


## BY TODD MATTHEWS





Standing along the creased, snow-covered spine of a thin trail leading to the top of Mount Denali in Alaska last year, Dave Ohlson — a physician, mountain climber, photographer, and filmmaker — had everything he needed to summit the highest peak in North America.

Experience? Check.

He had summited the two tallest mountains in the world: K2 (28,251 feet)

and Mount Everest (29,029 feet) in previous years.

For the Denali expedition last May, Ohlson joined five climbers with U.S. Expeditions and Explorations (USX), a nonprofit organization comprised of active and veteran military personnel who travel the world to combine outdoor adventure trips with scientific research, to summit the snow-caked face of the 20,310-foot-tall peak.

Equipment? Check.

The harnesses, ropes, crampons, helmets, and hiking poles protected Ohlson and his fellow climbers from a potentially fatal slide down the mountain face. Goggles, hardshell jackets and pants, and gloves shielded the team from the freezing elements. And the brightly colored tents pitched thousands of feet below offered respite during downtime.

But one item was a new addition to the team's gear: All climbers were equipped with



Cardea SOLO medical devices.

Lightweight and wing-shaped, Cardea SOLO — the product of Bellevue-based Cardiac Insight — is a wearable, wire-free electrocardiogram (ECG) sensor that records and stores a patient's every heartbeat for up to seven days. It detects arrhythmias and other cardiac abnormalities, all while providing physicians access to ECG data through the company's proprietary analysis software.

For Ohlson, cardiac health in high-altitude settings has interested him since he was a child growing up in the Bay Area of California. On weekends, Ohlson and his father would drive high into the Sierra Nevadas to camp and hike.

"I remember waking up gasping for breath on those first nights," Ohlson recalled. "As I got older, I learned more about why that happened to me, and why so many people experience Acute Mountain Sickness when they travel to high altitudes. The more I've learned, the more particular my questions get. Now, I'm finally in a position to answer questions for myself."

Credible researchers report a higher risk of sudden cardiac death exists specifically for older men unaccustomed to intense physical exertion and with certain risk factors. Heart attacks are the most common cause of non-traumatic death in men over age 34 while skiing or hiking at high altitude because, according to researchers, high altitude increases the



*Dave Hadley, Cardiac Insight senior VP of research and development*

# AN ARRESTING IDEA TO SAVE LIVES

***Kestra Medical Technologies in Kirkland is developing a wearable defibrillator for people at risk of cardiac arrest***



*Brian Webster, CEO*

Every year in the United States, approximately 350,000 people experience sudden cardiac arrest outside of a hospital setting. When it happens, it sets in motion an urgent race against time that could result in an individual's death within a matter of minutes.

"The problem with cardiac arrest is, time is your enemy," explained Brian Webster, president and CEO of Kestra Medical Technologies in Kirkland. "Your heart is not beating in a regular rhythm; it's therefore not allowing your system to produce blood that feeds oxygen to the brain. The chance of survival from cardiac arrest goes down by 10 percent per minute."

Even more daunting is that more than half of the medical emergencies happen when a person is alone and at home, with nobody around to call 911 — and even then, it takes several valuable minutes for skilled paramedics to arrive and administer care via a defibrillator's electric jolt to the heart.

For a long time, one of the best ways to improve your survival odds was by keeping Automated External Defibrillators, or AEDs, in schools or offices. But even then, somebody must administer the AED, an impossible task if a person is alone when he or she experience sudden cardiac arrest.

Kestra Medical Technologies aims to improve the odds for cardiac arrest survival by creating a wearable defibrillator. Proprietary algorithms will monitor a patient's cardiac health and detect if a patient is experiencing cardiac arrest. If that happens, the device will deliver a therapeutic dose of electricity to the heart.

Similar to an undergarment, the discreet wearable device would be washable and worn for several months.

Webster, who has worked in the medical device industry for 26 years, including 10 years as president and CEO of Physio-Control, the Redmond-based manufacturer of external defibrillators and monitors, thinks the device could be particularly helpful to patients who are already at risk for cardiac arrest, such as people who have suffered a heart attack and are poised to receive an implanted defibrillator, but must wait several months before undergoing surgery.

"They are at risk of having another serious event during that window," Webster explained. "What we are trying to do is bridge them to that long-term care by protecting them during that vulnerable period. It's not going to do away with the EMS guys or even the need for AEDs, certainly, because AEDs in the workplace are a great idea. But for those folks who are known to be at risk, we can protect pro-actively. It's a fantastic solution."

According to Webster, the company was started in August 2016, is financially backed by the private equity firm Bain Capital, and employs 90 people. The medical device is in the pre-clinical trial phase, added Webster, and the company expects to receive FDA approval and bring the device to market in the next 18 months.

"There are people dying who shouldn't be dying," Webster added. "They just shouldn't be because we can protect them. We have the technology. We have the know-how. We are going to bring a product out that's going to do just that."



likelihood of cardiac arrhythmias.

"That exposure to high altitudes causes abnormalities in the rhythm of the heart is not controversial, but it is not well-characterized," Ohlson, a doctor specializing in internal medicine at Bingham Memorial Hospital in Idaho, explained. "The medical device market is making it easier to gather data in situations that previously were not amenable to it. I was excited to carry out this project because I thought it would be an opportunity to demonstrate that a cardiac monitoring patch would be an excellent way to gather large amounts of data."

To that end, Ohlson approached Cardiac Insight to inquire about fitting his quintet of climbers with Cardea SOLO devices. In the end, Cardiac Insight donated nearly three dozen of the patch-like adhesive devices, which were worn by climbers during their 28-day expedition to climb Denali, reach the summit, and return to base camp.

Ohlson is still compiling the data recorded on Denali, but he's already discovered some telling bits of information. For example, one climber experienced 15 skipped heartbeats per night at the highest elevation, of a duration of about three seconds each.

Ohlson plans to publish a research paper in the next year and a half.

And although he is clear to point out that a study pool of five climbers is hardly definitive, Ohlson believes the data captured on the trip will help provide new insights into how frequently abnormal heart rhythms occur in healthy individuals at high altitude and also provide a model for larger studies in the future.

Cardiac Insight's path from biotech startup to the manufacturer of a medical device worn by adventurous mountaineers is about as circuitous as any



Brad Harlow, Cardiac Insight CEO

route up one of the world's tallest peaks.

In 2008, Dr. David Linker, a cardiologist at the University of Washington, and Brad Harlow, a veteran in the medical device field, partnered to begin to develop lightweight and inexpensive sensors that could be worn by patients to monitor cardiac health and abnormalities, such as the early diagnosis of atrial fibrillation, which could lead to increased risks of stroke and cardiovascular disease.

Meanwhile, Cardea Associates in Woodinville was developing CardeaScreen, a handheld ECG device that identified cardiovascular abnormalities that increase the risk of sudden cardiac arrest in high school,

## 3 CARDIAC FACTS

*Heart disease remains the No. 1 cause of death in the U.S.*

*The estimated annual incidence of heart attack in the U.S. is 720,000 new attacks and 335,000 repeat attacks. Average age at the first heart attack is 65.6 years for males and 72 years for females.*

*Approximately every 40 seconds, an American will have a heart attack.*

SOURCE: AMERICAN HEART ASSOCIATION





# SENSORIA SETS SIGHTS ON NEW SECTOR

*The Redmond-based company wants to step into the health-care space to provide data to researchers*

Can a pair of socks help monitor the health and wellness of individuals diagnosed with Parkinson's Disease?

One company in Redmond thinks it's possible.

Since 2010, Sensoria has made a name for itself developing wearable athletic apparel such as socks, shirts, and sports bras with built-in sensors that track distance, steps, and calories burned, while also monitoring an individual's heart rate, balance, stride, foot-strike technique, cadence, and weight distribution as they walk, run, or engage in other exercise activities. The information is transmitted to a smart phone app that records and interprets the data.

Sensoria's products are available on its website and Amazon.com, and marketed to athletes. Now, the company is entering the healthcare space, aiming to help physicians care for their patients.

"Smart footwear and wearable sensors have the potential to change the way in which physicians, patients, and the entire population view healthcare," explained Davide Vigano, Sensoria's CEO and co-founder.

As an example, Vigano, a former Microsoft software developer, noted Sensoria, along with researchers in Australia, was awarded a grant from the Michael J. Fox Foundation to help study the gaits of individuals diagnosed with Parkinson's Disease, which directly affects about 10 million people worldwide.

One way doctors can diagnose and

monitor the disease and its progression is by putting patients through a series of walking tests conducted in a hospital or clinical setting, according to Vigano and the team of researchers. Through the foundation's funding, more than 100 Parkinson's patients will be outfitted with Sensoria's smart socks, which will monitor mobility and locomotion, such as step-time variability, freezing of gait, and falls, without having to visit a clinic or hospital setting. The information will be transmitted from the smart socks to the researchers via wireless technology.

Sensoria also has partnered with researchers to develop footwear that will monitor foot pressure in patients receiving treatment for diabetic foot ulcers in order to reduce the risk of amputations. It also is working with researchers to develop a device to aid caregivers at assisted living facilities, sending alerts when a resident wakes up or is about to experience a fall.

"It's a completely new breed of devices, and we are super-excited about this," Vigano said.

And while the company still offers wearable apparel that monitors the health of athletes and weekend warriors, offering the same technology to the healthcare space is where Vigano would like see Sensoria move forward.

"We are not trying to replace the hospital systems," he added. "But if we can do this (monitor health) for healthy people (through our athletic gear), we can do this for patients, as well."

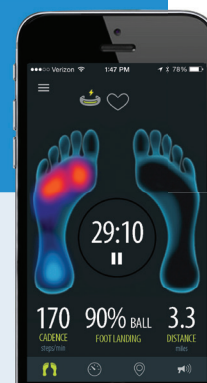


IMAGE COURTESY SENSORIA

**“A cardiac monitoring patch (like Cardea SOLO) is an excellent way to gather large amounts of data.”**

college, and professional athletes.

It's a serious issue, especially considering that sudden cardiac arrest is the number one medical cause of death in athletes, according to the American Heart Association, and it is estimated an athlete dies of sudden cardiac arrest in the U.S. every 72 hours.

What's more, the industry standard ECG tests for identifying risks were flawed, according to Dave Hadley, the former president of Cardea Associates.

“ECG devices that were being used for screening kids or young athletes were really more attuned for identifying heart attacks in older people,” said Hadley. “They didn't really account for the adaptation that a heart undergoes during athletic participation.”

As a result, according to Hadley, tests for cardiac abnormalities in young athletes were producing false positive results 25 percent of the time, worrying athletes and their families into thinking they had serious medical ailments. The expense of follow-up testing made cardiac screening cost-prohibitive.

“They just weren't real issues,” Hadley added. “They were things that are normal in young athletes, but look abnormal in an older person who isn't undergoing athletic training.”

In 2011, Hadley joined a group of cardiologists (including Jonathan Drezner at the University of Washington Center for Sports Cardiology) to co-author a research paper that set new criteria for screening young athletes, and it was published in a leading medical journal. From there, Hadley set out to develop what would become the CardeaScreen, which received FDA approval in 2013, and dropped the false-positive rate down to about two percent.

Cardiac Insight acquired Cardea Associates two years later.

“I needed to put a couple of million dollars into the company to build a sales



*Lightweight and wireless, Cardea SOLO is a wearable ECG sensor.*

## 7 FINANCIAL FACTS

**\$749 Billion**

Estimated total direct medical costs of cardiovascular disease by 2035.

**\$220.9 Billion**

The projected total direct costs of high blood pressure by 2035.

**\$9 Billion**

Cost of treating coronary heart disease in U.S. hospitals.

**\$1.7 Billion**

The estimated value of the U.S. market for mobile cardiac rhythm monitoring.

**\$329.7 Billion**

Estimated total direct and indirect costs of total cardiovascular diseases and strokes.

**\$12.1 Billion**

Cost of treating heart attacks in U.S. hospitals.

**\$6 Billion**

The estimated annual cost of U. S. healthcare related to atrial fibrillation.

SOURCE: AMERICAN HEART ASSOCIATION; CARDIAC INSIGHT



**“It’s exciting. We are changing the way athletes are screened for sudden cardiac death, and the way patients are found to have atrial fibrillation. They are advances on technology that have been around for years, but really have been put into faster and newer capabilities.”**

and marketing team,” explained Hadley, who is Cardiac Insight’s senior vice president of research and development. “I have known (Cardiac Insight CEO) Brad (Harlow) for ages. Brad had a sales and marketing team, and I had electronics and software. It seemed like a marriage made in heaven.”

Following the acquisition, CardeaScreen was rebranded as the Cardea 20/20 ECG. Today, many teams within the National Football League, National Basketball Association, Major League Baseball, National Hockey League, and the PAC-12 Conference are among the many organizations that have incorporated Cardea 20/20 ECG on scouting trips to check the heart health of athletes.

“One of my very first customers were the (Milwaukee) Brewers baseball team,” said Hadley. “They love it because they can put it in a suitcase when they go to South America to recruit. The kid doesn’t get a contract until they do an ECG. They are buying a high-value asset. They want to know what they are buying.”

**F**or some medical device companies, creating a product that helps save the lives of young people is enough of an accomplishment. But Cardiac Insight acquired Cardea Associates to help bring to market its innovative and wearable cardiac monitor.

For decades, bulky and cumbersome Holter monitors were the industry standard for cardiac monitoring. Boxy, battery-powered devices rigged with wires, Holter monitors worked for 24 to 48 hours, patients couldn’t shower

with them, and some hospital emergency rooms didn’t allow patients to take these expensive devices home. Not that it mattered. Most patients didn’t want to wear such

an obtrusive device, which, with new technology over the years, went from being about the size of a Walkman and was clipped to one’s belt, to about the size of an iPhone but still wired and uncomfortable to wear.

Cardiac Insight saw an opportunity to improve upon the device through Cardea SOLO.

Disposable and water-resistant, Cardea SOLO, which received FDA clearance in March 2017, is a wing-shaped device that houses a small CPU module, or uProcessor, and ECG chip integrated with two adhesive-backed electrodes. Once the single-channel device is applied to a patient’s chest and activated, the electronics go to work recording 250 samples of the heart every second, detecting arrhythmias and other cardiac abnormalities.

If a patient experiences a bout of dizziness, lightheadedness, or chest pain, he or she can touch a button on the device, which will flag the incident for the doctor to review once the data are downloaded. Otherwise, patients can go about their day exercising, working, and even showering while wearing the device.

At the end of the prescribed wear period, the patient returns to his or her physician, who removes the Cardea SOLO and accesses the electronics module under the protective cover, and separates it from the electrodes. The module is plugged into a smart cable connected to a PC, and the data are downloaded directly to the doctor’s computer. Within five minutes, a comprehensive ambulatory ECG report is produced.



Last spring, physician Dave Ohlson and a team of active and veteran military personnel traveled to Alaska to climb Mount Denali. Along with the usual gear, the team was outfitted with Cardea SOLO devices — wearable, lightweight, and wireless electrocardiogram sensors that are produced by Bellevue-based Cardiac Insight and record and store an individual’s heart rate for about seven days. The climbers wore the patch-like adhesives during their 28-day trek up and down the snow-caked face of the 20,310-foot-tall peak. Dr. Ohlson is compiling the data and will publish a report that, in the end, might offer insights into high-altitude cardiac health. — TM

**T**oday, the U.S. market for mobile cardiac rhythm monitors is estimated to be \$1.7 billion, and Cardiac Insight isn’t without its competitors. Some hospitals still use Holter monitors, for example. And the company’s closest competitor is San Francisco-based iRhythm Technologies, a publicly traded company with a market cap of \$1.8 billion, and that produces a cardiac monitor called Zio, which can be worn longer than Cardea SOLO.

Still, Cardiac Insight believes it has an edge over its competitor — namely,





in the immediacy of its data.

Data gathered by the Zio patch are sent to an outside agency for the analysis required to generate reports, adding days or weeks before the doctor receives the results, makes a diagnosis, and prescribes a treatment plan.

“With the Cardea SOLO, we do our interpretation,” said Dr. Mohammed Abuzahra, a cardiologist at Baltimore Heart Associates who uses Cardiac Insight’s device in his daily practice. “We download the data, and the physician goes through

it. With the Zio patch, it goes back to the company, and the company does a preliminary interpretation. With the Cardea SOLO, the patients bring it back directly to our office, and from there it is interpreted by us.”

Currently, Cardea SOLO is approved for use only in the United States. But Harlow and his team plan to seek regulatory authorization in Europe and Asia over the next 18 months. Although Harlow would not share revenue information, he said Cardiac Insight, which has raised more than \$20 million

from investors, is profitable and exceeds sales expectations.

The company has approximately 20 employees, and it recently moved from its headquarters in Kirkland’s Carillon Point to a larger space in Bellevue.

“It’s exciting,” Harlow said. “We are changing the way athletes are screened for sudden cardiac death, and we are changing the way patients are found to have atrial fibrillation. They are advances on technology that have been around for years, but really have been put into faster and newer, if you will, capabilities.” ■