rate EKG" is recommended to establish your resting heart rate baseline. We recommend taking that EKG when you first rise in the morning; the time of day when the body is most rested. "Guest EKG" is the recommended option when a family member or friend needs to record an EKG.

2. Rest two or more fingers (it doesn't matter which fingers) on Kardia Mobile; your right hand should contact the electrode closest to the bottom of the smartphone or tablet, and your left hand should contact the electrode closest to the top of the smartphone or tablet. This is a Lead I EKG.

3. While recording your EKG, 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 ECG, the left knee should contact the electrode closer to the top of the smartphone or tablet and the right hand should contact the electrode closer to the bottom of the smartphone or tablet.
- For an Anterior Precordial Lead, the device can be placed on the lower left side of the chest, just below the pectoral muscle. The bottom of the smartphone or tablet should be pointing towards the center of the body.

4.2. To take an EKG recording with the Kardia Band, 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 watch app on the Apple Watch to open the application.
2. With your right hand, grasp your left hand. Rest your right thumb on the outer electrode on the Kardia Band EKG. The inner electrode should be in contact with the skin of your left wrist. This is a Lead I EKG.
3. Tap the "Record EKG" button. A 3-second countdown will appear; ensure that your hands and fingers are in the proper position (described above).
4. While recording your EKG, speak your symptoms (e.g. "I'm feeling palpitations.") into 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 phone app.
5. The recording takes 40 seconds.

Additionally, you may add notes or tags to the recording in the Kardia phone app. Tags include symptoms, activities, diet, etc. that are relevant to heart health:

- When your recording is complete, you will arrive at the Data Entry screen where you may add notes or tags such as symptoms, activities, diet, etc.
- Alternatively, you may go to the Journal 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.

NOTES:

- The Kardia Mobile and Kardia Band do not require a Wi-Fi or mobile 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 phone app. If you do not have a Wi-Fi or mobile 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.

- Kardia Mobile may be used up to a distance of 30 cm (1 ft.) from the smartphone or tablet. Using Kardia Mobile at a distance greater than 30 cm (1 ft.) may lead to communication issues between the devices and your recording may not be successful.

- Kardia Band must be attached to the Apple Watch. Using Kardia Band at a greater distance may lead to communication issues between the devices and our recording may not be successful.

- To reduce muscle noise, rest your arms on a flat surface to increase stability while you are recording.

- You must maintain contact with the electrodes for at least 10 seconds for the recording to be saved. If you remove contact after 10 seconds, but before the selected recording duration is complete, the EKG will be saved and you will be able to review it.

- The recording must be at least 30 seconds long for the detectors to work.

- If you are in a noisy area (e.g. train station, coffee shop, etc.), the voice recording with the Kardia Band 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 phone app.

5. ONCE THE RECORDING IS FINISHED

5.1. For Kardia phone app:

- Immediately after recording, you will be shown an analysis of your EKG if it is available.

- 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 you may also edit the transcribed voice memo. After making your choices, tap "Save" to continue.

- You may review the EKG in the Journal 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 Journal 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 Journal screen, or on the EKG Review screen.

5.2. For Kardia watch app:

- Immediately after recording, you have the option to save the recording by tapping "Save" or delete the recording by tapping "Cancel."

- If an EKG was successfully recorded, an analysis result for your EKG appears, if one is available. Dismiss the result by tapping "Close."

- Use the digital crown to scroll the EKG tracing.

- Force touch the EKG tracing to replay the audio, invert the EKG, or delete the recording.

- On the Home screen in the Kardia watch app, tap the "Record EKG" button to take another EKG recording or view the last EKG recorded.

- Force touch the Home screen to view a tutorial and how to contact customer support.

NOTE: The EKG recordings with a green " " are ones that have been synced to the AliveCor servers; those marked with a red "x" have not been synced to the AliveCor servers. Those EKG recordings that have not been synced will sync once the Apple Watch has connected to the Kardia phone app on the iPhone. Note, the Kardia watch app will store all unsynced recordings until the sync has completed with the Kardia phone app.

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

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

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

- Tap Journal, then tap the blue "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 Journal screen in chronological order, and may be edited anytime by selecting the dropdown arrow to the right of the event on the Journal screen.

7. SETTINGS AND ADJUSTMENTS (KARDIA PHONE APP ONLY)

7.1. Recording Adjustments
- **Paper Speed.** Paper speed of the EKG in the PDF report can be set to 12.5mm/s, 25mm/s, or 50mm/s. This option is only available to health professionals. These changes can be made prior to the recording. Alternately, you can pinch and zoom when viewing the recording as a PDF (tap the envelope icon and tap "PDF").
- **Gain**. Gain of the EKG in the PDF report may be set to 5mm/mV, 10mm/mV or 20mm/mV. This option is only available to health professionals. These changes can be made prior to the recording. Alternately, you can pinch and zoom when viewing the recording as a PDF (tap the envelope icon and tap "PDF").
- **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 Kardia Mobile 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.

7.2. Adjustable Settings
To access the Settings, tap the "More" icon at the upper right and then tap "Settings".

- **Duration**. Recording Duration is the maximum length of time the Kardia phone app will record a single EKG recording. For example, if the recording duration is set to 30 seconds, the Kardia phone app will automatically stop recording after 30 seconds of data has been collected.
- **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, set the frequency, and time for the reminder. You can also turn the AF Detector on or off, and modify your medication reminders.
- **Mode**. Tap to modify device transmission settings. Normal mode is recommended for most users. If your facility or location limits wireless communication, the Airplane/ICU setting may be selected.

8. EMAIL, PRINT, OR DELETE RECORDINGS

You may email/print recordings from either the Kardia phone app or your account on the server (www.alivecor.com).

To email a recording from the Kardia phone 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.

1. Tap the envelope icon next to the EKG you would like to email/print on the Journal 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.

To print a recording from the Kardia phone app, you must have an AirPrint compatible printer set up on your smartphone or tablet (iOS only). If you need assistance setting up an AirPrint compatible printer or troubleshooting your AirPrint compatible printer, contact your smartphone or tablet provider for assistance.

1. Tap the envelope icon next to the EKG that you would like to email/print on the Journal screen. Alternatively, you may tap the EKG, then tap the envelope icon on the EKG Review screen
2. Tap Print.

To print a recording from the website:
1. Go to www.alivecor.com.
2. Click the "SIGN IN" and enter your email address and password.
3. Select the desired recording by clicking the appropriate "View EKG" button on the right.
4. Click the "View PDF" link.
5. Print from your computer as you would any PDF.

To delete a recording:

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

To delete or invert a recording in the Kardia watch app:
1. Go to the Home screen in the Kardia watch app.
2. Tap the EKG recording that you wish to delete.
3. Firmly press (force touch) the recording. A new screen will appear providing options to delete or invert the recording.
4. Tap the appropriate option – "Delete" or "Invert". Tap anywhere else on the screen to cancel. "Cancel" if you do not wish to delete or invert the recording.

9. JOURNAL (KARDIA PHONE APP ONLY)

Journal is a premium feature where your previously recorded EKG recordings are displayed. To access it, tap the "Journal" icon.

- Launch the Kardia phone app.
- Tap Journal 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.

10. SEARCH OR FILTER RECORDINGS (KARDIA PHONE APP ONLY)

You may search or filter the events in the Journal 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 Journal 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 Journal 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.

11. VIEW AN EKG RECORDING ON THE ALIVECOR WEBSITE

To view an EKG recording on the AliveCor website, follow the instructions below:

- On your web browser, go to www.alivecor.com and click "SIGN IN"
- Enter your email address and the password you created when you set up your AliveCor account. Click "Sign In".
- The EKG recordings you collected were automatically synced to the AliveCor server and will appear in list form, and each transmission is stored as an Adobe Acrobat PDF file and can also be viewed in HTML. Click the "View EKG" button.
- Click the back button in your browser to return to your AliveCor account homepage.

12. CLINICIAN REVIEW (KARDIA PHONE APP ONLY)

The Kardia phone 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.

To request a Clinician Review:

1. Tap Journal 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 "Journal".
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.

13. DETECTORS (ATRIAL FIBRILLATION, NORMAL, UNREADABLE)

NOTE: Your EKG must be at least 30 seconds long to use the Atrial Fibrillation and Normal detectors. If an EKG is recorded that is less than 30 seconds, neither the Atrial Fibrillation nor the Normal detector will display a result.

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. You should contact your physician to review any EKG recording in which atrial fibrillation was detected, or send it to EKG Analysis. If you are experiencing any symptoms or concerns contact a medical professional.

The AF detector monitors 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.

The AF detector only monitors for AF while you are taking a recording. It does not continuously monitor your heart and therefore cannot alert you if AF happens at any other time.

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. 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 this recording to be normal.

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 is "Unreadable" and given some suggestions for acquiring the best 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.

13.1. What is Atrial Fibrillation?

The most common type of non-sinus tachyarrhythmia is atrial fibrillation. In this case, 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 problems, namely, 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.

13.2. AF, Normal, Unreadable, and Unclassified Recordings in EKG review screen and Journal

All tracings analyzed as positive for atrial fibrillation, normal, or unreadable will have a tag for future review. The Kardia phone app and Kardia watch app may display the "Unclassified" message for a tracing that is not Normal and not AF, and interference was not detected. An example of an unclassified tracing is one where tachycardia is observed. These tags will be visible in the Journal screen, Data Entry screen, and the EKG review screen.

13.3. Activation of the Detectors

The Unreadable and Unclassified detectors can be turned on or off in the settings of the Kardia phone app only.

13.4. Detector Usage

Note that 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, reliance on the analysis messages (e.g. "Normal", "Unreadable", etc.) of these recordings is not recommended.

14. MEDICATIONS (KARDIA PHONE APP – IOS ONLY)

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

- Tap "Insights" in the Menu at the bottom of the screen. Scroll to the bottom of the Insights screen and tap "Log Medications". You may edit your medications or select those taken that day.
- 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 also edit your medications by accessing your Profile. Tap ". . . ", "Profile", "Medications".
- You may view medications selected on the Insights screen.
- You may select a medication more than once per day by tapping "Medications Logged" at the bottom of the Insights screen, and tapping the specific medication again. The number to the right of the medication will update.

15. INSIGHTS (KARDIA PHONE APP ONLY)

Insights is a premium feature where your data will be graphed over time. To access it, tap the "Insights" icon. The following items are graphed in Insights over a 7-day period, and over a 14-day period (iOS only) when the Kardia phone app is turned to landscape view:

- Number of EKGs recorded, including the number of AF recordings and Normal Recordings
- Heart rate (bpm) in each EKG recording
- Symptoms, activities, diet, etc.
- Medications that were selected (iOS only)

NOTE: Your Insights are also available by logging into your account on www.alivecor.com. Insights data is available in 30-day increments, from when you first created your account. Note that this feature is available for individual users only, not for medical professionals.

16. HEALTH APP AND GOOGLE FIT INTEGRATION

The Kardia phone app is integrated with the Apple Health and Google Fit apps. Information about your activities and vitals helps us provide you with a monthly (premium) Personal Report. 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 phone app shares the following pieces of information with the Apple Health and Google Fit app:

- Heart Rate
- Height
- Weight

The Kardia phone 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

17. REFERRAL CODE

If you were prescribed Kardia by your doctor or through a cardiac monitoring service, you should have received 12-character referral code. The code may be entered during account creation or may be entered by tapping the heart icon located at the top right of the Home screen on the Kardia phone app. Once a valid code has 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 heart icon located at the top right of the Home screen.

18. BLOOD PRESSURE

iOS

AliveCor has formed a partnership with Omron. The partnership allows us to upload blood pressure readings directly into the Kardia phone app.

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

1. From the Home screen, tap Blood Pressure.
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 phone app to begin pairing.

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

Upload your blood pressure readings into the Kardia phone 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 phone app.

NOTE: *Only Omron blood pressure monitors that are compatible with the Apple iPhone. Check with Omron for more information.

Android

Blood pressure measurements may be transferred from Google Fit or manually entered into the Kardia phone app. If you have a blood pressure monitor that is connected to Google Fit, you may transfer your blood pressure measurements from Google Fit into the Kardia phone app.

Connect to Google Fit

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.

19. WEIGHT

Track your weight over time in the Kardia phone app. You have the option to enter your weight manually or the Kardia phone app my gather the weight data from the Apple Health or Google Fit app.

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.

Manual entry

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 Journal screen and tap Weight.

20. PERSONAL REPORT

The Personal Report, a premium feature, is a monthly report that displays any associations between your Kardia data and your activity data. The Personal Report provides you with analysis, insights, and actionable advice to help you care for your heart. The report quality improves as you share more of your activity data through the Apple Health app.

21. ACCESSING HELP

Learn more about using your Kardia Mobile by tapping the menu icon at the top left of the home screen. Tap "Support" to see all the options available.

- **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 Kardia Band by tapping the information icon accessed through the Home screen in the Kardia watch app (force touch on the Home screen). Instructions for accessing the user manual will appear.

22. EDITING USER PROFILE (KARDIA PHONE APP ONLY)

- Launch the Kardia phone app.
- Tap menu icon at the top left of the home screen.
- Tap "Your Profile".

- All user details can be edited.

23. ACCESSING EDUCATION (KARDIA PHONE APP ONLY)

- Launch the Kardia phone app.
- Tap menu icon at the top left of the home screen.
- Tap "Heart Education". Users have the ability to learn about:
    - Cardiac Anatomy
    - What is an EKG
    - Arrhythmia Library
    - 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.

24. PROVIDER DASHBOARD (WEB APP ONLY)

The Provider Dashboard allows medical professionals the ability to view their patients' recordings automatically from their own account. To create a medical professional account, download the Kardia phone app and follow the prompts to create a new account.

To view a patient's future recordings, you must send them an invite via email. To send an email invite:

1. Go to www.alivecor.com
2. Click "SIGN IN" and enter your email address and password
3. Click "PATIENT MANAGEMENT"
4. Click "Invite a Patient"
5. Type in the patient's email address (this must be the email address they use for their AliveCor account)
6. Click "Send Email"

25. TROUBLESHOOTING

Problem	Solution

My Kardia Mobile is not working.	If you're taking your first recording, ensure that your Apple iPhone "Portrait Orientation Lock" is not on as you must be able to turn your phone to landscape orientation (bottom of the iPhone in your right hand) in order to take a recording.
	
	If you're using iOS 7 or greater, ensure that the Kardia phone app has access to the iPhone microphone:
	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 Kardia Mobile:
	
	    a. Remove the case from the smartphone or tablet by pushing the iPhone through the camera cutout, while peeling back Kardia Mobile from this corner.
	
	    OR
	
	    b. Remove Kardia Mobile from the attachment plate:
	
	        1. AC-001 - AC-007: Place your thumbs on the electrodes and press down firmly. Turn counterclockwise about 45 degrees to "unlock" Kardia Mobile. Once it's "unlocked", Kardia Mobile can then be lifted out of the plate.
	
	        2. AC-009: Use your thumbs to slide Kardia Mobile 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.

Problem	Solution
My Kardia Band is not working.	Ensure that the Kardia watch app has access to the smartwatch'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. Remove the Kardia Band from the watch. Gently pull the watchband and gently push the Kardia Band sensor from the groove of the watchband. 2. Remove the battery door. Use a 1.6mm Phillips screwdriver, press down firmly and turn counterclockwise to remove the screw in the battery door. 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.
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 Kardia Mobile 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 Kardia Mobile rest on the hands. Do not squeeze Kardia Mobile. • 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 phone app Settings.

Problem	Solution
The EKG rhythms appear upside down	In the future, ensure that the left hand contacts the electrode closer to the top of the smartphone or tablet, and the right hand contacts the electrode closer to the bottom of the smartphone or tablet. To invert a recording on your smartphone or tablet, see "Invert the EKG recording" under "Recording Adjustments".
I forgot my password and I'm unable to reset it	To reset your password, go to www.alivecor.com and click "Sign In" at the bottom of the screen. Click "Forgot your password?" link below the Password field, enter your email address, and click Submit. Follow the reset instructions in the email. Note, the reset link contained in the email is only active for a short while.
The PDF Report looks slightly different on the Web and in my App	There is a 2.5 millisecond (thousandth of a second) difference in where the PDF starts for the Web Application and the Mobile Application. There is no difference in the recording and it will not impact how your EKG is interpreted.
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.
The HUD symbol is covered up when I rotate my phone	The heads up display (HUD) symbol can sometimes be partially obstructed when you rotate your phone while it's busy. This isn't a concern; the HUD symbol is just letting you know that the app is working. This doesn't impact your recording or any of your information.
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 a very rare problem that lasts until your first heartbeat is seen in the app and doesn't affect the rest of your recording.
The real-time display of my EKG recording is lagging and jumps	If you are using an iPhone 4 and syncing a large amount of recordings from the server the real-time display of your EKG may be slow. This is an issue that has been reported for iPhone 4 and occurs after an update or after a new install of the application on a new phone. This does not impact the EKG recording itself. Waiting for sync to complete (can take up to 30 minutes) after re-installing the application will prevent this error from occurring.
The EKG was lost when I was recording it	Rotating your phone while recording so that the screen "flips" from portrait to landscape mode will automatically stop the recording and that EKG will not be saved. Please do not rotate your phone while recording as this will impact the quality of your recording.

Problem	Solution
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 you 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, and Spanish.

26. KARDIA 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 .... 3V Coin Cell

Battery life (Kardia Mobile) .... min. 200 Hours Operational Time, 12 months typical use

Battery life (Kardia Band)..................... 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/Attachment Plate). 28 grams 89 x 48 x 9 mm 10cm^2 Electrode

AC-009 ....18 grams 82 x 32 x 3.5 mm 9 cm^2 Electrode

AC-009-DI-A ....18 grams 82 x 32 x 3.5 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 .... -20 to +60 degrees C

Storage Humidity .... 10% to 95% (non-condensing)

User Interface

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

27. 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

28. ALIVECOR CONTACT INFORMATION

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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

29. ELECTRICAL SAFETY

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

Guidance and manufacturer's declaration—electromagnetic immunity

Kardia Mobile and Kardia Band are intended for use in the electromagnetic environment specified below. The customer or the user of Kardia Mobile or Kardia Band 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 Kardia Mobile or Kardia Band requires continued operation during power mains interruptions, it is recommended that the Kardia Mobile or Kardia Band 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.

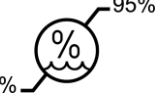| Guidance and manufacturer's declaration—electromagnetic immunity			
Kardia Mobile and Kardia Band are intended for use in the electromagnetic environment specified below. The customer or the user of Kardia Mobile or Kardia Band should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of Kardia Mobile or Kardia Band, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $$d = [\frac{3.5}{V_1}]\sqrt{P}$$ $$d = [\frac{3.5}{E_1}]\sqrt{P} \quad \text{80 MHz to 800 MHz}$$ $$d = [\frac{7}{E_1}]\sqrt{P} \quad \text{800 MHz to 2.5 GHz}$$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	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:
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 Kardia Mobile or Kardia Band is used exceeds the applicable RF compliance level above, Kardia Mobile and Kardia Band should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Kardia Mobile or Kardia Band. [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 Kardia Mobile or Kardia Band			
Kardia Mobile and Kardia Band are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Kardia Mobile or Kardia Band can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Kardia Mobile or Kardia Band 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.			

30. SYMBOLS USED SYSTEM OR PACKAGE LABELING

	Type BF Applied Part (Kardia Band)
	Type CF Applied Part (Kardia Mobile)
CE 0123	European Conformity Mark
	WEEE – Properly Dispose of Electronic Waste
	Consult Instructions for Use / User Manual
	Manufacturer
45°C 10°C	Temperature Limits (Operational)
95% 10%	Relative Humidity Limits (Operational)
REF	Model Number
SN	Serial Number
	Radio Frequency