



Airway Health refers to the status of the channels through which air is moved between the atmosphere and the lungs to provide oxygen to fuel the body and remove the carbon dioxide produced by the body. Airways range from relatively large, such as the trachea, to extremely small, such as the network woven through the lungs. A variety of diseases manifest themselves by compromised performance of the airways, each having a substantial impact on the quality of life of the sufferer. Asthma reduces the ability of air to flow through both the large and small airways, whereas chronic obstructive pulmonary disease (COPD) is characterized by difficulty expiring air which can result in the lungs becoming uncomfortably full, and causing feelings of difficulty breathing (dyspnea).

Assessment of airway health has traditionally relied upon discreet laboratory measurements of maximal breathing efforts (Forced Expiratory Volume in 1 second or 6 seconds; FEV1; FEV6). These techniques are at best a poor reflection of the continual daily challenges that individuals with compromised airways face with every breath. The discreet nature of these measurements reduces their value for both clinical assessment and research purposes as they fail to reflect transient changes in the airways and are disconnected from the normal activities of daily living pursued by individual patients.

The LifeShirt® System from VivoMetrics® provides an unprecedented ability to continuously monitor airway health, in environments both inside and outside the laboratory, and can be used to discern drug treatment effects. The LifeShirt can quantify airflow during every breath and identify characteristic changes in breathing that reflect the presence of airway limitations. With the LifeShirt's accelerometer, heart-rate, and pulse oximeter, the physiologic context and impact of the airway limitations can be understood and accounted for in both clinical assessment and research. With the LifeShirt's external flow-meter, the system can provide the established discreet laboratory quality pulmonary function test data in synchrony with continuous breath-to-breath and activity data.

Body position and activity inputs from the LifeShirt System allow objective observation of the functional state of LifeShirt wearers by quantifying variables such as time spent upright versus supine, the number of steps taken in a day, and restlessness and breathing difficulties during sleep.

The LifeShirt System synchronizes objective, physiologic data with subjective patient self-reporting, enabling the monitoring and assessment of disease progression, treatment effects, activity levels, nocturnal events, and symptom impact on patients' quality of life, 24 hours a day. It is both simple enough for patients to put on without assistance and sophisticated enough to monitor every breath, enabling greater understanding of changes in breathing patterns, giving researchers critical insight to airway health.

How It Works

- Trial subjects go about their daily activity wearing a comfortable, lycra shirt that captures ventilation, ECG, posture, and activity data. The shirt is similar to a cycling jersey and only weighs 8 ounces (260g).
- Respiratory variables related to bronchoconstriction, operating lung volume, and resistance to airflow can be continuously collected.
- Cough, activity and sleep quality can be quantified continuously.
- Data are uploaded from the clinical trials site via secure Internet connection.
- Encrypted data sets are delivered securely via the Internet or FTP.



Airway Health

LifeShirt System reduces cost and shortens study time for clinical trials.

- **Better quality data**
 - Continuous collection of over 30 physiologic variables, synchronized with patient reported outcomes, provides traditional endpoints with “real-life” physiological and subjective context
 - Researchers can truly observe patients at baseline and during treatment
 - Earlier go/no go decisions can be made
- **Improved patient recruitment and retention**
 - Data collection is comfortable
 - Flexibility in data collection environments enhances subject convenience
 - Study participation causes minimal disruption
- **Focused subject enrollment**
 - Improved application of inclusion and exclusion criteria
 - Patient stratification
- **Ease-of-use minimizes subject training requirements**

VivoMetrics understands the business of clinical trials.

In today's competitive market, VivoMetrics continues to emerge as the leader within the clinical data collection industry. The company possesses a breadth of scientific knowledge and a renowned Scientific Advisory Board, attracting key opinion leaders to the LifeShirt System for use in some of the top clinical trials across the world.



We provide end-to-end solutions including:

- Project management expertise.
- 24 hours a day, 7 days a week support in 170 local languages.
- Data collected, analyzed and delivered in Oracle Clinical, SAS or custom data sets via secure Internet.
- Delivery of encrypted data sets securely from a 21 CFR Part 11 compliant data center.

Used by leading pharmaceutical companies, academic institutions, research facilities and US Government agencies, the LifeShirt breathes new life into the science of drug development.

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