

**Award Description**

The Frost & Sullivan Award for Product Innovation of the Year is presented each year to the company that has demonstrated excellence in new products and technologies within their 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 R&D spending, products in development, and new product features and modifications. This is accomplished through interviews with all 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 describe 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 their industry
- Competitive advantage of new product(s) in their industry
- Product innovation in terms of unique or revolutionary technology
- Product acceptance in the marketplace
- New product value-added services provided to customers

**2007 North America Respiratory Devices  
Product Innovation of the Year Award  
Award Recipient: Respiratory Technology Corporation**

The Frost & Sullivan 2007 North America Product Innovation of the Year Award in the field of respiratory devices goes to Respiratory Technology Corporation (Restech) of Poway, Calif. for its development of the Dx-pH Measurement System™. The system provides real-time detection of laryngopharyngeal reflux (LPR), by measuring and recording pH in the oropharynx or upper airway as opposed to traditional pH catheters that measure liquid reflux in the esophagus. By monitoring aerosolized pH events in the airway, the system is the first of its kind to measure and record ph of breath in real time, while facilitating greater patient comfort.

**Introduction**

Restech is a San Diego-area respiratory device manufacturer. The company is engaged in developing innovative solutions that aid physicians in the diagnosis of reflux related problems quickly and reliably. The team at Restech includes professionals with strong medical device expertise and is led by Leo Roucher, an industry veteran with over 20 years experience in leading companies such as SciMed, Medtronic, Versaflex, and USC1. He also founded Navius Corporation, which was later acquired by Endosonics. Restech is advised by a Scientific Board that consists of several pre-eminent surgeons and physicians including Tom DeMeester, Chairman of the University of Southern California Medical School's Surgery Department, Stanford

Gastroenterology Professor George Triadafilopoulos, and Joel Richter, Chairman of The Department of Medicine at Temple University in Philadelphia.

## **Technology Overviews**

LPR is characterized by the back flow of stomach acid and an activated proteolytic enzyme called pepsin that moves up the esophagus and into the throat and voice box. This is primarily a result of the nonfunctioning of the upper esophageal sphincter, one of the two muscles located in the esophagus. Typical diagnostic tools for LPR include laryngoscopy, pH probe testing, empirical PPI testing and upper GI endoscopy. Conventional pH catheters require immersion in a liquid medium to read pH values, and usually employ ordinary sensors that are not self-condensing. If the reference sensor is not in intimate contact with the fluid, a “dry out” occurs causing a loss of signal, which results in pseudo reflux or drift. More so, when reflux is aerosolized, conventional pH sensors render themselves ineffective in measuring the pH activity. The complexity is enhanced due to the size and the positioning of the pharyngeal sensors, which make the reading of the pH almost impossible. Another disadvantage is the requirement of manometry to determine the proper positioning of the pharyngeal sensor, which is time-consuming and typically takes about more than 30 minutes during deployment.

## **Innovative Features**

The Restech Dx-pH Measurement System overcomes many of the constraints of current technology and provides physicians across the healthcare continuum a platform to better analyze the effects of gastric reflux on their patient’s health, which has shown to exacerbate diseases such as asthma, chronic cough, sleep apnea as well as promote throat disorders such as hoarseness and chronic throat clearing. The system provides a graphical recording of the patient’s reflux pattern in real time for 24 hours to 48 hours.

Significantly, the miniaturized Coplanar Ionic Bridge pH sensor at the tip of the Dx-pH probe is self-condensing and does not require to be immersed in any fluid medium. It is capable of measuring the acidity and alkalinity of gaseous reflux in the airway and the readings occur at a sample rate of 2 Hz for increased sensitivity. The sensor face design is less than 1 mm and helps enhance patient comfort.

Furthermore, the teardrop shape of the sensor minimizes fouling and reduces mucosal masking. The sensor positions itself behind the soft palate, three centimeters higher than the conventional pharyngeal sensor, and the placement of the probe takes only seven minutes vs. its conventional counterpart, which is often positioned too low for the proper detection of LPR. The insertion of the probe takes place trans-nasally after numbing the patient’s naris with a topical anesthetic. The tip of the Dx-pH probe contains a red light-emitting diode to visually assist in proper oropharyngeal placement.

The Dx-pH probe is calibrated with pH4 and pH7 standard buffer solutions. The calibration kits associated with these systems allow easy set up and prevent buffer contamination and spillage. The system has also been engineered in a way that protects against loss of data and inaccuracies, which may occur as a result of interference, accidental shutoff, dry out periods, missed transmissions or mucosal contact. In this regard the use of a hydration sensing circuit also makes the system more reliable.

In addition, by using the “plug and play” Dx-Sleep Adapter™ accessory, clinicians can track pH events in real time using the existing monitoring equipment, and, since the data transferred is using wireless telemetry, there are no extra leads available from the patient.

The data obtained is transmitted through wireless channels and stored in a Secure Digital (SD) memory card. The data can be subsequently reviewed using the Dx-pH DataView software program, and the physician can see graphical details and print detailed reports.

Restech is the product of a partnership between a seasoned team of industry professionals and research physicians. As a result the company has been able to create an innovative, sophisticated product with strong industry relevance. At the core of its success, lie the company’s focus on research and development. The company is advised by leading real-world practitioners and clinical researchers who know what physicians and patients are seeking in terms of diagnosis of reflux-related health problems.

Restech has an extensive IP portfolio and holds rights to over 30 patents in a variety of areas such as sensor technology, data recording and monitoring systems and other medical devices. Recently the company obtained approval of ‘Real-Time Sensing of Airway pH and other Breath Chemistries’ (U.S patent 7,101,341). Other patents, particularly those covering the pH sensor technology used in the Dx-pH Measurement System, are pending with the US patent office. Overall Restech has over one dozen patent applications including 3 international patents. In addition many patents are licensed under agreement from Sierra Medical.

Restech has also invested heavily in clinical work. In a recent study conducted to test the efficacy of the Dx-ph Measurement system, to determine the gastric reflux in infants and children, the airway reflux detection system passed the Childproof Test. This validates the company’s technology for use in this key end user demographic.

## **Conclusion**

In summary, Frost & Sullivan’s Award for Product Innovation of the Year recognizes Respiratory Technology Corporation for its development of the innovative Dx-pH Measurement System, which will provide effective real-time pH measurement in the upper airway while delivering greater patient comfort, as well as the company’s

overall efforts and contributions to product development and innovation in respiratory devices.

### **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.

### **About Frost & Sullivan**

Frost & Sullivan, a global growth consulting company, has been partnering with clients to support the development of innovative strategies for more than 40 years. The company's industry expertise integrates growth consulting, growth partnership services, and corporate management training to identify and develop opportunities. Frost & Sullivan serves an extensive clientele that includes Global 1000 companies, emerging companies, and the investment community by providing comprehensive industry coverage that reflects a unique global perspective and combines ongoing analysis of markets, technologies, econometrics, and demographics. For more information, visit [www.frost.com](http://www.frost.com).