

Kardia

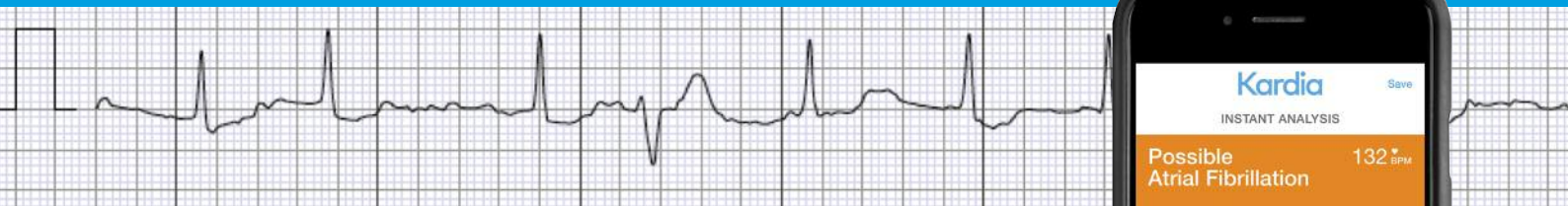
AliveCor®



Introducing the Kardia™ Mobile ECG

Innovative technology to improve patient outcomes

Kardia™ Mobile is a hand-held, clinical quality, single channel (Lead I) ECG recorder. It is small, lightweight and simple to use, giving health professionals and their patients the ability to perform accurate ECG recordings at the surgery or on-the-go.



The Kardia™ Mobile device includes automated software that instantly confirms normal sinus rhythm or the detection of atrial fibrillation (AF). With the option to attach to a smartphone, it is ideal for capturing arrhythmia during normal activities, without the need for wires and patches. The free Kardia™ app can securely store and upload traces that can be printed, emailed or accessed remotely by health professionals. Kardia™ Mobile is not linked to a particular device or patient so can be easily transferred between practice staff or family members. It can be used in several clinical settings including routine appointments/patient registration, health screening events, investigation of symptomatic patients and monitoring of patients with known conditions. The ease-of-use, cost-effectiveness and benefits, in terms of peace of mind for symptomatic patients and early detection of potentially life-threatening arrhythmia, has led to selection of this technology by the **NHS Innovation Accelerator** programme for systematic adoption throughout the NHS.



“ We have been using Kardia™ Mobile clinically since its launch and it is difficult to imagine now working without it. We hold annual heart screening events and have a team of cardiac nurse specialists who all use the device in the day to day clinical practice. They run independent clinics and it is really helpful to get a quick assessment of the person’s heart rhythm”

Dr Andrew Mitchell, Consultant Cardiologist, Jersey General Hospital

HOW DOES KARDIA™ MOBILE WORK?

Kardia™ Mobile is used within a metre radius of a mobile device, such as a smartphone or tablet, or can be attached directly via an adhesive attachment plate or an integrated phone case. It uses ultrasound to transmit the ECG recording to the device where the installed Kardia™ app (available through Apple or Android) records an ECG trace, including a measure of average heart rate, with the option to add notes or tags to each recording (voice-to-text or manually). In-built software will notify the user whether the trace is 'normal', 'possible AF detected' or 'unclassified' (if the ECG is abnormal, i.e. outside the range for sinus rhythm, but not AF). To access all services, doctors and their patients are both required to set up an AliveCor account on their Kardia™ app. Doctors can link to the account of their patient through the secure Provider Dashboard (Login at eu.alivecor.com) and via the Kardia Pro Platform (available from late 2016). When Wi-Fi or mobile connection is available, the traces will automatically upload to the AliveCor cloud server. The user can save the trace, email or create a PDF to print.



TAKING A READING

Kardia™ Mobile incorporates two electrodes. For a Lead I recording, one or two fingers should be placed on each electrode for at least 30 seconds. Within a few seconds the ECG trace appears on the screen. If the trace is of low amplitude, there is an additional option for taking a Lead II recording by placing the left-hand electrode on the left knee and fingers of the right hand on the right-hand electrode. This may improve the amplitude, improving visibility of the P wave thus making interpretation easier for patients with situations such as vertical heart axis. A third option is taking an Anterior Precordial Lead recording by placing the device on the lower left side of the chest, with the bottom of the phone pointing towards the centre of the body. Note that the automated analysis should not be relied upon for these alternative positions. A brief appointment with a healthcare assistant is usually sufficient for training patients and instructions for use are also contained in the user manual. Applying hand sanitizer prior to use may improve contact and warming up cold hands can help for those with poor circulation or conditions like Raynaud's.



HOW SENSITIVE/ACCURATE IS IT?

In a study where patient-recorded traces were interpreted by Electrophysiologists sinus rhythm was accurately detected 97% of the time and AF/flutter 100% of the time.¹ Kardia™ Mobile has also demonstrated a high degree of accuracy in studies versus 12-lead ECG.^{2,3} The automated software has an overall accuracy of 97% using 12-lead ECG as a reference,² and 98.5% sensitivity and 91.4% specificity using a cardiologists' diagnosis from the Kardia™ Mobile reading as the reference.⁴

FLEXIBILITY FOR DIFFERENT PATIENT SETTINGS

Kardia™ Mobile is an ideal tool for screening in the community or primary care. It can also be used to aid diagnosis, to rule-out AF in symptomatic patients or for regular monitoring of at-risk patients, e.g. after ablation procedure.¹ Palpitations are a common trigger for secondary referral but are difficult to capture during a 12-lead ECG. Traditional options for ambulatory recording include the Holter monitor, which has limited success for intermittent symptoms, and the invasive implantation of a subcutaneous loop recorder. Since many patients have smartphone access 24 hours a day, these traditional monitors could be replaced by Kardia™ Mobile in some instances, especially low-risk palpitations with infrequent symptoms or patients requiring a less invasive method of ECG recording.

“ The high negative-predictive values suggest that this test is a good ‘rule-out’ test for AF in a population with a prevalence of AF, such as we have in England”

J. Williams et al. 2015⁵

Early detection in the community

Kardia™ Mobile has the potential to overcome many of the cost, resource and logistical issues that limit the implementation of cardiac screening in the community. It has been found to be cost-effective for the early detection of undiagnosed AF in the community versus standard methods⁴ and is highly acceptable to patients, nursing staff and GPs.^{1,6-8} Furthermore, the rapid acquisition of data, with the option to interpret remotely, has significant logistical advantages.⁹ Clinical evaluation of Kardia™ Mobile demonstrates a high sensitivity and specificity for the detection of AF.^{2,8-10} During a recent free heart-screening event in Jersey, 954 members of the general public (aged 12 to 99) were screened with Kardia™ Mobile attached to an Apple (CA, USA) iPhone 4 or 5.⁸ Fifty four (6%) people were identified as having potential abnormalities and subsequent 12-lead ECG led to new diagnoses in 23, or 2.4%, of the total patients screened. Kardia™ Mobile is currently being piloted in practices in Eccles and Irlam, where in-surgery screening is being offered to adults over 40 years of age as part of their routine appointments.¹¹

Diagnosis of symptoms

Failure to capture arrhythmia in patients with symptoms can be frustrating for both health professionals and their patients. Patient groups have distributed 1500 Kardia™ Mobile monitors and feedback included instances of AF capture and diagnosis but also where AF had been ruled out and symptoms attributed to anxiety.¹⁰ A published case study example of this involves a 22 year old who was admitted to hospital for tachycardia (150 BPM).¹² Despite symptoms occurring around every 3 months no abnormalities were captured by exercise ECG, 24-hour ambulatory ECG or use of a patient-activated event recorder. The patient then purchased a Kardia™ Mobile and recorded a Lead II ECG upon subsequent palpitations. Based on this recording the patient was diagnosed with atrioventricular nodal re-entrant tachycardia.¹² Further trials and case studies describe diagnoses of conditions, such as bundle branch block, left ventricular hypertrophy, cardiomyopathy and asymptomatic ST segment depression.^{8,13}

Long-term monitoring and self-care

In clinical comparisons with the Holter monitor, ambulatory monitoring with Kardia™ Mobile achieved greater detection of arrhythmias in patients with palpitations and greater patient satisfaction, with a similar workload for physicians.¹⁴ In a recent trial where the two devices were used simultaneously Kardia™ Mobile diagnosed arrhythmia in 91% of cases, and the Holter monitor in 86.5% of cases.¹⁵

Kardia™ Mobile may have potential for the 'Pill in Pocket' strategy¹⁶ where patients need to be able to recognise the onset of AF before self-administering medication, or for the cardiovascular element of the multifactorial falls risk assessment (MFFRA).¹⁷ In this context Kardia™ Mobile has been reported as useful for excluding rhythm disorder and confirming that patients are rate-controlled.

HOW MUCH DOES IT COST?

Kardia™ Mobile costs £82.50 plus VAT*. The Kardia™ app is free of charge, and the monitor uses a 3 volt battery which will need to be replaced every 6 to 12 months. The cost of 12-lead ECG is estimated by NICE to be £36.33 and ambulatory ECG as £170. An Australian study found that community-based screening for undiagnosed AF using Kardia™ Mobile was cost-effective versus screening with a standard 12-lead ECG.⁴ A saving of just one cardiology outpatient visit pays for the Kardia™ Mobile, since NHS Tariff draft prices for 2016/17 range from £230 plus VAT (first visit, multi-professional) to follow-up (single professional), £96 plus VAT.¹⁸

*Correct as of June 2016

“ We have detected a number of different abnormalities including someone in complete heart block whom I listed directly for a pacemaker based on the Kardia™ Mobile ECG recording.”

**Dr Andrew Mitchell,
Consultant Cardiologist,
Jersey General Hospital**

“ A smartphone-based ECG monitor can be used as a first approach for the diagnosis of palpitations.”

D. Narasimha et al. 2016¹⁵

“ We find a 50-50 split among patients regarding the purchase of Kardia™ Mobile. The more health-conscious patients think that Kardia™ Mobile is inexpensive considering the potential benefits but around half of patients are unwilling to pay for one themselves.”

**Dr Andrew Mitchell,
Consultant Cardiologist,
Jersey General Hospital**

FREQUENTLY ASKED QUESTIONS

Are there any instances where Kardia™ Mobile use is inappropriate?

Kardia™ Mobile is not recommended for those with a cardiac pacemaker or other implanted electronic devices, mainly due to potential proximity of a mobile phone. It cannot be used for assessment of ischaemia nor is it intended for complete diagnosis of cardiac conditions. Users should be advised to seek medical assistance urgently if they experience chest pain, regardless of a normal trace. Users in USA should note that specific clearances by the FDA may differ from CE in Europe.

What action should a patient be advised to take when ECG notification is...

Normal? Contact their GP or cardiologist if symptoms are present.

AF? Contact their GP or cardiologist.

Unclassified? Repeat the recording and if it is still unclassified get reviewed by the Kardia™ in-app service or doctor. Please note that all recordings above 100 BPM, if not AF, are “unclassified”.

Is the technology easy for older people to use?

Arrhythmia charities report that older people have given positive feedback about using the recorder.¹⁰ In a trial of 60 post-ablation therapy patients, only 2% reported finding the device difficult to use.¹

What is the risk of false positives?

Studies demonstrate low false-positive rates (specificity >90%) for detection of AF using the Kardia™ monitor and app.¹⁰ False-negative rates are also low, (sensitivity >85%) which is important not to miss cases.¹⁰ The high negative-predictive value makes Kardia™ a good ‘rule-out’ test for AF that is more sensitive than assessing pulse regularity alone.^{5,19}

What is the length of the recording?

Kardia™ Mobile is not intended for long term monitoring, but rather for conveniently and instantly capturing short ECG rhythm strips. The duration of the recording is established by the Kardia™ app and has a default setting of 30 seconds. Alternative settings of 1, 2, 3, 4 or 5 minutes are available to help capture events where appropriate.

Where can a Kardia™ Mobile monitor be purchased?

The monitor is available through NHS Supply Chain, [REDACTED]

“ The AliveCor Heart Monitor [Kardia™ Mobile] could be a useful monitoring tool, with high sensitivity, specificity and user satisfaction.”

NICE National Institute for Health and Care Excellence
Medtech innovation briefing.
Published: 5 August 2015
[nice.org.uk/guidance/mib35](https://www.nice.org.uk/guidance/mib35)



“ If we capture AF on Kardia™ Mobile it is enough for me without a confirmatory 12-Lead ECG, although any new diagnoses requires a 12-Lead ECG to check for underlying conditions such as cardiomyopathy.”

Dr Andrew Mitchell,
Consultant Cardiologist,
Jersey General Hospital

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