

User Manual for Kardia™ Mobile by AliveCor®

© 2011-2017 AliveCor, Inc. All rights reserved. US Patent No: 8,301,232 and Patents Pending. AliveCor and Kardia are trademarks and trade names of AliveCor, Inc. in the United States and other countries.

00LB17 Revision 4 | 21 APR 2017

Contents

1. PRODUCT DESCRIPTION	2
2. CAUTIONS.....	3
3. SET UP KARDIA MOBILE AND TAKE THE FIRST EKG RECORDING	4
4. RECORD EKG RHYTHMS	5
5. ONCE THE RECORDING IS FINISHED	7
6. ENTER AN EVENT WITHOUT AN EKG (KARDIA PHONE APP ONLY).....	7
7. SETTINGS AND ADJUSTMENTS (KARDIA PHONE APP ONLY)	7
8. EMAIL, PRINT, OR DELETE RECORDINGS	8
9. JOURNAL (KARDIA PHONE APP ONLY).....	8
10. SEARCH OR FILTER RECORDINGS (KARDIA PHONE APP ONLY).....	9
11. CLINICIAN REVIEW (KARDIA PHONE APP ONLY).....	9
12. DETECTORS (ATRIAL FIBRILLATION, NORMAL, UNREADABLE)	10
13. MEDICATIONS (KARDIA PHONE APP – IOS ONLY)	12
14. INSIGHTS (KARDIA PHONE APP ONLY).....	12
15. HEALTH APP AND GOOGLE FIT INTEGRATION.....	13
16. REFERRAL CODE.....	13
17. BLOOD PRESSURE	13
18. WEIGHT	14
19. LEARNING YOUR EKG.....	15
20. PERSONAL REPORT	15
21. ACCESSING HELP.....	15
22. EDITING USER PROFILE (KARDIA PHONE APP ONLY).....	16
23. ACCESSING EDUCATION (KARDIA PHONE APP ONLY)	16
24. TROUBLESHOOTING	17
25. KARDIA SPECIFICATIONS.....	20
26. EUROPEAN AUTHORIZED REPRESENTATIVE.....	21
27. ALIVECOR CONTACT INFORMATION	21
28. ELECTRICAL SAFETY	22
29. SYMBOLS USED SYSTEM OR PACKAGE LABELING	26

1. PRODUCT DESCRIPTION

Kardia™ by AliveCor® is a mobile, clinical-quality electrocardiogram (EKG or ECG) recorder. Users may record EKGs using Kardia™ Mobile with their smartphone or tablet.

The duration of the recording is established by the Kardia phone app 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.

Patients with known or suspected heart conditions and health-conscious individuals may use Kardia Mobile 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.

The Kardia Mobile product consists of:

1. Kardia Mobile
2. Kardia phone app
3. A user-supplied compatible smartphone or tablet

CAUTION: The Kardia Mobile product has 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 product enables users to:

- Collect and store (premium) 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.
- 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. (premium).

After creating an account on the Kardia phone app and receiving an EKG analysis, the Kardia Mobile enables 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, adult patients with known or suspected heart conditions and health conscious individuals. The product has not been tested and it is not intended for pediatric use.

1.2. Contraindications

There are no known contraindications for the Kardia Mobile product, 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 a recording while driving or during physical activity.
- DO NOT use Kardia Mobile while charging your phone.
- 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 Mobile

- DO NOT use with a cardiac pacemaker, ICDs, or other implanted electronic devices.
- DO NOT drop or bump with excessive force.
- DO NOT continue use until further instructed by a physician if your skin is irritated or inflamed around the sensor or molding.
- DO NOT use to diagnose heart related conditions.
- DO NOT expose the device to a magnetic resonance (MR) environment.
- DO NOT wear during cautery and external defibrillation procedures.
- After ECG analysis, the app may incorrectly identify ventricular flutter, ventricular bigeminy, and ventricular trigeminy heart conditions as unreadable. Please consult with your physician.
- 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.

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

3.1. Decide which smartphone or tablet to use

Kardia Mobile is compatible with the smartphones and tablets listed on AliveCor's website at <https://store.alivecor.com/#compatibility>.

3.2. Unpack Kardia Mobile (Kardia Mobile Users)

1. Remove Kardia Mobile from the box.
2. Choose Kardia Mobile placement. This step is optional – Kardia Mobile must be less than 1 foot (30 cm) from the smartphone or tablet to ensure communication between the devices.
 - a) For Kardia Mobile cases, place Kardia Mobile on your phone as you would any standard phone case.
 - b) Kardia Mobile may 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 a tablet, AliveCor does not recommend attaching Kardia. Instead, rest Kardia Mobile in both hands or place it on a flat surface less than 1 foot (30 cm) away from the tablet to record EKGs.

3.3. 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: Downloading the Kardia app to your iPad – in the App Store, search for “Kardia” and select “iPhone Only” in the upper left corner in the search results.

3.4. Set up an AliveCor Account

Tap the Kardia phone app and follow the onscreen instructions to create an account. Use your AliveCor account to access, print, and save your EKG recordings stored on the Kardia phone app.

NOTE: If you were prescribed Kardia by your physician or through a cardiac monitoring service, you should have received 12-character referral code. Enter the code when prompted by the Kardia phone app. Once a valid code has entered, EKGs taken by you will be shared with the cardiac monitoring service.

3.5. 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 to purchase a subscription.

Basic features include:

- EKG recording
- Instant Analysis

Premium features include:

- Unlimited storage and history
- Reports for your physician
- Blood pressure monitoring
- Tracking weight and medication
- Monthly analysis of your trends

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 a recording:

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

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,” a premium feature, 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. If you do not wish to record a voice memo, tap “Turn voice recording off” on the Record EKG screen.

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.

Also, 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, the Instant Analysis screen appears.
 - At the bottom right of the screen, tap Add Note.
 - Add notes or tags such as symptoms, activities, diet, etc.
- Alternatively, go to the Journal screen.
 - Tap the dropdown arrow to the right of the EKG recording.
 - Tap Edit.
 - On the Add Entry Details screen, add or edit notes and tags.

NOTES:

- The Kardia Mobile does not require a Wi-Fi or cellular connection to record an EKG and save it to the device’s local memory; however, it does 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 cellular connection at the time of the EKG recording, wait until you are connected prior to performing those actions.
- Kardia Mobile may be used up to a distance of 1 foot (30 cm) 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 for the detectors to work.

5. ONCE THE RECORDING IS FINISHED

5.1. For Kardia phone app:

- Immediately after recording, an Instant Analysis of your EKG is displayed.
- After a recording, you have the option to add tags such as symptoms, activities, diet, etc. Tap Add Note to add that information. In addition to adding, personalized tags or notes, you may also edit the transcribed voice memo. After making your choices, tap Save to continue.
- Review the EKG in Journal (premium) or go to Insights (premium) to view the trending of your EKGs, heart rate, symptoms, activities, etc. Tap the EKG on the Journal screen for a larger view of the EKG on the EKG Review screen. EKGs may be starred, emailed, shared, or sent for analysis from the Journal screen, or on the EKG Review screen.

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

In Journal, enter a tag or note without an EKG at anytime. This feature 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.
- On Add Entry Details , enter notes, or select tags such as symptoms, activities, diet, etc., or create personalized tags.
- In the Add Entry Details screen, 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 appear on 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

- **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. The Kardia phone app automatically inverts an EKG. You may undo the inversion by tapping the “Undo” link on the Instant Analysis screen.

7.2. Adjustable Settings

To access the Settings, tap the “More” icon at the upper left 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 the Kardia phone app. 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. On the Journal screen, tap the envelope icon next to the EKG you would like to email/print. Alternatively, 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. On the Journal screen, tap the envelope icon next to the EKG that you would like to email/print. Alternatively, tap the EKG, then tap the envelope icon on the EKG Review screen.
2. Tap Print.

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”.

9. JOURNAL (KARDIA PHONE APP ONLY)

Journal is a premium feature where your previously recorded EKGs, blood pressure, and weight measurements are displayed. To access it, tap the “Journal” icon.

- Tap Journal to see a list of EKG recordings from the trial or Premium periods on your smartphone or tablet (excluding any previously deleted).
- Tap the EKG recording you wish to view.
- Tap Blood Pressure or Weight to view past measurements.

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. The EKGs that meet the filter criteria appear.
4. Disable the filter by tapping the “x” icon next to the filter name at the upper right of the 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 to hide the keyboard for better scrolling.
5. 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. 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.
2. Tap the envelope icon to the right of the recording, then “Clinician Review”. Alternatively, tap the EKG, and then tap the envelope icon at the top right of the EKG Review screen.
3. Select one of the listed options.
4. 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”.
5. Select or enter your credit card information. Enter your card details and tap “Next”.
6. Confirm that the purchase order is correct and tap "PURCHASE" to place the order.

As your order is processing, an email confirmation will be sent to you. 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.

12. 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 record 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.

12.1. 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.

12.2. 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 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, Add Entry Details screen, and the EKG review screen.

12.3. Activation of the Detectors

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

12.4. 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.

13. MEDICATIONS (KARDIA PHONE APP – IOS ONLY)

You may track your medications (premium feature) 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.
- Edit your medications by accessing your Profile. Tap “. . .”, “Profile”, “Medications”.
- View medications selected on the Insights screen.
- To select a medication more than once per day, tap “Medications Logged” at the bottom of the Insights screen, and tap the specific medication again. The number to the right of the medication will update.

14. 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: This feature is available for individual users only, not for medical professionals.

15. 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
- Blood pressure
- 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

16. REFERRAL CODE

If you were prescribed Kardia by your physician 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 in 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.

17. BLOOD PRESSURE

iOS

AliveCor has formed a partnership with Omron. The partnership allows us to upload blood pressure measurements directly into the Kardia phone app. This feature is a premium feature.

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. Only supported for US customers only.

Android

Blood pressure measurements may be transferred from Google Fit or manually entered into the Kardia phone app (premium feature). 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.

18. WEIGHT

Track your weight over time in the Kardia phone app (premium feature). You have the option to enter your weight manually or have the Kardia phone app 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 Journal and tap Weight.

19. LEARNING YOUR EKG

As you record EKGs, the app begins to learn your heart profile. The process includes the app surveying you for a few EKG recordings, i.e. we will ask you if you recorded the EKG. Once we have a few surveys have been completed, the app displays whether the EKG is yours or a guest’s recording. If the app displays that a recording was taken by a guest, but it was really you, tap “Guest” on the Instant Analysis screen and select your name.

20. PERSONAL REPORT

The personal report, a premium feature, summarizes EKGs recorded within the last 30 days of when you generate the report. It’s a report to take with you to your next doctor’s appointment. To access the personal report, enter the Journal feature (premium) and tap the Download report button. Note, the personal report is only available when Premium is purchased – it is not available during the trial period.

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.
 - Recording an EKG
 - Alternate Recording Positions
- **Reference.** Access the user manual and provide feedback.
 - User Manual

- Feedback

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 may 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 problems.

24. TROUBLESHOOTING

Problem	Solution
<p>My Kardia Mobile is not working.</p>	<p>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.</p> <p>If you're using iOS 7 or greater, ensure that the Kardia phone app has access to the iPhone microphone:</p> <ol style="list-style-type: none"> 1. Tap "Settings". 2. Tap "Privacy". 3. Tap "Microphone". 4. Ensure that "Kardia" is turned on (the background of the slider is green). <p>Change the battery</p> <ol style="list-style-type: none"> 1. Expose the battery door at the back of Kardia Mobile: <ol style="list-style-type: none"> 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. <p>OR</p> <ol style="list-style-type: none"> b. Remove Kardia Mobile from the attachment plate: <ol style="list-style-type: none"> 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: <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 (writing side up). Remove the protective sticker from the battery, as applicable.

Problem	Solution
<p>I have a lot of artifact, noise or interference in my recording, or the EKG does not appear</p>	<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. • If you wear hearing aids, turn them off prior to recording. • 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. • If the issue persists, contact support@alivecor.com.
<p>The EKG rhythms appear upside down</p>	<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>
<p>I forgot my password and I’m unable to reset it</p>	<p>On the Sign In screen, click "Forgot your password?" link below the Password field, enter your email address, and click Submit.</p> <p>Follow the reset instructions in the email. Note, the reset link contained in the email is only active for a short while.</p>
<p>The PDF Report looks slightly different on the Web and in my App</p>	<p>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.</p>
<p>My personal information (name, DOB, etc.) disappears when I’m trying to create an account</p>	<p>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.</p>

Problem	Solution
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 problem is very rare 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 issue 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 the sync to complete (may 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.
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. Consider using initials for your first or last name in order to ensure your age is visible.
My credit card isn't being accepted	In rare occasions, the error message indicating that your credit card is incorrect or invalid is automatically cleared by rotating the phone from portrait to landscape or vice versa. Please ensure that your credit card information is valid before processing payments.
I need a printed version of the manual	Contact support@livecor.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.

25. 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

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

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.
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

28. ELECTRICAL SAFETY

Guidance and manufacturer's declaration - electromagnetic emissions		
Kardia Mobile is intended for use in the electromagnetic environment specified below. The customer or the user of Kardia Mobile should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	Kardia Mobile uses RF energy only for its internal function. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. Kardia Mobile 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.
RF emissions CISPR 11	Class B	
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 is intended for use in the electromagnetic environment specified below. The customer or the user of Kardia Mobile 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 requires continued operation during power mains interruptions, it is recommended that the Kardia Mobile 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 is intended for use in the electromagnetic environment specified below. The customer or the user of Kardia Mobile 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, 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.






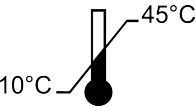
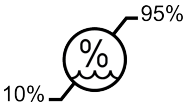
NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people

^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 is used exceeds the applicable RF compliance level above, Kardia Mobile 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.

^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			
Kardia Mobile is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Kardia Mobile can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Kardia Mobile 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 (Kardia Mobile)</p>
	<p>European Conformity Mark</p>
	<p>Do not dispose with household waste</p>
	<p>Read instructions before use</p>
	<p>Manufacturer</p>
	<p>Temperature range</p>
	<p>Humidity range</p>
<p>REF</p>	<p>Model number</p>
<p>SN</p>	<p>Serial number</p>