

## COMPANY ANNOUNCEMENT

### Update of Latest Product Flyers

**7<sup>th</sup> July 2009:** Attached to this release are the latest Product Flyers covering the Company’s key devices, namely:

- PulmoTrack®
- PulmoTrack-CC™ (Cough Count)
- WheezoMeter™
- Wholter™

These flyers describe the main features of each product and are being used to promote the clinical use of the products. They are used by the Company as well as by its associated territorial distributors in exhibits and in direct contacts with physicians.

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KarmelSonix Ltd. focuses on supplying innovative non-invasive acoustic tools for disease management of asthma and related pulmonary disorders. Asthma affects 6-16% of the population in developed countries with a cost exceeding \$US15 billion in the US alone.

Acoustic Asthma Management is a breakthrough in monitoring of the asthmatic patient of all ages, including the very young, very old and others who cannot perform currently available tests. The technology that comes from extensive R&D and clinical validation in the US, Israel and Australia, facilitate continuous monitoring of patients at home, in the ICU and even during sleep. The company is focused on early commercialization of its products with special emphasis on the European and North American markets.

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# WheezeRATE™

A New Paradigm in Asthma Management



## PulmoTrack®

An Innovative New System for Wheeze Identification & Quantification

**Asthma is reversible airflow obstruction, associated with a state of increased responsiveness of the tracheobronchial tree to many different stimuli (that do not affect normal individuals).**

**...Patients experience dyspnea, cough and wheezing as the major complaints.**

*Tintinalli: Emergency Medicine, American College of Emergency Physicians*

**PulmoTrack® enables the continuous monitoring of wheeze and cough\*.**

This easy, quick and noninvasive system provides:

- Wheeze by wheeze identification
- Accurate measurement of **WheezeRATE™**
- Classification of wheeze as inspiratory or expiratory
- Respiratory rate and I/E ratio
- Cough\* Counting

## Acoustic Respiratory Monitoring

The **PulmoTrack®** Respiratory Acoustic Monitor can be used for:

- **Bronchodilatation Test:** Measurement of response to treatment.
- **Bronchoprovocation Test** particularly for infants or other non-cooperative patients.
- **Performance of physical examination** in a pulmonary function testing environment to identify and quantify the presence of wheezing.

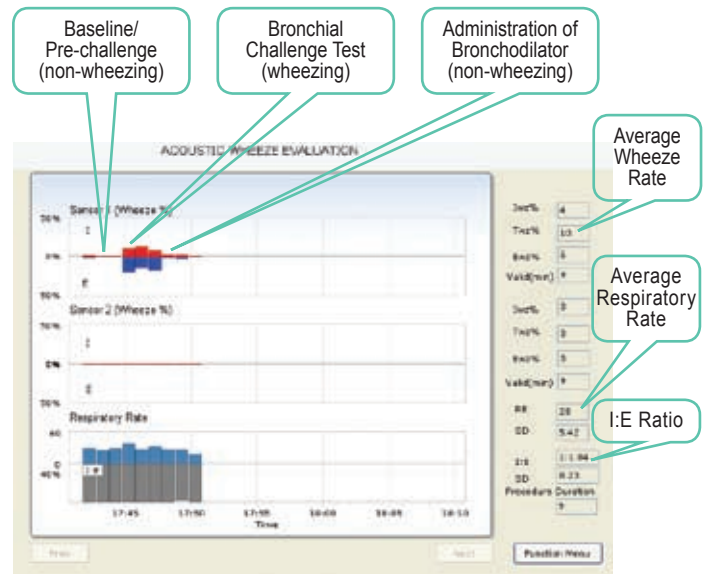


**WheezeRATE™: Proportion of the respiratory cycle duration occupied by wheezing – Tw/Ttot**

The **PulmoTrack® Respiratory Acoustic Monitor** system consists of two acoustic sensors attached to the skin over the trachea and chest with disposable acoustic insulating adhesive pads, a pneumograph belt sensor for documenting breathing activity, and an ambient microphone to filter environmental noises.

Wheeze detection is carried out by patented\* software using advanced algorithms that apply strict criteria to determine the presence of wheezing, as defined by CORSA (Computerized Respiratory Sound Analysis) guidelines<sup>1</sup>.

<sup>1</sup> Sovijärvi ARA, Dalmaso F, Vanderschoot J, Malmberg LP, Righini G, Stoneman SAT, Definition of terms for application of respiratory sounds. Eur Respir Rev 2000;10:597-610



## PulmoTrack® facilitates improved patient management.

- **Minimum patient active effort** offers previously unavailable objective pulmonary symptoms documentation in all age groups and continuous overnight monitoring.
- **Precise measurement of wheeze rate** provides quantitative patient data.
- **Archivable and retrievable reports over a period of time** enable the following of symptom trends.
- **Detailed graphical spectral display and acoustic playback features** allow review of specific records for secondary data analysis.

## PulmoTrack® Specifications

System Components	<ul style="list-style-type: none"> <li>• 2-ppg™ Sensors</li> <li>• Respiratory Sensor including belt</li> <li>• Signal conditioning unit</li> <li>• Analog/digital converting unit</li> <li>• Laptop computer</li> <li>• Acoustic adhesive pads</li> <li>• System case</li> </ul>
Sensors	Piezoelectric, useful range - 75-4000Hz
Adhesive Pads	Biocompatible, noise shield
Software	KarmelSonix dedicated software
Software Features	<ul style="list-style-type: none"> <li>• Data analysis – wheeze detection</li> <li>• Wheeze rate %</li> <li>• Respiratory rate</li> <li>• I:E Ratio</li> <li>• Data archiving &amp; retrieval</li> <li>• Zooming</li> <li>• Audio playback</li> <li>• Printable reports</li> </ul>

\*PulmoTrack® is protected by patent numbers: US 6,168,568, US 6,261,238 & EP 0944355. PulmoTrack™ is FDA, CE & TGA cleared.

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# CoughCOUNT™

Objective Quantitative Symptom Score



## PulmoTrack-CC®

The Validated\* CoughCOUNT™ Technology from KarmelSonix

Chronic cough is among the most frequent presenting symptom in primary care, but its assessment is subjective and often inaccurate. The distribution and extent of cough can indicate:

- Asthma
- COPD or Chronic Bronchitis
- Cystic Fibrosis
- Gastroesophageal Reflux (GER)
- Upper Airway Syndrome (Post Nasal Drip)

Objective Quantitative CoughCOUNT™ with the PulmoTrack-CC™ is essential in:

- Evaluation of cough severity
- Documenting nocturnal cough
- Determination of response to treatment
- Occupational medicine
- Drug development and validation

\* Validation of a Robust Cough Monitoring and Counting Application, ATS, 2009

# Cough Monitor

**Overnight or 24 hour cough monitoring provides minute-by-minute cough count with exact timing of each cough event (i.e. burst associated with a single inspiration) and component.** This facilitates temporal association with:

- Administration of treatment
- Reflux events and Meals
- Wheeze
- Change of body posture/activity
- Exercise and exposure to cold
- Exposure to noxious gases and ambient particles
- Primary and secondary cigarette smoke



CoughCOUNT™: Number of coughs per unit time (minute or hour)

\*FDA Pending

# Cough Monitor

# PulmoTrack-CC<sup>®</sup>

The Validated\* CoughCOUNT™ Technology

The **PulmoTrack-CC™** is an optional patented\* software application that can be used as part of the **PulmoTrack®** Wheeze real-time Acoustic Respiratory Monitor (ARM) or with the **Wholter™** 8-24 hours recorder. For data acquisition, the **PulmoTrack-CC™** uses the same sensors and hardware as the **PulmoTrack®** and the **Wholter™**. The application detects **Cough Events** which are either single or multiple **Component Coughs** as well as individual components. The User Interface is shown in **Figures 1-2**.

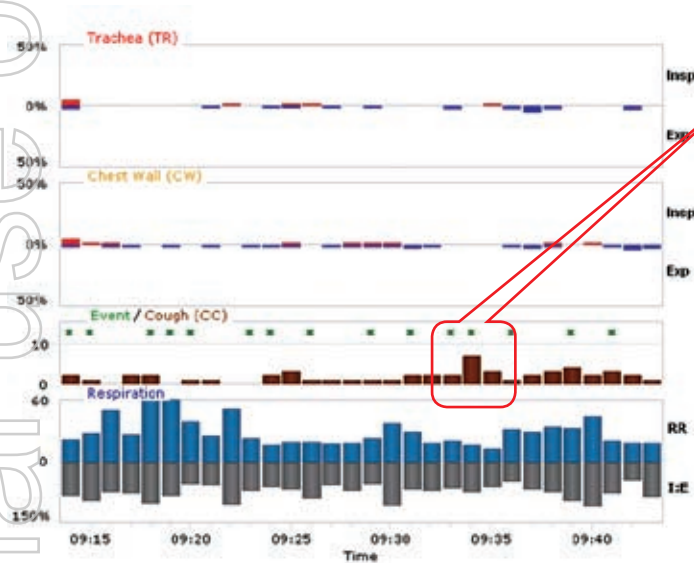


Fig. 1: The PulmoTrack-CC™ Monitor interface shows minute-by-minute information on Tracheal and Chest Wall WheezeRATE™ (bars in top 2 panels) and CoughCOUNT™ per minute (3rd panel). The bottom panel shows the Respiratory Rate (blue) and I:E Ratio (gray). Time is in minutes.

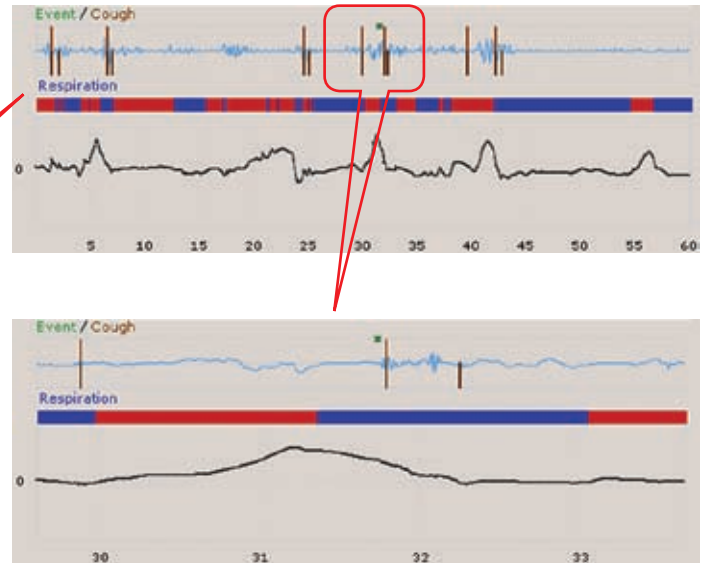


Fig. 2a: Clicking an individual minute bar opens a detail panel showing the timing of the Cough Events in long lines and secondary Components in shorter lines. Fig. 2b: Shows the expanded time scale plot [in seconds] of one single-component and one two-component cough.

The **PulmoTrack-CC™** is intended for detecting, counting, and recording coughs in patients when there is a need for objective documentation of the presence of cough in unrestricted environments.

## PulmoTrack® Specifications

Data Input Requirements	<ul style="list-style-type: none"> <li>From PulmoTrack® Monitor; or</li> <li>From Wholter™ Recorder</li> </ul>
Analysis Requirement	<ul style="list-style-type: none"> <li>PulmoTrack® with activated CC™ Option</li> </ul>
Reporting	<ul style="list-style-type: none"> <li>CoughCOUNT™ as Events and Components per minute</li> </ul>
Timing	<ul style="list-style-type: none"> <li>Timing of Events and Components</li> </ul>

PulmoTrack-CC™ is protected by patents 6,168,568; 6,261,238, and by pending US and international patents. PulmoTrack-CC™, WheezeRATE™, CoughCOUNT™ are trademarked by KarmelSonix.

Specifications are subject to change without prior notice.

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# WheezoMeter™

The Only Point-of-Care Wheeze Detector



## WheezoMeter™

State-of-the-Art Wheeze Measuring Device

*The WheezoMeter™ analyzes 30 seconds of breath sounds using advanced signal processing algorithms to detect, quantify and objectively document the presence of wheeze and its extent, the WheezeRATE™.*

- The **WheezoMeter™** is calibrated and validated as determined by consensus of a panel of experts who evaluated and scored many recordings for presence of wheeze.
- The **WheezoMeter™** uses a cascade of 6 proprietary technologies to "defend" the signals against false detection of ambient noises as wheeze.

## Acoustic Respiratory Monitoring

The WheezoMeter™ can be used by:

- **Physicians:** Pediatricians, GPs, internists, asthma/allergy specialists.
- **Nurses:** Emergency, ICU/PICU/NICU, ward, asthma nurses, school nurses.
- **Technicians and Paramedics:** Respiratory therapists, EMS personnel, military medics, sports paramedics, occupational health officers.
- **Patients and Caregivers:** Under guidance of a healthcare professional.



WheezeRATE™: Proportion of the respiratory cycle duration occupied by wheezing – Tw/Ttot

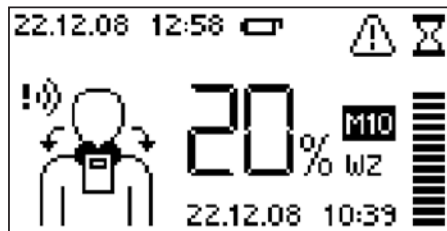
# Acoustic Respiratory Monitoring

# WheezoMeter™

A state-of-the-art Point-of-Care wheeze detector

The **WheezoMeter™** design is based on ergonomic human-interfacing principles as dictated by functional and anatomical requirements in a state-of-the-art attractive form.

- Facilitates the correct anatomical placement of the device in contact with the trachea at the correct contact force.
- Provides stable contact with the skin surface for the duration of the test.
- Isolates the measuring head and sensor from vibrations and tremor of the hand holding the **WheezoMeter™**.



The **Wheezometer™** provides a simple and intuitive user interface with clear Wz% readout, time and date of test as well as specific icon indicators for unstable sensor contact and for excessive ambient or patient noise.



The **Infant Sensor™** (optional) is used for babies and toddlers who typically have a short neck.

## WheezoMeter™ uses:

- Obtain a "spot check" measurement of present wheeze activity, any time, any place, as often as needed without any patient effort.
- Measure **WheezeRATE™** before and after administration of a bronchodilator ("pre-post" test).
- Communicate status of homebound or remote patient to physician or healthcare professional.

## Personal WheezoMeter™ Specifications

System Components	<ul style="list-style-type: none"> <li>• <b>WheezoMeter™</b> with embedded Black Fin® processor. Self-contained cushioned built-in silicone-coated PPG Sensor</li> <li>• Carrying case</li> </ul>
Sensor	<ul style="list-style-type: none"> <li>• PPG Sensor with broad spectrum frequency response, &gt;60 dB dynamic range and superior ambient noise rejection</li> </ul>
Software	<ul style="list-style-type: none"> <li>• Proprietary KarmelSonix Wheeze Detection algorithms plus comprehensive ambient noise rejection capability.</li> </ul>
Capacity	<ul style="list-style-type: none"> <li>• Allows scrolling of the last 10 measurements for review</li> </ul>
Batteries	<ul style="list-style-type: none"> <li>• 2 AA batteries (not included)</li> </ul>
Auxiliary Input	<ul style="list-style-type: none"> <li>• Infant sensor holder for babies and toddlers (optional)</li> </ul>
Warranty	<ul style="list-style-type: none"> <li>• One year limited warranty</li> </ul>

WheezoMeter™ is protected by international and US patents 6,168,568; 6,261,238. Specifications are subject to change without prior notice.

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# WHolter™

## Ambulatory Wheeze and Cough Holter



# WHolter™

## 24-Hour Symptoms Recorder in a Patient's Own Environment

Ever wonder what the patient is experiencing overnight, during exercise, after a meal, at the work place? The WHolter™ is the first ambulatory wheeze and cough 24-hour recorder that can document objectively and quantitatively patients with:

- Nocturnal Asthma
- COPD or Chronic Bronchitis
- Occupational Asthma
- Chronic Cough
- Allergies

The WHolter™ is used to continuously determine and provide a detailed report on:

- WheezeRATE™, wheeze time over total time
- Inspiratory and Expiratory WheezeRATE™
- CoughCOUNT™, number of coughs per minute/hour
- Respiratory Rate
- I:E Ratio

# Ambulatory Monitor

Overnight or 24-hour WHolter™ recording can be used to:

- Document Nocturnal Asthma, assess its severity and provide a clear temporal pattern of overnight wheeze activity
- Evaluate level of Asthma control and need for Step-up or Step-down of Asthma treatment
- Evaluate Chronic Cough patients, symptom association (e.g. exposure) and response to treatment
- Objectively document effect of occupational and environmental (e.g. fragrances) pollutants and allergens



WHolter™: Listens to your patient when you can't...

\*FDA Pending

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# Ambulatory Monitor

# WHolter™

24-Hour Symptoms Recorder in a Patient's Own Environment

The **WHolter™** overnight or 24 hours recorder is prescribed by a physician to assess symptoms, diagnose nocturnal asthma, chronic cough etc. Dispensing the unit, including patient education, correct application of the sensors in the right locations and activation of the recorder is done in a specialized clinic, e.g. PFT Lab, Sleep Lab, Holter (cardiac, hypertension, asthma/allergy specialist) or at the physician's office/clinic. At the end of 24 hours or 8 hours (if only nocturnal WHolter study is indicated) the patient returns the unit, the data is uploaded and sent for analysis and interpretation.

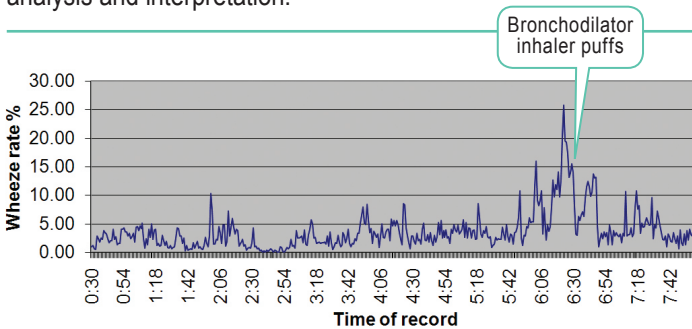


Fig. 1: The **WHolter™** WheezeRATE™ overnight record of a 24 years old asthma patient. Note the early-morning wheeze that eventually woke the patient up to administer Albuterol. The overnight average WheezeRATE was 3.7% with 86 minutes (18.6% of the night) with WheezeRATE > 5%.

The **WHolter™** consists of a Data Logger recording unit with a 24 hours digital recording capacity to store continuous information from 2 PPG sensors, pneumogram belt and ambient microphone. The **WHolter™** is supplied with a Check-in/Check-out software that allows registering a patient when the device is dispensed, upload the recorded data to the computer and prepare the unit for the next patient. Data Analysis is performed by the PulmoTrack® software package sold separately, or as part of a PulmoTrack®-WHolter™. Use of ambient microphone for event recording.

The **WHolter™** is intended for performing ambulatory lung sounds and respiratory activity recording on those patients who may benefit from such a recording, including, but not limited to, those with complaints of shortness of breath, wheezing, cough, and when there is a need for performing continuous acoustic pulmonary function measurements.



## WHolter™ Specifications

Data logger capacity	<ul style="list-style-type: none"> <li>BGB digital recorder</li> <li>Continuous recording for 24 h</li> </ul>
Analog input	<ul style="list-style-type: none"> <li>Two sound contact sensors</li> <li>Pneumograph belt</li> <li>Ambient microphone</li> </ul>
Data Acquisition	<ul style="list-style-type: none"> <li>16-bit, at 8250 samples per second, per channel</li> </ul>
Contact Sensors	<ul style="list-style-type: none"> <li>Two PPG sensors</li> <li>Frequency range: 80-2400 Hz</li> </ul>
Required Batteries	<ul style="list-style-type: none"> <li>2 AA NiMH &gt;2900AH</li> <li>Rechargeable batteries (not included)</li> </ul>
Dimensions and Weight	<ul style="list-style-type: none"> <li>13.8 x 7.6 x 2.6 cm</li> <li>210 gr (with batteries)</li> </ul>
Check-In/Out Software	<ul style="list-style-type: none"> <li>Supplied on a CD, used to login patient and upload of data</li> </ul>

WHolter™ is protected by patents 6,168,568; 6,261,238, and by pending US and international patents. PulmoTrack-CC™, WheezeRATE™, CoughCOUNT™ are trademarks by KarmelSonix.

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