EN

Instructions for Use (IFU)
for the
KardiaMobile 6L System (AC-019)

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KardiaMobile 6L System

Introduction

The KardiaMobile 6L System by AliveCor consists of (1) the KardiaMobile 6L System Hardware (KardiaMobile 6L or KardiaMobile 6L Max device (AC-019)), and an associated mobile application (App). The App can be downloaded in the App Store or Google Play Store (refer to Table 1 for compatible Apps).

1. KardiaMobile 6L System hardware are 3-electrode, personal EKG devices that record your EKG and wirelessly transmits the data to your smartphone or tablet. The KardiaMobile 6L Max hardware device is a white variant and comes with one year of a KardiaCare membership service. **KardiaMobile 6L Max will only work with an active KardiaCare membership**. The KardiaMobile 6L hardware device is a black variant and functions with or without a membership plan.
    a. Contains two electrodes on the top surface, for use with the left and right hands, and one on the bottom surface, for use with the bare skin of the left leg.
    b. Powered by a replaceable battery located under the bottom electrode.
    c. Bluetooth wirelessly transmits EKG data to your smartphone or tablet.

2. KardiaMobile 6L System hardware is capable of recording two EKG types:
    a. A **Single-Lead EKG**: provides a single view of the heart's electrical activity (EKG taken with top two electrodes)
    b. A **Six-Lead EKG**: provides six views of the heart's electrical activity (EKG taken using all three electrodes).

3. An instant algorithmic analysis ("**Instant Analysis**") of your heart rhythm is provided upon completion of your EKG recording. See the EKG Instant Analysis section for more details.
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4. KardiaMobile 6L System requires a **compatible smartphone or tablet** with either a Kardia application variant (i.e., **Kardia App, KardiaRx App** or **KardiaStation App), or an AliveCor-powered, third-party app with Kardia EKG functionality.** The list of compatible devices can be viewed at kardia.com/compatibility. The mobile applications are discussed below in the **Associated Mobile Device Applications (Apps)** section.

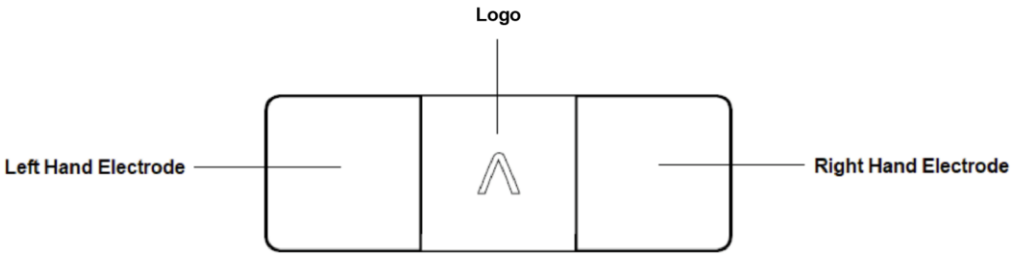
NOTE: KardiaMobile 6L Max is only compatible with the Kardia App and will only work with an active KardiaCare membership.

5. The KardiaMobile 6L System does not require a Wi-Fi or mobile data connection to record an EKG and save it to the device's local memory; it does require a connection to sync automatically with the AliveCor server, email an EKG, or print an EKG. If you do not have a Wi-Fi or mobile data connection at the time of the EKG recording, you may email or print the

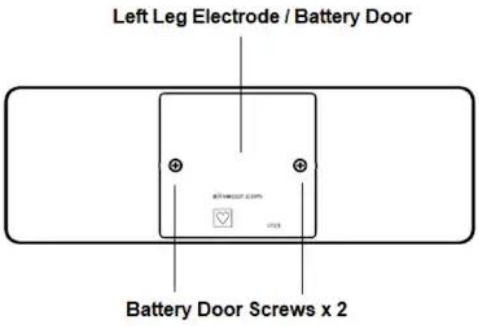
data later when you have such a connection, and the sync will happen automatically at that time.

Guide to Parts

TOP VIEW



BOTTOM VIEW



Contraindications

There are no known contraindications.

Warnings

1. AliveCor does not guarantee that you are not experiencing an arrhythmia or other health conditions with any EKG result, including normal. You should notify your physician for possible changes in your health. DO use this device to record heart rate and heart rhythm only.
2. DO NOT use to diagnose heart-related conditions.
3. DO NOT use to self-diagnose heart related conditions. Consult with your physician before making any medical decision, including altering your use of any drug or treatment.

4. DO NOT continue use until further instructed by a physician if your skin is irritated or inflamed around the electrode.
5. 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.
6. The device has not been tested for and is not intended for pediatric use.
7. Keep device away from young children. Contents may be harmful if swallowed. Device contains a coin cell battery that is not accessible during normal use but, if exposed, can be a choking hazard and may cause severe tissue injury if ingested.
8. DO NOT replace the battery when device is in use.
9. DO NOT use the electrode on a portion of the body with too much body fat, body hair or very dry skin, as a successful recording may not be possible.
10. DO NOT take a recording while driving or during physical activity.
11. DO NOT store in extremely hot, cold, humid, wet, or bright conditions.
12. DO NOT take a recording if electrodes are dirty. Clean them first.
13. DO NOT use alcohol-based or abrasive cleaners and materials as these products could adversely affect product performance.
14. DO NOT immerse device or expose device to excessive liquid.
15. DO NOT use while charging your phone. If the device is attached to your phone remove it prior to wireless charging the phone. DO NOT place the device on top of your phone while wirelessly charging the phone.
16. DO NOT drop or bump with excessive force.
17. DO NOT expose to strong electromagnetic fields.
18. DO NOT expose the device to a magnetic resonance (MR) environment.
19. DO NOT use with a cardiac pacemaker, ICDs, or other implanted electronic devices.
20. DO NOT use during cautery and external defibrillation procedures.
21. DO NOT place electrodes in contact with other conductive parts including earth.
22. DO NOT use with un-approved accessories. Use of non-AliveCor approved accessories or transducers and cables could result in electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.
23. DO NOT use adjacent to or stacked with other equipment because it could result in improper operation.
24. DO NOT use portable RF communications equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 inches) to any part of the KardiaMobile 6L System hardware. Otherwise, degradation of the performance of the KardiaMobile 6L System could result.

Cautions

1. KardiaMobile 6L System does not detect heart attack.
2. DO NOT change your medication without talking to your doctor.

3. Detection of arrhythmias in your EKG results is not to be used for diagnosis. If you are experiencing any concerning symptoms, contact your physician.
4. Please consult with your physician should you receive consistent identifications of any arrhythmia.
5. “Unreadable” EKG results determine that you didn't have proper EKG recording for analysis. You may try to re-record your EKG.
6. The app may incorrectly identify Ventricular Flutter, Ventricular Bigeminy, and Ventricular Trigeminy heart conditions as “Unreadable”. Please consult with your physician.
7. EKG reports viewed at any magnification other than 100% may appear distorted and could lead to misdiagnosis.

Indications For Use

The KardiaMobile 6L System is intended to record, store and transfer one- and two-channel electrocardiogram (EKG) rhythms. In single channel mode, the KardiaMobile 6L System can record Lead-I. In two channel mode, the KardiaMobile 6L System can record Lead-I and Lead-II simultaneously and derive Lead-III and unipolar limb leads aVR, aVF and aVL. The KardiaMobile 6L System also displays EKG rhythms and output of EKG analysis from AliveCor’s KardiaAI platform including detecting the presence of normal sinus rhythm, atrial fibrillation, bradycardia, tachycardia, and others. The KardiaMobile 6L System is intended for use by healthcare professionals, patients with known or suspected heart conditions and health conscious individuals. The device has not been tested and is not intended for pediatric use.

Features & Functionality

KardiaMobile 6L System is a 3-electrode personal EKG device that is capable of recording two kinds of EKGs: a Single-Lead EKG and a Six-Lead EKG, which provides more data for you to share with your doctor. Both EKG types detect normal sinus rhythm, atrial fibrillation, bradycardia, tachycardia, and indeterminate results (errors or unclassified rhythms).

The KardiaMobile 6L System hardware has two electrodes on the top surface and one on the bottom surface. It is powered by a replaceable battery, which is located under the bottom electrode. Bluetooth is used to wirelessly transmit EKG data from the device to your smartphone or tablet.

What is an EKG?
Also known as an electrocardiogram, an EKG is a test that detects and records the strength and timing of the electrical activity in your heart. Each heartbeat is triggered by an electrical impulse. Your EKG represents the timing and strength of these impulses as they travel through your heart.

Single-lead EKG

A Single-Lead EKG is the simplest way to record your heart rhythm. It measures a single view of the heart. It is taken by laying the device on a flat surface near your smartphone and placing fingers or thumbs from the left and right hand on the top two electrodes of the device. This is comparable to Lead I on standard EKG machines used in the hospital or doctor's office.

Six-Lead EKG
A Six-Lead EKG uses three electrodes to provide information about your heart rhythm from six different viewpoints. It is done by resting the bottom electrode on the bare skin of your left leg (knee or inside of the ankle), and placing the fingers or thumbs from your left and right hand on the top two electrodes. This is comparable to Leads I, II, III, aVF, aVL, and aVR on standard EKG machines used in the hospital or doctor's office.

Note: The KardiaMobile 6L System does not require calibration prior to use.

Associated Mobile Device Applications (Apps)

The mobile device application function of the KardiaMobile 6L System can be performed by any of the available app variants provided by AliveCor or third party implementers that have integrated KardiaMobile 6L software functions that provide an end to end EKG functionality that is 'powered by AliveCor'.

NOTE: KardiaMobile 6L Max is only compatible with the Kardia App.

Table 1: Mobile device application variants for the KardiaMobile 6L System

App Name	**Model Number**	Icon	**Notes**
Kardia	002001 (iOS) 002002 (Android)		Standard Application for most users. For use with KardiaMobile 6L System
KardiaRx	002013 (Android) 002014 (iOS)	Rx	KardiaRx is for patient use under the care of a health care professional/provider. Requires invitation from your provider/ health care professional. See "Setting up your KardiaMobile 6L System for the first time"

KardiaStation	002005 (iOS) 002009 (Android)	Station	The KardiaStation app is only for use by health care professionals.* See “Setting up your KardiaMobile 6L System for the first time"
KardiaComplete	002015 (iOS) 002016 (Android)	Complete	Requires an invitation to create an account. For use by employee plan members.
Third party apps that are ‘Powered By AliveCor’	002017 (iOS) 002018 (Android)	Various	Mobile device application variants ‘Powered by AliveCor’ that are distributed by third parties authorized by AliveCor.

Using Your KardiaMobile 6L System

Setting up your KardiaMobile 6L System for the first time

1. Remove your KardiaMobile 6L or KardiaMobile 6L Max hardware device from the packaging.

2. The KardiaMobile 6L device can be used with any of the mobile device applications (Apps) noted in Table 1. KardiaMobile 6L Max device may only be used with the Kardia App. See Table 1 for the available applications and the name to search for them within the Apple App Store or Google Play Store.
3. Download the desired App to your compatible mobile device.

4. Make sure **Bluetooth is turned on** in your smartphone or tablet settings.

5. Launch the desired App and continue to the application start screen. Create or login to your account. The ability to freely create an account or have a connection code for access

depends on which application is being used.

6. For Kardia app users: Follow the on-screen instructions to create or login to your account (no connection code required). If you are enrolled in a KardiaCare subscription, follow the on-screen instructions to set up your KardiaCare account.

   If you need assistance setting up your subscription account, contact technical support at (855) 338-8800 or at support@alivecor.com.

7. For KardiaRx app users: A connection code for the app will be provided by your health care professional/provider. This code can be entered by selecting “Login” from the start screen, then entering your provided code. Note: Demographic information that is a part of your patient file, or the name and contact information of your provider may be displayed in the app during this login process.

8. For KardiaStation app users: (HCPs only) Select Login from the start screen and enter your existing KardiaPro login information. Once logged in, you will be at the application home screen which allows access to the EKG recording functionality.

Recording a Single-Lead EKG

Follow the instructions below to record a Single-Lead EKG. (Note: For the KardiaRx and KardiaStation App, users may not have an option to record single lead, as this is selected by the managing health care professional)

1. From the application home screen, initiate the EKG functionality by selecting the button labeled **"Record your EKG"** or “**Record EKG”**

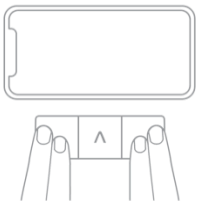
2. If this is your first time using the KardiaMobile 6L System, follow the on-screen instructions to set up and pair your device.

1. Select the **Single-Lead EKG** option. (Note: the single lead option may be turned off by your health-care professional if using a health care model app such as KardiaRx or KardiaStation)

3. Lay the device on a flat surface near your smartphone.
   - Make sure the device is in the correct orientation with the “Λ“ logo pointing away from you.

4. When ready, place two fingers or thumbs from each hand on the top two electrodes.

- There's no need to squeeze or press down firmly.



5. The App will indicate when you have good contact as you begin your recording.

6. Hold still as you watch the timer count down from 30 seconds, until your EKG recording is complete.

NOTE: If you are experiencing difficulty getting a recording, please refer to the Troubleshooting section.

Recording a Six-Lead EKG

Follow the instructions below to record a Six-Lead EKG.

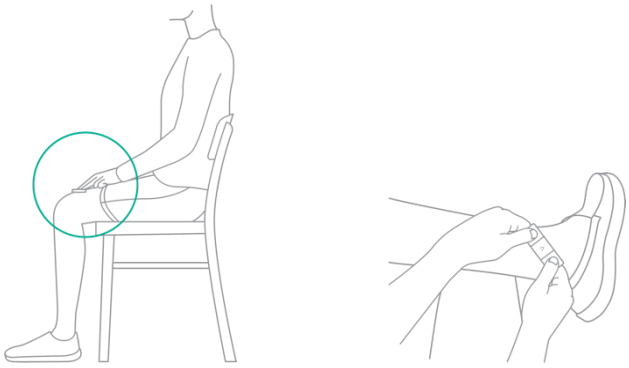
1. From the application home screen, initiate the EKG functionality by selecting the button labeled "Record your EKG" or “Record EKG”.

2. If this is your first time using KardiaMobile 6L System, follow the on-screen instructions to set up and pair your device.

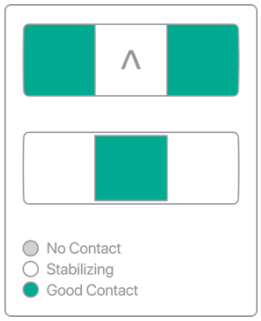
3. Select the **Six-Lead EKG** option.

4. When ready, rest two or more fingers (it does not matter which fingers) or thumbs on the electrodes, with the right hand on one electrode and the left hand on the other..
   - There's no need to squeeze or press down firmly.
   - Make sure the device is in the correct orientation with the “Λ“ logo pointing away from you.

5. With your fingers or thumbs resting on the top two electrodes, place the EKG device on the bare skin of your left leg (knee or inside of the ankle).
   - The bottom electrode should contact the skin.



6. The app will indicate when you have good contact as you begin your recording.



7. Hold still as you watch the timer count down from 30 seconds, until your EKG recording is complete.

8. Once the recording is complete, you may remove your fingers or thumbs from the electrodes and the device from your leg.

NOTE: If you are experiencing difficulty getting a recording, please refer to the Troubleshooting section.

Healthcare Professional Review

Health care professionals (HCPs)/providers may review and analyze the recorded EKG. HCPs can review the EKG PDF to perform rhythm assessments as well as measure the QT interval.

App users have the ability to provide recorded EKGs to HCPs in different ways depending on which app is being used.

KardiaRx and KardiaStation App users by default automatically transfer all available EKG recordings to their health care providers via the KardiaPro physician portal.

The Kardia App provides the optional use of a connection code which, if entered by the end user, creates a connection to their provider during which that connection is active and all EKG

recordings are automatically transferred to their provider via KardiaPro. If the user ends the connection, no further data is provided to the health care professional.

Kardia App users can also manually provide EKG PDFs to the HCP via methods such as email.

Note: An EKG from the KardiaMobile 6L System is recorded in a sitting position (unlike a diagnostic that is recorded supine) leading to positional effects on the QT interval; this effect may be mitigated with the use of the heart-rate corrected QT interval. A summary of the clinical validation to demonstrate the accuracy of measuring the heart-rate corrected QT interval (QT_c) using KardiaMobile 6L System is provided in the section titled "Clinical Safety and Performance".

WARNING: Manual EKG analysis is only intended for trained HCPs and lay untrained users should not analyze an EKG nor make any diagnostic assessments.

EKG Instant Analysis

Upon completion of your EKG recording the EKG is then processed by AliveCor's Instant Analysis algorithms. Determinations provided in your EKG Instant Analysis results are not to be used for diagnosis. If you are experiencing any concerning symptoms, contact your physician.

The App will display your full Single-Lead or Six-Lead EKG and the Instant Analysis result with description.

Note: For KardiaRx and KardiaStation app users, the Instant Analysis result is only displayed if configured to do so by the managing health care provider.

Representative Instant Analysis results, descriptions, and additional information are displayed in the table below. Note that Instant Analyses noted as "Advanced Determinations" will be provided only if you have access to them, such as through a KardiaCare, KardiaCare Plus, or KardiaComplete membership. "Advanced Determinations" are also provided to KardiaMobile 6L Max users with a valid membership.

Instant Analysis	Description	Additional information
Normal Sinus Rhythm	Your EKG shows sinus rhythm and no rhythm or rate abnormalities are detected in your EKG; your heart rate was 50-100 beats per minute (bpm).	Kardia does not check for heart attack. If you believe you are having a medical emergency, call emergency services. Do not change your medication without talking to your doctor.
Atrial Fibrillation	Your EKG shows signs of atrial fibrillation.	Kardia does not check for heart attack. If you believe you are having a medical emergency, call emergency services. Do not change your medication without talking to your doctor.

Instant Analysis	Description	Additional information
Bradycardia	Your heart rate is less than 50 beats per minute, which is slower than normal for most people. Atrial fibrillation is not detected.	Kardia does not check for heart attack. If you believe you are having a medical emergency, call emergency services. Do not change your medication without talking to your doctor.
Tachycardia	Your heart rate is faster than 100 beats per minute. This can be normal with stress or physical activity. Atrial fibrillation is not detected.	Kardia does not check for heart attack. If you believe you are having a medical emergency, call emergency services. Do not change your medication without talking to your doctor.
Sinus Rhythm with Supraventricular Ectopy **(Advanced Determination)**	Your EKG shows sinus rhythm with occasional supraventricular ectopy (SVE). This can be present in healthy adults and in adults with heart conditions.	Kardia does not check for heart attack. If you believe you are having a medical emergency, call emergency services. Do not change your medication without talking to your doctor.
Sinus Rhythm with Wide QRS **(Advanced Determination)**	Your EKG shows sinus rhythm with Wide QRS. This can be present in healthy adults and in adults with heart conditions.	Kardia does not check for heart attack. If you believe you are having a medical emergency, call emergency services. Do not change your medication without talking to your doctor.
Sinus Rhythm with Premature Ventricular Contractions **(Advanced Determination)**	Your EKG shows sinus rhythm with occasional premature ventricular contractions (PVCs). This can be present in healthy adults and in adults with heart conditions.	Kardia does not check for heart attack. If you believe you are having a medical emergency, call emergency services. Do not change your medication without talking to your doctor.
Too short	Your EKG recording must be at least 30 seconds to allow Instant Analysis algorithms to perform an analysis.	Re-record the EKG. Try to relax and hold still, rest your arms, or move to a quiet location that will allow for a full 30 second recording.
Unclassified	Atrial fibrillation was not detected and your EKG does not fall under the algorithmic classifications of Normal, Bradycardia, or Tachycardia. This may be caused by other arrhythmias, unusually fast or slow heart rates, or poor quality recordings.	Kardia does not check for heart attack. If you believe you are having a medical emergency, call emergency services. Do not change your medication without talking to your doctor.
Unreadable	There is too much interference in this recording. Please re-record the EKG. Try to relax and hold still, rest your arms, or move to a quiet	Kardia does not check for heart attack. If you believe you are having a medical emergency, call emergency services. Do not change

Instant Analysis	Description	Additional information
	location or away from electronics and machinery.	your medication without talking to your doctor.

NOTE: All historical EKGs and Instant Analysis results can be viewed, downloaded, and emailed from the “History” section of the Kardia app.

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

WARNING: EKG reports viewed at any magnification other than 100% may appear distorted and could lead to misdiagnosis.

Heart Rate

During your EKG recording, your real-time heart rate will be shown. When reviewing previous EKGs, the average heart rate taken during that recording is displayed.

Heart rate is calculated as the time interval between consecutive heart beats; or more specifically as the inverse of the time interval between consecutive R-waves in your QRS complex. During an EKG recording, the current heart rate is measured using the inverse of the median R-R interval taken over the last five seconds. For stored EKGs, the heart rate is measured using the inverse of the median R-R interval taken over all good signal segments identified within the 30 sec recording.

Troubleshooting

If you experience difficulties using your KardiaMobile 6L System, refer to the troubleshooting guide below or contact technical support at (855) 338-8800 or at support@alivecor.com.

I'm having trouble getting a clear recording.

- Clean the electrodes using a damp soft cloth. Wash your hands with soap and water. Use a small amount of water to moisten the skin where your fingers or thumbs make contact with the electrodes.

- If recording a Six-Lead EKG, it is important to place the device on your left leg (knee or inside of the ankle). The device must be used on bare skin for an accurate recording. You can also moisten the skin on your leg with a small amount of water to improve contact with the electrode.

- Ensure that your arms, hands and left leg remain still to reduce muscle noise. Do not apply too much pressure to the electrodes.

- Avoid close proximity to items that may cause electrical interference (electronic equipment, computers, chargers, routers, etc.)

- If you wear hearing aids, turn them off prior to recording.

My KardiaMobile 6L System hardware will not connect or is not working.

- Make sure Bluetooth is turned on in your smartphone or tablet settings and follow the steps in "Record a Single-Lead EKG" or "Record a Six-Lead EKG."

- If Bluetooth is on, try to un-pair and pair again to your KardiaMobile 6L System hardware device.

- If Bluetooth is on and your device is not connecting or pairing it's possible that your battery needs to be replaced. Follow the "Maintenance" instructions to replace the battery, which is located under the bottom electrode of the device.

- If you have a KardiaMobile 6L Max hardware device, ensure that you have activated your included KardiaCare membership. A membership is required for KardiaMobile 6L Max to function.

I want to take a Six-Lead EKG, but only a Single-Lead EKG appears while recording.

- Make sure the **Six-Lead EKG** option is selected.

- Ensure that the bottom electrode is touching the skin above your left knee or your left ankle. The device must be used on bare skin for an accurate recording.

On my EKG, the recording appears upside down.

- *Six-Lead EKG*
    - Make sure the AliveCor logo is in the correct orientation.
    - Make sure your thumbs are touching the 2 top electrodes and that the bottom electrode is touching the skin above your left knee or your left ankle.

- *Single-Lead EKG*
    - Make sure the AliveCor logo is in the correct orientation.
    - On the EKG tracing, select the "Invert" option to flip the orientation of the EKG.

Clinical Safety and Performance

The performance of the KardiaMobile 6L System for recording a 6-lead EKG was validated in a clinical study. Overall, 44 subjects participated in the study, comprising nearly equal numbers of healthy volunteers and arrhythmia patients. EKG recordings were simultaneously taken by the KardiaMobile 6L device and a standard clinical-grade 12-lead EKG device. Qualitative and quantitative analyses of equivalence were performed on the 44 pairs of EKG results.

For qualitative assessment, two board-certified electrophysiologists compared 6-lead EKG rhythm strips acquired from the KardiaMobile 6L device and the corresponding leads from the reference standard 12-lead EKG device for diagnostic equivalence. All paired recordings (100%, n=44 subjects), were deemed equivalent for assessing cardiac arrhythmias by both electrophysiologists. The results of the assessment determined that the subject device records a 6-lead EKG that is qualitatively equivalent to the recordings of corresponding leads from a gold standard 12-lead EKG device.

For quantitative equivalence, median beat cross correlation for Lead I and II and RMS error for all 6 limb leads were computed between the paired EKGs for each subject. This analysis was conducted on the unfiltered EKG output as well as the enhanced filtered (EF) EKG output. KardiaMobile 6L device EKGs had a minimum correlation of 0.96 and a maximum RMS error of 47 µV as compared to the corresponding lead of the 12-lead EKG. The results of the quantitative analysis of the EKG recordings further confirmed that the KardiaMobile 6L device EKG has equivalent output to that of the gold standard 12-lead EKG device.
During this clinical study, no adverse events were observed.
Additionally, in a separate study, the accuracy of measuring the heart-rate corrected QT interval (QT_c) using KardiaMobile 6L was clinically validated. In this study, EKGs were concurrently recorded using KardiaMobile 6L and a 12-lead diagnostic EKG device from 313 patients. An independent core lab measured the QT and RR intervals using the procedure used in Thorough QT studies, as described below:

- Interval duration measurements were made on a single lead. With the 6-lead EKGs, the intervals were measured on lead II after applying AliveCor's Enhanced Filter. When Lead II was not analyzable, the secondary measurement lead was Lead I, and the tertiary measurement lead was Lead III. In the case of the 12-lead, the interval duration measurements were performed on Lead II without filtering. When the 12-lead's Lead-II was not analyzable, the secondary measurement lead was V5, and the tertiary measurement lead was V2.
- QT interval measurements were performed on the first 3 beats and the average of the three was used as the QT for the EKG.
- The heart-rate corrected QT was computed using both the Bazett's and Fridericia's formulas. For each of the three beats used to measure the QT, the RR-interval to the subsequent beat was measured and the beat's QT was corrected using the appropriate formula. The average of the three beat's heart-rate corrected QT was used as the final measured QT_c.

The mean interval difference between the QTc measured from both devices was found to be ≤ 10 ms. In a separate analysis, the mean interval difference between the global heart-rate corrected QTc measured using a standard-of-care 510(k)-cleared automated algorithm was also found to be ≤ 10 ms. The results of the quantitative analysis confirmed that the QTc measured from EKG recorded using KardiaMobile 6L in a sitting position was equivalent to that measured from a gold standard diagnostic 12-lead EKG device recorded in a supine position. During this clinical study, no adverse events were observed.

Environmental Specifications

Operational Temperature:	+10°C to +45°C
Operational Humidity:	10% to 95% (non-condensing)
Storage Temperature:	0°C to +40°C
Storage Humidity:	10% to 95% (non-condensing)

Expected Service Life

The expected service life for the KardiaMobile 6L System hardware is 2 years.

Cybersecurity

Users are advised to follow best security practice measures for their personal mobile device when using the KardiaMobile 6L System.

Ensure your mobile device hardware and operating system are compatible. The list of compatible devices (iOS/Android) can be viewed at kardia.com/compatibility.

For optimal performance, ensure your mobile device is up-to-date on the latest version of the App and iOS/Android operating system in order to have the latest software updates and security patches.

For Apps such as Kardia app that require an account creation and password, all passwords must meet the minimum required security criteria. For connection code based accounts, unique connection codes are provided to the user.

Maintenance

1. No service or repair should be performed on the KardiaMobile 6L hardware other than the maintenance listed in this section.

2. Clean the electrodes by wiping with a soft cloth dampened with water or one of the following approved cleaners:
    - Soap and water, or
    - Bleach solution as recommended by the CDC (5 tablespoons bleach per gallon of water OR 4 teaspoons bleach per quart of water, which is equivalent to 20ml bleach per liter of water)

    a. To clean, spray the cleaner on a soft cloth and thoroughly wipe the device.
    b. Ensure the device is sufficiently dried.

    WARNING:
    - DO NOT use alcohol-based or abrasive cleaners and materials as these products could adversely affect product performance.
    - DO NOT immerse or expose the device to excessive liquid.

3. Exterior Visual Inspection:
    - Inspect electrodes for warping, surface damage, or corrosion
    - Check for any other form of damage

4. For battery replacement, AliveCor recommends that you bring your KardiaMobile 6L hardware to a watch repair or hearing-aid repair shop.
    - Battery Type: CR2016 Coin Cell that is IEC 60086-4 compliant
    - Ensure proper orientation of the battery with battery information and (+) terminal facing up

    WARNING:
    - During replacement, keep device away from young children. Contents may be harmful if swallowed. Device contains a coin cell battery that can be a choking hazard and may cause severe tissue injury if ingested.
    - DO NOT replace the battery when device is in use.

Device Disposal

This device contains a coin-cell battery and electronic components. Do not dispose of the device in household waste. Dispose of the device and battery in accordance with local regulations for electronic waste and battery recycling. Improper disposal may pose a risk of environmental harm or injury.

Electromagnetic & Other Interferences

KardiaMobile 6L System has been tested and deemed in conformance with the relevant requirements in IEC 60601-1-2:2014/AMD1:2020/ ANSI/AAMI/IEC 60601-1-2:2020 Class B for Electromagnetic Compatibility (EMC).

FCC Compliance

FCC ID: 2ASFFAC019

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:
1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

CAUTION: Changes or modifications not expressly approved by AliveCor could void your authority to use this equipment.

To view FCC information on the Kardia App:

1. On the home screen, tap 

on the bottom right of the button bar, then tap  at the top right of the screen to access the app Settings.
2. Tap “About Kardia” to view the FCC ID and other applicable regulatory information.

Industry Canada Compliance

IC ID: 25747-AC019 (KardiaMobile 6L Hardware only)

This device complies with Industry Canada’s license-exempt RSSs. Operation is subject to the following two conditions:
(1) This device may not cause interference; and
(2) This device must accept any interference, including interference that may cause undesired operation of the device.

Ingress Protection Marking

KardiaMobile 6L System hardware is IP22 rated. KardiaMobile 6L System hardware is protected against insertion of fingers and is not affected by vertically dripping water. KardiaMobile 6L System hardware has been tested with relevant requirement standard IEC 60601-1-11:2015/AMD1:2020.

Applied Parts

The 3 electrodes (Left Hand Electrode, Right Hand Electrode, and Left Leg Electrode) are Type CF Applied Parts.
Operational temperature of the device is +10°C to +45°C. If ambient temperature exceeds +41°C, Applied Parts can exceed +41°C.

Electrical Safety

Guidance and manufacturer's declaration - electromagnetic emissions		
KardiaMobile 6L System hardware is intended for use in the electromagnetic environment specified below. The customer or the user of KardiaMobile 6L System hardware should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	KardiaMobile 6L uses RF energy only for its internal function. RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	KardiaMobile 6L is intended for use in domestic surroundings.
Harmonic emissions IEC 61000-3-2	N/A	KardiaMobile 6L is powered from a lithium coin cell battery and does not require AC mains power.
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration—electromagnetic immunity			
KardiaMobile 6L System hardware is intended for use in the electromagnetic environment specified below. The customer or the user of KardiaMobile 6L System hardware 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	±2 kV contact ±4 kV contact ±6 kV contact ±8 kV contact ±2 kV air ±4 kV air ±8 kV air ±15 kV air	±2 kV contact ±4 kV contact ±6 kV contact ±8 kV contact ±2 kV air ±4 kV air ±8 kV air ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	N/A	N/A	KardiaMobile 6L is powered from a lithium coin cell battery and does not require AC main power.
Surge IEC 61000-4-5	N/A	N/A	

Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	N/A	N/A	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration—electromagnetic immunity			
KardiaMobile 6L System hardware is intended for use in the electromagnetic environment specified below. The customer or the user of KardiaMobile 6L System hardware should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of KardiaMobile 6L, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3.5}{V_1}]\sqrt{P}$ < 80MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.7 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol:

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 strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which KardiaMobile 6L is used exceeds the applicable RF compliance level above, KardiaMobile 6L should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating KardiaMobile 6L.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and KardiaMobile 6L

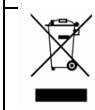
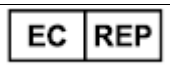
KardiaMobile 6L System hardware is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of KardiaMobile 6L System hardware can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and KardiaMobile 6L System hardware as recommended below, according to the maximum output power of the communications equipment.

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

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1—At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Equipment Symbols

These symbols will be used in the packaging and other labeling of the KardiaMobile 6L System.

Symbol	Description
	Manufacturer
	Catalogue Number
	Medical Device
 alivecor.com/quickstart	Consult instructions for use or consult electronic instructions for use at the specified website
	Follow Instructions for Use
	MR Unsafe
	Type CF Applied Part
	Do not dispose with household waste
	Temperature limit
	Humidity limitation
	CE Mark (EU, 0123=TUV SUD)
	Authorized Representative in the European Community (EU)
	Importer (EU)
 YYYY-MM-DD	Country of Manufacture, Manufacturing Date CC=CN for Made in China CC=MY for Made in Malaysia

Symbol	Description
	YYYY-MM-DD=Date of Manufacture
SN	Serial Number
UDI	Unique Device Identifier