

# CAM LT-ECG vs. Preventice MCT Clinical Study Summary

## Human Control, Continuous Recording, and Signal Clarity Matter in Long-Term ECG Monitoring

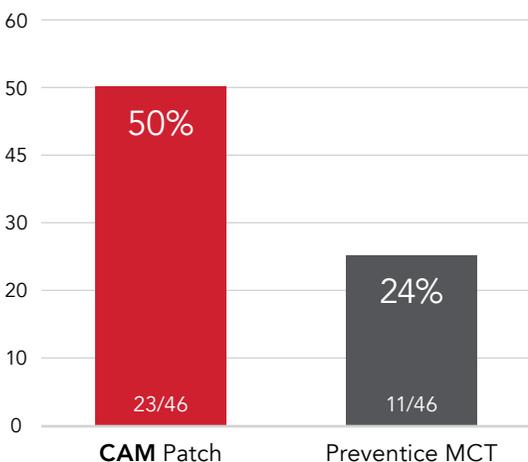
Continuous ECG Monitoring Versus Mobile Telemetry: A Comparison of Arrhythmia Diagnostics Between Human and Algorithmic-Dependent Systems. Willcox ME, et al, Heart Rhythm O2 Volume 2, Issue 6, p543-559, 2021 [http://www.heartrythmopen.com/article/S2666-5018\(21\)00190-2/fulltext](http://www.heartrythmopen.com/article/S2666-5018(21)00190-2/fulltext)

### Carnation Ambulatory Monitor (CAM) Patch outperformed Preventice Mobile Cardiac Telemetry (MCT) Solutions in diagnostic accuracy

- Human-oversight of raw continuous ECG recordings provided greater diagnostic accuracy than algorithmic-dependent MCT analysis of recordings.
- The **CAM** Report demonstrated greater rhythm diagnostic sensitivity and specificity.
- Human knowledge and continuity of recordings, coupled with signal clarity, led to a higher arrhythmia diagnostic yield with **CAM**.

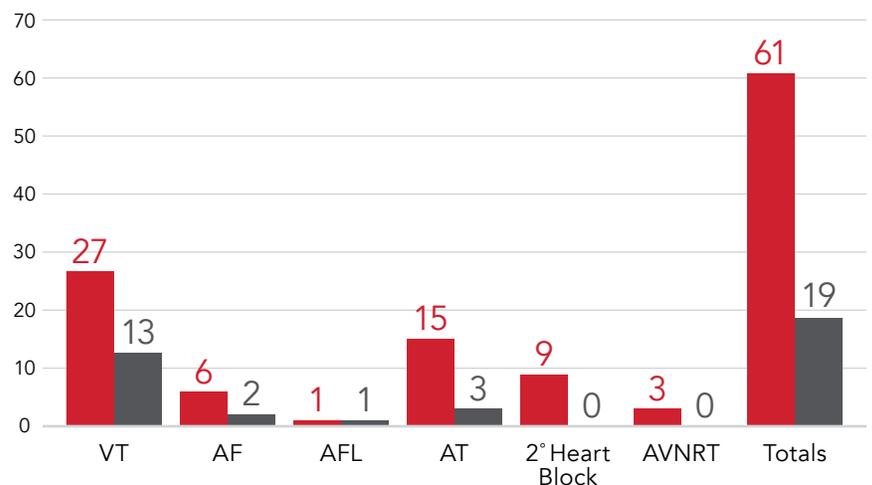
#### 2X as Many Patients Diagnosed

Number of Patients with Significant Arrhythmias



#### 3X as Many Episodes Diagnosed

Number of Significant Arrhythmia Episodes



## Methods

- 50 patients simultaneously wore a 30-day Preventice MCT/CEM device and a 14-day long-term continuous electrocardiogram (LT-ECG) **CAM** Patch from **Bardy Diagnostics**.
- Readers in both IDTFs were unaware of patients' clinical trial status and processed monitors per standard operating procedures.
- All reports were reviewed and discussed by 2 independent electrophysiologists.

## Key Findings

- Compared to Preventice MCT, the **CAM** Patch picked up 3 times the number of clinically relevant arrhythmias (61 vs 19) in twice as many patients (23 vs 11), across a broad spectrum of arrhythmias including: ventricular tachycardia, atrioventricular (AV) block, AV node reentrant tachycardia, atrial tachycardia, and atrial fibrillation over the same time period in the same patients.

Significant Arrhythmia	CAM Patch Patients (Episodes)	Preventice MCT Patients (Episodes)
Ventricular Tachycardia (VT)	13 (27)	7 (13)
Atrial Fibrillation (AF) >10 seconds	2 (6)	2 (2)
Atrial Flutter (AFL) >10 seconds	1 (1)	1 (1)
Atrial Tachycardia (AT) >20 beats	11 (15)	3 (3)
2 Degree AV Block	3 (9)	0 (0)
Atrioventricular Nodal Reentrant Tachycardia (AVNRT)	2 (3)	0 (0)
<b>Total Patients with Significant Arrhythmias</b>	<b>23 (61)</b>	<b>11 (19)</b>

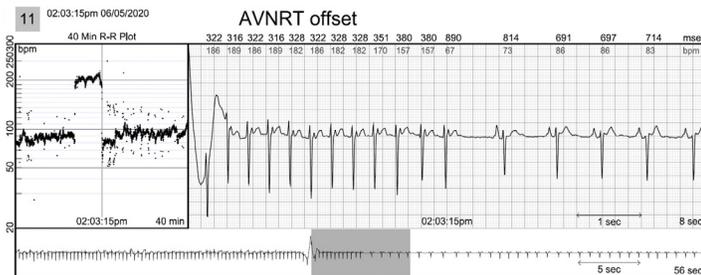
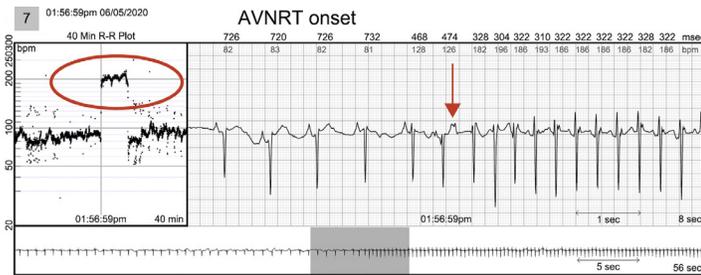
P=0.018 (P=<0.001)

- Fundamental differences in ECG data processing exist between **CAM** Patch and Preventice MCT, with **CAM** Patch using human-based detection while Preventice MCT uses algorithmic-based detection.
- In addition, differences in the ECG quality, P-wave morphology, and clinical context provided in the reports may explain the improved specificity of the **CAM** Patch.
- These findings indicate that **not all external monitors are equal**.



Differences highlighted in this study prompt further comparative analyses and appropriate scrutiny of artificial intelligence-based detection.

## AVNRT diagnosed only on CAM, misdiagnosed by simultaneous Preventice MCT.



Results from a 56-year-old female patient with a history of palpitations, showing a 6.3-minute episode of atrioventricular node reentrant tachycardia (AVNRT) at 182-220 beats/min subsequently confirmed as AVNRT by electrophysiology study.

**Top Image:** Onset of the AVNRT. Note second premature atrial contraction (red arrow) conducts over the slow pathway (long PR interval) followed by an echo beat at the terminus of the QRS seen in every beat thereafter. Note rapid rise and fall in heart rate in the R-R plot (red oval) characteristic of abrupt AVNRT onset and offset.

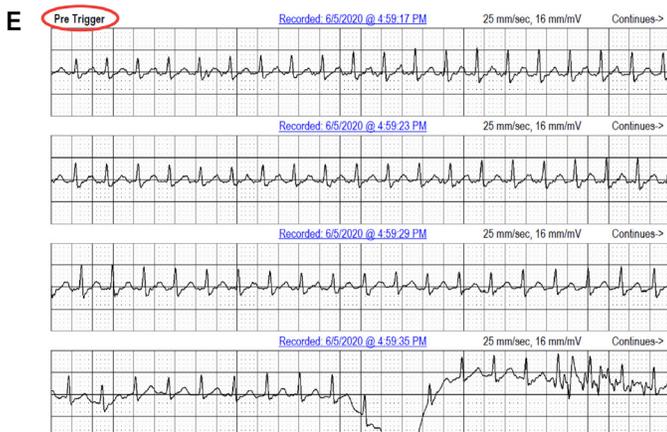
**Bottom image:** Offset of AVNRT with classic termination with a retrograde P-wave.

One patient went on to an electrophysiology study that confirmed and ablated typical AVNRT, which may not have been the case if MCT alone had been used.

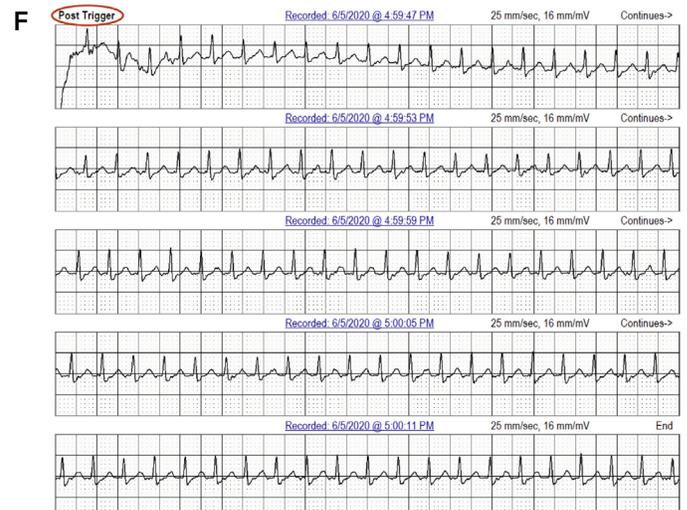
## Preventice MCT misdiagnosed AVNRT as Sinus Tachycardia, despite being triggered by patient activation.

Simultaneous recordings from the Preventive mobile carrier telemetry (MCT) recorder are shown below.

**Left image below:** Pre-trigger episode provided in the Preventive MCT report without arrhythmia onset.

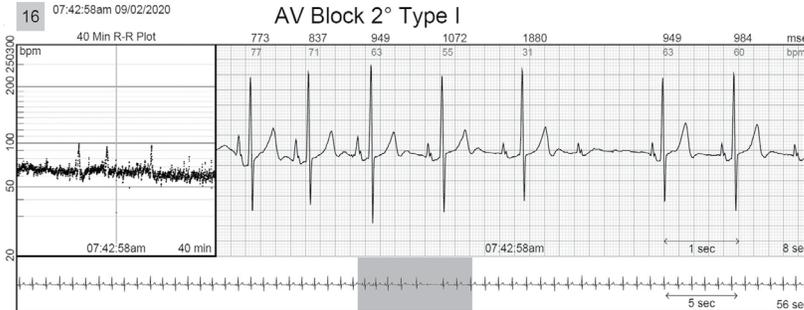


**Right image below:** Post-trigger strips do not provide an offset of this episode, another diagnostic limitation.



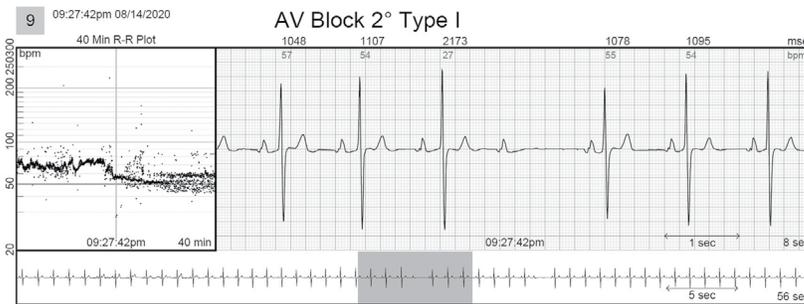
# 2<sup>nd</sup> Degree AV Block and VT seen only on CAM Patch, missed by simultaneously worn Preventice MCT

**Patient 1**



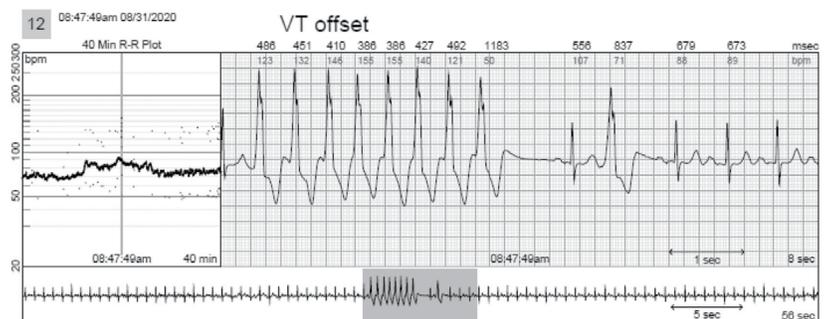
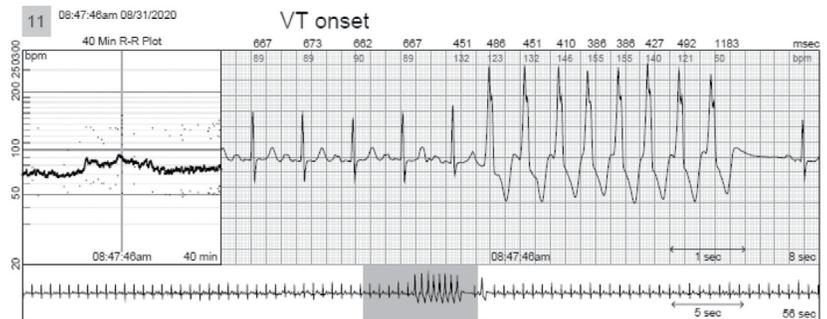
Patient 1 and 2 had second-degree atrioventricular (AV) block Mobitz I recorded by **CAM** Patch. None of these episodes was captured on the simultaneously recorded Preventice MCT in any of these patients.

**Patient 2**



Patient 3 is an example of ventricular tachycardia (VT) that was only identified by **CAM** Patch and not seen on the simultaneously recorded Preventice MCT report.

**Patient 3**



The Carnation Ambulatory Monitor is intended for ambulatory collection of ECG data. **Rx only.** For safe and proper use of the products mentioned herein, please refer to the Instructions for Use.

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