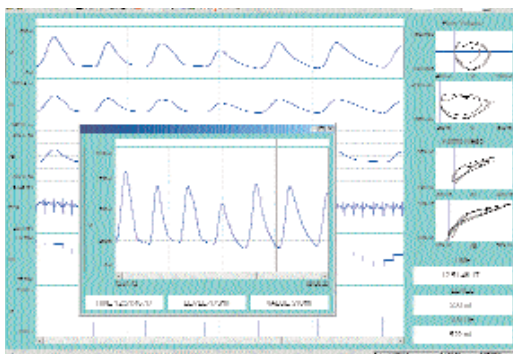


VivoMetrics® Clinical Trials



The LifeShirt system allows clinical researchers and investigator staff to monitor subjects continuously and correlate subjective digital patient diary data with objective physiologic data.

The LifeShirt® System is changing the way clinical research is conducted. From improving the screening of trial subjects to providing physiologic endpoints that enable earlier "Go/No-Go" decisions, the LifeShirt System is a powerful tool that assists the biopharmaceutical industry in improving the efficiency of the clinical trial process.



"Major obstacles to new drug development include the lack of objective screening methods for entry into clinical trials as well as lack of physiologic outcome measures. The LifeShirt may significantly alleviate both of these problems."

—Donald Klein, M.D., Columbia University



LifeShirt System Benefits

Through continuous ambulatory monitoring, the LifeShirt System gives a comprehensive view of subjects' health 24/7 in the real-world environment:

- Based on patented technology validated in hundreds of peer reviewed scientific papers.
- Quantitative and qualitative data provide an objective standard for decisions about moving forward with, adjusting or terminating trials.
- More effective screening of subjects ensure all inclusion criteria are met.
- Increased comfort, safety and convenience enhance subject recruitment and retention.
- Electronic data capture, transmission and archiving conforms with 21 CFR part 11 rule regarding digital collection and submission of data.
- Adverse events reporting.
- Records physiologic responses to real-world events.
- Correlates multiple respiratory and cardiac functions over time.
- Correlates digital patient diary information with physiologic data.
- Reveals trends and interactions through parameter groupings.
- Displays full-disclosure, high-resolution waveforms and summary reports using VivoLogic® Software.
- Pediatric through adult sizes.

The LifeShirt System

The LifeShirt System is based on inductive plethysmography, a cardiopulmonary monitoring technique for detection of a range of physiologic parameters not possible with any other single monitoring system. The LifeShirt System includes the following components:



- **LifeShirt Garment**

A lightweight (8 oz.), machine washable, comfortable, easy-to-use shirt with embedded sensors. To measure respiratory function, sensors are woven into the shirt around the patient's chest and abdomen. A single channel ECG measures heart rate, and a three-axis accelerometer records patient posture and activity level. Optional peripheral devices measure blood pressure, blood oxygen saturation, end tidal CO₂ and other physiologic parameters.



- **LifeShirt Recorder and VivoLog® Digital Patient Diary**

The LifeShirt System includes an integrated PDA that continuously encrypts and stores the patient's physiologic data on a compact flash memory card. Patients may also record time/date-stamped symptom, mood and activity information in the recorder's diary, allowing researchers and clinicians to correlate subjective patient input with objectively measured physiologic parameters.



- **VivoLogic Software**

Proprietary PC-based software decrypts and processes recorded data using patented algorithms. VivoLogic includes viewing and reporting features that enable researchers and clinicians to view the full-disclosure, high-resolution waveforms or look at trends over time. In addition, summary reports can be generated that present processed data in concise, easy-to-interpret graphical and numeric formats.



- **VivoMetrics Data Center**

Houses a staff of data analysts that can conduct over-reads for customers who do not want to process their data locally. Data can be uploaded via the Internet or mailed to the Data Center where they are processed using VivoLogic Software. A summary report is then generated and delivered via e-mail, fax or mail, along with digital files containing full-disclosure waveforms. The Data Center staff also provides technical support for customers using VivoLogic Software on their personal computers.

Licenses

VivoMetrics licenses the LifeShirt System based on usage and provides an integrated set of support services including: training, software support, upgrades and customer service. VivoMetrics is prepared to make available scientific consultation to qualified researchers.

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