

VivoMetrics monitors growing opportunities for LifeShirt

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VENTURA, California – The overcast, rain-filled skies recently obscured the usual view of the offshore Channel Islands available from the offices of **VivoMetrics** on a hillside above this city's downtown area.

But the conditions outside belied the sunny outlook for a company that is seeing expanded use of one of the more intriguing medical technologies of recent years.

VivoMetrics is the developer of the LifeShirt, whose role in monitoring, diagnosis and early assessment of health risk has numerous potential applications. To date, only the surface has been scratched insofar as possible markets for the product and its underlying technology are concerned.

Director of Marketing Elizabeth Gravatte, who joined the five-year-old company about a year ago, is enthusiastic about what VivoMetrics has accomplished thus far in its relatively brief existence, and even more so in terms of where it is headed.

Early on, the major commercial use of the LifeShirt has been in the area of clinical research, involving both academic and government researchers, pharmaceutical companies and med-tech firms.

"Our technology is built on scientific validation," she said. "The first group of users was academic researchers," using the LifeShirt to study such topics as anxiety, autism, stress in college students and a wide range of physiological performance data.

Among others, the Australian Olympic rowing and British cycling teams have used the technology to assess the impact of training on their athletes.

From academic research, the jump to use of the LifeShirt in pharmaceutical trials was a logical one. "There are lots of linkages between academics and pharma companies," Gravatte noted.

While the system can be tailored to the specific needs of any given clinical trial, its general use is to measure the effects of drug candidates on a variety of parameters ranging from respiratory rate to tidal volume, temperature to pulse rate, oxygen saturation to ECG and EEG.

"The LifeShirt gathers a tremendous amount of information," Gravatte said. "The data recorder, or 'black box,' can have various other peripherals added, depending on a firm's study parameters."

The RIP – for respiratory inductive plethysmography – technology is fitted into a lightweight (8 ounces) garment that is imbedded with insulated copper wire and has sensors attached to gather data that is sent to the data recorder which is worn on a patient's belt or carried in a "fanny pack" worn around the waist.

The collected data is downloaded and sent wirelessly or via Internet or phone modem to either mobile or fixed data centers, where it is processed by the proprietary VivoLogic Software. Reports are available as full-disclosure waveforms or in summary fashion.

The intellectual property behind the RIP technology was acquired by VivoMetrics from **Non-Invasive Monitoring Systems** (North Bay Village, Florida) in 1999, the year the company was founded. VivoMetrics engineers adapted the wearable, hospital-based respiratory/cardiac output monitoring sensors to ambulatory use and the LifeShirt was born.

Besides the clinical research market – which has expanded to the point that the company now has offices in Princeton, New Jersey, and Lausanne, Switzerland, to coordinate studies in regions occupied by major drug companies – VivoMetrics is looking to enhance its opportunities in several other sectors.

Chief among them are sleep disorder diagnostics, disease monitoring, athletic training and use by military personnel and first responders. The latter is a particularly "hot" segment, so much so that an entirely new unit – VivoMetrics Government Services – has been formed to maximize the company's push in that area (*Medical Device Daily*, June 4, 2004).

As Andrew Behar, company founder and VivoMetrics Government Services CEO, describes it, the focus in that sector is to utilize the technology to gather "critical life

signs data during . . . high-stress situations.” He calls the ability to assess such data in real-time “a huge benefit.”

Gravatte noted in this week’s conversation that the contract the company acquired with the **U.S. Army Research Institute of Environmental Medicine** (Natick, Massachusetts) offered a good example of how exposure to VivoMetrics’ technology can lead to other possible commercial uses.

“The Army originally bought just the respiratory component” for integration into its Warfighter Physical Status Monitor-Initial Capability (WPSM-IC) program, she said. The technology is expected to be integrated into a LifeShirt-like uniform that will be worn by soldiers in both training and combat operations. With the collection of key data, medics will be able to more quickly provide needed treatment.

“After the Army contract became known,” Gravatte said, “someone from the **Department of Homeland Security** called regarding possible use of our technology by first responders to weapons of mass destruction.” Those responsible for directing the activities of such responders want to be sure their protective suits and equipment are working, she said, thus the possibility of LifeShirt being able to fill such a need.

Such uses, including the wearing of LifeShirts by firefighters and other first responders in high-pressure, anxiety-producing situations, are a logical expansion of the technology from its clinical studies roots.

One key difference for such applications is the addition of wireless capabilities to the data recorder unit. “High-resolution waveforms in the black box allow the data to be transmitted in real time to a central command computer,” Gravatte said. As demonstrated in a promotional DVD produced for the company, such monitoring of first-responder manpower allows timely rotation of personnel out of say, a firefighting scene, as warranted by the physiological parameters shown on the command computer.

Michael Coyle, PhD, vice president, clinical development, offered some thoughts about the sleep diagnostics area, which VivoMetrics is targeting as a major potential opportunity. “Primary care physicians and cardiologists are understanding more about sleep disorders and their relationship to other medical problems such as congestive heart failure (CHF),” he said.

He noted that the ability to monitor sleep breathing in the home setting, rather than in “sleep laboratories” at hospitals and other care sites, likely would greatly aid in the diagnosis of obstructive sleep apnea and other sleep disorders.

Saying that “people don’t really know that they’re not sleeping well,” or at least not why they aren’t doing so, Coyle cited sleep monitoring as helping provide answers to the relationship between sleep and strokes, sleep and CHF, and attention deficit disorder in both children and adults.

One important sleep study in children, using the pediatric version of the LifeShirt, is being conducted by the Colorado arm of **Kaiser Permanente** (Oakland, California).

Gravatte offered a small sneak peak of a major sleep-disorder study on truckers, saying a more detailed announcement would be coming in the near future.

That’s a future likely to bring even more news about a company whose technology appears ready to garner both more public attention and expanded commercial opportunities in a time when the ability to monitor and assess health parameters can help maintain and improve one’s health, while at the same time offering at least some hope of controlling the cost of doing so. ■