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Cardio Conversations: 'Much More Than Just A Patch,' iRhythm CEO Blackford Talks AI Arrhythmia Diagnostics

by Reed Miller

iRhythm CEO Quentin Blackford returned to *Medtech Insight*'s Cardio Conversations podcast to talk about the launch of his company's new Zio monitor patch supported by a sophisticated neural network. He also addressed the company's plans to improve its position in the mobile cardiac telemetry market, the impact of pulsed field ablation on the cardiac monitoring business, and more.

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Cardiac monitoring company *iRhythm Technologies* entered 2024 with momentum following the launch of its new Zio monitor for long-term electrocardiography monitoring.

Zio monitor is an upgraded version of the company's Zio XT in a lighter, smaller, more comfortable patch. The company launched Zio monitor in September and has rolled it out across the us in 2024. In January also received a CE mark along with the Zio electrocardiogram utilization software (ZEUS) system. (Also see "*News We're Watching: Free COVID-19 Tests, Edwards Antitrust Investigation, McKinsey Calls For Medtech 'Reinvention'*" - Medtech Insight, 29 Sep, 2023.)

The Zio monitor "continues to improve upon the patient experience in a significant way relative

to Zio XT," iRhythm CEO Quentin Blackford told *Medtech Insight* in a recent interview. "Demand for it has been much more than what we had anticipated out of the gate."

While iRhythm continues to refine its patch technology to ensure patients can wear it for the full 14-day monitoring period, the company's main message to physicians and investors remains: "We're more than just a product or a patch company. We're a platform company."

The electrocardiogram data collected by the Zio patches is fed into algorithms "powered by billions of hours of curated ECG data and truly advanced [artificial intelligence] capabilities that then allow us to provide a diagnosis or a recommended diagnosis," Blackford explained.

"We're at a very interesting time and place where artificial intelligence is getting a lot of conversation today, [so] we have the opportunity to truly sit down and educate [customers] on the different types of AI," Blackford said.

"Most all of our competitors are either using an '*expert rule AI'* capability or a *machine-learning* AI capability. We utilize a true *deep neural network*, which is a much more sophisticated type of artificial intelligence, and that's enabled by the fact that we have billions of hours of heartbeat data that we can now use to power those neural networks."

Recently published results from CAMELOT, a retrospective study of Medicare claims data from over 300,000 patients, showed that long-term cardiac monitoring with Zio patches and iRhythm's services led to a higher diagnostic yield for specified arrhythmias than any other ambulatory cardiac monitoring approach.

"What that CAMELOT data found, very clearly, was not only was long-term cardiac patch-based monitoring far superior to event recorders, Holter monitors or even [mobile cardiac telemetry (MCT)] devices within the long-term cardiac monitoring category, but also that Zio, in particular, was far superior to any other competitive offering," Blackford said.

"For the first time, we have, out of the [Medicare] data set, a very clear perspective of exactly what product has been the best product over the last, several years, and that is Zio," he said. "CAMELOT ends up being the way to really sit down – with payers and our physicians and differentiate – as to is the best product, unequivocally."

The company is now trying to bring this message to the front of the referral chain. Every year in the US, about 15 million patients are seen by a primary care physician with "cardiac palpitations" already noted in their medical records. "Our own cardiologist and [electrophysiologist customers] in these big networks ... are actually inviting the general practitioner, the primary care physician, to the table, and educating them on why they should start to prescribe [Zio] in their office."

The company also recently announced that it will use Aura – the specialty diagnostics and devices suite developed by electronic medical records company Epic – to streamline access to its services to improve operational efficiency for clinicians. With this partnership, iRhythm is the first medical device company to join the "Epic community."

For early adopters, Zio services will be integrated into the Aura network by the end of 2024, and the company expects to begin offering this option to existing and new Zio customers in early 2025.

New MCT On The Horizon

At the recent JP Morgan Healthcare Conference, Blackford said iRhythm currently claims about 70% of the US long-term cardiac monitoring market and 25-30% of the overall US ambulatory cardiac monitoring market – which includes about 6.4 million cardiac monitoring procedures annually.

The part of the market iRhythm does not occupy mostly relies on either traditional Holter monitors or mobile cardiac telemetry (MCT) devices. iRhythm markets the Zio AT MCT patch and monitoring service for continuous, uninterrupted cardiac recording, but it is not good enough, Blackford said.

“We have 7% market share in MCT and 70% market share in long-term cardiac monitoring; the difference is the fact that our Zio AT product is just not as competitive as the other MCT solutions [on the market,]” he said. “[But] we think we can close that gap dramatically.”

The Zio AT business is also hindered by an FDA Warning Letter related to the company’s Cypress, CA facility. The company expects to resolve that letter soon following the submission of two new 510(k) applications: a ‘catch-up’ for changes previously made as a Letter to File to the Zio AT system before the receipt of the warning letter; and, a second 510(k) capturing changes to design features and labeling updates following the company’s interaction with the FDA. (Also see "*Facility Inspection Leads To FDA Warning For iRhythm*" - Medtech Insight, 31 May, 2023.)

Even as it resolves that warning letter, iRhythm is developing a new MCT product; the company plans to submit it to the US Food and Drug Administration by the end of 2024 and launch it in the US market in 2025.

Improving its position in the MCT market is “one of the most exciting opportunities in front of us, because every 10 points of market share is about $100m of incremental revenue to iRhythm.”

In the interview with Medtech Insight*, Blackford also addressed the company’s plans for expansion outside the US – especially Japan – the potential of pulsed field ablation technology to boost demand for arrhythmia monitoring, and more.*

You can listen to the complete interview using the SoundCloud player above or search for 'Cardio Conversations' on any of the leading podcast platforms.

Further Reading:

Facility Inspection Leads To FDA Warning For iRhythm

Cardio Conversations: iRhythm Prepares To Deliver 'Standard-Of-Care' Cardiac Monitoring

CMS Proposes National Payments For Long-Term Continuous Electrocardiogram Monitoring

FDA Clears iRhythm's Afib-Detecting Wearable Running Software Co-Developed By Verily

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