

# The MedTech STRATEGIST

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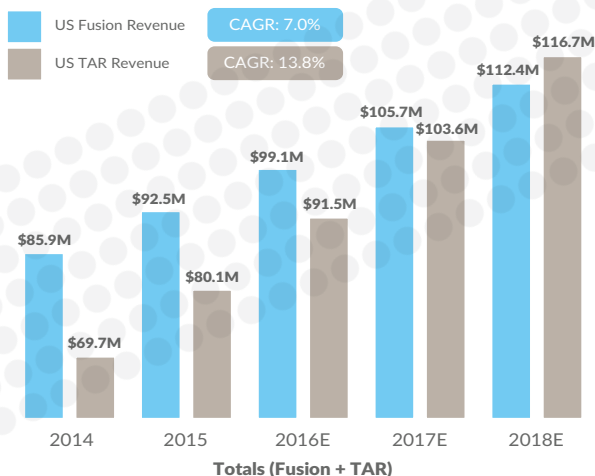
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US Fusion/  
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KIRKLAND  
WASHINGTON

## CONTACT

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## YEAR FOUNDED

2008

## WHO'S BEHIND IT

Brad Harlow, CEO and Co-Founder, Chairman of CBC Partners, a private commercial lender, former SVP of Data Critical (sold to GE Medical) and Managing Director of B.Harlow & Associates, LLC, a firm that has helped raise over \$250 million for cardiology and medtech companies

## UNMET CLINICAL NEED

Patients with transient symptoms of potentially dangerous cardiac arrhythmias must currently wait days or weeks for a definitive diagnosis while a third-party service center analyzes the data from mobile devices and prepares a diagnostic report

## SOLUTION

The **CARDEA SOLO** wearable ECG sensor device collects continuous ECG data over a seven-day period, after which time, the data is analyzed and a diagnostic report is prepared in a matter of minutes on the physician's computer during the follow-up visit. This enables patients to get diagnosed and begin treatment much faster, gives physicians more control over the diagnostic process, and greatly simplifies billing

## MEDICAL ADVISORS

Robert Hauser, MD, past president HRS, senior consulting cardiologist (retired), Minneapolis Heart Institute; Victor Froelicher, director Sports Cardiology Clinic, Stanford University

# CARDIAC INSIGHT: UPENDING THE MOBILE CARDIAC MONITORING BUSINESS

*Mobile cardiac monitoring is a relatively inefficient process—the data is analyzed and interpreted by an outside service provider, and patients sometimes wait for weeks to get a definitive diagnosis. Start-up Cardiac Insight is aiming to change that paradigm with a seven-day disposable, wearable ECG sensor system and software algorithm that enables physicians to analyze the data on their own computers and obtain a diagnosis within minutes at the point-of-care.*

by  
MARY THOMPSON

The mobile cardiac rhythm monitoring market is a billion-dollar-plus opportunity in the US alone, but even though significant technology advances have been achieved in this arena in recent years, the current monitoring paradigm remains fairly inefficient. All of the mobile heart monitoring technologies in widespread use today—ranging from traditional, cumbersome Holter monitors, which record event-based data for only 24 to 48 hours, to **iRhythm Technologies Inc.**'s wearable **ZIO** patch, which collects continuous ECG data

*When the monitoring period is over, the wearable sensor is removed and a complete diagnostic report is prepared in the doctor's office in a matter of minutes.*

for up to 14 days—are sent to an outside location for data analysis and report generation. That means it can take days to weeks before the physician receives the report back and the patient has a diagnosis and a treatment plan.

Start-up **Cardiac Insight Inc.** has set its sights on changing that paradigm, which the company says is burdensome and unnecessarily costly for providers and patients and delays appropriate treatment.

Cardiac Insight was spun out of the University of Washington about eight years ago by Brad

Harlow, the firm's current CEO, and UW cardiologist David Linker, MD. Linker had developed some algorithms and obtained some patents related to wearable technology, says Harlow, and the company was started around that technology. However, it wasn't until about five years ago that the firm was financed. At that time, Harlow brought in a board of directors made up of medtech CEOs and clinicians. "I collected a group of national and Seattle medtech leaders who I knew," Harlow recalls, "and they did the first financing with me."

The company then hired a management team, including Bill Willis, who came on as company president about three years ago. Willis and Harlow had known each other for years, and Willis brought a unique expertise to his new role, having served previously as president and CEO of iRhythm, and before that, as founder of iCardia Healthcare. Cardiac Insight obtained some early 510(k) clearances for wearable sensors, but the technology wasn't quite ready for commercialization. When Willis came on board, says Harlow, "we put all of our resources towards developing an ultra-low cost, disposable, seven-day ECG sensor."

That sensor system—called the **CARDEA SOLO**—received FDA clearance just last month and is now in a "soft" launch in the US. It is designed for the diagnosis of patients with transient cardiac symptoms and events—such as pre-syncope, syncope, and "everything up to atrial fibrillation," explains Harlow. All going well, the

firm plans to begin a broader commercial launch of the device in June.

The *CARDEA SOLO* builds on technology the company obtained in October 2015 when it acquired Cardea Associates, which had an FDA-cleared, handheld, Bluetooth-enabled 12-lead ECG system for screening athletes for heart rhythm abnormalities that Cardiac Insight sells in the US as the *CARDEA 20/20 ECG*. That device, says Harlow, has a “tremendous following.” According to the company, it is the “only system automated with Refined Seattle Criteria”—a method of data interpretation the firm says is more accurate, enabling the device to offer the industry’s lowest rate of false positives (3%), which limits unnecessary follow-up testing.

When the company purchased Cardea Associates, one of that firm’s co-founders, David Hadley, PhD, also came on board with Cardiac Insight and began leading the firm’s development efforts on the wearable sensor. That led to the current *CARDEA SOLO* device, which uses the Cardea Associates technology as a baseline algorithm.

Harlow says the *CARDEA SOLO* sensor is a “game-changer” for this field. First and foremost, he points out, it’s a product, not a service, so a clinician can just take it off the shelf and use it. And that is what most profoundly differentiates the device from other products on the market. *CARDEA SOLO* is a wearable sensor that continuously records up to seven full days of ECG data (see *Figure 1*). Importantly, it records heartbeat-to-heartbeat data, which Harlow says “we know is the right type of data that physicians want for diagnostic purposes, the most thorough in that [seven-day] time period, and seems to be the most efficient in terms of diagnostic yield.”

The device is largely differentiated on the back-end of the diagnostic process. When the monitoring period is over, the patient goes back to their doctor’s office, where the patch is removed. An electronic data-recording pod housed inside the patch is then taken out and placed into a “smart cable,” which is tethered to the physician’s laptop or desktop computer, into which the Cardiac Insight data analysis software has been installed (see *Figure 2*).

All of the data collected is then processed locally, and a complete diagnostic report is prepared and formatted by the software on the physician’s computer—all in a matter of three to four minutes. In addition, the physician, if so desired, has instant access to all of the raw data used to generate that report, so “if they want to see a particular element of raw data on day three, for example, that contributed to a finding of AF,” says Harlow, “they can go right into the full-disclosure report and look at that raw data almost immediately. That’s very proprietary to our product. And that enables physicians to participate in the diagnostic process to a greater degree, which is something they really value.”

Not only does *CARDEA SOLO* give physicians more control over the diagnostic process, but, notes the company, it also alleviates several of the substantial operating expenses providers experience with service-oriented heart monitoring models. “Cardiac Insight is not a cardiac diagnostic service company, as are all other companies in this space,” Harlow points out. “Rather, Cardiac Insight is the provider of a diagnostic device that healthcare providers acquire and then use in the diagnostic process.” Therefore, providers can

**Figure 1**

### The *CARDEA SOLO* Wearable ECG Sensor



Source: Cardiac Insight

**Figure 2**

### Cardiac Insight’s Smart Cable with Data Recording Pod



Source: Cardiac Insight

benefit from a greatly simplified billing process, and most importantly, they are able to produce a high-quality diagnostic report with the patient right there with them in their office in a matter of minutes.

As mentioned, the company has a full launch slated for June, when it will begin by targeting cardiology practices and electrophysiologists across the US. “We believe the product is extremely well-placed [in those two markets] where these patients exist today in large numbers,” notes Harlow, “and where most of the testing for tran-

sient arrhythmia diagnostics occurs.” In addition, he says the product is also well suited to hospital and clinic settings, especially emergency rooms, where there’s an “enormous population” of patients who present with transient cardiac symptoms. “There’s very little that can be done for those patients in today’s healthcare model in the ER,” he asserts, “because most emergency rooms would not allow you to leave with a Holter device. How-

ever, a single-use disposable, low-cost, highly efficient diagnostic-yield device is the perfect solution for an ER.”

The company has a partnership with Welch Allyn (part of **Hill-Rom**) to bring the product to the market in primary care and family practice settings as well. Welch Allyn, which is a lead strategic investor in Cardiac Insight, will market the device in those settings under its own private-label name, with

a launch possible later this year, Harlow says.

What sets Cardiac Insight apart is its focus on an entirely new business model in a field dominated by service revenues, as well as its progress to date—from development through FDA clearance—which has been achieved in a very cost-efficient manner. Notes Harlow, “We’ve kept very lean—we’ve tried to do very little bricks and mortar. The product is manufactured for us by a contract manufacturer in the United States, and we contract out other services, including human resources and payroll. So really, all we control is development and engineering, and going forward, distribution and sales.”

The company has about 13 employees right now, although Harlow says that will increase quickly once full-launch gets underway. But, he continues, “it’s highly cost-effective selling through the distribution that we have with the costs we have, so it doesn’t take a large amount of personnel and dollars to move this through, and then it becomes a re-order product.” The company has raised \$15.5 million to date to develop and commercialize the *CARDEA SOLO* device, and Harlow says the firm recently initiated a new, C round of funding to support the commercial launch.

Cardiac Insight is anticipating strong demand for the *CARDEA SOLO* going forward. “This product is unique,” notes Harlow. “It meets an unmet need for faster access to a diagnostic result and for greater physician ownership of the diagnostic process. I think physicians view this as a breakthrough and a substantial improvement in efficiency. Our comments back from focus groups have been extraordinarily positive.”

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