

This document is to inform you about device use / storage safety / cleaning procedure / identifying patients / possible outcomes / recommended actions

Patient Selection

The AliveCor device is more accurate than the traditional use of pulse checking for detecting patients with Atrial Fibrillation. Specificity rates are up to 97% compared to 60-70% for traditional methods. Sensitivity rates are above 85%.

We would like you to use the device in the same cohort of patients that you would perform pulse checks on normally.

These should be patients who:

- DO NOT have a pre-existing diagnosis of AF
- DO NOT have a pacemaker
- Attend for an annual Chronic Disease / CVD clinic
- Are on disease registers for:
 - Diabetes
 - Heart Failure
 - COPD
 - PAD
 - Hypertension Ischaemic Heart Disease
 - Stroke

Software & Equipment

Download and install the **AliveCor App (Kardia)** from the App Store/Play Store. The App is needed to synchronize the clock and to download the ECG rhythm strip for attaching to clinical notes or sending as an email attachment.

Charging Device

The AliveCor Heart Monitor does not need to be charged. The internal battery in the monitor will last for up to 100 hours of continuous use (or approximately 12,000 30-second recordings). The battery may prematurely drain if a connection is continually made with both electrodes to skin or metal.

Cleaning

The user should clean the AliveCor device in between each patient using a sterile wipe.

NICE Advice on AliveCor

The AliveCor Mobile ECG has been reviewed by the National Institute for Health and Care Excellence (NICE). A copy of their report is available at www.nice.org.uk/advice/mib35

Device Use



1. Assume a comfortable position and relax to obtain the best results. It is recommended that the forearms rest comfortably on a table or on your knee.



2. Hold the AliveCor device as indicated (but do not squeeze). The device will activate and start recording for 30 seconds. There is a countdown clock on the app to show the progress of the recording.



3. Wait until the AliveCor clock completes a full circle to signal the end of the recording. The app will indicate a normal or abnormal rhythm.

Customer services number: +44 (0) 333 301 0433



4. Release the device.



5. If the result is normal, record this in the patient notes with no further action.



6. If the result is abnormal, download the ECG as a PDF file for attaching to clinical notes and emailing for review.



7. If you are having trouble taking a reading please refer to unclassified and unreadable recommended actions overleaf.

Handy Tip 1 - Consider using a local read code to record that the AliveCor device has been used.

Handy Tip 2 - For GDPR Compliance you will need to disable cloud saving. You can do this by going into the app Settings, EKG Settings, scroll to the bottom to GDPR Compliance, turn on Disable EKG Storage.

Possible Outcomes	Recommended Action
Normal	No follow up action needed. Offer participant AF Association (AFA) "Know your Pulse" factsheet for general information and preventative advice.
Possible AF	<p>Reassure the participant that this is not a confirmed diagnosis, but simply advise that they require further diagnostic testing. Check with participant that they do not already have a diagnosis of atrial fibrillation (AF), atrial flutter, or atrial tachycardia.</p> <p>Offer the participant further information e.g. AFA "AF Patient Information" Booklet and relevant preventative advice. Explain that this is not a confirmed diagnosis, and further investigations are needed. They will need to receive a 12-Lead ECG which is usually arranged through their GP. If appropriate explain that we will be contacting their GP practice to let them know that possible AF was detected, or ask the patient, if appropriate to contact their GP explaining they had a test showing possible AF and this needs further investigation. Whilst the findings may not be the ideal outcome, it does however mean that therapy can be started early to help minimise the risk of complications. Either let the GP know by emailing immediately, so as not to lose the trace when the device is next used, uploading PDF single lead rhythm strip report and sending to them or follow your agreed process to alert the GP.</p> <p>Remember to abide by the information governance advice of using an @nhs.net email.</p>
Unclassified	<p>Repeat the single lead rhythm strip recording again (maximum two repeats), ensure that the participant is calm, sits still, does not talk and relaxes their arms and shoulders.</p> <p>If still unclassified, the participant's single lead rhythm strip must be reviewed for other abnormalities and further investigations carried out. NB: If the participants pulse rate is below 50bpm the reading will be classified as Bradycardia. If the pulse rate is above 100bpm, it will be classified as Tachycardia. Offer the participant further information e.g. AFA "Know Your Pulse" factsheet and relevant preventative advice. Reassure the participant that this is not a confirmed diagnosis and is not necessarily abnormal, but simply advise that their results require further review. Whilst the findings may not be the ideal outcome, it does however mean that if there is an abnormality this can be sorted out early to help minimise the risk of complications. Either let the GP know by emailing immediately, so as not to lose the trace when the device is next used, uploading PDF single lead rhythm strip report and sending to them or follow your agreed process to alert the GP.</p> <p>Remember to abide by the information governance advice of using an @nhs.net email.</p>
Unreadable	<p>This means that the Kardia Mobile algorithms have not been able to interpret the reading that has been taken. This may be due to:</p> <ul style="list-style-type: none"> • too much background noise. • poor connectivity between the patient and the sensors e.g. patient recently used hand cream, cold hands, holding the device too tightly and holding with tips of fingers. • too much movement in the patient's limbs. <p>Repeat the test ensuring the device use steps overleaf are followed.</p> <p>In some individuals it will not be possible to record a good quality single lead rhythm strip due to anatomical and physiological differences e.g. a tremor or arthritic hands or dexterity issues. If still unreadable, place the device centrally, in a vertical position just above the participant's xiphisternum. Ensure the AliveCor electrodes are against the participant's skin. You can ask the patient to hold the device there whilst the reading is taken. As a last resort, and if appropriate to do so, take a manual pulse. If still unreadable, offer the participant further information e.g. AFA "Know Your Pulse" factsheet and relevant preventative advice. Reassure the participant that this is not a confirmed diagnosis and is not necessarily abnormal, but simply advise that they require further review. Whilst the findings may not be the ideal outcome, it does however mean that if there is an abnormality this can be sorted out early to help minimise the risk of complications.</p>