



KardiaMobile System by AliveCor®

Instructions For Use

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EC REP Obelis SA
BD General Wahis 53
1030, Brussels
Belgium

CE
0123
Made in China

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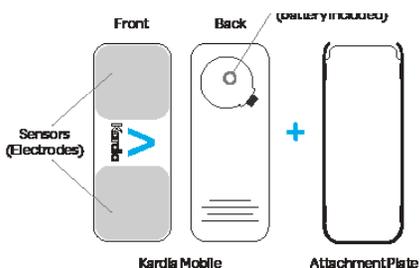
INTENDED USE

The KardiaMobile System is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The KardiaMobile 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 (when prescribed or used under the care of a healthcare professional). The KardiaMobile 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.

USING KARDIAMOBILE

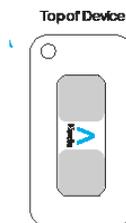
1. Attach KardiaMobile Hardware to Your Phone (Optional)

- Remove KardiaMobile Hardware from the box.

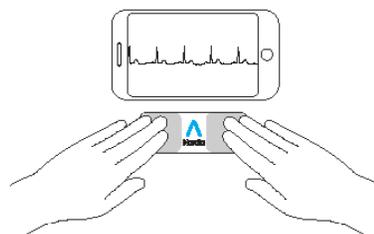


- If you choose to attach KardiaMobile Hardware to the phone, adhere the optional attachment plate to the back of the phone.

- While holding the phone upright (camera at top), slide KardiaMobile Hardware into the attachment plate so that the logo is pointing to the right ">".



NOTE: KardiaMobile Hardware may be used up to a distance of 30 cm (1 ft.) from the smartphone or tablet. You have the option of adhering it to the phone.



2. Download Kardia App & Create An Account

- On your compatible iOS or Android Phone (www.alivecor.com/compatibility), download the Kardia app from the App Store or Google Play store.
- Open the Kardia app and follow the onscreen instructions to create an account.

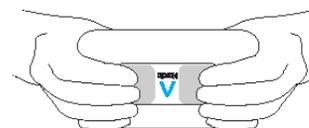
3. Recording Your First ECG

Do not use KardiaMobile System while charging your phone.

Do not take a recording while driving or during physical activity.

Do not take a recording if the electrodes are dirty. Clean them first.

- Tap the Kardia app on your phone to open the application.
- Rest two or more fingers on KardiaMobile Hardware; your right hand should contact the sensor (electrode) closest to the bottom of the smartphone, and your left hand should contact the electrode closest to the top of the smartphone.



- Rest your arms on a flat surface. Remain still with your fingers on the electrodes for 30 sec.
- Your first ECG is sent for analysis (U.S. only).

Free medical interpretation of your first ECG reading



For the United States only.

A U.S. board-certified cardiologist will automatically review your first recording for free and will provide a medical interpretation of your ECG within 24 hours. Due to FDA regulations, the heart rhythm for your first recording will not be visible on your smartphone or tablet screen and you will not be able to record any additional ECGs while the cardiologist is preparing your report. After you receive your report notification email, you will be able to record and view as many ECGs as you like.

4. ECG Analysis

Subsequent recordings:

- Tap "Record now" on the Standard EKG screen.
- Follow instructions for "Recording Your First ECG."
- After ECG recording is complete, the ECG is analyzed to determine if it is at least 30 seconds long, if it is Normal, Unclassified, possible Atrial Fibrillation, Tachycardia or Bradycardia or if it is too noisy to interpret.

Presence of possible Atrial Fibrillation (AF) in your ECG results may present only potential findings. If you are experiencing any symptoms or have concerns, contact your physician.

Normal results mean your heart rate is between 50 and 100 beats per minute, and shape, timing and duration of each beat is considered normal.

Bradycardia results mean your heart rate is between 40 and 50 beats per minute, and shape, timing and duration of each beat is considered normal.

Tachycardia results mean your heart rate is between 100 and 140 beats per minute, and shape, timing and duration of each beat is considered normal.

An Unclassified message means the tracing is not Normal, possible AF, Tachycardia or Bradycardia and interference was not detected. An example of an Unclassified tracing is one where tachycardia is observed.

Unreadable ECG results determines that you didn't have proper ECG recording for analysis. You may try to re-record your ECG.

ECG reports viewed at any magnification other than 100% may appear distorted and could lead to misdiagnosis.

TROUBLE SHOOTING

If you experience difficulties in operating your Kardia products, refer to the troubleshooting guide below or contact technical support at support@alivecor.com.

Problem:

My KardiaMobile is not working

Solution

Option 1: Ensure that the Kardia app has access to the phone's microphone. On the iPhone, go to Settings and tap the Kardia app. Tap the microphone toggle.

Option 2: Change the battery. Remove KardiaMobile Hardware from the attachment plate (if applicable), and remove the battery door with a pen, pencil, or other similarly shaped object into the cutout next to the battery door to pop the battery off.

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 and hands remain still during recordings.

Option 3: Clean the electrodes on the Kardia Mobile with an alcohol-based sanitizer.

Option 4: If your hands are very dry, use a water-based lotion before recording.

Option 5: When recording, relax your arms and hands to reduce muscle noise. Rest the forearms and hands on a flat surface.

Option 6: If you wear hearing aids, turn them off prior to recording.

Problem:

The ECG rhythms appear upside down.

Solution

Option: Ensure that the left hand contacts the electrode closer to the top of the smartphone and the right hand contacts the electrode to the bottom of the smartphone.

CAUTIONS:

General:

DO NOT store in extremely hot, cold, humid, wet, or bright conditions.

DO NOT expose to strong electromagnetic fields.

DO NOT take recordings in close vicinity to other equipment emitting ultrasonic acoustics.

DO keep components out of reach of children.

DO use this device to record heart rate and heart rhythm only.

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.

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.

KardiaMobile System

DO NOT use with a cardiac pacemaker, ICDs, or other implanted electronic devices.

DO NOT continue use until further instructed by a physician if your skin is irritated or inflamed around the sensor.

DO NOT drop or bump with excessive force.

DO NOT use to diagnose heart-related conditions.

DO NOT wear during magnetic resonance imaging (MRI), cautery and external defibrillation procedures.

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

CAUTION: 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.

KARDIAMOBILE HARDWARE SPECIFICATIONS

Battery: Coin Cell

Storage Conditions: Original package under normal room temperature and humidity

ELECTROMAGNETIC & OTHER INTERFERENCES

KardiaMobile Hardware has been tested and deemed in conformance with the relevant requirements in EN60601-1-2:2007 Class B for Electromagnetic Compatibility (EMC).

EQUIPMENT SYMBOLS



Type CF Applied Part



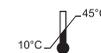
Do not dispose with household waste



Read instructions before use



Manufacturer



Temperature range



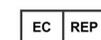
Humidity range

REF

Model number

SN

Serial number



European Authorized Representative

ADDITIONAL INFORMATION

For more detailed troubleshooting and technical information, please visit: <https://www.alivecor.com/quickstart>