

iRhythm® Technologies Continues to Fuel Innovation in Cardiac Monitoring and Unveils Two FDA Clearances for Superior Patient Care

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The new Zio® monitor is designed to significantly improve patient comfort, while enhanced AI capabilities raise the bar on cardiac arrhythmia detection

SAN FRANCISCO, May 24, 2021 (GLOBE NEWSWIRE) -- iRhythm Technologies, Inc. (NASDAQ: IRTC), a leading digital healthcare solutions company focused on the advancement of cardiac care, today announced two new 510K clearances – one for a new and improved design of its flagship monitor and a second for updated artificial intelligence (AI) capabilities. The new Zio monitor is designed to significantly improve patient comfort while the advancements to its AI capabilities will further improve rhythm and beat diagnostic accuracy. The clearances demonstrate the company's ongoing commitment to improving the patient and provider experience – by investing in next-generation capabilities across its diagnostic platform.

"iRhythm's new Zio monitor and enhanced AI further illustrates our commitment to raising the standard of cardiac care for the providers and patients we serve," said Mike Coyle, CEO of iRhythm. "By improving patient comfort and experience we can continue to maximize patient compliance, which is an essential element for collecting high-quality data for analysis. And with the power of our next generation AI, we can help physicians better identify, diagnose and manage a wide array of significant arrhythmias, including atrial fibrillation."

The new Zio monitor: The new Zio monitor is designed to be effortless to wear with increased adherence and better patient comfort. It's small enough for patients to forget they are wearing it through exercise, showering, and sleeping. The new design is more than 50% lighter than the current generation and includes a new breathable and waterproof outer layer. It also has an improved 'stay-put' adhesive and a more flexible design for a secure attachment. These refinements will allow for a more comfortable wear and, therefore, more complete, accurate diagnostic data.

"iRhythm started with the patient in mind first," said Judy Lenane, RN, Chief Clinical Officer and Executive Vice President of Products at iRhythm. "We asked ourselves what it would take to give patients the best, most comfortable experience, and designed it from there. We're excited to offer more patients around the world access, as well as an improved patient experience, which will enable far more insight into the data."

Enhanced AI: iRhythm has made significant system improvements to its deep-learned AI algorithm. The company has collected over 750 million hours of curated heartbeat data, creating the largest repository of labelled ECG patient data in the world. This allows for expanded training of the algorithm across a larger database, resulting in enhanced AI diagnostic accuracy and better quality assurance. On top of the record expansion, iRhythm now has a much more technologically advanced AI backbone – moving from machine-learned to deep-learned capabilities. With AI, the average rhythm detection sensitivity of iRhythm's detection algorithm has improved by 21% since its creation in 2010.

iRhythm has led the cardiac monitoring industry in using FDA-cleared, deep-learned algorithms for classifying and characterizing diverse heart rhythms. iRhythm is now using AI to detect beats, beat types and heart rates – on top of the deep-learned rhythm detection capability introduced and clinically validated in 2019. This allows for AI-based detection of heart activity at a much more granular level, with an enhanced level of accuracy.

"With this clearance, we are excited to be further improving on our AI-based detection capabilities, raising the bar for the cardiac monitoring industry," said Mark Day, Executive Vice President of Research and Development at iRhythm. "This new AI algorithm will enable the Zio Service to be even more accurate and scalable, delivering more clinical insight for cardiologists and payers."

The updated AI capabilities will be introduced later this quarter for the US-based Zio Service, while the new Zio monitor platform will begin limited release later this year.

About iRhythm Technologies, Inc.

iRhythm is a leading digital health care company redefining the way cardiac arrhythmias are clinically diagnosed. The company combines wearable biosensor devices worn for up to 14 days and cloud-based data analytics with powerful proprietary algorithms that distill data from millions of heartbeats into clinically actionable information. The company believes improvements in arrhythmia detection and characterization have the potential to change clinical management of patients.

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A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/9a1e54c2-b48c-46a9-87c1-29d638f18e2e



Figure 1



Images of the new Zio monitor