

Volume 2 Number 2 April-May 2007

# Respiratory Therapy™

The Journal of Pulmonary Technique

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## The Big Picture: Intelligent Solutions for Ventilator Safety

David Costa

David Costa is Vice President, Hamilton Medical, former airline pilot and current instructor pilot specializing in high performance aircraft.

Error reduction, patient safety and risk reduction are hot topics of discussion in the medical community. Who is not concerned about the safety of a loved one when they enter the health care system? Commercial aviation, with all its potential risks, is classified as one of the safest industries today. What can the medical community learn from their success?

Imagine your reaction if, sitting on an airplane, ready to depart you heard this. "Ladies and Gentlemen, this is your Captain speaking. I want to inform you today of a common occurrence called Aircraft Induced Passenger Injury. We know that if you stay on this flight long enough, it will happen. There is nothing wrong with the aircraft, but there is a high probability that we will not set the flight controls properly and you may be hurt in the process." Can you imagine the public outcry?

Here is a challenge for the medical community. Eliminate ventilator induced lung injury. Despite healthcare professionals working tirelessly every day, this is a fact of placing someone on a mechanical ventilator. If lung protective ventilation is not a constant focus, the ventilator will do damage. Remember, "First, do no harm."

Comparisons between the safety records of health care and commercial aviation are not new. One of the more recent comparisons was from the October 31, 2006 issue of the New York Times, "What Pilots Can Teach Hospitals about Patient Safety". This article discussed how many hospitals are using pilots as consultants to help them address patient safety and error reduction. Another example, Jean-Louis Vincent, MD, in an editorial to *ICU Management* 6:1:2006 said it best. "Over the years, healthcare services have developed a 'cover-up' culture where mistakes have been hidden ... However, this traditional attitude is beginning to change as we learn from other industries where great harm is possible, e.g. aviation and nuclear power, which approach the concept of safety with a no-fault or limited fault approach."

Once an industry accepts that certain risks are present, correction can be implemented. Many airline pilots have had the opportunity to participate in no-fault or limited fault disclosures that have resulted in great strides in passenger safety. Want proof? In 1999, the American Hospital Association reported that there were somewhere between 44,000 and 98,000 deaths every year due to medical errors. Compare this to National Transportation Safety Board statistics for 2004, where there were 11 fatalities due to commercial aviation. Despite the recent focus on safety statistics, experts assure us that the health system in the United States is safe. But its safety record is a far cry from the record of the similarly complex aviation industry, which is being held up as an example for the medical community. A person would have to fly nonstop for 438 years before expecting to be involved in a deadly airplane crash, based on recent airline accident statistics. The Institute of Medicine has stated that health care is at least a decade behind aviation in safeguarding consumers' lives and health. Of course there are dramatic differences between commercial aviation and health care, and there is not a "one size fits all" solution. It is, however, hard to argue with the fact that improvement is needed.

Human error is still the leading cause of accidents. At the airlines, we addressed this with Crew Resource Management (CRM), and aircraft-type specific training, conducted with advanced simulations. Airline crews have procedures, profiles and flows to address each element of routine, abnormal and emergency situations in a

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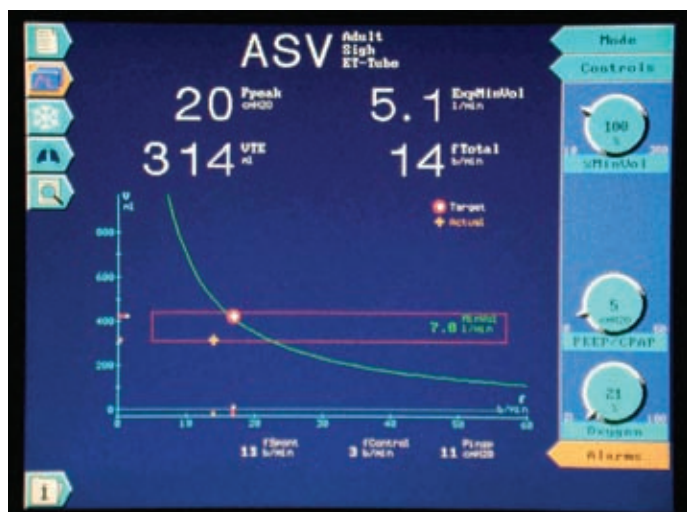
standardized fashion. Medical device companies offer little, if any, of this kind of training, and hospitals are rarely offering it either. With literally thousands of jet engine starts in my flying career, I still use a checklist. I use a checklist for safety and to eliminate mistakes. Is there a checklist for immediate actions to take in the event of a suspected ventilator malfunction? The Federal Aviation Administration requires any pilot flying a turbojet aircraft to have type-specific training and certification before they may act as the pilot in command. How many different types of medical instrumentation does the average healthcare professional come in contact with on a given day? Is current training provided by sales people and clinical support representatives really adequate? Look at the facts. The Joint

Commission on Accreditation of Healthcare Organizations published a Sentinel Event Alert 26.2.2002, "Root Cause Analysis of 23 deaths or injuries related to long term ventilation," where inadequate orientation/training was found to be a factor in 87% of these cases. The second leading factor in this study was "communication breakdown among staff members." These are issues that can improve with more effective training, what is being done today is simply not working.

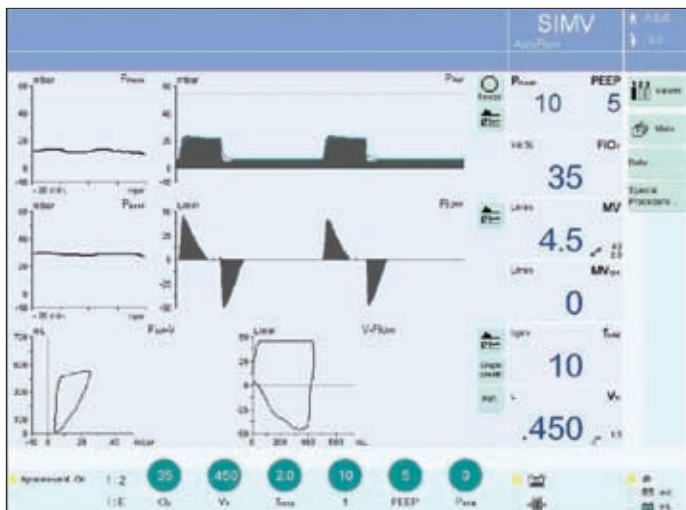
Every pilot knows that flying is extremely dynamic. Weather, air traffic control, the aircraft and many other factors require the pilot to assemble a "big picture" regarding the status of their flight - constantly and correctly. The same can be said for patient care in the ICU where the situation is also extremely dynamic. This is precisely why airline pilots are trained in simulators before ever carrying passengers. Were you aware of the fact that an airline pilot essentially puts their job on the line every six months? Standardization, procedures, immediate action items, etc. are so important to safety that crews are given practical examinations on a routine basis. Safety issues can be addressed before something goes wrong. Hospitals can no longer afford the costs of medical errors and increased lengths of stay due to improper actions by staff, yet the investment in advanced training is inadequate.

### A safe operation has three elements

Safety is predicated upon three basic elements. These are the operator, the machine and the environment. Imagine a three-legged stool. If any one of these elements is weak then the entire system can fall apart.







The Operator (pilot or clinician) needs to be in good physical and mental condition to perform safely. Errors are much more likely when the Operator has worked long hours or needs to function with a team that has little standardization. Most importantly, Operators must maintain what pilots refer to as “situational awareness” (SA). Situational awareness is defined as, “the degree of accuracy by which one’s perception of his current environment mirrors reality.” Pilots simplify this definition: *aviate, navigate and communicate*. The ability to maintain situational awareness is a major factor in determining the skill level of a pilot. Manipulation of the flight controls is often the easiest aspect of good piloting skills. Getting a pilot to the point where they exhibit a high degree of situational awareness skills and can anticipate what will happen next is what separates the average pilots from those most able to conduct safe flight operations under all conditions. This also relates very closely to health care within the ICU. There are many inputs and many decisions that need to be made. The clinician must keep the big picture of appropriate care, patient safety, and effectiveness while responding correctly to minor deviations. Those teams who do this with consistency generate the best patient outcomes.

Research into situational awareness has uncovered some compelling information. A pilot’s perception of reality is often influenced or degraded by internal (mental) and external (environmental) forces. The pilot’s ability to process incoming information is subject to certain expectations and biases. Problems are most likely to emerge when expectations distort, conflict with or mute incoming information.



Does this kind of statement sound familiar? It should. Clinicians in the ICU are under the same kind of influences. The problem is, that until recently, clinicians have rarely been given any training in situational awareness, much less evaluated on their ability to handle complex and dynamic environments. Developing and maintaining situational awareness is clearly important, but where to start? Pilots learn that situational awareness is not easy to keep, so they develop their own method of developing and maintaining it.

For you or that pilot to have any chance of seeing the big picture, you must always, at any time be able to answer 5 simple questions:

- Where have I been?
- Where am I?
- Where am I going?
- What should I be doing?
- What might impact my plans along the way?

If at any point in the cockpit or during the care for your patient you cannot answer these five questions, situational awareness is not possible. With the correct answers to these questions (note: correct answers) situational awareness can be rebuilt.

Fortunately pilots and clinicians do not have to do this all on their own. There are lots of tools, some obvious, some not – that can assist in developing and maintaining situational awareness. Aviation uses the term CRM (Crew Resource Management), because time and time again it has been proven that it is people *not* working together that is a major factor in losing situational awareness and creating unsafe conditions.

Open channels of communication allow individuals to express opinions. There have been plenty of aviation accidents that could have been prevented if the cockpit crew had communicated more effectively. In fact, an NTSB study of 37 accidents found that 31 could have been prevented if one or more crewmembers had spoken up about errors and/or situational awareness concerns. This holds true in clinical practice as well. This is exactly why the Joint Commission listed “communication breakdown” as the number two reason for ventilator injuries or deaths in the report cited earlier.

Another supportive tool for a pilot is a checklist. Use of checklists, even for very simple tasks, are excellent outlines that

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guide pilots through problems or routine procedures in a methodical way, which, in turn, allows their focus to remain on the big picture, not the routine or rote. Hospitals are now trying to utilize this idea as well, but still many procedures or “protocols” are performed from memory, not by direct reference to a printed card, graphical user interface on the instrumentation, etc.

The second element to safety is the machine (aircraft, ventilator or other instrumentation). Modern mechanical ventilators are all very manual devices. Equipment reliability from all manufacturers has improved over the years and the equipment is designed to protect the patient in the event of a failure. But Ventilator Induced Lung Injury does not normally result from an equipment failure, but rather from incorrect ventilator settings that were set by a human operator. Until very recently, the mechanical ventilator even with so called “dual modes” relies on the clinician to select a mode, and make static settings. The modern mechanical ventilator, with rare exception is like having the pilot flying the airliner by hand all the time, in all kinds of weather. Not the best for safety. A mechanical ventilator is a potential killing machine. It is really a time machine. The ventilator does not heal, but mainly “buys time” for the patient to improve. So the fact that the ventilator causes harm to the patient very routinely, says little for what manufacturers have to offer the clinician.

Aircraft instrumentation has come a long way and safety has improved in line with those advances. The airliner cockpit used to be filled with dials and gauges, and progressed to digital displays. But, because situational awareness is so critical to the safety of the passengers on board a modern airliner, the aviation community is always exploring new ways to help pilots maintain it. The modern “glass cockpit” uses pictures rather than dials and numbers to help pilots formulate answers to those five questions mentioned before. Such displays can put contingency plans at a pilot’s fingertips, while greatly simplifying many of the aspects of the flight. The goal of modern aircraft panels is to provide the pilots a clear, unobstructed view of the flight path regardless of time of day or severity of the weather. In stressful circumstances, the cockpit offers “intelligent” displays that allow the pilot to focus only on what is important to the task at hand.

We can see evidence that the medical community is venturing down this pathway as well, but with mixed results. Fancy “boxes” and displays only can help the clinician if they know how to use them effectively. Little time is spent with the clinician in training on this area of operation of each particular device. Operational errors or misunderstandings can destroy situational awareness very rapidly. High tech toys can sometimes lull pilots and clinicians into losing situational awareness. Serious concentration on these displays can distract from other required tasks. Take the trend in ventilator graphics for instance, an early attempt at giving a mechanical ventilator some kind of “picture” to help assess the patient. The respiratory therapist or physician will agree that waveform interpretation is not a simple task. What is needed is a display for the mechanical ventilator that gives instant confirmation that the patient is being treated appropriately. This is available today on a mechanical ventilator with much research being devoted to take ventilator displays to a whole new level.

The third key factor related to safety is the Environment (the

weather or the patient and facility). The modern ICU is a flurry of activity. The patient is dynamic. The patient care team is diverse, dynamic and not always working as a team. The clinician is presented with a situation that is difficult or impossible to control. Despite these challenges, clinicians work long hard shifts to care for the patients that we all serve. Pilots learn to develop contingency plans to manage elements beyond their control. The clinician needs better tools to not only let them manage what is happening real time, but allow them to anticipate the elements that are not in their control. The goal is to anticipate not simply react.

### **How does this affect the next generation of mechanical ventilators?**

Those three elements critical to safety (operator, machine, environment) must be considered together, to reach the goal of eliminating Ventilator Induced Lung Injury.

Tools and technology are not enough to ensure safety and situational awareness. Mental conditioning is required to keep your situational awareness in top form. You must eliminate any belief that you can always do everything yourself. Pilots and clinicians by nature are independent thinkers. When times are busy however, teamwork is essential. Dividing duties is critical to every type of operation – some should be flying the airplane, while another should be working on the other issues.

Pilots have one huge advantage over the clinician in the ICU. They rely on cockpit automation to maintain situational awareness and divide duties between the team. The autopilot has dramatically improved the safety of airline travel. We are just now seeing independent thinking medical device companies offering “autopilots” on their medical devices as well. The mechanical ventilator forces a breathing pattern on a patient, based upon manual settings by a clinician who may or may not have situational awareness of the current situation. The term Ventilator Induced Lung Injury should really be clinician induced lung injury. Patients don’t fight ventilators, ventilators fight patients. There has to be a better way than sedation to allow the ventilator to do its work.

There is a very famous airline crash that is often used to demonstrate how the loss of situational awareness can have dire consequences. An Eastern Airlines crew of a Lockheed Tri-Star airliner crashed into the Florida Everglades due strictly to pilot error and loss of situational awareness. Everyone in the cockpit was focused on a landing gear problem, but nobody was watching the airplane. Actually, there was nothing wrong with the landing gear. A 29 cent light bulb had simply blown out. In this crew of three, not one had assumed responsibility to actually fly the aircraft. They all focused on the “perceived” problem and flew a perfectly good aircraft into the Florida everglades killing many people.

Mechanical ventilators, that do not employ advanced technology like an autopilot, offer almost no safety net for the clinician. In the hands of an appropriately trained clinician at the bedside at all times the ventilator can be readily manipulated. It is impossible for a clinician to be at the bedside all the time. There are common problems with mechanical ventilators however that the industry is ignoring. There are too many modes. Clinicians are rarely experts at all the modes on modern ventilators, not to mention the differences between how these modes operate  
*Continued on page 74...*

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## BE PREPARED

According to Jeff Borriak, BS, RRT, writing in Hamilton Medical's Intelligent Ventilation Newsletter: The 5th anniversary of the 9-11 attacks on our country, the recent failed terror plot to bring down several passenger aircraft heading to the United States, and other recent world events should remind us of the importance of every hospital, regardless of location, to be prepared and able to respond to a multiple-casualty terror attack if and when it happens.

An article published in *Critical Care* last year by Gabriella Aschkenasy-Steuer et al presented the approach taken by Hadassah-Hebrew University Medical Center to multiple-casualty events. According to the authors, Hadassah-Hebrew University Medical Center is the only Level 1 trauma center in Jerusalem and has therefore gained important experience in caring for critically injured patients. A retrospective review of the hospital's response to multiple-casualty terror incidents was performed on events that occurred between October 1st 2000 and September 1st 2004. This review included 33 major terror attacks, 20 of which involved more than 10 wounded. Most of the injuries to the victims of these terror attacks involved a combination of penetrating injuries, blunt trauma, and burns, generally involving several parts of the body. The focus of the report was on the organizational steps needed to provide operational flexibility within the hospital, and discussion of issues related to the diagnosis and management of specific injuries (i.e. acute lung injury, brain injuries, orthopedic injuries, and abdominal blast injuries) commonly associated with terror events.

A previous e-news article discussion included some of the organizational steps that can be taken by hospitals to help them prepare for a terror attack, as suggested by Aschkenasy-Steuer et al, if and when it occurs. Although typical injuries after multiple-casualty traumas include brain injuries, orthopedic injuries, abdominal blast injuries, and acute lung injuries (ALI), in this e-news article the discussion will focus on important issues related to the diagnosis and management of victims with acute lung injury at Hadassah-Hebrew University Medical Center.

Many of the patients included in the retrospective review at Hadassah-Hebrew University Medical Center were victims of bombing injuries. Bombing injuries are caused by a combination of blast injury (due to changes in atmospheric pressure), blunt trauma (due to body displacement caused by expanding gases), penetrating injuries (due to shrapnel), and burns. Fifty-two percent of the patients injured in bombings had some type of acute lung injury (ALI). Lung injuries after bombings include lung contusions, penetrating injuries, barotrauma, hemorrhage, bronchopleural fistulae, acute respiratory distress syndrome (ARDS) and superimposed pneumonia. Severely injured lungs

are prone to the development of superimposed infections, and many of these patients can develop severe pneumonias within a few days, which may significantly prolong their recovery.

Aschkenasy-Steuer et al diagnose ALI by considering the mechanism of injury and the patient's oxygenation state, and then confirm the diagnosis by either chest X-ray or computed tomography (CT). Patients with severe blast injuries can develop symptoms compatible with ALI as early as several minutes to a few hours after their injuries.

The respiratory management of these patients can be challenging and complicated because they may present with any combination of penetrating injuries, lung contusions, bronchopleural fistulae, burns, etc. The presence of hypovolemia, brain injuries, sepsis, etc can further complicate the management of these patients because each of these entities may require somewhat contradictory therapies. For example, managing a patient with ALI may require a high positive end expiratory pressure (PEEP) level for lung recruitment, which could exacerbate a leak from a bronchopleural fistulae, potentially increase intracranial pressure in a patient with a brain injury, or induce hypotension in an already hypovolemic patient. A high level of awareness is required to manage these patients appropriately.

A lung protective ventilatory strategy is started as soon as the patient demonstrates any signs of ALI. All patients admitted to Hadassah-Hebrew University Medical Center with blast injuries, or with a combination of blast and penetrating injuries, are ventilated with low tidal volumes (5 to 7ml/kg). Pressure control ventilation is utilized with a PEEP level of 10 to 20cmH<sub>2</sub>O. The goal for ventilatory pressures is to keep peak inspiratory pressures lower than 35cmH<sub>2</sub>O, and plateau pressures lower than 25cmH<sub>2</sub>O. The lowest fraction of inspired oxygen (FiO<sub>2</sub>) is allowed to maintain an oxygen hemoglobin saturation of about 90%, and, if necessary, permissive hypercapnia is allowed. This ventilatory strategy is often utilized in conjunction with appropriate hemodynamic support, and the treatment and management of brain injuries, orthopedic injuries, and abdominal blast injuries, which the authors further describe in the article.

It is the hope of the authors that their experience in dealing with multiple-casualty events can be useful for others caring for this unique group of trauma victims and will result in favorable outcomes, although it is also hoped that their experience gained through these events will not be needed in the future in any part of the world.

## GET OUT OF THE STREET

Children who grow up near busy roads or highways with traffic pollution have poorer lung function and are more likely to suffer long term respiratory and heart-related health problems than those who live further away, according to a study by the Keck School of Medicine at USC, published in *Lancet*. Researchers examined the effects of traffic pollution on 3,677 children who grew up in Southern California over an 8-year period between the ages of 10 and 18. The results showed that the lungs of kids who lived within 500 yards of a busy highway or road with traffic pollution were less developed and had lower lung capacity than those who had lived at least 1,500 yards away. Scientists said a child who has been breathing in that level of pollution in their growing years was likely to have poorer lung

function the rest of its life. For each year over the 8-year period scientists tested the lung function of each child, such as how forcefully they could breathe out and how much volume of air they could breathe out and take in. They also recorded how far away the child's home was from busy roads and highways and took into account the air quality and level of traffic pollution in each case. Living near traffic pollution means that more of the ultrafine particles and carbon emitted from vehicle exhausts, particularly from diesel fumes, get deep into the lungs. Toxic chemicals are also present in traffic pollution, such as nitrogen dioxide which affects the ability of the lungs to exchange oxygen and carbon dioxide with the bloodstream. (Written by Catharine Paddock, Medical News Today.)

## GIVE 'EM THE GAS

Researchers at the University of Pittsburgh have demonstrated that low-dose carbon monoxide administered in conjunction with oxygen therapy markedly inhibits oxygen-induced damage to lung cells, according to a report in the *Journal of Biological Chemistry*, reported in *Medical News Today*. Recent studies in animals have shown that prolonged exposure to an elevated level of oxygen, or hyperoxia, can cause long-term lung injury that resembles ARDS. Based on previous research showing that low-dose carbon monoxide has potent anti-inflammatory effects in a number of tissues, the Pitt researchers cultured lung cells from mice in a medium with a high concentration of oxygen, with and without low levels of CO. They then monitored the cells for hyperoxia-induced toxicity. The presence of CO in the hyperoxic medium significantly inhibited the destruction of lung cells as well as the production of molecules in the cells that are known to induce cell suicide, or apoptosis. In contrast, more than half of the mouse lung cells incubated in hyperoxic media without CO died within 72 hours, compared to about 25 percent of the CO-treated cells, and they produced high levels of apoptotic molecules. Last year, a study by the National Institutes of Health demonstrated that administering small amounts of inhaled CO to normal individuals was not damaging to their health.

## HOW IT HAPPENED

In a study of non-human primates infected with the influenza virus that killed 50 million people in 1918, an international team of scientists has found a critical clue to how the virus killed so quickly and efficiently. The work suggests that it may be possible in future outbreaks of highly pathogenic flu to stem the tide of death through early intervention. The study reconstructed the virus from genes obtained from the tissues of victims of the great pandemic in a reverse genetics process that enables scientists to make fully functioning viruses. By infecting monkeys with the virus, the team was able to show that the 1918 virus prompted a deadly respiratory infection that echoed historical accounts of how the disease claimed its victims. Results showed that infection with the virus prompted an immune response that derailed the body's typical reaction to viral infection and unleashed an attack by the immune system on the lungs. As immune cells attacked the respiratory system, the lungs filled with fluid and victims drowned. The same excessive immune reaction is characteristic of avian flu. In the study, seven primates were infected with the reconstructed 1918 virus. Clinical signs of disease were apparent within 24 hours of infection and within eight days euthanization was necessary. The rapid course of the disease mirrored how quickly the disease ran its course in its human victims in 1918.

## TAKE TWO ASPIRIN

Taking a low dose of aspirin every other day lowers the risk of getting asthma by 22%, according to a study involving 22,071 male physicians. Researchers at the Division of Aging at Brigham and Women's Hospital in Massachusetts studied physicians ages 40 to 84 over a period of about five years. Among the 11,037 individuals who took aspirin, 113 new cases of asthma were diagnosed, as contrasted to 145 in the placebo group. There was no implication that aspirin does anything for people who already have asthma. The lower risk of newly-diagnosed asthma was not affected by smoking, body mass index or age.

## ONE TWO PUNCH

Patients with COPD get better results when they combine a long-acting bronchodilator with an inhaled corticosteroid, reducing exacerbations by 35%, according to researchers at Maingau Hospital in Frankfurt am Main, Germany. Participants in the study had less than a 50% predicted lung function capability for their age group. The researchers treated 487 patients with salmeterol, a long-acting bronchodilator, and gave 507 a combination therapy of salmeterol and fluticasone propionate, an inhaled corticosteroid. Of the total cohort, 792 patients completed all phases of the 44-week study. In the combined therapy group, 324 patients experienced moderate to severe exacerbations, as compared to 464 in the control group. The researchers believe that this reduction in exacerbations is likely of clinical importance for patients with severe COPD. A relatively high dose of ICS was administered, which has often led to complications, particularly in older patients. Based on adverse event reporting, 23 cases of pneumonia occurred in the combined-treatment group compared with only seven in the salmeterol group. This difference is statistically significant and represents an excess pneumonia rate of about 3 per 100 patient years in patients given fluticasone. As such, researchers concluded that decisions to initiate ICS combined with a long-acting beta agonist should focus on severely symptomatic and exacerbation-prone patients and balance the recently demonstrated benefits against increased drug costs and adverse effects.

## JUST SAID NO

People living with severe asthma in Scotland may be denied access to a potentially life enhancing treatment. The Scottish Medicines Consortium, which advises NHS Scotland on new treatments, is expected to issue advice against Xolair on the grounds of cost, though Xolair has been proved to be safe and effective. One in ten people in Scotland with severe asthma symptoms say that once a week they have an asthma attack so severe they cannot speak. One in five is seriously concerned that the next asthma attack will kill them. The treatment of asthma across the UK costs the NHS about £889 million a year. Xolair was licensed for use in the UK in 2005 and is given as an add-on therapy in a fortnightly injection for people with asthma that is severe, persistent and allergic. According to a support group for asthmatics, "People living in rural areas can take hours to get to a hospital following an attack and by the time the ambulance reaches them, it may be too late. We're not asking for this drug to be made available to everyone but if it can make a difference to a select group of people then surely that is worth the cost."

## GOING UP

The use of corticosteroid inhalers will increase for the

treatment of asthma and COPD, according to Decision Resources. The company said, "Despite their criticisms of primary care physicians' use of inhaled corticosteroids, 39% of pulmonologists forecast that they will increase their use of these agents for treating COPD, presumably in large part because of the results of the TORCH study. For the treatment of asthma, physicians and experts concur that, over the next two years, they will likely increase their use of single-agent corticosteroid inhalers. Single-agent inhalers are becoming seen as the most appropriate first-line agent, though Advair use in this segment will continue to increase as well." The findings come from two new reports from Decision Resources: Treatment Algorithms in Asthma and Treatment Algorithms in COPD.

## RED MENACE

The Florida red tide can be harmful for people with asthma, according to researchers at the University of Miami Rosenstiel School of Marine and Atmospheric Science. Florida red tides, an annual event in areas along the Gulf of Mexico, are blooms of the ocean organism, *Karenia brevis* (*K brevis*), that are concentrated along shorelines and produce highly potent aerosolized toxins. New research reported in the January issue of CHEST, shows that Florida red tide toxins can impact respiratory function and increase respiratory symptoms in patients with asthma. In the normal population, inhaled aerosolized red tide toxins can lead to eye irritation, rhinorrhea, nonproductive cough, and wheezing. These toxins are likely to have a greater impact on patients with asthma. Researchers evaluated the exposures and effects of aerosolized Florida red tide brevetoxins in 97 subjects with asthma. Participants, who were all residents of Sarasota, FL, spent at least one hour at Sarasota's Siesta Beach during active *K brevis* bloom and during a period when there was no bloom. Detailed baseline information was collected, and all participants underwent pre- and post-beach evaluations, including medical history questionnaires, nasal swab sampling, and spirometry. Each participant also carried a personal air monitor while at the beach. Throughout exposure and nonexposure periods, researchers collected water and air samples and monitored air temperature, relative humidity, and wind speed and direction. During active *K brevis* bloom exposure periods, significant differences were found for all participants between pre- and post-beach report of symptoms and pre- and post-spirometry. During exposure periods, participants reported a significant increase in symptoms, predominantly chest tightness, and differences were measured objectively on lung function testing. In contrast, no significant differences were observed between pre- and post- beach symptoms or spirometry during nonexposure periods.

## CUT OUT

Should smokers be refused surgery? Denying operations is justified for specific conditions, argues Professor Matthew Peters from the Concord Repatriation General Hospital in Australia, in a debate published in *BMJ*. Peters says that smoking up to the time of any surgery increases cardiac and pulmonary complications, impairs tissue healing, and is associated with more infections. These effects increase the costs of care and also mean less opportunity to treat other patients, he writes. In healthcare systems with finite resources, preferring non-smokers over smokers for a limited number of procedures will therefore deliver greater clinical benefit to individuals and the community. He believes that, as long as everything is done to help patients to stop smoking, it is both

responsible and ethical to implement a policy that those unwilling or unable to stop should have low priority for, or be excluded from, certain elective procedures. Arguing for the opposite side, Professor Leonard Glantz from Boston University School of Public Health believes it is unacceptable discrimination. "It is astounding that doctors would question whether they should treat smokers," he said. "Doctors should certainly inform patients that they might reduce their risks of post-surgical complications if they stop smoking before the procedure. But should the price of not following the doctor's advice be the denial of beneficial surgery?" He noted that cost arguments are made to support the discriminatory non-treatment of smokers. But why focus our cost saving concerns on smokers? Patients are not required to visit fitness clubs, lose 25 pounds, or take drugs to lower blood pressure before surgery. Discriminating against smokers has become an acceptable norm, he writes. "It is shameful for doctors to be willing to treat everybody but smokers in a society that is supposed to be pluralistic and tolerant. Depriving smokers of surgery that would clearly enhance their wellbeing is not just wrong - it is mean," he concluded.

## COUGH IT UP

Adults ages 20 to 44 with normal lung function who later develop chronic cough and phlegm have a fourfold higher risk of developing COPD, according to a study by San Matteo Hospital and University of Pavia in Italy. The presence of chronic cough and phlegm among study participants was an independent and statistically significant predictor of COPD. Of the 5,002 individuals in the study cohort, 123 were diagnosed with COPD. All participants had normal lung function at baseline. In a large international cohort of individuals from ages 20 to 44, the 10-year cumulative incidence of COPD was 2.8%. It was 4.6% in adults aged 40 to 44. This finding points out that COPD is a major health problem even in young adults who are usually not considered to be at risk. In agreement with previous research, it was found that the progression toward airflow obstruction is a continuous and gradual process, where sudden changes are extremely unlikely. Among the study group, about 77% of the 123 COPD cases were smokers. In the sample as a whole, about 55% smoked. In addition to cough and phlegm in participants, researchers considered such factors as sex, age, dyspnea, smoking habits and level of education. All participants received lung function tests and blood workups at the beginning and end of the study. According to a commentary on the study, the predictive value of chronic cough and phlegm was probably more surprising given the fact that this cohort was young and had normal lung function at baseline.

## SLEEP NEWS

### BLOOD URIC LEVELS

Archivos de Broncomeumologia reports on "Blood Uric Acid Levels in Patients With Sleep-Disordered Breathing." Authors Garcia, et al studied recurrent hypoxia associated with sleep apnea-hypopnea syndrome (SAHS), which leads to an increase in the degradation of adenosine triphosphatase to xanthine and, secondarily, to an increase in uric acid concentrations. The aim of the study was to determine whether there is a correlation between uric acid levels in peripheral blood and sleep-disordered breathing, independently of known confounding factors. The authors carried out a retrospective cross-sectional

study of 1,135 patients evaluated for suspected SAHS. Biochemical analysis of venous blood and an overnight sleep study (with either conventional polysomnography or home monitoring) were carried out. The mean (SD) concentration of uric acid was 6.31 (1.5) mg/dL, and 36% of patients had concentrations above established normal values for their sex. Researchers found a significant correlation between uric acid levels and some sleep study parameters (number of respiratory events, number of desaturations, or the cumulative percentage of time with oxygen saturation less than 90%). Those patients with more respiratory events had higher uric acid levels than those with mild or no SAHS. However, this difference was not apparent in the univariate analysis of variance, in which body mass index and cholesterol and triglyceride levels were considered confounding factors. The authors concluded that uric acid levels are positively correlated with the number of obstructive respiratory episodes and oxygen desaturations during sleep, but this correlation seems to be influenced by other factors, such as obesity. For the complete paper, see Arch Bronconeumol 2006 Oct;42(10):492-500. The authors are with Unidad de Trastornos Respiratorios del Sueño. Unidad Médico-Quirúrgica de Enfermedades Respiratorias. Hospitales Universitarios Virgen del Rocío. Sevilla. España.

### ALLERGIC RHINITIS

Arch Intern Med reports on Allergic rhinitis and its consequences on quality of sleep: an unexplored area. Authors Leger et al worked from the premise that allergic rhinitis is common and has been shown to impair social life and sleep. Patients with severe symptoms may have more sleep disturbances than those with a mild form of the disease, but this has never been assessed using a validated tool. The objective of the study was to assess, in patients with AR, whether duration and severity of AR are associated with sleep impairment. A nationwide controlled cross-sectional epidemiological study was carried out. A representative sample of 260 French ear, nose, and throat and allergy specialists enrolled 591 patients with AR of at least 1 year's duration. Sleep disorders, sleep quality, and AR were assessed using validated tools (Sleep Disorders Questionnaire, Epworth Sleepiness Scale, and Score for Allergic Rhinitis). The severity of AR was assessed using the Allergic Rhinitis and its Impact on Asthma classification. All dimensions of sleep were impaired by AR, particularly by the severe type. Sleep was significantly more impaired in patients with severe AR than in those with the mild type. The duration of AR (intermittent or persistent) had no effect on sleep. The authors concluded: These data underline the close relationship between AR and sleep and highlight the need for clinicians, particularly general practitioners, to be attentive in this respect. See Arch Intern Med 2006 Sep 18;166(16):1744-8. The authors are with Centre du Sommeil et de la Vigilance de l'Hotel Dieu, Assistance Publique Hopitaux de Paris, Paris, France.

### CPAP AND PATIENTS WITH SLEEP APNEA

The European Respiratory Journal reports on the impact of continuous positive airway pressure (CPAP) treatment on the airway responsiveness of asthmatic subjects with obstructive sleep apnea, which has scarcely been studied. Authors Lafond et al performed a prospective study comparing the changes in airway responsiveness and quality of life, in stable asthmatic sleep apnea patients, before and 6 weeks after their nocturnal CPAP treatment. Twenty subjects completed the study. With the nocturnal CPAP treatment, the apnea-hypopnea index (AHI) dropped from 48.1+/-23.6.h(-1) to 2.6+/-2.5.h(-1) (p<0.001). There

were no significant changes in airway responsiveness after CPAP treatment compared with baseline. There was no significant change in FEV1 either. However, the asthma quality of life (QOLAs) of the subjects improved from 5.0+/-1.2 at baseline to 5.8+/- 0.9 at the end of the study. Nocturnal CPAP treatment did not alter airway responsiveness or FEV1 in subjects with stable mild-to-moderate asthma and newly-diagnosed obstructive sleep apnoea. However, nocturnal CPAP treatment did improve asthma quality of life. Published in Eur Respir J 2006 Oct 18.

### CEPHALOMETRY

Sleep Breath 2006 presented a study by Julia-Serda et al, Usefulness of cephalometry in sparing polysomnography of patients with suspected obstructive sleep apnea. The aim of the investigation was to evaluate the contribution of cephalometry to a statistical model integrating clinical, physical, and oximetric variables, to reduce demands for polysomnographies. Two hundred and twenty-five consecutive patients that had been referred to a sleep clinic for suspected obstructive sleep apnea (OSA) were studied. The clinical assessment of all patients consisted of a sleep related questionnaire, the Epworth sleepiness scale, and a physical examination. In addition, they all underwent spirometry, cephalometry, and a full polysomnography. The clinical variables related with OSA were questions concerning witnessing of apneas by bed partners, intensity of snoring, a history of hypertension, and nocturia. A significant relation was also found with score on the Epworth scale, sex, age, body mass index, neck and waist circumferences, total number and frequency of oxygen desaturations, and the lowest oxygen saturation value. Significant cephalometric measurements were: the linear distance from gonion to gnathion, from the hyoid bone to the mandibular plane, and from the posterior nasal spine to the tip of the soft palate, and the thickness of the uvula as well. A statistical model was built to estimate a patient's probability of having OSA based on clinical variables, physical examination, pulse oximetry, and cephalometry. The validation of this model demonstrated a remarkable ability in reducing the number of polysomnographic studies. We conclude that cephalometry combined with clinical variables, physical examination, and nocturnal oximetry is useful in the diagnosis of OSA and enables the sparing of a considerable number of polysomnographies. The paper was presented in Sleep Breath. 2006 Dec;10(4):181-7, a Springer publication. The authors are with Department of Pulmonary Medicine, Dr. Negrin Hospital, Las Palmas de Gran Canaria University, Las Palmas de Gran Canaria, Spain.

### ZOLPIDEM'S EFFECT ON CPAP

The journal Sleep recently published the paper, Effect of zolpidem on the efficacy of continuous positive airway pressure as treatment for obstructive sleep apnea. Authors Berry and Patel sought to assess the effect of the hypnotic zolpidem on the efficacy of nasal continuous positive airway pressure for treatment of Obstructive Sleep Apnea. The randomized double blind placebo controlled, cross-over study involved 16 patients with severe obstructive sleep apnea on CPAP therapy for at least 6 months. Three sleep studies were performed over three consecutive weeks. On night one the pressure level required to prevent apnea, hypopnea, and snoring was determined. On the second and third study nights, either placebo (P) or 10 mg of zolpidem (Z) was given (random order) and subjects slept on the CPAP level determined on the first night. Measurements were made for sleep architecture, apnea + hypopnea index, and

arterial oxygen saturation. The sleep architecture was similar on the placebo and zolpidem nights except for a decrease in the sleep latency and a small decrease in the arousal index on zolpidem nights. There was no significant difference between placebo and zolpidem nights in the apnea + hypopnea index, oxygen desaturation index, or the lowest SaO<sub>2</sub>. The authors concluded that acute administration of zolpidem 10 mg does not impair the efficacy of an effective level of CPAP in patients with severe obstructive sleep apnea. See *Sleep* 2006 Aug 1;29(8):1052-6. The authors are with Malcom Randall Veterans Administration Medical Center, Gainesville, FL.

## PRODUCTS

### THROAT-CLEARING

Dr Barry Kimberley of Somnograph (dba Neosom Clinics) discovered the cause of laryngeal damage to a 46-year-old woman with Restech's Dx-pH Measurement System and put to rest months of inconclusive testing and uncertainty. Three physicians treated the patient prior to Dr. Kimberley without eliciting sufficient evidence to make a diagnosis. The patient underwent standard testing for the symptoms presented: a conventional ambulatory impedance-pH test yielded unremarkable results; the Johnson-DeMeester esophageal reflux score was normal; and a vocal cord stripping produced benign results. Dr Kimberley administered the recently released Restech test and uncovered acute acid reflux above the esophagus. The Dx-pH Probe recorded extremely low pH (acid) events in the laryngopharyngeal region, which is believed to be far more sensitive and susceptible to reflux related injuries than is the esophagus. Conventional pH sensors do not function properly in the non-liquid environment of the upper airway and generally do not detect such pH drops. LPR has also caused a controversy between the Gastroenterology (GI) and Otolaryngology (ENT) fields. "Patients presenting these symptoms are very common. However, until the Restech System became available, patients slipped through the cracks of the GI-ENT relationship due to an unclear jurisdiction of symptoms," said Dr. Kimberley. Somnograph, a national leader in sleep disorders diagnosis and treatment, was an early adopter of the Restech System, which is now creating a buzz in the GI, ENT, and sleep medicine communities. "With the rise of research and published work relating acid reflux to sleep apnea, asthma and other respiratory diseases, we are confident that this is the only device that can reliably highlight these relationships," said Duke Naipohn, CEO, Somnograph. Contact [restech-corp.com](http://restech-corp.com).

### VERY CLEVER

CleveMed, Cleveland Medical Devices Inc, announced that it has been awarded \$2.3 million in NIH SBIR Phase II Continuation funding from the National Institute of Neurological Disorders and Stroke (NINDS). The grant will fund clinical inpatient evaluation of sleep disordered breathing (SDB) in cardiac patients preoperatively. In addition to completing development of a compact, telemetry-based PSG system better suited for sleep evaluation in that specific application, the grant will fund a large clinical trial that will be conducted at the Cleveland Clinic Foundation with Dr Nancy Foldvary-Schaefer and Dr Roop Kaw, a member of Respiratory Therapy's editorial advisory board. The trial will also be conducted at Johns Hopkins University with Dr Nancy Collop. Clinical superiority over currently used screening tools and SDB prevalence and

morbidity rates in the cardiovascular surgery population will be determined. "There is an urgent need to improve the diagnosis of sleep disordered breathing in surgical patients in order to avoid complications intraoperatively and postoperatively," said Dr Collop. Dr Foldvary said, "Preliminary data suggest that patients with sleep apnea may be at increased risk for postoperative complications with a greater need for intensive monitoring." CleveMed's Crystal Monitor PSG line of products was designed to make it easier for physicians to diagnose sleep disorders by making it possible to perform sleep studies not just in the traditional sleep labs, but also in a variety of non-traditional settings.

### ALL IN ONE

Nova Biomedical announced the incorporation of total bilirubin (tBil) to the comprehensive test menu on its Stat Profile Critical Care Xpress (CCX) "All-in-One" Analyzer. Bilirubin is an important indicator of liver function particularly in neonatal applications. With the addition of total bilirubin, the CCX analyzer now offers 20 measured tests, including pH, PCO<sub>2</sub>, PO<sub>2</sub>, SO<sub>2</sub>%, hematocrit and hemoglobin, sodium, potassium, chloride, ionized calcium, ionized magnesium, glucose, BUN, creatinine, lactate, deoxyhemoglobin, oxyhemoglobin, methemoglobin, and carboxyhemoglobin, in a single, compact instrument. While incorporating more on-board tests than any competitive analyzer, the Critical Care Xpress is 20 to 40% smaller and easily transported on its mobile cart. Key CCX features include a color touch screen interface for intuitive, on-screen prompted operation; a single, snap-in reagent pack that eliminates bulky gas tanks, regulators and humidifiers, and the waste containers needed in other analyzers; a fully automated, on-board Auto-Cartridge QC system that eliminates the manual quality control, dramatically reducing labor time and costs; and a unique automated maintenance system that allows the operator to initiate maintenance and then walk away from the analyzer. Contact [novabio.com](http://novabio.com).

### EXEC-CELLENCE

Viasys Healthcare Inc announced today several executive appointments including the naming of Ed Pulwer as Executive Vice President, Chief Operating Officer. Additional appointments included Greg Martin to Group President, Viasys International Operations and Arie Cohen as Group President, Viasys Respiratory Care. Randy Thurman, Chairman, President and Chief Executive Officer, said, "We are celebrating our fifth anniversary as a public company this year. During these five years, we have achieved significant and consistent growth throughout our organization. These achievements are the result of the leadership and commitment that has been the foundation of the Viasys success. Today's promotions recognize the outstanding professionals that have made Viasys what it is today. In just five years, we have experienced significant revenue growth across the entire spectrum of our business, and we are now the market leader in several of our product categories. With a best in class management team, we look forward to continued achievement across our businesses." Viasys also announced that Rebecca W. Rimel, President and CEO of The Pew Charitable Trusts has joined the Board of Directors of Viasys Healthcare Inc. She became President and CEO of the Trust in 1994. Contact [viasys.com](http://viasys.com).

### UPWARD SPIRAL

Viasys Respiratory Care Inc received approval to market its PulmoLife spirometry screener by the United States Food and



Drug Administration. The PulmoLife screener is a new device designed for quick and easy assessment of lung disease associated with airflow obstruction known as Chronic Obstructive Pulmonary Disease (COPD). According to the Center for Disease Control, COPD is currently the fourth leading cause of death in the US and is projected to be the third leading cause of death by the year 2020. There are an estimated 16 million people in the United States diagnosed with COPD and an additional 14 million undiagnosed. Smokers are at greater risk of developing COPD, but breathing in other kinds of lung irritants, like pollution, dust, or chemicals, over a long period of time may also cause or contribute to COPD. The PulmoLife device uses spirometry to measure lung function. According to the National Institutes of Health, "Spirometry is the most sensitive and commonly used test of lung functions. It can detect COPD long before you have significant symptoms." Early detection of decreased lung function by the PulmoLife device may help a smoker realize the damage smoking can cause and encourage them to seek smoking cessation advice as well as appropriate medical treatment. In other Viasys news, at the American College of Cardiology Tradeshow in New Orleans, Louisiana, VIASYS Healthcare will showcase the launch of the MasterScreen CPX, a product that combines 40 years of CPET experience into a compact unit. Careful note of clinician's requirements have been taken into consideration to create a small and partially mobile system that offers a full spectrum of cardiopulmonary measurements. MasterScreen CPX allows you to run a complete exercise test including stress ECG (option) quickly and easily. The patented digital Triple-V-Volume Sensor complies with ATS criteria, performs without drift and is completely insensitive to moisture. Contact [viasys.com](http://viasys.com).

### **FIFTH TIME'S THE CHARM**

Viasys Respiratory Care, a subsidiary of Viasys Healthcare Inc has again won the American Association for Respiratory Care (AARC) Zenith Award. It's the fifth time the company has won the award, which is the industry's top recognition award for respiratory care product and service providers, and was presented at AARC's 52nd Annual International Respiratory Congress in Las Vegas. "We are extremely honored to be recognized by the AARC with the Zenith Award for the fifth time," stated Randy Thurman, Chairman, President and Chief Executive Officer of Viasys Healthcare Inc. During the awards ceremony Thurman pledged the company's continued support for the AARC and the dedicated respiratory therapists throughout the world. The AARC established the Zenith Award program in 1989 to honor respiratory care product and service providers for exemplary service. All 35,000-plus members of the AARC choose the Zenith recipients in a special election. Candidates are judged on the quality of delivered goods, the accessibility and clinical helpfulness of the sales force, the responsiveness and service record of the service group, and the overall support provided by the company to respiratory care professionals. Contact [viasys.com](http://viasys.com).

### **TAKING THE PULSE**

Nonin Medical, Inc announced that it has entered into an agreement with MedAssets Supply Chain Systems, a leading US healthcare group purchasing organization (GPO), to make its comprehensive line of pulse oximeters and sensors, including the only wireless oximeter based on Bluetooth technology, available to MedAssets customers. Under the multi-year agreement with Nonin, MedAssets customers, numbering more than 1,500 acute care hospitals and 25,000 alternate-site

facilities nationwide, will have access to these pulse oximeters and sensors. Minneapolis-based Nonin Medical, Inc designs, manufactures and distributes a broad spectrum of physiological monitoring devices, currently used by health and medical professionals in more than 125 countries. The company draws upon its industry-leading capabilities in signal processing and sensor design to develop innovative pulse oximeters, sensors, accessories and software with features not available in competing products. MedAssets partners with healthcare providers to improve operating margins and cash flow while supporting quality of care goals. MedAssets implements integrated solutions to address the greatest opportunities for financial and process improvement and drives performance in revenue cycle, supply chain and clinical service line management. MedAssets is a business partner to more than 2,400 hospitals and 25,000 non-acute care healthcare providers. For more information, go to [medassets.com](http://medassets.com).

### **NIGHTY NIGHT**

Contour Living, a leader in the ergonomic support and comfort industry, announced today the introduction of the CPAP Sleep Aid, specifically designed for sleep apnea sufferers who use CPAP masks to address their condition. The CPAP Sleep Aid's patented design features hollowed-out areas on each of the pillow's lower sides, which accommodate patients' CPAP mask and hose, alleviating mask pressure against the face to dramatically improve comfort and help prevent mask leaks. These pressure-free mask zones allow CPAP patients to sleep on either their left or right side, and even on their stomachs. In addition to the pressure-free mask zones, the sleep aid has five additional design features specifically created for CPAP mask use. From ergonomically designed neck, head and shoulder support, to specifically molded spots for users' ears when sleeping on their sides, to inclined upper sides for forehead support to prevent rotating downward and crushing the mask and hose, the CPAP Sleep Aid addresses several key problems that interfere with CPAP patient compliance. It is designed to work with all major brands and styles of CPAP masks. Contact [contourliving.com](http://contourliving.com).

### **INSPIRATIONAL**

nSpire Health, LLC, a healthcare company dedicated to creating technical innovations that advance the care and quality of life for people with respiratory illness, announced the acquisition of Ferraris Respiratory, a Division of Ferraris Group, PLC. In addition, the company named Michael S. Sims as President and CEO. Sims is an experienced medical device executive with a proven track record in the health care marketplace, most recently as Group President of Ferraris Respiratory. The company reports that its growth rate is outpacing the market in each of its core product lines and business fundamentals continue improving. Additionally, it is developing unique technologies to address unmet needs in the rapidly growing multi-billion-dollar disease management market. Our patented technologies and proprietary know-how offer respiratory caregivers access to pre-symptomatic diagnostic data. These data permit advanced treatments options for patients with respiratory illnesses such as asthma and COPD, dramatically enhancing the precision of care and quality of life of respiratory patients. nSpire Health will maintain the former Ferraris Respiratory Business units, products and employees, including Ferraris Respiratory Europe, Ltd in the United Kingdom, ZAN Messgerate, GmbH in Germany and Ferraris Respiratory Inc, in the USA. All companies will rapidly assume the nSpire Health brand. Contact [nspirehealth.com](http://nspirehealth.com).

## MANAGEMENT

Tyco International Ltd announced the executive team that will lead Tyco Healthcare as it becomes a separate, independently traded company. Richard J. Meelia continues as the head of the team. Jose (Joe) Almeida, president of the medical devices business, is responsible for managing the advanced medical, respiratory, surgical and Valleylab global business units. James C. Clemmer, president of the medical supplies business, is responsible for day-to-day operations of the Ludlow, Curity and OEM business units, and for directing new product development and ongoing operations. Douglas E. Strohmeier, president of Tyco Healthcare's retail business, is responsible for managing the development, manufacturing and marketing of a wide variety of retail brand, private label products for retail markets in the US, Canada and Mexico. Tyco Healthcare includes Mallinckrodt, Nellcor, Puritan Bennett, and other units. Contact [tycohealthcare.com](http://tycohealthcare.com).

## A WINNER

Restech has been awarded the 2007 Frost & Sullivan Product Innovation of the Year Award in the field of Respiratory Devices. The Frost & Sullivan Award for Product Innovation of the Year is presented each year to the company that has demonstrated excellence in new products and technologies within their industry. The recipient company has shown innovation by launching a broad line of emerging products and technologies. The award goes to Restech for its development of the Dx-pH Measurement System. The system provides real-time detection of laryngopharyngeal reflux (LPR), by measuring and recording pH in the oropharynx or upper airway as opposed to traditional pH catheters that measure liquid reflux in the esophagus. By monitoring aerosolized pH events in the airway, the system is the first of its kind to measure and record pH of breath in real time, while facilitating greater patient comfort. Contact [restech.com](http://restech.com).

## ON VIEW

The Michigan Instruments' TTL and PneuView Systems provide a precise simulation of the patient by creating a realistic load to the ventilator or other respiratory care devices under evaluation. The systems are ideal for ensuring accurate calculation of inspired volume and flow rates, along with dozens of other important breath parameters, while accurately accounting for variables such as backpressure, gas temperature parameters and barometric pressure. The TTL and PneuView systems measure and rely upon such factors to directly calculate the volume of gas entering each lung. Displays include selectable real-time graphs of all waveform data and breath parameters, flow-volume and pressure-volume loops, numeric displays and charting of trend data. The full array of measured parameters may be organized into tables and annotated by the user for display, saving to files and/or printing in the form of concise reports. All parameters can be trended for up to 72 hours. This data may then be exported in a number of formats for use in reporting or with other applications. The Test Lung directly effects patient care, first in ventilator research and development. Ventilator manufacturers (critical care, anesthesia, transport, home health care), use the equipment for the development of respiratory care devices. Second, colleges and universities use the equipment to simulate real patient conditions as a teaching tool for their students. Third, hospital Bio-Medical Tech use the test lung to check respiratory equipment after it has been in for service to make sure that it is working properly. Overall aging of the population will increase

the demand for respiratory care and the therapeutic equipment use. More sophisticated respiratory care technology is growing throughout the world, particularly in developing countries and economies thus needing a respiratory testing device. Michigan Instruments strives to be on the cutting edge of this respiratory field. We are committed to continuous improvement and training. Michigan Instruments has been the leader of respiratory simulation products for over twenty years. For information or if you have any questions about the Test Lung uses or features, Michigan Instruments can be contacted at (800) 530-9939, or on the web at [michiganinstruments.com](http://michiganinstruments.com).

## GET SMART

Children's Medical Ventures (ChMV), a subsidiary of Respironics, Inc, announced the release of a new patient monitoring system for health care professionals called SmartMonitor 2 Professional Series Light (PS Light). The PS Light is the latest in a series of monitors from ChMV designed to track a patient's cardiorespiratory activity. SmartMonitor 2 PS Light is specifically intended for hospital use to measure and record a patient's pulse and respiration, and sounds an alarm if levels fall below defined limits. The "Light" designation refers to the PS Light's ability to provide high-quality, cost-effective heart and respiration monitoring parameters without integrated pulse oximetry. ChMV currently offers the SmartMonitor 2 PS for healthcare settings requiring patient monitoring with integrated pulse oximetry. SmartMonitor 2 PS Light is cleared for use with infant, pediatric, and adult patients making it ideal for documenting patient response to conscious sedation, post-anesthesia recovery, patient controlled analgesia, and general floor monitoring. The PS Light offers many of the same features found in ChMV's other cardiorespiratory monitors including separate digital readouts for pulse and respiratory rates, device and patient alarms, internal modem, lightweight design and battery backup. SmartMonitor 2 PS Light also incorporates universally recognized symbols that help simplify operation while reducing potential language barriers, utilizes Synergy-E Event Software to review patient event data and is compatible with ChMV's SmartRecorder. Contact [childmed.com](http://childmed.com) or [respironics.com](http://respironics.com).

## ON ITS WAY

Discovery Laboratories, Inc announced that it has received guidance from the FDA in a recent meeting regarding the key remaining steps necessary for potential approval of Surfaxin (lucinactant) for the prevention of RDS in premature infants. The guidance provides the clarity and defined pathway that Discovery believes is necessary to address key remaining issues identified by the FDA Approval Letter, followed by a six-month review cycle by the FDA for potential approval of its New Drug Application for Surfaxin. Surfaxin is a precision-engineered, peptide-containing, synthetic surfactant that is designed to closely mimic the function of natural human lung surfactant and represents a potential alternative to animal-derived surfactants. Contact [discoverylabs.com](http://discoverylabs.com).

## WHAT'S IN A NAME

Tyco Healthcare today announced that Covidien will be its new name once the global healthcare leader separates from parent company Tyco International this spring and becomes an independent, publicly traded company. Tyco Healthcare is a leading global manufacturer and distributor of medical products, with annual sales of nearly \$10 billion. Its product portfolio includes disposable medical supplies, monitoring

equipment, medical instruments and bulk analgesic pharmaceuticals. The Covidien brand will be the master identifier that unites Tyco Healthcare's brand names, including Autosuture, Kendall, Mallinckrodt, Nellcor, Puritan Bennett, Syneture, and Valleylab. Its upcoming separation from Tyco International will introduce a new era for the diversified healthcare products organization, which employs more than 43,000 people worldwide. As Covidien, the newly independent company will embark on a distinct new direction that focuses exclusively on healthcare and benefits from increased flexibility to invest in innovation and organic growth. Covidien is an original name, inspired by themes of collaboration and life. It was selected for its global meaning and appeal from among some 6,000 possible names in a rigorous process that began more than nine months ago.

## **PARTNERSHIP**

Draeger Medical, Inc was recently awarded membership into the American Association for Respiratory Care (AARC) Corporate Partner Program. Draeger Medical has earned elite Corporate Partner status because of its exceptional support of AARC and the respiratory care profession. "Without the level of support and commitment exhibited by Corporate Partners such as Draeger Medical, AARC would not be able to advance its mission to promote optimum respiratory care for patients with lung diseases," said AARC Executive Director Sam Giordano, MBA, RRT, FAARC. As a corporate partner, Draeger Medical provides support to the largest professional association for respiratory therapists and other professionals. Draeger Medical's support is used to provide much needed educational and research efforts aimed at ensuring that respiratory therapists have the information and tools they need to deliver top quality care to patients with asthma, chronic obstructive pulmonary disease, cystic fibrosis, and other respiratory problems. The Corporate Partner Program is comprised of best-in-class organizations interested in supporting the goals and work of the Association. The program aims to give respiratory care providers information, insights, and innovative approaches to improve performance and advance the health of their patients. Contact draeger.com.

## **CRITICAL CLEARANCE**

MAQUET Critical Care announced that they have received FDA 510(k) clearance for its breakthrough NAVA (Neurally Adjusted Ventilatory Assist) technology for optional use with the company's SERVO-i ventilator. The SERVO-i ventilator with NAVA option is intended for treatment and monitoring of all patients, neonatal, pediatric, and adults who require mechanical ventilation. The NAVA technology detects respiratory signals sent from the brain to the diaphragm (in cases where the brain-to-diaphragm electrical signal is intact) and transmits those signals to the SERVO-i ventilator. By enabling the respiratory signals from the patient's brain to control ventilator function, NAVA technology results in unprecedented coordination between diaphragmatic activation and ventilatory support throughout the breathing cycle. To initiate assistance and regulate their level of ventilatory support, conventional mechanical ventilators monitor airway pressure, flow or volume—variables that require greater patient effort with increasing ventilatory dysfunction. By contrast, NAVA senses the electrical activity of the diaphragm and regulates breath delivery from that signal known as Edi. Originating in the brain's respiratory control center, these signals travel through the phrenic nerve to the diaphragm. NAVA uses a series of microelectrodes which are embedded in a specially designed

naso-gastric tube to detect the electrical activity that excites the diaphragm, and this signal is then amplified and transmitted to the SERVO-i ventilator. With ventilator and diaphragm both responding to the same neural signal, NAVA represents a form of monitoring and assisted ventilation in which the patient's respiratory center controls the mechanical support provided throughout each breath. In its 510(k) clearance statement, it is stated that the NAVA option will improve synchrony between the ventilator and patients with no contraindication for insertion/exchange of a naso-gastric tube. The Edi signal is a useful indicator for monitoring weaning as it is also an indicator of the respiratory drive which gives additional clinical information about the patient's respiratory condition. Contact nava.info@maquet-inc.com.

## **EXECUTIVE PROFILES**

### **Alliance Tech Medical, Inc**

**John Snobarger**

John Snobarger is with Alliance Tech Medical, Inc.

Alliance Tech Medical, Inc is an international distribution, manufacturing and sales organization dedicated to the healthcare industry. We operate four regional offices in the United States. We have a growing network of representatives in the US, as well as expanded networks in Canada and Mexico. Our one point of domestic distribution is located in Rockdale, TX. ATM's purpose is to manufacture products and establish distribution agreements for North America with companies who have built a strategy of outsourcing their sales management and marketing efforts in the US, Canadian and Latin American markets. Our unique position is our expanded geographical management coverage as one Alliance Tech Medical, Inc entity. An additional aspect of our market presence is our manufacturer's sales organization capabilities. Our direct sales capabilities give the manufacturer nationwide promotional coverage under one Alliance Tech Medical, Inc, banner. ATM is currently working with Clement Clarke International as their exclusive North American master distributor for their highly reputable line of respiratory products which include; Mini-Wright and Airzone PFM, In-Check and In-Check DIAL inspiratory training and monitoring instruments, One Flow Spirometers and the piCO CO monitoring device. These products along with the All Flow Spirometer and All Flow filters from ATM, our valved holding chamber and disposable accessories provide us with a range of respiratory and affiliated products for the markets we serve. Please see our web site for a complete listing of our products.

#### **Describe your products and their unique features.**

Alliance Tech Medical products are used for diagnosis and measurement of patient's respiratory conditions, ie asthma, COPD, bronchitis, etc. We manufacture and distribute products that are accurate, high quality, easy to use and cost effective to the end user, physicians, hospitals, and the patient. Alliance Tech Medical distributes the MiniWright Standard and Low Range Peak flow meters, which are the Gold Standard for Peak Flows. The New MiniWright Digital has the MiniWright quality, with the added benefit of being water proof for easy cleaning

and disinfecting, and it is very durable. Our other Inspiratory flow meters are unique in the market as are our Pulmonary Function Filters with their two color set up and small mouth adapter for patients. Our spirometer meets and exceeds all ATS standards while being lite weight and portable. Our entire product line fits our corporate goal of quality products at cost effective prices keeping health care costs down enabling better disease management for the respiratory patient.

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

Each of our products is designed to provide accurate data to the end user so that they can make the proper decision on the treatment needed to maintain a good quality of life. The diagnostic equipment is easy to use and therefore does not intimidate patients for testing. Our filters are color coded for ease of use by clinicians as well as making them fun for patients during testing. The new product, MiniWright Digital enables patients to obtain two values so they may manage their respiratory condition even better. Our other products teach proper use of medication delivery, that assists in reducing side affects, along with the potential to reduce visits to physicians and the Emergency Room due to not using proper inspiratory technique. This improves patient compliance with medication prescribed improving the management of the disease the products were prescribed for. Our products work in co-operation with the drug manufacture's specifications to teach the patient proper technique. Our goal is to provide easy to use cost effective products to the market so that patients will use the products recommended or prescribed to them.

#### **Tell us about the latest advances in the area of your products.**

We continue to bring to market products that are easy to use while providing information to the end user to improve their disease management. For the clinician this is high tech easy to use equipment. Our MiniWright Digital is a one button easy to use instrument for the clinician as well as the patient. Our filters make it easy to attach to the equipment with the two tone system. Our spirometer line meets all ATS standards and is easy to use with any window based computer. Our inspiratory flow meters are unique and provide tools to improve management of the respiratory disease by the clinician and the patient.

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

The products we offer are individually calibrated providing improved accuracy and reproducibility. This applies to all the peak flow meter models, the inspiratory flow meters and our digital unit. Our other products have features that improve ease of use for the clinician and the patient, comfort for the patient and are cost effective.

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

We listen to the clinicians that use our products for improvements, as well as potential new products. We have the ability to react to market conditions in short order so that we can have the products that are needed by the end-user. With our medical advisors we are able to have products tested in the settings that they are targeted for in order to evaluate them. We can take feedback and make any corrections and move forward in a prompt and efficient manner based on the FDA guidelines.

#### **Discuss the Educational services you offer for use of the products.**

We offer educational CD's for several of our products, along

with training information on our web site. We support our products with brochures, user manuals, and in-services for the professionals. Our customer service is available daily to further answer questions. We continue to use educational materials and our Web site to support the products.

#### **Discuss the role of the clinician in developing and upgrading the products.**

The clinician and the patient are very important to our development programs. We listen to each group for their feedback and incorporate updates and improvements as we develop new models etc.

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

The ability to have devices that are digital is one area of growth. Digital technology that is low cost and accurate will improve the ability of the clinician and patient to manage their respiratory disease. The second area is to have a form of wireless communication that integrates data transmission with multiple software systems so that there is one area of data sources. The wireless technology will be of a nature that does not cause interference with other electronic units in an office, hospital or the patient's home.

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

Our products are distributed world-wide. We have to keep them competitive in cost so that they continue to be used in the market place. We have to currently follow world markets for the product area along with regulations so that we can remain competitive.

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

Conferences, seminars, and medical meetings are important for exposure to numbers of clinicians that the products are designed for. They are one avenue to expose and educate medical professionals to the products and their features and benefits. Meetings etc are also used to gather feedback from the clinicians along with seeing what the other manufacturers are doing with products and services in the market for respiratory disease management.

## **Hi-Tech Medical**

William Mack

William Mack is General Manager, Hi-Tech Medical

#### **Describe your products and their unique features.**

Hi-Tech Medical manufactures a variety of tubes and hoses for the respiratory market. A visit to our website at [hitechmedical.net](http://hitechmedical.net) is worth the investment in time by anyone in need of such products. All Hi-Tech Medical products feature smooth interior constructions allowing for extremely efficient flow characteristics. In addition, product constructions provide excellent crush resistance and bend characteristics. Products will not "kink" even in tight bend radius situations. All products are manufactured from 100% "virgin" FDA compliant materials in our clean room environment by trained technicians. Complete product traceability from raw materials through finished products on every item manufactured. Use of state-of-

the art technology and the newest raw materials available allow for customized product designs in addition to our current standard product offering. We offer both disposable tubes and tubes which can be sterilized suitable for any hospital care or home care Respiratory application.

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

Being light weight, durable, and flexible the product line offers improved patient therapy compliance for CPAP and other respiratory circuit applications. Excellent flow characteristics ensure efficient delivery while maintaining minimal noise. Crush resistant product properties reduce the possibility of flow restriction.

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

In the area of CPAP devices there is a growing awareness of Sleep Apnea and its link to other disorders such as Hypertension, Obesity, and Cardio-vascular disorders. In addition, there is a growing understanding of potential problems in neo-natal and pediatric patients as well as the adult population. All of this is resulting in smaller CPAP devices designed for maximum patient comfort resulting in improved patient therapy compliance. In the area of respiratory circuits likewise there is a growing appreciation of the fact that a better tube construction improves noise reduction while improving the efficiency of delivered stream flow.

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

We have designed products that are able to be sterilized without loss of clarity or color when exposed to gamma radiation. Only Hi-Tech Medical offers a tube that can be sterilized by autoclave technology that incorporates an injection molded end finish. This technology eliminates the traditional glued on Silicone end finish normally found on other similar products. Injection molded end finishes eliminate the offensive odor normally characteristic of the adhesives used to attach the Silicone parts and eliminates the possibility of leaks at the hose/ end finish interface due to human error when applying the adhesive and this technology provides for a much lower product cost. In fact Hi-Tech Medical's style 888 hose can in many cases be used in place of much more expensive Silicone tubes while significantly lowering the weight of the circuit. Finally, there is the peace of mind that comes from knowing that the products we offer are manufactured to the highest quality standards within our clean room, with complete traceability and documentation.

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

Hi-Tech Medical invests heavily in its R&D program, which over our ten year history has allowed the introduction of a steady flow of new products. That effort continues today. Our R&D efforts are the direct result of customer and market input. The key for us is we listen and develop solutions to marketplace problems, which is why our company slogan is "health solutions for life." We have a very strong commitment to design and development.

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

Normally at Hi-Tech Medical we do not like to jump the gun on new products but we do have a new tube under development that could provide a revolutionary ability to be extremely flexible and able to retain its shape even after being totally collapsed. We are also working on new technology to eliminate any interior product moisture condensation in a way not available today.

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

Our trained Sales staff is fully prepared to educate customers about any of our products as well as assist in the selection of the proper product for any respiratory care application. If we can not solve an issue we can and will refer a source that can. Being a part of the Smiths family of companies we have access to a vast array of companies and resources on a global basis.

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

We constantly solicit information and input from providers regarding applications and products at trade shows, meetings, sales calls and also through our Distributor and OEM contacts.

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

Hi-Tech Medical is a global enterprise. Even in today's highly competitive manufacturing market we remain competitive through cutting edge technology, state-of-the-art materials and by maintaining a global sales force. In addition to servicing customers in North and South America we also provide products to Europe and Asia. The global nature of our business allows us to gain market knowledge and input on an International basis.

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

We regularly participate in some of the best known conferences and trade shows. Hi-Tech Medical can be visited at the American Association for Respiratory Care Conference (AARC),

  
**HI-TECH MEDICAL™**  
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**An Industry first!  
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or visit us at [www.hitechmedical.net](http://www.hitechmedical.net)

\*Product is made with either Hytrel™ or equivalent material.

Medtrade Spring and Medtrade Fall, the Medica Exposition in Germany, and FOCUS. We participate in these opportunities on an annual basis.

## Mediserve Information Systems

Nahal Dousti

Nahal Dousti is Manager of Marketing Communications, MediServe Information Systems.

### Describe your product and its unique features.

MediLinks has proven itself scalable in numerous multi-facility health system implementations. MediServe does not place a limit on the number of concurrent users. Microsoft's SQL Server relational database has proven scalable throughout these installations. MediServe took a step in 2005 to provide an additional OLAP reporting product (ReportLink, requiring a separate MS SQL database) so that performance of the production system (OLTP) would not be affected by complex reporting queries. This will permit the best of real-time operational and retrospective reporting regardless of installation size, and preserves a high-quality user experience. MediLinks provides industry leading configurability and configuration tools allowing client and end-user configurability. This permits the client to incorporate template, flowsheet, and "branching logic" (question & answer) documentation as needed in their environment. No two MediServe clients are the same in this respect. MediLinks utilizes HL7 interfacing for providing

connectivity with existing HIS solutions and has hundreds of live interfaces with all major HIS vendors. MediServe does not permit clients to build separate applications *per se* (actually source code changes), but all client configurations can be brought forward through application upgrades.

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

MediLinks is MediServe's integrated point-of-care application suite that supports clinical information activities and tasks of the department including: charting/documentation, charge capture and revenue enhancement, automated protocols, outcomes measurement, automated financial reporting, order tracking and processing, and quality assurance management as well as supporting compliance with the Medicare Quality Initiatives, IHI 100,000 lives campaign and JCAHO requirements. MediLinks is powered by Microsoft's SQL Server relational database and supports applicable HIPAA and CMS standards.

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

MediServe differentiates itself from the market in several respects. First, the product workflow truly matches that of its user clinicians unlike competing enterprise systems, and the company possesses unmatched clinical expertise in the departments it serves, resulting in the MediLinks product being a true "clinician's choice" in several respects. Second, MediServe provides a significant increase in clinical and business efficiency of the department which can be documented. Such benefits enables MediServe to effectively compete against large hospital information system vendors because the HIS cannot show a comparable level of documented Return on Investment (ROI).

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

MediServe Information Systems hosts and participates in many industry events throughout the year. In addition to attending conferences such as the Healthcare Information Management Systems Society (HIMSS) and the American Association for Respiratory Care (AARC), MediServe hosts Regional Clinical Information Seminars. MediServe's Regional Clinical Information Seminars give attendees the opportunity to join us at a local venue and listen to leaders in their industry discuss topics such as protocols and automation while earning AARC CUL and networking with their peers. MediServe's largest event is an annual User Group Conference where clients from all across the country come together to compare best practices, attend classes, earn continuing education credits, and participate in networking activities. Registration information and details for each event are available on our home page, [mediserve.com](http://mediserve.com).



Find out how MediServe's MediLinks product provides the most effective and comprehensive benefits to Respiratory Care through:

- Interoperability
- Rapid Implementation
- Feature & Benefit Focused Pricing
- Clinical & Operational Efficiency

See how your peers are increasing productivity and revenue at [www.mediserve.com/results](http://www.mediserve.com/results)

## Genstar Technologies Co, Inc

Irving Quam

Irving Quam is National Sales Manager, Medical Gas Products, Genstar Technologies Co, Inc.

### Describe your products and their unique features.

Genstar Technologies started in 1965 as a manufacturer of industrial gas flow control equipment. Since that time, we have

grown to become a global leader in the manufacture of gas flow control equipment for the construction, metalworking, laboratory, instrumentation, and health care markets. Our commitment to the highest standards of quality and service has fueled this growth, and continues to be the catalyst for our product development and distribution systems.

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

Many of the products we manufacture are not physically attached to the patient, but they control the gases and vacuum which make patient care possible. As such, quality is of paramount importance. All medical gases and distribution systems are life safety products, and we carry this commitment to quality throughout our entire company.

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

Our R&D division, located in Taipei, Taiwan, has recently developed a new software system for monitoring and controlling medical gas systems. Further, we are in the process of developing a non-invasive patient monitoring system that will accurately monitor a number of parameters, reducing the number of devices that a patient must be connected to.

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

Quality has always been our measurement of success. Additionally, we carry most parts in inventory at all times, and can ship most orders within 48 hours of receipt.

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

Our R&D department is lead by four PhDs, each with multiple disciplines. They complement each other's strengths and weaknesses, and are very enthusiastic about their projects. Each is a stockholder, so they understand that their future is literally in their hands.

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

Complete the equipment monitoring and control system and the patient monitoring systems.

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

In addition to in-service training, we offer regular classes to all of our distributors. We encourage all employees to attend these training sessions, so that each has a greater knowledge of the products we build.

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

We listen to our end users and make adjustments accordingly. With over 50 engineers on staff, we can rapidly assess any suggestions and implement those that have a real benefit. These engineers also enable us to bring new and improved products to market very quickly.

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

All of our products undergo thorough life-cycle testing prior to releasing to production, and we pull random samples from the production lines to test for compliance to our established controls and procedures. Each product is tested at various stages of assembly. We also monitor our warranty claims, looking for patterns that may indicate a problem that may have been missed by random inspections.

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

Worldwide access to the internet; and technological advances for our patient monitoring system.

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

Genstar Technologies has always been a global organization. Our multi-national management team is able to develop and market products for many international requirements.

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

Genstar Technologies exhibited at over 150 trade shows worldwide in 2006, covering a wide variety of distribution channels. In 2007 we will scale back slightly, but will still be at over 100 shows. We use these events to speak with industry professionals regarding current standards and cutting edge developments, and to seek additional distribution opportunities.

## Sunrise Medical, Inc

**Doug Hudiburg**

Doug Hudiburg is Acting Director, Respiratory Marketing, Sunrise Medical, Inc. DeVilbiss is a division of Sunrise Medical, Inc.

**Describe your product and its unique features.**

We have a strong respiratory product offering in aerosol, suction, sleep, and oxygen but one of the products your readers might be most interested in hearing about is our new iFill Personal Oxygen station. iFill is a transfilling device that enables patients to easily fill their own portable cylinders at home.

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

iFill is all about freedom, ease of use, and flexibility for patients. Being in control of their own ambulatory oxygen supply helps make patients feel more empowered and in control. The net result is that it is easier for patients to maintain a healthy level of activity and go about their daily activities.

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

The technology behind iFill has significant patient advantages, but it is also beneficial to the overall system of providing ambulatory oxygen. Home Health Care Providers, for instance, are able to maintain a high level of patient care and service without all of the costs associated with delivering cylinders to the patient's house on a monthly or bi-monthly basis. Any advances in Oxygen, both now and in the future, have to be more than just technology – the need to address the changing reimbursement climate as well.

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

iFill is truly unique. It is a stand-alone unit that is very easy for patients to understand and operate. What that really means is that iFill fits unobtrusively into the patient's home and lifestyle. It can be kept in a laundry room or unused bedroom, which minimizes noise and disruption of daily life. Instead of taking bi-monthly delivery of cylinders and having to store up to 10 cylinders, patients can keep just a couple of cylinders on hand and re-fill as needed.

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

This is one of the things that I am really proud about at DeVilbiss. We are very good at spending a lot of time up-front to understand the needs of the clinical community, HHC Providers, and patients. Our process is built on stages. At every stage we validate our concepts and designs with all three key constituent groups. Sometimes, it takes us a little longer to do it this way, but the end result is that we are able to produce products that work very well for all key stakeholders.

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

We are constantly looking for ways to reduce time-to-market for new products – to be more responsive in this dynamic environment. Also, of course, we seek to reduce cost where we can while still maintaining the quality and patient care DeVilbiss is known for.

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

I'm glad you asked, because I believe that education is one of the reasons for our success. We conduct local courses and many via tele-seminar and webinar. Most, if not all, of our courses provide CEUs. You can find out more by visiting [www.DevilbissClinicalEducation.com](http://www.DevilbissClinicalEducation.com).

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

We, of course, do a lot of testing and validation before a product can even be used with patients. But when we get the product to the point that it can be tested in real-world situations, we work closely with our Provider Advisory Board and their clinical referral sources to select the right kinds of patients and monitor their early product usage. In the latter stages of product development, we are really looking to make sure the product performs the way we expect it to based on our laboratory testing, but also to improve things like patient instruction and education materials.

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

Everything is getting smaller and lighter, which really helps us improve our products. For instance, we now have the technology to significantly reduce the size and weight of our standard five LPM concentrator. So, in oxygen, you can expect to see more portability and quieter units in the future. In the sleep market, there is a lot of interesting progress being made on the diagnostic and screening side of the world as well as the smaller and lighter trend. Wireless technology and Internet connectivity are two areas we are heavily engaged in as well.

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

We are a global company and spend a lot of time interfacing with our in-country marketing and clinical resources to make sure we understand the needs of their individual markets and what we must provide in order to meet them. Global markets are much different than what happens here in the US. In order to compete effectively internationally, we really need to keep our ear to the ground and understand what is happening in all of the markets in which we compete.

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

Conferences, for us, are important because they give us the

chance to talk to a lot of people in a very short period of time. We always learn a lot and, of course, we are happy to be able to market our products as well. We like to focus on a few key products and have in-depth conversations about them with current and potential customers.

## Stellate

Dr Jean Gotman

Dr Jean Gotman is President and CEO, Stellate, Sleep Diagnostic Systems.

**Describe your products and their unique features.**

Stellate provides comprehensive solutions in the areas of Sleep Diagnostics, EEG, Epilepsy Monitoring and ICU Monitoring. Our products feature several proprietary data analysis tools based on original research and are designed for exceptional ease of use, simplified workflows and enhanced efficiencies. Our design approach ensures easy upgrading of features and the option of multiple applications (such as Sleep Diagnosis and EEG) on the same platform.

**How do your products directly affect patient care?**

Stellate products include advanced event detection algorithms that significantly enhance diagnostic accuracy, enabling users to promptly capture critical events as they occur and take appropriate action. Powerful and flexible analysis tools provide additional information to resolve difficult diagnostic situations. Components of our systems that directly interface with the patient are designed with a high emphasis on patient comfort and safety.

**Tell us about the latest advances in the area your products serve.**

Guidelines for the diagnosis of sleep disorders from the ASDA and AASM are becoming more definitive, especially in the areas of scoring and reviewing, calling for increasing use of automated analysis tools for event detection. Stellate's extensive work in this area allows our products to fulfill these requirements easily.

**What sets your products apart from others in the field?**

Our comprehensive suite of recording & analysis tools in conjunction with our extremely flexible, rugged hardware platform & outstanding customer service provide our users with the most effective turnkey solution for polysomnography. In addition our extensive commitment to research & development allows us to bring innovative tools to our users.

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

Stellate's R&D process uses two distinct approaches. Firstly, we actively seek input from our customers through focus groups, periodic surveys and the day-to-day interaction that our sales and customer support teams have with them, to identify what is really important to make their jobs easier. Secondly, we actively collaborate with many hospitals and academic institutions to develop cutting edge analysis techniques that subsequently find their way into our final products. We also run all our new features through a rigorous beta testing process to ensure their ease of use and effectiveness.

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

In the arena of sleep, the clinical use of ideas such as Flow-



Volume and Sleep Microstructure will play an important role in the next several years. Our R&D initiatives will focus on incorporating advanced analysis techniques into everyday tools that will become part of routine clinical usage. We will continue to develop solutions to simplify the assessment of electrophysiological data for fast and accurate patient care in line with emerging networking technologies.

**Discuss the educational services you offer for use of your products.**

We offer comprehensive applications and product training delivered by a highly qualified team of individuals that includes polysomnography and EEG technologists who have strong clinical experience. On-site and web-based training options customized to specific needs are made available to our customers. Our R&D staff offer seminars, presentations and lectures at important forums including major industry conferences to discuss advancements in the area.

**Discuss the role of critical care providers in developing and upgrading your products.**

Stellate actively seeks and uses inputs from clinicians from leading hospitals and clinics during new product development and ongoing product improvement. All new products are put through customer use tests to ensure they fully meet customer requirements and necessary modifications are incorporated before final product release.

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

Advances in communication technology enabling faster remote viewing of data with larger number of channels, faster CPUs leading to speedier data processing and developments in sensor technology enabling incorporation of additional physiological information are some of the major developments that we see as having an impact on sleep diagnostic equipment. The most important developments, however, will come from improved software technology, including analysis algorithms and user interface, which will greatly improve the accuracy and efficiency of sleep clinicians in performing their diagnostic and treatment work.

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

Stellate has an international presence in over 30 countries around the world. We maintain strong relationships with leading clinicians and researchers in these countries and our product development process takes into account unique needs identified by our international customers. Our presence in international markets enables us to be aware of new developments as they arise.

**Tell us how you utilize conferences, seminars and such to promote your products.**

We participate in leading national, international and regional conferences through exhibits and presentations. Product demonstration is actively conducted at such venues. Our products show their real value when the clinician goes through a scoring session and sees the impact of the many features that facilitates their work and allow in-depth analysis.

## Hill-Rom

Joe Raver

Joe Raver is VP and General Manager of Hill-Rom.

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

Our National Sales Trainer heads up training for internal personnel and involves professionals from Reimbursement, Product Management and Customer Service. Clinical Education provides customized and CEU-based training. Airway Clearance Therapy education programs are offered for both physicians and healthcare professionals in both the acute and post-acute setting. Product training for healthcare workers is provided by Account Managers in the acute, long-term care and post-acute settings. Licensed healthcare professionals train patients one-on-one in their homes.

**What types of education do you provide?**

Hill-Rom meets the continuing educational needs of its customers through In-servicing, Regional Airway Clearance Seminars, National Airway Clearance Seminars, Grand Rounds, speakers at state meetings, CEUs and Patient Perspective Talks. In addition, our account managers perform inservicing to ensure that all staff personnel have training and documentation of competency with the device.

**How do you manage "off-hours" assistance for clinical questions?**

Customer service is available 24 hours/day, 7 days/week.

**Do you provide technical service support, and of what nature?**

Our Customer Service and Technical Service Departments are available around the clock to support patients, physicians, and healthcare workers. We provide a variety of support services ranging from a technical service call center to immediate delivery of replacement products.

**What if any formal education programs does your company provide for biomedical training and service?**

Our device is self-calibrating and has internal checks built-in to make sure it is functioning properly. The Vest Airway Clearance System is not serviced in the field. We have a technical team available to help if needed.

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

We are known for our service which begins and ends with the customer, assures responsiveness and resolution, and includes 24 hour accessibility, prompt delivery, assistance through the insurance process, on-site training, and follow-up support.

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

We have over 80 representatives in the field supporting patient and physician needs across the care continuum. The Vest Airway Clearance System is in its 5th generation and has models designed to meet the needs in the acute care, long-term care and home care environments. In addition to promotion through its satisfied users, we are represented in Respiratory journals, tradeshows, on the web, and in printed collateral.

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A HILLENBRAND INDUSTRY

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

The Vest Airway Clearance System will continue its evolution through the use of market research, pulmonary advisory boards, and input from physicians, respiratory therapists, nurses and patients, as well as feedback from clinical national seminars and tradeshow.

### **What mechanisms are in place to assist hospitals in their educational requirements and ongoing education?**

Again, Hill-Rom meets the continuing educational needs of its customers through in-servicing, Regional Airway Clearance Seminars, National Airway Clearance Seminars, Grand Rounds, speakers at state meetings, CEUs and Patient Perspective Talks.

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

Hill-Rom will continue to incorporate clinical and patient feedback that increasingly provides value and enhances quality of life. We recognize the value of airway clearance therapy in general and high frequency chest wall oscillation in particular in enhancing the patient's ability to breathe and quality of life, as well as ensuring that our products exceed the expectations of the clinicians that utilize them.

## **Instrumentation Laboratory**

Ramon E. Benet-Ferran

Ramon E. Benet-Ferran is Vice President, Worldwide Marketing and US Sales and Service, Instrumentation Laboratory.

### **Who is Instrumentation Labs?**

For almost half a century, Instrumentation Laboratory (IL) has set the gold standard in the development, manufacturing, marketing and service of diagnostic instrument for clinical laboratories and point-of-care settings. Singular in our focus, we are the acknowledged world leader in critical care and hemostasis diagnostics. IL's history shines with innovation. In 1959, we were the first to introduce a bloodgas analyzer into routine clinical use; and today, we continue that leadership tradition with the new GEM® Premier 4000, the most comprehensive, flexible and user-friendly analyzer on the market. In between is a long history of industry innovation.

Over the years, IL has brought breakthrough clinical functionalities as well as automation, computerization and system integration into the marketplace and continues to pioneer new technologies. In 1967, we introduced CO-Oximetry testing, followed by chemistry and coagulation centrifugal analysis. In 1984, we debuted the first blood gas analyzer with built-in data management and video display. Introducing new levels of efficiency to the market, several years later IL offered a device with disposable cartridge technology. By 2000, IL touched off a revolution in the industry with its standardized critical care testing platform across all hospital locations.

Complementing this innovation has been an ongoing commitment to meeting the full range of needs of our customers and the patients they serve. Our research and development efforts have always been a high priority and driven by the

demands of the marketplace to make available the functionality and features our purchasers want and need. Similarly, unwavering dedication to product support and service is an integral part of our corporate philosophy.

### **How do you provide technical service and support and of what nature?**

IL has always been committed to providing a strong group of technical service representatives in the field who are highly skilled and dedicated to supporting our customers. We focus heavily on recruiting professionals with clinical experience so that they know firsthand the needs, goals and workplace of our customers. Our representatives are given extensive product training and are taught to cater to the needs of clients and to provide comprehensive education about the use of IL products. Additionally, we offer onsite product-specific training.

Finally, IL has a highly trained technical support staff accessible on the telephone 24/7 to answer all questions relating to applications, quality control and performance of its equipment. Recently, an independent research group found that IL outranked every other major manufacturer of critical care analyzers in a full range of measures of customer satisfaction. The study of U.S. hospitals at the point-of-care found that IL achieved the highest ratings in overall satisfaction as well as product satisfaction, ease of use, accuracy, ease of maintenance and much more.

### **How do you support customer's needs through product development?**

At IL, the customer's needs are a major driver, and customer satisfaction is key. Even more important than our support and training is our commitment to addressing the needs of our product purchasers through the design of our products themselves. As part of this philosophy, we are dedicated to offering the most technically advanced, yet user-friendly analyzers on the market.

Our newest technology has been created with several key goals in mind. In addition to cutting-edge, comprehensive clinical functionality, these goals are ease-of-use, reliable operation and results, automated QC procedures, as well as remote connectivity. In some clinical settings, standardization of results in decentralized testing scenarios also is crucial.

Perhaps the most important of these goals is automated quality control, which we address through our Intelligent Quality Management (iQM) system that brings new efficiency and reliability to the traditional, time-consuming blood gas quality control (QC) process. After all, no one chooses a career in healthcare to spend time with machines. With iQM, IL liberates therapists from traditionally time-consuming tasks. iQM provides a more efficient and accurate alternative to manual QC by automatically and continually checking the IL analyzer to deliver real-time system diagnostics. Time to error detection and correction is just minutes. iQM checks extend beyond analyzer electronics to include sensors and the chemical measurement process, which typically requires manual intervention, even on other advanced analyzers. The process automates all corrective actions, freeing up therapists from labor-intensive manual trouble-shooting, as well as eliminating lengthy equipment training and possible human error that might compromise test results. Also, all regulatory compliance documentation is automated. With this system, routine analyzer maintenance is

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eliminated through the use of a single cartridge that contains everything needed for whole blood testing. Every three weeks, a new cartridge is simply snapped into place and the analyzer is ready to function. A closed system, the PAK maintains the complete integrity of the testing process throughout the cartridge life. Another benefit of iQM is significant cost-savings realized through elimination of staff time spent with QC, which can amount to 48 hours monthly.

Also key to our product line is leveraging digital technologies to deliver advanced connectivity among our products to maximize efficiency and deliver a higher standard of care. A good example is our GEMweb technology and newest GEMweb Plus system for the GEM Premier 4000 analyzer. This unique suite of information management software enables clinicians, wherever located—across the hallway or the globe—to access and control multiple IL analyzers as if they were in the same room. This means that wherever and whenever needed, therapists and other clinicians can access and track test results, reports and current patient status as well as download and process orders and more. They can manage administrative tasks when convenient by remotely validating samples, accessing compliance documents and troubleshooting testing locations. The most advanced technologies in the world mean nothing if busy clinicians cannot take advantage of them. That's why user-friendly, easily accessible technology is one of our goals. Certainly, our advanced automated iQM and cartridge systems go a long way towards accomplishing that goal. But on a more micro-level, all our technology is designed to facilitate easy learning and operation. For example, our hardware controls are designed with clear, concise, intuitive menus and large touch-screen displays. Software screens are similarly intuitive and designed with an understanding of department workflow. Because critical care and hemostasis technology is our core business, we dedicate our full resources to the product category and make reliability a top priority across our entire product line.

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

Again, end-user needs and customer satisfaction drive our product development to a large extent. Our new GEM Premier 4000, ushers critical care analyzer technology into a new era of high performance and ease-of-use and clearly demonstrates our commitment. The GEM Premier 4000 is a state-of-the-art device that is the most complete on the market and is extremely sophisticated, yet simple to use. It standardizes, centralizes and controls patient testing throughout the institution—and beyond. A major benefit of the GEM Premier 4000 is the complete integration of CO-Oximetry testing for truly consolidated measurements with the efficiency of a single sample. This, combined with iQM and GEMweb Plus, adds up to another first in blood-gas monitoring. As technology continues to advance, IL is committed to serving the needs of our customers by staying in the forefront of critical care and hemostasis diagnostics.

## **nSpire Health, Inc**

Larry Murdock

Larry Murdock is Sr Vice President, Marketing, nSpire Health, Inc.

nSpire Health, Inc, formerly Ferraris Respiratory, is a leading provider of respiratory diagnostic products and core lab

services including PiKo®, the world's first personal respiratory home-monitoring device. We continue to develop and provide our Collins Pulmonary Diagnostics, ZAN Measuring Instruments, KoKo Diagnostic Spirometer, Wright Respirometer, and Asthma Management products to healthcare professionals throughout the world.

### **Who is responsible within your company for training and education of staff and customers?**

Jerry Davis, RRT

### **What types of education do you provide?**

The Education and Training department offers a wide variety of educational opportunities to our customers, both external and internal. For our external customers, we offer on-site basic training by our skilled field service personnel or our training specialists, and training classes at our Louisville facility given by our training specialists. The classes cover a wide range of equipment and delivered programs are specific to the type of equipment the end-user owns. Education for protocol specific research personnel is also provided per contract agreements with the Sponsor companies. In addition, continuing education is provided to nSpire personnel to increase their knowledge base and improve customer support.

### **How do you manage off hours assistance for clinical questions?**

Currently, technical sSupport is offered from 6a-6p MST, Monday through Friday for all commercial customers. If a customer calls outside of those hours, the customer has the option of calling back during regular business hours or leaving a message and the call will be returned on the next business day.

### **Do you provide technical service support, and of what nature?**

Yes, we staff our call center with credential, factory trained representatives. The representative can guide the customer through an equipment diagnostic procedure and offer remedial action, often over the telephone or on-line.

### **What formal education programs does your company provide for biomedical training and service?**

Currently, a Biomed Training program is offered to site Biomed personnel, but not to third party biomed services. This program uses a variety of venues to provide thorough training to the site personnel, including time with Depot Repair personnel, and other individuals that have a background in various software and hardware configurations.

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

For Education and Training, we are part of the complete nSpire product experience. From the initial contact with our Sales and Marketing staff, to the FSE that performs the installation to the first subject that they perform testing on, we are part of the nSpire team. After purchasing the new product, the unit is installed and either baseline training is performed by the FSE performing the setup, or, if other arrangements have been made, training by a Training Specialist is performed. Either way, if thorough training is performed, a better understanding of the equipment and software is obtained by the end-user and this will minimize the need for calls into Technical Support and minimize frustration.

**What activities does your company undertake to promote its product?**

Journal advertising, trade shows, direct mail, promotions, internet, and direct sales team.

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

We offer an nSpire Me! section on our website encouraging customers and healthcare professionals to share all their feedback with us. In addition, we release to customers technical bulletins called nSpiring News.

**What mechanisms are in place to assist hospitals in their education requirements and ongoing education?**

We are in the process of upgrading our courses to offer more CEU programs than in the past. Expect a new notice shortly.

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

Well, we always appreciate the feedback from our customers using our products in real-life situations. We have several R&D programs that will offer new applications and make diagnostic testing require less patient cooperation. In addition, several of our diagnostic products are being re-engineered for use in other environments.

## Meridian Healthcare Group

Branden Futch

Branden Futch is Director of Marketing, Meridian Healthcare Group.

**Describe your products.**

Meridian Healthcare Group is one of the largest providers of contract therapy and disease state management in the United States. Meridian has a national network of clinical programs in hospitals, skilled nursing facilities, outpatient clinics, homecare centers, polysomnography laboratories and respiratory pharmacies. Our client base ranges from independent healthcare providers to national public companies.

**Tell us the latest advances in the area your product serves.**

Chronic diseases have become an increasingly important cause of morbidity and mortality in the modern world. Chronic Obstructive Pulmonary Disease is a slowly progressive disease of the airways that is characterized by the loss of lung function. COPD is frequently thought of as a disease of the elderly yet 50% of all COPD patients are under 65 years old. The Centers for Disease Control estimated that COPD resulted in 119,000 deaths, 726,000 hospitalizations and 1.5 million emergency room visits in 2000 alone. COPD mortality increased 42% between 1979 and 1998. COPD is projected to be the third leading cause of death in the United States by 2020, despite reduced cigarette smoking rates. The National Heart, Lung and Blood Institute estimates the economic impact of chronic lung disease in the United States to be in excess of \$32 billion annually. There are over 30 million Americans that currently have pulmonary disease and would benefit from Meridian's programs. However, amazingly less than 15% of the COPD patients have access to pulmonary rehabilitation programs.

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

"The pent up demand creates a unique opportunity for Meridian. There is not a single week that we do not receive a call from a patient questioning why we don't have a clinic in their community," says Branden Futch, Meridian's Vice President of Marketing. Every year, more than 250,000 elderly patients with pulmonary disease are admitted to skilled nursing facilities. With the senior population rapidly rising and an estimated 80 million baby boomers knocking on the door to retirement, that number will soon look very small according to industry sources. Meridian has established a continuum of care that includes respiratory pharmacies, home medical equipment, pulmonary function laboratories, sleep centers, rehabilitation clinics as well as partnering with physicians, hospitals and skilled nursing facilities to provide care to their pulmonary patients. Pulmonary rehabilitation programs have been recommended as an integral part of the health management of patients with chronic obstructive lung disease. Meridian's pulmonary rehabilitation programs have been proven to reduce symptoms of dyspnea and improve exercise capacity and the overall quality of life of our patients.

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

Meridian attends a broad spectrum of tradeshow and seminars ranging from your state Health Care Association shows to your larger American Thoracic Society, Chest and AARC conventions. The smaller state shows are primarily for networking purposes and the larger shows are for development and recruitment.

Since the company's founding in 2001, Meridian has grown to become one of the largest providers of pulmonary medicine in the country. Meridian initially grew exclusively through organic development in physician clinics and skilled nursing facilities. Futch wanted to perfect his delivery model and be assured of the clinical outcomes before expanding nationally. The company must have gotten the recipe correct because the market response has been nothing short of phenomenal.

In June of 2005 Meridian made its first strategic acquisition — Symphony Respiratory Services ("Symphony"). Symphony immediately added critical mass to Meridian's existing network with its hospital and skilled nursing facility contracts. Symphony provided the missing pieces of Meridian's disease state management program with its respiratory pharmacy and home care centers which have now been renamed Golden Care.

Meridian intends to continue to expand its operations through (i) programmatic expansion of existing sites; (ii) organic development of programs in current services areas; (iii) development of additional programs with its corporate clients and (iv) select strategic acquisitions. "This strategy will capitalize on the growing demands for the company's services, the highly fragmented nature of the company's competitors and enable Meridian to leverage its existing client base," according to Futch. The elements for Meridian's Recipe for Success are: · Large Patient Population · Expanding Demand for Services · Proven Clinical Model · Access to Capital, and · Experienced Management Team.

# Expand Your Practice!



Some of the most successful physicians in the country are partnering with Meridian to develop pulmonary rehabilitation programs in their office.

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# OXIMETRY ROUNDTABLE

## Nellcor

Sharon Mahood

Sharon Mahood is with Nellcor.

### How has oximetry changed over the past 5 years?

Advances in sensor and monitor technology mean patients who were difficult to monitor in the past can now reap the safety benefits of pulse oximetry. Previously, conditions such as low peripheral perfusion, low saturation levels, patient motion and fragile skin were problematic, causing inaccurate or interrupted readings and increased nuisance alarms. However, Nellcor's expertise in signal processing algorithms combined with advances in microprocessor power has resulted in more accurate and reliable readings during signal interference. In addition, the unique digital calibration system of our OxiMax pulse oximetry platform enables us to create new types of sensors that solve specific patient care issues. For example, OxiMax Max-Fast and NeoMAX forehead sensors offer better performance in low peripheral perfusion. And our industry-leading LoSat expanded accuracy range in OxiMax adhesive sensors improves assessment of patients at low saturation levels.

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

Nellcor pioneered pulse oximetry in the early 1980s and has continually driven innovations as applications for the technology have expanded. With every product generation, we have introduced new methods to enhance performance in difficult patient conditions. As part of Tyco Healthcare, Nellcor's R&D efforts are well-supported, and numerous projects are in progress. Our product development is always based on feedback from the medical community. We identify real patient care issues and work to solve them, rather than indiscriminately adding "bells and whistles" to our products.

### How has the use of oximetry benefited patients?

Pulse oximetry has helped to dramatically reduce the number of deaths and risk of respiratory failure in critically ill patients. Pulse oximetry is now considered a key vital sign to check for patient assessment, and its use continues to extend into more care areas. To meet diverse clinical needs, Nellcor offers a variety of standalone and handheld monitors—including those with capnography (ETCO<sub>2</sub>) for more comprehensive ventilatory assessment. We also offer two types of remote monitoring systems to improve patient safety outside traditional critical care units where nurse-to-patient ratios are lower but patients are often at risk for respiratory events.

### How has oximetry proven to be cost effective and/or reduced overall costs?

Nellcor's remote monitoring systems make it cost-effective for hospitals to implement continuous SpO<sub>2</sub> and ETCO<sub>2</sub> monitoring on the general care floor. Here, the distance between patient rooms and noise in the unit can make bedside alarms difficult for nurses to hear. Remote monitoring systems augment bedside alarms through a central station display or pagers worn by clinical staff. They can help lower costs by enabling higher-acuity patients to be effectively managed in lower-cost areas of

the hospital, and by helping to reduce bounce back to the ICU that can occur if adverse respiratory events go undetected.

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

Nellcor offers an exceptional level of customer support and training resources that include: Pulse oximetry inservicing and additional guidance on best practices for sensor/monitor use in all clinical settings. Accredited online courses for respiratory care practitioners and nurses offered through our online Center for Clinical Excellence ([nellcor.com/ccexcellence](http://nellcor.com/ccexcellence)). A variety of educational and product training resource materials including case studies, white papers and reference notes, monographs, competency checklists and protocols.

### Describe your customer assistance program.

In addition to a fully staffed customer service department, Nellcor has a toll-free technical service hotline staffed 24/7 by knowledgeable representatives who can readily answer questions about product operation and clinical applications, and aid with troubleshooting. We also have a field team of Customer Support Engineers who perform certain types of service on-site for our hospital customers.

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

Clinician input has always played a key role in Nellcor's product development. The development of our nonadhesive sensors is a prime example of this relationship. The Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) and the National Association of Neonatal Nurses (NANN) issued a neonatal skin care clinical practice guideline that advocates minimizing the use of adhesives. Nellcor responded by working closely with neonatal nurses to develop OxiMax SoftCare nonadhesive sensors, which provide a sterile, single-patient-use alternative to adhesive sensors for patients with fragile skin.

### What hampers the effective use of oximetry?

Pulse oximetry has become very common and simple to use, yet caregivers often fail to properly apply the sensor according to its directions for use. Proper sensor use is critical to oximetry effectiveness. Placing a sensor incorrectly or using it on a site other than the one it was designed for can cause highly inaccurate SpO<sub>2</sub> readings. For example, placing a digit sensor on the forehead often significantly overestimates a patient's saturation level, giving false reassurance. Also, forehead sensors should be placed on the correct area of the forehead to ensure reliable readings. When applying Nellcor forehead sensors, caregivers should use the headband packaged with the sensors. It applies gentle pressure to help prevent venous pooling, a potential source of error in SpO<sub>2</sub> readings. Nellcor has materials available free of charge to support ongoing clinician education related to sensor selection and application.

## Oridion Capnography, Inc

Ron Prybella

Ron Prybella is with Global Marketing, Oridion Capnography, Inc.

### How has oximetry changed over the past 5 years?

Oximetry is a complementary technology to capnography. They monitor systems that are related and influenced by one another,



and used together they can be used to assess the ABC's of a patient. Over the last five years it is becoming clearer that together they form a powerful tool.

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

Oridion sees oximetry continue to develop. It is important for customers to have access to the latest oximetry technologies. We strive to continuously evaluate the latest advances and offer them with capnography technology.

#### **How has oximetry changed the standard of care in the ICU?**

Continuous monitoring of oxygenation has become almost automatic in the ICU. It is also a very convenient assessment of heart rate. Capnography is becoming more common to provide real time assessment of EtCO<sub>2</sub> and respiration rate not only for intubated patients, but also for non-intubated patients as well.

#### **Where do you see your product used most?**

Our Microstream products are available with many ICU monitors today. They are also found in areas of procedural sedation, post-operative pain management, emergency departments and pre-hospital usage. The technology is portable like oximetry and follows wherever it is used.

#### **How has oximetry proven to be cost effective or reduced overall costs?**

Like oximetry, capnography is a monitoring tool and is most effective at early detection of a change in clinical condition so that the healthcare professional can respond quickly. We have found that by evaluating the capnograph, respiratory conditions can be diagnosed early.<sup>1,2</sup> Also capnography can be used after extubation to provide continuous monitoring during this transition period.

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

Oridion provides a full complement of training and education opportunities. We provide on-site training and our web-based education is very popular. We also sponsor education forums throughout the country and at professional conferences.

#### **Describe your customer assistance program, and your relationship with end-users.**

Oridion is able to support customers on many levels. Our excellent distributor network is trained and prepared to support customers locally. They are augmented by clinical support people who are located regionally throughout the US and around the world. We feel a very strong relationship with our end user. They learn the benefits of capnography and really appreciate the value of this tool.

#### **What hampers the effective use of oximetry, and where do you see oximetry in the future?**

Like oximetry the biggest hurdle in benefiting from capnography is just using it. Capnography in the past was very complicated, time consuming, and not reliable. Technology today has greatly improved, reducing the sampling volumes to improve accuracy and not needing to calibrate before use. It is small and portable and results are now as quick and simple as oximetry. The principle hurdle is use itself. We see both technologies to continue to develop and improve. There may be applications that combine the technologies and provide more information to the clinician.

1 Hospodar, GJ. Conscious Sedation—Are we asleep at the wheel? *The Journal for Respiratory Care Practitioners*. February/March 2001.

2 Krauss B, Carroll P. Procedural sedation and analgesia: an evolving role for RCPs. *RT Magazine*. June/July 2000;13:31-35.

## **Smiths Medical**

Michael Hubbard, RN, BA; Brian Eisner, RRT, NPS

Michael Hubbard is Market Manager and Brian Eisner is Product Manager—Patient Monitoring & Ventilation, Smiths Medical.

#### **How has oximetry changed over the past 5 years?**

Increased development of motion and low perfusion technologies. Increasing competition from OUSA companies, especially Asian-based.

#### **How has oximetry changed the standard of care in the ICU?**

Oximetry has, over the years, allowed the clinician a fast, relatively accurate means of assessing oxygenation, thus improving patient care through improved vigilance and a reduction in invasive testing, eg, ABGs.

#### **How has the use of oximetry benefited patients?**

Patient care has improved due to the measures noted above, plus patients are less likely to be disturbed on a routine basis and are not subjected to painful blood draws just to assess O<sub>2</sub> saturation. Abnormal readings can be rapidly assessed and interventions begun early.

#### **Where do you see your product used most?**

In all areas, but especially respiratory care, med-surg units and EMS.

#### **How has oximetry proven to be cost effective and/or reduced overall costs?**

Oximeters have become relatively inexpensive compared to other capital equipment. Their use is easy to learn and a CNA can do spot checks on a number of patients, thus freeing up the nurse or RT to see to other, more pressing, duties.

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

Our sales reps are fully trained in the use of all our products, as are our distributor reps; they both in-service end-users directly. We have clinical specialists that have developed training and clinical support materials to aid the end user in using our product.

#### **Describe your customer assistance program.**

We maintain a 24/7 telephone help line that customers may call for product assistance.

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

We recognize our customers as clinical professionals whose work we support with reliable, quality products that contribute directly to the care of their patients.

#### **What hampers the effective use of oximetry?**

Poor motion and low perfusion tolerance has hampered effective use of pulse oximetry in certain patient populations.



## You'll never see us short of breadth.

Smiths Medical PM, Inc. offers a broad range of Pulse Oximetry, Capnography, and Transport Ventilator products for respiratory needs in hospital, clinic, ambulatory and homecare settings. Our monitors provide accurate, reliable data for patients, neonate to adult. They're easy to read, compact, portable, and the transport ventilators are MRI compatible. We've designed products with special features for a wide variety of applications. And our product accessories enable you to configure the equipment for specific respiratory parameters.

For more information on our patient monitoring and ventilation products, visit [www.smiths-medical.com](http://www.smiths-medical.com).

### **Smiths Medical PM, Inc.**

Patient Monitoring and Ventilation

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Even with advanced motion tolerance devices, pulse oximetry is still unreliable in some populations.

### **Where do you see oximetry in the future?**

Oximetry will continue to advance into new technologies with new uses. The parameters measured will change and be refined and the size and type of devices will change as the role of oximetry in medicine changes.

## **Masimo**

Tom McCall

Tom McCall is Vice President, Corporate Communications and Global Brand Strategy, Masimo Corporation.

### **How has oximetry changed over the past 5 years? How has your company pursued R&D efforts to continue improving this technology?**

For nearly 20 years, Masimo has been focused on a singular mission—to make noninvasive patient monitoring technologies that are needed, but due to scientific challenges were not available. That has meant we had to make some breakthroughs and solve some “unsolvable” problems. Breakthroughs, such as Masimo SET, dramatically improved pulse oximeters so that they work during challenging conditions, such as motion and low perfusion and made pulse oximetry a clinically useful tool. Prior to introduction of Masimo SET 70% to 90% of pulse oximeter alarms were false and pulse oximeters could not be used for diagnosis purposes. Masimo SET pulse oximeters have been shown to have sensitivity (ability to detect true alarms) and specificity (ability to reject false alarms) of 97%, and been vital to reduction of ROP in neonates and diagnosis of CHD in newborns.

Making noninvasive monitoring technologies that are needed has also meant taking measurements that could only be made by invasive procedures and making them noninvasive, such as the measurement of carbon monoxide and methemoglobin with Masimo Rainbow SET Pulse CO-Oximetry. Worldwide, there are nearly half a million Masimo SET Pulse Oximeters and Masimo Rainbow SET Pulse CO-Oximeters in use. And although we recently announced Masimo Rainbow SET V7, after over a decade, Masimo SET V1's motion and low perfusion performance has still not been matched by any pulse oximeter manufacturer.

Masimo has not only taken the leadership role in advancing the state of art in noninvasive blood constituent monitoring, but has also taken a leadership role in our community to ensure that clinicians have access to the technology they believe is best for patients. Masimo SET is the most accurate and reliable pulse oximetry technology in the world, clinically proven in more than 100 independent and objective studies to provide the most trustworthy SpO<sub>2</sub> readings even under the most difficult clinical conditions, including patient motion and low peripheral perfusion. These studies prove Masimo SET delivers improvements in outcomes, safety and efficiency while decreasing costs. Because of this, Masimo SET is considered the “gold standard,” with most if not all clinical studies comparing other technologies against Masimo SET.

Our unique and patented Read-Through Motion and Low Perfusion pulse oximetry uses sophisticated signal processing

technologies including parallel engines and adaptive filters to deliver accurate and reliable readings when conventional pulse oximetry technologies don't. By delivering meaningful alarms and alerts that can be trusted to reflect a patient's true oxygenation status, clinicians can maximize their efficiency by concentrating on caring for their patients, rather than chasing false alarms.

### **How has oximetry changed the standard of care in the ICU?**

The availability of Masimo Rainbow SET gives clinicians the ability to better monitor their patients' true oxygenation status—and that's just the beginning. Masimo Rainbow SET is a breakthrough noninvasive blood constituent monitoring platform that has the promise of measuring many blood constituents that previously required invasive procedures. Masimo Rainbow SET's first application is Pulse CO-Oximetry, the first and only technology platform capable of continuously and noninvasively measuring carboxyhemoglobin (SpCO) and methemoglobin (SpMet), in addition to oxyhemoglobin (SpO<sub>2</sub>), perfusion index (PI), pleth variability index (PVI) and pulse rate. By quickly and accurately determining levels of SpCO and SpMet—two critical dyshemoglobins proven to increase morbidity and mortality in a broad range of clinical settings—clinicians can accurately determine their patients' true oxygenation status. This allows for more precise and timely diagnosis and treatment.

Masimo Rainbow SET uses multiple (7+) wavelengths of light housed in a single, simple-to-apply sensor to accurately determine the dyshemoglobins SpCO and SpMet, as well as SpO<sub>2</sub>, PI, PVI and pulse rate. Conventional pulse oximetry technologies use only two wavelengths of light and lack the sensitivity to determine dyshemoglobin levels—as a result they overestimate SpO<sub>2</sub> saturation in the presence of dyshemoglobins. Built on the gold-standard Read-Through Motion and Low Perfusion Masimo SET technology, Masimo Rainbow SET is an upgradeable noninvasive technology platform that has the promise of measuring many blood constituents that currently require invasive procedures. Masimo scientists are currently at work using the data delivered by the multiple wavelengths of light to qualify additional noninvasive parameters, such as total hemoglobin (SpHb™), which can be field-installed on your Rainbow-ready monitoring devices through a simple software upgrade, so you can easily purchase and add them when they become available.

### **Where do you see your product used most? How has oximetry proven to be cost effective and/or reduced overall costs?**

As the “Gold Standard” in pulse oximetry, Masimo is at work in the world's most demanding hospitals. More than half of the top hospitals in the United States—including four of the top five—as listed on the US News & World Report Honor Roll, have adopted Masimo SET as their primary pulse oximetry platform. And most of those conversions were completed with flexible acquisition plans requiring little or no capital outlay and without increasing annual operating costs. And Masimo is easy to integrate into any clinical workflow. From EMS and Transport to the ED, OR, ICU, Step-Down Units and even General Care Floors, Masimo technology is at home in virtually any clinical setting. A complete array of sensors and multiple handheld and bedside devices—in addition to being integrated into more than 100 multiparameter monitors and 40 monitoring brands—means whatever type of patient monitor you need, you can get it with Masimo SET.

**What type of training and customer support programs do you have in place? • Describe your customer assistance program. • How do you view your relationship with the end user of your product?**

Masimo has what we believe to be an unmatched commitment to customer service and training. When you choose Masimo, you get a business and clinical partner committed to your success—both before and after the sale. As proof of our single-minded pursuit of our customers' total satisfaction, we have one of the largest teams of dedicated clinical specialists in the industry, 24 x 7 technical support, and on-line training tools to assist in making the switch to Masimo as smooth and rewarding as possible.

**Where do you see oximetry in the future?**

We believe that clinicians will continually look for more and better information to be delivered to them quickly and accurately in order to make better clinical decisions at the point of care. That's why we're continuing to push the boundaries and transform the capabilities of the technology. An example would be the Masimo Rainbow SET platform mentioned above.

Masimo Rainbow SET is a platform that allows for the noninvasive measurement of blood constituents that to date required invasive techniques. Current parameters of SpCO and SpMet are anticipated to be expanded to include Total Hemoglobin (pending FDA clearance) in late 2007. Extensive engineering and clinical research is currently underway to finalize the noninvasive and continuous measurement of total hemoglobin with Masimo Rainbow SET technology.

Total hemoglobin measurement is one of the most frequently ordered lab tests in hospitals and is critical not only to maintaining adequate blood and tissue oxygen levels, but to also warn of internal hemorrhaging. Current methods of total hemoglobin measurement are invasive, slow, and costly. A noninvasive method of quantifying total hemoglobin would speed diagnosis and proper treatment. Noninvasive continuous monitoring would provide for real-time trending and tracking of a patient's status, allowing for more timely and appropriate therapeutic interventions both inside and outside of the operating room. Initial independent clinical research presented in January '07 at the Society for Technology in Anesthesiology (STA) concluded that a Masimo engineering prototype was the first technology able to noninvasively and continuously measure total hemoglobin levels. Masimo was given the STA's prestigious "Excellence in Technology Innovation" award for this application. When approved and available, it is anticipated that the total hemoglobin parameter will be able to be field installed via a software upgrade to all Rainbow-ready monitoring devices.

## NEWS FEATURE

# Exhaled-Breath Condensate as an Assessment Tool

Melissa Turner, BA, RRT

Reprinted from Hamilton Medical's Intelligent Ventilation Newsletter.

The pH of exhaled-breath condensate (EBC) has been shown to be an indicator of airway inflammation. A normal, healthy airway pH is found in the range of 7.5 to 7.8. When the airway pH is acidic as indicated by EBC, airway inflammation is present or developing. An acidic EBC pH is found in several pulmonary inflammatory diseases such as asthma, chronic obstructive lung disease (COPD), cystic fibrosis, and acute respiratory distress syndrome (ARDS). Acidic pH was also found in EBC prior to diagnosis of ventilator-associated pneumonia. "A low EBC pH strongly suggests that there is an ongoing active pathologic airway or lung process."<sup>1</sup> It can be used as a diagnostic tool to alert the clinician that there is some process going on that further needs to be identified. If the pH of EBC decreases rapidly and /or transiently, it could be indicative of gastric-acid reflux and aspiration. Walsh et al also speculates that it could be indicative of "the occasional opening of individual airways, allowing renewed ventilation of distal acidic airways, which could then temporarily and mildly acidify the EBC."<sup>1</sup> If the change in pH is a more gradual one then it would suggest other processes such as COPD exacerbation, asthma exacerbation or some evolving infection.

It is possible that monitoring EBC pH may help with earlier diagnosis and therapy. It may also help to suggest etiologies other than those suspected, i.e., asthma exacerbation if the pH of EBC is normal. One example provided by Walsh et al, "we saw a patient who had an asthma history and was intubated for profound airway obstruction, presumed to be status asthmaticus. However, the EBC pH was high, prompting a more careful evaluation of her chest radiograph, which revealed a mass constricting her airway."<sup>1</sup> Once EBC pH is found to be low, the clinician is alerted that airway inflammation is likely. Gastric-acid reflux should be eliminated as a cause of the low pH if the patient is intubated. There are case studies that have shown that when EBC pH is low and the patient is subsequently treated with nebulized bicarbonate, airflow obstruction improves rapidly in patients with acute asthma or chlorine gas inhalation injury.<sup>2,5</sup> Unfortunately, the Food and Drug Administration has not approved the use of bicarbonate or any other medication to normalize airway pH. If the airway pH is already alkaline, bicarbonate will likely not be of any benefit, while an acidic airway will have the benefit of possibly "converting gel-phase mucus plugs at an acidic pH into more fluid phase at alkaline pH."<sup>1</sup>

The evidence is becoming increasingly clear that airway pH decreases during lung and airway disease. More studies need to be conducted to study the pH changes over the course of time. The EBC pH may become a useful assessment tool for clinicians in the near future. It may aid in faster diagnosis and therapy for

patients as well as treatment to maintain airway homeostasis to prevent bronchospasm and inflammation. Now that we are in the age of closed loop control ventilation, clinicians have more time for assessment of their patients. EBC pH may become yet another important tool to help in the clinicians' assessment of their patients in order to provide more appropriate and timely care while on mechanical ventilation.

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# Do Tracheostomies Affect Patient Outcomes?

Jeff Borrink, BS, RRT

Reprinted from Hamilton Medical's Intelligent Ventilation Newsletter

Little information is available regarding the time needed to wean tracheostomized patients from mechanical ventilation. The December, 2006 issue of *Respiratory Care* magazine published a study by Dr. WJ van der Lely et al. The purpose of the study was to determine the time it took to wean patients from mechanical ventilation in all tracheostomized intensive care unit (ICU) patients and in certain subgroups of patients, and how many hours per day these patients breathed spontaneously without help from the mechanical ventilator after tracheostomy.

This retrospective analysis from one single-center ICU was conducted on 1,917 consecutive patients during a 14 month period from November 1, 2003, through January 1, 2005. Although most of the tracheostomized patients could be weaned completely from mechanical ventilation within a week, they found that time to wean after tracheostomy differed among their ICU subgroups.

"Time to wean after tracheostomy" was defined as the time from day of tracheostomy until the day on which the patient breathed spontaneously without help of the mechanical ventilator for > 24 hours and had no need for mechanical ventilation for at least 7 days thereafter.

Patients were weaned utilizing a mechanical ventilation

protocol which called for pressure- controlled or pressure-support (PS) ventilation in all patients. PS ventilation was started as early as possible. Tidal volume was kept at 6-8mL/kg of predicted body weight in all patients, and peak airway pressures were kept below 35cmH<sub>2</sub>O. Positive end-expiratory pressure (PEEP) was initially set at 5cmH<sub>2</sub>O, and was then adjusted, along with the fraction of inspired oxygen (FI<sub>O2</sub>) to achieve a PaO<sub>2</sub> of 75mmHg. In PS ventilation the support level was set to reach a respiratory rate at which the patient was breathing comfortably. A spontaneous breathing trial was initiated when the PS level was < 15cmH<sub>2</sub>O and the PEEP level was less than 5-7cmH<sub>2</sub>O. During SBT's patients were connected to a T-piece with an FI<sub>O2</sub> of .5, and the duration of each session, which varied greatly, was chosen depending on the patient's condition. Some were started on SBT's for as many hours as possible during the day; others were started on 1 hour SBT's TID, then the length of each SBT was gradually increased each day. Patients who showed desaturation, rapid shallow breathing (RSB), or signs of fatigue during a SBT progressed more slowly through the protocol.

129 (7%) patients admitted to the ICU received a tracheostomy. Neurosurgery/neurology patients and patients admitted for acute conditions received significantly more tracheotomies (16% and 12%, respectively). Tracheostomy was performed a median of 8 days after ICU admission. Time until tracheostomy was significantly shorter in the neurosurgery/neurology and cardiology subgroups than in the other subgroups.

The median time to wean after tracheostomy was 5 days for all patients, but was significantly different among subgroups. Neurosurgery/neurology patients and patients in the cardiology subgroup also needed significantly less time to wean from mechanical ventilation than patients in other subgroups (3.4 days, and 3.0 days, respectively). However, these two subgroups had higher tracheostomy rates, so Dr. WJ van der Lely et al did not address whether or not this was statistically significant. Glasgow score was significantly associated with time to wean. With a lower Glasgow score, time to wean was shorter (4.5 days shorter than patients with a higher Glasgow score).

Within 1 week after tracheostomy, the probability of the patient having breathed spontaneously without ventilator assistance for > 4 hours/day was 89%, 78% for > 8 hours/day, and 72% for > 12 hours/day. By day 28, the probability of the patient having breathed spontaneously for > 4 hours/day was 98%, 97% for > 8 hours/day, and 94% for > 12 hours/day. The probability of the patient breathing spontaneously for > 24 hours without ventilator assistance for > 24 hours was 60% at day 7, and 93% at day 28.

Dr. WJ van der Lely et al concluded that most patients after tracheostomy are quickly able to breathe spontaneously without assistance from a mechanical ventilator for several hours per day, but time to wean from mechanical ventilation after tracheostomy differed among their ICU subgroups. A large portion of patients with tracheostomy were completely weaned within 1 week, particularly those patients in the neurosurgery/neurology subgroup and those patients in the cardiology subgroup. Glasgow score was significantly associated with admission diagnosis group, and the time to wean was shorter with lower neurological status, suggesting that these patients may have needed a tracheostomy merely for airway protection.

*continued on page 40...*

# Helping hospitals through the reimbursement maze



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## Inpatient Drug Reimbursement — How Can Respiratory Managers Deal With Increasingly Large Drug Budgets?

An interview with Ken Abreu, MRA, CMR

Now that Respiratory is paying for and dispensing expensive drugs, such as INOmax<sup>®</sup> (nitric oxide) for inhalation, Respiratory managers have to deal with larger budgets and the pressures to deal with financial issues. One way of dealing with large drug budgets — and justifying them to your administration — is to improve inpatient drug reimbursement. We interviewed Ken Abreu, MRA, CMR, Director of National Accounts and Managed Markets at INO Therapeutics, to learn more.

### **Is it true that inpatient drugs are reimbursable outside of current payment systems?**

Yes, that can be true, although that is not always the case. The more expensive the drug, the more likely it is that private payers will have some kind of special provision to pay for it.

Normally, all drugs used in an inpatient setting are covered by some kind of lump sum payment like a DRG or a per diem payment. However, payers understand that some drug costs are too high to be covered by the normal payment, so they make special provisions. Many private payers, including private Medicaid programs, which represent the majority of Medicaid patients, may have special payment plans for patients whose costs are outside the norm.

### **Is it true that reimbursements do not change based on length of stay or patient acuity?**

That is not always true. A lot depends on how the hospital is paid and what kinds of contracts the hospital makes with payers. That being said, there are a few common ways that hospitals can get extra reimbursement for drugs.

### **What separate reimbursement options may be available? Do I have to know all the details?**

There are a number of reimbursement options. Respiratory managers need not fully understand them because the hospital has experts who make it their business. However, it helps to know a little about them.

First, many payer contracts contain outlier clauses. An outlier clause essentially pays extra for patients whose costs or charges far exceed the normal payment.

Another way contracts can be structured is to have the payer “carve out” costs or charges for a certain drug. When a drug is carved out there are two calculations for payment. The first is the typical payment for the diagnosis. The higher-cost items, such as expensive drugs, can be carved out; in other words, they are paid for separately from the regular payment.

A third common approach to covering high-cost items is the stop-loss. A stop-loss clause in a contract allows for the standard payment up to the point a hospital has spent a certain amount of money. If the hospital gets to the point that they are losing a specified amount on a given case, the payer increases reimbursement to stop the hospital from losing too much money.

Some managed care contracts have special clauses that essentially obligate the payer to cover new technologies. Sometimes a drug is considered to be a new technology for a hospital, especially if it is new to the hospital.

While there are a few other ways for hospitals to get extra reimbursement for high-cost patients, these are the most common.

### **Is it true that Respiratory has to do all the work to get reimbursement for high budget items?**

No, not at all. In fact, Respiratory can contact a number of internal and external resources that can do the majority of the work.

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Ken Abreu, MRA, CMR, is Director of National Accounts and Managed Markets, INO Therapeutics. For more information, please contact Ken Abreu at ken.abreu@inotherapy.com.

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### What resources can help the Respiratory department with drug reimbursement?

Within the hospital are a number of people and departments who can work together to improve reimbursement. These include the hospital's finance department, managed care contracting department, and the chargemaster. The pharmacy may also be able to help. Respiratory managers can contact any or all of these internal resources for help.

Outside of the hospital, the drug's manufacturer may be able to help. Many companies, including INO Therapeutics, offer reimbursement information that Respiratory may find very useful. Another good source is professional organizations; the American Association for Respiratory Care (AARC) offers reimbursement information.

### What specific actions should Respiratory managers take to help with reimbursement?

The first thing Respiratory should do is contact the resources mentioned above. While Respiratory can take the lead on reimbursement, it is often a good idea for Respiratory to be the coordinator of the various hospital departments and external resources like the drug company. It is not uncommon that, because Respiratory is not always known as a department that pays for drugs, the hospital's administration does not even know that there is a lack of reimbursement there. Often just bringing everyone to the table starts a process that leads to a good outcome for the department.

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More studies are needed on both tracheostomized patients and non-tracheostomized patients to compare this data in order to draw some definitive conclusions, e.g. this study does not tell us whether a tracheotomy speeds up the weaning process as compared to patients left intubated. The study by Dr. WJ van der Lely et al did not address patient outcomes. Studies evaluating the association of tracheostomy with patient outcomes are rare and can be conflicting.

A recent study published in the January issue of Critical Care Medicine by Dr Christophe Clec'h et al looked at outcomes of tracheostomized patients requiring prolonged mechanical ventilation. The aim of the study was to yield a more accurate estimation of the association of tracheostomy with ICU and post-ICU mortality and to determine whether there was a difference in ICU mortality according to the timing of the tracheostomy and in post-ICU mortality according to whether the tracheostomy tube was removed before ICU discharge.

The study was conducted on 2,186 patients enrolled between 1997 and 2004 that required mechanical ventilation for 48 hours in 12 French medical or surgical intensive care units. Of the 2,186 patients, 177 (8.1%) received a tracheostomy. The median time to tracheostomy was 20 (14-32) days. Christophe Clec'h et al. found that tracheostomy did not improve intensive care unit survival. It made no difference whether tracheostomy was performed early (within 7 days of ventilation) or late (after 7 days of ventilation), which may be ascribable to the fact that early placement of tracheostomy is not always judicious.

Christophe Clec'h et al also assessed the relationship between tracheostomy and pneumonia, and found that the risk of pneumonia was not modified by tracheostomy.

The tracheostomized patients had increased length of time on mechanical ventilation, increased length of ICU stay, and increased length of post-ICU stay, which may have been due to the median time for tracheostomy (20 days), but more likely reflects the difficulties encountered when trying to discharge these patients from the ICU or hospital.

In patients discharged free from mechanical ventilation, tracheostomy was associated with increased post-ICU mortality when the tracheostomy tube was left in place. Several explanations may explain the increased post-ICU mortality when the tracheostomy tube was left in place. One explanation for this is that these patients had the most serious impairment of their respiratory function and were therefore more likely to die after ICU discharge and the tracheostomy tube was not responsible for the excess of mortality. Another explanation could be poor tracheostomy care in the post-ICU wards, which could be responsible for complications such as obstruction of the cannula, and subsequent increased mortality.

Regardless, Christophe Clec'h et al concluded that tracheostomy does not seem to reduce ICU mortality but may represent a burden after ICU discharge.





VENTILATION

# Ventilation Requires Perfect Balance

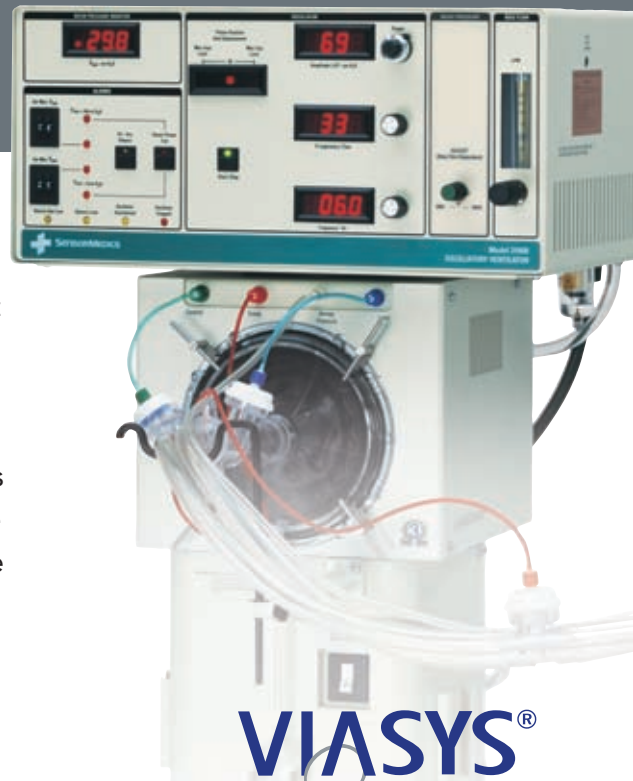


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# Refining and Validating a Risk Assessment Tool for HFOV Rescue of ARDS patients

Jean Johnson RRT , Thomas E Bachman MSHA

The use of High Frequency Oscillatory Ventilation (HFOV) for the treatment of infants with respiratory failure has been shown to reduce the incidence of death or chronic lung disease when used proactively. HFOV has also become a standard of care for treatment of infants and children failing conventional ventilation. An HFOV unit suitable for use with adults has also shown promise for treating ARDS. However, new “non-conventional” respiratory technologies are often first tried by clinicians facing last-ditch rescue circumstances. With the nominal survival of ARDS believed to be approximately 50%, one would expect that the mortality of an ARDS rescue technology in failing patients could be considerably worse, and still be effective, especially when used after standard therapies have failed. The existing acuity scoring systems that predict mortality are typically based on the physiological status at ICU admission and are not designed for assessing the risk of mortality in patients failing conventional ICU treatment.

Based on subjective experience with HFOV rescue and the HFOV rescue literature, we developed a simple risk assessment tool that could be used to project the likelihood of survival based on pre-rescue severity. The purpose of the tool was not to deny availability of rescue devices or discourage rescues in nearly futile situations, but rather to provide a reasonable baseline for survival expectations. With such a baseline in mind, short term physiological responses to HFOV intervention could be more appropriately evaluated. The Risk Assessment Score considers 8 parameters and assigns each a score of 0 - 3 based on severity. The 8 parameters cover gas exchange, ventilator pressures, days of pre-rescue CMV, and organ failures.

We evaluated the risk score in a series of 72 adult HFOV rescues, refined it and then tested it on an independent series of 37 rescue patients. A high Risk Assessment Score was highly associated with mortality ( $p < 0.01$ ) in both patient series, whether the score was treated as a continuous variable or

stratified into low, moderate and high risk groups. We have found the use of Risk Assessment Scores useful in managing expectations of clinicians considering adult HFOV rescue. We intend to refine the tool through continuing prospective validation.

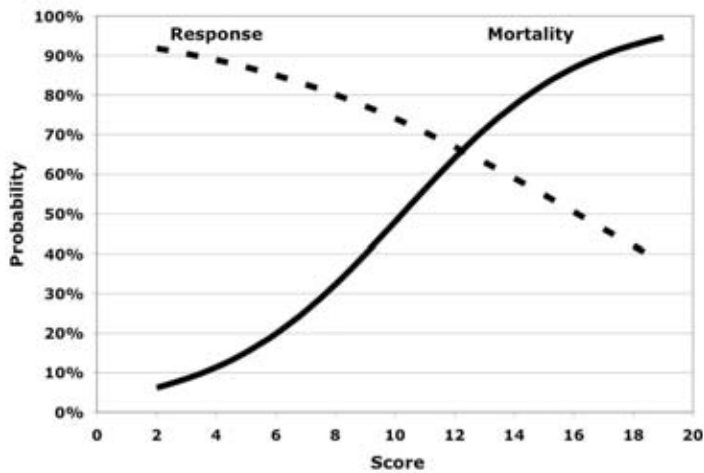
## Introduction

A recent mega-trial, consistent with trends seen in meta analyses of smaller trials, clearly demonstrated the potential for high frequency oscillatory ventilation (HFOV) to reduce ventilator induced lung injury in premature infants.<sup>1,2</sup> Over the last decade HFOV has become the standard of care for infants and children with significant respiratory failure.<sup>3</sup> Unlike the adoption of exogenous surfactant therapy, which became the standard of care shortly after its commercial introduction, use of HFOV in infants and children has evolved more slowly. In all but a few centers, the clinical introduction of HFOV was initially limited to patients failing conventional ventilation (CMV). While only a few studies suggest long term benefit for this rescue use,<sup>4,5,6</sup> anecdotal experience of dramatic reversals of deteriorating oxygenation and recovery in seemingly hopeless cases led to its more frequent, earlier use. An HFOV unit (model 3100B, SensorMedics, Yorba Linda, CA) suitable for adults has become widely available. Theoretically HFOV with an open lung strategy has the potential to be the ultimate low tidal volume strategy.<sup>7</sup> Early reports of its use and two multicenter randomized controlled trials support its safety, effectiveness and promise.<sup>8-17</sup>

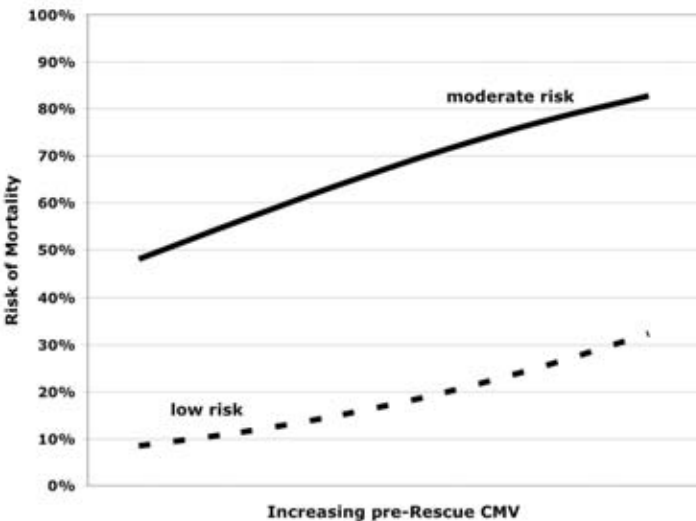
Unlike neonatal populations with primary surfactant deficiency, candidate adult populations with ARDS have significantly heterogeneous and severe underlying etiologies. The nominal survival rate in acute respiratory distress syndrome (ARDS) is believed to be approximately 50%, but varies somewhat depending on the triggering etiology and oxygen derangement. Accordingly, one would expect that the survival rate of any rescue therapy used to treat ARDS patients who are failing conventional therapy and expected to die, could be considerably worse than 50%, and still be effective. While the potential benefit of HFOV can be carefully evaluated in a large

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Jean Johnson is with Viasys Healthcare; Thomas E. Bachman is with California State University San Bernardino and Mountains Community Hospital. This study was sponsored by Viasys Healthcare.



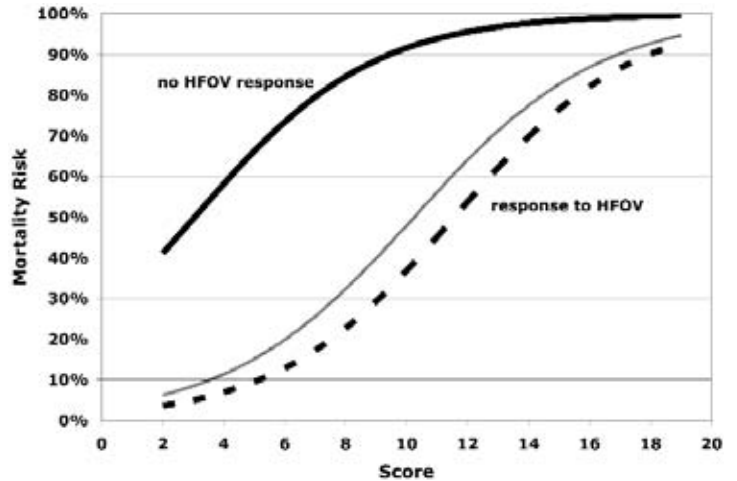
**Figure 1. Probability of Mortality and Response** The predicted probability of mortality and positive first day response to HFOV plotted against Risk Score. The score was highly significantly associated with both risk of mortality ( $p < 0.0001$ ), and response to HFOV ( $p = 0.01$ ).



**Figure 2. Mortality Risk with Delay in Intervention** The predicted risk of mortality for two hypothetical patients plotted against increasing combined score for length of conventional ventilation and length of ventilation with  $P/F < 200$  (i.e., 0-5). The low risk patient is characterized by an OI less than 20 that is worsening,  $PaCO_2$  between 35-55 with a PIP between 39-49. The patient of moderate risk is characterized by a higher OI of 20-30 that is dramatically worsening, a higher  $PaCO_2$  56-80, in spite of a PIP  $> 49$  and one organ failure in addition to pulmonary. With extended conventional mechanical ventilation prior to HFOV the predicted mortality nearly triples for the low risk patient and increases by more than 50% for the moderate risk patient.

controlled trial, establishing a reasonable expectation for initial response and outcome for a specific rescue candidate is generally very subjective and uncertain. Furthermore, as with any new technology, simply using it raises expectations of its effect. Years of previous experience overseeing HFOV rescues of infants and children at hundreds of institutions highlighted the criticality of managing expectations in this new application.

Mortality risk assessment systems for ICU patients have been available for over two decades.<sup>18</sup> Their development and validation is based on scoring/evaluation on the day of ICU admission, by definition precluding ICU interventions. Some researchers have evaluated the use of these standard baseline severity scores along with other physiological variables in patients with ARDS and have shown enhanced accuracy.<sup>19-22</sup>



**Figure 3. Mortality Risk and Response** The risk of mortality is plotted against Risk Score. The solid line is the predicted risk of mortality for a patient who does not respond to HFOV. The dotted line is the predicted risk of mortality for a patient who responds to HFOV. For reference the smaller grey line is the predicted baseline risk of mortality for patients prior to determining their response to HFOV.

Several investigators have also reported analyses of predictive criteria associated with HFOV rescue in ARDS.<sup>8,9,11,14</sup> While these reports are not contradictory, they do not approach a consensus on a standard for assessing ARDS patients failing conventional ventilation.

Based on published data and extensive personal experience with HFOV rescue in children and adults, in 2001 we developed a simple pre-HFOV rescue risk assessment tool for adults failing CMV. The initial assessment tool was developed with the intent of validating and refining it with data from clinical use. We report on the first validation and refinement.

### Description of Technique

The initial assessment tool included eight parameters. These parameters were: the number of days that the  $PaO_2/FiO_2$  had been less than 200, the number of days of conventional mechanical ventilation, peak inspiratory pressure,  $PaCO_2$ , number of organ failures, compromised immune system, oxygenation index and trend of oxygenation index. Based on our past clinical experience, each parameter was subjectively stratified into four levels of severity with an associated score of 0-3. Thus the total score could range between 0-24, with zero being the lowest risk/severity. Following the checking of the validity of the initial scoring system, an effort was made to refine the scoring system by adjusting the score thresholds for each of the eight parameters. To do this, a new threshold for increasing score for each parameter was selected such that the four scores for each parameter represented mortalities of less than 40%, 40-65%, 65-75% and greater than 75%, respectively. The new total score for each patient was then calculated. The initial and refined scoring system can be seen in table 1.

### Method of Evaluation

As part of a new product introduction plan, a program for shipment of 3100B's for HFOV rescue of adult patients was initiated and coordinated by a SensorMedics rescue program coordinator and logistics personnel. Prior to delivery of a 3100B for rescue use, a clinical specialist discussed the patient with the attending clinician, calculated the risk assessment score and commented on its relative magnitude. Scores under 8 were identified as relatively low probability of death and those above

Parameter / Score	0	1	2	3
Oxygenation Index				
original	≤ 24	25-45	46-60	>60
refined	<20	20-30	31-40	>40
OI Trend				
original	improving	stable	worsening	dramatically worsening
refined	Improving or stable		worsening	dramatically worsening
PaCO <sub>2</sub>				
original	35-50	51-80 or <30	81-95	>95
refined	35-55	<35	56-80	>80
PIP				
original	≤38	39-48	49-58	>58
refined	≤38	39-49	>49	
Days CMV				
original	<2	2-4	5-7	>7
refined	≤ 6	>6		
Days P/F < 200				
original	<2	2-4	5-7	>7
refined	<2	2-4	5-6	>6
Organ Failure				
original	pulmonary	1 other	2 other	3 other
refined	pulmonary	1 other		>1 other
Immune Compromise				
original	no	yes		
refined	no	yes		

**Table 1** Original and Refined Scoring System

Oxygenations Index (OI) = (FIO<sub>2</sub> \* mean airway pressure) / PaO<sub>2</sub> . Days CMV is the number of days the patient was on conventional mechanical ventilation prior to HFOV rescue consideration, Days P/F < 200 is the number of days the patient PaO<sub>2</sub>/FIO<sub>2</sub> was less than 200 prior to HFOV rescue intervention

12 as a relatively high probability of death. Every effort was taken to ensure this assessment was not a factor in deciding whether to conduct an HFOV rescue, but rather used as a basis to establish a baseline expectation of survival. The value and score for each of the 8 parameters were recorded. Within a few days of the HFOV rescue initiation a report was obtained to determine an objective clinical impression of whether the patient had a positive pulmonary system response. Additional follow up calls were placed to determine whether the patient survived. Survival was defined as alive at 30 days or discharged without respiratory support prior to 30 days.

In our analysis the scores were validated in two ways. In the first approach a contingency table for survival and response was constructed and stratified by low, medium and high risk. A chi-square test was used to determine whether the differences were statistically significant among the three risk categories. In the second approach a logistic regression model was used to determine whether the score, treated as a continuous variable, was significantly related to response and to survival. The logistic regression model was also used to graph response and survival as a function of score. The overall predictive effectiveness (sensitivity and specificity) of the score was also evaluated by calculating the area under the receiver operator curve.

Finally the new refined scoring system was tested with an independent data set of adults treated with HFOV to see if the scores and categorization were statistically significant.

In addition to chi-square and logistic regression tests described above, differences between the central tendency of variables were tested with a t-test or Wilcoxon rank sum test, as appropriate. A probability of less than 0.05 was considered statistically significant.

## RESULTS

### Patients Evaluated

In the 12 months between December 2001 and November 2002, there were 247 inquiries for adult HFOV rescues. Of those, 100 patients were scored according to the Risk Assessment Tool and 72 HFOV rescues were conducted. These rescues took place at 72 different institutions in the US. Twenty-eight patients were scored for risk assessment, but rescues were not conducted. Nearly half of these, 42%, died before HFOV treatment could be initiated. The next most common reasons for not conducting an HFOV rescue attempt were poor prognosis (26%) and cost of equipment rental (22%). As would be expected, the Risk Assessment Scores of those patients where a HFOV rescue was not attempted, were higher than those where HFOV rescue was tried (medians of 11 and 8, p=0.002)

Clinical data describing those patients treated with HFOV can be seen in table 2. These patients had significantly deranged oxygenation (25%-75% percentile OI = 25-50), which was deteriorating in over two-thirds of the patients. While the PaCO<sub>2</sub>'s were in a reasonable range in most of the patients (25%-75% percentile = 46-70 mmHg), this was accomplished at the cost of high peak inspiratory pressures (25%-75% percentile =

	%	median	25% -75%	range
Days of CMV		3	2-7	1-37
Days PaO <sub>2</sub> /FIO <sub>2</sub> < 200		2.5	1.75-4	1-16
Oxygenation Index (OI)		39	25-52	5-132
Improving OI	5%			
Stable OI	26%			
Worsening OI	55%			
Dramatically worsening OI	14%			
PaCO <sub>2</sub>		56	46-70	30-153
PIP		47	39-52	22-90
Organ Failure				
pulmonary only	27%			
1 additional	42%			
2 additional	24%			
3 or more additional	7%			
Immune Compromised	43%			

**Table 2** Baseline Physiological Status

Days CMV is the number of days the patient was on conventional mechanical ventilation prior to HFOV rescue consideration, Days P/F < 200 is the number of days the patient PaO<sub>2</sub>/FIO<sub>2</sub> was less than 200 prior to HFOV rescue intervention., Oxygenation Index (OI) = (FIO<sub>2</sub> \* mean airway pressure) / PaO<sub>2</sub>, 25%- 75% is the interquartile range.

39-52 cmH<sub>2</sub>O). Over 70% of the patients had multiple organ failures and 43% were immune compromised as well. Finally most of the patients had been treated with conventional ventilation for an extended period (25%-75% percentile = 2-7 days) before HFOV was initiated. Seventy-one percent of the patients responded positively to HFOV, and 47% survived.

### Initial Scoring System

The Risk Assessment Scores for these patients ranged between 1 and 17 with a median of 8 (25%-75% percentile 6-11). Ninety-four percent of the patients in the low risk category (scores less than 8) responded and only 20% died. Eighty-seven percent of the patients in the medium risk category (score 8-12) responded but 53% died. In the high risk category (scores greater than 12) only 60% of the patients responded, and 100% died. The difference in survival, but not response, was statistically significant among the risk categories (p=0.02). When analyzed as a continuous variable, increasing score was significantly associated with increasing mortality and non-response (p<0.0001, p=0.02 respectively). The area under the receiver operator curve (ROC) was 84.7%.

### Refined Scoring System

Analysis of the relative increase in risk of mortality associated with increases in the severity of each of the 8 individual risk parameters resulted in small changes in the scoring system. The original and refined scoring system can be seen in table 1. Less severe levels of oxygenation, PaCO<sub>2</sub> and PIP resulted in higher scores. The score for a compromised immune system was reduced, but the score for 2 or more organ failures in addition to pulmonary was increased. The risk score associated with number of days of CMV with a P/F ratio less than 200 increased slightly, while the risk score for total length of CMV decreased slightly.

The revised Risk Assessment Scoring of the 72 patients resulted in a median score of 10 out of a possible 20 (range 2-17) with the 25%-75% interquartile range of 6-13. The refined scoring criteria resulted in a slight predictive improvement over the

initial scoring criteria, based on higher significances in both categorical and continuous analysis. In the low risk group (scores < 8) 82% of the patients responded and only 18% died. In the moderate risk group (score 8-13) 81% responded but 55% died. In the high risk group (score>13) 42% responded and 89% died. The difference in survival, and response were now both statistically significant among risk categories (p=0.004, p=0.049 respectively). Likewise increasing score, when treated as a continuous variable, was also highly significantly associated with increasing mortality and decreasing likelihood of response (p<0.0001, p=0.01 respectively). The probability of mortality and response based on the revised risk assessment score can be seen in figure 1. Finally, the area under the ROC, 84.5%, remained high.

To verify the general applicability of the refined Risk Assessment Scoring, we checked it against a data set independent of the one from which it was refined. Scores were calculated from the data used to report on 37 adults treated with HFOV.<sup>10</sup> The differences between the mortality and response for the three risk ranges were both statistically significant (p=0.005 and p=0.017 respectively). Likewise the refined score, when treated as a continuous variable, was significantly related to mortality and response. (p=0.003 and p=0.006 respectively). The area under the ROC was 78.8%

### Discussion

We subjectively devised, quantitatively refined and then validated a simple scoring system to provide guidance as to the likely positive response and ultimate survival of adult ARDS patients failing conventional ventilation who were to receive a rescue trial of HFOV. The risk assessment score was found to be significantly related to response and mortality both as a continuous variable and for categorical groupings into low, moderate and high risk groups. The sensitivity and specificity of the scores for predicting mortality, as represented by the area under the receiver operator curve were about 80%, which is considered excellent.

Intensive care acuity scoring systems such as APACHEII, APACHEIII, MPM-II and SAPSII are in widespread use and have been well validated for assessment of risk of mortality upon ICU admission.<sup>18</sup> It has been long noted that administration of intensive care modifies these scores. That trend of changing scores has been reported to be useful but not calibrated for risk prediction.<sup>23-25</sup> Several research groups have identified the need to include other physiological parameters along with baseline acuity to improve mortality prediction of patients with ARDS.

Over a decade ago, Suchyta reported that older age, organ failure, sepsis syndrome and triggering etiologies other than aspiration, along with APACHE-II score were associated with increased mortality but that oxygenation, levels of respiratory support or respiratory compliance were not.<sup>19</sup>

Recently, Monchi and colleagues conducted a thorough multivariate analysis of baseline factors associated with mortality in 259 ARDS patients with 65% mortality treated in their hospital.<sup>20</sup> While they found SAPS-II score highly related to mortality, inclusion of a number of other factors improved the prediction model significantly. Of the nearly 2 dozen variables evaluated, they found right ventricular failure, cirrhosis, severity of sepsis, Oxygenation Index and length of mechanical ventilation prior to ARDS important contributors. In another

recent prospective study of pulmonary dead space in 179 patients with ARDS having a 42% mortality, Nuckton found pulmonary deadspace, respiratory compliance and SAPS-II contributed to the prediction of mortality in a multivariate model, but not pH, cirrhosis, acute organ failures, or oxygenation.<sup>21</sup>

Two multivariate analyses of the predictors of mortality in patients treated with HFOV have been conducted. Derdak found that in addition to APACHE-II, baseline pH and more than 5 days of conventional ventilation, added significantly to mortality prediction.<sup>14</sup> In addition, Derdak's findings were independent of whether conventional or high frequency ventilator was used for treatment in their randomized controlled trial.<sup>14</sup> Recently Mehta reported that age, baseline pH and days of conventional ventilation, in addition to APACHE-II, all contributed to the prediction of mortality in their retrospective analysis of 156 patients treated at three Toronto centers.<sup>11</sup>

Our rescue risk assessment score was envisioned to be used with patients that were failing conventional ventilation, whose ultimate mortality would be less associated with admission baseline conditions than with their current status. Therefore we did not include a standard risk assessment system as the foundation for our risk score. Nevertheless, our risk score includes immune compromise and organ failure, both capturing chronic conditions. Our risk score also includes oxygenation and ventilation parameters that would be expected to be correlated to variables found important by others. Length of mechanical ventilation prior to HFOV intervention also plays an important role in our Risk Score. This makes pathophysiological sense and is consistent with several of the multivariate analyses already described.

In several smaller series exploring HFOV rescue in ARDS patients, length of mechanical ventilation prior to HFOV intervention was reported as an important marker of outcome.<sup>8,10,11</sup> Figure 2 depicts the effect that delaying HFOV rescue has on predicted mortality based on a hypothetical moderate risk and low baseline risk patient. This analysis assumes no other deterioration in oxygenation, organ failure or ventilation, but rather just increasing length of ventilation prior to HFOV intervention and clearly demonstrates the importance of earlier intervention in our model.

In the two previously referenced multivariate analyses of baseline risk at HFOV intervention, Derdak and Mehta also found that improved Oxygenation Index within the first day of HFOV was highly significantly associated with improved outcome.<sup>11,14</sup> This is consistent with other reports in adult and pediatric populations.<sup>10, 24, 25</sup> Since our Risk Score was by definition, a prospective pre-HFOV metric, we did not consider oxygenation response as an independent variable. We did however identify general pulmonary response to HFOV as a dependent variable. When we included pulmonary response as an independent variable in the logistic regression model, on a post hoc basis, its impact was highly significant ( $p=0.003$ ). This is consistent with the findings of others who looked at Oxygenation Index improvement. In the patients in the low risk of mortality range (score 0-7) a lack of response was associated with 7.8 times the relative risk of mortality compared to responders. In the moderate risk group (score 8-12), a lack of response was associated with a relative risk of mortality of 2.6, and in a high risk group (score 13-20) a lack of response was

associated with a relative risk of mortality 1.25. The relationship between predicted mortality and HFOV response can be seen for patients of varying scores in figure 3.

This scoring system was not intended to discourage the use of HFOV rescue, but rather to establish a reasonable baseline for outcome expectation. The important contribution of response to HFOV on predicted mortality that we found, consistent with that reported by others, reiterates the importance of this point. Further, all mortality risk scoring systems, however complicated or refined, are more accurate for predictions of populations making them most useful for risk adjustments between ICU's, physicians or treatment strategies. We do feel that our approach of providing projected baseline mortality has been demonstrated to be useful to support clinical judgment and provide family expectation guidance. Our latest information supporting modification of that baseline data, based on first day response to HFOV rescue should enhance its value.

This effort is not complete. The revised Adult HFOV Rescue Risk Assessment Scoring tool includes additional information not included in the current Risk Score. After another 100 patients have been screened for rescue, we intend to evaluate the validity of the new Risk Score and determine if any of these new parameters might enhance our risk prediction model further.

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# High-Frequency Chest Compression: Advanced Therapy for Obstructive Lung Disease

Jane Braverman, PhD, Mario J. Nozzarella

## Abstract

First introduced nearly two decades ago, high frequency chest compression (HFCC) technology has become the preferred airway clearance therapy for patients with cystic fibrosis and a variety of other obstructive lung disorders. This paper describes the history of HFCC technology, supporting research, and the development of successive generations of HFCC machines including the inCourage System, which incorporates the most recent advances in technology and design.

## History

By the early 1960s, the contribution of excess pulmonary secretions to the progression of cystic fibrosis (CF) lung disease was well understood. Treatment protocols began to include aggressive daily secretion clearance therapy with the only available method, chest physiotherapy (CPT). By 1980, after more than a decade of routine CPT, dramatic improvements in patient health and survival established CPT as the cornerstone of CF care.<sup>1</sup> However, despite its clear benefits, CPT may not be the ideal therapy. An array of challenges may compromise its therapeutic benefits. Caregiver limitations including poor technique, inadequate physical strength and inconsistent availability and patient factors such as treatment contraindications, inability to tolerate required positioning and unwillingness to cooperate may contribute to suboptimal CPT effectiveness.<sup>2,3,4</sup> Recognition of the need for a more practical and consistent form of therapy led to the development of novel techniques and technologies including high frequency chest compression (HFCC).<sup>5</sup>

The earliest known clinical application of HFCC was described in 1966 by Dr Gustav Beck, a chest specialist and chief of the pulmonary laboratory at St. Clair's Hospital, New York City. Beck sought to develop a physio-mechanical intervention consistent with principles of pulmonary physiology to clear mucus from severely obstructed lungs. In a geriatrics journal, he described equipment that delivered an air stream with a positive

pressure of 30 cm H<sub>2</sub>O from a compressor passed over a vibrator operating at 30 Hz.<sup>6</sup> Therapy was applied to the upper abdomen and lower thorax with a thoracoabdominal belt. Ten of thirteen treated patients showed significant mucus expectoration, marked reduction of dyspnea and temporary or sustained benefit. The method attracted no particular interest and was not pursued further for nearly two decades.

In the early 1980s a group of Canadian scientists, led by Dr Malcolm King, undertook a series of in vitro and animal studies to investigate the potential of HFCC to enhance pulmonary mucus clearance. Their research demonstrated significant increases in both the rate of tracheal mucus clearance and in movement of secretions from peripheral lung regions.<sup>7,8</sup> Additional studies elucidated some of the mucokinetic and mucolytic actions of HFCC.<sup>9-12</sup> Observations include a reduction in the viscoelastic and cohesive properties of mucus, thus promoting clearability by the air-liquid interactions associated with cephalad airflow velocity bias,<sup>9-10</sup> and that HFCC frequencies in the range of 13-15 Hz may reinforce the mucus interaction with cilia and/or the natural harmonics of the chest wall.<sup>11</sup> Studies also found a correlation between HFCC action and improved ventilation.<sup>13</sup>

In 1985, the father of a cystic fibrosis patient offered funding to Dr Warren J Warwick, Professor of Pediatrics and Director of the University of Minnesota Cystic Fibrosis Center, to find a way to simplify her regimen of four daily CPT sessions. Inspired by King's work showing enhanced tracheal mucus clearance in dogs, Warwick and Leland Hansen, a University of Minnesota senior scientist, worked to develop a system for clinical use based upon those principles and technologies. Their first creation, a sine waveform device, was a complicated system composed of a motor, piston, an air spring rubber diaphragm and a rubber vest with a tailored plastic cover. This system worked so well that the young lady was able to administer her airway clearance therapy herself. Her treatment time was reduced from four hours to two hours daily.<sup>14</sup>

Warwick and Hansen experimented further to develop a

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waveform that would maintain a constant pressure during both the inspiration and expiration phases of HFCC therapy. The prototype, a square waveform machine, was so successful that fifteen other families raised money to have Hansen build machines for their children with CF. Observations on these additional patients showed HFCC to be more practical and more effective than standard chest physiotherapy (CPT). Follow-up results showed an unprecedented stabilization or improvement of pulmonary function in a disease where progressive deterioration and early death had been the rule.<sup>15</sup> Subsequently, long-term and short-term studies have demonstrated the impact of HFCC therapy on sustaining or improving pulmonary function.<sup>16-21</sup>

Over the years, Warwick and Hansen performed a series of laboratory and clinical studies that helped to identify strengths and weaknesses in their HFCC machines.<sup>22-28</sup> They used this information to guide them in making incremental improvements. Because they could not maintain production themselves, in 1988 they licensed a medical device company to manufacture and distribute their machine.

All HFCC devices consist of similar primary components; an air delivery device with a motor-driven valve and an inflatable jacket interconnected by one or two hoses. The air delivery device creates oscillating air pressure that is delivered to the jacket via the interconnecting hose/s. The rhythmic inflation and deflation of the jacket against the user's chest produces high-frequency chest compressions that create the oscillatory effects within the airways that help mobilize bronchial secretions.

All HFCC machines have received FDA clearance to market based upon a determination of generic equivalency to predicate devices meeting the specifications approved in the original Warwick/Hansen prototype. The frequency range of commercially available HFCC machines is from 5 Hz to 30Hz. Pressures may be adjusted downward from a maximum available pressure. Some investigators believe that HFCC efficacy may be influenced by factors including differences in the pulse waveform, pulse pressure, frequencies and jacket sizing.<sup>26, 27, 41-43</sup>

Past and current HFCC machines utilize three different applied waveforms—square, sine and triangle. All were first developed at the University of Minnesota Cystic Fibrosis Center by Warwick and Hansen. Several papers describe that work.<sup>13, 15, 21-27</sup> As an outcome of that research, four generations of commercially available machines with distinct technical and performance characteristics have emerged. Individual manufacturers have added their own design features and technical modifications.

#### A chronology of HFCC machines

- 1988-2002: Square waveform Model 101 and Model 102, American Biosystems, aka Advanced Respiratory, St Paul, MN.
- 1992-2003: Sine waveform Model 103, Hill-Rom, dba Advanced Respiratory, Inc (aka ARI), St. Paul, MN.
- 2003-present: Sine waveform Model 104, Hill-Rom.
- 2006-present: Sine waveform Model 205, Hill-Rom
- 1994-2002: Sine waveform Med Pulse Electromed, Inc. New Prague, MN.
- 2002-present: Sine waveform SmartVest, Electromed, Inc New Prague, MN.

- 2005-present: Triangle waveform: The InCourage System, Respiratory Technologies, Inc, dba RespirTech, St Paul, MN. [2005-present].

#### Triangle waveform, the newest HFCC technology

In a recent peer-reviewed study comparing the differences in output characteristics between the triangle waveform and a competing sine waveform machine, data suggest that therapeutic effects may be better with triangle waveform machines than those that rely upon the older technology.<sup>26</sup>

In eight participating CF subjects, therapy with a triangle waveform device yielded a 20% mean increase in volumes of mucus cleared, with a range of improvement up to 41%. The shape of the waveform delivered by HFCC machines appears to be important in maximizing mucus clearance. The triangle waveform, in contrast to the sine waveform, appears to be more effective because peak airflow and maximum lung volumes occur at the same frequencies. HFCC with the triangle waveform is judged more comfortable as a result of the shorter duration of peak pressure and venting to atmospheric pressure.

In a second study, the practical advantages of triangular waveform therapy surpass those of professionally administered CPT.<sup>27</sup> A third unpublished study comparing airway clearance efficacy of sine and triangular waveform HFCC machines in cystic fibrosis patients was presented as a paper and poster in 2006 at the Twentieth Annual North American Cystic Fibrosis Conference.<sup>44</sup>

Fifteen stable CF patients were randomly allocated to receive one 30-minute treatment with each of two high frequency chest compression (HFCC) machines, The Vest airway clearance system model 104 (Hill-Rom, St. Paul MN) and the inCourage System, aka ICS (RespirTech, St. Paul MN). A two-day washout interval separated sessions; double-blinding was attempted.

Several outcomes trended in favor of the triangle waveform inCourage System machine, including greater sputum production, lower residual lung volumes (suggesting less air-trapping), increased forced expiratory volume (FEV) (suggesting greater ability to generate a mucus-clearing cough), changes in mucus viscosity and elasticity and in mucus cough transportability.

Within a decade of its introduction, HFCC gained recognition as standard of care therapy for patients with mucociliary dysfunction arising from a broad range of causes. An estimated 70% of American CF patients use HFCC as their primary airway clearance modality. However, at least 85% of patients currently using HFCC have other primary diagnoses. An estimated 50,000 patients, 9,300 physicians, 2500 hospitals and 1,100 health plans have used, prescribed or reimbursed HFCC machines. Numerous peer-reviewed clinical trials demonstrate both safety and efficacy of the device in diverse patient populations.<sup>29-41</sup> The therapy is recognized as standard of care in the medical literature and respiratory medicine text books.<sup>46-47</sup> Among modern modalities for the management of airway secretions, HFCC is by far the most thoroughly studied.<sup>48, 49</sup>

#### Summary

All currently available HFCC machines provide clinically effective therapy. Differences in design and performance characteristics may influence factors including peak efficacy,

comfort, adherence to prescribed treatments and patient preference. Recent, limited evidence suggests that waveform may be an important component of machine performance and that the triangle waveform may offer advantages. The actual significance of waveform differences in HFCC machines remains unclear. Further research, some currently in progress, should improve understanding of that aspect of the technology.

Physicians, providers and patients alike constantly seek improved therapies to maximize outcomes, improve quality of life and distribute care more equitably. HFCC technology has played a considerable role in advancing those goals. The most recent improvements, available in the inCourage System, have the potential to advance them further. HFCC is here to stay and efforts to improve the technology continue.

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*Continued on page 56...*

# New Weaning Tool Brings New Hope For Difficult To Wean Patients

Cindy Merideth, RRT

Cindy Merideth is with Kindred St Louis St Anthony's.

A challenge for Long Term Acute Care (LTAC) facilities is removing ventilatory support from ventilator-dependent patients. With the new Cadence System, a high-flow transtracheal oxygen device from Respironics, we are able to bridge this gap and extubate some of our most challenging patients. In this case study, after 4 months and several failed weaning attempts, the Cadence System played a crucial role in transitioning the patient from mechanical ventilator support to conventional oxygen therapy.

**Profile:** A 65-year-old male, post-MVA with multiple fractures and closed head injury, trached and mechanically ventilated was admitted to the LTAC hospital. Patient had a history of smoking, recurrent upper respiratory infections and COPD. He had been on ventilatory support for 32 days prior to the LTAC admission.

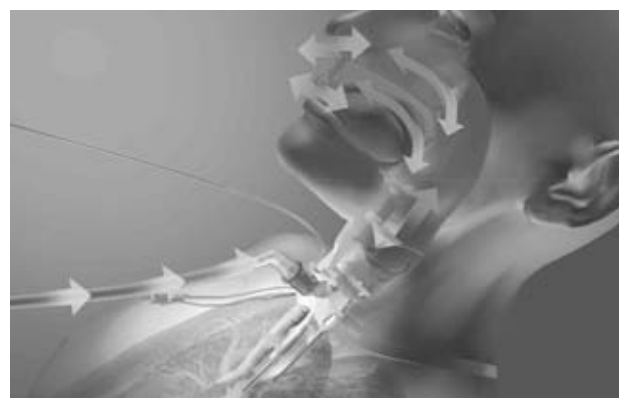
**Clinical Course:** Clinical status on admission: Patient looked older than his stated age, was alert and oriented to place and time. An increased anterior-posterior diameter was noted.

**Day 3:** Patient remained on CPAP for 3 days then developed increased work of breathing, increased respiratory rate to mid 30s, elevated heart rate in the 120s, and increased blood pressure. At this point, he was returned to the AC mode. Chest x-ray showed persistent basilar infiltrates as well as pleural effusions.

During the next few days, numerous attempts were made to wean from AC to CPAP, but each time the patient failed due to increase in respiratory rate. He complained of chest and abdominal pain, and developed problems with mucus plugging.

**Day 14:** Patient was discharged to the acute care hospital for lethargy and fever, ileus and abdominal pain, mucus plugging. Bronchoscopy removed secretions causing the mucus plugging. Four days later, after acute issues were resolved, the patient was returned to the LTAC hospital for another attempt to wean from mechanical ventilation.

**Two Months Later:** During the next two months, the patient repeatedly failed weaning attempts. He required re-admission to the acute care hospital and was treated for cardiac and iliac problems. On his third admission to the LTAC facility and his 134 day of mechanical ventilator support, the first Cadence™ Self-Breathing Trial was initiated. The patient was placed on 9 L/min of flow and a FIO<sub>2</sub> of 40%. His respiratory rate during the self-breathing trial was 22-24 BPM, and his heart rate was 88-100. He did not complain of shortness of breath or chest pains during the self-breathing trial. Four days later, mechanical ventilator support was removed and the patient placed on the Cadence Self-Breathing System. Three days later the trach was capped, and the patient was placed on conventional oxygen therapy until weaned to room air.



## Discussion

The Cadence Self-Breathing System is different from other methods used to conduct self-breathing trials. During a self-or spontaneous-breathing trial with a "T-Piece" or trach collar, the trach cuff is inflated, creating a closed system between the upper and lower airways. The patient is unable to breathe in and out normally through the vocal cords, nose and mouth.

The delivered gas blows by the trach opening, and the patient must work to draw the gas into the lungs.

In contrast, during a Cadence Self-Breathing Trial, the trach cuff is deflated, creating an open system that allows free-breathing. The patient is able to breathe normally in and out through the vocal cords, nose and mouth. The Cadence System delivers gas directly into the distal trachea, therefore, reducing the work required to draw the oxygen-enriched gas into the lungs. (Figure 1).

Ventilator Settings		Other Clinical Parameters	
Mode	CPAP	Respiratory Rate	31
PSV	20 cm H <sub>2</sub> O	Heart Rate	84
PEEP	5 cm H <sub>2</sub> O	Blood Pressure	130/70
FIO <sub>2</sub>	30%	Temperature	98° C
		Breath Sounds	Rhonchi and anterior wheezing

Ventilator Settings		Other Clinical Parameters	
Mode	AC	Respiratory Rate	28
Rate	10	Heart Rate	68
VT	500 ml	Blood Pressure	122/72
PEEP	5 cm H <sub>2</sub> O	Temperature	98.9° C
FIO <sub>2</sub>	30%	Breath Sounds	No rales or wheezes

# End Expiratory Oxygen Concentrations to Predict Central Venous Oxygen Saturation: An Observational Pilot Study

Alan E. Jones, Karl Kuehne, Michael Steuerwald and Jeffrey A. Kline

## Abstract

**Background:** A non-invasive surrogate measurement for central venous oxygen saturation (ScVO<sub>2</sub>) would be useful in the ED for assessing therapeutic interventions in critically ill patients. We hypothesized that either linear or nonlinear mathematical manipulation of the partial pressure of oxygen in breath at end expiration (EtO<sub>2</sub>) would accurately predict ScVO<sub>2</sub>.

**Methods:** Prospective observational study of a convenience sample of hemodialysis patients age > 17 years with existing upper extremity central venous catheters were enrolled. Using a portable respiratory device, we collected both tidal breathing and end expiratory oxygen and carbon dioxide concentrations, volume and flow on each patient. Simultaneous ScVO<sub>2</sub> measurements were obtained via blood samples collected from the hemodialysis catheter. Two models were used to predict ScVO<sub>2</sub>: 1) Best-fit multivariate linear regression equation incorporating all respiratory variables; 2) MathCAD to model the decay curve of EtO<sub>2</sub> versus expiratory volume using the least squares method to estimate the pO<sub>2</sub> that would occur at <20% of total lung capacity.

**Results:** From 21 patients, the correlation between EtO<sub>2</sub> and measured ScVO<sub>2</sub> yielded R<sup>2</sup> = 0.11. The best fit multivariate equation included EtCO<sub>2</sub> and EtO<sub>2</sub> and when solved for ScVO<sub>2</sub>, the equation yielded a mean absolute difference from the measured ScVO<sub>2</sub> of 8 ± 6% (range -18 to +17%). The predicted ScVO<sub>2</sub> value was within 10% of the actual value for 57% of the patients. Modeling of the EtO<sub>2</sub> curve did not accurately predict ScVO<sub>2</sub> at any lung volume.

**Conclusion:** We found no significant correlation between EtO<sub>2</sub> and ScVO<sub>2</sub>. A linear equation incorporating EtCO<sub>2</sub> and EtO<sub>2</sub> had at best modest predictive accuracy for ScVO<sub>2</sub>.

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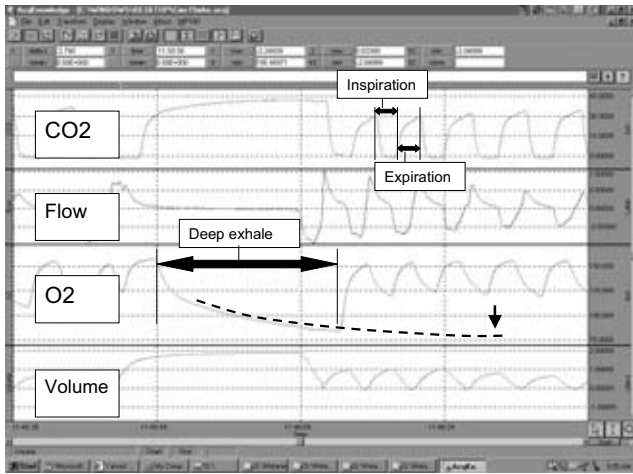
## Background

The mixed venous oxygen saturation (SVO<sub>2</sub>) is widely used in clinical practice to assess shock states and the physiologic response to resuscitation.<sup>1,2</sup> The central venous oxygen saturation (ScVO<sub>2</sub>) measurement correlates closely with SVO<sub>2</sub> and when necessary can be substituted as a less invasive surrogate to the SVO<sub>2</sub>.<sup>3</sup> When combined with other parameters, the use of ScVO<sub>2</sub> measurements for guiding resuscitation has been shown in one study to improve mortality in patients with septic shock.<sup>4</sup> Both the SVO<sub>2</sub> and ScVO<sub>2</sub> measurements require central venous cannulation and a catheter to be placed in either the right atrium or pulmonary artery, thus limiting the feasibility of this measurement in the emergency department (ED).<sup>5</sup> Accordingly, a non-invasive method to measure SVO<sub>2</sub> and ScVO<sub>2</sub> would be useful for critically ill ED patients requiring resuscitation.

Because the percentage of erythrocyte hemoglobin with bound oxygen varies with the partial pressure of oxygen in plasma according to a well-defined allosteric curve, the partial pressure of oxygen dissolved in plasma generally can be used with reasonable accuracy to predict the percentage of hemoglobin saturated with oxygen. Normally there is rapid equilibration of the partial pressure of oxygen between the alveolus and corresponding pulmonary arteriole at all intervals of the respiratory cycle. It would then seem logical that the partial pressure of oxygen in central venous blood would correlate directly with the nadir partial pressure of oxygen in deep expired breaths and thus provide a non-invasive method of estimating the ScVO<sub>2</sub>. The hypothesis of the present study states that the partial pressure of expired oxygen in end tidal breaths (EtO<sub>2</sub>) will correlate with ScVO<sub>2</sub>.

## Methods

We performed an observational proof of concept study of a convenience sample of ambulatory hemodialysis patients. This study was approved by the Institutional Review Board and Privacy Board of the Carolinas HealthCare System and all patients gave written informed consent to participate. The recommendations of the most current Helsinki Declaration were followed.



**Figure 1.** An example of the raw data that was analyzed from exhaled breath measurements. The third panel represents the partial pressure of expired oxygen. The long exhalation represents a voluntary deep exhalation, done on command as part of the data collection protocol. The superimposed dotted line hypothetically represents the regression equation where the zero slope portion, denoted by the arrow, represents the steady-state estimate of the partial pressure of oxygen in mixed venous blood. Inspiratory, expiratory and deep exhale cycles are annotated on the figure. CO<sub>2</sub> – carbon dioxide; Vol – volume; O<sub>2</sub> – oxygen.

Patients were recruited at the time they presented for routine hemodialysis at the kidney dialysis unit of Carolinas Medical Center, a large urban tertiary referral center with > 800 inpatient beds and an ED census of > 110,000 visits per year. The inclusion criteria for the study were age > 17 years and central venous hemodialysis catheter in either the internal jugular or subclavian vein. Exclusion criteria were a known heart condition resulting in either right to left or left to right cardiac shunting or non-invasive peripheral arterial oxygen saturation < 90%.

After subject identification and informed consent, we collected breaths using standardized protocol.<sup>6</sup> Briefly, just prior to initiation of hemodialysis and at the time the nurse accessed the central venous catheter, 2 mL of venous blood was obtained in a sodium heparin syringe, immediately placed on ice for analysis. Then, while in semi-Fowler's position, and wearing nose clips,

patients breathed into a duckbill-shaped mouthpiece in airtight connection with the airflow transducer. A research assistant provided help to the patient as needed. Patients delivered a sharp, rapid, deep exhalation to a maximum endpoint, starting from a midpoint of tidal breathing (ie, not delivered after a sigh inspiration) followed by a few normal breaths, and then a 30 second period of tidal breathing. This sequence was repeated three more times, yielding four deep exhalations and three 30-second samples of tidal breathing. At the time of enrollment patients were breathing room air.

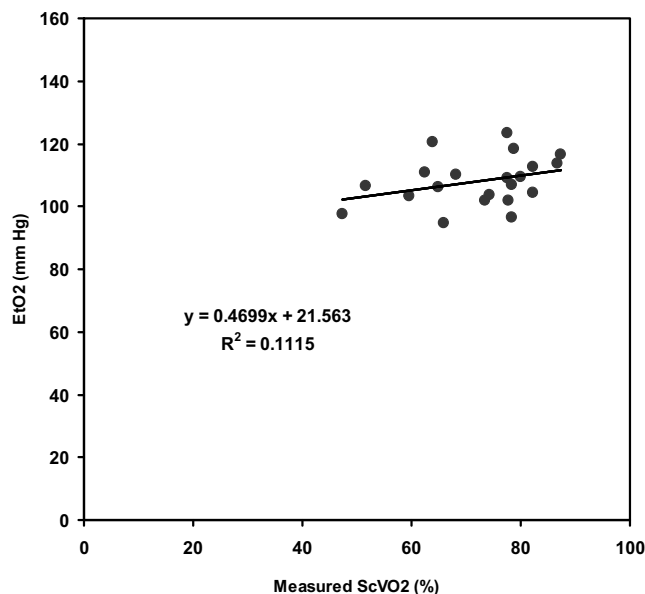
### Measurements

**Breath collection:** The device used to measure expired volume, expired partial pressure of carbon dioxide (EtCO<sub>2</sub>) and EtO<sub>2</sub> was constructed using commercially available components. Expired volume was quantitated by a pneumotach, airflow

**Table 1: Physiologic breath and blood measurements of all patients.**

Gender	Average Peak EtCO <sub>2</sub> (mmHg)	Average Minimum EtO <sub>2</sub> (mmHg)	Average Tidal Volume (L)	Average Peak Flow (L/sec)	Deep Exhaled Maximum EtCO <sub>2</sub> (mmHg)	Deep Exhaled Minimum EtO <sub>2</sub> (mmHg)	Average Measured ScVO <sub>2</sub> (%)	Predicted ScVO <sub>2</sub> (%)
F	28	107	0.10	0.25	38	99	63	67
F	35	115	0.21	0.32	38	111	82	74
F	47	97	0.23	0.14	52	79	78	72
M	29	125	0.40	0.13	38	105	77	76
M	40	108	0.50	0.10	41	107	78	75
M	47	101	0.10	0.10	44	106	82	76
M	36	111	0.51	0.55	40	99	80	70
F	39	106	0.20	0.20	37	107	73	68
F	45	100	0.12	0.13	49	93	78	75
M	38	116	0.40	0.40	42	104	87	78
F	46	112	0.25	0.30	50	105	77	83
M	21	123	0.30	0.60	33	114	47	59
M	37	114	0.30	0.25	40	106	52	70
M	32	123	0.33	0.34	40	110	64	76
M	44	100	0.21	0.32	45	100	66	69
F	33	109	0.23	0.50	32	113	74	66
M	31	116	0.30	0.40	34	103	86	68
M	37	111	0.34	0.50	40	107	65	71
M	45	108	0.24	0.15	50	97	60	77
M	35	122	0.14	0.33	43	114	79	78
M	40	123	0.41	0.43	42	114	68	81

EtO<sub>2</sub> – end-tidal oxygen; EtCO<sub>2</sub> – end-tidal carbon dioxide; ScVO<sub>2</sub> – central venous oxygen saturation; L – liters; mm Hg – millimeters of mercury; sec – second; M – male; F – female.



**Figure 2**

Regression analysis of the EtO<sub>2</sub> versus measured ScVO<sub>2</sub>. The Y-axis values were the average of four deep exhalation end tidal partial pressure of oxygen measurements and the X-axis values were the average of two duplicate oxygen saturation measurements of central venous blood specimens obtained from a hemodialysis catheter. EtO<sub>2</sub> – end-tidal oxygen; ScVO<sub>2</sub> – central venous oxygen saturation.

transducer (TSD127, Biopac Systems Inc, Santa Barbara, CA,) connected to a distal polycarbonate tube of same diameter fitted with a 4 millimeter lure-lock port for aspiration of gases. A low-resistance, 0.2 μm antimicrobial filter (1644 Intersurgical Inc., Liverpool, NY) was placed between the pneumotach and a duckbill-style mouthpiece (1565, Hudson Respiratory Care Inc, Temecula, CA). Expired carbon dioxide and oxygen were measured in side-stream fashion via separate vacuum pumps that each aspirated 12 milliliters/minute through 1 meter long, 3 millimeter internal diameter polyethylene tubing. Carbon dioxide and oxygen partial pressures were quantified in real time by infrared absorptometry and paramagnetic deviation (Biopac Systems Inc., Santa Barbara, CA). Both sensors were calibrated against two dry reference gases before each patient, and readings of reference gases were repeated immediately after data were collected from each patient to evaluate for calibration stability. The airflow transducer was tested against a volumetric calibration syringe (AFT 26 2L, Biopac Systems Inc., Santa Barbara, CA) immediately before and after each patient. Airflow, expired volume, continuous tracings of expired CO<sub>2</sub> and O<sub>2</sub> were recorded at body temperature, saturated with water and at ambient pressure, and were archived digitally using commercial analog-to-digital converter and commercial software (MP-100, and AcqKnowledge ACK100W, respectively, Biopac Instruments Inc., Santa Barbara, CA). For each measurement (flow, volume, EtO<sub>2</sub> and EtCO<sub>2</sub>) the average of the four different deep exhalation was used for data analysis.

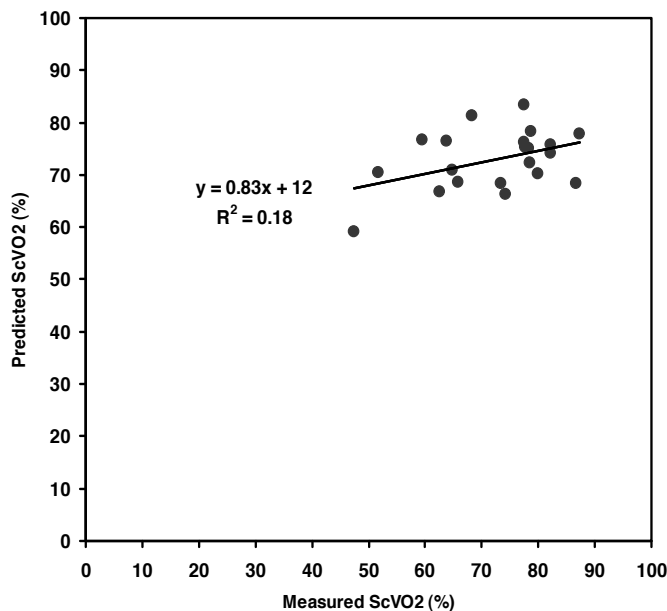
**Blood gas analysis:** Iced blood samples drawn from the hemodialysis catheters were transported within 3 minutes to a Stat Profile Ultra Analyzer (Nova Biomedical, Waltham, MA). Samples underwent analysis for measured percent oxygen saturation via co-oximetry. Samples were analyzed in duplicate and the average of the two readings was used for data analysis.

**Data analysis:** The breath measurements obtained were compared in a multivariate linear regression model to determine an equation that would best predict the ScVO<sub>2</sub> (Microsoft Excel,

Redmond, WA). The potential coefficients of the equation included EtO<sub>2</sub>, EtCO<sub>2</sub>, flow or volume. Figure 1 shows an example of the raw data that was analyzed. The third panel represents the partial pressure of expired oxygen. The long exhalation represents a voluntary deep exhalation, done on command as part of the data collection protocol. The superimposed dotted line hypothetically represents the regression equation where the zero slope portion, denoted by the arrow, represents the steady-state estimate of the partial pressure of oxygen in mixed venous blood. Additional analysis included modeling the decay curve of EtO<sub>2</sub> versus expiratory volume using the least squares method to estimate the EtO<sub>2</sub> that would occur at 5% increments between 0 and 20% of total lung capacity (MathCAD, Mathsoft, Cambridge, MA). Total lung capacity was estimated using standard curves based upon height, gender and age.<sup>7</sup> A sample size of 20 patients was estimated in order to generate sufficient raw breath data for extrapolation and modeling.

## Results

Twenty-one patients were enrolled over a 6 month period in 2004–2005. The average age was 51.4 years, 60 % were male, and the average hemoglobin concentration was 10.9 grams/deciliter (g/dl). No patients had a hemoglobin of < 9.5 g/dl. Figure 2 shows that there was no significant correlation between EtO<sub>2</sub> and measured ScVO<sub>2</sub> with an R<sup>2</sup> = 0.11. The best fit multivariate regression equation was ScVO<sub>2</sub> = -78.1 + 1.2 (EtCO<sub>2</sub>) + 0.95 (EtO<sub>2</sub>). When this equation was solved for ScVO<sub>2</sub>, as shown in Figure 3, there was no significant correlation between observed and predicted ScVO<sub>2</sub> values with an R<sup>2</sup> = 0.18, (P = 0.057 with power to detect 5% difference), standard error on slope 0.4, standard error for predicted ScVO<sub>2</sub> value = 2.3. When solved for ScVO<sub>2</sub>, the equation yielded a mean absolute difference from the measured ScVO<sub>2</sub> of 8 ± 6% (range -18 to +17%). The predicted ScVO<sub>2</sub> value was within ± 10% of the actual measured value for 12/21 (57%) of the patients. Table 1 shows the breath measurements for all patients. Least-squares modeling of the EtO<sub>2</sub> decay curve did not predict ScVO<sub>2</sub> at any lung volume with



**Figure 3**

Regression analysis of the predicted ScVO<sub>2</sub> versus measured ScVO<sub>2</sub>. The Y-axis values were derived from the equation Predicted ScVO<sub>2</sub> = -78.1 + 1.2(EtCO<sub>2</sub>) + 0.95(EtO<sub>2</sub>), and the X-axis values were the average of two duplicate oxygen saturation measurements of central venous blood specimens obtained from a hemodialysis catheter. EtO<sub>2</sub> – end-tidal oxygen; EtCO<sub>2</sub> – end-tidal carbon dioxide; ScVO<sub>2</sub> – central venous oxygen saturation.

any reasonable degree of accuracy (eg >50% of estimates at all lung volumes tested were more than 50% off of the target ScVO<sub>2</sub> value).

### Limitations

This report has several limitations to be addressed. First, because this was a feasibility study the sample size is small and which could contribute to an inaccurate estimation of the true predictive ability of exhaled breath measurements. Second, the patient population we studied were all hemodialysis patients. We chose hemodialysis patients because the ideal subjects for this study were ambulatory, not acutely ill, and had an indwelling central venous catheter that could be accessed for blood collection. We performed the measurements at the time of their routine dialysis so it is possible that sub-clinical pulmonary edema was present and led to inaccurate exhaled oxygen measurements. To the best of our knowledge none of the patients that we enrolled had upper extremity arterial-venous fistulas which could lead to shunting and confounding measurements. Additionally, expired gases were measured in side-stream fashion which could have resulted in inaccurate measurements. The deep exhaled pO<sub>2</sub> curve, measured by mainstream sampling with a rapid response oxygen probe and fitted by the least squares method may yield more accurate and precise estimations of ScVO<sub>2</sub>. Finally, we measured ScVO<sub>2</sub> ex vivo and it is possible if we had used a continuous central venous oximetry catheter or pulmonary artery catheter the results may have been different.

### Discussion

Development of an accurate and non-invasive method of measuring systemic oxygen balance would be extremely useful in the evaluation and management of critically ill patients in the ED. In this study we investigated the use of end expiratory breath measurements to predict central venous oxygen saturation. The best predictive equation we derived performed only modestly. We did not find sufficient predictive accuracy to justify further investigation of this method.

The importance of developing non-invasive methods of identifying and quantifying shock as well as guiding the resuscitation of critically ill patients is evidenced by the recent number of publications touting potential new methods and devices for these purposes. Impedance cardiography,<sup>8</sup> sublingual capnometry,<sup>9</sup> near infrared spectrometry to measure tissue oxygen hemoglobin saturation,<sup>10,11</sup> transcutaneous oxygen and carbon dioxide tensions,<sup>12</sup> vital signs<sup>13</sup> and combinations of these measurements<sup>14</sup> have all been reported to have value in identification and monitoring of shock. To our knowledge, no non-invasive technologies have gained widespread use in clinical practice for monitoring shock.

In this study we evaluated a relatively simplistic idea, that expired breath concentrations of oxygen or carbon dioxide would predict central venous oxygen saturation. These breath measurements are easy to obtain, non-invasive, not stressful for patients, and could be performed in spontaneously breathing or mechanically ventilated patients. This type of measurement would be ideal for evaluating and monitoring patients in an emergency department where more complex and invasive monitoring is often not feasible.<sup>5</sup> Unfortunately, we were unable to show any consistent or convincing relationship between exhaled breath measurements and central venous oxygen saturation.

### Conclusion

We found no significant correlation between EtO<sub>2</sub>, measured by side-stream oximetry and ScVO<sub>2</sub>. A linear equation incorporating EtCO<sub>2</sub> and EtO<sub>2</sub> had at best modest predictive accuracy. Least-squares extrapolation of the expired EtO<sub>2</sub> curve to low lung volumes produced erroneous estimations of ScVO<sub>2</sub>. We conclude that side-stream EtO<sub>2</sub> measurements cannot be used in a straight-forward mathematical model to estimate ScVO<sub>2</sub> at the bedside.

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# A Preliminary Study on the Monitoring of Mixed Venous Oxygen Saturation Through the Left Main Bronchus

Xiang-rui Wang, Yong-jun Zheng, Jie Tian, Zheng-hong Wang and Zhi-ying Pan

**Introduction:** The study sought to assess the feasibility and accuracy of measuring mixed venous oxygen saturation (SvO<sub>2</sub>) through the left main bronchus (SpO<sub>2</sub>trachea).

**Methods:** Twenty hybrid pigs of each sex were studied. After anesthesia, a Robertshaw double-lumen tracheal tube with a single-use pediatric pulse oximeter attached to the left lateral surface was introduced toward the left main bronchus of the pig by means of a fibrobronchoscope. Measurements of SpO<sub>2</sub>trachea and oxygen saturation from pulmonary artery samples (SvO<sub>2</sub>blood) were performed with an intracuff pressure of 0 to 60 cmH<sub>2</sub>O. After equilibration, hemorrhagic shock was induced in these pigs by bleeding to a mean arterial blood pressure of 40 mmHg. With the intracuff pressure maintained at 60 cmH<sub>2</sub>O, SpO<sub>2</sub>trachea and SvO<sub>2</sub>blood were obtained respectively during the pre-shock period, immediately after the onset of shock, 15 and 30 minutes after shock, and 15, 30, and 60 minutes after resuscitation.

**Results:** SpO<sub>2</sub>trachea was the same as SvO<sub>2</sub>blood at an intracuff pressure of 10, 20, 40, and 60 cmH<sub>2</sub>O, but was reduced when the intracuff pressure was zero ( $p < 0.001$  compared with SvO<sub>2</sub>blood) in hemodynamically stable states. Changes of SpO<sub>2</sub>trachea and SvO<sub>2</sub>blood corresponded with varieties of cardiac output during the hemorrhagic shock period. There was a significant correlation between the two methods at different time points.

**Conclusion:** Measurement of the left main bronchus SpO<sub>2</sub> is feasible and provides similar readings to SvO<sub>2</sub>blood in hemodynamically stable or in low saturation states. Tracheal oximetry readings are not primarily derived from the tracheal mucosa. The technique merits further evaluation.

## Introduction

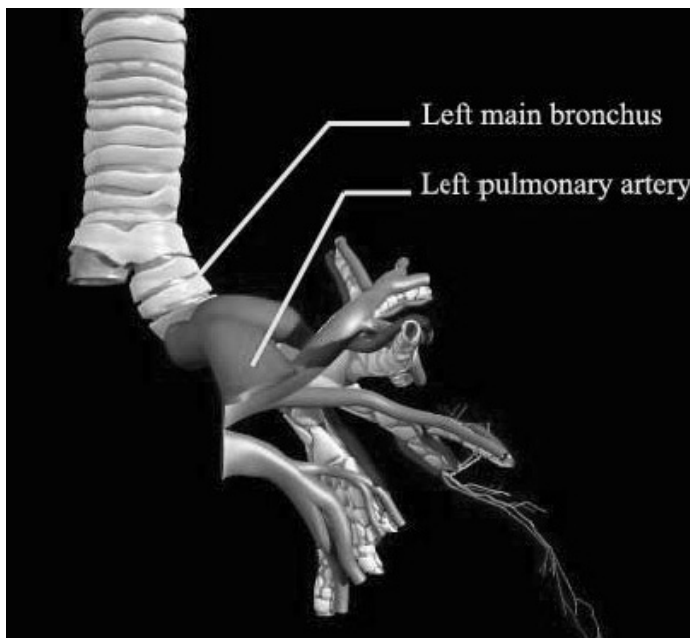
The saturation of haemoglobin with oxygen in the pulmonary artery is known as the mixed venous oxygen saturation (SvO<sub>2</sub>), which reflects the balance between the amount of oxygen delivered to the tissues and how much is used. It enables an estimate of the oxygen supply/demand balance to be made and hence enhances our comprehension of physiological concepts of hemodynamics and tissue oxygenation in critically ill patients. However, the routine measurement of SvO<sub>2</sub> requires the placement of a pulmonary artery catheter (PAC), which may not always be feasible. Furthermore, a substantial review of literature suggests at present that the use of PAC may lead to an overall increase in morbidity and mortality in critically ill patients,<sup>1,2</sup> stimulating the quest for a micro-invasive tool for assessing SvO<sub>2</sub>.

Pulse oximetry has been widely adopted in anesthesia and critical care medicine to provide noninvasive information about arterial oxygen saturation (SaO<sub>2</sub>). Several studies have demonstrated that oximeters placed in deep, vessel-rich areas such as the esophagus,<sup>3</sup> pharynx,<sup>4</sup> and trachea<sup>5</sup> seemed to provide more accurate readings than superficial oximetry. The tissue being sampled was once assumed to be the surrounding mucosa,<sup>3</sup> but recent studies have shown that the signals were derived primarily from deeper tissues, such as underlying large vessels around the esophagus and trachea.<sup>5,6</sup>

The pulmonary artery lies close to the bronchus, with nothing but some connective tissues between them, raising the possibility that an appropriately located and directed bronchial oximetry probe might be able to derive oximetry readings from mixed venous blood (Figure 1). The present study was undertaken to test the feasibility of measuring SvO<sub>2</sub> through the left main bronchus (SpO<sub>2</sub>trachea), and to compare SpO<sub>2</sub>trachea

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Anatomic relationship between the left main bronchus and the left pulmonary artery.

with oxygen saturation from pulmonary artery samples ( $SvO_2$ blood) in a healthy hybrid pig to improve our understanding of the hypothesis that bronchial oximetry readings are derived primarily from the pulmonary artery, not from the tracheal mucosa. Furthermore, the stability and accuracy of  $SpO_2$ trachea were evaluated by assessing the impact of altered cardiac output on tracheal  $SpO_2$  in hemorrhagic shock status.

### Materials and methods

**Anesthesia and surgical preparation:** The study was approved by the rules of Veterinary Medicine and Animal Care. After 12 hours of fasting, 20 Shanghai hybrid pigs (Shanghai University, Shanghai, China) of both sexes, weighing  $50.7 \pm 3.2$  kg, were premedicated intramuscularly with ketamine (20 mg  $kg^{-1}$ ) and atropine (0.04 mg  $kg^{-1}$ ). Anesthesia was maintained by the intermittent application of pentothal sodium (2.5%) and diazepam. After endotracheal intubation of a Robertshaw double-lumen tracheal tube (details are given in the section on fabrication of the measuring catheter and intubation), the animals were ventilated mechanically with oxygen. The ventilation rate was 16 breaths  $min^{-1}$ , and the respiratory tidal volume was set to 10 to 15 ml  $kg^{-1}$  body weight to adjust the end-expiratory partial pressure of  $CO_2$  to 4.5 to 6.0 kPa. The Inspire:Expire (I:E) ratio was 1:2. Respiratory rates, tidal volume and concentrations of oxygen and carbon dioxide were adjusted in accordance with periodic blood gas analysis to keep adequate blood pH. The right femoral artery was cannulated with a 22-gauge catheter connected to a pressure sensor to measure the mean artery pressure. The left femoral vein was cannulated with a 7F Swan-Ganz catheter, which was positioned according to the wave form, for intermittent sampling of pulmonary arterial blood for blood gas analysis. The right internal jugular vein was cannulated with a catheter to provide a venous line for infusion and anesthesia. Throughout the experiments, all animals received a Ringer lactate solution infusion at a rate of 10 ml  $kg^{-1}$  h<sup>-1</sup>. Electrocardiograph, heart rate and mean artery pressure were monitored continuously.

**Refitting the oximetry probe, and stability test:** Because a pulse oximeter stops working when in contact with water or another

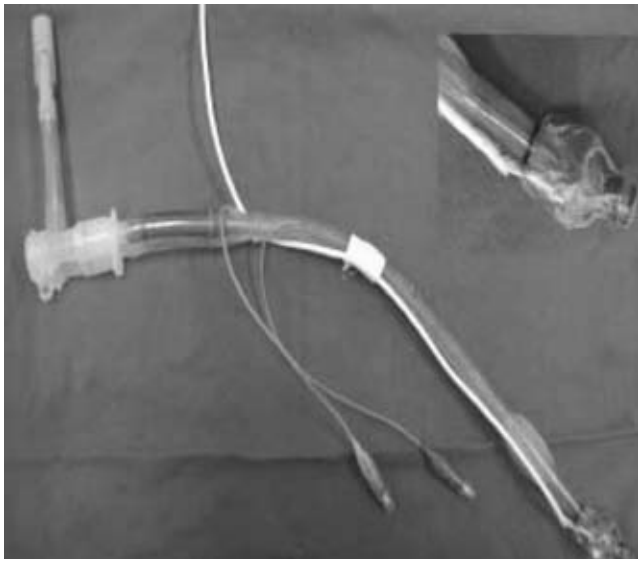
fluid, it should be waterproofed before use. The processing of disposable single-use pediatric pulse oximeters (Datex Medical Instrumentation, Helsinki, Finland) adopted in our experiments was as follows. First the fixed membrane was removed, the light emitter and sensor were exposed, then a surface coat of medical silica gel (provided by Shanghai Latex Institute) was applied, leaving it to solidify at normal temperature for 72 hours. Medical silica gel is made from pure silica gel with very thin texture. It is capable of forming a fine surface coating and can withstand a certain level of friction and tension after full solidification at normal temperature. Pulse oximetry of the tongue was obtained with both the refitted oximetry probe and the original probe. The readings were compared to test the stability and accuracy of the refitted probe.

**Fabrication of the measuring catheter, and intubation:** After inflation of the left lateral cuff portion of a Robertshaw double-lumen tracheal tube (37F), the light emitter and sensor of the waterproof oximeter were fixed along the longitudinal axis of the tracheal tube, and the infrared probe of the light emitter and the light-sensitive surface of the light sensor were faced in the same direction. The sensor was wrapped with copper foil except for a small window to expose the light-sensitive plate. A distance of 1 cm was left between the two terminals. Then the oximeter probe was fixed to the tube with a medical membrane, with two holes in the position of the light emitter and sensor to avoid any possible interference, as shown in Figure 2.

After anesthesia, the head and neck of the pig were positioned in the midline, with the occiput on a pillow 7 cm in height. The tracheal tube was inserted into the left main bronchus under the guidance of a pediatric fibrobronchoscope, and positioned at adequate depth and in an appropriate direction (the pilot open chest study had proved that a depth of 2 to 3 cm was adequate and that an appropriate direction was 15 to 20° leftleaning to the midline) to ensure that it was on the opposite side of the left pulmonary artery. Then the oximeter was connected to a monitor (Datex AS/3; Datex Medical Instrumentation) that had been previously checked and calibrated to ensure that it gave the same reading when attached to the same probe. The tracheal tube was fixed once the oxygen saturation curve had become a sine wave, and the position of the oximeter was confirmed by ultrasound and chest radiology (Figure 3).

**Changes in  $SvO_2$  with intracuff pressure:**  $SpO_2$ trachea was measured during a hemodynamically stable period of anesthesia. Readings were allowed to stabilize for two minutes before they were recorded. At the same time pulmonary arterial blood was collected and analyzed to measure  $SvO_2$ blood (Series 800; Chiron Diagnostics GmbH, Salzburg, Austria). The arterial blood gas monitor was accurate to 0.01% ( $SaO_2$ ) and calibrated before each case. Readings were taken with an intracuff pressure of 0, 10, 20, 40, and 60  $cmH_2O$ . The intracuff pressure was set with a digital cuff pressure monitor (Digital P-V Gauge; Mallinckrodt Medical). One set of observations was obtained in each animal at each cuff pressure. All observations were made in a hemodynamically stable period.

**Changes in  $SvO_2$  in hemorrhagic shock status:** The same 20 pigs were used in the present study. After instrumentation, pigs were allowed to equilibrate for 30 minutes; they then underwent a standardized controlled hemorrhage to a mean artery pressure of 40 mmHg and were maintained at this level for 60 minutes. During hemorrhage, the blood was stored in a closed reservoir



The Robertshaw double-lumen tracheal tube attached to a single-use pediatric pulse oximeter.



The position of the oximeter confirmed by ultrasound. A minor-axis cross-section of parasternal great vessels is shown, and is representative of 20 subjects. AV, aortic valve; PA, pulmonary artery; PV, pulmonary vein.

primed with sodium citrate and pig heparin to inhibit clot formation. At the end of 60 minutes, animals were resuscitated with the preserved shed blood, which was withdrawn from the pig to induce hypotension, and an equal volume of lactated Ringers to restore the baseline mean artery pressure. Cardiac output was assessed by the thermal dilution method during the procedure. The intracuff pressure was kept at 60 cmH<sub>2</sub>O. SpO<sub>2</sub>trachea and SvO<sub>2</sub>blood were measured at the pre-shock period, immediately after the onset of shock, 15 and 30 minutes after shock, and 15, 30 and 60 minutes after resuscitation.

Statistical analysis: Results are reported as means ± SEM and analyzed with a pair-matching t test and linear regression. To compare the accuracy of the new method, Bland–Altman plots were used.  $p < 0.05$  was considered statistically significant.

## Results

Stability and accuracy of the refitted oximetry probe: Pulse oximetry of the tongue was obtained with both the refitted oximetry probe (SpO<sub>2</sub>refit) and the original probe (SpO<sub>2</sub>origin) to test the stability and accuracy of the refitted probe. SpO<sub>2</sub>refit was similar to SpO<sub>2</sub>origin when the probe contacted tightly with the tongue ( $p > 0.05$ ). The readings did not vary with changing intracuff pressure, and there was significant correlation between the two kinds of probe ( $p < 0.01$ ; Table 1). However, SpO<sub>2</sub>refit was significantly lower than SpO<sub>2</sub>origin if there were spaces between the probe and the tongue ( $p < 0.001$ ).

Correlations between SpO<sub>2</sub>trachea and the intracuff pressure in normal situation: The age and weight ranges of the pigs were 6–8 months and 45–55 kg, respectively. The male:female ratio was 8:12. The mean (range) core temperature during the readings was 36.4°C (36.0 to 36.9°C) with the room temperature maintained at 21°C. SpO<sub>2</sub>trachea was the same as SvO<sub>2</sub>blood at an intracuff pressure of 10 to 60 cmH<sub>2</sub>O with no significant differences ( $p > 0.05$ ) but significant correlations ( $p < 0.01$ ) between each other (Tables 2 and 3). Values of SvO<sub>2</sub>blood did not vary with changing intracuff pressure, but SpO<sub>2</sub>trachea was lower when intracuff pressure was zero. There were significant differences between them ( $p < 0.001$ ; Tables 2 and 3).

Bland–Altman graphs for SpO<sub>2</sub>trachea versus SvO<sub>2</sub>blood are presented in Figure 4.

Changes in SpO<sub>2</sub>trachea in hemorrhagic shock status and correlations between SpO<sub>2</sub>trachea and SvO<sub>2</sub>blood: With the intracuff pressure maintained at 60 cmH<sub>2</sub>O, changes in SpO<sub>2</sub>trachea and SvO<sub>2</sub>blood were due to variations in cardiac output during the hemorrhagic shock period (Table 4). There was significant correlation between SpO<sub>2</sub>trachea and SvO<sub>2</sub>blood ( $p < 0.01$ ; Table 5). Bland–Altman analysis revealed excellent accordance between the two methods, with only a few points located outside the “limits of agreement” area (Figure 5).

## Discussion

SvO<sub>2</sub> reflects the balance between oxygen delivery and demand. It decreases when oxygen delivery has been compromised or systemic oxygen demands have exceeded supply. Its ability to give a real-time indication of tissue oxygenation makes it a preferred parameter for monitoring the adequacy of hemodynamics. In comparison with traditional parameters such as arterial oxygen saturation and cardiac output, SvO<sub>2</sub> allows a more precise understanding of the adequacy of cardiac and pulmonary function. Declines in SvO<sub>2</sub> precede the onset of inadequate myocardial function, shock, or the development of arrhythmias, even though vital signs may be normal. Its use as an end point for determining the adequacy of hemodynamics (blood pressure, cardiac output/cardiac index), measurement of right to left shunt, and prediction of potential hemodynamic instability makes this parameter invaluable for the knowledgeable clinician. There is now evidence that the timing of diagnostic and therapeutic intervention using this technology may be a critical determinant of outcome.<sup>7</sup>

The PAC, otherwise known as the Swan–Ganz catheter, was developed by cardiologists HJC Swan and William Ganz in 1970. It is a flexible balloon-tipped flow-directed catheter that, when inserted via central venous access, can be guided into a branch of the pulmonary artery. Its ability to provide continuous measurements of SvO<sub>2</sub> in critically ill patients makes its use invaluable in the provision of quality medical care. However,

**Table 1****Comparisons of pulse oximetry measurements on the tongue with the original and refitted oximetry probes**

Concentration of inspiratory oxygen (%)	<i>n</i>	Oxygen saturation (%)		Correlation coefficient ( <i>r</i> )
		SpO <sub>2refit</sub>	SpO <sub>2origin</sub>	
100	10	100	100	1.0
21	10	93.2 ± 2.4 (92–96)	93.4 ± 2.7 (91–96)	0.95
10	10	81.5 ± 2.2 (77–84)	81.1 ± 2.5 (78–85)	0.94

Values are means ± SEM (range). SpO<sub>2origin</sub>, pulse oximetry obtained with the original oximetry probe; SpO<sub>2refit</sub>, pulse oximetry obtained with the refitted oximetry probe.

**Table 2****Oxygen saturation measurements in physiological states**

Intracuff pressure (cmH <sub>2</sub> O)	<i>n</i>	Oxygen saturation (%)	
		SpO <sub>2trachea</sub>	SvO <sub>2blood</sub>
0	20	70.2 ± 6.2 (57–76)	74.4 ± 4.3 (62.6–76.4)
10	20	74.2 ± 4.7 (62–77)	74.4 ± 4.4 (62.5–76.9)
20	20	74.2 ± 4.8 (62–77)	74.3 ± 4.3 (62.4–76.7)
40	20	74.2 ± 4.6 (61–76)	74.4 ± 4.3 (62.3–76.9)
60	20	74.2 ± 4.6 (62–77)	74.3 ± 4.4 (62.5–77.1)
Overall	100	72.5 ± 6.8 (57–77)	74.4 ± 6.3 (61.9–77.2)
Overall excluding 0 cmH <sub>2</sub> O	80	74.2 ± 4.2 (61–77)	74.4 ± 4.3 (61.2–77.6)

Values are means ± SEM (range). SpO<sub>2trachea</sub>, mixed venous oxygen saturation measured through the left main bronchus; SvO<sub>2blood</sub>, oxygen saturation from pulmonary artery samples.

controversy surrounding the efficacy and safety of the PAC has been going on for many years. The complications can be categorized as those of the initial venous cannulation (subclavian or carotid artery laceration, pneumothorax, thoracic duct laceration, phrenic nerve injury, and air embolism) and those due to the catheter itself (ie, arrhythmias, infection, valvular damage, thrombosis, pulmonary infarction, and rupture of the pulmonary artery). At the same time, the device requires a trained operator and is time-consuming. Moreover, it is expensive, bringing high healthcare costs.

There is therefore a powerful need for a method to measure SvO<sub>2</sub> more safely. Other researchers have developed the technique of deriving oximetry readings of arterial blood through the trachea, or right and left ventricular oximetry through the esophagus.<sup>5,8</sup> The pulmonary artery is known to lie just proximal to the left bronchus. This evaluation of the anatomy made it practical to measure oximetry readings from the mixed venous circulation through the left main bronchus. However, so far no such studies have been reported. The present study establishes the first investigation to assess SvO<sub>2</sub> microinvasively according to the above anatomic and technological bases.

Waterproofing is crucial for the proper function of oximeters in the humid environment of the trachea. Our experiment employed medical silica gel as a surface coat, because silica gel is waterproof and is nontoxic to humans. It can solidify fully at normal temperature, thus avoiding potential damage to the oximeter caused by thermal treatment. Moreover, it can endure a certain level of friction and tension after solidification.

Because the pulmonary artery and the bronchus run nearly parallel, with sufficient overlapping area in the longitudinal direction, the light emitter and sensor of the oximeter are affixed along the same direction on the tracheal tube. As a result, the probe turned from a penetrating model (the light emitter and sensor being aligned opposite each other) into a reflecting model (the two terminals lying side by side). Experimental results indicate that the optimum distance between the emitter and sensor should be close to 1 cm. If the two terminals are too close, transmitting signals will be attenuated, which will affect the stability and accuracy of the data. Conversely, an increase in distance will negatively affect the reception efficiency of the infrared reflection signal.

Despite the above changes to the oximetry probe, high-quality signals were still available. We found that SpO<sub>2refit</sub> of the tongue was accurate at different inspiratory oxygen concentrations, in different head and neck positions, and over a prolonged period, suggesting good stability and sensitivity of the refitted probe.

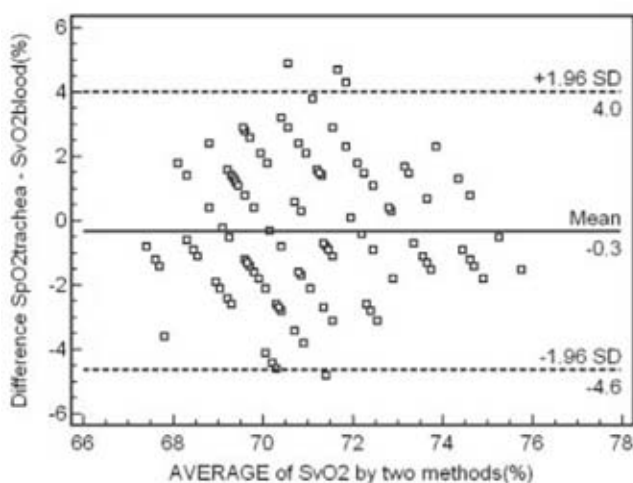
The ability to localize the oximetry probe accurately is pivotal to the experiment. An experiential position 2 to 3 cm deep in the bronchus and an orientation of 15 to 20° left-leaning to the midline for the tracheal tube was found in our pilot study. To ensure that the tube was advanced to the optimal location, the animal should be fixed beforehand, and the position of the tube should be confirmed by electrocardiography.

Supported by the foregoing statement, our data showed that the reading of SpO<sub>2trachea</sub> was close to SvO<sub>2blood</sub> in stable

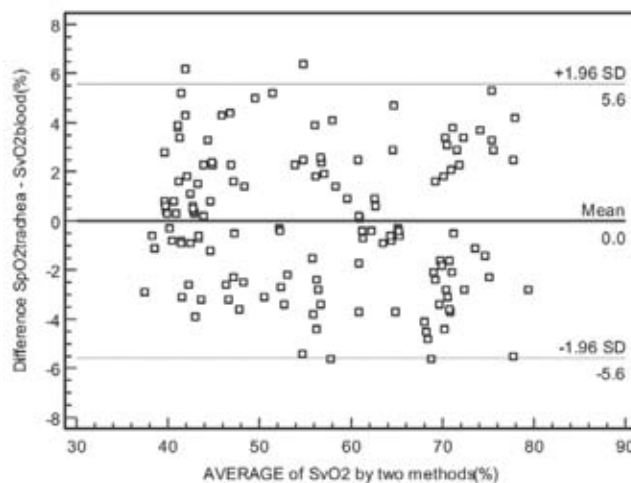
**Table 3****Between-method statistical comparisons for the oxygen saturation measurement (SpO<sub>2trachea</sub> versus SvO<sub>2blood</sub>)**

Intracuff pressure (cmH <sub>2</sub> O)	n	MD (%)	SD	SEM	LOA	SEL
0	20	4.87	3.10	0.73	-1.33 to 11.07	1.201
10	20	0.25	0.97	0.21	-1.69 to 2.19	0.376
20	20	0.22	0.89	0.19	-1.56 to 2.00	0.345
40	20	0.31	0.66	0.14	-1.01 to 1.63	0.256
60	20	0.17	0.74	0.18	-1.31 to 1.65	0.287
Overall	100	1.26	2.39	0.25	-3.52 to 6.04	0.414
Overall excluding 0 cmH <sub>2</sub> O	80	0.24	0.68	0.17	-1.12 to 1.6	0.132

LOA, limits of agreement (MD  $\pm$  1.96SD); MD, mean difference; SD, standard deviation of the difference; SEL, standard error of limit; SEM, standard error of the mean difference; SpO<sub>2trachea</sub>, mixed venous oxygen saturation measured through the left main bronchus; SvO<sub>2blood</sub>, oxygen saturation from pulmonary artery samples.

**Figure 4**

The accuracy of the new method in hemodynamically stable status. Shown is a Bland–Altman graph comparing the difference between mixed venous oxygen saturation through the left main bronchus (SpO<sub>2trachea</sub>) and oxygen saturation from pulmonary artery samples (SvO<sub>2blood</sub>) versus the mean oxygen saturation by the 'gold standard' and the new method in hemodynamically stable status.

**Figure 5**

The accuracy of the new method in hemorrhagic shock status. Shown is a Bland–Altman graph comparing the difference between mixed venous oxygen saturation through left main bronchus (SpO<sub>2trachea</sub>) and oxygen saturation from pulmonary artery samples (SvO<sub>2blood</sub>) versus the mean oxygen saturation by the 'gold standard' and the new method in hemorrhagic shock status.

physiological situations at 10 to 60 cmH<sub>2</sub>O cuff pressure. The readings obtained at zero cuff pressure were probably low because of a lack of contact between the probe and the trachea. The SpO<sub>2trachea</sub> was thought not to be derived primarily from the tracheal mucosa, because tracheal mucosal perfusion ceases when the intracuff pressure exceeds 50 cmH<sub>2</sub>O, and there was no decrease in the accuracy of SpO<sub>2trachea</sub> with increasing intracuff pressure. The blood flowing through the left pulmonary artery was speculated to be the mass of tissue sampled by the tracheal oximetry probe. At the same time, our study showed that SpO<sub>2trachea</sub> was consistent with SvO<sub>2blood</sub> in low cardiac output status during the hemorrhagic shock period. This measurement demonstrated that the precision of measuring SvO<sub>2</sub> through the left main bronchus was not influenced in a pathological state, suggesting great reliability of this technique in operation and for patients in intensive care units. Although ventilation with a double-lumen tube is itself an invasive procedure, its advantage in causing much fewer lesions than PAC cannulation, and in avoiding the multiple complications that accompany the PAC device, makes this

technique particularly appropriate for critically ill patients.

However, several limitations of the present investigation should be noted. First, our device was homemade, with the oximeter probe fixed to the endoscope by tape. Damage to the mucosa of the trachea is possible, and accidental inhalation would occur if the probe exfoliated. Furthermore, to reduce complications, a small tracheal tube and thin wire were required. However, it would be possible to incorporate the oximeter within the cuff and the wire within the tube and in so doing to reduce the complication of damage or accidental inhalation and allow a larger tube to be used to decrease the risk of trauma. Secondly, there were difficulties with locating the probe in the left bronchus. In addition to adjusting the tube repeatedly, ultrasound is required to confirm the position of the oximeter. The technique for location merits further investigation.

**Conclusion**

Measurement of SpO<sub>2</sub> via the left main bronchus is feasible and provides similar readings to SvO<sub>2blood</sub> in both

**Table 4****Changes in SpO<sub>2trachea</sub> and SvO<sub>2blood</sub> in hemorrhagic shock status**

Time	n	Oxygen saturation (%)	
		SpO <sub>2trachea</sub>	SvO <sub>2blood</sub>
Pre-shock period	20	74.6 ± 4.5 (62–78)	74.3 ± 4.7 (62.6–76.8)
Immediately after onset of shock	20	74.2 ± 4.3 (60–78)	74.8 ± 4.6 (61.9–77.2)
15 min after shock	20	61.2 ± 4.8 (52–67)	61.7 ± 4.3 (52.4–68.2)
30 min after shock	20	42.2 ± 4.6 (41–54)	42.8 ± 4.7 (41.3–55.9)
15 min after resuscitation	20	51.8 ± 4.6 (49–63)	51.3 ± 4.4 (49.5–62.6)
30 min after resuscitation	20	64.5 ± 6.8 (57–77)	64.2 ± 6.3 (57.9–77.2)
60 min after resuscitation	20	74.2 ± 4.2 (61–77)	74.4 ± 4.3 (61.2–77.6)

Values are means ± SEM (range). SpO<sub>2trachea</sub>, mixed venous oxygen saturation measured through the left main bronchus; SvO<sub>2blood</sub>, oxygen saturation from pulmonary artery samples.

**Table 5****Between-method statistical comparisons for oxygen saturation measurements in hemorrhagic shock status (SpO<sub>2trachea</sub> versus SvO<sub>2blood</sub>)**

Time	n	MD (%)	SD	SEM	LOA	SEL
Pre-shock period	20	-0.845	3.065	0.685	-6.975 to 5.285	1.187
Immediately after onset of shock	20	0.495	3.014	0.674	-5.533 to 6.523	1.167
15 min after shock	20	-0.165	3.210	0.718	-6.585 to 6.255	1.243
30 min after shock	20	-1.275	2.759	0.617	-6.793 to 4.243	1.069
15 min after resuscitation	20	-0.315	1.509	0.3374	-3.333 to 2.703	0.584
30 min after resuscitation	20	0.460	2.463	0.551	-4.466 to 5.386	0.954
60 min after resuscitation	20	1.865	2.844	0.636	-3.823 to 7.553	1.101

LOA, limits of agreement (MD ± 1.96SD); MD, mean difference; SD, standard deviation of the difference; SEL, standard error of limit; SEM, standard error of the mean difference; SpO<sub>2trachea</sub>, mixed venous oxygen saturation measured through the left main bronchus; SvO<sub>2blood</sub>, oxygen saturation from pulmonary artery samples.

hemodynamically stable status and hemorrhagic shock status. Tracheal oximetry readings are not derived primarily from the tracheal mucosa. This technique is capable of providing continuous and microinvasive measurements of SvO<sub>2</sub> despite the difficulty in achieving proper location of the probe. Further improvement is required for convenience of operation.

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# Dyspnea Assessment and Adverse Events During Sputum Induction in COPD

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## Abstract

**Background:** The inhalation of normal or hypertonic saline during sputum induction (SI) may act as an indirect bronchoconstrictive stimulus leading to dyspnea and lung function deterioration. Our aim was to assess dyspnea and adverse events in COPD patients who undergo SI following a safety protocol.

**Methods:** Sputum was induced by normal and hypertonic (4.5%) saline solution in 65 patients with COPD of varying severity. In order to minimize saline-induced bronchoconstriction a protocol based on the European Respiratory Society sputum induction Task group report was followed. Dyspnea change was scored using the Borg scale and lung function was assessed by spirometry and oximetry.

**Results:** Borg score changes [median(IQR) 1.5(0–2)] were observed during SI in 40 subjects; 16 patients required temporary discontinuation of the procedure due to dyspnea-general discomfort and 2 did not complete the session due to dyspnea-wheezing. The change in Borg dyspnea score was significantly correlated with oxygen saturation and heart rate changes and with discontinuation of the procedure due to undesired symptoms. 19 subjects presented an hyperresponsive reaction (decline >20% from baseline FEV<sub>1</sub>). No significant correlation between Borg changes and FEV<sub>1</sub> decline was found. Patients with advanced COPD presented significantly greater Borg and oxygen saturation changes than patients with less severe disease ( $p = 0.02$  and  $p = 0.001$ , respectively). Baseline FEV<sub>1</sub>, oxygen saturation and 6MWT demonstrated significant diagnostic values in distinguishing subjects who develop an adverse physiologic reaction during the procedure.

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**Conclusion:** COPD patients undergoing SI following a safety protocol do not experience major adverse events. Dyspnea and oxygen desaturation is more likely to occur in patients with disease in advanced stages, leading to short discontinuation or less frequently to termination of the procedure. Baseline FEV<sub>1</sub>, oxygen saturation and 6MWT may have a prognostic value for the development of these adverse events and might be useful to be evaluated in advance.

## Background

Induced sputum examination is a relatively non invasive method standardized by Pin et al<sup>1</sup> as an alternative to bronchoscopy procedure for collecting secretions and inflammatory cells from the airways of subjects with Chronic Obstructive Pulmonary Disease (COPD) and bronchial asthma. The method consists of the induction of airways secretions after the inhalation of progressively increased concentrations of saline aerosol. It is more feasible than bronchoscopy and is considered to provide repeatable and valid results.<sup>2</sup>

However, the inhalation of normal or hypertonic saline, may also act as an indirect bronchoconstrictive stimulus in subjects with airflow limitation, leading to further lung function deterioration and worsening of symptoms such as dyspnea.<sup>2</sup> Concerns about the safety of the procedure have been raised especially after the report of a fatal asthma attack, precipitated by inhalation of distilled water.<sup>3</sup> In asthma, the method is considered safe when standard guidelines are applied.<sup>4</sup>

In COPD lung function deterioration has been reported during the procedure.<sup>5-7</sup> European Respiratory Society (ERS) sputum induction Task group report<sup>5</sup> has underlined the lack of systematic studies addressing safety issues in patients with advanced COPD. In previous studies<sup>6-10</sup> the main objective was mainly the lung function changes and forced expiratory volume in one second (FEV<sub>1</sub>) decline during SI but, little attention was paid in the worsening of dyspnea. However, dyspnea development during SI may affect the tolerability of the method in COPD.<sup>8-10</sup> Thus, for research purposes or for clinical studies investigating cells or mediators measurable in sputum, it is

**Table 1: Baseline characteristics of all 65 COPD patients**

Age, yrs	66(1)
M/F	60(92)/5(8)
Current/ex smokers	21(32)/44(68)
Pack years	53(3.9)
FEV <sub>1</sub> (% predicted)	48(2.4)
FEV <sub>1</sub> /FVC	0.46(0.07)
Oxygen saturation %	92(0.4)
MRC dyspnea score	1 (0–4)
Chronic cough	44(6)
Chronic sputum	31(47)
Chronic wheeze	21(32)
Inhaled long acting b-agonists	41(63)
Inhaled corticosteroids	31(47)
6MWT, meters	311(18)
ΔBorg <sub>6MWT</sub>	2.1(0.2)

Continuous data are expressed as mean (SE), categorical data are expressed as n (%), MRC score is expressed as median (range).

important to realize the potential danger imminent in this procedure and to improve the tolerability of SI.

In the present study we performed SI by administrating normal and hypertonic saline in a group of COPD patients, as part of a longitudinal study of lung function decline. Our primary aim was 1) to assess dyspnea and adverse events during the procedure and, 2) to evaluate the relation between dyspnea and lung function change or oxygen desaturation that may occur during the procedure. A secondary endpoint in this study was to determine the diagnostic value of baseline parameters in distinguishing patients who will experience an adverse reaction during SI.

## Methods

**Subjects:** Sixty five patients, 21 current smokers and 44 ex-smokers, with stable COPD were recruited by consecutive sampling from a cohort of a longitudinal study of lung function decline in COPD and gave their consent to participate in the study. The diagnosis of COPD was based on the Global Initiative for Chronic Obstructive Lung Disease (GOLD) consensus criteria.<sup>11</sup> All patients with COPD had been free of an acute exacerbation for at least 4 weeks before the study and had not received antibiotics or corticosteroids (oral or inhaled) over the same period. No subject had a history of asthma or allergic rhinitis. Twenty patients had concomitant cardiovascular

disease in stable condition. The hospital ethical committee (Agios Georgios Chania General Hospital, Crete, Greece) approved the protocol.

**Study design:** Patients attended on two consecutive days. Short acting B<sub>2</sub> agonists and/or anticholinergic inhalers were withheld for a minimum of 8 hours and long acting B<sub>2</sub> agonists for 12 hours before each visit. The subjects were followed for the subsequent two weeks period in order to assign late adverse events.

**Baseline assessment (visit 1):** Baseline characteristics were evaluated<sup>12</sup> and 6MWT was performed according to standardized guidelines.<sup>13</sup> The 6MWT was performed indoors about the same time of day, along a 100-foot flat, straight, enclosed hallway with a hard surface that was seldom traveled. The walking course was 30 meters in length and it was marked every 3 meters. Instructions to patients were given according to accepted recommendations.<sup>13</sup> The patient should sit at rest in a chair, located near the starting position, for at least 10 minutes before the test started. Clothing and shoes should be appropriate for walking. During that time, oxygen saturation, pulse and blood pressure were measured and baseline dyspnea was assessed using the Borg scale. A physician should stand near the starting line during the test without walking with the patient. Only the standardized phrases for encouragement<sup>13</sup> were used during the test. When test was finished postwalk Borg dyspnea, oxygen saturation and pulse rate were recorded, as well as the total distance covered.

**Sputum induction (visit 2):** Sputum was induced via inhalation of saline solutions aerosol, generated by an ultrasonic nebulizer (Ultraneb 2000; DeVilbSis; Somerset, PA) modifying a previously described protocol.<sup>14</sup> Aerosols of normal saline and hypertonic saline (NaCl 4.5%) were inhaled for subsequent periods of 2 and 8 minutes each (4 periods, 20 minutes in total). The sample was determined to be adequate if at least 1 ml of sputum was collected into a sterile container.

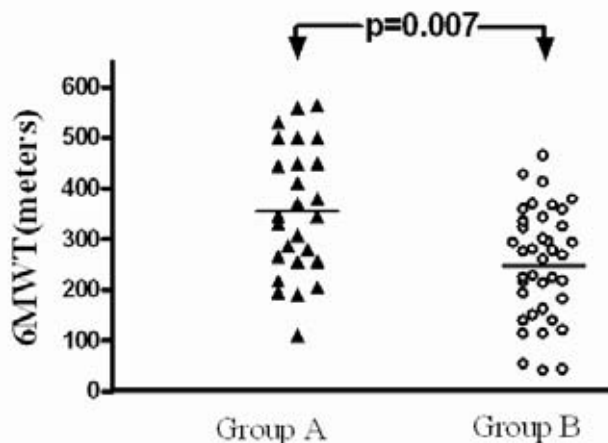
**Adverse events:** The patients were free to ask for discontinuation of the procedure in case they experienced undesired symptoms. At the end of sputum induction, they were asked to record these symptoms in a chart. Any discontinuation of the procedure due to undesired symptoms was termed as “mild adverse event”. Any discontinuation of the procedure due to symptoms requiring acute medical pharmaceutical intervention-hospitalization was termed as “major adverse event”.

**Table 2: Lung function, pulse oximetry and Borg dyspnea score during sputum induction, according to COPD severity.**

	Overall n = 65	COPD severity (GOLD stages)				p-value
		Stage I n = 5	Stage II n = 24	Stage III n = 22	Stage IV n = 14	
<b>Median (IQR) change*</b>						
<b>Borg</b>	1.5 (0, -2)	0 (0, 1)	1 (0, 1)	1.5 (0, 2)	1.5 (0, 3)	0.02
<b>SpO<sub>2</sub> %</b>	-1 (0, -2)	-0 (0, 0)	-1 (0, -1.5)	-1.5 (0, -3)	-2.5 (-1.5, -3)	0.001
<b>Heart rate</b>	25 (10, 33)	15 (8, 22)	17 (10, 25)	21 (12, 29)	32(10, 45)	0.09
<b>FEV<sub>1</sub></b>	-9.5 (-3, -15)	-11 (-3, -17)	-5 (0,-8)	-12 (-3, -17)	-9 (-3, -12)	0.32

\* change from the post-bronchodilation baseline value





**Figure 1**  
**6MWT distance in COPD patients according to Borg dyspnea score during sputum induction.** Group A represents patients with mean changes in Borg score = 0; Group B represents patients with mean changes in Borg score >0. Bars represent mean values.

**Dyspnea assessment:** Perception of dyspnea during SI was defined as sensation of bronchoconstriction or, chest tightness or, inability to take a deep breath or, sensation of effort to breathe. Dyspnea intensity was rated on the Borg dyspnea scale<sup>15</sup> immediately before each lung function measurement and at the end of sputum induction.

**Lung function measurement and O<sub>2</sub> desaturation:** Spirometry was performed at baseline and at the end of each time period with a computerized system (Lab, 2.12; Jaeger; Wuerzburg, Germany). This system, which meets the ATS standards, was calibrated every day with standardized techniques according to guidelines.<sup>16</sup> Pulse oximetric saturation (SpO<sub>2</sub>) was recorded immediately before each FEV<sub>1</sub> measurement using pulse oximetry (Nonin 8500 M; Nonin Medical; Minneapolis, MN).

**Safety protocol:** In order to minimize the bronchoconstrictive response to saline inhalation, a safety protocol was followed. The protocol was based on the European Respiratory Society sputum induction Task group report:<sup>5</sup>

- a) All subjects were premedicated with 200 µg salbutamol via metered-dose inhaler 30 minutes before spirometry.
- b) If mild adverse events took place, clinical evaluation was carried out.
- c) If major adverse events or life threatening adverse events occurred there was a termination of the procedure and patients were treated appropriately.
- d) Bronchodilators were administered at the end of SI in any subject who experienced dyspnea or decline of FEV<sub>1</sub>>20% from the baseline.

The reproducibility of the above was assessed on a pilot study on 10 subjects. These subjects were chosen from the outpatient clinics of Chania General Hospital, Crete, Greece. Five of them were selected based on a physician's diagnosis of stable COPD. The five other subjects chosen from the list of non respiratory outpatient clinics did not have any respiratory disease and did not complain of dyspnea. They were scheduled for two visits, 2

weeks apart. They underwent SI and dyspnea was evaluated by the Borg scale. The reproducibility in this sample was 95%.

**Statistical analysis:** Descriptive statistics were used to summarize the baseline characteristics and the results were expressed as means(SE) or stated otherwise. Normal distribution was assessed using the Kolmogorov-Smirnov Z test. The independent samples t-test was applied for the comparison of approximately normally-distributed variables and the Mann-Whitney U test where there was evidence of non-normality. Categorical variables were compared using the chi-square test. Borg score change (ΔBorg), adverse events were considered as outcome variables. Correlations between outcome variables and clinical or lung function variables were assessed appropriately either by Pearson's r<sup>2</sup> or by Spearman's rho. To determine the prognostic value of various parameters in distinguishing patients who will experience an adverse physiologic reaction (ΔBorg >0 and adverse events) during SI, receiver-operating-characteristic (ROC) curves were constructed to assign cut-off values and their diagnostic utility. A p value of less than 0.05 was considered as statistically significant. The statistical package SPSS 13.0, (Chicago, IL, USA) was used for the entire analysis.

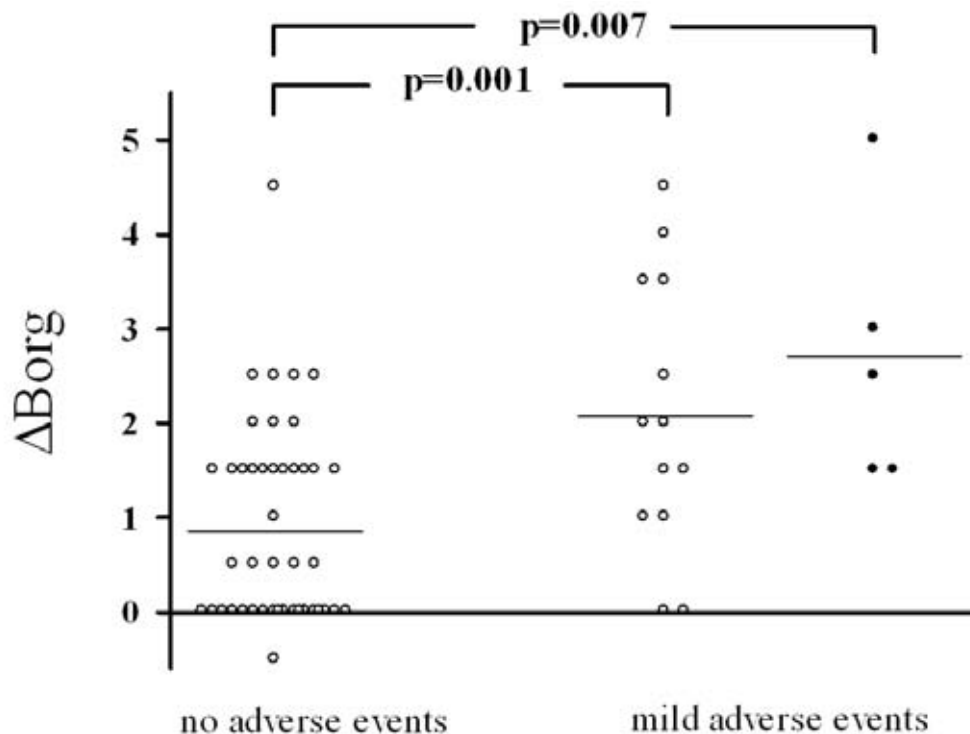
## Results

Patient's baseline characteristics are demonstrated in Table 1. 60 subjects (92%) produced acceptable sputum with a mean (SE) percentage viability 96(9) and squamous cells contamination 17.5(12). All five subjects that did not provide sufficient sputum samples experienced adverse events during the procedure: 2 dyspnea (chest tightness) – excessive wheezing; 2 dyspnea (sensation of effort to breathe) – general discomfort; 1 nausea. These subjects presented significantly greater ΔBorg [3(1) versus 1.5(1) p = 0.001], ΔSpO<sub>2</sub> [-2.5(-2) versus -1(1) p = 0.001] and ΔFEV<sub>1</sub> [-18(12) versus -10(8), p = 0.001], compared to all other patients. Unsuccessful session of sputum induction was more likely in the group of patients with COPD of stage IV than in patients with less severe disease [Relative Risk (RR) 18, 95%CI 1.7–80].

**Adverse events:** No major event requiring hospitalization occurred during the procedure. 18 of the 65 patients presented 28 minor adverse events: 16 dyspnea-general discomfort, 9 general discomfort, 1 nausea; 2 did not complete the session due to dyspnea-excessive wheezing. One patient with COPD stage IV experienced a COPD exacerbation two days later treated adequately at home. Patients with stage IV COPD had a significantly increased risk to be in this subgroup compared to patients with less severe disease (RR 2.9, 95%CI 1.4–6).

**Borg score dyspnea:** 40 subjects (61%) demonstrated ΔBorg>0. These patients had relatively advanced disease (Table 2), lower baseline SpO<sub>2</sub> [89(0.9) versus 93(0.4), p = 0.007], 6MWT (meters) [227(18) versus 352(26), p = 0.007] (Figure 1), compared to patients with ΔBorg = 0. Borg score changes were significantly greater in patients who experienced adverse events compared to the rest of the patients (Figure 2). There were no significant differences in ΔBorg between smokers and ex-smokers [1.4(0.5) versus 1.2(0.4), respectively p = 0.11].

**Lung function:** The average decline of FEV<sub>1</sub>(ΔFEV<sub>1</sub>) during the procedure is demonstrated in Figure 3. The mean(SE) change in FEV<sub>1</sub> was overall -9.9(2)% from the baseline. FEV<sub>1</sub> had already fallen by 9.5(2)% from the baseline 2 minutes after saline



**Figure 2**  
**Borg score changes in COPD patients during sputum induction, according to adverse events and success of procedure.** Individual values of average changes in Borg dyspnea scale during sputum induction. Mild adverse events were defined as discontinuations of the procedure due to undesired symptoms including dyspnea (sensation of bronchoconstriction, chest tightness, inability to take a deep breath, sensation of effort to breath), wheezing, nausea. Open circles represent patients that completed the procedure successfully; closed circles represent patients that did not complete the procedure successfully due to mild adverse events.

inhalation. 19 subjects out of 61 (31%) presented an hyperresponsive reaction to saline inhalation (loss of > 20% from the baseline FEV<sub>1</sub>).

**Correlations between Borg score and oxygen desaturation, lung function:** The average  $\Delta$ Borg was significantly correlated with average  $\Delta$ SpO<sub>2</sub>, ( $r = -0.38$ ,  $p = 0.001$ ) and adverse events ( $\rho = 0.51$ ,  $p = 0.01$ ). Significant correlations were also present between the  $\Delta$ Borg and  $\Delta$ SpO<sub>2</sub> when each time period was studied separately: 0 to 2 minutes, 2 to 10 minutes, 10 to 12 minutes and 12 to 20 minutes ( $r = -0.26$ ,  $p = 0.01$ ,  $r = -0.4$ ,  $p = 0.002$ ,  $r = -0.21$ ,  $p = 0.01$  and  $r = -0.45$ ,  $p = 0.001$ , respectively). In contrast there were no significant correlations between  $\Delta$ Borg and  $\Delta$ FEV<sub>1</sub> either considering the average or the values in each time period.

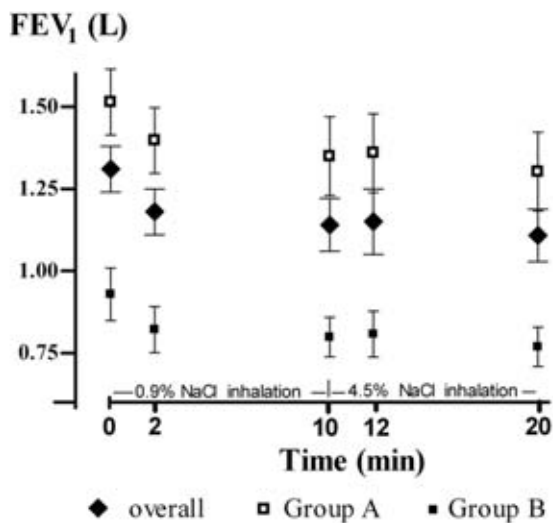
**Diagnostics:** Table 3 depicts the threshold values of various parameters in distinguishing patients that presented an adverse physiologic reaction during the procedure (defined as  $\Delta$ Borg > 0 + adverse events). Among them, 6MWT and MRC score demonstrated remarkable specificity with high positive and negative predictive values, while post-bronchodilation FEV<sub>1</sub> demonstrated the highest sensitivity.

### Discussion

This prospective study represents the largest systematic report of adverse events and dyspnea evaluation during sputum induction in COPD. Our results suggest that COPD patients who undergo sputum induction, following a safety protocol, do not

experience major adverse events. However, the patients may have an increased perception of dyspnea [overall increase in Borg score median[(IQR) 1.5(0–2)]] and desaturation and may require short discontinuation of the procedure due to undesired symptoms. We found that dyspnea changes during sputum induction were significantly correlated with oxygen saturation, heart rate changes and mild adverse events. This adverse physiologic reaction was more frequent in subjects with advanced COPD. Notably, patients of stage IV in GOLD staging of severity, presented an increased risk to have unsuccessful sputum induction and to have minor adverse events during the procedure compared to patients with less severe disease (RR 2.9, 95%CI 1.4–6). In addition we found that the baseline values of post-bronchodilation FEV<sub>1</sub>, of oxygen saturation and of 6MWT have a diagnostic value in distinguishing patients who develop an adverse reaction during SI. To the best of our knowledge this has not been reported.

In previous studies addressing SI safety in COPD, the measurement of FEV<sub>1</sub> was considered enough to diagnose acute lung responses.<sup>6,7,9</sup> However, an excessive fall in FEV<sub>1</sub> during SI is not always associated with clinical deterioration<sup>9</sup> or dyspnea development.<sup>6</sup> Thus, it is not unlikely that assessing only FEV<sub>1</sub> during the procedure, early signs of clinical deterioration may be undetected. Consequently, the development of adverse events may affect the tolerability of the procedure.<sup>8,9</sup> In our study, special attention was paid to evaluate dyspnea, in addition to FEV<sub>1</sub> assessment. We found that patients undergoing SI may experience an adverse physiologic reaction,



**Figure 3**  
**FEV<sub>1</sub> change during sputum induction.** Percentage change in FEV<sub>1</sub> with standard errors during sputum induction. Group A represents patients with mean changes in Borg score ≤0; Group B represents patients with mean changes in Borg score >0.

characterized by worsening of dyspnea, undesired symptoms and oxygen desaturation. This adverse reaction was not significantly related to FEV<sub>1</sub> decline but affected the tolerability of the procedure in a proportion of patients. This may have importance in research or clinical studies, especially in patients with advanced disease.

In the studied population, we included subjects with advanced disease since European Respiratory Society report has underlined the lack of systematic studies in this category of patients.<sup>5</sup> Normal and hypertonic saline was administered even in subjects with very severe disease. We found that COPD patients experienced significant Borg score and oxygen saturation changes, associated with disease severity. COPD subjects of stage IV had an increased risk of developing dyspnea, requiring subsequently discontinuation of the procedure. The degree of discomfort led eight out of 14 (57%) patients in this category to temporary discontinuation and two of them (14%) to early termination of the procedure. In addition, 4 out of 5 patients who did not provide sufficient sputum sample, had stage IV COPD. Hence, patients with advanced COPD may experience excessive dyspnea during sputum induction and they might be reluctant to repeat the procedure in the future. Therefore, sputum induction in this category of patients must be performed with great caution and in the ground of our findings careful monitoring of oxygen saturation and dyspnea is essential.

In the present study all subjects were premedicated with salbutamol. B<sub>2</sub>-agonists and anticholinergic inhalers were withheld before SI in order to standardize further our assessment. It is known that inhaled salbutamol does not provide full protection from bronchoconstriction as it has been demonstrated by the adverse responses after saline inhalation.<sup>7,9</sup> However, it remains unclear whether the magnitude of bronchoconstriction could be prevented by pretreatment with larger doses of inhaled salbutamol or with another type of

bronchodilator or antiinflammatory treatment.<sup>9,10</sup> A prospective study is necessary to test this hypothesis.

In this study, 31% of the patients demonstrated an excessive fall (>20%) of FEV<sub>1</sub>. According to previous reports, excessive FEV<sub>1</sub> decline ranges, between 11<sup>8</sup> and 50%,<sup>9</sup> depending on the COPD population studied. Interestingly, we found that FEV<sub>1</sub> decline had almost reached the average decline 2 minutes after saline inhalation and that FEV<sub>1</sub> did not return to baseline during the procedure. In previous studies in COPD patients,<sup>8-10</sup> there hasn't been any assessment before the 5th minute following saline inhalation. In these studies, the greatest decline in FEV<sub>1</sub> seems to occur constantly at the beginning of the procedure, following similar time course patterns to our assessments. The time course pattern of FEV<sub>1</sub> could be explained by the underlying mechanism of the bronchoconstrictive response. The inhalation of normal or hypertonic saline may trigger mast cell and basophil degranulation, in response to an increase of airway osmolarity.<sup>17-20</sup> The release of bronchoconstrictive mediators from mast cells is rapid and essentially completed by five minutes.<sup>21</sup> In line with this early inflammatory response, it has been reported in a time course assessment study in asthmatic patients,<sup>18</sup> that the maximal mean fall in FEV<sub>1</sub> occurs at 3 minutes post saline inhalation. In this ground, premedication of the patients with bronchodilators should be a standard safety measure of the procedure. Future studies of different design may identify which is the most effective bronchodilator to prevent this bronchoconstrictive response.

An interesting point in our study is that the development of dyspnea and the fall of the FEV<sub>1</sub> were not significantly correlated. One would expect patients with the most severe airway obstruction to be the most dyspnoeic. However, some patients with severe airway obstruction are minimally symptomatic, whereas others with little objective dysfunction appear to be very dyspnoeic.<sup>22</sup> Several studies have investigated the correlation between dyspnea and lung function.<sup>23</sup> Mahler et al reported that dyspnea and baseline pulmonary function are independent quantities in patients with COPD.<sup>24</sup> Subsequent studies employing newer techniques to quantify breathlessness found either no significant or weak correlations with FEV<sub>1</sub>.<sup>25,26</sup> Thus, an excessive fall in FEV<sub>1</sub> is not always correlated with symptoms development and with dyspnea scale scores in COPD.<sup>6,9</sup>

A reasonable explanation for this discrepancy between FEV<sub>1</sub> decline and clinical deterioration during SI, may be the subjectiveness of dyspnea perception.<sup>27</sup> Unlike asthmatic patients who experience episodic bronchoconstriction, those with COPD demonstrate chronic airflow limitation that might lead to desensitization. Ottanelli and colleagues have previously reported that a reduced perception of dyspnea during bronchoconstriction may be present in COPD patients.<sup>28</sup> A reduced perception of dyspnea might delay self referral or lead to underreport of discomfort during the procedure. In addition, it may be that some dyspnoeic patients in our study, did not develop their "potential maximal" drop in FEV<sub>1</sub>, because they felt uncomfortably and interrupted the procedure thus, demonstrating a submaximal effort in lung function testing. Furthermore, dyspnea during a bronchoconstrictive challenge is associated not only to airway obstruction but also to hyperinflation.<sup>29</sup> In fact, dyspnea perception may be better related with acute hyperinflation than with airflow obstruction sensation in patients with chronic airflow obstruction.<sup>28</sup> Patients

**Table 3: Diagnostic performance of baseline characteristics of COPD patients in distinguishing those with an adverse reaction during SI.**

	Cut-off value	Sensitivity	Specificity	Positive predictive value	Negative predictive value
<b>A<sup>2</sup>ge</b>	>70	65	52	42	77
<b>FEV<sub>1</sub> (% pred)</b>	<40	83	64	47	91
<b>ΔSpO<sub>2</sub> (%)</b>	≤91	74	78	54	88
<b>MRC score</b>	> 2	52	86	56	82
<b>Borg</b>	>4	66	55	44	80
<b>6MWT distance (m)</b>	≤155	52	98	90	84
<b>ΔBorg<sub>6MWT</sub></b>	>2	82	55	33	73

FEV<sub>1</sub> = post-bronchodilation forced expiratory volume in one second; ΔSpO<sub>2</sub> = oxygen saturation average changes; MRC = Medical Research Council; 6MWT = six minutes walking test; ΔBorg<sub>6MWT</sub> = Borg dyspnea score change after 6MWT.

with advanced COPD may develop dynamic hyperinflation in the setting of a bronchoconstrictive stimulus.<sup>9,29</sup> In the present study the most severely affected patients in terms of baseline disease severity presented the greatest perception of dyspnea during SI. Thus, it is likely that a proportion of patients may have experienced dyspnea during SI due to acute hyperinflation.

In this ground other lung function parameters may be considered in addition to FEV<sub>1</sub>, when addressing safety in SI. It has been demonstrated that forced inspiratory rather than expiratory parameters were more sensitive in detecting SI related lung function deterioration and were better associated to dyspnea.<sup>9,30</sup> Forced inspiratory volume in one second (FIV<sub>1</sub>) is less affected by airway collapse than FEV<sub>1</sub>, reflecting obstruction and hyperinflation.<sup>9</sup> In addition, acute inspiratory capacity changes (IC) account in part for the variability in the perception of dyspnoea after accounting for changes in FEV<sub>1</sub> during bronchoconstriction in patients with chronic airflow obstruction.<sup>28</sup> These data, along with the disassociation between dyspnea and FEV<sub>1</sub> in our study, suggest that possibly other parameters, like FIV<sub>1</sub> or IC should be brought forward to monitor lung function deterioration and adverse events development, during SI. In this ground a new insight for the reason of dyspnea during SI might also be provided. However, the present study was designed to assess dyspnea intensity and adverse events during SI based on ERS sputum induction task group report<sup>5</sup> and thus other lung function parameters were not assessed.

In the present investigation, ΔBorg was significantly correlated with ΔSpO<sub>2</sub>. However the correlations between dyspnoea intensity and oxygen saturation changes were weak. A plausible explanation may be that the relationship between hypoxia – ventilatory response and breathlessness in patients with COPD is not linear. Thus, the level of breathlessness is related to hypoxaemia but not in all levels of desaturation.<sup>31</sup> In addition, dyspnea sensation may result from pathophysiological abnormalities that can be related to non respiratory mechanisms.<sup>32</sup> Therefore, the weak correlations between dyspnea and oxygen saturation changes could be attributable to other factors (emotional, cognitive) which have not been evaluated in the present study.

In the present study, we evaluated the diagnostic performance of baseline clinical characteristics of the patients undergoing SI, in order to distinguish those who will develop an adverse physiologic response during SI. This is important because clinical parameters which can be measured in a simple way, before performing the test, give useful information in advance.

In addition, predictors of adverse events and lung function deterioration during SI are not yet widely known.<sup>6,9,27</sup> We found that the development of dyspnoeic events during SI, could be better predicted by the post-bronchodilation FEV<sub>1</sub>(%pred), the MRC score, the oxygen saturation and the 6MWT. To the best of our knowledge, this has not been reported until now.<sup>5,7,10</sup>

MRC score is a good predictor of exercise capacity. It has showed a consistent relationship with Borg rating and a significant correlation with breathlessness and dynamic hyperinflation measured during walking.<sup>33</sup> Baseline oxygen saturation is also reported to be associated with the hypoxemia during inhalation provocative tests.<sup>34</sup> In addition, our investigation showed that COPD patients with good performance status, by means of walking more than 155 meters during 6MWT, will be less prone to develop dyspnea during the procedure. This is likely to be due to dynamic hyperinflation. 6MWT performance is associated to the oxygen uptake, to the severity of chronic dyspnea in COPD patients and it may also be related with the dynamic hyperinflation which is developed in patients after certain stimuli.<sup>9,35</sup> We believe that since subjects with moderate to severe COPD are characterized by hyperinflation and low performance, 6MWT is possibly a good predictor of developing dyspnea after a stimulus such as the inhalation of saline.<sup>9,22</sup>

In summary, we found that normal and hypertonic saline-induced sputum is a safe technique, when certain precautions are taken, in patients with COPD. It is safe even for patients in an advanced stage of the disease. However, excessive dyspnea is more likely to occur in these patients, leading in temporary or permanent discontinuation, affecting tolerance and success of the procedure. Therefore, sputum induction must be performed with great caution and careful monitoring of dyspnea and oxygen saturation in patients with very severe COPD. Post-bronchodilation FEV<sub>1</sub>(%pred), oxygen saturation and 6MWT have a prognostic value for the development of dyspnea during SI and it would be useful to be evaluated in advance. We believe that this is important information and favors further the improvement of SI safety and tolerance especially in advanced COPD.

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# Nurses, Medical Errors, and the Culture of Blame

Gloria Ramsey

In June 2004, an article in the *American Journal of Nursing* reported the findings of a three-year study of the organizational culture, attitudes, and assignment of responsibility for patient safety in small, rural hospitals in nine Western states. The study found that most errors fall within the realm of nursing practice and that physicians, administrators, and nurses themselves tend to see patient safety as largely a nursing responsibility. Asked to identify which profession has primary responsibility for ensuring patient safety, 96 percent of the nurses and more than 90 percent of the physicians, administrators, and pharmacists assigned primary responsibility to nurses. Only 22 percent of the respondents believed that physicians, nurses, pharmacists, and administrators share responsibility for patient safety equally.

Unfortunately, however, nurses and physicians differed on the role of nurses in effecting change. Most of the nurses indicated that they had several responsibilities in reducing medical errors, including reporting them, educating themselves and colleagues, serving as role models, making recommendations for changes in procedure and policy, reviewing reported adverse patient-safety events, and participating in investigations. Only 8 percent of the physicians who responded to the survey identified nurses as members of the decisionmaking team.

Nurses have a genuine impact on patient safety. Studies have found a link between patient safety and RN staffing and an increased rate of error when the hospital nursing staff has a smaller proportion of RNs. These are worrisome findings in light of the severe national shortage of nurses. Part of the medical malpractice crisis, then, is the confusion in the health care system and how it affects the role of the nurse.

There is no confusion in the American Nurses Association's code of ethics. This document, first adopted in 1950 and revised in 2001 to reflect and embrace the role of today's nurse, consists of a set of planks that set out nurses' fundamental values and commitments. They also offer a starting point for understanding

how nurses should be involved in thinking about medical error, and why nurses blame themselves for medical errors.

The first few planks are the most important. These planks state that the nurse's primary commitment is to the patient (plank 2), and that the nurse promotes, advocates for, and strives to protect the health, safety, and rights of the patient (plank 3). "Interpretive Statements" that accompany the code add that nurses are committed to the patient's health, well-being, and safety throughout the patient's life span, and in all settings in which health care needs are addressed. Further, the code directs that, as an advocate for the patient, "the nurse must take appropriate actions regarding any instances of incompetent, unethical, and illegal practice by any member of the health care team or health care system or any action on the part of others that places the rights or best interest of the patient in jeopardy." For nurses to function effectively in this role, they must be knowledgeable about the code of ethics and their own organization's policies and procedures.

Moreover, when the nurse is aware of inappropriate or questionable practice in the provision or denial of health care, concerns should be expressed to the person engaging in the questionable practice. Attention should be called to the possible detrimental effect upon the patient's well-being or best interests, as well as to the integrity of nursing practice. When factors in the health care delivery system or health care organization threaten the welfare of the patient, concerns should be directed to the responsible administrator. If indicated, the problem should be reported to an appropriate higher authority within the institution or agency, or to an appropriate external authority.

The interpretive statements for the third plank also remind nurses that they have a responsibility to implement and maintain the standards of professional nursing practice. They recommend that nurses "participate in planning, establishing, implementing, and evaluating review mechanisms designed to safeguard patients and nurses, such as peer review processes or committees, credentialing processes, quality improvement initiatives, and ethics committees." Nurse administrators must

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ensure that nurses have access to and are included on institutional ethics committees. Nurses may consider forming their own ethics committee if the organizational ethics committee is not providing them a forum.

Lastly, the interpretive statements for the third plank recommend that when errors do occur, nurses follow institutional guidelines for reporting errors to the appropriate supervisory personnel and for assuring responsible disclosure to patients. Under no circumstances should a nurse participate in, or condone through silence, either an attempt to hide an error, or a punitive response that serves only to fix blame rather than to correct the conditions that led to it.

Given these obligations and duties, it is little wonder that nurses would blame themselves for errors in patient care. Little wonder, too, that nurses are morally burned out when they work in an environment that is not supporting of sound ethical practice. And little wonder that a nurse would feel caught in the middle when reminded about what it means to be a nurse.

In a November 2003 press release, Barbara Blakeney, president of the ANA, said, "improved patient safety and quality of care cannot be achieved without investing in and valuing nursing." Valuing nursing—now there's an idea. Nurses are the pulse of health care institutions. When new models of health care delivery were implemented in the 1990s, RNs represented the largest single expenditure for hospitals. But for exactly that reason, nurses were the first among health care professionals to feel the effects of downsizing. Layoffs, stagnant salaries, and the loss of nurse managers have further decreased the support, advocacy and resources that nurses need to provide good care. Today, nurses are even less involved in the decisionmaking process, yet the pressure on them has increased; and when our attention turns to patient safety, the pressure goes up a notch further. In medicine we blame the person at the end of the sentinel event, and the end point is usually nursing.

But if we look more deeply at what goes wrong in the typical medical error, it is almost never the nurse's actions alone. We must fix the *system* to prevent the error from recurring, and nurses alone should not accept the blame.

A nurse-attorney who conducts both litigation practice and clinical practice recently posed the following scenario to me. A woman in her mid-forties was admitted for chronic pain. At home, she took a medication called Talwin. The hospital did not have any Talwin, so staff allowed the patient to keep her own supply at the bedside. The nurse caring for this patient was a recent graduate with little clinical experience. She had a preceptor—a more experienced nurse who guides the learning and development of a novice—but the preceptor had her own heavy patient load. The physician wrote an order for 50mg intramuscular (IM) Talwin. Not wanting to bother the preceptor, the new nurse attempted to fill the order herself, but she drew up 16cc rather than 1.6cc and gave it intravenously (IV), rather than IM, because the physician's "m" looked like a "v." The patient died, and the nurse was blamed for the death.

Fortunately, the hospital administration sought to identify what had gone wrong in the system to make this error possible. One problem, it concluded, was that the preceptor was responsible for her own patients as well for mentoring a new nurse. Second, the Talwin should not have been kept at the patient's bedside. If

the physician's order had been filled by the hospital pharmacist, it would have arrived on the floor prepared for administration. If the medication had to be kept at the bedside, the patient should have controlled the dosage herself via a PCA pump. A third factor was the doctor's illegible handwriting. And lastly, the new nurse needed to be supported more both before *and* after the event. She should have been included in the review of the error and the decisionmaking process resulting from it. If hospitals continue to ignore the role nurses play in quality assurance and elect only to discipline them when an error occurs, they will continue to lose nurses, and the nursing shortage will become even more severe.

Because the ethics of care is the foundation of nursing practice, nurses as independent moral agents are responsible for patient safety and must be vigilant patient advocates. But at the same time, as a careful analysis of this case demonstrates, they and other health care professionals must accept that nurses do not bear the blame for medical errors. The responsibility for medical errors is shared by all.

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# Challenges in Critical Care: Scripps Mercy Hospital

Providing excellent patient care is a top priority for Scripps Mercy Hospital, the longest-operating hospital in San Diego, CA. To ensure state-of-the-art care in its respiratory services, the hospital recently replaced its entire fleet of ventilators with the SERVO-i ventilators equipped with BiVent.

BiVent is an effective mode of mechanical ventilation similar to Airway Pressure Release Ventilation (APRV), but with additional features. BiVent applies CPAP to maintain adequate lung volume and promote alveolar recruitment. BiVent also adds a time-cycled release phase to lower set pressure (P-low). In addition, spontaneous breathing can be integrated and is independent of the ventilator cycle.

Current research shows that APRV improves respiratory care in critically ill patients, especially patients with low compliance. In a study in *Critical Care Medicine* in 2005 (Vol 33 No 3, S228-240), Nader M. Habashi, MD, FCCP, an assistant professor at the University of Maryland in Baltimore, found that APRV has distinct clinical advantages for ventilator management of patients with ALI or ARDS. Among them are improvement in cardiac and renal function, decreased use of sedation, and near elimination of neuromuscular blockages. In his study, Habashi noted that some recent research suggests using APRV results in fewer ventilator days and shorter ICU stays for many patients. Although randomized controlled trials are still needed, Habashi expects APRV to become the gold standard for patients with ALI or ARDS.

BiVent is an improvement on APRV because it allows pressure support to be set independently. Also, it allows the practitioner to set auto PEEP when recruiting the lung. "Spontaneous breaths at the P-high improve dependent ventilation through pleural applied pressure changes, rather than the application of additional applied airway pressure," explains Jodi Brewer, RCP, RRT, an educator and clinical respiratory specialist in the Respiratory Therapy Department at Scripps. "The advantage is that the recruited lung requires less pressure than the recruiting lung."



BiVent allows Scripps' busy trauma unit to offer leading-edge respiratory care. "Since the arrival of these ventilators," says Stephen Kaminski, MD, FACS, a leading trauma service physician at Scripps, "we have been able to advance our ventilator care and our lung management to match state-of-the-art information."

Scripps Mercy demands such technology because it has one of the busiest emergency departments and trauma centers in San Diego and Chula Vista, the two communities that it has served for 113 years. Last year, the hospital treated more than 50,000 ER patients and 2,200 trauma patients.

Kaminski, who was trained on APRV during his fellowship, has noticed that his trauma patients are more comfortable on BiVent. Because they are able to breathe on their own, they are not bucking the respirator, as often happens with conventional ventilation, he explains.

It is widely recognized that the use of sedation makes it more difficult to wean a patient from a ventilator. Because patients on BiVent breathe spontaneously throughout the ventilatory cycle, the mode requires much less sedation and nearly eliminates paralytics.

Thus, Kaminski has found that patients who are on the mode are often easier to wean and may be able to be weaned sooner, lowering the risk of serious complications that are commonly associated with long-term mechanical ventilation.





Jodi Brewer, RCP, RRT, educator and clinical respiratory specialist in the Respiratory Therapy Department, in surgical intensive care unit with Eleanor Vallejos, RCP.

Anecdotally, physicians at Scripps have found that BiVent reduces patient stays in the ICU. The department plans to confirm its anecdotal findings with a retrospective study looking at patients with the same diagnoses before and after it acquired the SERVO-i ventilators.

Kaminski believes so strongly in the benefits of BiVent that he uses it prophylactically on all his trauma patients. The earlier the intervention with BiVent, the better the outcome, he says. The only exception is for those with severe head injuries. "Patients with head injuries might require control of carbon dioxide and therefore might be better managed by automode," he notes.

BiVent, Kaminski says, works well not only as lung protection strategy but also as a salvage method. "It's good for patients at risk of ARDS and for patients who are difficult to oxygenate."

When Kaminski introduced BiVent to the five other physicians in his trauma practice, they were eager to incorporate it as well. "They all adapted it with open arms, from our senior docs to our more junior partners," he says.

George Silva, RCP, a lead respiratory therapist, says that as a Level I Trauma Center, Scripps Mercy has always been dedicated to the highest level in trauma care. "So it is the perfect place to use the BiVent mode," he says.

BiVent is proving to be the best mode for acute-care patients at Scripps as well. At Scripps Mercy, BiVent is now not only the mode of choice for trauma patients, but is also becoming so for its critically ill medical/surgical patients.

"It gives us an extra dimension in being able to ventilate our patients, especially the very sick cases," says Julian Lichter, MD, who has been Medical Director of Respiratory Care Services at Scripps Mercy since 2002. The hospital has a total of 32 intensive care beds and is among the top hospitals for cancer and cardiac care as well as bariatric surgery.

Lichter says that on several occasions, BiVent has proven to be a lifesaving mode for some patients who are more difficult to ventilate because of their size or other pre-existing health conditions. "Before we had the BiVent capability, we probably

had 20% who we were not able to oxygenate or who oxygenated very poorly," Lichter says. "Now we can oxygenate upwards of 95% of patients.

While BiVent requires a change in thinking, it has become standard protocol in difficult cases, Lichter says. "In circumstances where we have patients who are difficult to ventilate, we will always use that mode to see if it helps them."

One advantage to BiVent, Lichter says, is that it can be used in conjunction with proning, which one small study suggests can improve gas exchange and survival rates among critical care patients. BiVent is easier to employ than proning because it is a matter of changing settings, whereas proning is more nurse-and-technician intense because it requires placing the patient on a special bed to be turned. Once the patients are on the bed and prone, it becomes more difficult to examine them, Lichter says. Also, he says, proning requires special care so tubes and other equipment are not displaced when the patient is turned. Still, he says, proning and BiVent can work well together when assisting difficult patients.

Another positive feature of BiVent is that it can be used in conjunction with pressure support, says Glenn Tanaka, RRT, RCP, Manager of Respiratory Care Services at Scripps Mercy. The SERVO-i allows the judicious addition of pressure support due to its floating exhalation valve, he explains.

"The idea is to use the tools so you don't have change to an oscillatory ventilation strategy," Tanaka says. "Thanks to BiVent, we reduced the need for oscillation."

Some researchers report success with BiVent in neonatal and pediatric populations as well as adults. For that reason, Scripps is looking at employing BiVent in its Neonatal Intensive Care Unit.

Physicians and staff are anxious to incorporate BiVent and help patients. As an educator, Brewer was pleasantly surprised at how well the staff embraced the new mode and other SERVO-i open-lung capabilities. "To be honest," she says, "I didn't expect people to be as enthusiastic as they were because when there is a new theory out there, it is often hard to get everyone thinking



SERVO-i in BiVent mode.



Members of the Respiratory Therapy Department at Scripps Mercy Hospital.

it is advantageous.” However, Brewer says, the respiratory therapists were eager to learn BiVent and to assist the physicians in using it in appropriate cases. Brewer is helping the hospital to write protocols for BiVent.

With the support of Maquet’s clinical applications specialists, a select group of specialists and RTS were trained first and they, in turn, trained others, including the nurses, on the use of BiVent. Maquet provides continued support as needed. Scripps Mercy believes in collaborative healthcare and thus cross-trains its staff, which was easy to do in this case because the ventilators and BiVent operate with a touch screen, Tanaka notes. “BiVent is very user-friendly,” he says.

The respiratory therapists favored the SERVO-I when the hospital was looking to provide new and more effective ventilation strategies. A committee had narrowed the choices on the recommendations of physicians and staff, Tanaka says.

“It is very important that the therapists appreciate the ventilator and are comfortable with all its modes because they are very closely involved with the equipment,” Lichter says. The hospital has 70 respiratory therapists and staff.

Tanaka says that like with everything new, the physicians and staff had to be convinced that BiVent works, but it did not take long once they saw how easily it could be employed, and how beneficial it could be for their trauma and medical patients. “Going forward,” Tanaka says, “we want to be able to provide the best care possible for our patients, and we believe that with BiVent, we can do that.”

The views, opinions and assertions stated by Scripps Mercy staff are those of the clinicians and administrators, and don’t necessarily reflect the views of Maquet. This article was provided to Respiratory Therapy by Maquet.

*Guest Commentary...continued from page 11*

between various models of ventilators. There is far too much complexity in the operation of a ventilator. There is a multitude of controls that all must be set by the clinician often using “best clinical judgment.” These settings are static, while the patient and the environment are dynamic.

Imagine a mechanical ventilator with an autopilot with capabilities very similar to what is used as routine by airline pilots. The clinician can determine the relevant clinical parameters very easily and let the ventilator run the routine manipulations and provide for automatic patient safety parameters that are not alarms, but an actual lung protective strategy built right into the device. The operation of the ventilator would be hassle-free with not many modes, but a single non-mode. The ventilator would simply provide the appropriate gas delivery in a manner that the patient is most comfortable with.

What next? Imagine a completely modern graphical user interface that provides what a pilot would call, an “artificial horizon.” Imagine being able to see what is actually happening to the lungs. Soon a clinician will be able to actually see a patient weaning from the ventilator, not by studying a list of data for various monitored parameters but with easy to understand graphics that interpret the data based upon established clinical principles. Training programs would make extensive use of advanced simulators so that scenario based training could reinforce the critical care protocols. There are already ventilation autopilots, but you will soon see this automation address more than ventilation but oxygenation, lung recruitment and setting appropriate PEEP. Ventilator electronic data will be more relevant to the clinical information systems as hospitals move toward the Electronic Health Record and automated care protocols.

Some in the health care industry are worried that their job may be lost to automation. Autopilots have been in commercial airliners now for over 50 years, and still there are two pilots up front. We are seeing robotic surgery, electronic ICUs, telemedicine and many more enhancements in medicine. The development of mechanical ventilators that are able to ventilate the patient independently will allow that RCP, nurse or physician more time to focus on the big picture, helping that patient get back home with their family as soon as possible. The best thing that could happen would be the development of preventative healthcare that would reduce or eliminate the need for mechanical ventilation in the first place. That would be truly best for the patient. If they must be intubated and placed on a device such as a mechanical ventilator, it is our obligation therefore, to at least do no harm. The need for qualified health care professionals is greater now than ever before. Advancements in instrumentation like the mechanical ventilator will free these clinicians to focus on patient care, rather than the instrumentation.

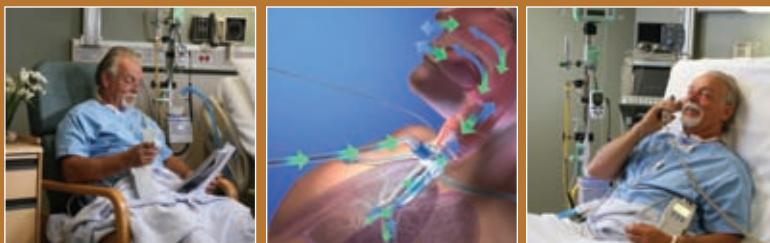
Now that you have been enlightened that there is a better way to ventilate patients, how can you continue to ventilate without automated lung protection, or without at least considering lung protection, and being able to validate it with each and every patient? The new standard of care in mechanical ventilation is here. Are you ready for it?



## CADENCE™ SELF-BREATHING TECHNOLOGY PROVIDING A BRIDGE TO LIBERATION.

Traditionally, a prolonged, mechanically ventilated patient who was ready to attempt a self-breathing trial had a daunting “all or nothing” choice: complete reliance on mechanical ventilation or attempting unassisted spontaneous breathing.

Today, the Cadence Self-Breathing System can act as an important bridge on the road to recovery because it augments a patient’s ability to breathe naturally and is designed to reduce hypoxemia. Results are often dramatic because this minimally invasive approach typically increases the patient’s exercise capacity and returns the use of the patient’s upper airway.



Our commitment to deliver Total Ventilation Solutions<sup>SM</sup> means we always search for better ways to improve how you treat, monitor and manage respiratory-impaired patients across the care continuum.



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## Now you won't have to do backflips to meet regulatory compliance.

Why? Because the **cobas b** 221 blood gas analyzer:

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