Clinical Summary

CAM vs. Zio XT Clinical Study

STUDY PURPOSE

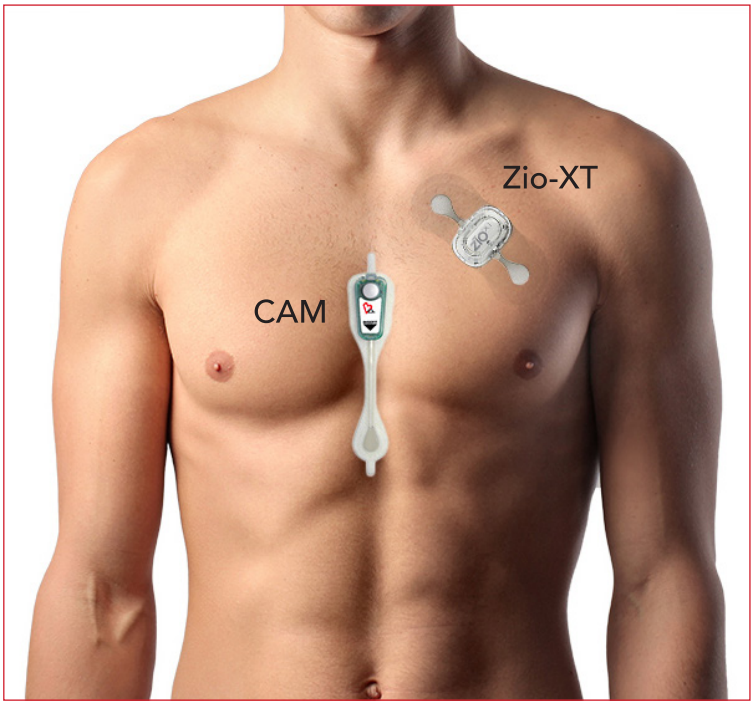
To compare the ECG signal quality and diagnostic utility of two patch ambulatory external monitors

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

STUDY METHODS

- Prospective comparison of two FDA-cleared and CE marked, single-vector patch AEMs:
  - — Carnation Ambulatory Monitor (CAM™) (Bardy Diagnostics, Inc.)
  - — Zio® XT (iRhythm Technologies, Inc.)
- 30 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 XT data for one patient
- Neither company reading centers were made aware that the ECG data received was 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
Primary	• ECG Clarity • Rhythm Types Diagnosed
Secondary	• Impact on Clinical Decision-Making • Assessment of Ease-of-Use and Comfort



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STUDY RESULTS

ECG CLARITY

The CAM ECG tracings were ranked higher in clarity compared to the Zio XT ECG tracings, providing the physician reviewers a greater degree of confidence in specific rhythm diagnosis and resulting clinical decisions.

	CAM	Zio XT	p Value
ECG Clarity (Ranked as "High") (Avg. of 2 Electrophysiologist Reviewers)	29/29 (100%)	4.5/29 (16%)	p<0.001

RHYTHM TYPES DIAGNOSED

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

	CAM	Zio XT	% Increase of CAM over Zio XT	p Value
Total Arrhythmias	121.7±2.1	86.7±0.6	40%	p<0.001
Total Tachycardia	22.3±0.6	8.7±3.2	156%	p<0.001
Atrial Flutter	3.00±0.00	0.67±5.8	348%	p<0.002
Non-Sustained VT	11.7±1.5	4.7±0.6	149%	p<0.001

Physician reviewers were unable to assign a specific rhythm diagnosis for one or more ECG strips marked as "SVT Unknown" on 15.7±2.2 Zio XT reports. 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 XT report, a different, more informed, clinical decision would have been made in 12 patients (41.4%) based on the CAM ECG report.

ASSESSMENT OF EASE-OF-USE AND 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 than the Zio XT patch. The superior ECG clarity, afforded by the ability to better visualize the P-wave and its relationship to the QRS, provided greater confidence in determining a specific rhythm diagnosis and corresponding clinical decisions.

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*. Manuscript published online April 5, 2018: doi:10.1016/j.ahj.2018.03.022

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