

VivoMetrics ...

Continuous Ambulatory Monitoring



VivoMetrics is a Unique Healthcare Monitoring and Information Company

- We provide physiologic data collection (devices and systems), analysis, and reporting for the drug development and healthcare industries
- We have:
 - A unique differentiated product offering
 - Proven, patented, scientifically-validated technology
 - A compelling value proposition to very large markets
- We are ready for market
 - Products available Q1 2001
 - Beta tests with 5 major institutions to begin in March



The VivoMetrics System is Unique ...

- Ambulatory
 - Used in normal life setting
 - Anywhere, anytime
- Robust
 - Monitors 40+ physiologic parameters
 - A complete physiological movie
- Continuous and Automatic
 - No active participation by user
- Unique evaluation capabilities:
 - Never-before monitored pulmonary activity a "Holter monitor" for the respiratory system
 - Correlation of pulmonary function with other systems
 - Asthma, COPD*, CHF*, CF*, PHT*, and Emphysema
 - Sleep apnea
 - Anxiety
- Integration of cardio-pulmonary data with subjective patient input diary.

input diary COPD: Chronic Obstructive Pulmonary Disease, CHF: Congestive Heart Failure,

CF: Cystic Fibrosis, PHT: Pulmonary Hypertension

Clinical Trial Applications

- Pre-study screening
- Phase I Full disclosure of cardiopulmonary parameters...early drug failure I.D.
- Phase II, III, IV continuous ambulatory monitoring
- Drug/Device Discovery/Development



A Complete Process for Secure 24X7 Data Collection, Transmission, Analysis & Reporting

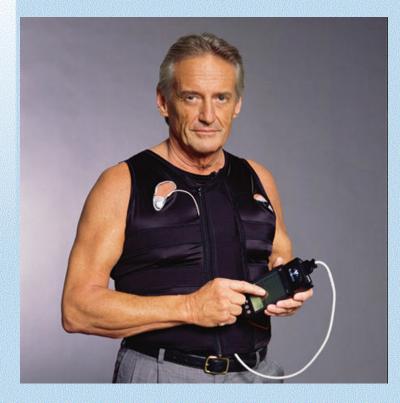
VivoReports

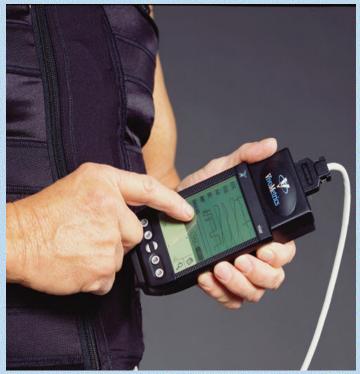
Sensors worn by the patient continuously monitor 40+ physiological signs and record the data in a small recorder. Patient data is encrypted in the recorder and sent to the VivoMetrics Data Center. At the Data Center, patient data is decrypted, scanned for artifacts, analyzed, and posted in our database. Data is displayed in easy-to-read graphical and numeric formats for clinical trials and physicians. Custom reports available for special audiences.



Data Collection is Done by the LifeShirt

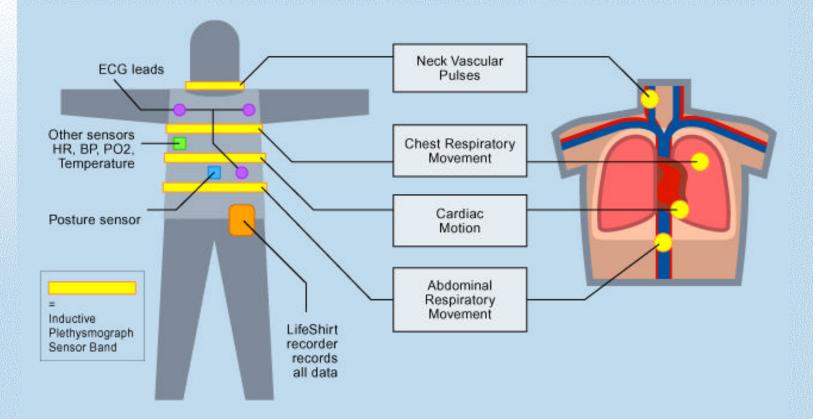
Data can be collected anywhere, anytime: at work, play or sleep







The LifeShirt: How it Works



Inductive Plethysmography

- All transport within the body results in measurable volume changes
- Complex because the volume changes are superimposed on one another
- The LifeShirt detects these volume changes, separates them from each other, eliminates the "noise" and provides a waveform
- Waveform is directly measured, not inferred

IP Physics

- Sensors consist of sinusoidal arrangement of insulated wire.
- Sensors are excited through low current, electrical oscillator circuit.
- No electricity passes through the monitored subject.
- Body movements covered by the sensors generate magnetic fields that are converted into voltage changes over time – waveforms.

IP Physics 2

- Waveforms are proportional to cross sectional area.
- Waveforms can be displayed as raw signals referenced to time or processed for their numerical, one-minute median trends.
- Location of sensors over the body part determines the type of waveform detected.

Specifications

LifeShirt Operating Specifications

- Respiratory Sampling Rate = 50 Hz
- Cardiac Sampling Rate = 200 Hz
- Power Supply = 7.2 V @ 1500 mAh
- Battery Life = 8 hours
- On-Board Memory = Up to 356 MB (8 hours = 64 MB)
- Serial Ports = 1
- IRDA = 1

40+ Parameters Continuously Acquired: For Every Breath You Take....

Timing and Volume Components of Breathing Pattern

- Respiratory Rate

- Tidal Volume

- -- Sigh Count
- Fractional Inspiratory Time
- Ventilation -- Respiratory Rate/Tidal Volume Ratio (f/Vt)

Respiratory Drive and Breathlessness Components of Breathing Pattern

- Peak Inspiratory Flow
 Ventilation/Peak Inspiratory Flow
- Peak Expiratory Flow
 Ventilation/Peak Inspiratory Acceleration

Upper Airway Flow Limitation and Upper Airway Resistance Syndrome

- Peak Inspiratory Flow/Mean Inspiratory Flow -- Peak Expiratory Flow/Mean Expiratory Flow

Thoracoabdominal Coordination and Sleep States

Phase Relation
 -- %RC/Vt

Apnea & Hypopnea Detection & Classification

- Apnea and hypopnea detection based on tidal volume thresholds
- Apnea and hypopnea classification based on effort phase relations

Cheyne-Stokes Respiration and Periodic Breathing

- Magnitude Periodic Oscillations
 -- Cycle Time
- Magnitude of changes in end-expiratory lung volume

40+ Parameters Continuously Acquired: For Every Beat of Your Heart

Systolic Time Intervals

- Pre-ejection Period (PEP) from Carotid Pulse
- PEP/LVET from Carotid Pulse

Central Venous Pressure and Venus Pulse

- Central Venous Pressure
- Jugular Venous Pulse Trace

Thoracocardiograph – Systolic Function

- Amplitude of Ventricular Volume Trace
- Amplitude of Ventricular Volume Trace times Heart Rate
- PEP
- 1st One Third Ejection/Stroke Volume

Thoracocardiograph – Diastolic Function

- E/A Ratio
- Time to Peak Filling Rate (TPFR)
- PFR/SV
- Deceleration Time of E Wave

Thoracocardiograph – Ventricular Wall Motion

- Wall Motion

40+ Parameters Continuously Acquired: Other Parameters

Posture and Activity

- Posture: Accelerometers indicate standing, sitting, supine, prone and lateral decubitus
- Activity: Accelerometers indicate walking or running
- Respiratory Sinus Arrhythmia
- Counts Method (sNN50)

Diary

- Symptoms: Visual Analog Scales
- Mood: Monk's Global Vigor and Visual Analog Scale
- Activity: Subject Description
- Medication Minder: Audio-Visual Alarm and Description

Blood Pressure Recorder

- Blood Pressure

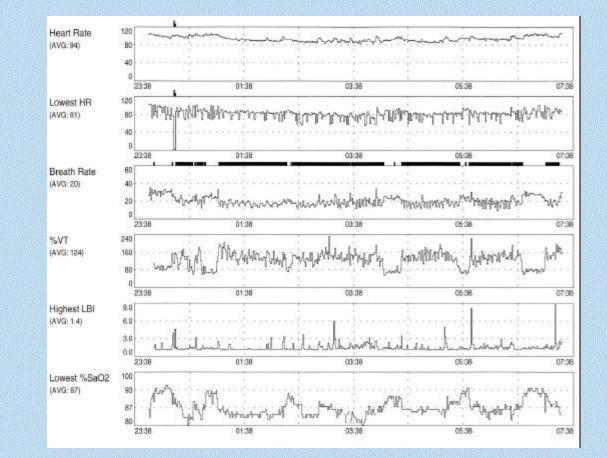
Body Temperature

- Monitored by Subject and Entered into PDA

Body Weight

- Monitored by Subject and Entered into PDA

Sample VivoLogic[™] Output



Sample VivoReport[™]

Sample VivoReport[™] **Report Date:** October 10, 20000 Patient Information Patient ID: CDH101099-1 Gender: M **Birth Date** 5/10/1954 **Study Information** Start Time: Oct 09, 2000 11:38 PM Finish Time: Oct 10, 2000 07:38 AM Elapsed Time: 480 Minutes (8.00 hours) Minute Trended Parameters Units Normal Heart Rate - Average (B/M) 60 - 90Heart Rate - Lowest (B/M) >50 **Breath Rate** (Br/M) 12 - 22 **Tidal Volume** (% Baseline) 80 - 120 LBI - Highest <1.3 ----Arterial OS Sat. - Lowest (%) >92 Apnea/Hypopnea Index <3 (events/hour) Apnea/Hypopnea Duration (% time) <1 (ML) **Tital Volume** 300 - 550 (L/M)Minute Ventilation 4 - 8 (Br/M /L) F/VT <105 # or minutes w/ TACHYCARDIA alarm 1 of 480 (0.2%)# or minutes w/ BRADYCARDIA alarm 2 of 480 (0.4%)

% Cov

6.1

13.4

25.8

27.3

50.6

3.8

31

27.3

54.6

Mean

93.7

80.6

19.7

123.9

1.4

86.8

55.8

37.5

496

9.41

44.6

(0.0%)

or minutes w/ BRADYCARDIA alarm2 of 480# or minutes w/ LABORED BREATH alarm0 of 480# or APNEA/HYPONEA events421



And We Are Ready to Deploy

- Version 1 completed January 2001
- 30 fully functional systems manufactured to date
- First commercial installations expected March 2001
- FDA
 - 510K approval received for most system components
 - 510K approval for complete integrated system expected late Q3, 2001
 - Compliant with 21 CFR Part 11 rule
- System works with existing telecommunications infrastructure



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