Instructions for Use (IFU)
for
KardiaMobile 6L (AC-019) with KardiaRx App

19LB46.2
March 2022

AliveCor, Inc.
189 N. Bernardo Avenue, Suite 100
Mountain View, CA 94043, USA

© AliveCor, Inc. 2022

AliveCor is a registered trademark of AliveCor, Inc.

Table of Contents

Introduction	3
Guide to Parts	3
Warnings	4
Cautions	5
Indications For Use	5
Features & Functionality	6
Setting up your KardiaMobile 6L hardware for the first time	6
Recording a Single-Lead EKG	7
Recording a Six-Lead EKG	8
Healthcare Professional Review (Rx Only)	9
EKG Instant Analysis	9
Heart Rate	11
KardiaRx Application Description	11
Clinical Safety and Performance	12
Environmental Specifications	14
Expected Service Life	14
Maintenance	14
Electromagnetic & Other Interferences	15
FCC Compliance	15
Industry Canada Compliance	15
Ingress Protection Marking	16
Applied Parts	16
Troubleshooting	16
Electrical Safety	17
Equipment Symbols	22

KardiaMobile 6L with KardiaRx App

Introduction

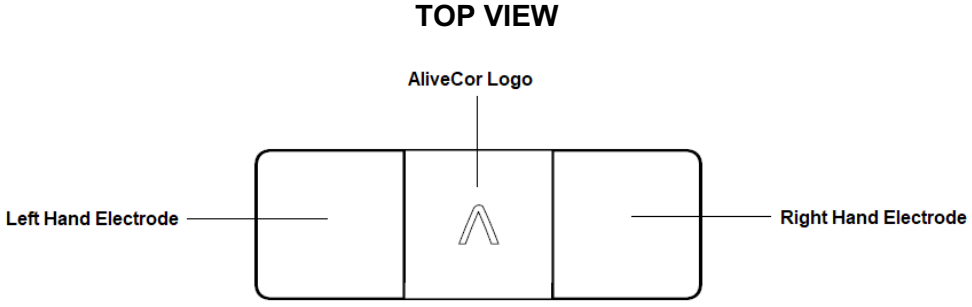
1. **KardiaMobile 6L** is a 3-electrode personal EKG device that records your EKG and wirelessly transmits the data to your smartphone or tablet.
    a. Contains two electrodes on the top surface, for use with the left and right hands, and one on the bottom surface, for use with the bare skin of the 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 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).

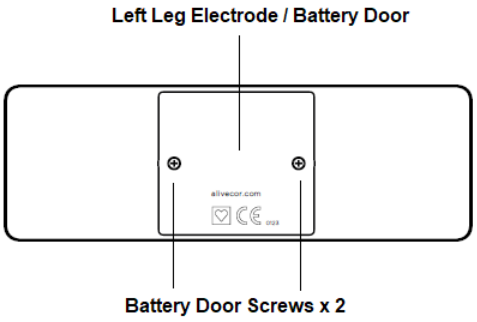
3. An instant algorithmic analysis ("**Instant Analysis**") of your heart rhythm is provided upon completion of your EKG recording when enabled to do so by your provider.
    a. Instant Analysis indicates normal sinus rhythm, atrial fibrillation, bradycardia, tachycardia, or an unclassified result for both Single-Lead and Six-Lead EKGs.
    b. Instant Analysis with Advanced Determinations include sinus rhythm with wide QRS, sinus rhythm with premature ventricular contractions (PVC), and sinus rhythm with supraventricular ectopy.

4. KardiaMobile 6L requires a **compatible smartphone or tablet** and the **Kardia Rx app**.
    a. The list of compatible devices can be viewed at www.alivecor.com/compatibility.
    b. The KardiaRx app can be downloaded in the App Store or the Google Play Store.

Guide to Parts



BOTTOM VIEW



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.
16. DO NOT drop or bump with excessive force.
17. DO NOT expose to strong electromagnetic fields.
18. MR-Unsafe. Do not expose the device to a magnetic resonance (MR) environment. The device may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnet core
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. Otherwise, degradation of the performance of the KardiaMobile 6L System could result.

Cautions

1. KardiaMobile 6L does not detect heart attack.
2. DO NOT change your medication without talking to your doctor.
3. Detection of possible Atrial Fibrillation (AF) in your EKG results are not to be used for diagnosis. If you are experiencing any concerning symptoms, contact your physician.
4. Result of "Bradycardia" or "Tachycardia" are designations of heart rate in the absence of AF, and are not to be used for diagnosis. Please consult with your physician should you receive consistent identifications of "Bradycardia" or "Tachycardia".
5. “Unreadable” EKG results determines that you didn't have proper EKG recording for analysis. You may try to re-record your EKG.

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 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).

KardiaMobile 6L 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 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 fingers 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.

Setting up your KardiaMobile 6L hardware for the first time

1. Remove your KardiaMobile 6L device from the packaging.

2. Download the **KardiaRx app** from the App Store or Google Play Store.
    - Be sure to use a compatible iOS or Android device (check the compatible device list at www.alivecor.com/compatibility).

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

4. Launch the KardiaRx app. To log in to the KardiaRx app, use the method specified by your provider (such as a connection code).

5. Follow the on-screen instructions to complete your account setup.

Recording a Single-Lead EKG

Your provider will decide whether to turn on this functionality.

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

1. Open the app and tap "**Record your EKG**".

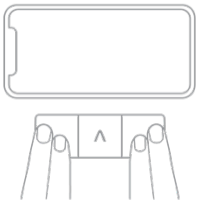
2. If this is your first time using the KardiaMobile 6L, follow the on-screen instructions to set up and pair your device.

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

4. Lay the device on a flat surface near your smartphone.
   - Make sure the device is in the correct orientation with the AliveCor "A" facing you.



5. When ready, place two fingers from each hand on the top two electrodes.
   - There's no need to squeeze or press down firmly.



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 the allotted duration, until your EKG recording is complete.

8. At the conclusion of the recording duration, you will be presented with a post-EKG screen that will confirm that your recording has completed and/or provide an EKG Instant analysis, depending on the configuration set by your provider.

9. If requested by your provider, record any symptoms by choosing all the options applicable from the symptoms checklist.

10. If requested by your provider, select activity level at the time of recording under activity checklist

Recording a Six-Lead EKG

Your provider will decide whether to turn on this functionality.

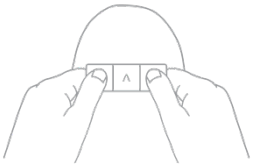
Follow the instructions below to record a Six-Lead EKG.

1. Open the app and tap "**Record your EKG**".

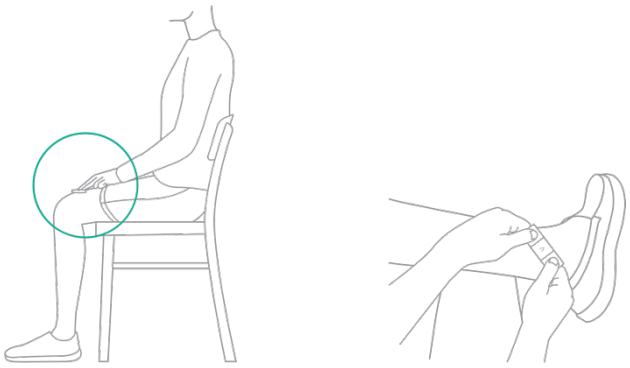
2. If this is your first time using the KardiaMobile 6L, follow the on-screen instructions to set up and pair your device.

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

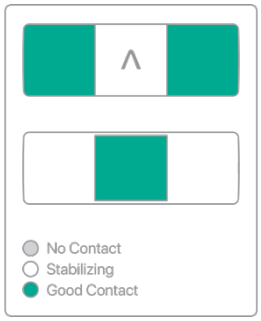
4. When ready, hold the EKG device with your thumbs touching the top two electrodes.
   - There's no need to squeeze or press down firmly.
   - Make sure the device is in the correct orientation with the AliveCor "A" facing you.



5. With your 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 to 0 seconds, at which point your EKG recording is complete.

Healthcare Professional Review- QT Interval

Health care professionals (HCPs) or providers may review and analyze the recorded EKG. When using KardiaRx, your EKG recordings are automatically transferred and made available to your provider. Providers can review the EKG PDF to perform rhythm assessments as well as measure the QT interval.

Note: An EKG from the KardiaMobile 6L 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 is provided in the section titled “Clinical Safety and Performance”.

WARNING: Manual EKG analysis is only intended for trained HCPs. 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. A Post EKG screen will be presented that optionally displays the EKG Instant analysis if configured to do so by your provider.

Representative Instant Analysis results, descriptions, and additional information are displayed in the table below. Note that Instant Analysis noted as “Advanced Determinations” will be provided only if you have access to them, such as through a KardiaCare 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.
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

Instant Analysis	Description	Additional information
		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 location or away from electronics and machinery.	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.

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.

NOTE: All historical EKGs and Instant Analysis results can be viewed, downloaded, and emailed by your provider.

Heart Rate

During your EKG recording, your real-time heart rate will be shown.
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 from an average of this inverse calculation over the last 5 seconds. For stored EKGs, the average heart rate is the average of this inverse calculation over the entire 30 seconds of the recording.

KardiaRx Application Description

The KardiaRx application is for patient use under the care of a healthcare professional (provider).

The EKG and heart rate collection are general functionality of the device. For the purpose of the KardiaRx application, the provider will choose the desired method of use of the medical device by managing a configuration based on adjustable settings for such things as which algorithm settings to use, and additional instruction or collection of physician desired metadata.

KardiaRx Account Setup

A healthcare professional will specify the method to setup the KardiaRx account, such as a connection code. The connection code or equivalent will link the participant's EKGs to the associated provider portal.

Download the **KardiaRx app** from the App Store or Google Play Store.

- Be sure to use a compatible iOS or Android device (check the compatible device list at www.alivecor.com/compatibility).

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.
- Follow the instructions to set up the KardiaMobile 6L Device and begin recording the EKG as directed by your provider.
- This app will transmit the EKG recorded by the KardiaMobile 6L to your ordering provider for review through the associated provider platform. EKG data will be collected if recorded during the entire monitoring period, the monitoring period duration is defined by your provider.

Clinical Safety and Performance

The quality 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 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 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 KardiaMobile 6L is 2 years.

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)

    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 device or expose 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.

Electromagnetic & Other Interferences

KardiaMobile 6L has been tested and deemed in conformance with the relevant requirements in IEC 60601-1 -2:2014 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 KardiaRx app:
1. Tap the Profile button on the bottom navigation area.
2. Tap the information icon to view the FCC ID and other applicable regulatory information.

Industry Canada Compliance

IC ID: 25747-AC019

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

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.

Troubleshooting

If you experience difficulties using your KardiaMobile 6L, refer to the troubleshooting guide below or contact technical support 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 make contact with the electrodes.
- If recording a Six-Lead EKG, it is important to place device on your left leg (knee or inside of the ankle). The device must be used on bare skin for an accurate recording.
- 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 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.
- 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.

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.

Electrical Safety

Guidance and manufacturer's declaration - electromagnetic emissions		
KardiaMobile 6L is intended for use in the electromagnetic environment specified below. The customer or the user of KardiaMobile 6L 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 is intended for use in the electromagnetic environment specified below. The customer or the user of KardiaMobile 6L 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 mains 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.

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration—electromagnetic immunity</th></tr>
<tr><td colspan="4">KardiaMobile 6L is intended for use in the electromagnetic environment specified below. The customer or the user of KardiaMobile 6L should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Radiated RF IEC 61000-4-3</td><td>10 V/m
80 MHz to 2.7 GHz</td><td>10 V/m</td><td>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:
</td></tr>
<tr><td colspan="4">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</td></tr>
<tr><td colspan="4">[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.</td></tr>
</table>

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

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



Type CF Applied Part



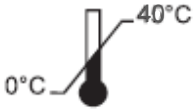
Do not dispose with household waste



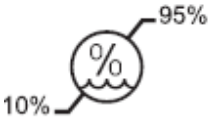
Read instructions before use



Manufacturer



Temperature range



Humidity range

REF

Model number

SN

Serial number