



Asthma represents a wide spectrum of pathophysiologies that result in reduced airway diameter. Bouts of asthma can be chronic or transient, and can be brought on by any number of causes from environmental irritants and allergens to cold, dry air or exercise.

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.

With the addition of an external flow meter, the LifeShirt System can provide laboratory quality pulmonary function test data in multiple environments. Used together, the LifeShirt and flow meter are analogous to a body-box, providing new insights to airway health.

This data provides never before available context around traditionally measured endpoints in asthma clinical trials (FEV₁, peak flow, etc.). Body position and activity inputs from the LifeShirt System allow objective observation of the functional state of asthma sufferers by quantifying variables such as time spent upright versus supine, the number of steps taken in a day and restlessness during sleep.

The LifeShirt System synchronizes objective, physiologic data with subjective patient self-reporting, enabling the monitoring and assessment of disease progression, treatment effects, nocturnal events and symptom impact on patients' activities and 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.

The LifeShirt® collects every breath and every heartbeat without any special effort from the patient, providing unprecedented monitoring of airway health in a continuous, ambulatory, "real life" way.

LifeShirts are available in pediatric sizes for ages 5–17, up to 5XL for patients weighing 650 lbs (295 kg).



How It Works

- The LifeShirt is a light weight, (8 oz, 260 g) comfortable garment that collects physiological data 24 hours a day, 7 days a week.
- Respiratory variables related to bronchoconstriction 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.

Asthma

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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