NICE National Institute for Health and Care Excellence

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

THEME: Data on device accuracy included in the assessment

Comment number	Name and organisation	Section number	Comment	NICE response
1	NHS England	4. Evidence. 4.6 Quality assessment of diagnostic accuracy studies	The EAG judged that all 9 studies in the diagnostic accuracy review had an "unclear risk of bias and a high level of concern for applicability". The 2017 European Heart Rhythm Association (EHRA) consensus Document on screening for atrial fibrillation (Mairesse et al 2017), note the risk of bias to be high for the study by Desteghe and colleagues (2017). **Reference for EHRA article:** Mairesse GH, Moran P, Van Gelder IC, Elsner C, Rosenqvist M, Mant J, et al. Screening for atrial fibrillation: a European Heart Rhythm Association (EHRA) consensus document endorsed by the Heart Rhythm Society (HRS), Asia Pacific Heart Rhythm Society (APHRS), and Sociedad Latinoamericana de Estimulacion Cardiaca y Electrofisiologia (SOLAECE). Europace. 2017;19(10):1589-623.	Thank you for your comment which the committee considered. The external assessment group (EAG) explained that the risk of bias tool used in Mairesse et al. (2017) was the Cochrane risk of bias tool (according to the appendix table). The EAG used the QUADAS-2 assessment of diagnostic test accuracy studies to assess Desteghe et al. These tools assess different aspects of the studies and therefore the risk of bias judgement for the study can differ depending on the tool used. The committee decided not to change the guidance document.
2	Cardiocity Limited	3.4	Kardia device never confirms a case of AF, merely suggests it is possible AF and does not distinguish between PVC's and AF thus confusing the issue and leading to a high number of PVC's being reported as possible AF.	Thank you for your comment which the committee considered.

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

THEME: Data on device accuracy included in the assessment

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				Section 3.4 of the guidance document notes that the Kardia Mobile's app can classify an ECG trace as normal, possible atrial fibrillation detected or unclassified. Section 5.3 of guidance document describes the committee's conclusion that it is important that decisions about treatment based on lead-I ECG traces are made only after review by a trained healthcare professional. The committee decided not to change the guidance document.
3	Cardiocity Limited	3.12	Cardiocity conducted the NIHR registered SLAF trial which generated a 6 lead and 1 lead ECG at the same time as the patient undertook a 12 lead ECG when a GP referred a patient to secondary care for a 12 lead Hospital, this trial data has been excluded from this study, but actually gave you same time 12 lead and leadI ECG analysis.	Thank you for your comment which the committee considered. The RhythmPad GP device has been removed from this guidance; please see section 3.1 of the guidance document.
4	Cardiocity Limited	4.1	The SLAF trial at St Peter's hospital generated exactly the data you claim is not available.	Thank you for your comment which the committee considered. The RhythmPad GP device has been removed from this guidance; please

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

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				see section 3.1 of the guidance document.
5	Cardiocity Limited	4.4	The Crockford study of 2013 was a paper presentation comparing off the market algorithms and not the algorithm within the RhythmPadGP product and as such this has skewed your data considerably.	Thank you for your comment which the committee considered. The RhythmPad GP device has been removed from this guidance; please see section 3.1 of the guidance document.
6	Cardiocity Limited	4.5	The performance of the algorithms in the Crockford study of 2013 looked at commercially available algorithms and not the algorithm utilised in the RhythmPadGP.	Thank you for your comment which the committee considered. The RhythmPad GP device has been removed from this guidance; please see section 3.1 of the guidance document.
7	Cardiocity Limited	4.32	Reads “An exception was for RhythmPad GP which had accuracy data based only on algorithm interpretation (although the available study did not use the device’s commercially available algorithm to produce these results” so why then have you included these unrelated sensitivities and specificities in Table 5?	Thank you for your comment which the committee considered. The RhythmPad GP device has been removed from this guidance; please see section 3.1 of the guidance document.
8	Cardiocity Limited	4.32	Cardiocity undertook 3 NHS trials over the years where the sensitivity and specificity of their developed algorithms were verified against analysis by a Cardiologist, but you have rejected these papers as being out of scope as they also contained our 6 lead performance data. To publish our sensitivity and specificity as you have in Table 5 is not only factually incorrect	Thank you for your comment which the committee considered. The RhythmPad GP device has been removed from this guidance; please

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

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				see section 3.1 of the guidance document.
9	Cardiocity Limited	5.5	Reads - *The company who makes RhythmPad GP explained that the accuracy estimates included by the EAG for RhythmPad GP were taken from a study that used the device with a different algorithm to that used currently and were not considered transferable. The EAG advised the committee that these were the only published data on the use of this device as a lead-I ECG.* We have up to date trials data published but this is for our 6 lead operation, the 1 lead data is in there but the EAG have rejected these papers. It beggars belief that the EAG are so commercially naïve as to accept that the 2013 paper uses different algorithms and then proceed with the publication of their incorrect assessment of the sensitivity and specificity of the device. But I suspect they are academics with no real world commercial experience.	Thank you for your comment which the committee considered. The RhythmPad GP device has been removed from this guidance; please see section 3.1 of the guidance document.

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

THEME: Population and setting the devices are assessed in

Comment number	Name and organisation	Section number	Comment	NICE response
10	Anticoagulation UK	5.2	Devices could be used in care homes (by managing clinicians) to aid detection of AF when irregular pulse detected but patients are unable to express/ describe any symptoms.	Thank you for your comment which the committee considered. The guidance does not specify that the testing has to be done in a GP surgery, it could be done in a care home or a patient's home during a home visit by a primary health care professional if an irregular pulse is detected during the clinical examination. The committee decided not to change the guidance.
11	Anticoagulation UK	General	Equality issues – With a growing aging population, early diagnosis is essential to protect the patient from debilitating AF stroke risk. People who are cognitively impaired or unable to communicate may benefit from the lead 1 diagnostic intervention which can be undertaken in a primary care setting, in the patients home or within the care setting in the first instance.	Thank you for your comment which the committee considered. The committee noted that the devices are also intended to be used to aid early diagnosis, but noted that population screening is outside of the scope of this assessment. This comment has been considered within the equality impact assessment for this guidance. The committee decided not to change the guidance.

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

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12	AHSN Network	Page 2 section 1	Up to 40% of all Atrial Fibrillation (AF) is asymptomatic, if this AF is paroxysmal, then patients are more likely to receive inadequate treatment making their risk of stroke higher. According to Estato et al (2017) 'Asymptomatic clinical status is associated with older age, male sex, more co-morbidities with a higher stroke risk profile, and a higher incidence of all-cause death in patients with Paroxysmal AF; these characteristics and outcomes were not seen in the Sustained AF group.' Therefore, in only considering the use of single lead ECG devices in patients with symptomatic AF the potential impact of these devices on preventing AF related strokes is not being fully realised. It is not reflective of the daily reality in clinical practice and the need to improve detection of AF in this cohort. Waiting for symptoms to appear is not a good way to manage this condition and opportunistic testing is therefore of value. We suspect this is a result of the NICE screening committee's 2014 decision not to recommend systematic screening for AF in the over 65's, however it is time this was reviewed for the following reasons: - There is no evidence to suggest the risk of an AF related stroke is less in the asymptomatic patient.	Thank you for your comment which the committee considered. Use of the devices for screening for atrial fibrillation in people without symptoms was outside the scope of the assessment, and falls under the remit of the UK National Screening Committee rather than NICE. Please see section 1.1 of the diagnostics assessment programme manual https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-diagnostics-guidance/Diagnostics-assessment-programme-manual.pdf. The recommendations in section 1 of the diagnostics consultation document and guidance document do not recommend doing a manual pulse palpation. The assessment related to the use of the lead-I ECGs after an irregular pulse was detected, and advice from clinicians suggested that manual pulse palpation would always be done as part of the assessment of people reporting symptoms of atrial fibrillation.

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

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			- In 2014 adequate anticoagulation pathways were not routinely in place across the NHS, work to improve this since then has seen the rate of anticoagulation those with a CHA_2Ds_2-VaSc score of >2 increase (now nationally at 84% QOF 2017/18), suggesting this issue is being addressed. - The use of single lead ECG device technology to preform pulse checks provides a more sensitive and specific result for AF than a manual pulse palpation. - The recent increases in DOAC prescribing over Warfarin has led to improved patient acceptance and adherence of anticoagulation therapy - The European Society of Cardiology recommend the systemic screening of AF in the over 75s. We feel that the recommendation to carry out a manual pulse palpation prior to the use of Kardia Mobile is unnecessary, it is a duplication of effort that can be ill afforded in a time pressured primary care clinic. As many of these devices have been proven to be more sensitive and specific for AF than manual pulse palpation this recommendation risks an AF diagnosis being missed. The resulting PDF trace from the use of a Kardia can also be added to the patients notes, this provides a huge reassurance	The committee decided not to change the guidance document.

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

THEME: Population and setting the devices are assessed in

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			when confirming the diagnosis in those patients with paroxysmal AF. This document relates to the use of single lead Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care, however it appears that definition of primary care in this instance pertains solely to general practice. Since Jan 2018, the 15 Academic Health Science Networks (AHSNs) have been undertaking a project designed to investigate the suitability and uptake of these devices in a wider range of community and primary care settings. Although the results of this study are due to be published in the Summer of 2019, anecdotal reports suggest that their use in a broader variety of Allied Health settings (such as Podiatry, Community Pharmacy, Optometry and Community Nursing) has proved beneficial in the identification of people with AF, especially in those with other comorbidities who may not routinely visit their GP, but who do access other healthcare services, or are housebound.	
13	AHSN Network	Page 35 section 5.7	The cost effectiveness modelling appears to have a narrow focus and is assuming GPs are the only health care professional who would use this technology. We would suggest revising this theory.	Thank you for your comment which the committee considered. Section 5.7 of the diagnostics consultation document refers to the EAG's use of data on the number of people per GP to estimate the costs of

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

THEME: Population and setting the devices are assessed in

Comment number	Name and organisation	Section number	Comment	NICE response
				the devices per patient. The guidance does not specify that the testing has to be done in a GP surgery, it could be done in a care home or a patient's home during a home visit by a primary health care professional if an irregular pulse is detected during the clinical examination. Use of the devices for population screening for atrial fibrillation in people without symptoms was outside the scope of the assessment, and falls under the remit of the UK National Screening Committee rather than NICE. Please see section 1.1 of the diagnostics assessment programme manual: https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-diagnostics-guidance/Diagnostics-assessment-programme-manual.pdf
14	AHSN Network	Page 39 Section 6.1	This further research should also include opportunistic testing for people without symptoms.	Thank you for your comment which the committee considered. Use of the devices for population screening for atrial fibrillation in people without symptoms was outside the scope of the assessment, and falls under the remit of the UK National Screening Committee rather than NICE. Please see section 1.1 of the diagnostics assessment programme manual: https://www.nice.org.uk/Media/Default/About/what-

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

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				we-do/NICE-guidance/NICE-diagnostics-guidance/Diagnostics-assessment-programme-manual.pdf The committee decided not to change the guidance document.

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

THEME: Test costs included in model

Comment number	Name and organisation	Section number	Comment	NICE response
15	NHS England	5.7 Cost effectiveness	The EAG conclude the uncertainty around how ECGs will be generated in primary care would be interpreted in practice and therefore the time and staff costs associated with lead-I ECG implementation is also therefore uncertain. It is likely that the specific type and method of reimbursement for the care provider will influence the implementation of this device use in 'real-world' practice. Perhaps this should be referenced in the consensus document.	Thank you for your comment which the committee considered. The committee noted that there is uncertainty about how lead-I ECGs generated in primary care would be interpreted in practice, and therefore the effect on staff time and costs associated with introducing lead-I ECGs into primary care (described in section 5.8 in the guidance document). Further research was recommended to assess this. In section 6.2 of the guidance document the committee recommended that data should be collected to evaluate the system impact of adopting the lead-I ECGs on both primary and secondary care. In particular, data should be collected on how ECGs generated by the devices would be interpreted in practice, including staff time needed to interpret the ECG traces and associated costs.

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

THEME: Test costs included in model

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				The committee decided not to change the guidance document.
16	AHSN Network	Pg.26 Section 4.36	Top paragraph. Is this cost related to Holter monitoring for 7 days?	Thank you for your comment which the committee considered. The EAG confirmed that this cost does relate to Holter monitoring for 7 days. This has been clarified in section 4.36 of the guidance document.
17	Cardiocity Limited	4.35	Table 6 shows RhythmPadGP as having a 1 year lifespan, this is incorrect, we recommend the device is professionally cleaned after a 12 month use period. The CE certified lifespan of the product is 5 years.	Thank you for your comment which the committee considered. The RhythmPad GP device has been removed from this guidance; please see section 3.1 of the guidance document.
18	Cardiocity Limited	4.35	Table 6 shows the RhythmPadGP as costing £1100 the RRP for the pad is now £399 not £1100	Thank you for your comment which the committee considered. The RhythmPad GP device has been removed from this guidance; please see section 3.1 of the guidance document.
19	Cardiocity Limited	4.44	The costings for the Smartphone or Tablet accompanying the KardiaMobile device do not include the minimal operating costs such as line rental, data etc nor do they take into consideration the costs of processing the data.	Thank you for your comment which the committee considered. The EAG explained that the threshold analysis done for the cost of the Kardia Mobile described in section 4.44 would also

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

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				assess the impact of any additional costs, including additional data related costs. Section 4.44 of the guidance document has been changed to reflect this.
20	MyDiagnostick Medical BV		We reviewed again the NICE report on lead-1 ECG, and revised our offering. We will realise a private cloud exclusive for NHS, to serve the physicians with upload/download data from MyDiagnostick, possible statistics, patient compliance and data reporting. This cloud service is based on CE (medical device class 2A) and FDA approved cloud services, and satisfies the EU privacy laws. Available within 6 months after the NHS order. Also, we can offer a wireless connection between MyDiagnostick and the current MyDiagnostick Management Studio software, and future cloud. Realisation of the NHS exclusive cloud will cost one-time 185000 Euro, for use with an unlimited number of MyDiagnostick devices in the UK. **At an order of 6000 devices, pricing (euro's, per device) is as follows (ex. VAT)**: MyDiagnostick with wireless connectivity (BT)	Thank you for your comment which the committee considered. The EAG re-ran the base case economic analysis using the proposed price of the device and software cloud solution, and assuming a lifetime of 10 years in an addendum to their report. The committee noted that this decreases the costs associated with using the MyDiagnostick but does not have a qualitative effect on the pairwise cost effectiveness analysis. Section 4.43 in the diagnostics guidance document has been amended to reflect this. The committee concluded that although there is plausible potential for the lead-I ECG devices to be cost effective when used for single time point testing in primary care (for people with signs and symptoms of atrial fibrillation with an irregular pulse), there was insufficient evidence at present to determine if the predicted benefits of using the devices

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

THEME: Test costs included in model

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			€165 MyDiagnostick as is now (USB wire) €160 Software cloud solution per device per month €6 We can offer swap warranty for MyDiagnostick at 10 years. The warranty for the BT adaptor is fixed at 3 years. Putting the figures together gives the following depreciation / cost overview, per device: **Warranty (in years):** **10** Depreciation of MyDiagnostick (with BT) per year €16,50 Cloud expense per year per device €72 Total (euro's) €88,50 **Total (GBP)** **€**76,56 Depreciation of MyDiagnostick (as is) per year €16	would be realised in practice (see section 5.12 of the diagnostics guidance document).

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

THEME: Test costs included in model

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			Cloud expense per year per device €72 Total (euro's) €88 Total (GBP) £76,12 Including VAT (GBP) £91,34	

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

THEME: Results of economic analysis

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21	Cardiocity Limited	4.43	States In fully incremental analyses across all the base cases, all lead-I ECG devices were dominated by Kardia Mobile – this should not be presented in this manner as it suggest that the committee are finding for Kardia Mobile.	Thank you for your comment which the committee considered. Detail on how expected cost-effectiveness results are presented in NICE diagnostics assessment programme assessments is explained in the diagnostic assessment programme manual, section 15.4.2. Section 5.13 has been added to the diagnostics guidance document to describe the committee's consideration of the fully incremental economic analyses. This explains that the committee concluded that there is considerable uncertainty about the relative cost effectiveness of the different lead-I ECG devices, and that a conclusion about which device was most cost effective could not be made from the available data.
22	Cardiocity Limited	4.44	The use of the terminology "dominated" should be rephrased as this shows the reports bias towards Kardia Mobile. The least you could do would be show the actual amounts difference.	Thank you for your comment which the committee considered. Detail on how expected cost-effectiveness results are presented in NICE diagnostics assessment programme assessments is explained in the diagnostic assessment programme manual, section 15.4.2.

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

THEME: Results of economic analysis

Comment number	Name and organisation	Section number	Comment	NICE response
				Section 5.13 has been added to the diagnostics guidance document to describe the committee's consideration of the fully incremental economic analyses. The committee concluded that there is considerable uncertainty about the relative cost effectiveness of the different lead-I ECG devices, and that a conclusion about which device was most cost effective could not be made from the available data. The incremental costs and QALYs generated for each of the devices in the assessment is shown in table 8 in the guidance document.
23	Cardiocity Limited	4.46	Reads - *In a probabilistic sensitivity analysis (done in base-case 1) all other lead-I ECG devices were dominated by Kardia Mobile in a fully incremental analysis.* Bearing in mind you have not used the correct sensitivity and specificity data, nor cost, not lifespan in your model	Thank you for your comment which the committee considered. Detail on how expected cost-effectiveness results are presented in NICE diagnostics assessment programme assessments is explained in the diagnostic assessment programme manual, section 15.4.2. Section 5.13 has been added to the diagnostics guidance document to describe

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

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				the committee's consideration of the fully incremental economic analyses. The committee concluded that there is considerable uncertainty about the relative cost effectiveness of the different lead-I ECG devices, and that a conclusion about which device was most cost effective could not be made from the available data.

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

THEME: Further research

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24	NHS England	6. Draft recommendations for further research	The 2017 EHRA review article raises some important points regarding future research perspective that I do not feel are adequately reflected in the consultation document. More detail in section 6 Draft recommendations for further research could be of benefit to the clinician in guiding formulation of appropriate research questions: - It's still unclear whether it is better, in the perspective of the health care system, to focus screening strategies on relatively few patients at very high risk, or, rather, to target these strategies to a wider proportion of subjects potentially exposed at an intermediate risk of stroke, if AF is detected. Assessments through economic studies of the return of investment related to these different strategies are needed. - Further, no studies have as yet reported the effect of screening for AF on stroke incidence or severity, so there remains a lack of evidence about the clinical benefit of earlier detection and treatment of screen detected patients However, the consensus document does refer to the current work by the Academic Health Science Network, which may target these areas of investigation moving forward.	Thank you for your comment which the committee considered. Use of the devices for population screening for atrial fibrillation in people without symptoms was outside the scope of the assessment, and falls under the remit of the UK National Screening Committee rather than NICE. Please see section 1.1 of the diagnostics assessment programme manual:https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-diagnostics-guidance/Diagnostics-assessment-programme-manual.pdf The committee decided not to change the guidance document.
25	Anticoagulation UK	6.1, 6.2	Acknowledge further data collection has been recommended and assume that ASHNs via their schemes will be capturing appropriate data and the evaluation of the impact of these devices expeditiously	Thank you for your comment which the committee considered. NICE reviews the evidence 3 years after publication of guidance to ensure that any relevant new

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

THEME: Further research

Comment number	Name and organisation	Section number	Comment	NICE response
			with any significant data being escalated for further consideration by NICE in a timely manner From the patient perspective, key to the uptake of introducing a 1lead device is ease of use and reliability. Interpreting the result and advising of next steps must be undertaken by a qualified HCP who has specific ECG knowledge with ability to respond to patients concerns/questions at the time of the test.	evidence is identified. However, NICE may review and update the guidance at any time if significant new evidence that is likely to have a material effect on the recommendations becomes available.
26	Kent, Surrey, Sussex AHSN	6.1	Kent, Surrey, Sussex AHSN received 560 AliveCor Kardia Lead 1 devices from the NHSE roll-out. We know they pick up AF but we don't have accurate data. Prior to distribution we asked every participating organisation to provide us with an implementation plan, outlining how and when the patient will have access to a 12 lead ECG. In addition to the AliveCor data we receive outlining the amount of traces taken and number of 'possible AF' and 'unclassified' results found, we asked the HCPs to email us any abnormal results and our clinical lead reviews a sample amount of traces for quality control. Interestingly quite a high number in the 'unclassified' group were confirmed AF. **KSS Phase 2: Detect:** Following the on-going distribution of the 560 Lead 1 ECG (AliveCor Kardia) devices, we are now tracking results from their use to date. As of November 2018, across KSS there have been 5,569 traces to date **(detecting 498 possible AF results)**, equating to approximately **20 AF-related strokes saved**, avoiding	Thank you for your comment which the committee considered.

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

THEME: Further research

Comment number	Name and organisation	Section number	Comment	NICE response
			debilitating effects on individuals and their families and provided all possible AF results are confirmed AF and anti-coagulated, **avoiding costs to state-funded Health & Social Care of over £910,000** over five years (KSS ROI model methodology).	
27	Kent, Surrey, Sussex AHSN	6.2	We plan now to amend our data collection, so that it demonstrates the effectiveness of a timely diagnosis. Our plan is to amend a SPAF Audit and Case Finding system that is about to launch and ensure it collects data to demonstrate effectiveness. In addition we will amend the system to capture new AF and method of detection used…i.e manual pulse, Lead 1 ECG device, 12 lead ECG device, diagnosis made in other clinical setting outside GP practice. **Data**: KSS AHSN plan to measure the impact in the three key focus areas of Detect, Review, Protect, via implementation of the Oberoi SPAF Audit and Case Finding Service in all the GP Practices. Funding secured for implementation in 15 practices using AliveCor devices and participating in the NHSE virtual clinic programme. We are exploring other funding streams to scale further across all practices. The e-portal enables practices to generate a re-audit report on a monthly basis, to enable them to evaluate and benchmark their	Thank you for your comment which the committee considered. The committee decided to add further detail on the type of data that could be collected to help address the recommendations for further research in section 6. Section 5.15 of the guidance document has been changed.

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

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			progress across participating practices, within their Local Health Economy. "Super-users" access a web-based dashboard to evaluate the progress being made at each practice, to share best practice. This link provides an example of the Oberoi SPAF Audit and Case Finding Service reports that the GP practices, CCGs and AHSN will be able to access monthly: https://www.oberoi-consulting.com/oberoi-spaf-and-case-finding/ We are very happy to work with NICE to progress this work.	
28	AHSN Network	Page.38 Section 5.13	**Background to the AHSN project** In 2016 Simon Stevens (NHS England CEO) highlighted that single lead ECGs were an area that Clinical Commission Groups should start innovating to improve the detection of AF. Shortly after this NHS England identified funding to stimulate the market and increase the uptake of mobile ECG technologies in primary and community care settings which would be channelled via the AHSNs. The funding provided a selection of devices (Kardia by Alivecor, Plessy by Impulse, MyDiagnostik, CardioCity and WatchBP) across all 15 AHSN geographies. The distribution of devices began in January 2018 and the impact is being assessed by a parallel evaluation. AHSNs identified suitable	Thank you for your comment which the committee considered. Section 5.14 of the diagnostics guidance document has been amended to reflect the additional information provided here. Section 5.14 of the diagnostics guidance document has also been amended to remove the comment that the AHSN project is mainly focussed on population screening for atrial fibrillation in an asymptomatic population.

Comment number	Name and organisation	Section number	Comment	NICE response
			sites and distributed devices within their agreed allocation (based on population statics and unit cost price). The focus of the evaluation of this project is on the extent of spread and adoption of the mobile ECG technology and will describe the optimum environment for implementing a national procured innovation, rather than the central procurement process itself. In addition, it is not an evaluation of the technology itself. The overarching research question which this project is aiming to answer is 'Can a system-wide procurement initiative improve the uptake of innovative technology (mobile ECG) and stimulate the market in primary and community settings, to better identify AF?" The independent evaluation will seek to answer the following six questions: • What environments are the devices most effective in? • What features of the implementation packages are most effective? What defines successful implantation? • What impact have the programme had on the market place? • What impact has the programme had on patient outcomes? • What health economic aspects has the programme achieved? • What is the impact on providers?	

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

THEME: Further research

Comment number	Name and organisation	Section number	Comment	NICE response
			Evaluation methods that will be used • Design and analysis informed by NASSS1 and NPT evidence-based frameworks • Quantitative data collection on device use • Qualitative methods – focus groups and interviews The AHSNs are not focused on screening for AF in an asymptotic population as reported, instead this programme has a much broader focus as outlined above, which will ultimately produce practical implementation recommendations based on those undertaking 'real world' spread and adoption. The quantitative data collected will provide information on the number of pulse checks undertaken and their possible outcomes, this is overlaid with information about the care setting and staff group. Information on high level patient outcomes and the long term or the pathway will be picked up through the qualitative methods. The AHSNs role is to assist the CCG in understanding how these devices could improve AF detection in their region and how the wider AF pathway can be improved to support this. This aligns the programme with the AHSN AF programmes overarching themes of Detect, Protect and Perfect.	

[1] Greenhalgh et al. Beyond adoption: A new framework for theorising and evaluating Non-adoption, Abandonment, and challenges to Scale-up, Spread and Sustainability (NASSS) of health and care technologies. August 2017.

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

THEME: Further research

Comment number	Name and organisation	Section number	Comment	NICE response
29	Arrhythmia Alliance & AF Association		With new research being published regularly I would recommend this being reviewed far sooner than three years. Data is showing that Lead-I ECG devices are being used more and more to detect AF in primary care. With the distribution of 6000 by NHS through the AHSN there will be even more evidence of use.	Thank you for your comment which the committee considered. NICE reviews the evidence 3 years after publication of guidance to ensure that any relevant new evidence is identified. However, NICE may review and update the guidance at any time if significant new evidence that is likely to have an impact on the recommendations becomes available.

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

THEME: Factual inaccuracies

Comment number	Name and organisation	Section number	Comment	NICE response
30	AHSN Network	Page 31 Section 5.2	The availability of 12-lead ECG in primary care. The statement around a lack of 12-lead ECG availability of ECGs is misleading. The large majority of GP practices have 12-lead ECG machines. See evidence https://bjcardio.co.uk/2008/05/availability-of-cardiac-equipment-in-general-practice-premises-in-a-cardiac-network-a-survey/ indicating 85% of practices in a regional survey reported having a 12-lead ECG machine in 2008. However, some 12-lead ECG machines in primary care are old and not fit for purpose. Even when a 12-lead ECG is available in a GP practice, there are not always used, due to a lack financial reward for performing this test in primary care with patients being referred to secondary care for the test. Universal availability of 12-lead ECG machines in GP practices, and staff training in ECG interpretation in England, is an issue that needs greater attention. As a result of the ongoing work into single lead ECG devices, AHSNs have discovered one of the many impacts of the use of this technology has been in the reduction of referrals for 12 Lead ECGs. This may be due to the increased sensitivity and specificity of the devices over manual pulse checks, and in the ability to enable patient pathways to be streamlined. More evidence of this will be captured in the single lead ECG project evaluation being undertaken by AHSNs.	Thank you for your comment which the committee considered. The committee heard from a clinical expert that only approximately 30% of primary care surgeries in their area had 12-lead ECGs, and additionally noted that the response rate in the cited study was about 40%. The committee concluded that there is likely to be variation in the availability of 12-lead ECGs across the NHS. Section 5.2 has been amended to note committee considerations that many GP practices cannot do a 12-lead ECG immediately because they do not have the equipment on site or because staff are not available to do, or interpret, the test.
31	Cardiocity Limited	2.1	Reads “Lead-I electrocardiograms (ECGs) are handheld devices” when it should read hand placement devices as RhythmPadGP is not hand held.	Thank you for your comment which the committee considered. The RhythmPad GP device has been removed from this guidance.

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

THEME: Factual inaccuracies

Comment number	Name and organisation	Section number	Comment	NICE response
32	Cardiocity Limited	2.1	Reads “The devices include touch electrodes” both the Cardiocity and Plessey devices utilise capacitive non-contact sensing and so the word “touch” is incorrect.	Thank you for your comment which the committee considered. The term ‘touch’ has been removed from section 2.1 in the diagnostics guidance document.
33	Cardiocity Limited	3.7	RhythmPadGP is a SIX lead device that can be operated in 1 lead mode.	Thank you for your comment which the committee considered. The RhythmPad GP device has been removed from this guidance.

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

THEME: General comments

Comment number	Name and organisation	Section number	Comment	NICE response
34	Anticoagulation UK	General	We are familiar with how the Kardia Mobile device works and via our networks are aware that these devices are currently being used in primary care settings across the UK as part of various ASHN innovation schemes. We understand that the use of these devices is to detect AF when a patient presents with symptoms and an irregular pulse with a lead 1ECG positive reading necessitating a 12 lead ECG.	Thank you for your comment which the committee considered.
35	Anticoagulation UK	2.2 - 2.8 DCD	The device has value to the diagnostic pathway if it can assist with the detection of AF in patients with paroxysmal AF which can be difficult to diagnose if the individual has intermittent bouts and the 12 lead ECG does not capture – this may require repeated ECGs which can impact on the individual and delay start of anticoagulation therapy and AF medications. Preventing AF stroke risk in the population is a health priority. The earlier the diagnosis the better outcomes if anticoagulation can be commenced to protect the individual from risk of stroke.	Thank you for your comment which the committee considered.
36	Anticoagulation UK	3.12	Delays in getting 12 lead ECGs can cause anxiety and distress to individuals with symptoms and a confirmed irregular pulse. It is of concern that patients may be experiencing delays due to regional variations for ECGs tests.	Thank you for your comment which the committee considered.
37	Anticoagulation UK	Draft DAR document Liverpool	Conclusions section Findings indicate that there is a cost benefit to the NHS when using these devices.	Thank you for your comment which the committee considered.

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

THEME: General comments

Comment number	Name and organisation	Section number	Comment	NICE response
38	AHSN Network	Page 28 Section 4.40	The model assumptions use QOF 2016/7 data, however 2017/8 data has changed considerably. Could the model be rerun with the latest figures before final publication please?	Thank you for your comment which the committee considered. The EAG commented that the 2017/18 QOF data had published after their final report had been submitted. The committee noted that the EAG had re-run the economic model (reported in an addendum) using figures from the 2017/18 QOF data, and that this had only a small effect on the model results.
39	AliveCor		We don't have any formal comments in response.	Thank you for your comment which the committee considered.
40	Cardiocity Limited	9	No details are provided of which committee members are registered users of the Kardia Mobile device, Zenicor, RhythmPadGP or ImPulse device. With the reports usage of "dominance" statistics it would appear that the report is biased towards Kardia Mobile.	Thank you for your comment which the committee considered. Detail on how expected cost-effectiveness results are presented in NICE diagnostics assessment programme assessments is explained in the diagnostic assessment programme manual, section 15.4.2.

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

THEME: Part 2

Comment number	Name and organisation	Section number	Comment	NICE response
41	Cardiocity Limited	3.3	[redacted] routes all data to [redacted] eventually. The companies practices with regards GDPR are [redacted] [redacted] is a [redacted] and as such the GDPR set up for the operation of this device is based around the GP signing up to [redacted] terms and conditions for [redacted]. To comply with GDPR the patient must be presented with a written statement explicitly informing the patient that an anonymised copy of their ECG data is being sent to [redacted] for their commercial gain. Failure to present the patient with this information is a breach of GDPR, likewise is annotating any patient details onto the data file and sending this to an NHS email address which will route the patient identifiable data via [redacted] email servers, thus providing [redacted] with a copy of the patients data. [redacted] is priced [redacted] and not [redacted]	Thank you for your comment which the committee considered. The committee noted the importance of information governance and concluded that centres should ensure appropriate information governance is in place when using lead-I ECG devices. Text has been added to section 5.14 of the guidance document to reflect this.
42	Cardiocity Limited	4.35	No operational costs are included in the evaluation, for Kardia and Zenicor a SIM card is required. Whilst the cost of a Tablet or SmartPhone was included in the later costings, there is no cost of	Thank you for your comment which the committee considered. The EAG explained that the threshold analysis done for the cost of the Kardia

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

THEME: Part 2

			operation for the sending or retrieving of data using a phone or data network. There is also no allowance for the processing of the data. Let us assume MyDiagnostic or RhythmPadGP find a case of AF, how does the GP actually get this data into usable form? In RhythmPadGP's case this is simple as each reading is represented as a PDF on the clinicians hard drive, to append this into the patient record is simply a case of pulling the file into DocMan and thus it is appended to the patients EHR. [redacted] how does the GP do this? In effect they have to email the patients annotated ECG to themselves, routing the patient identified data via [redacted] servers which are hosted on [redacted], then the mailing aspect of the software will route the patients record via [redacted] before forwarding the email back to the GP's server and into his mailbox. [redacted]. It is designed to [redacted] and here it is being adopted by GP's with no knowledge of the implications of GDPR routing the patient's data all over the internet before ending up in the GP's email inbox with no easy way of appending it to the patient record. At no point in your study do you address the true costs to the GP or HCA of using any of this technology.	Mobile described in section 4.44 would also assess the impact of any additional costs, including additional data related costs. Section 4.44 of the guidance document has been changed to reflect this. The committee noted the importance of information governance and concluded that centres should ensure appropriate information governance is in place when centres using lead-I ECG devices. Text has been added to section 5.14 of the guidance document to reflect this.

DIAGNOSTICS ASSESSMENT PROGRAMME

Lead-I ECG devices for detecting atrial fibrillation using single time point testing in primary care

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 13 February 2019

THEME: Part 2