

AliveCor's Kardia™ Mobile ECG – AliveCor 1 and 6 lead versions



Clinician user guide

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Disclaimer

All the ideas and suggestions in the content of this handbook are intended to inform the reader about the use of the AliveCor device in a general practice setting. Whilst every effort has been made to include accurate and up to date information, information governance requirements, medical knowledge and understanding are constantly evolving. So you need to use the information presented here to learn more about how you can use the device and weigh up the choices and guidance for your own circumstances. Use the device only in accordance with the manufacturer's instructions.

The resource was compiled originally by Drs John Marszal and Ruth Chambers; with additions for the updated version from expert AF nurse Kevin McGibbon & medical student Gabby Johnson. You are welcome to use this handbook and adopt or adapt it for your own, or your team's, use.

Take a look at the two videos that show a clinician engaging a patient in using the AliveCor 1-lead device and AliveCor-6 lead device:

Demonstration Videos:

Kevin McGibbon, arrhythmia clinical lead specialist, University Hospital of North Midlands demonstrates how to use the AliveCor 1 Lead <https://vimeo.com/460862027>

Kath Baddeley, practice nurse, Adderley Green medical services demonstrates how to use the AliveCor 6 Lead <https://vimeo.com/460862458>

Introduction

The AliveCor mobile ECG is a portable heart rate and rhythm monitor that is simply held in the patient's hand to obtain an ECG report. The device is easy to use for any healthcare professional and stores the recorded ECGs for future review by a health professional.

The benefits of the AliveCor device are that:

- *The device uses a single channel ECG monitor with automatic ECG evaluation to detect possible AF.*
- *An accompanying phone/tablet app allows real time visualisation of the ECG recording as well as storage of previous recordings for later review.*
- *The recorder is held in the hand without the need to expose the patient and takes a single lead ECG recording in 30 seconds.*
- *The device is not linked to a designated single phone/tablet and may be transferred between practice staff when needed.*
- *The device may be lent to patients for home use or monitoring.*
- *The user replaceable battery in the device should give normal device usage of around 12 months before needing to be replaced.*
- *High sensitivity and specificity of AliveCor-1 lead: shown by a Cleveland Clinic study as a viable post-ablation monitoring alternative to a trans telephonic monitor (TTM), with 100% sensitivity, 97% specificity for detection of atrial fibrillation and atrial flutter combined, and 92% patient preference for AliveCor vs traditional TTM.¹*
- *In the event of this being covered by the Innovation Tariff (in future), devices can be issued to patients without the need to recycle, clean, change battery etc.*

Data Protection

The AliveCor mobile ECG stores the patient's ECG trace and voice recording during the trace, both locally on the device used to take the recording and in the 'cloud' on AliveCor servers, which are uploaded to your personal AliveCor account once you have registered as a user.

The ECG trace and data collected at the time of the trace being taken are stored in AliveCor servers in the EU using industry standard encryption. This meets all EU data privacy rules. This allows you to change devices easily and retrieve your patients' recordings should anything happen to the phone/tablet used to take the original recording. In addition, you may log into your account from another device to review patients' results.

When using the AliveCor device in practice, do be aware of data protection and information governance rules regarding inclusion of patient identifiable information on the trace. For this reason, we recommend you only store a unique non-identifiable reference number to the trace or ensure that you delete the trace after use.

Please remember to password protect the device you use to take the ECG reading.

Warnings and contraindications to AliveCor mobile ECG use²

This device is not designed nor intended for complete diagnosis of cardiac conditions. This device should never be used as a basis for starting or modifying medication without independent confirmation by medical examination.

This device records heart rate and heart rhythm only. It does not detect or measure all heart rate, heart rhythm, and heart waveform changes, especially those related to ischaemic heart conditions.

Do not use the device in the presence of flammable anaesthetics, drugs or pressurized oxygen (such as in a hyperbaric chamber, ultraviolet sterilizer or oxygen tent).

AliveCor is not recommended for use on humans weighing less than 10kgms, nor for use with individuals with a cardiac pacemaker, ICDs or other implanted electronic devices.

Do not use this device with a defibrillator.

Using the AliveCor mobile ECG in practice

The device may be used anywhere in practice, being fully self-contained and battery powered. All that is needed is a suitable smart phone or tablet that has the Kardia app pre-installed.

Clinical studies have demonstrated the AliveCor Mobile ECG's accuracy is comparable to readings from lead 1 of standard ECG machines³.

The device is useful in many clinical areas. Below are the kinds of uses GPs/practice nurses are finding for AliveCor:

- *Use in pre-screening/registration of new patients to general practice. The device is a simple and quick diagnostic check of both the patient's pulse rate and rhythm regularity and to establish a baseline. It is suitable for all grades of healthcare staff to use the device confidently and have automated reporting of any potential AF.*
- *Take a follow-up recording for patients with AF or palpitations.*
- *Use for patients presenting with palpitation/ heart irregularities - as a quick and simple tool for assessment of AF. This can be done in 30 seconds while taking other readings such as blood pressure and temperature.*
- *Offer to patients during well woman/well man NHS health checks.*
- *Use during day to day clinics by any healthcare staff for a patient they believe could benefit e.g. during a practice COPD review a patient happens to mention that they feel their heart beat is irregular at times.*

Requirements to use AliveCor Mobile ECG

The mobile ECG is used in conjunction with a smart phone or tablet to take the ECG readings.

A simple tablet for practice use may be purchased solely to be used with the device instead of a nurse or doctor using their own mobile phone. A list of fully compatible devices may be found at <https://shop.gb.alivecor.com> - click on 'Compatibility' half way down the page.

The AliveCor device has been used with devices other than those in the compatibility list. In order to ensure compatibility with the app, the device used must be certified by either Android or Apple (in the majority of cases, this means that the device must have access to Google Play store or Apple App store).

In addition, the device must have a microphone incorporated into its design (most devices have this as standard). Devices of well-known brands bought from mainstream suppliers and high street stores should be fully compatible with Google Play Store or Apple Store. The only devices which may not be certified are those of lesser known brands and internet suppliers (in which case, please ask the retailer if the device is a certified Android or Apple device).

N.B. the decision and responsibility to purchase a device not on the AliveCor compatibility list is the users' own responsibility. It is therefore recommended purchasing from a retailer that will allow a trial period or exchange or refund if the device should not work with the AliveCor Kardia™ mobile ECG.

Although personal devices such as mobile phones may be used, the larger screen of a tablet is both easier to use for interpretation and for the patient experience of being able to watch their trace as it is acquired.

Software requirements:

- Apple iOS 5.1 and higher
- Android Version 4 and higher.

12 lead ECG access

When using the AliveCor mobile ECG in general practice, it is important to follow up any abnormal readings with a full 12 lead ECG to confirm diagnosis of any abnormalities (it might be that a cardiologist could rely on the Kardia trace if the AF is clearly visible).

In cases of paroxysmal AF, the follow up ECG must be done immediately on site, since if any time is allowed to elapse, the AF may fail to be detected on 12 lead ECG. For this reason, it is recommended that those using the AliveCor mobile ECG in general practice also have access to a 12 lead ECG on site.

Setting up the AliveCor device

Once unpacked, you'll see that the AliveCor mobile ECG device is already inserted into its attachment plate.

- *The front of the device has the metal pads used to take the ECG reading.*
- *The back of the device houses the battery compartment.*
- *The attachment plate has a sticky pad pre-attached if you wish to attach it to a single device / place.*

N.B. it is recommended that the device is not attached to a single device since the attachment plate is difficult to remove and may leave adhesive on the phone tablet.

- *The device's battery is pre-installed and should give approximately 12 months' use.*

Installing the Kardia App

The Kardia app is the software used to record and assess the patient's ECG.

1. Open your phone or tablet's App store. This is found by pressing the menu button on your phone or tablet to view your installed apps, then selecting either Apple App store or Play store (Android).
2. Search for the app 'Kardia'. You should see the appropriate logo when you have located the correct app.
3. Install the Kardia app, following any instructions on screen.
4. Locate the Kardia app on your device's home screen or app area and touch the Kardia app to launch it.

Setting up the Kardia app

When you initially launch the Kardia app you will need to create an account. Follow the onscreen instructions for this.

By creating an account, you gain the ability to access your ECG recordings from any device at any time. In addition, you are able to transfer your recordings in the case of an upgrade of phone or tablet.

Recording an ECG

The Kardia app gives several modes for recording an ECG:

- *Standard EKG**
- *Resting Heart Rate*
- *Guest EKG**

(*The AliveCor device and Kardia app were developed in the USA where the term EKG is used rather than the British term ECG. Both stand for 'electrocardiogram'.) You can navigate each of these options by swiping the image to the left or right:

When you have downloaded the app you will find this symbol on your screen:-



Just tap to open it.

- *For normal use in practice ensure the option of “Standard EKG” is selected as per the image above.*
- *Click on “Record Now”*

The screen will change to a simulated ECG trace paper. Ask the patient to hold the AliveCor mobile ECG device with their thumbs resting on each of the pads. If the patient struggles with this, they may rest their fingers on the pads with the AliveCor device resting on a desk.



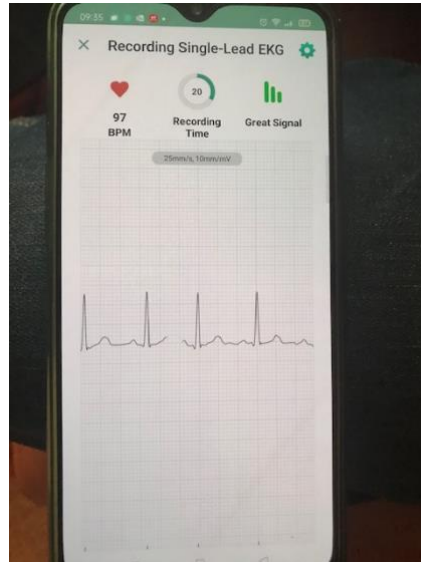
Smartphone or Tablet

- *The device communicates with your phone or tablet via its built in microphone. This will be where you speak if using a smart phone or if using a tablet is normally a small hole at the top or bottom edge of the tablet.*
- *The AliveCor device transmits ultrasonic signals which the phone or tablet listens to. This is then converted into the ECG on screen.*
- *Some devices may struggle to pick up the ultrasonic signal so try to ensure that you have the patient hold the mobile ECG close to the microphone on the phone/tablet.*
- *When working correctly you will see the screen change and the ECG trace appear.*
- *In the top left hand corner of the screen you will see green signal bars depicting that the device is communicating correctly and the quality of the signal. Move the mobile ECG closer if the bars are small to improve the communication signal.*

In the bottom right of the screen is a timer that counts down from 30 seconds. When the timer reaches zero, the ECG will be interpreted and the results given on screen.

Interpreting the results

Upon completion of the 30 seconds recording, you will be presented with an automated assessment of the patient's ECG, as shown below.



Possible outcomes and recommended actions to take

Normal ECG - No action needed. If patient continues to experience symptoms, then follow up with 12 lead ECG home monitoring/recorder (24-hour tape).

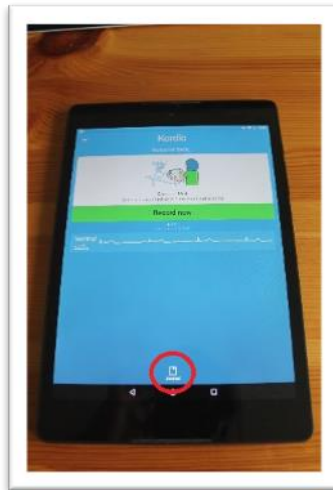
Possible AF - Patient needs full 12 lead ECG or 24-hour tape to confirm result/diagnosis. It is recommended that the 12 lead ECG be performed immediately due to the transient nature of paroxysmal AF.

Unreadable/indeterminate reading - Repeat the ECG recording again. If still indeterminate follow up patient with full 12 lead ECG.

Reviewing previous recordings and adding patient information to a recording

The journal feature of the Kardia app allows you to review all past recordings and you might append patient details such as age, gender and date of birth (but please see the earlier section on information governance). You also have the option to delete recordings.

1. Click the 'Journal' icon at the bottom of the main screen:



2. You will now see a list of previous recordings ordered by date.
3. To view the recording press on the image of the trace which will open for you to review. You may scroll left and right as well as pinch the screen to zoom in / out.
4. To enter patient details on the recording click the 'Edit Patient' box on the recording to which you wish to add information.

ECG recordings can also be reviewed online using an internet enabled computer. For instance, if you wish to review patient ECG traces on a home visit.

To review the recordings online visit <https://eu.alivecor.com/login>.

1. Enter your account details as you did for the AliveCor Kardia app.
2. At the top right hand of the ECG trace you wish to view click 'View PDF'.
3. A printable version of the ECG trace will now be displayed.

Comparing AliveCor KardiaMobile 1 and 6 Lead devices

The original KardiaMobile device is essentially a one lead (1L) ECG used in just 30 seconds to give an indication as to whether atrial fibrillation is likely or there is bradycardia or tachycardia. The operator just needs to put each thumb on an electrode on the KardiaMobile device; then hold the device 12 inches or closer to their mobile smartphone or tablet device such as an iPad, as they can. As the ECG is being taken they can see their heart tracing on screen as it is being recorded. Access to the KardiaMobile device is by downloading the Kardia app on to the smartphone or tablet. Recordings should be between the minimum 30 seconds to up to 5 minutes. This KardiaMobile 1L device has a 200 hours operational time and lifespan of 12 months on average. The KardiaMobile 1L device is supported by NICE advice as clinically proven. The Kardia app has the ability to record not only ECG recordings but track weight and blood pressure.

The KardiaMobile six lead (6L) is very similar to the original KardiaMobile 1 lead device but it records a 6 lead ECG instead of a 1 lead ECG. To do this it is the same as the original KardiaMobile but as well as the operator putting two thumbs on an electrode, they must also put a third electrode on their left knee which is on the opposite side of the device. The KardiaMobile 6L provides an ECG with

leads I, II, III, aVL, aVR, and aVF. This means that the KardiaMobile 6L can show screen traces of all 6 leads at the same time and can give a more detailed view of what is happening with their heart. The Kardia app allows someone to switch between the KardiaMobile 1L and KardiaMobile 6L devices so that they can use whichever device they prefer.

The AliveCor 1L transmits by sound waves and can be subject to environmental noise interference. The 6 lead transmits by blue tooth so has a longer range with less noise interference but your display must have Bluetooth capability. Some users have reported difficulties using the third electrode on the 6-lead due to clothing obstructing the patient's knee access for the contact point; but then it can also be used as a lead 1 device by operating with just the 2 electrodes

Evidence around sensitivity and specificity for the 1 lead KardiaMobile device is variable, as cited in the below articles/publications; ranging from a sensitivity of 85% - 96.6% and specificity of 76% - 94% versus manual palpation sensitivity of 87% - 91% and specificity 71% - 81%.

<https://www.nice.org.uk/advice/mib35/chapter/Summary>

<https://bjcardio.co.uk/2015/04/the-effectiveness-of-a-mobile-ecg-device-in-identifying-af-sensitivity-specificity-and-predictive-value/>

<https://www.pmsinstruments.co.uk/blog/category/ecg-event-recorders/alivecor/>

<http://www.londonscn.nhs.uk/wp-content/uploads/2017/06/hin-single-time-point-case-finding-af-methods-devices-0>

KardiaMobile devices are not recommended for those with pacemakers and ICDs.

From the patient's perspective

Tim Bevington, North Staffordshire CCGs governing body lay member and AF patient describes his use of AF Apps and AliveCor: <https://vimeo.com/460863262>

“As a patient with AF, one of my biggest frustrations was the lack of control over my heart rate and the anxiety from wondering whether every slight change in heart rate or rhythm meant I was back in AF. Buying my own AliveCor meant I could have instant confirmation whether I was in AF or it was just my increased anxiety and awareness making me over sensitive.

“The associated Kardia app offers a range of extra features and while there's a monthly subscription service which includes cloud storage of your ECGs and a 3-monthly review of the recordings by a cardiologist, I have found the basic free version provides all I need. I can email the recordings to myself and add notes about changes in medication and / or potential trigger factors such as caffeine, weight, alcohol, exercise etc. That means I can potentially share the results with clinicians or at the least ensure my consultation is far more accurate than relying on my memory and feelings!”

Frequently Asked Questions

<p>Is the patient data safe?</p>	<p>Patient data is held on the local device and in the cloud in AliveCor's servers in the EU. This complies with UK data protection laws.</p> <p>Your account is password protected and it is advised to also have a password enabled on the device e.g. the smartphone that you use with the AliveCor Device.</p>
<p>How long will the AliveCor battery last?</p>	<p>The AliveCor battery is expected to last for 12 months under normal use. The battery is user replaceable.</p>
<p>Must I do an ECG if the AliveCor shows an abnormality?</p>	<p>A cardiologist or qualified ECG reader can rely on the trace from Kardia if the AF is clearly visible. Many patients do not need a subsequent 12 lead, but if in doubt it is good practice to refer for one.</p>
<p>Why can I not just take someone's pulse as a way to screen for AF – why do I need AliveCor?</p>	<p>AliveCor may be used by a wide variety of healthcare professionals, some of which may not feel confident to interpret pulse directly. For this reason, AliveCor can help address differences in competencies and allow all staff to screen for AF.</p>
<p>What happens to the patients trace once taken?</p>	<p>The patient's AliveCor trace is stored on the device used to acquire the trace and when available, uploaded via the internet to AliveCor servers in the EU. The trace and data may be deleted at any time from the Kardia history section.</p>
<p>Where can I purchase the AliveCor device from?</p>	<p>The AliveCor device is available on NHS Supply Chain: NHS Supply Chain number: FBF2709 https://my.supplychain.nhs.uk/Catalogue/product/fbf2709</p>

References

- (1) Quoted from NICE medical innovation briefing 2015 from Khaldoun G. Tarakji et al. Using a Novel Wireless System in Monitoring Patients After Atrial Fibrillation Ablation Procedure. The iTransmit Study. HeartRhythm. November 2014.
<http://www.ncbi.nlm.nih.gov/pubmed/25460854>
- (2) AliveCor® Kardia™ Mobile User Manual for Android. <https://www.alivecor.com/android-user-manual/en.pdf>
- (3) Quoted from NICE medical innovation briefing 2015 from: Garabelli P et al. Accuracy and novelty of an inexpensive iPhone-based event recorder. Heart Rhythm 2012.
<http://www.abstractsonline.com/Plan/ViewAbstract.aspx?sKey=d2695427-e78e-4378-b26a-99ab3c784107&cKey=29c04967-5c66-4f5a-85d0-f3338f010359&mKey=%7BBAEF2DB4-7615-4F2C-851A-E5D7461EBD4E%7D>