Instructions for Use (IFU)
for
KardiaMobile® (Model AC-019)

19LB01.X13

AliveCor, Inc.
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Table of Contents

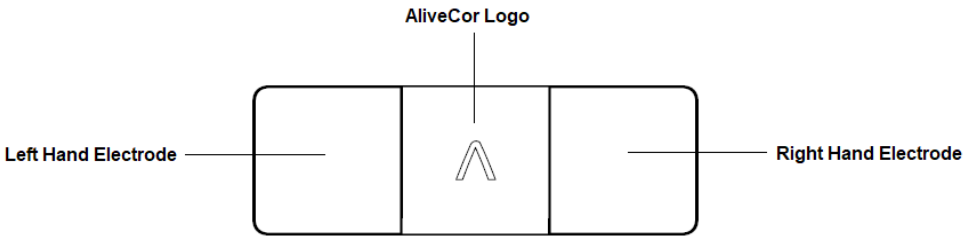
KardiaMobile® (Model AC-019)

Introduction

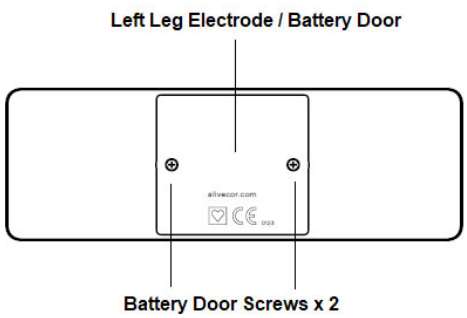
1. The KardiaMobile® (Model AC-019) System allows you to record a **Six-Lead** ECG and a **Single-Lead** ECG.
    a. It is recommended that you record a **Six-Lead** ECG (which provides more data to your cardiologist) when possible.
2. The KardiaMobile® (Model AC-019) hardware is used with a user-supplied compatible smartphone or tablet.
3. The KardiaMobile® (Model AC-019) System consists of:
    a. KardiaMobile® (Model AC-019) – a device that has 3 electrodes to sense and transmit 6-Lead ECG rhythms to the smartphone or tablet and that can optionally attach to your compatible smartphone with the sold-separately phone clip;
    b. Kardia app – SW application installed on a compatible smartphone or tablet used to collect, view, and save ECG recordings and to wirelessly transmit to the AliveCor server;

Guide to Parts

TOP VIEW



BOTTOM VIEW



Warnings

1. AliveCor does not guarantee that you are not experiencing an arrhythmia or other health conditions when labeling an ECG as 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, 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 immerse device or expose device to excessive liquid.
14. DO NOT use while charging your phone.
15. DO NOT drop or bump with excessive force.
16. DO NOT expose to strong electromagnetic fields.
17. DO NOT expose the device to a magnetic resonance (MR) environment.
18. DO NOT use with a cardiac pacemaker, ICDs, or other implanted electronic devices.
19. DO NOT use during cautery and external defibrillation procedures.
20. DO NOT place electrodes in contact with other conductive parts including earth.
21. 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.
22. DO NOT use adjacent to or stacked with other equipment because it could result in improper operation.
23. 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® (Model AC-019) System. Otherwise, degradation of the performance of the KardiaMobile® (Model AC-019) System could result.

Cautions

1. 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.
2. Result of "Bradycardia" or "Tachycardia" are designations of heart rate, not a clinical diagnosis of an arrhythmia. Please consult with your physician should you receive consistent identifications of "Bradycardia" or "Tachycardia".
3. “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® (Model AC-019) System is intended to record, store and transfer one- and two-channel electrocardiogram (ECG) rhythms. In single channel mode, the KardiaMobile® (Model AC-019) System can record Lead-I. In two channel mode, the KardiaMobile® (Model AC-019) System can record Lead-I and Lead-II simultaneously and derive Lead-III and unipolar limb leads aVR, aVF and aVL. The KardiaMobile® (Model AC-019) System also displays ECG rhythms and output of ECG analysis from AliveCor’s KardiaAI platform including detecting the presence of normal sinus rhythm, atrial fibrillation, bradycardia, tachycardia, and others. The KardiaMobile® (Model AC-019) 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.

Terms

ECG: Also known as an electrocardiogram, an ECG is a test that detects and records the strength and timing of the electrical activity in your heart. This information is recorded on a graph that shows each phase of the electrical signal as it travels through your heart.

Single-Lead ECG: When the 2 top electrodes (Left Hand Electrode and Right Hand Electrode) are used, the Kardia app will display a Single-Lead ECG that is comparable to Lead I on standard ECG machines.

Six-Lead ECG: When all 3 electrodes (Left Hand Electrode, Right Hand Electrode, and Left Leg Electrode) are used, the Kardia app will display a Six-lead ECG that is comparable to Leads I, II, III, aVF, aVL, and aVR on standard ECG machines. It is recommended that you record a Six-Lead ECG (which provides more data to your cardiologist) when possible.

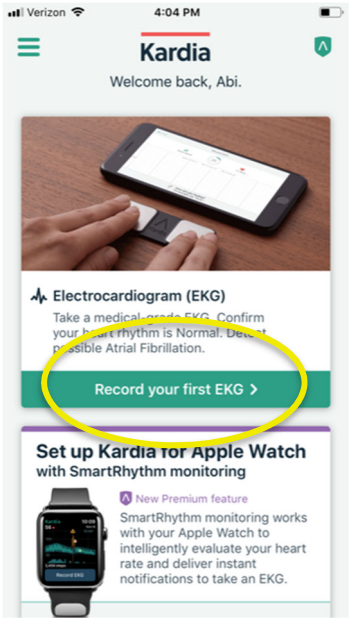
Setting up your KardiaMobile® (Model AC-019) hardware for the first time

1. Remove KardiaMobile® (Model AC-019) from packaging.

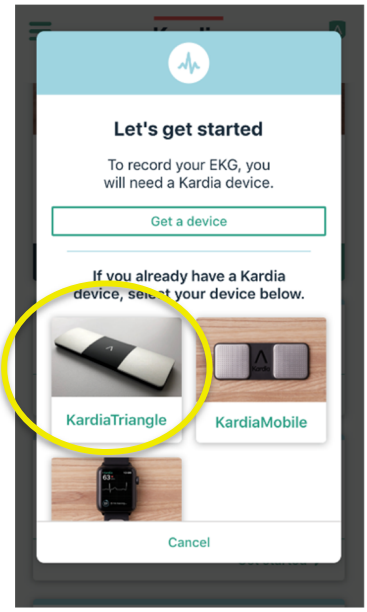
2. Setup KardiaMobile® (Model AC-019)
    - Download the Kardia app from the App Store or Google Play on your compatible iOS or Android device (check for compatibility at www.alivecor.com/compatibility).
    - Make sure you have Bluetooth turned on your smartphone (or tablet).

3. Tap  on your home screen to launch the Kardia app and tap **Create Account**.
    - Follow the onscreen instructions to create an account.

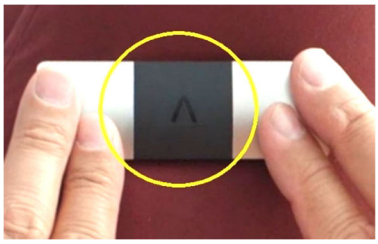
4. From the Kardia app home screen, tap **Record your first ECG.**



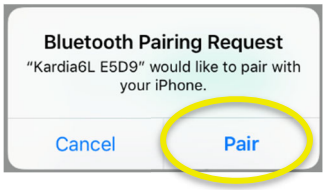
5. Select **KardiaMobile® (Model AC-019)** as your device



6. Tap lightly on the 2 top electrodes (Left Hand Electrode and Right Hand Electrode) for 5 seconds to wake up your KardiaMobile® (Model AC-019) hardware and initialize Bluetooth pairing.

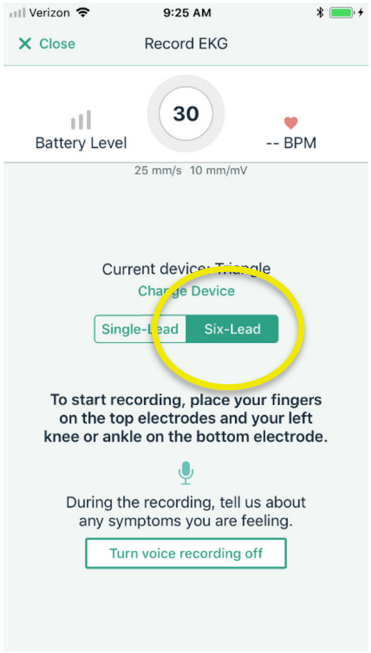


7. Select **Pair** to pair the KardiaMobile® (Model AC-019 hardware with your phone via Bluetooth.



Recording a Six-Lead ECG

1. Select **Six-Lead** on the Record ECG screen.

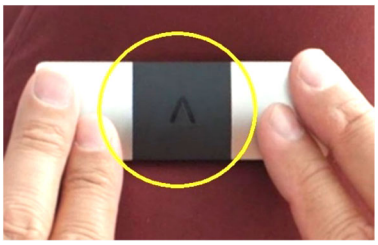


   NOTE: The **Six-Lead** option will be the default because it is recommended that you record a **Six-Lead** ECG (which provides more data to your cardiologist) when possible.
   If you prefer to record a **Single-Lead** ECG, follow the instructions in the section **Recording a Single-Lead ECG**.

2. Remain still and hold the device with your thumbs on the 2 top electrodes (Left Hand Electrode and Right Hand Electrode) and touch the bottom electrode (Left Leg Electrode) to the skin above your left knee or your left ankle.

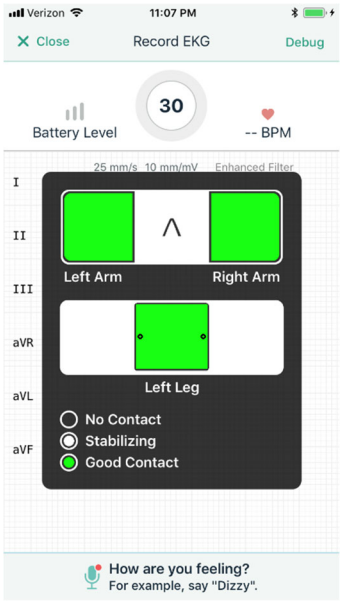
   NOTE: It is recommended that the bottom electrode (Left Leg Electrode) touches bare skin when you record a Six-Lead ECG.

3. Make sure that the AliveCor logo is in the correct orientation.

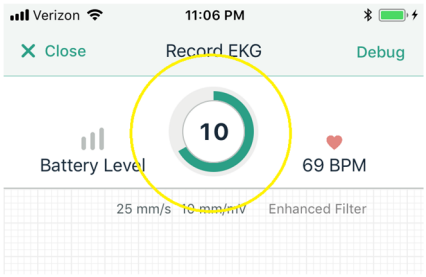


4. An ECG recording will take 30 seconds and will start once all three electrodes (Left Hand Electrode, Right Hand Electrode, and Left Leg Electrode) have good skin contact.

   NOTE: Good Contact will be indicated by green lights on the electrode diagram on-screen. An ECG recording will not start or will terminate when good skin contact is not obtained.
   NOTE: KardiaMobile® (Model AC-019) may be used up to a distance of 10 feet from the smartphone or tablet.



5. Hold steady while you watch the countdown timer decrease from 30 to 0 seconds.

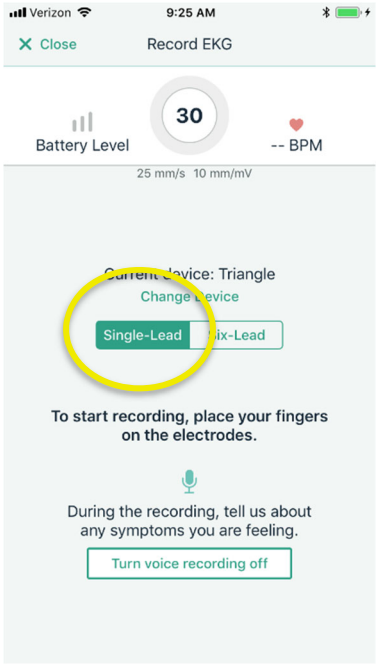


6. After 30 seconds, you will see your Six-Lead ECG with the ECG Analysis.

Recording a Single-Lead ECG

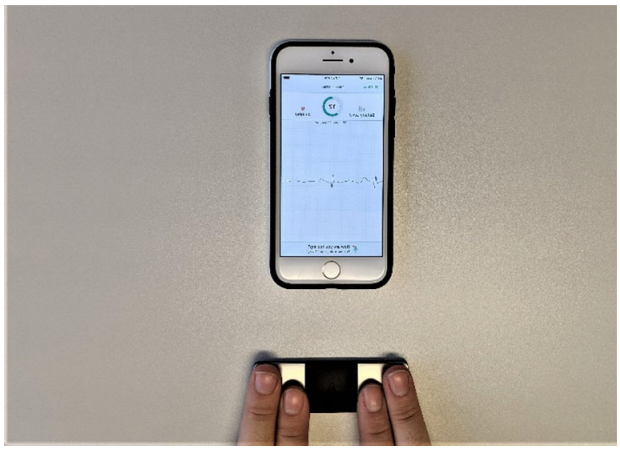
NOTE: It is recommended that you record a **Six-Lead** ECG (which provides more data to your cardiologist) when possible.

1. Select **Single-Lead** on the Record ECG screen.

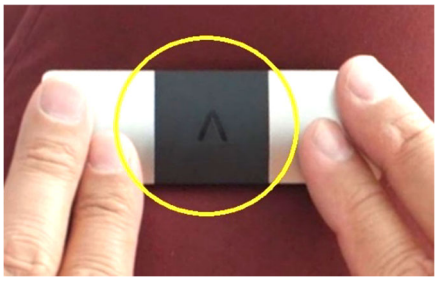


NOTE: If you prefer to record a **Six-Lead** ECG, follow the instructions in the section **Recording a Six-Lead ECG**.

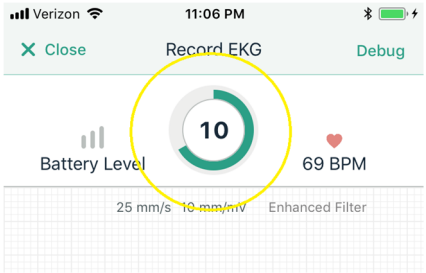
2. Rest your arms on a flat surface. Remain still and hold the device with your thumbs on the 2 top electrodes (Left Hand Electrode and Right Hand Electrode). Make sure your fingers don't touch the bottom electrode (Left Leg Electrode)



3. Make sure that the AliveCor logo is in the correct orientation.



4. An ECG recording will take 30 seconds and will start once the Left Hand Electrode and Right Hand Electrode have good skin contact. Hold steady while you watch the countdown timer decrease from 30 to 0 seconds.



   - **NOTE:** An ECG recording will not start or will terminate when good skin contact is not obtained.
   - **NOTE:** KardiaMobile® (Model AC-019) may be used up to a distance of 10 feet from the smartphone or tablet.

5. After 30 seconds, you will see your Single-Lead ECG with the ECG Analysis.

ECG Analysis

The KardiaMobile® (Model AC-019) hardware transmits the EKG signal from the electrodes to the Kardia app on a mobile computing platform to be analyzed and presented to the user. The KardiaMobile® (Model AC-019) System's Kardia app will display an EKG, single-lead (Lead I only) or six-lead EKGs (Lead I, Lead II, Lead III, aVL, aVR and aVF) and EKG Analysis.

The possible EKG Analysis Results that may be displayed based on the analysis of your EKG are presented in the table below. Each EKG analysis result option is described along with recommended action based on the result.

EKG Analysis Result	**Description**	**Recommended Actions**
Atrial Fibrillation	Your EKG shows signs of atrial fibrillation.	This is not a diagnosis, only a possible finding. Contact a physician if you have questions or are concerned about any symptoms.
Bradycardia	Your heart rate is less than 50 beats per minute, which is slower than normal for most people.	This is not a diagnosis, only a possible finding. Contact a physician if you have questions or are concerned about any symptoms.
Normal	No rhythm abnormalities are detected in your EKG.	This is not a diagnosis, only a possible finding. Contact a physician if you have questions or are concerned about any symptoms.
Tachycardia	Your heart rate is faster than 100 beats per minute. This can be normal with stress or physical activity.	This is not a diagnosis, only a possible finding. Contact a physician if you have questions or are concerned about any symptoms.
No Analysis	Your EKG recording is of insufficient duration. Instant Analysis is not able to provide an analysis on EKG recordings shorter than 30 seconds.	Record a new 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	Your EKG does not fall into the algorithmic classifications of Normal, Bradycardia, Tachycardia, or Atrial Fibrillation. This result may be caused by other physiological condition (for instance other arrhythmias, very fast or slow heart rates) or may be a result of poor quality recordings.	This is not a diagnosis, only a possible finding. Contact a physician if you have questions or are concerned about any symptoms. Record another EGK within hours or days of this recording.
Unreadable	There is too much interference in this recording.	Record a new EKG. Try to relax and hold still, rest your arms, or move to a quiet location with less interference.

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

Heart Rate

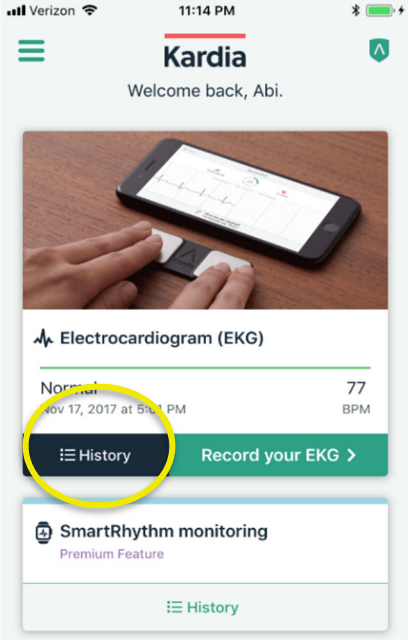
Current heart rate is displayed during an ECG recording and the average heart rate is displayed in completed ECG recordings along with the ECG Analysis.

The Kardia App has an internal QRS detector that is used to measure the heart rate, defined as the inverse of the R-R time interval. During an ECG recording, the current heart rate is measured from an average of this inverse calculation over the last 5 seconds.

For stored ECGs, the average heart rate is the average of this inverse calculation over the entire 30 seconds of the recording.

Previously Recorded ECGs

From the Kardia app home screen, tap **History** to access previously recorded ECGs.



Clinical Testing

The KardiaMobile® (Model AC-019) System was thoroughly evaluated in a clinical study to ensure users can get a medical grade ECG. Overall, 44 subjects participated in the study, that included patients with arrhythmias as well as normal subjects. The study showed that the KardiaMobile® (Model AC-019) device records a 6-lead ECG equivalent to the same leads on a standard FDA-cleared hospital 12-lead ECG device but at an ambulatory bandwidth. Clinical equivalence was shown qualitatively, through a review by two Board Certified Cardiac Electrophysiologists and quantitatively, through a statistical test of equivalence between the two sets of ECGs assessing various variables.

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® (Model AC-019) is 2 years.

Maintenance

1. No service or repair should be performed on the KardiaMobile® (Model AC-019) hardware other than the maintenance listed in this section.
2. It is important to keep the electrodes clean by spraying with an alcohol-based sanitizer and wiping with a soft cloth when needed.
    - Do use a clean, lint-free cloth
    - DO NOT use abrasive cleaners or materials
    - 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® (Model AC-019) 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:

1. 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.
2. DO NOT replace the battery when device is in use.

Electromagnetic & Other Interferences

KardiaMobile® (Model AC-019) 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 Kardia app:

1. On the home screen, tap  to access Kardia app Settings.
2. Tap “About Kardia” to the FCC ID and other applicable regulatory information.

Ingress Protection Marking

KardiaMobile® (Model AC-019) is IP22 rated. KardiaMobile® (Model AC-019) is protected against insertion of fingers and is not affected by vertically dripping water. KardiaMobile® (Model AC-019) 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 in operating your KardiaMobile® (Model AC-019) System, refer to the troubleshooting guide below or contact technical support at support@alivecor.com.

1. **Problem: My KardiaMobile® (Model AC-019) is not working.**
   Solution
   - Option 1: Make sure you have Bluetooth turned on your smartphone (or tablet).
   - Option 2: Change the battery. AliveCor recommends that you bring your KardiaMobile® (Model AC-019) hardware to a battery replacement shop for battery replacement.

2. **Problem: I have a lot of artifact, noise, or interference in my recording.**
   Solution
   - Option 1: Ensure that the “Enhanced Filter” is on.
   - Option 2: Ensure that your arms, hands, and left leg remain still during recordings to reduce muscle noise.
   - Option 3: Clean the electrodes on the KardiaMobile® (Model AC-019) by spraying with an alcohol-based sanitizer and wiping with a soft cloth.
   - Option 4: If your hands or left leg are very dry, use a water-based lotion before recording.

- Option 5: If you wear hearing aids, turn them off prior to recording.
- Option 6: Avoid close proximity to items that may cause electrical interference (electronic equipment, computers, chargers, routers, etc.)

3. **Problem: The ECG rhythm from Lead II does not appear while recording.**
   Solution
   - Ensure that the bottom electrode (Left Leg Electrode) is touching the skin above your left knee or your left ankle.
     NOTE: It is recommended that the bottom electrode (Left Leg Electrode) touches bare skin when you record a Six-Lead ECG.

4. **Problem: The ECG rhythms appear upside down.**
   Solution
   - Option 1: Make sure the AliveCor logo is in the correct orientation. Make sure your thumbs are touching the 2 top electrodes (left thumb on the Left Hand Electrode and right thumb on the Right Hand Electrode) and the bottom electrode (Left Leg Electrode) is touching the skin above your left knee or your left ankle.
     NOTE: It is recommended that the bottom electrode (Left Leg Electrode) touches bare skin when you record a Six-Lead ECG.

   - Option 2: Invert the ECG.
     - In the Instant Analysis screen, tap “Invert” on the top left corner to toggle it ON or OFF.
     - In the ECG Review screen, tap “MORE” at the bottom of the ECG Review screen, and then tap the “INVERT” switch to toggle it ON or OFF.

Electrical Safety

Guidance and manufacturer's declaration - electromagnetic emissions		
KardiaMobile® (Model AC-019) is intended for use in the electromagnetic environment specified below. The customer or the user of KardiaMobile® (Model AC-019) should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	KardiaMobile® (Model AC-019) 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® (Model AC-019) is intended for use in domestic surroundings.
Harmonic emissions IEC 61000-3-2	N/A	KardiaMobile® (Model AC-019) 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® (Model AC-019) is intended for use in the electromagnetic environment specified below. The customer or the user of KardiaMobile® (Model AC-019) 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® (Model AC-019) 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® (Model AC-019) is intended for use in the electromagnetic environment specified below. The customer or the user of KardiaMobile® (Model AC-019) 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® (Model AC-019), 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® (Model AC-019) is used exceeds the applicable RF compliance level above, KardiaMobile® (Model AC-019) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating KardiaMobile® (Model AC-019).</td></tr>
</table>

[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® (Model AC-019)

KardiaMobile® (Model AC-019) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of KardiaMobile® (Model AC-019) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and KardiaMobile® (Model AC-019) 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

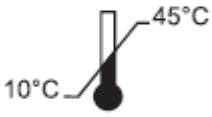
These symbols will be used in the packaging and other labeling of the KardiaMobile® (Model AC-019) hardware.

Type CF Applied Part

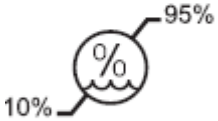
Do not dispose with household waste

Read instructions before use

Manufacturer



Temperature range



Humidity range

REF

Model number

SN

Serial number

EC REP

European Authorized Representative