

ALIVECOR KARDIA MOBILE ECG DEVICE STANDARD OPERATING PROCEDURE (SOP)

to measure QTc prolongation before initiating and during the monitoring of the use of anti-psychotic medication.

SOP currently under review – please continue to use this version until it is replaced by the next approved version

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VALIDITY – Policies should be accessed via the Trust intranet to ensure the current version is used.

CHANGE RECORD

Version	Date	Change details
1.0	4 April 2022	New SOP – Approved at Clinical Network (AMH) 4-April-22
1.1	10 Aug 2022	Reviewed at Physical Health and Medical Devices group - Approved as a Trust wide SOP with minor changes to sections 2 and 3.1.

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1. INTRODUCTION

This Standard Operating Procedure (SOP) covers the uses a portable ECG mobile device manufactured by AliveCor Kardia Mobile 6L to measure QTc prolongation before initiating and during the monitoring of the use of anti-psychotic medication.

All antipsychotics have a degree of cardiac risk including:

- Arrhythmias
- Syncope
- QT Prolongation
- Torsade de pointes (potentially life threatening heart arrhythmia)
- Sudden cardiac death

2. SCOPE

Whilst the AliveCor Kardia Device can be used in other clinical situations (see [KardiaMobile for detecting atrial fibrillation \(nice.org.uk\)](#) this SOP has been specifically developed to support the use of the device for the measurement of QTc prolongation before initiating and during the monitoring of the use of anti-psychotic medication.

It applies to all staff who use the Kardia Device for the delivery of patient care for this purpose.

This document should be read in conjunction with the *User Manual for Kardia Mobile by AliveCor and Omron Connect*.

3. PROCEDURES

KardiaMobile 6 Lead device is a handheld 6 lead ECG device which that has two electrodes on the top for your fingers, and one on the bottom to contact the skin of your left leg. KardiaMobile 6 Lead delivers ECG leads I, II, III, aVL, aVR, and aVF.

The device links to the Kardia App which can be downloaded on a Trust approved smartphone only. Go into the App store and download this app. Download the app 24 hour before your first appointment for using the device.

Infection Prevention and Control guidance must be followed and the device placed somewhere for the patient to collect e.g. a table to adhere to social distancing guidelines

To take a reading:

- 1 Register using a dummy name and D.O.B
- 2 Register the account to your nhs.net email address- this is where the ECG will be sent to. Once linked the device can take an ECG reading in 30 seconds. This produces an ECG trace in a PDF format.
- 3 Ask the patient to place the device on their **left** knee and place 2 fingers on each side of the device and the bottom electrode on their knee, as shown here. Alternatively, the patient can use the device on their **left** ankle.
- 4 Make sure the arrow on the device is facing away from the patient, as shown here and ask the service user to stay still



- 5 Ensure you click '6L' and **NOT** '1L'
- 6 Once in position, press 'Record ECG' on the app. Wait for 1 minute to ensure the ECG has recorded.
- 7 . Press 'Share PDF'
- 8 Press the share button. Press the Email icon ECG to nhs.net email address
- 9 Once the PDF is attached to the email, add the patient's forename, surname and NHS number to the body of the email.
- 10 Forward the ECG to the relevant agreed clinician to review

Interpreting ECG QT interval (for trained Clinicians only)

- 1 There are several formulas available to calculate QTc. There is no current consensus on which is preferable. However, we recommend that you use Fridericia's measurement for a number of reasons:
- 2 This is the most common measurement used as automated calculations by ECG machines, making comparison to previous readings easier.
 - It is more reliable at higher heart rates.
 - It is the measurement used to monitor other QTc-prolonging medications
 - Studies have shown it is a more accurate measure of all-cause mortality.

Reference "Which QT Correction Formulae to Use for QT Monitoring?" Bert Vandenberg, MD et al; J Am Heart Assoc. 2016 Jun; 5(6): e003264.

- 3 Measuring the QT is most commonly performed in lead II or aVR but please select the lead in which the QT interval is clearest/longest.
- 4 Select a QRS complex where the start of the QRS complex and end of the T wave is clear.
- 5 Enlarge the image so the QRS complex can be viewed easily.
- 6 **Calculate the QTc:** This can be done using the following online calculator (also available in the app store) <https://www.mdcalc.com/corrected-qt-interval-qt-c>

If the ECG looks abnormal, check whether the patient has any cardiac symptoms that could attribute to the abnormality, then consider a 12L ECG and/or opinion from a specialist.

3.1. Setting up the Kardia App

The AliveCor Kardia device and App will be used by staff in the Community Mental Health teams and other relevant services across the organisation for the purpose of initiating and monitoring of the use of anti-psychotic medication.

The Kardia App will be downloaded onto a Trust encrypted device (phone/tablet). The staff member will sign up to the device using their NHSmail account and will need to accept the terms and conditions.

Staff must switch off the voice recording function within the app.

3.2. Identification of patients for the Kardia Device

The device is to be used only to measure QTc prolongation before initiating and during the monitoring anti-psychotic medication.

This device is not suitable for use on patients under the age of 18

This device is not suitable for use on patient's with a cardiac pace-maker, ICD's or other electronic implantable devices

Do **not** use on patients who have identified at risk of swallowing

3.3. Consent

Consent to take an ECG with the device will be taken by the health care professional in the usual way as with performing any test in the context of healthcare.

The patient privacy notice detailed in Appendix A will be made available to the patient

3.4. Using the Device and App

Staff will follow the user manual when taking an ECG recording.

When taking a patient's ECG trace, staff will use the "Guest EKG" function. Patient identifiable information will not be entered.

3.5. Record keeping

For the purpose of clinical record keeping, details of the trace will be added to the clinical record. This will be done by:

Emailing the recording from an NHSmail account to another NHSmail account. Staff must include the patient's forename, surname and NHS number in the body of the email to ensure the correct patient identification. **Staff must not use add any of these identifiers into the Kardia App.**

The trace will then be uploaded to the correct patient record.

Staff will log out at the end of each session to ensure that the last trace taken is not stored on the Trust mobile device

3.6. Security of the equipment

The devices do not store any patient information and are not connected to the Trust network. They will be stored securely when not in use.

The Kardia App will only be stored on Trust encrypted devices.

3.7. Training

All staff using the device and App will be briefed on this procedure and the *User Manual for Kardia Mobile by AliveCor and Omron Connect*.

3.8. Business continuity

The clinician will refer to another clinician or use another device'

4. REFERENCES/DEFINITIONS

User Manual for Kardia Mobile by AliveCor and Omron Connect
<https://www.alivecor.com/app-user-manuals/00LB17.14-en.pdf>

[KardiaMobile for detecting atrial fibrillation \(nice.org.uk\)](https://www.nice.org.uk/guidance/TA171)

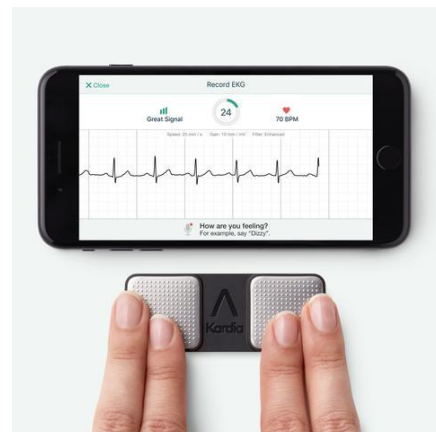
Appendix 1 – Privacy Notice

Privacy Notice relating to the use of AliveCor Kardia mobile devices (under the NHS England national roll out)

During your appointment today your heart was checked using an AliveCor Kardia device. You may have noticed that the device is linked to a smartphone or tablet computer to capture your ECG trace.

What information is collected about you and how will it be used?

- None of your personal information is added to the app or stored on the smart phone.
- Should your ECG trace require further assessment, your health care professional will securely transfer the trace using NHSmail (accounts ending in @nhs.net), only adding your essential personal information to the email and not into the app. NHS.net is a secure national email service which enables the safe and secure exchange of sensitive and patient identifiable information within the NHS.
- Your health care professional will add information about the ECG outcome to your local electronic health record.
- Your health care professional should use the Basic Kardia app which prevents the storage of any ECG traces within the app on the smartphone or tablet computer.



Will my data be shared?

- The AliveCor Kardia app is designed for personal or professional use. Your health care professional will have created their own Kardia account and will use the 'guest' function to take your trace. This ensures that none of your personal information is ever shared with AliveCor, only your anonymous ECG trace.
- All ECG traces taken in the EU using an AliveCor Kardia device are uploaded into the AliveCor servers in Germany. Each ECG has a unique ID and cannot be tied back to the user's account.
- All data is encrypted during transfer and at rest with AES encryption.

Kardia meet the requirements of EU data protection law and are HIPAA compliant in the USA. Any user data that leaves the EU is de-identified, complying with EU medical device regulations regarding security and privacy.

For any comments or queries please contact your local Academic Health Science Network.