

## COMPANY ANNOUNCEMENT

### FDA Grants Clearance for WHolter™ Recorder

#### Highlights

- Unique in market – New pocket-size WHolter™ collects respiratory symptom data for ambulatory diagnosis & verification, in hospital, home, workplace, and school – 24/7.
- Single-patient Use WHolter™ Test Kit & Interpretation Service allows physicians to utilize testing with no capital outlay.
- First available technology – Records all breathing sounds with blood-oxygen levels for analysis of wheezing, cough and upper airway changes.
- New CPT Code 0244T for continuous measurement of WheezeRATE™ during treatment assessment or documentation of nocturnal wheeze and cough for diagnostic evaluation, with interpretation and report.
- A significant advancement - diagnosticians can detect abnormal breath sound symptoms that occur beyond boundaries of the clinical environment.

**19<sup>th</sup> July 2010:** The Directors of KarmelSonix Limited (ASX: KSX) are pleased to announce that the American Food & Drug Administration (FDA) has granted 510k market clearance for the WHolter™ Recorder, the third acoustic respiratory monitoring product in the KarmelSonix product range, along with the award winning PulmoTrack® and the Personal WheezoMeter™ - first “asthma thermometer” for home management of asthma.

The Company estimates that the market potential for WHolter™ tests is of the order of 8.0 million tests per year (refer KSX announcement 22/6/10). Based on a conservative estimate of a yearly WHolter™ test for the severe asthmatic patient population and tests for the difficult-to-diagnose patient (especially for nocturnal asthma and cough), the Company estimates a 0.2% penetration of this available market in the next fiscal year. With an expected average reimbursement of \$250/test, and 50% margin for the Company, revenue only from this activity is anticipated to be of the order of a US\$1.0 million.

“Receiving FDA approval for the WHolter™ Recorder enables us to formally commence acoustic daytime and overnight testing”, stated Larry Murdock, GM of KarmelSonix US. “Our “clip of the ticket” testing program for doctors to use in the US can now begin in earnest, and in a market where the problem of childhood asthma and vocal cord dysfunction are so prevalent.”

## ***“Wheeze Rate – A New Paradigm in Asthma Management”***

Acoustic Sleep Testing is used to verify the symptoms of nocturnal asthma and cough-variant asthma. A recent study in The Journal of Asthma reported that children with Nocturnal Asthma wheeze intermittently during sleep; a condition that when correctly diagnosed, can easily be treated. Likewise, the availability of a 24 hours ambulatory recorder facilitates evaluation of occupational, sports-related and environmental-induced respiratory symptoms.

1. CPT is a registered trademark of the American Medical Association.

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**About KarmelSonix :** 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 now focussing its efforts on early commercialization of its products particularly in the AsiaPac, European and North American markets.

## ***“Wheeze Rate – A New Paradigm in Asthma Management”***

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