AliveCor Kardia Mobile: NHS England mobile ECG device project

Information and guidance for device recipients

Published 19 January 2018
Summary of key points
This page outlines the key information and ‘must do’ actions associated with the mobile ECG device roll-out. However, please ensure you read the full document (and all other listed documents) for more details.

- AliveCor Kardia Mobile devices have to be used with an IOS or android smartphone or tablet. These are not provided as part of the project
- You must be able to access your phone or device’s App Store and download the Kardia Mobile app
- Kardia Mobile app should be downloaded and set up using an nhs.net email address. If you don’t currently have one, please contact your local IT department
- Instructions for setting up the device and app can be found at: www.alivecor.com/support/#quickstart
- Any smart phone or tablet used in association with the device must have an nhs.net email address as the default email account
- No patient identifiable data should be added to the AliveCor ECG trace
- The device needs to be registered so that central data collection can take place
- Data security is the responsibility of every individual using the Kardia app, all local Information Governance leads should be made aware of the local use of Kardia
- The data collection will continue until at least March 2019
- Ownership of/responsibility of the mobile ECG device is transferred to the recipient organisation on signing the receipt. Devices cannot be released until the obligations receipt is signed and returned to the West of England Academic Health Science Network (AHSN)
- Recipient organisations are required to take part in the national evaluation.
- To drive the Atrial Fibrillation detection rates that NHS England seek, we encourage for every device to be used on average 24 times a week

Associated documents to be read in preparation for local device roll-out are:
- Mobile ECG device project information and guidance pack for device recipients (this document)
- Receipt, which includes user obligations – needs signature
- Privacy impact assessment (PIA) – requires completion
Introduction
This information and guidance document has been compiled by the West of England AHSN in association with the National AHSN Network atrial fibrillation (AF) team and is intended to support recipients of the NHS England funded mobile ECG devices.

This document provides device recipients with guidance on the AliveCor Kardia Mobile devices, their use, governance, data collection and evaluation. It is one of 3 documents associated with local roll-out (this document, the Privacy Impact Assessment (PIA) and receipt). It also establishes some core systematic processes to ensure consistency in the approach across the region.

The West of England AHSN will work with device recipients to ensure they understand the important information contained in this document.

Background
The West of England AHSN approach to the distribution of the AliveCor Kardia Mobile devices will be to focus on delivery to GP Practices where they can be used in consultations and suitable patient clinics, to identify potential AF sufferers from appropriate patient groups. The AHSN will work closely with Commissioning Groups (CCG) and Sustainability and Transformation Partnerships (STPs) to agree which practices will be offered a free device.

This initiative falls within the NHS England Innovation and Technology Tariff 2017-19, hence the national procurement of devices for distribution by the 15 Academic Health Science Networks (AHSNs) working alongside colleagues in your CCG.

The AliveCor Kardia Mobile device takes a 30 second ECG reading which, in most cases, immediately indicates if a person suffers with AF. A short video showing how the device works can be found here: https://www.alivecor.com/how-it-works/

The device works alongside a practice smart phone or tablet (not available under this initiative) and the Kardia Mobile BASIC app is downloaded to capture the heart rhythm reading. Where AF is detected, the reading can be emailed to a GP for diagnosis and treatment.

Aim
The main outcome for this project is to improve the detection of people with AF in order to reduce the number of strokes. To drive the AF detection rates that NHS England seeks, we encourage for every device to be used on average 24 times a week.

NHS England also wishes to test whether a system-wide procurement initiative improves the uptake of innovative technology and stimulates the market in primary and community settings to better identify AF.

Each AHSN will also monitor use of the devices and provide implementation guidance in supporting the objectives of their programmes to reduce strokes. They will work with the national evaluation team to ensure effective data collection and dissemination of learning. Once issued the devices will remain the property of the recipient organisation for continued use beyond the end of this project.
Metrics

NHS England has agreed the following metrics will be used to assess the impact of this initiative. Data will be collected at AHSN and CCG level. This includes data provided by AliveCor Ltd.

Agreed metrics for the mobile ECG device roll out:

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Data source</th>
<th>Frequency and duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of devices deployed</td>
<td>West of England AHSN</td>
<td>Quarterly from March 2018</td>
</tr>
<tr>
<td>Description of settings into which devices have been deployed</td>
<td>West of England AHSN</td>
<td>Monthly</td>
</tr>
<tr>
<td>Sustained use of devices</td>
<td>AliveCor via central registration</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Number of people screened using all devices</td>
<td>AliveCor via central registration</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Number of people with ‘possible AF’, (and, where possible, unclassified / unreadable outcomes)</td>
<td>AliveCor via central registration</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Reduction in the gap between expected and actual prevalence of AF</td>
<td>QOF register</td>
<td>National QoF dataset from 2017/18 available Oct 2018 and 2018/19 available Oct 2019</td>
</tr>
</tbody>
</table>

Additionally the AHSN will continue to monitor the following metrics to understand the impact of the treatment of AF in CCG localities.

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of people with AF as a percentage of the registered population</td>
<td>QoF AF001</td>
</tr>
<tr>
<td>Percentage of patients with AF with a CHA\textsubscript{2}DS\textsubscript{2}-VASc score of 2 or more who are currently treated with anti-coagulation drug therapy</td>
<td>QoF AF007</td>
</tr>
<tr>
<td>Percentage of patients with AF admitted to hospital for stroke</td>
<td>SSNAP</td>
</tr>
<tr>
<td>Percentage of patients with AF admitted to hospital for stroke who had not been prescribed anticoagulation prior to their stroke</td>
<td>SSNAP</td>
</tr>
</tbody>
</table>
Data governance, transmission and security

Throughout this project it is the responsibility of all individuals to ensure that national and local information governance requirements are adhered to. These guidance notes give careful consideration to the importance of data security and outline how digital tools such as AliveCor Kardia mobile ECG device and application (app) can be used in NHS settings whilst striving to ensure patient data remains secure.

Digital technology and regulation is fast evolving, the recommendations outlined within this document have been approved by NHS Caldicott guardians and are correct the time of publication. Each recipient of a mobile ECG device should be aware of their responsibility to maintain data security when using these devices.

All data should be:
• held securely and confidentially;
• obtained fairly and lawfully;
• recorded accurately and reliably;
• used effectively and ethically;
• shared and disclosed appropriately and lawfully.

The following Caldicott2 principles should be adhered to:

Justify the purpose(s)
Every proposed use or transfer of personal confidential data within or from an organisation should be clearly defined, scrutinised and documented, with continuing uses regularly reviewed, by an appropriate guardian.

Don’t use personal confidential data unless it is absolutely necessary
Personal confidential data items should not be included unless it is essential for the specified purpose(s) of that flow. The need for patients to be identified should be considered at each stage of satisfying the purpose(s).

Use the minimum necessary personal confidential data
Where use of personal confidential data is considered to be essential, the inclusion of each individual item of data should be considered and justified so that the minimum amount of personal confidential data is transferred or accessible as is necessary for a given function to be carried out.

Access to personal confidential data should be on a strict need-to-know basis
Only those individuals who need access to personal confidential data should have access to it, and they should only have access to the data items that they need to see. This may mean introducing access controls or splitting data flows where one data flow is used for several purposes.

Everyone with access to personal confidential data should be aware of their responsibilities Action should be taken to ensure that those handling personal confidential data — both clinical and non-clinical staff — are made fully aware of their responsibilities and obligations to respect patient confidentiality.

Comply with the law
Every use of personal confidential data must be lawful. Someone in each organisation handling personal confidential data should be responsible for ensuring that the organization complies with legal requirements.
The duty to share information can be as important as the duty to protect patient confidentiality. Health and social care professionals should have the confidence to share information in the best interests of their patients within the framework set out by these principles. They should be supported by the policies of their employers, regulators and professional bodies.

A number of existing national guidelines outline the basic information governance requirements when working within the NHS including:


MHRA Managing Medical Devices 2015:


Information to Share or Not to Share: The Information Governance Review:

**EU General Data Protection Regulation (GDPR)**

The Information Governance landscape is changing with the EU ‘General Data Protection Regulation’ (GDPR) coming formally into force from 25 May 2018.


Major changes as a result of this legislation are highlighted here: http://www.eugdpr.org/key-changes.html

NHS organisations are currently implementing the necessary policies and procedures to comply with this new legislation which will continue to apply post-Brexit. All organisations involved in this roll out must comply with this legislation and device recipients should discuss and seek approval from the local Data Protection Officer responsible for that area.

As of 25 May 2018 a Privacy Impact Assessment (PIA) will need to be completed for each project/provider area using AliveCor Kardia mobile ECG and App. It is advisable for Recipient Organisations to complete a PIA before their project commences.

**An example is provided at appendix 1 of this guide, which you can update and adopt if appropriate.**

Further NHS Digital guidance on the implications of GDPR is awaited, latest briefing at the time of writing can be found at: https://digital.nhs.uk/article/6921/Changes-to-Data-Protection-legislation-why-this-matters-to-you
Key recommendations for the use of KardiaMobile device and app

People/patients undertaking a pulse rhythm check via the KardiaMobile app give implied consent for the transmission of their anonymous ECG trace. If an ECG requires further referral/assessment the patient should be made aware and the process explained.

As no Patient Identifiable Data (PID) is recorded or transmitted outside of secure NHS digital networks formal consent is not required. A patient privacy notice regarding the use of KardiaMobile and how digital information is transmitted can be found in Appendix 2. This document should be available for patients to read.

- No Patient/Personal Identifiable Data should be transmitted or stored outside of secure NHS systems.

- Recipients of mobile ECG devices should be aware of their responsibility to maintain data security when using mobile ECG devices. It is essential that all smart phones or tablet devices used with the Kardia device and application should have an nhs.net email account configured as the default email server, in order to transfer ECG traces securely if required.

- Instructions for the use of the devices are illustrated in the “setting up” flow diagram overleaf. As you will see, to prevent traces being stored locally on the mobile phone or tablet the app should be logged out at the end of each session. We do not recommend using personal devices.

- All traces should be taken in the ‘guest’ mode function as outlined in the flow diagram.

- No PID or pseudonymised data (including NHS or EMIS numbers) should be stored on any device or added to any ECG traces within the Kardia Mobile app.

- Should an ECG trace require further review it must be emailed immediately by exporting a PDF file of the trace securely from Kardia Mobile app. To do this:
  1. Click the email EKG icon at the bottom of the page.
  2. Select NHS.net as the email from which the file is to be sent and the PDF file will appear as an attachment within an email.
  3. Any additional patient identifiable information should be added to the body of the email.
  4. This email should then be sent to a recipient NHS.net account.
  5. Document the outcome of the ECG trace and referral notes in the patient record as usual and, if possible, save the exported PDF to the patient’s electronic record.

The process for the transmission of ECG traces taken from the use of KardiaMobile device and application is outlined in the following flow diagram.
Recommended procedure and information governance for the use of the AliveCor Kardia Mobile

Setting up

**Configure** smart phone/tablet device to NHS.net as default email. NHS digital guidance on configuring mobile devices with nhs.net can be found on [www.weahsn.net/kardia](http://www.weahsn.net/kardia).

**Download** Kardia app from app store, create an account using your NHS.net email address. Any personal data you enter will be visible to AliveCor Ltd. If you do not wish to share your personal information a pseudonym will suffice, however the date of birth entered must be for an individual over the age of 18. Read full set up instructions and complete the AHSN online registration form at [https://ecgod.co.uk/ahsn](https://ecgod.co.uk/ahsn).

Go into device settings within the app and turn off notifications, reminders and voice recording.

The AHSN Network recommends use of the Kardia BASIC app. The premium app will be provided for free for the first 30 days (this service will store any traces taken). We advise all traces taken using the free premium app are deleted to prevent any patient data being stored on a personal device. No personal identifiable information (PID) should be added to any traces. IGNORE PROMPTS TO UPGRADE TO PREMIUM.

Taking an ECG trace

Open BASIC app

Click ‘record now’ (place fingers on AliveCor). ECG trace will be provided in 30 seconds

Once ECG is complete a pop up message will appear asking you to confirm if you recorded the EKG. Click NO to use as guest mode.

Possible outcomes of traces and required action

**Possible AF / AFib**
- Do not add any PID into ‘add note’ function of the trace.
- To send a trace for referral, click the email EKG icon at the bottom of the trace.
- Send trace by email from your NHS.net to a recipient NHS.net.
- Add relevant PID into the body of email.

ONLY NHS.net to NHS.net will ensure the secure transfer of PID. No other email provider should be used for this purpose. Email immediately so not to lose trace when device is next used.

**Normal / No Abnormality Detected**
No referral required, patient notes should be updated accordingly.

**Unclassified / Unreadable**
Repeat trace once:
- Limit background noise.
- Apply gentle pressure to AliveCor, do not squeeze.
- If heart rate is >100 or <50, traces will be unclassified so allow time for heart rate to stabilise.
- Use an alcohol spray/wipe on the device and ensure there is sufficient moisture on fingers.

If second trace is unclassified or unreadable send for referral via email NHS.net to NHS.net.

Log out of the Kardia app at the end of each session to ensure that the last trace taken is not stored on the mobile phone/tablet.
Data/metrics collection
Process for data collection from KardiaMobile by AliveCor

Key data will be collected centrally on behalf of NHS England by AliveCor Ltd. It is therefore essential that each healthcare professional that uses the device with a patient completes the online registration form for Kardia accounts. This form will enable AliveCor Ltd to report the activity data associated with each account including the total usage, the number of possible AF, normal and unclassified readings, whilst still maintaining data security.

As each Kardia device may be used by multiple users, it is essential that each user creates their own Kardia Mobile account and registers their account by completing the online registration form https://ecgod.co.uk/ahsn.

The form provides a step by step guide on how to use the device according to the AHSN guidance and it must be completed upon receipt of the Kardia device. If a healthcare professional has a pre-existing Kardia Mobile account (established with their nhs.net email address) they should also complete the registration form to ensure their activity data can be tracked. The registration form will only accept nhs.net email addresses.

The online registration form will require users to provide the following information:

- NHS.net email address (used to create their Kardia account)
- The serial number of the device (this ensures only the correct devices are tracked)
- The AHSN who provided the device (select West of England AHSN from drop down list)
- Their local CCG - if known (from a drop down list - collated by AHSN)
- Their occupation group (from a drop down list)
- The setting in which the individual works most frequently (from a drop down list)

The registration form has been developed with support from Technomed, who are providing this digital service. Technomed cannot use any of the information entered into the registration form for any other purposes.

Device management policy
As per MHRA guidance (Managing Medical devices, 2015) recipients are encouraged to follow their local device management policy to help ensure that any risks associated with the device are minimised or eliminated. The basic guidance on delivery checks; table 5.1 page 23 and 24 provides a useful summary of checks to be completed.

All devices will need to have serial numbers and deployment details recorded by the West of England AHSN.

End of mobile ECG device roll out and evaluation

This project will be evaluated by an independent evaluation team from Wessex AHSN using a mixed methods approach of qualitative and quantitative data.

It is planned that usage data from the devices should be collected until 31 March 2019 in order to demonstrate the impact of this initiative over time.
Roles and responsibilities
All devices procured as part of the AHSN mobile ECG work programme have met all EU safety, health and environment requirements as per MHRA requirements for medical devices. The user manuals and FAQs can be found via links provided below. Guidance on the use and storage of the respective devices can be also found in this document.

Devices become the property and responsibility of the recipient organisation upon receipt of the goods from the West of England AHSN. This includes responsibility for storage, cleaning (wipe with alcohol cloth), user training, maintenance and disposal. Recipient organisations are responsible for the clinical use of these devices. Manufacturers’ guarantees are transferred to the end recipient.

Should an organisation lose or break a KardiaMobile by AliveCor Ltd device it should notify the West of England AHSN who will inform the evaluation team. No charge will be made however a replacement will not be provided. The device is available for purchase through other suppliers, at relatively low cost.

Recipient organisations and/or providers acting on their behalf are responsible for the clinical use of these devices, and adherence to the required standards outlined in this document.

Recipient organisations are required to sign the receipt which sets out obligations of the user organisation and transfers ownership and responsibility for the device before it is issued. Training and information on the local referral pathways remains the responsibility of the recipient organisation.

All recipients of mobile ECG devices may also be subject to evaluation and may be contacted by the national evaluation team. It is therefore essential that every individual completes the online registration form.

Associated documents to be read in preparation for the use of the device are:

- Mobile ECG project information and guidance notes
- Receipt to be signed at the point of receiving the device
- Privacy Impact Assessment (PIA) template
- User manual and video
- Patient Privacy Notice

These are available in this document and on our website www.weahsn.net/kardia/

The West of England AHSN look forward to working with you to support the roll-out of mobile ECG devices to detect more AF and reduce the number of strokes.

Please don’t hesitate to get in touch with our team at enterprise@weahsn.net if you have any questions.

A copy of the AliveCor Kardia Mobile user manual is available at: https://www.alivecor.com/ifus/kardiamobile/02LB49.2-en.pdf
FAQs www.alivecor.com/faq/

For technical support, contact AliveCor directly:
Telephone – 0333 301 0433
Email - uksupport@alivecor.com
https://www.alivecor.com/
Appendix 1
Privacy Impact Assessment Template

Section 1: Background Information

Project Name: NHS England funded Mobile ECG device roll out

Organisation: 
Assessment completed By: 
Job Title: 
Date completed:

Phone: 
E-mail: 

Project/Change Outline - What is it that is being planned? If you have already produced this as part of the project’s Project Initiation Document or Business Case etc. you may make reference to this, however a brief description of the project/process being assessed is still required.

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia. The prevalence of AF in England is likely to be close to 2.0%, which equates to about 835,000 people living with the condition. If left untreated atrial fibrillation is a significant risk factor for stroke and other morbidities. People with AF have a higher prevalence of heart failure, myocardial infarction, hypertension, angina and diabetes and AF is associated with a 5-fold increase in the risk of stroke.

1 NICE Medtech innovation briefing [MIB35] AliveCor Heart Monitor and AliveECG app (Kardia Mobile) for detecting atrial fibrillation, published date: August 2015

Please see https://www.nice.org.uk/guidance/cg180/chapter/1-Recommendations#diagnosis-and-assessment for more information.
AF may have non-specific symptoms or no symptoms at all. It is often only diagnosed following serious complications including stroke, thromboembolism and heart failure. The NICE guideline on atrial fibrillation states that assessing for an irregular pulse in patients presenting with certain symptoms, and performing an ECG for all patients in whom an irregular pulse has been detected, can detect AF before serious complications develop.\(^1\)\(^2\)

Mobile ECG devices were highlighted by Simon Stevens at NHS Confed 2016 as an area for NHS innovation. NHS England has identified funding to help stimulate the market and increase the uptake to innovative mobile ECG technologies in primary and community care. The West of England AHSN approach to the distribution of the AliveCor Kardia Mobile devices will be to focus on delivery to GP Practices where they can be used in consultations and suitable patient clinics, to identify potential AF sufferers from appropriate patient groups.

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The Innovation Agency will use the funding to purchase mobile ECG technology that can be used to detect AF in the community, on behalf of all Academic Health Science Networks (AHSNs) and they will lead the allocation and distribution of devices across participating AHSNs. The mobile ECG device available in the West of England footprint is the AliveCor Ltd KardiaMobile (this product has met product specification laid out by NHS England). Each AHSN has identified suitable sites for distribution based on the agreed device allocations (defined from population statistics). Each AHSN will monitor use of the devices and provide implementation support. They will work with an evaluation team to ensure the effective data collection and dissemination of learning. The national AHSN AF steering group will oversee progress. KardiaMobile is the only device which works with an app and has ECG traces stored by AliveCor Ltd and this will be the focus of the PIA.

### Purpose / Objectives - Why is it being undertaken?

This could be the objective of the process or the purpose of the system being implemented as part of the project.

The purpose of this project is to use Mobile ECG technology to facilitate more opportune and timelier detection of AF in primary care. This project has provided the AHSNs with the potential to collectively demonstrate their value, not just in supporting the distribution of these devices, but also by rigorous capture of their use and impact in clinical practice.

The objectives (as specified by the evaluation questions identified by NHS England), include:

- What environments are the devices most effective in?
- What features of the implementation packages are most effective?
- What impact has the programme had on the market place?
What health economic aspects has the programme achieved?
What impact has the programme had on providers?
What impact has the programme had on patient outcomes?
What is the impact on providers?

What is the purpose of collecting the information within the system? For example patient treatment, patient administration, research, audit, reporting, staff administration etc.

Introducing mobile ECG device technology into a clinical pathway creates the requirement for data to be collected on the outcome for 2 purposes:
- For the purpose of clinical record keeping and to facilitate onward referral if required.
- To demonstrate the impact of the use of mobile ECG technology in the detection of AF. This data will allow the evaluation team and AHSNs to answer the objectives outlined in the business case.

What are the potential privacy impacts of this proposal - how will this change impact upon the data subject? Provide a brief summary of what you feel these could be, it could be that specific information is being held that hasn't previously or that the level of information about an individual is increasing.

KardiaMobile:
This device works with the Kardia smartphone app, the privacy statement for which can be found at https://www.alivecor.com/privacy/en/.

Kardia - A health care professional (HCP) will download the app to their own or NHS smart-phone or tablet device. In doing so they accept the terms and conditions and enter their NHS.net email address, they should also switch off the voice recording function within the app.
We advise that they do not enter any personal or biometric information into the app.

When taking a patient’s ECG trace HCPs should use the “Guest EKG” function and never enter any patient identifiable information (PID) or voice recording to associate with the trace. This will ensure that the patient trace has no identifiable features when it is stored by AliveCor.
**Privacy impact:**
The Kardia app for new users has a ‘basic’ and a ‘premium’ (paid for - £10 monthly) version. The premium version is available free for the first month. The basic app allows the recording of a single ECG trace, which is not stored locally or online; whilst the premium service allows the user to store ECG traces locally (on the mobile phone or tablet device) and within a web-based version of the app which can be accessed online.

**Risks:**
Premium app is provided for free for the first 30 days, therefore users will be required to delete all traces from the journal (i.e. remove them from local storage on the app) and to follow the guidance (not adding any PID to the trace). Or should not use the app during this 30 day period. We advise ignoring the premium function.

**Transfer of data:**
AliveCor collect and monitor usage data on all traces taken such as human ECG data, including the ECG measurement itself, mobile device accelerometer data, average heart rate, the location on the body where the ECG recording was taken (e.g. hand or chest), local time, time zone and geographic location of ECG acquisition. If any PID or voice recording is added to a trace this will also be shared (we advise against this in the guidance).

The data server for European customers is located in the Republic of Ireland. Any user data that leaves the EU is de-identified, complying with EU medical device regulations.

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Provide details of any previous Privacy Impact Assessment or other form of personal data compliance assessment done on this initiative. If this is a change to an existing system, a PIA may have been undertaken during the project implementation

The AHSN Network has developed a guidance document for the use of mobile devices. This includes guidance recommends the use of the basic app as outlined above. Based on this information and guidelines the West of England AHSN has adapted the guidance reflecting the local context and distribution. The guidelines will be sent out to all participating GP surgeries providing recommendation to use the basic app as the supported app though this initiative.
Stakeholders - who is involved in this project/change? Please list stakeholders, including internal, external, organisations (public/private/third) and groups that may be affected by this system/change.

NHS England
Lancashire Care Foundation Trust
Academic Health Science Networks
West of England AHSN
Recipient organisations (for example, CCGs, GP’s, clinical primary care teams)

Section 2: The Data Involved

What data is being collected, shared or used?
(If there is a chart or diagram to explain attach it as an appendix)

<table>
<thead>
<tr>
<th>Data Type</th>
<th>Justifications – there must be justification for collecting the particular items and these must be specified here – consider which data items you could remove, without compromising the needs of the project?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information that identifies the individual and their personal characteristics</td>
<td></td>
</tr>
<tr>
<td>Name</td>
<td>☒ The HCP who installs the app on their mobile phone/tablet device will be required to add this information. This information is not collected about the patient as they are considered a “guest” when the app is in use.</td>
</tr>
<tr>
<td>Address</td>
<td>☐</td>
</tr>
<tr>
<td>Postcode</td>
<td>☐</td>
</tr>
<tr>
<td>Dob</td>
<td>☐</td>
</tr>
<tr>
<td>Age</td>
<td>☐</td>
</tr>
<tr>
<td>Sex</td>
<td>☐</td>
</tr>
<tr>
<td>Gender</td>
<td>☐</td>
</tr>
<tr>
<td>Racial/ethnic origin</td>
<td>☐</td>
</tr>
<tr>
<td>Tel no.</td>
<td>☐</td>
</tr>
<tr>
<td>Physical description</td>
<td>☐</td>
</tr>
<tr>
<td>NHS no.</td>
<td>☐</td>
</tr>
<tr>
<td>Mobile/home phone no.</td>
<td>☐</td>
</tr>
<tr>
<td>Email address</td>
<td>☒ Should a patient set up the Kardia app on their own device they would be accepting the terms and conditions of the App, which outlines how the data is stored. This is not advised under this roll out.</td>
</tr>
<tr>
<td></td>
<td></td>
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<tr>
<td></td>
<td>The employer of the HCP is the Data Controller for this process not LCFT or AHSN, and that the “name” will be the EKG Guest mode</td>
</tr>
<tr>
<td>Information</td>
<td>Yes</td>
</tr>
<tr>
<td>-------------------------------------------------</td>
<td>-----</td>
</tr>
<tr>
<td>Information relating to the individual’s physical or mental health or condition</td>
<td>☒</td>
</tr>
<tr>
<td>Information relating to the individual’s sexual life</td>
<td>☐</td>
</tr>
<tr>
<td>Information relating to the family of the individual and the individual’s lifestyle and social circumstances</td>
<td>☐</td>
</tr>
<tr>
<td>Information relating to any offences committed or alleged to be committed by the individual</td>
<td>☐</td>
</tr>
<tr>
<td>Information relating to criminal proceedings, outcomes and sentences regarding the individual</td>
<td>☐</td>
</tr>
<tr>
<td>Information which relates to the education and any professional training of the individual</td>
<td>☐</td>
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<tr>
<td>Employment and career history</td>
<td>☐</td>
</tr>
<tr>
<td>Information relating to the financial affairs of the individual</td>
<td>☐</td>
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<tr>
<td>Information relating to the individual’s religion or other beliefs</td>
<td>☐</td>
</tr>
<tr>
<td>Information relating to the individual’s membership of a trade union</td>
<td>☐</td>
</tr>
</tbody>
</table>
### Legal compliance – is it fair and lawful?

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
<th>Required Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the legal basis for processing the information? <em>This should include which conditions for processing under the Data Protection Act 1998 apply and the common law duty of confidentiality.</em></td>
<td>Health care purposes and medical research</td>
<td>E.g. Seek Information Governance advice</td>
</tr>
<tr>
<td>a - Is the processing of individual's information likely to interfere with the 'right to privacy' under Article 8 of the Human Rights Act?</td>
<td>No</td>
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<tr>
<td>b - Have you identified the social need and aims of the initiative and are the planned actions a proportionate response to the social need?</td>
<td>Yes</td>
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<td>It is important that individuals affected by the initiative are informed as to what is happening with their information. Is this covered by fair processing information already provided to individuals or is a new or revised communication needed?</td>
<td>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.</td>
<td>No additional consent is needed if the transferred is anonymised</td>
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</tbody>
</table>
If you are relying on consent to process personal data, how will consent be obtained and recorded, what information will be provided to support the consent process and what will you do if permission is withheld or given but later withdrawn?

This will be in keeping with carrying out medical tests in the course of a consultation. Data will be stored anonymously and therefore could not be accessed if patients wanted to remove it. If permission for the test is not granted it will not be performed. No additional consent is needed.

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Does the project involve the use of existing personal data for new purposes?</th>
<th>No</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Are potential new purposes likely to be identified as the scope of the project expands?</td>
<td>No</td>
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<tr>
<td>Adequacy</td>
<td>Is the information you are using likely to be of good enough quality for the purposes it is used for?</td>
<td>Yes</td>
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<tr>
<td>Accurate and up to date</td>
<td>Are you able to amend information when necessary to ensure it is up to date?</td>
<td>No</td>
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<td></td>
<td>How are you ensuring that personal data obtained from individuals or other organisations is accurate?</td>
<td>Kardia provides an initial diagnostic test to confirm a diagnosis the patients would be referred for a 12 lead ECG</td>
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<tr>
<td>Retention</td>
<td>What are the retention periods for the personal information and how will this be implemented?</td>
<td>It is anonymous, but the trace can be emailed to the clinician for inclusion into the clinical record</td>
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<td></td>
<td>Are there any exceptional circumstances for retaining certain data for longer than the normal period?</td>
<td>N/A</td>
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<td></td>
<td>How will information be fully anonymised or destroyed after it is no longer necessary?</td>
<td><a href="https://www.alivecor.com/privacy/en/">https://www.alivecor.com/privacy/en/</a> outlines how the data is processed and stored securely. Data is anonymised as per guidance given to the HCP. No PID is associated with the trace before it goes into the clinical record (if an abnormality is found).</td>
</tr>
<tr>
<td>Rights of the Individual</td>
<td>How will you action requests from individuals (or someone acting on their behalf) for access to their personal information once held?</td>
<td>No PID will be held. Removal of data from the Kardia app this will be in accordance with the AliveCor privacy policy <a href="https://www.alivecor.com/privacy/en/">https://www.alivecor.com/privacy/en/</a></td>
</tr>
<tr>
<td>Appropriate technical and organisational measures</td>
<td>What procedures are in place to ensure that all staff with access to the information have adequate information governance training?</td>
<td>Guidance on using the device will be given to all recipients of Kardia. Devices will be given to HCPs who are required to comply with NHS information governance standards</td>
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<td></td>
<td>If you are using an electronic system to process the information, what security measures are in place?</td>
<td>System securities and only non-personal data is being transferred</td>
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<td>How will the information be provided, collated and used?</td>
<td>By HCP from a patient, aggregated outcome data will be collected as part of the</td>
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<tr>
<td>What security measures will be used to transfer the identifiable information?</td>
<td>How data is stored is outlined here <a href="https://www.alivecor.com/privacy/en/">https://www.alivecor.com/privacy/en/</a> AliveCor use Amazon Web services to host their data cloud. AWS maintains certification with robust security standards, such as ISO 27001, SOC 1/2/3 and PCI DSS Level 1. AWS is responsible for the security of the underlying Cloud infrastructure (Security of the Cloud) and AliveCor is responsible for the security of their data and applications (Security in the Cloud). AWS has teams of Solutions Architects, Account Managers, Consultants, Cloud Security Best Practices are followed.</td>
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<tr>
<td>Will individual's personal information be disclosed internally/externally in identifiable form and if so to who, how and why?</td>
<td>No, it will only be used in an identifiable form as part of the clinical record</td>
<td></td>
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<tr>
<td>Will personal data be transferred to a country outside of the European Economic Area? If yes, what arrangements will be in place to safeguard the personal data?</td>
<td>N/A</td>
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<tr>
<td><strong>Consultation</strong></td>
<td>Who should you consult to identify the privacy risks and how will you do this? Identify both internal and external stakeholders. <em>Link back to stakeholders on page 3.</em></td>
<td>The Innovation Agency (hosted by Lancs Care) is responsible for the distribution of the Kardia devices (the project is funded by NHS England). Distribution will be made through the 15 AHSNs. Risks have been discussed with all these parties and specific IG advise sought from Lancashire Care who have supported this guidance and IG lead at Guys and St Thomas’ Foundation Trusts.</td>
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<td>Following the consultation – what privacy risks have been raised? E.g. Legal basis for collecting and using the information, security of the information in transit etc.</td>
<td>Issues which have been raised are: the transfer of PID - Guidance issued to mitigate this and the transfer and storage of anonymous data outside the NHS (on Amazon Web servers).</td>
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</table>
Section 4 – Privacy issues identified and risk analysis

Identify the privacy and related risks (see Appendix 1 for further information)

Nb. By allocating a reference number to each identified privacy issue will ensure you link back to this throughout the rest of the assessment. Column (a), (b) and/or (c) must be completed for each privacy issue identified in column

<table>
<thead>
<tr>
<th>Ref No.</th>
<th>Privacy issue – element of the initiative that gives rise to the risk</th>
<th>Risk to individuals (complete if appropriate to issue or put not applicable)</th>
<th>Compliance risk (complete if appropriate to issue or put not applicable)</th>
<th>Associated organisation/corporate risk (complete if appropriate to issue or put not applicable)</th>
</tr>
</thead>
</table>
| PR1     | Individuals are not aware that their data is being processed and held outside the NHS | Individuals not aware that their data is being held outside the NHS by a third party | Non-compliance with DPA principle 1 – fair and lawful processing | May lead to public mistrust  
May lead to negative view of technology and NHS |
| PR2     | HCP do not adhere to guidance and add PID to their ECG readings | Identifiable data is being held outside the NHS, which has not been discussed with the individual | Non-compliance with DPA principle 1 – fair and lawful processing | May lead to sanction by the Information Commissioners office (ICO)  
May lead to legal challenge  
May bring programme AHSN and NHS E into disrepute  
May lead to public mistrust |
<table>
<thead>
<tr>
<th>Ref No.</th>
<th>Risk – taken from column (a), (b) and/or (c) in table 1.</th>
<th>Risk score – see tables at Appendix 2</th>
<th>Proposed solution(s)/mitigating action(s)</th>
<th>Result: is the risk accepted, eliminated, or reduced?</th>
<th>Risk to individuals is now OK? Signed off by?</th>
</tr>
</thead>
<tbody>
<tr>
<td>PR1</td>
<td>Individuals not aware that their data is being held outside the NHS by a third party. Non-compliance with DPA principle 1 – fair and lawful processing May lead to public mistrust May lead to negative view of technology and NHS</td>
<td>1 4</td>
<td>Guidance to be developed and implemented by AHSNs to ensure that all recipients of Kardia mobiles are aware of discussing this with patients. Information is made available to patients about how their data is stored. Implementation of this will be overseen by the Community of practice and steering group.</td>
<td>Reduced to an acceptable level (it is not possible to eliminate at this stage as the Guidance and implementation will need to ensure it addresses all aspects to enable individuals to be fully informed.</td>
<td>Lancashire Care IG lead AHSN National IG Steering Group Risks will be assessed regularly, with feedback from AHSNs</td>
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<tr>
<td>HCP do not adhere to guidance and add PID to their ECG readings</td>
<td>1</td>
<td>5</td>
<td>This will be mitigated by:</td>
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<tr>
<td>Identifiable data is being held outside the NHS, which has not been discussed with the individual</td>
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<td>Production and implementation of guidance</td>
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<td>Training provided with the guidance</td>
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<tr>
<td><em>Non-compliance with DPA principle 1 – fair and lawful processing</em></td>
<td></td>
<td></td>
<td>Internal organisation IG training</td>
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<td><em>May lead to sanction by the Information Commissioners office (ICO)</em></td>
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<td>Advising the organisation who employs the individual of the project and this issues involved</td>
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<td><em>May lead to legal challenge</em></td>
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<td></td>
<td>Communication provided in the environment on using the devices</td>
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<td><em>May bring programme AHSN and NHS E into disrepute</em></td>
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<td><em>May lead to public mistrust</em></td>
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Integrate the PIA outcomes back into the project plan  
*NB. This must include any actions identified in Table 1 and Table 2.*

Who is responsible for integrating the PIA outcomes back in to the project plan and updating any project management paperwork? Who is responsible for implementing the solutions that have been approved? Who is the contact for any privacy concerns which may arise in the future?

<table>
<thead>
<tr>
<th>Ref No.</th>
<th>Action to be taken</th>
<th>Date for completion of actions</th>
<th>Anticipated risk score following mitigation</th>
<th>Responsibility for action – job title not names</th>
<th>Current status/progress</th>
</tr>
</thead>
<tbody>
<tr>
<td>PR1</td>
<td>Guidance is developed</td>
<td>December 2017</td>
<td>1 2</td>
<td>Project Manager to develop guidance and communication for data controllers and users of the App</td>
<td>Guidance is developed and communication in progress. All AHSN leads are tasked with implementing this when they distribute the devices</td>
</tr>
<tr>
<td>PR2</td>
<td>Sign off and agreement Governance process</td>
<td>December 2017</td>
<td>1 3</td>
<td></td>
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</tbody>
</table>
The AHSN Network recommends the use of the Kardia BASIC app. The Premium app is provided free for the first 30 days or to users registered before 1/8/17. The Premium service will store any ECG traces taken locally on the mobile device. We advise all traces taken using the free premium app are deleted to prevent this. NO PATIENT IDENTIFIABLE DATA SHOULD BE ADDED TO ANY TRACES. Ignore prompts to upgrade to premium.
Appendix 2

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

During your appointment today your pulse rhythm was checked using an AliveCor Kardia Mobile 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 healthcare professional will add information about the ECG outcome to your local electronic health record.

- Your health care professional should use the BASIC KardiaMobile app, which prevents the storage of any ECG traces within the app on the smartphone or table 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 Mobile device are uploaded into the AliveCor servers in Germany. Each ECG has an 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.

If you have any questions, please discuss with your health care professional.