



An adaptation for NHSScotland of guidance published by the National Institute for Health and Care Excellence

KardiaMobile® for detecting atrial fibrillation

Recommendation for NHSScotland

Single-lead KardiaMobile® is recommended as an option for detecting atrial fibrillation (AF) for people with suspected paroxysmal AF, who present with symptoms such as palpitations and are referred for ambulatory electrocardiogram (ECG) monitoring by a clinician.

The Scottish Health Technology Group (SHTG) recommendation is based on [guidance produced by the National Institute for Health and Care Excellence \(NICE\) in 2022](#).¹ This guidance was considered and modified following an SHTG adaptation process. NHSScotland is required to consider SHTG recommendations.

What were we asked to look at?

KardiaMobile® is a portable, credit-card sized, electrocardiogram (ECG) recorder for detecting atrial fibrillation (AF).

The [National Planning](#) team within NHSScotland have previously identified AF as an area that would benefit from further exploration. Following the publication of the NICE Medical Technologies Guidance on KardiaMobile® in January 2022, SHTG contacted clinical experts to investigate if there was interest from the clinical community for an adaptation of this guidance for NHSScotland. Clinical experts agreed that there would be value in producing adapted guidance, and this was supported by policy managers responsible for heart disease and stroke care within the Scottish Government.

Why is this important?

Medical technologies that permit ambulatory monitoring in patients with AF, or suspected AF, are rapidly evolving. An assessment published by [SHTG in May 2021](#) highlighted that this has led to variation in clinical practice, making it harder to ensure a consistent approach across NHSScotland. Guidance around the clinical effectiveness, cost effectiveness, safety and appropriate use of these technologies will help to ensure an effective and more consistent approach to care.

What was our approach?

We conducted an SHTG adaptation based on a review of guidance produced by [NICE in January 2022](#).¹ The European Network for Health Technology Assessment (EUnetHTA) adaptation toolkit was used to assess the relevance, reliability and transferability of the NICE guidance.

As part of the adaptation process, the views, perspectives and experience of topic experts were obtained via three rounds of questioning. The first draft of the SHTG adaptation was distributed to topic experts, along with a survey. The experts were asked to consider whether the NICE recommendations were appropriate for Scotland and if so, whether they should be adopted with no changes, or adapted to make them more relevant to the NHSScotland context.

Based on the responses received, the draft SHTG adaptation document was reviewed. A revised draft, along with anonymised responses to the first round of questioning, was returned to the experts for a second round of questioning. Further changes were made to the draft based on the responses received.

Topic experts' comments are captured within the SHTG adaptation including a detailed summary from each round of questioning. All experts' comments were available for consideration by SHTG Council to inform final recommendations.

What next?

SHTG's Recommendations on KardiaMobile® will be circulated to Scottish cardiac managed clinical networks, health boards and the Cardiovascular Risk Factor Subgroup of the Scottish Government's National Heart Disease Task Force (who have taken over the work of the AF group within National Planning).

Key points

1. It is estimated that 2.6% of the Scottish population, which is around 143,000 people, have AF. Many people remain undiagnosed and up to 40% of people with AF are asymptomatic.
2. The single-lead KardiaMobile® device has two electrodes on the top surface. When a person wants to record their ECG (for example, when they experience symptoms) they place two fingers from each hand on one of the electrodes. KardiaMobile® works with a compatible smart mobile device to run the KardiaMobile® app. The ECG recording is sent wirelessly to the mobile device, where it can be viewed on the app. After the ECG trace is closed by the user, and when the device has a Wi-Fi or mobile connection, the recording synchronises with a secure cloud server. The ECG trace can be forwarded to a healthcare professional.
3. Clinical evidence shows that significantly more people have AF detected using the KardiaMobile® single-lead device compared with standard care. The definition of standard care varies in the literature, and includes 24-hour Holter monitoring. The evidence base for KardiaMobile® is strongest in people with undiagnosed palpitations and people with a history of AF who need to monitor for AF recurrence.
4. Cost calculations demonstrate that, compared with Holter monitoring, KardiaMobile® has the potential to be cost saving over 2 years in people presenting with symptoms such as palpitations. Cost savings were driven by earlier diagnoses, which reduced follow-up assessments and adverse events costs.
5. When used for monitoring for the recurrence of AF in a population at a low risk of having a stroke, KardiaMobile® was estimated to be associated with an additional cost over 10 years compared with Holter monitors.
6. Most people find KardiaMobile® easy to use, but use relies on having access to a smartphone or device. There are barriers to use for some people, including those who cannot remain still for 30 seconds, those who do not have access to Wi-Fi, or those who have little/no experience of using smartphones or similar technologies.
7. There are several different technologies for ambulatory ECG monitoring available in NHSScotland. These often have to be fitted by a trained healthcare professional and worn continuously by a user for a limited period of time. KardiaMobile® does not need to be fitted and can be posted out to patients. KardiaMobile® has the potential to reduce use of ambulatory monitors and associated hospital appointments.

SHTG Council considerations

When formulating their recommendations, the Council took into account the NICE guidance and the evidence review underpinning it, and the views of the Scottish topic experts.

1. The Council noted that the 6-lead KardiaMobile® device (KardiaMobile-6L®) has extra functionality compared with the single-lead device. For example, the single-lead KardiaMobile® device sends the ECG recording wirelessly to a smartphone using high frequency sound waves, whereas the six-lead device uses Bluetooth which may be less influenced by background noise. The Council agreed that because the clinical and cost effectiveness evidence in the NICE guidance was only on the single-lead device, that the recommendation for NHSScotland should be limited to the single-lead device.
2. The Council accepted that most people find KardiaMobile® easy to use, and that the technology has the potential to improve access to care particularly for people in remote and rural areas. Consideration needs to be given to ensure equity of access across all populations. For example, where necessary, access to a smart device should be provided alongside KardiaMobile® to ensure otherwise eligible people are not excluded.
3. The Council felt that further consideration needs to be given to the impact of KardiaMobile® on the workload of healthcare professionals using the device. Devices like KardiaMobile® have the potential to reduce overall hospital appointments. KardiaMobile® traces may be quicker to analyse than the extensive data produced from some other ambulatory ECG monitors, yet provision of KardiaMobile® may make workloads less predictable compared to other types of monitors, and there may be training requirements for some professional groups (for example, staff in primary care).
4. There is no definitive guidance in the UK on whether a diagnosis of AF should rely on a standard 12-lead ECG recording. The Council noted guidelines from the European Society of Cardiology, which state that a single-lead ECG tracing of ≥ 30 seconds or 12-lead ECG showing AF analysed by a physician with expertise in ECG rhythm interpretation is necessary to establish a definitive diagnosis of AF.

Introduction

SHTG recommendations on the use of KardiaMobile® are based on a review of Medical Technologies Guidance produced by [NICE in January 2022](#).¹ This adaptation document summarises the information that was used to inform SHTG's recommendations.

Eleven topic experts from Scotland were consulted in the development of the recommendations for NHSScotland, including providing comments on the draft adaptation document.

Health technology description

KardiaMobile® is a portable, credit-card sized ECG recorder for detecting AF in adults. It is available as a single-lead or six-lead device. The single-lead device has two electrodes on the top surface. When a person wants to record their ECG, they place two fingers from each hand on the electrodes. The six-lead device has three electrodes, two on the top and one underneath. The one underneath is placed in connection with the left leg. The default length of a recording is 30 seconds although this can be extended up to 5 minutes. The device may be used at various time points during the day and/or when the user experiences symptoms. All available published evidence is on the single-lead KardiaMobile® device.

KardiaMobile® works with a compatible smart mobile device to run the KardiaMobile® app. The ECG recording is sent wirelessly to the mobile device, where it can be viewed on the app. The app classifies the ECG trace as either 'normal', 'possible AF', 'tachycardia', 'bradycardia' or 'unclassified'. Traces may be classified as unreadable if the ECG data cannot be interpreted because of possible interference. NICE reported that in studies, the proportion of ECG recordings deemed unreadable by the automated detection software was low (<2%). The proportion of ECG recordings unclassified by the software ranged between 9.6% and 27.6% but this has likely decreased over time, in line with software updates.² ECG data can be saved as a PDF file and emailed to healthcare professionals. People do not need internet access to record the ECG trace and to get the automatic ECG classification. When the device is connected to the internet, recordings automatically synchronise with a secure encrypted cloud service.

KardiaMobile® instructions for use state that all automated interpretations of ECG recordings should be reviewed by a healthcare professional and used to support clinical decision making. The NICE supporting documentation states that the KardiaMobile® output is not intended to be used as a standalone test to confirm the presence of AF but to help detect AF.²

NICE report that the single-lead KardiaMobile® device costs £82.50 (excluding VAT), and the six-lead device costs £124.20 (excluding VAT).² There is no additional cost for the KardiaMobile® app.

NICE diagnostics guidance (DG35, 2019) evaluated the use of single-lead ECG devices (including KardiaMobile®) for detecting symptomatic AF using single-time point testing in primary care.³ Single-time point detection of AF is not included in the scope of this assessment.

Epidemiology and predicted volume

AF is the most common sustained cardiac arrhythmia.¹ In 2016, 96,367 people in Scotland had been diagnosed with AF. Many people remain undiagnosed, and it is estimated that 2.6% of the Scottish population have AF, which is around 143,000 people.⁴

People with AF may present with breathlessness, heart palpitations, dizziness, fatigue or temporary loss of consciousness. The frequency and severity of symptoms fluctuates between people and can fluctuate over time in an individual. AF can be paroxysmal (intermittent). As many as 40% of people with AF do not have any symptoms. People with untreated AF have a five times increased risk of stroke relative to healthy controls without AF.⁴ The Heart Disease Action Plan, produced by the Scottish Government (2021), includes the detection, diagnosis and management of AF (amongst other risk factors) as priority areas.⁵

Adaptation toolkit

A robust and exhaustive [external assessment centre report](#) was prepared to inform the NICE guidance, which includes a synthesis of the clinical effectiveness and cost effectiveness evidence.² A [summary of the evidence](#) is also provided within the NICE documentation.

The European Network for Health Technology Assessment (EUnetHTA) adaptation toolkit was used to assess the relevance, reliability and transferability of the evidence. The toolkit focuses on five domains of a health technology assessment report:

- the use of the technology
- safety
- effectiveness
- economic evaluation
- organisational elements

No significant issues relating to relevance, reliability and transferability of the evidence underpinning the NICE guidance were identified via the toolkit. Other issues identified via the toolkit are described in the following sections.

Adverse events

NICE reports that adverse events associated with KardiaMobile® are unlikely, although clinical interpretation of all recorded ECGs is required to limit the possibility and impact of false negative and false positive results.

No adverse event reports for KardiaMobile® are listed in the UK Medicines and Healthcare products Regulatory Agency (MHRA) database.

NICE also searched the US Manufacturer and User Facility Device Experience (MAUDE) database, and identified eight adverse events.

- Five were cases where KardiaMobile® classified the ECG as normal sinus rhythm but the patient had a heart attack.
- One reported on a false positive for AF detection (causing patient anxiety).
- One reported a case where a patient's output displayed double the heart rate as a result of T-wave sensing.
- One reported on a patient who frequently had unclassified readings from the app (thought to be because of a low heart rate).

An update search of the MAUDE database was conducted on 17 March 2022 and no additional adverse event reports were identified.

Ease of use for patients and patient satisfaction

NICE identified nine studies which reported on the ease of use of KardiaMobile®. Together these suggest that most people (studies reported figures of 87% to 100%) find the device easy to use, with potential benefits including increased quality of life. One study reported that 52% of participants needed frequent reminders to transmit their ECG daily over a 6 month monitoring period.

NICE's public involvement programme conducted an online survey, to which 141 people responded.² The majority of respondents (89.4%) found KardiaMobile® easy to use. While most respondents found it straightforward to transfer the ECG trace to health care professionals, 8% reported that they found it quite difficult. Of the respondents who had used other ECG monitors (43.3%), they reported that KardiaMobile® was more compact, more convenient and provided instant feedback compared with other monitors.

Organisational issues / context

KardiaMobile® has the potential to increase the number of people diagnosed with AF, reduce the time to their diagnosis, and to provide reassurance for people in whom AF can be excluded.

There are several different technologies for ambulatory ECG monitoring available in NHSScotland, including Holter technologies, external loop recorders and patch devices. These devices are generally worn continuously by users for a period of time (for example, 24 hours, 48 hours, 7 days), and the data they record is downloaded and analysed by a trained healthcare provider, usually a cardiac physiologist. The devices often need to be fitted by a trained healthcare provider, and the analysis of the data they produce can be resource intensive. KardiaMobile® can be used to record ECGs daily (or more frequently), and/or when a user experiences symptoms. It also offers the opportunity to record ECGs over a longer period of time compared to other commonly-used ambulatory monitors. This would be beneficial for people with relatively infrequent symptoms of palpitations (less than once a week). While the output from one KardiaMobile® trace would generally be quicker and easier to analyse than the extensive data that can be produced from ambulatory ECG monitors, in reality, some users will generate numerous traces each day, and potentially over an extended period of time. The impact of increased use of KardiaMobile® on the workload of healthcare professionals, such as cardiac physiologists, is not clear.

AF detection technologies are evolving rapidly. Topic experts in Scotland stated that there is variation in the use of the technologies for ambulatory ECG monitoring across NHSScotland. KardiaMobile® is already used in both primary and secondary care, for example in cardiology clinics, although uptake is described as 'patchy'. NHS Lothian have been running a smartphone palpitation service since 2019.^{6,7} People are also choosing to buy the device directly from retailers.

NICE consulted with seven healthcare professionals who currently use KardiaMobile® (including a general practitioner, three consultant cardiologists, a nurse specialist, a professor in cardiovascular nursing and a pharmacist). KardiaMobile® was reported as straightforward to use, with no major organisational, logistical or IT issues. It was flagged that KardiaMobile® requires ECG interpretation skills, and so there may be a training requirement for non-specialists. The need to consider information governance issues around emailing and sharing patient data was also noted.

Similarly, topic experts consulted in the development of this recommendation for NHSScotland reported that KardiaMobile® was easy to use for most people, reliable (provided results were interpreted by a clinician) and had the potential to reduce waiting times. Questions were raised around training requirements for both clinicians and patients, the handling of the data generated by these devices and information governance issues. Two topic experts noted that traces used for clinical decision making should form part of the patient's clinical record. The safe and effective use of KardiaMobile® is dependent on clinical review of ECG traces before treatment decisions are made. Currently in Scotland, clinical ambulatory ECGs deployed for palpitations (including those generated via KardiaMobile®) are normally interpreted by highly specialist cardiac physiologists. This raises questions around changes to workload, and also about the appropriateness and feasibility of the use of KardiaMobile® in settings such as primary care.

Where does KardiaMobile sit in the current diagnostic pathway?

The eligible population considered in the NICE guidance was adults (18 years or older) with known or suspected AF who were referred for ambulatory ECG monitoring by a clinician in primary, secondary or tertiary care. The NICE supporting documentation states that the evidence base for KardiaMobile® is strongest in people with undiagnosed palpitations and people with a history of AF who need to monitor for AF recurrence.²

Scottish topic experts suggested that KardiaMobile® would not replace existing technologies, but should be an additional option within the current standard of care in NHSScotland. KardiaMobile® has the potential to reduce hospital appointments and demand for ambulatory Holter monitors.

There is no definitive guidance in the UK on whether a diagnosis of AF should be from a standard 12-lead ECG recording or a single-lead ECG tracing of >30 seconds. Guidelines from the European Society of Cardiology state:

When AF is detected by a screening tool, including mobile or wearable devices, a single-lead ECG tracing of ≥ 30 [seconds] or 12-lead ECG showing AF analysed by a physician with expertise in ECG rhythm interpretation is necessary to establish a definitive diagnosis of AF (devices capable of ECG recording enable direct analysis of the device-provided tracings).⁹

12-lead ECGs provide more detail, and one topic expert highlighted that 'normal sinus rhythm' on KardiaMobile® is not the same as 'normal sinus rhythm, normal ECG' on a 12-lead ECG. This is of particular importance as patients need to be aware that KardiaMobile® does not detect heart attacks.

Equalities considerations

There are barriers to the adoption of this technology in some groups of people.

KardiaMobile® is not approved for use in children and must not be used in adults with cardiac pacemakers, implantable cardioverter-defibrillators or other implanted electronic devices.

People are not able to use KardiaMobile® if they do not have a compatible smart device to access the app. The proportion of patients without access to this technology may be higher in some groups, for example older people (who are the greatest risk of AF) or those with lower income. The KardiaMobile® app may not be useable by people with visual impairments, people without access to the internet, or people who have limited or no experience of smart devices.

KardiaMobile® may not be suitable for people who cannot remain still or have problems holding the device; for example, people with a tremor may have difficulty recording an accurate trace. It also only works for people who have digits on both their right and left hand with reasonable circulation.

The app is available in several languages, but not in some which are spoken in Scotland, for example, Punjabi and Urdu.

Summary of Scottish topic experts' survey responses

Full details on the questions asked, and the responses received, can be obtained from SHTG on request.

Eleven topic experts responded to the first round of questioning (see acknowledgements below). The key issues raised are summarised as follows:

- All eleven experts strongly agreed or agreed with the NICE recommendations, and all said that the advice for NHSScotland should support the case for KardiaMobile® in people with suspected paroxysmal AF, who present with symptoms such as palpitations. Ten said that the NICE guidance was based on an accurate interpretation of the evidence. One was undecided as they did not go through all the included studies.
- One expert suggested that the recommendation was changed to 'single-lead' KardiaMobile®. Given that all the published evidence relates to the single-lead KardiaMobile® device, this change was made. The SHTG Council discussed and supported this change (see 'SHTG Council Considerations').
- Three experts said that this technology should be used as part of a service for patients with suspected intermittent arrhythmia.
- One expert noted that in order to not exclude certain groups of people, smart devices may need to be made available on loan. Another expert requested consideration of the broader health inequalities agenda and noted that implementation of a new process would require a robust equality impact assessment.
- One expert highlighted that when KardiaMobile® is used patients are often required to attend a physiologist appointment. This enables patients to take better quality recordings. If the technology is to be posted out, the expert suggested that a follow-up telephone call, practice tracing or option to join a group training session may be helpful.
- Topic experts were in agreement that KardiaMobile® should be an additional option within the current standard of care in NHSScotland.
- Topic experts felt that patients want portable ECG monitors to be free/cheap, discreet, easy to use, reliable and rapidly available. ECG monitors should enable communication with healthcare professionals, speed up diagnosis and treatment and reduce hospital appointments.
- Topic experts suggested that KardiaMobile® had the potential to empower patients, allowing them to monitor their symptoms with minimum disruption to their daily lives. It may ensure more timely treatment and/or provide reassurance to users.
- One topic expert advised that there are only three specialist nurses in AF in Scotland.

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References can be accessed via the internet (where addresses are provided), via the NHS Knowledge Network www.knowledge.scot.nhs.uk, or by contacting your local library and information service.

A glossary of commonly-used terms in HTA is available from htaglossary.net.

Acknowledgements

SHTG Executive would like to thank the following individuals who provided comments on the draft adaptation document and recommendation.

- Ms Kylie Barclay, Senior Policy Manager, Scottish Government
- Dr Ronnie Burns, General Practitioner, NHS Greater Glasgow and Clyde
- Professor Martin Dennis, Professor of Stroke Medicine, The University of Edinburgh
- Ms Morven Dunn, National Cardiac Audit Coordinator, Public Health Scotland
- Dr Neil Grubb, Consultant in Cardiac Electrophysiology, NHS Lothian
- Dr David Murdoch, Consultant Cardiologist, NHS Greater Glasgow and Clyde
- Dr Rachel Myles, Clinical Senior Lecturer, University of Glasgow and Honorary Consultant Cardiologist, NHS Greater Glasgow and Clyde
- Professor Lis Neubeck, Professor of Cardiovascular Health in the School of Health and Social Care, Edinburgh Napier University
- Professor Matthew Reed, RCEM Professor; Consultant and NRS Fellow in Emergency Medicine, NHS Lothian; Research Director Emergency Medicine Research Group Edinburgh; Honorary Reader, Acute Care Edinburgh, Usher Institute, University of Edinburgh

SHTG Executive would like to thank the following organisations who provided comments on the draft adaptation document and recommendation:

- Ms Trudie Lobban, Founder of non-profit organisation, Arrhythmia Alliance / AF Association and STARS (Syncope Trust)
- Mr Richard Forsyth, Health Systems Insight Manager, The British Heart Foundation

Declarations of interest were sought from all reviewers. All contributions from reviewers were considered by the SHTG Evidence Review Team and the SHTG Council. However, reviewers had no role in authorship or editorial control and the views expressed are those of Healthcare Improvement Scotland and the SHTG Council.

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SHTG Executive would like to thank the following individuals on the SHTG Evidence Review Team who provided comments on the draft review which were considered by the authors:

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SHTG Executive would like to thank the following individuals on the SHTG Council for developing the recommendation for NHSScotland:

- Dr Paul Campbell, Council Vice Chair, Clinical Director, Clinical Informatics, National Services Scotland
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- Mr Mark Cook, Director of Re-imburement and Government Affairs, Association of British Healthcare Industries
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- Dr Karen Facey, Evidence Based Health Policy Consultant
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- Ms Alison Harrison, Healthcare Quality and Improvement Directorate, DG Health and Social Care, Scottish Government
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Published 20 July 2022

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Suggested citation: Kelly, J; Aslam, U; Berg, G; Kandulu, J; Michael, M; Stewart, J. (2022). *KardiaMobile® for detecting atrial fibrillation. Glasgow/Edinburgh. NHS Healthcare Improvement Scotland.*

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