EN

ALIVECOR®

Instructions for Use (IFU)
for
K1000 (AC-029)

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℞ Only

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

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K1000

Introduction

1. **K1000** is a 6-lead, personal EKG device that uses three electrodes to record an EKG and wirelessly transmit the data to a 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.

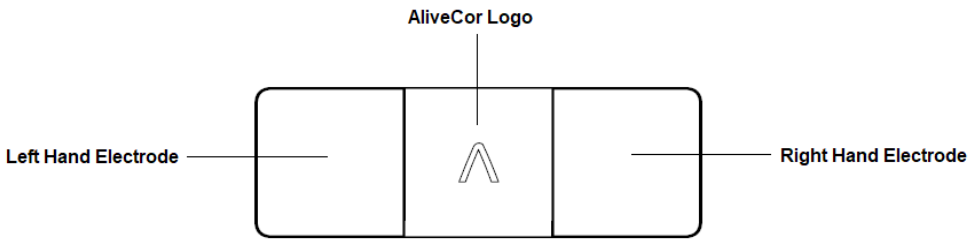
2. K1000 is capable of recording a 6-lead EKG which provides six views of the heart's electrical activity (taken using three electrodes).

3. The EKG recordings are automatically shared with a doctor or clinician for review.

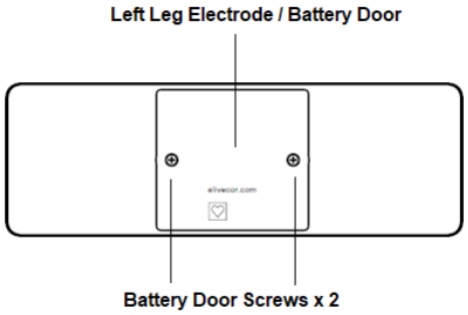
4. K1000 requires a **compatible smartphone or tablet** with the KardiaStation application.
    a. The list of compatible devices can be viewed at www.alivecor.com/compatibility.
    b. The KardiaStationapplication can be downloaded in the App Store or the Google Play Store.

Guide to Parts

TOP VIEW



BOTTOM VIEW



Contraindications

There are no known contraindications.

Warnings

1. AliveCor does not guarantee that you are not experiencing an arrhythmia or other health conditions with any EKG result, including normal. You should notify your physician for possible changes in your health. DO use this device to record heart rate and heart rhythm only.
2. DO NOT use to diagnose heart-related conditions.
3. DO NOT use to self-diagnose heart related conditions. Consult with your physician before making any medical decision, including altering your use of any drug or treatment.
4. DO NOT continue use until further instructed by a physician if your skin is irritated or inflamed around the electrode.
5. AliveCor makes no warranty for any data or information that is collected erroneously by the device, or misuse or malfunction as a result of abuse, accidents, alteration, misuse, neglect, or failure to maintain the products as instructed. Interpretations made by this device are potential findings, not a complete diagnosis of cardiac conditions. All interpretations should be reviewed by a medical professional for clinical decision-making.
6. The device has not been tested for and is not intended for pediatric use.
7. Keep device away from young children. Contents may be harmful if swallowed. Device contains a coin cell battery that is not accessible during normal use but, if exposed, can be a choking hazard and may cause severe tissue injury if ingested.
8. DO NOT replace the battery when device is in use.
9. DO NOT use the electrode on a portion of the body with too much body fat, body hair or very dry skin, as a successful recording may not be possible.
10. DO NOT take a recording while driving or during physical activity.
11. DO NOT store in extremely hot, cold, humid, wet, or bright conditions.
12. DO NOT take a recording if electrodes are dirty. Clean them first.

13. DO NOT use abrasive cleaners and materials as these products could adversely affect product performance.
14. DO NOT immerse device or expose device to excessive liquid.
15. DO NOT use while charging your phone. If the device is attached to your phone remove it prior to wireless charging the phone. DO NOT place the device on top of your phone while wirelessly charging the phone.
16. DO NOT drop or bump with excessive force.
17. DO NOT expose to strong electromagnetic fields.
18. DO NOT expose the device to a magnetic resonance (MR) environment.
19. DO NOT use with a cardiac pacemaker, ICDs, or other implanted electronic devices.
20. DO NOT use during cautery and external defibrillation procedures.
21. DO NOT place electrodes in contact with other conductive parts including earth.
22. DO NOT use with un-approved accessories. Use of non-AliveCor approved accessories or transducers and cables could result in electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.
23. DO NOT use adjacent to or stacked with other equipment because it could result in improper operation.
24. DO NOT use portable RF communications equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 inches) to any part of the K1000 System. Otherwise, degradation of the performance of the K1000 System could result.

Cautions

1. K1000 does not detect heart attack.
2. DO NOT adjust medication based on results of EKG recording without talking to your doctor.
3. Detection of possible Atrial Fibrillation (AF) in EKG results are not to be used for diagnosis. If you are experiencing any concerning symptoms, contact your physician.
4. A 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 determine that a proper EKG for analysis was not recorded. You may try to re-record the EKG.
6. The app may incorrectly identify Ventricular Flutter, Ventricular Bigeminy, and Ventricular Trigeminy heart conditions as “Unreadable”. Please consult with your physician.
7. ECG reports viewed at any magnification other than 100% may appear distorted and could lead to misdiagnosis.

Indications For Use

The K1000 System is intended to record, store and transfer two-channel electrocardiogram (EKG) rhythms. The K1000 System can record Lead-I and Lead-II simultaneously and derive Lead-III and unipolar limb leads aVR, aVF and aVL. The K1000 System can also display EKG

rhythms and output of EKG analysis from AliveCor's KardiaAI platform. The K1000 System detects the presence of normal sinus rhythm as well as arrhythmias such as atrial fibrillation, bradycardia, tachycardia, sinus rhythm with premature ventricular contraction (PVCs), sinus rhythm with supraventricular ectopy (SVE) and sinus rhythm with wide QRS. The K1000 System is intended only for use by patients under direction from a healthcare professional. The device has not been tested and is not intended for pediatric use.

Features & Functionality

K1000 is a 3-electrode personal EKG device that is capable of recording a 6-Lead EKG, which provides the healthcare professional more data than a single lead EKG.

K1000 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 a smartphone or tablet.

What is an EKG (or ECG)?
Also known as an electrocardiogram, an EKG, or ECG, 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.

6-Lead EKG
A 6-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 or thumbs from your left and right hand on the top two electrodes. This is comparable to Leads I, II, III, aVF, aVL, and aVR on standard EKG machines used in the hospital or doctor's office.

Note: The K1000 does not require calibration prior to use.

Setting up the K1000 hardware for the first time

1. Remove the K1000 device from the packaging.

2. Download the **KardiaStation 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.

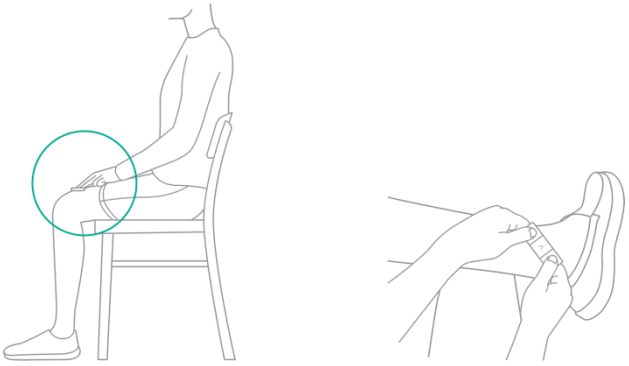
4. Launch the KardiaStation App and continue to the application start screen. Login to your account.

Recording an EKG (for Clinicians Using the KardiaStation App to Take a Patient's Recording):

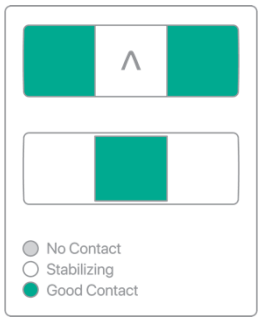
Use the following instructions to record an EKG with a patient.:

1. Open the app and tap "**Record your EKG**".
2. Enter the patient identification number, typically a medical record number (MRN)
3. For the 6-lead EKG, instruct the patient to rest two or more fingers (it does not matter which fingers) or thumbs on K1000's electrodes, with the right hand on one electrode and the left hand on the other. The AliveCor "A" logo should be facing the patient.

4. The patient should then place the EKG device on the bare skin of the left leg (knee or inside of the ankle). As soon as the fingers or thumbs from each hand, and bare skin of the left leg make good contact with the electrodes, the EKG recording will begin automatically. You will observe the EKG tracing on the screen.



5. The patient must keep good contact with the electrodes and follow the on-screen timer until it goes to zero. There is no need to squeeze or press down as this may cause interference.



6. Once the recording is complete, the patient may remove their fingers or thumbs from the electrodes and the device from their leg. The patient may notify the healthcare professional that the recording is complete.

EKG Analysis

Upon completion of the EKG recording, K1000 transmits the EKG data to the KardiaStation app. The EKG is then processed by AliveCor's Instant Analysis algorithms. **T**he app will display the full-6-Lead EKG and the Instant Analysis result.

Representative Instant Analysis results, descriptions, and additional information are displayed in the table below.

Instant Analysis Results, Descriptions, and Additional Information

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 between 40-50 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 between 100-140	Kardia does not check for heart

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

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 +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 K1000 is 2 years.

Maintenance

1. No service or repair should be performed on the K1000 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
    - Bleach solution as recommended by the CDC (5 tablespoons bleach per gallon of water OR 4 teaspoons bleach per quart of water, which is equivalent to 20ml bleach per liter of water)
    - Isopropyl alcohol (70% or 90%)

    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 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 K1000 hardware to a watch repair or hearing-aid repair shop.
    - Battery Type: CR2016 Coin Cell that is IEC 60086-4 compliant
    - Ensure proper orientation of the battery with battery information and (+) terminal facing up

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

Device Disposal

Do not dispose of the device with household waste. Dispose of the device according to applicable local regulations. Unlawful disposal may cause environmental pollution.

Electromagnetic & Other Interferences

K1000 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 KardiaStation app:

1. On the home screen, select the hamburger menu ☰, then enter your password..
2. Go to the About KardiaStation section to view the FCC ID and other applicable regulatory information.

Ingress Protection Marking

K1000 is IP22 rated. K1000 is protected against insertion of fingers and is not affected by vertically dripping water. K1000 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 K1000, refer to the troubleshooting guide below or contact technical support at clinicalsupport@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 6-Lead EKG, it is important to place the device on your left leg (knee or inside of the ankle). The device must be used on bare skin for an accurate recording.
- 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 K1000 will not connect.

- Make sure Bluetooth is turned on in your smartphone or tablet settings and follow the steps to "Record a 6-Lead EKG."

- If Bluetooth is on, try to un-pair and pair again to your K1000.

- 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.

On my EKG, the recording appears upside down.

- Make sure the AliveCor logo is in the correct orientation (it should look like an "A", to the patient).
- Make sure the fingers or thumbs are touching the top two electrodes and that the bottom electrode is touching the skin above the left knee or left ankle.

Electrical Safety

Guidance and manufacturer's declaration - electromagnetic emissions		
K1000 is intended for use in the electromagnetic environment specified below. The customer or the user of K1000 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	K1000 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	K1000 is intended for use in domestic surroundings.
Harmonic emissions IEC 61000-3-2	N/A	K1000 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			
K1000 is intended for use in the electromagnetic environment specified below. The customer or the user of K1000 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	±2 kV contact ±4 kV contact ±6 kV contact	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material,

	±8 kV contact ±2 kV air ±4 kV air ±8 kV air ±15 kV air	±8 kV contact ±2 kV air ±4 kV air ±8 kV air ±15 kV air	the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	N/A	N/A	K1000 is powered from a lithium coin cell battery and does not require AC mains power. Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
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	

Guidance and manufacturer's declaration—electromagnetic immunity			
K1000 is intended for use in the electromagnetic environment specified below. The customer or the user of K1000 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 K1000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3.5}{V_1}]\sqrt{P}$ < 80MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.7 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the

			transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people

[a] Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which K1000 is used exceeds the applicable RF compliance level above, K1000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating K1000.

[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 K1000

K1000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of K1000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and K1000 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.

Symbols Glossary

These symbols will be used in the packaging and other labeling of the K1000 hardware.

Symbol	Description
	Manufacturer
	Model/Catalogue Number
	Medical Device
 alivecor.com/quickstart	Consult instructions for use or consult electronic instructions for use at the specified website
	Type CF Applied Part
	Do not dispose with household waste
	Temperature limits
	Humidity limitation
	Serial Number
	Unique Device Identifier