

iRhythm Presents New Real-World Data on Ambulatory Cardiac Monitoring at HRS 2025 Reinforcing Clinical Superiority of Zio Long-Term Continuous Monitoring

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- Findings in a younger, commercially insured population build on Medicare-based CAMELOT results, expanding the generalizability of Zio LTCM's clinical impact across patient groups.
- Latest data showed Zio LTCM was associated with higher diagnostic yield and lower likelihood of repeat testing and cardiovascular events compared to all other LTCM products.

SAN FRANCISCO, April 28, 2025 (GLOBE NEWSWIRE) -- **iRhythm Technologies, Inc.** (NASDAQ:IRTC) announced results from a large real-world retrospective analysis presented at the Heart Rhythm Society's annual meeting, HRS2025, held April 24-27 in San Diego, CA, The Assessment of Variation in Ambulatory Cardiac MONitoring: Real-World Evidence of Commercially Insured Beneficiaries (AVALON) study—drawing on claims data from a cohort of 428,707 commercially insured patients—represents the largest real-world comparative evaluation of ambulatory cardiac monitoring (ACM) among this population to date, and reinforces the clinical superiority of the Zio® long-term continuous monitoring (LTCM) service.

The Zio LTCM service consists of a prescription-only, patch-based ECG monitoring device that captures up to 14 days of continuous, uninterrupted data, and the ZEUS® (Zio ECG Utilization Software) system with an FDA-cleared AI algorithm clinically proven to perform at the level of cardiologists.¹ The system delivers an end-of-wear report that is reviewed and validated by qualified cardiac technicians, with a 99% physician agreement rate.²

Building on findings from the CAMELOT (Cardiac Ambulatory Monitor Evaluation of Outcomes and Time to Events) study—published in the **American Heart Journal**—which demonstrated the clinical superiority of the Zio LTCM service among a Medicare population, the AVALON study evaluated a younger, commercially insured population (mean age: 46 years). Like CAMELOT, the AVALON data showed that Zio LTCM service was associated with the highest diagnostic yield compared to other ACM modalities and all other LTCM services, and a lower likelihood of

repeat testing compared to all other LTCM services. AVALON also found that Zio LTCM service was associated with a lower likelihood of cardiovascular (CV) events compared to other ACM modalities and all other LTCM services.

Also at HRS, as part of a separate analysis, data were also presented showing that use of the MyZio® App, a patient smartphone accessory app designed to improve patient engagement and enable digital symptom logging, was associated with increased symptom reporting, improved symptom-rhythm correlation, and a greater rate of arrhythmia-correlated diary entries compared to non-users — demonstrating that digital apps can provide additional contextual clinical information and reinforcing the value of digital engagement alongside ambulatory cardiac monitoring.

“Once again, we have strong real-world evidence that compellingly demonstrates the superiority of Zio’s 14-day, uninterrupted, patch-based monitoring — AVALON extends findings beyond Medicare to patients in common commercial insurance plans,” said Mintu Turakhia, MD, iRhythm Chief Medical and Scientific Officer and EVP of Product Innovation. “We’re also proud of MyZio, which enriches the patient experience and provides more information to their doctor. As a Top 40 Medical App, our iOS App has a 4.7 rating — a rare accomplishment among medical device connected apps.”

AVALON Study Evaluates Clinical Outcomes in Real-World Cardiac Monitoring

The AVALON study aimed to assess the impact of ambulatory cardiac monitoring strategy on three key clinical outcomes: diagnostic yield, likelihood of repeat testing, and likelihood of cardiovascular (CV) events.³ These outcomes reflect both the immediate diagnostic effectiveness of ambulatory cardiac monitoring and its longer-term clinical implications.

Diagnostic yield—the ability to identify clinically relevant arrhythmias during a monitoring period—is a critical measure of effectiveness, as it enables earlier, more confident treatment decisions and may reduce the need for additional testing. Arrhythmias are commonly paroxysmal and infrequent. Therefore, device design, and performance AI, and quality of technician review can all affect whether arrhythmias are identified. Repeat testing may reflect diagnostic uncertainty, which can delay care and increase the burden on both patients and clinicians. In real-world settings, retest rates offer practical insight into diagnostic efficiency. CV events, such as cardiac arrest, myocardial infarction (MI), embolic stroke, or heart failure, represent meaningful long-term outcomes. Reducing the likelihood of these CV events is a key goal in arrhythmia management and may reflect the broader clinical impact of monitoring strategy.

Using closed claims data,⁴ investigators identified 428,707 commercially insured patients who were diagnostically naïve — defined as having no prior cardiac monitoring, arrhythmia diagnosis, or arrhythmia-related procedures or medications in the 12 months prior to the index date (baseline period). Of the records analyzed, 36% of patients

used LTCM, 36% used a Holter monitor, and 27% used an ambulatory event monitor (AEM). The mean age ranged from 45 to 46 years across ACM cohorts.

Diagnostic Yield and Likelihood of Retest and Cardiovascular Events

New arrhythmia diagnosis — as documented in clinical encounter claims using ICD-10 codes for specified arrhythmias, within the first 90 days was highest for Zio LTCM service (26.5%), followed by non-iRhythm LTCM (18.4%), AEM (17.0%), and Holter monitoring (14.7%).

Zio LTCM service was associated with the highest adjusted odds of a new arrhythmia encounter diagnosis compared to other ACM modalities and all other LTCM services. Compared to Holter monitors, Zio LTCM service was 2.04 times more likely to have a new arrhythmia encounter diagnosis within 90-days. Compared to AEM, Zio LTCM was 1.69 times more likely to have a new arrhythmia encounter diagnosis within 90-days. Compared to non-iRhythm LTCM services, Zio LTCM service was 1.56 times more likely to have a new arrhythmia encounter diagnosis within 90-days. Compared to Bardy LTCM service, Zio LTCM service was 1.12 times more likely to have a new arrhythmia encounter diagnosis within 90-days. Compared to Biotelemetry LTCM service, Zio LTCM service was 1.72 times more likely to have a new arrhythmia encounter diagnosis within 90-days. Compared to Preventice LTCM service, Zio LTCM service was 1.69 times more likely to have a new arrhythmia encounter diagnosis within 90-days. Compared to “Other LTCM,” Zio LTCM service was 1.61 times more likely to have a new arrhythmia encounter diagnosis within 90-days.

Zio LTCM service was associated with lowest adjusted odds of retesting within 180 days compared to all other LTCMs from service providers in the same extended monitoring category. Compared to Zio LTCM service, all non-iRhythm LTCMs were 1.95 times more likely to result in a retest. Across the providers in the LTCM space, Bardy, BioTelemetry, Preventice, and “Other LTCM” providers were associated, respectively, as 1.41, 1.39, 1.30, and 3.52 times more likely to result in a retest within 180 days compared to Zio LTCM.³

Zio LTCM service was associated with lowest adjusted odds of cardiovascular events within 1-year compared to ACM modalities and all other LTCMs from service providers in the same extended monitoring category.

Holter monitors were 1.13 times more likely and AEM were 1.21 times more likely to have a CV event within 1-year compared to Zio LTCM service. Compared to Zio LTCM service, non-iRhythm LTCMs were 1.23 times more likely to have a CV event within 1-year after accounting for baseline patient differences. Across the providers in the LTCM space, Bardy, BioTelemetry, Preventice, and “Other LTCM” providers were 1.11, 1.24, 1.19, and 1.23 times more likely, respectively, to have a CV event within 1-year compared to Zio LTCM.³

iRhythm’s Expanding Clinical Evidence Base

These new data build on iRhythm's comprehensive clinical evidence program, encompassing more than 125 original research manuscripts,⁵ insights derived from over 2 billion hours of curated heartbeat data⁶ and more than 10 million patient reports posted since the company's inception—underscoring the company's ongoing commitment to expanding evidence that supports improved patient outcomes.

About the iRhythm Studies Presented at HRS2025

AVALON: Assessment of Variation in Ambulatory Cardiac Monitoring: Real-World Evidence of Commercially Insured Beneficiaries study

Ambulatory cardiac monitors (ACM) enable heart rhythm monitoring for various durations, including Holter monitors (0–48 hours), long-term continuous monitoring (LTCM, 3–14 days), and external ambulatory event monitors (AEM, up to 30 days). These devices detect intermittent or asymptomatic arrhythmias that might go unnoticed with a standard electrocardiogram. The prior CAMELOT study explored variations in ACM use among older and sicker Medicare beneficiaries (Mean Age: 76 years; Charlson Comorbidity Index [CCI]: 2.4), but differences among commercially insured patients remained unclear, until now.

The retrospective cohort study sought to assess the incidence of clinical outcomes among commercially insured diagnostic naïve patients who received their first ACM, using a large commercial claims database focused on patients without prior arrhythmia diagnoses who underwent their first ACM between 2016 and 2023. Outcomes included new arrhythmia diagnoses (based on ICD-10 codes) within 90 days, repeat ACM testing within 180 days, and cardiovascular events within 365 days of initiating ACM use. Results were stratified by major ACM manufacturers using national provider identifiers (NPI). To minimize confounding, inverse probability of treatment weighting (IPTW) balanced covariates, and adjusted regression models were used to evaluate outcomes during follow-up. Of 428,707 patients meeting inclusion, 36% used LTCM, 36% Holter, and 27% AEM.

Adjusted analyses showed Zio LTCM service was associated with higher odds of arrhythmia diagnoses, fewer retests (except AEM), and lower odds of cardiovascular events compared to other modalities and all other LTCM manufacturers.

Clinical outcomes vary by ACM type among commercially insured patients. Zio LTCM service demonstrated superior performance, with higher rates of arrhythmia diagnoses, fewer repeat tests, and fewer cardiovascular events compared to other ACM types and all other LTCM providers.

The AVALON study was funded by iRhythm Technologies, Inc; statistical analysis was independently performed by Blue Health Intelligence (BHI).

Digital Engagement With A Patient Smartphone App Is Associated With Increased Symptom Reporting And Symptom-Rhythm Correlation In Patients Undergoing Ambulatory Cardiac Monitoring

Patient-reported symptoms are the most common indication for ambulatory cardiac monitoring (ACM) and a key component of arrhythmia management used to guide treatment decisions. Symptom severity and context are useful in risk stratification and were traditionally captured in paper diaries. MyZio® mobile app is an optional patient smartphone app for use with Zio® ACMs (including LTCM and mobile cardiac telemetry devices) designed to improve engagement and enable digital symptom logging.

The retrospective study sought to evaluate the impact of MyZio App digital symptom logging, as compared to paper patient diaries, on symptom-rhythm correlation (SRC), and evaluated >164,000 randomly sampled ECG records from among patients ≥18 yrs prescribed Zio ACM for ≤14 days between Jan 1 and Jun 30, 2024. Symptoms were recorded by 1) a patient-activated button incorporated into the ACM, 2) entries in a paper diary provided with the ACM, or 3) entries in a digital diary available to app users. Continuous ECG data were analyzed using an FDA cleared deep learning algorithm for arrhythmia classification. Symptoms documented within ±45 seconds of an arrhythmia were considered rhythm correlated. We calculated the percentage of symptomatic episodes based on button presses or diary entry and per-patient SRC.

Among 164,563 patients, 18.4% used the MyZio App. App users were younger and more likely to be female than non-users. App use was associated with increased odds of rhythm-correlated symptoms by button press (OR=1.86; 95%CI 1.84-1.89) and diary entry (OR=3.44; 95%CI 3.38-3.50). Overall engagement was greater among App users vs. non-users, with a higher rate of episodes identified by button press alone and per-patient SRC (16.0% vs. 13.9%). Use of the MyZio App was associated with a 1.85-fold increase in rate of rhythm-correlated diary entries (OR 1.85, 95%CI 1.81-1.89) over the increase in rate of rhythm-correlated button presses alone.

In patch-based ACM, use of the MyZio App was associated with increased symptom logging, greater SRC and higher odds of rhythm-correlated diary entries. Use of a patient digital app as an adjunct to ACM can provide greater contextual clinical information.

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. To learn more about iRhythm and its Zio® portfolio of products and services, please visit <https://www.irhythmtech.com/>.

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¹ Hannun et al. Cardiologist-level arrhythmia detection and classification in ambulatory electrocardiograms using a deep neural network. Nat Med. 2019;25:65-69. <https://doi.org/10.1038/s41591-018-0268-3>

² 99% of physicians agree with the comprehensive end-of-wear report. Based on a review of all online Zio XT, Zio monitor, and Zio AT end-of-wear reports. Data on file. iRhythm Technologies, 2023.

³ Cardiovascular Events defined as cardiac arrest, MI, arterial embolism and thrombosis, embolic stroke, systemic embolism, coronary heart disease, chronic obstructive pulmonary disease, cerebrovascular disease, heart failure

⁴ The analysis was conducted using closed claims data from a large, national commercial health plan dataset maintained by BHI (Blue Health Intelligence).

⁵ Data on file. iRhythm Technologies, 2025.

⁶ Data on file. iRhythm Technologies, 2024.

Source: iRhythm