



VIVOMETRICS' LIFESHIRT® SYSTEM RECEIVES U.S. FOOD AND DRUG ADMINISTRATION 510(K) MARKET CLEARANCE

Powerful Tool for Health Decision-Making Now Available to U.S. Researchers and Clinicians

VENTURA, Calif. - April 22, 2002 - VivoMetrics Inc. has received U.S. Food and Drug Administration (FDA) clearance to market its LifeShirt™ System, a suite of products and services for the continuous collection, analysis and reporting of ambulatory physiologic data. This clears the way for immediate commercialization of the LifeShirt System, which is designed to provide pharmaceutical/medical researchers and clinicians with comprehensive, real-world physiologic data for making better research decisions and improving patient care around the globe.

The LifeShirt System is the first non-invasive, continuous ambulatory monitoring system that can collect data on cardiopulmonary function and other physiological and subjective patient parameters, and correlate them over time. Using data from the LifeShirt System, researchers and clinicians gain a clear view of how various physiologic systems interact, giving them a more thorough understanding of patients' health.

"With the LifeShirt System, researchers and clinicians have an unprecedented window into everyday human physiology," said Paul Kennedy, president and chief executive officer of VivoMetrics. "Having this data at their fingertips will allow them to see signatures and predictors of disease that no one has been able to identify before, ultimately improving the care of patients and the development of new medicines."

Market Focus

VivoMetrics' initial commercial focus will center on three markets: clinical trials for new drugs and medical devices; home sleep diagnostics; and academic research into causes and prevention of respiratory, cardiovascular, behavioral health and sleep-related disorders.

"The LifeShirt System is a powerful tool for evaluating a drug's effects in the natural environment of patients," said Frank Wilhelm, a senior research scholar at the Department of Psychiatry and Behavioral Sciences, Stanford University School of Medicine. "The system's monitoring technology and signal analysis software are so advanced that it can automatically detect and classify apneas or hypopneas, Cheyne-Stokes respiration, sighs, and coughs, and correlate these with cardiac or other parameters — all outside of the laboratory or clinical setting. The LifeShirt System should be of great use in understanding how different bodily systems interact in health and disease."

LifeShirt System Technology

The LifeShirt System's central component is a lightweight, comfortable, washable garment that has sensors embedded in its fabric. The system features an enhanced, ambulatory version of the technology that is currently the gold standard for in-hospital, non-invasive respiratory monitoring and apnea detection. Other sensors monitor heart function, posture and physical activity, and an electronic patient diary function captures subjective patient experiences, such as moods, symptoms and the activities of daily living. The LifeShirt System correlates the various physiologic and subjective data over time, supplying a comprehensive "movie" of patients' health.

In addition to bringing standard-setting monitoring technology out of the hospital to outpatient settings, the LifeShirt System will help researchers and clinicians comply with new government mandates for submission of clinical trial and research data. Information collected by the LifeShirt garment is encrypted and recorded in the LifeShirt Recorder, a small, easy-to-use handheld computer. Data are then processed and analyzed using VivoLogic[®] software and presented to researchers and clinicians as full-disclosure, high-resolution waveforms or as easy-to-interpret summary reports. All data produced by the system meet standards set forth in the FDA's rule 21 CFR Part 11, which governs the digital collection, presentation and archiving of physiologic data.

Regulatory Status

FDA clearance for the LifeShirt System is the latest in a series of regulatory successes for VivoMetrics. In November 2001 the LifeShirt System received CE Mark certification, clearing the way for commercialization of the system in the European Economic Area. Also in November, VivoMetrics announced receipt of ISO 9001 registration, a globally recognized quality-assurance standard governed by the International Organization of Standardization.

Video News Release Available

A video news release will be available via satellite on April 22 at 10 a.m. and 1 p.m. EDT on Telstar 6 [C-Band] Transponder 11; Downlink Freq 3920 Vertical; Audio 6.20/6.80.

Stacey Williams
Director of Marketing
VivoMetrics Inc.
805.275.5864
swilliams@vivometrics.com

Aimee Corso
WeissComm Partners
for VivoMetrics
310.780.2661
acorso@weisscommpartners.com