Healthcare Improvement Scotland | SHTG Advice on health technologies

Innovative Medical Technology Overview | December 2024.

# Electrocardiogram (ECG) patch monitors for the detection of cardiac rhythm abnormalities.

## Key points

- ECG patches are designed to provide ambulatory continuous monitoring for up to 14 days to detect cardiac rhythm abnormalities.
- Evidence suggests that ECG patches can improve the detection rate of possible cardiac rhythm abnormalities compared with traditional 24-hour Holter monitors and cardiac event recorders (CER). There are no data on the diagnostic accuracy of ECG patches and their impact on clinical outcomes remains uncertain based on the published evidence.
- Patients generally find ECG patches comfortable and easy to wear due to their compact size, discreet design and simple application. Patients valued the convenience of wearing the patch while engaging in daily activities like showering. This can lead to higher patient compliance and longer wear time compared with traditional devices such as Holter monitors.
- The use of ECG patches offers potential benefits for improving access to cardiac monitoring. For example, people living in rural areas, or who face difficulties in attending hospital appointments, can have the patch fitted during the initial appointment and return it via the post once the monitoring period is complete, reducing the need for additional trips to healthcare facilities.
- A cost analysis conducted by the National Institute for Health and Care Excellence (NICE) looking at the use of ECG patches in a post-cryptogenic stroke population found they were associated with an increase in per patient costs. This result was highly sensitive to the cost of the ECG patch device which was £310 per patient. There would have been no cost impact if the cost for ECG patches was £229 per patient.
- The NICE cost analysis may underestimate the value of ECG patches to the National Health Service (NHS) by constraining its time horizon to 1 year and therefore omitting potential longer-term patient and service benefits.

# Definitions

**Ambulatory ECG monitoring**: continuous and prolonged monitoring of a patient's cardiac rhythm while they go about daily activities in their natural environment.[1]

**Contact dermatitis**: type of dry and irritated skin condition caused by contact with a particular substance.[2]

**Cryptogenic stroke**: a stroke with no definite cause.[3]

**Holter monitor**: a device that continuously records ECG signals as a person goes about their daily activities.[4]

**Paroxysmal atrial fibrillation (pAF)**: episodes of irregular cardiac rhythm that start and stop on their own, usually resolving within 48 hours without treatment.[5]

**Transient ischaemic attack (TIA)**: caused by a temporary disruption in the blood supply to part of the brain. Also referred to as mini stroke.[6]

# The technology and its use

ECG patch monitors (or ECG patches) are small, single-lead, lightweight, wireless, water-resistant biosensors that are used to detect cardiac rhythm abnormalities over extended periods of time (up to 14 days) in asymptomatic patients or people who suffer from transient symptoms.[7] ECG patches are designed to continuously record the electrical activity of the heart, allowing for uninterrupted recording during daily activities (including showering, light physical activity or sleep) while wearing the device. Data are reviewed and analysed by trained clinical staff after patients have completed the monitoring period.[7, 8]

There are a number of ECG patch manufacturers. Two types of patches that have been assessed in the published literature are described below.

## Zio XT® Service

The Zio XT® service is developed by iRhythm Technologies (iRhythm Technologies, Inc; San Francisco, California). It includes three components: the Zio XT® biosensor, the Zio ECG Utilisation Service (ZEUS) system and the Zio XT® technical report.[7]

The Zio XT® biosensor is a 2-by-5 inch (5.08 cm by 12.7 cm) adhesive patch with a single-lead ambulatory ECG recorder.[9] It uses the ZEUS system as its software platform to organise, analyse and store the ECG data recorded by the biosensor. The ECG data is reviewed and analysed by trained clinical staff as part of the Zio Service. A technical report is prepared that provides an actionable clinical summary of the recorded data.[7]

The Zio XT® biosensor is applied to the upper left chest and continuously records a beat-to-beat ECG for up to 14 days. Each patch is for single-patient use and wearers can maintain their usual activities throughout the monitoring period. The device includes a trigger button that

patients can press when they experience symptoms. This captures the recording from 45 seconds before to 45 seconds after the button is pressed. Patients are encouraged to maintain a paper log of their symptoms, including what they were doing at the time, to allow for a symptom-rhythm correlation in the final technical report.[7]

At the end of the monitoring period, the patient removes the patch and returns it to iRhythm via Royal Mail Freepost. There are no personal identifiable data on or in the Zio XT® patch, ensuring data privacy and security in case of physical interception. The recorded data is analysed by the ZEUS system and reviewed by accredited cardiac physiologists at Zio. Once the data is analysed a technical report is sent electronically to the patient's clinician via a secure platform. The report provides details about any arrhythmia episodes, wear time and any events marked by the patient. Clinicians can request additional information or modifications to the report if needed.[7]

## Carnation Ambulatory Monitor® (CAM)

CAM is a P-wave centric ECG patch monitor designed for remote monitoring of people with suspected cardiac arrhythmias. It provides up to 14 days of continuous monitoring and is worn along the sternum to optimise P-wave signal capture. The adhesive patch is suitable for sensitive skin. A recorder begins recording when activated by the patient when they experience symptoms. Patients can also press a button during symptoms to mark specific events, which they document in a patient diary. For the first 24 hours after applying the CAM patch, users are advised to avoid activities or environments that may involve fully submerging the device in water (like showering, swimming and bathing) or engaging in strenuous exercise that can cause excessive sweating. [10]

After the monitoring period, the CAM patch is returned to the hospital or a processing centre for data analysis. The recorded ECG data is uploaded to a secure, web-based portal, where it is analysed either by the hospital's team or by ECG technicians from the manufacturer. A reported is then generated by the manufacturer. This report is available within two working days and includes detailed ECG traces over various timeframes (8 seconds, 56 seconds and 40 minutes).[10]

## What is innovative about the technology?

The main innovation of the ECG patch is its extended wear time and continuous monitoring capabilities of up to 14 days compared with traditional Holter monitors, which are typically used to record for 24 to 48 hours or at most up to seven days.[7]

ECG patch monitors are discreet and can be worn under clothing unlike Holter monitors, which require external wires and are worn in a pouch around the waist or neck or carried in a pocket. An ECG patch monitor is water resistant so can be worn during baths or showers, allowing patients to more easily maintain normal daily routines.[7]

The Zio XT® biosensor has no external leads or wires and is resistant to interference from physical movement. This is intended to reduce noise artefacts in the data.[7] The CAM device has a low noise floor, which enables it to detect clear signals.[10]

## Regulatory information

Both the Zio XT® and CAM patches are Class IIa CE-marked medical devices.[7, 10] iRhythm Technologies is registered with the United Kingdom (UK) Care Quality Commission (CQC) to provide screening and diagnostic services as of 25 July 2018,[7] and was rated as 'good' in the last CQC inspection in August 2022.[11]

## Population, setting and intended use

Cardiac arrhythmias are abnormal heart rhythms which can be too slow, too fast or irregular.[7, 8] Cardiac arrhythmias can significantly impact on a person's quality of life and their daily activities. While some arrhythmias are benign and may not cause symptoms or pose a risk, others can be severe and life threatening, potentially leading to stroke or heart failure.[8]

Atrial fibrillation (AF) is often a focus in monitoring strategies as it is the most common type of arrhythmia. AF affects around 2% of the adult population[12] AF is characterised by breathlessness and palpitation, and requires accurate diagnosis through ECG monitoring.[7] It can also be asymptomatic and undiagnosed. AF is responsible for about 20% of all strokes and is associated with higher mortality rates in stroke patients.[12] Early diagnosis could reduce the risk of stroke and other cardiac-related conditions.

NICE recommends the use of a 12-lead ECG for the initial assessment of arrhythmias and transient loss of consciousness in individuals aged 16 and over. If further evaluation is needed beyond a standard ECG, ambulatory ECG monitoring (using devices such as Holter monitors or CERs) is typically employed. Holter monitoring is commonly used to detect arrhythmias and is suitable for people experiencing regular symptoms or intermittent events. Monitoring can range from 24 to 48 hours for regular symptoms. For less frequent symptoms, monitoring can extend up to 7 days.[7]

ECG patches offer another option for ambulatory ECG monitoring for detecting cardiac arrhythmia. ECG patches are intended for people experiencing symptoms of cardiac arrhythmias, who require continuous or prolonged monitoring and those for whom arrhythmia has not been captured by standard ECGs. People in these groups may experience intermittent symptoms (such as dizziness, palpitations, syncope [fainting] or transient loss of consciousness) that are difficult to capture during a short clinic visit. For patients with infrequent symptoms, traditional monitoring may fail to capture the arrhythmia, making extended monitoring with devices like ECG patches advantageous.[7]

ECG patches are most often prescribed by a cardiologist in secondary or tertiary care, or by a general practitioner (GP) in primary care. They may also be prescribed by a stroke clinician or neurologist. ECG patches are mainly used in outpatient or ambulatory settings. Patients can wear the patch while going about their daily activities, providing a more comprehensive assessment of heart rhythm under real-world conditions. The non-invasive nature of ECG patches makes them suitable for home use.[7]

## Current care pathway in Scotland

The detection of arrhythmias typically begins with an ECG for initial assessment, followed by Holter monitoring for patients with suspected arrhythmias. If arrhythmias are not detected in the first 24–48 hours, patients may undergo extended monitoring with CERs or Holter devices for up to 7 days.

Patients suspected of TIA or stroke, but not requiring hospitalisation, are referred by their GP to a TIA or minor stroke clinic. The referral process takes approximately 3 days and if AF or another cause of stroke is suspected but not confirmed, patients are referred for cardiac monitoring. Outpatient appointments for Holter monitor application typically occur within 3 to 4 weeks. During these appointments, the cardiac physiologist prepares the patient for monitoring, fits a 3-lead Holter monitor, provides instructions for use and offers a contact number for any device-related issues.[13]

Regulatory guidelines recommend a minimum of 72 hours of cardiac screening.[13] Limitations in device availability and battery life frequently result in shorter monitoring periods. Some patients may need to visit the hospital every 24 hours to have their Holter monitor batteries replaced with the associated administrative burden of organising this. [13]

Once the device is returned, the Holter monitor data is analysed by senior cardiac physiologists using a software program (Space Labs Life Screen). The review process can take between 20 and 45 minutes depending on the length of the monitoring period. The resulting report is uploaded to an online clinical portal or forwarded via internal mail to the relevant health professionals, such as stroke consultants or GPs, who then decide on the patient's treatment pathway. This process depends on staff availability, which could affect the speed of data interpretation and report generation.[13]

## Equality and access considerations

Cardiac arrhythmias can develop at any age but are more prevalent in people above 60 years. Women have a higher risk of certain arrhythmias and men are three times more likely to develop AF at any age. Among people that develop AF, women have a much higher incidence of mortality and morbidity.[10]

Certain patients, particularly those affected by stroke, may experience cognitive or physical limitations that affect their ability to engage fully with medical devices; stroke survivors with cognitive impairments or those with reduced dexterity may struggle to manage the device or adhere to monitoring protocols over extended periods. Although ECG patches do not require frequent maintenance or interaction compared with traditional Holter monitors, patients are still required to document symptomatic episodes and wear the device continuously, which could present challenges for those with cognitive impairments. Older adults or individuals with disabilities may find the lengthy monitoring period tiring or challenging to manage.[13]

ECG patches offer potential benefits for improving access to cardiac monitoring, particularly for people living in rural areas, people with limited transport options or who face other difficulties in attending hospital appointments. The biosensor can be fitted during the initial appointment

and can be returned via post and once monitoring is complete. This reduces the need for additional trips to healthcare facilities.[7]

Fewer required hospital visits could be beneficial for socioeconomically disadvantaged groups or those with caregiving responsibilities, potentially improving adherence and overall access to care. Further evidence is needed to fully understand the impact on these populations.[7]

ECG patch application may require shaving body hair to ensure the electrode sticks to the skin. For individuals whose religious beliefs or cultural practices forbid cutting or shaving body hair, this requirement could create a barrier to using the device. NICE notes that this is unlikely to restrict access for patients as similar considerations apply to traditional ECG monitoring methods, where hair shaving is often required for the placement of electrodes.[7, 10] Most people consented to shaving when using ECG patches.[7]

## Summary of clinical evidence

We identified a NICE medical technology guidance (MTG) published in 2020 and a NICE medtech innovation briefing (MIB) published in 2021. The MTG considered a single ECG patch monitor technology (Zio XT®) compared with traditional Holter monitors or CERs for detecting cardiac arrhythmia.[7] The MIB considered the CAM for ambulatory detection of cardiac arrhythmias.[10]

The clinical evidence reviewed in the MTG included 17 published studies (169,063 patients referred for ambulatory monitoring) and 13 abstracts. The published studies included one UK-based randomised controlled trial (RCT), three prospective comparative studies, six prospective non-comparative studies and seven retrospective non-comparative studies. The studies were published between 2013 and 2019.

Four comparative studies were central to the NICE recommendations. Three studies, including the RCT, compared the Zio XT®'s 14-day monitoring period with a 24-hour Holter monitor and one compared Zio XT® with an external loop recorder (Novacor R. Test). These studies involved 357 participants, including people with stroke, TIA, pacemakers, diagnosed AF, or suspected arrhythmia. The UK-based RCT was considered the highest quality among the studies, while the other three comparative studies were judged to be of adequate quality. Meta-analysis could not be performed due to heterogeneity across studies.[7]

In the UK RCT, participants with stroke or TIA were randomised to undergo monitoring with either the Zio XT® patch (14 days) or a Holter monitor (24 hours). There was a high withdrawal rate, particularly from the Holter group, where 20% of patients refused to use the device.[7]

The Zio XT® patch provided a higher diagnostic yield for detecting arrhythmias over total wear time compared with the 24-hour Holter monitor in three comparative studies. One study suggested that Zio XT® was more effective in identifying AF than an external loop recorder (Novacor R. Test) but less accurate than data from pacemakers.[7]

The diagnostic accuracy of the Zio XT® patch was unclear. Studies comparing the accuracy of

the Zio XT® patch with that of Holter monitors presented mixed results. One study found significant agreement between the two devices over the same 24-hour period. Another study found that, over a simultaneous 24-hour monitoring period, the Holter monitor detected 11 arrhythmias, which were missed by the Zio XT® patch. The study reported that nine of these were attributed to algorithm and human reviewer errors. Despite evidence of increased diagnostic yield, there was no evidence demonstrating that Zio XT® leads to improved clinical outcomes. The MTG emphasised the need for more information about the diagnostic accuracy and the appropriateness of treatment changes resulting from Zio XT® monitoring.[7]

The MTG concluded that the diagnostic accuracy of Zio XT® and its impact on clinical outcomes remain uncertain based on the published evidence. Further evidence on the long-term clinical effectiveness and reliability of ECG patches in detecting cardiac arrhythmias in different populations is required.[7]

The NICE MTG stated that "Zio XT® is recommended as an option for people with suspected cardiac arrhythmias who would benefit from ambulatory ECG monitoring for longer than 24 hours only if NHS organisations collect information on:

- resource use associated with use of Zio XT®
- longer-term clinical consequences for people who have monitoring with Zio XT® (such as incidences of further stroke, TIA and other thromboembolisms, arrhythmia-related hospitalisations, mortality, uptake of anticoagulants or other changes in medication related to the monitoring result)."[7]

The NICE MIB[10] assessed evidence from two studies comparing CAM with traditional Holter monitors and a similar external cardiac monitor (Novacor 'R' test 4) for detecting AF. One study was a UK randomised trial comparing CAM with Novacor 'R' test 4 for 2 weeks in 21 adults with implanted dual chamber permanent pacemakers, which is not generalisable to the AF population. The second study was a prospective study comparing CAM with traditional Holter monitors over 24 hours in 50 adults, requiring continuous ECG monitoring in the United States (US) and New Zealand.[10]

Overall, results showed that CAM is at least as effective as traditional Holter monitors and other ambulatory cardiac monitors in adults with suspected arrhythmias. The UK randomised study demonstrated that CAM was more effective than the Novacor 'R' test 4 in identifying AF episodes (95% confidence interval (CI) 1.1 to 32.1, odds ratio 5.8, p=0.042). CAM was significantly more comfortable than Novacor 'R' test 4 during initial application (p=0.024). There was no significant difference in comfort between CAM and Novacor 'R' test 4 during the recording phase. In the second prospective study, CAM patch identified abnormal rhythms in 23 people (46%) that changed management, compared with six in the Holter group (12%; p<0.01). The CAM patch also identified all six Holter recordings with clinically significant arrhythmias. The majority of patients (n=48 or 96%) preferred wearing the CAM patch.[10]

The evidence base on CAM is limited by small sample sizes and a lack of long-term monitoring studies. One of the reviewed studies employed CAM for 24 hours, limiting insights into its performance during the full 14-day monitoring period. Although the MIB report noted that

CAM is used in 18 NHS hospitals, it recommended that further research is needed to fully assess its long-term usability and safety.[10]

### Evidence published after NICE reports

Two systematic reviews published after the NICE reports were identified.[9, 14] The reviews examined the different methods available for extended ECG monitoring in detecting AF after a cryptogenic stroke.

The first review[9] included two prospective studies investigating the use of wearable device monitoring after cryptogenic or embolic stroke. Both studies found that the Zio XT® patch had comparable detection rates with Holter monitors in patients with stroke or TIA. The median time to device application was found to be lower for the Zio XT® patch than Holter monitors. One study analysed a cohort of 467 patients with TIA, cryptogenic stroke or syncope with unknown aetiology and found that 3.9% of patients experienced at least one episode of pAF lasting more than 30 seconds, while 13.3% experienced ventricular tachycardia. Meta-analysis did not find a statistically significant difference between wearable devices and conventional Holter monitoring in AF detection in cryptogenic stroke.[9]

The review concluded that wearable devices that use ECG technology are effective in detecting pAF after cryptogenic or embolic stroke, showing detection comparable rates to traditional Holter monitors. The review noted that, while several devices are already approved for patient use, ongoing clinical trials and further research are needed to assess the reliability, safety, patient acceptability and clinical significance of AF detected by these wearable devices.

The second review[14] examined devices for extended monitoring. Three studies (17.6%), including 221 patients, assessed the use of ECG patches. The pooled rate of AF for ECG patch monitoring was reported as 9.1% (95% CI 3.3% to 22.6%, $I^2$=6.4%, p=0.34). The review concluded that mobile devices may serve as reasonable alternatives for AF screening for patients with cryptogenic stroke.[14]

## Summary of safety evidence

The NICE MTG noted that there were no relevant reports from the Medicines & Healthcare products Regulatory Agency (MHRA) on the safety of ECG monitors. There were 138 incidents listed on the US Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database. The majority of issues involved contact dermatitis (113 cases), followed by adhesive failures (6 cases) and incorrect or false negative diagnoses (12 cases). Device or patient management failures were reported in 8 instances.[15]

The primary concern that could impact on the safety of the device was the accuracy of the detection algorithm and the actionable report. The patch itself was considered to pose minimal safety risks as long as it records data reliably.[15]

The MIB did not identify major safety concerns associated with the CAM device. Reports of adverse events, such as contact dermatitis, were minor and in line with those of other similar

ECG patches. Occasional cases of false negatives or incorrect diagnoses were traced to technical issues in data interpretation. None of these errors resulted in delayed treatment or inappropriate care.[10]

## Summary of economic evidence

The NICE MTG[7] assessed the cost effectiveness of a single ECG patch monitor technology (Zio XT®) compared with traditional Holter monitors or CER for the diagnosis of cardiac arrhythmia. The MTG included a systematic review of the economic literature for the Zio XT® device and a cost analysis based on an economic model submitted by the manufacturer of the Zio XT® device. The cost analyses were also conducted using NICE preferred values for key model parameters.[7]

The report identified five studies considered relevant to the decision problem, which were described as highly heterogenous due to differences in scope and design. Two studies concluded that ECG patch monitors were more expensive than alternative technologies.[16, 17] One study concluded that they were cost saving compared to 72-hour Holter monitoring and [18] one concluded that compared to a Holter-based strategy, Zio XT® was associated with NHS and social care cost savings of £466,598 for a population of 1,053 patients over 5 years.[19] Another study found that the technology increased health care resource use for treating AF but decreased all-cause emergency department visits and inpatient days.[20]

Two of the economic models included costs associated with the diagnostic process only in a cardiology population (syncope and palpitations) and a stroke population. These models found an increased per patient cost (when using NICE preferred parameters) of £70.81 in the stroke model and £0.82 in the cardiology model.

A third model, in a post-cryptogenic stroke population, included difference in costs of subsequent stroke treatment which was based on the diagnostic yield and time to diagnosis with Zio XT® compared to Holter monitors. This analysis incorporated an extrapolation of the risk of recurrent stroke in patients with untreated AF while they awaited an AF diagnosis or if their diagnosis was missed.

The model was a simple decision tree from an NHS perspective and adopted a 1-year time horizon. The technology was 14-day Zio XT® patch, analysis of the ECG output by the company and a report generated for clinician review. The comparator was a blended strategy based on 24-hour Holter monitor or CER. The NICE preferred parameter values to be used to generate results in the company's economic model are listed in *Appendix 3*. Technology costs for the comparators in the model are shown in *Table 1*.

*Table 1: NICE, preferred technology costs for the company's model*

| Variable | Value | Source |
|---|---|---|
| **Technology costs** | | |
| Zio XT® monitor | £310* | Company, quoted in NICE MTG External Assessment Centre (EAC) report[15] |
| 24-hour Holter monitor | £168.12 | NHS Reference Costs 2017/2018[21] + FOI request |
| CER monitor | £168.12 | Assumption (same as Holter monitor) |

Abbreviations: FOI = freedom of information.
*Updated cost provided to NICE for MTG (see table 3 below) but was not used to generate model results

The results of the EAC base case analysis are shown in *Table 2*. The per patient cost for the standard of care pathway was £1,216.62. The per patient cost of the pathway with the ECG patch monitor was £1,237.45. This resulted in an incremental cost increase of £20.83 per patient. The increase in per test costs with Zio XT® compared with the Holter and CER monitors was partially offset by a reduction in secondary strokes via fewer missed cases of pAF and through improvements in time to treatment.

Sensitivity analysis was performed by one-way sensitivity analysis (OWSA) which varied all parameters over a range of +/-20%. The results of the OWSA showed that the results were most sensitive to the costs of the Zio XT® service. The breakeven point for the cost of the Zio XT® service was reported to be £229.

*Table 2: EAC Base Case Results*

| | Per patient cost | Incremental per patient cost |
|---|---|---|
| Standard of care | £1,216.62 | - |
| ECG patch monitor (Zio XT®) | £1,237.45 | £20.83 |

There are several limitations to the analysis published by NICE that would affect the generalisability of the conclusions to potential use of ECG patches in Scotland. These include limiting the use of the ECG patch in the model to post-cryptogenic stroke, whereas decision-makers are likely to be interested in the value of the technology for use in other populations. Another limitation was that Holter monitoring was limited to 24 hours, whereas patients may undergo up to 72-hour monitoring with this device. Similarly, the Zio XT® monitor was assumed

to be worn for 14-days but other (potentially shorter) durations are likely to have different costs and diagnostic yields.

The analysis may underestimate the value of ECG patch technology to NHSScotland by excluding measures of benefit such as health related quality of life (HRQoL) gains from avoided sequalae of untreated AF. Limiting the analysis to 1-year may also underestimate the cost savings from the avoidance of stroke which continue to accrue over time. Time from referral to diagnosis in the NICE analysis may not be generalisable to those experienced in Scottish clinical practice.

## Updated costs and key modelling parameters (where available)

We searched for updated costs that could be included in an updated analysis. Where these were available, they are presented in *Table 3*.

An updated analysis could be more favourable in terms of net cost for ECG patches compared to the NICE analysis. For instance, the per patch costs for CAM and Zio XT® were lower than in the NICE analysis, and the cost for the CAM patch is below the breakeven threshold identified for the Zio XT® patch. Additionally, the cost of caring for someone in the years following a secondary stroke were found to be considerable. This would likely favour an ECG patch in a comparison with Holter monitoring in an analysis with longer time horizon.

*Table 3: Costs and key modelling parameters*

| Variable | Value | Source |
|---|---|---|
| **Technology costs, standard of care** | | |
| Cost of Holter monitor | £177.93 | National schedule of costs 2022/23[22] + FOI from NICE MTG EAC report[15] |
| CER monitor (KardiaMobile® single lead) | £82.50 | NICE MTG64[23] |
| **Technology costs, ECG patch monitors** | | |
| Zio XT® (14-day) | £265 | NICE MTG52[7] |
| Carnation Ambulatory Monitor® | 2-day monitoring £110<br>7-day monitoring £125<br>14-day monitoring £140 | NICE MIB276[10] |

| | | |
|---|---|---|
| | Reporting costs<br>2-day and 7-day service £40<br>14-day service £55<br><br>Postage £5 (not applicable if fitted in clinic)<br><br>Total for 14-day monitoring £200 | |
| **Health care resource costs** | | |
| Cardiology outpatient visit | £150.93 | National schedule of costs 2022/23[22] |
| First year cost of ischaemic stroke | £9,741 | Sentinel Stroke National Audit Programme (SSNAP)[24] (including NHS and social care costs) |
| First year secondary minor stroke | £19,776 | |
| First year secondary moderate stroke | £26,160 | |
| First year secondary major stroke | £33,445 | |
| Subsequent year cost of ischaemic stroke (no secondary event) | £5,994 | |
| Subsequent year annual cost post-secondary minor stroke | £9,015 | |
| Subsequent year annual cost post-secondary moderate stroke | £10,154 | |
| Subsequent year annual cost post-secondary major stroke | £13,035 | |

### Value proposition of ECG patches

An economic evaluation from the perspective of the NHS in Scotland could address key uncertainties in the existing economic evidence for the use of ECG patches. A Scottish model could incorporate the value proposition of ECG patches to NHSScotland (*Table 4*), taking into account different populations and clinical settings and the effect of ECG patches on costs and consequences over time horizons relevant for decision making.

*Table 4: Value proposition of ECG patches to NHSScotland*

| Value proposition components |
| --- |
| • Compared with Holter monitoring, patients are more likely to find an ECG patch monitor comfortable and convenient meaning that there may be improvements in compliance and that longer duration of data collection is feasible.<br>• Longer data collection duration and improved compliance could lead to improved diagnostic yield compared to current standard of care (Holter and CER monitoring). Fewer cases of cardiac arrhythmia are missed per diagnostic procedure.<br>• Improved patient outcomes through earlier diagnosis and initiation of preventative treatment (such as anticoagulants) potentially leading to a reduction in the occurrence of clinical sequelae of arrhythmia such as syncope, stroke and heart failure which are associated with health service costs and resource use in addition to significant morbidity, mortality and HRQoL loss.<br>• Reductions in costs associated with repeat testing of people with negative Holter or CER monitoring results when a clinical suspicion remains.<br>• Reduction in staff, estate and capital equipment resource use in the ambulatory ECG monitoring pathway due to reduced repeat testing, reduced in-clinic analysis of ECG recordings and reduced outpatient appointments.<br>• ECG patch monitors can be posted to patients' own homes which could reduce number of outpatient visits, increase patient access, reduce health inequalities and save travel costs for patients and travel reimbursement costs for the health service. |

## Patient/user experience

We identified four studies assessing patient and user experience of ECG patches: the NICE MTG[7] and MIB[10], one systematic review[9] and a process evaluation[13] for technology enabled AF screening after a stroke in Scotland.

Among stroke patients, the identified studies suggests that ECG patches show good usability and high patient acceptability.

The NICE MTG reported that patients found the Zio XT® patch acceptable. This included people with suspected arrhythmia, people with diagnosed atrial fibrillation or pacemakers, and people with a recent stroke or transient ischaemic attack. Patients were reported to wear the patch for most of the intended 14 days, with median wear times ranging from 10.8 to 12.8 days.[7] A comparison of patient comfort found that 93.7% of participants reported the Zio XT® as being comfortable to wear, compared with 51.7% for the Holter monitor. A survey of patients from a UK cardiology clinic found a statistically significant preference for the Zio XT® over Holter monitoring, with regards to its practicality, comfort, shape and the ease of returning the device.[7]

The MIB reported that patient feedback on CAM was positive, with 96% of participants (n= 48 people) preferring CAM over Holter monitors. This included people with diagnosed atrial fibrillation and people with implanted pacemakers. CAM was preferred due to its wireless design, comfortable adhesive patch, and extended wearability. Its discreet, sternum-worn design added to its patient acceptability as it offers greater ease during daily activities, including showering and moderate exercise. Some limitations were noted, such as recommendations to avoid strenuous activity and environments that induce excessive sweating, which could reduce adhesion quality. These recommendations slightly limit its functionality in certain active environments.[10]

A systematic review reported that over 80% of cryptogenic stroke and TIA patients found the Zio XT® patch easy to use, comfortable and suitable for normal daily activities. The review noted that future development and implementation of the device could benefit from simpler interfaces, better battery life and in-person training to improve usability.[9]

We also identified a process evaluation that aimed to investigate the experiences and acceptance of ECG patches by patients, clinicians and organisations. The focus was on adopting and scaling a new technology-enabled service for 14-day continuous monitoring within the AF screening pathway in secondary care.[13]

Patients generally found ECG patches, like the BARDY CAM™ device, to be easy to use, comfortable and convenient, with many patients appreciating the ability to continue activities such as showering while wearing the device. Some users experienced skin irritation, discomfort and issues with adhesive patch durability, especially in warmer weather or after multiple days of use. Despite these challenges, patients preferred the ECG patches over Holter monitors, because of their ease of use and less disruption to daily life.[13]

Although most patients valued ECG patch technology, some expressed concerns about the trustworthiness of the data, particularly regarding who was analysing the results and whether the reports were accurate. There was some apprehension about the lack of direct oversight in the reporting process, with some preferring human analysis over automated systems.[13]

The report emphasised that future studies need to focus on the implementation process of continuous cardiac monitoring. Improving device regulations, sensitivity and patient comfort were highlighted as some key considerations required for the implementation of these innovative devices. Devices should be developed with patient involvement to ensure suitability for diverse populations, especially including patients with specific physical limitations, such as

stroke survivors. Reducing device size, enhancing user acceptability and managing costs were also noted as important for broader adoption.[13]

## Conclusions

ECG patch monitors offer an alternative to traditional Holter monitors for detecting cardiac rhythm abnormalities in patients with cryptogenic stroke and other cardiovascular conditions. ECG patches provide continuous monitoring for extended periods (up to 14 days), with the potential to improve diagnostic yield and patient compliance due to their ease of use, convenience, comfort and portability. ECG patches are more likely to increase the detection of AF, potentially leading to better stroke prevention.

Skin irritation due to ECG patches and issues related to adhesive failure or device durability were occasionally reported. The overall patient experience has been positive, with patients in four studies preferring ECG patches over Holter monitors. Addressing issues related to device wearability, skin sensitivity and improving patient training could further enhance usability.

Concerns regarding the accuracy of detection algorithms and the interpretation of the data remain. Further studies are required to validate the diagnostic accuracy of these devices compared with conventional monitors to ensure optimal outcomes in clinical practice.

While a published cost analysis of ECG patch monitors found that they were cost incurring compared to standard of care including Holter and CER monitors, limitations were identified for decision-making. An economic evaluation from the perspective of the NHS in Scotland could address key uncertainties in the existing economic evidence for the use of ECG patches in Scottish clinical practice. Key uncertainties that could be addressed include use in different populations and clinical settings, their effect on costs and consequences over time horizons relevant for decision-making. An economic evaluation from the perspective of the NHS in Scotland could identify where and when costs and savings occur and estimate their magnitude.

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# Appendix 1: Abbreviations

| | |
|---|---|
| **AF** | atrial fibrillation |
| **CER** | cardiac event recorders |
| **CQC** | Care Quality Commission |
| **CI** | confidence interval |
| **CRYSTAL AF** | cryptogenic stroke and underlying atrial fibrillation |
| **ECG** | electrocardiogram |
| **EAC** | External Assessment Centre |
| **FDA** | Food and Drug Administration |
| **FOI** | freedom of information |
| **GP** | general practitioner |
| **HRQoL** | health related quality of life |
| **HES** | hospital episode statistics |
| **IMTO** | Innovative Medical Technology Overview |
| **MAUDE** | Manufacturer and User Facility Device Experience |
| **MHRA** | Medicines & Healthcare products Regulatory Agency |
| **MTG** | medical technology guidance |
| **MIB** | medtech innovation briefing |
| **NHS** | National Health Service |
| **NICE** | National Institute for Health and Care Excellence |
| **OWSA** | one-way sensitivity analysis |
| **pAF** | paroxysmal AF |
| **RCT** | randomised controlled trial |
| **SSNAP** | Sentinel Stroke National Audit Programme |
| **TIA** | transient ischaemic attack |
| **UK** | United Kingdom |
| **US** | United States |
| **ZEUS** | Zio ECG Utilisation Service |

# Appendix 2

*Table A: NICE, preferred value for key parameters for the company's model*

| Variable | Value | Source |
|---|---|---|
| **Clinical parameters** | | |
| True prevalence of AF in selected population | 30% | Sanna (2014) (CRYSTAL AF study)[25] |
| Probability of Holter monitor yielding a positive result | 2.1% | Kaura (2019)[19] |
| Probability of CER monitor yielding a positive result | 7.4% | Gladstone (2014)[26] |
| Probability of Zio monitor yielding a positive result | 16.1% | Kaura (2019)[19] |
| Probability of no repeat test if first test negative (Holter™ and CER monitors only) | 73% | Company's analysis based on hospital episode statistics (HES) data[15] |
| Risk of stroke in AF free patients | 5.28% | Diamantopoulos 2016[27] |
| Risk of stroke in undetected AF patients | 7.85% | |
| Risk of stroke in detected AF patients | 3.1% | |
| Time to diagnosis with Holter monitor | 70 days | Company's analysis based on HES data and FOI requests[15] |
| Time to diagnosis with CER monitor | 88 days | |

| | | |
|---|---|---|
| Time to diagnosis with Zio monitor | 19 days | Company's retrospective data[15] |
| Mean number of additional tests if repetition is decided | 1.465 | Data from HES reported in NICE MTG EAC report[15] |
| **Resource costs** | | |
| Cardiology outpatient visit | £142 | NHS Reference Costs 2017/2018[21] |
| Cost of stroke | £13,452 | Xu (2018) [NHS costs only][28] |
| Costs of anticoagulation therapy including cost of bleeds | £452 | NICE Clinical Guideline CG180 AF management.[12] |

Abbreviations are provided in Appendix 1.