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Guidant Boosts CHF Resynchronization Therapy R&D With VivoMetrics Deal

Guidant looks to use VivoMetrics' *LifeShirt* ambulatory monitoring system in an upcoming congestive heart failure registry after reaching a purchasing agreement with the firm Dec. 4.

Approved in April via 510(k), the LifeShirt is a noninvasive continuous monitoring system that collects data on cardiac and respiratory performance in addition to other physiological parameters that can be tracked over time using a variety of sensors.

The monitoring system is intended for use in clinical trials, academic research and home sleep diagnostics to assess obstructive sleep apnea.

The sensors monitor heart function, posture, physical activity, blood oxygen levels, blood pressure, and includes a diary function/recorder to capture subjective patient experiences.

The four-year agreement, which includes licensed rights to analysis software, was reached following a Guidant-sponsored evaluation study of 10 patients who wore the LifeShirt for seven days, the firm maintains.

Guidant says they chose to continue using the LifeShirt because it is the only FDA-cleared monitoring system that provides the appropriate sensors to measure cardiopulmonary performance in CHF patients.

"Prior to [the LifeShirt], it has not been practical to gather data with high fidelity continuously, day after day, as the patients go about their normal daily activities," Guidant's managing scientist for the project John Hatlestad said in a Dec. 4 release announcing the agreement.

The wearable vest uses inductive plethysmography noninvasive respiratory monitoring technology, which VivoMetrics claims is the only FDA-cited technology capable of differentiating between various types of sleep apnea.

The system monitors breathing patterns by passing a continuous, low-voltage electrical current through externally placed sinusoidal arrays of wires that surround the rib cage and abdomen.

The monitor reduces signal interference and distortion, allowing physicians to collect accurate measurements of patients' respiratory functions, according to the firm.

Another competitive advantage cited by VivoMetrics is the LifeShirt's ability to measure respiratory volumes quantitatively and to detect both central and obstructive apnea. The company hopes to expand the system's diagnostic capabilities to monitor mechanical function of the heart.

The VivoMetrics purchasing contract builds on Guidant's burgeoning CHF franchise, which currently offers the *Contak CD* cardiac resynchronization therapy system with ICD backup, and could help Guidant better understand and define appropriate CRT populations in developing next-generation diagnostic and therapeutic CHF devices.

The Guidant-sponsored COMPANION study was halted prematurely in November by an independent data and safety monitoring board after CRT therapy resulted in approximately a 20% reduction in a combination of all-cause mortality and all-cause hospitalization compared to best medical drug therapy.

If the study data hold up, it could expand the current U.S. CRT market covering 750,000 patients by an additional 300,000-400,000 patients ([1] "The Gray Sheet" Nov. 25, 2002 , p. 5).

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The registry will provide physicians with a standard collection of patient management profiles, clinical events and outcomes of patients in their natural setting. Enrollment will begin in early 2003.

The Guidant agreement is the second major contract for Ventura, Calif.-based VivoMetrics. The privately held company signed a cooperative research and development agreement (CRADA) with the U.S. Air Force Institute of Technology (AFIT) in February.

AFIT intends to integrate a space-based global positioning system and long-range wireless capabilities into the LifeShirt system in order to create a more advanced method for real-time location and physiological monitoring of field military personnel.