

**NEWS RELEASE** 

# iRhythm Unveils New Real-World Data at ACC.25 Demonstrating the Benefits of Zio® Long-Term Continuous Monitoring for Arrhythmia Detection

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Two large studies of over one million patients reveal that short-term Holter-duration monitoring frequently misses actionable arrhythmias and that patient-reported symptoms are an unreliable predictor of arrhythmic events SAN FRANCISCO, March 31, 2025 (GLOBE NEWSWIRE) -- iRhythm Technologies, Inc. (NASDAQ:IRTC) today announced results from two large real-world retrospective analyses presented at the American College of Cardiology (ACC) 2025 Scientific Sessions in Chicago, IL. Drawing on data from more than 1.1 million patients who used iRhythm's Zio® long-term continuous monitoring (LTCM) ECG devices, these studies demonstrate that short-term (24–48-hour) monitoring, such as with Holter devices, fails to detect a significant proportion of actionable arrhythmias—even in patients reporting "daily symptoms"—and that Symptom–Rhythm Correlation (SRC) is notably low for most arrhythmias, underscoring that selection of monitoring duration based on the frequency of symptoms alone can lead to undetected (missed) actionable<sup>1</sup> arrhythmias. Together, these findings highlight the benefits of Zio® long-term continuous monitoring (LTCM)<sup>2</sup> and the limitations in 24–48-hour Holter monitoring still prevalent in current clinical practices and payer policies.

### Zio LTCM "Daily Symptoms" Study: Gaps in Short-Term Holter Monitoring

- 64% Undetected in the First 48 Hours: Among daily-symptom patients—those with daily or greater symptom frequency— diagnosed with actionable arrhythmias, nearly two-thirds went undetected through two days monitoring—indicating that 24–48-hour monitoring, such as with Holter, would have failed to detect them.
- Higher Yield for Non-Daily Symptom Patients: Non-daily symptom patients—those with symptoms occurring with a frequency less than once per day—had an 80.9% arrhythmia yield versus 69.1% in daily-symptom patients, demonstrating that greater symptom frequency does not necessarily reflect increased arrhythmia burden.
- Mean Time to First Episode Exceeds 48 Hours: Across all arrhythmia types, the mean time to the first detected

episode was greater than 48 hours—regardless of symptom frequency—underscoring the limitations of short-term monitoring.

## Zio LTCM "Symptom-Rhythm Correlation (SRC)" Study: Symptoms Alone Are Unreliable

- Less Than 20% Correlation: In most arrhythmia types, fewer than one in five patients in the analysis documented a symptom coinciding with an arrhythmic episode. Symptom-rhythm correlation was higher for patients reporting daily vs. non-daily symptoms.
- AF Often Asymptomatic: Even for atrial fibrillation (AF)—the most commonly symptomatic arrhythmia—over half of all cases were asymptomatic.
- Serious Arrhythmias Frequently Not Correlated with Symptoms: Ventricular tachycardia, AV block, and significant pauses were frequently detected by Zio LTCM without patient-reported symptoms, suggesting that selection of monitor duration should not be based on symptom frequency alone, and that long-term continuous monitoring may offer advantages over other monitoring types with shorter duration or those which rely on patient triggered events to initiate recording.

"These findings challenge the long-held assumption that frequent symptoms justify short-duration monitoring," said Mintu Turakhia, MD, iRhythm Chief Medical and Scientific Officer and EVP of Product Innovation. "They reinforce the limitations of Holter-duration monitoring and highlight the value of Zio long-term continuous monitoring up to 14 days. Once again, iRhythm's real-world data are contributing evidence that can help guide both clinical practice and payer policy."

Arrhythmias: A Growing Burden for Patients and Health Systems

Up to five percent of the general population—around 16 million Americans—experience arrhythmias,<sup>3</sup> in which the heart may beat too quickly, too slowly, or sporadically. If left untreated, certain arrhythmias can damage the heart, brain, or other organs<sup>4</sup> and increase the risk of stroke or death.<sup>5,6,7</sup> Beyond these clinical concerns, the financial toll of undiagnosed arrhythmias is substantial. It's estimated that undiagnosed atrial fibrillation alone costs the U.S. \$3 billion per year,<sup>8</sup> while heart failure costs could reach \$70 billion by 2030.<sup>9</sup> Taken together, these figures illustrate both the clinical urgency and health-economic rationale for long-term continuous monitoring.

Implications for Clinical Care and Payer Policy

While 24–48-hour Holter monitoring is widely used in current clinical practice and historically supported by payer policies—especially for patients reporting daily symptoms—these new findings indicate that 64% of daily-symptom patients with actionable arrhythmias remain undetected following the first 48 hours of monitoring, which could lead to missed diagnoses and delayed care. In contrast, Zio LTCM provides uninterrupted, continuous monitoring

for up to 14 days, enabling more accurate and timely detection of actionable arrhythmias. The Cardiac Ambulatory Monitor EvaLuation of Outcomes and Time to Events (CAMELOT) study, published in the **American Heart Journal**, further demonstrated that Zio LTCM service had the highest yield of specified arrhythmia diagnosis and the lowest likelihood of repeat testing compared to all other monitoring services. <sup>10,11,12,13</sup> As healthcare systems increasingly adopt value-based care models, extending monitoring beyond 48 hours can improve patient outcomes, reduce missed diagnoses, and help contain healthcare resource utilization.

New Data Add to iRhythm's Clinical Evidence Base for LTCM

These new data build on iRhythm's comprehensive clinical evidence program, encompassing more than 125 original research manuscripts,<sup>14</sup> insights derived from over 2 billion hours of curated heartbeat data<sup>15</sup> 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 ACC.25

# "Arrhythmias in Patients with Daily vs. Non-Daily Symptoms Undergoing Long-Term Continuous Patch ECG Monitoring"

Holter monitoring of 24-48 hours remains in common use for patients with frequent or daily symptoms based on clinician or payer preferences. This retrospective cohort study sought to determine the percentage of arrhythmias detected by LTCM before and after 48 hours of monitoring in patients with daily (≥ 1/day) and non-daily (<1/day) symptoms. Researchers compared yield in patients ≥18 years prescribed a Zio<sup>®</sup> monitor or Zio<sup>®</sup> XT LTCM worn for >7 to 14 days from June 2023 to July 2024. These devices include a patient-activated button to document symptomatic episodes. Symptom frequency was measured as button presses/day and stratified by daily (≥1/day) or non-daily (<1/day). ECG data was analyzed via a deep-learned AI algorithm and confirmed by cardiographic technicians. Nearly two thirds (64%) of daily-symptom patients with actionable arrhythmias were undetected in the first 48 hours and the man time to first detected arrhythmia was >48 hours for all arrhythmia types, regardless of symptom frequency, suggesting that Holter (<48 hour) may be inadequate even for these patients.

## "Symptom-Rhythm Correlation Patterns in Patients Undergoing Ambulatory ECG Monitoring: Analysis of Over 1 Million Patients"

Symptoms are the most common indication for ambulatory cardiac monitoring, yet Symptom–Rhythm Correlation (SRC) has not been well described across various arrhythmias. Researchers assessed SRC in patients ≥18 years who wore a Zio<sup>®</sup> monitor or Zio<sup>®</sup> XT LTCM for >7 to 14 days between June 2023 and July 2024. These devices include a patient-activated button to mark symptomatic episodes, and episodes within ±45 seconds of a recorded arrhythmia

were considered rhythm-correlated. ECG data was analyzed via a deep-learned AI algorithm and confirmed by cardiographic technicians. Atrial fibrillation (AF) and ectopic beats were the rhythms most-correlated with patient symptoms. Overall symptom-rhythm correlation was low (i.e., <20% for most rhythms), but higher for patients with Daily Symptoms than Non-Daily Symptoms.

#### 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, please visit https://www.irhythmtech.com/.

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<sup>&</sup>lt;sup>1</sup> Actionable Arrhythmias defined as Atrial Fibrillation ≥30 sec, Supraventricular Tachycardia ≥90 bpm & ≥30s, Ventricular Tachycardia ≥100 bpm & ≥4 beats, any Ventricular Fibrillation, Pause ≥3 sec, and/or Atrioventricular Block (any 2nd Degree or Complete Heart Block).

<sup>&</sup>lt;sup>2</sup> The Zio monitor is a prescription-only, single-use ECG monitor that continuously records data for up to 14 days. It is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, lightheadedness, pre-syncope, syncope, fatigue, or anxiety.

<sup>&</sup>lt;sup>3</sup> Desai et al. Arrhythmias. In: StatPearls. Treasure Island (FL): StatPearls Publishing; June 5, 2023. https://pubmed.ncbi.nlm.nih.gov/32644349/

<sup>&</sup>lt;sup>4</sup> National Heart, Lung, and Blood Institute. Arrhythmias - What Is an Arrhythmia? www.nhlbi.nih.gov. Published March 24, 2022. Accessed April 25, 2024. https://www.nhlbi.nih.gov/health/arrhythmias

<sup>&</sup>lt;sup>5</sup> Ataklte et al. Meta-analysis of ventricular premature complexes and their relation to cardiac mortality in general populations. The American Journal of Cardiology. 2013;112(8):1263-1270. doi:10.1016/j.amjcard.2013.05.065 
<sup>6</sup> Lin et al. Long-term outcome of non-sustained ventricular tachycardia in structurally normal hearts. PLOS ONE. 2016;11(8). doi:10.1371/journal.pone.0160181

<sup>&</sup>lt;sup>7</sup> Wolf et al. Atrial fibrillation as an independent risk factor for stroke: The Framingham Study. Stroke.

1991;22(8):983-988. doi:10.1161/01.str.22.8.983

<sup>8</sup> Turakhia et al. Economic Burden of Undiagnosed Nonvalvular Atrial Fibrillation in the United States. The American Journal of Cardiology. 2015;116(5):733-739. doi:https://doi.org/10.1016/j.amjcard.2015.05.045

<sup>9</sup> Heidenreich et al. Forecasting the Impact of Heart Failure in the United States: A Policy Statement From the American Heart Association. Circulation: Heart Failure. 2013;6(3):606-619.

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- <sup>10</sup> Reynolds et al. Comparative effectiveness and healthcare utilization for ambulatory cardiac monitoring strategies in Medicare beneficiaries. Am Heart J. 2024;269:25–34. https://doi.org/10.1016/j.ahj.2023.12.002
- <sup>11</sup> A specified arrhythmia refers to an arrhythmia encounter diagnosis as per Hierarchical Condition Categories (HCC) 96.
- <sup>12</sup> Based on previous generation Zio XT device data. Zio monitor utilizes the same operating principles and ECG algorithm. Additional data on file.
- <sup>13</sup> Zio LTCM service refers to Zio XT and Zio monitor service.
- <sup>14</sup> Data on file. iRhythm Technologies, 2025.
- <sup>15</sup> Data on file. iRhythm Technologies, 2024.

Source: iRhythm