

# Chronic Obstructive Pulmonary Disease



Chronic Obstructive Pulmonary Disease (COPD) is characterized by progressively deteriorating airway performance. There are a variety of causes and subtypes of COPD, but all patients with COPD experience difficulty breathing and are susceptible to hyperinflation. These breathing challenges lead to dyspnea and substantial functional limitations.

The LifeShirt® System from VivoMetrics® continuously collects cardio-pulmonary, kinetic and patient reported data in multiple environments. Researchers conducting COPD clinical trials can now collect continuous, long-term data while freeing patients from frequent visits to the laboratory.

The LifeShirt allows measurements that were previously only possible in the laboratory to be made in multiple research environments. With the LifeShirt, cough, a common symptom of COPD, can be objectively quantified and sleep quality assessed. In addition, the LifeShirt also discriminates between abdominal and thoracic movement throughout the breathing cycle and enables researchers to observe mechanical changes that are associated with hyperinflation and airway health.

With the addition of an external flow meter, airway health can be evaluated, providing greater insight to patient status throughout the clinical trial. Used together, the LifeShirt and flow meter are analogous to a body-box. Body position and activity inputs from the LifeShirt allow objective observation of the functional capacity of COPD sufferers by quantifying variables such as time spent upright versus supine, the number of steps taken in a day and restlessness during sleep, giving objective assessments of functional capacity that are related to activities of daily living.

The LifeShirt frees COPD patients from the laboratory while continuously collecting data in an ambulatory environment.

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 the work of breathing are continuously collected.
- The LifeShirt identifies a cough “fingerprint” from multiple inputs.
- Data are uploaded from the clinical trials site via secure Internet connection.
- Encrypted data sets are delivered securely via the Internet or FTP.

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## LifeShirt 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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