


Volume 7 Number 5 October-November 2012

# Respiratory Therapy™

The Journal of Pulmonary Technique



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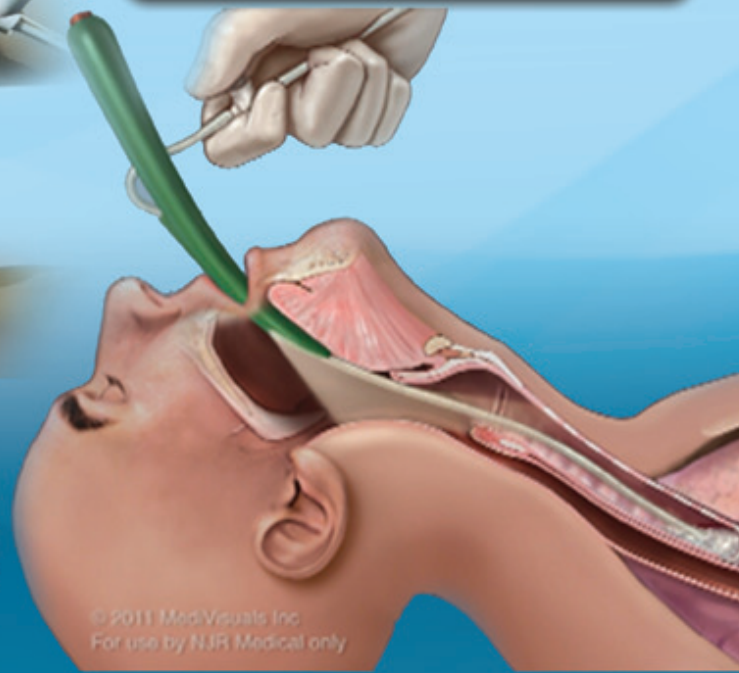
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## Respiratory Therapy™

The Journal of Pulmonary Technique

Vol. 7 No. 5  
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## Editorial

### No Respect?

Douglas Farrago reports in Authentic Medicine Gazette: “In the continuing saga of physician disrespect, the FDA is looking at more ways for patients to get prescriptions without seeing a doctor. This is the same country where many states don’t allow doctors to do telemedicine across state lines. So, in the latter case, doctors can’t give prescriptions but patients would be able to self-diagnose and get the prescription on their own. Huh? The new model, as explained in American Medical News, being considered by the FDA would do the following: Allow some drugs for chronic conditions, such as asthma and allergies, to be sold under “conditions of safe use,” a proposed category that would describe prescription drugs sold over the counter. To determine whether patients meet conditions of safe use of the drug, the FDA is recommending the development of new technology to help diagnose and assess patients’ needs. Under the proposal, criteria of safe conditions would be measured using technology such as patient kiosks, remote diagnostic tools and online questionnaires that determine patients’ needs and help match them to the right medication. The proposal also would expand the role of pharmacists, who would help determine patients’ needs for certain medications and help verify their self-diagnoses. Just another way to break up the physician-patient relationship. Isn’t it amazing that others are always trying to replace doctors with something – new technology, pharmacists, grand-aides, NPs, PAs and on and on. Will this crap never end?”

If you want to see more of Dr Farrago’s commentaries on a wide variety of subjects, visit his website, and check out our news sections for more of his opinions. He’s always contrarian, and interesting, even if you don’t agree with what he says, and I often don’t.

Les Plesko

PS: Just a reminder that we’re always looking for original contributions from our readers and all others in the respiratory care community. Our submission guidelines are incredibly simple: send your material to our e-mail address, [s.gold4@verizon.com](mailto:s.gold4@verizon.com), and we will review it and get back to you in a matter of days. Short items for the news section typically run about 500 words; articles can be any length, though a minimum of 800 is ideal. There’s no max, though most run no more than 3,000 words. If you have any questions, contact us at any time.

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Published six times each year by

**Goldstein and Associates, Inc.**

10940 Wilshire Blvd., Suite 600

Los Angeles, CA 90024 USA

Tel: 310-443-4109 · Fax: 310-443-4110

E-mail: s.gold4@verizon.net

Website: www.respiratorytherapy.ca

**Publisher** Steve Goldstein

**Editor** Les Plesko

**Associate Editor** Jordana Hammeke

**Assistant Editor** Laszlo Sandor

**Design & Production** www.accugraphics.net

**Circulation, Coverage, Advertising**

**Rates:** Complete details regarding circulation, coverage, advertising rates, space sizes, and similar information are available to prospective advertisers. Closing date is 45 days preceding date of issue.

**Change of Address** notices should be sent promptly to Circulation Department. Provide old mailing label as well as new address. Allow two months for change.

**Editorial Contributions** will be handled with reasonable care. However, publishers assume no responsibility for the safety of artwork, photographs or manuscripts. All submissions may be emailed to s.gold4@verizon.net. Every precaution is taken to ensure accuracy, but the publishers cannot accept responsibility for the correctness or accuracy of information supplied herein or for any opinion expressed. Editorial closing date is the first day of the month preceding month of issue.

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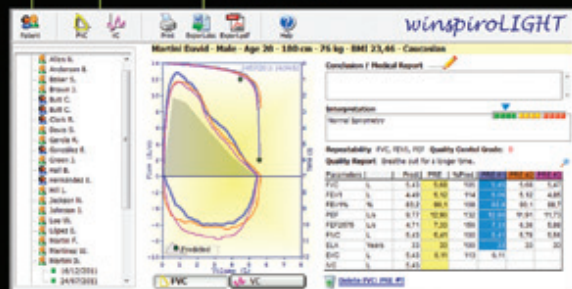


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The article index incorrectly named the author of the following article: Use of the Passy-Muir Valve for Weaning in Long Term Acute Care Hospitals, Julie Kobak, MA, CCC-SLP, Vol 6 No 4, p 44, Aug/Sept 2011.

## ALERT FATIGUE

From Douglas Farrago, MD, authenticmedicine.com: There is a new term going around in medicine. It is called "alert fatigue." I had blogged before about nurses having alarm alert fatigue in Boston. With so many monitors on so many patients the nurses were constantly dashing to see patients for overly sensitive warnings. This led them to start missing or ignoring some of those warnings. Now physicians are having the same alert fatigue with their EMRs. The damn things are so sensitive to any drug interaction that it seems that they have pop up warnings any time you touch the damn thing. As an article in the American Medical News states, "The alerts are designed to inform physicians of possible patient safety issues, but their frequency and often lack of necessity make them the electronic equivalent of the boy who cried wolf." It looks like research is ongoing to cut these alerts down so that we doctors can actually pay attention to the ones that matter. The problem with the current system is that EVERYONE is covering their asses and no one wants to get sued. The only way for the EMR companies to protect themselves is to warn about everything. Once again, litigation wags the dog.

## HACK, COUGH

Douglas Farrago reports in Authentic Medicine Gazette: Based on a review of evidence, including a large National Cancer Institute study involving more than 53,000 people with a history of smoking at least one cigarette pack daily for 30 years or two



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packs for 15 years, new guidelines are recommending that they receive annual low-dose CT scans of their lungs. The advice applies only to those aged 55 to 74, which would make 8 million Americans eligible for screening but possibly prevent 4,000 lung cancer deaths per year. The groups recommending this are the American College of Chest Physicians, the American Society of Clinical Oncology and the National Comprehensive Cancer Network. Of course the cost of such a venture really isn't discussed and neither is the issue that the smoker did choose to put himself or herself in harm's way. This is an easy recommendation for these cancer groups but it really is an ethical dilemma. Would it actually hinder people from quitting smoking because they know they will be getting an annual CT scan? Is this the best way to spend limited resources (on smokers in their 70s who have a very small chance of quitting)?

#### CELL STUDY

A research team led by Xian Chang Li, MD, PhD, Brigham and Women's Hospital (BWH) Transplantation Research Center, has shed light on how a population of lymphocytes, called CD4+ T cells, mature into various subsets of adult T helper cells. In particular, the team uncovered that a particular cell surface molecule, known as OX40, is a powerful inducer of new T helper cells that make copious amounts of interleukin-9 (IL-9) (and therefore called T<sub>H</sub>9 cells) *in vitro*; such T<sub>H</sub>9 cells are responsible for ongoing inflammation in the airways in the lungs in vivo. The study was published online in *Nature Immunology*. In their studies, the researchers found that mice with hyper-active OX40 activities had signs of tissue inflammation, particularly in tissues lining the airway. A high amount of cells in these tissues,

as much as 30% percent, were mucin-producing cells. Mucin-producing cells produce gel-like secretions that, when combined with other secretions, can form mucus or saliva. In addition to this translational finding, Li and his team made strides in better understanding OX40's role in the molecular mechanisms of the pathway responsible for T<sub>H</sub>9 cell induction.

#### EFFECTIVE

CPAP is also effective in patients with mild and moderately severe OSA and daytime sleepiness, according to a study at the University of Illinois at Chicago College of Nursing. In the study, 239 patients with newly diagnosed milder OSA and self-reported daytime sleepiness (an Epworth Sleepiness Scale (ESS) score > 10) were randomized to eight weeks of active or sham CPAP treatment. After the eight-week intervention, patients in the sham arm were crossed over to eight weeks of active treatment. The primary outcome measure was total score on the Functional Outcomes of Sleep Questionnaire (FOSQ), which measures the impact of daytime sleepiness on activities of daily living. The adjusted mean change in FOSQ total score after the initial eight-week intervention was 0.89 for actively treated patients and -0.06 for sham-treated patients ( $p = 0.006$ ). Mean improvement in FOSQ total score from the beginning to the end of the cross-over phase of the study was  $1.73 \pm 2.50$  ( $p < 0.00001$ ). Significant improvements with active treatment were also seen in ESS scores, Physical Component scores on the Short-Form 36 health survey, and Total Mood Disturbance scores on the Profile of Mood States scale. The study was conducted at both large and smaller clinical practice sites, making the results highly generalizable.



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## FOREIGN INVASION

When hospital patients are placed on a mechanical ventilator for days at a time, their lungs react to the pressure generated by the ventilator with an out-of-control immune response that can lead to excessive inflammation, according to researchers at Ohio State. They determined that mechanical pressures trigger an innate immune response, the same immune response that the body launches to begin its fight against any kind of infection. The rhythmic pressure of ventilation stimulated the production of pro-inflammatory chemicals by activating toll-like receptors in lung cells. The researchers found two things that may help: microRNAs and two TLRs in the innate immunity pathway. At least one tiny piece of RNA, a microRNA, is influential in this immune response because its behavior regulates the activation of the toll-like receptor proteins. The findings suggest that manipulating levels of either the microRNA or TLRs could be the basis for potential new treatment options for acute lung injury that requires ventilation. The researchers first characterized inflammatory effects of mechanical pressure in experiments using human small airway cells from deep inside the lungs, where ventilation pressure tends to do the most damage. These tests showed that as little as four hours of exposure to ventilation pressure and breathing rates that mimic the clinical environment raised levels of three proinflammatory cytokines. The scientists then tested these same cells to examine what role microRNAs (miRs) might have in the lung's inflammatory response to ventilation. The activation of the micro RNA miR-146a increased in the cells as experimental levels of cyclic ventilation pressure increased. Dramatically driving up levels of miR-146a in human small airway cells under mechanical ventilation conditions lowered the activity of the two TLRs,

which in turn led to very little cytokine secretion—meaning inflammation was held at bay.

## ANTI-INFLAMMATORY

Researchers at the Nutritional Immunology and Molecular Medicine Laboratory (NIMML) have discovered that abscisic acid has anti-inflammatory effects in the lungs as well as in the gut. While the immune effects of abscisic acid are well understood in the gut, less was known about its effects in the respiratory tract. The researchers showed that not only does abscisic acid ameliorate disease activity and lung inflammatory pathology, it also aids recovery and survival in influenza-infected mice. Abscisic acid has been shown to be most effective at about seven to ten days into the infection, targeting the immune response rather than the virus itself, which many researchers feel is a safer way to reduce flu-associated fatalities.

## BREATHE EASIER

Establishing a more stringent ozone standard in the US would significantly reduce ozone-related premature mortality and morbidity, according to a new study at Johns Hopkins. Using national ozone monitoring data for 2005-07 and concentration-response data obtained or derived from the epidemiological literature, the authors applied health impact assessment methodology using the Environmental Benefits Mapping and Analysis Program (BenMAP) to estimate the numbers of deaths and other adverse health outcomes that would have been avoided during this time period if the current eight-hour average ozone standard (75ppb) or lower standards had been met. The researchers estimated that if the current ozone standard of 75ppb had been met, 1,410 to 2,480 ozone-related premature deaths would have been avoided during the study period. At a lower standard of 70ppb, 2,450 to 4,130 deaths would have been avoided, and at a standard of 60ppb, 5,210 to 7,990 deaths would have been avoided. At the 75ppb standard, acute respiratory symptoms would have been reduced by three million cases and school-loss days by one million cases annually. Even greater avoided mortalities and morbidities would have been achieved at 70ppb and 60 ppb standards.

## EARLY HOLIDAY GIFT

Did you know that frankincense (Boswellia resin) has anti-inflammatory substances? Yes, and researchers at Friedrich Schiller University Jena, Germany say these substances can be very beneficial in therapies against diseases like asthma, rheumatoid arthritis or atopic dermatitis. They noted that Boswellia resin has been used for thousands of years in Ayurvedic medicine. But now researchers have shown just exactly where the boswellic acids actually interfere in the process of inflammation. They interact with proteins that are part of inflammatory reactions, but most of all with the enzyme which is responsible for the synthesis of prostaglandin E2. Boswellic acids block this enzyme and thereby reduces the inflammatory reaction. Boswellic acids are expected to have less side effects than today's anti-inflammatory treatments like diclofenac or indometacin. The most potent of the acids, Boswellia papyrifera, occurs mostly in Northeast Africa, and in Yemen and Oman. Trees are the only source of its active ingredients, but the trees are often already an endangered species.

## TAKING ADVANTAGE

Researchers at Brigham and Women's Hospital (BWH) have discovered a new vaccine candidate for the bacterium

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*Pseudomonas aeruginosa* taking advantage of a new mechanism of immunity. The investigators designed a screen for Th17-stimulating protein antigens expressed by a molecular library of DNA encoding *Pseudomonas* proteins. The screen discovered that the *Pseudomonas* protein PopB is a very effective stimulator of Th17 immunity, and immunization with purified PopB protected mice from lethal pneumonia in an antibody-independent fashion. The researchers are constructing conjugate vaccines using PopB as a protein carrier with the hopes of improving the effectiveness of the vaccine. They hope that the PopB-based vaccine might one day be used to prevent *Pseudomonas* infections in hospitalized patients and in people with cystic fibrosis. They found that asthma-promoting immune cells could be rewired so they no longer cause inflammation.

### LOWER PRICE

Treatment Action Group (TAG) and the European AIDS Treatment Group (EATG) welcome the announcement that a deal has been reached among PEPFAR, USAID, UNITAID, and the Bill & Melinda Gates Foundation to reduce the price of the GeneXpert MTB/RIF rapid test for tuberculosis. The molecular diagnostic system accurately diagnoses both TB and some common drug-resistance mutations within two hours. The agreement reduces the cost of individual Xpert cartridges by 40%, from \$16.98 to \$9.98 and locks in that price from further increases until 2022. However, the price reduction for the cartridges will only be applicable to a set number of pre-approved purchasers in resource-poor countries with high burdens of multi-drug resistant TB (MDR-TB) and co-infection of HIV and TB. Middle-income countries in Eastern Europe and Asia with high TB burdens are currently excluded from this agreement. Moreover, the price of the diagnostic system itself is still unacceptably high at \$17,000 per device. Further costs associated with recalibrating the machine make it unattainable in many TB-affected settings. The test reduces the time to diagnosis for TB or suspected MDR-TB from the weeks it takes for the standard TB culture to grow to two hours.

### ATHLETES AND ASTHMA

A study by the University of Western Australia has identified those athletes with asthma and airway hyper-responsiveness, based on data from the last five Olympics. With a prevalence of around 8%, they are the most common chronic conditions among Olympic athletes, and could be related to intense training. The researchers identified those athletes with documented asthma and AHR from among those who used inhaled beta-2 agonists (IBA), a drug frequently used by elite athletes as an anti-asthma treatment. The athletes with asthma and AHR have continually beaten their colleagues, although there is no scientific evidence that the treatments provided improve performance.

### NEED SLEEP TOO

A recent study has shown that vaccines are much less effective if the person who received the vaccine is not getting the recommended amount of sleep. It was noted that with the emergence of our 24-hour lifestyle, longer working hours, and the rise in the use of technology, chronic sleep deprivation has become a way of life for many Americans. A study at the University of Pennsylvania recruited 120 non-smoking adults between age 40 and 60; 55 were male and 70 were female. The researchers gave each of the volunteers the normal hepatitis B vaccine. The volunteers' antibody levels were tested before they were given their second and third vaccines and again 6 months after the last vaccine injection. This would decide if they had

a clinically protective response. The volunteers were asked to keep a record of their sleep habits, and 88 wore actigraphs. The results showed that people who did not sleep more than 6 hours a night were 11.5 times more likely to not be protected by the hepatitis B vaccine than people who were sleeping at least 7 hours a night. Quality of sleep did not affect the outcome of the study at all, and 18 of the 125 volunteers did not end up with admissible vaccine protection. Based on information reported by Medical News Today, written by Christine Kearney, copyright Medical News Today.

### LONG NIGHT

Researchers at Johns Hopkins have discovered another possible benefit of a night of restful and uninterrupted sleep. According to a new study, fragmented or interrupted sleep could predict future placement in a nursing home or assisted living facility. Results showed that in community-dwelling older women, more fragmented sleep is associated with a greater risk of being placed in a nursing home or in a personal care home. Those who spent the most time awake after first falling asleep had about 3 times the odds of placement in a nursing home. Individuals with the lowest sleep efficiency, those who spent the smallest proportion of their time in bed actually sleeping, also had about 3 times the odds of nursing home placement. The authors found similar patterns of associations between disturbed sleep and placement in personal care homes, such as assisted-living facilities. Participants with a mean range of 83 years old wore actigraphs on their non-dominant wrists for at least three days. Demographic information as well as place of residence at initial interview and at 5-year follow-up was also provided.

## True or False?

*It takes the same amount of force to achieve effective CPR on each of these patients.*



**False.** Different anatomies require different amounts of force to deliver effective CPR.



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## SLEEP REGULATION

Spanish researchers have discovered a new function of dopamine in controlling sleep regulation. It was long believed that norepinephrine receptors acted independently of other proteins, but in the study, researchers discovered that the receptors collaborate with other dopamine receptors forming “heteromers.” When dopamine then interacts with its receptors, it inhibits the effects of norepinephrine—which means a decrease in the production and release of melatonin. The researchers found that these dopamine receptors only appear in the pineal gland towards the end of the night, as the dark period closes. Therefore, the researchers conclude, the formation of these heteromers is an effective mechanism to stop melatonin production when the day begins and to wake up the brain. The discovery of this new function of dopamine could be useful when designing new treatments to help mitigate circadian rhythm disturbances, such as those related to jet lag, those found among people who work at night, and in cases of sleep disorders in general.

## STAY AWAKE!

Sleep deprivation in the first few

hours after exposure to a significantly stressful threat reduces the risk of Post-Traumatic Stress Disorder, according to a study by researchers from Ben-Gurion University and Tel Aviv University. Sleep deprivation of approximately six hours immediately after exposure to a traumatic event reduced the development of post-trauma-like behavioral responses. In the experiments, rats that underwent sleep deprivation after exposure to trauma (predator scent stress exposure), later did not exhibit behavior indicating memory of the event, while a control group of rats that was allowed to sleep after the stress exposure did remember, as shown by their post-trauma-like behavior.

## BETTER SEX

Men who suffer from OSA are seeing another potential benefit from CPAP: improved sexual function and satisfaction. Researchers at Walter Reed National Military Medical Center assessed the erectile function and libido of 92 men who were newly diagnosed with OSA and starting CPAP therapy. Erectile dysfunction is common in OSA patients, and nearly half of the men in the Walter Reed study reported the presence of ED. Patients were assessed again after one, three and six months of CPAP therapy. The results showed that CPAP improved sexual function and satisfaction in the majority of men in the study regardless of their level of erectile function reported at the start. Those with ED had more robust improvements and many without ED reported improved sexual function and satisfaction.

## SCAREDY CATS

A study of Toronto college students revealed that a contributing factor of insomnia is fear of the dark. Nearly half of the students who reported having poor sleep also reported this fear. Researchers confirmed this objectively by measuring blink responses to sudden noise bursts in light and dark surroundings. Good sleepers became accustomed to the noise bursts but the poor sleepers were more easily startled in the dark. Most effective insomnia treatments encourage people to leave the dark bedroom and go into a lit room; however, this would not be a way to treat a dark-related phobia.

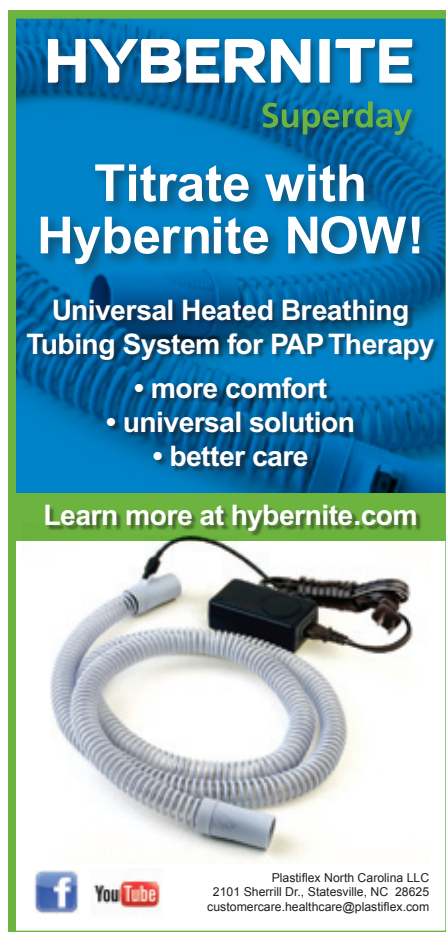
## SDB AND CANCER

Sleep disordered breathing, already associated with an increased risk of adverse cardiovascular events and psychopathological outcomes, is also associated with an increased risk

of cancer mortality, according to a study at the University of Wisconsin. The researchers examined 22-year mortality data on 1,522 subjects. SDB was assessed by polysomnography at baseline. Compared to subjects without SDB, the adjusted relative hazards of cancer mortality were 1.1 for study participants with mild SDB, 2.0 for those with moderate SDB, and 4.8 for those with severe SDB. The researchers said in vitro and animal studies suggest that intermittent hypoxia promotes angiogenesis and tumor growth, which can explain these observations.

## ACCESS TO RESEARCH

In our last issue, we wrote about protests about the high cost of medical journals. Below is a copy of a correspondence we received from Harvard, titled, “Faculty Advisory Council Memorandum on Journal Pricing—Major Periodical Subscriptions Cannot Be Sustained.” It said: “To: Faculty Members in all Schools, Faculties, and Units. We write to communicate an untenable situation facing the Harvard Library. Many large journal publishers have made the scholarly communication environment fiscally unsustainable and academically restrictive. This situation is exacerbated by efforts of certain publishers (called “providers”) to acquire, bundle, and increase the pricing on journals. Harvard’s annual cost for journals from these providers now approaches \$3.75M. In 2010, the comparable amount accounted for more than 20% of all periodical subscription costs and just under 10% of all collection costs for everything the Library acquires. Some journals cost as much as \$40,000 per year, others in the tens of thousands. Prices for online content from two providers have increased by about 145% over the past six years, which far exceeds not only the consumer price index, but also the higher education and the library price indices. These journals therefore claim an ever-increasing share of our overall collection budget. Even though scholarly output continues to grow and publishing can be expensive, profit margins of 35% and more suggest that the prices we must pay do not solely result from an increasing supply of new articles... The Faculty Advisory Council to the Library, representing university faculty in all schools and in consultation with the Harvard Library leadership, reached this conclusion: major periodical subscriptions, especially to electronic journals published by historically key providers, cannot be




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sustained: continuing these subscriptions on their current footing is financially untenable. Doing so would seriously erode collection efforts in many other areas, already compromised. It is untenable for contracts with at least two major providers to continue on the basis identical with past agreements. Costs are now prohibitive. Moreover, some providers bundle many journals as one subscription, with major, high-use journals bundled in with journals consulted far less frequently.” Harvard suggested that its researchers: “Consider submitting articles to open-access journals, or to ones that have reasonable, sustainable subscription costs; move prestige to open access. If on the editorial board of a journal involved, determine if it can be published as open access material, or independently from publishers that practice pricing described above. If not, consider resigning...”

### SOOT NOT GOOD

Medical News Today reported that The Journal of Aerosol Science has recently published the first in-depth study on 10 healthy volunteers to establish how diesel soot gets stuck in people’s lungs. Researchers at Lund University showed that over half of all inhaled soot particles remain in the body, higher than most other particles. For example, 20% of wood smoke and other biomass combustion particles remain in the lungs. One potential explanation could be that because diesel soot consists of smaller particles, these particles are able to penetrate deeper into the lungs and get deposited there. Information from an article written by Petra Rattue, copyright Medical News Today.

### INTERNATIONAL

ISAF 2012, The International Severe Asthma Forum, is being held October 11 to 13 in Gothenburg, Sweden. It offers a comprehensive program that covers all aspects of severe asthma, from how to define it to “epidemiology of asthma exacerbations.” Contact [info@news.eaaci.org](mailto:info@news.eaaci.org).

### INFRARED

An article published on BioMed Central recently reported on neonatal respiratory monitoring using real-time infrared thermography. The paper described non-contact monitoring of neonatal vital signals to track the spontaneous respiration rate of the neonates. The article showed that the respiration rate of neonates can be monitored based on analysis of the anterior naris (nostrils) temperature profile associated with the inspiration and expiration phases successively. Continuous wavelet transformation based on Debauches wavelet function was applied to detect the breathing signal within an image stream. Respiration was successfully monitored based on a 0.3°C to 0.5°C temperature difference between the inspiration and expiration phases. For more visit BioMed Central and type the full title, Neonatal Non-contact Respiratory Monitoring based on Real-time Infrared Thermography, Abbas K. Abbas et al.

### BMC NEWS

BMC Research Notes has published its first case reports. BioMed Central’s dedicated case report journal, Journal of Medical Case Reports, already publishes case reports of unique or unusual clinical conditions, and BMC Research Notes will now provide a venue for those reports that feature more every day, common cases that will build an important body of literature of educational value. All cases in BMC Research Notes and Journal of Medical Case Reports will be added to BioMed Central’s forthcoming Cases Database, a continuously updated, freely accessible database allowing users to explore peer-reviewed

case reports. Learn more about case reporting at BioMed Central from its blog... Multidisciplinary Respiratory Medicine has begun publishing open access articles with BioMed Central. The journal, originally published by Novamedia srl, launched in 2006 as the official scientific journal of the Interdisciplinary Association for Research in Lung Diseases, AIMAR.

### MUTANT VIRUS!

The news website Raw Story reported: Scientists who created a mutant virus to explore a key aspect of influenza published their research recently after a four-month storm that brewed fears of bioterrorism and accusations of censorship. The controversy began in December when teams in the United States and the Netherlands separately said they had engineered a hybrid virus in high-security labs. Their goal was to understand how a highly lethal strain of flu which spreads among birds but is hard to transmit to mammals could mutate into a variant that is contagious among humans. A 23-member expert panel that advises the US government called for manuscript changes before the work could be published in a journal, the traditional arena for displaying and discussing scientific work. It feared that full disclosure could help a rogue state or bioterror group make a virus against which no-one would be immune. But some scientists lashed out at the recommendation, saying it was an attempt to censor or stifle scientific discourse. Two journals put the papers on hold while they consulted the researchers and the panel, the National Science Advisory Board for Biosecurity (NSABB). The British journal Nature finally published one of the studies, conducted by a team led by Yoshihiro Kawaoka at the University of Wisconsin. “The essential scientific elements (in the original manuscript) were unchanged,” the journal said, adding

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<sup>1</sup>Timmerman S et al. *Resuscitation*. 2004;61(3):273-80.  
<sup>2</sup>Swanson, et al. *Circulation*. 2008;118:5767.

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it was publishing the paper after receiving “several independent pieces of biosecurity advice.” Nature showed journalists a report from “a bio-defence agency outside the US,” which it declined to name, that said the benefits of publication outweighed the risks. “This information could be used by an aggressor and shows one of the building blocks for the development of a potential BW [biowarfare] weapon,” the report said. “[Such skill] is a demanding capability, probably beyond the capacity of the majority of those groupings of concern,” it said. “On the other hand, not publishing this information would slow, or even block, the development of a vaccine against a virus that still has the potential to mutate naturally to a pandemic form, which could cause huge numbers of fatalities worldwide.” Touching on the tension between freedom of expression and scientific responsibility, Nature said it was “desirable” to have a forum such as NSABB but in this case the panel had over-reacted. “There are justified concerns among the research community about the NSABB’s processes, and these processes should be reviewed.” The above is an edited version of the original story that appeared in Raw Story.

## LICENSING AND TRUCKING

RT Sleepworld on the web reported that The Michigan Office of Regulatory Reinvention is recommending the elimination of occupational licensing regulations for respiratory therapists... The Federal Motor Carrier Safety Administration wants to adopt sleep apnea recommendations, and has outlined triggers for testing and treatment with PAP. For more visit RT Sleepworld.

## NEWS FEATURE

### Noninvasive Ventilation and Humidification

Carl Sprow, RCP

Noninvasive ventilation (NIV) is often used in the treatment of patients that have chronic obstructive pulmonary disease (COPD) to prevent intubation. Bronchodilators and secretion clearance are two other therapies that play a part in the overall success of NIV. But, does humidification play a role in this success as well? The jury is still out but let’s take a look at some of the pro and cons.

Mouth dryness is one of the biggest complaints from patients that require NIV and experience an adverse effect. Patients that require NIV often have a higher than normal minute ventilation, fever, and dehydration, all of which contribute to upper airway dryness and discomfort. Heated humidification not only improves patient comfort and compliance with NIV but also reduce the potential for sinus infections and pneumonias. There are currently two ways of providing humidification. One is a heated humidifier with a power source and water supply and the other is an HME (heat-and -moisture exchanger) which recycles the patient’s own heat and humidity. HMEs, in our view, should not be used due to the typical leaks found with NIV and the additional deadspace.

During NIV without heated humidification, airway mucosa are cooled off. This leads to heat and moisture loss and drying which, in turn, increases airway resistance. Patients using pressure targeted nasal NIV had a 12% reduction in their expired

tidal volume due to the increased resistance. Patients that used a mask during NIV had complications due to high and unidirectional flow and ever present leaks, also leading to the drying of the mucosa and secretions. As the mucosa dries out and secretions are retained in the oropharynx, a patient failing NIV at this stage can cause a very difficult intubation.

Cost considerations are always something that comes into play with all medical procedures, including NIV. With no concrete supportive evidence, do the costs of humidification outweigh the benefits? Additional equipment needed for NIV humidification will increase the materials cost; however, if humidification improves patient comfort and tolerance and prevents intubation, the cost may well be worth the well being of the patient.

The debate of whether or not to use humidification during NIV continues. Patient comfort is critical as it is related to the tolerance of NIV. Further studies need to be done comparing humidified gas versus ambient gas and look at intubation rates and improvement in patient symptoms.

Carl Sprow is Clinical Application Specialist with Hamilton Medical, Inc. This article is from Hamilton’s newsletter.

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<sup>1</sup>Timerman S et al. *Resuscitation*. 2004;61(3):273-80.

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The NEW G5 FREEDOM Airway Clearance System from General Physiotherapy, Inc, is the most advanced technology for Chest Postural Drainage developed by General Physiotherapy, originator and manufacturer of the famous G5 Percussor product line used world-wide in medical institutions and homecare environments. The G5 FREEDOM System is hands-free and contains 8 percussion pods that incorporate High Frequency Chest Wall Percussion (HFCWP) to effectively loosen, liquefy, and mobilize thick tenacious lung secretions. A hand-held control module allows medical professionals to prescribe the exact cycle per second range for each Percussion Pod and activate them individually, sequentially, or all at one time. The G5 FREEDOM System operates without an air compressor so it is almost silent. You can review this game-changing respiratory therapy device at [www.g5.com](http://www.g5.com). See it at AARC, Booth 106.

## **TEAMWORK**

Covidien announced the launch of its Nellcor SpO<sub>2</sub> single parameter module for use with the Philips IntelliVue patient monitoring platform. The Nellcor SpO<sub>2</sub> module incorporates Nellcor OxiMax pulse oximetry technology, providing a cost-effective means for clinicians to detect and treat potentially life-threatening events by creating a more complete picture of a patient's respiratory function status. The single parameter module is available in North America, the European Economic Area (EEA) and other select international markets. Use of the Covidien Nellcor OxiMax pulse oximetry technology with Philips monitoring platforms can lead to enhanced patient care by providing clinicians with cardiac-based readings of SpO<sub>2</sub> and pulse rate. The Nellcor SpO<sub>2</sub> single parameter module is also compatible with the full line of Covidien Nellcor sensors, including: the Nellcor forehead sensor, which gives readings when conventional finger sensors fail, detects changes in oxygen saturation earlier than conventional sensors and is approved for use with ventilated patients; Nellcor non-adhesive sensors, which protect sensitive skin, a particular benefit to patients in the NICU; and single-patient-use oximetry sensors, which protect against hospital-acquired infections. The Nellcor SpO<sub>2</sub> single parameter module is compatible with the Philips IntelliVue MP40 through MP90 monitors and the Philips IntelliVue MX 600, MX 700 and MX 800 monitors. Covidien also announced that the FDA has granted the company 510(k) clearance to market the Covidien Nellcor Bedside SpO<sub>2</sub> Patient Monitoring System. The new patient monitoring system is now available for sale in the US. The Nellcor Bedside SpO<sub>2</sub> system with OxiMax technology continuously monitors SpO<sub>2</sub> and pulse rate for adult, pediatric and neonatal patients, giving clinicians instant access

to comprehensive trending respiratory information. This enables clinicians to detect subtle, yet critical, heart rate and SpO<sub>2</sub> variations earlier and thus address respiratory complications sooner. The Nellcor Bedside SpO<sub>2</sub> Patient Monitoring System also features enhanced digital signal processing for precise SpO<sub>2</sub> readings during low perfusion or other challenging conditions that make it difficult to accurately track these patients. Its SatSeconds alarm management technology differentiates between serious and minor events to reduce clinically insignificant oxygen desaturation alarms. The monitor further offers an intuitive, multicolor screen that is easy to read in any light and from many angles. Additionally, hospital technicians can set institutional defaults, replace the battery, perform diagnostics and generally maintain the monitor within the hospital, saving time and resources. Contact [covidien.com](http://covidien.com).

## **APPROVED FOR VETS**

Breathe Technologies, Inc received official approval from the Department of Veterans Affairs for its Non-Invasive Open Ventilation (NIOV) System to be added to the Federal Supply Schedule (FSS). The NIOV System has important benefits for patients with later stage chronic obstructive pulmonary disease (COPD), which is fairly common among the veteran population. Breathe has partnered with Jordan Reses Supply Company, a specialty respiratory distributor to the VA, to lead commercialization efforts. Jordan Reses, a leading small business contractor with a Federal Supply Schedule, specializes in respiratory products. The NIOV System is an innovative one-pound ventilation system with a proprietary patient interface. It is designed to facilitate ambulation for adult patients with moderate to severe respiratory insufficiency. It is FDA cleared for adult use in inpatient, outpatient and homecare settings. Contact [breathetechnologies.com](http://breathetechnologies.com).

## **INVESTMENT**

Ringadoc, a health company that brings virtual medical visits to any phone or computer on demand, announced that it has received \$750K in a seed round led by FF Angel, the seed investment vehicle of Founders Fund, the San Francisco-based venture capital firm. The round also includes participation from board member Ryan Howard, CEO and founder of fast-growing physician-patient community Practice Fusion, and Curious Minds, a Los Angeles-based technology incubator. Ringadoc currently facilitates on demand virtual visits over any phone, smartphone, or computer. This direct-to-consumer product connects people to licensed, verified physicians, who can provide health advice, diagnoses, and even prescriptions when warranted. Powering the service is an instant routing technology that enables patients to receive quality medical care on demand, without the need to schedule an appointment or visit a facility in person. The company will use the seed funding to build a new product offering for physicians to use directly in their offices as well as for key hires. Contact [ringadoc.com](http://ringadoc.com).

## **STIMULATING**

Dr Daniel Rodenstein presented data during a poster session at this year's American Thoracic Society International Conference (ATS). He reported the results of a 1 year study of targeted hypoglossal neurostimulation (THN) for severe obstructive sleep apnea conducted with ImThera's aura6000 THN System, including the observation of a THN stimulation benefit that persists for days after stimulation is interrupted. This is the first report of a persistent beneficial stimulation effect with any hypoglossal nerve stimulation technique. ImThera's

proprietary Targeted Hypoglossal Neurostimulation (THN Sleep Therapy) delivers stimulation to key muscles of the tongue during sleep, opening the upper airway and substantially reducing or eliminating OSA events. Dr Daniel Rodenstein is the principal investigator of the THN Feasibility Study (Center for sleep medicine at Cliniques universitaires Saint-Luc, Université catholique de Louvain, Brussels, Belgium). Contact [intheramedical.com](http://intheramedical.com).

### TAKE A BREATH

The Breathe Non-Invasive OPEN Ventilation (NIOV) System is an FDA 510(k) cleared, wearable ventilation system designed for adult patients with respiratory insufficiency. It is particularly well-suited to help patients who have difficulty breathing while performing everyday activities of daily living (ADLs). The NIOV System is designed to increase mobility and promote ambulation by helping patients to participate more fully in life. The NIOV System is an easy-to-use, volume augmentation ventilator, delivering both ventilation and supplemental oxygen. The heart of the system is a small, one pound, battery-powered ventilator that can be easily worn at the waist while ambulating, exercising or performing activities of daily living. An external source of high pressure oxygen is required. The unique OPEN ventilation technology uses a small, nasal pillow interface that is open to ambient air. The system senses the patient's spontaneous breath through sense ports in the nasal interface, and then delivers the selected volume of oxygen at up to 40 breaths per minute. As oxygen is delivered, ambient air is entrained through the entrainment ports, and positive pressure is developed within the mask to supplement the patient's spontaneous breathing, reducing the work of breathing, supplementing the volume of air inhaled and improving oxygen delivery. The NIOV System typically produces airway pressures of 2-9 cm H<sub>2</sub>O, and is limited to a maximum of approximately 15 cm H<sub>2</sub>O lung pressure at maximum settings and conditions. The NIOV System may be customized to each patient's needs using clinician customized settings. Volume delivery settings ranging from 50 ml to 250 ml are easily programmed by the clinician for three activity levels, and are accessed using a password protected clinician menu. Patients are then able to self-select which of the three activity settings best meets their breathing needs simply by pushing the desired activity level buttons. A user-friendly LCD touch screen is provided to allow both patients and clinicians quick access to ventilator functions and readouts. Breathe Technologies, Inc has conducted multiple studies with the NIOV System. In its first randomized, controlled trial (NOVEL I), a mean improvement in six minute walk distance (6MWD) of 37 meters was observed (n=30), with a 43 meter improvement seen in a subset of patients with severe COPD. In a follow-up trial (NOVEL II), a mean improvement in 6MWD of 36 meters was observed (n=32), while a subset of patients with baseline 6MWD <300 showed a mean improvement of 73 meters. In a third trial (PRIDE), 18 subjects with severe COPD completed five consecutive, 6-hour clinic days in using the NIOV System during rest, ADLs, and while exercising. Study participants found the NIOV System to be comfortable and reported that the study device resulted in less dyspnea, reduced work of breathing, and greater mobility and exercise endurance compared to their current oxygen systems. The Non-Invasive Open Ventilation (NIOV) System was recently awarded a prestigious Medical Design Excellence Award (MDEA). The MDEA is the medical device industry's premier design awards competition and is the only awards program that exclusively recognizes contributions and advances in the design of medical products. Contact [breathetechnologies.com](http://breathetechnologies.com).

### APPROVAL SOUGHT

Janssen Research & Development, LLC announced it has submitted a New Drug Application (NDA) to the FDA seeking accelerated approval for the use of the investigational drug bedaquiline (TMC207) as an oral treatment, to be used as part of combination therapy for pulmonary, multi-drug resistant tuberculosis (MDR-TB) in adults. If approved by the FDA, bedaquiline would be the first drug with a new mechanism of action for TB in more than 40 years and the first and only one specifically indicated for MDR-TB. Bedaquiline's unique mechanism of action targets adenosine triphosphate (ATP) synthase, which Mycobacterium tuberculosis, the bacterium that causes tuberculosis, requires to generate its energy. The regulatory submission is supported by 24-week data from the Phase II clinical development program, which includes an open-label study and a controlled, randomized trial that evaluated the safety and efficacy of bedaquiline versus placebo in the treatment of patients with pulmonary MDR-TB in combination with a background regimen. Contact [janssenrnd.com](http://janssenrnd.com).

### PATIENT STORY

Vapotherm reported in its newsletter: Joel Ray, known as J-Ray to his friends and family, was diagnosed with idiopathic pulmonary fibrosis 4 years ago. In the third year of his diagnosis the disease advanced to the point that Ray needed a bilateral lung transplant to live. Ray underwent a transtracheal procedure because his respiratory demands could not be met with traditional oxygen cannula therapy. After the procedure he was put on 6 liters per minute of oxygen but was unhappy with the treatment, stating, "The dry oxygen was killing me." Ray's physician decided to prescribe Vapotherm to provide needed respiratory support and comfort. "It was so smooth, I didn't cough once and was able to sleep with it all night," Ray recalls. Ray's work as an estimator for a heating and air conditioning company demands that he talks to customers all day. By utilizing Vapotherm, he was able to continue working for the entire year while he waited for his lung transplant surgery. Now 59 years old, J-Ray has made a full recovery and regularly goes to the gym and plays golf every Saturday. "The device not only saved my life; it saved my quality of life too," Ray shared. At Vapotherm, stories like this provide the motivation for our work. We could not be more pleased with the outcome of J-Ray's experience using our technology. Contact [vtherm.com](http://vtherm.com).

### WINNERS

Kimberly-Clark Health Care today announced the recipients of the second annual HAI WATCHDOG Awards, created to recognize the efforts of dedicated healthcare professionals working together to prevent healthcare-associated infections (HAIs). The awards program, an initiative of the HAI WATCHDOG Community, facilitates the sharing of best practices among clinicians and recognizes four exceptional participants with an educational grant. The winners are Mary Black Memorial Hospital, Spartanburg, SC; Barnes-Jewish Hospital, St Louis; Michael E. DeBakey VA Medical Center, Houston; and Hallmark Health System, Medford, MA. Contact [haiwatchdog.com](http://haiwatchdog.com) or [kchealthcare.com](http://kchealthcare.com).

### OK TO MARKET

Kimberly-Clark Health Care announced that it has received 510(k) clearance from the FDA to market the KIMGUARD ONE-STEP portfolio with one-year maintenance of package integrity (MPI) for KC300 to KC600 for Pre-vacuum Steam and Ethylene Oxide (EO). Users can now have confidence that their

instruments wrapped with KIMGUARD ONE-STEP Sterilization Wrap will maintain sterility on the shelf for at least 365 days. The KIMGUARD ONE-STEP shelf-life is currently 12 times longer than any other sterilization wrap's shelf-life that has been previously cleared and marketed. With the most recent FDA clearance for Amsco V-PRO maX Low Temperature Sterilization System (Flexible Cycle), the KIMGUARD ONE-STEP Sterilization Wrap is now FDA cleared for use with all cycles in the three Amsco V-PRO Sterilization Systems. With this announcement, KIMGUARD Sterilization Wrap has the most 510(k) clearances of any sterilization wrap, including use with: Pre-vacuum Steam – up to 1 Year MPI; Ethylene Oxide (EO) – up to 1 Year MPI; Amsco V-PRO maX (V-PRO Lumen, Non Lumen and Flexible Cycles); Amsco V-PRO 1 Plus (V-PRO Lumen and Non Lumen Cycles); and Amsco V-PRO 1 (V-PRO Lumen Cycle). Contact [khealthcare.com](http://khealthcare.com).

### LIVE IT UP

The LIFE StartSystem from LIFE Corporation weighs only 8 pounds, smaller than a briefcase at 12"x12"x3", durable and water resistant, complete with LIFE-O2 6&12 LPM "Norm & High" Emergency Oxygen in Disposable/Replaceable (or refillable) 15+ minute supply aluminum cylinder and LIFE CPR Mask universally fits adult & child; for first-aid emergency oxygen administration, and if needed before fibrillation or after successful defibrillation (purchase Philips "OnSite" AED separately). Contact [lifecorporation.com](http://lifecorporation.com), (800) 700-0202.

### ACQUISITION

Chart Industries, Inc announced that it has entered into a definitive agreement to acquire AirSep Corporation for \$170 million in cash and up to \$10 million in assumed debt. AirSep is a leading manufacturer of oxygen generating systems for medical and industrial applications. The company designs and manufactures stationary and portable oxygen concentrators for medical use, such as the ultra lightweight Focus, FreeStyle and VisionAire. AirSep is expected to add approximately \$130 million in annual revenues to Chart's BioMedical segment. Contact [airsep.com](http://airsep.com) or [chartindustries.com](http://chartindustries.com).

### GO WITH THE FLO

Maxtec, Salt Lake City UT is pleased to announce our new MaxFLO<sub>2</sub>. The MaxFLO<sub>2</sub> provides an affordable method for mixing and monitoring air and oxygen in both high flow (0-50 liters per minute) and low flow (0-10 liters per minute) applications. Each unit comes equipped with dual flow meters and a mixed gas analysis port for intermittent or continuous monitoring of FiO<sub>2</sub>. When used in conjunction with our MaxO<sub>2</sub>+A handheld oxygen analyzer, users can mix and measure accurate oxygen concentrations with added confidence. Gas ratios are also visibly identified on the face of the unit to allow for fast, accurate flow settings. Every unit also includes a built-in pole mount and is backed by a Maxtec 24 month warranty. Contact (800) 748-5355, [maxtecinc.com](http://maxtecinc.com).

### HIRED

MADA International Ltd announced the hiring of Rafael Bassi as International Sales Manager for Latin America. Rafael is a native of Colombia, SA and earned his BBA degree from Corp Universitaria Simon Bolivar in Barranquilla, Colombia. He brings over 10 years of sales experience focused on Latin America. For over 42 years Mada has been a leading manufacturer of Respiratory Therapy and Infection Control Products. Contact [madainternational.com](http://madainternational.com).

### STAY SAFE

Mercury Medical has introduced the Flow-Safe II Disposable CPAP System for emergency care, which offers over 50% less oxygen consumption, with high FiO<sub>2</sub> delivery, which is a major advantage for long transport, and uses standard flowmeters. The lightweight contoured mask provides a better seal, while the nylon headpiece and quick release front clips maximize patient comfort. Its built-in manometer and pressure relief valve verifies consistent delivered CPAP pressure. It requires no assembly of separate apparatus, and the pressure relief valve automatically adjusts to avoid excess pressure. The nebulizer, with in-line capability, allows administration of meds without mask removal. Contact (800) 237-6418, [mercurymed.com](http://mercurymed.com).

### MAKING SENSE

Nonin Medical, Inc announced the US market release of its EQUANOX Advance Model 8004CB Series neonatal/pediatric sensor. The EQUANOX Advance 8004CB Series Sensor with Nonin's patent-pending Dynamic Compensation algorithm is the first and only cerebral/somatic sensor to automatically account for pediatric brain-tissue-development variation when measuring oxygen saturation levels. The sensors are designed for use with Nonin's EQUANOX Advance Model 7600 Oximetry System in cerebral or somatic positions on patients weighing less than 40 kg. EQUANOX is a near infra-red spectroscopy (NIRS)-based monitoring device that noninvasively and continuously detects oxygen saturation status in brain and other tissue. The device allows clinicians to quickly react to reverse harmful tissue ischemia events before they become critical. The EQUANOX Advance 8004CB and 8004CB-NA (non-adhesive) Neonatal/Pediatric Sensors, along with the Model 7600 Oximetry System, provide additional advantages including: cerebral and somatic monitoring – up to four channels displayed on one screen for monitoring oxygen saturation in the brain and somatic sites on the body, including kidney and liver sites. Patented dual-light emitters and detectors with four wavelength accuracy – the first and only device that utilizes a dual-light emitting and detecting sensor architecture, which has been shown to more effectively target the cerebral cortex, eliminating surface artifacts that interfere with measurement accuracy. Absolute accuracy – assures accurate measure of tissue saturation at a point in time, not just relative or trending accuracy of changes. Consistency and reliability – rapid, reliable response to change without signal instability and interruptions from ambient electrical and light interferences. Portability and connectivity – lightweight, durable monitor with long battery life and pole-mounting capability for continually monitoring patients during intra-hospital transport. Data output available via Bluetooth wireless technology or RS232 connection. Interfaces with Philips VueLink (through Philips IntelliVue Monitor), Philips CompuRecord Anesthesia Information System, Spectrum Medical VIPER Independent Data Management System and Sorin Perfusion Data Management System. Contact (800) 356-8874, [noninequanox.com](http://noninequanox.com).

### COMBO

Philips Respironics recently introduced the Pro-Tech ezRIP combination module/wireset sensor, designed to provide a low initial RIP investment for sleep labs. ezRIP effort modules operate with Pro-Tech zRIP DuraBelt effort sensor belts to help minimize bedside module congestion. ezRIP provides easy configurability for sleep lab technicians. The driver module clips directly onto the zRIP DuraBelt or legacy zRIP belt. By plugging the ezRIP wireset into the belt effort sensor and the PSG headbox, the driver module is kept out of the way. Patients

can enjoy the movement and freedom associated with minimal RIP equipment being used in the sleep study. The device includes non-replaceable batteries and a one-year warranty. Contact [Philips.com/sleepdx](http://Philips.com/sleepdx).

#### **PARTNERED**

Nonin Medical, Inc announced that it has been named a Platinum Partner by Tri-anim Health Services, Inc. Tri-anim Health Services sells and distributes products for hospitals, extended care, surgical, home care, and long-term acute care in the United States. Tri-anim is owned by Sarnova, Inc, the nation's leading specialty distributor of healthcare products in the respiratory and emergency medical services markets. Contact [nonin.com](http://nonin.com).

#### **HOSPITAL POC**

Roche announced the US introduction of the cobas b 123 POC system, a mobile blood gas analyzer designed for hospital point-of-care settings. The system's next-generation technology helps ensure reliable performance by virtually eliminating the formation of blood clots that can contribute to analyzer downtime and negatively impact patient care. With patented thick-film sensor technology and a broad assay menu that includes lactate, the cobas b 123 POC system offers fast turnaround time for 15 important critical-care blood gas electrolyte tests. It has a mobile cart to facilitate use in a variety of areas, from the intensive care unit to the patient floor. The analyzer features an unparalleled four-level clot protection system that helps prevent downtime caused by the introduction of clots that lead to reagent pack failures—a major issue for healthcare facilities because replacing the pack takes time away from patient care and wastes usable reagent. In addition, the reagent packs for the cobas b 123 POC system require no refrigeration and include smart chips, allowing them to be easily transferred between similar devices and helping hospitals control material and labor costs. The cobas b 123 POC system offers automatic linearity testing and calibration to simplify both workflow and regulatory compliance. Roche's Electronic Quality Assurance Program (eQAP) also gives hospitals access to anonymous linearity and quality control peer performance data to make it easier to benchmark their QC data. Contact [roche.com](http://roche.com).

#### **SHOWCASED**

Philips Respironics, a unit of Royal Philips Electronics showcased the latest innovations for diagnosing, treating and managing the full spectrum of sleep-disordered breathing patients at SLEEP 2012, the 26<sup>th</sup> Annual Meeting of the Associated Professional Sleep Societies (APSS). Philips Respironics' interactive exhibit chronicled a "day in the life" of a clinician and two obstructive sleep apnea (OSA) patients from diagnosis to therapy. Several new products were also displayed: The Amara full-face mask, the Fit for Life resupply program, the SleepMapper self-management system, and the System One REMstar Pro and REMstar Auto devices. Philips Respironics also launched its revitalized website, [SleepApnea.com](http://SleepApnea.com). Contact [healthcare.philips.com](http://healthcare.philips.com).

#### **COMPLIANCE**

ResMed Inc announced that it has acquired an innovative data services technology provider, Umbian Inc. Headquartered in Halifax, Nova Scotia, Umbian offers a comprehensive patient compliance management solution called U-Sleep, which monitors continuous positive airway pressure (CPAP) devices and provides a suite of interactive follow-up services for

healthcare providers. U-Sleep provides an original and flexible compliance solution that monitors CPAP device usage and helps HMEs to coach their patients during their initial acclimatization and ongoing therapy. For HME providers, U-Sleep is an effective tool to reduce cost and improve business efficiency. U-Sleep supports CPAP devices from the leading CPAP manufacturers so that usage data can be consolidated and viewed from one software interface. The technology is able to assess a patient's compliance using a flexible set of rules that have been set up for that individual and provide immediate notification of compliance outcomes via email, phone or text message. U-Sleep's simple yet powerful design also provides multiple reporting options tailored to the varying needs of CPAP providers, patients, referring physicians, employers and payors. Users can customize U-Sleep's compliance parameters based on a variety of insurance requirements. Contact [u-sleep.com](http://u-sleep.com) or [resmed.com](http://resmed.com).

#### **ROAD TRIP**

On July 24th, 69-year-old Mark Junge embarked on a 10-day, 225 mile bicycle journey through Alaska. With a Philips Respironics SimplyGo portable oxygen concentrator (POC) strapped to the back of his bike to help him breathe more easily on his trip, Junge helped raise awareness for COPD and encouraged oxygen-dependent people to stay as active as possible. The Philips Respironics SimplyGo portable oxygen concentrator (POC) strapped to the back of Junge's bike helped him breathe more easily on his journey. The approximate 10-day ride began in Homer, Alaska. Junge said, "My bike adventure shows the world that living with portable oxygen can't stop me—and it shouldn't stop anyone—from living the life they want. SimplyGo makes breathing easier for oxygen users. I am grateful for the chance to be an inspiration to millions while I pursue my passion."

#### **POINT OF CARE**

A 100-test sensor cassette is available for Radiometer's ABL90 FLEX point-of-care blood gas analyzer. The new cassette allows lower volume customers – those who run fewer than 100 tests per month – to take advantage of the speed and time savings of the ABL90 FLEX without wasting patient tests. With the addition of the 100-test capacity, the ABL90 FLEX now offers 100-, 300-, 600- and 900-test sensor cassettes. The ABL90 FLEX point-of-care analyzer measures 17 parameters from just 65 µL in only 35 seconds. Cassette operation, easy replacements, uptime of over 23.5 hours per day and automatic quality management saves steps, reduces errors, and lets you stay focused on patient care. (Bilirubin not currently available in the US.) Contact [radiometeramerica.com](http://radiometeramerica.com).

#### **COMPREHENSIVE**

Rigel Pharmaceuticals, Inc is expanding its respiratory franchise by focusing on two innovative, comprehensive treatment alternatives for patients with asthma. One of these agents, R343, an inhaled SYK inhibitor, entered a Phase 2 clinical study this summer in mild to moderate asthmatic patients. The other, R256, an inhaled IL13 signaling/JAK inhibitor, is potentially useful in controlling moderate to severe as well as chronic forms of the disorder. To view Rigel's R343 Asthma Animation, go to [rigel.com/rigel/aa](http://rigel.com/rigel/aa).

#### **APPROVED**

Siemens Healthcare Diagnostics received CE Mark approval to offer pleural fluid pH testing on its RAPIDPoint 500 Blood Gas System, providing laboratories and point-of-care coordinators in Europe with an important new diagnostic tool for use in critical

care situations. While measurements can be taken using pH meters or indicator sticks, multiple studies have shown these methods to be less accurate than readings conducted using a blood gas analyzer. The addition of pleural fluid pH testing on the company's RAPIDPoint 500 system complements the analyzer's comprehensive critical care menu, which includes tests for blood gases, electrolytes, glucose and lactate and full CO-oximetry, including neonatal total bilirubin and total hemoglobin. The RAPIDPoint 500 system leverages proven Siemens technology to deliver laboratory-quality results in approximately 60 seconds from a single, whole blood sample. Further, the analyzer's measurement cartridges last up to 28 days and contain a full complement of tests, which reduces downtime. For commercial availability and more info about pleural testing on the RAPIDPoint 500 system, visit [siemens.com/rp500pf](http://siemens.com/rp500pf).

### CUSTOMIZED TREATMENT

For clinicians focused on delivering optimal humidification, the Teleflex, Inc (Hudson RCI Respiratory), ConchaTherm Neptune humidification system is designed to customize treatment for your individual patient's needs. Easily integrated into clinician workflow, the ConchaTherm Neptune with ISO-GARD Drain Circuit Technology allows you to tailor your patients' humidification requirements in a simple, safe and effective manner. The ISO-GARD family of products are simple, effective respiratory solutions that isolate contaminants and guard against patient and caregiver exposure. The ISO-GARD Drain Circuit Technology "Closed System" Advantage offers: *Simplicity* – easily integrated into clinician workflow, the ISO-GARD Drain is designed to be emptied at a frequency convenient to established suction protocols. *Safety* – Protect the Patient: The ISO-GARD Drain closed system design minimizes circuit breaks, minimizing the risk of cross contamination and VAP. Protect the Clinician: Ventilator circuit condensation is considered to be infectious waste and the ISO-GARD Drain minimizes the risk of caregiver exposure. Protect the Ventilator: The ISO-GARD Drain will collect condensate in the expiratory limb, reducing the risk of moisture entering the ventilator. *Improved Performance* – The Neptune Heated Humidifier allows you to follow important AARC Clinical Practice Guidelines and deliver 37° C, 44mg H<sub>2</sub>O/L and 100% relative humidity at the patient. The ISO-GARD closed system Circuit Technology reduces the need to interrupt ventilation, promoting continuous PEEP and gas exchange. Contact [teleflexmedical.com](http://teleflexmedical.com).

### COMPLETE LINE

TRACOE medical offers a complete product line consisting of various product families which complement each other, from tracheostomy tubes to items for postoperative care and rehabilitation. The most outstanding feature of **TRACOE twist** is an anatomically shaped neck flange that moves around two axes, allowing patients to turn their head and neck without the tube exerting pressure on the trachea. TRACOE *twist* tubes are made of tissue-friendly polyurethane (free of DEHP). TRACOE *twist* tubes have very thin walls, which ensure maximum air flow (1/3 as thick as conventional tubes), therefore they are well-tolerated by patients. The **TRACOE mini** is for newborns, infants and children. TRACOE *mini* tracheostomy tubes are particularly soft and equipped with a neck flange with a slanted bottom, providing the tube with an optimized and atraumatic fit. It is available in 12 different sizes (starting with size 2.5): 4 for neonates and 8 for pediatric use. The **TRACOE vario** comes in seven different models: reinforced with a metal spiral or as a clear, nonreinforced version (with an X-ray contrast line).

This soft and flexible single lumen tube has a patented, variably adjustable neck flange which can be moved along the tube by a simple and easy push-button mechanism on the body of the flange. **TRACOE comfort** tubes are mainly used for long-term wearing. They do not have to be removed for X-ray or cobalt therapy. A TRACOE comfort tube weighs only about one-third of a silver tube of the same size. The **TRACOE phon assist I** is a speaking valve for fenestrated TRACOE *twist* and *twist plus* tracheostomy tubes and stoma buttons and adhesive carrier. Like the *twist* and *comfort* range, the *mini* tubes are DEHP-free. Contact [tracoe.com](http://tracoe.com) or [bryanmedical.net](http://bryanmedical.net).

### NEW TUBING

Saint-Gobain Performance Plastics' Healthcare Markets Business Unit, a leading supplier of high-performance products for the most demanding medical applications, introduced a new silicone tubing technology. The new technology builds on the company's extensive experience in silicone extrusion and custom material compounding to provide customers with unparalleled quality control through real-time manufacturing metrics and superior performance compared to extruded tubes currently on the market. The technology features a new extrusion process that enables Saint-Gobain to constantly access in-process dimensional data about its tubing solutions, ensuring product consistency for medical applications. Saint-Gobain will also leverage its custom material compounding capability with the new extrusion process to specially engineer materials that meet customers' exact performance needs. Working collaboratively to understand an application's specific needs, the company can fine-tune silicone material properties, including tear strength, compression set, tensile/elongation, modulus, and durometer. Contact [plastics.saint-gobain.com](http://plastics.saint-gobain.com).

### SAFE SOLUTIONS

Covidien announced its support for The Joint Commission's recent Sentinel Alert recommendations for the "Safe use of opioids in hospitals." The Joint Commission's newly published recommendations address the risks of opioids by urging hospitals to establish procedures for accurate pain-level assessment as well as continuous monitoring of patients' blood oxygenation and ventilation through pulse oximetry and capnography. The Joint Commission's guidelines align with recommendations issued by the Anesthesia Patient Safety Foundation (APSF) and the Institute for Safe Medication Practices (ISMP) calling for continuous monitoring of ventilation of hospitalized patients receiving opioids postoperatively. Covidien offers respiratory function technologies and a complete portfolio of monitoring solutions that can help hospitals meet The Joint Commission, APSF and ISMP recommendations. The company's technologies include Integrated Pulmonary Index and a recently expanded suite of Nellcor pulse oximetry solutions. Covidien also helps hospitals comply with patient safety standards by partnering with healthcare providers to offer education and training. Contact [covidien.com](http://covidien.com).

### EMERGENCY

The LIFE Start System for industrial and office workplace first-aid programs and first responders, provides 15+ minute supply for first-aid emergency oxygen administration, and if needed before fibrillation or after successful defibrillation. Smaller than a briefcase at 12"x12"x3" it weighs only 8 pounds. It is durable and water resistant, complete with LIFE-O<sub>2</sub> Emergency Oxygen unit with 6&12 LPM "Norm & High" Regulator which provides AHA recommended 100% inspired oxygen.



Disposable/Replaceable (or refillable) 113 liter Cylinder, non-prescription, shipped full ready-to-use, with knurled-knob On/Off valve, constant reading supply gauge with simple full-to-empty symbols, always visible through clear window, and LIFE CPR Mask that universally fits Adult & Child. (Purchase Philips OnSite AED separately) #LIFE-O2-LSS – LIFE StartSystem, includes LIFE-O2 Emergency Oxygen with 6&12 LPM regulator for AHA recommended 100% inspired oxygen @12 LPM #LIFE-O2-101 - Replacement Cylinder, including valve, gauge and oxygen filled Additional options: for EMTs, include a pulse oximeter and/or capnometer, for measuring SpO2 - Saturation of peripheral Oxygen PR & PS - Pulse Rate & Strength EtCO2 - End-tidal breath Carbon Dioxide. FDA Regulation minimum capability is 6 LPM flow rate. LIFE 612 models deliver both the minimum of 6 LPM and the AHA recommended 100% inspired oxygen at 12 LPM, in just two simple settings which read “NORM” & “HIGH”. Only LIFE Corporation offers the simple 6&12 LPM flow rates.

## AARC PREVIEW

### Aerogen

Booth 416

#### What new products will you be presenting?

We are very excited to be exhibiting our Continuous Nebulization Tube Set (CNTS). The continuous nebulization tube set is an accessory to the Aeronex Solo nebulizer system and is intended to enable safer continuous infusion of liquid medication for aerosolization into the Aeronex Solo nebulizer, while reducing the risk of a potential misconnection of a feed-line from another source. The tube set accessory has been designed to incorporate non standard, over sized luer connectors, ensuring that the risk of misconnection with standard luer connectors such as those in use in IV and enteral applications is eradicated. Additionally, the tube set has a unique blue coloration that immediately helps distinguish it from other tube sets typically found in the clinical setting.

#### What products will you be featuring that are of particular current importance?

Aerogen has developed the continuous nebulization tube set to eliminate any potential risk of misconnection between different luer connectors. Aerogen is committed to patient safety and is constantly working on improving the working environment for both respiratory therapists and patients.

#### Why should AARC participants visit your display?

RTs should stop by our booth (#416) if they want a hands on demonstration of our unique CNTS system. Aerogen provide the most technically advanced nebulizers on the market today with the Aeronex Solo and Aeronex Pro systems. RTs can learn more about how to improve the quality of ventilated patients' lives through the use of our highly efficient nebulizers. We will demonstrate how our nebulizer range saves RTs' valuable time as our products operate without changing patient ventilator parameters therefore not setting off ventilator alarms and can be refilled without interrupting ventilation. It may change the way you nebulizer forever. AARC offers us an excellent opportunity to meet with Aeronex users and hear about their experiences and needs with the technology.

## AG Industries

Booth 337

#### What products will you be presenting?

CPAP, Respiratory & O2 Filters & Accessories

#### What new products will you be featuring that are of current importance?

AG is introducing new CPAP Retail Packs & The Sopora Pediatric Mask with optional McCoy & Lulu headgear

#### Why should AARC participants visit your display

Come by AG Industries' booth for a hands-on introduction to the Sopora Pediatric CPAP Mask – see the innovative optional McCoy & Lulu headgear, and feel the uniquely designed silicone cushion and forehead pad. Also, be sure to inquire about being one of the first companies to receive a variety of AG retail packaging, including filters, chinstraps, tubing & cleaners.

## Alere, Inc

Booth 538

#### What products will you be presenting?

Alere will be presenting the epoc Blood Analysis System.

#### What new products will you be featuring that are of current importance?

Our relationship with Informatics Companies MAS and LDS.

#### Discuss educational/training materials you'll be promoting.

New White Papers focusing on epoc versus Near-Care systems, its impact to the total cost equation and error reduction, as well as assay creatinine & chloride comparison data (pending FDA 510k, not for sale within the United States).

#### What speakers or papers will your company be featuring?

The Pinnacle Experience paper.

#### Why should AARC participants visit your display?

Participants will learn firsthand what makes the epoc Blood Analysis System the next generation of choice, a cost effective bedside testing platform, focusing on how the system improves patient safety, provider satisfaction, workflow and operational efficiencies.

## CareFusion

Booth 601

#### What new products will you be featuring that are of current importance?

CareFusion has recently introduced the CareFusion Ventilation System—a suite of software applications comprised of the Respiratory Knowledge Portal and the Respiratory Documentation Application. These applications integrate with the CareFusion AVEA, VELA and EnVe ventilators. The CareFusion Ventilation System is designed to move respiratory care to a higher level by providing clinical analytics to help enhance patient care and by increasing the efficiency and accuracy of ventilator documentation.

**Respiratory Knowledge Portal:** The Respiratory Knowledge Portal is primarily a cloud based application that provides clinicians and administrators retrospective analytics on clinical and process variability that is typically unavailable. This information is then used in combination with hospital protocols such as weaning and lung protective strategies which may help hospitals improve patient outcomes and lower the cost of care. The key components of the system which support the Respiratory Knowledge Portal are: • *CareFusion Ventilator Connectivity Adapter\** – Renders ventilator data for transport over the hospital network. • *CareFusion Coordination Engine* – The interface building block for CareFusion products, it provides integration capabilities to hospital systems. • *CareFusion Knowledge Portal* – Hosted data center providing respiratory analytics and reporting. Data is accessible via any web-enabled device, including smartphones, tablets, laptops, etc.

**Respiratory Documentation Application:** The Respiratory Documentation Application is designed to provide more efficient and accurate documentation associated with respiratory therapy. It uses a handheld device to implement positive patient identification and collect ventilation data at the point of care. Once collected, this information is then signed off by the clinician and wirelessly transmitted to the hospital EMR. Automating this process significantly improves accuracy and efficiency when compared to a manual entry process. The key components of the system which support the Respiratory Documentation Application are: • *CareFusion Respiratory Documentation Handheld* – Wireless handheld used for positive patient association to the ventilator and data collection/entry at the bedside. • *CareFusion Ventilator Connectivity Adapter\** – Renders ventilator data for transport over the hospital network. • *CareFusion Respiratory Documentation Application Server* – Collects and stores ventilator data for access by the handheld. Also provides reporting capabilities. • *CareFusion Coordination Engine* – The interface building block for CareFusion products, it provides integration capabilities to hospital systems. Through the development of a new system approach to ventilator therapy, CareFusion plans to enable hospitals and clinicians to better address compelling clinical and operational challenges in ventilator therapy which may help improve patient outcomes, reduce costs, and improve staff workflow. [\*CareFusion ventilators can also use third-party device connection systems for access to the hospital network.]

**CareFusion AARC activities and location:** CareFusion will be attending AARC; our location is Booth 601. We will be hosting in-booth lectures on a variety of hot topics including new requirements for Ventilator Associated Conditions, Optimizing PEEP titration using Transpulmonary Pressure Monitoring and a guide to using High Frequency Oscillation in Adults. We have some great new products launching this year; we look forward to seeing you in New Orleans!

## CAIRE SeQual

### What products will you be presenting?

CAIRE SeQual manufactures oxygen therapy systems for the home healthcare industry. CAIRE's core product lines include liquid oxygen bases, ranging in size from 10-60 liters, and portable units, with sizes ranging from 4-8 lbs. with estimated

operation from 7-34 hours at 2 LPM. The SeQual Eclipse POC meets the ambulatory and round-the-clock oxygen needs of LTOT patients. For any product-related questions, please call CAIRE at (800) 482-2473.

### What new products will you be featuring that are of current importance?

The addition of the SeQual Eclipse and SeQual Integra market-leading portable and stationary oxygen concentrators to CAIRE's LOX solutions has broadened and complemented the portfolio. The SeQual Eclipse POC meets the ambulatory and round-the-clock oxygen needs of LTOT patients with technology that makes them smaller, quieter, and more reliable.

### Why should AARC participants visit your display?

With product lines of the Eclipse, Stroller, HELIOS, Companion and Liberator, CAIRE has become the one source for a provider's oxygen needs.

## Covidien Respiratory and Monitoring Solutions

Booth 201

### What products will you be presenting?

Covidien will present additions to its growing portfolio of respiratory care products: **Nellcor Oxinet III remote monitoring system** offers a cost-effective method for implementing continuous pulse oximetry monitoring in areas with lower nurse-to-patient ratios, such as the general care floor, step-down units and specialty care areas. The system provides continuous central station monitoring of up to 24 Nellcor pulse oximeters with OxiMax technology, providing earlier notification of developing respiratory events. **Nellcor Bedside SpO2 Patient Monitoring System** with OxiMax technology provides continuous SpO2 and pulse rate monitoring, trending data and SatSeconds alarm management in an intuitive, easy-to-use and easy-to-read, color user interface making it simpler for clinicians to access the most critical information regarding their patients' respiratory status. **Vital Sync Virtual Patient Monitoring Platform** streamlines clinical workflow by enabling remote monitoring of Puritan Bennett 840 ventilator data on wireless devices. **Mallinckrodt endotracheal tubes with TaperGuard cuff** have a unique taper-shaped cuff clinically shown to reduce microaspiration by 90 percent by providing a more effective fluid seal, in comparison to a standard Mallinckrodt Hi-Lo cuff.<sup>1</sup> **INVOS cerebral/somatic oximetry** provides real-time monitoring of changes in regional oxygen saturation (rSO2) of blood in the brain or other body tissues beneath the sensor for effective oxygen monitoring for adults, children, infants and neonates in any clinical setting. Other products presented by Covidien will include the Puritan Bennett 840 ventilator, Shiley adult and pediatric tracheostomy tubes, and the McGRATH MAC video laryngoscope. [1. FDA 510(k) clearance. Covidien is the sole acute care distributor for the McGRATH MAC video laryngoscope in the US, UK, Japan, Latin America, Australia and New Zealand. The McGRATH MAC video laryngoscope complies with EN 60601-1 and EN 60601-1-2 safety standards. The CE mark indicates that it meets the requirements of European Council Directive 93/42/EEC concerning medical devices. The device is regulated in the USA under FDA Regulation Number 868.5540 and device listed under the name "McGRATH MAC." "McGRATH" and "Aircraft" are registered trademarks of Aircraft Medical Limited. "CameraStick" is a trademark of Aircraft Medical Limited.]

### **What new products will you be featuring that are of current importance?**

Covidien is excited to present innovative products recently added to its portfolio per its acquisition of Newport Medical Instruments—the Newport HT70 Plus and the e360 ventilators. The Newport HT70 Plus ventilator is one of the newest portable ventilators on the market, offering clinical proficiency, mobility and a resilient design. It is ideal for home care, transport and emergency preparedness planning. The Newport e360 ventilator supports patients from infants to adults in critical care or long-term care settings. Covidien has also recently added capnography to its portfolio of respiratory function solutions per the recent acquisition of Oridion. Oridion develops Microstream capnography monitors and modules, in conjunction with specialized algorithms, as well as etCO<sub>2</sub> breath sampling lines. Together, these products monitor adequacy of ventilation and provide an early indication of airway compromise to make patient care safer and easier.

### **Why should AARC participants visit your display?**

Covidien is committed to providing innovative medical solutions that meet the needs of clinicians and help them address the challenges they face daily. Products presented at our booth, as noted above, will provide visitors a view of the range of technologies that help to make a direct impact in the field of respiratory care. [COVIDIEN, COVIDIEN with logo, Covidien logo and *positive results for life* are US and internationally registered trademarks of Covidien AG. Other brands are trademarks of a Covidien company. © 2012 Covidien.]

## **Discovery Laboratories, Inc**

Booth 908, 910

### **What products will you be presenting?**

SURFAXIN (lucinactant) Intratracheal Suspension and AFECTAIR neonatal airway connector

### **What new products will you be featuring that are of current importance?**

SURFAXIN (lucinactant) Intratracheal Suspension and AFECTAIR neonatal airway connector.

### **What speakers or papers will your company be featuring?**

Discovery Laboratories, Inc (Discovery Labs) intends to sponsor a satellite symposium related to the challenges of treating infants receiving positive pressure ventilator support. In addition, there are two abstracts that have been submitted for presentation at the upcoming AARC meeting that pertain to AFECTAIR: 1. Utilization of INO When Using a Novel Ventilator Circuit Connector Under Simulated Neonatal Mechanical Ventilation Conditions, an In Vitro Study, Number 1427625; and 2. Compatibility of a Novel Aerosol Delivery System with Three Neonatal Ventilators: VN-500, Servo-i and Ave, Number 1426952.

### **Why should AARC participants visit your display?**

Discovery Laboratories, Inc will be showcasing the recently FDA-approved surfactant. Discovery Laboratories, Inc will also be showcasing AFECTAIR, a proprietary ventilator circuit patient interface connector that replaces a conventional wye connector in a neonatal circuit. AFECTAIR serves to simplify the aerosol delivery circuit set-up and facilitate delivery proximal to the patient interface without significantly increasing deadspace.

## **Dräger**

Booth 1000

### **What new products will you be presenting?**

Dräger has completely revolutionized its portfolio of mechanical ventilation products. The Evita Infinity V500, Babylog VN500, Savina 300, Carina and the Oxylog 3000 plus will all be showcased at this year's congress.

### **What products will you be featuring that are of particular importance?**

The **Evita Infinity V500** is a comprehensive critical care workstation that can provide for the needs of neonatal, pediatric, and adult populations. Newest features include a “Smart Pulmonary View,” standardized nomenclature, PC-APRV with auto-release, and customizable weaning protocols. The **Babylog VN500** is a neonatal-pediatric specific ventilator which offers a wide array of therapies including oxygen therapy, non-invasive ventilation, and invasive modes. Critical to ventilating premature infants, is proper monitoring and compensation; the VN500 provides for effective leakage identification and compensation and has the option to volume ventilate small babies to a TV of 2 cc's. The **Savina 300** focuses on the essential elements of ventilation. Whether in volume or pressure ventilation, the Savina 300 provides for both adult and pediatric patients in settings such as acute, emergency, sub-acute, or post-operative care areas. Both invasive and non-invasive ventilation is available to provide clinicians a greater degree of flexibility for patient care. The **Carina** has a variety of uses for both invasive and non-invasive applications, in both the intensive care areas and general care areas. The **Oxylog 3000 plus** is a compact transport ventilator that can provide for adult and pediatric patients down to 50 cc's tidal volume. In addition to an array of volume, pressure, and spontaneous modes of ventilation, the Oxylog 3000 plus can provide AutoFlow as well. Additionally, the Oxylog 3000 plus can provide for integrated capnography and data management/export.

### **Discuss educational/training materials you'll be promoting.**

The Draeger Academy “Basics of Respiration and Ventilation” will be made available to all attendees. This program has been approved for 4.0 contact hours CRCE credit by the AARC. Additionally, our new website “A Breath Ahead” will be showcased where educators, clinicians, and managers can access opinions and network with key leaders in the respiratory care field. Recorded educational conference webinars can also be accessed to review a variety of clinical topics.

### **What speakers will your company be working with or featuring?**

Stop by the booth to see the theater schedule to hear case studies from your colleagues, including Michael Finelli, RRT from Hospital for Sick Children, Robert Elliott, RRT from Hotel-Dieu Grace Hospital, and Brian King, RRT from Forsyth Medical Center in Winston-Salem, NC.

## **EMS/Pulmodyne, Inc**

Booth 235

### **What products will you be presenting?**

Blom Tracheostomy Tubes and Unique Inner Cannulas, O<sub>2</sub>-MAX Disposable CPAP, and BiTrac Select NIV Masks.

## What new products will you be featuring that are of current importance?

New multiple elbows on our BiTrac NIV Mask line.

## Discuss educational/training materials you'll be promoting.

We will have our Clinical Specialist providing demonstrations of various ventilators working with the Blom Tracheostomy Tube system.

## Why should AARC participants visit your display?

Advancements in NIV care along with advancements in secretion management and cuff-up speech for tracheostomized patients.

## Fisher & Paykel Homecare

Booth 823

## What products will you be presenting?

• F&P ICON • F&P Masks • F&P Technologies

## What new products will you be featuring that are of current importance?

**SensAwake** responsive pressure relief now available in F&P ICON Auto and Premo. SensAwake promotes better overall sleep. We all experience subconscious waking through the night – at which time pressure intolerance is likely to occur. SensAwake responsive pressure relief: • Detects wakefulness • Promptly relieves pressure • Eases the return to sleep. Whereas other pressure relief technologies provide partial relief during expiration, SensAwake provides a prompt and significant relief in pressure to the lowest most comfortable level upon waking. This eases the return to sleep and allows effective treatment to resume. SensAwake can be compared to the simple concept of a Ramp but without the need for patient involvement. This action simulates a sleep technician's intuitive response to a waking patient and is in line with peer-reviewed guidelines<sup>1</sup> for manual CPAP titration. **F&P Pilairo Nasal Pillows Mask:** The F&P Pilairo is light on the patient, is big on performance, and is our lightest nasal pillows mask (1.83 ounces). The Pilairo integrates a new self-inflating AirPillow Seal and minimalist Stetchwise Headgear. As a result, the patient experiences freedom of movement coupled with stability they can trust. The design of the F&P Pilairo was inspired by the aerodynamic flight of the world's lightest little bird – the hummingbird. The hummingbird can rotate its fine wings in a circle; it is the only bird able to fly forwards, backwards, up, down and sideways and can hover in mid-air. This drove the design of a mask seal which self-inflates around the nares in a "hover-like way" while providing total freedom of movement. Experience easier therapy with F&P Pilairo. • One convenient size. • Quick and easy to fit. • No more messy straps and no complicated headgear adjustments necessary. • Only three simple parts to clean. **F&P Eson Nasal Mask:** F&P Eson is designed to automatically perform in tune with you and your needs. F&P Eson's three simple components, the RollFit Seal, ErgoFit Headgear and Easy Frame, work in harmony to deliver the comfort, seal and easy use that Fisher & Paykel Masks are known for. 1. RollFit Seal: As the name suggests, the one-piece seal "rolls" back and forth on the bridge of the nose to adjust automatically. In doing so, the RollFit Technology minimizes pressure on the bridge of the nose. 2. ErgoFit Headgear: This breathable, ergonomically designed headgear has been designed to self-locate high on the rear of the head allowing for maximum head movement (sideways, up

and down) without mask dislodgement. 3. Easy Frame: This low-profile frame is stable, durable and small, and ensures a clear line of sight. The one frame fits all three seal sizes and has an "Easy-Clip" frame attachment for effortless assembly after cleaning. Three small, streamlined mask components work in harmony for greater performance, stability and auto-adjusting comfort. This compact nasal mask is packed with technological innovations orchestrated to make SleepLife easier. F&P Eson is "easy on you." It has been designed to perform automatically in tune with every aspect of SleepLife. F&P Eson maximizes no-fuss comfort and simplicity by minimizing manual adjustments, parts and noise. **F&P InfoSmart Web:** The InfoSmart Web Dashboard gives you an instant overview of patient adherence. From this screen, you can navigate to individual patient data with a single click of the mouse. This allows early intervention when needed to optimise patient adherence.

## Discuss educational/training materials you'll be promoting.

Product literature will be available at our booth. Clinical studies results are also available on request. Clinical studies have shown: • SensAwake accurately detects the transition from sleep to wake using the flow signal alone.<sup>2</sup> • AutoCPAP devices with SensAwake treat OSA as effectively and at a lower overall mean pressure than a traditional AutoCPAP.<sup>3</sup> • CPAP devices with SensAwake treat OSA as effectively as conventional CPAP.<sup>4</sup> • Patients prefer CPAP with SensAwake to conventional CPAP.<sup>4,5</sup> [References: 1. Kushida CA et al. J Clin Sleep Med 2008; 4(2): 157-71. 2. Ayappa I et al. Sleep 2009; 32(1): 99-104. 3. Dungan GC 2nd et al. J Clin Sleep Med 2011; 7(3): 261-7. 4. Cumin D et al. Sleep Med 2011; 12(suppl 1): S75. 5. Powell ED et al. Sleep Med 2011; 12(suppl 1): S72.]

## Why should AARC participants visit your display?

We have a range of innovative new products on display that could re-define patient comfort and healthcare provider efficiency.

## Fisher & Paykel Healthcare

Booth 823

## What new products will you be featuring that are of current importance?

Fisher & Paykel Healthcare is proudly launching three new products: **Evaqua 2** high-performance breathing circuits, **Optiflow Junior** cannula and the **Bubble CPAP System**. Evaqua 2 is the next generation of high performance breathing circuit technology that minimizes mobile condensate in the expiratory limb by allowing water vapor to diffuse through the tubing wall. Optiflow Junior is a revolutionary step between low-flow oxygen therapy and CPAP that combines anatomically contoured pediatric and neonatal nasal cannula with comfortable humidified high flow. The Bubble CPAP System is the first complete Bubble CPAP product and includes the new FlexiTrunk CPAP Interface and new CPAP Nasal Masks.

## What other products will you be presenting?

Along with the three exciting new products above, we will be showcasing Optiflow for nasal high flow and the Neopuff Infant T-Piece Resuscitator. Optiflow comfortably delivers a complete range of oxygen concentrations and flows to extend the traditional boundaries of oxygen therapy. The Neopuff Infant T-Piece Resuscitator provides safe, trusted and proved T-Piece

resuscitation, while facilitating the delivery of warm humidified gas to help protect the pulmonary epithelium and reduce heat and moisture loss especially during prolonged resuscitation.

### **Discuss educational/training materials you will be promoting at the convention?**

We invite you to Booth 823 to experience hands-on training and education for all featured products and to learn more about the AARC and AACN approved educational programs for our product families.

### **Why should AARC participants visit your display?**

Why wouldn't you want to visit Booth 823? AARC participants who visit can wear and experience simply better oxygen therapy with an Optiflow cannula, set up the new Evaqua 2 breathing circuit on an MR850 humidifier and then gently resuscitate a premature baby on the Resuscitation Simulator! Please make your time in New Orleans even more productive and enjoyable by joining us at Booth 823 to evaluate and discuss any of Fisher & Paykel Healthcare's products.

## **General Physiotherapy, Inc**

Booth 106

The NEW G5 FREEDOM Airway Clearance System is the most advanced technology for Chest Postural Drainage developed by General Physiotherapy, originator & manufacturer of the famous G5 Percussor product line used world-wide in medical institutions and homecare environments. The G5 FREEDOM System is hands-free and contains 8 Percussion Pods that

incorporate High Frequency Chest Wall Percussion (HFCWP) to effectively loosen, liquefy, and mobilize thick tenacious lung secretions. A hand-held control module allows medical professionals to prescribe the exact cycle per second range for each Percussion Pod and activate them individually, sequentially, or all at one time. You can visit our Booth # 106 and personally test this game-changing respiratory therapy device.

## **Impact Instrumentation, Inc**

Booth 712

### **What products will you be presenting?**

Impact will be showing the Eagle II full featured portable ventilator on a roll stand and the newly released Eagle II MRI Conditional ventilator for use in MRI suites.

### **What new products will you be featuring that are of current importance?**

The Eagle II MR Conditional full featured ventilator which offers volume and pressure targeted breaths, pressure support and CPAP NPPV with automatic leak compensation. It can ventilate infant through adult patients.

### **Why should AARC participants visit your display?**

Because Impact ventilators are lightweight for ease of transport and for bedside use, full featured offering all modes necessary to ventilate infant to adult patients and offers CPAP NPPV with automatic leak compensation which improves patients synchrony and comfort.



**MGC** DIAGNOSTICS®



PROVIDE UNMATCHED  
SERVICE AND SUPPORT



RELENTLESSLY MAKE  
IMPROVEMENTS



ANTICIPATE AND SOLVE  
UNMET NEEDS

COME BY AND SEE THE **NEW MEDGRAPHICS** AT AARC, BOOTH #917

## Mercury Medical

Booth 817/819

### What products will you be presenting?

Mercury Medical will be launching the new Flow-Safe II CPAP system that represents a major leap in product innovation. Taking emergency care to a whole new level, Flow-Safe II is the ONLY disposable CPAP system on the market that provides over 50% less oxygen consumption while delivering high FiO<sub>2</sub>, and uses standard flowmeters. Also being displayed is the new Neo-Tee with in-line adjustable PIP controller. It's the industry's first and ONLY disposable Infant T-Piece Resuscitator with Built-In Pressure Relief and Color-Coded Manometer on the Tee. Mercury is the ONLY company with three types of resuscitation systems, CPR, Hyperinflation and now a T-Piece. Economical, high-quality disposable CPR bags in a variety of configurations will be exhibited along with the colormetric CO<sub>2</sub> line, including Neo-StatCO<sub>2</sub><Kg, the ONLY CO<sub>2</sub> detector specifically designed for tiny babies with an expanded patient weight range of 0.25kg to 6kgs. The brand new air-Qsp (Self-Pressurizing) complements the family of Masked Laryngeal Airways. The air-Qsp design is the ONLY Masked Laryngeal Airway that prevents potential for overinflation. When delivering PPV, the increased airway pressure increases the pressure within the cuff creating a good seal, (consistently over 20 cm H<sub>2</sub>O). Increase in cuff seal pressure occurs at the exact time you need it... during the upstroke of ventilation. Key advantages: • Simpler: No Inflation Line or pilot balloon—eliminates the extra step of inflation and guesswork of adding air to the mask cuff; • Eliminates mask cuff over inflation; • The removable color coded connector allows intubation through it using standard ET tubes. Mercury Medical will also be showing a new gauge design (-60 cm H<sub>2</sub>O) for the ONLY disposable NIFometer on the market.

### What new products will you be featuring that are of current importance?

Mercury's new products mentioned previously (Flow-Safe II, Neo-Tee with in-line controller, Neo-StatCO<sub>2</sub><Kg, air-Qsp and NIFometer) all improve patient outcomes at an economical cost.

### Discuss what educational/training materials you'll be promoting?

Full product training will be provided at the booth by Mercury Medical Product Specialists. We will provide product information brochures, wall charts/posters with specifications and offer free samples. The samples will be provided by fully trained sales representatives who will provide comprehensive product inservicing at the attendees facilities.

### Why should AARC participants visit your display?

Mercury is a leading manufacturer of respiratory products and is highlighting several key industry first disposable products that save money for the hospital and health facility and improve patient outcomes at the same time. Mercury is the ONLY company that has introduced the product types mentioned previously: Flow-Safe II, Neo-Tee with in-line controller, Neo-StatCO<sub>2</sub><Kg, air-Qsp and NIFometer. Due to the changing NRP guidelines, it will be important for clinicians like RT Directors and NICU nurses to visit our display as they are actively looking for neonatal resuscitation devices that meet these NRP guideline requirements. For instance, the Neo-Tee offers more consistent inspiratory and expiratory pressure than other devices. It is affordable for use at

every NICU, L&D and ED bedside. One of the latest requirements is that every NICU stock "size one" laryngeal mask for rescue airways. air-Q is the infant rescue airway solution for meeting this requirement. Furthermore, NRP recommends using a colormetric CO<sub>2</sub> on the supraglottic airway connector to ensure proper placement with rapid color change. Mercury provides the ONLY disposable CO<sub>2</sub> detector solution for premature infants below 1 kg with the Neo-StatCO<sub>2</sub>. Clinicians should visit our display to get a first-hand view of our products and advantages.

## MGC Diagnostics

Booth 917

### What products will you be presenting?

MGC Diagnostics will feature recent product developments and technology advancements, including BreezeSuite WebReview for test interpretation anywhere, anytime; Platinum Elite Plethysmograph and Ultima Series with Real Time Diffusion (RTD) MultiGas Technology, delivering clinically significant graphic data and immediate results; together with our latest version of BreezeSuite software incorporating the latest HIPAA – HITECH Security Safeguards protecting your patient's Identifiable Health Information. We will also be featuring our CCM Express Indirect Calorimeter, CPX Express Cardiopulmonary Exercise system, and our CPFS/D USB full function spirometer.

### What new products will you be featuring that are of current importance?

MGC Diagnostics will be introducing the Resmon Pro FOT (Forced Oscillation Technique) System providing the latest innovation in quiet breathing detection of expiratory flow limitation, assessment of the degree of heterogeneity of airway obstruction, the evaluation of bronchial reversibility and bronchial challenge.

### Discuss educational/training materials you'll be promoting.

Managing the MGC Diagnostics exhibit will be our best in class clinical, sales and support staff available to answer not only your product questions, but provide expert consultation for your clinical application and cardiorespiratory business needs.

### Why should AARC participants visit your display?

MGC Diagnostics delivers diagnostic solutions for detection, classification and management of cardiorespiratory patients worldwide. Our enduring experience and single-minded focus give us unmatched insight into the real needs of our category. These invaluable assets make us uniquely qualified to solve today's challenges and uncover inspired solutions for tomorrow's opportunities.

## Nonin Medical, Inc

Booth 1022

### What products will you be presenting?

Nonin Medical, Inc will present the Onyx Vantage 9590 Professional Finger Pulse Oximeter and the WristOx<sub>2</sub> Model 3150 Wrist-Worn Oximeter.

### What new products will you be featuring that are of current importance?

Nonin Medical will feature the Onyx Vantage 9590 Professional

Finger Pulse Oximeter. Nonin Medical is pleased to announce that the Onyx Vantage 9590 finger pulse oximeter now provides accurate readings on thumbs and toes, too. The Onyx Vantage is the only finger pulse oximeter with accuracy claims for use on fingers, thumbs and toes. In addition, Onyx's accuracy and performance claims are supported by published peer-reviewed, clinical studies. The Onyx Vantage 9590 provides accurate data for actionable decision making.

### **Discuss educational/training materials you'll be promoting.**

Nonin Medical will be providing education materials that can be passed on to patients, including *Oximetry for People with Lung Disease* by Brian Tjep, MD, and *Your Personal Oximeter: A Guide for Patients* by Thomas L. Petty, MD.

### **Why should AARC participants visit your display?**

Nonin Medical, Inc invented fingertip pulse oximetry and is a global leader in designing and manufacturing noninvasive medical monitoring solutions. The company's industry-leading processing and design capabilities, coupled with its ongoing integration of features not available in competitive products, provide the foundation for delivering monitoring accuracy in the widest range of patient populations and settings. Visitors can see the Onyx Vantage 9590 Professional Finger Pulse Oximeter. The Onyx Vantage 9590 finger pulse oximeter with PureSAT technology quickly and accurately captures SpO<sub>2</sub> and pulse rate measurements—even on patients with darker skin tones and where low perfusion is a challenge. The Onyx Vantage 9590 has proven accuracy on fingers, thumbs and toes, providing versatility where fingers are not available or there is difficulty gaining readings on a finger such as with pediatric patients. And the Onyx Vantage 9590 has been tested for use in motion; contact Nonin's Regulatory Department for more information on motion testing. Visitors can also see the WristOx<sub>2</sub> Model 3150 Wrist-Worn Pulse Oximeter. Engineered with Nonin Medical's proven PureSAT SpO<sub>2</sub> signal processing technology, the WristOx<sub>2</sub> is the most advanced wrist-worn pulse oximeter available. Simple to use, the 3150 is worn like a watch, is small, comfortable and unobtrusive for patients. It is ideal for daily activity monitoring, six-minute walk tests, and overnight studies.

## **Passy-Muir Inc**

Booth 727

### **What new products will you be presenting?**

This year at AARC, Passy-Muir Inc will present the new **Passy-Muir Cleaning Tablets**. The New Cleaning Tablets for Passy-Muir Valves are made from a detergent that is biodegradable and leaves no residue on the valves as do some commercially available soaps. The Passy-Muir Cleaning tablets are sold in both a 5 tablet packet, and a convenient one month supply of 30 tablets. Free samples will be provided.

### **What new products will you be featuring that are of current importance?**

**The Pocket T.O.M.** is a more portable pocket-sized version of our popular Tracheostomy T.O.M. Tracheostomy Teaching and Observation Model. The new Pocket T.O.M. displays the same cutaway view of the upper aero-digestive tract and anatomy with tracheostomy, and can be easily taken to the bedside for patient education. It is great for spontaneous staff teaching as well. The Pocket T.O.M. includes model, cuffed tracheostomy tube,

syringe, 3 Passy-Muir Valves, and simulated nasogastric tubing. It can be easily cleaned between patients.

### **Discuss educational/training materials you'll be promoting.**

At AARC, the Ventilator Instructional Tracheostomy Observation (VITO) mannequin will be featured to demonstrate the ventilator application of the Passy-Muir Valve. This simulated ventilator demonstration will aid clinicians in the understanding of the important aspects of ventilator application. Early Passy-Muir Valve placement may result in a faster weaning and shorter length of stay for the tracheostomized and ventilator dependent patient. Passy-Muir, Inc has always held education and clinical support for professionals and patients to be of primary importance. Our latest FREE web-based continuing education opportunities will be featured, along with the new, pocket sized quick reference guide.

### **What speakers or papers will your company be featuring?**

The following abstract will be presented at the AARC Open Forum on November 11, 2012 from 12:30-2:25 pm: Ventilator Function and Effective Alarms during Speaking Valve Use in a Critical Care Setting: A Bench Study, by Kathy Grilliot, MS Ed, RRT-NPS, CPFT, Assistant Dean, Respiratory Therapy Program, Northern Virginia Community College.

### **Why should AARC participants visit your display?**

The Passy-Muir Tracheostomy and Ventilator Swallowing and Speaking Valve is a small device with a huge impact on the lives of tracheostomized and ventilator dependent individuals. Respiratory care professionals are key players in helping these individuals maximize their potential in all environments of health care. A visit to the Passy-Muir, Inc booth will help provide the respiratory professional with the knowledge and tools needed to make the difference in the tracheostomized person's life and care, and will help the respiratory therapist advance as a primary partner in tracheostomized patient outcome management.

## **Philips Respironics**

Booth 401

### **What products will you be presenting?**

At Philips Respironics, we design a range of complementary products that span both the hospital and home settings. Follow the patient pathway from hospital to home and learn how our products can help transition your patients from one stage of care to another. **Hospital Respiratory Care:** From our patient interface line, we will be showing our Respironics **AF531** NIV mask system with interchangeable elbow connectors that allow one mask to be used for specialized procedures, such as bronchoscopy and medication nebulization. The AF531 also allows the connection of the same mask to dual-limb or single-limb circuits. In addition to the AF531, we will be showing our XL Respironics **PerforMax** mask, designed to better fit larger patients. The AF531 and PerforMax masks are for hospital use only. On the ventilator side, we will be showing our flagship **V60** ventilator, with its exciting proportional pressure (PPV) ventilation option. Several of the noninvasive features on our industry-leading V60 ventilator can also be found on our **Trilogy** ventilator. In addition, home CPAP innovations such as C-Flex and Ramp have been incorporated into the V60, highlighting our dedication to providing hospital to home solutions. We

will also be showing our **Focus** ventilator as well as the **NM3** respiratory profile monitor with VentAssist. These products are for hospital use only. **Home Healthcare Solutions:** From our home oxygen business, we will be showing **SimplyGo**—the only portable oxygen concentrator to offer continuous flow and pulse-dose delivery in a single device weighing ten pounds or less. That means that homecare providers can now meet the portable oxygen needs of nearly all patients with just one POC. SimplyGo also helps providers to manage inventory, lower costs, and streamline services. We will also be showing **UltraFill**—an advanced home oxygen system that combines a stationary oxygen concentrator, filling station, and high-capacity cylinders to meet the needs of a wide range of oxygen patients, including those who are highly active or require continuous flow oxygen. UltraFill also has the needs of homecare providers in mind with features intended to save money by using existing inventory. Other featured home healthcare products include the **CoughAssist**—our noninvasive therapy that effectively and comfortably removes secretions in patients with an ineffective ability to cough. CoughAssist clears secretions by gradually applying a positive pressure to the airway, then rapidly shifting to negative pressure. This rapid shift in pressure produces a high expiratory flow, simulating a natural cough. This product can be used to treat pediatric and adult patients and can be used with a face mask, mouthpiece, or adapter to endotracheal or tracheostomy tubes. The **Trilogy200** homecare ventilator is a portable life-support ventilator designed for use in the home and alternative care sites. It provides noninvasive and invasive ventilator support with added sensitivity for a wide range of adult and pediatric patients (> 5 kg). Using a single-limb circuit and proximal flow sensor, Trilogy200 offers triggering and leak compensation that allows for a more sensitive delivery of therapy. Home Healthcare Solutions' Respiratory Drug Delivery business offers the **OptiChamber Diamond** antistatic valved holding chamber (VHC) which is designed for ease-of-use, to help maximize delivery of pMDI medications to the lungs, and to encourage compliance for patients of all ages—at home or in the hospital. Diamond is one of the smallest, full-function VHCs available. In addition, the **LiteTouch** valved holding chamber mask is designed to provide comfort and an optimal facial seal. The mask uses a unique design that molds a clear, hard shell to an exclusive soft-seal interface that contours to the face with a minimum amount of pressure to promote aerosol therapy comfort and compliance. The recently released enhanced **System One** sleep therapy system includes several new features to deliver exceptional therapy, increase patient comfort, and provide essential compliance tools. The new features include a heated tube humidification option, Opti-Start which provides a customized starting pressure, and CPAP-Check mode which “checks” on the user every 30 hours to determine if the therapy pressure is optimal.

### What new products will you be featuring that are of current importance?

We will be showing our new hospital masks for pediatric patients (one year or older and > 7 kg) for whom positive airway pressure therapy has been prescribed. The **PerforMax** pediatric masks are new “total” style masks designed to be used with single limb NIV ventilators and dual limb ventilators that have NIV capabilities for this patient population, which has been historically underserved with respect to NIV interface products. The XXS (extra, extra small) and XS (extra small) size masks have many of the same attributes as the adult size PerforMax and

some features designed specifically for the pediatric population. Our innovative advancements in patient interface offerings extend to the homecare side as well with our latest full-face mask, Amara. Amara has a modular design that is lighter, smaller, and has significantly fewer parts than leading traditional full-face masks. Amara requires just a single “click” to disassemble and reassemble the cushion and mask frame for cleaning and replacement.

### Discuss educational/training materials you'll be promoting.

Our Hospital Respiratory Care Education Manager will have an internet connection showing clinicians how to access the Philips Online Learning Center to take courses for CEU credit as well as to demonstrate product. We will also have clinical pocket guides and interactive CD programs for some of our ventilators and monitors.

### What speakers or papers will your company be featuring?

Hospital Respiratory Care will be featuring the following abstract: *Enhanced Aerosol Drug Delivery Via Vibrating Mesh Nebulizer During Noninvasive Ventilation*. It presents the results from a study comparing the effectiveness of the NIVO electronic mesh nebulizer designed for use with a mask during noninvasive ventilation and an SVN (small volume nebulizer) placed in the NIV single limb circuit. The results demonstrate differences in the Inhaled Aerosol Percentage (%) at different NIV pressure settings and using different modes of ventilation.

### Why should AARC participants visit your display?

Philips' Hospital-to-Home pathway is a unique educational and interactive experience that engages attendees—broadening their understanding of the products and services we offer. Additionally, AARC visitors know us as leaders in noninvasive ventilation and home healthcare solutions. We always enjoy visiting with our valued customers and friends, and hearing how they are using our products to make a difference in patients' lives.

## Respiralogsics

Booth 836

Respiralogsics is a provider of innovative products for NICU, PICU, Adult Critical Care and special care units. We are dedicated to providing patients and health care providers exceptional products. Respiralogsics will present the Babi.Plus Bubble CPAP System, the Danny Ties trach ties and the Sil.Flex Stoma Pads and TC Pads.

**Babi.Plus Bubble CPAP System:** Bubble CPAP, a breathing assistance system, is showing promising results in decreasing the incidence of chronic lung disease among premature infants. CPAP is a breathing system commonly used in the NICU to deliver heated and humidified airflow and pressure to an infant's lungs via short nasal prongs in the nose that assists in keeping the infant's lungs open at end exhalation while allowing them to spontaneously breathe. Adding bubbles to the CPAP is proving to be of benefit in effectively treating these infants and allowing them to breathe on their own. The Babi.Plus Bubble nCPAP System was designed to provide a simple method for delivery of Bubble CPAP that will allow for focus on the infant and not the devices. The patent pending design delivers accuracy and stability throughout the course of therapy.



**Danny Ties:** Danny Ties are unique tracheostomy tube holders with a softer and more comfortable fit around the neck for patients of all ages. The patient with a tracheostomy needs to have a tube holder that securely holds the artificial airway in place to prevent accidental decannulation. As important, the tube holder needs to provide a soft, comfortable fit about the neck while minimizing skin irritation under the collar. Danny Ties are made of soft, absorbent cotton that lays smooth at the edges of the collar, minimize skin irritation and reduce skin breakdown under the collar. The patent pending design of the Danny Ties evenly distributes the quilted collar around the neck to minimize pressure points on the skin.

**Sil.Flex Stoma Pads and TC Pads:** The Sil.Flex TC Pad and Sil.Flex Stoma Pad are designed to cushion the area between the flange and the stoma site reducing movement and pressure at the site from the time of the procedure. The contoured surface of the Sil.Flex Pads provides a stable, comfortable interface between the flange and the patient's neck. Early use of the Sil.Flex Pads may assist in reducing irritation and tissue breakdown at the stoma site as well stabilize the tracheostomy tube. Use of the Sil.Flex Pads may decrease the air leak around the stoma site during trach weaning or during speech therapy by improving the seal between the pad the stoma.

**Education & Training Materials:** The strong clinical background of our staff and strategic partners serve you well in presentation of new concepts for delivery of patient care, exploration of your requirements to meet clinical needs and assistance with justification through the value analysis process. Most important, we are there to provide ongoing support for your team.

Stop by the Respiralogs booth #836 at the AARC Conference for a demonstration of Bubble CPAP to see how easy it is to implement a Bubble CPAP program in your NICU. Take the time to see our unique solutions and products that provide patients a better quality of life and clinician's new tools to deliver effective care, implement quality initiatives and improve patient outcomes.

## Thayer Medical

Booth 717

### What new products will you be presenting?

Thayer Medical, Tucson, Arizona is pleased to introduce additions to its MiniSpacer MDI adapter family: 15mm OD/ID (1543) and the new A series, (1543A -15mm OD/ID, 1024A - 22mm OD/OD & 1025A - 22mm OD/ID). The MiniSpacer: A series will increment common canister dose-counters. Standard MiniSpacer versions (1024, 1025 & 1543) will actuate canisters with integrated dose-counters without incrementing the counter. Using patented dual-spray design, the MiniSpacer optimizes medication delivery. MiniSpacer remains in-line between treatments and is used for single-patient use. With the most extensive product family of inline actuators for intermittent MDI medication delivery, the MiniSpacer MDI adapter family offers versatility to meet user needs.

### What products will you be featuring that are of particular current importance?

The new MiniSpacer A series, (1543A -15mm OD/ID, 1024A -

22mm OD/OD & 1025A - 22mm OD/ID) is designed to increment common canister dose-counters in response to the recent introduction of pMDI drugs with dose counters.

### Why should AARC participants visit your display?

In addition to the additions to the MiniSpacer MDI adapter family, Thayer Medical will feature its innovative MDI holding chamber—the LiteAire. The LiteAire is the only dual-valved, holding chamber constructed of paperboard. It is offered in a dispenser box of twenty-five individually packaged devices allowing for easy access and storage. It is re-usable for up to a week for single patients and is ideal for PFT labs, emergency departments and in-patient floors. The LiteAire is a low-cost, alternative to plastic holding chambers in many environments. Generous quantities of LiteAire samples will be provided to qualified clinical sites. Participants should also visit the Thayer Medical booth to learn about the cost-savings available with the originally designed, US manufactured, Valved Tee family of ventilator circuit components.

## Tri-Anim

Booth 116

### What products will you be presenting?

Tri-anim will be presenting products such as: **Smith's Acapella**—A vibratory PEP Therapy System and **EzPap**—Positive Airway Pressure System, **Philip's AF531** NIV mask, **Monaghan Medical AeroEclipse II** Breath—Actuated Nebulizer, **Aerogen Aeronex** Solo Nebulizer—A single patient use nebulizer for aerosol therapy, **Vapotherm** Precision Flow—A high flow heat and humidification device, **Flexicare** BrightBlade Pro—a 100% metal disposable fiber optic blade designed for single patient use and **BrightBlade Handle**—a single patient use fiber optic handle system which comprises of a disposable handle and a reusable light source. Also from Flexicare, the **Dual Capnography Cannula**—a single patient use cannula which provides patient CO<sub>2</sub> sampling and oxygen delivery and **Dual Mask**—a single patient use capnography mask that provides accurate CO<sub>2</sub> sampling and oxygen delivery, **Nonin** LifeSense and RespSense—Waveform capnography that provides real-time feedback on how the patient is breathing or ventilated, **Precision Medical's** preset vacuum regulators, **B&B Medical** products such as the **Babi.Plus** Bubble PAP valve, bite blocks and endotracheal tube holders, and **Curaplex** CuffSentry—a cuff pressure management device that monitors and maintains ET tube cuff pressure.

### What new products will you be featuring that are of current importance?

**IPI Medical** ET-Care—a cutting edge endotracheal fixation device that reduces the incidence of VAP and accidental extubation through firm fixation and improved ease of oral care for intubated patients. **Curaplex** CuffSentry—a cuff pressure management device that monitors and maintains ET tube cuff pressure. It can help minimize complications associated with under-inflation or over-inflation, including the risk of VAP, secretion leakage and tracheal damage.

### Discuss educational/training materials you'll be promoting at the convention.

We will be providing visitors with *Respiratory Notes: Respiratory Therapist's Pocket Guide* as well as have the latest clinical research supporting our featured products.  
*Continued on page 74...*

# An Introduction to the Non-invasive Non-contact Assessment of Respiratory Function

Dr Irisz Levai, Dr Virpi Sidoroff, Dr Richard Iles

## Abstract

There are a number of different techniques that either directly measure, or give an interpretation of respiratory function. This article will briefly consider the alternatives to traditional spirometry and body box plethysmography, and introduce a new technology, namely, Structured Light Plethysmography (SLP).

SLP uses a visible or infra-red light; a grid is projected onto the chest and abdomen, allowing respiratory movements to be tracked or “visualized” by a digital camera system, and respiratory or spirometric data derived. In addition, dynamic three-dimensional representations of chest and abdominal movement can be generated. This technology was developed in order to be able to make ventilatory assessments in those in whom conventional spirometry is difficult or impossible, such as small children. Detailed analysis of the regional waveforms derived may potentially have a role augmenting conventional spirometry, or to study regional chest wall function and other aspects of breathing. As the technology is non-contact there are reduced consumables and potentially less infection risk. This technology is commercially available, and will continue to be developed by PneumaCare Ltd, a UK based company.

## Introduction

There are a number of techniques to measure lung volumes directly or give an interpretation of respiratory function. Pulmonary function tests can be broadly divided into those that measure volume (plethysmography) and those that measure flow (pneumotachography). A peak flow rate meter measures flow and a spirometer measures both flow and volume (Cala SJ, Kenyon C, Ferrigno C, Carnevali P, Aliverti A, Pedotti A, Macklem PT, Rochester DF. Chest wall and lung volume estimation by optical reflectance motion analysis. *J Appl Physiol* 1996;81:2680-2689.) In this paper we introduce Structured Light Plethysmography (SLP) a novel non-invasive method that uses structured light to perform lung function testing and assess chest wall motion without any physical contact with a patient.<sup>1</sup>

## Background

Researchers have been interested in human breathing since early times. Galen was probably the first investigator on human ventilation; however, he did no absolute measurement of lung

volumes. The earliest “pulmometers” date back to the early 19<sup>th</sup> century when ventilatory volumes were measured using water displacement in an inverted bell jar standing in water. An extension of this concept led to the development of whole body plethysmography in 1969.<sup>3</sup> In this technique the subject is placed inside a sealed chamber with a single mouthpiece. Changes in total-body volume are measured indirectly through changes in air pressure. Elastomeric plethysmography is a technique in which an elastic belt is fastened around the chest or abdomen and changes in tension as the chest or abdomen expand or contract are measured and converted to a voltage using a piezo-electric sensor. Impedance plethysmography is a technique in which a number of electrodes are attached to the skin, and a weak alternating electrical current is passed through them in order to measure changes in whole body impedance as the cross-section of the body expands and contracts. During pulmonary inductance plethysmography, an elastic belt is worn around the chest and abdomen and an alternating current passed through it to generate a magnetic field that changes with the cross-section of the body. (Filatriau JJ, Dubusis T, Reboursiere L, Todoroff T. Breathing for Opera. *QPSR* June 2008; Vol1 No2: 53-65.) (West JB. *Respiratory Physiology – the Essentials* 5<sup>th</sup> Edition. Baltimore, Williams & Wilkins, 1995:151-165.)

In 1974, Campbell et al presented the light weight peak flow meter.<sup>4</sup> In the 1980s raised volume techniques had been developed to measure infant and neonatal lung volumes. A few years later a less invasive method of neonatal chest wall motion analysis called Respiratory Induced Plethysmography (RIP) was introduced.<sup>7</sup>

Advances in the field of computer graphics, computer vision and image processing have led to the development of techniques that track multiple points on the body, such as Opto-Electronic Plethysmography (OEP).<sup>2,10,11</sup> This technology uses an optical reflectance motion analysis to measure the volume change of the chest wall and abdomen during respiration by computing the 3D coordinates of physical markers fixed on the chest and abdomen.<sup>10</sup>

Plethysmography techniques measure volume indirectly. Spirometric measurements require good cooperation so they are unlikely to be successfully performed by children, intensive care patients or by elderlies. Investigations suitable for children under the age of 3 are invasive and require the infant to be sedated to allow face masks to be applied.<sup>9</sup> They are very

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The authors are with Department of Respiratory Paediatrics, Addenbrookes Hospital, Cambridge University NHS Trusts, Cambridge, UK. This article was provided by PneumaCare Ltd.

laborious, and the infants often wake from sleep, and the study has to be abandoned.

### **Structured Light Plethysmography**

Structured Light Plethysmography is novel in that it does away with fixed physical markers and instead, scans and interprets changes in a projected structured light grid while the subject is being observed by two cameras. Corner features from the projected light pattern are extracted and tracked. Using specific algorithms the collected data is expressed in the form of spirometric traces. Also, the data can be presented as a 3D visualization of thoraco-abdominal movement allowing us to examine either side of the thorax separately from each other and can also give a better understanding of thorax and abdomen synchrony. This enables new clinical applications, and can improve knowledge of breathing in different clinical conditions.

The software to analyze the video data has been specifically designed to generate outputs which conform to current ATS/ERS spirometry standards.<sup>5</sup> The system does not need calibration, nor references to barometric pressure, temperature or humidity.

SLP is being developed by PneumaCare Ltd. A detailed description of the technology and mathematical proofs has been recently published (de Boer et al 2010).

### **Methodology**

SLP implemented lung function testing can be performed either in seated, supine or standing position. For obtaining optimal measurement the subject has to stay still with head and back fixed against a wall or mattress. Having followed a general setup, a checkerboard pattern of light covering the area from the clavicles to the iliac crest line is projected onto the subject's torso. The two cameras inserted in the head of the device are placed at different known positions and angles and record the subject's chest during breathing. Grid intersection points (ie grid square corners) are "tracked" over time, and brought into correspondence between cameras. The subtle deformation of the projected grid pattern carries information about the geometry of the chest area. Given the known camera and projector positions and angles, and the intersection point correspondences, a three-dimensional surface representation of the frontal chest area can be reconstructed. Chest wall volume changes can be inferred and estimated from the chest area reconstruction. The chest wall is reconstructed using the camera calibration; it is cleaned up and filled-in if needed. From the reconstruction of chest wall and knowledge of the work bench volume changes can be calculated over time. The relative shape and movement of the grid defines the thoracic volume from which flows are calculated.

### **SLP's correlation to spirometry**

The clinical study to compare SLP against spirometry is ongoing. Chest wall volume changes seem to correlate well with spirometric values. Pilot studies have been published in abstracts.<sup>12-15</sup> Tidal breathing results have been reported from 23 healthy adult subjects, aged 19-61.<sup>15</sup> Data were collected in lying, sitting and standing positions (N=69). Standard spirometry (Pneumatach) and SLP signals were collected for one minute in each position, at same time. Tidal volume (TV) correlation between SLP and spirometry in Pearson correlation was  $r^2=0.967$  ( $p<0.001$ ). Different body positions made no statistically significant difference in correlation between SLP and spirometry.

Similar methodology was used for 41 healthy subjects for forced expiratory maneuvers, has been published also in abstract.<sup>14</sup> In this instance the subject's back was fixed to the wall at three different points (the occiput, the upper back and the pubic crests) to minimise posterior movement. Spirometric measurements were undertaken using ATS/ERS standards. A strong correlation between SLP and spirometry has been found; FVC ( $r^2=1$ ), FEV<sub>1</sub> ( $r^2=0.95$ ), FEV<sub>1</sub>/FVC ( $r^2=0.84$ ), FEF<sub>75</sub> ( $r^2=0.76$ ), FEF<sub>50</sub> ( $r^2=0.69$ ) and FEF<sub>25</sub> ( $r^2=0.65$ ). Modified Bland Altman plots were also produced, which showed good agreement between SLP and spirometry.<sup>14</sup>

### **Discussion of clinical applications**

Several studies have been undertaken in diverse patient groups both at Addenbrooke's and Papworth Hospital NHS Foundation Trusts. One study is focusing on age-related changes in lung function on a defined patient group of age 6-80 years and different clinical conditions. We are hoping this will allow us to understand how the lungs change as we grow and age and will help guide future age-specific treatments.

In the clinical trial study we are looking for volume changes in COPD, asthma and cystic fibrosis patients. Correlation and differences between SLP and Simultaneous spirometry in specific patient groups, and also variability of SLP measurements between these groups are under investigation. The aim of our study is to investigate the ability of SLP to detect different types of breathing deficiencies. Data of the pilot study is under analysis and further investigations are planned with both adult and children participation.

Studies have shown a link between obesity and dysfunction of the lungs. The breathing difficulties of overweight patients are proven to be related to changes in breathing mechanics like chest wall compliance and reduced lung volumes.<sup>16</sup> In our ongoing study, our aim is, by using motion and regional analysis, to investigate the physiological phenomena that develops in patients with high BMI index.

A feasibility study was undertaken at Papworth Hospital to examine the potential role of SLP in patients undergoing thoracic surgery. Half of the measured subjects underwent serial scans including pre-operative testing and scans followed by their surgical intervention. They were scanned during 4-5 normal breaths and then were asked to perform a forced maximal inspiration and then forced expiration maneuver. This technology gives novel data on chest and abdominal wall movement after thoracic surgery. In some patients this may be useful to monitor the "recovery trajectory" and to identify potential problems. SLP may also provide a positive feedback tool to patients and their carers in assisting with post-operative mobilisation. Further studies are planned.

Some patients due to numerous reasons are unable to competently and accurately perform traditional lung function testing. In these cases SLP can successfully be implemented. The new project within the study investigating age related changes in lung function takes place at Rosie Maternity Hospital and concentrates one measuring lung function in newborn infants. Because of the limitations of current methods, we have limited information on normal breathing pattern of newborns and we are also limited amount of normative lung function data on this patient group.<sup>7,9</sup> Using SLP enables us to investigate breathing rate, breathing rhythm changes, inspiratory and expiratory

times and phase angle shifts between chest and abdomen during breathing in non sedated infants without a pneumatic. In a pilot study we are looking at normal breathing in clinically stable term- and pre-term babies and changes in breathing related to pre- and post-feeding. In another study we are collecting data from babies at age 12, 24 and 48 hours to determine any possible changes in breathing in the first days of life. We are also collecting data on pre-term babies to investigate lung growth. In future, we are planning on implementing tidal volume measurements in ventilated infants and children.

Bronchiolitis is the most common reason for hospitalization for children under 2 years of age and is shown to be associated with decreased lung function due to viral infection. However, because of the limitations of current lung function testing, the degree of pulmonary dysfunction has not yet been measured. We are planning on commencing a study on infants with bronchiolitis in Winter 2012/13.

### Conclusion

SLP is novel non-invasive method to measure lung function. Strong correlation to spirometry has been shown in pilot studies. The method is free from calibration and can be used in patient groups whom lung function have not been able to measure earlier. SLP gives assessment of breathing pattern and thoraco-abdominal movements as well as information about thoracic volume changes. All these characteristics support its clinical applications in the future.

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# High Flow Therapy Clinical Review

Thomas L. Miller, PhD

## Summary

High Flow Nasal Cannula (HFNC) or High Flow Therapy (HFT) is the use of nasal cannula to deliver heated and humidified medical gas mixtures at flow rates which exceed a patient's inspiratory flow rate.

Flow rates typically range from 25 - 35 L/min in adults and 4 - 8 L/min in infants to accomplish two objectives:

- 1) provide a volume of gas that exceeds inhalation so that desired inspiratory gas fractions are maintained without the entrainment of room air
- 2) purge end-expiratory gas from the nasopharynx to provide a ventilatory effect that can accomplish at least 11% -13% of a patient's ventilatory work effort.

HFT requires the use of a device capable of heating and humidifying gas to saturation with water vapor at a given set temperature. Conditioning is necessary to avoid drying and destruction of nasal tissues.

The concept of HFT was introduced in 2000 by Vapotherm and is a relatively new treatment modality. HFT has been shown to be safe and effective through translational research models and clinical studies in adult, pediatric and neonatal patient populations.

## LITERATURE REVIEW ON HIGH FLOW THERAPY

In 2000, Vapotherm introduced the first High Flow delivery system that utilizes patented humidification membrane technology to efficiently condition gas to within normal physiological range. These systems saturate the gas with water vapor and use a water-jacketed delivery tube to maintain the energy state of the conditioned gas as it is delivered to the patient. Moreover, these systems were uniquely designed to function under the high internal device pressure associated with the action of pushing high flow rates through a nasal cannula.

High Flow Therapy has been used extensively in clinical settings and is well studied. This section represents a synopsis of the literature.

## Humidification of Breathing Gases

The nasal mucosa warms and humidifies breathing gas prior to entering the conducting airways and the lungs.<sup>1</sup> Exposing the nasopharyngeal tissues to improperly conditioned medical

gas at flow rates greater than what is associated with a normal minute ventilation can overload these tissues. This can result in significant dysfunction, drying and damage to the nasal mucosa<sup>2-5</sup> which is known to contribute to staphylococcal sepsis.<sup>6</sup>

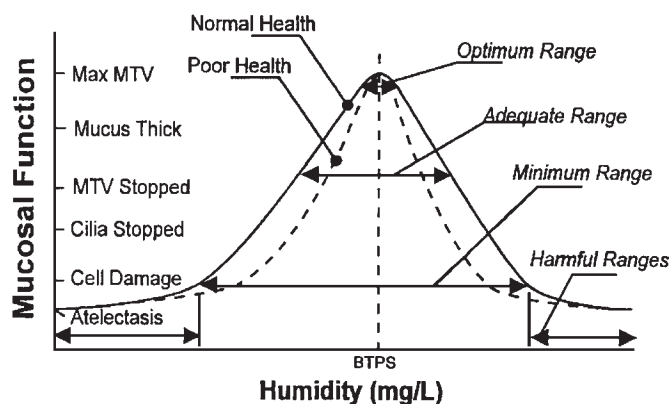


Figure 1. This figure, from Williams et al,<sup>2</sup> shows that mucosal function is dramatically impacted by absolute humidity, which is a function of both relative humidity and temperature. Here BTPS represents body conditions where gas contains 44 mg·L<sup>-1</sup> of water vapor. MTV = mucus transport velocity.

In addition, conventional nasal cannula therapy is uncomfortable and raises numerous patient complaints, particularly related to dry nose and mouth.<sup>7</sup> Ideally, inspiratory gas should be warmed to body temperature and humidified to 100% relative humidity (Figure 1).<sup>2,8,9</sup>

For flows greater than 6 L/min, the American Society for Testing and Materials (ASTM) requires humidification systems to produce inspiratory gas with a minimum of 60% relative humidity at ambient temperatures.<sup>10</sup> The Vapotherm HFT devices use a membrane technology to transfer heated water vapor into the gas stream at 99.9% relative humidity (noncondensing state) and use a water jacketed delivery tube system to protect the gas from energy loss (Figure 2). Humidification with true vapor is the least likely to cause airway and lung injury by latent heat loss and deposition of water droplets.<sup>9</sup>

Independent investigators have demonstrated the effectiveness of Vapotherm products in conditioning respiratory gas and preserving the integrity of the nasal tissues during HFT.

In a bench study, Drs Waugh and Granger evaluated the capability of two HFT gas conditioning systems to meet the American Association for Respiratory Care (AARC) guidelines and manufacturers' claims.<sup>10</sup> These data showed the Vapotherm

Tom Miller, PhD, is Director of Clinical Research and Education at Vapotherm, Inc, Stevensville, Maryland and Assistant Professor of Pediatrics at Jefferson Medical College, Philadelphia, PA. Contact tom.miller@vtherm.com. This paper was provided by Vapotherm.

device produced inspiratory gas at body temperature (37°C) and 99.9% ± 0.0% relative humidity.

In a randomized crossover clinical study, Woodhead and colleagues evaluated the impact of VapoTherm compared to conventional high flow cannula on the nasal mucosa of preterm infants post-extubation.<sup>11</sup> Thirty infants received either VapoTherm or conventional therapy for 24 hrs, and then switched to the opposite modality (conventional or VapoTherm) for an additional 24 hrs. Using a blinded scoring system (range: 2-10) to account for nasal erythmia, edema, thick mucus and hemorrhage, infants treated with VapoTherm had much better tolerance compared to conventional humidification (2.7 ± 1.2 vs 7.8 ± 1.7; p < 0.001).

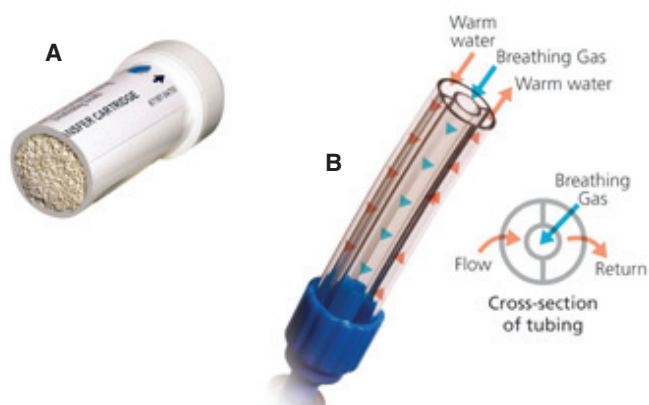


Figure 2. Technologies such as the VapoTherm Vapor Transfer Cartridge (A) have improved the task of gas conditioning. The large surface area of the hollow tube, vapor permeable fibers allow the respiratory gas passing through to be instantly warmed to a precise temperature and humidified to saturation. VapoTherm's water jacketed patient delivery tube (B) is able to maintain the conditioning state of the patient gas in the center lumen by way of a dynamic insulation system. In this tube design, water circulated out and back in the outer jacket is at the temperature the gas is intended to be.

### Mechanisms of Action for VapoTherm HFT

Proper conditioning of respiratory gas, as defined above, allows for the administration of flow rates that would otherwise result in significant damage to the nasal mucosa.<sup>3,4,11</sup> The use of these higher cannula flow rates result in interactions with spontaneous breathing to improve ventilatory efficiency and therefore reduce work of breathing.

The evidence supporting the mechanisms of action for HFT is listed below.

- 1) High Flow Therapy washes out the dead space in the nasopharynx and improves the fraction of alveolar gases with respect to carbon dioxide and oxygen.<sup>12</sup>
- 2) HFT provides flow rates that match inspiratory flow and reduces inspiratory resistance normally caused by the encroachment of nasopharyngeal tissues associated with negative upper airway pressure,<sup>13</sup> and the related work of breathing.
- 3) Warm and humidified gas improves conductance and pulmonary compliance.<sup>14</sup>
- 4) Warm and humidified gas through the nasopharynx reduces the metabolic work associated with gas conditioning.
- 5) Flushing the nasopharynx with high flow can provide positive distending pressure for lung recruitment.<sup>15-17</sup>

### Washout of the Nasopharyngeal Dead Space

Using HFT, gas flow rates that exceed inspiratory flow rates purge the nasopharyngeal cavity during the late expiratory phase

and end-expiratory pause of the breathing cycle. This purging of anatomical dead space removes expiratory gas that is high in carbon dioxide and relatively depleted of oxygen, and creates an anatomical reservoir of the intended inspiratory gas mixture. Under these conditions, the subsequent breath is composed of less rebreathed expiratory gas and more delivered cannula gas. The new alveolar gas equilibrium supports alveolar ventilation with less minute ventilation. Work of breathing is reduced while supporting better elimination of carbon dioxide and more efficient oxygen delivery.

The concept of purging dead space is predicated by tracheal gas insufflation (TGI), which has been demonstrated to improve minute ventilation by promoting CO<sub>2</sub> elimination.<sup>18-22</sup> By reducing dead space, TGI facilitates pulmonary gas exchange and reduces lung inflation pressure and volume requirements<sup>23,24</sup> as well PaCO<sub>2</sub> in spontaneously breathing patients.<sup>25</sup> Data from published clinical studies on HFT confirm the reduction of dead space because of the immediate impact on ventilation rates. A study by Dewan and Bell investigated the effect of low and high flow oxygen delivery on exercise tolerance in COPD patients receiving respiratory support.<sup>12</sup> Nasal cannulae were compared with transtracheal catheters (TTC), which are catheters placed in the patient's trachea for the direct purpose of increasing respiratory efficiency by TGI dead space washout. The investigators found that the use of high flow oxygen via nasal cannula and TTC were both as effective for increasing exercise tolerance in COPD patients, compared with low flow oxygen.

In a study of adult COPD patients, Chatila and colleagues demonstrated that HFT enhanced oxygenation as well as ventilation during exercise compared with conventional low flow oxygen delivery through nasal prongs.<sup>26</sup> During matched workloads and with matched inspiratory oxygen fraction, exercising patients maintained greater arterial oxygen tension (p < 0.001) despite a reduction in respiratory rate (p < 0.05) while using VapoTherm HFT. With HFT, these patients were able to exercise longer (10 ± 2 min vs 8 ± 4 min; p < 0.05), and they maintained arterial CO<sub>2</sub> and pH while breathing less frequently with no change in tidal volumes.

In the neonatal community, a number of trials support the conclusion that dead space washout provides a ventilation effect. Dr Holleman-Duray and colleagues showed that infants were able to be extubated to HFT from significantly greater ventilator rates (33 ± 8 vs 28 ± 8 breaths/min; p < 0.05) compared with other noninvasive support modes.<sup>27</sup> In another pediatric example, a published case report on a pediatric burn patient showed that respiratory rate decreased immediately following initiation of VapoTherm HFT (63 to 38 breaths/min), with a secondary sustained decrease in heart rate (175 to 144 beats/min) after a short period.<sup>28</sup>

### Reduction of Inspiratory Resistance (Work of Breathing) by Providing Adequate Flow

The design of the nasopharynx is to facilitate humidification and warming of inspired gas by contact with the large surface area. By definition, this large wet surface area and nasopharyngeal gas volume can account for an appreciable resistance to gas flow. In addition, after analyzing nasal and oral flow-volume loops, Shepard and Burger showed that the nasopharynx has a distensibility that makes for variable resistance.<sup>13</sup> When inspiratory gas is drawn across this large surface area, a retraction of the nasopharyngeal boundaries

results in a significantly increased inspiratory resistance compared to expiratory resistance. CPAP has been shown to reduce this supraglottic resistance up to 60% by mechanically splinting the airways.<sup>29</sup> However, HFT most likely minimizes the inspiratory resistance associated with the nasopharynx by providing nasopharyngeal gas flows that match or exceed a patient's peak inspiratory flow. This change in resistance translates to a change in resistive work of breathing. Saslow and colleagues published data from neonates indicating that work of breathing with HFT between 3 and 5 L/min was equivalent to that with nasal CPAP set to 6 cmH<sub>2</sub>O.<sup>30</sup> This reported equivalency was shown despite a significantly lower esophageal pressure ( $1.32 \pm 0.77$  vs  $1.76 \pm 1.46$  cmH<sub>2</sub>O;  $p < 0.05$ ); thus, there is a mechanism of action other than distending pressure effecting work of breathing with HFT.

### **Improved Mechanics by Supplying Adequately Warmed and Humidified Gas**

Studies from the 1990s demonstrated the negative effects of using non-warmed, non-humidified gas to support breathing. Dr Greenspan and colleagues demonstrated that just five minutes of ventilation with ambient gas, not warmed or humidified, in ventilated infants resulted in a significant decrease in both pulmonary compliance and conductance.<sup>14</sup>

Furthermore, Fontanari and colleagues showed that receptors in the nasal mucosa respond to cold and dry gas to elicit a protective bronchoconstrictor response in both normal subjects<sup>31</sup> and asthmatics.<sup>32</sup> On and colleagues showed this cool, dry air induced bronchoconstriction response to be associated with muscarinic receptors in the nasal mucosa.<sup>33</sup>

In non-intubated infants receiving respiratory support by nasal cannula, Saslow and colleagues showed that Vapotherm HFT had important positive effects on respiratory mechanics compared to conventional CPAP using a standard humidification unit.<sup>30</sup> Respiratory compliance was significantly improved in infants receiving 5 L/min of Vapotherm conditioned gas compared to 6 cmH<sub>2</sub>O of CPAP ( $1.03 \pm 0.47$  vs  $0.83 \pm 0.49$  mL/cmH<sub>2</sub>O/kg). The improvement in respiratory compliance occurred even with a significantly lower distending pressure in the Vapotherm-treated infants ( $p < 0.05$ ), indicating that adequacy of conditioning for breathing gas does effect lung tissue characteristics.

These study findings agree with those of Dr Greenspan and colleagues who show that gas conditioning alone can significantly improve lung compliance and airway resistance.<sup>14</sup>

### **Reduction in the Metabolic Cost of Gas Conditioning**

Under normal physiologic functioning of the respiratory tract, the nasal air passages warm inspiratory air from ambient to approximately 37°C and humidify the incoming air to approximately 100% relative humidity (RH).<sup>1,34,35</sup> Whereas many of the factors involved in this process are unclear or not easily definable, we believe that it can be ascertained that there is significant energy cost to the process of gas conditioning.

By definition, gas that is at 100% RH holds as much water as possible before water droplets begin to spontaneously form. Furthermore, Dalton's law dictates that as gas gets warmer, it holds more water vapor per unit volume at any percent RH. Thus, as gas is conditioned by the nasal mucosa, heat energy is required not only to warm the air, but also vaporize water into the air. This process of water vaporization requires a significant

amount of heat energy in the same way that sweating cools our bodies on a warm day.<sup>36</sup>

The nasal airways are very efficient at capturing heat and moisture from expired gas to be recycled on subsequent inspirations.<sup>1,34,35</sup> Nonetheless, without 100% efficiency heat and vaporization energy is required to condition inspired air. Furthermore, with lung pathologies there is a rise in minute ventilation resulting in greater gas volumes to be conditioned.

Conventional noninvasive therapies supply dry or minimally humidified gas flows to the nasal passages that can exceed minute volumes inspired to the lungs. In this regard, utilizing HFT with a device that completely warms and humidifies inspiratory gas likely impacts oxygen need and reduces CO<sub>2</sub> production by reducing this energy requirement. This presumption is supported in part by the clinical data indicating improved weight gain in infants on Vapotherm compared to those on conventional CPAP support.<sup>27</sup>

### **Provision of Distending Pressure**

The form of noninvasive respiratory support most common in the neonatal intensive care setting is continuous positive airway pressure (CPAP).<sup>37</sup> It is believed that providing distending pressure to the lungs results in improved ventilatory mechanics by optimizing lung compliance and assists with gas exchange by maintaining patency of alveoli<sup>38-40</sup> whereas HFT is not necessarily intended to provide CPAP. If HFT gas flow and nasal prong dimensions are set appropriately for patient size, distending pressure can be accomplished. Most of the literature discussing the development of distending pressure has been done in the neonatal population because of the greater concern with these small patients. The following text will summarize the factors associated with pressure generation from this literature, and then present the literature on what pressures can be expected in the adult population.

Nasal cannula size is a critical factor in determining airway pressure generation as it relates to air leak around the cannula prongs. Dr Locke and colleagues showed in infants that using 2.0 cm OD nasal prongs with conventional oxygen therapy ( $\geq 2$  L/min) does not generate significant esophageal pressures or impact breathing patterns; however, using larger, 3.0 cm OD cannulae in the same infants produced a positive correlation between gas flow and esophageal pressure ( $r = 0.92$ ), reaching a mean pressure of 9.8 cmH<sub>2</sub>O at 2.0 L/min of flow.<sup>41</sup> Therefore, distending pressure provided by nasal cannula and respiratory gas flow is dependent on leak rate, determined by the nasopharyngeal anatomy as well as the relationship between nasal prong size and nares of the nose.

In fact, a bench study by Kahn and colleagues showed that even CPAP results in appreciable overshoots of pharyngeal pressure when the nasal prong size relative to the nares allows for too little leakage, and too much leakage essentially negates the generation of intended pharyngeal pressure.<sup>42</sup>

Wilkinson and colleagues showed that pharyngeal pressure development during HFT is directly related to flow, and inversely related to infant size.<sup>43</sup> This study provides further evidence to support the fundamental relationship between pressure and flow where pressure is directly proportional to flow and resistance ( $P \sim F \times R$ ). Therefore, in smaller patients, the pressure resulting from any increase in flow rate increases as a

result of the resistance provided by the smaller anatomy. If HFT is administered at a flow rate that is relative to patient demands (ie their spontaneous inspiratory flow rate) then pressure development becomes predictable.

A substantial number of studies have now been published that evaluate the pressure development in neonatal,<sup>15,30,44-46</sup> pediatric<sup>17</sup> and adult patients<sup>16,47,48</sup> using HFT. The studies show that, in neonates, airway pressure development will be not more than the equivalent of a CPAP of 6 cmH<sub>2</sub>O; in pediatric patients the expiratory airway pressure will be approximately 4 cmH<sub>2</sub>O and in adults the end-expiratory airway pressure will be approximately 3-to-4 cmH<sub>2</sub>O.

### **Safety and Efficacy of HFT in the Adult, Pediatric and Neonatal Populations**

HFT has been widely utilized in both adult and neonatal/pediatric populations as an alternative therapy for respiratory distress secondary to numerous pathologies. The growing body of clinical research supports the hypotheses regarding the impact of the mechanisms of action for HFT. Independent investigator-initiated and industry-funded studies have demonstrated that HFT improves ventilation as well as oxygenation, reduces work of breathing, improves the efficiency of each breath, and favorably impacts other outcomes such as extubation indices, disease exacerbations and infant growth.

Some of these studies are summarized below and are compiled for the neonatal/pediatric and adult applications independently.

#### **Neonatal/Pediatric Applications**

A number of clinical trials in the neonatal intensive care unit (NICU) setting have been conducted to demonstrate the efficacy of HFT via nasal cannula, compared to the conventional noninvasive respiratory support therapies. Although these studies have not been designed to directly assess mechanisms of action for HFT, they all attest to its safety and efficacy, as well as provide subjective feedback on the comfort of their patients.

In a study of patients' tolerance of high flow nasal cannula support of extubation efforts, Dr Woodhead and colleagues tested Vapotherm HFT against a conventional humidifier.<sup>11</sup> Thirty neonatal patients intended to be extubated to HFT ( $\geq 1$  L/min) were randomized to either Vapotherm or conventional humidifier for 24 hrs, and then crossed over to the opposite modality (conventional or Vapotherm) for an additional 24 hrs. During exposure to each therapy, a score for the condition of the nasal mucosa, the rate of respiration and scores for chest wall retractions were recorded by blinded neonatologists and research nurses. These authors reported that during the Vapotherm phase of treatment these infants had improved nasal exam scores ( $p < 0.001$ ) and respiratory effort scores ( $p < 0.05$ ). While on conventional cannula with humidifier, these infants had more nasal erythema, edema and hemorrhage, as well as greater chest wall retraction compared to Vapotherm HFT. Furthermore, two infants failed extubation in the first 24 hrs while on conventional humidifier whereas no infant failed extubation to Vapotherm. During the second 24-hr phase, five infants who had been switched from Vapotherm to conventional HFT failed to tolerate the change and were put back on Vapotherm.

In 2007, Dr Shoemaker and colleagues published a report of outcomes from two NICUs during a period where nasal cannula

HFT usage increased 64% and nasal CPAP usage decreased from 19% to 4%.<sup>49</sup> During the period of HFT introduction, 95% of the infants born after 30 weeks gestation or more received Vapotherm HFT; only 12% received conventional CPAP. Despite the large population receiving HFT, there were no differences in adverse outcomes or chronic lung disease. However, ventilator days per patient were reduced from 19.4% to 9.9%. Furthermore, more infants in this cohort were intubated and mechanically-ventilated as a result of failing nasal CPAP (40%) compared to HFT (18%).

The main objectives of noninvasive respiratory support in the NICU is to limit exposure to mechanical ventilation. Preterm infants in particular often require respiratory support in the face of incomplete alveolar development and surfactant insufficiency. A well-known consequence of mechanical ventilation is bronchopulmonary dysplasia, which is keynoted by a cessation of alveolar development and remodeling of the lung<sup>50</sup> as well as pronounced injury to the conducting airways.<sup>51</sup> Therefore, avoidance of exposure to mechanical ventilation, or at least early extubation is paramount to normal lung development.

A published study from Drs Holleman-Duray, Kaupie and Weiss at Loyola University Medical Center in Maywood, IL trialed an early extubation protocol in preterm infants of 25-29 wks gestation.<sup>27</sup> This study showed a number of clinically significant benefits in neonates extubated to Vapotherm HFT (4-6 L/min; their new standard of care) versus historical patients extubated to either nasal CPAP (+8 cmH<sub>2</sub>O), nasal cannula (1-2 L/min) or room air. Foremost, the investigators concluded that HFT via nasal cannula appeared safe and well-tolerated without any change in adverse events compared to other forms of noninvasive respiratory support.

Beyond the subjective interpretations, objective data showed that infants extubated to HFT spent less time on a ventilator ( $11 \pm 13$  vs  $19 \pm 21$  d;  $p < 0.05$ ), and were extubated from greater ventilator rates ( $33 \pm 8$  vs  $28 \pm 8$  breaths/min;  $p < 0.05$ ), supporting the premise that HFT impacts ventilation over conventional post-extubation therapies. The investigators conclude that the difference in ventilation time may have a causal relationship to the lower incidence of ventilator-associated pneumonia in the HFT group (2% vs 8%;  $p < 0.05$ ). Furthermore, the investigators propose that a decreased work of breathing in the HFT group may have contributed to the greater weight at discharge in this group ( $2758 \pm 499$  vs  $2493 \pm 622$ ;  $p < 0.05$ ) without a difference in length of stay.

Because the most common form of noninvasive respiratory support in the NICU setting is CPAP, there is much debate on the pressure generated by HFT. The basis of this debate is likely derived from the methodology used to create CPAP with conventional nasal cannula applications. Low flow rates (1-3 L/min) through nasal cannulae can lead to small amounts of end-distending pressure to the lung, and therefore it may seem intuitive that greater flow rates equate to greater pressure generation.

However, the CPAP generated with low flow rates is accomplished by using large enough cannulae sizes relative to the nares of the nose and a closed mouth to limit air leaks, and thus provide back pressure.<sup>42,52</sup> However, numerous clinical studies agree that the distending airway pressure generated during HFT is not substantial.<sup>15,30,44-46</sup> Moreover, the mechanistic



literature affirms that efficacy of HFT is not primarily a function of distending pressure.<sup>53</sup>

### **Adult Applications**

Virtually all adult patients with chronic pulmonary disorders in need of supplemental oxygen use nasal cannulae. Typically, this is a low flow system designed to primarily support oxygenation by low flows of 100% oxygen. This therapy is typically not conceptualized to address CO<sub>2</sub> retention and work of breathing. However with HFT, higher cannula flow rates can impact ventilation indices, as well as deliver up to 100% oxygen, and therefore substantially widen the range of opportunity to treat patients with respiratory distress using a nasal cannula at higher flow rates.

In an early article on HFT, Walsh showed efficacy of the therapy on ten adult patients with congestive heart failure that presented to the emergency room.<sup>54</sup> Using flow rates between 20 L/min and 40 L/min, HFT resulted in significant reductions in heart rate ( $118 \pm 21$  vs  $108 \pm 21$ ;  $p < 0.001$ ), respiratory rate ( $38 \pm 10$  vs  $30 \pm 9$ ;  $p < 0.001$ ) and increased oxyhemoglobin saturation ( $88 \pm 7$  vs  $97 \pm 1$ ;  $p < 0.001$ ). Following this preliminary assessment, numerous investigators have evaluated the use of HFT in various adult respiratory pathologies.

Two more recent studies have demonstrated that HFT is superior to conventional frontline respiratory therapies. Roca and colleagues evaluated HFT compared to an oxygen mask using a crossover study design in patients with acute respiratory failure.<sup>55</sup> With a sample of twenty adult patients (mean age of 57 years), the high flow cannula resulted in significantly improved patient tolerability indices including reduced dyspnea ( $p = 0.001$ ), dry mouth ( $p < 0.001$ ) and increased comfort ( $p < 0.001$ ). Physiologically, the high flow cannula increased arterial oxygen pressure ( $p < 0.01$ ) and reduced respiratory rate ( $p < 0.001$ ) without changing PaCO<sub>2</sub>. Parke and colleagues evaluated high flow cannula compared to a high flow oxygen mask in patients with mild hypoxemic respiratory failure.<sup>56</sup> High flow cannula resulted in significantly greater therapeutic success than a high flow mask ( $p = 0.006$ ). Additionally, fewer patients progressed to NIV (10% with cannula versus 30% with mask;  $p = 0.10$ ), and the nasal cannula group had fewer desaturations ( $P = 0.009$ ).

These papers demonstrate the impact of HFT on oxygenation as well as ventilation associated with purging the anatomical dead space as opposed to a mask therapy that does not purge the nasopharynx.

With more of a mechanistic focus, Dr Chatila and colleagues performed a study at the Temple University Hospital Lung Center on ten COPD patients' exercise tolerance, comparing HFT with conventional low flow cannula therapy.<sup>26</sup> In this repeated measures study, COPD patients needing oxygen therapy to support physical work were tested in cycle ergometry with matched workloads for low flow therapy (3.9 L/min) and then Vapotherm HFT (20 L/min). During the work periods, the flow source was fed through a mouthpiece distal to a flow transducer, and the inspiratory oxygen fraction was set the same at the beginning of each work period for each patient. At rest prior to exercise, patients maintained greater oxyhemoglobin saturation ( $98 \pm 2\%$  vs  $95 \pm 3\%$ ;  $p < 0.05$ ) and arterial oxygen tension ( $128 \pm 34$  mmHg vs  $74 \pm 6$  mmHg;  $p = 0.05$ ) with HFT versus low flow. During exercise patients maintained greater arterial oxygen tension ( $p < 0.001$ ) despite a reduction in respiratory rate ( $p <$

0.05) while on HFT. While using HFT these patients were able to exercise longer ( $10 \pm 2$  min vs  $8 \pm 4$  min;  $p < 0.05$ ) with a lower mean arterial pressure ( $p < 0.05$ ), whereas three patients needed their inspiratory oxygen fraction increased during exercise with low flow. During exercise, these patients maintained arterial CO<sub>2</sub> and pH while breathing less frequently with no change in tidal volumes.

These data confirm that breathing is more efficient with HFT, supporting the notion of dead space elimination. There was no difference in esophageal pressure, indicating no effect of lung recruitment. The lack of difference in work of breathing is likely an artifact of the flow source being distal to the flow sensor, thus not optimally supporting inspiratory efforts.

Humidification is another area of specific interest with adult chronic respiratory diseases. A common complaint with chronic respiratory disease sufferers is the development and retention of airway secretions. Attenuation of secretion retention will open airways and reduce hospitalizations associated with disease exacerbation. Dr Hasani and colleagues addressed this issue with a study using daily treatments with heated, humidified high flow cannula as a humidification therapy for improving secretion mobilization.<sup>57</sup> These authors had bronchiectatic patients breathe from a home-based high flow cannula device for 3 hrs per day for 7 days to condition the airways with humidified breathing gas. They used a method to quantify clearance of radiolabeled markers before and after the week of high flow cannula use to show that following humidification treatment, lung mucociliary clearance was significantly improved.

Rea and colleagues investigated the long-term use of high flow cannula for humidification therapy in 108 COPD patients randomized to receive their typical care or high flow cannula for 12 months.<sup>58</sup> Patients on high flow cannula had significantly fewer exacerbation days (18.2 vs 33.5 days;  $p = 0.045$ ), increased time to first exacerbation (median 52 vs 27 days;  $p = 0.0495$ ), and reduced exacerbation frequency (2.97/patient/year vs 3.63/patient/year;  $p = 0.067$ ) compared with typical care. Additionally, patients on high flow cannula had improvement in quality of life scores and lung function compared with typical care. A limitation of this publication is that the effects were all attributed to humidification therapy, whereas the other aforementioned mechanisms of action may have also played a significant role in the clinical improvement. Nonetheless, the outcomes seen in this large trial are impressive and robust.

### **Summary**

HFT is defined as nasal cannula gas flows which exceed a patient's spontaneous inspiratory flow rate while purging nasopharyngeal dead space during exhalation. Moreover, this technique requires heated-humidification systems that can adequately condition breathing gases to preserve airway mucosa thus making this therapy tolerable, and in fact comfortable. HFT results in a number of fundamental physiologic interactions that result in improved respiratory efficiency that support patients with respiratory distress. HFT has been used for more than ten years and has been shown safe and effective. Efficacy has been shown to supersede that of conventional front line therapies and have advantages over noninvasive pressure support therapies.

## Research Category: Neonatal and Pediatric Research on Vapotherm and High Flow Therapy

This section summarizes the major research that pertains to the use of HFT in the neonatal population. These works include reports published in peer-reviewed journals that address the general safety and efficacy in infants.

STUDY	MAJOR CONCLUSIONS
Woodhead et al. <sup>11</sup>	A 15-patient, prospective, randomized, cross-over trial among NICU patients following extubation Vapotherm performed better than conventional high flow nasal cannula in maintaining a normal appearing mucosa, a lower respiratory score and averting re-intubation.
Shoemaker et al. <sup>49</sup>	Retrospective study at 2 centers with 65 NICU patients High flow nasal cannula was well tolerated compared to infants managed with a nasal positive pressure based therapy; there were no differences in adverse outcomes following the introduction of high flow cannula. Fewer infants require re-intubation using high flow cannula (40%) compared to nasal positive pressure therapy (80%).
Saslow et al. <sup>30</sup>	Randomized 18-patient NICU study HFT supported work of breathing similar to, but improved respiratory compliance over the use of CPAP therapy. Showed that airway pressure with up to 5 LPM is not more than with a CPAP setting of 6 cm H <sub>2</sub> O
Holleman-Duray et al. <sup>27</sup>	Compared NICU outcomes with HFT to historical controls HFT use resulted in extubation from higher ventilator rates ( $p < 0.01$ ) and fewer days on ventilators ( $p < 0.05$ ). Furthermore, incidence of ventilator-associated pneumonia was reduced ( $p < 0.05$ ), and infants were discharged with greater weights ( $p < 0.05$ ).
Byerly et al. <sup>28</sup>	Case study discussing the impact of HFT on a pediatric burn patient in respiratory distress Patient saw an immediate drop in respiratory rate, indicative of the washout of nasopharyngeal dead space.
Spentas et al. <sup>17</sup>	Pediatric patients with respiratory distress receiving HFT Demonstrated an improvement in comfort and oxygenation Showed that only mild pressure develops in the nasopharynx ( $4 \pm 2$ cmH <sub>2</sub> O)

## Research Category: Adult Research on Vapotherm and High Flow Therapy

This section summarizes the major research that pertains to the use of HFT in the application of adult respiratory care. These works include reports published in peer-reviewed journals that address the general safety and efficacy in adults.

STUDY	MAJOR CONCLUSIONS
Dysart et al. <sup>59</sup>	Comprehensive literature review describing the mechanisms of action for HFT: Washout of the nasopharynx <ul style="list-style-type: none"> <li>• Attenuates the inspiratory resistance associated with the nasopharynx</li> <li>• Improves conductance and pulmonary compliance compared to dry, cooler gas</li> <li>• Reduces the metabolic work associated with gas conditioning</li> <li>• Provides positive distending pressure for lung recruitment</li> </ul>
Chatila, et al. <sup>26</sup>	Crossover trial in 10 COPD patient prospective High flows of humidified oxygen improved exercise performance and oxygen dependency, in part by enhancing oxygenation. Patients could exercise longer on higher flows with less dyspnea, better breathing pattern and lower arterial pressure compared to low flow oxygen delivery.
Roca et al. <sup>55</sup>	Crossover trial in Acute Respiratory Failure: high flow cannula compared to face mask oxygen therapy. High flow cannula resulted in higher blood oxygenation and lower respiratory rate without changing blood pCO <sub>2</sub> . Patients found the cannula interface to be more tolerable and more comfortable.
Parke et al. <sup>56</sup>	High flow cannula compared to mask therapy in hypoxemic respiratory failure Greater therapeutic success with high flow cannula compared to high flow mask Fewer patients required NIV. Fewer desaturations with high flow cannula
Calvano et al. <sup>60</sup>	Case study of an end-stage respiratory failure patient with multi-lobar pneumonia Patient had a DNR order and could not tolerate a NIV mask. High flow cannula reduced her agitation and improved her dyspnea, oxygenation, tolerance of oxygen therapy, and comfort at the end of life.
Dewan & Bell. <sup>12</sup>	Prospective trial of 10 COPD patients who were receiving trans-tracheal oxygen (TTO) through a stoma TTO compared to both high and low flow nasal cannula oxygen High flow cannula, but not low flow nasal cannula, resulted in the same exercise tolerance and dyspnea score as TTO.
Parke et al. <sup>16</sup>	Prospective trial in post-operative cardiac patients Aim was to demonstrate the level of airway pressure generated by high flow cannula in adults High flow cannula generates a low level of distending pressure in adults: $2.7 \pm 1.04$ cmH <sub>2</sub> O.
Hasani et al. <sup>57</sup>	Prospective trial in bronchiectasis patients Aim to investigate the impact of high flow cannula on airway clearance High flow cannula with humidified breathing gas improves airway function via enhanced mucociliary clearance.
Rea et al. <sup>58</sup>	Long-term (1 yr) use of high flow cannula in the home 108 COPD patients randomized to typical care or high flow cannula High flow cannula resulted in fewer exacerbation days, increased time to first exacerbation and reduced exacerbation frequency. High flow cannula resulted in improved quality of life scores and lung function.

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# A Respiratory Advantage: valuable insights to the toughest clinical questions

### Background

"We discussed it privately and said 'yes, this is what we need, this is what we want, this is awesome technology,'" recalls Kevin Taylor, Director of Respiratory Care, Sleep Disorder Center, Neuro EEG Lab, and CPAP Care Center at Cullman Regional Medical Center. He and Chief Medical Director, Dr Scott Warner had just seen the Philips Respironics NICO2 respiratory profile monitor demonstrated at Duke University. The NICO2 respiratory profile monitor is the predecessor of the Philips Respironics NM3 respiratory profile monitor.

Taylor continues, "When we needed to replace our ventilators, I was 95% sure I was going to go with another vendor. But I gave Philips a chance to show me the Esprit ventilator. When I saw the Esprit/NICO2 combination, I said wait a minute." The Esprit ventilator is the predecessor of the V200 ventilator.

### Better together

Taylor was unacquainted with the benefits of a ventilator/respiratory monitor pairing. "I was impressed by the Esprit," says Taylor. "But when tied to the NICO2, the real-time data is tremendous. I can tell you breath-by-breath if the patient is doing better, or worse." The NICO2 allows us to make accurate decisions, which may help us to wean patients faster."

### Performance improvement

Situated in the middle of the state, Cullman Regional Medical Center serves more than 150,000 residents in six Alabama counties. The 145-bed facility is designated a Level III Trauma Center and is recognized for its use of innovative medical technology.

As Director of Respiratory Care, Taylor is responsible for the smooth operation and productivity in each of his departments. After discovering the capabilities of the NICO2 monitor, he ordered six Esprit/NICO2 packages to replace a fleet of poorly functioning ventilators.

Taylor was certain that by introducing the ventilator/monitor combination into the departmental process, potential advantages would soon present themselves. "Inclusion of the NICO2 respiratory monitor with the Esprit ventilator brought a dramatic improvement to Cullman."

### Simple answers

Mechanically ventilated patients are constantly challenging clinicians with complex questions regarding their current respiratory status and the adequacy of ventilatory support. The NICO2 monitors volumetric (VCO<sub>2</sub>) and end-tidal (EtCO<sub>2</sub>) capnography, as well as a host of accessory parameters. These valuable insights help respiratory therapists answer some of the toughest clinical questions, throughout the continuum of care.

For Taylor's staff, use of the respiratory monitor was a new aspect of ventilator care. As he explains, "Traditionally, we'd simply put the patient on a ventilator, do a blood gas and make changes from there. But the blood gas gives just a snapshot of patient status at that moment. The rest of the time we'd have to observe carefully to do a patient assessment – listen to their breathing, look at their heart rate, check their blood pressure, and then make an educated guess as to their status – if they are doing well, or poorly. It's very subjective."

The NICO2 offers physiologic information in a breath-by-breath fashion. Ventilation, circulation, and metabolic reaction to treatment therapy become quickly apparent on the easy-to-read screen. "Now we know with much more certainty how well the patient is doing because we can see the waveform. We've got real-time data on the volumetric CO<sub>2</sub>, the PEEP levels, and cardiac output."

### Making a difference

"Soon after we had the Esprit/NICO2 units in place, we received a patient who had already coded several times," says Taylor. Brought into the ICU in a heavily sedated state, she was ventilated with the Esprit and hooked up to the NICO2. The NICO2 cardiopulmonary management system immediately calculated her cardiac output, allowing ICU clinical staff to know when her heart was under critical stress.

Taylor continues, "By looking at the cardiac output, we could see it dropping long before any actual event. We were able to tell before she coded that she was about to code and stop it from happening." Nurses administered drugs via IV push to keep the woman's cardiac output at a life-sustaining level. Clinicians monitored the PEEP levels to maintain proper ventilation/oxygenation. They closely watched the volumetric CO<sub>2</sub> to determine if the patient was in danger of "shunting." Reading the on-screen display in real-time, the NICO2 values were entered  
*Continued on page 58...*

# Keeping Patients Active

Nishith Patel, RRT-NPS, CPFT

Alpha<sub>1</sub> Antitrypsin Deficiency (AAT) is a genetic condition, passed from parents to their children. This inherited disorder increases the risk of developing Chronic Obstructive Pulmonary Disease (COPD), liver disease, and several other conditions. The deficiency of the protein, alpha<sub>1</sub> antitrypsin, can lead to emphysema and is often misdiagnosed as asthma or smoking-related COPD. AAT deficiency related lung disease presents with common respiratory symptoms including shortness of breath, chronic cough and sputum production, wheezing, decreased exercise tolerance, frequent lower respiratory tract infections, bronchiectasis and history of suspected allergies and/or asthma. Although previously considered a disease of Caucasians, recent data show that AAT deficiency exists in all racial subgroups worldwide.<sup>1</sup> While there is no cure for AAT deficiency, several effective treatments are available including smoking cessation, management of COPD/emphysema and other complications, and augmentation therapy with purified alpha<sub>1</sub> antitrypsin protein.

Exercise and activity limitation are characteristic features of COPD. This intolerance to exercise results in ventilator limitations, cardiovascular impairment and/or skeletal muscle dysfunction which can ultimately lead to a sedentary lifestyle, limited physical function, and diminished quality of life.

Various types of exercise training involving both lower and upper extremities, and respiratory muscles have been shown to improve muscle function, exercise endurance, and quality of life, while decreasing the level of dyspnea for patients with COPD. Following a regular, sustained exercise program should be part of a comprehensive therapy for lung disease patients as this has shown to increase 6-minute walk distance, exercise capacity, and several indicators of quality of life.

A recent study was conducted at the Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center (LA BioMed) using the Breathe Technologies Non-Invasive OPEN Ventilation (NIOV) System. The NIOV System is an ultra-light weight, wearable, volume augmentation ventilation system, designed to help improve breathing and facilitate mobility.

This study evaluated the physiologic effects of using the NIOV System during constant work rate exercise in subjects with COPD. Providing both supplemental oxygen and augmented ventilation, the NIOV System has the potential to promote rehabilitation and improve the health-related quality of life (QOL) in patients with



respiratory insufficiency. From previous studies on the NIOV System, subjects have reported that while using the system they experienced less dyspnea, reduced work of breathing and greater mobility and exercise endurance compared to their current oxygen only systems.<sup>2</sup> Physical activity is an important clinical parameter related to morbidity and mortality and is potentially a key aspect to target as an outcome measure for the NIOV System. Improving physical activity allows the patient to better participate in daily life and perhaps more importantly may spin-off long term-health benefits.<sup>3</sup>

Dana Jones, an AAT deficient patient, was initially introduced to the NIOV System when he volunteered to participate in the LA BioMed study. Mr Jones experienced such a dramatic improvement in his shortness of breath and exercise tolerance while using the NIOV System, that he immediately requested a prescription to enable him to use the NIOV System at home.



Mr Jones was diagnosed with AAT deficiency in 1999. Within a year after diagnosis, he initiated AAT augmentation therapy with weekly intravenous Prolastin infusion. As his disease and symptoms progressed, by mid-2009, Mr Jones required supplemental oxygen and was experiencing respiratory insufficiency even during mild physical activity. Using the NIOV

System, his shortness of breath and fatigue were noticeably reduced. Mr Jones understands that exercise is essential and that lack of it can lead to both central and peripheral deconditioning, and as a result he could experience greater dyspnea and intolerance to exertion, and further loss of functional capacity. Thus, to improve his mental outlook, stamina, and physical well-being, Mr Jones routinely exercises.

As dyspnea and exercise capacity worsen, the need for medical care increases and the patient's ability for self-care decreases. These functional limitations and dependence on others can lead to a sense of loss of control, with consequent depression and anxiety. In Mr Jones' case, the portable NIOV System provides utility in improving mobility and exercise tolerance. By optimizing conditioning, and supporting ventilatory function at various levels of physical activity, the NIOV System has the potential to improve health-related QOL, while promoting participation in activities of daily living.

Mr Jones now routinely uses the NIOV System during exercise sessions with his respiratory therapy group. Endurance exercise on the treadmill in conjunction with NIOV therapy has helped improve Mr Jones' aerobic capacity, ventilatory muscle function, and his skeletal muscle performance. The NIOV System allows

This article was provided by Breathe Technologies.



patients to select from three volume settings and can therefore be used during both high and low-intensity exercise. When comparing his exercise endurance using a traditional nasal oxygen cannula to the NIOV System, Mr Jones has noticed a dramatic improvement in his exercise endurance.

Resistance exercise, like lifting weights has the potential to improve thoracic cage muscles of ventilation and the ability to perform the activities of daily living at home, work and play. The picture gallery includes a photo showing Mr Jones using the NIOV System to match his ventilatory and oxygen needs during weight lifting. Using the NIOV System during resistance exercise has decreased his symptoms of dyspnea and fatigue.



Patients with chronic lung disease frequently experience activity restrictions and discomfort during activities of daily living (ADLs). For most individuals with moderate-to-severe chronic lung disease, even basic daily activities can be strenuous and daunting. For Mr Jones, ADLs including walking stairs, carrying and lifting objects, bending down and rising from a seated position have been significantly enhanced using the NIOV System. For many patients, including Mr Jones, bathing, dressing, and grooming require a great deal of energy consumption and oxygen use. While performing these daily tasks, especially showering and shaving, Mr Jones reports experiencing significantly less dyspnea and greater control of his breathing with the NIOV System.

In other photos, Mr Jones can be seen working on his classic 1971 Mini Cooper, which he cherishes greatly. The NIOV System has enabled him to continue his hobbies and given him greater independence to perform the activities he enjoys most.



Chronic lung diseases, like AAT deficiency, are progressive diseases that slowly rob patients of exercise tolerance, health-related QOL and independence. Exercise in conjunction with education and other components of formal pulmonary rehabilitation have clearly been shown to improve functional status, dyspnea, and health-related QOL in patients with lung disease. A higher level of physical activity can reduce the number of hospital admissions due to exacerbations,<sup>4,6</sup> as well as decrease respiratory mortality.<sup>5</sup> For Mr Jones, the NIOV System has significantly increased his functional exercise level of daily

physical activities by reducing his work of breathings while effectively supplementing his oxygen intake. The system has not only improved Mr Jones' independence and security, it has also made a significant improvement in his level of dyspnea, and exercise endurance.

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# Rain-Out: Condensation in Oxygen Tubing; causes and solutions.

## Abstract

Condensation that develops, collects, and exits the oxygen tubing when a humidifier is used with an oxygen source, specifically an oxygen concentrator, is referred to as rain-out. Because all commonly used oxygen sources are devoid of humidity, rain-out occurs only with the addition of an external humidifier.

The quantity of condensation is related to the temperature gradient of the humidified gas as it travels through the oxygen tubing and cannula. If the condensation progresses to the point that it exits the cannula, a home medical equipment (HME) provider will need to take action to alleviate the situation for the patient.

The most important step in preventing rain-out is to eliminate the humidifier. Research indicates no clinical benefit to humidified oxygen for patients on low-flow oxygen therapy: flows  $\leq 5$  L/min. Over the years, humidifier use with oxygen therapy has been significantly reduced at a great savings to health care facilities, providers, and insurers.

## Contributing Factors

### *The Humidifier*

A humidifier, commonly called a bubble humidifier or simply, a bubbler, contains water to humidify the dry oxygen from an oxygen source. The humidifier supplies the water that develops into rain-out. As oxygen passes through the humidifier, it combines with water vapor. The ability of a gas to become humidified is related to the temperature of the gas, temperature and pressure in the humidifier, efficiency of the diffuser, and the flow rate. A warmer gas, whether due to a humidifier heater or an elevated outlet gas source, holds more water molecules. When the oxygen is 100% humidified and can no longer maintain water molecules in vapor form at a specific temperature, rain-out is produced.

The humidifier's diffuser breaks the gas into smaller bubbles, increasing surface contact with the water. Water consumption in the humidifier does not increase in a linear manner. A flow rate of 5 liters per minute (L/min) does not necessitate refilling the humidifier five times as often as a flow rate of 1 L/min. Bubble humidifiers typically contribute only a few ounces of water per day.

### *The Oxygen Source*

The occurrence of rain-out increases as the temperature gradient of the outlet gas and the oxygen-carrying accessories increases. Factors that raise the outlet gas temperature or allow for rapid cooling of humidified oxygen as it travels through oxygen-carrying accessories increase condensation and rain-out.

Outlet gas temperature is dependent upon the delivery source. Cylinders, liquid oxygen systems, and oxygen concentrators have inherently different operating temperatures. Gas cylinders have an outlet gas temperature equal to the room ambient temperature, unless they have been recently installed or are located near an external heating source.

The outlet gas temperature of a liquid oxygen system is cooler than the ambient temperature because oxygen is converted from an extremely cold liquid state to a gaseous state. This necessitates a heat exchanger to warm the gas for patient comfort. Condensation may develop externally on coils of the heat exchanger; however, due to its lower outlet gas temperature, it is rarely present in the delivery gas.

An oxygen concentrator is an electro-mechanical device that utilizes an air compressor and sieve beds to separate the oxygen from the nitrogen, which is present in room air. Oxygen concentrators, due to the process of air compression and electrical use, have higher internal operating and outlet gas temperatures than the ambient temperature. Models that operate more efficiently, with less electrical power consumption, will generally have lower operating temperatures and lower outlet gas temperatures than less efficient models.

Conditions that increase the operating temperature of the oxygen concentrator increase the outlet gas temperature exiting from the unit. When the outlet gas temperature is higher than the ambient temperature, there is a greater possibility that condensation will be created in the tubing when the humidified oxygen cools down.

A concentrator relies on unrestricted air flow for internal cooling, and some models have a cabinet filter. As this filter becomes occluded, air flow is reduced, causing the unit to operate at a higher temperature. This not only increases outlet gas temperature, but may accelerate wear of temperature-sensitive components, leading to reduced oxygen production, and an eventual thermal shut-down of the unit. The cabinet filter(s), if equipped, must be maintained according to manufacturers' requirements.



Air flow is also affected when intake or exhaust vents are obstructed or blocked. Intake and exhaust vents on some concentrators are positioned at the back of the units, increasing the likelihood that recirculation may occur when these models are placed too close to a wall, compounding the rain-out issues.

If the concentrator model is vented on the bottom, it may be more sensitive to placement on carpeting.

#### *Floor Temperature*

Floor temperature greatly impacts the amount of rain-out produced. Factors that affect floor temperature include construction materials, insulation, and weather conditions. During winter months, ceramic tile and hardwood floors may be substantially cooler than the overall temperature of the room, particularly if built over a poorly insulated area. As the tubing, especially long lengths, contacts these cold surfaces, the humidified oxygen gas may cool and rain-out. Although the combination of winter months with cooler floor temperatures may exacerbate rain-out, it may also occur when oxygen tubing is allowed to coil over air conditioning floor vents. Frequently, rain-out may be traced to changes in temperature caused by nighttime settings on automatic thermostats. Since the delivery of therapeutic oxygen is essentially a “closed loop” system and the condensation occurs within the tubing, the room’s relative humidity has no effect on rain-out.

#### **Preventing and Reducing Rain-Out**

The best way to prevent rain-out is to eliminate the humidifier. Throughout the years, humidifier use with oxygen therapy has significantly decreased, especially for patients on low flows. Research by Campbell (1988), Andres (1997), and Estey (1982) indicates that using humidifiers on oxygen equipment with flow rates up to 4 or 5 L/min merely adds cost and does not benefit the patient. The American Association for Respiratory Care guidelines specify that oxygen supplied via nasal cannula at flow rates  $\leq 4$  L/min does not need humidification (2002, 2007). The American Thoracic Society and European Respiratory Society standards for the care of COPD patients describe the lack of evidence supporting the use of humidification when oxygen is delivered via nasal cannula at flows  $\leq 5$  L/min (2004).

HME providers have achieved the most success in reducing rain-out by removing the tip of the diffuser or the diffuser tube completely to form a pass-over system, as with continuous positive airway pressure (CPAP) therapy. Care should be taken not to overfill the humidifier or to add warm water. Some humidifiers have internal designs that minimize the expulsion of water droplets directly into the oxygen tubing. Regardless of its origin, once water is present in the tubing, it will likely remain there until the humidifier is removed, or the water emptied, to allow the flow of oxygen gas to dry the tubing.

It is beneficial to locate the concentrator in a cool, shaded, well-ventilated area to reduce the temperature gradient, which causes condensation. Appropriate location selection includes maintaining adequate distance from walls, furniture, privacy curtains and other objects to allow room air to freely circulate around the concentrator. It may be beneficial to turn the concentrator at a 90° angle to the wall to maintain this distance.

The concentrator should not be permitted to directly pull in warm air from a heating source or become heated externally by the sun, as would occur in a sunny location, or if positioned

too close to heating registers or ducts. Inappropriate unit placement in the home care environment may include confined areas such as bathrooms, closets, and under desks, since warm exhaust gas may become localized, heat the area, and re-circulate back into the unit. To improve the clearance and circulation, the concentrator can be placed on a mat, such as a carpet sample or welcome mat, even upside down if there is deep pile carpeting. A mat may also reduce rain-out by insulating the tubing from a cold surface. Shortening the length of tubing may reduce the production of rain-out by reducing the time available for the oxygen to cool. The concentrator’s cabinet filter, if equipped, must be kept clean and requires more frequent attention in dirty environments.

Some HME providers use in-line water traps to collect the condensation when a large temperature difference exists between an oxygen unit’s outlet gas and the surface of the floor, making rain-out unavoidable. This device consists of a chamber that accumulates water and prevents it from reaching the patient. For maximum effectiveness, locate the water trap close to the patient.

#### **Alternatives to Oxygen Humidification**

Oxygen therapy-dependent and other acutely ill patients are prone to dehydration. This causes the mucus membranes to dry out, which may be misinterpreted as a side-effect of the oxygen therapy (Wotton, Crannitch, & Munt, 2008). It is important to maintain hydration with adequate fluid intake. Irritation from the cannula tips may be treated with a petroleum-free, water-based nasal moisturizer.

When continuous flow oxygen therapy is initiated, patients may initially experience dryness of the upper airway, which decreases with time. This decrease in symptoms occurs with or without the use of humidification (Andres, Thurston, Brant, Flemons, Fofonoff, Ruttimann, Sveinson, & Neil, 1997). Research does not support the use of humidification to reduce initial dryness complaints or the severity of symptoms (American Thoracic Society/European Respiratory Society, 2004).

Humidified oxygen does not compensate for an inherently dry environment, since the patient inhales a majority (83 to 96%) of room air along with therapeutic oxygen. Inspired oxygen levels of 24%, 28%, and 32% correspond to ratios of 25:1, 11:1, and 6:1 parts, respectively, of room air inhaled to therapeutic oxygen (American Thoracic Society/European Respiratory Society, 2004). For dry environments, consider the use of an inexpensive ultrasonic humidifier, which increases the relative humidity of the room. Many of these models sell for less than \$70 USD, and add one to two gallons (3.8 to 7.6 liters) of water into the environment within a 24-hour period.

#### **Discussion**

The trend to eliminate the bubble humidifier continues, as research does not find the demonstration of any advantage to humidified oxygen for patients on low-flow oxygen therapy. In addition to causing rain-out, if the humidifier is not properly cleaned and assembled according to the manufacturer’s instructions, other secondary issues can be created. The risk of bacterial contamination is associated with humidifier use (American Association for Respiratory Care, 2007). Contamination is most frequently caused by skin flora introduced during refill or reassembly of the humidifier

(Henderson, et al, 1993). The humidifier is also a potential source of leaks or reduced oxygen flow to the patient.

The number and severity of patient complaints are comparable between humidified and non-humidified groups. A possible explanation may be that patients need time to become accustomed to oxygen cannulas, as one does to eye glasses. Patients require adequate fluid intake for proper hydration to maintain airway health. HME providers have struggled with periodic complaints relating to rain-out from oxygen patients. The frequency of rain-out may be reduced by analyzing the oxygen source and set-up and taking corrective action. Depending upon the location or installation of the oxygen therapy equipment, rain-out may be unavoidable, but its occurrence is likely temporary. Removing the bubble humidifier will eliminate rain-out without creating additional issues for the patient. Proper hydration, room humidifiers, and oxygen-compatible, water-based nasal moisturizers will improve patient comfort, in conjunction with the use and frequent replacement of a high-quality cannula to ensure soft and hygienic nasal prongs.

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*Respiratory Advantage...continued from page 53*

into the regular, routine ventilator checks so physicians could evaluate the trending and provide care accordingly.

After several days in the ICU, the woman began to improve. "In any other situation, I would have said this patient would not make it," insists Taylor, "but we were able to get accurate real-time information from the NICO2. I think she walked out of the hospital because we had that machine on that ventilator, helping us make timely decisions."

## Efficiencies benefit all

While it has become standard protocol at Cullman to use the ventilator/monitor combination on every patient requiring respiratory care, it took a while for the staff to comfortably rely on the monitor. "They'd insist on a central line to compare to the NICO2," says Taylor. "They soon realized this unit was just as accurate and in synch real-time with the ventilator."

"Now we do just one blood gas at the beginning to correlate with the NICO2. We don't have to stop, stick the patient, take it to the lab, and run the blood analysis. For what little time is added to the process by having to record data, it has saved us a whole lot more. We work quickly, reliably, and confidently."

Taylor also believes the system strengthens the relationship between respiratory therapists and nurses. He says, "With the kind of information available, they can really work together – make decisions together – find new areas of common ground. Together they can wean their patients from the ventilator with confidence and improve workflow in the department."

## A solid relationship

Taylor and Cullman Regional Medical Center have been satisfied Philips customers since the purchase of the Esprit/NICO2 equipment seven years ago. In fact, Taylor just upgraded all his Esprit ventilators to V200 units and added the TraceMasterVue ECG Management System for cardiograph workflow management.

"I don't just get an excellent product for a good price from Philips," says Taylor, "but the service after the sale is awesome. Nothing is going to work 100% all the time. It's how you deal with those issues that make the difference. If you go to bat for your customer like Philips has done for me, that's the total package."

# The Science of Improving CPR

Paul F. Nuccio, MS, RRT, FAARC; Gary Hochstetler, BS, RRT

## Introduction

During cardiopulmonary resuscitation (CPR), management of the patient's airway, ventilation, and chest compressions requires a diligent effort and sophisticated technology to maximize successful outcomes.

Survival rates from sudden cardiac arrest in hospitals have been dismal and static for decades. However, very active research in the past decade has led to an exponential increase in our knowledge concerning the physiology of resuscitation and therapy. Factors attributed to improving outcomes include high-quality CPR, early coronary angiography intervention, advanced circulatory support, advanced airway management, and therapeutic hypothermia.

Based on current science, the focus on CPR technique has increased, with the 2010 American Heart Association (AHA) Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care stressing the importance of high-quality CPR.<sup>1</sup>

The key AHA recommendations for effective CPR are:

- During CPR, rescuers should give chest compressions a little faster, at a rate of at least 100 per minute.
- Rescuers should push deeper on the chest, compressing at least two inches in adults and children and 1.5 inches in infants.
- Between each compression, rescuers should avoid leaning on the chest to allow it to return to its starting position.
- Rescuers should avoid stopping chest compressions and avoid excessive ventilation.

What will it take to get to “high quality” in the real world, and how can we quantify it?

## How is blood flow created during CPR?

Manual (sternal) CPR is based on the “cardiac pump” theory. It holds that direct compression of the left and right ventricles between the sternum and vertebral column creates a pressure gradient between the ventricle and aorta. This pressure gradient moves blood forward out of the ventricle with refill during the

decompression phase. Piston-driven mechanical CPR devices are also based on this theory.

A second theory known as the “thoracic pump” theory postulates that external chest compression increases intrathoracic pressure, forcing blood flow from the thoracic cavity to the systemic circulation. Flow from the right side of the heart into the systemic veins is prevented by the venous valves. The thoracic pump theory is accomplished with a load-distributing band delivered by a mechanical CPR device.

## How good is our CPR performance?

Studies of CPR provided during in-hospital cardiac arrest have demonstrated that the quality of CPR, eg, depth and rate of chest compressions, is often inconsistent or suboptimal.<sup>2,3</sup>

In one study that included 97 cardiac arrests over an 18-month period, Abella, et al measured the compression rate in 1,626 30-second segments of CPR. The recommended rate for compressions based on the AHA guidelines at the time of the study was at least 100 per minute, yet rates were between 90 and 110 per minute in just 36.9% of these segments<sup>2</sup> (Figure 1).

CPR is difficult. High-quality CPR—providing compressions at proper depth, at proper rate, with correct release, and with limited interruptions—even more so. Rate, depth, continuity, velocity, duty cycle, relaxation, and the length of time the compression is held all determine the impact of CPR. Meeting

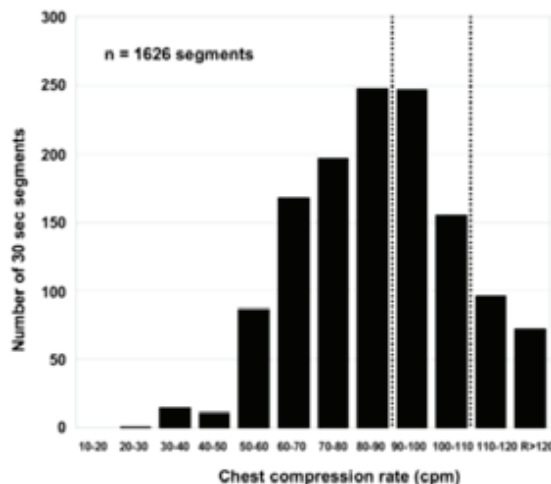


Figure 1: Abella BS, et al. *Circulation*. 2005 Feb 1;111(4):428-34.

Paul Nuccio is Director of Pulmonary Services, Brigham and Women's Hospital, Boston, MA; Gary Hochstetler is Marketing Manager, Circulation, ZOLL Medical Corporation, Chelmsford, MA. This article was provided by ZOLL Medical Corporation.

these guidelines is simply more than most rescuers can physically achieve and certainly more than anyone can sustain beyond a few minutes.

Although the AHA guidelines advise minimizing interruptions in compressions to 10 seconds or less, in reality, it's not uncommon for compressions to be interrupted more frequently, resulting in a drop in circulation and potentially worse outcomes.

### What is the influence of ventilation on circulation?

During CPR, the purpose of ventilation is to maintain sufficient oxygenation and to eliminate carbon dioxide. How artificial ventilation is administered during CPR can greatly influence the opportunity for the victim to return to spontaneous circulation.

Ventilation may be unnecessary during the first few minutes of CPR, but under conditions of prolonged CPR, lack of adequate oxygenation will affect regaining spontaneous circulation (ROSC) and survival.

Excessive ventilation during CPR for victims with advanced airways may result in decreased cardiac output. If excessive ventilation creates increased intrathoracic pressures, venous return most likely will decrease, affecting circulation.<sup>4</sup>

### How much oxygen does a patient need during CPR?

The AHA has changed the CPR sequence from A-B-C (Airway-Breathing-Compressions) to C-A-B (Compressions-Airway-Breathing). And although it is said that people can survive cardiac arrest if they receive only chest compressions during cardiopulmonary resuscitation, Ohio researchers insist that at some point, oxygen must be added. They tested different scenarios in an experimental model of cardiac arrest in rats. The rats received either 100% oxygen, 21% oxygen—the equivalent of room air—or no oxygen (100% nitrogen) at the same time they received CPR. About 80% of the rats survived regardless of the percentage of oxygen they received along with chest compressions. However, in the group receiving no oxygen, only one animal could be resuscitated.<sup>5</sup>

We know that it is important to avoid hyperventilation, which results in decreased cerebral blood flow and lowers cardiac output. After a cardiac arrest, many patients have lung problems due to aspiration, lower cardiac output, and high inspired oxygen, all of which increase the risk of acute respiratory distress syndrome. The aim is to achieve an oxygen saturation of 94% to 98%, monitored by pulse oximetry, to avoid very high or very low oxygen levels.

### When is circulation "good enough"?

Studies have suggested that during optimal CPR, cardiac output is between 25% and 40% of pre-arrest values. Coronary perfusion occurs during the release, or decompression phase, of CPR. Changes in coronary perfusion are related to changes in coronary perfusion pressure (CPP), the pressure in the coronary arteries immediately upon diastole.

Obtaining CPP is an invasive procedure that is neither routinely available nor practical in the resuscitation setting. Nonetheless, CPP has tremendous clinical significance, as demonstrated by Paradis, who measured the coronary perfusion pressure of patients undergoing CPR in an ICU.

In Paradis' study, no patient achieved ROSC with a coronary

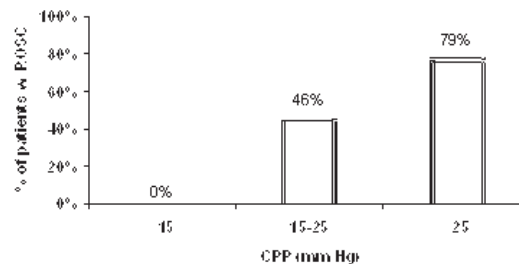


Figure 2.

perfusion pressure of less than 15 mm Hg, while ROSC was achieved in 79% of patients with a CPP greater than 25 mm Hg<sup>6</sup> this data is represented in Figure 2.

Non-invasive options for assessing the adequacy of blood flow generated by cardiac compressions include palpating pulses, measuring blood pressure, and monitoring end-tidal carbon dioxide (EtCO<sub>2</sub>) levels.

During cardiac arrest, CO<sub>2</sub> delivery to the lungs decreases due to poor pulmonary perfusion. A decrease in pulmonary blood flow will cause the accumulation of CO<sub>2</sub> in the venous circuit even with adequate ventilation. The significance of EtCO<sub>2</sub> monitoring during CPR was first noted by Kalenda, who observed and monitored pulmonary perfusion by means of EtCO<sub>2</sub> and reported its role in assessing rescuer exhaustion.<sup>7</sup> He found that with external cardiac massage, there was a slight improvement in EtCO<sub>2</sub>, which diminished as the rescuer became tired. Replacing the fatigued rescuer with a fresh rescuer resulted in an improvement in EtCO<sub>2</sub>, as shown in Figure 3.



Figure 3.

Several additional studies have demonstrated the correlation between EtCO<sub>2</sub> with cardiac output and CPP, and the 2010 AHA Guidelines designate continuous EtCO<sub>2</sub> monitoring as a Class I recommendation.

### Good CPR leads to successful defibrillation

A growing body of evidence suggests that beyond a delay of about three minutes, reestablishing blood flow before defibrillation may improve the efficacy of the shock. In fact, animal studies have demonstrated increased survival when, after several minutes of arrest, subjects receive a brief round of CPR before defibrillation.<sup>8</sup>

Over 70% of cardiac arrests outside the hospital occur at home, where no AED is available, so the vast majority of cardiac arrest patients do not receive defibrillation within the crucial first three minutes.<sup>9</sup> More importantly, defibrillation is not initially indicated for at least half of all cardiac arrest patients since most patients do not exhibit ventricular fibrillation (VF) or ventricular tachycardia (VT) when the rescuer arrives.<sup>10</sup>

So, while defibrillation is the definitive treatment for VF and VT,

shock alone does not ensure survival from sudden cardiac arrest. Recognition of these facts has led to a search for additional strategies to improve myocardial perfusion as a means of increasing survival from cardiac arrest.

Circulation is critical for survival. It not only provides oxygen to preserve vital organ function, it also helps to convert non-shockable rhythms such as asystole and PEA to a shockable rhythm, VF or VT. Performing good CPR improves circulation and restores myocardial ATP,<sup>11</sup> as shown in Figure 4.

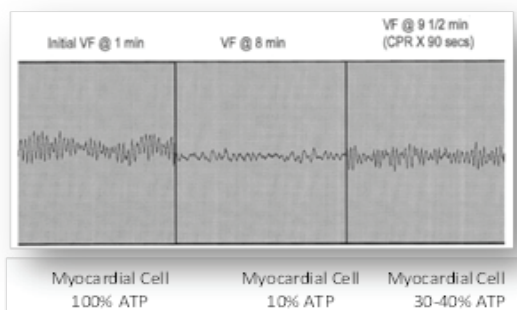


Figure 4.

### Quantifying CPR quality

The quality of CPR is directly related to patient outcome after cardiac arrest.<sup>12</sup> In 2007, an international collaborative group presented recommendations for standardizing the measurement and reporting of CPR quality, with a goal of enabling meaningful comparisons in clinical research.<sup>13</sup> Quantifying cardiopulmonary resuscitation quality was integral to the design of the CIRC (Circulation Improving Resuscitation Care) trial.<sup>14</sup> This large, multisite randomized trial compared rates of survival to discharge from out-of-hospital cardiac arrest in patients treated with a mechanical CPR system to those receiving manual CPR.

The CIRC trial researchers gauged CPR quality by measuring the CPR fraction, the percentage of time that chest compressions are actually delivered during resuscitation. Recent studies have demonstrated the important relationship between CPR fraction and survival, reinforcing its significance as a quality indicator. “No-flow time,” a parameter measured and reported in some clinical trials, is synonymous with CPR fraction and emphasizes the adverse effects of interruptions in chest compressions.

The CPR fractions reported in the literature vary significantly, with values between 54% and 71% typical in large multicenter trials, and higher values reported in smaller studies. It is reasonable to assume that the CPR fractions reported in clinical trials are higher than those seen in daily practice. Today, most hospitals and EMS services do not measure CPR fraction unless they debrief resuscitation events using data recorded by a defibrillator. You can't improve what you don't measure.

### Steps we can take to deliver high-quality CPR

Resuscitation experts believe that “real-world” CPR fractions are probably in the 50% to 60% range, at best. In systems that have focused on improving their CPR quality, both in and out of the hospital, survival rates from sudden cardiac arrest have doubled, or even tripled.<sup>15,16</sup>

According to the 2010 AHA guidelines, “Several studies have demonstrated improvement in chest compression rate, depth, chest recoil, ventilation rate, and indicators of blood flow such as end-tidal CO<sub>2</sub> (PETCO<sub>2</sub>) when real-time feedback or prompt

devices are used to guide CPR performance.” The guidelines also emphasize the importance of post-event review and analysis.

Steps we can take to improve the quality of CPR include the following:

- Invest in better and more frequent CPR training.
- Use defibrillators and AEDs with audiovisual CPR feedback to improve the quality of chest compressions performed by health care providers and lay rescuers alike.
- Debrief every event.
- Incorporate mechanical CPR technology that provides thoracic compressions.

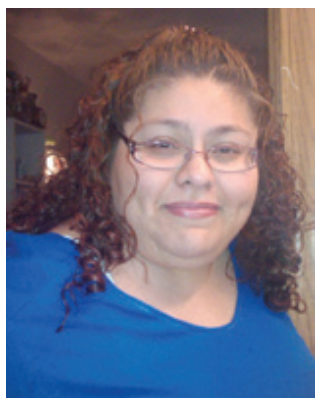
The investment in training and frequent retraining paid off in the CIRC trial, where the aggregate CPR fractions in both arms of the trial (mechanical and manual CPR) exceeded 80% during the first 20 minutes of CPR, the highest rate ever reported in a large multisite trial. And the survival-to-discharge rates were among the highest ever reported in a prospective randomized trial among patients who had suffered cardiac arrest, regardless of heart rhythm [trials that included more than 2,000 patients]. It should be noted that achieving this level of manual CPR required a significant investment of time and money.

Getting to high-quality CPR requires an all-hands-on-deck mentality and a multipronged approach. It requires more frequent training of both hospital and EMS staff, monitoring of CPR quality and addressing deficiencies, and incorporating mechanical CPR into the mix much more frequently. Using a bundle of interventions in resuscitation that includes training and technology can significantly change patient outcomes.

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# High-tech Ventilator Improves Care at Adventist Hinsdale Hospital



A particularly virulent form of pneumonia nearly killed Christina Colon – until a new ventilator at Adventist Hinsdale Hospital provided the support she needed. “It wasn’t looking good for me until a respiratory therapist switched me to this new machine,” said the 34-year-old Downers Grove resident. “That’s when I started breathing better.”

Adventist Hinsdale Hospital is the first hospital in Illinois to

use the device, a G5 Hamilton intensive care unit ventilator. Designed to be simpler for the user and safer for the patient, its unique features continually protect patients’ lungs while they are on the ventilator.

“The machine self-adjusts according to the individual patient’s needs,” said Michael Beechler, Colon’s respiratory therapist. “It’s better for the patient because it can ventilate without damaging the lungs.”

In Colon’s case, this new adaptive support mode protected Colon’s lungs by finding her optimal positive end-expiratory pressure (PEEP), a measurement that allowed caregivers to reduce unnecessary pressure into her lungs.

Colon’s trouble began last year when she developed hand discomfort that was initially diagnosed as carpal tunnel syndrome and then arthritis. By July, Colon was taking antibiotics for pneumonia, but soon began experiencing back pain and passing brown urine. When Colon started coughing up blood, she went to Adventist Hinsdale Hospital’s emergency department.

Testing showed Colon was actually battling Wegener’s granulomatosis, an incurable and often fatal disorder that attacks major organs, such as the ears, eyes, lungs and kidneys.

Treatment is lifelong; Colon is currently seeing a nephrologist and pulmonologist along with her primary care physician. Nevertheless, Colon is extremely thankful for the excellent care she received at Adventist Hinsdale Hospital, which initiated the road to her recovery.

“The nurses were very helpful; the doctors were informative; and Michael came in every day to check on my breathing and to answer my questions,” Colon said.

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This article was provided by Hamilton Medical. Adventist Midwest Health includes Adventist Bolingbrook Hospital, Adventist GlenOaks Hospital, Adventist Hinsdale Hospital and Adventist La Grange Memorial Hospital.

# Volume-Targeted vs Pressure-Limited Ventilation in the Neonate

Karl Kaminski, RRT-NPS; Ray Braxton, RRT

There is a saying in practicing respiratory therapy that if you wait long enough, the practices of earlier decades will become the new practices of the future. During the late 1970s, I [Kaminski] remember utilizing the Bourns LS 104-150 piston-driven volume targeted ventilator for support of difficult to ventilate neonates. Generally, the practice that I experienced working with neonates at that time was to start all infants utilizing pressure-limited ventilation (PLV) on the Bear BP 200 ventilator and to convert to volume targeted ventilation (VTV) on the Bourns LS 104-150 if the infant experienced uncontrolled fluctuating PaCO<sub>2</sub> levels. The LS 104-150 had an ancillary volume monitoring unit that the respiratory therapist used to adjust targeted tidal volume delivery. In the early 1980s, efforts at VTV were mostly abandoned with the further development in time-cycled, pressure-limited, constant-flow ventilators, which have been the primary method of ventilating infants for the past 30 years. Recent improvements in signal processing, servo-controlling and volume monitoring have made VTV a reality again for even the smallest of patients.

In 2011, a Cochrane Review was published that addressed the question of whether to ventilate a neonate with volume or with pressure modes of ventilation. The background for this review centered on evidence that points to damage caused by lung over distention (volutrauma) or under-distension (atelectrauma) leading to the development of bronchopulmonary dysplasia (BPD) in newborns requiring mechanical ventilatory support.<sup>1</sup> The objective for this review was to determine whether volume-targeted ventilation compared with pressure-limited ventilation leads to reduced rates of death and development of BPD. Secondary objectives were to determine whether use of VTV affected outcomes including air leak, cranial ultrasound findings and neurodevelopment. The authors' conclusion from this review found improvements in important outcomes that favor a VTV strategy. Compared with PLV, infants ventilated using VTV had reduced deaths/BPD, shortened duration of ventilation and less incidents of pneumothoraces, hypocarbia and periventricular leukomalacia/severe intraventricular hemorrhage.

Tracheal tube (TT) air leak related to the use of uncuffed neonatal endotracheal tubes often poses a challenge to the clinician. Accurate measurement and delivery of appropriate tidal volumes during mechanical ventilation can be problematic.

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Karl Kaminski is Manager, Respiratory Care, New Hanover Regional Medical Center. Ray Braxton is Clinical Application Specialist, Hamilton Medical, Inc. This article is from Hamilton's newsletter

A recently released retrospective clinical study conducted by Ramadan, et al<sup>2</sup> concluded that:

- Volume monitoring in mechanically ventilated neonates is a prerequisite for lung-protective mechanical ventilation.
- TT leaks of > 40% indicate that the displayed VT was underestimated by 1.2 mL/kg (about 24% of target VT). (This was specific to [one particular brand of] infant ventilator, however; the same underestimation of actual delivered volume would occur anytime expired volume was used to assess achieving the set volume target.)
- High TT leak increased with smaller TT diameter, reduced birth weight, and extended duration of mechanical ventilation, indicating that very low-birth-weight infants are at greater risk of TT leak.

There are many different ways of delivering, monitoring and adjusting tidal volumes. Targeting a set pressure demands close vigilance of delivered tidal volumes. With changes in resistance or compliance, clinicians may observe large changes in tidal volume. Maintaining appropriate ventilation (as evidenced by stable blood gas results) may prove difficult.

In the face of significant leaks, optimizing the performance of some ventilators in VTV modes can be challenging for the respiratory therapist. The characteristics of ventilators used to provide support to neonates may influence success with VTV. For instance, a ventilator that uses inspired volumes as a target reference for delivered tidal volume may tend to underventilate patients in the presence of an airleak around an uncuffed endotracheal tube. On the other hand, ventilators targeting expired volumes exclusively, need to have protective mechanisms or volume limitations imposed to avoid an excessively large volume being delivered, should the air leak go away with repositioning or changing physiologic factors.

Surfactant replacement for infants experiencing respiratory distress has become routine therapy. It is not uncommon to see dramatic changes in an infant's lung mechanics within minutes of receiving surfactant.

Often, delivered tidal volumes in a pressure-limited mode dramatically increase leading to hypocarbia for the infant and long term neurological sequelae related to cystic brain lesions (periventricular leukomalacia). Volume targeted ventilation has the advantage of keeping tidal volumes consistent, thereby avoiding these tidal volume changes.

*Continued on page 66...*

# Nasal EPAP for the Treatment of Obstructive Sleep Apnea (Provent) and Snoring (Theravent)

Rajiv Doshi, MD; Mari Bernal, CRT; Philip Westbrook, MD

## Introduction

Nasal expiratory positive airway pressure (EPAP) represents an important new class of therapy to treat sleep-disordered breathing, ranging from primary snoring to all severities of obstructive sleep apnea (OSA). Provent Sleep Apnea Therapy (Provent) is FDA-cleared and indicated to treat OSA, and Theravent Advanced Nightly Snore Therapy (Theravent) is FDA-cleared and indicated to reduce or eliminate snoring. This article offers healthcare providers a brief overview of both products including information on EPAP mechanism of action, published clinical data, and patient selection recommendations.

## About Nasal EPAP

The use of EPAP to treat sleep-disordered breathing dates back to 1983 when Mahadevia et al demonstrated that the passive application of 10cm H<sub>2</sub>O of EPAP significantly improved the apnea index and oxygen desaturation index.<sup>1</sup> There were few studies of EPAP for the subsequent 20 years. More recently, there has been renewed interest in nasal EPAP and its physiologic effects on lung volumes in patients with sleep-disordered breathing. There has also been a series of well-designed prospective studies that have demonstrated the safety and efficacy of nasal EPAP for the treatment of OSA and snoring.

## Mechanism of Action

OSA and snoring are generally thought of as inspiratory conditions. However, it is also known that the closure of the upper airway begins at the end of expiration, when the pressure in the airway is zero. Morrell et al demonstrated that the upper airway cross sectional area progressively decreased in the breaths prior to an obstructive apneic event, with this area smallest at the end of expiration. They concluded that this narrowing made it more likely for the airway to fully collapse during the next inspiration.<sup>2</sup> Nasal EPAP has been shown to increase expiratory pressure which is maintained through the end of expiration and until the start of the subsequent inspiration, thus reducing the likelihood of airway collapse during the vulnerable end-expiratory period.

The most likely mechanisms through which EPAP improves sleep-disordered breathing include:<sup>3,4</sup>

- 1) Positive end-expiratory pressure (PEEP) leading to an increased end-expiratory lung volume that increases longitudinal traction on the pharynx, making it less collapsible (“tracheal tug”).

- 2) Dilatation of the upper airway which carries over until the start of the next inspiration.
- 3) Mild hypercapnia due to hypoventilation leading to increased respiratory drive to the upper airway dilator muscles.

## Provent Sleep Apnea Therapy

Introduced in 2008, Provent is FDA-cleared and indicated to treat OSA (Figure 1). With seven published studies in *SLEEP*, *Journal of Clinical Sleep Medicine*, *Sleep Medicine* and *Journal of Applied Physiology*, the device has demonstrated significant improvements across mild, moderate and severe OSA.<sup>3-9</sup> Provent is particularly relevant for the approximately 50% of all patients diagnosed with OSA who are non-compliant with CPAP.

Provent is a disposable device that consists of a small valve attached externally to each nostril with hypoallergenic adhesive. The device acts as a one-way resistor, permitting nearly unobstructed inspiration. During expiration, the airflow is partially restricted, increasing resistance and creating EPAP (Figure 2).

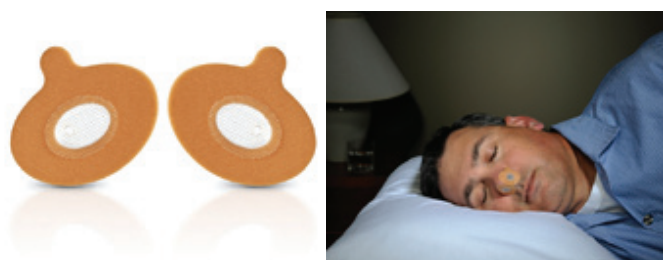


Figure 1. Provent Sleep Apnea Therapy, a prescription nasal EPAP device indicated to treat OSA. Provent Therapy is effective across mild, moderate and severe OSA.



Figure 2. During inspiration (left) the valve opens to allow for nearly unobstructed airflow. Then, during expiration (right) the valve closes, restricting airflow to create EPAP and maintain pressure in the airway through the start of the next inspiration.

The most comprehensive of the published studies was a 250 patient, 19 center prospective, parallel-group, sham controlled, randomized double-blind trial with three month follow up.<sup>5</sup> In

This article was provided by Ventus Medical.



this study, Provent was studied alone, without the addition of adjunctive therapies such as chin straps and positional therapy. The AHI reduction by severity in the Provent treatment group is shown in Figure 3a.

In the real world, adjunctive therapies, including chin straps and positional therapy, are easily implementable and can be used to further reduce the AHI. A recent study by Adams demonstrated impressive reductions in AHI for all classes of OSA severity.<sup>10</sup> Adjunctive therapies were used in roughly half of patients. Approximately 80% of patients, including some with AHI up to 100, were able to achieve a treatment AHI of <10 (Figure 3b).

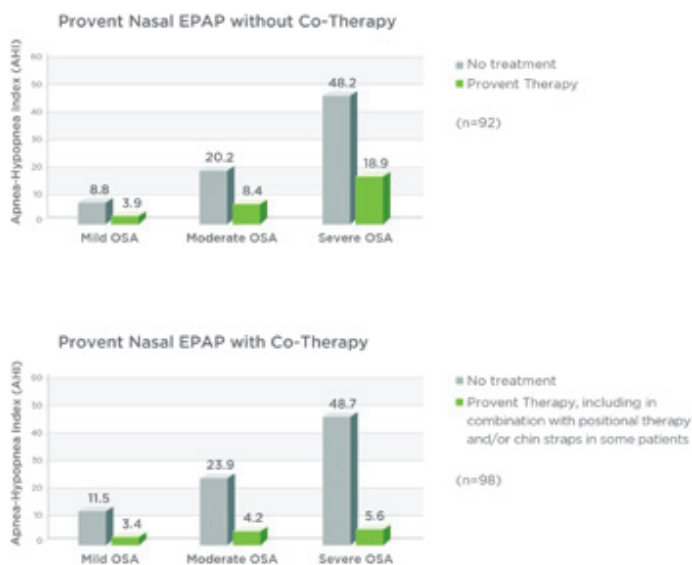


Figure 3a and 3b. Median AHI reduction when Provent is used without co-therapies (top panel) and when Provent is used with co-therapies (chin straps and/or positional therapy) in some patients (bottom panel).

The published studies of Provent<sup>3-9</sup> have demonstrated high nightly compliance rates of 88-94%, significant reductions in daytime sleepiness (comparable to improvements typically seen with CPAP), and significant improvements in oxygen saturation. Further, 83% of patients had reductions in snoring as assessed using vibratory sensors.<sup>8</sup>

Recommended patients for Provent include:<sup>11</sup>

- 1) Patients (mild, moderate or severe) who have rejected or are non-compliant with prescribed CPAP
- 2) Newly diagnosed mild/moderate OSA patients without significant co-morbidities
- 3) CPAP compliant patients looking for therapy alternatives for travel

As AHI reduction with Provent can be heterogeneous, it is important to test efficacy, which can be done using a specialized nasal cannula system that attaches to the Provent device and interfaces with in laboratory PSG and/or portable monitoring systems. Those patients who do not achieve successful AHI reductions may benefit from the addition of chin straps and/or positional therapy as described previously (Figure 4).



Figure 4. The Provent Nasal Cannula system for use with in lab PSG and portable monitors.

### Theravent Advanced Nightly Snore Therapy

Recently cleared by the FDA as a non-prescription device for the intended use of reducing or eliminating snoring, Theravent utilizes microvalves set within a hypoallergenic adhesive patch that surrounds the user's nostrils (Figure 5). These valves open during inspiration and close during expiration, during which air is directed through a central hole in the device, creating resistance and EPAP (Figure 6). The expiratory resistance created by Theravent is a fraction of the resistance created by Provent and is therefore better suited to treat snoring.



Figure 5. Theravent Advanced Nightly Snore Therapy, a non-prescription nasal EPAP device indicated to reduce or eliminate snoring.

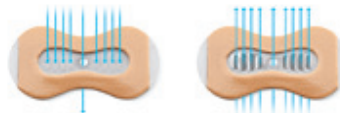


Figure 6. During expiration (left), the microvalves are closed, creating resistance and EPAP. During inspiration, the microvalves open, allowing nearly unobstructed breathing.

Theravent has been validated in three separate clinical studies. The most rigorous of the studies was a prospective, randomized, single-center trial that used decibel meters to evaluate snoring volume and duration in a population of primary snorers (without OSA).<sup>12</sup> Forty-nine patients were tested on control nights (using no therapy), using Theravent and using external nasal dilator strips. Additionally, patients and their bed partners completed daily logs and an end of study survey.

The average percent of sleep time snoring above 40 dB was significantly reduced for Theravent compared to control ( $p < 0.001$ ). For the external nasal strips, snoring was not significantly different compared to control ( $p = 0.309$ ). As assessed by decibel meter, 76% of patients using Theravent had a reduction in snoring. Among responders to Theravent (those with at least a 50% reduction in snoring), the mean reduction in snoring was 76% according to the decibel meter.

The study also showed that bed partners experienced significantly less sleep disruption and reported highly significant decreases in both snoring duration ( $p < 0.001$ ) and snoring volume ( $p < 0.001$ ) compared to control, based on subjective assessment.

This study was one of the few studies of non-prescription snoring products that has ever shown both subjective and objective improvements in snoring.

## Conclusion

Provent Sleep Apnea Therapy and Theravent Advanced Nightly Snore Therapy represent two important new nasal EPAP treatment options for healthcare practitioners to recommend to their patients with OSA and snoring respectively.

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*Ventilation in the Neonate...continued from page 63*

Another advantage of VTV is during "BPD" spells. Though much less common today, acute episodes of desaturation and bradycardia are often seen in infants with BPD. Extremely low birth weight infants breathing air months before they are physiologically prepared to do so experience abnormal alveolar, small airway, and vascular development. The resultant hyperactivity of the airway and impaired airway clearance results in acute bouts of cyanosis and bradycardia. In PLV, the patient still receives the same level of pressure but the volumes to the baby are dramatically reduced resulting in cyanosis, hypercarbia and bradycardia. During VTV, volumes are noted to decrease so the ventilator increases pressure to bring the volume to the pre-set value resulting in improved ventilation, decreasing the number of episodes experienced by the infant.

Over the past several years there has been resurgence in providing VTV to the neonatal population of patients for various reasons. Whether your practice with the neonatal population of patients centers on PLV versus VTV depends heavily on the capabilities of the selected ventilator to provide accurate and reliable information to the respiratory therapist and is able to react to the ever-changing pulmonary dynamics of the neonate.

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# Report on the Application of Continuous and Biphasic Noninvasive Ventilation in 11,330 Neonates: Indications and Outcomes

Michael Skrzypek, PhD; Thomas Bachman, MS; Janusz Swietlinski, MD, PhD, DSC

## Background

The application of noninvasive ventilation in the NICU has grown significantly over the last 20 years. Evidence has long supported its use in transitioning from mechanical ventilation, and its elective application to avoid intubation is also common.<sup>1,2</sup> A recent mega trial confirmed the notion garnered from anecdotal reports and smaller trials that it is effective as a first intention treatment for RDS, with administration of surfactant and intubation reserved for those failing NCPAP.<sup>3</sup> More recently small studies have suggested that biphasic or noninvasive ventilation might be more effective than continuous positive pressure ventilation<sup>4,5</sup> but a large recently completed trial found no difference.<sup>6</sup>

Widespread use of noninvasive ventilation has been the standard of care in some regions. A decade ago the Polish Neonatal Society successfully undertook such a transformation to a bias towards noninvasive respiratory support.<sup>7</sup> As part of that transition, the Infant Flow Advance (CareFusion Corporation, Yorba Linda, CA, USA) was selected as the standard of care because of its low work of breathing, ease of use and biphasic support mode.

There is little in the literature about the application of noninvasive ventilation for uses other than weaning and RDS or about the general experience with its use outside of well-defined trials in extremely premature infants. The aim of our report is to share our experience with the use of Infant Flow across all neonatal sizes and indications.

## Methods

As a part of the adoption of the noninvasive respiratory support program a registry and database were established to collect baseline, treatment and outcome data on every infant treated with Infant Flow in Poland.<sup>7</sup> Compliance with the data collection was ensured, as the availability of the Infant Flow devices was tied to grant funding for the entire project. In addition, the database management including site monitors was also grant funded. The Great Orchestra of Christmas Charity provided these most generous grants, which have helped transform neonatal care in Poland. The board of the Noninvasive Respiratory

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Skrzypek is with the Medical University of Silesia, Katowice, Poland; Bachman is with Econometdtrix, Lake Arrowhead, CA; Swietlinski is with The Medical Centre of Postgraduate Education, Warsaw, Poland. On behalf of the Noninvasive Respiratory Support Group of the Polish Neonatal Society.

Support Group of the Polish Neonatal Society oversaw the overall process.

The data for this report comes from the experience between 2005 and 2009. Ten percent of the centers are tertiary referral centers, with and without obstetric services; the balance are split equally between the two lower levels of centers.

The database categorizes infants based on their first use of Infant Flow into 8 diagnostic categories. Repeat uses of Infant Flow for the initial indication are captured, uses of Infant Flow later in the course of treatment are also included.

All data from the analysis period was extracted and cross-tabulated in prospectively defined tables. Backward stepwise multivariate logistic regression was used to identify factors associated with treatment failure and selection of NCPAP or SiPAP (PASW version 18, IBM). Differences were considered statistically significant if  $p < 0.05$ .

## Results

Over the 5-year study period 11,330 neonates were treated with Infant Flow in the 110 NICUs. Infants under 1,000 grams represented 13% of the total. Infants between 1,000-2,000 grams made up 42% of the population and those larger than 2,000 grams made up the balance (45%). As would be expected the most prevalent indication was treatment of RDS (69%). Weaning from invasive ventilation accounted for 16%. The next most prevalent indication was for treatment of apnea of prematurity (7%). The balance, 8%, were labeled as "other," which includes 5 diverse categories. Overall 81% of the Infant Flow treatments we deemed successful (ie, no need for intubation or reintubation within 3 days of completion of Infant Flow use). Less than 3% of these infants died before discharge. Of course these two outcomes varied widely according to weight category and indication.

The initial characteristics of the infants for each of the three weight categories and 4 indications are provided in Table 1 a-c. The time that Infant Flow treatment was initiated is also included. As would be expected, the use for RDS was lowest in the smallest category of infants, who were more likely to be intubated. It was however, still prevalent. There were no clinically relevant differences among the gas exchange or Apgar scores. For all but the weaning indication Infant Flow was generally started early in the first day of life. Because weaning, by definition, followed a course of invasive ventilation these infants tended to be a week or older when Infant Flow was initiated.

1a. <1000 grams				
	RDS	Weaning	Apnea	other
n	487	730	178	122
% wt group	32%	48%	12%	8%
EGA	27 (26-29)	26 (25-28)	27 (26-28)	26 (25-28)
BW	850 (750-940)	800 (700-900)	850 (760-933)	800 (698-873)
Apgar 5	6 (5-7)	6 (4-7)	6 (5-7)	6 (3-7)
hr IF Start	3 (1-5)	19 (5-35) day	21 (9-37)	26 (0-47)
pH	7.28 (7.22-7.34)	7.28 (7.22-7.33)	7.29 (7.23-7.35)	7.29 (7.22-7.33)
PaCO <sub>2</sub>	46 (38-55)	47 (40-54)	48 (40-59)	53 (46-59)
FiO <sub>2</sub> %	30 (25-40)	30 (26-40)	30 (25-40)	30 (25-40)
PF O <sub>2</sub>	147 (113-196)	147 (113-196)	153 (104-193)	136 (105-202)
1b. 1000-2000 grams				
	RDS	Weaning	Apnea	other
n	3265	853	424	265
% wt group	68%	18%	9%	6%
EGA	31 (30-33)	29 (28-31)	30 (29-32)	31 (29-32)
BW	1566 (1320-1800)	1300 (1130-1530)	1380 (1170-1638)	1450 (1215-1740)
Apgar 5	7 (6-8)	6 (5-7)	7 (6-8)	7 (6-8)
hr IF Start	1 (1-3)	7 (3-15) day	8 (2-16)	1 (0-30)
pH	7.29 (7.24-7.34)	7.28 (7.22-7.33)	7.29 (7.24-7.34)	7.29 (7.22-7.33)
PCO <sub>2</sub>	51 (42-58)	45 (38-53)	49 (41-58)	50 (41-59)
FiO <sub>2</sub> %	35 (30-40)	30 (25-40)	30 (25-40)	30 (27-40)
PF O <sub>2</sub>	136 (102-183)	144 (109-191)	147 (106-200)	156 (108-213)
1c. >2000 grams				
	RDS	Weaning	Apnea	other
n	4129	287	142	594
% wt group	80%	6%	3%	12%
EGA	36 (34-38)	37 (34-39)	35 (34-37)	38 (36-40)
BW (kg)	2.7 (2.4-3.2)	2.9 (2.4-3.3)	2.5 (2.2-3.0)	3.1 (2.6-3.6)
Apgar 5	8 (6-9)	7 (5-9)	8 (7-9)	8 (7-9)
hr IF Start	2 (1-6)	7 (4-18) day	2 (1-4)	1 (1-1)
pH	7.29 (7.24-7.35)	7.28 (7.22-7.33)	7.28 (7.22-7.33)	7.30 (7.24-7.35)
PCO <sub>2</sub>	52 (44-60)	48 (41-57)	46 (39-55)	49 (41-59)
FiO <sub>2</sub> %	35 (30-40)	35 (27-50)	32 (27-40)	40 (30-50)
PF O <sub>2</sub>	133 (99-176)	136 (93-173)	137 (105-180)	129 (94-176)

Table 1 Baseline Characteristics

Discrete variables displayed as percent and continuous variables as median (IQR).

The course of treatment, survival and major morbidity for the three weight categories and indications are shown in Table 2 a-c. The use of bilevel support (SiPAP) was quite prevalent, most common in the smaller infants and for weaning. It is also of note that when used, SiPAP was primarily used from the initiation of noninvasive support.

As is apparent in Table 2, the multivariate analysis confirmed that treatment failure was independently associated with EGA ( $p < 0.001$ ). The baseline oxygenation (PF O<sub>2</sub> ratio  $< 150$ ) was also independently associated ( $p < 0.001$ ) with treatment failure in the RDS infants. We also explored factors associated with the selection of SiPAP as the initial mode of noninvasive support. The diagnostic indication, maturity and clinical status all were independently associated with selection of SiPAP. Specifically these included: weight category ( $p < 0.001$ ), diagnostic category ( $< 0.001$ ), Apgar 5 ( $< 0.001$ ) and gas exchange ( $pH < 7.25$   $0 = 0.016$

and  $PF < 150$   $p = 0.001$ ). Finally, the selection of triggered versus time-cycled SiPAP seemed to be associate with individual clinicians preference and not clinical indicators, the time cycled being the most prevalent.

## Discussion

This is, to our knowledge, the first report of the general use of noninvasive respiratory support stratified by weight and diagnostic categories in a very large population. Our previous report, while general, was much smaller and reflected the adoption period.<sup>7</sup> This descriptive experience, by itself, should prove useful for those exploring the expansion of the use of noninvasive ventilation in their practice. With regard to indications and larger infants, where there is little evidence of relative effectiveness to guide adoption, our outcomes and experience should be comforting.

2a. <1000 grams				
	RDS	Weaning	Apnea	other
n	487	730	178	122
Initial mode SiPAP	37%	50%	39%	48%
SiPAP mode during	44%	60%	47%	58%
days InfantFlow	6 (2-14)	9 (4-17)	7 (3-14)	7 (4-15)
days vent support	14 (3-30)	30 (20-53)	22 (10-35)	30 (7-54)
wks PCA of vent sup	30 (28-32)	31 (30-34)	30 (29-32)	31 (29-33)
Surfactant any	43%	71%	41%	56%
1 dose only	76%	77%	86%	74%
Treatment Failure	46%	45%	34%	43%
Survival	89%	94%	94%	97%
CLD	19%	41%	28%	39%
severe ROP	14%	3.3%	22%	33%
severe neurological	5%	14%	8%	12%

2b. 1000-2000 grams				
	RDS	Weaning	Apnea	other
n	3265	853	424	265
Initial mode SiPAP	30%	47%	28%	35%
SiPAP mode during	35%	51%	37%	39%
days InfantFlow	2 (1-4)	5 (2-7)	4 (2-7)	3 (2-7)
days vent support	3 (1-6)	14 (7-25)	6 (3-13)	4 (2-11)
wks PCA of vent sup	32 (31-33)	32 (31-34)	32 (30-33)	32 (31-33)
Surfactant any	13%	65%	24%	25%
1 dose only	84%	78%	85%	75%
Treatment Failure	18%	26%	18%	25%
Survival	97%	97%	98%	97%
CLD	2%	15%	7%	9%
severe ROP	2%	1%	5%	13%
severe neurological	2%	10%	4%	4%

2c. >2000 grams				
	RDS	Weaning	Apnea	other
n	4129	287	142	594
Initial mode SiPAP	19%	40%	30%	15%
SiPAP mode during	24%	46%	36%	28%
days InfantFlow	2 (1-3)	3 (2-4)	2 (1-4)	2 (1-3)
days vent support	2 (1-3)	8 (5-15)	8 (5-15)	2 (1-4)
wks PCA of vent sup	36 (34-38)	38 (36-41)	35 (34-37)	39 (36-40)
Surfactant any	3%	21%	4%	4%
1 dose only	83%	75%	0%	0%
Treatment Failure	10%	28%	9%	12%
Survival	98%	96%	98%	99%
CLD	0.4%	5.4%	1.7%	1%
severe ROP	0.3%	1.5%	1.4%	0.5%
severe neurological	0.5%	3.4%	1%	0.7%

Table 2 Course of Treatment and Outcomes

Discrete variables displayed as percent and continuous variables as median (IQR). Length of "vent support" included Infant Flow, other noninvasive ventilation and invasive ventilation. Treatment failure was defined as no need for 72 hours for intubation or reintubation after weaning from Infant Flow. Survival was defined as discharge from the hospital. The morbidity rates are among survivors. They were defined as follows: CLD (need for oxygen or ventilation at 36 weeks PCA), severe ROP (need for laser treatment) and severe neurological (grade 3 or 4 IVH or PVL).

It is not surprising that SiPAP tended to be used slightly less in infants with RDS than for the other indications. Most likely those with severe RDS and higher ventilatory demands were intubated. Likewise it is predictable that SiPAP would be used more frequently for weaning, where inadequate ventilation is often a common mode of weaning failure. Large studies or performance improvement projects need to be conducted to explore practice guidelines for the addition of noninvasive biphasic support, much as there are evolving guidelines for the criteria for intubation.

Many of the important parameters of care are not addressed in this report. The selection of the initial CPAP pressure and, if applied, the rate and size of biphasic pressures and all their adjustments based on clinical response are for the most part left to the attending physician, and not recorded in the database. However for the purposes of the database, treatment failure was defined.

Finally, care must be used in evaluating the data with regard to indication, because of the structure of the database. One example is that weaning includes only those infants first intubated and not those who were intubated after failing elective Infant Flow. Apnea of prematurity primarily includes those infants without RDS treated in the first days of life and not infants with problems associated with chronic lung disease. Likewise the database does not include infants treated with ventilator based CPAP. However, use of Infant Flow represents, in our estimation, about two-thirds of the non-invasive respiratory support.

To date we have treated over 25,600 infants with the noninvasive Infant Flow system in Poland. We have published results of several research projects<sup>8,9,10</sup> focused on some of the questions identified above and hope to continue our work.

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# Time Required for Effective FiO<sub>2</sub>-Titration in Preterm Infants: a Comparison

Maria Wilinska MD, PhD; Thomas Bachman, MS; Janusz Swietlinski, MD, PhD, DSc

## Introduction

Proper targeting of SpO<sub>2</sub> in preterm infants has become a topic of increasing interest over the last decade. Prior to that time, the pulse oximeter was used primarily to alert nurses to episodes of severe desaturations, or slow deterioration of oxygenation. Subsequently, reports confirmed the physiological rationale that lowering SpO<sub>2</sub> target levels would result in significant reductions in pulmonary and retinal morbidity without apparent increases in developmental and neurological outcomes or mortality.<sup>1-3</sup> As part of a massive research effort to determine the optimum SpO<sub>2</sub> target range, two recently concluded mega RCTs found that dropping the target range too low (85%-89%), while further improving retinal and pulmonary morbidity, resulted in increased mortality.<sup>4</sup> Recommendations for SpO<sub>2</sub> targeting are expected in 2014 after integration of the results of three large studies and evaluation of long term outcomes.<sup>5</sup>

Evaluation of these studies and selection of the best SpO<sub>2</sub> target range is, however, complicated by several factors. Disordered breathing and changes in extrapulmonary shunt result in episodes of significant desaturation, in addition to continual wandering of the SpO<sub>2</sub> outside of the desired target range. Staff training<sup>6,7</sup> and workload<sup>8,9</sup> have both been shown to be barriers to effective SpO<sub>2</sub> management of preterm infants. The oxygen saturation of many preterm infants is quite unstable. As a result, studies have shown that preterm infants receiving respiratory support spend only about half of the time within the intended target range.<sup>3,10</sup>

There is very little in the literature describing or testing the relative effectiveness of specific FiO<sub>2</sub>-titration strategies for infants during respiratory support. FiO<sub>2</sub>-titration strategies should consider not only the timing and magnitude of an increase in FiO<sub>2</sub> needed to address SpO<sub>2</sub> levels below the target range, but also the timing and magnitude of response to SpO<sub>2</sub> levels above the target range, the latter being either a result of either improving oxygenation or a need to wean a previous FiO<sub>2</sub> increase. Some have suggested that many desaturations resolve quickly and unless prolonged are best not addressed. This thinking is intended to avoid the frequent need to wean FiO<sub>2</sub> to mitigate hyperoxemia.<sup>1,11</sup> This delayed approach also has the advantage of reducing the amount of time required by nursing staff to address SpO<sub>2</sub> alarms. Regardless of approach, it is generally accepted that an effective clinical strategy includes nursing observation of the infant with a persistent alarm or following an FiO<sub>2</sub> adjustment.

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Authors Wilinska and Swietlinski are with The Medical Centre of Postgraduate Education, Warsaw, Poland; Bachman is with Economedtrix, Lake Arrowhead, CA. Economedtrix is a clinical research consultancy which provides services to CareFusion, the manufacturer of the automated system.

Automated FiO<sub>2</sub> control systems for neonates have been tested and show promise of improved SpO<sub>2</sub> control.<sup>12,13,14</sup> Moreover, the potential for labor savings associated with automation is of great interest. One system is commercially available outside the US (CLiO<sub>2</sub> option for the Avea ventilator, CareFusion, Yorba Linda, CA).<sup>15</sup> We recently compared CLiO<sub>2</sub> with two different, strictly applied, manual FiO<sub>2</sub>-titration strategies.<sup>16</sup> We found CLiO<sub>2</sub> generally more effective and safer than either of the manual strategies.

The aim of this analysis is to determine the nursing time needed for adjustment and monitoring to implement each of the three FiO<sub>2</sub>-titration approaches.

## Methods

Nursing time associated with FiO<sub>2</sub>-titration includes the time to adjust the FiO<sub>2</sub> and observe the infants response, as well as time to observe persistent alarms, even when adjustment of FiO<sub>2</sub> is not deemed necessary. This need is applicable not only to the manual methods, but also to CLiO<sub>2</sub>. We defined, what was to our thinking, optimal practice guidelines. We made the following baseline assumptions: 1) alarms were set for silence for 20 seconds; 2) when the FiO<sub>2</sub> was changed the nurse would stay with the patient and observe its response for 3 minutes if the SpO<sub>2</sub> was at extremes (<80% >98%), and 2 minutes if just outside the target range; 3) for alarms that persisted for 1 minute or more but did not result in an FiO<sub>2</sub> adjustment, 1 minute of time was allocated for observation; and, 4) for less persistent alarms, 30 seconds was allocated for observation.

Our previous study identified two distinct groups of infants. The first group experienced frequent severe desaturations (average 4 per hour). They spent about half of the time in the intended target range and during manual control more than 10% of the time at extreme saturations (either above 98% or below 80% SpO<sub>2</sub>). The second group with less frequent severe desaturations (average 1 per hour) spent about three-quarters of the time in the intended target range. During manual control they spent less than 5% of the time at extreme saturations. In all cases we found CLiO<sub>2</sub> tended to result in better control. Our database includes FiO<sub>2</sub> and SpO<sub>2</sub> readings for every 5 seconds for 113 hours of monitoring of 8 infants. We analyzed this database to determine the frequency, duration and magnitude of episodes outside the SpO<sub>2</sub> target range and tabulated it for the two categories of infants.

In our previous study a dedicated operator implemented the two manual titration strategies. They were labeled Attentive and Observative. In both, response to episodes of SpO<sub>2</sub><80% or >98% was faster than to small SpO<sub>2</sub> excursions (Attentive within 30 sec and 1 min, Observative within 2 min and 3 min, respectively).

We built an Excel (Microsoft, Redmond, WA) model based on the frequency, magnitude and duration of the episodes for each of

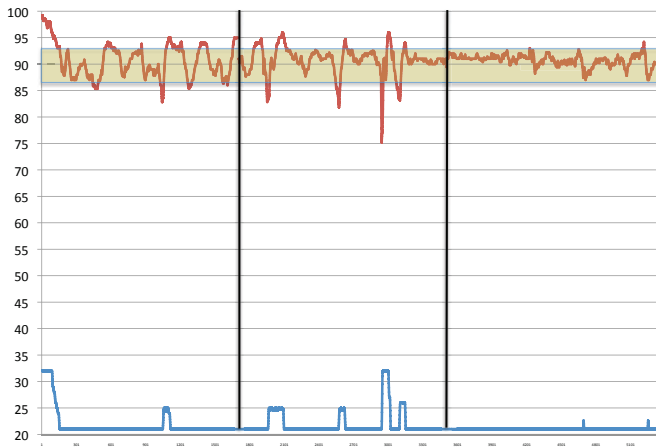


Figure 1a. Typical SpO<sub>2</sub> and FiO<sub>2</sub> in Stable Infant: 7.5 hours  
 This 690-gram female was born at 27 weeks EGA. She was intubated on day one and studied on day 5. The upper line is the SpO<sub>2</sub>% and the lower line the FiO<sub>2</sub>%. The shaded area is the intended SpO<sub>2</sub> Target Range. The order of control strategies was Observative, Attentive and CLiO<sub>2</sub>. Oxygenation stability is apparent as she spent most of the day on room air, with only a few SpO<sub>2</sub> desaturations below the intended target range. These spells were generally followed by high saturations during the periods of manual control (first two panels). During CLiO<sub>2</sub> control there were only two very small short adjustments that appear to have headed off desaturations below the target range, and did not result in an overshoot.

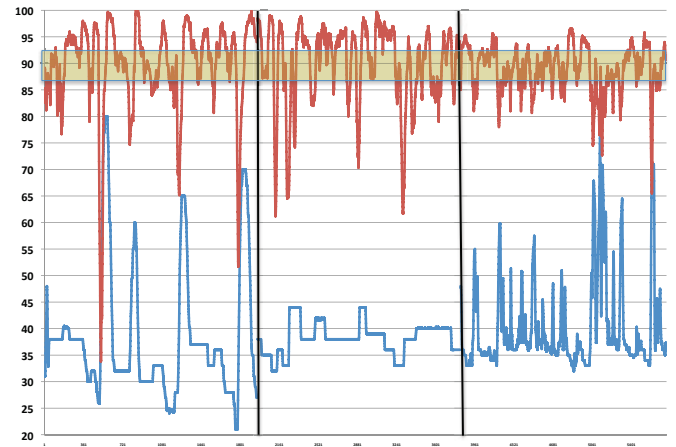


Figure 1b. Typical SpO<sub>2</sub> and FiO<sub>2</sub> in Unstable Infants: 7.5 hours  
 This 740-gram male was born at 27 weeks EGA. He was intubated on day one and studied on day 7. The upper line is the SpO<sub>2</sub>% and the lower line the FiO<sub>2</sub>%. The shaded area is the intended SpO<sub>2</sub> Target Range. The order of control strategies was Attentive, Observative and CLiO<sub>2</sub>. He is still on moderate levels of oxygen and also highly unstable. This infant is typical of those in the unstable category with 2.7 desaturations below 80% SpO<sub>2</sub> per hour, some being much more profound. Increases in FiO<sub>2</sub> in response to these episodes were typically followed with overshoot above the target range. This overshoot is much more marked during the two periods of manual control with their more prolonged increases in FiO<sub>2</sub>. As is typical in the study, more time was spent in the target range during CLiO<sub>2</sub> control.

the categories of infants. It calculated the nursing time required to implement, with the defined oversight, for the three control methods.

## Results

Infants with infrequent severe desaturations spend about three-quarters of the time within the target range, experiencing episodes outside the target range an average of every 4.4 minutes. About half of these did not trigger an audible alarm, and an adjustment was only required once or twice per hour (Observative, Attentive respectively). In contrast the infants with frequent severe desaturations spent about half the time in the target range, with episodes outside the target range every 1.2 minutes. About half of these did not trigger an audible alarm, but an adjustment was only required every 13 (Observative) or 9 minutes (Attentive). Our previous study showed that during CLiO<sub>2</sub> control no FiO<sub>2</sub> adjustments were required and that persistent episodes were less frequent.

The charts of FiO<sub>2</sub> and SpO<sub>2</sub> shown in Figure 1a, b illustrate a typical test run of 7.5 hours for the three control methods for each of the two infant stability categories. The contrast between the stable and unstable oxygenation groups is apparent in these two infants. In the more stable infant group we found the percent time below and above the Target range (87%-93% SpO<sub>2</sub>) were similar, though favoring CLiO<sub>2</sub> slightly. (12%/11% CLiO<sub>2</sub>, 19%/9% Observative, and 15%/11% Attentive). In the less stable group the difference >93% SpO<sub>2</sub> is more marked (15%/22% CLiO<sub>2</sub>, 30%/21% Observative, 21%/23% Attentive).<sup>16</sup>

The amount of estimated nursing time needed per hour to implement the three strategies is shown in Figure 2. For the more stable group of infants it is modest (4.3 minutes per hour for CLiO<sub>2</sub> and 6.8 minutes per hour for Observative and 8.3 minutes per hour for Attentive). For the unstable group the time requirements become excessive for the two manual approaches

(33 minutes per hour for Observative and 45.5 minutes per hour for Attentive), but not for CLiO<sub>2</sub> (9.5 minutes per hour).

Nearly three quarters of the time projected for the two manual strategies in managing the unstable infants was associated with observation following adjustments. That was also the case during the Attentive strategy in stable patients, while it reflected only about one third of the time during the Observational strategy.

## Discussion

Our model of the time requirement to implement an ideal practice of FiO<sub>2</sub>-titration suggests that use of an automated system would require 10 minutes of nursing time per hour in the most unstable group of infants. This, in itself, is an important finding, as automated FiO<sub>2</sub> control is not an autopilot, but rather requires oversight.

In contrast to CLiO<sub>2</sub>, the two manual approaches would require 30 and 45 minutes per hour, respectively, to ideally manage the unstable patient. This amount of time is clearly not practical, even with a 1:1 nursing patient ratio.

Our previous study suggests better control with CLiO<sub>2</sub> than either of these strategies in stable and unstable infants.<sup>16</sup> Claire et al also reported, in a group of 32 relatively unstable infants, better control with CLiO<sub>2</sub> than with routine care over a 24-hour period.<sup>15</sup> In that study, routine care required an adjustment every 13 minutes and CLiO<sub>2</sub> only every 150 minutes. This is consistent with our model for unstable infants (every 9-13 minutes). However, Claire's report did not address the time associated with observing the infant with a persistent alarm or following an FiO<sub>2</sub> adjustment.

This factor of how quickly one responds to an unacceptably persistent SpO<sub>2</sub> can be characterized as attentiveness. Included in attentiveness is the necessary time to observe the infant's



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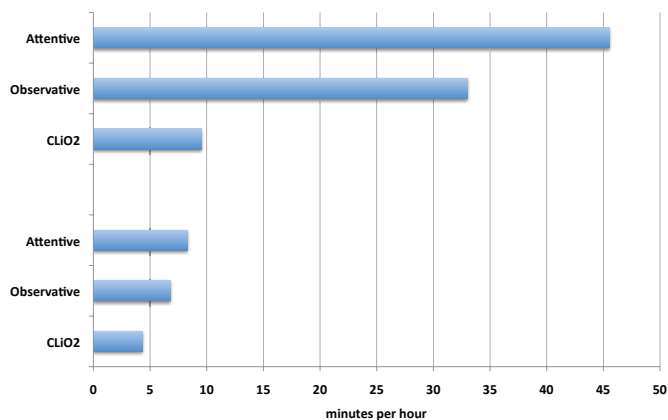


Figure 2. Nursing Time Requirements

The horizontal denotes the projected time in minutes per hour. The vertical axis is categorical split into two groups. The upper group is the unstable infants, and the lower group the stable infants. Within each infant group are the three FiO<sub>2</sub>-titration strategies.

response. In contrast to attentiveness is vigilance. Our model assumes constant vigilance; 60 minutes per hour, 24 hours a day. This is a significant benefit of an effective automated approach. Claire et al reported significantly more prolonged episodes of low saturations during routine care.<sup>15</sup> Our report of the two manual strategies, implemented with a dedicated operator and excellent vigilance, suggested better maintenance of a target range and less time in extreme saturations than generally reported in routine care.<sup>16</sup> These two observations tend to confirm the benefit of attentiveness and vigilance with an automated system. Some have reported more frequent desaturations with lower target ranges.<sup>17</sup> Others have reported an important difference in the time in extreme saturations with relatively small shifts in target range.<sup>18</sup> We speculate that these three issues might also be associated with or exacerbated by a lack of vigilance.

Our analysis, while provocative, clearly has limitations. Other manual FiO<sub>2</sub>-titrations strategies would have different results. Certainly a more permissive approach to observing the persistent alarm conditions or timing of FiO<sub>2</sub> adjustments would require less time. Nevertheless, we previously reported that more attentive response led to better SpO<sub>2</sub> control, albeit with an impractical time requirement.<sup>16</sup> Thus it is reasonable to expect a significantly more permissive approach, while reducing time requirements, would likely result in poorer SpO<sub>2</sub> control. It is not clear, however, what level of actual SpO<sub>2</sub> control is necessary for optimal outcomes.

We conclude that, in infants with frequent severe desaturations, the time demands of optimal saturation management, without automatic control, are impractical in the NICU. In contrast, in those more stable infants the time savings of automatic control are not significant, and its only advantage would be improved SpO<sub>2</sub> control as a result of vigilance. Finally we suggest the need for further evaluation of the limitations of effectiveness of manual SpO<sub>2</sub> control approaches. This should address both attentiveness and vigilance. Attentiveness relates to staffing and practical guidelines suited for manual FiO<sub>2</sub> adjustments and SpO<sub>2</sub> targeting. It is also important to understand what degree a lack of vigilance plays in shortfalls in achieving desired SpO<sub>2</sub> control in the routine environment.

AARC Preview continued from page 41

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