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Cardio Catch-Up: Updates From B-Secur, egnite, Vektor, And Other Under-The-Radar Companies

by [Reed Miller](#)

This edition of *Medtech Insight's* Cardiovascular Catch-Up features highlights from recent interviews with leaders of some not-so-famous companies addressing cardiovascular health from a variety of angles – from improving the traditional stethoscope to non-invasive 3D mapping of arrhythmias and more.

[Editor's Note: The original version of this article misplaced egnite's headquarters in California. The company is based in Aliso Viejo in southern Orange County – not Silicon Valley. We regret the error and corrected this article on 23 June.]

B-Secur Rolls Out HeartKey 2.0 To Interpret ECG Signals

Belfast-based B-Secur is rolling out HeartKey 2.0, cloud-based software that significantly reduces the noise in electrocardiograms (ECG or EKG) while improving the interpretation of EKGs to facilitate more effective remote cardiac monitoring.

The company formally launched HeartKey 2.0 at the recent Heart Rhythm Society meeting in San Francisco. The system builds upon the company's HeartKey software library, which was [cleared by the US Food and Drug Administration](#) to enhance and refine EKG data from Holter monitors, wearables, and implantable devices.

When it was founded in 2015, the company focused on providing that library to “some very big [undisclosed] names, and some small companies as well, [to be] the engine of other people's technology,” B-Secur's chief technology officer Adrian Condon told *Medtech Insight*.

The company continues to develop software to interpret data from a variety of devices, including game controllers or even car steering wheels, but HeartKey 2.0 puts the company's EKG-interpretation capability onto The Cloud so B-Secur can offer it as a software-as-a-service product, he explained.

“The biggest challenges [with EKG] whether its from a consumer device or a medical device, is signal noise.” – Adrian Condon

“We can now tap into existing medical devices that that are out there and ... we believe we have the most accurate ECG software,” he said. “The biggest challenges [with EKGs] – whether its from a consumer device or a medical device – is signal noise.”

For example, he said that only about half of data collected from Holter monitors is interpretable, but B-Secur can improve that ratio to near 100%.

“The human is still the gold standard [for EKG testing] because they still have to do a lot of interpretation of the signal, [but] we can take those really noisy signals make them much clearer and cleaner, which speeds up their time, and allows them to make more confident diagnosis,” Condon explained.

B-Secur can also add new features to its software to put the EKG data into the patients’ real-world context, including information on their sleep patterns and stress levels. He also pointed out that the company is investing in material science and hardware expertise to help other company's design “the whole interface.”

“We work really closely with our partners,” Condon said. “They are creating better capabilities from a hardware point of view, and we really understand the material science and we also have the algorithms so we're sort of a one stop shop for somebody to go from, for example, and optical [sensor] on a smartwatch for example, right through to a full medical device.”

“We're able to basically get an EKG off of anything [you touch or wear] and catch conditions really early. Then we can really make a difference.” – Adrian Condon

B-Secur has doubled its workforce this year to more than 75 employees across offices in the US, the UK and Ireland, as the health and wellness wearable devices market is set to grow to \$47bn by 2025 and the global remote patient monitoring market will grow to \$109bn, according to the company.

“We've been able to come up with new use cases and new technologies that people haven't seen before, to be able to derive a continuous EKG [signal],” Condon said. “We're able to basically get an EKG off of anything [you touch or wear] and catch conditions really early. Then we can really make a difference.”

Validation Data Support Vektor's vMap Arrhythmia Mapping System

[Results from 225 patients in the VMAP validation study](#) show Vektor Medical's vMAP non-invasive, three-dimensional electrophysiology mapping system can accurately identify the location of a premature ventricular complex in nearly 99% of cases.

[VMAP](#) is a retrospective study using medical records data to validate performance of Vektor's vMap, a computational mapping system that identifies potential arrhythmia source locations based on 12-lead electrocardiogram (ECG/EKG) data. [The FDA cleared it in 2021](#) for analysis and storage of cardiac electrophysiology data and maps.

The data were presented by David Krummen of the University of California San Diego at the Heart Rhythm Society conference in San Francisco on 28 April.

“These results represent an exciting development in cardiac arrhythmia care and a significant step forward for the [electrophysiology] community in being able to better understand where arrhythmia sources are located,” Krummen said. “vMap offers physicians the opportunity to provide higher quality of care for patients by improving first pass ablation success, lowering risks from invasive mapping and fluoroscopy exposure, and reducing procedure times, all while fitting into the clinical workflow.”

Rob Krummen, Vektor's chief operating officer, told *Medtech Insight* that ablation to treat cardiac arrhythmias is often only 40-60% successful, depending on which study one looks at. “That's not good enough for a massively invasive procedure,” he said. “We need to know more about the origins of arrhythmia and how to treat it better.” [Editor's note: *Rob Krummen was named Vektor's CEO on 22 June as Mike Monko transitioned from CEO to executive chairman.*]

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examining the intelligence that is in their own ECG, and adjust the procedure accordingly, then you're going to have better outcomes. It just makes sense." – Rob Krummen

Vektor leverages computational intelligence to use non-invasive 12-lead ECG data to accurately identify the source of an arrhythmia and thereby improve that chances that an intervention will be successful. For example, most atrial fibrillation ablation procedures "go in and burn around the pulmonary veins, regardless of whether or not the source of the arrhythmia has anything to do with the pulmonary veins," Krummen said.

"We think that if you spend some time looking at that patient specifically and examining the intelligence that is in their own ECG, and adjust the procedure accordingly, then you're going to have better outcomes. It just makes sense."

Edwards Spin-Off egnite Expands Into Atrial Fibrillation

Southern California-based egnite, Inc. is expanding its CardioCare artificial intelligence platform into detection of atrial fibrillation (AF), aspiring to be hospitals' "single-source solution" to help guide treatment of AF.

The company also has "what we believe is the largest database of echocardiograms in the industry ... fed on a daily basis from our customers," egnite CEO Joel Portice told *Medtech Insight*.

The company also has developed natural language processing capabilities to harness data from electronic medical records. "We can we bring together all of these different data sources and it is the combination of those data sources with our [echocardiography data] and the application of our natural language processing algorithms and our AI ... that is creating this detection ... capability that I just haven't seen anywhere in the industry."

"What makes us so unique is that we combine data from different sources that [currently] just don't talk to one another within a hospital." – Joel Portice

The company's early analysis of over 154,000 patients with AF showed that 52% of potentially eligible AF patients were not prescribed anticoagulation and had an elevated risk for stroke even though this medication increases the patients' three-year survival rate by 10%, he said.

"In the US, there are low treatment rates across the board for that [AF] patient population and we think that we can not only close the gap, but ensure these patients are receiving proper and timely treatment," he said.

The company markets CardioCare as a software-as-a-service product and is, so-far, working with more than 50 hospitals.

Currently, hospitals and cardiology practices "are not really digital...they'll be the first to admit that they're not as digital as they want to be," Portice said. "We are a pure digital company, so when I talk about the amplification of their digital initiatives, it resonates [with them] because it's real and it's not just a buzzword. It has a real impact on their ability to prioritize resources and become as efficient as possible, especially in the [post-COVID-19] era when they're all struggling with labor shortages." (Also see "[Philips Asks Health Care Leaders: How Ready Are You For The Global Health Care Challenge?](#)" - Medtech Insight, 8 Jun, 2022.)

[Edwards Lifesciences](#) spun-off egnite in 2021 to further advance its CardioCare AI-powered analytics platform. Consistent with Edwards' focus on structural heart disease and heart valve replacement and repair devices, CardioCare was originally focused on compiling and interpreting echocardiography data from 35 institutions.

For example, a group led by J. Matthew Brennan of Duke University used CardioCare to analyze more than 929,000 echocardiograms from more than 700,000 patients. Results of that study, now published in the [Journal of the American College of Cardiology](#) confirmed the prevalence of aortic stenosis, aortic regurgitation, mitral stenosis, mitral regurgitation, and tricuspid regurgitation.

[Results of a study recently published in Intelligence-Based Medicine](#) showed CardioCare can accurately predict the progression of aortic stenosis from moderate to severe. And [results of another](#)

Cardio Catch-Up: More Conferences, More New Data From Abbott And Medtronic

By [Reed Miller](#)

16 Jun 2022

Medtech Insight's Cardiovascular Catch-Up highlights some of the recent news on cardiovascular tech innovations in the last two months. This edition focuses on news from conferences, held over the last two months, including the Heart Rhythm Society and the TVT Structural Heart Summit.

[study, published in the same journal](#),

confirmed that the algorithm is highly accurate in identifying patients at risk of developing severe aortic stenosis, which could help physicians prioritize follow-up examinations for patients who may have undiagnosed severe disease.

[Read the full article here](#)

“What makes us so unique is that we combine data from different sources that [currently] just don't talk to one another within a hospital,” Portice explained. “We help identify the hospital's entire cardiovascular, structural heart and valvular heart disease populations, uncover the gaps in care, and prioritize the high-risk patients to improve the quality of the patient care and to better prioritize the hospital resources.”

Eko Rolls Out New App To Screen For Heart Disease

Eko's new mobile app is using heart sounds to screen for cardiovascular disease.

According to the company, routine physical exams miss as many as 80% of abnormal heart sounds because of the shortcomings of traditional stethoscopes. Eko's electronic stethoscopes paired with the automated disease detection software in [Eko App](#), uses artificial intelligence algorithms to detect heart murmurs and atrial fibrillation (AF) with comparable performance to human experts.

The company's analysis software is [FDA-cleared](#) for use with its Core and Duo stethoscopes to detect atrial fibrillation, and calculate heart rate, QRS duration, and electromechanical activation time.

“Frontline healthcare professionals are our best line of defense in catching cardiovascular disease early on, but they are challenged to do so by outdated tools, insufficient time, and inadequate resources,” said Eko CEO and co-founder Connor Landgraf. “With a disease that is so pervasive in our society, it is imperative that we provide every healthcare professional with a solution that helps them diagnose with more confidence and give their patients the best care possible.”

The company is developing a heart murmur-characterization algorithm that will serve as a screening tool for structural heart disease and heart failure screening algorithm which will rely on data from a single-lead EKG/ECG sensor embedded into the stethoscope.

Cardio Catch-Up: Gel For Fixing Heart Attacks, 'Uncaged' Coronary Stents, And More

By [Reed Miller](#)

“We've built the foundation with the digital stethoscopes and the software,” Landgraf told *Medtech Insight*. “Now we're coming up with suites of algorithms that, essentially, allow the clinician ... to capture 15 seconds of audio and analyze it for a variety of conditions.”

[Data from the company's validation database](#) – which, according to the

company, is the largest study on AI analysis of cardiac murmurs to date – showed the system has a sensitivity of

87.6% and specificity of 87.8% for detecting heart murmurs. The system also has a sensitivity of 98.9% and a specificity of 96.9% for detecting atrial fibrillation according to the company.

“By putting an ECG and a stethoscope in one tool, in 15 seconds, you can do a quick rhythm screening and valve assessment on a single patient,” Landgraf said. “That's unprecedented in the wellness exam.”

HeartBeam Is Developing A Heart Attack Detector

HeartBeam hopes to bring its remote myocardial infarction-detection device to the US market within the next year.

Silicon Valley-based HeartBeam has developed a credit-card-sized heart attack detection device, which records a 30-second, three-dimensional vector electrocardiogram (ECG/EKG) and sends it to a cloud system help physicians assess the patients' risk of a myocardial infarction (heart attack).

The company recently signed a co-development deal with Triple Ring, a Silicon Valley company specializing in early R&D, product development, manufacturing, regulatory approval, market access, strategic investment and incubation.

The companies expect to submit a 510(k) to the FDA for the HeartBeam Telehealth 3D-Vector ECG by the end of 2022.

HeartBeam also recently announced a partnership agreement with Livmor Inc. to build a HeartBeam-branded version of [Livmor's Halo+ remote patient monitoring system](#), which earned a 510(k) in 2020.

HeartBeam also talking to contract manufacturers

16 Jun 2022

Medtech Insight's Cardiovascular Catch-Up highlights recent news on cardiovascular tech innovations in the last two months. Part II of this month's update includes innovative research and development news from smaller companies and research labs that you may have missed.

[Read the full article here](#)

about producing the product.

The market is now full of consumer-oriented devices that can record an ECG, including the popular Apple Watch and AliveCor's line of pocket-sized ECG devices. However, none of those are FDA-cleared to detect myocardial infarctions, HeartBeam CEO Branislav Vajdic pointed out in an interview with *Medtech Insight*. (Also see "[Cardiovascular Catch-Up: Abbott Launches Trial Of Dual-Chamber Leadless Pacer; Cardialen Studies Low-Energy Arrhythmia Treatment; And More](#)" - Medtech Insight, 9 Feb, 2022.)

“Our [device] is equivalent to a 12-lead ECG ... We record in 3D – x, y, and z [vectors] – and we are also able to detect [atrial fibrillation] and other arrhythmias as well,” he said. “There are companies that would suggest that you could carry a pouch with electrodes and wires with you and attach those wires to your body [to detect a myocardial infarction]. But who is going to carry that pouch with them 24/7 in expectation of a heart attack?”

Delayed treatment of myocardial infarction leads to heart failure in about 300,000 patients in the US each year. On the other hand, about 85% of the patients that go to the emergency room with chest pain are not actually suffering a heart attack, Vajdic said. “That means that billions of dollars are basically unnecessary; ED visits that are very expensive.”



HEARTBEAM 3D VECTOR ECG RECORDING
DEVICE Source: HeartBeam

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– Branislav Vajdic

To help resolve both of those problems, HeartBeam is targeting the roughly 8 million people in US who have survived one myocardial infarction and are at risk for another one.

“They have anxiety. They are in high fear of another one coming because they know that they're

super-high risk,” he said. “These are the patients that are super-motivated to have an easy-to-use, always-with-them technology that can address their fear [and/or] or get them to the intervention in time to save their heart muscle.”

In addition to those “super-high risk” patients, HeartBeam hopes to address the 18 million people who have coronary artery disease that may be at risk for a heart attack.

The data collected by the HeartBeam system can be instantly integrated into a “televisit” so that the physician can readily discuss the data with the patient, Vajdic explained. “These televisits become much more meaningful if it’s [informed by] the data, as opposed to [the doctor just asking the patient] ‘How do you feel? Do you know what happened?’”

“That then motivates physicians, just as much as motivates the patient, because that televisit and that joint-decision on how to proceed is based on the data,” he said.