AliveCor®

Guide to Kardia Mobile ECG recordings and what to do with them.

Kardia mobile

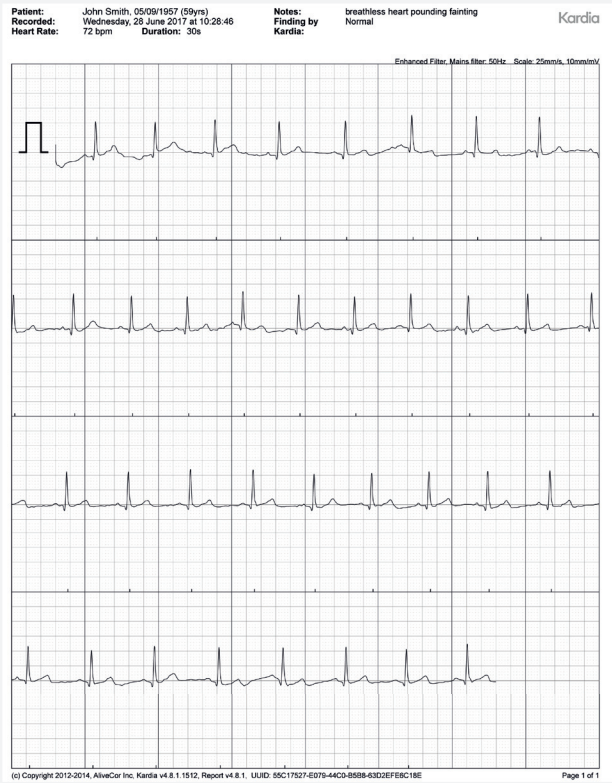

Patient: John Smith, 05/09/1957 (59yrs)
Recorded: Wednesday, 28 June 2017 at 10:28:46
Heart Rate: 72 bpm Duration: 30s
Notes: breathless heart pounding fainting
Finding by Normal
Kardia
Enhanced Filter, Mains filter: 50Hz Scale: 25mm/s, 10mm/mV
(c) Copyright 2012-2014, AliveCor Inc, Kardia v4.8.1.1512, Report v4.8.1, UUID: 55C17527-E079-44C0-B5B8-63D2EFE8C18E
Page 1 of 1

Fig 8

So you've taken your first ECG with a Kardia Mobile device or a patient has emailed you their recording.

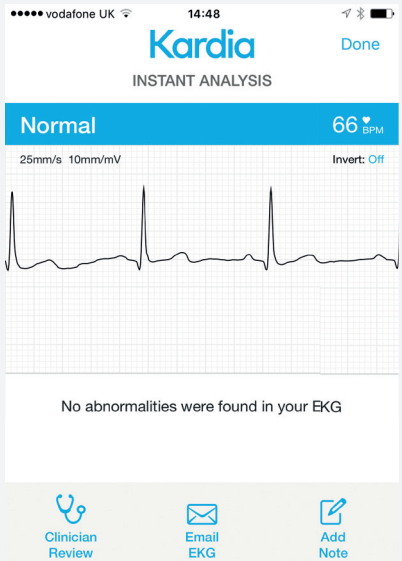


Fig 1

What do you do now?

If you have just recorded your patient's ECG, you should see a screen similar to Fig1 once it's completed. The analysis result is given on the left side of the blue bar; in this case, it's given as 'Normal'. Other result examples are given later in this guide.

You can scroll through the recording as it is by swiping right or left. If you would like to view it in more detail, tap 'Done' in the top right corner (this will appear as a tick on Android devices). You will then return to the 'Record now' page. Your new recording can be seen as a clip at the bottom of the page. Tap on the clip and the full recording can be viewed 'full screen'.

To provide a larger image you can turn your device on its side and the recording will rotate to landscape mode (Fig 2).

If you are using an Android device, you can use your thumb and forefinger in a swiping apart motion to increase the size of the trace. This is useful if you wish to view a particular QRS complex in detail.

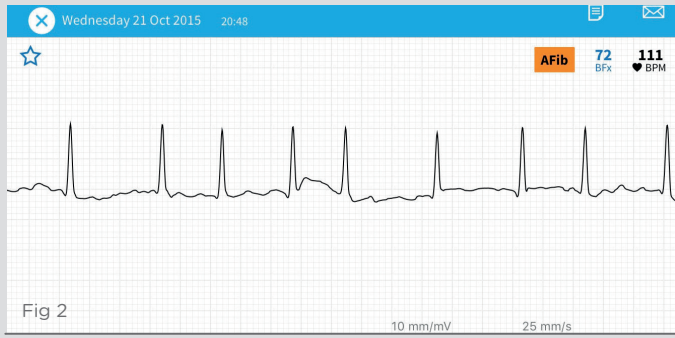


Fig 2

Guidance from the European Society of Cardiology recommends the use of an ECG rhythm strip for diagnosis of AF: 'By accepted convention, an AF episode lasting at least 30 seconds is diagnostic.'[1] Kardia's lead I rhythm strip will be of at least 30 seconds duration (longer settings can be selected) so it is sufficient to diagnose AF. By using Kardia Mobile, a single patient visit can achieve.

- Screening
- Diagnosis
- Documentation
- Prescription of anticoagulation therapy if required

This can save significant time between the patient first presenting with symptoms and subsequently commencing therapy. It also provides a cost efficient method of diagnosis. If you do not wish to keep the recording, it can be deleted. Press the 'Done' button in the top right corner (this is a 'tick' if you are using an Android device). The screen will then return to the 'Home' page where it says 'Record now'. Then follow the instructions on page 9 to delete the file.

However, if you wish to keep the ECG or send it to another clinician, you have several options.

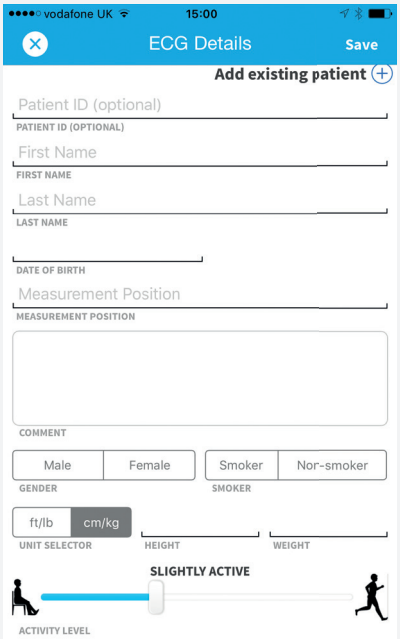


Fig 3

Firstly, you can add notes to the recording

Click on the 'Add Note' icon (Fig 1). The following page (Fig 3) then allows you to enter details such as an ID number, initials, date of birth and gender. The software will give you the opportunity to add an existing patient if you already have their data on your device. Tap on 'Add existing patient' and a list will appear. If your patient isn't listed, simply tap 'Unnamed' to return to the previous screen and enter the details.

You can also add height, weight and whether the patient is a smoker. The patient's stated activity level can be entered using the sliding bar. Known medical conditions may also be included by tapping the grey bar at the bottom of the screen. A list of some of the most common cardiac conditions is revealed and you can check the tick boxes of those that are relevant. Click the 'Back' button and then press 'Save' in the top right hand corner. You are then returned to your original recording page.

You can also email the recording to another clinician for a second opinion

Tap the ‘Email EKG’ button at the bottom of the screen if you are looking at Fig 1 or the top of the screen if you are looking at Fig 2. You will see an email page appears with the pdf of the ECG recoding already attached (Fig 4). It will also list basic details such as the date, time and duration of the recording along with heart rate. Additional details, if previously entered on page 5, will also be included. Enter the email address to which you wish to send the recording. You are able to enter free text in the body of the email if required. Once ready, tap the ‘Send’ button in the top right hand corner and your recording will be sent. Please note: you do need to have an email service set up on your device for this to function correctly.

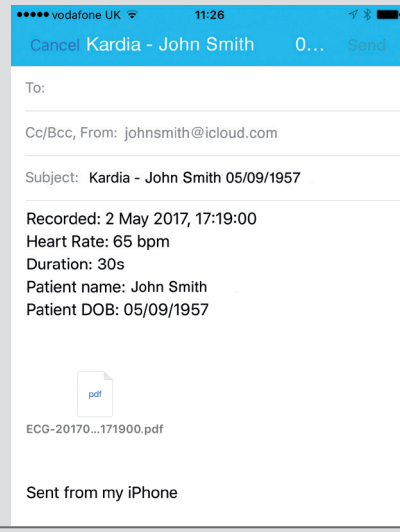


Fig 4

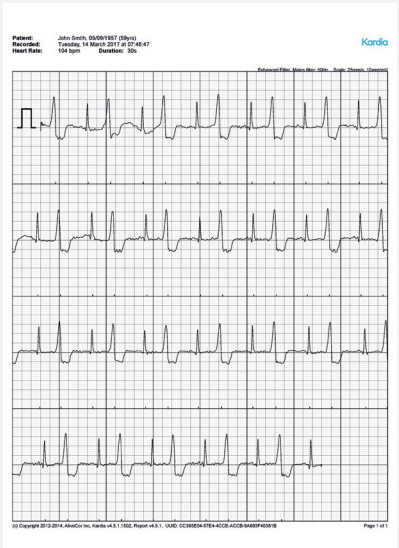
Print the recording or save it as a pdf to store in your electronic health records

Once you have made your recording, if you’re not emailing it immediately, but you would like to save it as a pdf or print it out, tap the ‘Done‘ button in the top right corner. Your recording then appears as a clip at the bottom of the following page and it will state ‘previous recording’. Tap the recording and it will then appear in detail. Tap the envelop icon at the top right of the recording page.

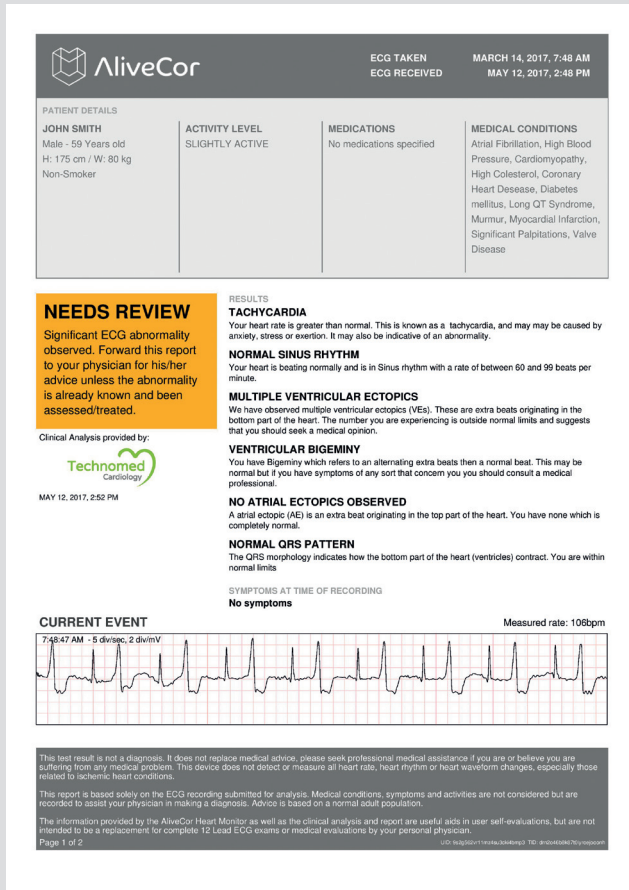
Email and print your recording

You can then select ‘Print’, ‘Email’ or ‘PDF’. If you select PDF, a picture of the resulting file will appear. Tapping the icon at the bottom of the page (iOS) or at the top (Android) will bring up various options of what you can do with the file. These options will depend on what device you are using and the apps you have installed. However, you will be able to download it and then save it to your electronic records system. You can select a Cloud storage to download an ECG. Once you select the app and the folder, tap ‘Done’ and the file will be saved in that location. If you use a Mac, you can tap AirDrop and it will instantly be transferred.

Should you choose to print the file, select the ‘Print’ option from the menu. It will then ask you how many copies you require. You should then press ‘select printer’. It’s important that you have the right printer driver installed in your device. If you have a wireless printer, it will work directly with that printer. Alternatively, you would need to connect using an appropriate cable. Once your device identifies the printer, you will be able to tap ‘Print’ and an A4 print out of your recording is produced. The quality of the print out, will of course, depend on the quality of the printer and paper in use.



This is a paid service based in the UK.



AliveCor

ECG TAKEN MARCH 14, 2017, 7:48 AM
ECG RECEIVED MAY 12, 2017, 2:48 PM

PATIENT DETAILS

JOHN SMITH
Male - 59 Years old
H: 175 cm / W: 80 kg
Non-Smoker

ACTIVITY LEVEL
SLIGHTLY ACTIVE

MEDICATIONS
No medications specified

MEDICAL CONDITIONS
Atrial Fibrillation, High Blood Pressure, Cardiomyopathy, High Colesterol, Coronary Heart Desease, Diabetes mellitus, Long QT Syndrome, Murmur, Myocardial Infarction, Significant Palpitations, Valve Disease

NEEDS REVIEW

Significant ECG abnormality observed. Forward this report to your physician for his/her advice unless the abnormality is already known and been assessed/treated.

Clinical Analysis provided by:

Technomed Cardiology

MAY 12, 2017, 2:52 PM

RESULTS

TACHYCARDIA
Your heart rate is greater than normal. This is known as a tachycardia, and may may be caused by anxiety, stress or exertion. It may also be indicative of an abnormality.

NORMAL SINUS RHYTHM
Your heart is beating normally and is in Sinus rhythm with a rate of between 60 and 99 beats per minute.

MULTIPLE VENTRICULAR ECTOPICS
We have observed multiple ventricular ectopics (VEs). These are extra beats originating in the bottom part of the heart. The number you are experiencing is outside normal limits and suggests that you should seek a medical opinion.

VENTRICULAR BIGEMINY
You have Bigeminy which refers to an alternating extra beats then a normal beat. This may be normal but if you have symptoms of any sort that concern you you should consult a medical professional.

NO ATRIAL ECTOPICS OBSERVED
A atrial ectopic (AE) is an extra beat originating in the top part of the heart. You have none which is completely normal.

NORMAL QRS PATTERN
The QRS morphology indicates how the bottom part of the heart (ventricles) contract. You are within normal limits

SYMPTOMS AT TIME OF RECORDING
No symptoms

CURRENT EVENT

Measured rate: 106bpm

7:48:47 AM - 5 div/sec, 2 div/mV

This test result is not a diagnosis. It does not replace medical advice, please seek professional medical assistance if you are or believe you are suffering from any medical problem. This device does not detect or measure all heart rate, heart rhythm or heart waveform changes, especially those related to ischemic heart conditions.

This report is based solely on the ECG recording submitted for analysis. Medical conditions, symptoms and activities are not considered but are recorded to assist your physician in making a diagnosis. Advice is based on a normal adult population.

The information provided by the AliveCor Heart Monitor as well as the clinical analysis and report are useful aids in user self-evaluations, but are not intended to be a replacement for complete 12 Lead ECG exams or medical evaluations by your personal physician.

Page 1 of 2

As an alternative to sending ECG's to a consultant cardiologist for review, you can send them to our recommended partner company, Technomed Ltd, to be analysed. They will provide a full professional interpretation with recommendations within 24 hours of receiving the recording. This service costs £5 per ECG. Should you wish to use this, tap the 'Clinician review' button and a screen will appear explaining the service. Press 'Select' and the following screen shows a 'Purchase' button. Tap on that button and the card payment page will appear. Enter your card details and press 'Pay'.

Editing ECG's

Once you have recorded several ECG's from patients, you will notice that there is a 'Journal' button on the 'Record now' home page. If your tap the journal button, you will see a list of all ECG 'clips' taken from your patients ordered by time and date.

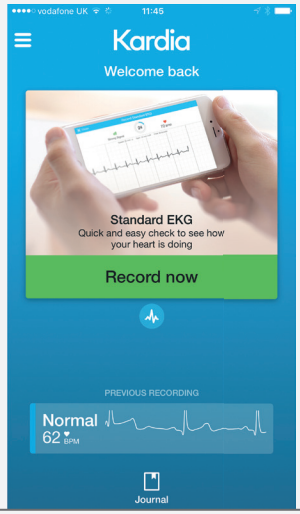


Fig 5

A duplicate of the Journal can be found by logging into the website eu.alivecor.com. ECG's can be reviewed and PDFs can be downloaded but not deleted from this view.

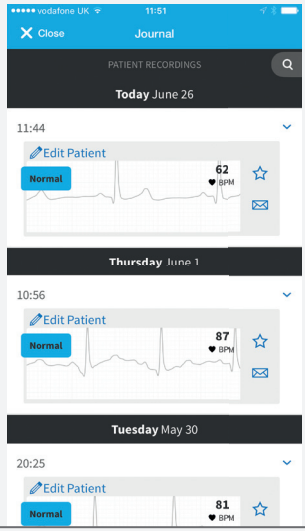


Fig 6

You can scroll through the list to find the one you need or you can use the search option at the top of the page. This has some preselection options such as AF or those recordings with analysis reports. Alternatively, you can search by patient name. If you give the patient the option to make a voice recording of their symptoms, the playback button appears above the clip.' Speech is also converted to text and written-in to the pdf of the recording (Fig 8). There is an option to highlight recordings with a gold star. Just tap on the star to the right of the ECG clip. You can also print, email or pdf from here.

Once you have selected the ECG you wish to view, tap on the clip, and the full recording will appear. When in this view, you will notice a 'More' button at the bottom of the screen. If you tap this, you have the option to invert the trace or remove the filtering on the ECG. If a patient records their ECG 'upside down', it's not a problem. It will automatically correct itself at the end of the recording.

Edit or Delete ECG's

ECG's can be deleted from inside the 'Journal'. Tap the 'Journal' button on the 'Home' page and you will see a list of your recordings. Scroll through these until you find the one you want. They are listed by time and date. You can also use the search function at the top of the page. Tap the small downward arrow to the right of the one you wish to delete. It will then ask you to confirm your request. Once 'Yes' is selected, the ECG is deleted and cannot be retrieved.

Receiving ECG's

When you receive an email with an ECG recording from a patient, the recording will be attached as a pdf. You can download this and save it to your desktop device or electronic health records for review and printing. The download process will depend on what device and software you use. The body of the email will contain the following as a minimum:

Recorded: 11 May 2017 11:32:15 am

Heart Rate: 64bpm

Duration: 30s

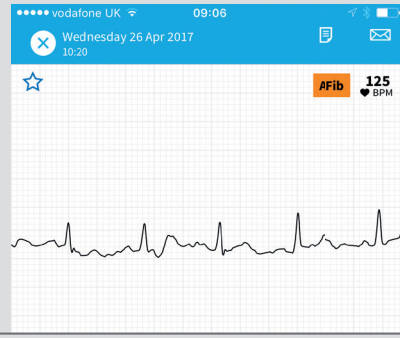
Patient name: John Jones

Patient DOB: 05/09/1967

If the patient records other symptoms such as palpitations or fast heart rate, they will also be included in the body of the text. The patient may make use of the voice recording system where they speak their symptoms into the device while the ECG is recording. If they have done this, the voice recording will be included in the attached pdf for you to hear. It will also be converted to text on the report.

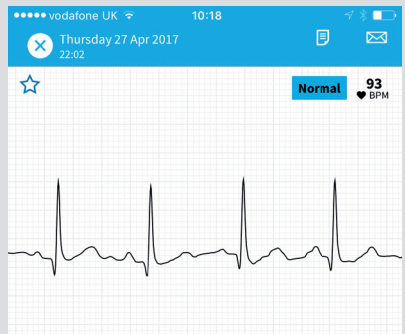
Should you experience problems receiving Kardia emails from patients, we recommend checking with your IT resource to ensure they are not being blocked or automatically being placed into Spam.

Patients must have an email service working on their device to allow them to send an ECG.



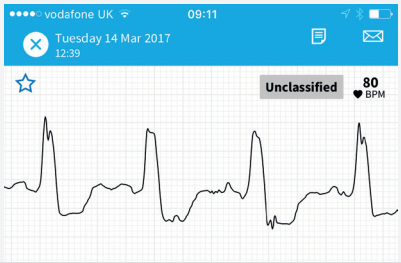
Atrial Fibrillation

The algorithm will notify you to the presence of atrial fibrillation with 98% sensitivity and 97% specificity. If AF is detected, you will see the message “Possible AF Detected.” You may wish to confirm this with another clinician or to run a 12 lead ECG to check for other possible abnormalities.



Normal

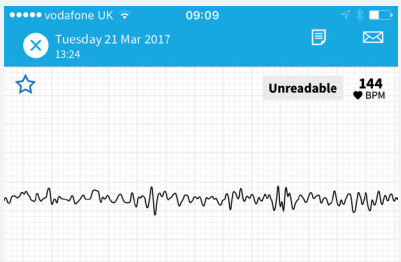
If no abnormalities are detected, you will receive the message ‘Normal’. This means that the heart rate is between 50 and 100 BPM, there are no or very few abnormal beats, and the shape, timing and duration of each beat is considered normal.



Unclassified

An ‘Unclassified’ message means that the sensors could not classify your ECG recording as ‘Normal’, ‘Unreadable’ or ‘AF’. There could be many reasons why this is the finding. The most common is simply that the heart rate exceeds 100 bpm. Other abnormalities detected in the ECG recording, may also give an ‘Unclassified’ result.

However, you should make further investigations to rule out any other abnormalities by requesting a review of the rhythm strip by a cardiologist or suitably qualified ECG physiologist.



Unreadable

‘Unreadable’ implies that there was too much interference during this recording. This could be electrical or sound interference.

You can advise the patient to do the following:

- Try to relax and hold still, rest your arms or move to a quiet location
- Ensure your smartphone or tablet is not plugged in, charging or syncing during recording
- Keep your Kardia electrodes clean using a hand sanitiser

- Apply a water-based lotion to your hands prior to taking an EKG recording if your hands are very dry
- Enable the 'enhanced filter' in the app

If the patient is still experiencing difficulty achieving a 'clean' signal, one option is to try lead II instead of lead I. This can be achieved by placing the left sensor on the left knee whilst keeping the right hand fingers on the right sensor as usual. If clothing is present, it should either be removed or dampened to ensure good contact. Please note: the auto analysis in the algorithm has not been validated on lead II so this view should only be used as a guide and further testing is advised.

One possible cause of a 'noisy' recording can be axis deviation of the heart. It's reported that left axis deviation occurs in approximately 10% of the population.

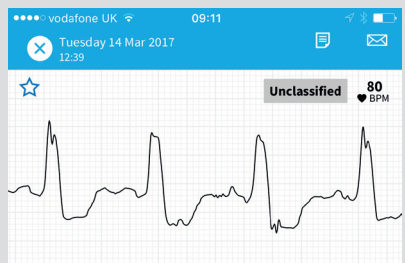


Fig 7

Other arrhythmias

Kardia Mobile records ECG's by using the fingers of both hands equivalent to the left arm and right arm electrodes. It therefore produces a trace of Lead I. Currently Kardia is only validated to diagnose atrial fibrillation. However, as it is diagnostic quality ECG, it will show any other abnormalities that you would normally see when viewing lead I.

In Fig 4, Kardia's recording gave an 'Unclassified' result. The heart rate was in the normal range, but the algorithm was able to detect that there was an abnormality in the QRS complex. This recording was taken from a patient who was subsequently diagnosed with left bundle branch block.

If you are not qualified to make this type of diagnosis, you should always refer the patient to an appropriate clinician for further investigations.

For a full instruction manual, detailed troubleshooting and technical information, please visit:
www.alivecor.com/quickstart

All patient data is encrypted during transfer and at rest. Any user data that leaves the EU is de-identified, complying with EU medical device regulations regarding security and privacy.

Our data server for European customers is located in the Republic of Ireland.

1. 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS, Paulus Kirchhof et al, European Heart Journal doi:10.1093/eurheartj/ehw210

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