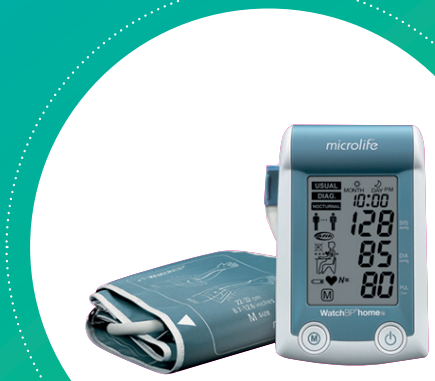
Health Innovation Network South London



Single time point case finding for Atrial Fibrillation:

A review of methods of delivery and devices

May 2017

Health Innovation Network South London

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Foreword

There is a plethora of technologies and software designs to consider when choosing the optimal device for the detection of atrial fibrillation (AF). These devices can be used to assess the heart rhythm by determining the pulse irregularity or by mapping the electrical activity of the heart. This report reviews the current technology and software designs suitable for single-time point case-finding for AF. Their use for continuous or repeated daily monitoring to improve the detection of paroxysmal AF is outside the scope of this report.

This report aims to capture current practice, summarise the evidence base and provide measures to support decision making that tailors the technology and software design to local service needs. The information in this reports includes:

- National and international evidence for AF screening: Sets the scene by demonstrating the benefits of early AF detection and highlights the adoption of screening recommendations into international guidance, including the use of technology as an alternative to pulse palpation.
- Strategies for AF detection and predicted number needed to screen during AF detection programmes: Summarises the current AF detection strategies and highlights opportunistic screening of those aged over 65 years as the most cost effective option. The predicted number needed to screen in AF detection programmes to identify one new AF case will assist commissioners and healthcare workers to estimate the impact of any proposed case finding strategy on local prevalence.
- Technology to facilitate AF case-finding: Describes the choice of technologies and software designs available to facilitate early detection of AF.
- Evidence for technology accuracy and use in community settings to increase the detected prevalence of AF: Features a summary of the published reviews and meta-analyses which evaluate the accuracy of different device technologies in various settings. There is also an outline of further studies demonstrating an increase in prevalence with case-finding programmes using a range of AF detection devices.
- Enablers and barriers for implementing device into practice: The success and accuracy of any technology device and software used as an AF detection tool is highly dependent on population selected, staff involved, as well as the setting of the AF case-finding programme. Published literature on key enablers and barriers that affect the use of AF detection devices are highlighted to support the development of cost-effective case-finding programmes that will improve local AF detected prevalence.
- Checklist to support informed decision making when choosing a device: Provides a list of key questions and factors to support the decision-making process for choosing and implementing an AF detection device within local case-finding programmes.
- Product specifications for selected devices: A summary of specific named devices has been included for consideration when choosing an AF detection device. This list is not exhaustive and provides a template of key features which will inform decision making relevant to local case-finding programmes.

Overall technologies and software designs have the potential to be incorporated into AF case-finding programmes.

We hope that you will find the information provided in this report useful in supporting decision-making regarding the most appropriate AF detection device(s) for use within local AF screening programmes.

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List of abbreviations

AHSN	Academic Health Science Network
AF	Atrial Fibrillation
BP	Blood Pressure
CEP	Centre for Evidence-based Purchasing
CCG	Clinical Commissioning Group
CI	Confidence Interval
CE	Conformité Européene
CINAL	Cumulative Index to Nursing & Allied Health
ECG	Electrocardiogram
EEA	European Economic Area
EPCCS	European Primary Care Cardiovascular Society
ESC	European Society of Cardiology
FDA	Food and Drug Administration
GP	General Practitioner
IHB	Irregular heartbeat
Ltd	Limited
MHRA	Medicines and Healthcare Product Regulatory Agency
NHS	National Health Service
NIA	National Innovation Accelerator
NICE	National Institute for Health and Care Excellence
PAF	Paroxysmal Atrial Fibrillation
PPG	Photoplethysmographic
PASA	Purchasing and Supply Agency
SAFE	Screening for Atrial Fibrillation in the Elderly
SEARCH-AF	Screening Education and Recognition in Community pHarmacies of Atrial Fibrillation
TIA	Transient Ischaemic Attack
UK	United Kingdom
USA	United States of America
USB	Universal Serial Bus

1. Introduction

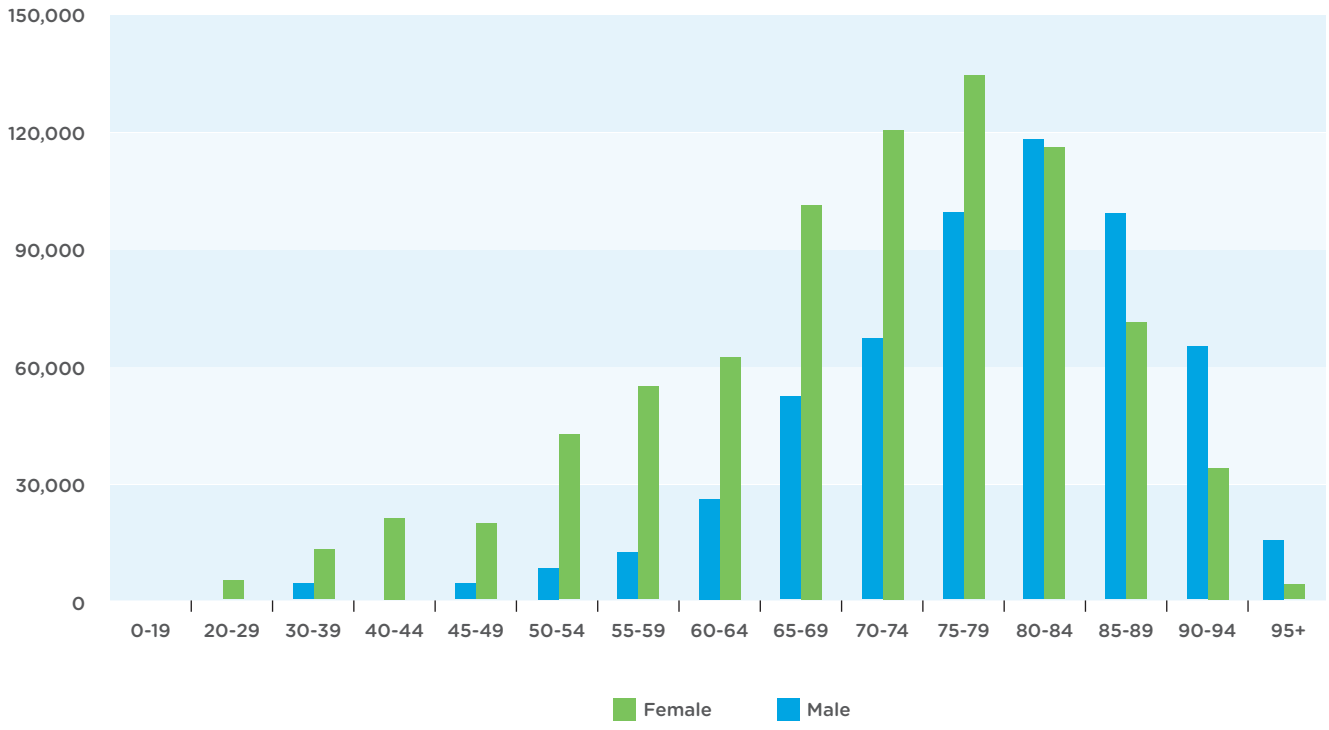
Atrial Fibrillation (AF) is the most common cardiac arrhythmia encountered in clinical practice and significantly increases the risk of ischaemic stroke. AF-related strokes are often more severe than non-AF-related strokes with a poorer prognosis, greater disability and increased healthcare costs[1-4]. Reducing the risk of AF-related stroke by early detection and initiation of appropriate treatment strategies will have substantial economic and patient benefits[5-7].

1.0 Introduction

The current prevalence of AF in England is estimated to be 2.4%, which translates to approximately 1.36 million people living with the condition. Of these, approximately 65% (890,000) have been diagnosed while the remaining 35% (474,000) are living with the condition undetected. Prevalence increases with age, with an estimated median age for AF of 75 years with the result that approximately 70% of people with AF are between the ages of 65 and 85 years. AF is more common in males than females, although the absolute number of both genders with AF is similar, given that females outnumber males in the older age groups. In England, the highest number of estimated cases of AF in males occurs in the 75 to 79 year age group while in females this peak occurs in the 80 to 84-year age group (Figure 1)[8]. Estimated prevalence of AF has also been mapped across the country at Clinical Commissioning Group (CCG) level, ranging from 1.0% to 3.8% (Figure 2). This variation is thought to reflect in part the differences in population demography, particularly increasing age[8].

> ***Of the 1.36m people in England living with AF, over 450,000 have the condition undiagnosed"***

Figure 1. *Estimated AF prevalence in England based on age and gender 2014[8]*



In addition to increasing age, a number of factors have been shown to contribute to the AF burden[9,10]. These include:

- Non-modifiable risk factors for developing AF, such as rheumatic heart disease, heart failure and genetics
- Modifiable risk factors for developing AF, such as hypertension, diabetes mellitus, obesity, smoking and pre-existing cardiac disease
- Other risk factors including; obstructive sleep apnoea, aortic stiffness and metabolic syndrome

The irregularity of heart rhythm caused by AF can be detected by pulse palpation. It may be present in people with symptoms such as palpitations, dizziness, blackouts and/or breathlessness but can also be found incidentally during routine examination in approximately one third of people who have no symptoms[11-14]. Some people may have intermittent symptoms, making it difficult to detect and subsequently diagnose the underlying rhythm of AF.

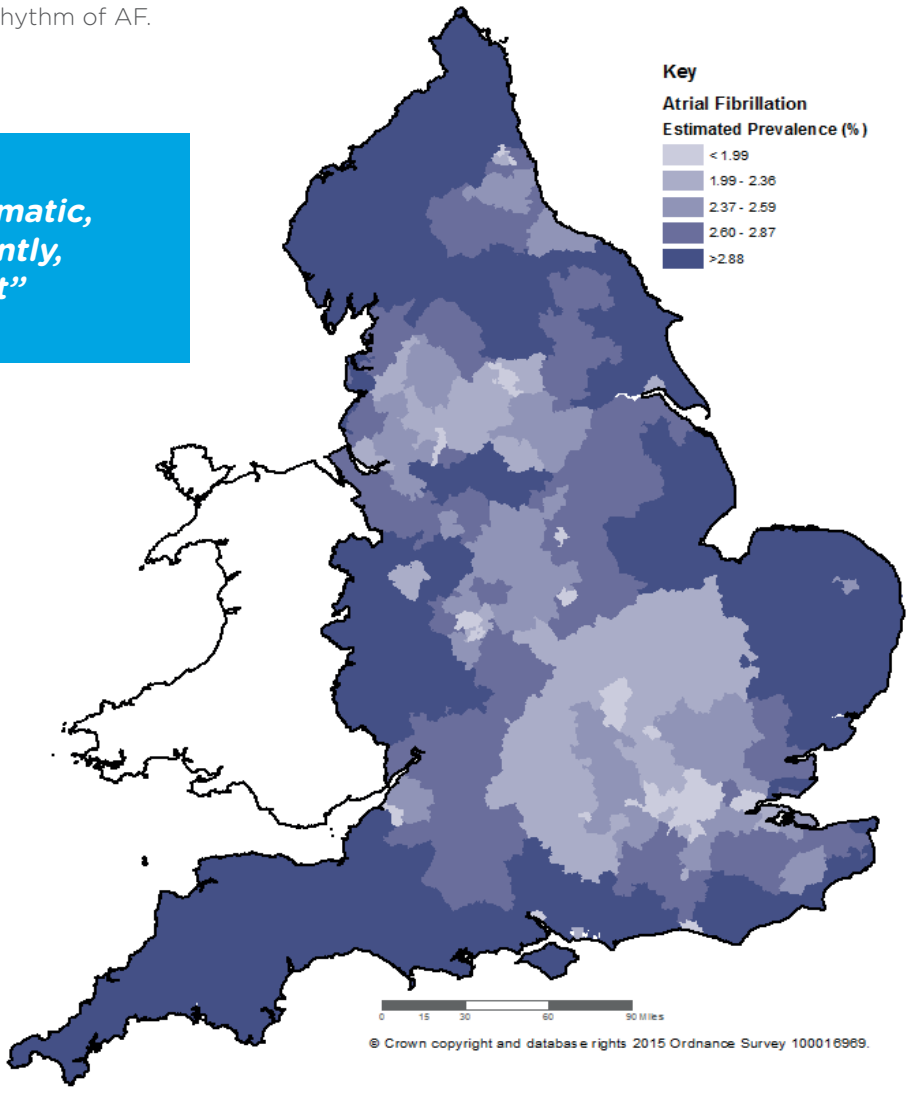
> ***AF is frequently asymptomatic, and may occur intermittently, making detection difficult"***

The pattern of AF can be classified into paroxysmal, persistent or permanent, based on its frequency, duration of symptoms and response to therapy. Irrespective of the classification, all forms of AF carry a similar risk of ischaemic stroke[11,14].

The diagnosis of AF requires a rhythm recording displaying the electrical activity of the heart using an electrocardiogram (ECG), showing characteristic features of AF including absence of P-waves and completely irregular R-R distances[11,14]. This has been traditionally carried out using a standard 12-lead ECG or continuous ambulatory ECG monitoring[9,12]. The ECG changes can be subtle and therefore interpretation should be performed by a competent clinical practitioner to ensure accuracy.

Figure 2.

Map of estimated AF prevalence across England at CCG level[8]



1.2 Strategies for AF detection

The importance of initiating anticoagulant therapies and reducing the incidence of AF-related stroke is well recognised by all the cardiovascular guidelines[11,14]. Guidelines in the area of AF detection have undergone continuous adaptation as research has endeavoured to establish the most effective approach for identifying people with asymptomatic AF and those who are symptomatic but remain undiagnosed in local populations. AF detection is currently a two-stage process. Firstly, people with an irregular pulse rhythm are identified and then AF is confirmed or excluded using a 12-lead ECG or continuous ambulatory ECG over 24 hours or longer[15].

Potential strategies to identify people with AF include; single time-point case finding or systematic screening. In the former, an individual's pulse or heart rhythm is checked during a routine consultation with a healthcare worker. In contrast, systematic screening targets a specific group of the population that are then prospectively invited to have their pulse or heart rhythm checked. This form of screening can be targeted to certain groups that maybe at high risk of having AF or groups that can otherwise be singled out for screening. In contrast, population-based screening programmes are offered to everyone in a particular population who are at high risk and have not previously been diagnosed with AF. These screening programmes may differ in terms of population screened, detection strategy employed (i.e. manual pulse palpation or AF detection device) and / or the healthcare worker(s) involved in carrying out the screening process and interpreting the results[16,17].

AF case-finding programmes using single-time point assessment may fail to identify paroxysmal atrial fibrillation (PAF), as individuals may be in sinus rhythm at the time of the check. There is emerging evidence that suggests prolonged repeated daily ECG monitoring enhances the detection of PAF. This can be achieved by using a 'patient-operated' device or by extending the duration of monitoring by using continuous ECG monitoring in the form of skin patches or implantable loop recorders[11,18]. **Extended detection programmes using new technologies beyond single-time point strategies are outside the scope of this document.**

The SAFE study showed that opportunistic case-finding for AF in the over 65s is a cost effective strategy"

Screening for Atrial Fibrillation in the Elderly (SAFE) was a landmark study which compared three strategies of screening for AF in patients over 65 years of age in primary care: systematic screening of the target population using ECG, opportunistic screening via pulse palpation of patients in the target population visiting general practitioner (GP) practices for other medical reasons and routine care, where new cases of AF in the target population were identified on clinical presentation. The study demonstrated opportunistic screening to be more effective than routine care and more cost-effective than systematic screening[19].

1.3 Number needed to screen in AF detection programmes to identify one additional case

The Cochrane Collaboration analysed all randomised controlled trials focusing on AF detection of people over 65 years of age and drew similar conclusions to those of the SAFE study[16]. The data estimated the number needed to screen to detect one additional case compared with routine practice was 172 (95% Confidence Interval (CI) 94 – 927) for systematic screening and 167 (95% CI 92-806) for opportunistic screening. A sub-group analysis demonstrated both systematic and opportunistic screening were more effective in males than females and this difference was statistically significant for the systematic screening strategy. There was no association between socioeconomic status and effectiveness of the two screening programmes and no data was reported on different ethnic groups.

Lowres et al carried out a more recent systematic review of screening for unknown AF using single time-point programmes[20]. Thirty studies were used for the evaluation, representing 122,571 individuals. Undiagnosed AF was found in 1% of the overall population of the studies and 1.4% of those were aged 65 years or older. This data indicates that the number needed to screen to detect one case of undiagnosed AF in general population is 100, and in those aged 65 years or older is 71.[18,20]

The largest systematic review to date concluded that the number needed to screen to identify one new case of AF in the over 65s is 71"

1.4 National & International guidelines on AF Detection

The United Kingdom (UK) National Screening Committee addressed the question as to whether a national AF screening programme should be recommended in 2014 and their current position is; *"Screening for AF in the over 65-year-old population is not recommended as it is uncertain that screening will do more good than harm to people identified during screening for AF"*. This statement was taking into account factors such as; the treatment and care of people with diagnosed AF at the time was not optimal and the tests used for AF detection needed to be improved and standardised[21]. The diagnosis and management of AF is a major focus for the Academic Health Science Networks (AHSNs) in England, with the aim of preventing an additional 5,000 AF-related strokes over the next five years[22].

The outcomes of the AHSN programme, alongside updated national AF data, may impact on the next review of policy by the UK National Screening Committee, which is due to start in 2017/18.

The National Institute for Health and Care Excellence (NICE) guidelines for AF were last updated in 2014 and recommend an ECG must be performed in all people, whether symptomatic or not, in whom AF is suspected because an irregular pulse has been detected[23]. Whilst not endorsing widespread screening for AF, NICE have also published a technology appraisal on the use of an automated blood pressure (BP) monitor with an integrated AF algorithm for the opportunistic detection of AF during the diagnosis and monitoring of hypertension, as well as a medical technology innovation briefing on the use of a mobile application for detecting AF[24,25].

Recent international guidelines do endorse screening for AF. The European Primary Care Cardiovascular Society (EPCCS) consensus guidance on stroke prevention in AF recommends opportunistic case finding in all people 65 years and over and in anyone who receives routine cardiovascular follow up[14]. They highlight that:

a) Pulse palpation, at least once a year could be incorporated into existing medical visits such as annual reviews, during flu vaccinations and/or pharmacy visits. Those with a positive pulse palpation should have a 12-lead ECG follow up performed shortly after the pulse assessment by a practitioner who is competent in ECG interpretation.

b) Modified sphygmomanometers (i.e. BP monitors) or devices using a single-lead ECG trace to detect an irregular pulse may be used, but only when they have been subject to independent validation with a 12-lead ECG.

> ***Whenever AF is detected by pulse check or device, a timely referral for a 12-lead ECG is required to confirm the diagnosis"***

Table 1. *ESC recommendations for screening for atrial fibrillation*[11].

Recommendations	Class[a]	Level[b]
Opportunistic screening for AF is recommended by pulse taking or ECG rhythm strip in patients >65 years of age.	I	B
In patients with TIA or ischaemic stroke, screening for AF is recommended by short-term ECG recording followed by continuous ECG monitoring for at least 72 hours.	I	B
It is recommended to interrogate pacemakers and ICDs on a regular basis for atrial high rate episodes (AHRE). Patients with AHRE should undergo further ECG monitoring to document AF before initiating AF therapy.	I	B
In stroke patients, additional ECG monitoring by long-term non-invasive ECG monitors or implanted loop recorders should be considered to document silent atrial fibrillation.	IIa	B
Systematic ECG screening may be considered to detect AF in patients aged >75 years, or those at high stroke risk.	IIb	B

The European Society of Cardiology (ESC) published an updated guideline for the management of AF in August 2016, which reflects the emerging data on improved strategies and makes recommendations beyond opportunistic screening for all those over the age of 65 years in community settings using either short term ECG or pulse palpation (followed by ECG in those with an irregular pulse). The guideline suggests systematic ECG screening may be considered in those over the age of 75 years or at a high risk of stroke, with recognition of the need to further evaluate these strategies prior to full implementation in routine clinical practice. The ESC recommendations for AF screening have recently been reviewed and extended to include short and long term ECG recording in selected patient groups (table 1)[11].

1.5 Manual Pulse Palpation

For decades, pulse palpation has been the primary method of identifying AF in clinical practice. It is a simple and inexpensive detection technique for determining an irregular pulse rhythm and has been shown to have a moderate accuracy for identifying AF. The accuracy of nurse pulse rhythm assessment varies between studies, with a sensitivity range of 87% to 97% and a specificity ranging from 71% to 81%[26,27].

NICE guidance on BP monitoring highlights automated devices does not measure BP accurately in the presence of an irregular pulse. Hence in patients with an irregular pulse, BP should be measured manually using direct auscultation over the brachial artery. In practice this means people who have their BP measured should also have their radial or brachial pulses palpated to identify irregularities; effectively an opportunity to check for AF. However, despite recommendations in national and international clinical guidelines, manual pulse palpation is often not routinely performed in clinical practice, resulting in a missed opportunity to identify AF in those living with the condition undetected [19,26,27].

Advances in technology have allowed the development of a number of new devices with built-in AF algorithms for auto-analysis that have the potential to facilitate more effective AF detection programmes. These devices have reported sensitivity in the range of 90 to 100% and specificity in the range of 86 to 97%. At present the optimal device for AF detection has not yet been determined[15].

1.6 Scope

This report reviews the different AF detection devices currently available which can be used for single-time point case-finding for AF in primary care and community settings. The information presented incorporates evidence from the literature to support their use, accuracy of the devices in terms of sensitivity and specificity to identify AF and data from the manufacturers' product information.

Much of the information provided is sourced from medical literature identified using research databases (MEDLINE, EMBASE, CINAHL, Global Health, The Health Management Information Consortium and Cochrane Library), guidelines, National Health Service (NHS) reports and literature on device specifications obtained from the companies and / or their websites (including user's manual). The Food and Drug Administration (FDA) and Medicines and Healthcare Product Regulatory Agency (MHRA) websites were searched for any manufacturer field safety notices, Medical Device Alerts or Recalls.

2. Types of technology available for detecting AF

There are numerous devices that can detect AF based on either pulse irregularity or rhythm analysis. They are available in various designs from BP monitors to smartphone applications (apps). Updated European guidance recommends 'the use of modified sphygmomanometers or other non 12-lead ECG devices to detect an irregular pulse or rhythm, as an alternative approach to pulse palpation as part of AF screening programmes[11,14].

2.1 Automated BP sphygmomanometers for detecting AF

Some automated BP sphygmomanometers have a built-in AF algorithm to analyse any irregularity of the pulse rate and apply a threshold for detecting AF. These are referred to as 'AF detectors' and are specific for detecting AF. They differ from BP sphygmomanometers with an irregular heartbeat (IHB) algorithm (also known as arrhythmia detectors) which are not designed or approved for AF detection; they have an algorithm which signals when the heart beat rhythm varies by more than 25% from the average during the course of the BP measurement[28]. The main purpose of IHB detector is to serve as a warning message indicating that the BP reading may not be accurate due to the presence of arrhythmia, rather than specifically indicating the presence of AF[28]. This is intended to ensure that the BP is measured manually using direct auscultation over the brachial artery in those with an irregular pulse, as the readings from an automated sphygmomanometer can be inaccurate in this setting.

Currently, Microlife has a range of automated BP sphygmomanometers with a built-in AF algorithm that have been approved by the FDA and the European Economic Area (AEE) for the detection of AF. WatchBP Home A (Microlife Health Management Ltd) is the only monitor to have a medical technology appraisal recommendation from NICE for opportunistic detection of AF during the diagnosis and monitoring of hypertension[24]. At the time of publication, the Microlife range are the only models of automated BP sphygmomanometers with a built-in AF algorithm (figure 2). All other automated BP monitor models on the market with built in arrhythmia detection rely on an IHB algorithm.

> ***Microlife Watch BP Home A has a built in AF detection algorithm and is endorsed by NICE for opportunistic AF detection"***

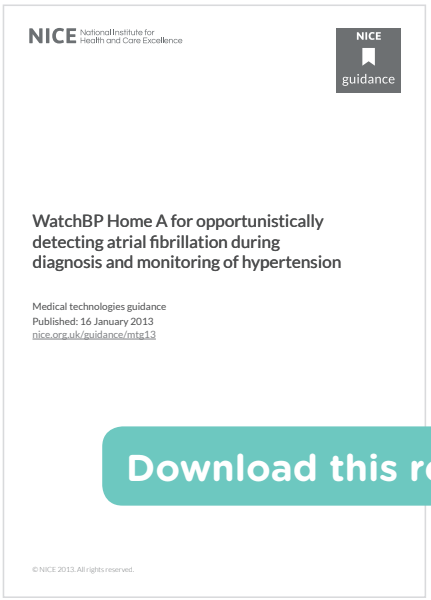
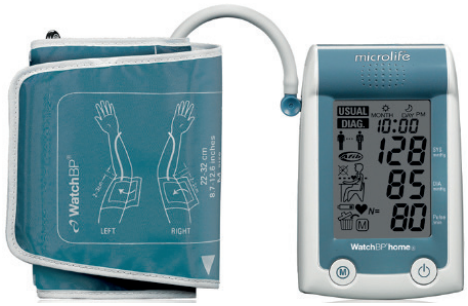


Figure 2.
Examples of Microlife automated blood pressure monitors with built-in AF algorithm

WatchBP Home A



WatchBP Office

2.2 Handheld ECGs

ECG devices evaluate the electrical activity generated by the heart and are being widely adopted in primary care AF detection programmes. A 12-lead ECG interpreted by a competent practitioner remains the gold standard for AF diagnosis[14, 19].

Since the introduction of portable ECGs in 1957, there has been a rapid advancement in microelectronics that has transformed the initially large bulky devices into portable, miniaturized and easy to use ambulatory ECG recorders[29]. The new devices have improved functionality such as, better display, wireless capability and advanced integrated diagnostic software. They are predominantly used to investigate suspected symptoms of arrhythmias (including AF), which have not been detected by a 12 lead-ECG[29-31]. Traditionally these devices have been defined into two categories known as continuous or event ECG monitors.

2.2.1 Continuous ECG Monitors

A continuous ECG monitor (Holters) can continuously record cardiac electrical activity, typically for 24 to 48 hours. This period has now been extended to several weeks with the newer monitoring systems. These devices are used to investigate suspected occasional arrhythmias which have not been detected during shorter, single-time point ECG recordings[29-31]. NICE guidelines on AF management recommend: *'use of the 24-hour ECG recorder in people with suspected PAF with symptomatic episodes less than 24 hours apart'*[23].

Continuous ECG devices used to rely on electrodes and wires but, over recent years, have been transformed into simple disposable patch-like devices. Examples of the different types of devices are listed in table 2. A patient-operated button, activated whenever symptoms occur, allows the device to timestamp the ECG to identify points during the recording at which symptoms were experienced. Implantable loop recorders such as Reveal (Medtronics UK) can be used to record heart rate and rhythm over extended periods of 6 months or more.[29-31] **Use of continuous ECG monitors for detecting PAF is not within the scope of this document, and will not be discussed further.**

Table 2.
Examples of continuous ECG recorders

Continuous ECG recorders
Continuous ECG monitor
BEAM ECG (I.E.M GmbH)
BodyGurdian Holter (Preentice Solutions Inc)
C.Net5000 (Cardionetics Ltd)
CardioCall VS20 or ST80 (Spacelabs Healthcare)
Dicare m1CC colour (Dimetek Medical Technology)
Easy ECG PC-80 (Shenzhen Creative Industry Co. Ltd)
Lifecard CF (Spacelabs)
Miniscope M3 (Schiller)
myPatch (DMS service LLC)
Novi patch (The ScottCare Cardiovascular Solutions)
Philips DigiTrak XT Holter (Philips Healthcare)
Reka E100 (Reka Health Pte Ltd)
R Test evolution 3 (Novacor (UK) Ltd)
SEER Holter recorder (GE Healthcare)
V-patch (Intelesens)
Zio Patch (CardioLogic Ltd)

2.2.2 Event ECG monitors

An event ECG device allows intermittent recording of the electrical activity of the heart and is usually given to patients who experience infrequent symptoms and require monitoring over a longer period of time. Patients will initiate an ECG reading when they experience symptoms of arrhythmia (for example: breathlessness, palpitations and/ or light-headiness). NICE guidelines for AF recommend: *'use of an event ECG recorder in patients with symptomatic episodes more than 24 hours apart'*[23].

These devices can operate using ECG cables and electrodes or may have integrated chest and / or finger electrodes. The latter can be activated by placing the thumbs, fingers or palms on the device or, in some instances, are held directly against the chest to record a short ECG. Some devices have built-in AF algorithms for auto-analysis to instantly inform the user of the outcome[30,31]. Alternatively, the ECG can be interpreted by a practitioner or transmitted to a telemedicine service for analysis. Examples of event recorders with CE mark are summarised in table 3. These devices have the potential of being used in single-time point AF case-finding programmes. Manufacturers, such as MyDiagnostick Medical BV and Cardiocity Ltd, have taken this concept further by improving the ergonomics of the single lead ECG device (figure 4). MyDiagnostick, a single lead ECG recorder, is shaped as a stick with metallic handles encompassing the electrodes, which an individual grips to record an ECG rhythm strip. It has a built-in AF algorithm that will provide an instant interpretation of the results on connection of the device to a computer via USB. Rhythmpad and kiosk developed by Cardiocity Ltd allow the patient to record an ECG by placing their hands on the pad.

> ***Any device capable of producing a readable ECG trace can be used to detect AF. However some devices are more practical for use for single time point case-finding in AF detection programmes"***

Table 3.
Examples of event ECG recorders

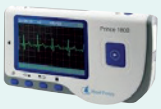
Handheld ECG monitors	
Dicare m1CC	NO IMAGE
HCG-801 Heartscan	NO IMAGE
HeartCheck	
MD100 A/B/E	NO IMAGE
Prince 180 a/b	
Zenicor	

Figure 4.
Examples of ECG Event monitor designs suitable for AF detection programmes

There are also platforms which incorporate single lead ECG and mobile cardiac telemetry technology into a single device. Docobo is an example, and uses technology known as connected health, which can provide healthcare services remotely, encompassing telemedicine, patient monitoring and digital health disease and lifestyle management. Other devices are designed with multiple functions such as Zensor (Zensor Medical Systems AB), a remote vital sign system that facilitates the detection of cardiac arrhythmia, heart rate and respiration rate monitoring in the community. This device has the ability to carry out continuous ECG monitoring (up to 7 days).

2.2.3 NHS published support procurement

In 2009, The Centre for Evidence-based Purchasing (CEP), an executive body of the NHS Purchasing and Supply Agency (PASA) published a Buyers' guide on patient-activated ECG event recorders[32]. The report provides a review of 23 portable patient-activated ECG recorders that were available in the UK market during 2007. CEP was decommissioned and PASA closed on 31st March 2010. The guide has since become out of date due to the market's highly dynamic nature with accelerated development of new technology and devices.

PASA roles and responsibilities have been transferred to other organisations within the Department of Health including the NHS Supply Chain, which offers a framework agreement for the purchase of selected ECG equipment and related accessories. This document is predominantly directed at secondary care and lists a variety of devices including: ECG machines, continuous ECG monitors, event recorders, stress test equipment and ambulatory BP monitors that are included on the basis of an agreed specification[33]. The use of this agreement by manufacturers supplying devices to the NHS is currently not compulsory.

NHS supply chain also has a product purchase catalogue that includes the sale of hand held ECG event recorders and mobile applications, as well as automated BP monitors. At the time of publication of this report, Heartscan HCG 801 (Omeron Healthcare UK Ltd), Kardia ECG Mobile and App (formally known as AliveCor) and Microlife's WatchBP Home A and office models were listed in the catalogue.

The Small Business Research Initiative for Healthcare (SBRI Healthcare) is an NHS England initiative launched in 2009 that enables the development of innovative products and services through the public procurement of research and development. The AHSNs are responsible for the overseeing the delivery of the programme and table 4 shows current ECG devices in development and are supported by SBRI Healthcare.

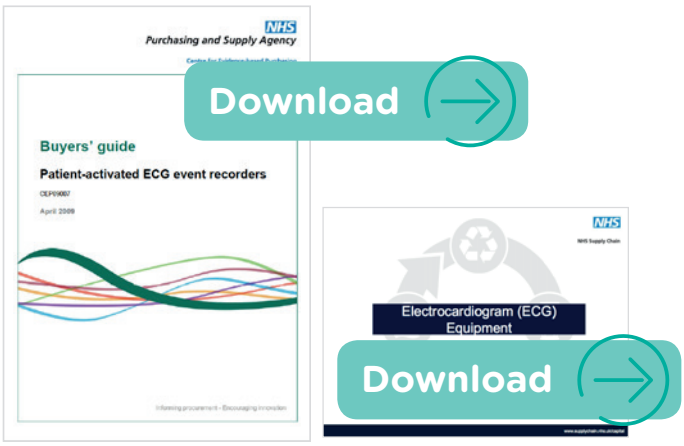


Table 4. *ECG devices supported by the SBRI healthcare*

Name of Device		AHSN
imPulse handheld ECG device (Plessy Semiconductors) A single lead ECG device that automatically identifies arrhythmias		South West
Rapid Rhythm ECG handset device Economic validation and accelerated adoption of a rapid one-step ECG handset device to replace traditional 12-lead ECG for use in primary care and/ or acute care	**NO IMAGE**	North West Coast

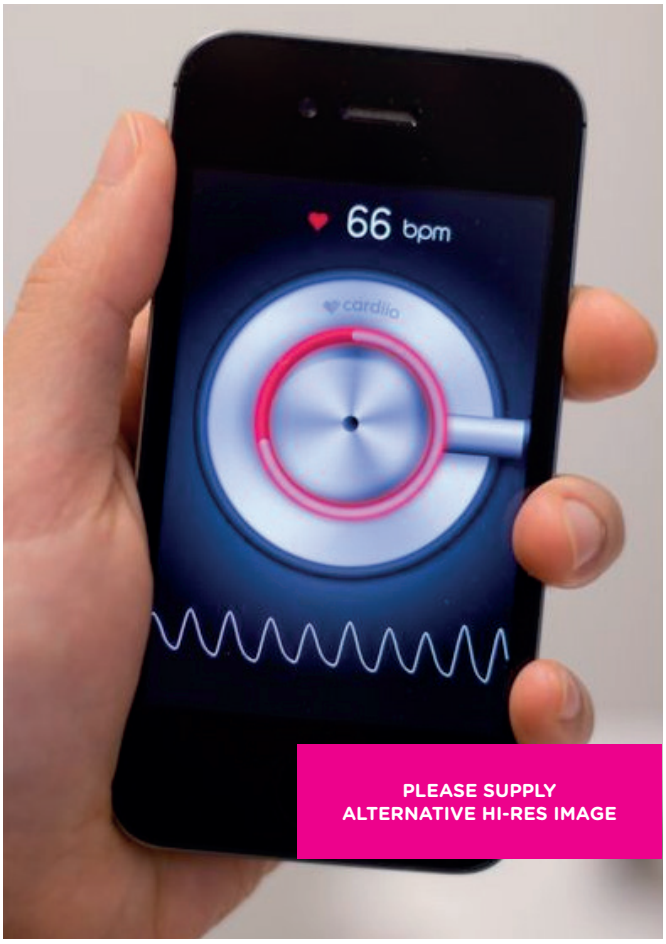
2.3 Mobile applications

Further advances in design and technology are allowing non-healthcare equipment, such as smartphones and tablet computers, to become medical devices with the incorporation of biological sensors or electrodes.

2.3.1 Smartphone photoplethysmographic applications

Several smartphone apps already exist to determine heart rate using the built-in camera. These apps use the smart phone flash or light source and camera to obtain a photoplethysmographic (PPG) recording of pulse waves. This principle has been used to measure heart rate, primarily during fitness and exercise, but more recently an AF algorithm similar to that used in automated BP sphygmomanometers has been developed to analyse the regularity of the pulse waves and detect AF or sinus rhythm. Examples of such smartphone apps are Cardiio Rhythm heart app and Fibricheck (figure 5)[34]. These apps have emerging data for their accuracy but at present have not been endorsed by any guideline for use in AF detection programmes.

Figure 5.
Example of a mobile application using the smartphone built-in camera to detect AF



2.3.2 Mobile ECG recorder and applications

Other systems allow electrode attachments to connect with a compatible mobile device (smartphone or tablet computer) and transmit, record, auto-analyse, store and view an ECG recording using a dedicated app. These include the following CE marked devices: Kardia Mobile ECG and app (AliveCor, Inc.)[1], ECG Check (Cardiac Design Inc) and EPI Mini ECG Portable Monitoring System (EPI Mobile Health Solutions Pte Ltd), as shown in figure 6[35]. Fingertip contact on the monitoring device with the embedded electrodes (or placing it on the chest) will transmit an ECG signal to a compatible mobile device using frequency modulation of an ultrasonic or Bluetooth signal that is received via the microphone of a smartphone or tablet computer. The ECG is captured digitally and can be viewed and transmitted to a secure server. The apps also have built-in AF detection algorithms that provides an instant interpretation to the user[35]. Kardia mobile ECG and app (AliveCor, Inc.) is currently the main mobile application used in the UK.

In 2015, NICE published a Medtech Innovation briefing on the use of the AliveCor's Kardia mobile ECG and app for detecting AF. This document did not constitute a formal recommendation from NICE and its purpose was to provide objective information on the diagnostic technology to aid local decision making and support the NHS Five Year Forward View to accelerate innovation in new treatments and diagnostics. The briefing describes the AliveCor's Kardia as a portable ECG recorder that is designed to monitor heart rhythm and heart rate with a potential use in any setting for detecting AF. At the time of publication, it was deemed to be suitable for use by the patient at home to aid in the detection of PAF[25].

AliveCor Company was successfully selected in the 2015/16 NHS Innovation Accelerator (NIA) programme and is currently working with the innovation agencies: Imperial College Health Partners, North East and North Cumbria, Oxford and University College London Partners AHSNs to speed up AF diagnosis and reduce outpatient appointments in secondary care.

> ***Environmental noise will interfere with the recording of an accurate ECG trace for any device that relies on an ultrasonic signal. This should be taken into account when deciding on venues for AF detection programmes"***

> ***Kardia ECG mobile and app by AliveCor can generate a single lead ECG trace when attached to a smartphone and has been highlighted by NICE in a MedTech Innovation briefing"***

Figure 6.

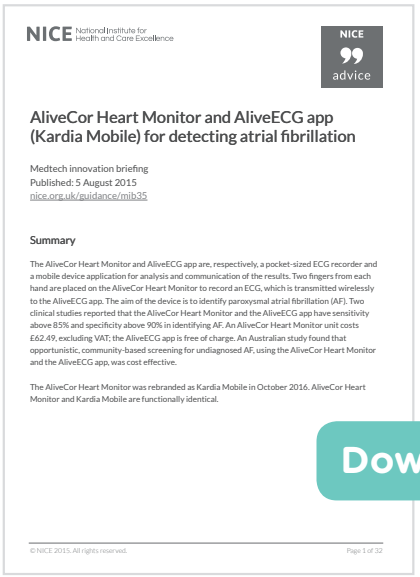
Mobile applications requiring small fingertip contact plates with embedded electrodes and built-in algorithms to detect AF.

Kardia ECG & Kardia App (AliveCor[1], Inc.) (Pictured)

ECG Check (Cardiac Design Inc)

EPI Mini ECG Portable Monitoring System (EPI Mobile Health Solutions Ltd)

[1] AliveCor Company has re-introduced its first device, the AliveCor Mobile ECG and AliveECG App under the new brand name Kardia Mobile and Kardia App. Note both names may be used in the literature.



NICE National Institute for Health and Care Excellence

NICE advice

AliveCor Heart Monitor and AliveECG app (Kardia Mobile) for detecting atrial fibrillation

Medtech innovation briefing
Published: 5 August 2015
nice.org.uk/guidance/mib35

Summary

The AliveCor Heart Monitor and AliveECG app are, respectively, a pocket-sized ECG recorder and a mobile device application for analysis and communication of the results. Two fingers from each hand are placed on the AliveCor Heart Monitor to record an ECG, which is transmitted wirelessly to the AliveECG app. The aim of the device is to identify paroxysmal atrial fibrillation (AF). Two clinical studies reported that the AliveCor Heart Monitor and the AliveECG app have sensitivity above 85% and specificity above 90% in identifying AF. An AliveCor Heart Monitor unit costs £62.49, excluding VAT; the AliveECG app is free of charge. An Australian study found that opportunistic, community-based screening for undiagnosed AF, using the AliveCor Heart Monitor and the AliveECG app, was cost effective.

The AliveCor Heart Monitor was rebranded as Kardia Mobile in October 2016. AliveCor Heart Monitor and Kardia Mobile are functionally identical.

Download

3. Diagnostic accuracy of devices for detecting AF

Currently, there are no national or international published guidelines that have completed a single evaluation of all the current technologies to provide a recommendation for any specific devices that are suitable for a single time point AF detection programme.

3.0 Diagnostic accuracy of devices for detecting AF

In 2013, NICE published a medical technology guidance which evaluated WatchBP Home A (Microlife Health Management Ltd). In view of its high diagnostic accuracy, with a sensitivity and specificity ranging from 90 to 100%, NICE concluded that the use of WatchBP Home A for the detection of suspected AF in patients being screened or monitored for hypertension could be beneficial in primary care[24]. It anticipated, this will potentially reduce fatal strokes in range of 53 to 117 and non-fatal stroke by 28 to 65 per 100,000 patients, depending on age.

The performance of WatchBP Home A has since been assessed alongside two single lead ECG devices (Merlin ECG wrist watch (now discontinued) and Omron heart scan HCG-801) against a 12-lead ECG for the detection of AF in primary care among 1,000 patients over 75 years of age. Although all three devices showed a high sensitivity (93.9 to 98.7%), WatchBP Home A was more specific; 89.7% (95% CI; 87.5-91.6) than Omron Heartscan HCG 801 auto analysis; 76% (95% CI 73% to 79%)[36]. The authors concluded WatchBP Home A could lower the rate of referral for 12-lead ECGs and reinforced the NICE recommendation supporting its use in primary care to detect AF during the diagnosis and management of hypertension.

> ***Repeated sequential measurements improve the accuracy of automated blood pressure monitors and minimise unnecessary referrals for 12-lead ECGs"***

The first study to assess the diagnostic accuracy of an AF algorithm built into an automated BP sphygmomanometer compared to a 12 lead ECG included 450 individuals who were recruited from outpatient clinics[37]. When a single reading was used to detect AF, the sensitivity was 100% (95% CI 97% to 100%) and the specificity 84% (95% CI 81% to 96%), but this improved when two sequential positive readings for AF were used, with a sensitivity of 100% (95% CI 94% to 100%) and specificity of 92% (95% CI 87% to 93%). As approximately 80% of patients with AF are known to have hypertension, utilising automated BP sphygmomanometers with built in AF detection algorithms during BP monitoring can be an effective strategy for an AF detection programme.

Table 5 summarises key published clinical studies investigating the diagnostic accuracy of AF detection with automated BP sphygmomanometers compared to a 12-lead ECG interpreted by a cardiologist. These studies have been pooled together and evaluated by Verberk et al in a meta-analysis using a random rather than fixed effects model in order to allow for variations in study size effects. The analysis assumed homogeneity of the studies and showed a pooled estimate for sensitivity at 0.98 (95% CI 0.95-1.00) and specificity of 0.92 (95% 0.88-0.96). This accuracy was improved when more measurements were taken and the authors concluded that three sequential readings, with at least two detecting AF should be used in routine practice prior to referring for a 12-lead ECG to confirm an AF diagnosis[28].

Table 5.

Studies assessing accuracy of Microlife AF algorithm for automated BP sphygmomanometers against 12 lead ECG interpreted by cardiologist.

Device	Setting, population, sample size and age	AF prevalence/proportion			Reading measurement		Outcomes (95% CI)		Study
		Medical History	12-lead ECG at study visit	New identified case	Used	Used for diagnosis	Sensitivity	Specificity	
Microlife BP3MQ1-2D (Microlife USA)	Italy; cardiology outpatient; 207 patients with a mean age 77.7 ± 11.34 years	Not specified	18.4% (38/207)	Not specified	3	3	0.89 (0.77-0.96)	0.99 (0.96-1.00)	Gandolfo 2015[39]
WatchBP (Microlife, Switzerland)	UK; primary care; 999 patients aged ≥75 years	11% (110/999)	6.7% (67/999)	1.2% (11/889)	3	3	0.95 (0.88-0.99)	0.90 (0.88-0.92)	Kearley 2014[36]
Microlife BB3MQ1-2D (Microlife USA)	USA; secondary care; 199 patients ≥65 years	Not specified	15% (30/199)	Not specified	1	1	0.97 (0.81-1.00)	0.90 (0.84-0.94)	Wiesel 2014[40]
					3	2	1.00 (0.86-1.00)	0.92 (0.86-0.96)	
Microlife BP A100 Plus (Microlife, Switzerland)	Greece; Secondary care; 73 patients from outpatient hypertension clinic & health volunteers with a mean age 70.5±10.6 years	37% (27/73)	37% (27/73)	Not specified	1	1	0.93 (0.74-0.99)	0.89 (0.76-0.96)	Stergiou 2009[41]
					2	1	1.00 (0.84-1.00)	0.76 (0.60-0.87)	
					3	1	1.00 (0.84-1.00)	0.69 (0.56-0.81)	
					3	2	1.00 (0.84-1.00)	0.89 (0.75-0.96)	
Microlife BP3MQ1-2D (Microlife USA)	USA; secondary care; 405 patients from outpatient clinic, mean age 73 years	Not specified	23% (93/405)	Not specified	1	1	0.95 (0.93-0.98)	0.86 (0.84-0.89)	Wiesel 2009[42]
					3	2	0.97 (0.91-0.99)	0.89 (0.85-0.92)	
Omeron 712C (Discontinued)	USA, secondary care; 450 patients from outpatient clinic	Not specified	12% (43/450)	Not specified	1	1	1.00 (0.97-1.00)	0.84 (0.81-0.86)	Wiesel 2004[37]
					2	2	1.00 (0.94-1.00)	0.92 (0.87-0.93)	

Kane et al further evaluated the use of automated BP sphygmomanometers for the detection of AF in primary care settings compared to the gold standard method of a 12-lead ECG interpreted by an experienced cardiologist[38]. The study favoured the use of automated BP sphygmomanometers in comparison to manual pulse palpation and reported specificity >85% and a sensitivity >90%. In view of their different heterogeneous populations studied, methodologies used and potential for bias, the authors concluded more studies are needed to establish the accuracy of automated BP sphygmomanometers with built-in AF detection algorithms for opportunistic case-finding of AF during routine BP measurement.

Table 6.

Meta-analysis pooled data[15]

Method	Sensitivity (95%CI)	Specificity (95%CI)	Positive Likelihood Ratio (95%CI)	Negative Likelihood Ratio (95%CI)
Pulse palpation	0.92 (0.85-0.96)	0.82(0.76-0.88)	5.2 (3.8-7.2)	0.1 (0.05-0.18)
BP monitor	0.98 (0.92-1.00)	0.92 (0.88-0.95)	12 (8.20-17.80)	0.02 (0.00-0.09)
Non-12-lead ECG	0.91 (0.86-0.94)	0.95 (0.92-0.97)	20 (12-33.7)	0.09 (0.06-0.14)
Smartphone application	0.97 (0.95-0.99)	0.95 (0.88-0.98)	19 (8-45)	0.03 (0.01-0.05)

The diagnostic accuracy of automated BP sphygmomanometers has also been compared with a number of different technologies (non-12-lead ECGs and smart phone applications) alongside pulse palpation for AF detection by Taggar et al[15]. In this meta-analysis, the authors concluded that, compared to 12-lead ECGs, automated BP sphygmomanometers and non-12-lead ECG devices had the greatest diagnostic accuracy (table 6). The study data also suggested that smartphone apps for detecting suspected AF have a similar diagnostic accuracy to automated BP sphygmomanometers; however, this finding needs to be interpreted with caution in view of the small sample size in the studies used for this analysis.

This meta-analysis supports the potential use of newer devices with built-in AF algorithms as an alternative to pulse palpation for identifying suspected AF as part of any AF detection programme. Table 7 summarises the studies of handheld ECGs and smart phone applications used in the meta-analysis. Some devices such as RhythmPad (Cardiocity Ltd) were not included, as there were no published articles focusing on the performance of the embedded algorithms specific to AF detection for this device at the time of the analysis. A subsequent literature search revealed two studies published as a single abstract in Europace[50-51]. The first was completed in 2011 with 500 patients attending a flu vaccination clinic and an anticoagulant clinic, while the second study completed in 2012 reviewed the Rhythm Pad system use with a cohort of patients in secondary care who were referred to an electrophysiology department[50]. 250 single lead ECG readings were compared with a 12-lead ECG as part of routine investigation. This included a visual inspection of the ECG recordings and the output of the 12-lead automated analysis, compared to that of the single lead ECG after running through two analysis algorithms[51].

The results of the two studies revealed that a single lead ECG could be acquired in 98.4% of cases using the RhythmPad (Cardiocity Ltd). In 1.6% of cases an ECG could not be recorded through simple hand placement due to the presence of tremors leading to unstable readings. The first study identified 366 patients as having sinus rhythm or sinus tachycardia, 124 ECG readings identified other arrhythmias or an undetermined rhythm and 10 ECG recordings could not be read. In the second study twenty-one 12-lead ECGs showed AF. The RhythmPad auto-analysis matched the 12-lead ECG for 14 of these 21 patients with AF, but failed to identify AF in the remaining in 7[50,51]. From this limited trial, sensitivity of the RhythmPad (Cardiocity Ltd) was calculated as 67% with a specificity of 97%. Data to support RhythmPad (Cardiocity Ltd) in AF case-finding is still accruing. Currently, there is a one-year evaluation programme using the Rhythm Kiosk (Cardiocity Ltd) for AF detection, taking place in 30 GP practices across UK called Safe-2-Screen.

> ***Meta-analysis has demonstrated that screening devices with built-in AF algorithms are more accurate than manual pulse checks"***

Table 7.

Summary of studies for the handheld ECG and smart phone applications data used in the meta-analysis conducted by Tagger et al[15]

Device	Setting, population, sample size and age	AF prevalence/proportion			Index test (s)	Reference	Outcomes (95% CI)		Study
		Medical History	12-lead ECG at study visit	New identified case			Sensitivity	Specificity	
Hand-held ECG data:									
Prototype 6-lead frontal plane ECG using 4 electrodes ***Note: Rhythm Pad based on this prototype***	UK; Secondary care, 157 patients from anticoagulant clinic	49.7% (78/157)	Not specified	Not specified	Prototype 6-lead frontal plane ECG using 4 electrodes	12-lead ECG	0.96	0.97	Caldwell 2012[43]
Zenicor (Zenicor Medical Systems)	Sweden; secondary care; 100 patients recruited from cardiology outpatient clinic; mean age 64 (43-87) years	12% (12/100)	Not specified	Not specified	Single lead ECG	12 Lead ECG interpreted by cardiologist	0.92	0.96	Doliwa 2009[44]
Heartscan HCG-801 (Omeron Healthcare Ltd)	UK; primary care; 999 patients aged ≥75 years	11% (110/999)	6.7% (67/999)	1.2% (11/889)	Heartscan 801 interpreted by automated software	12-Lead ECG interpreted by 2 independent cardiologist	0.99 (0.93-1.00)	0.76 (0.73-0.79)	Kearley 2014[36]
Heartscan HCG-801 (Omeron Healthcare Ltd)	Belgium, secondary care; 177 patients attending emergency department or hospital wards; mean age was 55 (18-94) years	7.3% (13/177)	Not specified	Not specified	Omeron Heartscan device interpreted by 2 GPs and automated software	12-Lead ECG interpreted by cardiologist	GP interpretation: 0.69% (0.39-0.91) Software auto-analysis interpretation: 92.3% (64.0-99.8)	GP interpretation: 94.5% (89.8-97.5) Software auto-analysis interpretation: 100% (97.8-100)	Renier 2012[45]
MyDiagnostick (MyDiagnostick Medical BV)	Belgium; primary care; 191 patients from general practice with a mean age 74.6±97 (range 50-99) years	84% (161/191)	53.9% (103/191)	Not specified	MyDiagnostic device with an automated software analysis	12-Lead ECG interpreted by cardiologist	0.94 (0.87-0.98)	0.93 (0.85-0.97)	Vaes 2014[46]

Table 7 (Continued).

Summary of studies for the handheld ECG and smart phone applications data used in the meta-analysis conducted by Tagger et al[15]

Device	Setting, population, sample size and age	AF prevalence/proportion			Index test (s)	Reference	Outcomes (95% CI)		Study
		Medical History	12-lead ECG at study visit	New identified case			Sensitivity	Specificity	
Smartphone applications									
Kardia mobile ECG and app (AliveCor, Inc.)	USA; secondary care; 381 individuals from (123) university athletics society, medical students and (128) cardiology clinic; mean age 59±15 years	Not specified	Not specified	Not specified	iphone based single lead ECG interpreted by software and electrophysiologist	12 Lead ECG interpreted by automated software and 2 electrophysiologists	94.4%	99.4%	Haberman 2015[47]
Kardia mobile ECG and app (AliveCor, Inc.)	Australia, 313 patients; setting unknown. 109 assessed the initial algorithm and 204 used to validate the optimised algorithm	Initial group 35.8% (39/109) Validated set23.5% (48/204)	Not specified	Not specified	109 patients were part of learning set and 204 patients were used to validate the optimised algorithm	12-Lead ECG interpreted by cardiologist	Optimised algorithm in learning set: 100% Validation optimised software algorithm: 98% (98-100)	Optimised algorithm in learning set: 96% Validation optimised software algorithm: 97% (93-99)	Lau 2012[48]
Smart phone application to detect finger pulse waveform	USA; secondary care; 76 AF patients attending elective cardioversion	100% (76/76)	Not specified	Not specified	Detection of fingertip pulse waveform using an iPhone 4S Analysis by 3 methods of automated software (RMSSD, Shannon entropy and combination of the two)	12 Lead ECG or telemetry interpreted by a trained physician	RMSSD: 0.98 Shannon entropy: 0.98 Combination: 0.96	RMSSD: 0.92 Shannon entropy: 0.82 Combination: 0.97	McManus 2013[49]

4. Prevalence following AF detection programmes using devices

There are a number of publications illustrating the use of these devices in AF detection programmes in various settings.

4.0 Prevalence following AF detection programmes using devices

A systemic review of AF detection at a single-time point in unselected patients in the community was carried out by Lowers et al. This included thirty studies with a total of 122,571 patients that were recruited from GP surgeries, outpatient clinics or population screening programmes. The overall prevalence of AF in the study population was 2.3% (95% CI 2.2-2.4), increasing to 4.4% (95% CI; 4.1-4.60) in those aged over 65 years. The incidence of undiagnosed AF was found to be 1% (95% CI 0.89-1.04) in the whole study group increasing to 1.4% (95% CI; 1.2-1.6%) in those over the age of 65 years. The authors conclude novel technologies may facilitate the implementation of case-finding programmes in patients over 65 years[20].

Table 8.

Studies of AF detection programmes in primary care using different devices

Device	Setting	Country	Type of Detection programmes	Screening process	Number of participant screened	Age (years)	History AF	New detected AF	Reference
Kardia mobile ECG and app (AliveCor, Inc.)	Community Pharmacy	Australia	Opportunistic	Single time point screening, with single lead ECG	966	≥65	9% (87/966)	1.6% (15/966)	Lowers 2014[52]
Kardia mobile ECG and app (AliveCor, Inc.)	Community pharmacy	New Zealand	Opportunistic	Single time point screening, with single lead ECG	121	≥55	17% (20/17)	1.7% (2/121)	Walker 2014[53]
WatchBP Office (Microlife Health Management Ltd)	Community pharmacy	Italy	Opportunistic	Single time point screening, using at least two of three measurements to detected AF	220	>18	Not specified	1.8% (4/220)	Omboni 2016[54]
MyDiagnostick (MyDiagnostick Medical BV)	Primary care (Influenza vaccination)	Netherlands	Opportunistic	Single time point screening, with single lead ECG	3269	69.4±8.9	2.6% (84/3269)	1.1% (37/3269)	Kaasenbrood 2016[55]
Heartscan HCG-801 (Omeron Healthcare Ltd)	Primary care screening programme 'Week of heart rhythm'	Belgium	Opportunistic	Single time point screening, with single lead ECG	13,564 of whom 10,758 were ≥ 40 years	59±11	7.2% (771/10,758)	2% (228/10,758)	Claes 2012[56]
Rhythm Kiosk (CardiocityLtd)	Primacy care (GP surgery)	UK	Opportunistic	Single time point screening, with single lead ECG	To date 21069	Not specified	Not specified	0.38% (81/21069)	Not published as still on-going. The safe-2-screen programme (unpublished)
Zenicor (Zenicor Medical Systems)	Patients Home	Sweden	Systematic	Intermittent ECG screening for 2 weeks	7173	75-76	9.2% (666/7173)	3% (218/7173)	Svennberg 2015[57]
Zenicor (Zenicor Medical Systems)	Patients Home	Sweden	Systematic	Intermittent ECG screening for 2 weeks.	403	75-76	9.6% (81/848)	7.4% (30/403)	Engdahl 201358

Table 8 summarises recent examples of published studies in primary care settings using different devices to detect AF. Although different technologies and devices have been validated in a number of settings, including event monitoring and case finding for AF, the quality of data reporting is not homogenous across these studies. Limitations of the data reported include lack of participants' age and AF history. It is also important to note that detection methods relying on single time point assessment will often fail to detect PAF. In other words, a negative result simply illustrates an individual is in sinus rhythm at the point of testing and cannot exclude potential PAF[18]. This must be communicated effectively to individuals who are screened for AF and detection programmes should take this into account. Studies assessing rhythm over an extended period or at multiple time points have been shown to identify a higher incidence of PAF. **Devices used in this type of screening are outside the scope of this report.**

> ***It should be recognised that AF detection programmes based on single time point assessment will often fail to detect PAF"***

5. Barriers and enablers for AF detection programmes using devices

The development of technologies and software utilised in the new generation of devices for AF detection has outpaced real-world validation; hence large scale, pragmatic studies are still needed to substantiate their accuracy and practicability for use in single point AF detection programmes in primary care and community settings.

5.0 Barriers and enablers for AF detection programmes using devices

Data from on-going studies is crucial to determine safety, efficacy, feasibility and cost effectiveness. The success of any AF detection programme using devices will not only depend on the accuracy of the device used but also on the local population selected, staff using the device and setting. A greater understanding of the acceptability of new devices, as well as the required knowledge and skills, from a staff user and patient perspective is essential to inform selection of an appropriate device. A number of small pilot studies have demonstrated the feasibility of introducing new technology and software designs for AF detection in different primary care settings and used by different healthcare workers[59, 60].

GP-SEARCH is a qualitative pilot study using a single-lead smartphone ECG (Kardia mobile ECG and app, AliveCor, Inc.) to detect AF in primary care. It involved three practices in Australia who trained their receptionists, practice nurses and GPs to use Kardia mobile ECG and app (AliveCor, Inc.) to assess patients aged 65 years and over, while attending routine appointments[59]. The authors found the smartphone ECG to be feasible for use in an AF detection programme in the GP practice. The enablers and barriers for healthcare workers and patients identified by the pilot are summarised in table 9.

> ***"Identifying and addressing enablers and barriers to delivery of an AF detection programme will be critical to its success"***

Table 9.

Enablers and barriers for healthcare workers from GP practice carrying out AF case-finding during their routine practice[59]

Healthcare worker	Enablers	Barriers
General Practitioners	• Like the portability & instant result provision • Positive results add value • Negative results provide reassurance • Acts as a prompt • ECG rhythm allows review for other conditions e.g. ectopics	• Relying on others to perform the AF detection process • Not having the required software • Practice IT blocked access to application • Remember to charge the phone • Technology not working
Practice Nurses	• Like the built in AF algorithm for auto-analysis • Confident and knowledge in explaining the AF detection process • AF detection process performed in treatment rooms allowed privacy & clinical focus	• Availability of device at required time • Needs a review by the GP if possible AF or abnormal
Receptionists	• Ease of iPhone use	• Lack of confidence • Lack of knowledge to explain or respond to patients' questions • Competing tasks • Relevance to role • Technology failure • Time taken (including completing consent forms)
Patients	• Liked the technology • Interested in seeing the heart rhythm	• Poor understanding of AF and aim of AF detection programme • If negative result, will disengage with the process • Focus on more pressing health concerns

The Screening Education and Recognition in Community pHarmacies of Atrial Fibrillation (SEARCH-AF) pilot study from Australia demonstrated that community pharmacists can undertake community-based AF detection and have the opportunity to reach people who do not attend their general practice[52]. The AF detection process involved a brief medical history, pulse palpation measured for 30 to 60 seconds, and a single lead ECG strip using the Kardia mobile ECG and app by AliveCor, Inc. A qualitative review of the service implementation from the pharmacists' perspective highlighted some of the benefits, barriers and challenges to delivering an AF detection programme from community pharmacies. Overall the pharmacists were positive about the service, and the use of the AF detection device to facilitate AF case-finding was accepted by both pharmacists and customers. Other perceived benefits included pharmacist job satisfaction with the opportunity to learn and apply new skills that could be combined with other existing services, such as BP monitoring. The authors identified a number of potential barriers that were supplemented with enablers and additional strategies that can lead to a successful service (summarised in table 10)[59].

Table 10.

Enablers and barriers identified by community pharmacists who carried out an AF detection programme in their community pharmacy[59]

	Barriers	Enablers & Strategies
Engaging with customers	• Lack of service awareness • Perception of pharmacist traditional role does not include AF detection activities • Fear of being screened	• Use promotion flyers & engage directly with customer. Also link to national education/AF awareness campaigns • Awareness building through primary care campaigns • Spend time discussing their fears & apprehensions
Engaging with clinicians	• Negative reaction to pharmacist performing AF detection activities	• Improve relationships by discussing services directly with local clinicians • Develop effective methods of information sharing and referral pathways to facilitate collaboration
Recruitment	• Lack of time to engage with customers & discuss AF detection programme • Relying on advertising to engage with customers	• Up-skill staff to perform initial discussion +/- risk assessment • Utilise a checklist/guideline for consistency • Workflow management • Combine AF detection with other detection programmes • Specific staff roles +/- member staff to champion the service • Set targets • Use layered approach: Have prominent advertising, directly approach customers • Temporary area with small display that looks professional and inviting
Implementation	• Workflow challenges/ time • Poor familiarity with protocol • Paperwork	• Service remuneration • Provide combined detection programme package • Combine on-the-spot & appointments for AF detection services • Sufficient training & on-going support • Establish permanent area for AF detection resources

These studies demonstrate the importance of developing a structured AF detection programme that is incorporated into an AF care pathway and funded through local or national incentives [59-61]. Staff members who are part of the programme should receive appropriate training and support to ensure they are confident in discussing the AF detection process with patients, addressing their concerns, using the device(s) and explaining the results.

6. Key issues to consider when choosing a device

This report has shown AF detection devices have the potential to be used in AF case-finding programmes across primary care and community settings by various healthcare workers (for example: doctors, pharmacists, nurses or reception staff).

6.0 Key issues to consider when choosing a device

Table 11 provides a list of key factors to consider when choosing the most appropriate device to use in the correct setting and the appropriate healthcare worker(s) to facilitate an effective AF detection programme.

Table 11.

Issues to consider when purchasing devices for AF detection

Setting of the AF detection programme

- **GP Practice?**
  Medical visits, annual review, flu vaccination, embedded in routine blood pressure monitoring, specific clinics, awareness campaigns?
- **Community pharmacy?**
- **Residential or care homes?**
- **Podiatry?**
- **Outreach in community settings?**
  - **Shopping Centres?**
  - **Train stations?**
  - **Libraries?**

Staff involved in the AF detection programme

- What are the staff training requirements?
- What on-going support is required?
- What are the local referral pathways for possible AF and abnormal ECGs?

Device EU safety, health and environmental requirements

- Does the device have a CE marking?
- Does the device comply with the EU Directive and relevant UK legislations for performances and safety?

Accuracy of device

- Does the device have a built-in AF algorithm for auto-analysis? What is the quoted sensitivity and specificity? Has this been externally validated?
- Does the ECG rhythm data require interpretation by:
  a. In-house trained practitioners?
  b. Telemedicine service provision (will this service include provision of AF detection devices)?
- What factors can cause artefact and how will these be minimised?
- Does the device require regular calibration to ensure accuracy?

Data transmission & security

- Do you need an internet connection or Wi-Fi?
- What information will be transmitted digitally?
- Is this in line with the NHS Data confidentiality and security?
- Has this been discussed with the local information governance team?

Memory capacity

- Is there a limited memory for storage of ECG readings?
- If applicable, how does the device overwrite the oldest recording?

ECG electrodes connectivity

- Does the device have integrated finger or thumb electrodes and is it simple to use?

Hardware

- Is additional hardware required (e.g. a smartphone or tablet)?

Consumables

- Are there any consumables that require replenishment or need to be purchased in addition to the device?

Cost

- Is the device purchased or leased?
- Are there any costs associated with consumables, additional hardware and/or calibration?
- What is the life span of the device?
- Is there a cost associated with ECG interpretation?

MHRA guidance on managing medical devices

- Review roles & responsibility
- Ensure local policies are consistent with applicable standards

6.1 Setting for the AF detection programme

The setting for the AF case-finding programmes may influence the choice of device used. For example, BP sphygmomanometer with a built-in AF algorithm maybe particularly suitable in settings that provide routine BP monitoring. WatchBP Home A (Microlife Health Management Ltd) requires at least two BP measurements and will automatically undertake a second reading after a 15 second pause; a third or fourth reading may be required and patients need to remain relaxed throughout this automated process, which does take some time. In contrast, an automated BP sphygmomanometer with a built-in AF algorithm may not be an appropriate choice for AF detection programmes that are taking place during flu vaccination clinics. In this setting, devices that require minimal time to perform the AF detection process are desirable, such as those that produce an ECG rhythm strip within 30 seconds.

It is important to ensure the venue used is appropriate in terms of space and environment. For instance, a train station is likely to have a high level of background noise which may interfere with the recording of a single lead ECG, depending on the device chosen.

6.2 Staff role in AF detection programme

It is also important to establish which members within the healthcare team will be undertaking the AF detection process. Alternatively, a standalone device, such as the RhythmPad kiosk (Cardiocity Ltd) may be considered, as it requires minimal staff involvement. It is important to determine the skill mix, training and continued support provided to staff and the needs of the people who are offered the AF detection service(s). GP-SEARCH study highlighted the reluctance of the receptionist in GP practices to perform AF detection due to lack of confidence and knowledge. Such barriers need to be identified and addressed to ensure the success of AF case-finding programmes[59-61].

6.3 Accuracy of devices

The device of choice should ideally provide real-time AF detection data that is readily available with a high sensitivity and specificity for AF, to minimise unnecessary referrals for a 12-lead ECG. When reviewing published data, it is important to ensure this is viewed in the context of all factors that influence the accuracy of the device.

6.3.1 Automated BP sphygmomanometer with a built-in AF algorithm

The accuracy of an automated BP sphygmomanometer with a built-in AF algorithm is dependent on the number of readings. Data has illustrated a triplicate reading; in which two of the readings are positive is the optimal accurate approach. It is therefore important to ensure staff using such a device are aware of the need to take three readings, and that two out of three should be positive to indicate possible AF. This will improve the specificity and result in fewer referrals for 12-lead ECGs[15,28,38]. Models of practice that only have access to automated BP sphygmomanometer with a built-in AF algorithm should ensure this is incorporated into their standard operating procedures. Services that also have access to single-lead ECG may consider using this following the first AF positive reading from an automated BP sphygmomanometer. This has the potential to improve the efficiency of the consultation; however there is currently no published data to support this approach. All existing studies have investigated the use of a single device.

There is evidence to suggest that the chance of a false positive finding can be increased in the presence of multiple premature ventricular (specificity 62%) or atrial beats (specificity 43%), as well as with sinus arrhythmia. Therefore, automated BP sphygmomanometers should not be used in children or throughout pregnancy to detect AF[28].

> ***Automated BP monitors with AF detection algorithms are not suitable for use in children and throughout pregnancy due to increased risk of false positives"***

6.3.2 ECG devices (event recorders or mobile ECG and apps)

It is important to establish if the device used has a built-in AF algorithm or if the ECG rhythm strip requires interpretation. The experience of the healthcare worker in ECG interpretation is a powerful factor in determining the accuracy of AF detection. This was demonstrated in the SAFE study, which compared the AF diagnosis made by GPs using a 12-lead ECG with the support of a computer software algorithm, to a reference diagnosis made by two cardiologists. The GPs accurately interpreted the 12 lead ECGs with an 80% sensitivity and 92% specificity[19]. This diagnostic performance improved marginally when the GPs took into account the interpretive computer software to a sensitivity of 92% and specificity of 91%. Devices with validated AF detection algorithms are able to produce an immediate result that is standardised and not reliant on accurate ECG interpretation by healthcare staff. As a result, these devices can be used in multiple settings and by a plurality of staff groups. If telemedicine service is used to interpret the ECG recordings remotely from an AF detection device(s), it is important to ensure the service is carried out by trained practitioners and that there is a process in place that allows the results to be available in a timely manner.

> ***Artefact can significantly impair the quality of all ECG traces and is potential issue in the older age group that are more commonly affected by AF"***

The quality of the trace from a single lead ECG can be affected by artefact and noise. Patients performing arm movements, with essential tremor or unable to hold the device firmly enough can affect the accuracy of the automated AF algorithm interpretation. This was demonstrated in a study that reviewed the performance of AliveCor's Kardia and MyDiagnostick devices in a cardiology and geriatric setting[62]. The patients had a mean age of 67.9 ± 14.6 years. Cardiology patients using MyDiagnostick (MyDiagnostic Medical BV) for AF detection demonstrated a sensitivity of 60.5% and specificity of 93.3%, whereas the same patients using Kardia mobile ECG and app (AliveCor, Inc.) had a lower sensitivity of 36.8% and a higher specificity of 96.1%. The sensitivity for both devices improved without major impact on specificity following a manual review of the ECG recording by an electrophysiologist and the exclusion of patients with implanted devices (pacemaker or cardioverter defibrillator). The sensitivity of the automated analysis of MyDiagnostick (MyDiagnostic Medical BV) increased to 81.8% and was shown to be even higher than interpretation by the two electrophysiologists (77.3% and 72.7%). Interestingly, for AliveCor's Kardia device, the auto-analysis sensitivity improved to 54.5%, and was lower than that of the two electrophysiologists (90.9%). For geriatric patients, AliveCor's Kardia did better, with a sensitivity of 89.5% and specificity of 95.7%, whereas MyDiagnostick (MyDiagnostick Medical BV) demonstrated 78.9% and 97.9% respectively. This is explained in part by the authors as being due to fewer patients having an implanted pacemaker in the geriatric group. Also, it was noted that when an electrode solution spray was used to moisturise the patients' hands before holding the device, the ECG recording quality for AliveCor's Kardia improved, whereas it made no difference to the results with MyDiagnostick (MyDiagnostic Medical BV).

These findings differ substantially from previous studies that had shown the accuracy of both devices to have a higher sensitivity and specificity (i.e. Kardia mobile ECG and app (AliveCor, Inc.) sensitivity ranging from 98 to 100% and specificity of 96 to 97% and MyDiagnostick (MyDiagnostic Medical BV) sensitivity between 94 to 100% and specificity between 93 to 95.9% compared to a 12-lead ECG)[48,63-65]. The authors suggested patients may have been from a selected population tested under more controlled conditions, such as recruiting patients with known AF and excluding patients with implantable devices. Interestingly, the authors also noted that the interpretation of the ECG recordings in previous studies was carried out by a single cardiologist - this will minimise the effect of variability between physicians. Within this study the experience and knowledge level of those performing the AF detection process and interpreting the results was not defined and this could potentially have an impact on accuracy[62].

> ***Devices with validated AF detection algorithms are able to produce an immediate result that is standardised and not reliant on ECG interpretation by healthcare staff"***

Another potential explanation may be different methodologies as some of the details are not explicitly stated in the study reports. For example, whether the 12-lead ECG was recorded contemporaneously or at a different time from the recording from the single lead ECG device; or whether consecutive repeated readings were taken from the device in order to enhance the accuracy.

The AliveCor's Kardia ECG-based automated AF detector was recently compared to Cardiio Rhythm heart app, a smartphone camera-based PPG pulse waveform measurement. In this study, AliveCor showed a low sensitivity of 71.4% and the authors suggested this could be attributed to the updated version of the automated AF algorithm that is currently in use. Previous studies with the higher sensitivity were carried out using an older version of the automated AF-algorithm[34].

6.4 Data transmission & Security

Installation of Wi-Fi may be necessary for data transmission to allow the ability to forward ECGs to the patients, GPs or secondary care where the device is used in an external setting. Medical information being transmitted over wireless networks needs to conform to the requirements for NHS Data security to ensure the security and confidentiality of patient identifiable data. It is important to ensure that the dissemination of electronic medical data to mobile and cloud-based technology is encrypted and uses secure networks. Further advice should be sought from the local Information Governance team. Companies storing NHS related data should be listed in the NHS Information Governance toolkit and registered with Care Quality Commission (CQC).

> ***Information governance issues should be identified and addressed for any device where data is to be transmitted electronically"***

6.5 Memory Capacity

It is important to determine if devices have unlimited storage using software that uploads readings to a cloud or, where data is held internally within the device, whether there is a limitation to the in-built capacity – this will result in overwriting of the oldest recordings once maximum capacity is reached.

6.6 ECG electrode connectivity

Ideally devices should be simple to use with integrated electrodes requiring simple activation with no need to connect ECG cables. Some devices may include an option of using extra leads such as RhythmPad (Cardiocity Ltd) that offers an optional third lead to enable recording of a 6-lead ECG.

6.7 Additional Hardware

It is important to note that some devices such as Kardia mobile and app (AliveCor, Inc.), require a smartphone or tablet computer to function. Detection programmes need to consider how this hardware will be provided and factor in the associated cost.

6.8 Consumables

Usually the monitor is the only component of the kit that is classified as non-consumable. It is important to establish if there are any parts of the device that require replenishment and this should be included in the cost. For example, cuff sizes for BP machines; usually the machines are supplied with only the standard adult sized cuff, to ensure the accuracy of measurements small and large cuffs will need to be purchased.

6.9 Cost

The devices available for single time-point AF detection programme(s) differ substantially in cost, ranging from approximately £100 to £2500 for a standalone device. Discounts for purchase at volume may be possible and should be considered when negotiating prices with the manufacturer or suppliers. Some devices, such as Kardia mobile ECG and app (AliveCor, Inc.), require additional hardware (i.e. smartphone or tablet computer) which are not accounted for in the list price. Further costs may be incurred for additional consumables or if the device requires regular calibration. Depending on the device chosen, there may be an option to lease rather than buy which may reduce the initial financial outlay. Some CCGs have used the opportunity presented by re-procurement of their cardiac diagnostic services to include the requirement to supply all GP practices with one or more AF detection devices. Finally, it is important to establish if there are ongoing costs associated with ECG interpretation. For example; the RhythmPad (Cardiocity Ltd) analysis service costs £3 per day whilst Kardia mobile ECG and app (AliveCor, Inc.) provides auto-analysis free of charge but a more detailed analysis can be requested for a fee of £5.

The cost of these devices may be offset by a reduction in referrals for unnecessary 12-lead ECGs and by facilitating the early detection and management of AF, which will reduce the incidence of AF-related stroke. To date, only Microlife BP Home A (Microlife Health Management Ltd) is supported by published cost evidence data (NICE medical technology guidance 13), highlighting the cost and consequences of using WatchBP Home A (Microlife Health Management Ltd)[24]. At the time of the analysis NICE concluded '*WatchBP Home A was cost saving and could provide significant clinical benefits when used for opportunistic atrial fibrillation detection in asymptomatic patients being screened or monitored for hypertension in primary care'.*

> ***When making purchasing decisions, it is important to consider not only the cost of the device, but any other associated costs such as hardware, consumables, calibration and ECG interpretation"***

6.10 MHRA guidance on managing medical devices

As with all devices it is important to follow guidance from the MHRA on managing devices, which highlights the necessary governance requirements and helps to address related elements including access, storage, infection control, safe appropriate use and disposal. Full details can be accessed by clicking on to this document.

6.11 Safety notices, Medical Device Alerts or Recalls

In 2015, AliveCor recalled version 2.1.2 of its iOS app under an FDA class 3 recall (the least hazardous recall category) due to the app crashing upon its use[66]. Version 2.1.2 was never distributed outside the USA and pulled from distribution promptly and updated with version 2.1.3 on iTunes. There are no other safety notices, medical alerts or recalls for these devices noted on FDA or MHRA websites.

7.0 Product Specifications of selected devices

This report highlights a variety of different technologies with the potential to facilitate AF detection programmes in primary care and community settings. On the following pages we have provided product specifications for five devices (Kardia mobile ECG and app, RhythmPad, MyDiagnostick, WatchBP Home A and Zenicor) that could have a role in single time point case-finding for AF.

These specific devices have been highlighted for a number of reasons:

1. All are suitable for use in primary care and community settings for single time point AF detection.
2. At the time of publication, all are supported by published studies focusing on AF case-finding.
3. All are CE marked.
4. All are available for purchase within the UK.

The five devices are listed in alphabetical order by name. If you are considering other alternatives, do use the list in Table 11 to support your decision.

Kardia ECG & Kardia app[2] (AliveCor, Inc.) (Multiple suppliers:, MS instruments, Technomed Group, NHS supplies Chain, G Cloud)	
	
Model description	AliveCor's Kardia Mobile ECG is a single-channel cardiac event monitor. It consists of a device and app that enables the user to record, share and review ECG trace(s). The device can attach to the back of most iOS (iPhone, iPod and iPad) and android devices which are required to generate the ECG rhythm trace and display the results
User manual	Click here to view, Quick Start and Full Manuals https://www.alivecor.com/en/quickstart/
Patient connection	Single-lead ECG event recorder with integrated two electrodes within the rectangular device that can be attached directly to a mobile device or be within 30cm of the mobile device during operation. Voice to text for simultaneous symptom capture and annotation during recording
Heart rate range	30 – 300 beats per minute
Display	ECG transmitted wirelessly to the Kardia app. In addition to a full rhythm trace, a message is displayed as: Atrial fibrillation ("AFib"), Normal, unreadable recording. For traces that are not normal, AF or had no interference detected will display message "unclassified"
Memory type	Software application, uses smartphone/tablet and EU compliant encrypted cloud
Recording capacity	Software application can store 1000s of recording on a smart phone or tablet. These are accessible through authorised cloud based provider dashboard
Data transfer	Share, print or email a PDF of the rhythm trace on the smartphone, download PDF from eu.alivecor.com Optional: Cardiac Physiologist report returned in-app within 24 hours for £5 incl. VAT per recording
Printing	E-mail as a PDF, print or upload from device. Individuals and Healthcare workers can also access the recordings through login at eu.alivecor.com
Power	3V CR2016 Coin Cell
Battery lifespan	Minimum 200 hours operating time, 12 months typical use
Physical Size (LxWxH)	8.2 cm x 3.2cm x 0.35cm
Weight	Not specified
List price	£82.50 (+VAT)
Supplied accessories (Batteries & user manual assumed)	Attachment plate with adhesive
Warranty	1 year
Website	www.alivecor.com

[2]AliveCor Company has re-introduced its first device, the AliveCor Mobile ECG and AliveECG App under the new brand name Kardia™ Mobile and Kardia App. Note both names may be used in the literature.

MyDiagnostick (MyDiagnostick Medical B.V) (Multiple Suppliers: Cardiologic Ltd, TechnoMed, or direct)	
	
Model description	ECG event recorder
User manual	MyDiagnostickDeviceManual.pdf
Patient connection	Single lead, integrated two electrodes within the device that has a shape of a stick
Heart rate range	Not specified
Display	Device has indicator that will turn green for normal cardiac rhythm and red in case of AF
Memory type	It consists of an internal priority storage scheme
Recording capacity	Up to 140 x 60 to 70 seconds ECG recordings. Note: Device will overwrite oldest recordings in the following order: a) Recordings during which an error has occurred b) Recordings with no AF detection c) Recordings with AF detection
Data transfer	USB connection to computer to download a recorded file
Printing	ECG recordings can be retrieved from device using appropriate MyDiagnostic software
Battery lifespan	2 x NiMH 1.2V 2000 mAh rechargeable (via USB connector)
Battery lifespan	Minimum 500 recordings at 60 to 70 s or 2 months regular use if the device while measuring 3 to 5 times per day
Physical Size (Lengthxdiameter)	260 x 22mm
Weight	180g
List price	£650 (excluding VAT and Carriage)
Supplied accessories (Batteries & user manual assumed)	USB cable, additional information obtainable from website.
Warranty	2 years. The warranty only applies to failures that are the result of manufacturing faults and/or material defects.
Website	www.mydiagnostick.com/home-en

RhythmPad (Cardiocity Ltd)	
 	
Model description	ECG detection tool that is suitable for continuous operation
User manual	Click here to view **user guide**
Patient connection	1 or 6 channel, integrated electrodes within the device.
Heart rate range	Not specified
Display	Utilises a Windows PC or Tablet screen to display either the full lead 1 or 6 lead ECG. Uses the PC or Tablet screen as data entry to take in patient details, shows patient video of how to place hands on pad to take reading.
Memory type	Utilise the processing of a Windows based PC or Tablet PC running windows 7 or later.
Recording capacity	Software suite records all readings onto PC or Tablet Hard Drive. All readings are stored as PDF and are time stamped. This allows for readings to be moved into Electronic Patient Records through third party tools such as DocMan. Software suite also allows for readings to be emailed to nominated email address or printed out A4 to any networked Windows Printer. Software suite can be configured to connect to Cardiocity's cloud and arrange for automatic interpretation of ECG recording strip via Cardiocity's online Electrophysiology review service. All cloud connectivity was designed in conjunction with Information Commissioners Office to ensure compliance with Data Protection Act. **It is the responsibility of the user to ensure that they are operating the RhythmPadGP product in accordance to their local data protection policy**
Data transfer	Wired through USB 2.0 port
Printing	Export the data in PDF or PNG form to any third party system.
Power	USB 5.0vDC supplied from Windows PC or Tablet
Dimensions (RhythmPad):	135 x 80.6 x 44.8 mm
Weight (RhythmPad):	165g
List price	RhythmPadGP (running on your own PC) £1099 RhythmPadGP-Portable (Supplied in portable conference folder with Tablet PC) £1699 RhythmPadGP Kiosk £2500 RhythmPad Analysis Service £3/day Optional: Third Electrode – to enable 6 lead readings £200
Supplied accessories (Batteries & user manual assumed)	Supplied with Instructions for Use, USB cable. Manual is available for download as is full software suite
Warranty	1 year
Instruction selection mode	English, Italian, French, German, Spanish, Russian, Portuguese and Polish
Website	www.cardiocity.com

Watch BP Home A (Microlife Health Management Ltd) (Multiple suppliers: Oncall medical supplies, Mortara Dolby, Intermedical)	
	
Model description	A modified oscillometric BP machine that flashes when it detects Atrial Fibrillation (AF) during automatic BP measurement. Device can be used either in: a) 'Diagnostic' mode (For 7 day scheduling with average morning, evening and overall BP readings tabulating in easy to read format) or b) Usual mode' (single measurement taken at any time). AF is detected in all readings of triple measurement in 'usual' mode or all four readings of one day in 'diagnostic mode to confirm AF
User manual	Click here to view **user guide**
Measuring procedure	Oscillometric, corresponding to Korotkoff
Measurement range Blood pressure Pulse	 30 – 280mmHg 40 – 200 beats per minute
Display	Displays blood pressure measurement (SBP and DBP values), Pulse indicator (AFIB or Normal) and pulse rate
Memory type	Results are stored in an internal memory and can be downloaded to a removable memory device for clinicians evaluation
Recording capacity	250 measurements in usual mode
Data transfer	PC connectivity – transmits BP measurement data to any PC via USB connectivity
Power	4 x 1.5 V Batteries: size AA (Main adaptor: DC 6V, 600mA (optional))
Battery lifespan	Not specified
Dimensions	150 x 100 x 50 mm
Weight	385g (including batteries)
List price	£100
Supplied accessories (Batteries & user manual assumed)	Supplied with medium (22 - 32cm) size cuff. Other cuffs in Small (17 - 22cm) and Large (32 - 42cm) size are available to purchase separately
Warrenty	5 years
Website	www.watchbp.co.uk

Zenicor (Zenicor Medical Systems AB)	
	
Model description	ECG intermittent event recorder
Instruction manual	Not available
Patient Connection	Single lead, integrated thumb electrodes
Heart rate range	Not specified
Display	No. The ECG results are transferred to a database that can be accessed from any Internet connected computer with a user name and password. No installation or specific software is required
Memory type	Up to 200 ECG readings
Recording capacity	Up to 200 ECG readings
Data transfer	Built-in phone enables automatic sending of the ECG to an internet connected database
Printing	Direct from central database using a computer
Power	3 x 1.5V AA batteries
Battery lifespan	Upto 200 readings and sending
Dimensions	145 x 65 x 25mm
Weight	135g (excluding batteries)
List price	Not specified
Supplied accessories (Batteries & user manual assumed)	Software accessible through internet with user names & password
Warranty	Not specified
Website	www.zenicor.com

10. References

1. LinHJ, Wolf PA, Kelly-Hayes M, et al. Stroke severity in atrial fibrillation. *The Framingham study Stroke1996;*27:1760-1764.
2. CarlssonJ, Miketic S, Flicker E, et al. Neurological events in patients with atrial fibrillation. Outcome and preventive practices. Z Kardiol 2000;89:1090-1097.
3. LamassaM, Di Carlo A, Pracucci G, et al. Characteristics, outcome and care of stroke associated with atrial fibrillation in Europe. *Stroke 2001*;32:392-398.
4. DulliDA, Stanko H, Levine RL. Atrial fibrillation is associated with severe acute ischemic stroke. *Neuroepidemiology* 2003;22:118-123
5. Sussman M, Menzin J, Lin I. Impact of atrial fibrillation on stroke-related healthcare costs. J Am Heart Assoc 2013;2(6): e000479 http://jaha.ahajournals.org/content/2/6/e000479.full.pdf+html
6. The Office of Health Economics. Estimating the direct costs of atrial fibrillation to the NHS in the constituent countries of the UK and at SHA level in England, 2008. London: The Office of Health Economics; 2009
7. Kassianos G, Arden C, Hogan S et al. The non-anticoagulation costs of atrial fibrillation management: findings from an observational study in NHS Primary care. Drug Context 2014; 3:1-11. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3989509/pdf/dic_212254.pdf
8. Public Health England. Atrial Fibrillation prevalence estimates in England: Application of recent population estimates of AF in Sweden. 2015 file:///G:/pharmacy%20london%20show/AtrialfibrillationprevalenceestimatesinEngland.pdf
9. Gallagher C, Hendricks JML, Mahajan R, et al. Lifestyle management to prevent and treat atrial fibrillation. Expert Rev of Cardiovasc Ther 2016; 14(7): 799-809
10. Huxley RR, Lopez FL, Folsom AR, et al. Absolute and attributable risks of atrial fibrillation in relation to optimal and borderline risk factors: the atherosclerosis risk in communities (ARIC) study. Circulation. 2011;123(14):1501–1508 http://circ.ahajournals.org/content/123/14/1501
11. European Heart Rhythm Association, European Association for cardio-Thoracic (EACTS), Kirchhof P, Benussi S, Kotecha D, et al. 2016 ESC Guideline for the management of atrial fibrillation developed in collaboration with EACTS. *Eurospace 2016*. 1-90 file:///G:/clinical%20articles%20on%20NOACs/CCG/Devices/ESC%20AF%20guideline%202016.pdf
12. Healey JS, Conolly SJ, Gold MR,et al. Subclinial atrial fibrillation and the risk of stroke. N Eng J Med 2012; 366:120-129
13. Hannon N, Sheehan O, Kelly L, *et al.* Stroke associated with atrial fibrillation – incidence and early outcomes in the North Dublin population stroke study. Cerebrovasc Dis 2010; 29: 43-49
14. Hobbs FDR, Taylor CJ, Geersing GJ, et al. European Primary Care Cardiovascular Society (EPCCS) consensus guidance on stroke prevention in atrial fibrillation in primary care. Eur J Prev Cardiol 2016; 23(5): 460-473
15. Taggar JS, Coleman T, Lewis S, et al. Accuracy of methods for detecting an irregular pulse and suspected atrial fibrillation: a systematic review and meta-analysis. Eur J Prev Cardiol 2016; 23(12):1330-1338.
16. Moran PS, Flattery C, Teljeur M et al. *Effectiveness of systematic screening for the detection of atrial fibrillation. Cochrane Database Syst Rev* 2013. CD009586
17. Wilson J, Jungner G. Principles and practice of screening for disease. *WHO Public Health paper no. 34*. Geneva: World Healh Organisation; 1968
18. Quinn FR, Gladstone D. Screening for undiagnosed atrial fibrillation in the community. *Curr Opin Cardiol 2014*; 29(1): 28-35
19. Hobbs FDR, Fitzmaurice DA, Mant J, et al. A randomised controlled trial and cost effectiveness study of systematic screening (targeted and total population screening) versus routine practice for detection of atrial fibrillation in people over 65 years and over. The SAFE study. *Health Technol Assess 2005*; 9:1-74.
20. Lowres N, Neubeck L, Redfern J, Freedman SB. Screening to identify unknown atrial fibrillation: a systematic review. Thromb Haemost 2013;110:213–222.
21. Solutions for Public Health. Screening for atrial fibrillation in people aged 65 years and over. A report for the National Screening Committee 2014.
22. Public Health England. Transforming services: A system based approach 2016. https://publichealthmatters.blog.gov.uk/2016/07/14/transforming-services-a-systems-based-approach/
23. National Institute for Health and Care Excellence. Atrial fibrillation: the management of atrial fibrillation. Clinical Guidelines, methods, evidence and recommendation 2014 https://www.nice.org.uk/guidance/cg180/evidence/atrial-fibrillation-update-full-guideline-243739981

24. National Institute for Health and Care Excellence. WatchBP Home A for opportunistically detecting atrial fibrillation during diagnosis and monitoring of hypertension. Medical technology guidance [MTG13] 2013 https://www.nice.org.uk/guidance/mtg13

25. National Institute for Health and Care Excellence. AliveCor Heart monitor and AliveECG app for detecting atrial fibrillation. Medtech innovation briefing 2015. https://www.nice.org.uk/guidance/mib35/resources/alivecor-heart-monitor-and-aliveecg-app-for-detecting-atrial-fibrillation-63499107274693

26. Sudlow M, Rodgers H, Kenny RA, et al. Identification of patients with atrial fibrillation in general practice: a study of screening methods. BMJ 1998; 317:327

27. Morgan S, Mant D. Randomisation trial of two approaches to screening for atrial fibrillation in UK general practices. *Br J Genral Pract* 2002; 52:373-80

28. Verbeck WJ, Omboni S, Kollia A et al. Screening for atrial fibrillation with automated blood pressure measurement: Research evidence and practice recommendations. *Int J Cardiol* 2016; 203:465-473

29. Crawford MH, Bernstein SJ, Deedwania PC, *et al.* ACC/AHA guidelines for ambulatory electrocardiography. A report of the American of Cardiology/American Heart Association Task Force on practice guidelines developed in collaboration in collaboration with the North American Society for pacing and electrophysiology. *Journal of the American College of Cardiology 1999*; 34(3):913-939. http://content.onlinejacc.org/article.aspx?articleid=1125943

30. Zimetbaum P, Goldman A. Ambulatory Arrhythmia Monitoring. Circulation 2010; 122:1629-1636.

31. Fung E. Jarvelin M, Doshi RN, et al. Electrocardiogram patch devices and contermporary wireless cardiac monitoring. *Frontiers in physiology* 2015; 6: 1-8.

32. National Health Service Purchasing and Supply Agency. Buyers' guide. Patient-activated ECG event recorders CEP09007. 2009 file:///G:/clinical%20articles%20on%20NOACs/CCG/Devices/Summaries/CEP%20buyers%20guide%20to%20patient%20activated%20ECG%20event%20recorders.pdf

33. National Health Service NHS Supply Chain. Electrocardiogram (ECG) equipment framework 2014 to 2018.

34. Chan P, Wong C, Poh YC et al. Diagnostic performance of a smartphone-based photoplethysmographic application fr atrial fibrillation screening in a primary care setting. J Am Heart Assoc 2016; 5:e003428 doi: 10.1161/JAHA.116.003428

35. Walsh JA, Topol EJ, Steinhubl SR. Novel wireless devices for cardiac monitoring. Circulation 1024; 130: 573-581.

36. Kearley K, Selwood M, Van den Bruel A, *et al.* Triage tests for identifying atrial fibrillation in primary care: a diagnostic accuracy study comparing single-lead ECG and modified BP monitors. *BMJ Open* 2014; 4: e004565.

37. Wiesel J, Wiesel D, Suri R *et al.* The use of a modified sphygmomanometer to detect atrial fibrillation in outpatients. Pacing Clin Electrophysiol 2004; 27: 639-634.

38. Kane SA, Blake JR, McArdle FJ et al. Opportunistic detection of atrial fibrillation using blood pressure monitors: a systematic review. Open Heart 2016; 3(1): e000362 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4836305/pdf/openhrt-2015-000362.pdf

39. Gandolfo C, Balestrino M, Bruno C *et al.* Validation of a simple methods for atrial fibrillation screening in patients with stroke. *Neuro* 2015; 36(9): 1657-1678

40. Wiesel J, Arbesfeld B, Schechter D. Comparison of the Microlife blood pressure monitor with the Omeron blood pressure monitor for detecting atrial fibrillation. Am J Cardiol 2014;114:1046-1048

41. Stergiou GS, Karpettas N, Protogerou A, e al. Diagnostic accuracy of a home blood pressure monitor to detect atrial fibrillation. J hum Hypertension 2009;23: 654-658 http://www.atrialfibrillation.org.uk/app/webroot/files/file/News/Diagnostic%20accuracy%20of%20home%20blood%20pressure%20monitor.pdf

42. Wiesel J, Fitzig L, Herschman Y, et al. Detection of atrial fibrillation using a modified Microlife blood pressure monitor. *Am J Hypertens* 2009;22:848-852

43. Caldwell JC, Borbas Z, Donald A, et al. Simplified electrocardiogram sampling maintains high diagnostic capability for atrial fibrillation: implications for opportunistic atrial fibrillation screening in primary care. *Europace* 2012; 14 (2): 191–196. DOI: http://dx.doi.org/10.1093/europace/eur304

44. Doliwa PS, Frykman V and Rosenqvist M. Short-term ECG for out of hospital detection of silent atrial fibrillation episodes. Scand Cardiovasc J 2009; 43: 163–168.

45. Renier W, Geelen M, Steverlynck L, et al. Can the heartscan be used for diagnosis and monitoring of emergencies in general practice? Acta Cardiol 2012; 67: 525–531

46. Vaes B, Stalpaert S, Tavernier K, et al. The diagnostic accuracy of the MyDiagnostick to detect atrial fibrillation in primary care. BMC Fam Pract 2014; 15: 113.

47. Haberman ZC, Jahn RT, Bose R, et al. Wireless smartphone ECG enables large scale screening in diverse populations. J Cardiovasc Electrophysiol 2015; 26: 5206.

48. Lau J, Lowres N, Neubeck L, et al. Validation of an iphone ECG application suitable for community screening for silent atrial fibrillation: A novel way to prevent stroke. Circulation 2012; 126: A16810.

49. McManus DD, Lee J, Maitas O, et al. A novel application for the detection of an irregular pulse using an iPhone 4S in patients with atrial fibrillation. Heart Rhythm 2013; 10: 315–319.

50. Crockford CJ, Ahmed O, Kaba R, et al. 47 An analysis of the applicability of lead 1 screening for cardiac arrhythmia in primary care settings using novel sensing technology and multiple commercial algorithms for automating detection to increase ppv of referrals for further investigations [Abstract]. *Eurospace* 2013; 15(4):iv19-iv21

51. Crockford CJ, Ahmed O, Kaba R, *et al.* An analysis of applicability of lead 1 screening for cardiac arrhythmia in primary care setting using novel sensing technology and multiple commercial algorithm for automating detection to increase ppv of referral for further investigation. *Eurospace* [abstract] 2013; 15: iv2

52. Lowres N, Neubeck L, Salkeld G, *et al.* Feasibility and cost-effectiveness of stroke prevention through community screening for atrial fibrillation using iPhone ECG in pharmacies. The SEARCH-AF study. Throm Haemost 2014; 111(6): 1167-1176

53. Walker N, Pharmacy-based screening for atrial fibrillation in high Maori and Pacific populations. *N Z Med* J 2014; 127 (1398):128-131

54. Omboni S, Verberk WJ. Opportunistic screening of atrial fibrillation by automatic blood pressure measurement in the community. *BMJ Open* 2016;6: e010745 doi:10.1136/bmjopen-2015-010745

55. Kaasenbrood F, Hollander M, Rutten FR, *et al.* Yield of screening for atrial fibrillation in primary care with a hand-held, single-lead electrocardiogram device during influenza vaccination. Eurospace 2016; 18(10): 1514-1520. doi: 10.1093/europace/euv426

56. Claes N, an Laethem C, Gowthals M, *et al.* Prevalence of atrial fibrillation in adults participating in a large-scale voluntary screening programme in Belgium. *Acta Cardiol 2012*; 67(3): 273-278

57. Svennberg E, Engdahl J, Al-Khalili F. Mass Screening for Untreated Atrial Fibrillation: The STROKESTOP Study (Main study). *Circulation* 2015; 131(25):2176-84

58. Engdahl J, Andersson L, Mirskaya M et al. Stepwise screening of atrial fibrillation in a 75-Year Old Population: Implications for Stroke Prevention (STROKESTOP pilot). Circulation 2013; 127: 930-937

59. Orchard J, Freedman SB, Lowres N, *et al.* iPhone ECG screening by practice nurses and receptionists for atrial fibrillation in general practice: the GP-SEARCH qualitative pilot study. *Aust Fam Physician* 2014; 43(5):15-19

60. Lowres N, Krass I, Neubeck L et al. Atrial fibrillation screening in pharmacies using iPhone ECG: a qualitative review of implementation. *Int J Clin Pharm* 2015; 37: 1111-1120

61. Orchard J, Lowres N, Freedman SB, et al. Feasibility of screening for atrial fibrillation in primary care: Just a heartbeat away? *Eur J Prev Cardiol 2016*;23(16):1783-1784

62. Desteghe L, Raymaekers Z, Lutin M *et al.* Performance of handheld electrocardiogram devices to detect atrial fibrillation in a cardiology and geriatric ward setting. Eurospace 2016. Pii:euw025

63. Lau JK,LowresN, Neubeck et al. iPhoneECG application for community screening to detect silent atrial fibrillation: a novel technology to prevent stroke. Int J Cardiol 2013;165:193–4

64. Vaes B, Stalpaert S, Tavernier K, et al. The diagnostic accuracy of the MyDiagnostick to detect atrial fibrillation in primary care. BMC Fam Pract 2014;15:113

65. Tieleman RG, Plantinga Y, Rinkes D, et al. Validation and clinical use of a novel diagnostic device for screening of atrial fibrillation. Europace 2014;16:1291–5.

66. The Food and Drug Administration (FDA) Class 3 Device Recall AliveECG App version 2.1.2 used with AliveCor Heart Monitor https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?id=133315

11. GLOSSARY

95% Confidence interval (CI)	The range of values between which we could be 95% certain that this result would lie if the intervention is applied to the whole population
Sensitivity	Probability that a test will be positive when the disease is present (i.e. true positive rate). A low sensitivity will lead to the identification of a large number of false positive results.
Specificity	Probability that a test result will be negative when the disease is not present (i.e. true negative rate). A low specificity will lead to the identification of a large number of false negative results
Negative Likelihood ratio	Ratio between the probability of a negative test result given the presence of the disease and the probability of a negative test result given the absence of the disease (i.e. False negative rate / True negative rate)
Positive Likelihood ratio	Ratio between the probability of a positive result given the presence of the disease and the probability of a positive test result given the absence of the disease (i.e. True positive rate / False positive rate)
Sphygmomanometers	A device used to measure blood pressure. Also referred to as blood pressure meter or blood pressure monitor

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Manufactures and suppliers contacted:

Aseptika Ltd

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Limitations

This report is based on information available at the time when the searches were undertaken and does not contain data on subsequent developments or improvements of the technology which is continually evolving.

Declaration of Conflict of Interest

The authors declare that they will not receive either benefit or harm from publication of this report. None of the authors have or have held shares or consultancies with any of the producers of the devices assessed in this document.

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