

iRhythm Clinical Publications

Publications from peer-reviewed journals demonstrate the clinical value of Zio.

Journal/ Author & Institution	Publication Title/ Key Findings	Study Type/ Sample Size
JAMA Cardiology, 2021 Gladstone, et al. Sunnybrook Research Institute, University of Toronto	Screening for Atrial Fibrillation in the Older Population – A Randomized Clinical Trial <ul style="list-style-type: none">• AF screening, for participants without known AF, with a wearable ECG monitor increased AF detection by 10-fold. New AF was detected in 5.3% of the screening group vs. 0.5% of the control group.• Median AF duration on continuous electrocardiographic (cECG) monitoring was 6.3 hours, and anticoagulation was prescribed to 75.0% of the participants with screen-detected atrial fibrillation.• AF screening with a wearable cECG monitor was well tolerated Read article >	Prospective N = 856

Journal/
Author & Institution

Publication Title/
Key Findings

Study Type/
Sample Size

Heart Rhythm O², 2020
Waalén, et al.
Scripps Research
Translational Institute

Healthcare resource utilization following ECG sensor patch screening for atrial fibrillation

Prospective
N = 1,718

- Screening for AF with a continuous electrocardiogram (ECG) sensor for 2 weeks twice during a 4-month period among an asymptomatic, moderate-risk population identified from members of a large insurance plan was associated with significantly different healthcare utilization patterns in the 1 year following screening compared with a matched observational control group identified from the same insurance plan.
- The actively monitored group had higher rates of outpatient cardiology visits but lower rates of emergency department (ED) use or hospitalizations compared with the control group.
- Among individuals receiving a new diagnosis of AF, utilization patterns were also markedly different between the groups, with those in the actively monitored cohort having significantly lower rates of ED use and hospitalizations compared with those in the observational control group. There was no difference in rates of outpatient cardiology visits between the 2 groups.
- Of the 65 individuals found to have AF on the ECG patch, 41 (63%) had a claim for at least 1 clinic visit or hospitalization with an AF diagnosis during the 1-year follow-up. Among those with pharmacy data available, anticoagulation rates for individuals of this group (60%) were similar to individuals with newly diagnosed AF in the matched control cohort (65.6%).

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European Journal
of Medical Research, 2019
Kaura, et al.
King's College Hospital

Early Prolonged Ambulatory Cardiac Monitoring in Stroke (EPACS): An Open-Label Randomised Controlled Trial

Prospective
N = 56

- Detection of paroxysmal AF (PAF) by Zio was 16.3% vs. Holter monitoring at 2.1%.
- Economic model showed that implementing Zio service would result in 10.8 more strokes avoided per year compared to current Holter monitoring and associated yearly saving in direct medical costs.
- Zio monitoring after an index stroke or TIA is superior to short-duration Holter monitoring in the detection of PAF and likely cost-effective for preventing recurrent strokes.

[Read article >](#)

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<p>Current Medical Research and Opinion, 2019</p> <p>Yenikomshian, et al.</p> <p>Analysis Group, Inc.</p>	<p>Cardiac Arrhythmia Detection Outcomes Among Patients Monitored With the Zio Patch System: A Systematic Literature Review</p> <ul style="list-style-type: none"> • Across 22 studies reviewed, unweighted mean wear time = 10.4 days. • Rate of arrhythmia detection increased with monitoring durations >48 hours and continued to increase beyond 7 days of monitoring. • Findings suggest that long-term, continuous, uninterrupted monitoring with Zio results in longer patient wear times and higher arrhythmia detection rates. <p>Read article ></p>	<p>Systematic Literature Review</p> <p>N/A</p>
<p>Heart Rhythm, 2019</p> <p>Mullis, et al.</p> <p>University of Florida,</p> <p>University of Kentucky</p>	<p>Fluctuations in Premature Ventricular Contraction Burden Can Affect Medical Assessment and Management</p> <ul style="list-style-type: none"> • Median of mean 14-day PVC burden = 9.0% • Median of maximum 24-hour PVC burden = 16.2% • Median of minimum 24-hour PVC burden = 4.5% <p>There is a significant variation in 24-hour PVC burden when measured over a 14-day period in patients with PVC burden of more than 5%. This variation can impact critical clinical decisions in a significant proportion of such patients.</p> <p>Read article ></p>	<p>Prospective</p> <p>N = 59</p>
<p>Journal of Interventional Cardiac Electrophysiology, 2019</p> <p>Eysenck, et al.</p> <p>Eastbourne</p> <p>General Hospital</p>	<p>A Randomized Trial Evaluating the Accuracy of AF Detection by Four External Ambulatory ECG Monitors Compared to Permanent Pacemaker AF Detection</p> <ul style="list-style-type: none"> • Zio is as accurate as the industry gold standard (implanted pacemaker) in detecting AF burden. ($R^2 = 0.9999$ MSE = 0.2371). • Zio is more accurate than other ECMs at detecting AF burden (including an event monitor and Bardy CAM). • Study highlights the Zio monitor's superior data accuracy and superior clinical performance. <p>Read article ></p>	<p>Prospective</p> <p>N = 21</p>

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<p>Nature Medicine, 2019 Hannun, et al. Stanford University</p>	<p>Cardiologist-Level Arrhythmia Detection and Classification in Ambulatory Electrocardiograms Using a Deep Neural Network</p> <ul style="list-style-type: none"> • Using Zio data, researchers developed a deep-neural network (DNN) that can diagnose arrhythmias at a high diagnostic performance similar to that of expert cardiologists. • The DNN model met or exceeded the performance of cardiologists for all 12 rhythm classes and recapitulated the misclassifications made by cardiologists. • This approach could reduce the amount of misdiagnosed computerized ECG interpretations and improve the efficiency of expert human ECG interpretation by accurately triaging or prioritizing the most urgent conditions. <p>Read article ></p>	<p>Evaluation Study N = 91,232</p>
<p>Heart Rhythm Journal, 2019 Wineinger, et al. Scripps Translational Science Institute</p>	<p>Identification of Paroxysmal Atrial Fibrillation Subtypes in Over 13,000 Individuals</p> <ul style="list-style-type: none"> • Over 50% of individuals with paroxysmal AF (PAF) did not display a PAF episode within first day of monitoring. PAF would have been missed if using Holter monitors. • Extended monitoring to 1 week would reduce the number of missed PAF cases by 80%. • Conventionally, phenotype of AF is broadly classified on duration and permanence of AF and treatment strategies remain general. This study showed that quantifying the variation in rhythm patterns of PAF is the first step in developing individualized risk assessment and treatment approaches. <p>Read article ></p>	<p>Retrospective N = 13,293</p>

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<p>Journal of Electrocardiology, 2018 Heckbert, et al.</p> <p>University of Washington</p>	<p>Yield and Consistency of Arrhythmia Detection With Patch Electrocardiographic Monitoring: The Multi-Ethnic Study of Atherosclerosis</p> <ul style="list-style-type: none"> • Among participants with no prior AF/flutter history and at least 12 days of monitoring, 4% AF/flutter was detected, representing new diagnosis. In 38% of these, AF/flutter was detected at days 3-12 of monitoring. • The yield of AF/flutter increased with longer monitoring time. • In an older general population sample, the use of a 14-day ECG monitor was feasible and provided analyzable rhythm data for nearly all of the wear time. <p>Read article ></p>	<p>Prospective N = 1,122</p>
<p>Emergency Care Journal, 2018 Reed, et al.</p> <p>Royal Infirmary of Edinburgh</p>	<p>Brain Natriuretic Peptide and High-Sensitivity Troponin at 3 Hours Post Emergency Department Attendance With Unexplained Syncope Predict 90 Day Outcome</p> <p>Syncope is a common ED presentation, but the underlying diagnosis is not clear. Study showed that the combination of Brain Natriuretic Peptide (BNP) and high-sensitivity troponin I at 3 hours mark showed promise as a potential predictive marker for serious arrhythmia and serious outcome at 90 days.</p> <p>Read article ></p>	<p>Prospective N = 86</p>
<p>Nutrients, 2018 Lutsey, et al.</p> <p>University of Minnesota</p>	<p>A Pilot Randomized Trial of Oral Magnesium Supplementation on Supraventricular Arrhythmias</p> <p>Study showed that compliance, adherence to oral magnesium supplementation was very good, and acceptance of the Zio monitor was excellent (Zio worn 13 of requested 14 days).</p> <p>Read article ></p>	<p>Prospective N = 59</p>

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JAMA, 2018 Steinhubl, et al. Scripps Translational Science Institute	<p>Effect of a Home-Based Wearable Continuous ECG Monitoring Patch on Detection of Undiagnosed Atrial Fibrillation: The mSToPS Randomized Clinical Trial</p> <ul style="list-style-type: none"> • At 4 months, Zio led to a significantly higher rate of AF diagnosis (3.9%) vs. those who received routine care (0.9%). • At 1 year, Zio led to a significantly higher rate of AF diagnosis (6.7%) vs. those who received routine care (2.6%). • Zio also detected other actionable arrhythmias including VT, pause, AV block and SVT. • Active monitoring with Zio was associated with increased initiation of anticoagulants (5.7%), antiarrhythmic drugs (0.8%) and new pacemakers (0.8%). • Among individuals at increased risk for AF, use of a wearable ECG patch facilitated AF diagnosis. <p>Read article ></p>	Prospective N = 2,659

Emergency Medicine Journal, 2018 Reed, et al. Royal Infirmary of Edinburgh	<p>Diagnostic Yield of an Ambulatory Patch Monitor in Patients with Unexplained Syncope After Initial Evaluation in the Emergency Department: The PATCH-ED Study</p> <ul style="list-style-type: none"> • At primary endpoint, Zio detected 10.5% of arrhythmias vs. 2.0% in control group. • Study showed that early ambulatory monitoring in ED patients with unexplained syncope is likely warranted and has the potential to change current management of syncope patients. • Zio has the potential to reduce hospital admissions and change first-line monitoring devices from low diagnostic yield to higher yield. <p>Read article ></p>	Prospective N = 86
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<p>JAMA Cardiology, 2018 Go, et al. Kaiser Permanente Northern California</p>	<p>Association of Burden of Atrial Fibrillation With Risk of Ischemic Stroke in Adults With Paroxysmal Atrial Fibrillation: The KP-RHYTHM Study</p> <ul style="list-style-type: none"> • AF burden greater than 11.4% led to a more than 3x increase of stroke or thromboembolism (TE) events. • Data showed no association between duration of the longest AF episode and risk of stroke. • Data showed no association between standard risk scores (CHA₂DS₂-VASc) and risk of stroke. • Characterizing AF burden in PAF patients could assist patients and physicians in having a more informed, shared decision-making discussion about stroke prevention strategies, including the initiation of anticoagulants. <p>Read article ></p>	<p>Retrospective N = 1,965</p>
<p>PLOS Medicine, 2018 Muse, et al. Scripps Translational Science Institute</p>	<p>Validation of a Genetic Risk Score for Atrial Fibrillation: A Prospective Multicenter Cohort Study</p> <ul style="list-style-type: none"> • Individuals with the highest AF genetic risk scores were 3x more likely to be diagnosed with AF than those with the lowest risk scores. • Genetic risk factors could be incorporated into the overall risk assessment strategy to better identify AF in individuals with the highest risk of developing AF. <p>Read article ></p>	<p>Prospective N = 904</p>
<p>Wilderness and Environmental Medicine, 2016 Verba, et al. Slippery Rock University</p>	<p>Electrocardiographic Responses to Deer Hunting in Men and Women</p> <ul style="list-style-type: none"> • Men and women with and without cardiovascular disease recorded substantial increases in HR and clinically relevant arrhythmias while deer hunting. • Zio's unobtrusive profile resulted in high subject compliance and device adherence during exercise. <p>Read article ></p>	<p>Prospective N = 19</p>

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<p>American Heart Journal, 2016</p> <p>Steinhubl, et al.</p> <p>Scripps Translational Science Institute</p>	<p>Rationale and Design of a Home-Based Trial Using Wearable Sensors To Detect Asymptomatic Atrial Fibrillation in a Targeted Population: The mHealth Screening to Prevent Strokes (mSToPS) Trial</p> <p>Zio was selected to identify patients with asymptomatic AF in a home-based clinical trial.</p> <p>Read article ></p>	<p>Study Protocol</p> <p>N/A</p>
<p>Journal of the American College of Cardiology, 2016</p> <p>Chen, et al.</p> <p>University of Minnesota</p>	<p>Persistent but not Paroxysmal Atrial Fibrillation Is Independently Associated With Lower Cognitive Function: ARIC Study</p> <ul style="list-style-type: none"> • Higher AF burden may be related to lower cognitive function. • Continuous monitoring and analysis are required to determine AF burden, and not just the presence or absence of AF. <p>Read article ></p>	<p>Prospective</p> <p>N = 325</p>
<p>Circulation: Heart Failure, 2016</p> <p>Olivotto, et al.</p> <p>Careggi University Hospital, Gilead Sciences</p>	<p>Novel Approach Targeting the Complex Pathophysiology of Hypertrophic Cardiomyopathy: The Impact of Late Sodium Current Inhibition on Exercise Capacity in Subjects with Symptomatic Hypertrophic Cardiomyopathy (LIBERTY-HCM) Trial</p> <p>Zio was selected by a leading biotechnology company to help determine efficacy of investigational treatment for hypertrophic cardiomyopathy.</p> <p>Read article ></p>	<p>Study Protocol</p> <p>N/A</p>
<p>BMC Cardiovascular Disorders, 2016</p> <p>Solomon, et al.</p> <p>Kaiser Permanente Northern California</p>	<p>Incidence and Timing of Potentially High-Risk Arrhythmias Detected Through Long Term Continuous Ambulatory Electrocardiographic Monitoring</p> <ul style="list-style-type: none"> • A significant percent of potentially high-risk arrhythmias (e.g., VT, sinus pause, high-grade heart block) were identified after 48 hours of monitoring. • Longer term monitoring finds more potentially high-risk arrhythmias. <p>Read article ></p>	<p>Retrospective</p> <p>N = 122,815</p>

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Frontiers in Physiology, 2015 Fung, et al. University of Southern California	Electrocardiographic Patch Devices and Contemporary Wireless Cardiac Monitoring <ul style="list-style-type: none"> • Studies support the use of prolonged ECG monitoring in most patients suspected to have atrial arrhythmias and/or neurologic symptoms. • AF diagnosed after a median of 7 days in a cryptogenic stroke study. Read article >	Review N/A
Heart, 2015 Keach, et al. University of Colorado	Early Detection of Occult Atrial Fibrillation and Stroke Prevention <p>The Zio system demonstrated superiority to Holter monitoring for detection of any arrhythmia, and effectively detects AF.</p> Read article >	Review N/A
Clinical Cardiology Journal, 2015 Turakhia, et al. VA Palo Alto Health Care System, Stanford University	Feasibility of Extended Ambulatory Electrocardiogram Monitoring to Identify Silent Atrial Fibrillation in High-Risk Patients: The Screening Study for Undiagnosed Atrial Fibrillation (STUDY-AF) <ul style="list-style-type: none"> • In asymptomatic patients with known AF risk factors, Zio found a combined prevalence of 11% AT/AF along with frequent supraventricular ectopic complexes. • These findings may be relevant to development of AF or stroke, and indicate primary screening for AF could have a significant impact on public health. Read article >	Prospective N = 75
Journal of Health Economics and Outcomes Research, 2015 Arnold, et al. Quorum Consulting, Mt. Sinai School of Medicine, University of Colorado	Cost Analysis and Clinical Outcomes of Ambulatory Care Monitoring in Medicare Patients: Describing the Diagnostic Odyssey <ul style="list-style-type: none"> • Clinicians were unable to rule-in or rule-out arrhythmias in 11% of Medicare claims evaluated, despite repeated Holter monitoring. • Repeat testing resulted in total allowed charge of \$23,000 per patient. Read article >	Retrospective N = 17,887

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<p>Frontiers in Neurology, 2015</p> <p>Tung, et al.</p> <p>Stanford University</p>	<p>Diagnostic Yield of Extended Cardiac Patch Monitoring in Patients With Stroke or TIA</p> <ul style="list-style-type: none"> • Zio had high patient compliance and high analyzable time (98.7%). • AF was present in 5% of reports, with average AF burden of 12.7%, demonstrating transient nature of the arrhythmia. • High rate of SVT (70%) may indicate precursor to AF. <p>Read article ></p>	<p>Retrospective N = 1,171</p>
<p>The Journal of Innovations in Cardiac Rhythm Management, 2014</p> <p>Eisenberg, et al.</p> <p>University of Southern California</p>	<p>Chronic Ambulatory Monitoring: Results of a Large Single-Center Experience</p> <ul style="list-style-type: none"> • Zio detected arrhythmias in all subjects referred to academic EP practice. • Most clinically significant arrhythmias were AF/flutter, non-sustained VT. • Over one third of initial arrhythmias were recorded after 48 hours. • Patient-reported symptoms did not correlate with arrhythmias in half of all symptom recordings. • Majority of AF episodes were asymptomatic. <p>Read article ></p>	<p>Retrospective N = 524</p>
<p>Western Journal of Emergency Medicine, 2014</p> <p>Schreiber, et al.</p> <p>Stanford University</p>	<p>Ambulatory Cardiac Monitoring for Discharged Emergency Department Patients With Possible Cardiac Arrhythmias</p> <ul style="list-style-type: none"> • Zio provided prompt diagnoses for ED patients, documenting normal sinus rhythm in symptomatic patients and serious asymptomatic arrhythmias in others. • Zio system achieved a 63% diagnostic yield in low risk patients discharged from the ED, compared to 15% with Holter monitors. • VT and pauses >3 sec were first triggered on average at 3.1 and 4.2 days, respectively (outside of Holter detection window). <p>Read article ></p>	<p>Prospective N = 174</p>

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American Journal of Medicine, 2014 Barrett, et al. Scripps Translational Science Institute	Comparison of 24-Hour Holter Monitoring Versus 14-Day Novel Adhesive Patch Electrocardiographic Monitoring <ul style="list-style-type: none"> • Zio detected 57% more arrhythmia events than 24-hour Holter monitors. • 90% of physicians achieved a definitive diagnosis using the Zio system, compared to 64% for Holter monitors. • 81% of patients preferred Zio over Holter monitors, preference led to longer wear time and improved arrhythmia detection. Read article >	Prospective N = 146
Journal of Cardiovascular Electrophysiology, 2014 Camm, et al. Johns Hopkins University	Premature Ventricular Contraction Variability in Arrhythmogenic Right Ventricular Dysplasia/Cardiomyopathy Zio system selected to monitor PVC counts in ARVD/C patients for 7 days; detected statistically significant variation day to day. Read article >	Prospective N = 40
Journal of Intensive Care Medicine, 2014 Ray, et al. Mayo Clinic, Jacksonville	Syncope <ul style="list-style-type: none"> • Zio is best suited for individuals with a history of frequently undiagnosed syncope when episodes are likely to occur during the 14 day monitoring period. • Diagnosis yield of Zio is 66% while Holter monitoring is 1-2%. Read article >	Review N/A
Progress in Cardiovascular Diseases, 2013 Lobodzinski California State University, Long Beach	ECG Patch Monitors for Assessment of Cardiac Rhythm Abnormalities Compared to Holter monitors, long-term ECG patch monitors result in an improvement in clinical accuracy, the detection of potentially malignant arrhythmias, and a meaningful change in clinical management. Read article >	Review N/A

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<p>The American Journal of Cardiology, 2013</p> <p>Turakhia, et al.</p> <p>Veteran Affairs Palo Alto Health Care System, Stanford University</p>	<p>Diagnostic Utility of a Novel Leadless Arrhythmia Monitoring Device</p> <p>After 48 hours, Zio detected that:</p> <ul style="list-style-type: none"> • 51% of patients had their first symptom-triggered arrhythmia. • 47% of patients experienced their first symptomatic episode of AF. • 37% of patients had their first symptomatic episode with AV block. • 30% of patients had their first arrhythmia of any type. <p>Read article ></p>	<p>Retrospective N = 27,751</p>
<p>Pacing and Clinical Electrophysiology, 2013</p> <p>Rosenberg, et al.</p> <p>Beth Israel Deaconess Medical Center</p>	<p>Use of a Noninvasive Continuous Monitoring Device in the Management of Atrial Fibrillation: A Pilot Study</p> <ul style="list-style-type: none"> • Over 24-hour period, Holter and Zio monitors detected identical AF episodes in patients. • Long-term monitoring with Zio changed clinical management in 28% of paroxysmal AF patients. <p>Read article ></p>	<p>Prospective N = 74</p>

