



Guidant to use LifeShirt in development of CHF devices

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6 December 2002

Cardiovascular device powerhouse **Guidant** (Indianapolis, Indiana) has signed a contract to use **VivoMetrics'** (Ventura, California) LifeShirt System to help develop new diagnostic and therapeutic features for future generations of heart failure devices.

Guidant said it will purchase LifeShirt System monitoring over the next four years, and has licensed use of the company's VivoLogic software for processing and analyzing the collected data. Details of the contract were not disclosed.

The LifeShirt System, granted 510(k) approval by the FDA in April, is the first non-invasive, continuous ambulatory monitoring system that can collect data on cardiac and respiratory function and other physiological parameters, and correlate them over time. Its sensors monitor heart function, posture and physical activity, and it features an enhanced, ambulatory version of the technology that is currently the gold standard for in-hospital, non-invasive respiratory monitoring and apnea detection. It also includes a diary function to capture subjective patient experiences. Such systems also are called "smart" shirts because of their ability to perform numerous indication-specific tasks.

According to John Hatlestad, Guidant's managing scientist for the project, who works in the company's heart failure research division, the company plans to use the LifeShirt System to monitor changes in physiological signals associated with congestive heart failure (CHF).

"CHF is a complex disease that involves cardiovascular and other physiological systems of the body," Hatlestad said. "The LifeShirt System will allow us, for the first time, to obtain data gathered simultaneously from a suite of physiological sensors on a long-term, ambulatory basis. Prior to this, it has not been practical to gather data with high fidelity continuously, day after day, as the patients go about their normal daily activities."

John Kennedy, CEO of Vivometrics, said the Guidant purchase represents the first significant revenue stream in the research arena that his company is able to talk about. "It's very exciting that a company like Guidant is using this," he told *Medical Device Daily*, noting that it is the engineering side of Guidant rather than clinical trial side of the company that is utilizing the Lifeshirt technology. "They're using this to help in the way that they're actually building and looking at their devices." He added that other companies already are using the technology in a clinical setting. "We have this going with Guidant [and] we have several projects going with pharmaceutical companies in clinical trials."

The contract follows a preliminary, Guidant-sponsored evaluation study involving 10 subjects, each of whom wore the LifeShirt System for seven consecutive days. "We chose to continue working with the LifeShirt System because it is the only commercially available, FDA-cleared system that provides the combination of sensors we are interested in monitoring," Hatlestad said.

Kennedy said VivoMetrics feels that Guidant's contract validates his company's technology. "We regard it as a major endorsement that they're coming back [after the initial testing] with this kind of a deal with us."

The LifeShirt - an 18-ounce vest - is imbedded with insulated copper wire and sensors are attached to the abdominal section of the shirt's fabric. The wires expand and contract with breathing. The breathing motion is converted to voltage. Data is collected 50 times a second and sent, via a cable imbedded in the shirt, to a hand-held computer attached to a patient's belt. The data is recorded and encrypted on a 64 Mb flashcard and can be sent to VivoMetrics' processing center via the Internet, phone modem or standard mail. The turnaround time from the center to a patient's physician takes an hour or less.

According to Kennedy, Guidant plans to use the VivoMetrics technology completely in-house. "What we're going to do is provide them with the technology and with training on our software and provide consulting to them." He noted that the Guidant model is one that the company expects to see more of from the engineering sector, however, he said that in the case of clinical trials, "those are people that really want to have data services provided to them," and VivoMetrics is more than willing to provide those premium services.

Aside from clinical trials for new drugs and medical devices, the company said its initial commercial focus will also center on two additional markets: home sleep diagnostics and academic research into causes and prevention of respiratory, cardiovascular, behavioral health and sleep-related disorders. Additionally, VivoMetrics is working with the U.S. military to bring the smart shirt technology to the battlefield of tomorrow. A modified version of the LifeShirt is being tested on fighter pilots and another on soldiers in the field

via a cooperative research and development agreement with the **U.S. Air Force Institute of Technology** at Wright Patterson Air Force Base (Dayton, Ohio).

"The understanding of normal and abnormal physiology gained through long-term, continuous ambulatory monitoring using the LifeShirt System will be an invaluable contribution to the understanding of CHF and other complex diseases," Kennedy said. "It is our mission to help companies like Guidant, and other leading medical device and pharmaceutical companies, bring new, improved technologies and therapeutics to the market," he added.