

AliveCor® Kardia™ Mobile

User Manual for Android

NOTE: For the current information on your product, visit <http://www.alivecor.com/user-manual>

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1. PRODUCT DESCRIPTION

The Kardia™ Mobile by AliveCor® (Kardia Mobile) is a mobile, clinical-quality electrocardiogram (EKG or ECG) recorder. The duration of the recording is established by the Kardia Phone App with a default setting of 30 seconds and 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, Inc. (AliveCor) servers (www.alivecor.com).

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

The device consists of three components:

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.

CAUTION: Kardia Mobile has features that are only available to users who are under the care of a physician. These features are available to prescription users only.

Kardia Mobile enables users to:

- Collect and store single-channel EKG recordings using the smartphone 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, activity, etc.

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

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

1.1. Indications for Use - US

Kardia Mobile by AliveCor is intended to record, store, and transfer single-channel electrocardiogram (EKG or ECG) rhythms. Kardia Mobile by AliveCor 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). Kardia Mobile by AliveCor is intended

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

1.2. Indications for Use - OUS

Kardia Mobile by AliveCor is intended to record, display, store, and transfer single-channel electrocardiogram (EKG or ECG) rhythms. Kardia Mobile by AliveCor also detects the presence of atrial fibrillation and normal sinus rhythm in each recording. Kardia Mobile by AliveCor is intended for use by healthcare professionals, patients with known or suspected heart conditions, and health conscious individuals.

1.3. Contraindications

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

2. GENERAL SAFETY PRECAUTIONS

- The device should not be used near water, or in a wet environment.
- Do not use this device in locations subject to high or low temperatures or humidity. It should be used within the temperature and humidity range according to the product label.
- Do not sterilize this device with an autoclave or glass sterilizer.
- Audio and video products and similar equipment may cause interference. Please stay away from such equipment when you are recording.
- Do not take recordings in a location where the device will be exposed to strong electromagnetic forces, such as near an arc welder, high-power radio transmitter, etc.
- Signal quality may degrade by detecting signals from other ultrasonic acoustic sources. Do not use the device in close vicinity to other equipment emitting ultrasonic acoustics such as espresso machines, some ventilation systems or another Kardia Mobile.
- The smartphone or tablet power adapter may degrade signal detection. Do not use Kardia Mobile while charging the smartphone or tablet.
- Disperse any static electricity from your body before using the device.
- Do not take recordings in a moving vehicle.
- Do not expose the device to strong shocks or vibrations.
- Do not disassemble, repair, or modify the device.
- Do not insert battery with polarity reversed.
- Do not use batteries of a type other than that specified for use with the device.
- Do not take a recording if the electrodes are dirty. Clean them first.
- Do not use for any purpose other than obtaining an electrocardiogram.
- If the portion of the body where the electrode is applied has too much body fat, body hair, or very dry skin, a successful recording may not be possible.

- Some children and adults with very sensitive auditory ability may hear a high-pitched hum or buzz emitting from the device when activated. This is due to normal device function.

3. STORAGE, HANDLING AND MAINTENANCE

Do not store the device in:

- Locations exposed to direct sunlight
- Locations subject to high temperatures and high humidity
- Wet or damp locations where water may get on the device
- Dusty locations
- Near fires or open flames
- Locations exposed to strong vibration
- Locations exposed to strong electromagnetic fields

No maintenance of this system is required, except:

- The battery should be replaced when necessary.
- The electrodes should be cleaned using an alcohol-based sanitizer before each use.
- To prevent potential cross-infection of diseases between users, clean the device using alcohol prior to each use.

4. WARNINGS

- This device is not designed or intended for complete diagnosis of cardiac conditions. This device should never be used as a basis for starting or modifying treatment without independent confirmation by medical examination.
- This device records heart rate and heart rhythm only.
- This device does not detect or measure all heart rate, heart rhythm, and heart waveform changes, especially those related to ischemic heart conditions.
- Do not attempt self-diagnosis or self-treatment based on the recording results and analysis. Self-diagnosis or self-treatment may lead to deterioration of your health.
- Users should always consult their physician if they notice changes in their health.
- Do not use in the presence of flammable anesthetics, drugs, or pressurized oxygen (such as in a hyperbaric chamber, ultraviolet sterilizer or oxygen tent).
- Do not use this device during an MRI scan.
- Keep out of reach of infants, small children, or anyone incapable of using the device properly.
- The device has not been tested for use on infants weighing less than 10kg. AliveCor does not recommend using on humans less than 10kg.
- It is not recommended to place a mobile phone directly next to a pacemaker on the chest.
- Do not use this device with a defibrillator.
- AliveCor does not recommend using on individuals with a cardiac pacemaker, ICDs, or other implanted electronic devices.

- Do not attempt EKG data acquisition while there is an external microphone plugged into the smartphone or tablet.
- EKG reports viewed or printed at any magnification other than 100% may appear distorted and could lead to misdiagnosis.
- The heart rate is based on the heart rhythm; therefore, the rate is only valid if there is a valid rhythm (QRS complex visible).
- The Unreadable Detector may incorrectly identify ventricular flutter, ventricular bigeminy, and ventricular trigeminy as unreadable. If you have been diagnosed with one or more of these arrhythmias, we recommend turning off the Unreadable Detector in your Settings.
- AliveCor cannot guarantee that you are not experiencing an arrhythmia or other health condition when labeling an EKG as normal. You should notify your doctor of a possible change in your health.

5. SET UP KARDIA MOBILE AND TAKE THE FIRST EKG RECORDING

5.1. Decide which smartphone or tablet to use

Your Kardia Mobile is compatible with all of the smartphones and tablets listed on AliveCor's website: <http://www.alivecor.com/compatibility>, including:

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

The Kardia phone app is compatible with the Android Operating System versions 4.0 – 6.0.1.

You can use Kardia Mobile with Universal Attachment Plate on all compatible smartphones or tablets as listed on the Compatibility Chart.

5.2. Unpack Kardia Mobile by AliveCor

- Remove Kardia Mobile from the box.
- Kardia Mobile with Universal Attachment Plate can be attached to the smartphone or tablet directly or to the case of your choosing (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: With the AliveCor logo right side up, the top of the smartphone or tablet should be at the top.

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

5.3. Download the Kardia phone app

- Using your smartphone or tablet, search for “AliveCor” in the Google Play Store.

- Download and install the Kardia phone app.

5.4. 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. Signing up for an AliveCor account also enables you to send an EKG for analysis (select countries only). EKG analysis can be used any time you want a medical professional to interpret your EKG recording and is required if you would like to view your recordings or utilize Kardia's Detectors.

6. RECORD EKG RHYTHMS USING KARDIA MOBILE

Before taking each recording:

- Disconnect headphones, charger cables, or any other connected devices.
 - Clean the two electrodes with an alcohol-based sanitizer.
 - Using your smartphone or tablet, launch the Kardia phone app.
1. Rest two or more fingers (it does not 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.
 2. 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.

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.

Additionally, you can add notes or tags to the recording. 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 can add notes or tags such as symptoms, activities, diet, etc.
- Alternatively, you can 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 can add or edit notes and tags.

NOTES:

- Kardia Mobile does not require a Wi-Fi or mobile connection to record an EKG and save it to the smartphone or tablet, however it does require one of these 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 can email or print the data later when you have such a connection and the sync will happen automatically at that time.
- Kardia Mobile can 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.
- 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 in order for the Detectors to work.

7. ONCE THE RECORDING IS FINISHED

- 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 can also enter personalized tags or notes, and you may also edit the transcribed voice memo. After making your choices, tap “Save” to continue.
- You will be asked if this recording was a Guest recording or yours. You can edit the Guest name by tapping on “Guest” for the EKG recording on the Journal screen at any time.
- You can review the EKG in the Journal screen, or go to Insights and view the trending of your EKGs, heart rate, symptoms, activities, etc. You can 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 in the Journal screen, or on the EKG Review screen.

8. ENTER AN EVENT WITHOUT AN EKG

You can 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 can enter notes, or select tags such as symptoms, activities, diet, etc., or create personalized tags.
- In the Data Entry screen, you can 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 can be edited anytime by selecting the dropdown arrow to the right of the event on the Journal screen.

9. SETTINGS AND ADJUSTMENTS

9.1. Recording Adjustments

- **Sweep Speed.** Sweep 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.
- **Gain.** Gain of the EKG in the PDF report can be set to 5mm/mV, 10mm/mV or 20mm/mV. This option is only available to health professionals.
- **Enhanced Filter.** The Enhanced Filter suppresses noise in the EKG. The filter can 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 on the 'Enhanced Filter' 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 can be toggled on a particular EKG from the EKG Review screen. Tap “MORE” at the bottom of the EKG Review screen, and then tap on the 'Invert' switch to toggle it ON or OFF.

9.2. Adjustable Settings

To access Settings, tap the “More” icon, which is the vertical 3 dots at the top right of the app’s navigation, then tap “Settings”.

- **Recording 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. The recording duration can also be set to Continuous, where the system will record as long as the user maintains contact with the electrodes (up to 5 minutes).
- **AC Mains Filter.** The AC Mains Filter removes any mains interference from the

EKG; usually you should leave this set to Auto, where the app will select the appropriate frequency of the alternating current (AC) used in your country or region. For the United States, Canada and Mexico, this is 60 Hz; in most other countries, it is 50 Hz. If required, you can override the auto-selected value and set this to 50 Hz or 60 Hz.

- **Units.** Select this option to set the units for weight and height to Metric (cm, kg) or Imperial (lb., in).
- **PDF Reports.** Sets various options for the PDF report that you can View, Print, Email, and share. These settings affect the PDF report only. They do not affect the EKG display on the device or the analysis reports that are provided by our analysis partners.

10. EMAIL, PRINT, OR DELETE RECORDINGS

NOTE: If you are not enrolled in Kardia's EKG Analysis service, you will not be able to view the recording (US Only). AliveCor will unlock this feature if you are under the guidance of a physician.

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 mobile device. If you need assistance setting up an email account or troubleshooting your email account, contact your mobile device provider for assistance.

1. Tap the "Share" icon next to the EKG you would like to email/print on the Journal screen. Alternatively, you can tap the EKG in the Journal screen, then select "Share" on the EKG Review screen.
2. Tap Email. The PDF version of the EKG recording will be attached to a new email in whatever email account you have set up on your mobile device.

Note: Support for printing depends on the built-in printing options installed on your smartphone or tablet. Depending on your printer and Android smartphone or tablet, you may need to install a printer app from the Google Play Store.

To print a recording from the server:

1. Go to www.alivecor.com.
2. Click on "SIGN IN" and enter your email address and password.
3. Select the desired recording by clicking on 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”.

11. VIEW PREVIOUSLY RECORDED EKG RECORDINGS ON YOUR SMARTPHONE OR TABLET

NOTE: If you are not enrolled in Kardia’s EKG Analysis service, you will not be able to view the recording (US only). AliveCor will unlock this feature if you are under the guidance of a physician.

- Launch the Kardia phone app.
- Tap Journal in the menu to see a list of all EKG recordings on your mobile device (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.

12. SEARCH OR FILTER RECORDINGS

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 on the search icon on the top right.
2. Select one of the existing filters. The filters allow you to choose one of the following: Starred, Atrial Fibrillation, Analysis Reports, My EKGs, and Guest EKGs.
3. Your Journal page will show you EKGs that meet the filter criteria until you disable the filter.
4. You can disable the filter by tapping on the “x” icon next to the filter name on the top right of the Journal screen.

To search:

1. Tap the search icon on 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 can disable the search view by tapping “Cancel” on the top right of screen or edit your search term by tapping in the search bar and entering another term.

13. VIEW AN EKG RECORDING ON THE ALIVECOR SERVER

NOTE: If you are not enrolled in Kardia’s EKG Analysis service, you will not be able to view the recording (US only). AliveCor will unlock this feature if you are under the guidance of a physician.

- On your web browser, go to www.alivecor.com and click “SIGN IN”.
- Enter your email address and 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. 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.

14. EKG ANALYSIS

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 an EKG Analysis Report:

1. Tap Journal and find the EKG you would like to send for analysis. Tap “Share” to the right of the recording, then “EKG Analysis”. Alternatively, you can tap on the EKG in the Journal screen, and then tap “Analysis” at the top right of the EKG Review screen.
2. Select one of the listed Analysis Report options.
3. If you have not already entered your name, date of birth, and gender, you will be prompted to enter these details. Enter the required details and tap 'Save'.
4. You will then be prompted to 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 ‘Analysis’ 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 can access EKG Analysis Reports from the EKG Review screen by tapping on “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.

15. DETECTORS (ATRIAL FIBRILLATION, NORMAL, UNREADABLE)

NOTE: If you are not enrolled in Kardia’s EKG Analysis service, you will not be able to view the recording (US only). AliveCor will unlock this feature if you are under the guidance of a physician.

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 in the Kardia phone app 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 in the Kardia phone app 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 Kardia Mobile is 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.

WARNING: AliveCor cannot guarantee that you are not experiencing an arrhythmia or other health condition when labeling an EKG as normal. You should notify your doctor of a possible change in your health.

Unreadable Detector

The Unreadable Detector in the Kardia phone app 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.

WARNING: The Unreadable Detector may incorrectly identify ventricular flutter, ventricular bigeminy, and ventricular trigeminy as unreadable. If you have been diagnosed with one or more of these arrhythmias, we recommend turning off the Unreadable Detector in your Settings.

15.1 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.

15.2 AF, Normal, and Unreadable 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 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 screens.

15.3 Activation of the Detectors

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

15.4 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.

16. INSIGHTS

Your data will be graphed in the Insights section of the Kardia phone app. To access it, tap the “Insights” icon in the menu at top of the screen. The following items are graphed in Insights over a 7-day period:

- Number of EKGs recorded, including the number of AF recordings and Normal Recordings
- Heart rate (bpm) in each EKG recording
- Symptoms, activities, diet, etc

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.

17. HEALTH APP INTEGRATION

The Kardia phone app is integrated with the Google Fit app. Information about your activities and vitals helps us provide you with a monthly (premium) Personal Report – sharing more information, the better. You have the option of turning off the integration within the Google Fit app; however, doing so will limit the information available in your Premium Report. The Kardia phone app shares the following pieces of information with the Google Fit app:

- Heart Rate
- Height
- Weight

The Kardia phone app collects the following pieces of information from the Google Fit app:

- 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

18. PERSONAL REPORT

The Personal Report is a monthly report that displays any associations between your AliveCor 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 Google Fit app.

19. ACCESSING HELP

To access Help, tap the “More” icon (vertical 3 dots) at the top right of the navigation and select the menu item.

Learn more about using your AliveCor Kardia Mobile from the following tutorials included in the Kardia phone app:

- **Tutorials.** Review these tutorials to learn how to navigate all the features of the app.
 - Quick Tutorial
 - Recording an EKG
 - Sending an EKG for Analysis
 - Reviewing an Analysis Report
 - Alternate Recording Positions
- **Reference.** Learn about EKG analysis; access the user manual, feedback, and privacy and terms
 - User Manual
 - Privacy Notice
 - Terms of Service

20. EDITING USER PROFILE

To access Settings, tap the “More” icon (vertical 3 dots) at the top right of the navigation, and select the menu item.

- name@emailaddress.com: Email address of the current AliveCor account.
- User Profile: Details of the account holder.
 - For health professionals, enter your name and organization, which will be stored with each EKG recorded and printed on the reports.
 - For individual users enter your name and other details that will be stored with each new EKG recording.
- Credit Cards: Add or remove credit card details for purchasing EKG analysis reports.
- Sign In/Log out: Allows you to Log in or setup a new AliveCor account, or to log out if you are already logged in.

21. ACCESSING EDUCATION

To learn about different arrhythmias, cardiac anatomy and EKGs:

- Tap the “More” icon (vertical 3 dots) at the top right of the navigation.
- Tap Education.

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.

22. PROVIDER DASHBOARD

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 "Invite a Patient".
4. Type in the patient's email address (this must be the email address they use for their AliveCor account).
5. Click "Send Email".

23. ELECTRONIC HEALTH RECORD (EHR) INTEGRATION

Send to EHR: If you are a physician and your AliveCor account has been setup for integration with an Electronic Health Record system (EHR) you can send EKG recordings to your EHR. Tap the 'Send to EHR' icon to send the EKG.

24. TROUBLESHOOTING

| Problem | Solution |
|--|---|
| My Kardia Mobile is not working. | <p>Change the battery</p> <ol style="list-style-type: none"> 1. Expose the battery door at the back of Kardia Mobile. Remove the Kardia Mobile from the plate: <ol style="list-style-type: none"> a. 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. b. AC-009: Use your thumbs to slide Kardia Mobile toward the open end of the plate. 2. Remove the battery door: <ol style="list-style-type: none"> 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. |
| I have a lot of artifact, noise or interference in my recording. | <p>Try the following tips for acquiring the best quality EKG recording:</p> <ul style="list-style-type: none"> • 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. |
| The EKG rhythms appear upside down. | <p>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”.</p> |
| I forgot my password and I’m unable to reset it. | <p>To reset your password, go to www.alivecor.com and click on "SIGN IN" in the upper right corner and click on the "Forgot your password?" link below the Password field. On the Forgot Password screen, 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.</p> |
| The EKG was lost when I was recording it | <p>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.</p> |
| I can’t see my age in the PDF report | <p>If your first and last name 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.</p> |

| Problem | Solution |
|--|---|
| 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 double check that your credit card information is valid before processing payments. |
| I need a printed version of the manual | Please contact support@livecor.com for a printed copy of this manual. |
| Is the manual available in another language? | This manual is available in English and French. |

25. ALIVECOR KARDIA MOBILE 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 | min. 200 Hours Operational Time, 12 months typical use |

Physical Characteristics

| | | | |
|---|----------|------------------|-----------------------------|
| 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 |

Environmental Specifications

| | |
|-------------------------------|--|
| Operational Temperature | +10 to +45 degrees C |
| Operational Humidity | 10% to 95% (non-condensing) |
| Operational Altitude | based on your smartphone 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.



26. EUROPEAN AUTHORIZED REPRESENTATIVE

Obelis SA
BD General Wahis 53
1030, Brussels
Belgium
Tel: [+\(32\) 2. 732.59.54](tel:+3227325954)
Fax: [+\(32\) 2.732.60.03](tel:+3227326003)
E-Mail: mail@obelis.net


27. ALIVECOR CONTACT INFORMATION

AliveCor, Inc.
30 Maiden Lane, Suite 600
San Francisco, CA
94108 United States
www.alivecor.com

28. ELECTRICAL SAFETY









| Guidance and manufacturer's declaration - electromagnetic emissions | | |
|---|-------------------|---|
| Kardia Mobile by AliveCor is intended for use in the electromagnetic environment specified below. The customer or the user of Kardia Mobile by AliveCor should assure that it is used in such an environment. | | |
| Emissions test | Compliance | Electromagnetic environment - guidance |
| RF emissions CISPR 11 | Group 1 | Kardia Mobile by AliveCor 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 | Kardia Mobile by AliveCor is 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. |
| Harmonic emissions IEC 61000-3-2 | N/A | |
| Voltage fluctuations / flicker emissions IEC 61000-3-3 | N/A | |

| Guidance and manufacturer's declaration—electromagnetic immunity | | | |
|---|---|---|--|
| Kardia Mobile by AliveCor is intended for use in the electromagnetic environment specified below. The customer or the user of Kardia Mobile by AliveCor 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 by AliveCor requires continued operation during power mains interruptions, it is recommended that Kardia Mobile by AliveCor 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 by AliveCor is intended for use in the electromagnetic environment specified below. The customer or the user of Kardia Mobile by AliveCor 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 | <p>Portable and mobile RF communications equipment should be used no closer to any part of Kardia Mobile by AliveCor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>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).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 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 Kardia Mobile by AliveCor is used exceeds the applicable RF compliance level above, Kardia Mobile by AliveCor 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 by AliveCor. | | | |
| ^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 by AliveCor | | | |
|---|--|--|---|
| Kardia Mobile by AliveCor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Kardia Mobile by AliveCor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Kardia Mobile by AliveCor 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 $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ | 80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ | 800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ |
| 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. | | | |

29. SYMBOLS USED SYSTEM OR PACKAGE LABELING

| | |
|---|--|
|  | <p>Type CF Applied Part</p> |
|  | <p>European Conformity Mark</p> |
|  | <p>WEEE – Properly Dispose of Electronic Waste</p> |
|  | <p>Consult Instructions for Use / User Manual</p> |
|  | <p>Manufacturer</p> |
|  | <p>Temperature Limits (Operational)</p> |
|  | <p>Relative Humidity Limits (Operational)</p> |
| <p>REF</p> | <p>Model Number</p> |
| <p>SN</p> | <p>Serial Number</p> |
|  | <p>Direct Current Power Source</p> |