NICE advice

# Carnation Ambulatory Monitor for ambulatory detection of cardiac arrythmias

Medtech innovation briefing
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## Summary


- The **technology** described in this briefing is Carnation Ambulatory Monitor (CAM). It is an ambulatory cardiac monitor used for detecting cardiac arrhythmias.
- The **innovative aspects** are a low noise floor, leading to more accurate and clearer signal detection. The device can also be worn for up to 14 days.
- The intended **place in therapy** would be as an alternative to existing ambulatory cardiac monitors in people with suspected arrhythmias.
- The **main points from the evidence** summarised in this briefing are from 4 studies (including 3 prospective comparative studies and 1 retrospective study in children) including a total of 125 adults and children. They show that CAM is at least as effective as other ambulatory cardiac monitors in adults with suspected arrhythmias.
- **Key uncertainties** around the evidence are that the study sample sizes are small.

- The **cost** of CAM is between £110 and £145 per person (if the analysis is done in the hospital) or £150 to £200 per person (if the analysis is done externally by the company; all excluding VAT), depending on the number of days recorded, if the device is posted and analysis costs. The cost of standard care for electrocardiogram monitoring or stress testing is £127 for outpatients and £62 as a directly accessed diagnostic service.

# The technology

Carnation Ambulatory Monitor (CAM; Bardy Diagnostics, Inc.) is a P-wave centric electrocardiogram (ECG) patch monitor for people with suspected cardiac arrhythmias. The device can monitor a person remotely for up to 14 days. The device is placed along the sternum to optimise P-wave signal capture. The device comprises of a battrode which has 2 electrodes, one below where the monitor will clip in and the second located on the xyphoid point. The battrode has a slim hourglass shape and has long-term adhesive (suitable for sensitive skin) to hold the device in place on the skin. A recorder clips into the battrode before being attached to the sternum. The recorder has a button which is pressed to start recording and is then additionally pressed when the patient is experiencing a symptom. The timings of the start of the recordings and symptom events needs to be recorded in the supplied patient diary.

After the CAM patch has collected recordings for up to 14 days, the device is posted back to the hospital or external data processing centre for analysis. The CAM patch is linked to ECG analysis services and tools. After data are collected, a secure web-based portal is used for uploading and analysing ECG data, accessing and managing patient reports. The data can be analysed internally or by the company's ECG technicians who will prepare a report. The cardiologist would receive a full report within 2 working days. The report shows the ECG traces with different time scales (8 seconds, 56 seconds and 40 minutes) to provide context around an episode or event.

# Innovations

The company claims the device has a low noise floor, leading to more accurate and clearer signal detection than similar devices. The device can be worn for up to 14 days, unlike a Holter monitor which is generally used for between 24 and 48 hours, which makes it suitable for people with symptoms of arrhythmia that happen more than 24 hours apart. The device is also wire free and is water resistant, meaning that it can be worn in the

shower and during exercise. However, users are advised to avoid showering or strenuous exercise for at least 24 hours after applying the patch. They also recommend avoiding environments or activities that lead to excessive sweating and advise against any activity which involves fully submerging the device in water, such as swimming or submerging the device whilst bathing.

# Current care pathway

The CAM is intended for use in those who need extended duration cardiac monitoring for people with suspected cardiac arrhythmias.

NICE's guideline on atrial fibrillation states that standard care for people with suspected arrhythmias is assessment using manual pulse palpation followed by an ECG. In people with suspected paroxysmal atrial fibrillation undetected by standard ECG recording, use of a 24-hour ambulatory ECG monitor is recommended in people with suspected episodes less than 24 hours apart. An event recorder ECG is recommended for people with symptomatic episodes more than 24 hours apart.

The following publications have been identified as relevant to this care pathway:

- NICE's guideline on atrial fibrillation
- NICE's guideline on transient loss of consciousness ('blackouts') in over 16s
- NICE's medical technologies guidance on Zio XT for detecting cardiac arrythmias
- NICE's medical technologies guidance on WatchBP Home A for opportunistically detecting atrial fibrillation during diagnosis and monitoring of hypertension.

# Population, setting and intended user

The CAM is indicated for detecting cardiac arrythmias in anyone weighing 10 kg or more. This includes using the device for diagnosing paediatric arrhythmias. The device can be fitted in a clinic or at home by a patient. Once used, the device can be posted back to the hospital or an external centre for analysis. The device pack comes with instructions for placing and activating the device and a patient diary. The device would be prescribed by a consultant cardiologist in a secondary or tertiary care setting. Patients need to press the button on the device and record the time and date in their diary if they experience any

symptoms of their suspected arrhythmia.

# Costs

## Technology costs

The cost of the device depends on the number of days the device is used for, if the analysis is done externally, and if the device is posted. This leads to a cost between £110 and £145 per person (if the analysis is done in the hospital) or £150 to £200 per person (if the analysis is done externally by the company):

- 2-day monitoring, £110 (excluding VAT)
- 7-day monitoring, £125 (excluding VAT)
- 14-day monitoring, £140 (excluding VAT).

Reporting costs are £40 per person for the 2- and 7-day service and £55 for the 14-day report. If the reporting is done in the hospital there are no reporting costs. If the device is directly mailed to the patient, there is an extra charge of £5 for the postage and administration costs. If the device is fitted in a clinic there are no additional postage charges. The company states that most devices would be fitted in a clinic.

## Costs of standard care

ECG monitoring or stress testing is £127 for outpatients and £62 for directly accessed diagnostic services (EY51Z, National schedule of NHS costs for 2019 to 2020).

The Zio XT monitoring services cost £265 per patient (excluding VAT). This figure includes the cost of the biosensor and the cost of analysing and reporting the data.

# Resource consequences

The CAM patch is currently being used at 18 NHS hospitals. It is a single-use device which could be used as an alternative to the Holter monitor. This device can be used for up to 14 days, meaning that longer recordings can be done compared with Holter monitors. Because the device can be posted back, an additional hospital appointment is not needed.

The company offers free training on device usage, fitting and data analysis (using their software). The software is provided for free and can be installed on as many computers in the hospital as needed.

# Regulatory information

Carnation Ambulatory Monitor is a CE-marked class IIa medical device.

# Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Cardiac arrhythmias can develop in people of any age but are more common in those aged over 60. Women tend to be at higher risk of certain arrhythmias, whereas men are 3 times more likely to develop atrial fibrillation at any age. However, of those people who develop atrial fibrillation, women have a much higher incidence of morbidity and mortality. The area of where the Carnation Ambulatory Monitor patch is applied will need shaving if hair is present. Some religions forbid cutting or shaving bodily hair. To show the device is working correctly, an LED light flashes when the recorder is attached to the battrode. People with a visual impairment may need help to check that the device is assembled and placed correctly. Religion, disability, age and sex are protected characteristics under the Equality Act 2010.

# Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement for medtech innovation briefings. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

## Published evidence

Four studies are summarised in this briefing.

This includes 3 prospective comparative studies in adults and 1 retrospective single-arm study in children. A total of 125 people were included in the studies.

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

# Overall assessment of the evidence

Two of the included full text papers compare using Carnation Ambulatory Monitor (CAM) with either Holter monitors or Zio XT. One study compared 4 external cardiac monitors and uses an implanted pacemaker to test for recording accuracy. These studies found that the CAM device led to equivalent or enhanced detection of atrial fibrillation. There was positive patient experience in wearing the device, particularly when compared with Holter monitor use. Two of the studies show CAM use over 24 hours to 48 hours. This could be considered as a limitation because the CAM device can be used for up to 2 weeks and may be more appropriate for longer term use where arrhythmias may not be detected within a 48-hour period. The evidence is also limited by having small sample sizes. In the single-arm study in children, the CAM device was being used in those under 10 kg, which is not recommended by the company. Only 1 study was done in the UK, which could limit the generalisability of the evidence to the NHS.

## Eysenck et al. (2020)

### Study size, design and location

Prospective randomised study comparing 4 external cardiac monitors on 21 adults with implanted pacemakers and known atrial fibrillation in the UK.

### Intervention and comparator

All patients acted as their own control and wore 4 external cardiac monitors (Zio XT, NUUBO vest, CAM, Novacor 'R' test 4) for 2 weeks each in randomised order. All patients also had dual chamber permanent pacemakers implanted, which detect arrhythmias to a high level of sensitivity and specificity.

### Key outcomes

CAM measures of atrial fibrillation burden were compared with the implanted pacemaker. The CAM device was found to correlate with the pacemaker (R-square value 0.9618). CAM more accurately identified the presence or absence of atrial fibrillation than the Novacor 'R' test 4 device (odds ratio 5.8; 95% confidence interval [CI] 1.1 to 32.1; p=0.042). Zio XT was also significantly more accurate than Novacor 'R' test 4 (odds ratio 12.3; 95% CI 1.4 to 110.3; p=0.02). CAM was significantly more comfortable during initial application than Novacor 'R' test 4 (p=0.024), but there was no significant different in comfort between the devices during the recording phase. All the devices were found to be more expensive than Novacor 'T' test 4 when both device and clinical care costs were considered.

### Strengths and limitations

This randomised study was done in the UK but was limited by having a small sample size. Most of the comparisons are with the Novacor 'R' test 4 device because it was viewed to be the most commonly used external cardiac monitor in the UK that can record for more than 48 hours. The study reviewed the 4 devices at separate intervals rather than at the same time which limits the comparability between devices. However, this was thought to be reasonable because of the risk of artefacts being generated on the recordings. People in the study had dual chamber permanent pacemakers implanted which is not generalisable to the atrial fibrillation population.

## Rho et al. (2018)

### Study size, design and location

Prospective comparative single centre study of 29 adults needing ambulatory electrocardiogram (ECG) monitoring in the US.

### Intervention and comparator

All patients simultaneously wore a CAM and Zio XT monitor for 7 days.

### Key outcomes

A total of 86.7 plus or minus 0.6 arrhythmias were detected using Zio XT and 121.7 plus or minus 2.1 for CAM (p<0.001). Of the arrhythmias identified, atrial tachycardia was most

diagnosed, and was more frequently identified with CAM than Zio XT (22.3 plus or minus 0.6 compared with 8.7 plus or minus 3.2, p<0.001). ECG clarity was ranked as high in all 29 CAM reports (100%) and on 4.5 (16%) of the Zio XT reports (p<0.001). Higher ECG clarity was mostly because of the greater ability to see P-waves when using the CAM device. Patient experiences were comparable and positive for both devices.

### Strengths and limitations

This prospective study had a small sample size. The analysis was done using multiple reviewers with averaged rhythms decisions to compensate for subjectivity in individual reviewing opinions. Company analysis centres were also unaware of the research to prevent analysis bias.

## Smith et al. (2017)

### Study size, design and location

Prospective comparative study including 50 adults needing continuous ECG recording in the US and New Zealand.

### Intervention and comparator

All patients simultaneously wore a CAM and Holter monitor for 24 hours.

### Key outcomes

The CAM patch identified rhythms in 23 people (46%) that changed management, compared with 6 in the Holter group (12%; p<0.01). All 6 Holter recordings with clinically significant arrhythmias were also found when using the CAM patch. The CAM patch ECG intervals PR, QRS and QT correlated well with the Holter ECG intervals having correlation coefficients of 0.93, 0.86, and 0.94, respectively. In terms of comfort, 48 people (96%) preferred wearing the CAM patch.

### Strengths and limitations

The study compared 2 devices at the same time on the same person, which allowed direct data comparison. However, the CAM patch was only used for 24 hours (in line with normal

Holter monitor use) which limits the evidence on comfort of CAM patch use for up to 14 days.

## Romme et al. (2021)

### Study size, design and location

Retrospective study of 25 children aged 0 to 15 months needing ECG monitoring in the US.

### Intervention and comparator

CAM patches worn for 48 hours. Five children wore a secondary CAM patch horizontally (leading to a total of 33 reports).

### Key outcomes

The mean age was 4.2 plus or minus 5 months and the mean weight was 5.3 plus or minus 2.4 kg. P-waves were identifiable in all 33 reports and led to changes in medical management in 30% of children. Horizontal patch placement led to smaller amplitude P-waves.

### Strengths and limitations

This study included children who weighed less than 10 kg. The company specify that their device is for use in children and adults weighing more than 10 kg. The retrospective study sample size was small and the monitoring time was limited to 48 hours, which may not be reflective of real-world use.

# Sustainability

The company claims the technology will reduce the number of clinic visits needed. The device is also smaller than other patch monitors and the battrode can be recycled. The device packaging is made of paper and cardboard which can be recycled. There is no published evidence to support these claims.

## Recent and ongoing studies

- Optimized Continuous 7-day Detection of Arrhythmias in Dialysis Population by a Patch With a High Resolution Differentiation of Atrial Activity. ClinicalTrials.gov identifier: NCT04071054. Status: unknown. Indication: arrhythmia, dialysis complications. Devices: CAM. Estimated study completion date: December 2020. Austria.
- Comparative Study of the CarnationTM Ambulatory Monitoring Sternal ECG Patch System With a Conventional 24-Hour 7 Lead Holter Monitor Recorder. ClinicalTrials.gov identifier: NCT04241692. Status: enrolling by invitation. Indication: children with known or suspected cardiac arrhythmia. Devices: CAM, 7-lead Holter Monitor recorder. Estimated study completion date: March 2023. US.

# Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

All 3 of the experts were familiar with or had used this technology before.

## Level of innovation

All experts acknowledged that this technology was not as innovative as other ambulatory cardiac monitors available. One expert said that the device was a novel solution during the COVID-19 pandemic to manage diagnostic waits for cardiac monitors. Two experts said that device would be more comfortable for people to use than standard care which uses Holter monitors. This is because Holter monitors uses standard electrocardiogram (ECG) electrodes with wires connecting to a recording box. The experts agreed the patch-type devices are less intrusive than standard ambulatory monitors and are becoming more widely used in the NHS.

## Potential patient impact

Two experts said that when compared with Holter monitors, these patch-type devices are less intrusive because there is no need for cables and they are smaller and water resistant

(and so does not need to be removed when showering). One expert said that longer monitoring is also likely to improve diagnostic yield, especially in those with relatively infrequent symptoms. If diagnostic yield is improved it is also likely to reduce the need for more invasive procedures. Two experts noted that the device can be sent via post and be self-applied by the patient and then posted back after the monitoring period. This could be more convenient than other monitoring options available and reduce the need for hospital visits. One expert further commented that this will also benefit people with poor mobility, where attending hospital appointments may be more difficult.

# Potential system impact

One expert said that the diagnostic pathway is unlikely to change. However, because of improved comfort compared with Holter monitors, people are more likely to use the device for the entire monitoring period. This could lead to increased diagnostic yield through having a longer, continuous, monitoring period. The device could also reduce in-hospital work through reports being done externally and could lead to time savings for device preparation because of the device being single use. One expert said that the cost of the device is likely to be offset by an improved diagnostic yield, which can reduce need for repeat testing or repeat appointments. It could also reduce hospital physiologist time needed for data analysis and reporting, if the assessment was done externally. One expert further said that this would reduce hospital waiting times for cardiac monitoring. Applying the device at home and posting it back would also reduce the hospital time needed. One expert said that the training would be simple and similar to other technologies and that further training would be supported by the company. One expert also said that the instructions to use the device are simple and the patch is easy to apply. Another expert said that familiarisation was needed for registering patients onto the device portal and that some training would be needed for trusts wanting to use their own technicians to analyse data.

# General comments

One expert stated that this is a very low risk technology and any risks would be shared by other ECG monitors. The most common adverse reaction to these devices is a skin reaction to the adhesive material, although they say the incidence of this is low. One expert said that it would be useful to have a 14-day monitoring study comparing other similar patch-type devices used in the NHS. One expert said that larger population studies would be needed. One expert said that cost compared with Holter monitors would be a

barrier to wider uptake of the device. They said that there would be a reduction in capital cost but an increase in consumables cost if the device replaced Holter monitoring.

# Patient organisation comments

Representatives from 3 patient organisations, Syncope Trust And Reflex anoxic Seizures (STARS), AF Association, and Arrhythmia Alliance, gave the following comments.

The benefits of the device are that its more comfortable than a Holter monitor and is less obstructive when doing everyday activities. This includes being able to wear the device while showering and exercising. It is also discrete, which reduces the risk of social stigma or embarrassment because of wearing the device. They also said that the device is easy to apply and remove. The results were also received quickly. Earlier detection of arrhythmias could lead to faster treatment and reduce the risk of adverse outcomes including strokes.

This device may particularly benefit people with intermittent symptoms which may be hard to identify when using a 12-lead electrocardiogram or a Holter monitor for up to 48 hours. This includes people with syncope who may only faint once or twice a month or those with paroxysmal atrial fibrillation. This could prevent repeat hospital appointments which could reduce the costs and time associated with traveling to and waiting for multiple appointments.

# Expert commentators

The following clinicians contributed to this briefing:

- Dr Rhys Beynon, consultant cardiologist and electrophysiologist, University Hospital of the North Midlands. Did not declare any interests.
- Dr Mark Tanner, consultant cardiologist and honorary clinical senior lecturer, University Hospitals Sussex NHS Foundation Trust and Imperial College London. Dr Tanner has had a consultancy agreement with I Rhythm Technologies (manufacturer of Zio XT), providing expert opinion for an electrocardiogram validation study in 2020.
- Vince Walker, senior chief cardiac physiologist and electrophysiology lead, University Hospitals of North Midlands. Did not declare any interests.

Representatives from the following patient organisations contributed to this briefing:

- Syncope Trust And Reflex anoxic Seizures (STARS)
- AF Association
- Arrhythmia Alliance.

# Development of this briefing

This briefing was developed by NICE. The interim process and methods statement for medtech innovation briefings sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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