



iRhythm Data Presented at the American Heart Association 2024 Scientific Sessions Reinforce Clinical and Health Economic Value of Zio Long-Term Continuous Monitoring

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Five new studies span three focus areas for LTCM devices: digital engagement and patient satisfaction, arrhythmia patterns during sleep and activity, and the potential health care resource and economic impact of early arrhythmia detection in patients with type 2 diabetes and COPD

SAN FRANCISCO, Nov. 18, 2024 (GLOBE NEWSWIRE) -- [iRhythm Technologies, Inc.](#) (NASDAQ:IRTC) today announced the results of five new studies presented at the American Heart Association's 2024 Scientific Sessions in Chicago, IL. The findings underscore iRhythm's commitment to advancing ambulatory cardiac monitoring services to improve patient outcomes, enhance healthcare resource utilization, and provide access to affordable care, including for patients with chronic conditions.

The five studies presented by iRhythm span three focus areas for long-term continuous monitoring (LTCM): patient engagement and satisfaction through digital tools and patient-centered product enhancements, evaluating arrhythmia patterns during periods of sleep and activity, and assessing the potential healthcare resource and economic impact of early arrhythmia detection in patients with type 2 diabetes and chronic obstructive pulmonary disease (COPD).

"These new findings underscore iRhythm's commitment to rigorous scientific evidence," said Mintu Turakhia, MD, iRhythm's Chief Medical and Scientific Officer and EVP of Product Innovation. "Our data demonstrates the significant health economic benefits of early arrhythmia detection in often-overlooked conditions like diabetes and COPD, highlights greater patient engagement through our patient-centered digital tools that complement our services, and reveals distinct arrhythmia patterns associated with sleep and activity."

LTCM Patient Engagement and Satisfaction Through Digital Tool and Product Enhancements

Two studies validated the impact of digital health tools on improving patient compliance with timely device return and demonstrate the value of using patient-centric feedback to guide enhancements in the latest Zio® monitor.

- "Digital Engagement With a Patient Smartphone App and Text Messaging is Associated with Increased Compliance in Patients Undergoing Long-Term Continuous Ambulatory Cardiac Monitoring"
- "Feasibility of Point-Of-Wear Patient Satisfaction Surveys to Validate Patient-Centered Product Enhancements: Results From Over 300,000 Patients for Long-Term Ambulatory Cardiac Monitoring"

Evaluating Sleep and Activity Arrhythmia Patterns Using LTCM

Two studies assessed the feasibility and clinical utility of using the Zio system to monitor arrhythmias in relation to sleep and activity patterns.¹ Analyzing and classifying arrhythmia occurrences during sleep and physical exertion provides insights that may inform more personalized arrhythmia management.

- "Determining the Accuracy of Sleep and Activity Patterns in Patients Undergoing Long-Term Ambulatory ECG Monitoring"
- "Characterization of Arrhythmia Occurrence During Sleep and Activity in Patients Undergoing Long-Term Continuous Ambulatory ECG Monitoring"

Potential Healthcare Resource and Economic Value of Early Arrhythmia Detection in Patients with Type 2 Diabetes and Chronic Obstructive Pulmonary Disease (COPD)

This retrospective analysis of medical claims data examined the healthcare resource burden and medical costs of managing undiagnosed and untreated arrhythmias in patients with type 2 diabetes (T2D) and chronic obstructive pulmonary disease (COPD). The analysis was conducted by Eversana (Overland Park, KS, USA) and the preliminary findings suggest that early detection with arrhythmia monitoring devices has the combined potential to help prevent serious outcomes like stroke and heart failure and significantly reduce acute care utilization and related costs in these populations.

- "Real World Evidence on Health Care Resources Utilization and Economic Burden of Arrhythmias in Patients with Type 2 Diabetes (T2D) and Chronic Obstructive Pulmonary Disease (COPD)"

These data, presented at the American Heart Association's 2024 Scientific Sessions, are part of iRhythm's comprehensive clinical evidence program, encompassing over 100 original research publications² and insights from over 1.5 billion hours of curated heartbeat data.² This ongoing commitment reflects iRhythm's dedication to expanding clinical evidence that supports improved patient outcomes.

iRhythm's AHA Presentations Details:

["Digital engagement with a patient smartphone app and text messaging is associated with increased compliance in patients undergoing long-term continuous ambulatory cardiac monitoring" study](#)

This study sought to determine if two optional direct-to-patient digital interventions, the MyZio smartphone app and short messages services (SMS) text notifications, impacts patient compliance (i.e., activation, wear, and device return within 45 days) in patients who self-applied and activated a Zio 14-day patch-based long-term continuous ambulatory monitoring (LTCM) device shipped directly to their home. Distribution of the use of digital tools

and compliance outcomes was evaluated in 169,131 patients. Device activation, usage, and return compliance was highest (94.8%) when both the app and text messaging were used vs. 74.6% in cases where neither digital intervention was used. Opting in to SMS text was associated with compliance improvement vs. no digital intervention but was inferior to app use. These data support the use of patient digital health interventions in home-based diagnostics and underscore the importance of post-implementation evaluation of outcomes.

[“Feasibility of point-of-wear patient satisfaction surveys to validate patient-centered product enhancements: results from over 300,000 patients for long-term ambulatory cardiac monitoring” survey](#)

Researchers sought to understand the feasibility and value of collecting patient survey data at the point of care to assess quality improvements associated with use of a novel 14-day patch-based long-term continuous ambulatory ECG monitor (LTCM). Specifically, the study compared product experience and patient satisfaction associated with the prior generation LTCM (Zio[®] XT) to that of a next-generation, FDA-cleared LTCM product (Zio[®] monitor) designed with patient-centered features, including a more breathable adhesive, waterproof housing,^{3,4} thinner profile, and lighter weight.² Among 334,054 respondents, the new LTCM was associated with a greater proportion of affirmative responses across all survey categories, including a 14-percentage point improvement in wear comfort as compared to the prior generation device (79.1% vs. 64.7%, $p < 0.001$). The finding demonstrated patient survey data for post-market quality assessment is feasible for digital health technologies, in this case leading to over 300,000 total respondents in one year. Measures of patient satisfaction were higher with the new device, which may be due to patient-centered product enhancements.

[“Determining the Accuracy of Sleep and Activity Patterns in Patients Undergoing Long-Term Ambulatory ECG Monitoring” study](#)

Researchers sought to develop and assess performance of an algorithm to classify periods of sleep, activity (>2mph walking), and inactivity¹ using a novel ambulatory ECG (AECG) patch (Zio[®] monitor) with embedded accelerometry. A prospective clinical study enrolled participants across four American Academy of Sleep Medicine- (AASM) qualified sleep centers to support algorithm training and validation. Eighty-one (81) study participants wore the Zio[®] monitor AECG patch and a commercially available actigraphy reference device simultaneously over a 14-day study period, which included in-clinic overnight polysomnography (PSG) sleep testing and a 6-minute walk test. Data acquired were split into training ($n=40$) and validation ($n=41$) sets. Feature and model selection utilized five-fold cross-validation on the training set, focusing on total activity and body angle. Algorithm sensitivity and specificity (assessed over 1-minute epochs vs. PSG reference) in sleep detection were 88.8% and 54.0%, respectively for the validation set. Sensitivity and specificity in activity detection were 97.0% and 100%, respectively. Study authors concluded the assessment of sleep and activity during AECG is feasible, with performance comparable to FDA-cleared actigraphy and consumer devices.⁵ This feature offers insights into patient wellness patterns, highlighting its potential for personalized healthcare monitoring.

[“Characterization of Arrhythmia Occurrence During Sleep and Activity in Patients Undergoing Long-Term Continuous Ambulatory ECG Monitoring” study](#)

Researchers sought to quantify the occurrence of arrhythmias detected by long-term (≤ 14 days) continuous ambulatory ECG monitoring (LTCM) during periods of sleep, activity and inactivity.¹ The analysis is the largest study of its kind, and included 23,962 patients (57.7% female, age 60.9 ± 18.0 years) who underwent monitoring with a next generation LTCM (Zio[®] monitor) device. An AI algorithm previously developed and validated was used to classify periods of sleep and activity using LTCM accelerometry data (see study *Accuracy of Sleep and Activity Patterns* study described above). Rhythms were classified by an FDA-cleared deep learning algorithm,⁶ confirmed by a cardiographic technician and time-aligned to the algorithm-generated sleep/wake and activity/inactivity labels. Odds ratios (OR) associated with time in arrhythmia for sleep and activity periods were calculated by rhythm type. Among the rhythms having the highest association with sleep (vs. wake) were pause (OR=2.58; 95% CI 2.55-2.60) and 3rd degree heart block, (OR=1.37; 95% CI 1.37-1.37). Notably, the analysis identified ventricular tachycardia (VT) was among the arrhythmias least likely to occur during sleep (OR=0.51; 95% CI 0.50-0.51). Ventricular tachycardia and 3rd degree heart block had the highest OR associated with periods of activity. Results demonstrate the feasibility of integrating sleep and activity labeling with LTCM findings and the potential to give context to arrhythmias, such onset or termination during sleep, wake, or exertion.

[“Real World Evidence on Health Care Resources Utilization and Economic Burden of Arrhythmias in Patients with Diabetes and COPD” study](#)

This study examined healthcare resource utilization (HCRU) and medical costs of managing arrhythmias in T2D and COPD, and the potential impact of early detection on the rate of hospitalization and ER visits. Research included a retrospective claims analysis using the Merative MarketScan and the Symphony Integrated Dataverse databases. Study participants were > 18 years with claims for T2D or COPD or both T2D and COPD (T2D-COPD) and assigned into groups: Target: patients without prior history of arrhythmias, followed by arrhythmias claims. Control: patients with either of the conditions, but without arrhythmia claims. Target and control were matched 1:1 on demographic, year of first episode of arrhythmia, risk (ECI, DSI, Goki criteria). HCRU and medical cost drivers over 24 months were analyzed. HCRU of patients with the primary comorbidity and an associated arrhythmia was compared to those without an arrhythmia. The total cost of care per patient / year was significantly higher for all target patients compared to control (T2D \$34,171/ \$18,687; COPD \$37,719/\$25,656; T2D COPD \$46,484/\$30,824). The per patient / year cost of hospitalization was higher in the target patient's vs control (T2D \$28,316/\$19,439; COPD \$25,098/\$17,906; T2D COPD \$28,694/\$19,352). Much of this cost difference was also higher in the target patient's vs control in the 30 days post index date (arrhythmia diagnosis) (T2D \$18,414/\$1,928; COPD \$17,920/\$3,278; T2D COPD \$18,415/\$4,162). ER cost per patient/year was 35%-50% higher in the target cohort. Arrhythmia patients were hospitalized more than 2x per 1,000 cohort patients per year than non-arrhythmia patients, and of the diabetes, COPD and combined cohorts, 49%, 68%, and 74% of the patients were hospitalized respectively. The length of stay increased by 2-5 days for arrhythmia patients, with the diabetes, COPD and combined cohorts having an average length of stay of 10, 13, and 16 days respectively. The rate of ER visits were more than 2x for the arrhythmia cohort relative to the non-arrhythmia cohort, and of the diabetes, COPD and combined cohorts, 66%, 83%, and 86% of the patients have been hospitalized respectively. The preliminary study findings suggest that arrhythmias significantly increase HCRU and total cost for T2D and COPD, particularly in patients requiring ER visits and hospitalization, and that early detection with arrhythmia monitoring devices, could reduce the utilization of acute care and associated costs.

About iRhythm Technologies

iRhythm is a leading digital health care company that creates trusted solutions that detect, predict, and prevent disease. Combining wearable biosensors and cloud-based data analytics with powerful proprietary algorithms, iRhythm distills data from millions of heartbeats into clinically actionable information. Through a relentless focus on patient care, iRhythm's vision is to deliver better data, better insights, and better health for all.

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¹ The accelerometer data and the sleep and activity classification algorithm presented in this study are intended exclusively for research purposes and are not available for any commercial use.

² Data on file. iRhythm Technologies, 2023.

³ Data on file. iRhythm Technologies, 2017, 2023.

⁴ The Zio monitor device should not be submerged in water. During a bath, keep the device above water. Please refer to the Zio monitor labeling instructions or Patient Guide for the full set of details.

⁵ Chinoy ED, Cuellar JA, Huwa KE, Jameson JT, Watson CH, Bessman SC, Hirsch DA, Cooper AD, Drummond SPA, Markwald RR. Performance of seven consumer sleep-tracking devices compared with polysomnography. *Sleep*. 2021 May 14;44(5):zsaa291.

⁶ Hannun AY, Rajpurkar P, Haghpanahi M, Tison GH, Bourn C, Turakhia MP, Ng AY. Cardiologist-level arrhythmia detection and classification in ambulatory electrocardiograms using a deep neural network. *Nat Med*. 2019 Jan;25(1):65-69. Current FDA-cleared rhythm classification algorithm: K222389.

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