

2009 European Asthma Monitoring Product Innovation of the Year Award**KarmelSonix Ltd.**

The 2009 European Frost & Sullivan Product Innovation of the Year Award in the field of asthma monitoring goes to Australian/Israeli-based KarmelSonix Ltd. to recognize the company's development of the innovative PulmoTrack® product line. PulmoTrack® is a quick, easy, and noninvasive system that monitors wheezing and coughs continuously without requiring active patient cooperation. It is considered as the best alternative management tool for asthmatic patients who cannot perform spirometry.

Company Background

KarmelSonix Ltd. (KSL) is listed on the Australian Stock Exchange (ASX) and traded under the symbol KSL. The board's Chairman is Peter Marks of Australia and the Executive Director is Prof. Noam Gavriely, who is also the Company's CMO. The Company's governance also includes Prof. Nathan Intrator and Dr. Henry Pinski (Directors) and Prof. Simon Godfrey, Chairman of the Medical and Scientific Advisory Board.

KarmelSonix Ltd. represents the union of KarmelSonix of Israel and PulmoSonix of Australia, each of whom possesses unique respiratory acoustic technologies. Both companies specialize in pulmonary acoustics as diagnostic and non-invasive monitoring tools for various pulmonary disorders. However, the distinction is that KarmelSonix uses passive technology, which is a creative technique to listen and understand the various acoustic signals of the lung produced during respiration. On the other hand PulmoSonix employs active technology that inserts sounds into the thorax and detects varying signals at different places to arrive at the diagnosis from the sound propagation data thus generated.

KarmelSonix was established to merge and improve both these technologies in a way that is unique and that is able to solve pertinent clinical problems. In this context, KarmelSonix has introduced a range of novel solutions based on the PulmoTrack® core technology, including the Wholter™, and the Personal Wheezometer™. The Wholter™ is a 24 hour wheezing and cough recorder used for assessment of nocturnal asthma. The Personal Wheezometer™, a hand held Point-of-Care device, enables asthma patients and their care-givers to measure their wheeze rate within 30 seconds.

Relevance in the Market Place

Worldwide, asthma is estimated to afflict 6 to 16% of the population and treatment cost is in the range of \$15 billion a year in the US alone. Although it is regarded as a chronic condition, asthma can be fatal when not diagnosed and treated properly at an early stage. This is critical, especially in children who are unaware of the gravity of their health condition and may not be able to communicate or cooperate with performing spirometry, the traditional method for assessing airway obstruction. In fact, asthma has often been cited as a key reason behind hospitalization and school-absenteeism in children. With difficulties in diagnosing asthma sometimes attributable to parent's insufficient involvement, technology becomes important. Having a solution that enables the monitoring of respiratory tract disorders that can analyze and detect asthma attacks even with minimal or no cooperation from the patient is a pressing need.

How It Works

KarmelSonix's PulmoTrack® solution is able to detect and quantify sounds emanating from the thorax and trachea while accurately identifying any wheezing and coughing. The device allows continuous monitoring of a wide variety of patients including preschool children, the elderly and disabled patients throughout the day. As such, the device can find extensive application in clinics, hospitals (including ER, ICU and Pulmonary Function Testing Laboratories), sleep labs, occupational medicine, military installations, and research centers including pharmaceutical R&D. The device's unique features include: wheeze by wheeze identification, accurate measurement of wheeze rate, identification of inspiratory and expiratory wheezes, respiratory rate and inspiratory to expiratory time (I/E) ratio, and cough counts. Moreover, the device functions without requiring any cooperation or effort from the patient, which is especially important when dealing with children, the disabled and the elderly.

The PulmoTrack® device consists of two acoustic sensors attached to the skin above the trachea and chest and has disposable acoustic adhesive pads, a pneumograph belt sensor that records breathing activity, and an ambient microphone that effectively filters environmental noises. The device uses patented software and advanced algorithms to detect wheezing based on certain strict criteria, which are defined by CORSA (computerized respiratory sound analysis) guidelines. The PulmoTrack® can be used for bronchodilation tests to measure the response to treatment as well as to

perform bronchoprovocation test in infants and children. The patients can be at home, in the ICU, or even asleep, so the monitoring can take place without interruption. As such, the PulmoTrack® technology is also particularly useful in detecting nocturnal asthma and night-time exacerbations of COPD and chronic cough, conditions that are currently poorly diagnosed in the absence of objective and quantitative tools to evaluate the sleeping patient.

Business, Patents, & Partnerships

PulmoTrack® has been approved by the US FDA and the Conformité Européenne or European Conformity and Australian Therapeutic Goods Administration (TGA) for use as a respiratory acoustic monitor. The technology, on which the product is designed, is the result of extensive research and development that has run through various clinical trials worldwide, including the US, Europe, Australia, and Israel.

With such a strong, patented portfolio on a global scale, KarmelSonix aims to enter the global market in the near future. KarmelSonix Ltd. has established partnerships with distributors in Europe (Benelux, Italy, UK, Greece, Israel), Asia Pacific (Taiwan, China, Korea, Australia) and in North America (USA, Canada).

Conclusion

PulmoTrack® is clearly a very useful solution for the management of pulmonary disorders such as asthma and wheezing. It is able to provide an easy way to monitor such disorders using a quick, non-invasive approach that does not require effort or cooperation from the patient, so it can be very useful for infants, children, and other potentially uncooperative patient populations as well as everyone during sleep and in critical care. For its development of the PulmoTrack® device, KarmelSonix is recognized with the 2009 European Frost & Sullivan Award for Product Innovation of the Year.

Award Description

The Frost & Sullivan Award for Product Innovation is presented each year to the company that has demonstrated excellence in new products and technologies within its industry. The recipient company has shown innovation by launching a broad line of emerging products and technologies.

Research Methodology

To choose a recipient of this Award, the analyst team tracks all new product launches, research and development (R&D) spending, products in development, and new product features and modifications. This is accomplished through interviews with the market participants and extensive secondary and technology research. All new product launches and new products in development in each company are compared and evaluated based on degree of innovation and customer satisfaction. Companies are then ranked by number of new product launches and new products in development.

Measurement Criteria

In addition to the methodology described above, there are specific criteria used to determine final competitor rankings in this industry. The recipient of this Award has excelled based on one or more of the following criteria:

- Significance of new product(s) in its industry
- Competitive advantage of new product(s) in its industry
- Product innovation in terms of unique or revolutionary technology
- Product acceptance in the marketplace
- New product value-added services provided to customers
- Number of competitors with similar product(s).

About Best Practices

Frost & Sullivan Best Practices Awards recognize companies in a variety of regional and global markets for demonstrating outstanding achievement and superior performance in areas such as leadership, technological innovation, customer service, and strategic product development. Industry analysts compare market participants and measure performance through in-depth interviews, analysis, and extensive secondary research in order to identify best practices in the industry.

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