



444 Castro Street, Suite 600
Mountain View, CA. 94041

DOCUMENT NUMBER:
DOCUMENT TITLE:
DOCUMENT NOTES:

Document Information

Revision:	Vault:
Doc Type:	Status:

Date Information

Effective Date:	Next Review Date:
Release Date:	Expiration Date:

Control Information

Author:	Previous Number:
Owner:	Change Number:

All dates and times are in



**Instructions for Use (IFU)
for
KardiaMobile Card (AC-021)**

21LB01.X2
April 2021



**AliveCor, Inc.
444 Castro Street, 6th Floor,
Mountain View, CA 94041, USA**

© 2021 AliveCor, Inc.

Table of Contents

Introduction	3
Guide to Parts	4
Warnings and Precautions	4
Indications For Use	6
Features & Functionality	6
Setting up your KardiaMobile Card device for the first time	7
Recording an EKG	7
EKG Analysis	8
Heart Rate	10
Environmental Specifications	10
Expected Service Life	10
Maintenance	10
Device Disposal	11
Electromagnetic & Other Interferences	11
FCC Compliance	11
Ingress Protection Marking	12
Applied Parts	12
Troubleshooting	12
Electrical Safety	14
Equipment Symbols	17

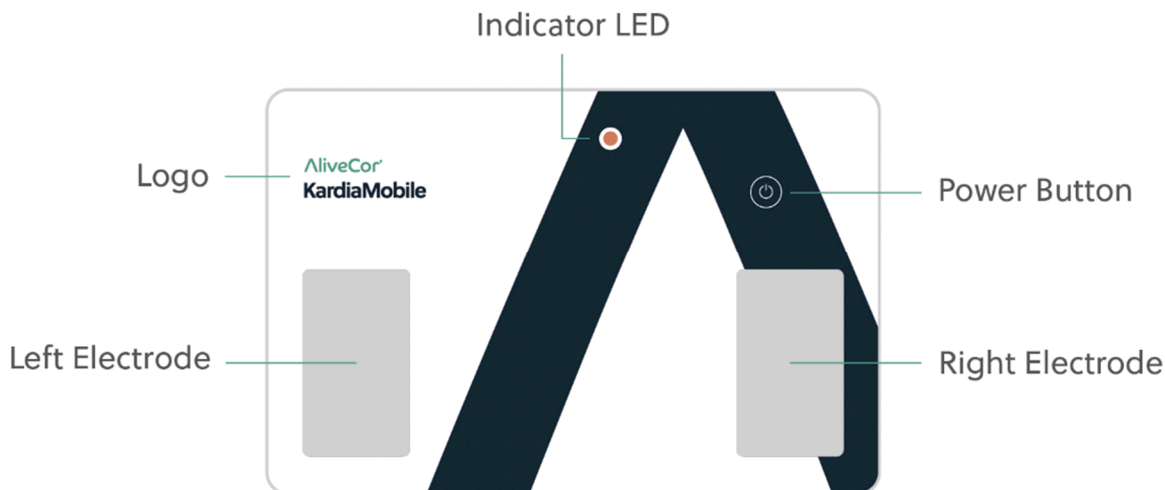
KardiaMobile Card

Introduction

1. **KardiaMobile Card** is a personal EKG device that records your EKG and wirelessly transmits the data to the **Kardia app** installed on your smartphone or tablet.
 - a. Contains two electrodes on the top surface, for use with the left and right hands.
 - b. Powered by a non-replaceable battery.
 - c. Bluetooth wirelessly transmits EKG data to your smartphone or tablet.
2. KardiaMobile Card is capable of recording a **Single-Lead EKG** that provides a single view of the heart's electrical activity.
3. An instant algorithmic analysis ("**Instant Analysis**") of your heart rhythm is provided upon completion of your EKG recording. See the EKG Analysis section for more details.
4. KardiaMobile Card requires a **compatible smartphone or tablet** and the **Kardia app**.
 - a. The list of compatible devices can be viewed at www.alivecor.com/compatibility.
 - b. The Kardia app can be downloaded in the App Store or the Google Play Store.
5. The KardiaMobile Card 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, or print directly from the Kardia app. 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

FRONT VIEW



BACK VIEW



Warnings and Precautions

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 or if you are experiencing any concerning symptoms.
2. Chest pain or pressure is a medical emergency. Heart disease and heart attack can occur in the presence of any EKG result. Contact a physician or emergency services if you are experiencing any symptoms or have concerns.

3. Use this device to record heart rate and heart rhythm only.
4. Do not use this device to diagnose heart-related conditions.
5. KardiaMobile Card does not check for heart attack.
6. Detection of possible Atrial Fibrillation (AF) in your EKG results are not to be used for diagnosis.
7. 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".
8. "Unreadable" EKG result determines that you didn't have proper EKG recording for analysis. You may try to re-record your EKG.
9. 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. Do not change or adjust your medication without talking to your doctor.
10. Do not continue use until further instructed by a physician if your skin is irritated or inflamed around the electrode contact area.
11. 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.
12. The device has not been tested for and is not intended for pediatric use.
13. Device contains a lithium manganese dioxide battery that is not removable or replaceable.
14. 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.
15. Do not take a recording while driving or during physical activity.
16. Do not store in extremely hot, cold, humid, wet, or bright conditions.
17. Do not take a recording if electrodes are dirty. Clean them first (see cleaning instructions under "Maintenance" section).
18. Do not use abrasive cleaners and materials as these products could adversely affect product performance.
19. Do not immerse device or expose device to excessive liquid.
20. Do not use while charging your phone.
21. Do not drop or bump with excessive force.
22. Do not expose to strong electromagnetic fields. Do not take recordings when the device is in close vicinity to strong electromagnetic fields (e.g. electromagnetic anti-theft systems, metal detectors).
23. Do not expose the device to a magnetic resonance (MR) environment.
24. Do not use with a cardiac pacemaker, ICDs, or other implanted electronic devices.
25. Do not use during a medical procedure (e.g. magnetic resonance imaging, diathermy, lithotripsy, cautery and external defibrillation procedures).
26. Do not place electrodes in contact with other conductive parts including earth.
27. 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.

28. Do not use adjacent to or stacked with other equipment because it could result in improper operation.
29. 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 Card System. Otherwise, degradation of the performance of the KardiaMobile Card System could result.
30. Do not take a recording during physical activity.
31. After EKG analysis, the app may incorrectly identify ventricular flutter as “Unreadable”. Contact a physician if you are experiencing any symptoms or have concerns.

Indications For Use

The KardiaMobile Card System is intended to record, store and transfer single-channel electrocardiogram (ECG/EKG) rhythms. The KardiaMobile Card 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 Card 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 use¹.

Features & Functionality

KardiaMobile Card is a personal EKG device that is capable of recording a Single-Lead EKG. It has two electrodes on the top surface and is powered by a non-replaceable battery. 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 or ECG, 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.

¹ Pediatric use is defined as 21 years and under

Setting up your KardiaMobile Card device for the first time

1. Remove your KardiaMobile Card device from the packaging.
2. Download the **Kardia app**  from the App Store or Google Play Store.
 - o 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 Kardia app and tap "**Create Account**".
5. Follow the on-screen instructions to complete your account setup.

Recording an EKG

1. Open the app and tap "**Record your EKG**".
2. If this is your first time using the KardiaMobile Card, follow the on-screen instructions to set up and choose your device.
3. Pick up the KardiaMobile Card using your index finger and thumb; and press the power button using your thumb.



4. Lay the device on a flat surface. Make sure the device is in the correct orientation with the AliveCor logo and brand name “KardiaMobile” in the top left.
5. When ready, place a finger or the thumb 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 30 seconds, until your EKG recording is complete.
8. The device will turn off automatically after use.

EKG Analysis

Upon completion of your EKG recording the EKG is processed by AliveCor’s Instant Analysis algorithms in the Kardia app. The app will display your full EKG and the Instant Analysis result with description.

All possible Instant Analysis results, descriptions, and additional information are displayed in the table below:

Instant Analysis	Description	Additional information
Possible 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.	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.
Normal	No rhythm abnormalities detected in your EKG.	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.	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.
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	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.

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 from the “History” section of the Kardia app.

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 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.

Environmental Specifications

Operational Temperature:	-10°C to +40°C
Operational Humidity:	Up to 95% (non-condensing)
Storage Temperature:	+0°C to +40°C
Storage Humidity:	Up to 95% (non-condensing)
Atmospheric Pressure:	76 to 101 kPa

Expected Service Life

The expected service life for the KardiaMobile Card is 2 years.

Maintenance

1. No service or repair should be performed on the KardiaMobile Card device other than the maintenance listed in this section.

To clean the device, wipe with a soft cloth damp with one of the following approved cleaners:

- a. Soap and water,
- b. 70% isopropanol or ethanol alcohol, or
- c. 0.55% bleach

You may also use a pre-prepared wipe with one of the approved cleaners listed above.

After cleaning, allow the device to dry before using or placing it back in any storage containers.

WARNING:

- Do not use abrasive cleaners and materials as these products could adversely affect product performance.

- Do not immerse device or expose device to excessive liquid.
2. Exterior Visual Inspection:
- Inspect electrodes for warping, surface damage, or corrosion
 - Check for any other form of damage

Device Disposal

Do not dispose of the device with household waste. Dispose of the device according to applicable local regulations. Unlawful disposal may cause environmental pollution. Do not cut, shred or attempt to destroy device.

Electromagnetic & Other Interferences

KardiaMobile Card has been tested and deemed in conformance with the relevant requirements in IEC 60601-1-2:2014 (+A1:2020) Class B for Electromagnetic Compatibility (EMC).

FCC and Industry Canada (IC) Compliance

FCC ID: 2ASFFAC021

IC: 25747-AC021



This device complies with Part 15 of the FCC Rules and with Industry Canada's license-exempt RSSs.

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 and IC information on the Kardia app:

1. On the home screen, tap  to access your profile.
2. From the profile tap  to access the Kardia app Settings.
3. Tap "About Kardia" to view the FCC and IC IDs and other applicable regulatory information.

Ingress Protection Marking

KardiaMobile Card is IPx8 rated. KardiaMobile Card is protected against immersion in water up to 2 meters for 1 hour. KardiaMobile Card has been tested with relevant requirement standard IEC 60601-1-11:2015 (+A1:2020).

Applied Parts


The 2 electrodes (Left Hand Electrode and Right Hand Electrode) are Type BF Applied Parts.

Operational temperature of the device is -10°C to +40°C. If ambient temperature exceeds +41°C, Applied Parts can exceed +41°C.

Troubleshooting

If you experience difficulties using your KardiaMobile Card, refer to the troubleshooting guide below or contact technical support at support@alivecor.com.

1. My KardiaMobile Card is not working.

- Make sure the Kardia app on your phone is open, the KardiaMobile Card device is selected and is ready to pair.
- Make sure the amber LED light turns on when you press the white power button (located inside the “A” symbol on the right corner of the KardiaMobile Card).
 - Hold the card between your thumb and index finger with your thumb on the front of the device over the power button . Press down firmly with your thumb until you see the LED solid light or blinking light (you may also hear a click). A blinking LED light indicates that the device is trying to establish a connection with your phone/tablet.
 - If the light does not turn on the battery could be depleted.

If the amber light does turn on:

- Make sure Bluetooth is turned on in your smartphone or tablet settings and follow the steps on your screen.
- If Bluetooth is on, try to un-pair and pair again to your KardiaMobile Card.

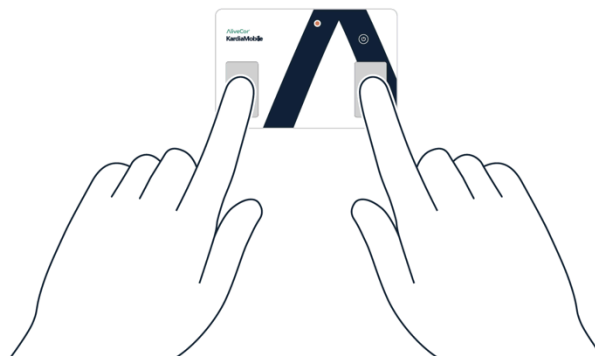
2. I'm having trouble getting a clear recording.

- 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.

- When recording, relax your arms and hands to reduce muscle noise. Rest the forearms and hands on a flat surface. 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.
- Ensure that your smartphone or tablet is not charging/syncing and you are not using headphones with your smartphone or tablet during the recording.
- Ensure that the “Enhanced Filter” is on.
- Make sure Mains Filter is set appropriately for your geographical location. This can be adjusted under the Kardia app Settings

3. On my EKG, the recording appears upside down.

- Make sure the device is in the correct orientation with the AliveCor logo and brand name “KardiaMobile” in the top left.
- On the EKG tracing, select the “Invert” option to flip the orientation of the EKG.




4. I see large spikes at the start of my recording

- Large amounts of noise/artifact can be seen for the first few milliseconds of a recording when the Enhanced Filter is looking for your heartbeat. This is very rare and only lasts until your first heartbeat is seen in the app; this doesn't affect the rest of your recording.

Electrical Safety

Guidance and manufacturer's declaration - electromagnetic emissions		
KardiaMobile Card is intended for use in the electromagnetic environment specified below. The customer or the user of KardiaMobile Card should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	KardiaMobile Card 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 Card is intended for use in domestic surroundings.
Harmonic emissions IEC 61000-3-2	N/A	KardiaMobile Card is powered from a lithium manganese dioxide 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 Card is intended for use in the electromagnetic environment specified below. The customer or the user of KardiaMobile Card 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 Card is powered from a lithium manganese dioxide 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.

Guidance and manufacturer’s declaration—electromagnetic immunity			
KardiaMobile is intended for use in the electromagnetic environment specified below. The customer or the user of KardiaMobile Card 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	<p>Portable and mobile RF communications equipment should be used no closer to any part of KardiaMobile Card, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3.5}{V_1} \right] \sqrt{P} \quad < 80\text{MHz}$ $d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80\text{ MHz to } 800\text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800\text{ MHz to } 2.7\text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
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 Card is used exceeds the applicable RF compliance level above, KardiaMobile Card should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating KardiaMobile Card.			
^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 Card			
KardiaMobile Card is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of KardiaMobile Card can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and KardiaMobile Card 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	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	$d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1—At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Equipment Symbols

These symbols may be used in the packaging and other labeling of the KardiaMobile Card device:

Symbol	Interpretation	Symbol	Interpretation
	Manufacturer		Refer to instruction manual/booklet
	Read instructions before use		Do not dispose with household waste
	Temperature range		Do not cut, shred or attempt to destroy device
	Humidity range		Model number
	Atmospheric pressure range		Serial number
	Type BF Applied Part		Protected against immersion in water up to 2 meters for 1 hour

Signature Manifest

Document Number: 21LB01

Revision: X2

Title: KardiaCard Instructions For Use (IFU)

All dates and times are in Pacific Standard Time.

21LB01 KardiaMobile Card IFU Rev X2 (pre-prod.)

Change Request

Name/Signature	Title	Date	Meaning/Reason
Shani Frenkel (SFRENKEL)	Regulatory Affairs Manager	30 Mar 2021, 11:23:43 PM	Approved

Regulatory Affairs

Name/Signature	Title	Date	Meaning/Reason
Saket Bhatt (SBHATT)	VP, RAQA-(MR)		
Shani Frenkel (SFRENKEL)	Regulatory Affairs Manager	08 Apr 2021, 10:47:15 PM	Approved

Marketing

Name/Signature	Title	Date	Meaning/Reason
Amy Speed (ASPEED)	Physician Marketing Manager	08 Apr 2021, 09:41:23 AM	Approved

Clinical

Name/Signature	Title	Date	Meaning/Reason
Aman Bhatti (ABHATTI)	VP, Biopharma • Clinical		
David Albert (DALBERT)	Founder, Chief Scientist	08 Apr 2021, 10:08:18 AM	Approved

Program Management

Name/Signature	Title	Date	Meaning/Reason
Baru Lopez (BLOPEZ)	Dir, Tech Prog Mgmt		
Josef Friedmann (JFRIEDMANN)	Engineering Program Manager	08 Apr 2021, 08:46:56 AM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Saket Bhatt (SBHATT)	VP, RAQA-(MR)		
Nidhi Sullivan (NSULLIVAN)	Quality Manager	09 Apr 2021, 09:22:56 AM	Approved

Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Tasneem Alich (TALICHI)	Quality Systems Manager		
Terry Medina (TMEDINA)	Quality Sys/DC Specialist	09 Apr 2021, 09:26:35 AM	Approved