

# CAM vs. Zio<sup>®</sup> XT Clinical Study

## STUDY PURPOSE

To compare the ECG signal quality and diagnostic utility of two patch ambulatory external monitors (AEM)

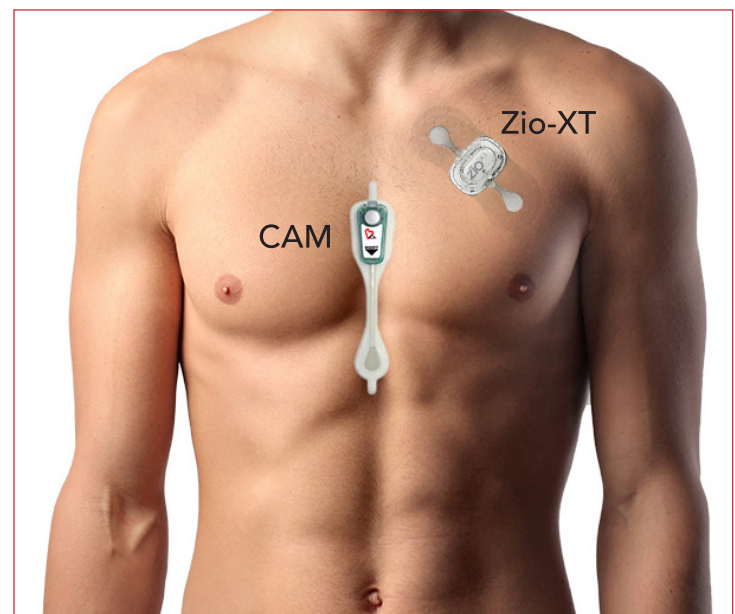
To identify any differences in clinical decisions based on data reported from each monitor

## STUDY METHODS

- Prospective comparison of two FDA-cleared, single-vector patch AEMs:
  - **Carnation Ambulatory Monitor (CAM)**(Bardy Diagnostics, Inc.)
  - Zio<sup>®</sup> XT (iRhythm Technologies, Inc.)
- 30 adult patients enrolled from a single center
  - Both devices simultaneously applied and removed after 7 days
  - Study data based on 29 of the 30 subjects due to unavailability of Zio<sup>®</sup> XT data for one patient
- Neither company reading centers were made aware that the ECG data received were part of a clinical study
  - Reports were prepared and provided to the physicians according to the standard operating procedures of each reading center
- Three physicians (one cardiologist and two electrophysiologists) reviewed the ECG reports prepared from each device

## OUTCOME MEASURES

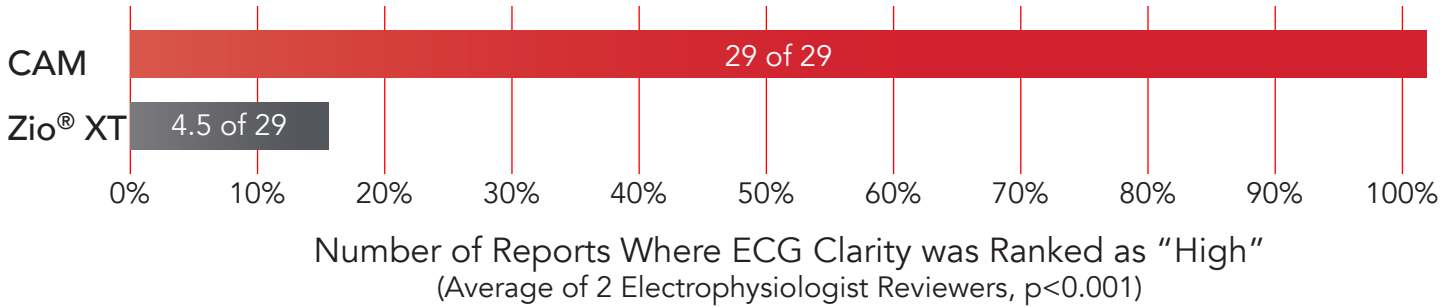
OUTCOME MEASURES	
<b>Primary</b>	<ul style="list-style-type: none"><li>• ECG Clarity</li><li>• Differences in Rhythm Types Diagnosed</li></ul>
<b>Secondary</b>	<ul style="list-style-type: none"><li>• Impact on Clinical Decision-Making</li><li>• Assessment of Ease-of-Use and Comfort</li></ul>



## STUDY RESULTS

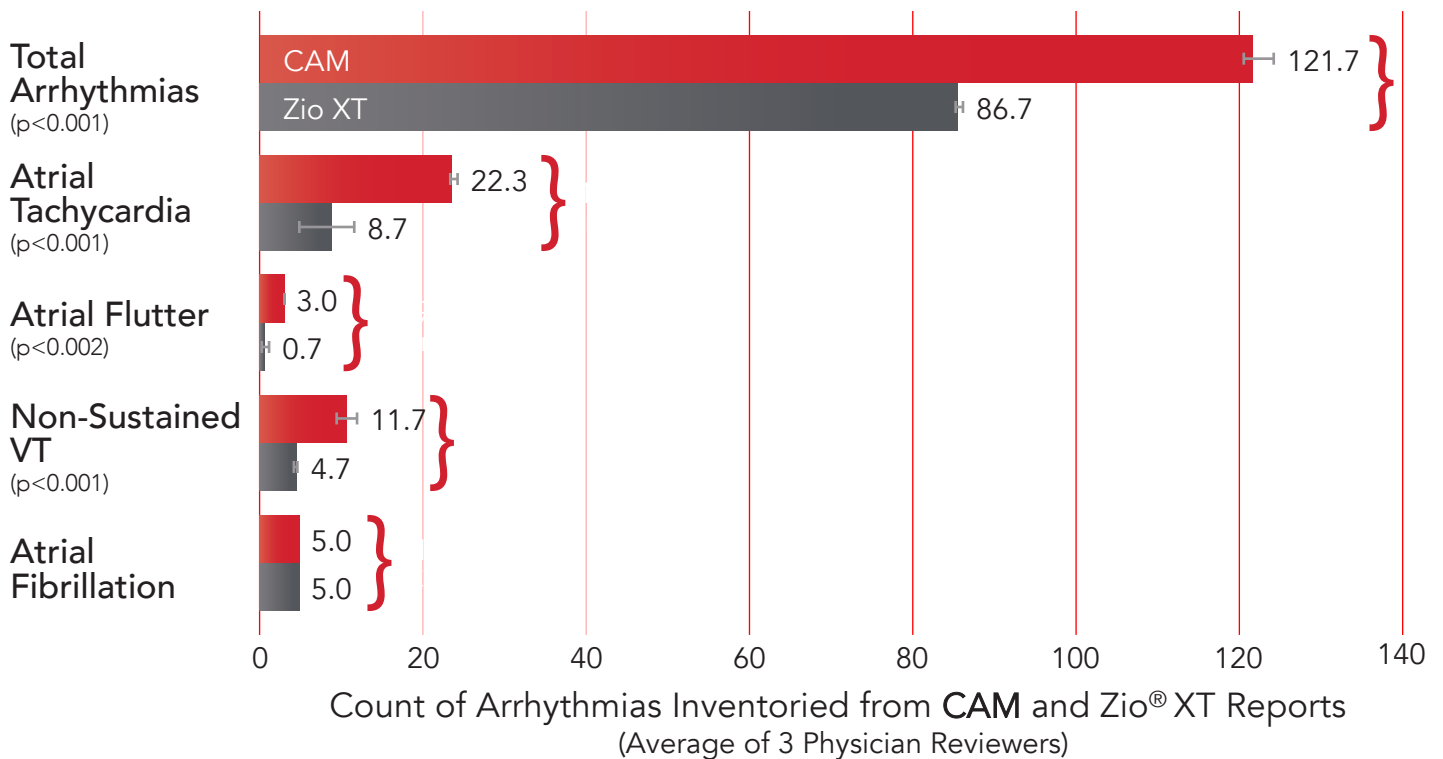
### ECG CLARITY

The **CAM** ECG tracings were ranked higher in clarity compared to the Zio<sup>®</sup> XT ECG tracings, allowing physician reviewers more confidence in making a specific rhythm diagnosis and may result in differences in clinical decision making.



### RHYTHM TYPES DIAGNOSED

The **CAM** Patch reported more and different arrhythmias (particularly atrial tachycardia, atrial flutter, and non-sustained VT) than the Zio<sup>®</sup> XT patch. Both monitors performed equally in identifying atrial fibrillation.



Physician reviewers were unable to assign a specific rhythm diagnosis for one or more ECG strips marked as "SVT Unknown" on  $15.7 \pm 2.2$  Zio<sup>®</sup> XT reports (54%). In contrast, reviewers were able to assign a specific rhythm diagnosis to all narrow complex arrhythmias presented on the **CAM** reports.


#### IMPACT ON CLINICAL DECISION-MAKING

} Based on physician reviewer interpretations of each **CAM** and Zio<sup>®</sup> XT report, a different, informed, clinical decision would have been made in 12 of 29 patients (41%) based on the **CAM** ECG report.

#### ASSESSMENT OF EASE-OF-USE & COMFORT

} Both AEMs were considered user-friendly. Patient experiences were comparable and favorable for both devices. The **CAM** Patch was associated with fewer incidences of skin reaction.

### STUDY CONCLUSION

 The **CAM** Patch recorded higher rhythm specificity and ranked higher in clarity compared to the Zio<sup>®</sup> XT. The P-wave visualization and its relationship to the QRS provided greater confidence in determining a specific rhythm diagnosis and allowed the ability to make corresponding clinical decisions.

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.

*Source: Rho R, Vossler M, Blancher S, Poole JE. Comparison of two ambulatory patch ECG monitors: The benefit of the P-wave and signal clarity. American Heart Journal. 2018;203:109-117.*

*doi:10.1016/j.ahj.2018.03.022.*

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