

Volume 2 Number 1 February-March 2007

# Respiratory Therapy™

The Journal of Pulmonary Technique



Special Report: Ventilation  
Tracheostomy  
Effective Strategies  
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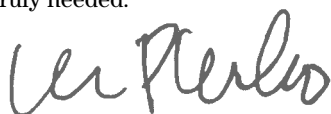


## KEEP BREATHING

Welcome to our special report on ventilation. This special issue of *Respiratory Therapy* covers the gamut of the latest in ventilation therapies, technologies, research, equipment, and more. Included are special news features, discussions of legislative issues, case studies of applied technology, ventilatory strategies, and roundtable discussions of where ventilation is headed.

But perhaps the most prescient commentary in this issue comes from David Costa of Hamilton Medical, who notes, on page 29, in our Ventilation Roundtable, “The reality is that there have not been many advances in technology for the mechanically ventilated patient over the past five years. Most people are still using the same modes of ventilation and ventilating patients with manual ventilator settings. Even the so-called dual modes of ventilation are not automated, but rely on the human operator to determine the ventilator’s status. The major advances in improving patient outcomes have been the recognition of how lung protective strategies should be applied in order to prevent lung injury and in recognizing the need to get patients off the ventilator as soon as possible. We need to look at how technology can contribute to a systems approach to reliably apply evidence-based medicine and reduce errors.” Costa goes on to note that the very technology that is supposed to be the most beneficial brings with it inherent problems endemic to the technology itself, in that operating a complex ventilator increases the chances for operator error. He notes, “Short staffed ICUs and long hours increases the chance for errors. Fifty to a hundred percent more errors occur in the hospital when staff works more than 8.5 hours per shift. No one clinician can be an expert on all of the different modes of ventilation yet alone all of the differences in theory of operation among various equipment in the modern ICU.” He notes that the challenge is to automate what works best in ventilator technology, so the clinician can pay attention to the patient, not the instrument. As such, it is important for ventilators to present information in a way that can be of most benefit to the clinician.

At the same time, money considerations must become part of the ventilatory paradigm. But the ventilator can’t be viewed as simply a brute instrument costing X amount of dollars; cost-analyses must be tied to the function of the technology as far as it reduces overall costs, not just in terms of initial outlay for hardware. Says Costa, “The cost of acquiring and operating a ventilator is small when compared with the results of an improperly managed ventilator program. We are focused on the big picture, much like a health care administrator. Let’s take a look at the entire process and look for real savings for the patient and the health care continuum as a whole. The mechanical ventilator can be referred to as a killing machine. We don’t often see an organization with the courage to speak so frankly, but it holds all of us to a higher standard when we speak truthfully about the potential dangers involved in providing the best care for the patients that we all serve. It is estimated that it costs roughly \$5,000 per ventilator day in the ICU. Ventilator Acquired Pneumonia is the leading cause of death among hospital-acquired infections and prolongs time spent on the ventilator. Each incidence of VAP can add \$40,000 to the cost of the hospital admission. It seems that with the cost of operating any ventilator, that even a modest improvement in length of stay would have a dramatic effect on the entire facility. The term “sedation vacation” is relatively common today. We all know the reasons for this. A mechanical ventilator should free the patient to begin breathing on their own as soon as possible without need for human intervention to start the weaning process. Wean from the start. Getting the patient breathing on their own and off the ventilator is of paramount importance to saving costs to a hospital.” He concludes that ventilator manufacturers need to pay attention to just this issue when promoting their products. “Fair pricing that is simple and easy to understand allows for companies to offer the other elements that provide those results that are truly needed.”



Les Plesko, Editor



## Respiratory Therapy™

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## Table of Contents

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### DEPARTMENTS

9 Editorial: Keep Breathing

13 News

14 Products

18 Executive Profiles

### SPECIAL REPORT: VENTILATION

20 Ventilation News

21 Understanding APRV

22 Products/Spotlight

24 Ventilation Roundtable

40 Executive Profile

40 f/Vt Ratio

42 Early Tracheostomy

43 Protective Ventilation Strategies

44 Facility Profile: AnMed Health

46 Hydrocarbon Poisoning

49 High-Frequency Ventilation

55 Case Study: Pediatric Asthma

### ARTICLES

58 Herbal Medicine and Coughing

66 Cough Sounds

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## CAN'T BREATHE

Theories come and theories go, but asthma remains a mystery, according to a recent article in the *New York Times*. Statistics suggest that from 1980 to 2003, the prevalence of asthma in children rose from 3.6 to 5.8%, an increase of 60%. Asthma rates for younger children jumped 160% from 1980 to 1994. About 20 million people in the US have asthma, and 5,000 people a year die from it, according to the CDC. But why the increase? Dust, mites, dust-mites – a whole industry has grown up around purifying our air, according to the *Times*. Also blamed are pets, allergies, genes, weight gain, vitamins, antioxidants, diets, hygiene. One recent theory is that growing up in too clean an environment doesn't allow for building up immunities to substances. Recent studies say kids raised on farms are less prone to asthma, perhaps because of exposure to microbes in barns and stables. Another notion is that the prevalent use of antibiotics has led to new types of bacteria that cause asthma. Yet another suggestion is that acetaminophen may be linked. But none of these theories have been proved. Reported by Denise Grady in *The New York Times*.

## FROM MICE TO MEN

Acute lung injury caused by cell death, high and potentially toxic concentrations of oxygen (hyperoxia), and the resulting excess fluid in the lungs (pulmonary edema), may be controlled by modulating levels of the angiopoietin2 (Ang2) protein, researchers at Yale School of Medicine reported. The study looked at the response to hyperoxic acute lung injury (HALI), first in mice and then in human adults and babies. The team found that mice in which the Ang2 gene was genetically eliminated or silenced lived longer and had evidence of decreased lung injury compared to mice in which the gene and protein were intact. Levels of the Ang2 protein were then measured in the blood and lung fluid of adult patients and babies with acute lung damage and pulmonary edema. The team found that levels of Ang2, which is known to increase leaks in blood vessels and causes the death of endothelial cells that line the blood vessels, were higher in adult patients with acute lung injury and in babies born with respiratory distress syndrome who either went on to develop bronchopulmonary dysplasia or died. Mice without Ang2 seemed to be protected against hyperoxia. The protein seemed to be a mediator of cell death in the settings of high oxygen concentrations in the lung causing acute lung injury and pulmonary edema. In addition to acute lung injury and pulmonary edema, an increase in Ang2 and cell death could be seen in other disorders such as heart attacks, stroke, eye disease in diabetics and brain tumors.

## FIX IT YOURSELF

The lungs of patients suffering COPD attempt to repair damaged elastic fibers, according to a new finding that contradicts the conventional wisdom on the capabilities of the adult lung. The study "Evidence for attempted regional elastic fiber repair in

severe emphysema," by Jason Woods, et al, found that synthesis of elastin, a gene linked to elastic fiber growth, is increased in the moderately diseased tissue of COPD patients. Elastic fibers allow the lung to expand and contract with breathing. "We've found elastin synthesis to increase in the air sacs (alveoli) and airways of the lungs of patients suffering severe or end-stage COPD," Woods explained. "This shows that the lung may be attempting to repair itself." The finding is important because it could pave the way to develop a drug to 'turn on' key genes to allow the lung to grow new alveoli, he said. Alveoli play a role in the exchange of oxygen and carbon dioxide between the lungs and the circulatory system. Very young children who suffer lung injuries increase elastin expression and produce new elastic fibers inside the alveoli, Woods said. Adults do not have that ability and that has led physiologists to conclude that the elastin gene must shut off after we reach a certain age, ending elastin fiber production. In a preliminary study, the researchers examined two diseased lungs removed from end-stage COPD patients undergoing lung transplants. COPD develops as a result of exposure to toxins such as cigarette smoke, resulting in inflammation to the small airways and destruction of elastic fibers within alveoli. The patients suffered from emphysema. The team used hyperpolarized magnetic resonance imaging (MRI) to characterize the regions of the lung showing moderate emphysema and regions showing severe emphysema. They found that new elastin synthesis was initiated in moderately diseased specimens. The researchers did a second study using 10 lungs from end-stage COPD patients who had undergone transplants. Again, they found the greatest amount of elastin gene expression in the moderately diseased areas of the lungs, Woods said. There was no variability in elastin levels within the control lungs. Further, the team found that the increase in elastin expression occurred on the alveolar walls, the same area where elastin occurs during the lung's development in children. This shows the lung is attempting to repair the elastic fibers in end-stage emphysema, the authors concluded.

## HALF THE CARE

A study in the December issue of the medical journal *Chest* shows that Americans with chronic obstructive pulmonary disease (COPD) receive only about half of the recommended medical care, with care varying significantly based on individual conditions. COPD is the fourth leading cause of death in the United States. In the *Chest* article, the authors state, "We can estimate excess mortality that might result from failure to provide care specified in individual indicators. For example, only 32% of COPD patients with baseline hypoxia received home oxygen for routine management. From estimates of the numbers of hypoxic patients in the United States and the mortality reduction demonstrated from the Nocturnal Oxygen Therapy Trial, 27,000 to 54,000 annual deaths may have been reduced by appropriate oxygen use." The National Heart, Lung, and Blood Institute (NHLBI), part of the National Institutes of Health, is launching with the Centers for Medicare & Medicaid Services a six-year, \$28 million randomized clinical trial of the effectiveness of long-term, home oxygen therapy for COPD. In this Long-term Oxygen Treatment Trial, researchers at 14 clinical centers across the United States will study about 3,500 patients with moderate COPD to determine whether supplemental oxygen will help them lead "longer, more active, and better quality lives," said a statement from NHLBI. The study aims to help CMS decide whether to extend coverage for home oxygen treatment to patients with moderate COPD. Currently, Medicare limits coverage of home oxygen therapy to

beneficiaries with severe COPD (very low blood oxygen levels while resting). Patient recruitment for the trial is expected to begin in late 2007. Participants will be randomly selected to receive or not to receive supplemental oxygen for approximately three years.

## **ANTI-BRONCHITIS**

Antibiotics are routinely prescribed unnecessarily for acute bronchitis, according to Virginia Commonwealth University. The VCU School of Medicine researchers concluded there is no evidence in current literature to support prescribing antibiotics for the treatment of short-term bronchitis as almost all the causes of such infections are viral and therefore don't respond to the therapy, according to the study.

Researchers examined studies and clinical trials regarding acute bronchitis as they related to individuals, pathology, diagnosis, treatment strategies and any data supporting the potential benefits of anti-bacterial agents. They found that almost all the known causes of acute bronchitis are viral and are caused by organisms that have no known therapy and cannot be influenced by antibiotic treatment. Only a small percentage of acute bronchitis cases are caused by bacteria that physicians can treat, such as whooping cough. Researchers said that, nonetheless, approximately 70 percent to 80 percent of individuals are prescribed antibiotics for treatment lasting five to 10 days. In addition to little evidence supporting the effectiveness of antibiotics for the treatment of acute bronchitis, antibiotics can be expensive and may cause adverse side effects such as abdominal pain, diarrhea and rash that may require further treatment. Furthermore, induced resistance to antibiotics makes them less useful for treatment against other infections.

Researchers also found that although prescription cough medications are prescribed in almost 100 percent of acute bronchitis cases, the literature showed little evidence of any effect.

## **NOT SO FAST**

Data presented at the North America Cystic Fibrosis Conference (NACFC) showed that cystic fibrosis patients who used Pulmozyme experienced a slower rate of lung function decline and an immediate improvement in lung function, as compared to cystic fibrosis patients not treated with Pulmozyme. This data is important because progressive lung dysfunction and deterioration in patients with cystic fibrosis (CF) contributes to respiratory failure which causes 90% of all deaths associated with the disease. CF is the most common fatal genetic disease affecting approximately 30,000 people in the U.S. People diagnosed with CF have a genetic defect that causes thick secretions in the lungs that can lead to airway obstruction, persistent lung infections and progressive deterioration of lung function. The data was from the study "Pulmozyme (dornase alfa) Use is Associated with a Slower Rate of Lung Function Decline in Patients with Cystic Fibrosis," by Dr Michael Konstan, Rainbow Babies and Children's Hospital, Cleveland, Ohio.

## **TOO FAT TO FIX**

Healthcare providers treating obese patients are often up against problems endemic to overweight patients, according to a paper by Brown and Velhamos, "The consequences of obesity on trauma, emergency surgery, and surgical critical care," in the

World Journal of Emergency Surgery. According to the authors, "Central to the pulmonary pathophysiology associated with obesity is an increased work of breathing due to variety of factors including increased chest wall resistance, increased abdominal pressure altering diaphragmatic position, and even respiratory muscle dysfunction. In fact, many pulmonary function measurements are decreased in obese individuals including tidal volume, vital capacity, total lung capacity, and function residual capacity. However, despite lower lung volumes, obese patients actually have higher minute ventilation (due to an increased respiratory rate) in an attempt to compensate for an associated increase in oxygen consumption and carbon dioxide production.

Two other common pulmonary comorbidities, which may impact the care of obese surgical patients, include the Obesity Hypoventilation Syndrome and Obstructive Sleep Apnea. The Obesity Hypoventilation Syndrome, usually seen in the super-obese is characterized by hypercapnic respiratory failure and alveolar hypoventilation. The clinical implication of this syndrome is a worsening of the chronic hypoxia and hypercapnia of obesity leading to even higher minute ventilation. In severe cases the extreme pulmonary compromise associated with Obesity Hypoventilation Syndrome may even lead to right heart failure. Obstructive Sleep Apnea will complicate the care of the obese surgical patient." The authors point out that, "obesity is generally considered a risk factor for a difficult airway. Despite difficulties most obese patients should be able to be orotracheally intubated. However, salvage techniques such as laryngeal mask airway and awake fiberoptic intubation may be necessary. The salvage airway for a surgeon, a cricothyroidotomy, may prove difficult in an obese patient due to a large neck, deep position of the trachea, distorted anatomy and inability to use standard length tracheostomy tubes. Once a definitive airway has been established issues with mechanical ventilation must be considered, keeping in mind the deranged pulmonary physiology of obese patients. When placing an obese patient on the ventilator, calculations of tidal volume should use ideal body weight rather than actual weight in order to minimize barotraumas or volutrauma. As obese patients present with chronic hypoxia and hypercapnia, simple measures such as reverse Trendelenburg positioning, positive end-expiratory pressure, or continuous positive airway pressure in the sleep apnea patient may improve pulmonary function. Obesity seems to be associated with adverse pulmonary outcomes in the surgical ICU, and trauma patients admitted to the ICU more often had ARDS, required two more days of mechanical ventilation, and more often failed attempted extubation." Reported in the World Journal of Emergency Surgery 2006, © 2006 Brown and Velmahos; licensee BioMed Central Ltd, an Open Access article distributed under the terms of the Creative Commons Attribution License.

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## HOT AND HUMID

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## NEWS FROM MASIMO

**Dräger Medical AG & Co KG** today announced that it has expanded its relationship with Masimo and will integrate **Masimo Rainbow SET** platform as its principal pulse oximetry technology. The Rainbow SET platform offers Masimo SET Read-Through Motion and Low Perfusion pulse oximetry plus upgradeability to add other parameters in the future. Upgrades are available today for carboxyhemoglobin (carbon monoxide) and methemoglobin and others are planned for the future. Dräger Medical will be incorporating Masimo Rainbow SET into major acute care products. For future product developments, Dräger Medical will replace its Oxisure+ oximetry with Masimo technology... Masimo, the inventor of Pulse CO-Oximetry and read-through motion and low perfusion pulse oximetry, reported that multiple independent studies were presented last week at the 2006 American Society of Anesthesiology (ASA) Annual Meeting in Chicago, each reinforcing the superiority of **Masimo SET** in providing accurate, reliable pulse oximetry readings. In the studies, Masimo SET was shown to "work better for patient safety" during the most difficult clinical conditions of motion and low peripheral perfusion... Masimo announced it has received FDA clearance for **Masimo Radical-7**, the first bedside monitor to feature the award winning Rainbow technology, which was introduced at the Annual Meeting of the American Association of Anesthesiologists October 14-18 in Chicago. Two new Radical-7 bedside monitors with different user interfaces including a color display are available with Masimo SET with Rainbow technology, the first and only way for clinicians to continuously and noninvasively monitor their patients' carboxyhemoglobin (SpCO), methemoglobin (SpMet), oxygen saturation (SpO2), pulse rate, and perfusion index.

Masimo SET with Rainbow Technology has already proven to be effective in detecting carbon monoxide and methemoglobin poisoning in critical situations, allowing accurate diagnosis and

early treatment of life-threatening conditions. Last month at a hospital in Southern California, a patient was diagnosed with a Rainbow monitor to have a dangerously high level of methemoglobin. Because of this timely diagnosis, the patient was immediately treated and the patient's life was saved... Masimo announced it has received a prestigious **Medical Design Excellence Gold Award** for its innovative new Masimo Rainbow SET Rad-57 Pulse CO-Oximeter. Masimo has also recently received **FDA clearance** for the noninvasive measurement of methemoglobin levels in the blood. A recent Johns Hopkins study found that methemoglobinemia, a potentially lethal condition that starves the tissues of oxygen, is much more common in hospitalized patients than previously realized... **Respironics, Inc** announced that it has decided to expand its relationship with Masimo and to adopt Masimo's pulse oximetry solution for situations requiring read through motion technology across all of its business units. Until now Respironics has only used Masimo SET in certain of its sleep and respiratory products. Respironics will be gradually incorporating Rainbow SET in all Respironics products where the improved capabilities will provide clear clinical improvements. Contact [masimo.com](http://masimo.com).

## SHOWCASED

PARI Respiratory Equipment's Hydrate, the first heat and humidification system which uses C-Force technology, was unveiled at the 52nd International Respiratory Congress held by the American Association of Respiratory Care December 11-14 in Las Vegas. "PARI's Hydrate is a great example of partnership collaboration that results in a profound benefit for patients," said Werner Gutmann, president of PARI Respiratory Equipment. "Hospitalized patients that are put on oxygen, whether through a nasal cannula or ventilator, need fully humidified gas at the correct temperature for proper treatment. Hydrate not only delivers completely saturated and heated gas but is small and light enough to introduce the therapy near the patient, eliminating the need for large bore tubing or heated wires." When higher flows of oxygen are administered to patients by means of mechanical ventilation, the upper respiratory tract is bypassed entirely and there is no opportunity for the body to heat and humidify the incoming gas. When high flows of oxygen are administered non-invasively (such as with a nasal cannula), the upper respiratory tract has difficulty adding adequate amounts of heat and humidity before the supplemental oxygen is delivered to the lower respiratory tract (trachea and lungs). The PARI Hydrate G.33 with C-Force Technology uses a capillary force vaporizer, which is about the size of a large aspirin tablet and made of ceramic to heat and humidify up to 40 L/min of gas flow. When liquid is supplied to the bottom of the disc, capillary forces lift the liquid through the disc – similar to the way water is brought to the top of a tree. Heat is then applied through the top of the disc and the water undergoes phase transition into a vapor, expands, and is released under pressure through an opening. The PARI Hydrate for high flow gas therapy will be available for distribution this month pending FDA clearance. PARI's Hydrate features C-Force Technology that uses a capillary force vaporizer licensed from Vapore, Inc. Founded in 2001, Vapore, Inc is the creator of a new method of liquid vaporization – the capillary force vaporizer. Contact [pari.com](http://pari.com).

## SLEEP TIGHT

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to save you time and improve your results. Inspirex provides manual and automated tools for smooth data collection, rapid analysis, flexible reporting, data management, synchronized MPEG4 digital video, patient scheduling, quality assurance, and security and privacy features. Inspirex is used with the Connex amplifier for fixed and portable studies and the Trex amplifier for ambulatory recordings. Both these rugged amplifiers have superior signal quality and stability and can be used for EEG studies as well. Connex has 50 clearly labeled input channels – including an integrated MasimoSET oximeter – and TCP/IP and USB connectivity for quick and easy installation. Trex is small and lightweight making it comfortable for all your patients and can record for up to 96 hours. (800) 387-7516; sleep@xltek.com; xltek.com.

### SOUND SLEEP

The following was reported by Linda Loyd, in *The Inquirer*: In Philadelphia and across the country, sleep-diagnostic centers are popping up and people once aggravated by a lousy night's sleep are getting help. One beneficiary of the push for more testing is a local company, Viasys Healthcare Inc, which makes medical equipment including devices to diagnose and treat sleep ailments like sleep apnea, a condition in which breathing stops repeatedly for brief periods during sleep. In the five years since Viasys was spun off from a Boston-area company, Thermo Electron Corp, sales of its respiratory and sleep-diagnostic equipment have grown, and now account for 63 percent of its \$600 million in annual revenue. With products sold in 140 countries, Viasys is one of the world's largest manufacturers of sleep-diagnostic equipment used by physicians and sleep labs, including the Drexel University College of Medicine Sleep Center in Manayunk.

Viasys is number 2 in market share in sleep diagnostics. When Viasys was spun off in 2001, it had 14 divisions that were consolidated or sold. Since then, the company has acquired 13 businesses and spent \$100 million on research and product development. Today, Viasys focuses on four medical-technology areas: neurology diagnostics and monitoring, medical disposables such as feeding tubes and catheters, orthopedic products including artificial hips and knees, and respiratory devices. Its largest and fastest-growing business is respiratory care: mechanical ventilators, lung-function-testing equipment, and sleep-diagnostic devices. Where Viasys wants to get bigger is in sleep therapy. Viasys has acquired two CPAP manufacturers, Tiara Medical Systems and Hoffman Laboratories Inc. Hoffman Labs makes a wearable CPAP device with a built-in rechargeable battery that does not need to be plugged in. Viasys is headquartered in Conshohocken, PA, with manufacturing sites in Yorba Linda and Palm Springs, CA and elsewhere. It employs 2,400 workers and oversees hundreds of product distributors.

### eVentFUL

On November third eVent became a subsidiary of Kobayashi Medical America LLC, a subsidiary of Kobayashi Pharmaceutical Japan. The company was founded in 2000, and has released five ventilators in its Inspiration line. Kobayashi Medical, serving the healthcare market in Japan, is a \$2.1 billion healthcare company. The leadership of eVent is now in the hands of Kirk Inoue, the founder and former CEO of Newport Medical for 18 years and long-time participant in the ventilator care industry. Inoue will serve as the Chairman and Chief Executive Officer. Stephen Tunnell RRT, co-founder of eVent Medical, will serve as President, Chief Operating Officer and member of the board. The company expects to accelerate its record of releasing innovation and customer focused services that exceed the expectations of the Global Respiratory Care market. Contact event-medical.com.

### BACK TO MARKET

Vapotherm, Inc announced that its 2000i High Flow Humidification Device has been reintroduced to the market after agreement by the FDA that the company can begin shipping the devices to customers. The company is notifying its hospital and homecare customers to arrange for shipment of devices. The devices are being returned to customers with new instructions for use, including the recommendation to utilize only sterile water in the system. "Vapotherm is pleased to return the 2000i and High Flow Therapy to our users," said Robert Storey, President and CEO... "During the recall period, we received a tremendous outpouring of support from health care practitioners, patients and their families, all voicing the importance of this technology in providing non-invasive respiratory support. We extend our sincere appreciation to our customers and partners for their patience and support during this period." Complete information on the corrective actions, recall, product operation and safety is available on the Vapotherm 2000i Reintroduction Information website at <http://www.vtherm.com/customers/education.asp?section=1>. For additional information or to schedule an in-service session, please email [info@vtherm.com](mailto:info@vtherm.com). Vapotherm, Inc is a privately held manufacturer of respiratory care devices for hospitals and home care use based in Stevensville, Maryland. The company is dedicated to the development of innovative, noninvasive technologies for respiratory therapy especially for the treatment of chronic lung and acute breathing disorders. For more information, call (410) 604-3977 or visit [vtherm.com](http://vtherm.com).

## PRODUCTS ROUNDUP

**LifeGas** introduced its Helontix Vent, a noninvasive delivery system for administering helium-oxygen mixtures to patients. The system functionality allows for adjusting important parameters for noninvasive ventilation. Contact lifegas.com...

**eVent Medical** released a series of review papers about the following subjects: a review of the auto mode for post-operative patients, heliox ventilation, and quantifying clinically significant ventilator performance. The company recently became a subsidiary of Kobayashi Medical America LLC. For more contact event-medical.com... The Board of Directors of **AARC** has approved a legislative initiative aimed at providing Medicare patients with greater access to respiratory therapy services that are not difficult or impossible to obtain. The initiative will take the form of a legislative revision to current sections of Medicare Part B. The changes would allow Medicare to cover the delivery of respiratory services in a variety of patient care settings outside of the hospital... The AARC honored the following companies at its 52<sup>nd</sup> Congress's **Zenith Awards**: Cardinal Health, INO Therapeutics, Maquet, Nellcor Puritan Bennett, Respironics, and Viasys Healthcare... **Cardinal Health** signed an agreement with **Fisher & Paykel** Healthcare to distribute new ventilation masks and high flow therapy products. The noninvasive mask products include full-face masks and nasal masks. The high flow oxygen therapy products deliver humidified flows that meet peak inspiratory demand. Contact cardinal.com... **Parker Hannifin** announced the release of its HF 200 high performance valve, a high flow proportional valve that provides flows up to more than 200 slpm while consuming less than 2 watts of power. The compact valve features both barbed and face seam manifold bodies, and is ideal for applications requiring low hysteresis and fast response. Also available from the company is the HF Pro, a high flow proportional valve and VSO-EP, a module for precision control

of critical system pressures. The company's Pneutronics Division announced expanded pressure capability and the highest flow available from its T Squared family of diaphragm pumps with the release of the T2-06, a compact diaphragm pump. Contact pneutronics.com... **Parker Life Sciences** offers its LQX, a 12 mm diaphragm isolation solenoid valve that provides space savings, flexibility, reliability and application-specific performance. Contact parker.com... **Smiths Medical** launched its Acapella duet vibratory PEP therapy system. It features a built in port that accommodates most small volume nebulizers, and clinicians will be able to deliver small-volume nebulizer treatments and mobilize secretions at the same time. The unit can also be used as a standalone therapy. Contact smiths-medical.com... **Oridion Systems Ltd** was selected as the recipient of the 2006 Growth Strategy Leadership Award by Frost & Sullivan. The award recognized the quality of Oridion's Microstream technology and the company's strategy in launching capnography monitoring into hospital and pre-hospital environments outside the operating room. Contact oridion.com.

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1 Todd Ellen, RPSGT-Sleep Review™ Sept. 2005  
2 Richard Berry, MD-CHEST Sept. 2005  
3 William Orr, PhD-APSS 2003



## EXECUTIVE PROFILES

### Dymedix

Dianne Marth

Dianne Marth is with Dymedix.

#### **Who is responsible within your company, by title or name or job description, for training and education of your staff and your customers?**

The Technical Sales Manager is responsible for training the staff of Dymedix. In addition, our Project Manager will perform monthly review of new products on ongoing technology enhancements. Each Regional Representative is then responsible for performing product in-service on the use of our sensors.

#### **How do you manage “off-hours” assistance for clinical questions? Do you provide technical service support, and of what nature?**

An R.Psg.T provides all of our “off hours” assistance 24 hours. As a sleep sensor manufacturer, all of our products are plug and play and require very little, if any technical assistance. We do provide a toll-free 24 hour number that is answered 24/365.

#### **What do you feel is important to support the customer/end-user of your product?**

The most important aspect in support of our product is educating the end-user on our technology. We are not a thermistor, not a pressure transducer and not a pneumotach. Yet, based on our patented technology PVDF (polyvinylidene fluoride), we are able to provide the same quality signal as an air-pressure transducer, pneumotach and esophageal balloon, without the practical and technical limitations of those invasive products.

#### **What activities does your company undertake to promote the product?**

Dymedix actively advertises in trade journals, including feature pieces published in Chest and Sleep Diagnosis and Therapy. In addition, Dymedix is aggressive and actively participates in regional trade shows and symposiums. Furthermore, Dymedix makes itself available to perform product in-services, including 30-day product evaluation at no charge.

#### **How does your company reach out to its customers regarding product performance and R&D?**

This is a very important aspect of our business. We have struggled with R&D over the past 5 years. We were focused on ourselves without listening to the customer. This has changed. We now proactively solicit customer input in everything we do. The most important person to help us improve our products is the end user. We currently have 20 new products in the pipeline that will be introduced within the next 18 months. We would not have been able to this unless we listened to our customer's wants and needs.

#### **Where do you see the future of your product in relation to end-user requirements?**

We look at the future in several ways. First, we are the only sensor company in the market that provides a complete line of

reusable and disposable sensors that are capable of producing the most clinically appropriate waveform based on the customer's needs. Reimbursement criteria differ from state to state and payer to payer. Based on the customer's needs, we can offer a thermistor quality signal, air pressure transducer quality signal, or our RERA, pneumotach/esophageal balloon quality signal. Second, we have a complete line of disposable pediatric, infant and neonatal sensors that provide a very accurate signal to meet the needs of these demanding patients. We see the future of pediatric sleep studies as the fastest segment of the sleep market. Lastly, as our mission statement mandates “Helping advance the science of sleep medicine,” we are constantly searching for “new-new” technology. We know we can produce a sensor even more sensitive than our RERA sensor, and have recently discovered a potential clinical application. This will be a giant leap forward in advancing the science of sleep medicine.

### Somnotech

R. Patrick Karem

R. Patrick Karem is CEO and Founder of Somnotech.

#### **Please describe your products or product line and what sets it apart from other products in the field.**

Somnotech was formed in 2005 to be a distribution channel for sleep products that are made in Germany. We are partnered with two of the largest sleep products companies who have been long established in Europe, are market leaders, and wanted to enter the US market. What sets the Somnotech product line apart from the other manufacturers, is simply, better engineering and better quality. The Somnotech product line, everything from masks to CPAP units are the quietest most reliable units on the market today.

#### **How does your product or improvements in your products directly affect patient care?**

If you ask most CPAP patients what are the two biggest complaints they have, they will tell you comfort and noise are the biggest issues patients have today. Most mask products on the market today lay flat on the face and require a very tight headgear to achieve a good seal and are very noisy to sleep with. The SomnoPlus and Soyala mask products are designed to fit all the contours of the face with very little pressure and are 15% quieter than anything on the market today.

#### **Describe the future for Somnotech and for sleep in general?**

Well, the future for Somnotech looks fantastic. We are becoming known in this market and patients are starting to ask for our products specifically. Once we introduce the complete line of products to the US, the potential is endless. In 2007 we will introduce two new CPAP units and 3 new masks. One of the largest growth areas will be in the area of pediatric sleep. Many physicians and clinicians are just starting to understand pediatric sleep, and the role that it has in the overall health of children today. I am very pleased that manufacturers are starting to address this market and assist our children in sleeping better.

# The Respiratory Group (TRG)

Mycalene Berkbuegler

Mycalene Berkbuegler is Advertising and Trade Show Coordinator for TRG.

## **What led you to develop the products you wish to discuss?**

The Escort ultra lightweight portable LOX hit the market in 2001 because we felt there was a need for more options for liquid oxygen patients. We promote freedom by offering lightweight reliable systems and it's our mission to develop quality low-cost oxygen products to providers of healthcare in an effort to grow their businesses and in turn provide more options for patients. Quality and versatility were most important in the original design. We've developed both a 20 and 50-psi system, with the option of a pneumatic or electronic Escort. Also, our customers are able to choose from a variety of fill ports. They are then able to fill the Escort with their existing reservoir base units. Since our Escort hit the market we've continually gathered feedback which has led us to the introduction of the New Electronic Escort. This portable is entirely shaped around patient's needs and customer's requests. The batteries last around 3 months, cutting down on maintenance calls. The conserver is more durable. Also, patients feel that the new dark chic color helps conceal their oxygen system.

## **What level of user input has gone into the design and development of your product? How do you coordinate comments from clinicians and users into your design and production?**

User/patient input is number one around here. It has to be. Our customer, the provider, works very closely with the patient and when they receive feedback, pass the information on to the manufacturer, us. It happens immediately and is a somewhat constant process. We work very close with our customers when developing new products and improving or tweaking existing products. TRG's engineering and manufacturing capabilities are unlimited and at times a product may be developed solely because of interests or requests from customers. The feedback received is analyzed, of course taken very seriously and then utilized by our engineering department.

## **What is your wish list for future improvements and advances for this product?**

Our wish list includes introducing an oxygen system that is smaller, lighter and less expensive.

## **How did you determine the price for this product and how do you apportion costs for R&D into the design/production/sales process?**

It is important for us to keep prices low to give providers more options and yet our main focus is manufacturing a high quality oxygen system. We make sure never to sacrifice quality to make a profit. We believe in value. Giving your customer the best value is what is most important. We do not have a large sales force to visit customers, doctors and other healthcare providers nor do we have a huge advertising budget. As far as R&D and sales are concerned we rely on the close relationships we keep with our customers, the few advertisements we post in the trade magazines and of course word of mouth.

## **Please discuss your company's quality control process and the benefits for the provider of healthcare.**

All of our oxygen systems and products have great warranties which add an extra level of comfort for providers. Along with great warranties, we have training and support to ensure the customer is happy with their oxygen systems. In the event of a return, our Quality Control collects detailed data and examines each individual situation closely. They work together with the engineers who handle feedback to improve training processes for our customers and end users and also work toward user friendly changes to our liquid systems.

## **Discuss support you provide for product users.**

The toll free Customer Care number, (877) 877-3774, is printed on the product's user manuals and we encourage patients to call with questions and comments. Also, our technical support team will visit customers to train and answer questions.

## **Discuss any other important product features.**

The liquid oxygen capacity of the Escort portable is .38 liters. It weighs 4 lbs when completely full and lasts up to 7 hrs and 50 min. I would like to also mention that the quality, versatility and value you find with the Escort, you will also find in all our products manufactured at TRG, Inc. The Respiratory Group is certified for the design, manufacture, final inspection and distribution of liquid oxygen systems, oxygen cylinders and oxygen regulators. TRG holds the following certifications: DIN ISO 13485:2003 Quality Systems for Medical Devices, ISO 13485:2003 DQS Canadian Standards and EU Council Directive 93/42/EEC concerning Medical Devices with the EU authorized representative being MDSS.

# Ventilation News

□ Special Report on Ventilation

## BOTTOM LINE

DRGs: Could they impact your hospital's bottom line? That's the question Paul Garbarini, MS, RRT, asks in a recent issue of Hamilton Medical's Intelligent Ventilation newsletter: The current issue of AARC times reports that the CMS (Centers for Medicare and Medicaid Services) has created several new ventilator DRG's. To quote the AARC times, "The data clearly show that DRG 416 septicemia patients who are on mechanical ventilation for 96 or more hours have a significantly greater severity of illness level and use greater resources than do other patients in DRG 416. Those patients on mechanical ventilation for 96 or more hours had average charges of \$94,994 compared to \$25,709 for other patients in DRG 416. We found no cases in DRG 417 with patients who reported mechanical ventilation for 96 or more hours. Therefore, we agree with the commenter's that patients in DRG 416 who are on long term mechanical ventilation of 96 or more hours have greater severity of illness and use significantly greater resources. These patients should be assigned to a separate DRG to better reflect their higher severity level. Because we have no data on patients in DRG 417, we are not modifying that DRG at this time. Because the data on DRG 416 are compelling, we are deleting DRG 416 and splitting these cases into two new DRGs based on whether or not the patient is on mechanical ventilation for 96 or more hours. These two new DRGs are as follows: DRG 575 (Septicemia with Mechanical Ventilation 96 + Hours Age >17) DRG 576 (Septicemia without Mechanical Ventilation 96 + Hours Age >17). Cases will be assigned to DRG 575 when they have a principal diagnosis from current DRG 416 and code 96.72 (Continuous mechanical ventilation for 96 consecutive hours or more). Cases will be assigned to DRG 576 when they have a principal diagnosis from current DRG 416 and do not have code 96.72."

## BETTER BREATHING

Healthcare professionals need to develop greater understanding of the quality of life issues facing the growing number of children who use a portable mechanical ventilator to help them breathe, according to research in the latest Journal of Advanced Nursing. The six-year study - which asked children and parents for their views - discovered that most of the under 18s create their own ventilator-dependent lifestyles and have a good quality of life, but low self esteem and social exclusion remain major problems. Professor Jane Noyes from the University of Wales, Bangor, carried out in-depth interviews with 53 ventilator-dependent children, together with 50 mothers and 17 fathers. A third of the 53 children included in the study, who ranged from one to 18 years-old, had received spinal or head injuries. The remainder had congenital conditions. Professor Noyes found that the children's health improved when they were ventilated and that they were able to experience life more fully if they had

sufficient breath. "I have better speech, I can taste better, smell better" said an eight year-old on 24-hour ventilation via a tracheostomy. And a teenager who had just acquired a car under a motability scheme spoke of how he wanted to pass his test and "do everything everybody else does." Spending less time in hospital and feeling less tired were other positive benefits of home ventilation. The level of ventilator use appeared to have no bearing on children's perception of their overall health, but it did have an impact on their quality of life. Some children didn't realize that their life was that different from non-ventilated children, while others realised that children who didn't need to use a ventilator enjoyed far more freedom and varied life experiences than they did. Children who were being ventilated as a result of a serious illness or accident were particularly depressed at the way people now viewed them as a ventilator-dependent child and angry at the many barriers that prevented them from taking part in the activities they once enjoyed. Another was upset that friends had drifted away. "They used to come here every day - but now they don't. I wanted to be friends but they didn't." In contrast, children who had depended on ventilation for all or most of their lives, and knew nothing different, appeared to have adapted to their circumstances. However, many still disliked being treated differently to non-ventilated children. Children in the study generally associated a good life with a number of quality of life experiences, including: being treated with respect, being able to communicate effectively, being able to live at home in quality housing, receiving quality services, being able to get out of the home and take holidays, having a good social life, receiving a good education and being able to make decisions and gain independence. The children featured in the six-year study lived in a number of locations throughout the UK. They covered a wide age range - 11 were under five, 24 were aged six to 12 and 18 were teenagers. A quarter were from single parent families, a quarter were from ethnic minority groups and six per cent were in care. Some needed to be ventilated 24-hours a day, while other only needed to be ventilated overnight or when they were asleep. Ventilator use frequently increased during periods of acute illness.

## DEADLY FUMES

The Miami Herald Reports: When the security guard arrived in the hospital emergency room, he was dizzy and had a headache - vague symptoms that a nurse could have brushed off easily. But in this case, the nurse, aided by a new device, triggered a series of events that led to the evacuation of 100 persons from a 20-story condo that had lethal levels of carbon monoxide, perhaps saving untold lives. "I can't tell you definitely that people could have died, but it came close enough that it shook us up big-time," said Mary Russell, an ER nurse at Boca Raton Community Hospital. The Boca case began at 1:50 p.m. on Sept. 7. "We had a very astute charge nurse, and when he mentioned he smelled some fumes, she asked if he had been around generators," said Russell, a research preparedness specialist at the hospital. "He said yeah. Construction was going on in the building. Carbon monoxide was already very much on our radar screen, and we had just gotten this new device, a Masimo Rad-57." Until the arrival of this device, testing carbon monoxide levels in humans was a long and painful process, involving the removal of blood from an artery and getting a lab result. "That is exquisitely painful," said Russell. "Trust me, you don't want to do it." For that reason, most nurses avoid giving the test unless



it's absolutely necessary. But Boca had recently purchased the Rad-57, for about \$3,000, which measures carbon monoxide levels by simply attaching a sensor to a finger tip. The first device of its kind, it was introduced less than a year ago, says Tom McCall of the California-based Masimo. In the case of the security guard, his levels were extremely high. The hospital called Boca Raton Fire Rescue, which rushed its HazMed unit to the building. "They got a reading of 900 parts per million in the lobby," said Glenn Joseph of Fire Rescue. "That's 100 times higher than normal." Other areas showed readings of 500. The condo had been undergoing hurricane repairs, and the construction crews had generators going in the garage area, said Joseph. "We had them stop all operations." Rescue crews went floor by floor, telling the 100 or so persons in the building they needed to leave. Only one other person was taken to the hospital, said Russell. That person and the security guard were given oxygen and recovered quickly. For ER nurses, the problem is that carbon monoxide poisoning can often present itself merely as flu-like symptoms or food poisoning. Once in the ER, patients can tend to recover quickly since they're no longer near the fumes — complicating the ability to discover the cause. Masimo now has 41 Rad-57 units in the field in Florida, either in emergency rooms or possessed by "first responders" to the scene, McCall said.

## NEWS FEATURE

# Understanding APRV

Melissa Turner, BA, RRT

Melissa Turner is with Hamilton Medical, Inc. This article is from the company's Intelligent Ventilation newsletter.

The progress that has been made in medicine and technology has been phenomenal. Mechanical ventilation has also grown by leaps and bounds through application and research. However, there is some contention that clinicians are still unaware of how to best use modes of ventilation, or at least how to apply modes correctly. There are even modes available to the clinician that goes unutilized because of a lack of familiarity or education. Understanding all modes and tools that are available to use with mechanical ventilation would better serve the clinician and patient in order to achieve better care.

One would agree that no matter what mode is employed, there is a current set of goals that practitioners will strive to meet during the application of mechanical ventilation. First of all, ventilator induced lung injury should be avoided. Oxygen toxicity should also be kept to a minimum through the manipulation of mean airway pressure and/or PEEP. Recruitment of alveoli is done by increasing mean airway pressures and increasing positive end expiratory pressures. Inspiratory time may also be prolonged to increase mean airway pressures. These strategies are employed not only to help recruitment, but also to prevent derecruitment. Other goals are to minimize plateau pressures and optimize patient/ventilator synchrony. Lastly, another goal is to use sedation and paralysis

conservatively. As these goals of ventilation are pondered, practitioners may think of different ways in which they apply ventilation to achieve each of those goals specifically. There are several strategies that could be called upon to achieve the aforementioned goals. Some of the more familiar strategies include using the ARDSnet protocol which uses lower tidal volumes to limit plateau pressures and PEEP according to oxygenation requirements. Other lung protective strategies may be to use PEEP according to an individual patient's pressure/volume curve as well as using recruitment maneuvers. Closed Loop Control technology has even simplified attainment of ventilatory goals by implementing lung protective strategies. In this article, we will take a closer look at APRV (Airway Pressure Release Ventilation), as it is another strategy that can be used, but is often misunderstood. APRV has been described as "continuous positive airway pressure (CPAP) with regular, brief, intermittent releases in airway pressure."<sup>1</sup> The release produces a mandatory tidal volume to aid in carbon dioxide clearance. The CPAP level is elevated in order to achieve a mean airway pressure to aid in oxygenation while limiting peak airway pressures. The patient is able to breathe spontaneously anytime during any part of the cycle in APRV. Some of the indications for use of APRV are acute lung injury and low compliance where oxygenation and peak airway pressures are of concern. APRV also aids in airway disease as it unloads the respiratory muscles and helps to decrease work of breathing. It is also very helpful for hypoxemia due to shunting and decreased functional residual capacity. The advantages of APRV are many. Peak and plateau pressures are decreased. Use of sedation is decreased along with a near elimination of neuromuscular blocking agents. Alveolar recruitment is facilitated and diffusion of gases enhanced. Alveolar units with slow time constants are allowed time to fill by augmenting collateral ventilation while preventing over distention. The minute ventilation requirement is reduced suggesting less dead space ventilation. Circulatory function and tissue oxygenation is not compromised and there is a positive effect on the venous thoracic pump mechanism. Patients on APRV also have improved hemodynamics and a reduced need for pressure support. Spontaneous breathing during APRV improves ventilation-perfusion matching by preferentially aerating the dependent lung regions which are well perfused. Mechanically delivered breaths tend to ventilate non-dependent regions of the lung causing shunt to occur. APRV helps to prevent lung injury because the elevated baseline pressure produces continuous recruitment which minimizes low volume lung injury from cyclic recruitment. It is also less likely to produce over inflation or high volume lung injury since pressures are lowered to produce tidal ventilation. Some disadvantages of APRV are that the compliance and resistance of the lung does affect volume changes and should be monitored. APRV is a time-cycled mode and could create dyssynchrony during the release phase which could cause some discomfort to the patient. To date, this has not been identified a problem. Not all ventilators can deliver APRV which can be a problem for patients that are transferred from one area to another where APRV may not be available. APRV utilizes high mean airway pressures and there is no easy way to identify the optimal mean airway pressure to apply. How much is too much? Is it necessary to fully recruit the lung and does that overdistend adjacent 'normal' alveoli? Some feel that we should 'rest' the lung (ECMO being the ultimate example). Lastly, research is limited, but hopefully more utilization of this

mode will help to provide more research and reference. APRV has been available in the United States since the mid-1990s. Considering all of the advantages and the lung protective strategies employed by this mode, it seems it is possible that APRV has been under utilized. It has become available on more ventilators and is found under names such as APRV, DuoPAP+, Bi-Phasic and Bi-Vent. The under utilization of this mode may be a result of availability as well as education about the mode and how to apply it.

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## PRODUCTS

All information in the products section of the journal was provided by the companies named. It is Respiratory Therapy's policy not to print trademarks or registration marks.

### HAM IT UP

News from Hamilton Medical, Inc: The company launched a new website featuring "Intelligent Ventilation," which now has an expanded technologies section and user reports. There are also several new online presentations. Visit [hamilton-medical.com](http://hamilton-medical.com)... The company expanded its North American sales force. Joining the company are Richard Sobel, MS, RRT; Jennifer Hunter, RRT; William Nehring, RRT; and Tiffany Kirk, RRT. They'll be focusing on ASV, Adaptive Support Ventilation... The FDA has granted Hamilton 510(k) market clearance for its Galileo Gold Ventilator with ASV. ASV is a closed-loop technology developed to increase the safety and effectiveness of respiratory instrumentation... A hospital ventilator dubbed "the autopilot" has been introduced. It can protect patients' delicate lungs. The ventilator is similar to current products but uses advanced computer technology to make decisions regarding the patient's ventilator needs. Contact [hamilton-medical.com](http://hamilton-medical.com).

### INTUITIVE

Newport Medical Instruments, Inc announces the release of their newest generation of ventilators, the Newport e360. The Newport e360 Ventilator is simple to use and provides comprehensive mode selections, with graphics and extensive monitoring built into a single compact package. The e360 can easily transition from invasive to non-invasive ventilation for Adult, Pediatric or Infant patients. The e360 provides the latest features to help clinicians to improve comfort and speed weaning of patients from ventilation. With a truly intuitive user

interface, the e360 is quick to set up and easy to learn. The Newport e360's compact size, comprehensive features, safety management and low cost of ownership make it ideal for today's hospital and sub-acute facilities. Contact Newport today for more information. Contact (800) 451-3111, [ventilators.com](http://ventilators.com).

### NEW FOR EMERGENCIES

Draeger Medical, Inc announces the launch of its newest ventilation system, the Oxylog 3000, into the US market. The Oxylog 3000 received FDA clearance, offers ICU-level performance and mode range for adults and children. Designed for the demanding emergency and transport environments, the Oxylog 3000 is ideal for supporting critical-care patients in transfer situations. With its combination of volume and pressure-controlled and pressure support ventilation across the entire breathing cycle, the Oxylog 3000 delivers the high-end performance sought by today's caregivers. Oxylog 3000 provides the flexibility of both comprehensive invasive or non-invasive ventilation support, including the ability to provide automatic back-up support for spontaneously breathing patients in the event of apneas. In addition, the Oxylog 3000 features integrated PEEP, and 100% oxygen flush – providing three minutes of pre-oxygenation and inspiration hold, for use during X-ray imaging. The Oxylog 3000's tidal volume begins at just 50ml so it can be used for small children and adults alike. And its patented blender permits oxygen concentration adjustments between 40 percent and 100 percent with greater precision and range than previously possible. Designed and manufactured with the same attention to detail and performance as Dräger's high-end Evita ICU ventilators, the Oxylog 3000 represents a significant advance in emergency and transport ventilation systems. "From its large, high contrast display screen to its fast and easy control system, the Oxylog 3000 is built to support the needs of respiratory care professionals in a wide range of situations," noted Tim Scharn, marketing manager for Pre- and Post-Hospital Care at Draeger Medical, Inc. "We've greatly expanded the Oxylog's capabilities so that patients and caregivers benefit from its improved functionality, greater flexibility, and reliability. Featuring an entirely new design, the Oxylog 3000 is light, compact and easy to carry and use. It features a combination of the well-known Oxylog "knobs," for quickly setting the most vital parameters, and Dräger's familiar centralized rotary wheel for setting individual parameters. In addition, its robust, spray-proof construction and suitability for use in helicopters mean that the Oxylog 3000 can stand up to aggressive use in even the most extreme environments. Additional information is available on the Company's website, [draeger.com](http://draeger.com).

## SPOTLIGHT ON VENTILATION

### SMORGASBORD

SensorMedics offers the following products: The **SensorMedics 3100A** HFOV was first approved for use in 1991 and is the only HFV approved for early intervention treatment of neonatal respiratory failure. Use for pediatric patients failing conventional mechanical ventilation have been approved since 1995. The 3100A provides the ultimate in lung protection by inflating the lung with continuous distending pressure and superimposing very small pressure and volume swings.

Numerous publications have reported improved benefits and outcomes associated with the use of HFOV. The 3100A is the standard of care in more than 90% of Level III nurseries and 75% of Pediatric Intensive Care Units in the US... The

**SensorMedics 3100B** signals the arrival of the next generation of High Frequency Oscillatory Ventilators. Based on the established technology of the Model 3100A ventilator, the 3100B HFOV adds the enhanced performance capabilities necessary for adult ventilation and is approved for the treatment of acute respiratory failure in adults and large children weighing more than 35 kilograms. The 3100B allows the application of continuous distending pressures up to 55 cmH<sub>2</sub>O to recruit and normalize lung architecture while ventilating the patient with near deadspace tidal volumes for the ultimate in low stretch lung protection... **Avea** is an integrated ventilator and advanced monitoring system that meets the demanding needs of critical care practitioners. Neonatal through adult applications are provided as standard features on all models. Bicare advanced pulmonary monitoring and Heliox administration provides clinicians with the tools to improve clinical outcomes. Innovative engineering is evident in Avea's scroll pump compressor, the smallest, quietest medical air compressor on the market. Coupled with the ability to operate on battery power for up to two hours, this feature takes safety and wall independence to a new level. The Avea is a Viasys Healthcare Respiratory Care Inc product... Viasys is proud to include **Bird Blenders** in its family of products. The quality, reliability and versatility of Bird Blenders have made them the blenders of choice for more than thirty years. The worldwide reputation for consistent durability of the Bird Blender is recognized and honored. Customers have remained confident in the steady accuracy of delivered gas from Bird Blenders. Viasys provides a diverse line of blenders to meet the needs for a variety of purposes. Specific units have been designed for MRI facilities and nitrous oxide delivery. The company's precise, low-flow blenders are essential for NICUs and labor and delivery applications... The **Infant Flow Nasal CPAP** system was originally developed by **EME** as a single level nasal CPAP delivery system for the treatment of infants with respiratory distress. Since its introduction, the basic system has evolved into a bi-level device - Infant Flow SiPAP. Infant Flow SiPAP combined with the patented Infant Flow generator technology expands the clinician's non invasive treatment options with Biphasic and Biphasicr (international only), at the lowest work of breathing with maximum pressure stability... The **Vela Ventilator** from Viasys Healthcare has been sold successfully worldwide since 2002 into Intensive Care Units, Sub Acute departments and the Emergency Rooms. The Vela Ventilator is a versatile ventilator with comprehensive modalities for the patient requiring invasive or noninvasive ventilatory support. The new **Vela Diamond** ventilator features a new brilliant display screen, further enhancements to the graphical display with color coded waveforms denoting spontaneous breathing, and color coded icons to denote control advanced settings. The Diamond has increased processing power for greater upgrade capability with integrated communication capabilities. Visually the Diamond ventilator will have a new expiratory housing to contain and protect the expiratory flow sensor and exhalation assembly. The new Vela Diamond ventilator is the right choice for your invasive and noninvasive ventilatory needs... The **Vela** ventilator exemplifies the term "seamless ventilation." It has the ability to treat patients in any area of the hospital, a standard

six-hour battery to transport patients between departments and considers an endotracheal tube to be an optional interface. Masks and speaking valves pose no problem for Vela. Advanced monitoring such as 24-hour trending, loops, waveforms and weaning parameters give Vela all of the tools demanded by today's clinicians. Small in size, yet big on value and performance, Vela is the perfect choice for an all-round ventilator. Contact [viasyshealthcare.com](http://viasyshealthcare.com).

#### ASSISTANCE PLUS

Proportional Assist Ventilation Plus (PAV+) is a revolutionary new software option from Puritan Bennett. Designed exclusively for the 840 ventilator, PAV+ delivers positive airway pressure in direct proportion to a patient's own spontaneous effort to breathe. A sophisticated software algorithm then dynamically adjusts ventilator pressure to maintain a clinician-set level of support. At a setting of 60%, for example, the ventilator performs 60% of the work of inspiration and the patient performs 40%. A unique "Work of Breathing" bar provides clinicians with feedback on the adequacy of a chosen %Support setting with assessments of patient and total work of inspiration. Proportional Assist and PAV are trademarks of The University of Manitoba and are used under license by Puritan Bennett. Contact [puritanbennett.com](http://puritanbennett.com).

#### DO IT YOURSELF

Respironics, Inc announces the release of the Cadence Self-Breathing System. The System uses continuous high flow technology to treat hypoxemia (low blood oxygen) and potentially improve exercise capacity in hospitalized adults recovering from respiratory failure. The Cadence System augments self-breathing by delivering a high transtracheal flow of heated, humidified air and oxygen directly into the distal trachea through a fenestrated tracheostomy tube with a deflated cuff. "The Cadence Self-Breathing System is an innovative alternative to mechanical ventilation and other traditional therapies," says Steven McBrayer, product manager, Respironics, Inc. "Physicians who are considering self- or spontaneous-breathing trials for their prolonged mechanically ventilated patients should explore what this minimally invasive technology has to offer." In conventional treatments using a tracheostomy collar, T-piece or mechanical ventilation, air enters and exits the patient through the tracheostomy tube. However, due to the closed system created by the inflated tracheostomy cuff, the patient is not able to breathe normally through the upper airway. With the Cadence Self-Breathing System, warm, moist air and oxygen enter the lungs via a patented catheter system. In addition to this high flow technology, the patient is able to self-breathe in a normal, unrestricted fashion through the vocal cords, nose and mouth. The Cadence System also has the potential to improve a patients' exercise capacity, an essential component of successful pulmonary rehabilitation. The benefits of an improved capacity include less dyspnea and increased ambulatory ability, allowing the patient to perform everyday tasks more comfortably. In ICUs and LTACs, the Cadence Self-Breathing System should be considered for hospitalized patients recovering from severe lung injury or an exacerbation of chronic lung disease. Patients may improve exercise capacity and functional status. The system is designed to be a bridge to liberation for prolonged, mechanically ventilated patients who are ready to attempt a self-breathing trial. Use of the Cadence



Self-Breathing System is intuitive for physicians, nurses, respiratory therapists and other health care providers managing patients recovering from respiratory failure. Respiroics provides complete training and continuing education on Cadence through demonstrations, manuals and customer support. Contact [respiroics.com](http://respiroics.com).

## VENTILATION ROUNDTABLE

### Bunnell Incorporated

David Platt

David Platt is Marketing Director of Bunnell Incorporated.

#### What ventilation products do you currently offer?

Bunnell Incorporated specializes in high-frequency ventilation. The Life Pulse was the first high-frequency ventilator approved for use with infants. With more than twenty years of clinical experience the Life Pulse has stood the test of time. Sales and utilization of the Life Pulse have increased steadily for the last ten years. Bunnell will sell more ventilators this year than at any time in the company's history.

#### How has technology changed over the past five years?

The core technology has not changed in the last five years because we have a proven, stable platform. Refinements in hardware and software have taken place over the history of the Life Pulse to make it the robust and reliable ventilator it is today. There are Bunnell ventilators in clinical use today that were manufactured in 1985!

#### What are the latest advances in technology that you have introduced?

The latest advancement to the Life Pulse ventilator is the introduction of a new inspiratory valve design incorporated in the "WhisperJet" patient box. The new valve design reduces noise output by as much as 75%. Bunnell is constantly striving to stay in synch with evolving standards of care in the NICU.

#### How has your company pursued R&D efforts to continue improving this technology?

Bunnell has formal and informal mechanisms for gathering feedback from clinicians about the Life Pulse. Management reviews this information quarterly and evaluates when changes need to be made and how those changes are implemented by the R&D staff. The "WhisperJet" patient box is an example of how these mechanisms work to implement improvements in the Life Pulse.

#### How have you streamlined your cost of ownership?

Cost of ownership is held down by maintaining a stable platform and providing upgrades and training at no charge to the customer. The Life Pulse is a reliable ventilator with very little downtime. Typically, the only service requirement is an annual preventive maintenance. Even this cost can be minimized by having the hospitals biomedical technicians trained to complete on-site preventive maintenance.

#### What type of training and customer support programs do you have in place?

Bunnell provides all initial and on-going clinical training on-site at no charge. Technical training is offered each year at our headquarters in Salt Lake City, Utah. The two day program for biomedical technicians covers troubleshooting, minor repairs, and preventive maintenance. Technical and clinical support is also available on our website, [www.bunl.com](http://www.bunl.com).

#### Describe your customer assistance program for technical or clinical issues.

Customer assistance is available 24/7 via the Bunnell Hotline, (800) 800-4358. Clinical specialists with 15 plus years of experience are ready to handle a full range of technical and clinical questions. This is one of the most important services we provide. If clinicians have a question about the Life Pulse, the fastest way to get an answer is to call our hotline.

#### How do you view your relationship with the end user of your product?

The "relationship" is all-important. Being professional, friendly, and helpful is our goal in every interaction we have with our customers. Honest open communication is the cornerstone that Bunnell is built on. Independent organizations consistently rank Bunnell high in customer satisfaction.

#### What in terms of cost-savings/benefits does your technology bring?

The benefits of the Life Pulse High-Frequency ventilator are simple and straightforward. The Life Pulse, when used properly, helps save patients that have failed other ventilator systems. In addition to rescuing failing patients, many clinicians use the Life Pulse to speed the recovery of patients with particular respiratory disorders, specifically PIE and other air leaks. Safely and effectively managing critically ill patients avoids costly and destabilizing transports.

## Pulmonetic Systems

Jim Homuth

Jim Homuth is Senior Director of Marketing, Pulmonetic Systems, a Division of Viasys Healthcare.

#### What ventilation products do you currently offer?

Pulmonetic Systems, a Division of Viasys Healthcare, designs, manufactures and markets the LTV Series of ventilators which include the LTV 800, LTV 900, LTV 950, LTV 1000 and LTV 1200. We also offer a variety of accessories that complement the LTV Series, such as the TBS (Transport Battery System), the UPS (Universal Power Supply) and the LTM (LapTop Monitor).

#### How has technology changed over the past five years?

Pulmonetic Systems has successfully introduced portable ventilation solutions in the medical marketplace. These smaller form-factors and improved designs, for many of our customers, have improved their quality of life. Portability without compromised performance has facilitated applications in the home, hospital, transport, and military.



## Experience the Freedom of Portable ICU Ventilation



### Unified Preparedness Begins with the LTV Introducing the LTV® 1200

In busy hospitals where clinical resources are stretched, the LTV 1200 ventilator offers ease of use and versatility to help ensure optimal patient care across clinical settings. Whether in the ICU, PICU, ED or Patient Transport, the LTV 1200 has the flexibility to adapt to changing respiratory needs, for patients as small as 5kg, providing invasive and non-invasive modes of ventilation. At a fraction of the size of comparably equipped systems, the LTV 1200 moves seamlessly with the patient. Experience why the LTV Series has become the ventilation platform chosen by clinicians worldwide.



For more information on the LTV 1200 and unified preparedness applications, please contact a Customer Care Representative at 1-800-754-1914.

**VIASYS**<sup>®</sup>  
HEALTHCARE  
*Excellence For Life*

**Pulmonetic Systems**

### What are the latest advances in technology that you have introduced?

- Spontaneous Breathing Trial – utilizes Rapid Shallow Breathing Index (RSBI) criteria to assess a patient's ability to be weaned from mechanical ventilation.
- Patient Presets – the ventilator automatically configures initial ventilation settings for Infants, Pediatrics or Adults based on the patient type selected by the Clinician.
- Enhanced Non-Invasive Mode – walks the Clinician through setup of IPAP and EPAP to initiate non-invasive ventilation.
- O<sub>2</sub> Cylinder Duration – ideal for transport applications, this feature calculates the remaining time left in an O<sub>2</sub> cylinder based on the ventilator settings and cylinder type.

### How has your company pursued R&D efforts to continue improving this technology?

We believe in listening to our customers and taking their feedback to improve our products and technology so that we can provide innovative respiratory care products worldwide.

### How have you streamlined your cost of ownership?

Internal PEEP on the LTV 1200 reduces customer costs by allowing them to purchase a PEEP-less circuit.

### What type of training and customer support programs do you have in place?

Pulmonetic Systems offers clinical and customer support twenty-four hours a day, seven days a week. Our on-staff credentialed clinical specialists possess a broad base of knowledge and experience covering transport, homecare, sub-acute and acute care applications.

### Describe your customer assistance program for technical or clinical issues.

Pulmonetic Systems offers two types of training programs to our customers, Clinical Training (CEU Programs) as well as LTV Service Training. The CEU Programs provide the customer with continuing education credits supported through our Clinical Department. These CEU credits are awarded through a variety of programs such as Mechanical Ventilation, Troubleshooting, Discharge Planning and Transport. For additional information, please contact our Clinical Department at (800) 754-1914 or email us at [info@pulmonetic.com](mailto:info@pulmonetic.com). The LTV Field Service Training consists of several training classes throughout the year at minimal cost to the customer. These classes cover training on the complete line of LTV Series Ventilators (800, 900, 1000, and 1200). In order to provide the highest quality of instruction, class sizes are limited to ten students. Classes will fill quickly and we do recommend that you register well in advance. Registrations are accepted on a first-come, first served basis and only if accompanied by a valid purchase order number. For companies wishing to register several students, training can be arranged at the customer site. For further information, please contact our Technical Support department at (800) 754-1914 or (763) 398-8500, or email us at [service@pulmonetic.com](mailto:service@pulmonetic.com).

### How do you view your relationship with the end user of your product?

We take great pride in working directly with our customers and staying in touch with them through various avenues such as tradeshow, on-site visits and trainings in addition to participating in nationwide sponsored events.

### What in terms of cost-savings/benefits does your technology bring?

Due to the fact that the LTV Series of ventilators can be used across multiple sites of care such as the ICU, PICU, ED or patient transport, it cuts down on the need to purchase several different types of ventilators for each clinical setting.

## Puritan Bennett

Gary Milne

Gary Milne is Senior Clinical Marketing Specialist, Puritan Bennett.

### What ventilation products do you currently offer?

Puritan Bennett offers the 840 ventilator system, the 700 Series ventilators and the Achieva portable ventilator.

### How has technology changed over the past five years?

Over the past year, new modes of ventilation have evolved with an emphasis on reducing sedation, paralysis and ventilation time. New modes are also incorporating closed-loop algorithms designed to improve patient-ventilator synchrony, comfort and, potentially, ventilating pressures.

### What are the latest advances in technology that you have introduced?

Puritan Bennett recently released the Proportional Assist Ventilation Plus (PAV+) software option for the 840 ventilator. PAV+ is the first of its kind in the US to deliver positive airway pressure in direct proportion to a patient's spontaneous effort to breathe. The software increases or decreases breathing support in response to changing patient demand, and a sophisticated algorithm in PAV+ dynamically adjusts ventilator assist to help maintain an appropriate degree of support throughout each breath. A clinician simply sets the target level of assist desired (shown on the monitor as %Support). At a setting of 60% support, for example, the ventilator performs 60% of the work of inspiration and the patient performs 40%. In addition, PAV+ displays real-time assessments of patient and total work of breathing in the form of an easy-to-read "Work of Breathing" bar. This feature can give a more complete picture of patient recovery status, and provides clinicians with valuable feedback on the adequacy of a chosen %Support setting.

### How has your company pursued R&D efforts to continue improving this technology?

We have a full complement of R&D engineers and are constantly researching new hardware and software solutions for our customers. Additionally, we work with leading clinical researchers to develop new options for patient care. Most recently, Puritan Bennett has partnered with Dr. Magdy Younes, inventor of Proportional Assist Ventilation, to bring this closed-loop mode of ventilation to the US market in the form of PAV+.

### How have you streamlined your cost of ownership?

We have looked at the maintenance costs associated with our ventilators and have recently made some significant reductions in ownership cost to the 840 ventilator. For example, with the implementation of a new GUI screen, we were able to eliminate the scheduled changing of the lights that illuminated the screen during the 10,000-hour preventive maintenance.

### **What type of training and customer support programs do you have in place?**

We offer a variety of training programs based on customer needs. Traditionally, we offer initial onsite operational training for hospitals and their staff. We then follow this up as requested by the customer to ensure staff remains current.

### **Describe your customer assistance program for technical or clinical issues.**

Puritan Bennett has a full-time group of Customer Service Engineers, based in the field and ready to respond to any technical or maintenance needs. Additionally, Puritan Bennett customers have access to a 24-hour Technical Support hotline, as well as a new online self-service knowledge base we call the SolvIt Center. With the SolvIt Center, customers can go online 24/7 and browse through frequently asked questions listed by product. They can search the database for specific topics, ask a new question and even look up part numbers if needed for order entry. The SolvIt Center resource addresses both clinical and technical questions. For hands – on training, our service headquarters in Carlsbad, California features a full offering of service schools to educate our customer's biomedical engineers.

### **How do you view your relationship with the end user of your product?**

Our customer relationships are very important to us, and we look to a number of indicators to tell us how we're doing. For example, Puritan Bennett has been a recipient of the American Association for Respiratory Care's prestigious Zenith Award for 17 years. The Zenith Award is presented annually to manufacturers, service organizations and supply companies that have done the most outstanding job during the previous 12 months in the areas of quality of equipment and/or supplies, accessibility and helpfulness of sales personnel, responsiveness, service record, truth in advertising and support of the respiratory care profession. AARC members have nominated Puritan Bennett for this award more times than any other company, from a pool of 300 to 400 possible companies. We feel that this is a very positive reflection of the relationships we have with our customers and are very proud of this achievement.

### **What, in terms of cost-savings/benefits, does your technology bring?**

The 840 ventilator system is designed to meet the ventilation needs of neonates to adults, thus reducing the need to keep inventories of two separate ventilators. Its simple maintenance keeps the ventilators up and running with less frequent intervals for preventive maintenance. The design of the Responsive Active Exhalation Valve has been shown to decrease the amount of sedation required by the ICU patient. Dual modes like VC+ have been tested and compared to other similar ventilator modes, and have been found to be superior in certain aspects. The release of the PAV+ software option holds the potential to put the patient back into control of their breathing, so additional costs associated with dyschrony and fighting the machine may be reduced.

## **MAQUET, Inc.**

Ed Coombs, MA RRT

Ed Coombs is Product Manager - Critical Care Division, Maquet, Inc.

### **What ventilation products do you currently offer?**

Maquet manufactures, sells, and supports the SERVO ventilator product line. The SERVO-i is used in neonatal, pediatric, and adult critical care units, while the SERVO-s is designed for chronic patient care areas.

### **How has technology changed over the past five years?**

Maquet has been on the forefront of technology through its commitment to research and development. The SERVO-i ventilator uses an "open architecture" system design which allows customers to upgrade their units to the latest in technology.

### **What are the latest advances in technology that you have introduced?**

Since the initial introduction of the SERVO-i, Maquet has released new clinical features every year. With input from clinicians, Maquet has introduced features such as the Open Lung Tool with dynamic compliance for lung recruitment, non-invasive ventilation, nasal CPAP, and a proximal airway sensor option. Maquet is committed to continuing to release new features to help clinicians better care for their patients. Maquet is currently developing NAVA – Neurally Adjusted Ventilatory Assist, which is new technology based on neurally driven ventilation, in contrast to pneumatically driven ventilation which has existed up to this point. This new technology option for the Servo-i is pending 510(k) review, and is not commercially available in the US.

### **How has your company pursued R&D efforts to continue improving this technology?**

Research and development have played a pivotal role in Maquet's core philosophy. Approximately 10% of revenue is reinvested in R&D efforts. The SERVO product line (900, 300A, SVI) has introduced many changes to the mechanical ventilation field such as pressure support, PRVC, volume support, Automode, and the Open Lung Tool. Maquet will continue its efforts with the clinician in mind bringing new technologies to the field.

### **How have you streamlined your cost of ownership?**

The cost of maintaining equipment is a major concern for any department. The SERVO-i platform is software based and has very few mechanical parts that require replacement over time. Maquet has also introduced its ultrasonic O<sub>2</sub> sensor that can be used as an alternative to the conventional O<sub>2</sub> cell. This new technology will be cost effective over time in that it does not have a galvanic cell that expires and requires replacement.

### **What type of training and customer support programs do you have in place?**

Proper training and customer support are of paramount importance to Maquet. Our clinical applications staff has grown to 20 nationwide in the US. Onsite training for clinicians is done during installation and follow-up thereafter. Our clinical lecture series has 21 approved CRCEs from the American Association



for Respiratory Care which in part is given in conjunction with product training. On a global basis, Maquet hosts an annual international symposium on the latest topics pertaining to mechanical ventilation. Our most recent symposium in August 2006 was held in New York City which had over 250 participants from around the world. The next scheduled symposium will be in Mumbai India this coming January 2007. More information can be found at our website, [maquet.com/symposium](http://maquet.com/symposium).

#### **Describe your customer assistance program for technical or clinical issues.**

We have a technical support center that operates 24x7 for our customers. The toll free phone number is 1-888-MAQUET3. Calls are handled by our technical support specialists who will assist customers in technical troubleshooting and clinical support referrals are handled by the clinical applications specialists, all of whom are registered respiratory therapists.

#### **How do you view your relationship with the end user of your product?**

Our field staff and support staff value the strong relationship that develops between the manufacturer and the end-user. When dealing with life support equipment it is essential to have a mutual partnership that allows for customer feedback, assures clinical support, and to have products that continuously meet the needs and demands of clinicians.

## **Viasys**

Mark Rogers, BS, RCP, RRT

Mark Rogers is Clinical Applications Manager, Advanced Product Development.

#### **What ventilation products do you currently offer?**

Viasys Healthcare offers a comprehensive range of neonatal through adult mechanical ventilation products for homecare, sub-acute and critical care areas. The Avea is our flagship critical care ventilator. The Avea offers neonatal through adult ventilation capabilities and features some of the most advanced pulmonary mechanics using Bicare technology and integrated heliox functionality. With some of the newest technology available, the Avea platform can grow as your needs grow. The Vela is a pediatric through adult ventilator that has a small footprint yet has many of the same advanced features of the Avea. The Vela boasts noninvasive ventilation, a six-hour battery and advanced turbine technology. All of this makes the Vela ideal for hospitals that need a capable all purpose and mobile ventilator. The Pulmonetic LTV series of ventilators is synonymous with extreme portability, ease of use and versatility. The LTV series can be employed in institutional settings as well as in the home. The rich feature set and small size make it suitable for moving patients from one place to another, whether by air, ambulance, or just through the hospital. The development of the Infant Flow nCPAP system with its unique generator provides a clinically-proven, gentle and non-invasive method of breathing support offering an alternative to more invasive forms of ventilation. It delivers stable nCPAP while reducing work of breathing. Infant Flow SiPAP extends the functionality of Infant Flow by providing ventilatory assistance with bi-level pressures. Powered by a rechargeable

battery with a life of up to four hours, treatment can begin immediately after delivery and during transfer to neonatal units, providing benefit during the crucial early stages. Whether for neonates, pediatrics or adults, Viasys offers the ultimate in lung protection with its 3100 series high frequency oscillatory ventilators. The 3100A neonatal/pediatric HFOV and the 3100B pediatric/adult HFOV provides a continuous distending pressure to recruit and normalize lung architecture while ventilating with near dead space tidal volumes for definitive low stretch lung protection. As opposed to other high frequency ventilators, the 3100A and 3100B do not require a second ventilator to provide conventional (and potentially injurious) breaths.

The intuitive Simple Touch interface in many of our products makes training and competency testing straightforward.

#### **How has technology changed over the past five years?**

Technology has changed dramatically over the past five years. Microprocessors and memory are much smaller and less expensive, allowing us to pack more processing power in smaller places. Components such as solenoids and turbines are smaller than ever and require less energy to run allowing manufactures to create more efficient, compact devices. Ventilators or CPAP devices that can be held in one hand; or pulmonary function equipment that once required a small room can now take to the bedside, are all realities.

#### **How has your company pursued R&D efforts to continue improving this technology?**

Working with our Marketing group, our R&D engineers are continually developing new technology to ensure we maintain a technology leadership position in the industry. As new advances are identified, they are worked into our existing product line and/or evaluated for use in upcoming products and features. This is not limited to hardware based technology, but also includes advances in software/firmware.

#### **How have you streamlined your cost of ownership?**

We have streamlined cost of ownership by developing technology and methods that require little maintenance and prolong lifespan. Additionally, we've added options that allow technical support staff to remotely access some products over the internet to diagnose, troubleshoot and configure devices minimizing costly downtime.

#### **What type of training and customer support programs do you have in place?**

Viasys is committed to customer education. We offer comprehensive training on all of our products. Viasys offers regional advanced courses for some of our conventional and high frequency oscillation ventilators. We also support third-party workshops, and make these available to our customers as they become available. All courses are listed on our website ([www.viasyshealthcare.com](http://www.viasyshealthcare.com)).

#### **Describe your customer assistance program for technical or clinical issues.**

Our technical and clinical support personnel are all Registered Respiratory Therapists and are on-call 24 hours a day. By dialing a toll free number anytime of the day or night, our customers are placed in contact with our staff to help troubleshoot devices as well as clinical problems.

### **How do you view your relationship with the end user of your product?**

We have an excellent track record with our customers. The partnership we have created is mutually beneficial and has culminated in our Centers of Excellence program.

## **Hamilton Medical, Inc**

David Costa

David Costa is Vice President and COO of Hamilton Medical.

### **What ventilation products do you currently offer?**

Hamilton Medical, Inc offers a one-stop shop for the respiratory therapy department. We offer Hamilton critical care ventilators with Intelligent Ventilation as well as humidifiers, circuits, masks for non-invasive ventilation, the Arabella Infant NCPAP system and more. Hamilton also offers rental programs, service agreements and asset management programs.

### **How has technology changed over the past five years?**

The reality is that there have not been many advances in technology for the mechanically ventilated patient over the past five years. Most people are still using the same modes of ventilation and ventilating patients with manual ventilator settings. Even the so called dual modes of ventilation are not automated, but rely on the human operator to determine the ventilator's status. The major advances in improving patient outcomes have been the recognition of how lung protective strategies should be applied in order to prevent lung injury and in recognizing the need to get patients off the ventilator as soon as possible. We need to look at how technology can contribute to a systems approach to reliably apply evidence-based medicine and reduce errors.

Hamilton Medical is on a mission to simplify ventilator operation. The complexity of operating a modern intensive care ventilator creates many opportunities for operator error. Short staffed ICU's and long hours increases the chance for errors. 50-100% more errors occur in the hospital when staff works more than 8.5 hours per shift. No one clinician can be an expert on all of the different modes of ventilation yet alone all of the differences in theory of operation among various equipment in the modern ICU. There is a better way. Technology cannot change the laws of gas physics. Technology has often been used to correct problems with ventilator mechanics. Modern ventilators have decent gas delivery systems. Today the technological challenge is to automate what we know works to free the clinician to focus on the patient, not the instrument. Hamilton's technology offers exactly this kind of benefit.

In the future we will see a totally automated suite of instrumentation in the ICU. Technology will focus on the presentation of data to the clinician in such a way that they have an absolutely clear picture of their patient's condition. Most importantly, technology will allow the clinician to predict next steps and reduce time in the ICU and time in the healthcare continuum.

### **What are the latest advances in technology that you have introduced?**

Hamilton Medical has introduced three new advances to the medical community, with more to come in the future. We combine these advances under one simple term: Intelligent Ventilation. Adaptive Support Ventilation is the first "non-mode" of ventilation. This is a proven modality with literally millions of patient-ventilator hours worldwide. The FDA cleared Adaptive Support Ventilation in the USA in July 2006. This is a huge leap forward for patient safety in the USA. Ventilators are too complicated and have too many modes. There is no standardization between modes from different ventilator manufacturers. All these complications increase the chance for error. Even in the hands of the most skilled RTs and physicians, ventilators without Intelligent Ventilation can not respond to the dynamic nature of the patient. The therapist or physician may only set the ventilator manually for a specific patient condition. Look at the airline industry. Airline pilots are among the most competent and best trained professionals in the world. They have years of experience before ever entering the modern airline cockpit. Despite all of this preparation, the industry has learned that automation in the cockpit makes air travel safer and allows for all of the crew's expertise to be focused on the big picture of getting the aircraft from point A to point B safely. It is absolutely imperative that this same level of automation be brought to the mechanical ventilator. Hamilton Medical is the only ventilator company with this capability. Clinicians are far better utilized when they are able to focus on the patient, rather than become a slave to the equipment. Hamilton's PV Tool is also truly unique. You must employ safe and automated strategies to determine the optimal PEEP to keep the lung open. But the key component to lung protective ventilation is to open the lung in the first place. Only the Hamilton PV Tool with its advanced method of constant pressure, rather than the constant flow method used on other devices, gives an additional clinical benefit of being able to recruit the lung as well as determine the best PEEP for the patient.

The third advance that Hamilton offers is airline-style training that we call Critical Events Training. We are partnering with key facilities around the US to incorporate realistic simulations that allow clinicians to be certified to address key mechanical event failure modes and react quickly to keep the patient safe. The Joint Commission has listed improper training as the number one reason why patient injuries occur on mechanical ventilators. Commercial aviation has pioneered SBT (Scenario Based Training) that has proven to enhance crew effectiveness during high workload and high stress situations so that they can respond correctly when the situation presents itself in real practice. Hamilton Medical now offers this type of training to the medical community. Hamilton offers this unique service to anyone who works with mechanical ventilators, regardless of make or model.

### **How has your company pursued R&D efforts to continue improving this technology?**

Hamilton Medical invests significant resources into research and development. Our vision at Hamilton Medical is very clear: patient safety and staff effectiveness that relates directly to error reduction.

We are currently involved in exciting research involving the

Intelligent  Ventilation

98%  
of invasive ventilation days  
1  
non-mode

For a no obligation demonstration, call 800-426-6331, Ext. 208

Too good to be true? Well, studies<sup>1</sup> prove that the Intelligent Ventilation non-mode ASV can be used in 98% of the ventilatory time in a mixed population of critically ill ICU patients. ASV is more than a mode, because it adapts to the patient's lung mechanics and employs lung-protective rules, from intubation to extubation. It also reduces ventilation time<sup>2</sup>, promoting weaning from minute one. And to help you focus on the patient, it

requires less user interaction and causes fewer alarms<sup>3</sup>. ASV is a safer, more efficient way to ventilate.

Intelligent Ventilation with ASV is only available on the GALILEO ventilators from HAMILTON MEDICAL. Interested? [sales@hamiltonmedical.net](mailto:sales@hamiltonmedical.net)

1. Annals of Intensive Care Medicine 2004;9:284  
2. Salzer C. Anesthesiology 2001;95:1339-45  
3. Patten AH. Anesth Analg 2003;97:1743-50

[www.hamilton-medical.com](http://www.hamilton-medical.com), [www.IntelligentVentilation.org](http://www.IntelligentVentilation.org)

**HAMILTON**  
**MEDICAL**

ventilator GUI (graphical user interface). The goal is to present the correct information to the clinician at the right time, without complexity. Easy to understand information shown only when appropriate, allows the clinician to maintain what airline pilots call, “situational awareness” during all phases of patient care. Hamilton Medical is highly focused on the Intelligent Ventilation concept. Our R&D efforts are focused on simplification of ventilator operations and improved user interfaces for the clinician in order to achieve better situational awareness. The goal is to give the clinician tools to anticipate patient status. Hamilton’s safety initiatives are all designed to eliminate ventilator induced lung injury so that the clinician can address the patient disease process or lung insults without having to cope with damage that is caused by the very life sustaining tool they employ with the best intention. Hamilton Medical is also investing in new technologies and seeking acquisitions on unique and relevant technologies that support the ventilator such as electronic records, patient monitoring and other technologies. Our aggressive growth and stable corporate ownership have allowed us great flexibility to grow our R&D efforts.

#### **How have you streamlined your cost of ownership?**

The cost of operating a ventilator is inconsequential to the costs required to provide respiratory care to a patient. I am amazed at the fact that some facilities will take issue with the fact that Hamilton ventilators use a flow sensor at the airway that does have some minimal cost, but is located at the best place to measure pressures, flows and timing signals. The costs involving the big picture in healthcare are far more significant, than issues like this. Hospitals are under immense pressure to reduce costs. At the same time, they must improve patient outcomes and improve patient safety. The cost of acquiring and operating a ventilator is small when compared with the results of an improperly managed ventilator program. We are focused on the big picture, much like a health care administrator. Let’s take a look at the entire process and look for real savings for the patient and the health care continuum as a whole. The mechanical ventilator can be referred to as a killing machine. We don’t often see an organization with the courage to speak so frankly, but it holds all of us to a higher standard when we speak truthfully about the potential dangers involved in providing the best care for the patients that we all serve. It is estimated that it costs roughly \$5,000 per ventilator day in the ICU. Ventilator Acquired Pneumonia (VAP) is the leading cause of death among hospital-acquired infections and prolongs time spent on the ventilator. Each incidence of VAP can add \$40,000 to the cost of the hospital admission. It seems that with the cost of operating any ventilator, that even a modest improvement in length of stay would have a dramatic effect on the entire facility. The term “sedation vacation” is relatively common today. We all know the reasons for this. A mechanical ventilator should free the patient to begin breathing on their own as soon as possible without need for human intervention to start the weaning process. Wean from the start. Getting the patient breathing on their own and off the ventilator is of paramount importance to saving costs to a hospital.

The costs involved with these issues are where the ventilator manufacturers need to focus. Heavy discounts and “voodoo pricing tactics” may appease a department director or a purchasing manager, but they do absolutely nothing to address

the issue of providing answers to any of the issues that I have just raised. Fair pricing that is simple and easy to understand allows for companies like Hamilton to offer the other elements that provide those results that are truly needed. I don’t compete on the price of the ventilator. Cheap ventilators to buy market share is not our business. We offer solutions that directly impact the hospital bottom line when given the opportunity to step up.

It is the obligation of medical device companies like Hamilton Medical to interface with all levels of hospital management to become part of a solution strategy rather than simply a vendor. Hamilton Medical has the capability to become consultants to the administrators as well as the clinicians. I want my team involved with the process, not just the respiratory department. We need to look at the entire critical care continuum for Hamilton Medical to maximize the cost savings to the facility.

When I was an airline pilot, a key element to safe operational flying was involvement of the entire crew and the entire aviation network for the safe operation of my aircraft. This included the flight attendants, ground personnel, air traffic control and systems operational personnel in addition to the two of us sitting up front in the best seat in the house. Pilots have learned to put ego aside and understand that flying the aircraft is just one small element of safety and no one element of the team is any less important than the other.

#### **What type of training and customer support programs do you have in place?**

There is a reason why industry groups rate Hamilton Medical at the top in regards to training, service and support. The reason is focus. The Joint Commission of Accreditation of Healthcare Organizations cited inadequate orientation/training and communication breakdown among staff members as the top two root causes for death or injury on ventilators. With this in mind, Hamilton considers training and customer support a top priority. Hamilton’s focus is on the patient and the customer before we look at our own situation. We therefore invest more than the industry average in our support structure. Hamilton Medical, Inc. in the USA has almost tripled the size of our sales team in recent months. We know that before we can court new business we must support our existing customers. This is precisely why before we did anything with sales team expansion, we enhanced our field clinical support team. We offer CEU credit for our educational programs and offer live web-based training on demand (in addition to our field operations). In short, we will not rest until we have 100% customer satisfaction. Our customers deserve nothing less.

#### **Describe your customer assistance program for technical or clinical issues?**

Hamilton Medical offers several layers of customer assistance for technical and clinical support issues. All telephone customer support is available, free of charge, 24 hours a day, everyday. All customers are just a phone call away from a Respiratory Therapist or a trained Biomedical Technician. Any customer may attend any of the biomedical training classes held in Reno, Nevada at regular intervals each year. We offer in-house biomedical training where appropriate. Hamilton realizes that many facilities wish to maintain their own equipment. Hamilton instruments are easily maintained by competent hospital staff. We fully support in-house maintenance of Hamilton ventilators



and offer a package of comprehensive test equipment along with some of our programs. Hamilton also maintains a complete field service organization. We also provide complete service plans and extended warranty coverage options.

Clinical support begins with anyone with a desire to learn about Intelligent Ventilation. We offer a series of Clinical Experts Workshops around the country where physicians and high-level respiratory therapists come together to learn about lung protective ventilation. No sales pitch, no company commercial, just a fantastic clinical education opportunity. We are currently launching an Intelligent Ventilation Focus Group that allows our clinical partners to openly discuss clinical issues, present case studies and get real time feedback from our clinical and R&D teams. We are building a strong cadre of physician and RT speakers as well. No coaching or prompting of our lecture cadre is ever tolerated. We want their opinions to be completely based upon their experience with Intelligent Ventilation.

#### **How do you view your relationship with the end user of your product?**

Our relationship with the end user of Hamilton products and services is undefined, unstructured and open-ended. We consider our team to be partners in patient care so the script is not written. The patients we serve and the goals of our partners determine the scope of our relationship. Patients must be safer. Ventilation must be safer. With Intelligent Ventilation, the patient will be safer. We have set a high bar and a close relationship with our end user which includes the patients. This is a challenge that we are ready to accept.

#### **What in terms of cost-savings/benefits does your technology bring?**

Elimination of Ventilator-Induced Lung Injury (VILI) can offer dramatic cost savings to the healthcare continuum. We compare the safety records of commercial aviation and medicine with great frequency. Can you imagine the reaction of the flying public to the term "Aircraft-Induced Passenger Injury"? It is our mission at Hamilton Medical to eliminate VILI from our lexicon. Here is another example that directly shows one instance of how Hamilton's Intelligent Ventilation impacts patient care. It is widely known that ARDS has a high mortality rate. It is also widely accepted that lung protective ventilation saves lives. What does lung protective ventilation really mean and is it really being used in all facilities? The answers may surprise you. In ARDS, lung protective ventilation means:

- Smaller tidal volumes to avoid overdistention. Hamilton's ASV automatically selects the lowest appropriate tidal volume based on the lung mechanics of the patient.
- Correct PEEP to keep the lung open. Hamilton's PV Tools automate this task and allow the clinician to complete this task simply and easily.
- Perform a lung recruitment maneuver as soon as possible. Hamilton PV Tool with its constant pressure maneuver is the only such product available today. Does Hamilton offer clearly defined cost savings and benefits due to our technology? You bet!

## **eVent MEDICAL**

Written by the eVent Management Team.

#### **What ventilation products do you currently offer?**

eVent Medical currently offers both Infant only ventilators (the Inspiration Infant and the Inspiration Infant LS) as well as our full range, infant to adult ventilators (the Inspiration and Inspiration LS models).

#### **How has technology changed over the past five years?**

Ventilator breath delivery performance as well as choice of modes and monitoring have improved significantly in recent years while many of the newer ventilators offer similar modalities. Economic pressures in healthcare have resulted in high performance and safety/reliability requirements but housed in more cost effective packages. Graphical user interfaces have allowed much more upgradeability and improved ease of use. Connectivity and information sharing promises hope for improved practice and reduced errors by providing real time access to critical patient data.

#### **What are the latest advances in technology that you have introduced?**

eVent Medical has designed, developed and patented a high performance breath delivery design that has significantly fewer parts and utilizes a more versatile breath control system to provide active breathing in all of the ventilators comprehensive modes. Important Safety features such as comprehensive alarms, an internal compressor and the long lasting internal batteries have given clinicians a peace of mind. These same standard features make the ventilator ideal for transport. Our built in MiniWeb internal server allows 21st century Ethernet communications at the bedside, with hospital networks or available distribution anywhere through the internet with proper password protection for privacy.

#### **How has your company pursued R&D efforts to continue improving this technology?**

eVent Medical is a unique company founded by clinicians and engineers. The company values its R&D efforts as its life blood. eVent has spent over its life an average 20% of its revenues and all of its profit on R&D. Our mission is to provide useful clinician driven innovation. We employ engineering and clinical personnel that work to assure we have captured and translated customer requirements to R&D. Additionally, our engineers are always reviewing new technical products for their application and improvement of our existing products. User feedback through our quality and market research systems drive our efforts toward continuous improvement.

#### **How have you streamlined your cost of ownership?**

As mentioned previously our innovative patented design has a reduced number of parts. Fewer parts mean fewer parts that require maintenance or repair. You are carrying a lower risk of future expense immediately with our new product design. But eVent doesn't believe that cost of ownership is only captured in the repair room. Cost of ownership involves ease of use, training costs, time spent to change out one ventilator to another one with more modalities or non invasive capabilities and turn around time spent making the ventilator ready for the

next patient. All of these are real costs to the delivery system. Our clinical backgrounds allow us to keep focused on developing effective products that address these issues.

### **What type of training and customer support programs do you have in place?**

Our eVent sales personnel are primarily clinicians. On site training programs extend beyond ventilator function but include training for best practices to help implement current trends and protocols. Training programs are structured to support CEU credit where applicable. Clinical education materials are provided in formats that allow clinicians and educators the flexibility to utilize and modify these materials to best meet individual needs. Word documents, PowerPoint presentations, and videos cover specific product application as well as generic mechanical ventilation education support. Web based education programs are planned for the near future.

### **Describe your customer assistance program for technical or clinical issues.**

Our customers have access to our clinical or technical team 24 hours a day, 7 days a week. Most of our staff are respiratory therapists including much of our sales force and management. We are a clinician focused company, run by clinicians who have worked for other ventilator companies until settling in our company due to its singular focus – the respiratory patient.

### **How do you view your relationship with the end user of your product?**

Being clinicians ourselves we enjoy the benefits of teaching and being taught by the end users. It is our view that clinicians in industry make the process of product development and improvement so much easier. We strive to keep this relationship one of camaraderie and appreciate open and frank input. The products we create must meet the needs of the clinical community at large and so we keep an open mind to any and all input and suggestions.

### **What in terms of cost-savings/benefits does your technology bring?**

Cost of ownership savings has already been described above. Ease of use can translate to training cost savings as well as improved safety. Simple and inexpensive preventative maintenance also saves on biomedical training. Expanded transport capabilities allow less additional equipment to be purchased. NCPAP capabilities allow the same ventilator to be used for patients freshly extubated. Combining volume targeted modes with our Auto mode allows patients to easily and automatically transition from full support to readiness to liberate from ventilation with decreased need for staff intervention. Post anesthesia patients are typical patients to benefit from this kind of support which can lead to shorter time on the ventilator. Modes like these coupled with active exhalation valves improve patient ventilator synchrony and decrease the need for heavy sedation and paralysis which have been associated with longer time on the ventilator and increased hospital costs.

## **Respironics, Inc.**

### **Bud Reeves**

Bud Reeves is Marketing Director, Critical Care Division, Hospital Group, Respironics, Inc.

### **What ventilation products do you currently offer?**

Respironics' Total Ventilation Solutions includes products that address patient needs in Invasive and Noninvasive ventilation and Cardiopulmonary monitoring. The Esprit is a full featured critical care ventilator that was the very first invasive ventilator to feature a bi-level noninvasive mode. Additionally, the Esprit features full graphics, respiratory mechanics, neonatal capability, self-contained air source for transport, and a unique feature called Flow-Trak, which makes additional flow/volume available per patient demand in volume ventilation. Other invasive ventilation products include the PLV Continuum and the PLV 102, both targeted at the homecare market.

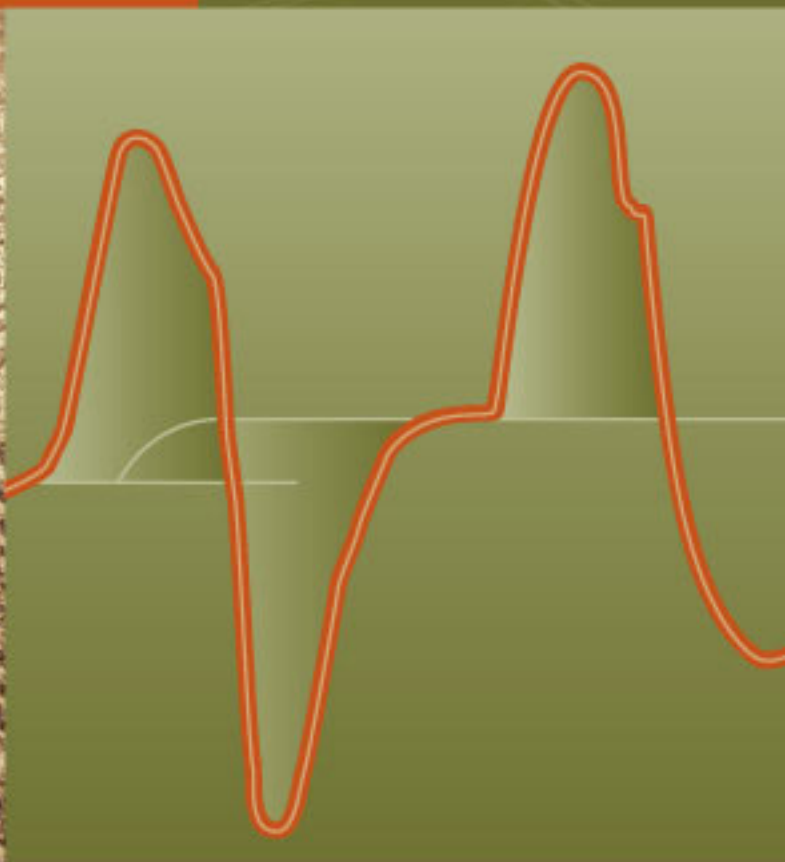
Noninvasively, Respironics leads the way with the comprehensive BiPAP Vision, which is FDA cleared for invasive use, as well. The BiPAP Vision provides integral oxygen blending, graphics, alarms, and a proprietary triggering algorithm called Auto-Trak. Auto-Trak compensates for mask leaks on a breath-by-breath basis and also changes triggering and cycling points automatically based on those leak rates. The BiPAP Focus is a noninvasive system that has similar performance as the BiPAP Vision, but without integral oxygen blending and graphics. The BiPAP® Focus also features the proprietary digital Auto-Trak capability and additionally provides battery backup capability for transport.

Our newly released Cadence product is indicated for the treatment of hypoxemia with delivery of transtracheal high flows of a heated and humidified air/oxygen mixture to spontaneously breathing patients with a cuff-deflated fenestrated tracheostomy tube. It is indicated for hospital use in adult patients and may improve exercise capacity in PMV (prolonged mechanical ventilation) patients. The ability to improve exercise capacity in PMV patients could facilitate weaning. Additionally, patients using Cadence are able to talk, since it is used with the tracheostomy cuff deflated.

Cardiopulmonary Monitoring is very important to optimize ventilation and the NICO<sub>2</sub> Cardiopulmonary Monitor provides data that may help determine appropriate PEEP levels (VCO<sub>2</sub>), readiness for a weaning attempt (Vd/Vt), and may help clinicians determine imminent ventilatory failure during a Spontaneous Breathing Trial (SBT).

### **How has technology changed over the last 5 years?**

Technology advancement has generally taken the form of better and faster computing power in many products. Additionally, miniaturization of components has been a focus of many manufacturers. The ability to use physiologic measurements to help adjust ventilator settings, whether in a closed loop fashion or on a manual basis, is giving information that allows us to make better ventilator settings decisions. Also, ventilation information management is becoming more important as hospitals and LTACHs are driven to reduce length of stay on a ventilator.



# CONSTANTLY ADAPTING. NATURALLY.

Breathing should be natural, even when it's assisted. To make mechanical ventilation more natural, you must constantly adapt to work around a patient's natural breathing patterns. So, it should come as no surprise that products like the **BiPAP® Vision®** with **Auto-Trak™ Sensitivity** define our commitment to leading the way to shorter, more comfortable and more cost-effective hospital stays. Our patented Auto-Trak algorithm is a revolutionary technology that tracks, detects and responds to breath-by-breath changes in leak rate and flow demand – which may reduce work of breathing and lead to more success in noninvasive ventilation. And it's just one of the ways that Respironics constantly adapts to the needs of medical professionals like you to improve ventilatory care for everyone. To see how the standard of care for noninvasive ventilation can improve patient outcomes and financial outcomes, contact us today for a pro forma assessment.



### **What are the latest advances in technology that you have introduced?**

While the specific gas delivery technology for our basic ventilation products (Esprit and Vision) has not changed appreciably, we have introduced new products (Cadence, BiPAP Focus, PLV Continuum) that either use established technology or modification of technology from sister products. Faster microprocessors that can handle more data more efficiently have been incorporated into our products. The Esprit ventilator has incorporated the Flow-Trak software technology that may aid in patient-ventilator synchrony in patients on volume ventilation. Our cardiopulmonary business unit has introduced new gas analysis technology that allows measurements and processing to take place in the sensor, leaving more room in the box for additional technology.

### **How has your company pursued R&D efforts to continue improving this technology?**

Respiroics is consistently working with the medical community's thought leaders to improve its current products and develop new products. We are involved with many clinical trials inside and outside the United States that evaluate new technologies and techniques to treat the respiratory impaired patient both invasively and noninvasively.

### **How have you streamlined your cost of ownership?**

This is a very important aspect of our continuing effort to find ways to decrease our cost of ownership. Respi-Link, our recently introduced software, allows remote software downloads and enables a customer service engineer to remotely diagnose any service related issues. This allows the hospital biomedical engineer to be the first responder and reduces cost of service to the hospital. This innovative product has allowed us to reduce the cost of our service agreements to hospitals that use the Respi-Link software. Currently this software can only be used on the Esprit ventilator, but soon customers that use the rest of our product portfolio will be able to enjoy reduced service costs with Respi-Link. Because of the implementation of this product, Respiroics was the recent recipient of 2 industry awards. We were awarded the Axeda Remote Service Leadership award – 2006 and the M2M Magazine First Place Award in the Healthcare Category. The M2M award recognizes companies that use technology to connect machine-to-machine or machine-to-man and provide better service to their customers. Respiroics is looking for additional ways to use this technology to decrease costs to our customers.

### **What type of training and customer support programs do you have in place?**

Respiroics Critical Care is very focused on Training and Customer support. A large part of our field sales organization is Total Ventilation Solutions Clinical Specialists. These TVCSs act as field clinical and technical trainers for all of our Critical Care Products. Customers can access CEU training online for many of our products. We also provide, at no charge, CEU hospital-based training for mask-fitting during noninvasive ventilation. Additionally, a more comprehensive CEU training on noninvasive Ventilation at the hospital site is available. We have recently implemented a customer training session on the clinical applications of the NICO<sub>2</sub> monitor at Duke University Medical Center.

As for service, our field-based customer service engineers support all of our products at the customer site. Phone clinical and technical support is available 24/7 and is staffed with clinicians familiar with the operation and application of Critical Care products. We have formal training for hospital biomedical engineers on the BiPAP Vision and Esprit both on site and in Carlsbad, California.

### **Describe your customer assistance program for technical or clinical issues; how do you view your relationship with the end user of your product?**

All technical and clinical issues are handled by phone on a 24/7 basis. We consider all customers our "Partners" in practice. This simply means that Respiroics' most important goal is to meet all of our customers' expectations, both clinical users and patients. Respiroics has won the AARC's coveted Zenith award again this year as evidence of our success in this goal. For those customers familiar with MDBuyline, I encourage them to seek the opinion of this impartial third party regarding the performance of our products, sales team, clinical team, and technical support.

### **What in terms of cost-savings/benefits does your technology bring?**

There are a number of cost-saving aspects to Respiroics products. Respiroics was a pioneer in developing products to promote noninvasive ventilation. By establishing an effective noninvasive ventilation program for CHF and COPD applications, studies conducted at some hospitals have realized significant cost savings over traditional invasive ventilation for the CHF and COPD application. Additionally, in at least one study abstract, the values obtained from the NICO cardiopulmonary monitor, have contributed to a reduction in length of ventilation time in pediatric patients.

## **Newport Medical Instruments, Inc.**

Janus Angus Baker

Janus Angus Baker is MarCom Manager, Newport Medical Instruments, Inc.

### **What ventilation products do you currently offer?**

For over 25 years Newport has focused on ventilators and the patients they serve. We offer a family of ventilators, with monitors, compressors and ventilation accessories to support them. For critical and subacute care we offer our flagship e500 Ventilator and our newest, the e360 Ventilator, both of which have built in graphical, pulmonary mechanics and F<sub>i</sub>O<sub>2</sub> monitoring. For general universal care we offer the E100M and E150 Ventilators. And for post acute, emergency intervention and home care, we offer our gas-generating portable ventilator, the HT50. Newport provides standard accessories for our products plus breathing circuits, masks for noninvasive ventilation, humidifiers, heated exhalation systems and test lungs.

### **How has technology changed over the past five years?**

There has been a materials technology explosion which has allowed Newport to improve ventilator structure, styling, and



economy. Newport has benefited from growth and competition in the computer industry. The cost of processors has gone down so there is a better cost-benefit ratio for the processors used in our ventilators. Processors are more powerful so they enable our ventilators to handle more complicated ventilation tasks. Processors are faster which enables our products to respond faster to patient needs. And because of high volumes, processors are more reliable so ventilators have less chance of malfunctioning due to microprocessor problems.

#### **What are the latest advances in technology that you have introduced?**

We continually work with our clinical partners to explore ways in which the latest technology can be used in our products to improve patient care while simplifying the user interface. Our patented dual-micro piston, gas-generating system, makes the Newport HT50 Ventilator the most power efficient portable ventilator in its class.

#### **How have you streamlined your cost of ownership?**

We approach it from all angles. Cost of ownership is impacted by purchase price, cost of continual maintenance, cost of repair, and both initial and ongoing training time/cost. Newport has invested significant R&D efforts into developing ventilators with high value purchase price, low product maintenance (parts and labor) costs/minimal ventilator down time and streamlined clinical/technical training. We keep materials costs low by selecting high quality, readily available and affordable components with a proven track record and long life capacity so that very few parts need to be replaced during scheduled maintenance. We keep labor costs low by designing ventilators that are structurally secure while allowing components to be accessed very easily by trained biomedical personnel. We provide regularly scheduled technical service and maintenance training programs that certify facility personnel to perform functional tests, calibrate, maintain and when necessary, repair Newport ventilators. We help ensure that clinical staff training time is minimized by designing products that are easy to set up and use in spite of their high level of sophistication. Newport is committed to producing ventilators that are not only clinically advanced and reliable but have a very low cost of ownership throughout the life of the product.

#### **What type of training and customer support programs do you have in place?**

**Training:** Newport offers comprehensive initial and ongoing training for all of our products both on-site and at Newport corporate offices. Training classes are taught by fully trained clinicians (for clinical training) and experienced technicians (for technical service training). The clinical training classes offer full value continuing education contact hours credit.

**Immediate Response for Immediate Needs:** Clinical and technical support is available 24/7 with our telephone helpline, at no charge.

**End User Support Materials:** Support materials include product-specific powerpoint presentations, training aids, handouts and competency evaluations. The HT50 Ventilator is also supported by an interactive "virtual ventilator" presentation with built-in training videos, alarm troubleshooting and printable competency reviews.

**Support Online:** The Newport website ([www.ventilators.com](http://www.ventilators.com)) offers customers access to Q&A discussions, product, clinical and technical bulletins and reference materials.

#### **Describe your customer assistance program for technical or clinical issues.**

Newport's Customer Support Team approach guarantees that trained clinical and technical staff is always available to assist both domestic and international customers with their immediate needs. The Team meets regularly to ensure that any open issues are fully resolved to the customer's satisfaction and that customer suggestions are passed along to appropriate product managers for consideration. The Newport 24/7 clinical and technical service telephone hotlines offer customer assistance at any time, day or night on all Newport products. Less urgent clinical and technical questions are answered readily by phone or email. The "Contact Us" section of the Newport website ([www.ventilators.com](http://www.ventilators.com)) lists telephone extensions and direct-link email addresses. The Education section of the Newport website posts Product and Clinical Bulletins that keep customers updated on new clinical information/applications for Newport products and FAQ's that answer the most commonly asked questions.

#### **How do you view your relationship with the end user of your product?**

Newport believes that our end users are our most valuable partners. Their feedback is essential to the growth of our product line and our company.

Through our network of professional localized distributors we maintain close, regular contact with our hospital based customers to ensure all their needs are met. Our homecare patients often call our clinical support team directly if they have specific questions or concerns. We are committed to 100% customer satisfaction and to providing rapid responses to any requests.

#### **What in terms of cost-savings/benefits does your technology bring?**

Newport's 25 years of ventilator manufacturing and design experience allows our customers to benefit from our history of reliability and value. All of our ventilator technology developments are based on our corporate mission of providing clinically effective ventilators at a cost affordable to every society. We continually strive to achieve the right balance of clinical benefits and cost so that we can offer safe, reliable, high quality products to all of our customers around the world.

## **Resmed**

Michael Farrell, Hillary Theakston

Michael Farrell is Vice President, Marketing; Hillary Theakston is Director of Communications, ResMed Corp.

#### **What ventilation products do you currently offer?**

ResMed offers the following range of ventilation products:

- VPAP III: A standard bilevel flow generator
- VPAP III ST: A bilevel flow generator with back-up rate
- VPAP III ST-A: A bilevel flow generator with back-up

rate and alarms

- VPAP Adapt SV: An adaptive servo-ventilation device

### How has technology changed over the past five years?

Advancements in technology have allowed us to treat a broader range of patients more comfortably and effectively than ever before. Positive airway pressure (PAP) treatment has come a long way since its invention in 1981, with a shift toward consumer-friendly products packed with more features to ensure comfortable therapy for patients as well as adherence and outcomes data for clinicians. For example, ResMed's VPAP range of devices includes ventilatory support systems for the treatment of adult patients with respiratory insufficiency or respiratory failure. We have also included the flexibility of setting minimum and maximum inspiratory time settings as well as trigger sensitivity (Vsync) adjustments for better synchronization of the VPAP with the patient's breathing effort. We have designed masks and flow generators for every type of sleeper and every type of nocturnal breathing disorder. Even the size of therapy products has changed over the past couple of years, with the introduction of more compact devices, like ResMed's S8 line of CPAP flow generators and our Mirage Swift nasal pillows system. Now more than ever, these lifestyle-oriented products are designed with the patient in mind to improve comfort and encourage long-term therapeutic adherence.

### What are the latest advances in technology that you have introduced?

This year, ResMed announced groundbreaking progress in its efforts to treat sleep-disordered breathing (SDB) with the launch of the VPAP Adapt SV in the United States. Our adaptive servo-ventilation technology has successfully treated thousands of patients with central sleep apnea and Cheyne-Stokes respiration with literally millions and millions of patient treatment hours on commercially sold devices. In Europe, our adaptive servo-ventilation technology is considered as an adjunct therapy in the treatment of heart failure patients. The VPAP Adapt SV is the first and only PAP device cleared for homecare use in the US to treat central sleep apnea, periodic breathing (Cheyne-Stokes respiration) and mixed apnea. It is receiving an enthusiastic response from sleep physicians who are often stymied in their attempts to treat patients with complex SDB. Historically, treatment options for patients with these challenging respiratory disorders have been limited to in-hospital ventilation, basic CPAP or bilevel. Our servo-ventilator device, the VPAP Adapt SV, fulfills the need for comfortable and effective homecare treatment options across the SDB spectrum.

### How has your company pursued R&D efforts to continue improving this technology?

We invest approximately 6-7% of revenues in R&D, which every year is a growing dollar figure. ResMed's team is focused on SDB and ventilation; we develop innovative therapies that increase patient comfort and convenience while improving health. We interact directly with customers on a daily basis through our field clinical and sales force, and our marketing team ensures that the customer's voice actively drives our product development life cycle. We delivered the S8 line, the Mirage Swift and the VPAP Adapt SV because we heard you, our customers, asking for smaller, more comfortable obstructive sleep apnea treatment, and for an answer to the issues of

central sleep apnea and mixed apnea. We are listening today and driving our R&D team toward your future needs with ongoing innovation.

### What type of training and customer support programs do you have in place?

ResMed's Clinical Education team is made up of a dedicated group of respiratory technicians and registered sleep technologists with extensive backgrounds in both cardiopulmonary medicine and sleep. The team works with our field representatives to assist hospitals, sleep centers and sleep labs with their educational needs. We offer specific training in ventilation, titration techniques and diagnostic procedures, with the opportunity for providing continuing education units (CEUs) to respiratory therapists, nurses, registered sleep technicians and case managers. We also have a team of technical experts as part of our Customer Service team; they are available to support our customers with technological questions and concerns regarding ResMed products.

### Describe your customer assistance program for technical or clinical issues.

Our team of clinical specialists support and assist our customers around the clock. They are trained in ventilation, titration techniques and diagnostic procedures to answer any clinical questions HME providers, physicians or sleep clinicians may have. In addition, our Customer Service representatives assist with day-to-day queries, from product support to clinical questions. We also offer multiple online resources, including therapy tips and product information for CPAP patients at MyResMed.com, as well as information for undiagnosed sleep apnea patients at HealthySleep.com. In addition, we offer a Reimbursement Hotline for customers with questions regarding insurance guidelines and procedures at 800.424.0737.

### How do you view your relationship with the end user of your product?

ResMed is committed to delivering world-class patient care based upon our diverse offerings of high-quality products. With a primary goal of maximizing patient adherence to therapy, our focus is on developing technologies that are more effective and more comfortable. Our patients and customers depend on us to deliver the most technically sophisticated and reliable products on the market. We continue to exceed customer expectations in this regard, particularly in the past year, with the full launch of the popular S8 and Swift treatment system for OSA. In addition to offering patient-friendly product lines, we provide our patients with the resources they need to achieve maximum benefit from their therapy. Patients undergoing treatment for SDB need substantial support in order to stay compliant. To augment the care patients may receive from their primary healthcare professionals, we have invested in developing an online support tool called MyResMed.com. The MyResMed site provides information specifically for CPAP users, which includes recent therapy tips, cleaning guides, answers on insurance questions, product information and customizable replacement reminders.

### What in terms of cost-savings/benefits does your technology bring?

ResMed's technology ensures that patients are receiving efficient and comfortable therapy, which leads to increased

adherence and, in turn, leads to long-term benefits for sleep centers, HME providers and, most of all, patients. Adherence to CPAP treatment is a win-win-win situation: the patient wins as they receive the associated health and quality of life improvements from CPAP; the HME wins as they have a satisfied and repeat customer; and the sleep center and sleep clinician win as they have a patient who feels great and may even tell their friends, neighbors and even strangers that Dr Smith or Nancy Jones, RT is an amazing clinician who “saved my life.”

Given the importance of patient comfort in driving lasting benefits, we spend our time developing technologies and systems that provide world-class comfort and effective outcomes. A prime example is our Mirage dual-wall cushion technology. From the first Mirage mask introduced many years ago to the Mirage Activa that we sell today, our dual-wall cushion and its patented technological design have driven significant comfort and adherence to CPAP treatment for millions of patients around the world. The key cost saving benefit derives from the success of these mask technology innovations: when patient comfort and satisfaction increases with a first-time fit, the number of complaints and re-fitting procedures decreases which saves unnecessary costs and simultaneously makes the patient happier and more likely to be successful with their positive airway pressure therapy. Our sleep center and sleep clinician partners are an integral part of that success. We successfully execute this job of treating SDB together every day we work better together and that is the best cost/benefit argument, period.

## Versamed

Kevin Plihal

Kevin Plihal is VP of Global Marketing and Business Development for VersaMed.

### What ventilation products do you currently offer?

VersaMed develops, manufactures and distributes the iVent201 to over 80 countries. The iVent is a compact critical care grade, transportable ventilator capable of providing invasive and non-invasive ventilation to pediatric through adult patients anywhere in the healthcare continuum; including the MRI suite.

### How has technology changed over the past five years?

In the past, mechanical ventilators were large cumbersome devices that were not really updateable and became obsolete very quickly. Today Versamed's ventilator is quite simply a computer capable of being upgraded through software enhancements to provide new features, modalities, or really anything that can be theorized by clinicians, for years to come.

### What are the latest advances in technology that you have introduced?

VersaMed's latest enhancement is the integration of pulse oximetry into the iVent201. This feature provides enhanced patient monitoring in a single device, and provides trending of both HR and SPO2 in addition to ventilation parameters for a 72 hour period of time.

### How has your company pursued R&D efforts to continue improving this technology?

By making use of the latest object oriented software technology and by incorporating the latest in multimedia and WiFi technology we are able to modify our graphical user interface easily to adapt to the latest technology that is evolving so rapidly. This allows us to bring new modalities to market quickly and at a low cost to our customers.

### How have you streamlined your cost of ownership?

We have worked very hard the past couple of years to refine our preventive maintenance and pneumatic overhaul requirements to ensure customers are not met with sticker shock every 1-3 years. All too often, this area is glossed over in the decision process and comes as a complete surprise to the customer at the end of the first ownership year. We took proactive steps to “stop the bleeding.”

### What type of training and customer support programs do you have in place?

VersaMed has a team of regional based clinical specialists that provide onsite clinical training to customers. In addition, we also offer an extensive online training program which can be scheduled at the customers convenience as well as an interactive training CD ROM with its own competency testing program.

VersaMed also offers biomedical training at its Pearl River, NY headquarters for those BMET's that wish to be fully service trained.

### Describe your customer assistance program for technical or clinical issues.

We offer 24x7 clinical and technical support via our toll free number.

### How do you view your relationship with the end user of your product?

In the end, this is the most important item to us. We see each of our customers as extended family members, and work hard to maintain a strong relationship with them. Our customers are our primary source for new product innovation and the driving force for product enhancement. We encourage our customers to speak with us freely and openly.

### What in terms of cost-savings/benefits does your technology bring?

Our technology demonstrates that full functionality and high-end features do not need to come with a high price tag. Where end users used to have to buy a transport ventilator, a non-invasive ventilator, and a general purpose ICU ventilator in separate packages, they now can purchase a single unit that can be deployed for any one of these purposes.

# iVent<sup>201</sup>

## Anytime...Anywhere.

Regardless of what your ventilation needs are; invasive or noninvasive, or where they take you; ICU, MRI, Transport, rest assured the iVent 201 has got you covered.

In short, no other compact ICU grade ventilator can match the iVent's list of standard features, and versatility.

Don't just take it from us; listen to what some of our customers are saying.

*"The iVent 201's versatility has really helped us to deal with the increased demands placed upon my department due to Hurricanes Katrina and Rita and proved to be an invaluable clinical tool"*

*-Ken D. Hargett, RRT*

*"I have been using the iVent for many years and have come to rely upon its ease of use and versatility. Its NIV capability is second to none!"*

*Joe Miro, RRT*

*"The varied clinical demands of the Emergency and Recovery Rooms is fully supported by my iVent 201. We do Invasive and Non-Invasive ventilation - sometimes on the same patient without difficulty"*

*Steven Nylund, Clinical Coordinator*

*"The patient comfort level and management of their ventilatory needs is greatly increased with the use of the iVent 201, and it plays an important role in the Combat Support Hospital setting."*

*Matthew Crown, SFC, U.S. Army*

VersaMed

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## EXECUTIVE PROFILE

### ARC Medical, Inc.

Hal Norris

Hal Norris is President of ARC Medical, Inc.

The ThermoFlo System is a passive humidifier designed to provide therapeutic levels of humidification to ventilator patients even at high minute volumes. The most serious untoward effect for passive humidification is an occluded ET tube. In more than 16 years of the use of ThermoFlo, there has never been an ET or Trach tube occlusion reported to the company, either officially or unofficially. There has been no product occlusions reported as well.

#### How does your product directly affect patient care?

By maintaining a functioning mucus elevator, the ThermoFlo System reduces VAP compared to patients using a heated water bath system. ARC is the only company that will guarantee a reduction in VAP when compared to heated humidification, or the facility will get 3 months of free product.

#### Tell us about the latest advances in the area your product serves.

At the AARC we introduced the ThermoFlo Midi. This product is designed for patients who are on a lung protective strategy. It has a smaller dead space but with our traditional high humidification capabilities.

#### What sets your product apart from others in the field?

ThermoFlo has the highest humidification numbers with the lowest resistance to flow of any of our competitors when compared with 3rd party testing. Our filter media is by 3M and has the highest respect among all filter media manufactured today.

#### Discuss your R&D process, including end-user input.

ARC is constantly looking for new products and new ideas from our end-users. If a product is good for one RCP, the chances are it will be a good fit for others.

#### What are your goals for R&D in the near future?

While our HME media is the finest extant, there are still some increases in humidification efficiency to be gained. We are working with RCPs to determine if those efficiencies are necessary.

#### Discuss the educational services you offer for use of your product.

The most important tool we have is our Sputum Evaluation Form. This tool allows the end-user to see how well we perform on a specific patient. We also provide videos and personal in-services for our customers.

#### Discuss the role of critical care providers in developing and upgrading your product.

Through the years, RCPs have offered suggestions and improvements that have been incorporated into the product. Our "Special" version came from the use by several of our

customers. The use of our device with nebulization was a direct result of end-user information.

#### Talk about how you test and evaluate your product in actual day to day use.

The Sputum Evaluation Form allows us to see how we are doing on a patient. <http://arcmedical.com/PDF/thermoflo-manufacturers-rec.pdf>

#### What new technology do you see as having the greatest impact on your area of expertise?

Until technology is invented to replace ventilators, there will be a need for humidification.

#### Discuss the international scope of your testing/marketing/development efforts.

My manufacturer has rights to the product internationally. We are a domestic company only.

#### Tell us how you utilize conferences, seminars and such to promote your product.

We exhibit at AARC and Focus as well as many state and local respiratory meetings.

## NEWS FEATURE

### f/Vt Ratio: A Useful Predictor of Weaning Success?

Tim France, BS, RRT

Reprinted from Hamilton Medical's Intelligent Ventilation Newsletter

A common practice in today's ICUs is the use of a daily wean screen to assess a patient's readiness liberation from mechanical ventilation. If a patient fails any component of the wean screen, they are not weaned that day. The f/Vt ratio is commonly used by bedside clinicians as a tool to assess the readiness for patients to undergo a spontaneous breathing trial (SBT) or as a predictor of successful extubation. (also known as the RSBI/rapid shallow breathing index). The f/Vt is independent of patient effort and can be easily obtained. The ratio is calculated by dividing the respiratory rate by the spontaneous Vt, with any ratio greater than 105 considered a failure. In a recent Critical Care Medicine article, Dr. Tanios and colleagues studied whether a weaning predictor such as the f/Vt is useful or even needed.

The randomized controlled study incorporated a simple weaning protocol that was used on all patients. All patients had the f/Vt measured, but roughly half of the patient's measurements were not used when making the decision to proceed with a SBT (the clinicians were blinded to the f/Vt results). In the study group, the f/Vt had to be less than 105 to proceed with the spontaneous weaning trial. The key outcome that was measured was weaning time. Weaning time was defined as the time elapsed from the

first daily screening to the time of extubation, 21 days from enrollment, tracheostomy placement, death or withdrawal of care. Other outcomes measured were total time of mechanical ventilation and the reintubation rate. In addition to the  $f/V_t$  measurement, the weaning incorporated five criteria. The criteria included an oxygenation assessment ( $PaO_2/FIO_2$  ratio  $\geq 150$  or  $O_2$  Sat  $> 90\%$  at  $FIO_2 \leq 40$ ),  $PEEP \leq 5$  cmH<sub>2</sub>O, mean arterial pressure  $\geq 60$  mmHg without vasopressors, whether the patient was awake or easily arousable and the patient had an adequate cough during suctioning and did not require suctioning more often than every 2 hours.<sup>1</sup>

The results of the study were quite surprising in that the group that used the  $f/V_t$  results had the longest weaning time. The weaning time for the non  $f/V_t$  group was 2 days compared to 3 days for the group that used the  $f/V_t$  as part of the wean screen assessment. The two groups had similar duration of time on mechanical ventilation (6 days). Complications such as reintubation rates, mortality and self extubation rates were similar for both groups.

The article cites a comprehensive study that states that weaning predictors fail to specify clinically relevant changes in the likelihood of weaning success or failure.<sup>2</sup> Adding a weaning predictor such as the  $f/V_t$  did not predict if a patient was ready to wean or extubated with any degree of accuracy. Dr. Tanios found that omitting the  $f/V_t$  as a weaning predictor did not change outcomes or increase adverse events. Furthermore, it was associated with a delay in extubation of one day.

Paul Garbarini, Clinical Operations Manager, offered the following commentary: On the surface, this RCT would support the elimination of the  $f/V_t$  as a weaning tool. On the other hand, there's several aspects of this study I'd like to explore.

The current study authors state that the  $f/V_t$  was obtained by removing the patient from the ventilator and connecting to a spirometer. (Yang and Tobin, the authors of the original  $f/V_t$  study also measured the  $f/V_t$  on room air). Yang and Tobin around the same time reported in *Crit Care Med.* 1991 Jan;19(1):49-53, that roughly half of the 15 patients in separate study failed the  $f/V_t$  threshold due to increases in VE while breathing room air. In the current study, the SBT's were conducted on up to 5cm CPAP and 7cm of pressure support and up to 40% O<sub>2</sub>. The current study did not report what the  $f/V_t$  was at either the start or end of the weaning trial (on CPAP/PS). It would have been interesting to know what the  $f/V_t$  was on CPAP/PS in that perhaps more of the patients would have 'passed' the eligibility criteria to perform a SBT. (I understand the intent of replicating the original  $f/V_t$  technique for this study). The reality in clinical practice is that most  $f/V_t$  measurements are done 'through the ventilator' on some 'minimal' level of CPAP +/- or PSV.

Having measured  $f/V_t$ 's hundreds of times at the start of a weaning trial, I rarely recorded the  $f/V_t$  obtained during the 1st minute, but rather waited up to 5 minutes for the patients respiratory pattern to (hopefully) stabilize. This was particularly true if the patient was rapidly transitioned from a 'rest' mode to a SBT. In a previous 'Enew's we reviewed the Kuo et.al. study that demonstrated the positive predictive value of the  $f/V_t$  measured at the END of the weaning trial period. Indeed, in the

current study the failure criteria of a  $RR > 35$  for greater than 10 minutes would support my contention that a single point measurement of  $f/V_t$  at one minute, as this study reports, is probably not of much value in predicting weaning outcome. Trending of  $f/V_t$ , RR etc. along with measuring the variability of the respiratory pattern over time during the weaning trial appear to be worthy of more study.

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## SHORT COMMUNICATION

## Early Tracheostomy in Critically Ill Trauma Patients, a Review

Tim France, BS, RRT

Bench to bedside: “Early tracheostomy in critically ill trauma patients” is a review of the available literature regarding the timing of tracheostomy in trauma patients and any advantages realized by early tracheostomy. Routinely, patients are evaluated for tracheostomy after 21 days on mechanical ventilation.<sup>1</sup> However, there is a trend toward tracheostomy earlier in a trauma patient’s ventilator stay. The article looks at the complications associated with tracheostomy, and any advantages of tracheostomy. The article also looked at indications for tracheostomy and predictors for tracheostomy.

Complications of prolonged endotracheal intubation are many. They include ulceration, scarring and stenosis. Others include glottic injury, subglottic injury and tracheal injury. Tracheal stenosis/malacia and sinusitis are also common complications. A complication that has received much press has been ventilator associated pneumonia (VAP). According to the literature reviewed the incidence for complications could be as low as 3% for laryngitis and as high as 90% for sinusitis.<sup>1</sup>

Tracheostomy has a number of advantages over endotracheal intubation. Tracheostomy reduces dead space ventilation, airway resistance, work of breathing and improves the weaning process. Tracheostomy also reduces the risk of airway damage. Patients are able to speak and eat. Tracheostomy also helps with airway hygiene and decreases the incidence of VAP. Trauma patients have a shorter length of stay both on the ventilator and in the hospital, enabling them to move thru the system a lot quicker, thus utilizing resources more efficiently.

Several retrospective studies identified indications for tracheostomy in trauma patients. Most included injury directly to the airway such as laryngotracheal injury or penetrating neck injury. Also identified were head injuries with the inability to protect the airway. The percentages found in retrospective studies ranged from three percent for maxillofacial injury to 100% for head injury patients.

Being able to predict if a patient will require a tracheostomy is very important when deciding to utilize tracheostomy early. Upon review of the literature the researchers found that the age of the patient and Glasgow Coma Score (GCS) were predictors, along with oxygenation status and Injury Severity Score (ISS). Witnessed aspiration, reintubation, hemodynamic instability and increased Simplified Acute Physiology Score (SAPS) were also predictors. Ross et al<sup>2</sup> found that patients >40 years old and with a GCS  $\leq 7$  and with poor oxygenation status were patients who had long ventilator stays and thus would require tracheostomy. Gurkin et al<sup>3</sup> found that a GCS  $\leq 8$  associated with an ISS  $\leq 25$  were predictors of tracheostomy. Several other studies found that combinations of the various predictors would indicate a prolonged ventilator length of stay requiring tracheostomy.

Traditionally, most patients have been considered for tracheostomy after they have been ventilated for two to three weeks. Trauma patients are a subset of patients where tracheostomy has been utilized more aggressively. The reason for this could be because of the nature of trauma injuries and the associated increased length of time on the ventilator. The authors of this article, Shirawi and Arabi stated that from the data that they reviewed, tracheostomy should be strongly considered if a patient will require an endotracheal tube for more than 7 to 10 days.

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## SHORT COMMUNICATION

# Protective Lung Ventilation Strategies in the PICU

Melissa Turner, MS, RRT

Protective Lung Ventilation Strategies in the PICU was a lecture presented by Jim Keenan BS, RRT-NPS, FAARC at the CSRC 38th Annual Convention in Rancho Mirage on June 30, 2006. In the lecture Keenan spoke of pitfalls, basic pediatric ventilation standards, protective lung strategies, and closed loop ventilation. This article will cover some of the high points of Keenan's lecture.

Some of the pitfalls associated with pediatric ventilation as identified by Keenan are as follows. Pediatric patients have long been treated as adults or neonates without recognizing that they fall somewhere in between both categories. For a long time, there was no pressure support or pulmonary graphics available for pediatric ventilation. Lastly, the tidal volumes used with pediatric patients tended to be on the high side.

Keenan went on to address some of the modes and settings used with pediatric patients as well as lung protective strategies within those settings. In order to employ lung protective strategies, tidal volumes of 6-8cc/kg should be used. This is based on studies on adults as there is no evidence of low tidal volume ventilation as a lung protective strategy with pediatric patients. Cardiac patients would use only a slightly higher tidal volume according to Keenan. Peak inspiratory pressure (PIP) for pediatric patients should be modest, not to exceed 30-45 cm H<sub>2</sub>O. As far as a PEEP strategy, it generally follows adult guidelines as well as there is only evidence for the adult, ie, ARDSnet studies. Pulmonary graphics should be used to identify critical opening pressures in order to set the PEEP and avoid overdistention. The PV curve was mentioned as being very useful in determining the lower inflection point (LIP) to find optimal PEEP as well as seeing a "bird's beak" will help to identify overdistention. Disconnects should also be avoided to prevent derecruitment. Pulmonary graphics should also be utilized to set appropriate flowrates. He mentioned the PV Tool by Hamilton Medical Inc. as a great tool to use to find the best PEEP for pediatric patients with whom he has worked.

There should be no "scoops" in the flow waveform. Keenan also pointed out that it is beneficial to have trending capabilities in addition to pulmonary graphics to be able to optimally manage the patient's settings.

Closed loop control, was said by Keenan to change ventilation as per the patient's change in condition. He also pointed out that many argue that "the ventilator is not going to dictate and manage my patients." Keenan's answer was that the ventilator software is the pulmonary expert! It was developed by the same people that we consider the experts and follow. He went on to talk about the desired effects of closed loop control which included auto-weaning, maintaining tidal volume, ensuring minute ventilation and the ability to adapt pressure for both mandatory and spontaneous breaths. Keenan identified AVtS as an incorporation of all the above as well as efficient weaning.

Also mentioned was the use of high frequency oscillation ventilation as well as APRV. Keenan says he has used APRV on the Galileo ventilator, which is DuoPAP+, in pediatric patients while getting the high frequency oscillator ready. He recommends trying the DuoPAP+ while setting up the oscillator as he has found that many patients do well on this mode and even avoid the oscillator. Keenan says that if the oscillator can be avoided, there is less sedation and complication and the patient is able to be weaned more quickly.

Keenan speaks from much experience, concluding again that there is little to no published pediatric data. He recommends understanding all modes and how and when to use them. It is very important to avoid disconnects and to incorporate pulmonary graphics and optimal PEEP while taking care of the ventilated pediatric patient. (Editorial note: Mr. Keenan's lecture was supported through an educational grant provided by Hamilton Medical, Inc.) For more information contact [hammed1.com](mailto:hammed1.com).

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Presented by Jim Keenan BS, RRT-NPS, FAARC. Reprinted from Hamilton Medical's Critical Ventilation newsletter.



## FACILITY PROFILE

# Meeting the Challenges of Critical Care: AnMed Health—Where Information and Ventilator Technology Meet

Physicians at AnMed Health Medical Center do not need to stand at their patients' bedsides in the ICU to check the parameters on their ventilators. They can do so from anywhere they have access to a computer terminal – whether that is in the hospital or on its campuses, their offices, or even their homes during off hours.

Such connectivity is part of the 600-bed, four hospital system's leading-edge philosophy that has been driving its care since its founding in 1908.

Located on a 16-acre campus near downtown Anderson, AnMed Health Medical Center is a teaching hospital that serves people living and working in eight counties in southwestern South Carolina, an area known as the Upstate, and eastern Georgia. "Even though a lot of people may never have heard of Anderson, South Carolina, we have always thought of ourselves as leading-edge," says Peggy Deane, RN, senior vice president for patient care services, who has been with the health system for 35 years.

As part of its progressive philosophy, the hospital has been working toward a paperless environment. It is already paperless once the patient leaves the hospital, and it expects to reach that goal on the floors within five years. When it comes to respiratory care, the hospital is well on its way toward its goal of having all medical records be electronic.

### Integrated Info

AnMed Health has 26 SERVO ventilators in its fleet. In early 2005, the hospital's information technology department connected its ventilators to its facility-wide computer system, so that all respiratory records can be produced and stored electronically. Even though the hospital has three generations of SERVO ventilators, it was able to easily integrate the entire fleet.

The project took less than four months, including building an ethernet port in each ICU patient room so that the ventilators could be connected to the system, says Darrell Hickman, Chief

Information Officer for the hospital. Green cables were used for the ethernet to distinguish it from the other cables needed to run critical-care equipment.

The hospital employs a Nursing Informatics Applications Specialist, Sheila McLaurin, RN. After listening to the needs of RTs and physicians, McLaurin was able to program the system so that they could click on just one button and have all the data from the ventilator pop onto the computer screen. "With one click, they can see up to 20 data points," she says. "The old, time-consuming way was to do it one at a time."

"Whatever is on the ventilator is charted in real time," adds Scott Small, RRT, RCP, clinical manager for respiratory services, who has been with the hospital 12 years.

Electronic medical records help improve care because they save time and reduce chances for errors, Hickman says. "The closer you push acquisition of data to delivery of care, the better it is because it makes the data more immediate and accurate," he says.

The hospital administrators are convinced that the connectivity between the ventilators and information systems has improved the accuracy and efficiency of its respiratory services, and thus, patient care throughout the health system.

Most importantly, Small says, the connectivity allows the respiratory therapists to spend more time caring for patients and less time charting numbers. "It has turned our therapists back into therapists instead of data-entry people," he says. "Because the data is entered automatically, the therapists can spend more time caring for patients and weaning them off the ventilators."

The electronic system also allows Small to be more efficient as a clinical manager – he is responsible for 11 respiratory therapists in the department, which has 77 full-time equivalents. "I can sit at my desk in the morning and find out what every patient is on without having to visit all four ICUs. I can prioritize

who I need to see first, and I am better prepared when I do go see the patients,” he says. AnMed has 46 intensive-care beds: 19 in its medical ICU; 15 in coronary care; six in cardiovascular; and six in neuro-ICU. Its emergency unit sees nearly 85,000 patients a year.

The hospital’s advanced information system in conjunction with the SERVO ventilators also allows physicians to make more informed clinical decisions, which have improved patient outcomes, Small says. From anywhere in the system, a physician can see trend data from the last 12 hours and decide whether to remove a patient from the ventilator. “The system provides a much better picture of the patient’s overall status than what a physician can see in a few minutes during rounds,” Small says.

### **Fast, Efficient**

AnMed Health has respiratory management protocols in place that allow its therapists to make some adjustments to ventilators as needed. When physicians need to make adjustments, they can look at the patient’s respiratory parameters from any computer terminal connected to the network system. Not having to wait for the physician to get to the ICU has resulted in less time on the ventilator for many patients, Small says.

Physicians often will stop Garrick Chidester, Vice President for Network Development, and tell him they appreciate having the ability to connect from wherever they are when they are paged. “They say the connectivity makes it possible for them to get the data they need to make more informed clinical decisions faster and more efficiently,” he says. “In the end, the patients are the ones who benefit the most.”

The connectivity also makes it easier for the hospital to recruit respiratory therapists because most RTs want to work where they do what they were trained for, not where they have to be clerks much of their shift, Small says. “I have always believed that we were able to recruit RTs here because we give RTs more input, more involvement in the care of patients,” agrees Chidester, who has been with the health system for 23 years.

The vast majority of ventilator patients at AnMed Health can be weaned in about three days, says Wanda Perry, RRT, RCP, M.Ed, who has been director of respiratory care for the last four years. That is a low length-of-stay, she says.

While connectivity clearly has helped to reduce ventilator stays for many patients, Perry says, the functional capabilities of the SERVO-i ventilators they have in their fleet also play an important role. The Open Lung Tool (OLT) is one such advantage with SERVO technology. SERVO-i ventilators, the newest in the SERVO product line by Maquet, have a unique Open Lung Tool (OLT) that provides the clinicians with the parameters they need to more easily perform lung recruitment maneuvers. Its graphic user interface provides information about end inspiratory pressure (EIP) and PEEP pressures, and inspiratory and expiratory tidal volume as well as dynamic compliance. Seeing these parameters, the clinician can analyze the extent of opening and closing the alveoli.

“There’s a window of opportunity to take the patients off the

ventilator and you don’t want to lose that,” Perry says. “The OLT allows us to take advantage of that opportunity.” Thirty-five patients were studied from January through June 2006. By utilizing OLT and a lung recruitment protocol, the AnMed Health team noticed a significant decrease in peak inspiratory pressure (PIP) and a significant increase in dynamic compliance; no changes in heart rate or arterial blood pressure were noted. “Our outcomes data validates using a lung recruitment maneuver as a ‘best practice’ strategy during mechanical ventilation,” Perry says.

SERVO-i’s OLT takes the guesswork out of lung recruitment, making it a safer and shorter procedure, says Small, who reports on the hospital’s use of the tool at meetings of respiratory care professionals.

In his presentations, Small tells colleagues the OLT is like a GPS guide to ventilating pressures. “It’s really a map that tells us what ventilating pressures we need to be ventilating our patients at. I could have found them without the OLT but it would have been a much longer process,” he says. “The OLT takes the guesswork out and that’s what makes our job so much easier now.”

### **Shorter Stays**

The ability to wean patients from ventilators more quickly is critical because every day a patient is on a ventilator, the chances of complications grow exponentially, Perry says.

Reduced ventilator stays mean a lower rate of ventilator-associated pneumonia, a common complication of mechanically ventilated patients. “We have a very low rate of ventilator-associated pneumonia because we are able to get our patients off the ventilator quickly,” Perry says.

The reduction in ventilator time also is cost-saving because patients who are on ventilators for a length of time are more likely to need medical procedures such as tracheotomies, Perry says. Tracheotomies are one of the most expensive diagnostic-related groups (DRGs) in any hospital, Small notes. “The average tracheotomy patient is in the hospital for more than 40 days, so if we can eliminate the patient getting a tracheotomy, it’s a significant savings to the health-care system.”

Because visitors to Anderson see a small community, they are often surprised to learn it is home to a major medical system offering leading-edge technology, Chidester says. However, he says, “If you just look at our respiratory department, it’s been a consistent philosophy for us to be cutting-edge.”

“Having the connectivity and the OLT,” Small adds, “I know we are positively affecting patient outcomes.”

# Predictors of Outcome in Children with Hydrocarbon Poisoning Receiving Intensive Care

M. Jayashree, S. Singhi and A. Gupta

The retrospective study included 48 children between 8.5 months – 10 years, admitted to the PICU of an urban, tertiary care, teaching hospital in northern India from January 1995 to December 2001. Eighteen (38%) patients were hypoxemic on arrival, of which 8 (45%) required mechanical ventilation. Compared to the non-hypoxemic children, the hypoxemic patients were more likely to have received gastric lavage before arrival to our center (Odds Ratio 23.2. 95% CI 2.4-560.7) and had higher frequency of severe respiratory distress and leucocytosis (Odds Ratio 8.0. 95% CI 1.79-38.6). On multiple regression analysis, we could not identify any particular variable that could predict hypoxemia. Secondary pneumonia developed in 16 (33.3%), with the duration of PICU stay being longer in these patients as against those who did not (144 hours vs 72 hours,  $p < 0.05$ ). Two (4.2%) children died and one suffered hypoxic sequelae. Prior lavage, hypoxemia at admission, need for ventilation, secondary sepsis and ventilator related complications were associated with poor outcome.

**Key words:** Hydrocarbon, Hypoxemia, Intensive Care, Lavage.

The morbidity and mortality associated with hydrocarbon ingestion in children are primarily related to the pulmonary aspiration and its subsequent complications.<sup>1</sup> There have been few studies from the developing countries focusing on the predictors of outcome<sup>2</sup> but none on the impact of intensive care in these patients. In this retrospective review we aim to highlight the predictors of outcome in children with hydrocarbon poisoning receiving intensive care. This can serve as a tool in early identification of the severity of illness and allow prioritization of intensive care especially in developing countries with limited resources.

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## Subjects and Methods

Forty-eight consecutive children with hydrocarbon poisoning admitted to the PICU of a multi-specialty tertiary care, urban teaching hospital with 1200 beds between January 1995 to December 2001 (7 years) were studied retrospectively. Patients were identified from the PICU admission register and data was retrieved from their case-records with respect to age, seasonal distribution, clinical features and occurrence of hypoxemia at presentation ( $\text{PaO}_2 < 60$  mmHg at room air), treatment, need for mechanical ventilation, complications and outcome. Outcome was defined as length of PICU stay, survival, death or survival with sequelae.

All patients presenting with hydrocarbon poisoning to our Emergency were admitted and treated with a standard protocol consisting of skin decontamination, maintenance of oxygenation, fluid and electrolyte balance and ventilation, if required. Monitoring was carried out as per standard guidelines. Hypoxemia was defined as  $\text{PaO}_2 < 60$  mmHg in room air on arrival. Before December 1997, all symptomatic patients were given antibiotics. After 1997, only patients with secondary pneumonia received parenteral antibiotics (cloxacillin and gentamicin) in usual doses.

Descriptive statistics, frequencies and mean  $\pm$  SD were used for data presentation. Measures of central value were compared by students to test for parametric data and by Mann-Whitney U test for nonparametric data. Categorical data were compared using the Chi-square test. Hypoxemic and non-hypoxemic children were also compared using a univariate and multiple logistic regression analysis to determine the significant predictors of hypoxemia. SPSS version 10.0 and Epi-Info 2000 were the statistical packages used in data analysis.

## Results

During the study period, 143 patients with poisoning were admitted to our PICU; 48 (34%) of these had ingested hydrocarbons. Of the hydrocarbon ingested, kerosene was the commonest 41 (85%) followed by petrol 3 (6%) turpentine oil 2 (4%) and diesel and sewing machine lubricant in one patient

**TABLE I**—Clinical features of 48 children with hydrocarbon poisoning admitted to PICU

Demographic features	
Age (years), median [Range]	2 [0.7 - 10]
< 5 years, n (%)	45 (94)
Sex, M: F	3.4: 1
Presenting features, n (%)	
Respiratory distress	48 (100)
Altered sensorium	22 (46)
Seizures	2 (4)
Vomiting	6 (13)
Fever	4 (8)
Onset of symptoms (hours) median [1 Q Range]	0.21 [0.16-1.6]
Chest radiograph abnormality n (%)	
Bilateral lower lobe infiltrates	34 (71)
Right lower lobe infiltrates	6 (12.5)
Left lower lobe infiltrates	3 (6.3)
Pleural Effusion	2 (4.1)
Pneumatocele	2 (2)
Pneumothorax	1 (2)
Leucocytosis, n (%)	18 (38)
Intensive care needs and outcome, n (%)	
Hypoxemia	18 (38)
Hypercarbia	2 (4.1)
Metabolic acidosis	2 (4.1)
Mechanical ventilation	8 (16.6)
Secondary pneumonia	16 (33.3)
Died	2 (4.2)
Hypoxic sequelae	1 (2.1)

each. The demographic and clinical characteristics of these patients are as shown in Table I. Almost all patients had onset of symptoms within 4 hours; only 2 had symptoms after 48 hours.

Of the 18 patients who were hypoxemic on arrival: 10 (55%) improved on supplemental oxygen (6 L/min) and 8 (45%) needed mechanical ventilation. Results of univariate analysis on comparison of hypoxemic vs. non-hypoxemic children are provided in Table II. On multiple regression analysis, we could not identify any particular variable that could predict hypoxemia.

Six of the ventilated children developed complications: pneumothorax (n = 3). ARDS with pneumothorax (n = 2) and ventilator associated pneumonia (n = 1). In 6 of 8 patients who were ventilated and survived, the median duration of PICU stay was 360 hours (range 192-2040 hours), in contrast to the non-ventilated group (40/48), where it was 72 hrs (range 24-216 hours) (p < 0.05 by Mann-Whitney U test).

Nine patients had received gastric lavage prior to reaching our center. These children were compared with thirty-nine others who had not received lavage (Table III). Patients in the lavage group presented significantly more often with severe respiratory distress (tachypnea, chest wall retractions and use of accessory muscles of respiration), were hypoxemic on arrival and needed mechanical ventilation. No difference was found in the incidence of neurological symptoms, secondary pneumonia and hospital stay between the two groups, but both the deaths in the study population occurred in patients in the lavage group.

Sixteen patients developed secondary pneumonia and received intravenous antibiotics. Twelve patients had received prophylactic antibiotics. The remaining twenty patients had no evidence of secondary pneumonia and hence did not receive any antibiotics.

Out of 48 patients, 46 survived, 2 died and one had hypoxic sequelae. Hypoxemia on arrival, prior lavage, higher need for ventilation and higher frequency of secondary pneumonia and ventilator-associated complications were associated with poor outcome.

**TABLE II**—Comparison of Hypoxemic vs Non-hypoxemic Children with Hydrocarbon Poisoning.

	Hypoxemic (n = 18)	Nonhypoxemic (n = 30)	Odds ratio	95%CI for OR
Age (years)	2.32 ± 2.12	2.02 ± 1.50**		
Mean ± SD				
Sex, M: F	2.6: 1	4.2: 1		
Lavage given, n(%)	8(44.4)	1 (3.3) *	23.2	2.43- 560.7
Signs of Respiratory distress, n (%)				
Tachypnea	18(100)	30(100)	Undefined	
Retractions	18(100)	14 (46.6) *	Undefined	
Nasal flare	14(77.8)	3 (10) *	31.5	5.05- 244.1
Head bob	8(44.4)	1 (3.3) *	23.2	2.35- 560.7
Leucocytosis, n (%)	12(66.7)	6 (20) *	8.0	1.79- 38.6
Secondary Pneumonia, n (%)	12(66.7)	4(13.3)*	13.0	2.58-73.65

\* P < 0.05 by Chi Square test; \*\* Students 't' test.



**TABLE III**—Comparison of Children who Received Gastric Lavage vs no Lavage Before Admission.

	Lavage group (n = 9)	No lavage (n = 39)
Age (years)		
Mean ± SD	1.61 ± 0.60	2.12 ± 1.8
Sex (M : F)	1.25: 1	5.1: 1
Signs of respiratory distress, n(%)		
Tachypnea	9(100)	39(100)
Nasal Flare	5(55.5)	12(30.7)
Retractions	8(88.9)	24(61.5)
Head bob	2(22.2)	7(17.9)
Hypoxemia, n(%)	8(88.9)	11*(28.2)
Leucocytosis, n(%)	5(55.5)	13*(33.3)
Need for mechanical ventilation, n(%)	5(55.5)	3*(7.6)

\* P < 0.05 by Chi Square test.

## Discussion

In our series, hydrocarbon ingestion constituted 35% of all poisonings admitted to PICU, kerosene being the commonest. Marked seasonal predilection for summer months could be attributed to kerosene being mistaken for water.<sup>3-6</sup> Most patients were symptomatic by 4 hours, which is similar to the previous observations.<sup>1,7</sup> Delayed presentation at 48 hours in 2 patients could be explained by superimposed bacterial infection. All symptomatic patients had chest radiographic abnormalities, the commonest being bilateral lower lobe infiltrates.<sup>2,4,6,8</sup>

Hypoxemia at admission was evident in nearly one third of our patients and was associated with poor outcome. These patients had signs of severe respiratory disease, higher frequency of lavage and leucocytosis and increased need for mechanical ventilation. Mechanical ventilation as a modality of therapy to overcome hypoxemia and pneumonia respiratory failure in hydrocarbon ingestion has been well described.<sup>3,4,9</sup> Nearly one sixth of our patients needed mechanical ventilation and three fourths of these went on to develop ventilator related complications over and above the primary disease. This tended to prolong the length of hospital stay as compared to the non-ventilated group. Need for mechanical ventilation by itself becomes a poor prognostic factor as it is associated with higher incidence of ventilator related complications and longer ICU stay. Development of secondary pneumonia similarly contributed to the increase in length of hospital stay, as compared to those who did not. We, however, did not find any significant difference in the median duration of hospital stay between the group that received prophylactic antibiotics in patients with hydrocarbon ingestion.

In our series, the severity of aspiration was higher in the lavage group, substantiating the earlier hypothesis that induced vomiting and lavage; by re-exposing the patient's glottic opening may increase the severity of pulmonary symptoms.<sup>1,10-12</sup>

Similarly, the higher morbidity and mortality in this group, reaffirms the fact that lavage should be avoided in hydrocarbon ingestion and if indicated should be performed only after proper airway protection. In a developing country like ours, with limited resources it may not be possible to shift all patients with hydrocarbon ingestion to an intensive care set up. Our findings may help in recognizing children with hydrocarbon poisoning who are at high risk for development of hypoxemia and therefore should get priority over others for intensive care management so as to improve the outcome.

## Conclusions

Hydrocarbon poisoning continues to be an important cause of poisoning related morbidity and mortality in developing countries. Most poisonings were accidental and occurred in the under five-age group. Hypoxemia on arrival, prior lavage, higher need for ventilation and higher frequency of secondary pneumonia and ventilator-associated complications were associated with poor outcome. In a developing country with scarce resources, patients at high risk for development of hypoxemia should hence be selected for intensive care, as the mortality and morbidity in these patients tends to be higher. This group should include patients with history of lavage, signs of severe respiratory disease and leucocytosis at admission. This approach can help in using the limited intensive care resources effectively.

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# Imposed Work of Breathing During High-Frequency Oscillatory Ventilation: A Bench Study

Marc van Heerde, Huib R. van Genderingen, Tom Leenhoven, Karel Roubik, Frans B. Plötz, Dick G. Markhorst

**Introduction:** The ventilator and the endotracheal tube impose additional workload in mechanically ventilated patients breathing spontaneously. The total work of breathing (WOB) includes elastic and resistive work. In a bench test we assessed the imposed WOB using 3100 A/3100 B SensorMedics high-frequency oscillatory ventilators.

**Methods:** A computer-controlled piston-driven test lung was used to simulate a spontaneously breathing patient. The test lung was connected to a high-frequency oscillatory ventilation (HFOV) ventilator by an endotracheal tube. The inspiratory and expiratory airway flows and pressures at various places were sampled. The spontaneous breath rate and volume, tube size and ventilator settings were simulated as representative of the newborn to adult range. The fresh gas flow rate was set at a low and a high level. The imposed WOB was calculated using the Campbell diagram.

**Results:** In the simulations for newborns (assumed body weight 3.5 kg) and infants (assumed body weight 10 kg) the imposed WOB (mean  $\pm$  standard deviation) was  $0.22 \pm 0.07$  and  $0.87 \pm 0.25$  J/l, respectively. Comparison of the imposed WOB in low and high fresh gas flow rate measurements yielded values of  $1.63 \pm 0.32$  and  $0.96 \pm 0.24$  J/l ( $P = 0.01$ ) in small children

(assumed body weight 25 kg), of  $1.81 \pm 0.30$  and  $1.10 \pm 0.27$  J/l ( $P < 0.001$ ) in large children (assumed body weight 40 kg), and of  $1.95 \pm 0.31$  and  $1.12 \pm 0.34$  J/l ( $P < 0.01$ ) in adults (assumed body weight 70 kg). High peak inspiratory flow and low fresh gas flow rate significantly increased the imposed WOB. Mean airway pressure in the breathing circuit decreased dramatically during spontaneous breathing, most markedly at the low fresh gas flow rate. This led to ventilator shut-off when the inspiratory flow exceeded the fresh gas flow.

**Conclusion:** Spontaneous breathing during HFOV resulted in considerable imposed WOB in pediatric and adult simulations, explaining the discomfort seen in those patients breathing spontaneously during HFOV. The level of imposed WOB was lower in the newborn and infant simulations, explaining why these patients tolerate spontaneous breathing during HFOV well. A high fresh gas flow rate reduced the imposed WOB. These findings suggest the need for a demand flow system based on patient need allowing spontaneous breathing during HFOV.

## Introduction

Maintenance of spontaneous breathing in mechanically ventilated patients augments ventilation perfusion matching and cardiopulmonary function, reduces sedative requirement and shortens the intensive care stay.<sup>1-6</sup> High-frequency oscillatory ventilation (HFOV) is a useful ventilatory mode for neonatal application<sup>7,8</sup> and it is gaining interest in both pediatric and adult intensive care.<sup>9-12</sup> Neonatal and small pediatric patients can easily breathe spontaneously during HFOV. Muscular paralysis is avoided and only mild sedation needs to be applied to tolerate ventilation and reduce stress. In larger children and adults, however, spontaneous breathing during HFOV is usually not well tolerated because of patient discomfort. The sedation level often has to be high and even muscular paralysis may be necessary.<sup>13</sup> We speculate that this discomfort is caused by a high imposed work of breathing (WOB). The imposed WOB is the work added to the physiologic WOB when patients breathe through a breathing apparatus. This includes work to overcome resistance added by the endotracheal tube, the breathing circuit

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and the humidification device, and work required to trigger the ventilator demand flow system. A physiologic WOB of 0.3–0.6 J/l is considered normal in a healthy adult.<sup>14</sup> Depending on the ventilator settings, the imposed WOB can contribute as much as 80% to the total work of breathing.<sup>15</sup> The imposed WOB is greatest during continuous positive airway pressure, where the patient performs all the effort required to ventilate.<sup>16</sup> HFOV may in this respect be regarded as super-continuous positive airway pressure.

In a physical sense, work is performed when a transmural pressure ( $P_{TM}$ ) changes the volume ( $V$ ) of a distensible structure:  $W = \int P_{TM} \cdot dV$ , most often expressed as Joules per liter (J/l). Applied to a breathing apparatus, the imposed WOB is calculated by integrating the pressure measured at the tracheal end of the endotracheal tube ( $P_{ETT}$ ) times the volume change: imposed WOB =  $\int P_{ETT} \cdot dV$ . As inspiration is active and expiration is usually passive, only the inspiratory imposed WOB is generally considered. In a SensorMedics HFOV ventilator (3100 A or 3100 B; SensorMedics, Yorba Linda, CA, USA), the imposed WOB is directly related to the breathing-related difference between the set mean airway pressure (MAP) and the  $P_{ETT}$ ; the greater the difference, the greater the imposed WOB and thus patient effort. MAP is regulated by a continuous fresh gas flow rate and an expiratory balloon valve. During inspiration of a patient, air is inhaled from the ventilator and the  $P_{ETT}$  level drops. The magnitude of this drop is influenced by the fresh gas flow rate, the endotracheal tube size and the inspiratory flow rate.<sup>14</sup>

In order to find a solution to better tolerate spontaneous breathing during HFOV in large pediatric and adult patients we performed a bench test, in which the inspiratory imposed WOB and pressure fluctuations in MAP were assessed for newborn to adult simulations. We evaluated which factors contributed to the imposed WOB in the SensorMedics HFOV ventilator: fresh gas flow rate, endotracheal tube size or inspiratory flow rate.

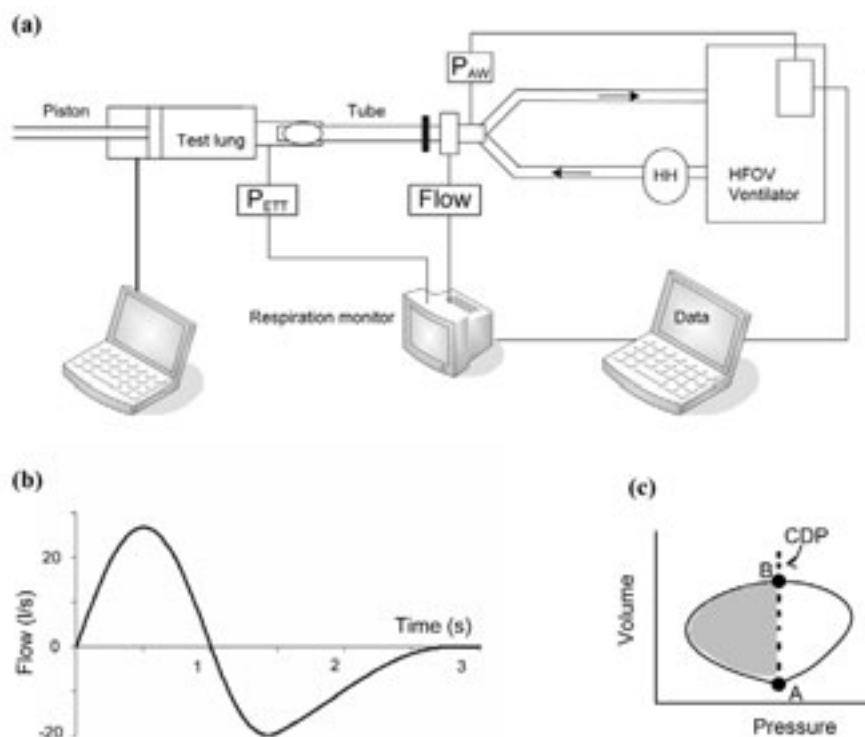
## Materials and methods

### Bench test set-up

A custom-made artificial lung was used to simulate a spontaneously breathing subject with variable age (Figure 1a). This test lung consisted of a tube 10 cm in diameter with a computer-controlled piston. A sinusoid flow simulated inspiration of spontaneous breathing, exponential decelerating flow expiration (Figure 1b). The test lung was connected to a HFOV ventilator (3100 A or 3100 B; SensorMedics) with an endotracheal tube (Rüschelit, Rüsch, Kernen, Germany). Different patient circuits were used for each HFOV ventilator (3100 A or 3100 B; SensorMedics). The same heated humidifier was used for both ventilators (MR225 humidification chamber; Fisher and Paykel, Auckland, New Zealand).

The inspiratory airway flow and the expiratory airway flow in the endotracheal tube were measured with a hot-wire anemometer (Florian; Acutronic Medical Systems AG, Hirzel, Switzerland). The tidal volume ( $V_T$ ) of spontaneous breathing was calculated by flow integration. The  $P_{ETT}$  value was measured using the Florian respiration monitor. The pressure at the Y-

Figure 1



Schematic drawing of the experimental set-up. (a) The ventilator circuit of a Sensor Medics 3100 A/B oscillator is connected to a piston-driven test lung by an endotracheal tube.  $P_{ETT}$  and  $P_{AW}$ , pressures in the test lung and in the ventilator circuit, respectively. Flow is measured at the proximal end of the endotracheal tube. HH, heated humidifier; HFOV, high-frequency oscillatory ventilation. (b) Simulated spontaneous breath. (c) Modified Campbell diagram, where A is the start of inspiration and B is the end of inspiration. The grey area represents the imposed inspiratory work of breathing, calculated using the modified Campbell diagram. CDP, continuous distending pressure.

**Table 1**

<b>Spontaneous breathing simulation and ventilator settings</b>					
	Newborn	Infant	Small child	Large child	Adult
Assumed weight (kg)	3.5	10	25	40	70
Spontaneous breathing simulation					
Respiratory rate (/min)	35	30	25	20	12
Tidal volume (ml/kg)/peak inspiratory flow (l/min)	5/2.6	5/6.3	5/13	5/17	5/18
	7/3.6	7/8.9	7/19	7/24	7/25
	10/5.1	10/12	10/27	10/34	10/36
Inspiratory/expiratory ratio	1:2				
Ventilator settings					
HFOV ventilator	3100 A	3100 A	3100 B	3100 B	3100 B
Tube inner diameter (mm)	3.0, 3.5, 4.0	4.0, 4.5, 5.0	5.5, 6.0, 6.5	6.5, 7.0, 7.5	7.5, 8.0, 8.5
Fresh gas flow rate (l/min)	15/20	20/40	20/60	20/60	20/60
Continuous distending pressure (cmH <sub>2</sub> O)	18	25	25	25	25
Proximal pressure amplitude (cmH <sub>2</sub> O)	35	50	50	50	50
Oscillation frequency (Hz)	10	8	8	6	6

HFOV ventilator, SensorMedics 3100 A or SensorMedics 3100 B high-frequency oscillatory ventilation ventilator.

piece in the ventilator circuit was measured using the unfiltered electronic signal of the internal pressure sensor of the HFOV ventilator. Flow and airway pressures were sampled at 100 Hz and were stored on a laptop computer for off-line analysis.

HFOV was set to a specific patient size as prescribed by the operator's manuals for management of acute respiratory distress syndrome.<sup>17,18</sup> We tested five patient weight ranges, from newborn to adult (Table 1). The ventilator fresh gas flow rate was set at two different levels: low and high. For all different patient sizes, three  $V_T$  levels of normal spontaneous breathing were simulated. The peak inspiratory flow rates that were generated with these  $V_T$  levels are also presented in Table 1. Three different sizes of endotracheal tubes were used for each patient size. In total, 90 different settings were tested.

### Imposed work of breathing

For each experimental condition, 12–20 breaths were recorded. The inspiratory imposed WOB was calculated for each simulated spontaneous breath, based on the modified Campbell diagram (Figure 1c):<sup>19,20</sup>

$$\text{Imposed WOB} = \sum_{\text{INSP}} (\text{CDP} - \text{MAP}_{\text{ETT}}) \cdot \Delta V \quad (1)$$

where CDP is the continuous distending pressure or set MAP level on the SensorMedics oscillator, and  $\text{MAP}_{\text{ETT}}$  is the mean airway pressure in the test lung. This was calculated by low-pass filtering (Butterworth filter with a cutoff frequency of 10 Hz) of the  $P_{\text{ETT}}$  signal to eliminate pressure changes on account of oscillations. The imposed WOB was averaged over all breaths (expressed as J/l).

### Airway pressure

Swings of the pressure in the ventilator circuit due to oscillations were removed by low-pass filtering. As a result, all

changes in airway pressure were attributable to the settings chosen to mimic spontaneous ventilation. Pressure fluctuations due to spontaneous breathing ( $\Phi\text{MAP}$ ) are expressed as the deviation from CDP (in cmH<sub>2</sub>O).  $\Phi\text{MAP}_{\text{INSP}}$  is the maximum deviation from the mean airway pressure during inspiration, and  $\Phi\text{MAP}_{\text{EXP}}$  is the maximum deviation from the mean airway pressure during expiration.  $\Phi\text{MAP}_{\text{INSP}}$  and  $\Phi\text{MAP}_{\text{EXP}}$  were calculated separately as the inspiratory and expiratory flow patterns of spontaneous breathing differed.

### Statistical analysis

Data are expressed as the mean  $\pm$  standard deviation. Comparison of means for normally distributed data was performed with an independent *t* test.  $P < 0.05$  was considered statistically significant. Linear regression was performed to explore relations between the imposed WOB, the endotracheal tube size, the fresh gas flow rate and the peak inspiratory flow. Statistical analyses were performed using SPSS 11.5 for Windows (SPSS Inc., Chicago, IL, USA).

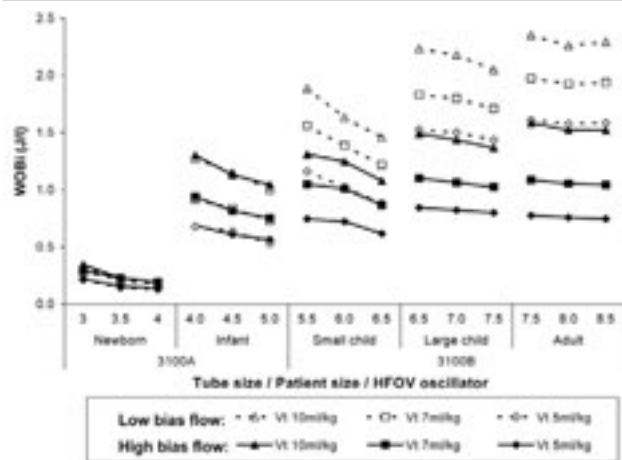
## Results

### Imposed work of breathing

The imposed WOB was  $0.22 \pm 0.07$  J/l for all measurements in the newborn (assumed body weight 3.5 kg) simulations and was  $0.87 \pm 0.25$  J/l in the infant (assumed body weight 10 kg) simulations (Figure 2). Linear regression showed that a high or a low fresh gas flow rate did not independently influence the imposed WOB in these measurements ( $P = 0.64$  for newborns and  $P = 0.94$  for infants) (3100 A oscillator; SensorMedics). An independent contributor to the imposed WOB was the peak inspiratory flow; a higher peak inspiratory flow increased the imposed WOB ( $P < 0.001$ ). The tube size did not independently contribute to the imposed WOB ( $P = 0.92$  for newborns and  $P = 0.92$  for infants).



Figure 2



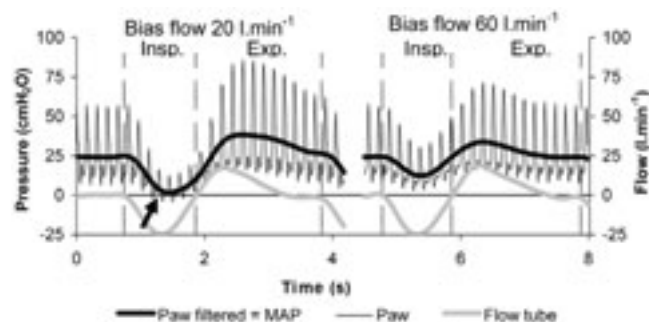
Imposed work of breathing (WOB<sub>i</sub>) for all simulations. Results for all measurements with the 3100 A and 3100 B SensorMedics oscillators. HFOV, high-frequency oscillatory ventilation; V<sub>T</sub>, tidal volume.

The imposed WOB for the larger pediatric and adult patient size simulations (3100 B oscillator; SensorMedics) was significantly higher in the low fresh gas flow rate condition in comparison with the high fresh gas flow rate condition. The results for the imposed WOB for low flow versus high flow were  $1.63 \pm 0.32$  versus  $0.96 \pm 0.24$  J/l ( $P = 0.01$ ) in the small child (assumed body weight 25 kg) simulation, were  $1.81 \pm 0.30$  versus  $1.10 \pm 0.27$  J/l ( $P < 0.001$ ) in the large child (assumed body weight 40 kg) simulation, and were  $1.95 \pm 0.31$  versus  $1.12 \pm 0.34$  J/l ( $P < 0.001$ ) in the adult (assumed body weight 70 kg) simulation. Independent contributors to the imposed WOB were the fresh gas flow rate ( $P < 0.001$ ) and the peak inspiratory flow ( $P < 0.001$ ). A high fresh gas flow rate decreased the imposed WOB, and a high peak inspiratory flow increased the imposed WOB. The tube size did not independently contribute to the imposed WOB ( $P = 0.07$ ).

### Airway pressure

The MAP in the ventilator circuit decreased dramatically during spontaneous breathing, most markedly at a low fresh gas flow rate (Figure 3). In this example the MAP in the ventilator circuit even becomes negative. This effect was observed when the fresh gas flow rate was low and with a V<sub>T</sub> of 7 or 10 ml/kg for the large child and adult patient simulations. In these simulations the peak inspiratory flow exceeded the fresh gas flow rate. This triggered the automatic ventilator shut-off, a safety feature of the SensorMedics oscillator.  $\phi$ MAP<sub>INSP</sub> and  $\phi$ MAP<sub>EXP</sub> for all measurements in the newborn (assumed body weight 3.5 kg) simulations were not significantly different comparing low and high fresh gas flow rates (Table 2). In the infant (assumed body weight 10 kg) simulations the  $\phi$ MAP<sub>INSP</sub> value was significantly lower in the high fresh gas flow rate condition in comparison with the low fresh gas flow rate testing ( $P = 0.002$ ). There was no difference in  $\phi$ MAP<sub>EXP</sub> measurements (3100 A; SensorMedics). For pediatric and adult simulations (3100 B oscillator; SensorMedics) the  $\phi$ MAP<sub>INSP</sub> and  $\phi$ MAP<sub>EXP</sub> values were significantly lower in the high fresh gas flow rate condition in comparison with the low fresh gas flow rate condition (Table 2).

Figure 3



Example of fluctuations in pressure in the ventilator circuit for both low and high fresh gas flow rates. P<sub>AW</sub>, unfiltered airway pressure; P<sub>AW</sub> filtered, mean airway pressure (MAP) calculated by low-pass filtering of the P<sub>AW</sub> signal. Example of the changes in P<sub>AW</sub> and P<sub>AW</sub> filtered during the simulation for a large child (assumed body weight 40 kg, tidal volume 280 ml), for both low and high fresh gas flow rates. Note that pressure changes decrease with a higher fresh gas flow rate and thus the imposed work of breathing decreases. In this example at the low fresh gas flow rate, the pressure in the ventilator circuit becomes negative as the inspiratory flow exceeds the fresh gas flow rate (arrow). Insp, inspiration; Exp, expiration.

### Discussion

The main result of this study is that the imposed WOB can be markedly increased during HFOV in pediatric and adult patients, especially at low fresh gas flow rates. This can be a good explanation for the discomfort seen in patients breathing spontaneously during HFOV. The fresh gas flow rate and peak inspiratory flow are both strongly related to the imposed WOB. The MAP is not maintained in the breathing circuit when inspiratory flow exceeds the fresh gas flow rate, and this can even lead to ventilator shutdown.

### Work of breathing

Compared with the WOB of a healthy adult (0.3–0.6 J/l), the imposed WOB is high if spontaneous breathing is simulated during HFOV.<sup>14</sup> As the physiologic WOB is not considered in this bench test, the total WOB is even higher in a patient breathing spontaneously during HFOV. An elevated WOB level results in dyspnea and discomfort.<sup>21,22</sup> The optimal workload for critically ill patients is unclear. Research focuses mainly on WOB in the weaning phase.<sup>23,24</sup> A WOB level in the physiologic range (approximately 0.5 J/l in adults) seems to correspond with an optimal workload. Full unloading (for instance, reducing the WOB to zero) induces loss of respiratory muscles. Excessive respiratory muscle loading may cause muscle fatigue and weaning failure.<sup>25</sup> The workload of 0.5 J/l seems to occur not only optimal during weaning, but also in the acute phase of respiratory failure.<sup>26,27</sup>

In the pediatric and adult simulations, the imposed WOB exceeded the normal physiologic WOB by as much as 200%. There are very few studies reporting normal WOB values for pediatric patients. WOB in healthy children and adolescents (6–18 years) ranges between 0.1 and 0.6 J/l.<sup>28</sup> In healthy preterm and full-term infants the WOB range is 0.02–0.2 J/l.<sup>29</sup> The optimal WOB during mechanical ventilation for these patients is even more unclear. Our results show that the level of imposed WOB is high during spontaneous breathing in HFOV. A high fresh gas flow rate in simulations for pediatric and adult patients reduces the imposed WOB, but not within the physiologic range of WOB.

**Table 2****Maximum deviation of the mean airway pressure from the set continuous distending pressure during inspiration and expiration**

	$\Delta\text{MAP}_{\text{INSP}}$ (cmH <sub>2</sub> O)			$\Delta\text{MAP}_{\text{EXP}}$ (cmH <sub>2</sub> O)		
	Low fresh gas flow rate <sup>a</sup>	High fresh gas flow rate <sup>b</sup>	<i>P</i> value	Low fresh gas flow rate <sup>a</sup>	High fresh gas flow rate <sup>b</sup>	<i>P</i> value
SensorMedics 3100 A ventilator						
Newborn	2.17 ± 0.24	1.75 ± 1.04	Not significant	0.83 ± 0.27	0.71 ± 0.44	Not significant
Infant	6.85 ± 1.34	4.56 ± 1.24	0.002	3.73 ± 1.77	3.59 ± 1.70	Not significant
SensorMedics 3100 B ventilator						
Small child	17.0 ± 3.11	8.91 ± 2.11	< 0.001	8.90 ± 2.49	5.21 ± 1.70	0.002
Large child	23.0 ± 2.60	12.8 ± 2.62	< 0.001	13.2 ± 2.01	8.76 ± 1.66	< 0.001
Adult	25.5 ± 2.51	13.7 ± 3.50	< 0.001	15.9 ± 2.97	8.34 ± 2.18	< 0.001

$\Delta\text{MAP}_{\text{INSP}}$ , maximum deviation of mean airway pressure from continuous distending pressure during inspiration;  $\Delta\text{MAP}_{\text{EXP}}$ , maximum deviation of mean airway pressure from continuous distending pressure during expiration. <sup>a</sup>Low fresh gas flow rate: 3100 A ventilator, 15 ml/min and 3100 B ventilator, 20 ml/min. <sup>b</sup>High fresh gas flow rate: 3100 A ventilator, 20 ml/min and 3100 B ventilator, 60 ml/min.

It seems logical to aim at a level of imposed WOB in the physiologic WOB range. However, there are no data to support this. An effective way to reduce imposed WOB in HFOV is desirable. Although we did not simulate this condition, a possible solution is to set the fresh gas flow rate to a higher rate. Another solution is the use of a demand flow system instead of the continuous fresh gas flow rate. In order to reduce the imposed WOB, the fresh gas flow rate has to far exceed the peak inspiratory flow. A reasonable suggestion would be the possibility to generate peak fresh gas flow rates comparable with conventional ventilation (approximately 140 l/min) depending on patient need.

Since the imposed WOB does not reflect the isovolumetric breathing effort, the pressure time product per breath was also calculated (data not included). As expected, results for the pressure time product per breath and the imposed WOB were identical. This is explained by the lung model we used for spontaneous breathing, in which the inspiratory and expiratory flows were programmed. The volume changes were imposed, so isovolumetric contraction did not occur. For the simulations for newborns and infants, the imposed WOB was not influenced by the fresh gas flow rate. This may be explained by the chosen small difference in levels of low and high fresh gas flow rate. Simulations for newborns show a low level of imposed WOB. This is in agreement with the fact that these patients tolerate spontaneous breathing during HFOV. Various factors define the imposed WOB. The endotracheal tube, the breathing circuit, the humidification device and the trigger settings impose the workload. Endotracheal tubes have the greatest effect on flow-resistive work.<sup>23</sup> This seems in contrast with our results, and is explained by the small differences in tube sizes used in our experiments, relative to the large variations in peak inspiratory flow.

### Airway pressure

Large fluctuations in the MAP in the breathing circuit are responsible for a high imposed WOB. They may also lead to unwanted alarms of the ventilator during HFOV, or even to shutdown. Upper and lower alarm limits are routinely set 3–5

cmH<sub>2</sub>O above and below the desired MAP.<sup>17,18</sup> This is a safety precaution against unnoticed MAP changes due to changes in respiratory system compliance, which may lead to alveolar derecruitment or overdistension. Airway pressure fluctuations exceeded the alarm limit of 5 cmH<sub>2</sub>O in all simulations on the SensorMedics 3100 B ventilator. In the simulations for smaller patient size, alarm limits of 3 cmH<sub>2</sub>O above and below the CDP were sufficient to avoid alarms – although in most other measurements the alarm limits had to be set wide to stop alarms, interfering with patient safety in a clinical setting.

If the peak inspiratory flow exceeded the fresh gas flow rate, this led to ventilator shutdown. This triggered the automatic ventilator shut-off, a safety feature of the SensorMedics oscillator.

### Limitations of the study

The imposed WOB is strongly related to the choice of  $V_T$ , respiratory rate, breathing pattern and tube size. In this *in vitro* study we aimed to choose realistic test conditions. However, *in vivo* conditions may differ from our bench test. In the lung model used only the imposed WOB can be evaluated. Patient or total work cannot be assessed. During HFOV the lungs can expand to high levels of end expiratory lung volume near the total lung capacity. At high levels of end expiratory lung volume the work of breathing will increase as a result of an increase in elastic work. The  $V_T$  levels used for simulations were fixed. The  $V_T$  level that a patient can generate is influenced by the level of end expiratory lung volume. Only shallow breathing is possible at levels of end expiratory lung volume near the total lung capacity. In this lung model we are not able to evaluate these effects on patient WOB and on total WOB. These findings need validation in clinical practice.

### Conclusion

The imposed WOB is considerable in spontaneous breathing in pediatric and adult patients during HFOV and is a good explanation for observed patient discomfort. A high fresh gas flow rate decreased the imposed WOB, but not sufficiently. Large swings in airway pressure complicate the setting of safe

alarm limits and can even lead to ventilator malfunction. In clinical practice it is reasonable to consider the level of the fresh gas flow rate. In order to minimize the imposed WOB and to allow at least shallow spontaneous breathing during HFOV, the fresh gas flow rate has to be set at a maximum level.

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# A 10-Year-Old Child With Status Asthmaticus, Hypercapnia and a Unilateral Dilated Pupil

Andrew Udy, BHB, MBChB

## Summary

This article reports the case of a 10-year-old child with an exacerbation of asthma requiring mechanical ventilation. His immediate course was complicated by significantly elevated arterial CO<sub>2</sub> tensions and a unilateral dilated pupil. A computed tomography scan of his brain failed to demonstrate any evidence of intracranial hypertension or cerebral edema, and he went on to make an uncomplicated recovery, with no evidence of neurological sequelae. The most likely diagnosis appeared to be local contamination with ipratropium when he was receiving frequent nebulizers prior to mechanical ventilation. Similar cases reported in the literature are reviewed, with a discussion of clinical management, implications of permissive hypercapnia and neurological complications in ventilating asthmatic patients and the importance of safe drug handling by staff members.

A 10-year-old, 30-kg boy with a history of recurrent exacerbations of asthma – requiring a home nebulizer – presented to the emergency department of a local general hospital with an acute history of respiratory distress. His mother reported a 2 day history of cough, runny nose and wheeze, and in addition he had exhausted his salbutamol metered dose inhaler (MDI) the previous day. His symptoms had started 30 min before, with worsening shortness of breath, wheeze and respiratory effort, which were unresponsive to two home salbutamol nebulizers. Triage by emergency staff revealed that he was speaking words, but displayed marked accessory muscle use and had oxygen saturations of 94% in air. He was tachypneic and tachycardic with a temperature of 36.9°C. Further ipratropium and salbutamol nebulizers were administered and he was transferred to the pediatric ward for further evaluation.

Pediatric review identified four exacerbations in the past year with two admissions to hospital, neither requiring intensive care nor mechanical ventilation. His regular medications included inhaled corticosteroids and beta-agonists. While undergoing

further assessment on the pediatric ward, he continued to deteriorate, unable to speak, with oxygen saturations of only 92% on high-flow oxygen (10 l·min<sup>-1</sup>). He had become bradycardic with a heart rate of 60 min<sup>-1</sup>, and auscultation of the chest revealed minimal air entry. Three intravenous bolus doses of salbutamol were administered with intravenous hydrocortisone and cefuroxime. An aminophylline infusion was started at 31 mg·h<sup>-1</sup>. A venous blood gas analysis revealed pH 6.96, pCO<sub>2</sub> 16.4 kPa (126 mmHg), pO<sub>2</sub> 12.9 kPa (99 mmHg), and base excess (BE)<sup>-5</sup>.

Anesthetic staff were involved and the child was intubated with a size 6.0 cuffed tracheal tube (TT) after rapid sequence induction with propofol and suxamethonium. Vecuronium was administered for muscle paralysis and the patient transferred to an anesthetic ventilator, with a respiratory rate of 14, an I : E ratio of 1 : 1.5, a maximum inspiratory pressure (PIP) of 27 cmH<sub>2</sub>O and positive end expiratory pressure (PEEP) of 5 cmH<sub>2</sub>O. Arterial gases taken after intubation showed pH 6.73, P<sub>a</sub>CO<sub>2</sub> 32.4 kPa (249 mmHg), P<sub>a</sub>O<sub>2</sub> 14.5 kPa (111 mmHg) and BE of -6. Advice from the regional Pediatric Intensive Care Unit (PICU) included starting a salbutamol infusion at 2 µg·kg<sup>-1</sup>·min<sup>-1</sup>, as well as a 1.2 g bolus dose of magnesium. Retrieval by PICU staff was requested.

Approximately 2 h after instituting mechanical ventilation the PICU retrieval team arrived. Repeat arterial blood gas analysis revealed pH 6.84, pCO<sub>2</sub> 25.5 kPa (196 mmHg), pO<sub>2</sub> 40.0 kPa (308 mmHg) and BE of -3. Ventilation parameters were now changed to a peak inspiratory pressure 40 cmH<sub>2</sub>O with PEEP of 5 cmH<sub>2</sub>O and the same rate and I:E ratio. It was also noted at this point that the child's left pupil was now dilated (6 mm) compared with the right (3 mm), and was reacting sluggishly. A 0.5 gm·kg<sup>-1</sup> bolus dose of mannitol was administered while the transfer was completed uneventfully. A 500 ml bolus of colloid was also given to maintain adequate mean arterial pressure following the diuretic. A computed tomography (CT) brain scan on arrival at the regional center did not demonstrate evidence of cerebral edema or raised intracranial pressure.

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After moving to the PICU, ventilation settings were a PIP 38 cmH<sub>2</sub>O, PEEP 5 cmH<sub>2</sub>O, rate 20 b·min<sup>-1</sup>, inspiratory time 1 s and FiO<sub>2</sub> 0.4 on an Evita 4 intensive care ventilator (Draeger Medizintechnik GmbH, Lüübeck, Germany). The pH had improved to 7.09 and pCO<sub>2</sub> was now 10.9 kPa (84 mmHg), however his mean arterial pressure had fallen to 58 mmHg and dopamine 5 µg·kg<sup>-1</sup>·min<sup>-1</sup> was commenced to improve cardiovascular function. His left pupil remained dilated and sluggish. The salbutamol, aminophylline, and dopamine infusions were continued for another 6 h and his ventilation was gradually weaned to PIP of 20 cmH<sub>2</sub>O and PEEP of 5 cm H<sub>2</sub>O. Intravenous corticosteroids were administered regularly.

Despite an episode of supraventricular tachycardia (likely a result of the salbutamol and dopamine infusions), this child was extubated without complication 10 h after presentation and subsequently discharged to respiratory services. He made a complete recovery with no evidence of any specific neurological sequelae, and his pupil inequality improved over the course of the next 12 h.

### Discussion

This case raises a number of important issues in the emergency and intensive care management of acute severe asthma in children. These include the appropriate disposition of ongoing care for children in status asthmaticus, the causes of unilateral mydriasis and the implications of permissive hypercapnia, and the importance of safe drug handling by medical and nursing staff.

The immediate course of acute severe asthma is not determined by the severity of symptoms or airway obstruction (as measured by peak flow), but rather by the acute response to treatment.<sup>1</sup> In this situation the attending emergency medical staff underestimated the severity of this patient's presentation and failed to document any appreciable improvement in symptoms prior to his transfer. For those patients who are not immediate candidates for intensive care, some clinicians have advocated 4–6 h of treatment in the emergency room before deciding on disposition.<sup>2</sup> In this respect, moving such a critically unwell child to a ward was a potentially unsafe procedure that may have contributed to his clinical course. Advice from the regional PICU could have been taken at this stage, including the benefits of early intubation either in the emergency room or theater.

Causes of a single dilated pupil can include: direct trauma to the eye, damage to the sympathetic trunk, spillage of anticholinergic or alpha-adrenergic agents into the eye, and raised intracranial pressure.<sup>3</sup> The child's mother reported no history of head or eye trauma and the medical notes regarding intubation do not document any eye trauma during this procedure. He had received multiple salbutamol and ipratropium nebulizers, but there is no record of any pupil inequality by nursing or medical staff prior to mechanical ventilation. The immediate focus therefore at the bedside was on the possibility of acute intracranial hypertension.

Permissive hypercapnia has become an established strategy for mechanical ventilation of patients with status asthmaticus.<sup>14</sup> It involves reduced alveolar ventilation (with acceptance of elevated CO<sub>2</sub> levels) in order to protect the lungs from the damaging inflammatory effects of large tidal volume ventilation

and the hemodynamic consequences of raised intrathoracic pressures.<sup>5</sup> Through a greater understanding of dynamic hyperinflation and intrinsic positive end expiratory pressure in asthmatic patients, the focus of mechanical ventilation has shifted to maintenance of adequate oxygenation as opposed to normal arterial CO<sub>2</sub> tensions and pH.<sup>6</sup> Correction of hypoxemia can be achieved with the addition of a small concentration of supplemental oxygen, while controlled hypoventilation normally involves a reduction in tidal volume or respiratory frequency, or both. It is also important to allow for adequate exhalation in order to prevent dangerous levels of dynamic hyperinflation.

While this strategy has improved the outcome for asthmatic patients requiring mechanical ventilation,<sup>7,8</sup> there remains no consensus on the level of hypercapnia that is safe, and most physicians avoid P<sub>a</sub>CO<sub>2</sub> levels >13 kPa (100 mmHg).<sup>9</sup> Indeed some cases reported in the literature document markedly elevated P<sub>a</sub>CO<sub>2</sub> concentrations, up to 25 kPa (192 mmHg) for >10 h, without any significant sequelae<sup>9,10</sup> and in part underlies the accepted safety of this approach. Mazzeo et al. have recently reported an arterial P<sub>a</sub>CO<sub>2</sub> level of 39 kPa (293 mmHg) in an 8-year-old child receiving mechanical ventilation for a near-fatal asthma attack, without any cardiovascular or neurological complications.<sup>11</sup> However in a small number of reports involving mechanical ventilation of asthmatic patients with a permissive hypercapnic approach, adverse neurological events have been reported. These include diffuse cerebral swelling,<sup>12</sup> subarachnoid hemorrhage,<sup>12,13</sup> and quadriplegia, hyperreflexia, and extensor plantar reflexes.<sup>14</sup> In each, permissive hypercapnia may have played a role in the etiology.

Elevated arterial CO<sub>2</sub> tensions will cause vasodilation of the cerebral vasculature and a consequent rise in cerebral blood flow and intracranial pressure (ICP). A study by van Hulst et al examining hypo- and hyperventilation in pigs demonstrated a linear relationship between arterial CO<sub>2</sub> tensions and ICP.<sup>15</sup> However, the investigators also demonstrated that this was well tolerated with only a minimal and insignificant reduction in cerebral perfusion pressure (CPP). Indeed some investigators have suggested that hypercapnic acidosis may be highly protective in acute organ injury,<sup>16</sup> and specifically hypoxic-ischemic cerebral insults.<sup>17</sup>

Laboratory data have extended this with evidence that extracellular acidosis results in greater neuronal cell viability after glucose-oxygen deprivation.<sup>18</sup> In this respect previous authors have surmised that high intrathoracic pressures resulting in reduced cerebral venous drainage, in addition to permissive hypercapnia, may play an important part in neurological complications encountered with mechanical ventilation of the asthmatic patient.<sup>3,12,13</sup>

A likely diagnosis for this patients' unilateral mydriasis is local contamination with ipratropium and is consistent with similar cases reported in the literature.<sup>19,20</sup> Ipratropium bromide is a synthetic quaternary ammonium compound chemically related to atropine, which acts as an anti-muscarinic bronchodilator. It has important known side-effects in the eye, such as pain and blurred vision, and may precipitate angle-closure glaucoma.<sup>21</sup> Mydriasis is not specifically mentioned by the drug manufacturer as an adverse event,<sup>22</sup> and we have forwarded appropriate notification to the Committee on Safety of



Medicines (CSM). It can also produce other general anticholinergic side-effects such as urinary retention, constipation and tachycardia.

While there is no documented evidence of ipratropium being splashed in this patient's eye, it does reinforce the importance of safe drug handling by medical and nursing staff. In this case it may have prevented the patient from receiving a dose of mannitol and subsequent CT scan. Furthermore, given that such effects can be encountered with the mist from nebulizers, it is important for pediatric staff to appreciate that this can occur even with routine use.

In conclusion, the management of severe asthma in children remains a significant challenge to the attending clinicians. Response to treatment is an important indication of clinical course and should be used to guide decisions on subsequent transfer. Even with new approaches to the mechanical ventilation of the asthmatic patient, this is a therapeutic intervention that continues to have potentially significant complications. However, it is reassuring that the literature suggests in most cases, even significant permissive hypercapnia is well tolerated, and may even have a possible therapeutic benefit. It remains crucial for the clinician to recognize the potential cerebral consequences of raised intrathoracic pressure and permissive hypercapnia, and intracranial hypertension remains an important contraindication to controlled hypoventilation. Local contamination with anticholinergic agents is an important differential in such patients with unilateral mydriasis and staff need to be familiar with such effects and ensure safe drug handling.

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## Effectiveness of a Chinese Herbal Medicine Preparation in the Treatment of Cough in Uncomplicated Upper Respiratory Tract Infection: A Randomized Double-Blinded Placebo-Control Trial

Wong WCW, Lee A, Lam AT, Li KT, Leung CYM, Leung PC, Wong ELY, Tang JL

### Abstract

**Background:** Rigorous scientific and well-designed clinical trials to evaluate the effect of traditional Chinese medicine (TCM) is lacking. We, therefore, designed this study to evaluate the effectiveness of a commonly used TCM preparation in treating acute cough of uncomplicated URTI in adults and to search for a safe, effective and affordable alternative treatment for this common condition.

**Methods:** A randomised, double-blinded, placebo-control study comparing this TCM preparation with a placebo was conducted in 82 patients who attended the Family Medicine Training Centre, Prince of Wales Hospital, Hong Kong between November and December, 2003. The TCM herbal preparation includes nine commonly used TCM herbs for cough such as chuanbei, fangfeng, jiegeng, gancao and baibu (see Table 1) The treatment lasted for 5 days and patients were followed-up for another 6 days. Patients were asked to fill in a cough score and validated Leicester cough questionnaire (LCQ).

**Results:** 62 patients (75.6%) had completed the trial and no adverse effects were reported. Both intervened and control groups had improved in cough score and LCQ in the follow up period, despite no overall statistical significance in the differences of scores between the two groups. Women taking

TCM had significantly fewer problems with sputum production ( $p = 0.03$ ) and older subjects ( $>35$  years of age) reported a significant improvement in hoarseness ( $p = 0.05$ ) when compared to those using placebo.

**Conclusion:** TCM was well-tolerated and received among the Hong Kong Chinese population. This TCM preparation appeared to have some benefits in the treatment of cough. Future research on TCM should concentrate more on commonly encountered conditions such as URTI and cough. Our experience on the sensitivity of assessment tools used in detecting subtle differences in an otherwise self-limiting illness and clinical trial methodology when applying the underlying theory of how TCM works in disease management was invaluable.

### Background

Acute cough is a common presentation of upper respiratory tract infections (URTI) encountered in general practice.<sup>1</sup> In Australia in 1999, cough was treated in 7.5% of general consultation.<sup>2</sup> Cough can lead to high morbidity and cause debilitating symptoms such as exhaustion, insomnia, hoarseness, musculoskeletal pain, sweating and even urinary incontinence.<sup>3,4</sup> The pressure produced during coughing could also potentially cause some kind of complication in nearly all organ systems.<sup>3</sup> More importantly, cough can be so profound that it may have an adverse effect on the patient's quality of life.<sup>4</sup>

In 1994, over-the-counter sales of anti-tussives products in the United States was worth US\$19 billion, which accounted for 38–50% of all respiratory sales.<sup>5</sup> The retail sale of cough mixtures in the United Kingdom rose by an annual rate of 3% to £94 m in 1999.<sup>6</sup> Statistics from Pharmacy of the Department of Health in Hong Kong showed that their outpatients alone had consumed 370,000 liters of anti-tussives worth over 2 million Hong Kong dollars (US\$1 = HK\$7.8) in 2000.<sup>7</sup>

However, the effectiveness of anti-tussives in western medicine remains doubtful despite its large market and wide

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consumption. Only a small number of clinical trials investigate the anti-tussives so that evidence on their effectiveness is rather limited. Schroeder et al.<sup>8</sup> published a systematic review of all randomised controlled trials on various types of anti-tussives in 2002. They identified five trials tested for anti-tussives with placebo. Two were on codeine and none was more effective than placebo. One of two studies of dextromethorphan<sup>9</sup> favoured active treatment over placebo whereas the other found no significant effect. Moguisteine (one trial) led to mean differences in cough scores of about 0.5 in groups with severe cough on days 2 and 3 ( $P < 0.05$ ), but there were no differences between groups at final follow up.<sup>10</sup>

It is well known that not every ill person consults a health care professional.<sup>11</sup> Social and cultural factors may influence the pattern of symptomatology and phenomenology.<sup>12</sup> Patients disappointed with ineffective conventional treatments naturally look for alternatives. Traditional Chinese Medicine (TCM) has been practiced in China for over 2000 years: Chinese patients take TCM for chronic health problems and they may also do that for some acute self-limiting problems.<sup>11</sup> TCM is considered to be a very acceptable alternative in Hong Kong and a sizable segment of the population consults TCM practitioners for their health problems.<sup>13</sup> In one survey, nearly half had previously consulted a TCM practitioner.<sup>14</sup> This is partly a cultural phenomenon but dissatisfaction with other forms of health care as in the case of cough was a commonly cited reason for resorting to TCM treatment.<sup>15</sup>

We therefore designed this study to evaluate the effectiveness of a TCM formulary in treating acute cough of uncomplicated URTIs in adults. TCM used in this study was extracted from nine commonly used herbs in treating cough and, their functions and side effects were well documented.<sup>16</sup> Literature search was performed and the formulary was recommended by a panel of three experienced Chinese herbalists. The nine ingredients used in this formulary are shown in Table 1. Bulbus Fritillariae Cirrhosae is the commonly used herb for the treatment of cough and it has been used for many centuries.<sup>17</sup> Animal studies showed that some alkaloids (imperialine, verticine and verticinone) extracted from Bulbus Fritillariae Cirrhosae acts like muscarinic receptor antagonist and are more potent than salbutamol and diphenhydramine in relaxing isolated rat trachea and bronchi.<sup>18</sup> Another major ingredient Radix platycodi has both antitussive and expectorant activities including the promotion of salivary and bronchial secretions.<sup>17</sup> Pericarpium Citri Reticulatae has expectorant activities and bronchodilatative effect.<sup>17</sup>

## Methods

**Study design:** This was a single-centre, randomised, double blind, placebo-controlled and parallel study comparing TCM with placebo in patients who had presented with cough resulting from uncomplicated upper respiratory tract infections.

**Study patients:** Patients were eligible for the study if they were over 18 years old, had cough due to clinically diagnosed URTIs that did not require antibiotics, not allergic to fexofenadine (Telfast®), not on other concurrent alternative medications for cough and were mentally capable to give an informed written consent and willing to comply with study requirements. We excluded patients who were pregnant or breastfeeding, current smokers, had lung disease (include asthma or chronic obstructive airway disease) or cardiac disease (including

valvular heart disease), had concurrent gastrointestinal symptoms such as nausea, vomiting, abdominal pain or diarrhoea) or if they were illiterate and had difficulties in filling in the diary.

**Study organization:** Patients were recruited from 17 Nov 2003 to 23 Dec 2003 at Prince of Wales Hospital Staff Clinic which mainly served Hospital Authority (HA) staff as well as their dependents such as spouse and children in New Territory East, one of the 6 districts in Hong Kong. Staff and students from the medical faculty might also attend. It mainly provided general medical consultations, specialty referrals, chronic disease management and pre-employment health checks.

**Study medication and dosage:** TCM used in this study and the matching placebo were manufactured by the Hong Kong Institute of Biotechnology Ltd, based on Good Manufacturing Practice. The TCM powder using extract granules had been formulated into uniform tablets under the supervision of the Institute of Chinese Medicine at the Chinese University of Hong Kong. The dosage of study drug was 3 tablets (500 mg per tablet) three times a day.

**Randomization:** Randomization and allocation took place on patients' first visit at the Staff Clinic. Informed consent was obtained according to the local laws and the Good Clinical Practices Guidelines, prior to the enrolment in this study and assignment of the subject study number. Subjects were given information regarding the nature, significance and scope of the study, tests to be performed and potential risks. They were also informed about their right to revoke their consent at any time without obligation to explain the reason and without prejudice to their further treatment.

**Outcome measures and data analysis:** Treatment period lasted for 5 days. During which, clinical assessments including history, examination and tests (if necessary) were performed at day 4 and day 7. The participants were asked to fill a questionnaire to grade the severity of a range of symptoms related to cough and the functional disturbance of cough is measured by LCQ, which had been validated and permission to use it in this study from the original author was obtained. The first primary safety outcome is tolerability, which was defined as a permanent discontinuation of the mixture of TCM as the result of an adverse event. The second efficacy outcomes were a change in the cough symptom score and in the vitality status. Subjects were encouraged to withdraw from the trial and to be treated accordingly if there were any signs of deterioration in clinical presentation. This study was done on intention-to-treat basis that patients initially treated but subsequently dropped out were included in the final analysis.

**Table 1: The components of TCM formulary in treating acute cough of uncomplicated URTIs**

Bulbus Fritillariae Cirrhosae	27.3%
Herba Schizonepetae	10.5%
Radix Ledebourii	10.5%
Radix Platycodi	10.5%
Radix Glycyrrhizae	4.4%
Radix Asteris	10.5%
Radix Stemonae	10.5%
Rhizoma Cynanchi Stannonii	10.5%
Pericarpium Citri Reticulatae	5.3%

**Table 2: Characteristics of participants and dropouts in two study groups**

Characteristic	Participants		Dropouts	
	TCM group N (%)	Placebo group N (%)	TCM group N (%)	Placebo group N (%)
	N = 41	N = 40	N = 11	N = 8
<b>Sex</b>				
Male	8 (19.5)	5(12.5)	3 (27)	2 (25)
Female	33 (80.5)	35 (87.5)	8 (73)	6 (75)
<b>Marital status</b>				
Single	16 (39.0)	12 (30.0)	2 (18)	4 (50)
Married	25 (61.0)	28 (70.0)	9 (82)	4 (50)
<b>Education level</b>				
< Primary level	5 (12.2)	3 (7.5)	1 (9)	0
< F.5	5 (12.2)	3 (7.5)	6(55)	5(63)
> F.5	16 (39.0)	17 (42.5)	1(9)	0
University level or above	15 (36.6)	17 (42.5)	3(27)	3(37)
<b>Status</b>				
HA/CU staff	36 (87.8)	38 (95.0)	11 (100)	8 (100)
Dependant of HA/CU staff	5 (12.2)	1 (2.5)	0	0
<b>Occupation</b>				
HA staff:	36 (44.4)	39 (48.1)		
Nurses	8 (19.5)	11 (27.5)	2(18)	1 (12)
Allied health	5 (12.2)	4 (10)	1(9)	3(38)
Technician/Researcher	2 (4.9)	3 (7.5)	0	0
HCA (Health Care Assistant)	2 (4.9)	1 (2.5)	1(9)	0
GSA/WS/Workman	9 (22.0)	5 (12.5)	2(18)	1(12)
Administration/Clerk	8 (19.5)	8 (20.0)	4(37)	2(26)
Medical student	2 (4.9)	5 (12.5)	1(9)	1(12)
Retired	0 (0)	1 (2.5)		
Chaplin	0 (0)	1 (2.5)		
Dependent of HA/CU staff	5 (6.2)	1 (1.2)		
Non-health professional	2 (4.9)	1 (2.5)		
White collar	1 (2.4)	0(0)		
Student	2 (4.9)	0(0)		
<b>Baseline</b>				
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Age	36.0 (10.9)	35.4 (8.5)	37.1(8.8)	31.8(5.8)
Days of cough onset for this episode	3.7 (2.6)	4.3 (6.5)	2.9(1.7)	1.6(0.7)
Height (cm)	159 (6.9)	158.9 (9.0)	159.7(8.0)	162.3(3.3)
Weight (kg)	58.7 (11.8)	56.1 (8.7)	60.8(11.9)	56.9(7.1)
SBP (mmHg)	125.5 (16.3)	121.3 (16.8)	131.4(12.0)	123.9(11.4)
DBP (mmHg)	73.6 (12.1)	69.8 (9.3)	79.3(11.0)	72.5(7.5)
Pulse/min	79.5 (9.6)	77.2 (11.7)	84.4(9.0)	73.8(8.3)
Temperature (°C)	36.5 (0.4)	36.5 (0.4)	36.5(0.5)	36.6(0.3)

Group data were expressed as the frequency unless otherwise specified. To analyse differences in the baseline parameters between TCM and placebo groups, student t-test was performed. The statistical significance of change differences between two study groups was tested by the Mann-Whitney U test in the comparison of cough symptoms and by the student t-test in the comparison of the results of quality of life scores. Subgroup analysis of age (those older than 35) and sex were performed using Mann-Whitney U test. All statistical tests were 2 sided and exact values for the rank sum. Data entry and analyses were performed with the SPSS software package.

## Results

Of the total numbers of 141 subjects screened, 81 consented to participate the study. Reasons for refusal included: Not willing to take TCM (41.7%), not available for study (13.3%), not willing to receive placebo (10%), not willing to take tablet (1.7%), not willing to do the questionnaire (1.7%), not interested in the study (1.7%), western medicine to TCM preferred (1.7%) and antitussive requested (1.7%). The baseline characteristics of patients in the intervened and control groups are shown in table 2.

**Table 3: Comparison of baseline parameters in two study groups**

	Study Group		
	TCM group N = 41 Mean (sd)	Placebo group N = 40 Mean (sd)	P-value
<b>Symptoms (score range 0: none – 4: very severe)</b>			
Day cough	1.6 (0.8)	1.5 (0.4)	0.500
Night cough	1.7 (1.1)	1.6 (1.0)	0.635
Sputum	1.5 (1.2)	1.2 (1.1)	0.228
Nasal congestion	1.6 (1.2)	1.2 (1.1)	0.895
Running nose	1.7 (1.2)	1.8 (1.4)	0.679
Sneezing	1.1 (0.9)	1.3 (1.3)	0.541
Hoarseness	1.7 (1.0)	1.6 (1.2)	0.536
Sore throat	2 (1.1)	2 (1.2)	0.842
Muscle pain	1.4 (1.2)	1.0 (1.1)	0.064
Chest pain	0.6 (0.9)	0.5 (0.8)	0.752
Headache	1.5 (1.3)	1.2 (1.4)	0.232
Total score (sum of above 11 symptoms: 0–44)	16.6 (6.7)	15.3 (7.0)	0.383
<b>QoLs (score range)</b>			
Physical domain (8–56)	4.7 (0.9)	4.5 (0.9)	0.278
Psychological domain (7–49)	4.9 (1.2)	4.9 (1.1)	0.955
Social domain (4–28)	4.8 (1.2)	4.7 (1.2)	0.636
Total score (sum of above 3 domains: 3–21)	14.4 (3.0)	14.0 (2.9)	0.616

There were 19 subjects subsequently withdrawn from the study (characteristics shown in table 2) and the reasons were: worsening symptoms (57.9%), over-the-counter cough medicine used (21.2%), cough improved and stopped (10.4%), conditions evolved and antibiotics required (5.3%) and difficulties in taking the tablets (5.3%). Nevertheless, none of the subjects had reported any adverse effect after taking TCM cough tablet.

The subjects had on average 4-days history of cough at presentation. Table 3 shows the baseline symptom severity and quality of life in physical, psychological and social domains measured by LCQ. No difference was observed in the symptoms and LCQ scores between the two groups at the start of the study. Based on clinical assessment, Fexofenadine (Telfast) was prescribed to 67 subjects (82.7%) for rhinitis, Paracetamol (Panadol) to 44 subjects (54.3%) for fever and myalgia, Benzydamine HCL (Difflam) to 15 subjects (18.5%) or Dequalinium (Dequadin) to 18 subjects (22.2%) with sore throat, Mefenamic acid (Ponstan) to 18 subjects (22.2%) with more severe myalgia, Ascorbic acid (Vitamin C) to 28 subjects (24.6%), Chlorpheniramine Maleate (Piriton) to 3 subjects (3.7%) with rhinitis, Promethazine HCL (Phenergan) to 2 subjects (2.5%) with worse nocturnal nasal symptom and Triacinolone acetone (Kenalog in orobase) to 1 subject (1.2%) with aphthous ulcer.

Tables 4 and 5 show the changes of the symptoms and LCQ at Day 4 and 7. A significant improvement in symptoms and LCQ scores were observed in both the treatment and control groups during the study period, but no difference was seen between the two groups except in coughing bouts when significantly more improvement was reported in the placebo group ( $p = 0.027$ ). Women taking TCM had significantly fewer problems with sputum production ( $p = 0.03$ ) and older subjects (>35 years of age) reported a significant improvement in hoarseness ( $p = 0.05$ ) when compared to those using placebo (Tables 6 and 7 respectively).

## Discussion

The present study aimed to look for an effective, safe and affordable alternative treatment of acute cough resulted from uncomplicated URTI. The results of this study confirmed that URTI was a usually self-limiting disease with its symptoms improved in the first week of presentation. However, the herbal combination used in this study showed it did not improve symptoms when compared to the placebo. This formulary was well tolerated with no adverse effects reported. This finding had significant clinical implications for the Chinese population because this formulary shared many components in commercially available ready-made TCM preparations in the market (for example, Pei Pa Kao). Other components of these preparations might have significant roles to play such as the soothing effect of a syrup preparation. In addition, this study also highlighted some difficulties when conducting a TCM research in a western clinical setting as discussed below.

Firstly, this study covered mainly young working adults, who had expected western treatment. There was an added possibility that, in a fast paced society such as Hong Kong, immediate relief of symptoms might outweigh the other advantages of TCM. This might account for high drop-out rates and the demand for concomitant use of other relieving medication such as antihistamine, NSAIDs and vitamin C, which could potentially have confounding effects on relieving cough symptoms of the TCM preparation. For example, cough induced by post-nasal drip could be reduced by the anti-histamines. However, clinicians usually found that, in reality, patients had expected the other symptoms to be controlled at first presentation and this reflected how the studied drug would be used in a normal clinical setting. Secondly, one might argue that it would be better to compare the TCM in study with a commonly used cough medicine, for example, dextromethorphan. However, it would be very difficult to blind the subjects as they were of very different preparation with different odor and taste (the TCM had its own distinct flavor), and when the effectiveness of currently available cough medicine was in question. Thirdly, the



Table 4: Change of Symptoms after taking either the TCM preparation or placebo in the studied patients

Symptom	Study Group						P value <sup>1</sup> (D4-D1)	P value <sup>1</sup> (D7-D4)	P value <sup>1</sup> (D4-D1)	P value <sup>2</sup> (trend difference)
	TCM group (N = 41)			Placebo group (N = 40)						
	Difference between D4 and D1	Difference between D7 and D4	Difference between D7 and D1	Difference between D4 and D1	Difference between D7 and D4	Difference between D7 and D1				
Day Cough	-0.17	-0.49	-0.66	-0.05	-0.70	-0.75	0.665	0.279	0.734	0.559
Night Cough	-0.34	-0.39	-0.73	-0.05	-0.78	-0.83	0.384	0.102	0.796	0.234
Sputum	-0.10	-0.41	-0.51	0.13	-0.20	-0.08	0.385	0.374	0.142	0.258
Nasal Congestion	-0.71	-0.27	-0.98	-0.80	-0.40	-1.20	0.749	0.541	0.502	0.763
Running Nose	-0.73	-0.24	-0.98	-0.73	-0.35	-1.08	0.982	0.664	0.730	0.911
Sneezing	-0.63	-0.10	-0.73	-0.63	-0.40	-1.02	0.973	0.178	0.273	0.399
Hoarseness	-0.76	-0.27	-1.02	-0.53	-0.55	-1.08	0.433	0.233	0.862	0.549
Sore Throat	-0.73	-0.49	-1.22	-0.63	-0.78	-1.40	0.738	0.286	0.523	0.605
Muscle Pain	-0.90	-0.07	-0.98	-0.70	0.00	-0.70	0.425	0.640	0.286	0.564
Chest Pain	-0.24	-0.15	-0.39	-0.40	-0.08	-0.48	0.461	0.444	0.662	0.672
Headache	-0.93	-0.20	-1.12	-0.85	-0.05	-0.90	0.783	0.503	0.468	0.718
Total Symptom Score	-6.24	-3.07	-9.92	-5.23	-4.28	-9.50	0.590	0.355	0.924	0.633

<sup>1</sup>by independent student t-test; <sup>2</sup>by repeated measure ANOVA; \*P < 0.05

**Table 5: Change of LCQ scores after taking either the TCM preparation or placebo in the studied patients**

Symptom	Study Group		P value <sup>1</sup> (D7-D1)
	TCM group (N = 41)	Placebo group (N = 40)	
	Difference between D7 and D1	Difference between D7 and D1	
Q1 chest/stomach pain	0.41	0.65	0.489
Q2 sputum	0.24	0.70	0.260
Q3 tired	0.95	1.60	0.169
Q4 felt in control	1.05	1.10	0.908
Q5 felt embarrassed	0.80	0.53	0.488
Q6 felt anxious	0.59	0.75	0.626
Q7 interfered with daily activities	0.73	0.68	0.899
Q8 interfered with life enjoyment	0.88	0.95	0.848
Q9 paints/fumes	0.00	0.68	0.067
Q10 sleep	0.76	1.35	0.169
Q11 coughing bouts	0.32	1.18	<b>0.027*</b>
Q12 felt frustrated	0.54	0.63	0.808
Q13 felt fed up	0.78	0.90	0.777
Q14 hoarse voice	1.32	1.25	0.863
Q15 energy	0.95	0.45	0.066
Q16 worry	0.73	0.88	0.642
Q17 concern with other people	0.88	0.60	0.404
Q18 conversation	0.46	0.90	0.267
Q19 annoyed friends	0.80	0.88	0.853
<b>Physical Domain</b>	0.62	0.98	0.161
<b>Psychological Domain</b>	0.77	0.77	0.996
<b>Social Domain</b>	0.72	0.85	0.683
<b>Total Score</b>	2.11	2.60	0.543

<sup>1</sup>by independent student t-test; \* P < 0.05

**Table 6: Differences in symptoms between the TCM and placebo groups in female subjects**

Parameters	Study Group		P Value
	TCM Group	Placebo Group	
	Median (range)	Median (range)	
<b>Symptoms</b>			
Day Cough	-1 (-3 - 4)	-1 (-3 - 3)	0.958
Nigh Cough	-1 (-3 - 4)	-1 (-3 - 3)	0.910
Sputum	-1 (-4 - 4)	0 (-2 - 4)	<b>0.029*</b>
Nasal Congestion	-1 (-3 - 2)	-1 (-4 - 3)	0.749
Running Nose	-1 (-3 - 4)	-1 (-3 - 3)	0.944
Sneezing	-1 (-3 - 3)	-1 (-3 - 1)	0.629
Hoarseness	-1 (-3 - 3)	-1 (-3 - 2)	0.594
Sore Throat	-1 (-3 - 2)	-1 (-4 - 1)	0.517
Muscle Pain	-1 (-4 - 1)	0 (-3 - 1)	0.374
Chest Pain	0 (-4 - 1)	0 (-3 - 0)	0.937
Headache	-1 (-4 - 1)	0 (-4 - 2)	0.510
<b>Total Score</b>	-11 (-26 - 16)	-10 (-27 - 15)	0.722

= visit 3 - visit 1

**Table 7: Differences in symptoms between the TCM and placebo groups in subjects >35**

Parameters	Study Group		P Value
	TCM Group	Placebo Group	
	Median (range)	Median (range)	
<b>Symptoms</b>			
Day Cough	0 (-3 - 1)	0 (-2 - 3)	0.163
Nigh Cough	0 (-3 - 2)	0 (-3 - 4)	0.885
Sputum	0 (-3 - 1)	0 (-2 - 3)	0.261
Nasal Congestion	-1 (-3 - 0)	0 (-3 - 2)	0.250
Running Nose	-1 (-2 - 1)	0 (-3 - 2)	0.281
Sneezing	-1 (-3 - 1)	0 (-3 - 1)	0.064
Hoarseness	-1 (-4 - 3)	0 (-2 - 1)	<b>0.048*</b>
Sore Throat	-1 (-3 - 3)	-1 (-3 - 4)	0.965
Muscle Pain	-1 (-4 - 0)	0 (-3 - 1)	0.159
Chest Pain	0 (-3 - 0)	0 (-3 - 1)	0.859
Headache	-1 (-3 - 0)	0 (-4 - 2)	0.235
<b>Total Score</b>	<b>-8.5 (-24 - 9)</b>	<b>-4 (-21 - 19)</b>	<b>0.143</b>

= visit 3 - visit 1

symptoms of URTI were usually very subtle and hence a very sensitive tool might be required to measure the changes in such a short period of time. LCQ was originally designed to measure changes in chronic cough and no tools tracking changes in acute cough was available.

Available research and evidence of using TCM in treating cough was limited and only two studies were found in literature search using Medline: one on tumeric oil<sup>19</sup> and the other on Feiyan Chuansou Oral Liquid (FCOL).<sup>20</sup>

It was found that turmeric volatile oil was significantly active in removing sputum, relieving cough and preventing asthma. FCOL were significantly better in its antitussive, expectorant, anti-asthmatic effect and resolution of dry and moist rale, and wheezing in treatment group than those in the control group. On the other hand, a recent study found the popular Echinacea to be ineffective in treating URTI in children age from 2 to 11 years old in the USA.<sup>21</sup> In all these studies, a standard herbal formula was used irrespective of "TCM differentiation". "TCM differentiation" was the fundamental to TCM care and treatment whereby TCM practitioners would choose different formulas for different types of cough based on TCM diagnoses made for individual patients. Much TCM research including this one used fixed formulas and did not deal with the rationale of such choice and hence the appropriation of the formulation is questionable. On the other hand, if we were to assess the efficacy of Chinese medicine without standardisation, this lack of standardization would introduce many confounding variables and make comparison impossible.

In Hong Kong, polypharmacy (a URTI patient received an average of 1.3 cough medicine) and using dangerous drugs such as theophylline or steroids at the risk of developing drugs interactions, side effects or complications, was common in the management of URTI.<sup>7</sup> The high prevalence and morbidity of this illness as well as its economic and social implications warrant further search for an effective treatment and measuring tools in this area.

**Conclusion**

In order to coincide with government's effort in reducing use of

antibiotics to treat URTI, patients were encouraged not to seek medical help at the first instance but try to selfmedicate for their symptoms. However, evidence on the effectiveness of different types of anti-tussive was inconclusive. At best, only a limited number of anti-tussive such as dextromethorphan and guaifenesin may be helpful in relieving this symptom. Since Chinese herbal medicine were widely used and accepted in Hong Kong, it might provide a good base to look into its role in relieving acute cough symptom as some TCM ingredients had already been shown to be effective. The studied combination in the tablet preparation did not show any overall self-reported improvement in terms of acute symptoms or quality of life. Other factors such as syrup preparation or placebo effects might have contributed to the popularity of herbal cough medicine available to the general public. Further search for a safe and effective TCM was warranted.

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# The Description of Cough Sounds by Healthcare Professionals

Jaclyn A. Smith, H. Louise Ashurst, Sandy Jack, Ashley A. Woodcock and John E. Earis

## Abstract

**Background:** Little is known of the language healthcare professionals use to describe cough sounds. We aimed to examine how they describe cough sounds and to assess whether these descriptions suggested they appreciate the basic sound qualities (as assessed by acoustic analysis) and the underlying diagnosis of the patient coughing.

**Methods:** 53 health professionals from two large respiratory tertiary referral centres were recruited; 22 doctors and 31 staff from professions allied to medicine. Participants listened to 9 sequences of spontaneous cough sounds from common respiratory diseases. For each cough they selected patient gender, the most appropriate descriptors and a diagnosis. Cluster analysis was performed to assess which cough sounds attracted similar descriptions.

**Results:** Gender was correctly identified in 93% of cases. The presence or absence of mucus was correct in 76.1% and wheeze in 39.3% of cases. However, identifying clinical diagnosis from cough was poor at 34.0%. Cluster analysis showed coughs with the same acoustics properties rather than the same diagnoses attracted the same descriptions.

**Conclusion:** These results suggest that healthcare professionals can recognise some of the qualities of cough sounds but are poor at making diagnoses from them. It remains to be seen

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whether in the future cough sound acoustics will provide useful clinical information and whether their study will lead to the development of useful new outcome measures in cough monitoring.

**Supplementary** material on the internet: To hear the cough sounds referred to in this article, go to <http://www.biomedcentral.com/content/supplementary/1745-9974-2-1-S1.mp3>. (All the files can be accessed by visiting sites - S1.mp3 through -S9.mp3.)

## Background

Cough is the commonest symptom for which patients seek medical advice<sup>1</sup> but the quality of cough sounds is currently largely ignored in the clinical examination of adults. Like many physical symptoms and signs in clinical medicine the value of assessing the cough sound is unclear. The inter-observer repeatability of the presence or absence of a range of respiratory physical signs falls midway between chance and total agreement.<sup>2</sup> However, medical textbooks describe different types of cough (ie dry, moist, productive, brassy, hoarse, wheezy, barking etc), implying these terms are of some clinical value. Paediatricians not uncommonly use the diagnostic value of different types of cough.<sup>3,4</sup> For example, whooping cough, bronchiolitis, croup, and cough associated with tracheo-oesophageal fistula have well recognised specific features. Though it is not uncommon to ask an adult patient to describe their cough during clinical assessment, one study has suggested that the patient's own description of the character, quality and timing is of no help in ascertaining the cause.<sup>5</sup>

Acoustic analysis can be used to assess objectively the sound properties of respiratory sounds. Studies examining the waveforms of voluntary cough sounds, tussiphonograms, suggest they may be of diagnostic use, but extensive validation has not been performed.<sup>6</sup> Investigation of the acoustic properties of spontaneous cough sounds has demonstrated some significant differences between cough in different diseases.<sup>7</sup> Examination of the waveforms and spectrograms (frequency content) can identify features of cough sounds



**Table 1: Characteristics of cough sounds; see additional files 1-9 for the sound files used in this study (converted to mp3 format).**

No.	Gender	Cough with mucus	Cough with wheeze	Diagnosis	Category
1	Female	no	no	Laryngitis	A
2	Male	yes	yes	COPD/Bronchiectasis	D
3	Female	no	yes	COPD	C
4	Male	no	no	IPF	A
5	Female	no	no	IPF	A
6	Female	no	yes	Asthma	C
7	Male	no	yes	Asthma	C
8	Male	yes	no	Bronchiectasis	B
9	Male	yes	yes	COPD	D

associated with mucus in the airways<sup>8,9</sup> and wheezing sounds.<sup>7,10</sup> The ability of health professionals to appreciate these basic features are unknown. If such qualitative differences can be reliably recognised by the trained ear, cough quality could contribute to the clinical examination.

Currently, little is known about how those who work in adult respiratory medicine use the many descriptions of cough available. In this study we have used spontaneous cough sounds from overnight cough recordings in patients with common respiratory conditions. We have investigated how physicians and other health care professionals choose to describe cough sounds, whether they appreciate the basic sound qualities of coughs and whether they can identify diagnosis from cough. We hypothesised that the use of cough descriptors would demonstrate an ability to detect the basic sound qualities of cough but that they would be poor at patient diagnosis.

## Methods

**Study subjects:** 53 observers (22 respiratory physicians and 31 other health professionals) were recruited at two hospital sites (North West Lung Centre, Manchester, UK and Aintree Chest Centre, Liverpool, UK). The physicians consisted of consultants (10) and respiratory trainee registrars (12). Healthcare professionals included clinical physiologists (12), physiotherapists (11) and specialist respiratory nurses (8).

**Study design:** Nine short sequences of spontaneous cough sounds (mean length 6.7 seconds) were selected from digital sound recordings and stored on a laptop computer attached to a stereo speaker system. Each sequence of cough sounds was played 3 times in succession, to groups of observers, using the same sound system. The observers completed a questionnaire for each cough sequence, identical instructions for questionnaire completion being given.

**Cough sounds:** The cough sounds were selected randomly from an extensive database of spontaneous cough sounds, recorded overnight, in patients with pulmonary diseases. The quality of these cough sounds was assessed by experienced cough research workers by listening to the cough sounds and then confirmed by sound analysis (examination of the waveforms and spectrograms). The patients' diagnosis and clinical information was not available to the experts when doing this. They were categorised as (A) cough alone (B) cough with mucus, (C) cough with wheeze, or (D) cough with wheeze and mucus (Table 1). Recordings had been made using a free field lapel microphone (AOI, ECM-1025 electret, condenser microphone) and digital recording device (Creative Labs Ltd, Singapore) at sampling rate of 16 kHz (16-bit). Recordings were made from patients with chronic obstructive pulmonary disease (COPD), asthma, idiopathic pulmonary fibrosis (IPF), laryngitis, and bronchiectasis. The diagnoses had been established by

respiratory physicians in a tertiary referral centre from investigations including pulmonary functions tests, histamine challenge, and thoracic CT scans.

**Sound analysis:** Cough sounds were analysed using custom written software with a visual and audio output, (programmed in Matlab 6.0 Release 12, The Mathworks Inc, MA, US). Typical cough sounds contain two or three phases.<sup>6,9,10</sup> These phases are most commonly referred to as the first cough sound, intermediate phase and second cough sound (when present). Cough waveforms were rectified and smoothed to produce a signal envelope from which the length of the cough phases can be determined, as described elsewhere.<sup>11</sup>

**Spectral analysis** was performed using the fast Fourier transform (FFT). Wheezes were defined according to CORSA guidelines (Computerized Respiratory Sound Analysis) i.e. a continuous sound, with musical characteristics, periodic waveforms, a dominant frequency >100 Hz and with a duration of >100 ms.<sup>12</sup> The acoustic differences between coughs with and without mucus have only previously been described from study of voluntary cough sounds:<sup>8,9</sup> specifically coughs with mucus have significantly longer second phases and clear vertical lines can be seen in the sound spectrum.

## Questionnaire Design and Analysis

For each cough sequence subjects were asked to identify the patient's gender, select appropriate descriptors and a diagnosis. Widely used and respected respiratory textbooks were used to collect descriptors of cough sounds.<sup>13-19</sup> The 10 most common descriptors were included in the questionnaire in random order (dry, moist, productive, brassy, bovine, barking, rattling, hoarse, wheezy and loose). Subjects were asked to circle the descriptors that fitted each cough sound; the selection of more than one descriptor was permitted. The opportunity was also given to make suggestions for other appropriate descriptors. Subjects were then asked to choose the most likely diagnosis from a list of 8 possibilities (asthma, COPD, bronchiectasis, idiopathic pulmonary fibrosis, vocal cord paralysis, acute laryngitis, cystic fibrosis, and tracheomalacia).

The proportions of correct observations of the gender and diagnoses were calculated. The scores for the different occupational groups were compared using a one-way ANOVA. Scores were also compared to those expected by chance alone (one sample t-test). The use of cough sound descriptors was examined in two different ways.

Firstly, the cough descriptors were grouped into those traditionally implying cough with mucus (moist, productive, rattling and loose), cough without mucus (dry, barking, hoarse) and cough with wheeze (wheezy). The choice of cough descriptors could then be compared to the acoustic analysis of

**Table 2: Frequency of use of cough descriptors for each cough sound (maximum score of 53 for each cough for each descriptor, if chosen by all subjects).**

No.	Dry	Brassy	Rattling	Loose	Productive	Moist	Bovine	Hoarse	Wheezy	Barking
1	50	4	1	0	0	3	0	12	11	5
2	1	2	23	12	31	21	3	6	17	6
3	29	7	9	5	1	10	0	9	24	2
4	41	10	2	1	0	2	3	6	4	6
5	45	3	1	1	0	2	0	12	17	6
6	22	6	4	1	3	1	8	18	26	30
7	26	5	3	8	10	5	7	5	13	11
8	0	0	23	37	47	30	0	2	8	0
9	8	5	23	19	22	11	4	12	27	5
Totals	222	42	89	84	114	85	25	82	147	71

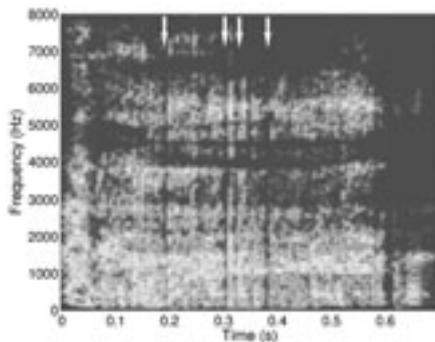
the cough sounds (Tables 1 and 2) and the proportion of responses correctly identifying the presence or absence of mucus and wheeze recorded. If the descriptors chosen were contradictory eg dry and rattling, the response was considered incorrect. The percentage of correct responses was then compared for different occupational groups (ANOVA).

Secondly, the use of descriptors was further explored using cluster analysis (agglomerative hierarchical clustering) to find which cough sounds provoked the same descriptions.<sup>20</sup> Squared Euclidean distance was used as the measure of dissimilarity. The results are presented in the form of a dendrogram beginning with 9 clusters (one for each separate cough sound). The clustering procedure progressively groups coughs sounds by descriptors until eventually one cluster, containing all the sounds is formed. The more similar the cough sounds are (in terms of description) the more rapidly they cluster together. All statistical analyses were performed using SPSS 11.0 (Chicago) and Prism 4 (Graphpad Ltd).

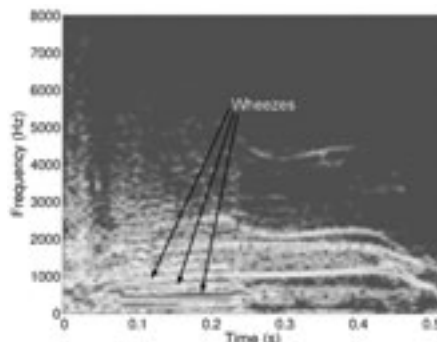
## Results

### Sound analysis

Table 1 shows a summary of the acoustics properties of the cough sounds and the consequent categories. Analysis of the cough phases found 8 of the 9 cough sounds had a 3 phases present. The coughs with mucus had significantly longer second phase ( $p = 0.02$ ) and total length ( $p = 0.02$ ) in keeping with previous reports.<sup>8,9</sup> The spectrograms in coughs with mucus all showed clear vertical lines in the second phase as reported by Murata (Figure 1),<sup>8</sup> unlike those without mucus. Four coughs contained wheezes in the intermediate phase with dominant frequencies 632, 766, 1162 and 1193 Hz and durations of 1951, 756, 275 and 202 ms respectively. Figure 2 shows a typical spectrogram of wheezes within the second phase of the cough sound.



**Figure 1**  
Spectrogram showing the change in frequency content over time in a male bronchiectasis cough (cough 8, no wheeze with mucus). Arrows show interruptions in sound spectrum.



**Figure 2**  
Spectrogram showing the change in frequency content over time in a female asthmatic cough (cough 6, wheeze with no mucus). Darker frequencies have higher amplitudes. Wheezing can be clearly seen represented by a series of horizontal bands.

### Questionnaire responses

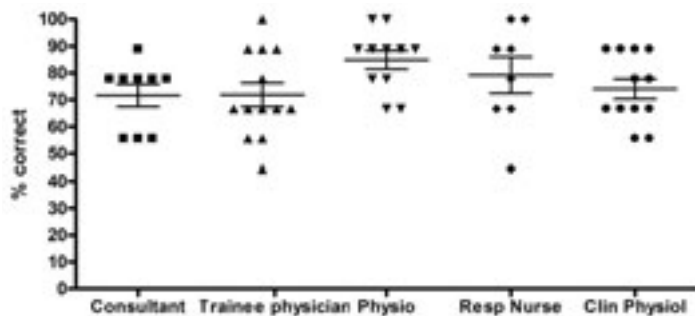
Subjects were very good at identifying gender: a mean of 93.0% were correct, averaged across all questions (standard deviation  $\pm 7.6\%$ ). They were also good at correctly differentiating cough with or without mucus ( $76.1\% \pm 14.8$ ) (Figure 3) but not cough with wheeze ( $39.3\% \pm 15.0$ ), but the ability to detect these qualities was more variable. Subjects were rarely able to use audible cough characteristics to correctly identify the clinical diagnosis from the seven diagnoses on offer ( $34.0\% \pm 29.0\%$ ), (Figure 4). Performance was still significantly better than the expected percentage correct by chance for all questions ( $p < 0.01$ , single sample t-tests). There were no statistically significant differences between the different occupational groups' ability to characterize basic cough quality (wheeze  $p = 0.54$  and mucus  $p = 0.38$ ) or to assign a diagnosis ( $p = 0.36$ ). There was no significant correlation between the ability to recognise gender and diagnosis ( $r = 0.09$ ,  $p = 0.54$ ).

### Cluster analysis

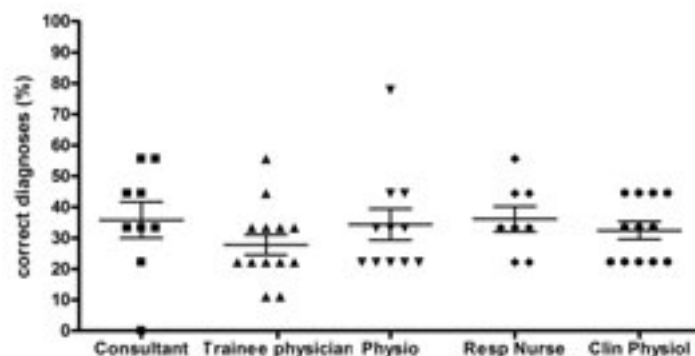
The frequency of use of the cough descriptors is shown in Table 2. Dry, productive and wheezy were the most popular descriptors but a range of different descriptors were chosen for each cough sound. Eighteen other descriptors were suggested by subjects, the most common being 'irritating', 'tight', and 'hard'. These were only used on 4 occasions each; the questionnaire descriptors were used on between 42 and 222 occasions each. Cluster analysis was performed in order to classify cough sounds sharing similar descriptors. The results are presented in the form of a dendrogram beginning with 9 clusters (one for each separate cough sound) (Figure 5). It can be seen from the dendrogram that cough sounds 1, 4, and 5 quickly form a cluster. This group of cough sounds share the same features by acoustic analysis i.e. cough without mucus or wheeze (category A, table 1). Coughs 6, 3 and 7 (cough with wheeze and no mucus, category C) and coughs 2 and 9 (cough with mucus and wheeze, category D) cluster next and are also in the same acoustic categories. At level 10 the cough sounds form 2 distinct clusters corresponding to the division between the cough with and without mucus. Hence, the cough descriptor choices cause the cough sounds to cluster by acoustic category rather than by diagnostic category.

### Discussion

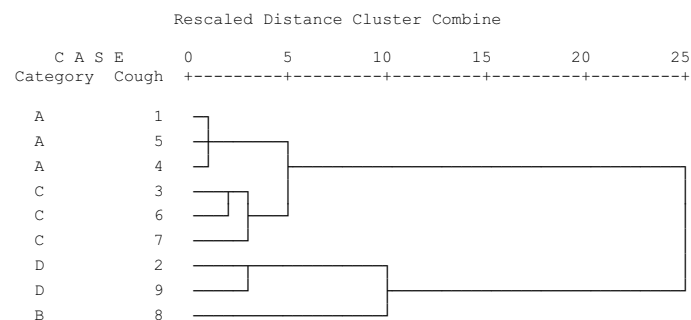
This is the first study to relate the descriptions of adult cough sounds to their acoustic analysis. We have shown that health professionals are good at identifying coughs with and without



**Figure 3.** Percentage of coughs with mucus correctly identified by job title (mean with 95% confidence intervals).



**Figure 4.** Percentage of diagnoses correct by job title (mean with 95% confident intervals).



**Figure 5.** Dendrogram resulting from cluster analysis of 9 cough sequences. The cough characteristics are shown in table 1. Coughs attracting similar descriptors combine at shorter distances.

mucus but are less successful at identifying wheezes in cough sounds. As predicted the ability to select the correct diagnosis for a cough from the sound alone was poor. A wide range of cough descriptors was used by our subjects and cluster analysis suggested they reflect the acoustic properties of the cough sounds rather than the diagnostic category. Only one previous study has investigated the quality of cough sounds.<sup>21</sup> This study was performed in children undergoing bronchoscopy and examined the agreement between descriptions of the cough as wet or dry (by clinicians and parents) and the bronchoscopic appearances. A novel system for categorising the airway appearances was devised and good agreement was found for both clinician's and parent's rating of coughs. These findings are in keeping with our study suggesting that wet or dry coughs can generally be distinguished.

The identification of wheezes in cough sounds was generally poor but the variability in performance was large with some

individuals performing very well and others very badly. This may be explained by the fact that health professionals are much more accustomed to identifying wheezes superimposed on breath sounds rather than cough sounds. Subjects were able to predict accurately the gender of the patient from the cough sound; this was probably due to the differences in frequency content.<sup>22</sup> Subjects could have used gender to predict likely diagnosis but there was no evidence of this; there was no correlation between gender scores and diagnosis scores. The acoustic features of wheezes are well described from the study of breath sounds and wheezes can be easily identified in the spectrogram (ie from the frequency components) (Figure 2). However there has been less interest in acoustic analysis of cough sounds. Only one study has described the effect of mucus on voluntary cough sounds in subjects with COPD.<sup>9</sup> It is our experience that these features can also be easily identified in the spectrogram of spontaneous cough sounds (Figure 1). We have not found the audiograms to be useful in identifying wheeze or mucus in cough sounds.

We included health professionals allied to medicine in our study as well as doctors because, to our knowledge, none of these groups receives any specific training in recognising the qualities of cough sounds. All participants included were working with adult respiratory patients on a daily basis and had extensive clinical experience with patients who cough. We found no significant differences in the performance of medically qualified health professionals and those qualified in professions allied to medicine. Indeed in the study by Chang<sup>21</sup> parents performed almost as well as clinicians in detecting cough with mucus.

It is possible that with training skills in recognising cough qualities could be improved. In a small study 5 physicians who had brief training to appreciate the features of cough waveforms from an audio-visual display could differentiate between voluntary coughs from patients with asthma and chronic bronchitis.<sup>23</sup> Their ability to differentiate the two conditions prior to training was not assessed and may represent the same ability to differentiate between coughs with mucus (chronic bronchitis) from cough without mucus (asthma), demonstrated by our un-trained subjects.

This study showed that health professionals tend to use a wide range of descriptors to describe cough sounds. Many more cough descriptors were used by our participants than were found in the textbooks. A total of eighteen additional cough descriptors were suggested but none was as frequently used as the textbook terms, suggesting that these were more broadly acceptable. A hierarchical cluster analysis was used to classify cough sounds in terms of the descriptors they attracted. This type of analysis has been used in an analogous study examining the language patients use to describe breathlessness.<sup>24</sup> Cluster analysis of the cough descriptors produced identical categories of cough sounds to acoustic analysis. This suggests that taken together the patterns of descriptors chosen reflect an appreciation of the underlying qualities of the cough sounds rather than the underlying patient diagnosis.

That diagnosis from cough sound alone is poor is not surprising. Previous work examining voluntary cough sounds has suggested that some differences occur between diagnostic groups.<sup>6</sup> In our experience of acoustic analysis of spontaneous cough sounds<sup>11</sup> the variability of acoustic parameters between individuals is considerable and greater than that between disease groups. One

of the possible explanations for this variability is that the presence of mucus in the airways during coughing or wheeze due to bronchospasm is likely to vary at different times of day, in different environments and with disease exacerbations. Therefore even if the health professional could accurately describe a cough sound during clinical assessment, this may not be of much clinical utility. Perhaps a more useful measure would be the cough quality over longer periods of time e.g. the proportion of coughs with mucus in 24 hours. It will only be possible to assess these kinds of endpoints once accurate automated cough detection systems are devised and after more extensive validation of cough sound acoustics.

## Conclusion

We conclude that health professionals are able to differentiate coughs with mucus from those without mucus, but are poor at identifying wheeze and diagnosis. The wide range of cough descriptors in use seems to be unjustified as they merely represent the basic sound qualities. This study underscores the lack of knowledge about one of the commonest symptoms in respiratory disease, the need for new techniques to measure and monitor cough, and to determine whether objective cough sound characteristics are useful.

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