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

21LB01.4
May 2023



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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
For Use with Kardia App	7
For Use with KardiaRx App	7
Recording an EKG	8
EKG Instant Analysis	9
Healthcare Professional Review (KardiaRx)	11
Heart Rate	11
Clinical Safety and Performance	12
Environmental Specifications	12
Expected Service Life	12
Maintenance	12
Device Disposal	13
Electromagnetic & Other Interferences	13
FCC and Industry Canada Compliance	13
Ingress Protection Marking	13
Applied Parts	14
Troubleshooting	14
Electrical Safety	15
Equipment Symbols	19

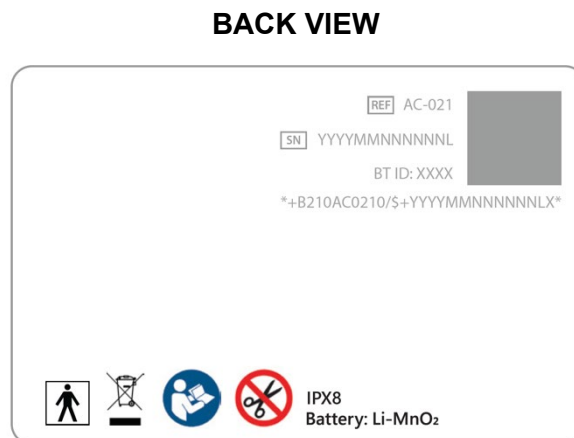
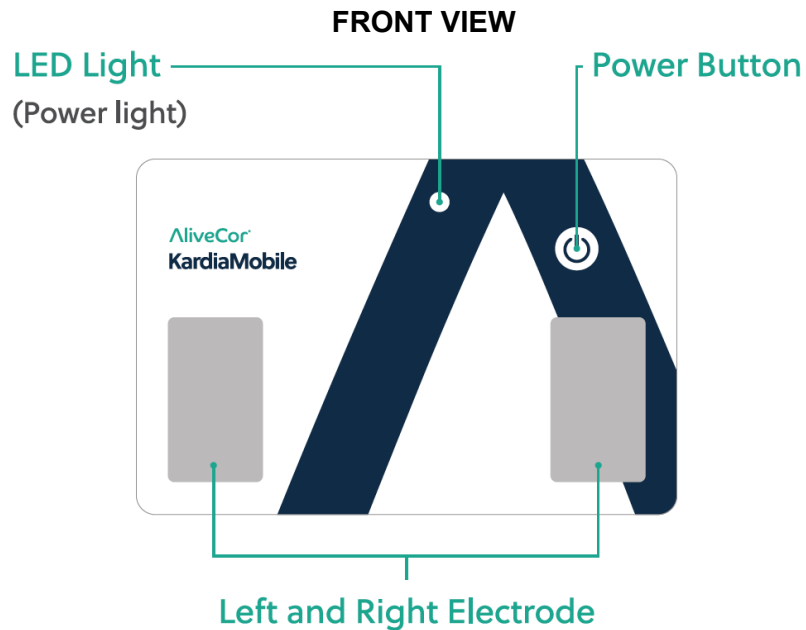
KardiaMobile Card

Introduction

1. **KardiaMobile Card** is a personal EKG device that records your EKG and wirelessly transmits the data to a Kardia application (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 Instant Analysis section for more details.
4. KardiaMobile Card requires a **compatible smartphone or tablet** and either the **Kardia App** or **KardiaRx App*** version of the **Kardia applications**.
 - a. The list of compatible devices can be viewed at www.alivecor.com/compatibility.
 - b. The appropriate Kardia application can be downloaded in the App Store or the Google Play Store.

*NOTE: The KardiaRx app is only available in certain geographies. Check with your healthcare provider to determine eligibility for KardiaRx.
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



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 (depth greater than two (2) meters OR duration greater than one (1) hour).
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 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 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 use.

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 a finger or thumb 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.

Setting up your KardiaMobile Card device for the first time

1. Remove your KardiaMobile Card device from the packaging.
2. Download the appropriate **Kardia application** from the App Store or Google Play Store. The KardiaMobile Card is compatible with either the **Kardia App** or, in some geographies, the **KardiaRx App**.
 - o Be sure to use a compatible iOS or Android device (check the compatible device list at www.alivecor.com/compatibility).

For Use with Kardia App

To create your account using the Kardia app:

1. Make sure **Bluetooth is turned on** in your smartphone or tablet settings.
2. Launch the Kardia app and follow the on-screen instructions to create your account.
3. Follow the on-screen instructions to complete your account setup.

For Use with KardiaRx App

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 metadata.

Note:

- Demographic information that is part of your patient file or health record, or the name and contact of your provider may be displayed in the app.
- Follow the instructions to set up the KardiaMobile Card and begin recording the EKG as directed by your provider.
- This app will transmit the EKG recorded by the KardiaMobile Card to your ordering provider for review through the associated provider platform. EKG data will be collected if recorded during the entire monitoring period, the duration of the monitoring period is defined by your provider.

To create your account using the KardiaRx app:

1. Make sure **Bluetooth is turned on** in your smartphone or tablet settings.
2. Launch the KardiaRx app. To log in to the KardiaRx app, use the method specified by your healthcare provider (such as a connection code).
3. 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. **If you are using the Kardia Rx app, at the conclusion of your recording, you will be presented with a post-EKG screen that will confirm your recording has been completed and/or provide an EKG instant analysis, depending on the configuration set by your healthcare provider.**
9. The device will turn off automatically after use.

EKG Instant 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.

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.

Instant Analysis	Description	Additional information
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 full 30 second recording.

Instant Analysis	Description	Additional information
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 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.

Healthcare Professional Review (KardiaRx)

Healthcare 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 verify instant analysis and/or perform rhythm assessments.

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

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.

Clinical Safety and Performance

The KardiaMobile family of devices has been extensively validated in clinical studies at several leading institutions. KardiaMobile and KardiaMobile 6L devices have been favorably compared to Lead I recordings of a standard FDA-cleared 12-lead device. Clinical equivalence of recordings from these Kardia devices and the 12-lead EKG device were also validated by board-certified Cardiac Electrophysiologists. See <https://www.alivecor.com/research/> for details.

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 Class B for Electromagnetic Compatibility (EMC).

FCC and Industry Canada 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 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 ID 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.

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 appropriate 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	
Surge IEC 61000-4-5	N/A	N/A	KardiaMobile Card is powered from a lithium manganese dioxide battery and does not require AC mains power.
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	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. Recommended separation distance

			$d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ <p style="text-align: right;">< 80MHz</p> $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ <p style="text-align: right;">80 MHz to 800 MHz</p> $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ <p style="text-align: right;">800 MHz to 2.7 GHz</p> <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). 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:</p> 
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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