

# Pediatric Sleep Studies



Sleep time and quality are important factors in many diseases but are often undiagnosed or unaccounted for by clinicians or researchers. This is particularly true in children. The LifeShirt® System from VivoMetrics® enables polysomnography (PSG) data collection while providing cost savings, as well as increased patient comfort and convenience compared to traditional lab based studies. The LifeShirt is both simple enough to use at home and sophisticated enough to provide full PSG sleep analyses. In recent pediatric sleep studies, the LifeShirt System cost less than half of traditional sleep lab studies, while allowing children to sleep at home in their own beds.

Traditionally, sleep studies in children have required a night in a hospital based sleep lab for both the child and their parents. The LifeShirt can be used across the spectrum of clinical and research settings including sleep labs, hospitals, and homes allowing data collection in the safest, most convenient, and most comfortable environments possible without compromising data quality.

" Children can sleep peacefully in the comfort of their own beds, avoiding the unfamiliar surroundings of a sleep lab. We get more accurate test results while the patients enjoy the freedom of movement in the safety and privacy of their own home. "

— Neil Mills, Coordinator, Kaiser Permanente Sleep Apnea Clinic

## How It Works

- Trial subjects sleep comfortably wearing a comfortable, lycra shirt that captures ventilation, ECG, SpO2, posture, EEG/EOG/EMG and periodic leg movement data. The shirt is similar to a cycling jersey and only weighs 8 ounces (260g).
- Data are uploaded from the clinical trial site via secure Internet connection.
- Sleep studies are scored by certified sleep technicians using VivoLogic® Software and reviewed by a physician.
- Encrypted data sets are delivered securely via the Internet or FTP.

## Clinical Endpoints

### EEG/EOG/EMG

- Sleep Staging
- Sleep Efficiency
- Sleep Latency
- Sleep Onset
- Awakenings
- MicroArousal Index
- Rem and Non-Rem sleep

### Respiratory

- Apnea Hypopnea Index
- Apnea
- Hypopnea

### Pulse Oximetry

- Oxygen Desaturation Index

### Leg Activity

- Kicks
- Restless Legs

The LifeShirt is based on respiratory inductive plethysmography, cited in the July 17, 2002 FDA Apnea Guidance Document as capable of differentiating between obstructive and central sleep apnea. The system collects, analyzes and reports ventilation, ECG, SpO2 and posture data as well as data from optional peripheral devices for EEG/EOG/EMG and periodic leg movement. Clinical endpoints include type, frequency and time distribution of sleep-disordered breathing events such as apneas, hypopneas, periods of oxygen desaturation, EEG/EOG/EMG derived measures of sleep time and stages of sleep.



VivoMetrics

# Pediatric Diagnostics

## 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
  - Data collection truly reflects patients at baseline and during treatment while minimizing environmental and ‘inconvenience’ confounding factors
- **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**

Patient sleeps comfortably while PSG data are collected. Results are delivered by certified sleep technicians to Principal Investigator and sponsor in Oracle Clinical or SAS format.



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

## VivoMetrics understands the business of clinical trials.

### 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 hospitals, sleep centers, 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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18:30	07:15
18:45	07:30
19:00	07:45
19:15	08:00
19:30	08:15
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