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[1]Hasani A et al. *Chron Respir Dis*. 2008;5(2):81-86. [2] Roca O et al. *Respir Care*. 2010;55(4):408-413.

* The softFlow is FDA cleared for flow rates up to 50 L/min and in hospital and long-term care facilities. The 60 L/min version and the home use version are being made available in the US under the FDA Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the COVID-19 Public Health Emergency.

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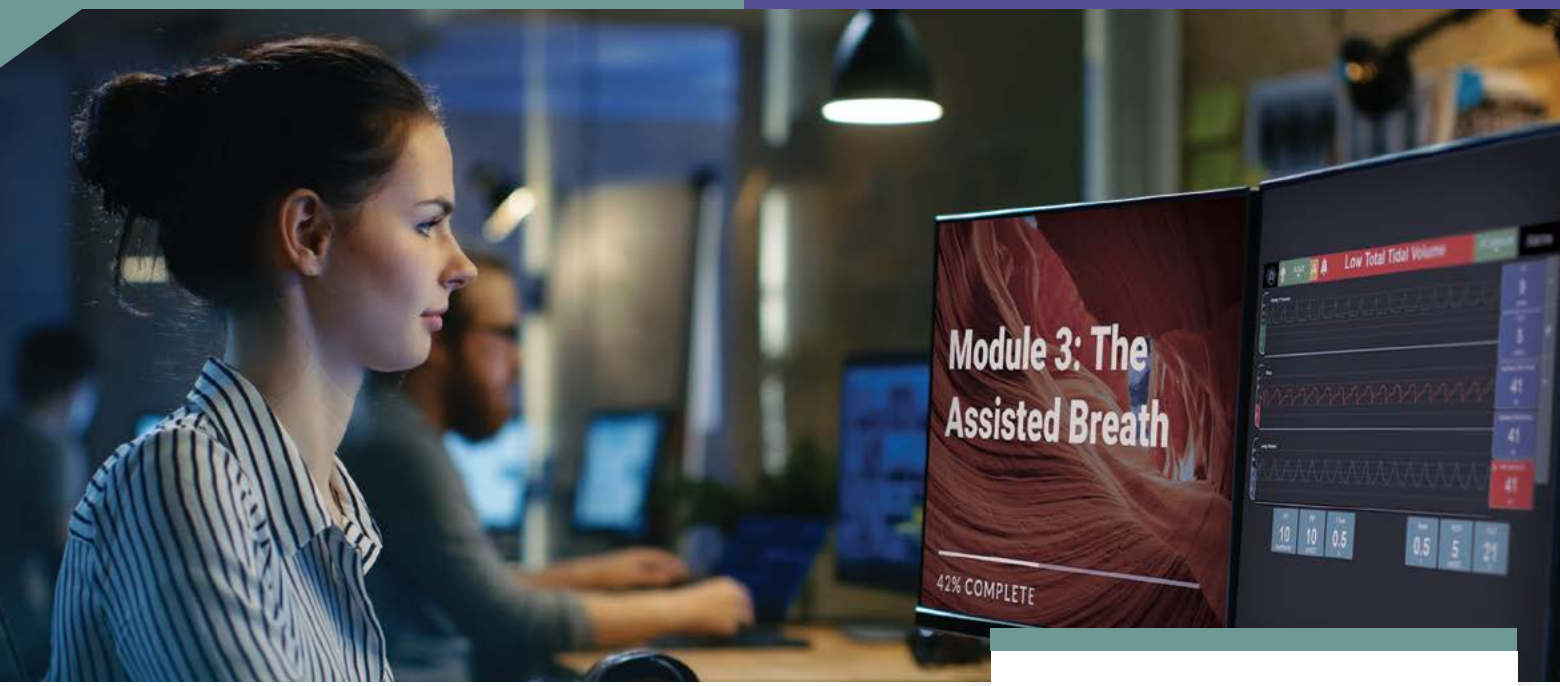

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News

■ Fall 2022

Nonin Medical Names New Chief Executive Officer

Nonin Medical announced that its board of directors has appointed healthcare industry veteran John M Hastings as its new Chief Executive Officer, effective August 29, 2022. Hastings brings global leadership and technical expertise in quality, research and development, manufacturing, regulatory affairs, engineering, supply chain and distribution, along with a demonstrated ability and passion to develop and advance effective business strategies. As leader of the organization, Hastings, along with the company's recently named board of directors, offers a diverse and unique set of experiences, combined with a passion for growth and innovation in the medical device and healthcare sectors. Together, they will provide Nonin Medical with strategic guidance and support to drive the company's growth. "The entire Board is looking forward to working with John as Nonin Medical's new CEO," said Phil Isaacson, Nonin Medical's Executive Chairman, Chief Technology Officer, and Founder. "John is directly aligned with our values of courage, agility, and ownership, and brings a strong belief in ongoing education and professional development. He also shares deep respect for our history, products, and commitment to improving people's lives—and sees tremendous potential for our technology and Nonin Medical's future opportunities." Healthcare technology is playing an increasingly important role in patient management, care and outcomes. Hastings will help Nonin Medical address the needs of a rapidly changing market and its patients, providers, payors and partners, using innovative technology and noninvasive medical solutions. "I sincerely appreciate the board's confidence in me, and I'm thrilled to have the opportunity to lead this exceptional organization," said Hastings. "With Phil's continued pursuit of innovation and our employees' commitment to our customers, I am highly confident in our future. Together, I look forward to further strengthening our position as a market leader while driving sustainable and profitable growth." Prior to Nonin Medical, Hastings served as Executive Vice President, Operations & Technology with Cardiovascular Systems, Inc., or CSI, a medical device company focused on developing and commercializing innovative solutions for treating vascular and coronary disease. Before joining CSI, he held leadership roles of increasing responsibility at Abbott Laboratories, St Jude Medical and American Medical Systems. Hastings is a Minnesota native and holds an MBA from the University of Saint Thomas and a degree in Mechanical Engineering from Minnesota State University, Mankato.

Breas Medical Releases Extended-life Battery for Vivo Ventilators

Breas Medical USA announced the release and immediate availability of the Xpac by Breas extended life battery. The Xpac enhances ventilator dependent patient mobility with boost of battery life of the Breas Vivo 50 and Vivo 65 by 12 hours and the Vivo 45 LS by 18 hours. With Xpac, the ultra-compact and lightweight Vivo 45 LS can now run 25.5 hours off the grid. "Breas is thrilled to provide the Xpac to the ventilator dependent community as a means to enhance quality of life by elimination of the worry of ventilator operation when away from power outlets for extended periods of time, improving the quality of life and ambulatory requirements for the patients we serve." said Chris Southerland, General Manager, Breas Americas. The Xpac consists of two high powered lithium-ion batteries which can be easily removed and replaced by the user. It's intuitive LED display shows the health of each battery, so you know when it is time to renew them. In addition, Xpac's batteries only take 4 hours to charge to full capacity. Engineered in its founding Swedish and USA offices, Breas delivers leading-edge innovations that can provide patient comfort and mobility needed to improve their quality of life.

Device Adds Respiratory Flexibility

Vitalograph announced Pneumotrac with RMS (Respiratory Muscle Strength) creating multiple respiratory diagnostic flexibility in one powerful device option. The Pneumotrac with RMS is a PC-based system that combines respiratory muscle strength measurements and

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spirometry—offering multiple testing possibilities on a single device that is as portable as your laptop. It can be used in various environments such as an in-clinic desktop, or it can be placed on a cart with a laptop for mobile use. The Pneumotrac with RMS creates a powerful, flexible, and reliable respiratory diagnostic functionality, particularly for COPD or neuromuscular diseases, at a relatively low cost. Alongside detailed spirometry testing, it provides a non-invasive and simple approach to mouth pressure and nasal pressure measurements in both adults and pediatrics. Assess diaphragmatic weakness in patients with neuromuscular disease (NMD). Assess respiratory muscle strength in patients undergoing pulmonary rehabilitation e.g., COPD patients. Monitor the response of respiratory muscle training. Meets 2019 ATS/ERS standardization of spirometry guidelines. Highly accurate, robust, and stable Fleisch flow measuring technology with no moving parts. Low running costs & environmentally friendly: no need for costly disposable sensors, turbines or flow tubes. Save time and money using Vitalograph Bacterial Viral Filters (BVF) with validated cross-contamination efficiency, protecting the device, patient, and operator. Instant quality feedback using the latest test/session acceptability, usability and repeatability criteria. EMR compatible.

New Unit Helps Technology-Assisted Patients Transition Home

Technology-assisted respiratory patients at Lucile Packard Children's Hospital Stanford now have a dedicated program that helps them focus on returning home and continuing their growth and development. The Stanford Technology-Assisted Respiratory (STAR) Program, which opened in August 2022, includes a dedicated team led by pediatric pulmonary providers that focuses on rehabilitation and education to empower the patient and family to take the next step: hospital discharge. The only pediatric program of its kind in Northern California, the STAR Program aims to improve outcomes and patient experience. Before this new program was created, the hospital's patients with tracheostomies requiring chronic mechanical ventilation were cared for only in intensive care units (NICU, PICU, and CVICU). However, there is a subset of these patients who are on portable ventilators and who are better served in a chronic care setting. This group of patients includes children who are preparing to be discharged home or to a long-term-care facility, children admitted for a nonrespiratory acute illness, or children admitted for an overnight stay after a procedure, such as an MRI that requires sedation. "There's an older practice in pediatric pulmonary medicine that is focused solely on liberating the patient from the tracheostomy and ventilator," said Michael Tracy, MD, a pediatric pulmonologist at Stanford Medicine Children's Health and medical director of the STAR Program, "but now that the technology has improved and ventilators are portable and easier to use, we like to think of the tracheostomy and ventilator as liberating the patient from the hospital so they can get home and focus on growing and developing." Research suggests that a dedicated multidisciplinary program for tracheostomy-and-ventilator-dependent children may achieve the following: Reduce the length of a child's hospital stay by focusing on preparing for the transition to home or a long-term care facility. Improve patient satisfaction as the patient gets to know the dedicated care team and feels more comfortable in a less acute care environment. Enhance neurodevelopmental outcomes as the care team prioritizes developmental activities. Decrease hospital readmissions, because a focus on education

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1. Alcoforado L, Ari A, Barcelar J, Brandão S, Fink J, de Andrade A. Impact of Gas Flow and Humidity on Trans-Nasal Aerosol Deposition via Nasal Cannula in Adults: A Randomized Cross-Over Study. Pharmaceutics 2019; 11: 320.

PM1170

means that families feel empowered to address emergencies safely at home.Improve survival by standardizing care, providing continuity, and optimizing communication. Patients in the STAR Program will benefit from access to a multidisciplinary team of specialists, including pulmonologists, respiratory care practitioners, occupational and physical therapists, speech-language pathologists, otolaryngologists, gastroenterologists, aerodigestive specialists, cardiologists, surgeons, dietitians, child life specialists, social workers, and case managers. "No one should have to stay in the ICU for longer than absolutely necessary," said Dr Tracy. "Our goal is to give patients and families a path to safely manage their care at home."

New Adapters for Use with Duckbill-style Tracheostomy Tubes

Passy-Muir, Inc. announced the release of two new products specifically designed for use with the new duckbill-style inner cannula tracheostomy tubes. The 15mm DigiSil Digital (Finger) Occlusion Adapter is a non-sterile, lightweight, single patient use, stretch-to-fit adapter for placement on the 15mm hub of a tracheostomy tube with a duckbill designed inner cannula to allow finger occlusion. The DigiSil adapter facilitates easy finger occlusion and comes with a PMV Secure-It, which secures the adapter to a patient's tracheostomy tie to prevent loss. The PM-DB15 Adapter is a non-sterile, lightweight, single patient use, low-profile adapter for placement on the 15mm hub of a tracheostomy tube with a duckbill designed inner cannula to allow finger occlusion or placement of a Passy Muir Valve, models PMV2000 or PMV2001. Both products are designed for use in clinical settings, including hospitals, sub-acute, rehabilitation, outpatient, skilled nursing, and long-term care, as well as in the home setting. Each adapter comes with detailed instructions for use, and each is manufactured in the United States. For more information, or to order, visit www.passymuir.com, or call 1-800-634-5397.

High Fidelity, Virtual Mechanical Ventilation Training

For over 25 years, IngMar Medical has provided the respiratory community with highly realistic tools for teaching mechanical ventilation. Historically, these tools required the use of your own real mechanical ventilator in conjunction with our ASL 5000 Breathing Simulator. We are now proud to introduce our new virtual learning environment, RespiSim eLearning. We believe this virtual learning space will help to strengthen learners' understanding of key mechanical ventilation concepts while paving the way for more effective simulation outcomes, and ultimately better patient care. Subscribers will have the opportunity to run interactive, software-based simulations utilizing the world-renowned ASL 5000 lung modeling technology in conjunction with our new Virtual Ventilator software. Our Virtual Ventilator software allows instructors to demonstrate critical patient-ventilator interaction concepts for remote or in-person learners. Additionally, learners can be given direct access to the Virtual Ventilator software to practice on their own time. Subscribers will also have access to a Learning Management System (LMS) which includes self-guided, e-learning content such as the acclaimed Standardized Education for Ventilatory Assistance (SEVA) curriculum, developed by the Cleveland Clinic. The e-learning courses can be used as an adjunct to current curriculums, and they can act as a self-study tool for

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your learners. We're also pleased to announce that successful completion of the SEVA e-learning courses will grant the learner 8 hours of Continuing Respiratory Care Education (CRCE) credit by the American Association for Respiratory Care. Additionally, the LMS platform includes a discussion forum where respiratory educators can share best practices and insights on key topics in mechanical ventilation and respiratory simulation. IngMar Medical believes that building a community of respiratory educators all over the world will lead to more standardization and ultimately better training outcomes. RespiSim eLearning represents a major step in the direction of building this community, and it demonstrates our commitment to providing affordable, high quality training solutions for ALL respiratory educators. For more information or to speak with a Product Specialist, contact sales@ingmarmed.com.

Breathe Easier with Spontaneous Breathing Lung Simulator from Michigan Instruments

Michigan Instruments, a leading manufacturer in Lung Simulators, announced the release of their new Spontaneous Breathing Lung Simulator (SBL). The SBL is capable of providing precision-based simulation of a breathing patient to aid in the research, training, and development of non-invasive and supportive modes of ventilation and oxygenation. The Spontaneous Breathing Lung Simulator offers an updated way to create spontaneous breathing. This is available as an independent device or an add-on to the current version of Michigan Instruments' TLL Training Test Lungs and PneuView systems. The addition of the SBL module, transforms the device into a spontaneous breathing system. "The Spontaneous Breathing Lung has been one of our most requested device capabilities for our Lung Simulators," said Chris Blanker, owner and president of Michigan Instruments. "We've had an alternative option using our Breath Simulation Module, but the Spontaneous Breathing Lung provides an easier way for researchers, educators and developers to access these capabilities on our devices." While the Spontaneous Breathing Lung is useful in any research requiring breathing, in training settings the Spontaneous Breathing Lung can help educators create a variety of scenarios and breathing patterns that can be used during student education in classrooms and simulation labs. While in testing settings, the simulator can help facilitate troubleshooting and testing of devices meant to operate on spontaneous breathing patients and test various device capabilities. The Spontaneous Breathing Lung is capable of providing users with a variety of real-time data, including: Breath rates of 2 to 30 breaths per minute; Inspiratory Time of .5 to 5.0 seconds in .1 second increments; Breath Volume of 100-1,800 ml; Flow Waveform: Square or Sinusoid.

Randomized Controlled Study Finds Masimo SedLine Brain Function Monitoring Can Help Guide Anesthesia

Masimo announced the findings of a randomized, controlled trial published in the *Journal of Clinical Anesthesia* in which Dr Melody H.Y. Long and colleagues from the KK Women's and Children's Hospital in Singapore evaluated the ability of electroencephalogram (EEG)-guided anesthesia, using Masimo SedLine brain function monitoring, to reduce the amount of the drug sevoflurane needed to maintain anesthesia in pediatric patients undergoing minor surgery. They found that use of SedLine to guide anesthesia reduced sevoflurane requirements and led to a reduced incidence of burst suppression, which has previously been reported to be associated with postoperative delirium. Noting the unique nature of pediatric brains, which are still developing, the importance that standard anesthesia practice places on minimizing the dosage of drugs needed to maintain anesthesia, and the lack of research into the use of new technology like real-time EEG spectrogram monitoring in children, the researchers devised a study that would investigate what impact such technology might have. They enrolled 195 children, aged 1 to 6 years, who were scheduled for minor surgery involving general anesthesia induced and maintained using sevoflurane. The children were randomized into either a Masimo SedLine EEG-guided group (n=100) or a standard care group (n=95). In the SedLine EEG group, anesthesiologists used SedLine to help guide administration of sevoflurane, with the goals of maintaining continuous slow/delta oscillations on the raw EEG and spectrogram, avoiding burst suppression, and maintaining a Patient State Index, or PSi—a propriety, processed EEG parameter developed by Masimo—between 25 and 50. In the standard care group, clinicians were blinded to the EEG data. As their primary outcome, the researchers looked at the average end-tidal concentration of sevoflurane used during induction and maintenance of anesthesia. They found that in the EEG group, the concentration was lower both during induction (4.80% compared to 5.67% in the control group, p=0.003) and maintenance (2.23% vs. 2.38%, p=0.005). As one of their secondary outcomes, the researchers compared the incidence and duration of intraoperative burst suppression, and found that the EEG group had a lower incidence of burst suppression (3.1% vs. 10.9% in the control group, p=0.0440). The authors concluded, "This is one of the first randomized control trials in the pediatric population showing that EEG-guided anesthesia care utilizing the spectrogram is feasible, and leads to a modest decrease in

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1. Martinez-Garcia, M. A., and M. Miravitlles. (2017). Bronchiectasis in COPD patients: more than a comorbidity?, Int J Chron Obstruct Pulmon Dis, 12: 1401-11
2. Seifer, et al. Health-care utilization and expenditures among patients with comorbid bronchiectasis and chronic obstructive pulmonary disease in US clinical practice. 2019. Chronic Respiratory Disease, Volume 16: 1–8.
3. Basavaraj A, Shah D, DeKoven M, et al. A Pre-Post Analysis Assessing the 3-Year Long-Term Impact of High Frequency Chest Wall Oscillation Therapy on Clinical Outcomes, Healthcare Cost and Utilization in Adult Patients with Non-Cystic Fibrosis Bronchiectasis in the U.S. Am J Respir Crit Care Med 2021;203:A3944 and poster presented at ATS 2021 (Hillrom reference APR219401).

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intraoperative sevoflurane dosage for induction and maintenance in young children aged 1 to 6 years. EEG guidance allows easy visualization of anesthesia-induced changes on the brain in real time, making it possible to determine which individuals require more (or less) anesthetic to maintain unconsciousness and titrate doses accordingly. This may be particularly important in children between 1 and 2 years old, who appear to require a higher concentration of sevoflurane during surgery, as well as in patients at risk of neurological injury. Our findings highlight the importance of EEG monitoring in complementing the current ASA standard monitors, to provide personalized anesthesia care." William C. Wilson, MD, MA, CMO and SVP of Clinical Research and Medical Affairs at Masimo, commented, "We believe the significant reduction in burst suppression noted in the EEG group—less than one-third the amount in the control group—is an important finding. In future studies with larger sample pools, this could demonstrate more profound outcome benefits." In the US, SedLine is currently indicated for pediatric use without the PSi parameter.

Probiotics Improve Physical Function in COPD

Probiotics improve strength and functional capacity in patients with COPD, based on a randomized, placebo-controlled trial. The improvements stem from decreased gut permeability, which reduces circulating inflammatory cytokines, leading to stabilization of neuromuscular junctions, reported lead author Asima Karim, MBBS, PhD, of the University of Sharjah, United Arab Emirates, and colleagues. "The manipulation of gut bacteria with probiotics may be an attractive therapeutic strategy to strengthen the intestinal barrier," the investigators write in *Archives of Gerontology and Geriatrics*. "Probiotic supplements reduce the pathological translocation of bacterial metabolites and ameliorate the systemic inflammatory state in multiple diseases." In COPD, both intestinal permeability and systemic inflammation have been linked with sarcopenia, suggesting a common, yet unexplored thread, according to Karim and colleagues. "To our knowledge, no previous study has investigated the effects of probiotics on sarcopenia in COPD patients," they write. "However, probiotics are shown to reduce lung inflammation and improve airway remodeling in experimental animal models of COPD." Their trial enrolled 104 men with COPD between 63-73 years of age. Patients were randomly assigned in 1:1 ratio to receive either placebo or a probiotic containing 112 billion live bacteria, including one strain of *Streptococcus*, three strains of *Bifidobacterium*, and four strains of *Lactobacillus*. At baseline and 16 weeks, the investigators measured handgrip strength, short physical performance battery (SPPB), gait speed, and appendicular skeletal mass index. In conjunction, six plasma biomarkers characterized intestinal permeability (zonulin, claudin-3), neuromuscular junction degradation (CAF22), systemic inflammation (CRP, creatine kinase), and oxidative stress (8-isoprostanes). Clinically, probiotic treatment was associated with significant improvements in handgrip strength, gait speed, and functional capacity (SPPB). Concurrently, patients in the probiotic group had significant improvements in gut permeability (zonulin, claudin-3), neuromuscular junction degradation (CAF22), systemic inflammation (CRP), and oxidative stress (8-isoprostanes). In contrast, patients in the placebo group showed no significant changes in clinical picture or biomarkers, apart from zonulin, which increased over time, suggesting worsened gut permeability. Creatine kinase, a measure of systemic inflammation, showed no change in either group.

Ventilator System Receives US FDA Clearance

Nihon Kohden OrangeMed, Inc. received US Food and Drug Administration (FDA) 510(k) clearance for its NKV-330 Ventilator System. The NKV-330 is a non-invasive ventilator that provides respiratory support to adult and pediatric patients. It offers not only non-invasive ventilation but also invasive ventilation as well as high flow oxygen therapy. In addition, it provides continuous monitoring of CO_2 when using our cap-ONE NIV mask. The cap-ONE mask is an NIV interface that allows quality CO_2 monitoring directly from the ventilator. "The NKV-330 ventilator can help hospitals who face a limited choice of new non-invasive ventilator platforms." said Dr Hong-Lin Du, CEO of Nihon Kohden OrangeMed. "The continuous monitoring of CO_2, the excellent portability, and many other features in the NKV-330 makes it a great choice for the hospitals and caregivers." The NKV-330 Ventilator System is distributed in the United States by Nihon Kohden America, Inc. and is expected to begin shipping in July 2022. It has been available outside of the United States since 2019.

Higher Hospital Readmission Rates Linked to Adverse Effects in Pneumonia

Adding to the debate over the value of hospital readmission rates, a new study links the data to higher rates of adverse events in patients treated for pneumonia. For each interquartile range increase in the readmission rate in a sample of 46,047 patients, the odds of adverse events grew by 13% (adjusted odds ratio, 1.13; 95% CI, 1.08-1.17), according to research. "The link between patient safety and overall hospital quality has not been explored in detail. This study supplements that knowledge and more specifically links readmission rate, which has been

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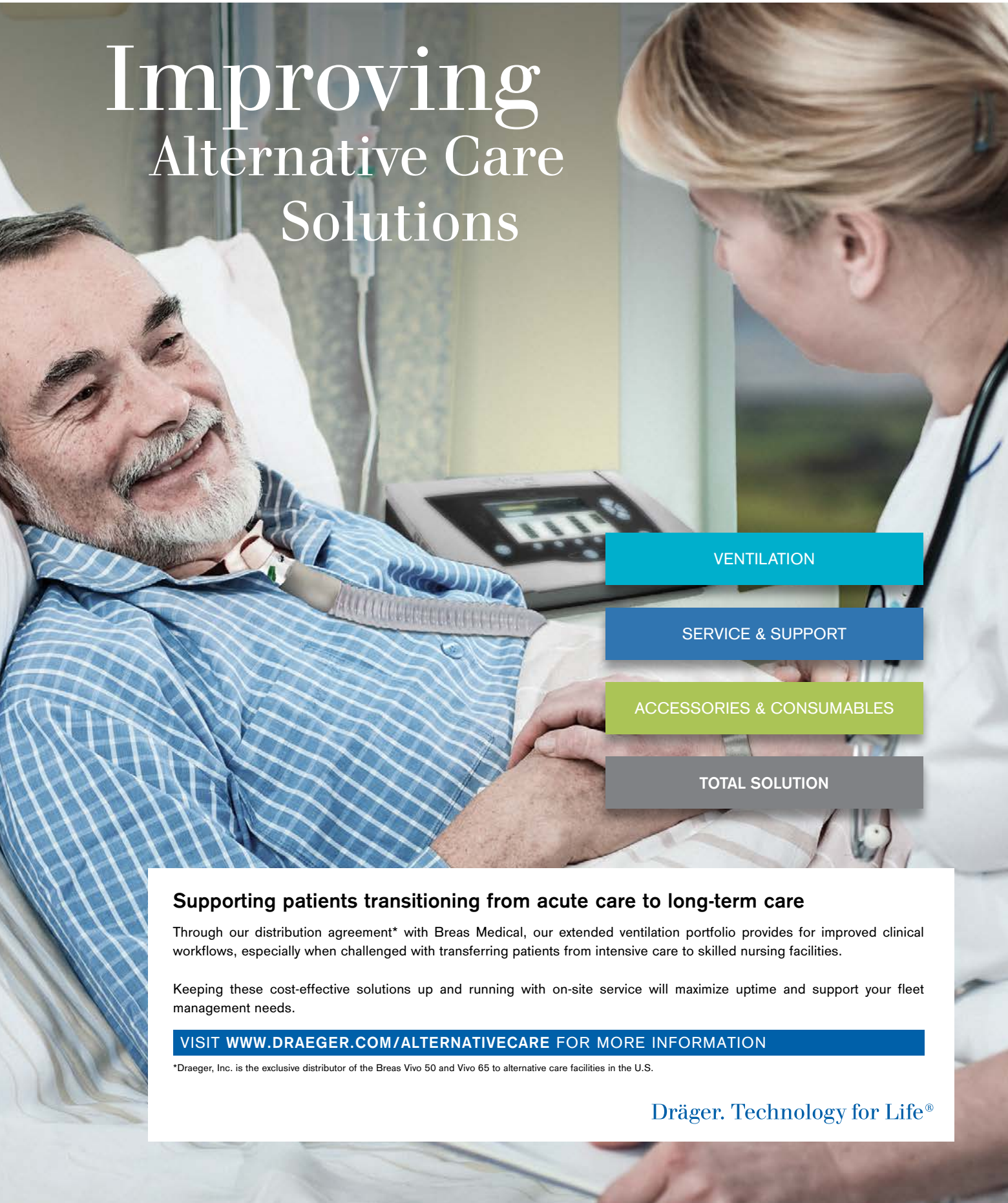

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criticized as a measure of quality, with patient safety," said pulmonologist Mark Metersky, MD, of UConn Health. According to Metersky, it's clear that readmissions are extensive and expensive. "We also know that many are not preventable and that efforts to lower readmission rates have not been highly successful overall, although there have been some positive studies," he said. "We also know that CMS [Centers for Medicare & Medicaid Services] does use readmission rates to adjust payments to hospitals, and many are penalized financially. We do not know how effective financial penalties are in driving quality improvement. In fact, the evidence is not strong." For the new study, he said, the researchers sought to understand more about readmission rates and pneumonia. "Both readmissions and patient safety are associated with the quality of hospital care, but it is unknown whether patients admitted to hospitals with higher risk-standardized readmission rates had a higher risk of in-hospital adverse events." The researchers tracked patients with pneumonia across 2590 hospitals from 2010-2019 (mean age, 71; 52% women; 82% White persons; 12% Black persons; 46% with chronic obstructive pulmonary disease; 7% with in-hospital mortality). "The median hospital-specific risk-standardized readmission rate was 17.0% (95% CI, 16.3%-17.7%), the occurrence rate of adverse events was 2.6% (95% CI, 2.54%-2.65%), and the number of adverse events per 1000 discharges was 157.3 (95% CI, 152.3-162.5)," the researchers reported. In addition to the findings about adverse events in patients, the researchers linked each interquartile range increase to 5.0 more adverse events per 1000 discharges at the hospital level (95% CI, 2.8-7.2). "Patients with pneumonia admitted to a hospital with a high readmission rate were more likely to suffer an adverse event while hospitalized, and hospitals with high readmission rates had higher rates of adverse events among their patients," Metersky said.

IL-6 Antibody Mitigates Mucus Hypersecretion in COPD

Treatment with an interleukin-6 neutralizing antibody significantly reduced airway mucus hypersecretion (AMH) in chronic obstructive pulmonary disease (COPD), based on data from human and mouse cells in a human organoid model. AMH plays a large part in aggravating airway obstruction in patients with COPD, Yuan-Yuan Wei, MD, of First Affiliated Hospital of Anhui Medical University, Hefei, China, and colleagues wrote. Current pharmacotherapies relieve COPD symptoms and improve exercise tolerance, but have not proven effective for relieving the airflow limitations caused by mucus accumulation that "leads to irreversible structural damage and an unfavorable prognosis," the researchers said. Although reducing AMH could help manage COPD, the molecular mechanisms of action have not been fully explored. In a study published in Biomedicine & Pharmacotherapy , the researchers examined the relationship between IL-6 and AMH. Since IL-6 has been shown to cause overexpression of the mucin-type protein known as Muc5ac, they hypothesized that IL-6 antibodies (IL-6Ab) might block this protein elevation. The researchers recruited 30 adults with COPD and 30 controls from a single center. Bronchial epithelial cells were isolated from the participants and measured the levels of Muc5ac protein and mRNA in the lung tissue. Compared with controls, COPD patients had elevated Muc5ac positively correlated with IL-6. The researchers then created an organoid model of a trachea for COPD patients and controls. In the model, Muc5ac was similarly elevated in COPD patients, compared with controls. "Furthermore, IL-6 significantly induced excessive secretion of mucus in the organoid model of trachea in COPD patients as observed under electron microscope, and IL-6Ab attenuated these effects," they noted. IL-6 significantly increased both Muc5ac mRNA and protein expression in the organoid model of trachea ($P < .0001$ and $P < .005$, respectively), but both of these significantly decreased when treated with IL-6Ab ($P < .0001$ and $P < .05$, respectively). The researchers also examined human and mouse cells to explore the mechanism of action of IL-6Ab. Using high-throughput sequencing, they found that the IL-6Ab induced nuclear translocation of the Nrt2 gene in COPD patients, and that this action promoted the effect of IL-6Ab on excessive mucus secretion. The study findings were limited by the relatively small study population from a single center, the researchers noted.

Race-Based Spirometry May Lead to Missed Diagnoses

It may be time to move beyond relying largely on spirometry to distinguish between healthy and abnormal lung function in diverse populations. That conclusion comes from investigators who looked at patients with ostensibly normal spirometry values in a large population-based study and found that using standard equations to adjust for racial differences in lung-function measures appeared to miss emphysema in a significant proportion of Black patients. "Our traditional measures of lung health based on spirometry may be underrecognizing impaired respiratory health in Black adults, and particularly Black men," said lead author Gabrielle Liu, MD, a fellow in the division of pulmonary and critical care medicine at the Northwestern University Feinberg School of Medicine in Chicago. "CT imaging may be useful in the evaluation of those with suspected impaired respiratory health and normal spirometry," she said in an oral abstract session at the American Thoracic Society International Conference 2022. Liu and colleagues studied the association between self-identified race and visually identified emphysema among 2674 participants in the Coronary Artery Risk Development in Young Adults (CARDIA) study. The patients had CT scans at a mean age of 50, and spirometry at a mean age of 55. Investigators found that among men with forced expiratory volume in 1 second (FEV_1) ranging from 100% to 120% of predicted according to race-adjusted formulas, 14.6% of Black men had emphysema, compared with only 1.7% of White men ($P < .001$). Respective emphysema rates in Black women and White women were 3.8% and 1.9%; this difference was not statistically significant. Among patients with FEV_1 80% to 99% of predicted according to race-specific measures, 15.5% of Black men had emphysema, compared with 4% of White men ($P < .001$). Respective rates of emphysema were 6.9% for Black women vs. 3.2% for White women ($P = .025$). When the investigators applied race-neutral spirometry reference equations to the same population, they found that it attenuated but did not completely eliminate the racial disparity in emphysema prevalence among patients with FEV_1 ranging from 80% to 120% of predicted.

Companies Establish a Canadian Distribution Agreement

Breas Medical USA and McArthur Medical Sales announced a Canadian distribution partnership for the Breas Medical's Vivo 1-2-3 family of Bi-level devices and a full line of Breas Vivo accessories. The Vivo 1-2-3 product family are bi-level ventilators designed for comfortable respiratory support across the continuum of care, both non-invasive and invasive (Vivo 3 only), for non-dependent patients with chronic breathing insufficiency. Featuring a built-in humidifier with heated wire circuit, a comprehensive set of modes with Auto-EPAP and High Flow Nasal Cannula therapy support plus SpO2 monitoring. "Breas is thrilled to partner with McArthur Medical Sales to

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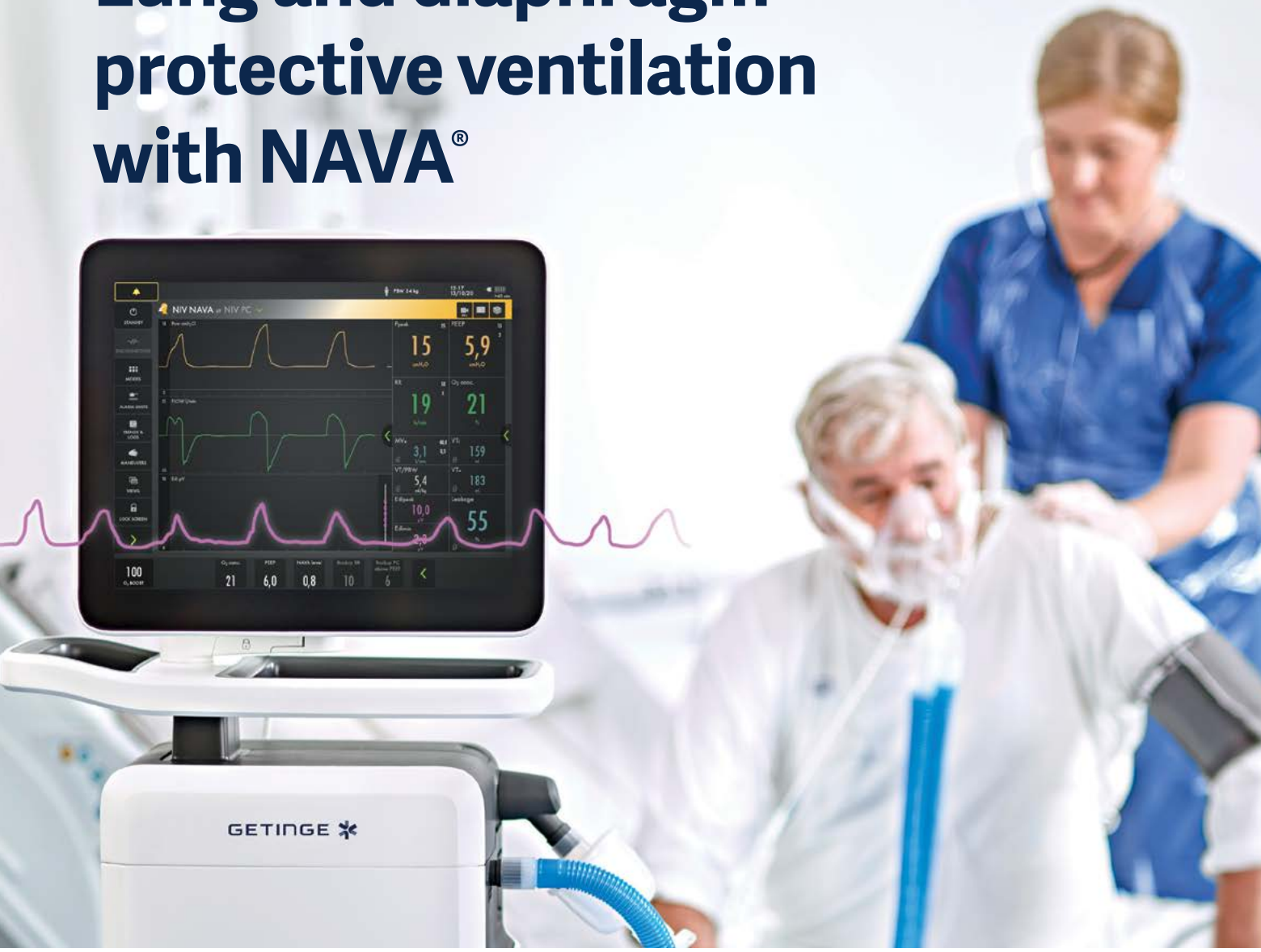
Lung and diaphragm protective ventilation with NAVA®



For some patients, conventional ventilation simply isn't enough. With personalized ventilation, the ventilator shows you what the patient wants, which may help you wean earlier with increased comfort and decreased sedation. NAVA, Getinge's patented Neurally Adjusted Ventilatory Assist technology, uses diaphragmatic activity to deliver assist adapted to the patient and shortens time of mechanical ventilation by almost 35%.[1]

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Learn more about Getinge's exclusive NAVA technology and all we have to offer at **www.getinge.com**

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GETINGE

A New Calibration Syringe Accessory

Brian L Graham, PhD

Calibration syringes are precision instruments. Proper use and care of calibration syringes is required for conducting top-quality spirometry. This article describes a new accessory that will enhance the use of calibration syringes.

Figure 1. The syringe handle is secured to the body of the calibration syringe.

A syringe handle (Figure 1) has been developed which provides three important aides to the use of a calibration syringe: 1) improved ability to conduct full excursions of the syringe in one smooth motion; 2) elimination of heat transfer through hand contact with the syringe body; and 3) protection of the syringe to avoid dropping while carrying or falls from the syringe rolling onto the floor.

The 2019 ATS/ERS spirometry standards[1] specify that 3-litre calibration syringes must be accurate to within 0.5%. Haynes et al[2] found that the temperature increase from "hugging" the syringe could result in a spirometer calibration error of up to 0.7%. Although smaller errors occur with normal hand contact, it may still be possible for the additional error caused by heating plus the existing volume error for the syringe to exceed the 0.5% overall tolerance. For top-quality spirometry, the goal should be to keep all errors to a minimum. Using a syringe handle is a practical solution to avoiding any additional error due to heat transfer.

The ATS/ERS spirometry standards also specify that a calibration syringe which is dropped or rolls off the counter and falls to floor should be considered to be out of calibration until its accuracy has been verified. The syringe handle provides a secure grip for carrying the syringe and the flat base of the handle prevents the syringe from rolling off a table or countertop.

Brian L Graham is with the Division of Respirology, Critical Care and Sleep Medicine University of Saskatchewan, Saskatoon, SK, Canada. Brian Graham is the inventor of the device described in the article and has a patent agreement for its production with Hans Rudolph Inc. In the past two years, Brian Graham has received speaker honoraria from MGC Diagnostics, Vyaire Medical and LungSask, and consulting fees from Chiesi Farmaceutici. Correspondence: Brian L Graham brian.graham@usask.ca

Figure 2. The syringe handle provides a firm anchor for holding the syringe when performing calibration maneuvers.

When performing calibrations, it is important to have a firm grip on the syringe. When emptying the syringe, this is often achieved by pushing the plunger handle with one hand while anchoring the distal end of the syringe with the other hand. For some technologists, this can be a long reach, which makes it difficult to achieve the desired flow in one smooth, steady push.

Having the grip mounted closer to the proximal end decreases the extent of the reach and provides a firm anchor point with no hand contact (Figure 2). Some spirometry systems are sensitive to jerks and stops in the motion of the calibration syringe which can result in the need for the calibration verification to be repeated. The syringe handle facilitates smooth, steady full excursions for filling and emptying the syringe.

In pulmonary function labs where diffusing capacity is measured, the ability to securely hold the calibration syringe at the mouthpiece will also aid in conducting the required gas analyser linearity checks.

Calibration syringes are a vital component of pulmonary function testing and must be handled with care. The syringe handle both protects the syringe and facilitates improved usage.

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Critical Care

Ventilation, Oxygenation, Perfusion, and Gas Exchange: The Importance of Accurate CO_2 Monitoring

In this feature, Respiratory Therapy adapts educational webinars delivered by clinicians and healthcare providers about the actual application of specific products and therapies. The webinar adapted below was presented by Margie White, BS, RRT-NPS, Clinical Application Specialist at Sentec.

Margie White: Why do we need to measure CO_2? Well, typically, we focus on oxygenation, and we understand how important it is. It's an easy value to get, by putting a pulse oximeter on. It's reliable, it's trusted, and well-tolerated by the patient. However, we need to remember that oxygenation and ventilation are separate functions. And to understand how each is working, we really need to measure them separately.

We can see instances in the literature where oxygenation does not reflect ventilation. One study showed that in 30% of patients with neuromuscular disorders, or restrictive lung disease, hypercapnia will be missed if sleep studies only monitor with pulse oximetry.[1] Another study that stated that "adding oxygen without monitoring CO_2 can lead to worsening hypoventilation."[2] That is something we are aware of, particularly in our COPD patients who are chronic CO_2 retainers. Researchers have found that continuous CO_2 monitoring alerted them to the need to make pressure adjustments in about 75% of IPAP settings and in 66% of EPAP settings.[3] The visibility to continuous CO_2 really helped them in deciding the best course for their patient.

Pulse Oximetry Is Not Enough

Let's discuss some scenarios where saturation monitoring alone has been shown to come up short in terms of representing the full picture of a patient's respiratory status. One study looked at the transcutaneous CO_2 values and the pulse oximetry values of patients who had neuromuscular disorders and nocturnal hypoventilation.

41% of these patients were found to have CO_2 abnormalities, and of those the majority maintained fairly normal pulse oximetry readings.[4]

The takeaway here is that while most of these patients were hypercapnic during the study, there's only a small number of them that would've been identified with pulse oximetry alone. The same authors also noted there was no correlation between the symptoms of sleep disordered breathing and CO_2 abnormalities. The study demonstrated that clinicians cannot rely on pulse oximetry alone, but also that they cannot rely on the symptoms of sleep disordered breathing to indicate the presence of nocturnal hypercapnia.

If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.

In a similar study, pulse oximetry alone was shown to be a poor predictor of hypercapnia in children who are on long-term noninvasive ventilation.[5] The data revealed that out of 50 children 42% had abnormal CO_2 values while maintaining pulse oximetry values above 90% - what we would consider to be fairly normal. So, what we would consider fairly normal. These results show, once more, that we commonly encounter abnormal CO_2 values with relatively normal pulse oximetry values. This also underlines that oxygenation and ventilation are different functions of the same system. Additionally, only 3 of the 21 patients who had abnormal nighttime CO_2 values had abnormal CO_2 on their daytime blood gases. A third study found that 85% of patients with nocturnal hypercapnia had normal CO_2 readings on arterial blood gases taken during the day.[6] Between these three studies, it's been shown that pulse oximetry cannot indicate nocturnal hypercapnia, neither can symptoms of sleep disordered breathing, and neither can CO_2 measurements taken during the day.

Three Methods for CO_2 Monitoring

Now that we've established the important of monitoring CO_2 directly during the night, let's discuss the different methods available. They include arterial blood gases (ABGs; CO_2), end tidal CO_2 or capnography (CO_2), and transcutaneous CO_2 monitoring (CO_2). Let's take a closer look at each of these methods.

Arterial Blood Gases

Arterial blood gases measure the arterial blood directly, so they are considered the gold standard for accurate measurement of CO_2. They also give you access to multiple parameters with one sample, such as your pH, your bi-carb and your O2 levels. However, they are difficult to perform and require trained staff. They are painful and invasive, so not the best choice for the sleep lab since they disrupt sleep. Daytime CO_2 values have been shown to not be reflective of nighttime levels,[5] and ultimately, they only reflect a point in time snapshot of the patient's potentially variable overnight ventilatory status.

Capnography (End Tidal)

End tidal CO_2 (CO_2), also referred to as capnography or capnometry, measures the level of CO_2 in a patient's exhaled breath, and has some advantages. First, it provides a nice breath to breath waveform. It's also continuous and painless, so it avoids those issues associated with ABGs.

However, there are some challenges associated with getting accurate CO_2 readings. End-tidal underestimates patients' CO_2 in general, but especially if they have a ventilation perfusion mismatch, which this article will expound upon further. You might change the way you ventilate a patient, and continuous end-tidal measurement before and after that change might not be possible. Also, end-tidal does not account for gas mixing, or gas leaking if a patient is on a non-invasive ventilation device. Patient compliance is an issue, especially in the pediatric population. Improper mask fit and mouth breathing can also lead to erroneous CO_2 values. And the nasal device used to monitor can be irritating.

Ventilation Perfusion (V/Q) Mismatch and CO_2 Monitoring

Let's take a closer look at ventilation perfusion (V/Q) mismatch. V/Q mismatch describes a scenario that occurs when either perfusion to the alveoli or airflow to the alveoli is restricted or blocked. And this leads to poor alveolar gas exchange. You see ventilation profusion mismatch in a high portion of patients who need any kind of respiratory care or support. V/Q mismatch is the main mechanism of gas exchange abnormality in patients who have asthma.[7]

Obstructive sleep apnea can lead to congestive heart failure,[8] which can lead to V/Q mismatch from pulmonary edema.[9] So can pulmonary edema caused by hypercapnic respiratory failure and obesity hypoventilation syndrome.[9] It's also the principal contributor to hypoxemia in COPD patients[10] because they've got airflow limitations and destruction of the pulmonary capillary bed, creating both ventilation *and* perfusion issues.

How does V/Q mismatch impact the monitoring of CO_2?

Take a deep breath in, and then exhale. Assuming we have healthy lungs, when we took a deep breath in, air came in, went to our alveoli and the oxygen in the air diffused into our bloodstream. At the same time, CO_2 diffused from our bloodstream through the alveoli and into our lungs, and we exhaled it. This is gas exchange.

When gas exchange is normal, the end tidal CO_2 measurement will be a pretty accurate representation of a patient's CO_2 . That's an amazing tool. However, our patients don't always have healthy lungs and airways.

Patients who have asthma, obstructive sleep apnea, COPD, chronic bronchitis, and tracheal or bronchial malacia all have V/Q mismatch due to impaired airflow.

They aren't getting air to or from their alveoli as well, and this means that the gas exchange doesn't happen as efficiently, and CO_2 builds up in the bloodstream. Additionally, because gas from the inhale isn't flowing inward effectively and gas in the blood stream isn't escaping effectively, the CO_2 measured in the breath through end tidal monitoring does not accurately represent the levels in the blood, in some cases underestimating them significantly.

In a more severe version of this V/Q mismatch situation there may be no airflow at all, i.e. shunting, for example due to an obstruction of the airway potentially from pneumonia, collapsed alveoli, pulmonary hypertension, or edema. In this scenario, oxygen cannot get to the blood stream, CO_2 can't get out of the blood stream, and the breath on exhale basically contains the same gas as the inhale, causing the disagreement between end-tidal CO_2 and arterial CO_2, even if the alveoli are adequately perfused.

V/Q mismatch can also occur due to impaired perfusion. In this case, the patient is breathing normally, and their lungs are functioning, but their perfusion is impaired for reasons that may include reduced cardiac output, vasoconstriction due to hypoxia, or even a result of positive pressure ventilation – where overdistension of the alveoli compresses the pulmonary capillaries, restricting blood flow. In this scenario, there may not be enough blood flow for the inhaled oxygen to dissolve into, and more than usual is exhaled instead.

Similarly, the CO_2 can't diffuse out of the bloodstream and into the lungs at an adequate rate, so more than usual builds up in the blood instead of being exhaled. The arterial CO_2 value increases, but the end-tidal CO_2 will stay low since the CO_2 isn't being exhaled. A more severe version of this V/Q mismatch scenario is the total absence of perfusion (and therefore total loss of alveolar gas exchange) to parts of the lung – called dead space. In this scenario, the oxygen is inhaled, and travels to the lungs, but has no blood to diffuse into.

Similarly, there is no blood in these alveoli for CO_2 to diffuse out of. CO_2 again will build up in the bloodstream, and once again, the patient will have a higher arterial CO_2 than when compared to the end-tidal CO_2. In all cases of ventilation perfusion mismatch, whether they're from perfusion issues or ventilation issues, or a combination of both, the CO_2 in the breath is not representative of the CO_2 in the blood, and end-tidal will be lower than the arterial CO_2 and unlikely to reflect your patient's true ventilatory status.

The other limitation that we see with measuring CO_2 using end-tidal is gas mixing. In patients with a respiratory assist device or on noninvasive ventilation, end tidal might not accurately represent the patient's arterial CO_2 because the gas sample within the mask contains more than just the patient's exhaled breath. The mixture of gas can include the patient's breath, of course, and the flow from the respiratory assist device. It can also include ambient air from any mask leaks that might be happening. End tidal will always rely on the interface to remain in place, which can be challenging especially for pediatric patients.

One researcher is quoted as saying that, "in stable intubated patients with no air leaks, end-tidal has an adequate correlation with CO_2. However, this cannot be achieved during noninvasive ventilation because of the continuous flow through the mask and because of air leaks." This researcher goes on to say that, "transcutaneous measuring of CO_2 appears to be more appropriate for the continuous monitoring of CO_2."[3]

Transcutaneous CO_2 Monitoring

Transcutaneous CO_2 monitoring works by placing a sensor on the skin which gently warms the site to encourage blood flow and the diffusion of gases across the skin. The CO_2 diffuses from the skin and into the sensor, and a measurable reaction takes place. Algorithms will then translate that data into an estimate of the arterial CO_2. Good perfusion to the site and regular calibration (i.e. every 8 hours) is imperative for an accurate reading. This type of monitoring allows for better detection of hypercapnia than pulse oximetry and has been shown to

reflect CO_2 more accurately than end tidal in neonates and infants,[10] obese patients,[11] COPD patients[12] and patients with other conditions related to V/Q Mismatch.[13] And it can be also used to guide ventilation titration. Transcutaneous monitoring is compatible with any type of ventilation, and it's accurate despite ventilation perfusion mismatch since it measures independently of respiratory rate and tidal volume and does not rely on the exhaled gas for sampling. This also means you can continuously monitor patients overnight without the need for a mask or cannula for CO_2 measurement.

The use of transcutaneous CO_2 monitoring has been included in guidelines from the AARC,[14] AASM,[15] AAST,[16] and other organizations globally including the French Health Authority[17] and German Sleep Society.[18]

Summary

We now know that only monitoring pulse oximetry overnight can cause clinicians to miss gas exchange abnormalities, hypercapnic events, and hypoventilation. Arterial blood gases, while accurate, are only a spot check and are not suitable for overnight monitoring. Additionally, blood gases taken during the day don't represent what's happening with the patient at night. End-tidal works well in some situations, but it underestimates arterial CO_2 in patients who have a ventilation perfusion mismatch or patients who are on noninvasive modalities.

Transcutaneous CO_2 has been shown to be accurate and safe. It's trusted by many respiratory organizations. It has better accuracy across many patient populations when compared to end tidal. It gives a continuous CO_2 reading noninvasively, works with any type of support or lung compromise, and is well-tolerated by patients. As more clinicians continue to take a closer look at CO_2 as a tool to optimize patient care through research and clinical practice, we may well see more transcutaneous monitors in use across patients and care settings.

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bring Vivo technology to the Canadian marketplace. We could not imagine working with a stronger, trusted, and successful partner to support Canadian clinicians and patients with Breas Vivo technology," said Chris Southerland, General Manager, Breas Americas. McArthur Medical is pleased to be partnering with Breas Medical and providing their innovative technology to support patient needs across the country. "The Vivo product family is going to allow for significant clinical advancement in bi-level therapy; our highly skilled team of clinicians are looking forward to introducing Vivo to the Canadian healthcare system. The Breas line of products will enhance patient outcomes," said Frank Fiorenza, Product Development and National Sales Manager, McArthur Medical Sales.

Monaghan Medical and Children's Hospital Association Join Forces to Improve Patient Outcomes

Monaghan Medical Corporation (Monaghan) and Children's Hospital Association (CHA) announced their agreement to a three-year contract creating a partnership between two industry leaders. The agreement recognizes the value of Monaghan's patient outcome evidence and gold standard medical devices, with CHA's desire to drive process efficiencies and value driven healthcare spending. The agreement will see Monaghan provide CHA members with devices in two categories: Respiratory Therapy Medication Delivery devices and Oscillatory Positive Expiratory Pressure/Positive Airway Pressure devices. Signing both categories' agreements together at once recognizes Monaghan's reputation for both industry leading technology and proven clinical outcomes. Monaghan is a US-based manufacturer based in Plattsburgh, New York. Monaghan and its affiliates are leaders in the development and manufacture of medical devices that improve the quality of life of patients with respiratory diseases like asthma, Cystic Fibrosis, and COPD. Monaghan's strength lies in product development and mechanical design supported by a world-class Aerosol and Research Laboratory. As the national voice of more than 220 children's hospitals, CHA is advancing child health through innovation in the quality, cost, and delivery of care in children's hospitals and health systems. Children's hospitals are essential providers, setting the standard for the highest quality pediatric care while training the next generation of pediatricians. Alongside their members, CHA champions policies, practices and performance improvements that enable children's hospitals to better serve children and families. "CHA is leading the way in rethinking how Children's Hospitals evaluate cost-effective supply chain decisions. They recognize that cost savings fully materialize when staff efficiencies, inventory consolidation, and patient outcomes all improve. In addition to our proven outcomes and hundreds of clinical studies, the fact that Monaghan's supply chain is primarily based in the United States and Canada also built confidence in our ability to respond to the rapidly changing healthcare environment," says Bill Seitz, Vice President of Sales and Marketing for Monaghan Medical. During the COVID-19 pandemic, Monaghan was able to respond quickly to fluctuating market demands, primarily because their suppliers are within driving distance from their production facility, which meant a quick response to the changing healthcare needs.

Telesair Secures Strategic OUS License Agreement for NextGen Respiratory Tech

Telesair, Inc., an innovator of next generation respiratory care, announced that it has closed a license agreement with a leading

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SIEMENS Healthineers

Improving the Safety and Quality of Radial Arterial Lines Through the Use of Proper Tools

Chris Campbell

Jury rigging a solution on the spot is something that's best left to your dad in a garage or an episode of the TV show *MacGyver*—not for critical care nurses trying to measure and provide continuous blood pressure for patients.

But that is exactly what is happening to critical care nurses when it comes to radial arterial lines, according to a new study that included extensive feedback from nurses who say they need better tools in order to do their job properly.

The study is by Nancy P Hanrahan, Lisa Letourneau, and Rachel Batty and is called "Nurse Management of Radial Arterial Lines: Quality & Safety." (*American Journal of Nursing Research*, vol. 10, no. 1 (2022): 7-15. doi: 10.12691/ajnr-10-1-2.)

The study was conducted in two phases, including a survey and a focus group, and was aimed at normalizing the use of tools for the management of RALs instead of nurses being forced to "jury rig" devices. The study details how doctors insert the RAL, but it's critical care nurses who are responsible for the monitoring and maintenance of them.

The problem, according to the study, is that the devices improvised by nurses to hold a patient's wrist in place are leading to negative health impacts ranging from infections to incorrect measurements in critical care patients.

RALs are frequently used to monitor continuous blood pressure and collect samples of arterial blood gas, says the study authors, and their use is common in a variety of hospital settings, including emergency departments.[1,2]

One problem the study found, however, was that despite the common use of RALs, information about management of this device is lacking.

"Despite the frequent use of radial arterial lines (RALs), little practice evidence exists in the literature about the nursing management of RALs," write the authors. "Specifically, new armboard devices for stabilizing the RAL wrist have emerged but have not been reviewed by critical care nurses. Thus, the purpose of this paper is to review new evidence for improved management of radial arterial lines that can guide nursing practice."

Chris Campbell is the Senior Editor of Respiratory Therapy.

That lack of information about management of RALs—and available tools to assist their use—has left critical care nurses looking for ways on their own to get the right wrist angle, the study authors write.

Finding the correct wrist angle is critical, the study authors say, to reduce the risk of something known as temporary occlusion and to collect accurate measurements.

"Although the radial artery site poses few risks for complications when compared to other potential cannulation sites, the most common complication is temporary occlusion of the artery," the study authors write. "A study by Cousins et al[3] reported that the instance of occlusion may range from 1.5% to 35%. Temporary occlusion of the artery generally has no serious consequences as adequate collateral circulation to the hand exists, yet, permanent occlusion, although rare, can provide very serious consequences.[3] Other researchers reported complications of indwelling radial arterial catheters increased with the length of time the catheter was left in place. For instance, risk of occlusion increased at the 48-72-hour mark and instance of infection and sepsis increased after 96 hours.[2] Infection was also associated with contamination by caregivers, the monitoring system, and the flushing device.[2] Failure of radial arterial lines have been associated with skin deterioration, accidental removal, inaccurate readings, and failed attempts to draw blood.[4]"

Nurse Feedback

To learn more about how critical care nurses are dealing with a lack of tools to find and maintain the correct wrist angle, the study authors looked to frontline staff for their stories.

This included a 21-question survey that asked for feedback on how they managed the RALs. Based on that survey, a group of expert nurses were selected for a more detail focus group in phase 2. The focus group members were recorded for the study.

The study authors detail how nurses have access to bedside alarms that are sensitive to any change in a patient's status, include a patient's change in wrist angle due them being agitated or anxious. That leaves nurses finding ways to keep the wrist angle in place, which the study authors called "jury rigging."

"Many alarms are triggered by technical factors related to the stabilization and position of the cannulated wrist,[5]" write the authors. "Mitigating the technical factors that may cause inaccurate alarms such as supporting the wrist to prevent

movement are necessary in acute care. However, the best tools for stabilizing the wrist are not well documented. Nurse's report using tape, wrapped towels, and rigid armboards to stabilize the cannulated wrist. These tools do not adequately stabilize the patient's wrist."

Nurse responses are included in the study and they detail some of the great lengths they go to in improvising a solution to maintain the RALs.

"To keep the RAL stabile, we often use rolled facecloths, tongue depressors, and tape to secure an arm because that is what is available," said an unnamed ICU nurse with 14 years of experience in the study. "However, when you need to move a patient, something always gets dislodged, and you need access to that site quickly. It takes time to remove all that tape to access the site."

Before the focus group took place, each nurse was given a sample of a rigid armboard and a flexible armboard to test out and then respond with feedback.

Make-Shift Armboard
A make-shift armboard is made up of various items such as towels, tape, gauze, and tongue depressors that the clinician needs to gather from various sources.

Rigid Armboard
A rigid armboard is prefabricated with a non-bendable cardboard or plastic center and usually covered with vinyl. Tape and gauze are often used to secure the rigid board to the cannulated wrist. Rolled up towels can be placed under the wrist to maintain a hyperextended position.

Pre-formed Armboard
A pre-formed armboard is frequently made of plastic and bent at a 30-degree angle. The armboard cannot be reshaped. The device is lined with foam padding and can include foam straps.

Flexible/bendable Armboard
The flexible/bendable armboard can be custom shaped or reshaped to any desired position. Easily adjustable elastic straps with hook and loop tabs secure the board to the cannulated wrist. The bendable armboard is covered with a soft foam padding.

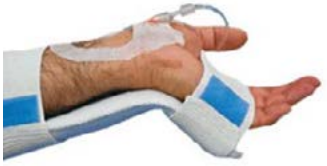

Figure 1. Different types of armboard

The study authors report that 70.5% of the nurses surveyed said that use of an armboard was "not hospital policy."

The study authors also say that "most nurses" preferred the use of the flexible/bendable armboard compared to a rigid armboard.

"The nurses' preference, however, was for the flexible/bendable armboard because it allowed them to a) adjust the armboard position or reshape it without removing it, b) maintain skin integrity with a soft comfortable product, c) eliminate tape which does not accommodate edema and can lead to skin breakdown, d) quickly and easily visualize the RAL site to monitor for infection and skin breakdown, e) easily adjust the wide elastic straps with hook and loop closures, giving nurses the best options for repositioning the wrist on the armboard," the study authors wrote.

The issue, according to the study authors, is that such tools as flexible/bendable armboards are not readily available, but that the majority of nurses think they should be.

In conclusion, the study authors issued this recommendation: "Hospital administrators need to pay attention to upgrading the tools nurses use."

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Monitoring Ventilation with Capnography in Post-Surgical Patients

Kerry Blakey, RN

Capnography or end-tidal carbon dioxide ($EtCO_2$) monitoring is a non-invasive continuous measure of exhaled carbon dioxide that provides real-time data on a patient's ventilation, perfusion, and metabolic status. Anesthesiologists throughout the world have monitored $EtCO_2$ in surgical patients for over 35 years. Since capnography became the standard of care during anesthesia, American anesthesiologists have seen a dramatic decrease in malpractice insurance payments not seen in other physician specialties.[1] Capnography continuously monitors breathing whether the patient is intubated or not intubated, and its use is increasing in post-surgical settings and other care areas outside of the operating suite because of its utility as a real-time, non-invasive measure of ventilation.

While Intensive Care Unit (ICU) and Operating Room (OR) patients are routinely monitored continuously with multiple parameters, respiratory monitoring for non-intubated post-surgical and general care floor patients typically consists of intermittent vital sign checks, including pulse oximetry (sometimes monitored continuously), and a respiratory rate counted via chest excursion. Capnography is still not widely used in post-surgical settings despite a growing body of professional society recommendations.

The COVID-19 pandemic highlighted the need for better monitoring in the sudden influx of critically ill patients requiring respiratory monitoring. The sickest patients were admitted to the ICU, while the less critically ill went to newly created COVID-19 isolation units. Many of these new units were care areas unaccustomed to continuous respiratory monitoring, but the critical care clinicians staffing them knew the benefits of continuous monitoring, and capnography was introduced into these areas.

Clinical Need for Capnography Monitoring for Post-Surgical Patients Receiving Analgesia

Opioid-induced respiratory depression (OIRD) is one of the leading causes of preventable patient death.[2,3] Acute respiratory compromise events are common on inpatient hospital wards and closed claims analyses suggest 97% of postoperative opioid-induced respiratory depression events were preventable with improved patient monitoring and intervention.[4,5]

In many post-anesthesia care units (PACUs) and lower acuity care settings oxygenation is routinely monitored by pulse oximetry, but ventilation is typically measured by visual assessment and counting a respiratory rate. Respiratory rates are often manually counted via chest excursion or by thoracic impedance if ECG is being monitored. A manually counted respiratory rate only shows the number of times a patient is moving their chest and attempting to breathe, regardless of any gas movement. Capnography continuously measures expired respiratory gas and displays a respiratory rate reflecting alveolar ventilation. Changes in expired respiratory gas can signal an adverse respiratory event. Capnography can identify respiratory depression and airway complications before basic clinical observation and can aid in early detection and treatment of patients experiencing respiratory compromise.[6,7]

Why are EtCO2 Respiratory Rates Different from Manually Counted Respiratory Rates?

Capnography measures the amount of CO_2 in every exhaled breath and only counts the ones containing enough CO_2 to qualify as a valid breath. That means shallow, ineffective breaths are rejected, and the respiratory rate displayed on the monitor is an accurate reflection of alveolar ventilation. The $EtCO_2$ respiratory rate may sometimes be lower than a manually counted respiratory rate because that method counts every chest movement, regardless of the amount of CO_2 exhaled. $EtCO_2$ provides a continuous, accurate respiratory rate, monitors for shallow breathing and airway obstruction, and alarms for no breath detected.

Kerry Blakey, RN is a Sr. OEM Clinical/Market Development Manager, Capnography & Gas Monitoring at Masimo.

Figure 1

Normal Ventilation and Hypoventilation in Post-Surgical Patients

Normally, breathing is involuntary, and the nervous system automatically adjusts respiration rate and volume to maintain normal gas exchange. If alveolar ventilation is inadequate, $PaCO_2$ increases, and pH decreases. Central chemoreceptors monitoring pH, $PaCO_2$, and PaO_2 sense the decreased pH and stimulate the respiratory center to increase the rate and depth of ventilation.[8]

Disease states, trauma, and medications can disrupt this process. Many of the medications used for pain control can depress minute ventilation leading to decreased respiratory rate and/or tidal volume in spontaneously breathing patients. In a busy post-surgical care unit this progression can go unnoticed.

Clinicians monitoring $EtCO_2$ to identify hypoventilation often expect to always see high or increasing levels of $EtCO_2$ during OIRD, but hypoventilation can occur due to breathing that is too shallow (hypopnea) just as often as it occurs with breathing that is too slow (bradypnea).

Patients experiencing hypoventilation may present with bradypnea, hypopnea, or a combination of both. Capnography identifies both types of hypoventilation. With bradypneic hypoventilation, the respiratory rate is affected proportionally greater than tidal volume. This type may be easier to observe because as the respiratory rate decreases the $EtCO_2$ increases[9]. See Figure 1 illustration.

With hypopneic hypoventilation tidal volume is affected more greatly than respiratory rate. This type may be more difficult to spot because the respiratory rate can be normal but as the tidal volume decreases the $EtCO_2$ also decreases.[9] See Figure 2 illustration.

During periods of slow or shallow breathing, the body is still producing CO_2, but the patient is not eliminating all of it, which can result in CO_2 retention. In post-surgical care settings, the focus is often on respiratory rate, but effective ventilation depends on both frequency and depth of ventilation. A change in either can indicate impending OIRD and a clinician who sees either type should assess the patient for airway obstruction, slow or shallow breathing, consider supplemental oxygen, cease or reduce medication dosage, and consider reversal if appropriate.[9]

Capnography is useful as a non-invasive trending monitor. Obtain a baseline measurement and watch for significant and sustained changes away from the baseline, >10-15 mmHg. Capnography provides breath-to-breath monitoring so fluctuations during sleep/wake cycles and activities of daily living are normal, but a significant sustained change, coupled with other clinical indicators is noteworthy.

How Low is Too Low for a Respiratory Rate?

Nursing care units have long-standing "call for" orders that trigger a notification to admitting physicians when their patient's respiratory rate drops below a pre-determined threshold. When using the capnography respiratory rate, consider both $EtCO_2$ AND respiratory rate trends as well as other clinical assessments to determine the adequacy of ventilation. For a non-intubated adult, a respiratory rate of 8-10 breaths per minute (bpm) may be too low for some patients but not necessarily all patients. Patient history, demographics, risk factors, medications, age, and type of surgery all factor into the assessment. Consider these examples of three different post-surgical adult patients with the same respiratory rate: (examples are for illustration purposes only). See Figure 3 illustration.

Also, consider the physician "call-for" orders were originally based on manually counted respiratory rates which are typically higher since patients are usually awakened for intermittent vital sign checks. In post-surgical care areas that are implementing capnography monitoring for the first time, standing "call for" orders may need to be reviewed and revised.

Pulse Oximetry and Capnography

Oxygenation and ventilation are two distinct physiological processes. Pulse oximetry measures oxygenation while capnography measures ventilation. SpO_2 and $EtCO_2$ are complementary and monitoring both together are useful because one parameter may be normal while the other is abnormal. Monitoring oxygenation or ventilation alone may not provide a complete picture of respiratory status.[10]

When patients are breathing room air pulse oximetry can be a sensitive indicator for hypoventilation, but adding supplemental oxygen, especially at rates above 1 L/min, can reduce or delay SpO_2's potential to detect respiratory decline.[10,11] Many post-surgical patients receive supplemental oxygen so relying on pulse oximetry alone can give a false sense of security. Consider this clinical scenario Figure 4.

Case Study

Ms. A, a 48-year-old female patient in good health with no comorbidities arrives in PACU at 9:00 am following a total abdominal hysterectomy under general anesthesia, with no complications. Ms. A is agitated and rates her pain level at 10 on a 0-10 scale. Her vital signs are normal with an O_2 saturation

Figure 2

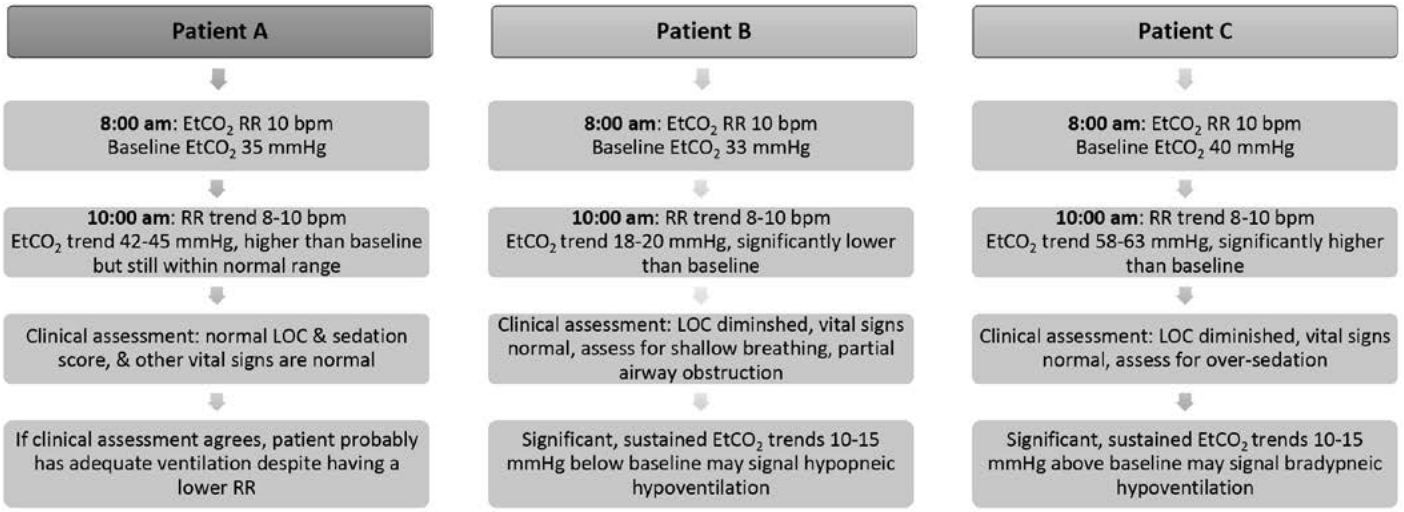

Figure 3.

of 96% and she is receiving 2 L/min of supplemental O_2 via nasal cannula. $EtCO_2$ is not monitored in the PACU unless patient-controlled analgesia (PCA) is ordered.

The PACU nurse administers Hydromorphone IV per physician order and Ms. A becomes slightly less agitated but still reports her pain at 8/10. 45 minutes later she reports a pain level of 10/10. Her vital signs are stable with SpO_2 at 94% and the nurse visually assesses her respiratory effort and administers another dose of IV Hydromorphone. Ms. A remains agitated throughout her PACU stay and continues to complain of pain but is otherwise stable, so she is transferred to the Med/Surg Unit despite the lack of pain control.

Over the next few hours, Ms. A continues to complain of severe pain and receives multiple doses of IV Hydromorphone without gaining any pain control. PCA is ordered and per policy, capnography monitoring is started. The initial $EtCO_2$ value is 45 mmHg with an $EtCO_2$ respiratory rate of 16 bpm and SpO_2 is 95%.

Ms. A's PCA delivered continuous and on-demand Hydromorphone and 90 minutes later her $EtCO_2$ was trending >60 mmHg while her respiratory rate declined to 5 bpm. Her SpO_2 trended > 92%. Ms. A was no longer agitated and more difficult to rouse. All other vital signs were normal.

Discussion of Case Study

Ms. A's pain was extremely difficult to control. It was only after multiple IV doses and finally an IV infusion via PCA that she finally got relief. By the time the medications caught up to her pain levels her respiratory status was compromised. Fortunately, her ventilation was being monitored with capnography and her nurse noted the significant and sustained change in trends.

A common first clinical intervention to her decreasing LOC and rising $EtCO_2$ levels might have been to stop the medication and immediately administer a reversal, which is not inappropriate. But the nursing staff had recently been trained in the use of capnography, and in consultation with Respiratory Therapy and Rapid Response clinicians, the team chose to immediately stop the PCA, support the airway, stimulate the patient to take deep breaths, and wait before administering a reversal, while continuing to monitor closely with capnography.

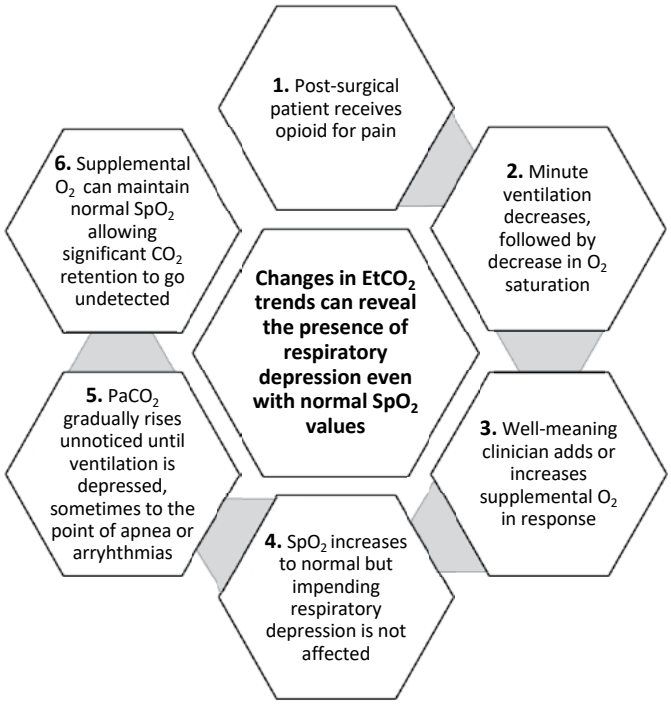

Figure 4. Clinical Scenario for Deteriorating Ventilation in a Post-Surgical Patient[7]

Over the next hour, Ms. A's LOC improved, her capnography trends returned to baseline, and the team preserved her remaining pain control by not having to administer Narcan. Capnography monitoring helped the clinicians identify Ms. A's deteriorating respiratory status quickly, facilitating an earlier intervention, and avoiding the use of a reversal and escalation to a higher acuity care area.

Conclusion

Capnography is the only single monitoring parameter that offers airway, breathing, metabolic, and circulation assessment. $EtCO_2$ detects respiratory compromise earlier and supports timelier clinical interventions.[6] There is no downside to adding $EtCO_2$ to a monitoring protocol, and the prevalence of newer technologies coupled with automation makes it easier and more cost-effective to include reliable ventilation monitoring for patients at risk for respiratory compromise.

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News…continued from page 22

global medical device manufacturer. Per the agreement, Telesair will utilize its patented technologies to develop a new respiratory platform for use initially only in an outside the United States (OUS) geography. In exchange, Telesair will earn a multi-million dollar upfront payment, a multi-million dollar milestone upon completion of its offering, and ongoing royalty payments based on sales of the device. "This partnership represents validation of Telesair's technical capabilities to produce advanced respiratory technologies not currently on the market today," said Telesair CEO, Bryan Liu. "Telesair management's ability to identify unmet needs in the market and develop technology to address those needs will create a continuum of respiratory care that extends from better managing patients in the hospital through facilitating an earlier transfer of patients to lower cost settings such as the home. We have one of the best R&D teams in the space, and with our technological innovations, we will continue to develop our own pipeline of proprietary solutions to address a wide array of diseases in the multi-billion dollar global respiratory market."

Best Practices Award Honors Commitment to Neonatal/ Respiratory Care

Dräger, an international leader in the fields of medical and safety technology, announced that Frost & Sullivan has selected the company for its 2022 Global New Product Innovation Leadership Award in the categories of neonatal and respiratory care. Dräger was the recipient of Frost & Sullivan's Global Technology Innovation Leadership Award for mechanical ventilation in 2014, 2017, and 2020, which are consecutive evaluation periods in this specific category. It remains unmatched in achieving this level of recognition as a single company during this time-period. Frost & Sullivan's award criteria evaluate companies on their devices and the overall value they deliver to healthcare. Reflective of this year's award, Dräger's approach goes beyond its extensive expertise and best-in-class capabilities, with customer value as a strategic imperative. "Healthcare executives are looking for value beyond devices to support care delivery in the NICU and critical care environments," said President and CEO for Draeger, Inc., Lothar Thielen. "This award validates our approach of combining best-in-class products, cost-effective accessories, and service solutions that deliver unmatched value for our hospital customers." Frost & Sullivan applauded Dräger's focus on improving outcomes for a baby's neonatal intensive care unit (NICU) stay, highlighting the *NICU by Dräger* concept, which is designed to achieve this goal. Through this single, comprehensive solution, Dräger supports clinicians in delivering flexible, family-oriented, and patient-centric care, providing best-in-class neonatal ventilation and lung protection solutions, thermoregulation, jaundice phototherapy devices, and neonatal care accessories, along with expert NICU design and workflow consultancy. "Dräger's new and purpose-built solution suite for neonatal care sets it apart from its competitors, with superior design, reliability, and quality as its central pillars," the award text reads. In its research, Frost & Sullivan noted a key differentiator for the company; its commitment to supporting customers' paths toward clinical needs, "Unlike competitors, Dräger builds its products by collaborating closely with a range of stakeholders and partners to evolve alongside market needs and trends. It works with leading physicians leveraging its advisory board, product managers, and research and development team to interact with key opinion leaders around the globe to understand the actual customer and market demands." The award also honors Dräger's commitment to

Continued on page 48…

Ruppel's Manual of Pulmonary Function

In this feature, Respiratory Therapy provides interviews of clinicians and healthcare providers about the actual application of specific products and therapies. Participating in the podcast interview is author of *Ruppel's Manual of Pulmonary Function* Carl Mottram, Associate Professor of Medicine and Board Member of the National Board for Respiratory Care.

Welcome to Exhale, a podcast series where we explore topics on spirometry and respiratory care. Your hosts are Mark Russell, Marketing Communications Manager, and Janson Lanier, National Sales Manager and Respiratory Therapist for Vitalograph US, a global leader in respiratory diagnostics.

Today, Mark and Janson review the new 12th edition of *Ruppel's Manual of Pulmonary Function*, with author Carl Mottram, Associate Professor of Medicine and Board Member of the National Board for Respiratory Care.

Host: Well, welcome, Carl to our podcast.

Carl Mottram: Thank you, happy to be here.

Host: Why don't you give our listeners an idea of your background on yourself, education, experience, and your current responsibilities?

Carl Mottram: Well, I went to the respiratory care program at the Mayo Clinic back in the 70s and came on board as a respiratory therapist, spent my first couple of years in the ICU as many of us do, and then became a part of the initial nurse respiratory therapist, neonatal transport team at Mayo.

I did that for about six years, and then a position became available in the lung function lab. And so I moved down into the lung function lab. From there. I went through a variety of positions and ended up as the technical director of the Mayo Clinic Pulmonary Function Lab. I became one of the only, actually, I think I'm the only associate professor of medicine in 150 years of Mayo Clinic that received that academic rank without having a terminal degree.

And currently I am the president of PFW Consulting, which is my consulting business, were I work mainly in the clinical trial space and laboratory accreditation.

Host: Great, why don't you tell us about this book that's coming out, the 12th edition. How did you have to prepare to update this edition?

Carl Mottram: Well, we should probably step back just to my introduction into lung function testing. As many respiratory therapists, as I mentioned I was in the ICU. I loved the critical care aspects and the required skill sets needed to work in the ICU/NICU, but after six years I was ready for a change and an opportunity came up in the Mayo Clinic PF laboratory. It was novel at the time as I was the first respiratory therapist hired into the outpatient PF lab. Prior to then it was personneled by technologists.

And I'm not sure if it was my personality or the fact I was the first respiratory therapist downtown, but the medical staff embraced me, not as an employee or laboratory manager, but more like a resident or fellow and later on as a colleague. And so I really had the opportunity to learn from the best.

In my initial training as an RT student, Dr Helmholtz, who is renowned in his work in lung volume measurements and the G-suit back in World War II, taught us pulmonary physiology.

When I was hired into the laboratory, Dr Robert Hyatt was the medical director at the time. Dr Hyatt was the first person to describe the flow volume loop. Prior to his description in 1959, there was only volume time curves. He recognized the various characteristics and pattern that are associated when actually displaying lung function data in a volume flow relationship versus a volume time relationship.

And of course he also described tests like respiratory muscle strength measurement and other lung function measurements. I had other highly esteemed mentors such as Dr David Driscoll, the chair of the Pediatric Cardiology division who started exercise testing at the Mayo Clinic using metabolic analysis also, and I came on board shortly after his arrival at Mayo. We tested many pediatric patients with congenital heart disease which really helped me understand their unique responses to exercise.

And so all of these experiences with these great mentors gave me a deep understanding of lung physiology, of pulmonary function testing, and other testing modalities associated with a pulmonary diagnostic lab.

At the same time I was developing my professional networking with my respiratory therapist colleagues, Greg Ruppel, Susan Blonshine, Jack Wanger. All of us were in our infancy in pulmonary diagnostics, but we'd meet at the national meeting and we started writing clinical practice guidelines and participating in other academic activities.

If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.

Greg Ruppel originally started this textbook out of some lab notes that he had. It was the textbook I used when I took my NBRC examination. Greg Ruppel's career was winding down, so he asked me to shepherd the textbook for the next generation of learners. The textbook is always evolving with new information, additional chapters, new learning adjuncts, etc. This is personally my third edition, although I had contributed chapters in the past editions.

Host: Great. How long does it take and how many people are involved in getting the update?

Carl Mottram: The process takes a little over one year for each new edition. This includes understand and including any new standards or guidelines, identifying new diagnostic tests or in some cases eliminating tests that are no longer performed. Then I identfy the guest authors, have them agree to their assignment, and then the writing begins. I have four subject matter experts in the 12th edition

Host: Wonderful.

Carl Mottram: Susan Blonshine has the chapter on quality assurance, quality control. Katrina Hynes has the chapter on pediatrics and specialized testing. Jeff Haynes has the lung volume chapter, and Dr David Kaminsky, I moved him from the lung volume chapter in the 11th edition to the interpretation chapter in this 12th edition. I thought it was really an appropriate move because not only is David a physician so he interprets tests every day. Dr Kaminsky is also chair of the writing group working on the ERS-ATS Interpretation Standard that was published right as we were in the final edits of the book. Although Dr Kaminsky was held to a confidentiality agreement, it was easy for him to make last minute adjustments to the textbook once the document was published because of his firsthand knowledge of the material.

Host: Sure. We know Susan, she has come out to our offices before the pandemic, and she basically did some NIOSH training for the region area. And just a plethora of information when it comes to pulmonary function testing. What are the drivers for this new addition? Do you do this annually or is it just on new information or updates that are in industry?

Carl Mottram: Well, typically Elsevier likes to have the new edition updated about every five to six years. I actually talked to them about updating this edition a year in advance of when the normal cycle would happen because of the plethora of new technical standards and information that has come out recently.

History has shown us that the technical standards are revised every 10-15 years and it just so happened that many were updated right after the 11th edition of my book was published in 2017. Since the 11th edition the American Thoracic Society and European Respiratory Society, the two main professional organizations which write the standards, have published eight new technical standards related to lung function testing. And then of course the Global Lung Initiative (GLI) that has been working diligently on upgrading and adding scientific rigor to the reference sets that we use.

They published two new reference sets, one on DLCO and one on lung volumes. So between these 10 new initiatives, it affected everything across the textbook itself. And some of them were on the basic tests such as spirometry and diffusing capacity.

So it was really important for the readership to have a updated resource because this book is often referred to as the Bible of our field, because it covers everything from A to Z.

And so there was really significant new information that needed to be included in the textbook, so that's why we upped the review process by a year to get it out a year earlier.

Host: Got it. How does the book prepare the students that are going through the NBRCs PFT credentialing exams?

Carl Mottram: First of all, I review the NBRCs PFT examination content matrix, which is available to the public. It shows from the job analysis surveys that we do every five years what is currently being practiced in laboratories and what the NBRC needs to validate through their assessment that practitioners are competent in the field.

I serve on the NBRC board and the PFT examination committee, so I'm in tune with the content matrix. I am under a confidentiality agreement with the NBRC so there is nothing specific to their examination, other than making sure the textbook covers everything on the content outline matrix.

Host: Yeah, we don't want any cheating on that at all.

Carl Mottram: Absolutely not, there is no cheating. The purpose of the examinations is to make sure that our patients are being tested by competent individuals, and that competency is validated through the NBRC examination process.

Host: Sure. So you spoke a lot about going from the ICU and then going into the PF Lab. How does working in the ICU prepare an RT professional to work in the pulmonary function lab?

Carl Mottram: Well, it really doesn't prepare them. I think one thing that has really changed in the last few years or decade is that when respiratory therapists graduate from their program, they have many options.

It used to be that RTs would only go into the intensive care unit, but now as they are going through their educational process, if they find that their particular skill set or their behaviors, or what they like is more suited for pulmonary rehab or pulmonary diagnostics or home care, or whatever it may be, they can go right into those professions without actually having to go into the hospital environment or into the intensive care environment.

The thing that's really important though is is that just because you're an RT doesn't mean that you're competent in all of those various fields.

I would use this analogy, it's like a GI nurse compared to a floor nurse or a cardiac nurse. There's additional training, knowledge, skills, and abilities that have to be learned once you go in there, even though your background is nursing or even though in our circumstance, your background is being a respiratory therapist.

So once you go into that subspecialty, you really need to have additional training, orientation, and evaluation of your competency, which is why the NBRC has their PFT examination credential that's available for those individuals who work in the field.

Host: Sure. So you highly recommend the CPFT or RPFT, correct?

Carl Mottram: Absolutely, the examination is actually one examination now, it used to be two separate examinations but a couple years ago we created a single examination. And depending on your end score, that's when you will be designated as minimally competent, which is the CPFT, or have an advanced level of competency, and that is recognized through the registry, the RPFT credential.

Host: So within pulmonary function, a lot of times there's MAs, there's nurses. Tell us the importance of an RT doing pulmonary function testing.

Carl Mottram: I would probably reposition that question into the realm that RTs are a good human resource pool to pull in to the pulmonary function laboratory? And to that, I would say absolutely. Their background training in respiratory physiology and pulmonary physiology allows them to take the tests that we provide in pulmonary diagnostics, understand them at a deeper level, and then because of that, be able to provide the service at that higher level of understanding.

So they're a perfect individual to come into the pulmonary function lab, whether or not they're coming directly out of school or they're coming after a storied history in the hospital or ICU, they are a very good individual to come into the lab.

I would also preface it with that other individuals can work in a pulmonary function lab if they are trained correctly or if they have the right background. Right now, you can sit for the NBRCs PFT examination if you have 62 hours of college credit and have worked in a laboratory under the supervision of a physician or other advanced provider, you're still eligible to take the NBRCs pulmonary function examinations. So that essentially means that if you have a two year associate degree and you've worked in a laboratory under the guidance and tutelage of someone in that laboratory, that you can still sit for that examination.

But it's important to realize that there's a lot of unique nuances to making sure that you get accurate and reliable data that clinicians can act on. And so you do not want to hand over even basic spirometry to an untrained individual and say, "Okay, you push this button, you tell the patient to take a deep breath, or the subject, and blast their air out." That is not adequate training, and there are other types of training that are available out there to make sure that individuals who are not RTs or not trained in pulmonary physiology or pulmonary function testing specifically, there are other methodologies to train those individuals so that they can be competent.

Host: Got you. Does this new addition deal with COVID or any other type of pandemics? Does it touch upon any of that since we've had a pandemic the last two years?

Carl Mottram: I actually did add a little section that talks about that in general, nothing specific related to COVID, but what do you do in the case of a pandemic in the lung function area? And so I did add in the introductory chapter some just general conversation or discussion about what you do in a pandemic related to lung function testing.

Host: Great. So for our audience out there, and most of them are respiratory therapists or want to be respiratory therapists, any other insight you can give them on this new edition that's coming out?

Carl Mottram: Well, as I said, the textbook has long been held in very high regards. It's either described as the definitive textbook or the Bible in the field. I always tell my students that if you simply read the textbook and answer the questions at the end of every one of the chapters, resource questions that are available that review the content of that particular chapter, it's my belief that you would pass the minimally confident level of the NBRCs PFT examination.

If you actually study the book and understand it a little bit more in detail, you'll probably pass that test at the RPFT level. And certainly if you're anywhere in the hospital or in a laboratory, and a physician comes to you and says, "Hey, I want to start up this service," or, "I want to start up this type of testing." And the testing may be basic. It may be spirometry, diffusing capacity, lung volumes, respiratory muscle strength measurement, or it may be more esoteric, like CO2 response tests or exhale nitric oxide tests or something else. You can go to this textbook and understand that it is very robust in describing that procedure, how it could be done, all the background associated with it so that you can provide that service to your physician.

But really what you're doing is providing that service to the patient. And you want to make sure that you're doing it right for that particular patient.

Host: Great. So when does this edition come out? I know it's coming out here shortly.

Carl Mottram: It's actually available on the Elsevier website currently for advanced orders, but it will hit the shelves on March 31st.

Host: Great. Great. Well, Carl, this was great information. I appreciate your time on this and thank you for being on our podcast.

Carl Mottram: It was my pleasure, and I embrace everybody who's out there wanting to learn more about pulmonary diagnostics. We need individuals in our field just like we need individuals in the general RT population also.

Host: Great, thanks again.

Carl Mottram: You're welcome.

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Top Challenges In Administering NIV Today – and 5 Ways to Overcome Them

Winnie Sywulak, BS, RRT-NPS

Non-invasive ventilation (NIV) has been shown to be effective in avoiding intubation and improving survival in patients with acute hypoxemic respiratory failure compared to conventional oxygen therapy. However, NIV is associated with high failure rates due, in most cases, to patient discomfort.[1]

So why does NIV fail for some patients? One of the primary reasons is mask intolerance.[2]

Researchers have found "the higher the patient's perceived comfort, the higher the likelihood of compliance with treatment;" therefore, "ensuring patient comfort is an important objective during NIV therapy."[3]

Here are five ways to improve mask comfort and fit for effective NIV administration, greater patient satisfaction and enhanced outcomes.

1. Properly fit the mask

A properly fitted NIV mask will help facilitate effective oxygen delivery and may contribute to improved patient comfort and satisfaction. But there is no one size fits all approach because patient anatomy can vary greatly.

Be sure to select the right mask size by using sizing gauges supplied by the mask manufacturer. Select a mask featuring an individually adjustable cushion, which allows the clinician to achieve an anatomical fit and effective seal. Selecting the correct type of interface greatly reduces painful skin breakdown and ulcerations.

2. Manage mask air leaks

Mask leaks are an inherent part of delivering NIV to patients. While intentional air leaks are incorporated in mask design and NIV circuits to permit CO_2 removal,[4] unintentional air leaks around the edge of the mask may result in inadequate inspiratory flow demand.

Therefore, managing leaks around the patient interface with a properly sized and fitted patient mask also requires a ventilator that can meet both patient and clinician requirements. The device should be able to meet and exceed the patient's flow demand all while in the presence of leaks. This combination may help improve patient comfort and ultimately successful NIV.

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3. Assess skin integrity

An analysis of medical-device-related pressure ulcers found 70% of the wounds caused by medical devices occurred on the head, face and neck.[5] Face masks for NIV have been associated with a high percentage of pressure ulcers, for which Medicare denies payment.[6]

To prevent pressure ulcers from forming, clinicians should regularly remove the patient's mask and examine the skin looking for redness, irritation and breaks in the skin.

4. Consider a skin barrier

For patients with skin irritation from the mask and/or for those who are at increased risk for pressure ulcers (e.g., age 60+, type-2 diabetes),[7] clinicians should consider the use of hydrocolloid and gel sheets that can be placed between the skin and NIV mask.

Research has shown hydrocolloid dressings placed over the nasal bridge in patients requiring NIV reduced the risk of developing grade 2 pressure ulcers.[8] Some masks feature built-in silicone gel technology to help reduce complications, such as pressure points and skin irritation.

5. Alternate mask types

Selecting the correct type of interface greatly reduces painful skin breakdown and ulcerations. For longer NIV therapy, it is recommended to alternate between different mask interfaces

to decrease skin breakdown by varying the pressure points on the skin. An alternating interface strategy not only reduces the points of highest pressure, but also improves NIV tolerance and efficacy.[9],[10]

Conclusion

The proper face mask design and fit can have a significant impact on NIV delivery—but the ventilator is as critically important. You need **the right mask paired with the right device** to meet your patient demands.

Select a NIV ventilator that is compatible for use with high-quality masks that are available in a wide range of sizes and shapes and can be adjusted to patient anatomy.

A ventilator that supports all modes of invasive and noninvasive ventilation allows a greater degree of treatment options for the patient. It also streamlines clinical workflows, especially for those patients that may need to escalate from NIV to invasive ventilation without delay.[11]

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Lung Volumes: Plethysmography vs Nitrogen Washout

Ralph Cook, BA, RRT, RPFT

The last ATS/ERS Standards on the measurement of lung volumes were published in 2005, with rumors of new standards being released late 2022 or early 2023. For the pulmonary function lab these standards covered whole body plethysmography, and two dilutional techniques: Nitrogen Washout and Helium Dilution. In the United States, practically all manufacturers have stopped offering Helium Dilution. Therefore, this article will look at body plethysmography and Nitrogen Washout only, although many of the points made also apply to helium dilution.

While both methods have their relative advantages and disadvantages, the consensus from most pulmonary function experts is that body plethysmography is the preferred method to measure lung volumes. One thing to keep in mind is that both methods only measure functional residual capacity (FRC), then a vital capacity with its' subdivisions inspiratory capacity (IC) & expiratory reserve volume (ERV) are used to calculate total lung capacity (TLC) & residual volume (RV).

In healthy individuals, FRC values obtained from both methods have minimal difference. However, how often are we testing healthy subjects? When the subject has lung disease associated with gas trapping, the FRC from plethysmography will generally be larger than the FRC obtained with N2 Washout—as explained below.

Measurement of FRC by body plethysmography (FRCpleth) is easy to do from a technical standpoint. During the actual measurement of FRC, when the shutter is closed, only mouth pressure and box pressure are being evaluated. The technique is to have the patient "puff" in and out against a closed shutter. As reported in the literature, issues can arise where the FRCpleth is larger than actual when the patient puffs either too hard or too fast. This can be mitigated by having the patient puff between 0.5 and 1.0 Hz - approximately once per second. The term "panting" is generally avoided as it infers fast and deep breaths which should be avoided.

Measurement of FRC via N2 Washout is also easy from a technical perspective. The patient breathes 100% oxygen, typically from a demand valve, while measuring tidal volumes and N2 percentages with each breath. However, patients with obstructive disease and impaired ventilation distribution may have to be on the system for 4-7 minutes. This means that at any time, if the patient leaks around the mouthpiece or there is a leak in the system, the FRC values will end up being unusable. Also, with multiple breaths over several minutes, any minor error in measuring tidal volumes or N2 percentage will accumulate and affect the FRC value.

Some people may argue that plethysmography testing is not a normal act and requires the patient to learn to perform the maneuver against the closed shutter, while N2 Washout has the patient simply breathe tidally. This may be true. However, using that logic would prevent us from performing FVC maneuvers with patients. An FVC effort is certainly not something most patients are familiar with, and many patients take multiple efforts to get one acceptable effort—if any at all. Just as with FVC testing, thorough instructions and demonstrations beforehand followed by feedback will allow most patients to perform quality efforts after 1 or 2 attempts. It should also be considered that on most systems, delivering the 100% oxygen for FRCN2 is done through a demand valve which is connected to wall O2 or an O2 gas tank. Most patients have never breathed on a demand valve, and some may find this difficult to do for several minutes.

Plethysmography has a clear advantage of being a faster test without sacrificing quality. It takes approximately 30 seconds to complete one FRCpleth maneuver, which includes tidal breathing and performing a slow vital capacity. Within a matter of 3-4 minutes, several FRCpleth measurements can be taken. Even if 2 or 3 of the plethysmograph efforts were unacceptable, you still have at least three acceptable efforts to average, which is the ATS recommendation. Meanwhile, after calibrating the gas analyzer(s) and setting up the system, the patient performing an N2 Washout is just getting started.

Most labs perform only one N2 Washout effort per patient. This is mainly due to the time involved in repeating the test. As stated earlier, it could take up to 7 minutes to perform one effort. If a second effort was to be attempted, the ATS recommends a waiting period of ≥15 minutes between trials. In patients with severe obstructive disease, they recommend ≥1 hour between trials. This means that two N2 Washout trials could take approximately 30 minutes or more to complete. If there was a leak, the test would have to be repeated. Would you ever do only one FVC effort or one DLCO effort? The answer of course is no. So why only do one N2 Washout effort when you don't have repeatability and don't know if the test results truly reflect

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the patient's clinical condition? Keep in mind that N2 Washout should not be performed before a DLCO effort without adequate time passing as the increased oxygenation of the patient will directly affect the DLCO values. Thus, performing DLCO between N2 Washout efforts is not advisable.

Labs may be concerned about patient claustrophobia and unwillingness to get into the plethysmograph cabin. The actual number of patients who are not willing to sit in the plethysmograph is extremely small. This can be alleviated for the most part by having the patient sit inside the cabin with the door open when performing spirometry and DLCO. When it comes time to close the door and perform FRCpleth measurements, the patient has already been sitting inside the cabin for 15-20 minutes and is relatively relaxed.

Most plethysmographs have the ability to perform lung volumes via N2 Washout as an option. This allows a backup method for those few patients who will not or cannot (i.e., broken leg) get into the cabin. The addition of N2 Washout to a plethysmograph also offers a method to calculate gas trapping by taking FRCpleth/FRCN2. In normal subjects the ratio is near 1.0 – meaning that both values are nearly identical. However, ratios over 1.0 may be indicative of an obstructive disease. Taking the difference in the actual TLC values from each method will also allow for the quantification of the volume of nonventilated lung due to disease, with the lung volumes from plethysmography generally being higher.

In disease, lung volumes by plethysmography are generally higher than dilution methods. FRCpleth includes nonventilated as well as ventilated lung compartments. This is because the plethysmograph is measuring pressure at the mouth, which theoretically equals alveolar pressure when there is no airflow. Because the plethysmograph is measuring pressure, no external test gas needs to reach all areas of the lung, thus more of the lung volume is measured. N2 washout on the other hand requires that the inhaled test gas (100% O2) reach all areas of the lung and wash out the nitrogen. If the nitrogen is not washed out because the O2 cannot reach parts of the lung, FRCN2 will be underestimated. The degree of underestimation depends on the severity of the obstructive disease. The more obstruction, the more the lung volumes will be undervalued.

Looking at the two different options for measuring lung volumes, a case can be made that body plethysmography has advantages over N2 Washout. They are:

1. **Speed of testing and enhanced quality:** Multiple FRCpleth efforts can be performed within the time it takes to do one FRCN2 effort.
2. **Repeatability:** Because of #1 above, the ATS repeatability criteria can be met much easier.
3. **Accuracy:** In the face of obstructive lung disease, plethysmography will provide more accurate measurements of FRC.
4. **Myth – Plethysmography is difficult:** As proven by thousands of labs around the world, body plethysmography is like any pulmonary function test. Once you have a trained and motivated technologist, FRCpleth is no more difficult than FVC testing.
5. **Options:** Body plethysmography gives you the option of performing both FRCpleth and FRCN2. A standard PF system cannot do this.
6. **Airway Resistance:** One thing that is not discussed here is the option of airway resistance testing. This functionality comes automatically and is built into every system.
7. **Cost:** A body plethysmograph may cost more than a standard pulmonary function system. However, the testing efficiency, a less expensive test, patient throughput, and accuracy of the system takes a short time to recoup the difference.

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Tetherless Techniques for Continuous Monitoring of Arterial Oxygen Saturation and Non-invasive Continuous Respiration Rate for Neonates

Leslie Altimier, DNP, RN, MSN, NE-BC

Abstract

In the last decades, photoplethysmography (PPG) has been used as a noninvasive technique for monitoring arterial oxygen saturation by pulse oximetry (PO). In addition, algorithms have been developed to extract respiration rate from these vital signs using datasets taken from adult or child respiration values so they may not accurately represent the respiration signals from infants. While oxygen saturation and respiration rate monitoring have played a key role in treating the most vulnerable patients in the NICU, wired connections can limit clinicians in the ability to improve neonatal comfort and enhance clinician workflows. As technology improves, the more we can eliminate cables and wires, and the more mobility and access to holding a baby will be available to parents of a baby in the neonatal intensive care units (NICUs). The promotion of tetherless technology will improve not only the ability of parents to easily access and hold their baby in the NICU but will also simplify clinicians' workflows.

Keywords: Photoplethysmography, PPG, wearables, noninvasive, tetherless, wireless, respiration rate, oxygen saturation, pulse oximetry, neonate

Background

The world is witnessing a rising number of preterm infants who are at significant risk of medical conditions and require continuous care in the NICU. Preterm is defined as babies born alive before 37 weeks of pregnancy are completed, and there are further sub-categories of preterm birth, based on gestational age: Extremely preterm (less than 28 weeks), very preterm (28 to 32 weeks), and moderate to late preterm (32 to 37 weeks). Preterm infants are at a significantly higher risk of medical and surgical morbidities in comparison to babies born at term (> 37 weeks). Therefore, preterm infants are specially cared for in the NICU for continuous medical monitoring of respiration rate (RR), heart rate (HR), electrocardiogram (ECG), and blood oxygen saturation (SpO_2 – also known as pulse oximetry). Medical parameters are continuously monitored in premature infants in the NICU using a set of wired, sticky electrodes attached to the body which can cause discomfort and irritation. In addition, respiration rate (RR) monitoring in the NICU faces challenges of accuracy and clinical quality because RR is extracted from the electrocardiogram (ECG) via impedance.

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In 2018, the World Health Organization (WHO) reported that an estimated 15 million babies are born preterm (before 37 completed weeks of gestation) globally, and this number is rising. That is more than 1 in 10 babies. Moreover, in almost all countries with reliable data, preterm birth rates are increasing. Preterm birth complications are also the leading cause of death among children under 5 years of age, responsible for approximately 1 million deaths in 2015 Three-quarters of these deaths could be prevented with current, cost-effective interventions. Across 184 countries, the rate of preterm birth ranges from 5% to 18% of babies born. Many survivors face a lifetime of disability, including learning disabilities and visual and hearing problems.

Inequalities in survival rates around the world are also stark. In low-income settings, half of the babies born at or below 32 weeks (2 months early) die due to a lack of feasible, cost-effective care, one of which is basic care for breathing difficulties. More than three-quarters of premature babies can be saved with feasible, cost-effective, kangaroo mother care (the baby is carried by the mother with skin-to-skin contact). Suboptimal use of technology in middle-income settings is causing an increased burden of disability among preterm babies who survive the neonatal period. WHO has developed new guidelines with recommendations for improving outcomes of preterm births. This set of key interventions can improve the chances of survival and health outcomes for preterm infants. The guidelines include interventions provided for the newborn baby — for example thermal care, feeding support, kangaroo mother care, safe oxygen use, and other treatments to help babies breathe more easily.

In the neonatal intensive care unit (NICU), heart rate, respiratory rate, and oxygen saturation are vital signs (VS) that are continuously monitored in infants, while blood pressure is often monitored continuously immediately after birth, or during critical illness. Although changes in VS can reflect infant physiology or circadian rhythms, persistent deviations in absolute values or complex changes in variability can indicate acute or chronic pathology.

Although changes in vital signs (VS) can reflect infant physiology or circadian rhythms, persistent deviations in absolute values or complex changes in variability can indicate acute or chronic pathology. Recent studies demonstrate that analysis of continuous VS trends can predict sepsis, necrotizing enterocolitis, brain injury, bronchopulmonary dysplasia,

cardiorespiratory decompensation, and mortality. Subtle changes in continuous VS patterns may not be discerned even by experienced clinicians reviewing spot VS data or VS trends captured in the monitor. In contrast, objective analysis of continuous VS data can improve neonatal outcomes by allowing heightened vigilance or preemptive interventions.

Preterm infants in the NICU are often unstable and have fluctuating vital signs. For example, a very low or high heart rate can indicate an underlying condition such as infection, pain, or illness. Abnormal respiratory rate values are often associated with hypoxemia (low level of oxygen in the blood), hypercapnia (high level of carbon dioxide in the blood), or acidosis (high level of acidity in the blood).

Preterm infants also often require some form of respiratory support with supplemental oxygen. Hyperoxia in preterm infants is associated with retinopathy of prematurity and bronchopulmonary dysplasia, whereas intermittent hypoxia is associated with increased mortality, severe retinopathy of prematurity, and pulmonary hypertension. Therefore, regulating oxygen exposure is essential. Continuous pulse oximetry (SpO_2) measured by high-resolution pulse oximeters is more accurate than hand-transcribed SpO_2 values, and more episodes of intermittent hypoxia are detected.

Current Monitoring Methods

To monitor their physiological status, specialized medical equipment is used depending on the unique needs of neonates. The standard vital signs usually monitored include heart rate (HR), respiratory rate (RR), blood pressure, temperature, and peripheral oxygen saturation (SpO_2). Below are some current monitoring methods for standard vital signs such as heart rate (HR), respiratory rate (RR), and peripheral oxygen saturation (SpO_2) used by clinicians:

- The Electrocardiogram (ECG) computes the heart rate. A pulse oximeter attaches to the infant's hand, foot, finger, or toe, which records the photoplethysmography (PPG) signal and computes the estimates of heart rate and SpO_2.
- The impedance pneumography (IP) waveform computes the respiratory rate, obtained by measuring changes in the electrical impedance of the patient's thorax using the ECG electrodes. The clinical staff also make manual measurements every 1 to 4 hours depending on the severity of the patient's condition.
- Other methods of respiratory rate monitoring include the manual counting of breaths by a caregiver, capnography, and transthoracic impedance measurement. Manual counting of breaths (such as auscultation) is an intermittent, labor-intensive, and unreliable method of measuring the respiratory rate.
- Continuous pulse oximetry is used to monitor oxygen saturation (SpO_2) and pulse rate and has been a valuable tool for Neonatologists since the early 1980s. In the last few decades, photoplethysmography (PPG) has been used as a noninvasive technique for monitoring arterial oxygen saturation by pulse oximetry (PO). Photoplethysmography (PPG) is a noninvasive circulatory signal related to the pulsatile blood volume in tissue and is displayed by the pulse oximeter. Pulse oximeters use photoplethysmography (PPG) to not only compute oxygen saturation and pulse rate, but the PPG also contains an abundance of information related to cardiac hemodynamics. The PPG is similar in appearance to the invasive arterial waveform but is noninvasive and ubiquitous in hospitals. Continuous monitoring of arterial oxygen saturation by pulse oximetry (SpO_2) is the main method to guide respiratory and oxygen support in neonates during postnatal stabilization and after admission to the neonatal intensive care unit. Titration of supplemental oxygen to maintain a narrow window of oxygen saturation is essential to reduce the risk of retinopathy of prematurity, bronchopulmonary dysplasia, and death. Continuous pulse oximetry (SpO_2) is superior to clinical observation alone; without it, desaturation can only be detected once arterial saturation (SaO_2) has dropped below 80% and cyanosis develops. Pulse oximetry also avoids frequent phlebotomy for blood gas analysis, which is painful and causes iatrogenic anemia.

Challenges with Current Monitoring Methods

Sensors used in current monitoring methods are attached either to the chest and/or extremities and pose several challenges that include:

- **Artifacts and false alarms:** Optical blood oxygenation and heart rate sensors are significantly vulnerable to motion artifacts such as limb movements, crying, coughing, and handling of the infant. Standard ECG electrodes also suffer from frequent false or non-actionable alarms due to loosely connected electrode leads and dry contacts.
- **Tethered connections:** Tethered, or wired connections, between sensors and equipment, can limit skin-to-skin contact (SSC)/kangaroo care (KC), which negatively impacts neonates and their parents.
- **Lack of direct respiration measurement:** Neonates also need continuous monitoring of vital signs such as respiration rate without being caused discomfort or irritation. Respiratory rate (RR) is one of the most sensitive markers of a patient's condition and a vital component of clinical assessment and monitoring. While end-tidal carbon dioxide monitors are the most accurate respiration monitoring technique, the cannulas may cause discomfort and are less well tolerated by non-intubated preterm babies. Infant respiration signals are generally extracted from ECG and pulse oximetry signals and through manual counting of chest excursions. With ECG or impedance-based respiratory rate, clinicians may not get an accurate measure of the patient's ventilation. With manual counting of the respiratory rate, clinicians are only able to get a snapshot of the vital signs and documentation may be prone to transcription errors.

Advancements in New Monitoring Solutions

Due to the ongoing needs and limitations of the current standard monitoring equipment used in NICUs, recent research has explored alternative technologies to address these issues. Advancements include improved accuracy of pulse oximeters, wearable devices, and acoustic respiration rate, which are discussed in the following sections.

Accuracy with Adaptive Signal Processing

Reliable and accurate pulse oximetry is paramount to optimal patient outcomes. The discovery of adaptive signal processing separates the true arterial signal from other sources of noise, creating the ability for pulse oximetry to measure-through motion and low perfusion. During neonatal care, accurate pulse oximetry is necessary to target SpO_2 during delivery room resuscitation, in situations associated with increased risks of hypoxemia, in the prevention of hyperoxia, and for screening of congenital heart disease. Accurate pulse oximetry has also

been shown to help clinicians better target oxygen levels and therefore reduce severe retinopathy of prematurity in neonates. In addition, accurate pulse oximeters can improve clinician confidence by limiting false positives and false negatives during CCHD screening in newborns and help improve patient outcomes. Some suggest that pulse oximetry is the fifth vital sign. Pulse oximetry sensors can have accuracy specifications down to 1.5% A_{RMS} during motion, in all patient populations, providing clinicians with even greater confidence that the SpO_2 values they rely on accurately reflect a neonate's physiological status while decreasing the number of alarms to help prevent alarm fatigue. The use of pulse oximetry can lead to fewer adverse events by capturing accurate readings, even during frequent movement and crying of babies and in low perfusion situations, such as in critically ill or unstable patients.

Wearable Technology

There is a growing demand, across the globe, for wearable health technology because of its wide-ranging benefits. It is assumed that by 2030 there will be about 100 billion network-connected devices. Medical device companies have launched wearable vital sensors at warp speed since the COVID-19 pandemic began.

Recent technological advances in pulse oximetry focusing on the morphologic analysis of the PPG waveform have defined new indices, such as the perfusion index, that are capable of assessing and monitoring the microcirculation and intravascular fluid volume status] of neonates while in the neonatal intensive care unit. Perfusion index is an assessment of the pulsatile strength at a specific monitoring site (e.g., the hand, finger, or foot), and as such is an indirect and noninvasive measure of peripheral perfusion. In recent years, the use of perfusion index has been suggested as an adjunct to pulse oximetry screening to detect non-cyanotic CCHD cases. Multiple studies have described perfusion index values in the first few days of life in term and preterm infants. Low values and reduced short-term variability of perfusion index on day 1 are associated with adverse outcomes. A lower perfusion index in neonates has been correlated with lower superior vena cava flow and shown to be a predictor of illness severity and subclinical chorioamnionitis, a major predictor of morbidity and mortality in very low birth weight (VLBW) neonates.

With recent advances in digital signal processing, PPG waveform can also be used to assess the microcirculation (perfusion index) and intravascular fluid status of neonates. Because of the success of pulse oximetry and recent advances in digital signal processing, there is growing research interest in seeking circulatory information from the PPG and developing techniques for a wide variety of novel applications.

It is well established that early skin-to-skin contact (SSC) between mother and newborn encourages bonding, facilitates early and successful breastfeeding, assists in thermoregulation and glucose control, provides cardiorespiratory stability, and decreases newborn pain. The World Health Organization and UNICEF strongly support early SSC. A tetherless pulse oximeter solution is of great interest for neonates, families, and clinicians in the NICU, since Skin-to-Skin Contact (SSC)/Kangaroo Care (KC) is the optimal environment for the care of neonates. SSC/KC involves a complex transfer process of moving the baby, with numerous wires, cables, and tubing, from the incubator to the chest of the parent. With babies in mind, an innovative and unique tetherless pulse oximetry solution have been developed, which combined with adaptive signal processing provide superb accuracy without the need for a cabled connection to a monitor. Such sensors are lightweight, comfortable to wear, and allow for the safe movement, transport, and transfer of a baby to the parent's chest, providing uninterrupted continuous pulse oximetry monitoring.

Acoustic Respiration Rate

Thoracic impedance respiratory monitoring (IM) is widely used in the neonatal intensive care unit (NICU) for apnea detection in preterm infants. However, IM may fail to identify apneic events by misinterpreting cardiac impedance changes as breathing, particularly during bradycardia. Such false negative episodes preclude alarm initiated intervention by nurses prior to the onset of apnea-associated bradycardia and/or hypoxia. Conversely, IM may fail to recognize shallow breathing, resulting in false-positive signaling of apnoea.

There is technology that can provide continuous, non-invasive respiratory monitoring with accurate respiratory rate measurements that is automated and recorded on connected devices. Such technology obtains respiratory rate by detecting acoustic signals produced by the turbulent airflow in the upper airway that occurs during inhalation and exhalation. The respiratory signal is separated and processed to display continuous respiration rate and an acoustic respiration waveform; a visualization of the signal caused by the patient's airflow. The visual waveform analyzes both the inspiratory and expiratory phases of respiration. For example, a longer expiration phase is noted when a child has RSV or asthma. Additionally, clinicians can monitor for any pauses in breathing over the time the neonate is being monitored.

Conclusion

Accuracy of all monitoring devices (wired or wireless) for our extremely tiny and critically ill neonates is of paramount importance. Accuracy Root Mean Squared (A_{RMS}) is a statistical calculation of the difference between device measurements and reference measurements. When evaluating monitoring equipment utilized on our most vulnerable patients, it is important to choose equipment with accuracy specifications that have the highest sensitivity and specificity to help clinicians make critical patient care decisions. Accurate wireless pulse oximetry is beneficial to encourage attachment and bonding between the parents and baby. We as caregivers for these vulnerable neonates should not compromise for such patients as they deserve the best care we have to offer.

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continuing education. Dräger's "A Breath Ahead" portal provides clinicians access to live and online continuing respiratory care education (CRCE) courses. Through its INSIGHTS program, Dräger shares ideas and innovations that can help hospitals achieve their goals by improving clinical outcomes, managing the cost of care, ensuring staff satisfaction, and enhancing the patient experience. "Dräger maximizes patient outcomes by improving safety, increasing the education level for clinicians, streamlining supply chain issues, and creating cost-effective and reliable biomedical solutions," said Bhaskar Vittal, industry principal for Frost & Sullivan. "Everything that makes a healthier hospital in terms of patients' safety, costs and outcomes for customers are the reasons driving Dräger's successful momentum and continuous development over decades."

Study Demonstrates Utility of MediPines AGM100 in Triaging COVID-19 Patients

In a study presented at the American Thoracic Society (ATS) International Conference 2022, the MediPines AGM100 was shown to provide data that helped identify patients who are at risk of respiratory failure and in need of escalated care due to COVID-19. The measurement of gas exchange impairment (known as Oxygen Deficit) helped physicians accurately determine the need for hospital admission and supplemental oxygen administration in the emergency department (ED). The ongoing study, titled *"Use of the Alveolar Gas Meter for Point-of-Care Triage in COVID-19 Patients"* was authored by a team of practicing ER physicians and scientists from the University of California San Diego (UCSD Health) and demonstrated the utility of non-invasive gas exchange analysis (AGM100) on patients who reported to the ED with symptoms of COVID-19. The data indicate that the AGM100 is useful for important hospital admission and supplemental oxygen administration decisions in COVID-19 patients. Additionally, the authors found that the AGM100 is able to identify patients at risk prior to obvious clinical deterioration, in a non-invasive, point-of-care fashion. Many high-risk patients, especially those infected with COVID, currently go unidentified due to the limitations of existing measurements available to physicians in the ED. Frequently, stand-alone oxygen saturation is utilized to make triage decisions, but the current study reinforced the notion that stand-alone oxygen saturation (≥92%) measurements failed to identify almost half of the patients who later required supplemental oxygen. This can lead to delayed treatment and devastating consequences for patients who are in immediate need of escalated care. By contrast, elevated Oxygen Deficit (>40 mmHg) was shown to be highly sensitive and specific in determining supplemental oxygen needs (ROC curve AUC: 0.97). Additionally, an elevated Oxygen Deficit (>30 mmHg) was effective in predicting the need for hospital admission (ROC curve AUC: 0.78). The MediPines gas exchange technology represents the only non-invasive, real-time method of obtaining Oxygen Deficit measurements, uniquely positioning it to provide significant clinical benefit for patients with (or at risk for) COVID-19 and other cardiopulmonary complications. "Oxygen Deficit is the most convenient and informative measure of impaired lung function (gas exchange) caused by disease process like COPD or sudden serious respiratory infection of lung parenchyma as in COVID," stated study co-author and leading global authority on respiratory physiology, John B. West, MD, PhD. The MediPines AGM100 is an FDA-cleared, advanced pulmonary gas exchange technology that provides Oxygen Deficit, a surrogate for the

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Evaluation of Continuous Quality Management System for Blood Gas, Electrolytes, Metabolites and CO-Oximetry

JH Nichols, T Cambridge, N Sanchez, D Marshall

Background

Quality management of point-of-care (POC) blood gas testing focuses on metrics for instrument accuracy and precision, in addition to performing intermittent daily quality control (QC) checks every 8 hours. At the POC and in the lab, systemic and transient sample-specific errors may negatively impact patient care.

Methods

We evaluated the performance of the GEM® Premier™ 5000 system with next generation Intelligent Quality Management 2 (iQM®2) (Werfen, Bedford, MA), from the analysis of 84,000 samples across 4 sites. Continuous iQM2 was compared to intermittent liquid QC, either manual or automated. Statistical characteristics of QC processes including, method sigma, and average detection time (ADT) for an error, were examined. An analysis of transient errors detected by iQM2 was included in the study.

Results

ADT was approximately 2 minutes with iQM2 and varied from hours to days with intermittent QC (Tables 1–3). The precision of iQM2 Process Control Solutions (PCS) was similar or better (>6 sigma for all analytes) than manual (sigma 3.0 for pO_2) or automated internal QC (sigma 1.3 for tHb and sigma 3.3 for pO_2). In addition, iQM2 flagged specific transient errors (e.g., micro-clots, benzalkonium chloride, optical interferences) in ~1.4% samples, providing an additional safeguard against reporting erroneous results.

Conclusions

The findings in this study demonstrate excellent performance of the GEM Premier 5000 system with iQM2, including >6 sigma precision for all analytes and faster error detection times. These benefits address risk in different phases of testing that are not easily detected by intermittent performance of liquid QC (manual or automated).

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Table 1. Summary data for continuous iQM2 PCS Level A-E on GEM Premier 5000

		pH	pCO_2 (mmHg)	pO_2 (mmHg)	Na^+ (mmol/L)	K^+ (mmol/L)	Ca^{2+} (mmol/L)	Cl^- (mmol/L)	Glucose (mg/dL)	Lactate (mmol/L)	tHb (g/dL)	O_2Hb (%)	COHb (%)	MetHb (%)	HHb (%)	tBili (mg/dL)
PCS A (n>45,000)	Mean	6.90	64	113	107	7.1	1.84	46	144	3.3	14.6	89.4	2.4	1.6	6.6	20.1
	SD (CV%)	0.003 (0.0)	0.5 (0.8)	1.1 (1.0)	0.4 (0.4)	0.03 (0.4)	0.015 (0.8)	0.2 (0.5)	2.1 (1.5)	0.06 (1.7)	0.03 (0.2)	0.01 (0.0)	0.01 (0.4)	0.00 (0.3)	0.00 (0.1)	0.03 (0.2)
PCS B (n>530,000)	Mean	7.41	33	181	156	2.0	0.79	85	0	0.0	0.0					0.0
	SD (CV%)	0.004 (0.1)	0.5 (1.4)	2.2 (1.2)	0.7 (0.5)	0.01 (0.5)	0.007 (0.9)	0.4 (0.4)	1.6 (N/A)	0.03 (N/A)	0.04 (N/A)	N/A	N/A	N/A	N/A	0.04 (N/A)
PCS C (n>6,000)	Mean	8.05	33	3.1	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	SD (CV%)	0.007 (0.1)	0.3 (1.0)	1.0 (32.5)												
PCS D (n>13,000)	Mean	7.35	24	48	165	7.3	1.22	142	349	8.0	7.4	80.0	4.1	4.0	11.9	10.4
	SD (CV%)	0.004 (0.1)	0.4 (1.5)	3.2 (6.6)	0.6 (0.4)	0.04 (0.6)	0.011 (0.9)	1.6 (1.1)	3.3 (1.0)	0.24 (3.0)	0.03 (0.4)	0.14 (0.2)	0.09 (2.1)	0.10 (2.6)	0.33 (2.8)	0.03 (0.3)
PCS E (n>13,000)	Mean	7.22	69	92	129	4.5	0.56	101	71	1.6	16.5	50.0	10.1	8.1	31.9	20.0
	SD (CV%)	0.005 (0.1)	1.0 (1.5)	2.2 (2.4)	0.5 (0.4)	0.03 (0.6)	0.008 (1.4)	0.8 (0.8)	1.0 (1.5)	0.06 (4.1)	0.07 (0.4)	0.11 (0.2)	0.05 (0.5)	0.07 (0.9)	0.23 (0.7)	0.07 (0.4)
Sigma Average		>6	>6	>6	>6	>6	>6	>6	>6	>6	>6	>6	>6	>6	>6	>6
Overall Pfr		0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.152	0.152	0.152	0.152	0.152	0.167
Overall Ped		0.974	0.953	0.938	0.412	0.979	0.990	0.950	0.097	0.933	0.997	1.000	0.957	0.957	0.998	1.000
Overall ADT (min)		2	2	2	5	2	2	2	21	2	2	2	2	2	2	2

Table 2. Summary data for intermittent auto-QC (Levels 1-4) analyzed every 6 hours on ABL800

		pH	pCO_2 (mmHg)	pO_2 (mmHg)	Na^+ (mmol/L)	K^+ (mmol/L)	Ca^{2+} (mmol/L)	Cl^- (mmol/L)	Glucose (mg/dL)	Lactate (mmol/L)	tHb (g/dL)	O_2Hb (%)	COHb (%)	MetHb (%)
S7835 (n≥110)	Mean	7.10	67	143	159	1.7	1.01	121	31	4.6	8.1	44.6	5.9	4.9
	SD (CV%)	0.005 (0.1)	1.6 (2.4)	6.3 (4.4)	0.7 (0.4)	0.00 (0.1)	0.009 (0.9)	0.9 (0.7)	1.0 (3.2)	0.09 (2.0)	0.86 (10.6)	0.09 (0.0)	0.18 (0.0)	0.05 (0.0)
S7845 (n≥93)	Mean	7.40	40	101	140	3.7	0.52	97	101	1.7	13.4	92.2	2.9	2.0
	SD (CV%)	0.003 (0.0)	0.7 (1.8)	2.4 (2.3)	0.6 (0.4)	0.03 (0.7)	0.010 (1.9)	0.3 (0.3)	1.6 (1.6)	0.05 (2.7)	0.66 (4.9)	0.08 (0.1)	0.20 (6.8)	0.05 (2.4)
S7855 (n≥105)	Mean	7.57	40	72	126	5.5	0.35	66	247	10.7	19.5	49.1	19.9	10.0
	SD (CV%)	0.007 (0.1)	0.6 (1.4)	3.2 (4.5)	0.6 (0.5)	0.03 (0.5)	0.027 (7.8)	1.0 (1.5)	4.0 (1.6)	0.50 (4.7)	0.65 (3.3)	0.09 (0.2)	0.17 (0.8)	0.05 (0.5)
S7865 (n≥96)	Mean	6.81	94	289	125	6.3	1.63	90	-2	-0.1	2.6	3.6	9.2	19.7
	SD (CV%)	0.006 (0.1)	1.8 (2.0)	7.5 (2.6)	0.4 (0.3)	0.00 (0.0)	0.0 (0.8)	0.750 (0.8)	0.6 (N/A)	0.00 (N/A)	0.39 (15.0)	0.01 (0.3)	0.05 (0.6)	0.03 (0.1)
Sigma Average		>6	5.8	3.3	>6	>6	>6	>6	>6	>6	1.3	>6	>6	>6
Overall Pfr		0.002	0.001	0.030	0.000	0.000	0.000	0.000	0.000	0.000	0.309	0.000	0.720	0.000
Overall Ped		0.943	0.487	0.094	0.049	1.000	0.275	0.017	0.000	0.084	0.067	1.000	1.390	1.000
Overall ADT (hours)		6	12	64	>100	6	22	>100	>100	72	89	6	8	6

Table 3. Summary data for iQM2 flags and estimated range of impact error, and average time to error correction (samples n=83,964)

Error detected by iQM2	Frequency of detection (%)	Time to corrective action or resolution of error (average)
Benzalkonium	18 (0.02)	2 minutes
Thiopental	1 (0.001)	2 minutes
Unspecified Interference	417 (0.5)	Immediate
Turbidity	22 (0.03)	Immediate
Methlyene Blue	64 (0.08)	Immediate
Micro-clots	259 (0.31)	11 minutes
IntraSpect	361 (0.426)	Immediate
	Total: 1142 (1.367)	

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Point-of-Care Blood Analysis: Meeting the Need for Accurate, Quality Testing in Critical Care

Susan Garramone

Point-of-care testing (POCT), laboratory testing conducted close to the site of patient care, has been possible for over 4 decades.[1,2] Numerous studies support how a patient-side testing approach can reduce turnaround time and lead to operational efficiencies while maintaining the accuracy and quality of a laboratory-based process.[3-5]

Clinical staff, the laboratory, and healthcare institutions can benefit by streamlining patient testing workflows to enhance patient care and deliver the most cost-effective and efficient use of hospital resources, allowing them to focus on delivering the most value to patients.[6] These benefits are driving factors for POCT adoption and market growth. In 2020, the global POC diagnostic market was reported to be $34.49 billion USD, with North America accounting for $14.09 billion of the market. Based on the prevalence of acute and chronic diseases worldwide, the demand for POC products is expected to continue.[7]

Point-of-care testing is a widely adopted diagnostic tool in various locations in the hospital, especially in critical care settings such as the intensive care unit (ICU), operating room (OR), and emergency department (ED).[8] One of the most frequently ordered tests in critical care is blood gas analysis.[9] A blood gas test measures the amount of oxygen and carbon dioxide in the blood. It is also used to determine the pH and acidic content of the blood. Imbalances in the oxygen, carbon dioxide, and pH levels of the blood are indicative of numerous cardiopulmonary and metabolic diseases, making blood gas analysis a key measurement in the diagnosis of conditions including kidney failure, heart failure, uncontrolled diabetes, hemorrhage, chemical poisoning, drug overdose, shock, asthma, and chronic obstructive pulmonary disorder.[10,11]

The first commercially available blood gas analyzers were introduced into clinical laboratories in the 1960s.[12] Over the past four decades, technological advances have translated into improvements in the performance and design of blood gas analyzers.[12-14] Modern analyzers can measure a broad menu of critical analytes and enable the testing of blood gas, electrolytes, and metabolites from a single patient sample.[14,15] These analyzers are now the mainstay of critical care patient management throughout hospital systems.[13]

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Due to technological advancements, blood gas analysis can now be done not only in the laboratory but also at the patient bedside, with point-of-care testing systems.[13] Availability of point-of-care blood analysis systems in critical care settings can rapidly inform clinical decisions, enabling expedited intervention and leading to improved patient outcomes. However, to realize these benefits, POCT systems must also provide strong analytical performance and rigorous quality assurance measures (QC/QA) as well as demonstrated user-friendliness and workflow efficiency.[13] Lastly, these systems must have IT security features to provide data protection in this world of increasing cybersecurity concerns.[13]

epoc Blood Analysis System[15]

Overview

The epoc® Blood Analysis System (Siemens Healthineers USA, Tarrytown, NY) is a patient-side test system that meets these requirements. This system has provided the benefit of POC testing across the critical care continuum since it first launched in 2006. This testing solution offers a full menu of laboratory-accurate tests, including blood gases, a basic metabolic panel, hematocrit, and lactate. In addition to 13 measured analytes, the system provides 18 calculated parameters from only 92 µL of arterial, venous, or capillary whole blood. Results are generated in less than 1 minute after sample insertion, making it ideal for acute patient populations.

The epoc system consists of three primary components: the epoc Reader; epoc NXS Host; and epoc blood gas, electrolyte, and metabolite (BGEM) Test Card. Each Test Card is bar-coded with lot number and expiration date for error-free test panel recognition. The Reader interprets electronic signals from the Test Card that are transferred via BLUETOOTH to the epoc NXS Host. The epoc NXS Host serves as a mobile primary user interface and analytical engine that generates test results and securely integrates with the LIS/HIS.

epoc Blood Analysis System with NXS Host

The epoc NXS Host is the first handheld diagnostic instrument to leverage the power of ANDROID, with enhanced processing power and performance, 2 GB of memory, and long battery life. The system has a vibrant, HD-resolution touchscreen that can be used with gloved fingers and features a large on-screen keyboard. The Host's user interface is designed to support both expert and novice operators and delivers a streamlined, intuitive, prompt-based testing workflow. The Host provides audio and visual prompts when action is required and offers a "Show me how" prompt where the screen expands and shows a large

The point-of-care, handheld epoc® Blood Analysis System with the epoc NXS Host.

animation that demonstrates the appropriate technique for the particular process step.

Testing process

In a few simple steps, a clinician can have clinically actionable test results without leaving the patient's bedside, from a solution that simplifies the testing process, automates quality assurance, and provides comprehensive, connected care. The process steps are described below:

Step 1: Test initiation. To initiate a test, the operator simply detaches the Host from the Reader and scans their user credentials to verify authorization to use the system. The Host is then returned to the Reader, and a series of electronic checks occurs to verify the system is ready.

Step 2: Test Card insertion and calibration. The system prompts the operator to insert a Test Card to initiate the calibration cycle. After insertion, the epoc system automatically checks the Test Card expiration date. If it is expired, the operator is prompted to insert a new, valid Test Card before continuing. This eliminates erroneous results caused by expired reagents. The system also performs a calibration process that ensures the quality of the Test Card. This key step mitigates the risk of losing a valuable patient sample and avoids sample redraws. Test Card calibration takes only 3 minutes, during which the patient ID and other information can be entered and the sample drawn.

The epoc system is integrated for patient safety, with a positive patient ID feature, automated quality assurance, and a simplified operating process. The operator scans the patient ID using the integrated 1D/2D bar-code scanner, and the system wirelessly matches the scanned ID with patient data in the LIS, positively confirming the patient ID. Ensuring a reliable match to the patient and result mitigates the risk of error and potential misidentification and gives caregivers confidence. Then the operator enters important information about the patient, sample, and tests to be run. A series of dropdown menu options facilitates entering the information, including patient demographics, sample type, and the types of tests to be run.

Step 3: Sample injection. The system prompts the operator to inject the sample into the Test Card, providing visual prompts and guidance regarding the appropriate sample injection technique. Following injection, the system analyzes the sample and displays results in less than 1 minute after sample introduction.

Step 4: Obtaining test results. When sample analysis is complete, blood test results are displayed in three groups: Gases+, Chem+, and Meta+. It is important to note that test results from the epoc Blood Analysis System correlate with those from leading benchtop blood gas and laboratory chemistry analyzers, demonstrating analytical precision, performance, and comparability to traditional laboratory methods as well as other near-patient and handheld systems on the market.[16]

Results on the epoc NXS Host are color-coded so the operator can easily identify those that are critical or out of range. Red denotes a critical result, yellow indicates a result out of range, and white indicates a normal result. If critical results need to be documented, the system prompts the operator, indicating at the top of the screen where critical results can be documented. With the push of a button, a screen appears from which the operator can notify the attending physician or other caregiver. The functionality to reject a test, if required, is also available.

Connectivity

The epoc system leverages a secure, wireless connection to instantly transmit results via data management software to the LIS/HIS. This ensures that current test results from each department are available to the care team and connects the patient, actionable test results, the care team, and the therapy delivered.

Bidirectional communication between the epoc system and the data management software enables remote, centralized management of devices, operators, inventory, and quality control and allows the proactive and secure management of data across the hospital, providing centralized control of decentralized testing.

Conclusion

Point-of-care testing brings results to the patient bedside, simplifying the testing process and shortening the time to clinical results.[17] POCT systems combine convenience and ease of use with resulting workflow efficiency for the staff and cost savings for hospital systems.[6] In critical care environments, accurate blood gas, electrolyte, and metabolite testing at the patient bedside, like that provided by the epoc Blood Analysis System with epoc NXS Host**,** enables clinicians to provide immediate, potentially lifesaving intervention. Technological innovation in this diagnostic arena has and will continue to improve the quality of patient care and lead to better patient outcomes.[6,17]

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alveolar to arterial oxygen difference (AaDO2), as well as $gPaO_2$, $PETCO_2$, and other sensitive measurements of pulmonary gas exchange. Designated by the World Health Organization (WHO) as an innovative and commercially available health technology for global priority diseases in its 2021 edition of the WHO Compendium of Innovative Health Technologies, the MediPines AGM100 is a portable system that is being used in emergency departments and throughout the continuum of care in hospitals. "Clinicians are asking for better methods to triage COVID-19 patients, especially as they recognize that COVID will likely become an endemic problem into the future," said MediPines CEO, Steve Lee. "This study demonstrates that the AGM100 has utility for physicians on the front lines of medicine to combat the rising chronic respiratory disease burden."

New Endotracheal Tube Holder Released

Dale Medical Products, Inc., the employee-owned company known for its high-quality, patient-friendly medical device securement solutions, is expanding its offering with its new BreezeLock Endotracheal Tube Holder. Like the Dale Stabilock Endotracheal Tube Holder, the new endotracheal tube holder features a soft, comfortable, flexible neckband with no hard plastic parts. The BreezeLock includes a Tube Track for easy repositioning of the endotracheal tube while still allowing easy access to the mouth for oral care. "Clinicians tell us they appreciate the improved ease of repositioning with the Tube Track and the security of Dale BreezeLock," says Robert Simpson, President of Dale. "We are pleased to expand the offering with our new endotracheal tube holder to help clinicians provide optimal care for their patients." For more information about Dale's new BreezeLock Endotracheal Tube Holder, or to request a product sample, visit www.dalemed.com/contact/request-samples or call 800-343-3980.

MGC Diagnostics Signs Global Distribution Agreement

MGC Diagnostics, a global medical technology company dedicated to cardiorespiratory health solutions and products focused on physician offices, laboratories, hospitals, and universities has partnered with UK med-tech company, Bedfont Scientific Ltd., a world leader in breath analysis, whose portfolio includes the NObreath fractional exhaled nitric oxide test monitor for use in the hospital or at remote locations. Branded the FeNObreath, MGC Diagnostics will leverage its cardiopulmonary products and diagnostic device experience by providing Fractional Exhaled Nitric Oxide (FeNO) testing to measure airway inflammation for the management and aid in diagnosis of conditions such as asthma. "We are proud that our partnership with Bedfont Scientific, Ltd. gives our customers access to proven and validated FeNO technology. Bedfont gives us the opportunity to bring a great product to our markets and to provide a simple and affordable solution to those looking for a FeNO monitor," said Ralph Cook, Vice President of Global Marketing and Product Management of MGC Diagnostics. The FeNObreath works by measuring FeNO through breath analysis, making the process quick, simple, and non-invasive for both the Healthcare Professional and the patient. Interpreting FeNO levels aids in identifying patients who do/do not require ongoing treatment while also differentiating between allergic (eosinophilic) and non-allergic asthma, and if used daily, FeNO measurements can help to predict and prevent exacerbations and attacks. "We're excited to be working with MGC Diagnostics," said Jason Smith, Managing Director at

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The 'Less Than' Obvious Requirements of the 2019 ATS/ERS Standards

Alex Stenzler

Whenever new standards are developed for a medical procedure, it requires significant retraining of those personnel that perform the procedure, and those that interpret the results of the procedure. In the case of spirometry, it's not only that there is a need to inform and train on the new procedures, but with the knowledge that the quality of personnel supervising spirometry is not as good as the current standards require, there are many bad habits that need to be broken in the process.

In November 2019, the Standards Committee of the American Thoracic Society (ATS) and the European Respiratory Society (ERS) (collectively ATS/ERS) released new standards for performing and evaluating pulmonary function tests (PFTs).[1] This eighteen page document was the first update since the last guidance document was issued in 2005.[2] In addition, the standards document was supported with an online Standards Supplement consisting of an additional 47 pages that provided more detailed specification and explanations, including many helpful images.[3]

The objective of the 2019 ATS/ERS Standards is to unify how spirometers are used, how tests are performed, and how measurements are evaluated for acceptability or usability. This Standards document was developed by an international team of fifteen pulmonary function testing experts. As with all Standards developed by a committee, it represents a consensus of opinions and not necessarily with a complete agreement by all members. In addition, to simplify how the Standards would be used, the main requirements made it into a table of absolute characteristics (Table 1 below). And these are the criteria that many personnel identify as the only important criteria. However, this left many "less than obvious" requirements within the verbiage of the text, and if every sentence was not read and acknowledged by a technologist or physician performing spirometry, there is a great likelihood that they will be generating test results that do not provide an accurate representation of the patient's lung function.

To address this written content of requirements that did not make it onto the "Absolute Table" described above, is a new table (Table 2 below) where the extracted words that state these "less than obvious" requirements are identified. The reference number following the statements in the table below reflects the page and column number in the 2019 Standard (e.g., E83.3=page e83, col 3), so that the sentence can be found in the document to provide context from where it was taken. Note that as with the E-Page number, an "S" before the "E" indicates that the page is from the Supplement and a "T" refers to a table.

From the Standard, the term "must" is used to indicate a requirement for meeting the standards, and "should" is used to indicate actions that may not be mandatory but are considered to be best practices. This paper excludes requirements for manufacturers of spirometers and is limited to requirements specific for personnel performing tests.

Discussion

Changing habits in medicine is one of the hardest things to do. Considering that there are millions of spirometers in use around the world, there are probably multiple millions of technicians and physicians supervising tests. The likelihood that all of these technicians and physicians would have read the entire standard and supplement is not high. The impact is that we are likely to find tens of millions of tests collected that don't meet the ATS/ERS standards. Hopefully, this article will contribute to informing those personnel who perform or interpret spirometry data to better obtain meaningful insight to their patients' health.

Alex Stenzler is the president of 12th Man Technologies, Inc. He was a Registered Pulmonary Function Technologist and has been working in the field of pulmonary function testing since 1968. He spent half of his career managing Respiratory Care Departments, COPD Clinics and Pulmonary Function Laboratories, or teaching pulmonary function technology as an Assistant Professor at the State University of New York at Stony Brook and twelve years at the Graduate School of Adelphi University. He has been the PI for two NIH and one DARPA grant and has extensive research experience. He has co-authored 18 peer-reviewed papers and one book chapter on pulmonary function testing. He holds 58 patents, most of which are related to pulmonary medicine.

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Table 1. Summary of Acceptability, Usability, and Repeatability Criteria for FEV_1 and FVC (Table 7 in the Standard)

	Required for Acceptability		Required for Usability	
Acceptability and Usability Criterion	**FEV_1**	**FVC**	**FEV_1**	**FVC**
Must have BEV ≤5% of FVC or 0.100 L, whichever is greater	Yes	Yes	Yes	Yes
Must have no evidence of a faulty zero-flow setting	Yes	Yes	Yes	Yes
Must have no cough in the first second of expiration*	Yes	No	Yes	No
Must have no glottic closure in the first second of expiration*	Yes	Yes	Yes	Yes
Must have no glottic closure after 1 s of expiration	No	Yes	No	No
Must achieve one of these three EOFE indicators:	No	Yes	No	No
1. Expiratory plateau (≤0.025 L in the last 1 s of expiration)				
2. Expiratory time ≥15 s				
3. FVC is within the repeatability tolerance of or is greater than the largest prior observed FVC†				
Must have no evidence of obstructed mouthpiece or spirometer	Yes	Yes	No	No
Must have no evidence of a leak	Yes	Yes	No	No
If the maximal inspiration after EOFE is greater than FVC, then FIVC - FVC must be ≤0.100 L or 5% of FVC, whichever is greater‡	Yes	Yes	No	No
Repeatability criteria (applied to acceptable FVC and FEV1 values)				
Age > 6 yr: The difference between the two largest FVC values must be ≤ 0.150 L, and the difference between the two largest FEV1 values must be ≤ 0.150 L Age ≤6 yr: The difference between the two largest FVC values must be ≤ 0.100 L or 10% of the highest value, whichever is greater, and the difference between the two largest FEV1 values must be ≤ 0.100 L or 10% of the highest value, whichever is greater.				
Definition of abbreviations: BEV = back-extrapolated volume; EOFE = end of forced expiration; FEV0.75 = forced expiratory volume in the first 0.75 seconds; FIVC = forced inspiratory VC. The grading system (Table 10) will inform the interpreter if values are reported from usable maneuvers not meeting all acceptability criteria. *For children aged 6 years or younger, must have at least 0.75 seconds of expiration without glottic closure or cough for acceptable or usable measurement of FEV0.75. †Occurs when the patient cannot expire long enough to achieve a plateau (e.g., children with high elastic recoil or patients with restrictive lung disease) or when the patient inspires or comes off the mouthpiece before a plateau. For within-maneuver acceptability, the FVC must be greater than or within the repeatability tolerance of the largest FVC observed before this maneuver within the current prebronchodilator or the current post-bronchodilator testing set. ‡Although the performance of a maximal forced inspiration is strongly recommended, its absence does not preclude a maneuver from being judged acceptable, unless extrathoracic obstruction is specifically being investigated.				

Table 2. Less Than Obvious Requirements

Slow Spirometry Statements	Discussion/Explanation
It is preferable that VC maneuvers be performed before FVC maneuvers because of the potential for muscular fatigue and volume history effects. E83.3	After maximal inspiratory efforts, some patients with severe airway obstruction return to a falsely high level of FRC or RV as a result of gas trapping or stress relaxation.
Stability is defined as having at least three tidal breaths with end- expiratory lung volume within 15% of the VT. E84.1	This provides an absolute and measurable definition of end-tidal stability.
If tidal breathing stability is not achieved within 10 breaths, the VC part of the maneuver may begin, but the IC will not be reliable. E84.1	For maneuvers in which stable end-expiratory tidal lung volume was not attained, IC is not reported.
There are the same plateau criteria as for FVC, and require that plateau flow is less than a 0.025-L change in volume for at least 1 second (a "plateau"). E84.2	This assures complete lung emptying.
Reporting Values	
Repeatability requirements for SVC are the same as for FVC. E84.2	This is just a reminder on selecting data to be reported.
For VC, the largest value from at least three acceptable maneuvers should be reported. E84.2	
For IC, the average value from the acceptable maneuvers should be reported. E84.2	

Updated standards are required for unattended home monitoring spirometry (128–130) and peak flow monitoring. E84.3; and Maximal voluntary ventilation maneuvers, separate peak flow maneuvers and unattended (home monitoring) spirometry are not included in these standards. SE3	This enables home spirometry measurements to be slightly less stringent than tests performed in a laboratory when taking into consideration that patients can't perform calibration on their own at home (requires spirometers that maintain stability over a long period) and many patients (particularly those with severe COPD) become too fatigued performing up to 8 measurements to attain repeatability. There are other approaches, such as Statistical Process Control that can address this requirement with home testing.[5,6]

Forced Spirometry Statements	Discussion/Explanation
Calibration verifications must be undertaken daily, or more frequently if specified by the manufacturer. E75.1	This is required before the first test of the day but should not be done between measurements on a single patient. It is only required on days when testing is being performed.
Calibration syringes must have a monthly leak test at more than one volume up to their maximum; E75.2	This is probably a procedure that many labs are not aware of. Note that calibration syringes require calibration themselves on a scheduled basis (typically every 2 years) and labs need spares with different calibration dates to cover when other syringes are out for recalibration.
Maximal inspiration after forced expiration. Upon completing the forced expiration, the patient should remain on the mouthpiece, and the operator should again coach the patient to rapidly inspire to full inflation. E77.2	If the volume of the maximal inspiration (i.e., FIVC) after EOFE is greater than FVC, then the patient did not start the maneuver from TLC. This would indicate that the FEV1 and FVC measurements would not be representative of the patient's true lung function. This also requires that the spirometer can measure inspiratory flow. Patients should be reminded to take a deeper breath after the forced exhalation if they don't breathe back to at least 90% of their FVC. This is probably the biggest change in how the measurement is performed, but also the most critical.
PEF should be achieved with a sharp rise and occur close to Time 0 as measured by the rise time from 10% to 90% of peak flow, which should be ≤150 ms but may be greater than this in a maneuver in a patient with upper airway obstruction. E78.1	Though time to peak flow is not a hard criterion, a rise time > 150 ms is often associated with a sub-maximal expiratory effort. Confirm whether this was a submaximal effort, and if so, the FEV1 and FVC should be flagged as unacceptable. SE30
Recommended procedure should include normal breathing on the spirometer before the forced maneuver. E78.T6	The benefit of a few tidal breaths before the forced maneuver is it allows the patient to settle in on the spirometer and helps prevent loss of volume and reduction in peak flow and FEV1 that can occur with spirometers brought to the mouth after maximum inhalation.
The goal is to achieve a minimum of three acceptable FEV1 and three acceptable FVC measurements. E80.3	If these criteria are not met in three maneuvers, additional trials **MUST** be attempted, up to eight maneuvers in adults, although more may be done in children. E80.3 Patients even meeting B grade repeatability should attempt up to 8 measurements to attain an A grade.
Although there may be some circumstances in which more than eight consecutive FVC maneuvers may be needed, eight is generally a practical upper limit for most adults. E81.1	More than 8 measurements can be collected if the patient is willing and able to perform more while failing to meet repeatability requirements.
Inspire completely and rapidly with a pause of <2 s at TLC. E78.T6	It is easier for a patient to transition from the inspiratory maneuver to forced exhalation without hesitation if the patient is doing quiet breaths before the maneuver.
The mean inspiratory flow of the breath just prior to forced expiration should be at least 2 L/s. SE30.1	Reductions in PEF and FEV1 have been shown when inspiration is slow. This also requires that the spirometer can measure inspiratory flow. This same flow rate requirement applies to the deep inspiration that follows the forced exhalation.
If the FEV1 from an acceptable test drops below 80% of the start value, the test procedure should be terminated in the interest of patient safety. E81.1	This is just a safety reminder.
When the first post-bronchodilator maneuver is initiated by the operator, the system must display the time elapsed since the last prebronchodilator maneuver. If the elapsed time is less than the wait time for the bronchodilator effect, then the system must provide a warning message to the operator. E81.3	This statement may reflect a limitation in spirometry systems but does not reflect what is actually required. The wait times as clarified in the Supplement, should be from the final MDI actuation (or nebulization completion) to the post bronchodilator measurement. SE32 and SE33
Reporting Values	
The largest FVC and the largest FEV1 observed from all of the acceptable values are reported (or largest usable values if none are acceptable). E81.3	This is just a reminder on selecting data to be reported.
Their ratio is used for FEV1/FVC, even though the largest FVC and the largest FEV1 may not necessarily come from the same maneuver. E81.3	
PEF is the largest value from maneuvers meeting the acceptability criteria for FEV1 that are started without hesitation from maximal lung inflation. E81.3	
The FET from the maneuver with the largest FVC is reported. E82.1	
The mean forced expiratory flow (FEF25-75) may be reported from the maneuver with the largest sum of FEV1 and FVC. E82.2	
The next two are related to plateau identification	
There is less than a 0.025-L change in volume for at least 1 second (a "plateau"). E78.2	A change of 0.025 L for 1 second requires a detectable flow down to 0.025 L/sec. Not all spirometers can record flows that low.[4]
The patient cannot expire long enough to achieve a plateau (e.g., children with high elastic recoil or patients with restrictive lung disease). In this case, the measure of whether EOFE has been reached is for the patient to repeatedly achieve the same FVC. E78.3	If the maneuver does not have a plateau and FET<15 seconds, it can provisionally meet this EOFE criterion for acceptability, subject to comparison with the FVC from subsequent maneuvers. It becomes acceptable if it is within the repeatability tolerance of, or is greater than, a subsequent FVC. Therefore, after attempting 8 efforts, repeatable FVC measurements without meeting EOFE can be considered acceptable.
Note that there is no requirement for a minimum FET. E79.1	Because the requirement for a minimum FET has been eliminated, increased vigilance by the operator and the interpreter is required in the assessment of whether expiration was complete or there was early termination. E79.3

3 Supplement to the 2019 ATS/ERS Standard: https://thoracic-prod-cdn.literatumonline.com/journals/content/ajrccm/2019/ajrccm.2019.200.issue-8/rccm.201908-1590st/20220527/suppl/graham_data_supplement.pdf?b92b4ad1b4f274c70877518516abb28bbebb6df1d1f51c8bc9fff6d7efc5c4b1197b8f7885f6e83f8abff918b19118b7db914f211897a4606c851e902f40f5a925f9f7785104fa786f868cf3aebbd88212ad756780e8d-d22b5b610d994a198ace246bac14c48d36a0576fb-933d9a3ac5188188270e74b9dcce3c1a5a7fd42a7fdf3d-b649ec36289198084ffa580d924fc8a1867f86081a4d64ec985bb63c24f00fc5
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Bedfont Scientific Ltd. "We are very impressed with their strong foothold in the respiratory market, their preceding reputation for product quality and customer support, and their commitment and enthusiasm to improving respiratory care. MGC Diagnostics is the perfect distribution partner to help us realise our goal of making FeNO monitoring more accessible globally."

MediPines Technology Now Being Used to Help Detect Pulmonary Embolism

An increasing number of physicians have been utilizing a unique gas exchange analyzer technology to enhance recognition and diagnosis of pulmonary embolism (PE) in patients. The device, called the MediPines AGM100, is an FDA-cleared advanced pulmonary gas exchange technology that can precisely and non-invasively measure patients' oxygen and carbon dioxide levels in the deepest part of the lungs (alveoli), as well as oxygen deficit (alveolar-arterial difference), which support assessment of respiratory impairment. A case study titled "*Use of a Non-Invasive Pulmonary Gas-Exchange Analyzer to Improve the Pretest Probability of Pulmonary Embolism in a Patient Classified as 'Low Risk'*" by Dylan Sieck Ph.D. and Pierre Ozon, MD was presented at the American Thoracic Society (ATS) International Conference last year. Since then, more and more clinicians and centers of excellence have been turning to the MediPines AGM100 as a diagnostic support tool to enhance recognition of PE. PE is one of the leading causes of death in the US and the third leading cause of death in hospitalized patients. Given the possibility of asymptomatic and atypical presentation, it is generally accepted that many cases of PE go undiagnosed. In the case study presented at ATS last year, the MediPines AGM100 device, a cardiopulmonary diagnostic support system, was shown to be a helpful adjunct tool in the diagnosis of PE and ideally suited to the task because of the quick and precise measurements it provides. The patient described in the case study was the first reported case of a non-invasive pulmonary gas-exchange analysis being used to improve pre-test probability of PE. Since then, more physicians have been turning to the technology as a diagnostic tool. "Having an objective measure of pulmonary gas exchange impairment can factor into the diagnosis and treatment decisions that must be made in a time sensitive manner," said Dr Pirre Ozon, an Emergency Physician, and one of the case study's authors. "The AGM100's multiple measurements including oxygen deficit measurement can be highly informative in narrowing differential diagnosis scenarios similar to this case and more research is needed to fully understand its potential." Designated by the World Health Organization (WHO) as one of 15 notably innovative and commercially available health technologies for the treatment of COVID-19 and other global priority diseases in its 2021 edition of the WHO Compendium of Innovative Health Technologies, the MediPines AGM100 is a portable system that can be used throughout hospitals or qualified health clinics.

Company Celebrates 21 Years of Clinical Trials

Vitalograph is celebrating 21 years of empowering respiratory research through clinical trials services, building on its legacy of manufacturing respiratory diagnostic devices since 1963. Team members from the UK, USA and Ireland will be marking this milestone by fundraising for local respiratory charities in support of Vitalograph's commitment to improve patient lives. "We are hugely proud of our team's dedication and innovation to drive quality across the growing range of services whilst maintaining

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MONITORED THERAPEUTICS INC

Weaning and Decannulation: Role of a No-leak Speaking Valve

Kristin King, PhD, CCC-SLP

Research demonstrates that early use of the Passy-Muir® Valve, including in-line application with mechanical ventilation, provides both pediatric and adult patients with many benefits, including augmenting and expediting ventilator weaning.[1-4] Beyond improving access to communication and allowing the patient to become a more motivated participant in treatment interventions for weaning and recovery, use of the Passy-Muir Valve re-establishes a closed aerodigestive system and restores physiologic positive end-expiratory pressure (PEEP), which improves oxygenation and may lead to reduced need for ventilatory support and tracheostomy.[1,6]

A study by Sutt et al. (2016) investigated use of the Passy-Muir Valve with adult cardiothoracic patients undergoing ventilator weaning in the ICU.[1] The study evaluated end expiratory lung impedance (EELI) and standard bedside respiratory parameters of these patients, before, during, and after use of a Passy-Muir Speaking Valve both in-line with mechanical ventilation and with high flow t-piece. An increase in EELI was observed following use of the Passy-Muir Valve and was maintained for at least 15 minutes following removal. Maintenance following removal of the Passy-Muir Valve was limited by the time constraints of the study, which allowed for 15 minutes of post-Valve monitoring only. Speaking valve use resulted in a reduced respiratory rate, reduced end-tidal carbon dioxide, and improved lung volumes.[1]

Benefits of Early Intervention

Additional research has shown that early intervention with use of a Passy-Muir Valve improves overall patient psychological well-being and assists with improving ventilator requirements for respiratory function. With the improved lung recruitment, patients demonstrated improved oxygenation when using the Valve. Weaning times also were found to be shortened with the implementation of a multi-disciplinary team, including a speech-language pathologist as a team member to increase use of the Passy-Muir Valve to facilitate communication and upper airway use.[7]

Kristin King, PhD, CCC-SLP: With 25 years of experience in medical, academic, and industry settings, Dr. King brings a unique perspective of medical speech pathology. Her research, publications, and teachings focus on traumatic brain injury, swallowing disorders, and critical care (tracheostomy and mechanical ventilation) for both pediatric and adult patient populations. She has been an invited speaker both domestically and internationally and has published in peer-reviewed journals. Currently, Dr. King is the Vice President of Clinical Education and Research for Passy-Muir, Inc.

Another study investigated the role of PEEP monitoring for weaning a patient from mechanical ventilation to tracheostomy (trach) collar.[6] Initially, the patients did not do well transitioning from a set PEEP on the ventilator to tracheostomy collar, with presumed zero-PEEP, due to the open tracheostomy tube. The protocol was changed to require the Passy-Muir Valve, a bias-closed, no-leak design, be used prior to transition to trach collar, and that the Passy-Muir Valve be used while on trach collar. The authors reported greater success with weaning and improved overall respiratory status when using the Passy-Muir Valve as a part of the weaning protocol.[6] This improved efficiency was attributed to restoring a closed system and more normal physiologic PEEP with use of the Passy-Muir Valve.[6]

In response to the COVID-19 pandemic, a group developed a new protocol that would address tracheostomy needs in their tracheotomy ward. The new protocols for treatment of patients with tracheostomy included use of the Passy-Muir Valve during the progression for ventilator weaning and return to oral diet.[8] The Passy-Muir Valve was implemented as part of the protocol, with use of a fenestrated tracheostomy tube and deflated cuff. Using this protocol, all 50 patients in the tracheotomy ward in this study were successfully weaned from mechanical ventilation and returned to an oral diet prior to discharge or transfer.[8]

Using the Valve as part of an established multidisciplinary approach to treating patients requiring mechanical ventilation may further assist with weaning outcomes. In a study by Black et al. (2012), the authors report on the implementation of a long-term weaning protocol in an intensive care unit (ICU) at a university teaching hospital in London, UK. This protocol included establishment of a multidisciplinary team with a physiotherapist, nurse consultant, dietician, and speech and language therapist. The findings following implementation of this protocol were that with use of speaking valves, they had improvement in ICU and hospital survival.[8] They also reported that the time requiring mechanical ventilation was reduced by an average of 11 days.

Another Consideration: Decannulation

For decannulation, most teams and physicians opt for occluding the tracheostomy tube with a cap. This cap covers the proximal end of the tracheostomy tube and blocks air from entering or exiting the tracheostomy tube, which forces the patient to inhale and exhale through their nose and mouth. The Passy-Muir Valve is a bias-closed position, no-leak valve that is also placed on the proximal end of the tracheostomy tube. However, unlike a

Use of the Passy-Muir Valve in-line with mechanical ventilation to assist with weaning. Photo submitted.

cap, the Passy-Muir Valve opens during inhalation and returns to the closed resting position during exhalation. This closure occurs to redirect airflow out through the upper airway, vocal folds, mouth, and nose. The Passy-Muir Valve can be used as an alternative to tracheal tube plugging/capping for patients who cannot tolerate the plugging/capping due to physiologic or emotional reasons. If a patient is only tolerating capping for short periods of time or not at all, the Valve may be used in the interim (between plugging/capping trials) as a step to assist the patient's transition from an open tracheostomy tube to trach tube capping. The Valve assists in the tracheostomy decannulation process by allowing the patient to begin adjusting to a more normal breathing pattern through the upper airway on exhalation. This allows the patient to gain confidence and the physician to assess for airway patency.

A patient must have a patent airway to use a cap or a Passy-Muir Valve. Some patients may find that capping increases the work of breathing since they are inhaling and exhaling around a tracheostomy tube to the mouth and nose. With use of a Passy-Muir Valve, the patient may experience less work of breathing and perhaps, less anxiety. Timing of Valve placement and use of capping versus Passy-Muir Valve in decannulation pathways vary. Martin et al. (2021) found that placement of a Passy-Muir Valve within 24 hours after a percutaneous tracheotomy led to faster decannulation than when Valves were placed greater than 48 hours after tracheotomy.[8]

Dubin et al. (2021) conducted a prospective, observational cohort study to investigate patient goals and functional outcomes for patients in a long-term care hospital. They found that 18-22% percent of the patients reported anxiety and depression.[9] When asked about their goals, the patients rated eating/drinking and speech as their top priorities. The Passy-Muir Valve was evaluated at the time of the swallowing evaluation and 92% of the patients achieved verbal communication.[9] The authors concluded that restoring speech was critical to patient recovery and to reduce anxiety. With reduced anxiety, patients progress faster towards decannulation.

Rathburn and Imber (2019) reported on a patient with stiff person syndrome who had extreme anxiety at the introduction of capping trials with the tracheostomy. Anxiety induced muscle spasms and led to acute hypoxic respiratory failure.[10] Anxiety to capping trials is often described as occurring due to the fear of not being able to breathe. Because of the difference in how breathing occurs with capping as compared to a Passy-Muir Valve, interim use of the Valve may reduce anxiety since there is not a sudden and drastic change in breathing pathways.

Maslan et al. (2017) conducted a retrospective study to investigate decannulation process and to identify successful steps for pediatric patients with chronic tracheostomy. The authors reported that 13% of the patients did not tolerate capping due to anxiety or age.[11] Most patients were decannulated after use of the both the Passy-Muir Valve and daytime capping. Of those patients with whom age was an issue, the authors reported that the child was six months old and too young to tolerate capping. It also was reported that Passy-Muir Valve use occurred prior to capping as a means of transitioning the patients towards capping and lower anxiety. Another procedure undertaken with anxiety was to conduct endoscopy during the sleep study. This allowed assessment for obstruction or other anatomical factors that may be impacting breathing and causing anxiety.

Summary

Anxiety with a change in respiration is common, even more so when a tracheostomy tube is capped. For the purposes of this discussion, this step, use of a Passy-Muir Valve, would be beneficial for the patient population with tracheostomies, and especially anxiety, due to how it works with the patient's breathing, allowing them to continue to breathe in through the Passy-Muir Valve and tracheostomy tube. These are typically steps in a decannulation protocol with the goal being removal of the tracheostomy tube. Some facilities use the Passy-Muir Valve as their marker for timing of decannulation.

Among its many benefits, placing the Passy-Muir Valve for patients with tracheostomy and mechanical ventilation, assists with weaning and decannulation. Research supports use of the Valve as part of a weaning program to wean patients off the ventilator. It also demonstrates that use of the Passy-Muir Valve leads to faster weaning from tracheostomy (decannulation) in both the pediatric and adult patient populations.

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a focus on sponsor and protocol-specific requirements. I am delighted that this is evidenced by excellent quality outcomes, returning customers and positive site feedback. Our ongoing mission is to improve patient lives through the delivery of clinical trial respiratory endpoints for the world's leading pharmaceutical companies," said Richard James, Clinical Trials Director. Vitalograph's Clinical Trials division offers expert clinical, project, and data management services along with their innovative device solutions, delivered by experienced teams who are known for their friendly, customer-centric approach. Vitalograph specialises in electronic data capture of physiological respiratory measures and eCOA, along with further endpoints commonly used in respiratory studies such as blood pressure and ECG. Through strategic investment in research and development of respiratory diagnostic products, Vitalograph offers ground-breaking data collection systems for clinical trials. Two such systems are VitaloJAK, a validated cough monitoring system for measuring objective cough frequency in commercial clinical trials, and In2itive e-Diary for collecting home ePRO and physiological respiratory measurements. As it looks to the future, Vitalograph is committed to continuing to deliver expert study services and to design unique respiratory diagnostic solutions that are validated, accurate and tailored to meet the needs of each clinical trial.

Study Shows Effectiveness in Treating Asthmas

A greater proportion of patients with severe, uncontrolled asthma had more significant clinical responses to tezepelumab than placebo, according to research published at the ATS 2022 international conference. The study showed that nearly half of those enrolled achieved complete response to treatment across measures of exacerbation reduction, asthma control, lung function, and clinician assessment. The study is a prespecified on-treatment analysis of responses to tezepelumab using data from the completed phase 3, double-blind, placebo-controlled NAVIGATOR trial (NCT03347279). Results of the trial were presented at ATS 2021 and published in a peer-reviewed medical journal. "Overall, these results align with the NAVIGATOR results reported at ATS 2021 and add an important patient-level perspective to the primary study results," said presenting author Njira Lugogo, MD, associate professor of internal medicine as well as medical director, Michigan Clinical Research Unit and director, Asthma Program, Division of Pulmonary and Critical Care Medicine, University of Michigan, Ann Arbor. "Across each measure, tezepelumab recipients were more likely to have a response; the greatest difference observed was for exacerbation reduction. In addition, 48 percent of patients receiving tezepelumab had a complete response and achieved significant and clinically relevant improvements in all four response measures." Both the tezepelumab and placebo patients continued to take their medium- or high-dose corticosteroid inhalers and at least one other asthma-control medication during the study. Four-hundred seventy-one patients receiving tezepelumab and 449 receiving placebo completed the on-treatment period and were included in the analysis. Across response criteria, the proportion of responders was higher in the tezepelumab than in the placebo group for exacerbation reduction (85.4 percent vs. 67.5 percent); Asthma Control Questionnaire (ACQ)-6 total score (86.9 percent vs. 76.6 percent); an improvement from baseline pre-bronchodilator forced expiratory volume in one second (FEV_1) (60.3 percent vs. 49.9 percent); and in Clinical Global Impression of Change (CGI-C) score (81.5 percent vs.
Continued on page 68…

Protective Lung Ventilation in Acute Hypoxemic Respiratory Failure

Marcelo Beraldo, PT, PhD and Mark Rogers, RCP, RRT, FAARC

Introduction

The focus of this white paper is on how to use a ventilator's recruitment tools to apply Protective Lung Ventilation (PLV) for a patient in acute hypoxemic respiratory failure (AHRF). These include recruitment maneuvers (RM), decremental PEEP titration (PEEP-T), and assessment of lung recruitability (RA) at the bedside using the NKV-550 Ventilator.

Protective Lung Ventilation is an approach to ventilation that adheres to the safety limits of lung mechanics to limit the mechanical stresses created by the massive alveolar collapse and cyclic lung reopening and overdistention during mechanical ventilation.[1,2,3] However, this approach challenges many clinicians, and its application requires substantial knowledge of mechanical ventilation. Specific features on ventilators can be used by clinicians to improve safety and outcomes, minimizing challenges at the bedside.[4]

The Pressure – Volume Curve of the Respiratory System

Figure 1 illustrates the pressure – volume curve of the respiratory system. It is important to note several aspects of this curve to understand why an RM, when indicated, should precede the setting of PEEP and why PEEP should be set by decremental trial.

First, note that there is a widening between the inflation and deflation limbs of the curve. This "widening" is called hysteresis. The distance between the two limbs widens with the progression of a disease process.

Second, on the inflation limb, there are generally two inflection points. The lower inflection point indicates the beginning of recruitment and shows a compliance increase. The upper inflection point indicates the beginning of overdistension and shows a compliance decrease.

Third, in general, the higher the pressure, the greater the lung volume recruited.

The most critical thing to note from this curve is that different PEEP settings will likely result in a different lung volume and functional lung size.

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As observed in Figure 1, for the same pressure, lung volume will be greater on the deflation limb than on the inflation limb. That is, the same amount of PEEP results in different end-expiratory lung volumes and different functional lung sizes depending on how the PEEP level is set.[5]

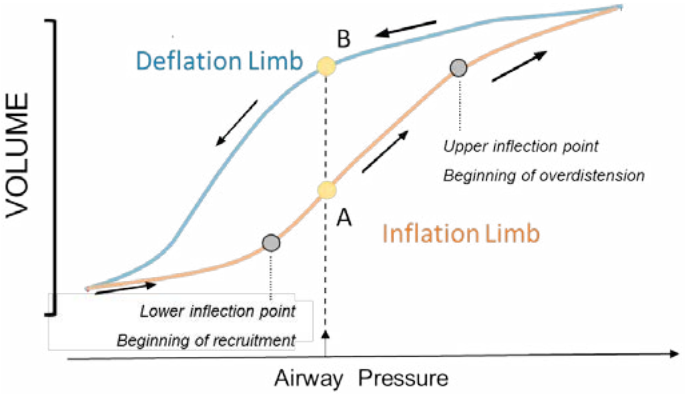

Figure 1. Pressure Volume Curve

Lung Recruitment and the Setting of PEEP

The goal of performing an RM is to open collapsed alveoli. In a stepwise RM, PEEP is increased in defined steps during pressure control ventilation (PCV). The PCV breaths are delivered with a fixed pressure control level (driving pressure) to a predetermined maximum peak pressure level. For adults, the pressure control level is typically set between 10 to 15 cmH2O, and the maximum peak inspiratory pressure is between 40 and 50 cmH2O, dependent upon the patient.[5,6,7] Normally, the RM starts at the current PEEP setting, and PEEP is subsequently increased by 3 to 5 cmH2O every 30 to 60s. The respiratory rate is typically set to 10 to 20 breaths per minute, with an I:E ratio of 1:1, and a FiO2 setting of 1.0. After the maximum peak inspiratory pressure is met, the patient typically continues to be ventilated at that level for one minute, then a PEEP titration is performed.

Figure 2 illustrates the Setup screen of the Nihon Kohden NKV-550 ventilator's automated recruitment maneuver (RM) app. The RM app simplifies the performing of a bedside RM by a clinician. From the Setup screen, the clinician sets the maximum inspiratory pressure, the size and time of the PEEP steps, the pressure control level (driving pressure), I:E ratio, respiratory rate, and FiO2.

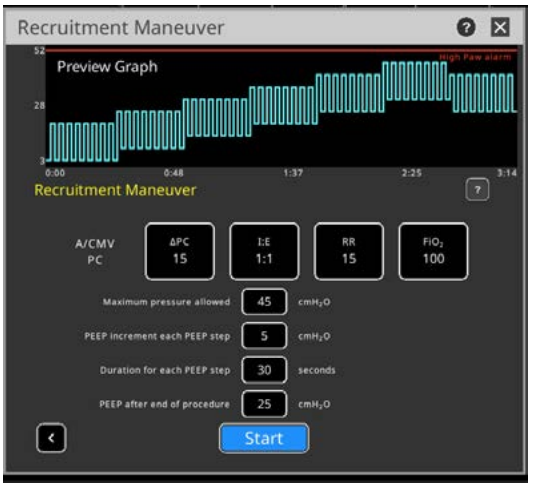

Figure 2. Recruitment Maneuver App: Startup screen

Figure 3 illustrates the initial activation of the RM app.

Figure 3. Recruitment Maneuver App: Execution in Progress

Figure 4 illustrates a completed RM.

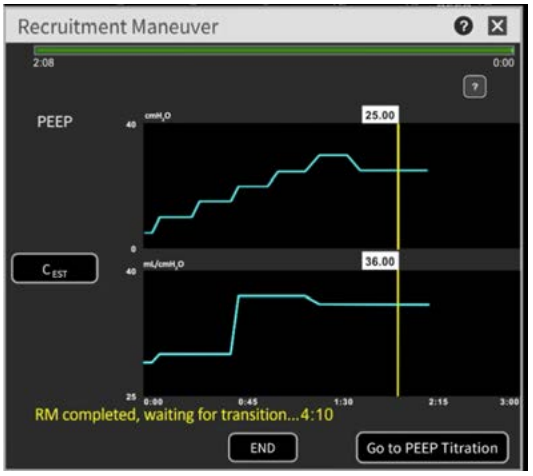

Figure 4. Recruitment Maneuver App: Result Screen

The goal of PEEP titration is to identify the PEEP setting that will result in the best compliance. PEEP titration is a stepwise decrease in PEEP resulting in the decremental respiratory system compliance curve. Generally, PEEP is decreased by 2 cmH2O until the PEEP at best compliance can be identified.

Figure 5 illustrates the Setup screen of the NKV-550's automated PEEP titration (PEEP-T) app. The PEEP-T app simplifies the performing of a bedside PEEP titration by a clinician. From the Startup screen, the clinician sets the starting and ending PEEP, PEEP decrement, and duration of each step. This is typically performed in the volume control mode so that dynamic respiratory system compliance can be easily calculated by the ventilator breath by breath.

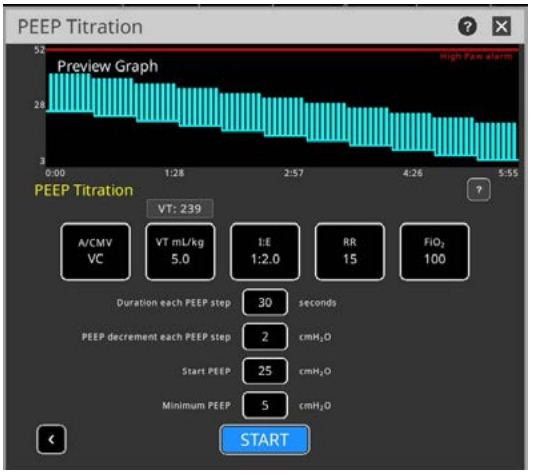

Figure 5. PEEP Titration App: Startup Screen

Figure 6 illustrates the initial activation of the PEEP-T app.

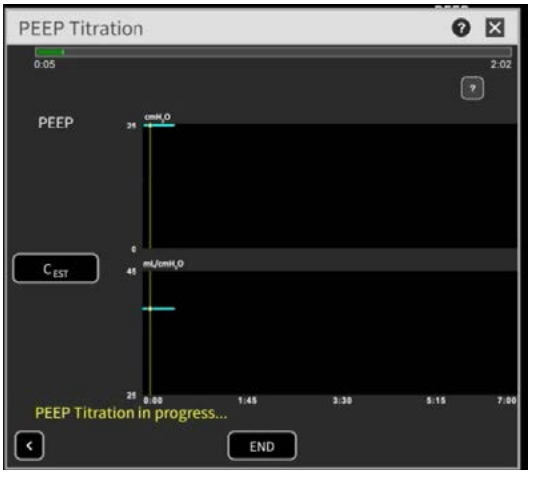

Figure 6. PEEP Titration App: Execution in Progress

Figure 7 illustrates a completed PEEP titration with the identification of the PEEP at best compliance.

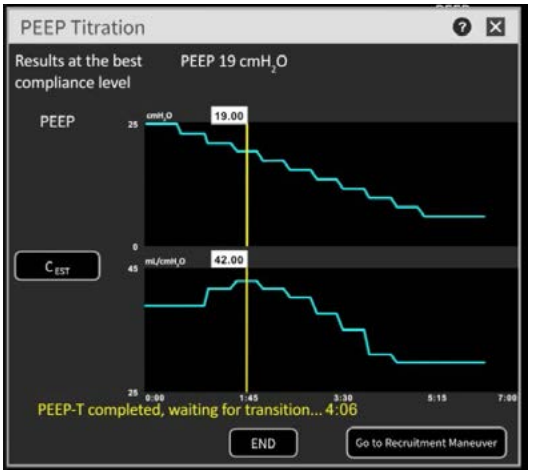

Figure 7. PEEP Titration App: Result Screen

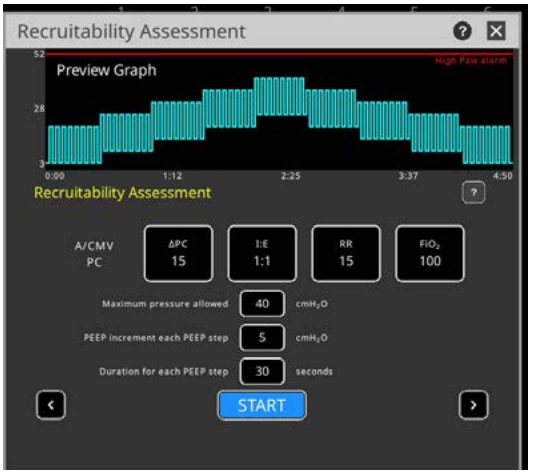

Figure 8. Recruitability Assessment App: Startup Screen

Following a PEEP titration, the RM should be repeated to regain the volume lost due to derecruitment that may have occurred during the PEEP-T. After completion of the RM, PEEP can then be set to the level identified by the PEEP-T. It should be noted that some institutions add 2 or 3 cmH2O to the PEEP identified by the PEEP-T maneuver to address the nonhomogeneous areas of the lung.[6,7]

Patients undergoing an RM and PEEP-T should be hemodynamically stable, sedated to apnea, receiving 100% oxygen, and have no indications of preexisting barotrauma or a history/presentation that would increase the likelihood of barotrauma. It should be noted that performing an RM and PEEP-T is not without risk. With this in mind, it would be helpful for the clinician to be able to predict the recruitability of the patient's lungs.

How to Predict Lung Recruitability

As indicated above, the two major concerns regarding performing RM's are hemodynamic instability and the development of barotrauma. As a result, RMs should only be applied to patients with recruitable lungs.

Recruitability[8] can be assessed by an abbreviated maneuver (short incremental PEEP step followed by a paired decremental PEEP step), where the clinician can assess the lung compliance behavior. Studies suggest that if there is a gain in compliance of 50% or more, the lungs are considered recruitable.[4,9] If compliance decreased or had a nominal gain, the lungs are considered not recruitable.

When the recruitability is low, the likelihood for an RM to be successful is very low[9,10] and the probability of hemodynamic compromise is very high.[6,7]

The NKV-550 has a unique recruitability tool called Recruitment Assessment (RA). Figure 8 illustrates the setup screen for the automated RA app. The clinician sets the pressure control level, I:E ratio, respiratory rate, and FiO2. In addition, the clinician also sets the maximum airway pressure, as well as the PEEP increment and duration of each step.

Figure 9 illustrates the RA app in progress. Upon completion of the assessment, the NKV-550 displays the recruitable volume and the gain in compliance (see Figure 10). In any patient where there is a question regarding recruitability, an assessment of recruitability should be performed before an RM.

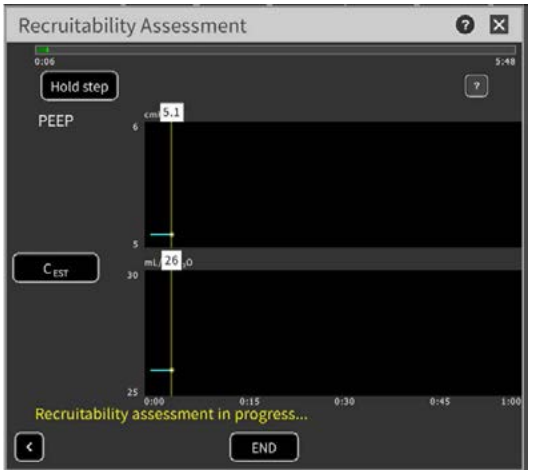

Figure 9. Recruitability Assessment App: Execution in Progress

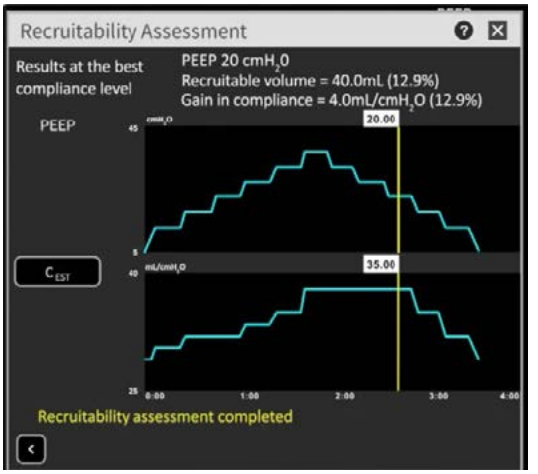

Figure 10. Recruitability Assessment App: Result Screen

Other Methods to Determine Ideal PEEP Level

Below are various methods that have been advocated to determine the optimal PEEP setting.

Suggested flow of process

ARDSnet table: This table combines PEEP and FiO2 levels that a panel of experts[1] considered appropriate when managing patients with AHRF.[1] Essentially, the table alternates increasing PEEP with increasing FiO2. However, this approach is not based on the individual patient's pathophysiology, but is simply a method of alternating increasing PEEP and FiO2 in response to blood oxygen levels (PaO2 or SpO2). Moreover, an RM is never associated with the use of this table. This approach is best suitable at the time of initiation of mechanical ventilation but is not the best approach for selecting the ideal PEEP level in AHRF.

Best Incremental PEEP Trial:[11,12] This approach has been used by many institutions for determining the setting of PEEP. The method involves a step-wise

Suggested flow of the process

increase in PEEP over time while maintaining a fixed Pressure Control level (driving pressure). The step that results in the highest compliance was thought to represent the best PEEP level. However, this approach does not take into account lung hysteresis (see Figure 1) and may underestimate where PEEP should be set to achieve the best lung volume and compliance.

Best Decremental PEEP without lung recruitment: This approach begins with ventilating at a higher PEEP level, followed by a step-wise decrease in PEEP while continuing ventilation. The step that resulted in the highest compliance was thought to represent the best PEEP level. However, this approach also does not take into account lung hysteresis (see Figure 1) and may underestimate where PEEP should be set to maintain the best compliance.

Esophageal Manometry: Figure 11 illustrates the relationship between pleural pressure and alveolar pressure and the calculation of transpulmonary pressure (alveolar pressure minus pleural pressure). Clinically, airway pressure estimates alveolar pressure during a hold maneuver when there is no flow. Esophageal pressure estimates plural pressure.

Direct measurement of pleural pressure is not clinically possible, but indirect measurement is accomplished using an esophageal balloon attached to a pressure transducer. Proper placement of the esophageal catheter and inflation of the esophageal balloon provides esophageal pressure (Pes), which is an indirect measurement of the pleural pressure. Esophageal pressure can be used to calculate transpulmonary pressure as shown in the equation in Figure 11.

Figure 11-A illustrates the normal relationship between pleural pressure and alveolar pressure. During normal breathing, pleural pressure at end exhalation is always negative, thus the transpulmonary pressure is always positive keeping the alveoli are stable and open. A positive end-expiratory transpulmonary pressure stabilizes alveoli and avoids alveolar collapse at end exhalation. Figure 11-B depicts the relationship between alveolar pressure and pleural pressure in AHRF. Regardless of the cause (e.g., pneumonia, atelectasis, obesity, ARDS, etc.), lung injury results in an increase in pleural pressure sometimes as high as positive 20 cmH2O. If alveolar pressure is still zero at end exhalation transpulmonary pressure becomes negative (0 cmH2O – 20 cmH2O = -20 cmH2O), resulting in alveolar collapse. Regardless of the approach to setting PEEP, the goal should be a positive end-expiratory transpulmonary pressure of about 1 to 3 cmH2O.[13,14]

Figure 11-C depicts the application of PEEP sufficient to overcome the increased pleural pressure and reestablish a positive end-expiratory transpulmonary pressure.

The challenge with esophageal manometry is that considerable expertise is required for the proper placement of the esophageal catheter and the interpretation of the resulting pressure waveform.

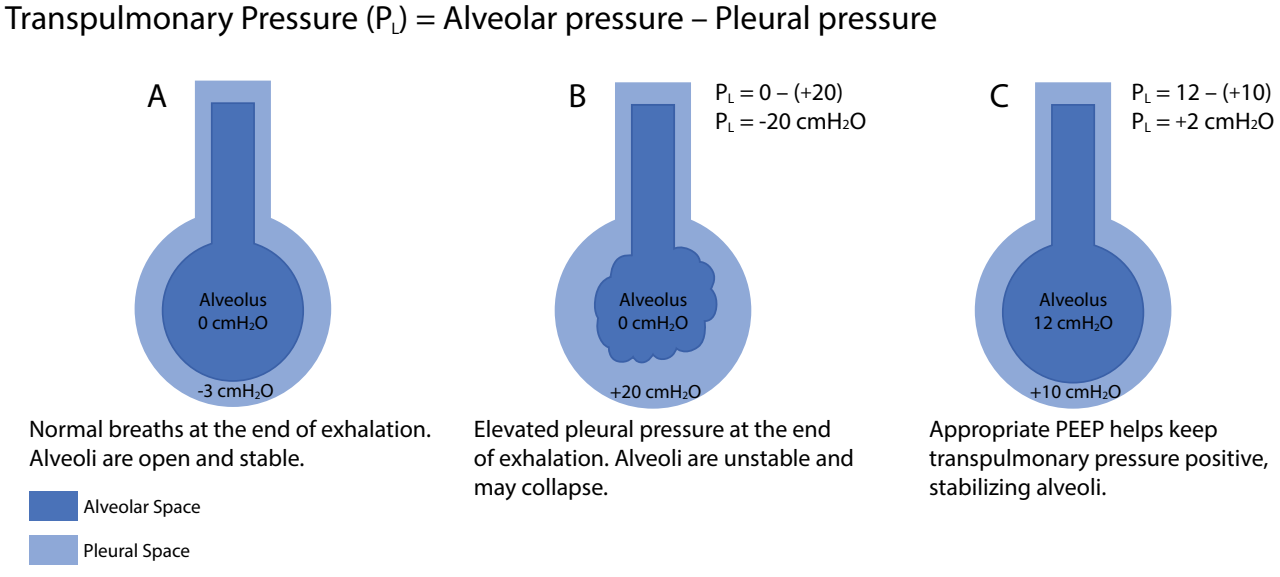

Figure 11. Relationship between pleural and alveolar pressures and the calculation of transpulmonary pressure

Figure 12 illustrates the transpulmonary pressure app in progress.

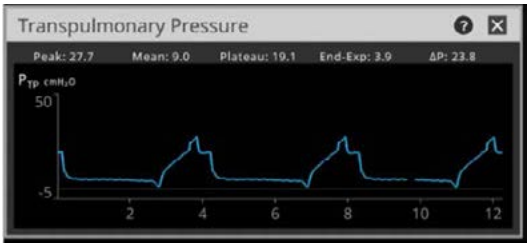

Figure 12. Transpulmonary Pressure App: Execution in Progress

Electrical Impedance Tomography (EIT): EIT is another method of identifying the ideal PEEP level post RM. EIT is a noninvasive, nonradioactive, portable imaging technique that can be used at the beside for intermittent or continuous monitoring of lung volume. This allows the visualization of the percentage of the lung that is collapsed and/or overinflated.[15]

Figure 13 depicts the PEEP selection screen. With this method, the ideal PEEP results in the least collapse and least overdistention.

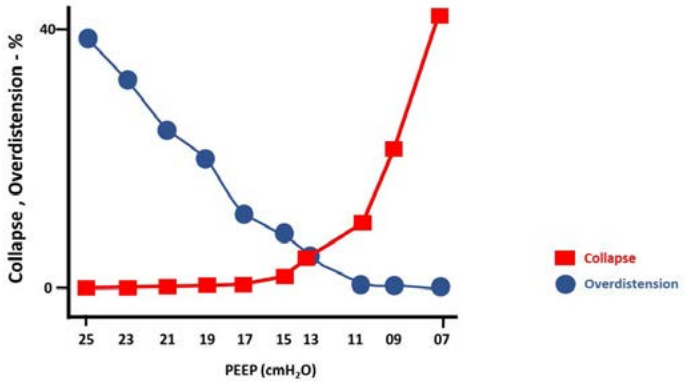

Figure 13. Relationship between collapse and overdistension lung tissue by EIT

Management of PEEP post RM and PEEP-T

Repeat Recruitment Maneuver: The frequency of repeated RM's is dependent on the patient's response.

In many patients, only one RM is necessary, while in others, daily RMs and reassessment of PEEP-T are needed. If the RM is successful (improved compliance and oxygenation) and the patient's status is constant or improving, there is no need to repeat the RM.

Some patients respond very well to the RM and PEEP-T and their status continues to improve over time. For these patients, repeat RM's are not necessary. However, in patients where improvement was marginal but the patient tolerated the RM without complications, the daily performance of the RM and PEEP-T is ideal. These types of patients will often show daily incremental improvement.

Many patients will require a repeat RM because of inadvertent disconnection of the ventilator circuit, as lung derecruitment occurs almost immediately. As a result, the lung will need to be re-recruited. In most cases, PEEP-T will not need to be repeated if there was no change in the status of the lung.

Weaning of PEEP: After the PEEP level identified by the RM and PEEP-T is established, PEEP is generally not altered for at least 24 hours. This allows time for the lung to stabilize and heal. When the decision to reduce PEEP is made, PEEP should only be reduced in 2 cmH2O increments every 8 hours.[6] A rapid decrease in PEEP will often result in derecruitment. If after decreasing PEEP the compliance and oxygenation decrease, the lung has likely derecruited and the prior PEEP should be reestablished following an RM.

Summary

The goal of the application of PLV in AHRF is to keep the ventilation and lungs as homogeneous (low cyclic lung reopening and overdistention) as possible. The use of an esophageal balloon or electrical impedance tomography results in the same PEEP level as performing an RM and PEEP-T. The RA, RM, and, PEEP-T apps in the NKV-550 provides tools for clinicians to apply a standardized approach to assess the patient's recruitability and determine what PEEP setting will result in a more homogeneous lung (PEEP at the best compliance). An RM may need to be applied daily if the patient has not responded well to the RM and PEEP-T. Weaning of PEEP should not occur for at least 24 hours and when decreased, should NOT result in derecruitment of the lung. A good guideline is to reduce PEEP no more than 2 cmH2O every 8 hours.[6]

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67.7 percent). The proportion of complete responders (those who achieved significant improvement on all measures) was higher in the tezepelumab group that in the placebo cohort (48.2 percent vs. 25.3 percent). Tezepelumab is a biologic — a medical treatment made from living cells. Dr Lugogo stated, "Responses to biologics in asthma are heterogenous and the impact of biologics on key asthma outcomes can vary between patients. We were interested in determining the impact of tezepelumab on the four clinical outcomes of most interest, which included exacerbation reduction, improvement in symptoms and lung function, and the treating clinician's impression of whether clinical improvement had occurred. There is increased interest in defining responses in patients with severe asthma on biologics. In this study, we identified both responses in each measure and combined responses overall." She also noted that these results can be used in shared decision making when discussing the start of tezepelumab therapy. "Patients are always interested in understanding the potential outcomes following therapy initiation and our results can guide clinicians in informing patients about the likelihood of both individual and complete response to therapy." This study was supported by AstraZeneca and AMGEN. Dr Lugogo has served on advisory boards for AstraZeneca and AMGEN and as a consultant for AstraZeneca. She has given talks sponsored by AstraZeneca, using her own content.

Inhaled Corticosteroid Shows Significant Impact

Full results from the positive MANDALA Phase III trial showed that PT027 (albuterol/budesonide) at two different strengths of budesonide, an inhaled corticosteroid (ICS), used as an as-needed rescue medicine, demonstrated a statistically significant reduction in the risk of a severe exacerbation versus albuterol rescue in patients with moderate to severe asthma. PT027 is a potential first-in-class inhaled, fixed-dose combination rescue medication containing albuterol, a short-acting beta2-agonist (SABA), and budesonide in the US. It is being developed by AstraZeneca and Avillion. Globally, more than 176 million asthma attacks are experienced each year. Compared with albuterol rescue, PT027 at the 180mcg albuterol/160mcg budesonide dose reduced the risk of a severe exacerbation by 27% ($p<0.001$) in adults and adolescents. In the trial, patients were randomized to receive PT027 or albuterol rescue, on top of their usually prescribed maintenance ICS, with or without additional controller medicines. In secondary endpoints, PT027 (180mcg albuterol/160mcg budesonide) demonstrated a 33% reduction in mean annualized total systemic corticosteroid exposure ($p=0.002$) and a 24% reduction in annualized severe exacerbation rate ($p=0.008$). A numerically higher odds of patients experiencing an improvement in symptom control and quality of life was also observed after 24 weeks of treatment with PT027 compared to albuterol rescue. Adverse events (AEs) were similar across the treatment groups in the trial and consistent with the known safety profiles of the individual components, with the most common AEs including nasopharyngitis and headache. Bradley E. Chipps, Past President of the American College of Allergy, Asthma & Immunology and Medical Director of Capital Allergy & Respiratory Disease Center in Sacramento, US, said: "The MANDALA Phase III trial results demonstrated that PT027, a novel fixed-dose combination of albuterol/budesonide used as-needed, provided additional anti-inflammatory treatment in response to patient symptoms, which led to a reduced risk of severe exacerbations compared with albuterol alone.
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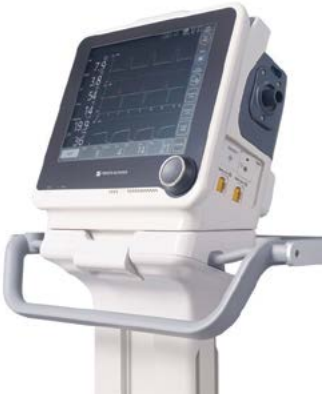

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Let's Talk Cough: Managing Patient Secretions

Gretchen Savage, RRT

As a Respiratory Therapist we spend most of our days managing a high volume of patient and administrative assignments. Today, with the shortage of RTs, those assignments are larger than ever, and prioritizing care is a necessity to manage the case load. Managing the respiratory patient can be complex and success depends on several factors. In this article we will discuss the importance of one of those factors, secretion management. Many people don't know that the average, healthy adult produces 10-100ml of secretions a day. Imagine the individual with an artificial airway, lung disease or an inflammatory response as seen in COVID-19—all of these disease states equate to increased secretions, which can result in poor patient health outcomes and quality of life.

Our natural lung defense is comprised of anatomical barriers, immune mechanisms, aerodynamic changes, mucocilliary clearance and cough. Cough, defined as a powerful physiological mechanism that protects the airways and lungs from aspiration, inhaled irritants, clears the air spaces of accumulated secretions and is a defense mechanism required to maintain the health of our lungs and is vital for secretion clearance. The physiological mechanism of cough can be divided into three phases:

- **Inspiratory Phase:** which generates the volume necessary for an effective cough
- **Compression Phase:** where closure of the glottis combined with contraction of chest, abdominal muscles, and diaphragm result in a rapid rise in intrathoracic pressure
- **Expiratory Phase:** the glottis opens, resulting in high expiratory airflow, these high flows dislodge secretions from the airways

This physiological reflex is the result of stimulation of the nerves associated with cough, known as the "Complex Reflex Arc" Impulses from stimulated cough receptors traverse an afferent pathway via the Vagus nerve to the cough center in the Medulla, the cough center generates an efferent signal that travels down the Vagus, Phrenic and Spinal motor nerves to the expiratory musculature to produce the cough.

Cough expiratory airflow can be measured via spirometry and is known as the peak cough flow; the average healthy adult range is 260-840 L/min. Evidence shows, peak cough flows >160 L/min is sufficient for airway clearance. A typical inspiration before cough reaches 80 to 90% of vital capacity, and a vital capacity >50% is needed for an effective cough. As respiratory therapist, we rely heavily on suctioning to clear the airways of secretions. However, Individuals with weak or impaired inspiratory and or expiratory muscles, with or without glottic closure issues as seen in bulbar insufficiency or with the presence of an artificial airway, will have a decreased cough reflex. Decreased or absent cough reflex will cause an increase in secretions, infections, alteration in normal VQ ratio, excessive muscle labor with risk of muscle fatigue and most importantly is a major cause of death. Today, 90% of episodes of respiratory failure in patients with muscular dystrophy is caused by an ineffective cough. That statistic alone, we should question "Why today is this still an issue with all the technology we have at our disposal?"

As respiratory therapist we can assist patients with secretion management and improve patient health outcomes by the implementation of airway clearance therapies (ACT). ACT, also known as Cough Augmentation, is designed to imitate the cough reflex, by utilizing a physical or mechanical means to manipulate air flow, aiding in the mobilization and evacuation of tracheal bronchial secretions. Commonly used airway techniques are:

- Chest Physiotherapy – CPT
- Forced exhalation technique – FET
- High-Frequency chest wall compression – HFCWC
- Intrapulmonary percussive ventilation – IPV
- Positive expiratory pressure – PEP
- Mechanical insufflation – exsufflation – MI-E (cough assist or cough therapy)

Airway clearance techniques are very effective in maintaining the health of individuals with a weak or impaired cough reflex and early intervention is important to reduce the number of lung infections, hospitalizations and most importantly reduce the number of deaths. Although airway clearance techniques offer health benefits, they come with challenges, i.e., adherence, tolerance, cost, time and need for a caregiver. A trained caregiver, time to perform the therapy, and the cost associated with purchasing devices, are not only challenges for the home patient, but applies to hospital and long-term care facilities as well, these three factors can affect adherence.

Although we have several airway clearance therapies at our disposal; Mechanical insufflation-exsufflation (MI-E) is one I would like to discuss in greater detail. MI-E or as some refer to as cough therapy, was introduced in the early 1950's as a method for improving cough and has been found to have health and lifestyle benefits when used regularly in both the home and

Gretchen Savage, RRT, is currently a Clinical Sales Trainer for Ventec Life Systems, which was recently acquired by React Health.

hospital environment. The mechanism of operation for a cough device works by delivering a deep inspiration (insufflation) to the lungs, followed immediately by expiration (exsufflation) by applying positive and negative pressures. Typical settings include inspiratory, expiratory and pause times, referred to as the cough cycle and inspiratory (positive) and expiratory (negative) pressure settings. The max pressures administered are intended to reach an intrapulmonary volume of close to 70% of the patient's vital capacity. The rapid switch from positive to negative pressures aims to simulate the airflow changes that occur during a normal cough, assisting with secretion clearance.

In the 1960's cough therapy was replaced with tracheal intubation, invasive positive pressure ventilation and airway suctioning. Endotracheal suctioning has become the standard of care; however, the amount of secretions removed from the peripheral airway is marginal and increased suctioning can lead to the risk of: Alveolar collapse, tracheal mucosa injury, and respiratory-hemodynamic impairment. In the 1980's cough therapy was resurrected for the use in patients with neuromuscular weakness. Fast forward to 2022, cough devices have advanced to become more than a positive-negative pressure device. Cough devices today are smaller, portable, and incorporate additional features designed to benefit individual patient needs. Outlined below are a few cough devices and their features:

Hillrom – Synclara Cough System: Portable, lightweight, and battery. Offers, PAP on pause, providing resting positive airway pressure between cough cycles. Synchrony, advanced tech adjusts the cough cycle to breathing pattern.

ABM – BiWaze Cough: Portable, lightweight (<9 lbs.), battery (up to 2 hours), has two blowers separating inhale and exhale air flow to ensure the inhaled air is not contaminated with mucus, auto mode, oscillation, and positive pressure flow during pause phase, creating a higher mean airway pressure which keeps functional residual capacity post exhale.

Philips – T70: Portable, lightweight, battery available, features Cough-Trak: pressure delivery sequence is synchronized with the patient's effort and Oscillation which can be set in both cough cycles (insufflation and exsufflation).

Ventec Life Systems – VOCSN: Portable, battery up to 9 hours, offers integrated therapies to include, a critical care ventilator, oxygen concentrator, cough assist, suction, and nebulizer. Mechanical cough therapy is delivered at the touch of a button, utilizing the same circuit, and with Breath Sync feature cough synchronizes with patients breathing effort, your patient can go from ventilating to cough, back to ventilating without missing a breath. Additionally, during cough therapy, suction can run simultaneously to assist with secretion clearance. The system is designed to reduce the gaps in ventilation, decrease the risk of patient misconnection, and minimize exposure to the patient's airway.

Cough therapy has been found to have health and lifestyle benefits when used regularly, no matter the shape, size, or features. We tend to think of cough devices as a treatment for the home neuromuscular patient; it is also indicated for spinal cord injuries, thoracic diseases, restrictive disorders with incapacity to perform diaphragmatic movements, traumatism or post-operative period of thoracoabdominal/abdominal surgery and prolonged mechanical ventilation. Studies have shown, patients admitted to an ICU with prolonged mechanical ventilation develop conditions comparable to neuromuscular diseases in terms of muscle weakness, atrophy, and fatigability.

A study performed at University Hospital of São João and Cristo Redentor Hospital in Portugal, assessed the reintubation rate, ICU length-of-stay, and non-invasive ventilation (NIV) failure rates on 75 patients that were ventilated >48 hours and tolerated spontaneous breathing trials. The patients were divided into two groups:

- Control Group A – followed standard protocol to extubate to NIV
- Reintubation: 48%
- ICU LOS: 6.7 days
- NIV Failure: 65%
- Control Group B – followed standard protocol to extubate to NIV with the addition of 3 daily sessions of MI-E
- Reintubation: 17%
- ICU LOS: 2.5 days
- NIV Failure: 14%

Group B had a significant improved outcome with the MI-E. The results found in this study suggest that secretion management with MI-E may work as a useful complementary technique to prevent reintubation in patients in whom acute respiratory failure develops in the first 48 hours after extubation.

In summary, after reviewing the lungs defense mechanisms, the physiology of the cough reflex, importance of secretion management and airway clearance techniques to aide in maintaining lung health of our patients; it is evident to consider incorporating cough therapy into the care plan. The benefits of cough therapy show decrease in reintubations, infections, doctor/ER/hospital visits, increased secretion removal and is more comfortable than suctioning. Cough devices are a great tool for managing patient secretions in both the critical care/LTAC patient and the patient in the home setting.

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These data further strengthen the growing body of evidence around the value of as-needed anti-inflammatory treatment in asthma and support PT027's potential to transform the current rescue treatment approach." Mene Pangalos, Executive Vice President, BioPharmaceuticals R&D, AstraZeneca, said: "Asthma is an inflammatory, variable disease and patients are at risk of experiencing a severe exacerbation regardless of disease severity and adherence to treatment. The results from these Phase III trials support the clinical benefit of PT027, an albuterol/budesonide rescue inhaler, which has the potential to be a first-in-class treatment approach that can prevent asthma attacks over and above their current maintenance therapies." In the MANDALA trial, PT027 at a lower budesonide dose (180mcg albuterol/80mcg budesonide), also demonstrated a statistically significant reduction of 17% in the risk of severe exacerbation versus albuterol rescue (p=0.041), when used as an as-needed rescue medicine in adults, adolescents, and children aged 4-11 years. The results were published in the *New England Journal of Medicine* and will be presented at the American Thoracic Society (ATS) 2022 International Conference.

New Partnership Announced on Health Monitoring

VitalFlo announced that it has partnered with Vitalograph to provide smart respiratory health monitoring through Vitalograph's range of remote monitoring spirometry devices. This partnership enables patients to perform reliable lung function tests anytime, anywhere as a critical element in the ongoing management of their respiratory health. "For us, the key characteristics we look for in spirometry devices are accuracy, ease of use, and affordability," said Luke Marshall, CEO of VitalFlo. "With nearly 60 years experience, Vitalograph is a great fit for us as we strive to bring lung function testing and monitoring to the patient." Using VitalFlo's innovative digital healthcare platform, Vitalograph's range of remote monitoring solutions enable clinical teams to provide proactive and routine management of respiratory diseases and conditions. This in turn improves the quality of life of those affected and empowers respiratory healthcare professionals to perform their job to the best of their abilities, and to better manage resources. Executive Vice President of Vitalograph's Sales & Operations for North America, Troy Pridgeon added: "This is a very exciting opportunity to work with VItalFlo because they see healthcare as a connected whole. A digitally transformed space helping patients and healthcare workers to manage and prevent illness more quickly, conveniently, and seamlessly. Vitalograph is proud to include our devices for respiratory monitoring into this impressive digital healthcare system."

Masimo SedLine Brain Function Monitoring Reduced the Use of Anesthetic Agents and Opioids

Masimo announced the findings of a retrospective study published in the *Journal of Cardiothoracic and Vascular Anesthesia* in which Dr André Denault and colleagues at the Montreal Heart Institute and Centre Hospitalier de l'Université de Montréal investigated the impact of anesthesia during cardiac surgery guided by Masimo SedLine Brain Function Monitoring, in particular by SedLine's processed electroencephalography (pEEG) feature, the Patient State Index (PSi). This study is the first to primarily explore the impact of pEEG-guided anesthesia on vasoactive and inotropic drugs — drugs that affect the diameter of blood vessels and that modify the force of the heart's contractions, respectively — in the ICU. The researchers found

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Spinal Muscular Atrophy Type 1 – Vivo 45 LS is a Valid Option for Long-Term Ventilation

Mirella Gaboli, MD, PhD and Macarena Borrero Rodríguez, DUE Seville (Spain)

A five-day old newborn with a normal pregnancy but, with decreased foetal movements in the last week of pregnancy was admitted for assessment. Apgar test results were 9/10/10 at birth, and no resuscitation was required. The parents reported hypotonia since birth. Key features on examination were, soft cry, severe hypotonia and poor spontaneous movement, poor feeding with a low weight. Paradoxical breathing with a respiratory rate 70-78 breaths per minute.

At Day14, genetic results confirmed the clinical suspicion of spinal muscular atrophy (SMA) presenting during the neonatal period and the child was diagnosed with SMA type 1.

Vivo 45 LS

SMA is a genetically determined, congenital neuromuscular disorder, which presents with the progressive deterioration of the motor neurons in the anterior horn cells of the spinal cord. This leads to progressive muscle wasting including the respiratory muscles. SMA is classified on a functional scale.

Type 1 are unable to sit unaided, type 2 are unable to walk unaided and type 3 who can walk unaided. Within the types there is a wide range of weakness. SMA type 1 is the severest form and therefore has the poorest prognosis due to the severe involvement of the respiratory muscles. Those patients that present with respiratory symptoms at birth or close to birth are classified further as SMA type 1a. In recent years, there are some treatments that can change the natural course of the disease but the effect on the bulbar and respiratory symptoms are not fully known. It is for this reason that, despite new medications, ventilation, preferably non-invasive, remains an essential support for these children with SMA type 1.

Due to the severe hypotonia and the bulbar involvement. Non-invasive ventilation (NIV) was indicated to alleviate the symptoms of breathing difficulties, maintain a more stable airway, prevent pectus excavatum, facilitate the drainage of secretions and slow down the progress of the disease to terminal respiratory failure in addition to other therapies previously highlighted.

This patient with SMA type 1a, was offered NIV. However, there were several different challenges:

1) The patient's weight means limited licenced ventilators
2) The patient's high respiratory rate, which results in very short inspiration times
3) The need for very high inspiration and expiration sensitivity to enable in spontaneous triggering
4) High daily usage due to sleep wake pattern of infants.
5) Finally, it would be desirable if the equipment was small, light and resistant.

Table 1. Initiation of NIV with Vivo 45 LS

Ventilation mode	PCV(A+TgV)
Target Volume	50 ml
Breath Rate	40 bpm
Maximum inspiratory pressure	14 cmH2O
Minimum inspiratory pressure	10 cmH2O
PEEP	6 cmH2O
Inspiratory trigger	1
Rise time	2

During sleep the Vivo 45 LS was used with a nasal mask and a 15 mm passive circuit with active humidification. At that time the total RR was around 38-40 and each breath had an estimated

Table 2. The course of some of the clinical parameters

	Chest circumference (cm)	Head circumference (cm)	Chest/head circumference	SpO2 (%)	PVCO2	EtCO2	Median HR (beats per minute)	Median RR (breaths per minute)
Day 1 of NIV	30.5	34	0.897	98	50	48	140	70
Day 10 of NIV	32	34.5	0.927	99	47	44	130	60
Day 40 of NIV	37	37	1	100	42	42	120	40

Vt of around 40-45 ml. When awake spontaneous triggering was around 30-60% and asynchrony was only present during periods of tachypnoea (RR 90bpm). The patient was generally comfortable when sleeping and with SpO2 100% without supplementary oxygen and normal transcutaneous carbon dioxide levels (TcCO2 42 mmHg). See Table 2.

At two months, the patient was discharged home with the Vivo 45 LS, using it for 12 hours a day. However, during the first month at home, the patient was readmitted due to increased bulbar symptoms such as difficulties in swallowing and laryngospasm leading to a respiratory tract infection. On admission, NIV continued with oxygen entrained. The Vivo 45 LS settings were changed, RR increased to 60 bpm and maximum inspiratory pressure to 30cmH2O to achieve the same Vt. However, due to the progressive hypoxaemia and the instability of the airway, the patient required intubation and ventilation. After 21 days of IMV and two failed attempts of extubation, the decision was made to perform a tracheotomy and continue with invasive home mechanical ventilation.

At four months old, the Vivo 45 LS settings were further modified. Current average usage was 18 hours per day. Taking advantage of the programable profiles, three profiles were set: Profile 1, aimed at supportive awake ventilation was pressure support ventilation with target volume (PSV(TgV)). Profile 2, aimed for ventilatory support whilst sleeping and was set to pressure control with target volume (PCV(TgV)). Profile 3, aimed to be used when nebulising was assisted pressure control ventilation PCV(A). All profiles had disconnection and rebreathing alarms set. The family was instructed on how to change from one profile to the other and were given instructions on how and when to use each profile.

The patient remained stable during the following months. When the patient reached the age of one, they continued with invasive respiratory support on average of 10-12 hours a day. Settings were adjusted, in accordance with the patient's change in weight and respiratory pattern being his spontaneous respiratory rate much lower and his respiratory effort more effective. Further adjustments were made but, by 1 year old the child used pressure support mode and only required assist control mode when unwell or extremely fatigued.

Discussion

In infants, the available technology is limited and adapting a ventilator to a small child, both in invasive and non-invasive ventilation, can be challenging. The most significant problem is asynchrony: the device needs to have a high sensitivity of the inspiratory and expiratory triggers to allow synchronisation at high respiratory rates. It is technically challenging to support breathing in a child whose respiratory rate is greater than 40 bpm. Short inspiratory times, in very young children, are often insufficient to activate the inspiratory trigger and do not cycle into expiration appropriately. Also if the trigger is very sensitive it can be activated by any small movement in the circuit (e.g. water), causing auto-triggering and ineffective breathing. To eliminate asynchrony, we used a 15mm active circuit, with a higher back-up respiratory rate and an appropriate Target Volume for the patient. In our case, during an initial period of non-invasive respiratory support in a patient with estimated tidal volume less than 50 ml, the use of a PCV(A+TgV) mode allowed two inspiratory pressure levels to be programmed, which, at times of increased resistance in the airway, enabled ventilation to remain more or less uniform at the expense of small variations in inspiratory pressure.

> "the sensitivity of the triggers, and the precise measuring systems facilitate the adaptation of the ventilator to the child."

Secondly, due to the progression of the natural history of the illness, it was necessary to initiate prolonged invasive ventilation, by tracheostomy. Ventilators need to have appropriate modes and alarms for life support. In this case, the presence of fewer leaks, the sensitivity of the triggers, and the precise measuring systems facilitate the adaptation of the ventilator to the child, thus allowing the use of a support mode, PSV(TgV), which is more suited to the spontaneous breathing pattern of the child. All of this possible with the same ventilator the Vivo 45 LS.

Conclusions

In very young children it is essential that a ventilator has the ability to use different circuits, very sensitive inspiratory and expiratory triggers, the possibility to cope with a high respiratory rate (>60 bpm) and the possibility of ensuring a tidal volume of 50 ml. If the progress of the disease results in the need for invasive ventilation, as in the case presented, the possibility of using the same equipment, with multiple programable profiles and with different ventilation modes facilitates the process of adaptation to prolonged respiratory support at home.

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Future of Nasal Ventilation in Preterm Infants

Shabih Manzar, MD

Nasal ventilation in preterm infants has been shown to decrease the re-intubation rates.[1-3] Ali et al[1] described the feasibility of nasal high-frequency oscillatory ventilation (NHFOV) as a prophylactic or rescue mode of non-invasive ventilation (NIV) following extubation. They reported fewer apneas without significant changes in PCO_2 or oxygen requirements with the use of NHFOV.

Recent reports have shown the promising result of neurally adjusted ventilatory assist (NAVA) as a NIV mode in preterm infants.[2,3] Benn et al[2] showed an improvement in the growth trajectory with the use of NAVA ventilation in premature infants. Piątek et al[3] studied the implementation of NAVA and its effects on pulmonary and central nervous system outcomes. By comparing pre-implementation and postimplementation cohorts, they showed an improvement in brain MRI findings and cognitive outcomes with the use of NAVA.

As both modes, NHFOV and NAVA, have shown to be superior to nasal cannula and continuous positive airway pressure, it would be interesting to see future trials comparing these two modes of NIV in preterm infants.

Abbreviation

NHFOV-nasal high-frequency oscillatory ventilation
NIV-non-invasive ventilation
NAVA- neurally adjusted ventilatory assist

Image supplied

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that pEEG-guided anesthesia was associated with a reduction in the use of such drugs, as well as less use of anesthetic agents and opioids in the OR, lower central venous pressure (CVP), less fluid administration, less intraoperative bleeding, and shorter duration on mechanical ventilation. Noting that pEEG-guided anesthesia may improve hemodynamic stability and that high postoperative doses of vasoactive and inotropic drugs have been associated with mortality and renal dysfunction, the researchers sought to determine whether use of pEEG-guided anesthesia might improve outcomes by reducing use of such agents during cardiac surgery and at arrival in the ICU. Their primary goal was to determine whether pEEG-guided anesthesia would be associated with reduced hemodynamic instability during cardiopulmonary bypass (CPB) separation, measured by stratifying the operation into three categories: "easy" (use of only one vasoactive or one inotropic agent), "difficult" (use of at least two different classes of agents), or "complex" (requiring a return to CPB or use of mechanical circulatory support). Their secondary goal was to determine if pEEG-guided anesthesia would lead to the hypothesized reduction in vasoactive and inotropic drug administration in the ICU, measured by vasoactive and inotropic score (VIS). The researchers compiled a retrospective cohort of 300 adult patients who underwent cardiac surgery using CPB between 2013 and 2020 at the Montreal Heart Institute. The patients were divided into two groups, depending on whether anesthesia was guided by pEEG, which became a standard of care in 2017. Patients in the pEEG group (n=150) had their brain function monitored, from the moment they entered the OR to arrival in the ICU, using Masimo SedLine. In the pEEG group, patients received fewer vasoactive and inotropic drugs in the first hour after ICU admission, resulting in lower VIS scores (pEEG: 5 [0-10], control: 8 [2-15], p=0.003). Being in the pEEG group reduced the odds of being in a higher VIS category by 57% (OR=0.43; 95% confidence interval: 0.26-0.73; p=0.002). In addition, in the pEEG group, several additional outcomes were lower: duration of mechanical ventilation (pEEG: 3 hours [2-4 hours], control: 4 hours [3-7 hours], p<0.001), intraoperative fluid balance (pEEG: 758 mL [351-1329 mL], control: 500 mL [300-700 mL], p=0.002), and the amount of bleeding (pEEG: 400 mL [282-500 mL], control: 500 mL [300-700 mL], p=0.002). A lower proportion of patients experienced unsuccessful (difficult or complex) CPB separation in the pEEG group than the control group (60% vs. 72%, p=0.028). However, after adjusting for other parameters using multiple logistic regression, use of pEEG-guided anesthesia was not independently associated with successful CPB separation; instead, as the researchers note, *unsuccessful* separation was associated with several independent known predictors of hemodynamic complications. The researchers concluded, "pEEG-guided anesthesia is associated with a reduction in the use of inotropic or vasoactive drugs at arrival in the ICU. In addition, its implementation was associated with lower requirements of anesthetic agents and opioids in the OR, lower CVP, fluid requirements, intraoperative bleeding, and shorter duration of mechanical ventilation. However, its use did not facilitate weaning from CPB compared to a group where pEEG was unavailable. Future research is needed to confirm these results in prospective randomized clinical trials."

Stationary Oxygen Concentrators Launching in Latin America

Global oxygen equipment manufacturer CAIRE Inc. is expanding its portfolio of solutions in Latin America. The Companion 5 and NewLife Intensity 10 stationary oxygen concentrators are expected to launch in July, following an anticipated approval by the Brazilian Health Regularity Agency (Anvisa). "During the past two years, the COVID-19 pandemic oxygen shortages throughout South America have underscored the need to expand CAIRE's portfolio of equipment available to providers to serve patients prescribed oxygen as they are discharged from the hospital," said Barry Hassett, Vice President of Global of Marketing. Currently CAIRE products available in Brazil include the award-winning FreeStyle Comfort portable oxygen concentrator, the clinically-proven Eclipse 5 transportable oxygen concentrator, and liquid oxygen (LOX) systems including the Stroller portable and Liberator reservoir. The FreeStyle Comfort and Eclipse 5 can produce unlimited oxygen drawing in ambient air, filtering it, and delivering up to 95 percent pure oxygen to the user via nasal cannula. Both medical devices are designed for oxygen users during activity and travel, and are powered by battery or electrical power. Both come equipped with CAIRE's proprietary, smart O2 delivery technologies, including autoSAT that ensures the user receives the oxygen they need with every breath. LOX systems require regular refills from a gas provider, but are an excellent solution for oxygen users who require high flow prescriptions. Users stay mobile with a lightweight portable, while reservoirs support their needs for at-home use. The addition of the two stationary oxygen concentrators (SOCs) is a major step in providing distributors with equipment for their patients' at-home oxygen needs using the full breadth of CAIRE's industry-leading portfolio. SOCs offer the oxygen user the ability to receive continuous flow oxygen as they move about their home, engaging in daily living activities. The Companion 5 is a 5 liters per minute (LPM) concentrator offering a small footprint and energy efficiency for the user. Global medical equipment providers frequently supply this concentrator to the respiratory patient along with the FreeStyle Comfort as a complete non-delivery solution for both active and at home oxygen needs. The rugged, time-proven NewLife Intensity 10 has been a long-time trusted, go-to device, supporting specialty applications in more than 100 countries. It offers up to 10 LPM and an output of 20 PSI. It is often paired with CAIRE's SureFlow oxygen system, allowing healthcare workers to deliver oxygen up to five patients simultaneously in clinical settings.

User Centric Software Solution Now Available

PulManage, Inc announced that their user centric software solution is now available for remote spirometry and respiratory monitoring. The product was developed specifically to address issues surrounding diagnosis and management of chronic lung disease. The PulManage software uniquely connects and presents the signals from lung function data in conjunction with symptoms in real-time. This allows healthcare providers to monitor their patients between office visits and alleviates the burden of the patient calling the office to provide updates. The COPD population is underserved both for diagnosis and monitoring. CEO and founder Amanda Clark, RRT says, "PulManage fills a tremendous need in the market that has been spotlighted during the pandemic." The use of spirometry to correctly identify lung disease is critical to maintain quality of life, effectively manage, and reduce the overall burden of COPD. Features: PulManage is a unique software platform that connects patients and providers. This multi-sided software includes a web portal for clinicians and a native mobile application paired with a bluetooth lung function device for patients. The system is quite distinctive and offers both remote physiologic monitoring (RPM) and remote therapeutic monitoring (RTM) capabilities

for clinicians. According to Dr. Charlie Strange, Chief Medical Officer, "Having this platform in the physician's office is a way to let patients remotely monitor themselves while bringing in signals that providers can use to determine the right diagnosis and treat accordingly." He continued his statement, "To do this in the patient's home is an important way to bring technology into healthcare improvement." The dual RPM and RTM functionality connects lung function data in conjunction with symptoms in real-time for a complete clinical assessment.

New Faces on Company's Board

Nonin Medical announced the appointment of five new members to the company's board of directors. The new directors bring a diverse and unique set of experiences, along with a passion for growth and innovation in the medical device and healthcare sectors. Together, they will provide Nonin with strategic guidance and support the company's continued growth.

The new board members are:

- Waqaas Al-Siddiq, Founder and CEO of Biotricity
- Larry Betterley, President and CEO of Lexington Advisors, LLC
- Angela Dillow, Strategic Consultant and Board Director at Regions Hospital
- Laura Gillund, Corporate Board Director and Global Human Resources Executive
- Robert Rajalingam, President, US Medical Products & Distribution, Cardinal Health

"We have assembled a team of world-class board members with successful track records in the industry who will provide valuable business insights as we accelerate our growth trajectory and serve customers across the globe. Looking to the future of Nonin, we are confident the new board members are uniquely qualified to support the next growth phase of the company," stated Phil Isaacson, Executive Chairman, Chief Technology Officer and Founder, Nonin Medical. With healthcare technology playing a major role in the management of the global pandemic, the Nonin leadership team recognized the need for a new board of directors to help the company address rapidly changing market needs and meet the demands of providers, payors, and other audiences using health-driven digital and data solutions. Phil Isaacson will continue in his board role. The biographies of the new board are available at Nonin.com.

Company Celebrates 20th Anniversary of Launch of the First Portable Oxygen Concentrator

Two decades ago, oxygen users all over the world had two therapeutic options for mobility — gas cylinders or a portable liquid oxygen device. Many lived life tethered to an at-home oxygen source, and were very limited in their ability to travel or maintain a healthy level of activity. That changed with the launch of the first portable oxygen concentrator, the LifeStyle — developed and marketed by CAIRE — dramatically improving the quality of life for oxygen users worldwide. "For us, pioneering the first portable oxygen concentrator has long been both a point of pride, and an ongoing incentive to continue to innovate and develop those technologies that will ensure clinically efficacious oxygen delivery and an improved quality of life for all of our users around the world," said Earl Lawson, CEO of CAIRE Inc. Introduced under CAIRE's AirSep brand, the LifeStyle portable oxygen concentrator, was the brainchild of then Vice President of Research and Development, Norman "Norm" McCombs, who modeled the size and weight of the device on his wife's handbag which weighed in at 9.75 lbs. Harnessing specialized technology to separate the components of air, the portable oxygen concentrator operates by taking ambient air, filtering and compressing it and then delivering up to 95 percent purified oxygen to the user via a nasal cannula. Operational via battery, electrical, or motor vehicle power, the device allowed the user the convenience of taking their oxygen source anywhere, with the ability to plug-in and recharge extending their time away from home and encouraging them to live an active lifestyle with few restrictions. The LifeStyle would be the first POC to gain FAA approval for commercial air flights in 2005, paving the way for all POCs that would come after. McCombs was recognized for his contributions by US President Barack Obama in 2013 who presented him with the National Medal of Technology and Innovation at the White House. The award acknowledged McCombs's development and commercialization of pressure swing adsorption oxygen-supply systems with a wide range of medical and commercial applications, leading to improved health, substantially reduced healthcare costs and positive impacts on the environment. The LIfeStyle paved the way for the FreeStyle series, and the world's smallest portable oxygen concentrator, the Focus. These products lead the way in innovations in portable oxygen concentrators — lighter weight, expanded settings, clinical features — culminating in today's FreeStyle Comfort. Introduced in 2018, this therapeutic medical device expands on the innovations of the past 20 years — recently outperforming six competitive devices in seven out of eight breathing scenarios through a COPD simulated protocol designed to assess the ability of these devices to effectively deliver oxygen to patients. Equipped with propriety, smart oxygen delivery technologies, the FreeStyle Comfort is designed to ensure effective oxygen delivery to best support long-term oxygen therapy patients maintain an active, healthy, and fulfilled lifestyle. UltraSense technology detects the pressure change in the nasal cannula as the patient takes a breath and ensures that the bolus, or puff of oxygen, is delivered in conjunction with the breath rate, and autoDOSE responsive technology delivers oxygen automatically even if no breath is detected. Additionally, the FreeStyle Comfort can wirelessly connect to the myCAIRE telehealth solution uniquely designed for medical equipment providers who want to enhance care for their oxygen users.

Benefits of Portable Oxygen Concentrator Confirmed in Study

CAIRE's premier portable oxygen concentrator, the FreeStyle Comfort, outperformed other market leading devices in a recent study designed to assess the effectiveness of these devices in delivering oxygen to patients. The study, "Comparison of portable oxygen concentrators using a COPD patient simulation model," was conducted by Rachel Culbreth, PhD, MPH, RRT; Robert Murray, MS, RRT; Kyle Brandenberger, PhD; Douglas S. Gardenhire, EdD, RRT, RRT-NPS, FAARC with the Department of Respiratory Therapy, Byrdine F. Lewis College of Nursing and Health Professions at Georgia State University in Atlanta, GA. Researchers compared the oxygen output of eight competitive devices that currently comprise the majority of the portable oxygen therapy market, along with control group systems including a stationary oxygen concentrator and wall output oxygen similar to what a patient would receive in a clinical environment. Each device was assessed based on its ability to deliver oxygen in a variety of situations intended to model real-life use. In the US, it has been reported by the Annals of the American Thoracic Society that more than 1.5 million adults use supplemental oxygen for a variety of respiratory disorders. If

prescribed and used properly, supplemental oxygen can improve the quality of life and prolong survival for these individuals. The GSU study demonstrated the CAIRE FreeStyle Comfort achieved higher FiO2 compared to all other POCs in seven out of the eight scenarios. FiO2 is defined as the percentage or concentration of oxygen a person inhales. Based on this information, the study concluded that clinical providers should account for their patients' respiratory rate demands when recommending specific POCs. Presentations of the data were shared at the virtual 2021 Congresses hosted by the European Respiratory Society (ERS) and the American Association for Respiratory Care (AARC). GSU researchers will be publishing the accompanying white paper in a medical journal in the coming months. Introduced in 2018, the FreeStyle Comfort has earned recognition from its peers, and has been distributed to hundreds of thousands oxygen users globally. Offering smart oxygen delivery features, the FDA-cleared FreeStyle Comfort offers UltraSense sensitive breath detection, autoDOSE safety technology, and can be connected to the myCAIRE telehealth solution. Outside of the US, the FreeStyle Comfort offers the additional autoSAT technology which adjusts flow to keep pace with the user's breath rate during rest or activity. "Portable oxygen concentrators are intended to allow patients to maintain a more active lifestyle despite the constraints which COPD or other respiratory conditions might introduce. The FreeStyle Comfort was specifically designed to optimize oxygen delivery in situations where the patient is not at rest in order to enable them to comfortably enjoy life outside the home," said Barry Hassett, Vice President of Global Marketing. "This study confirms that the FreeStyle Comfort meets those objectives — ensuring patients get the oxygen they need when they need it."

Companies Partner for RT R&D

Three leading companies in their respective fields - DFE Pharma (excipients solution provider), Harro Höfliger (equipment supplier), and Sterling (API manufacturer) - announced a unique partnership with the establishment of "Inhalation Together" (INTO) in the field of dry powder inhalation (DPI). This initiative provides R&D services to pharmaceutical companies in the respiratory field, making formulation development simpler, faster, and easier to manage. INTO offers a coordinated and aligned suite of services, leveraging the expertise and complementary skill sets of its three partners. Developing a DPI formulation is a complex process, with a strong interdependency between process, powder, device, and patient. This increases the need for high-quality customer support. To address the specific customer needs, the INTO services range from initial consultancy and problem statement development to a stepwise formulation development program. The individual services include, among others, solid-state characterization and sono-crystallization of APIs and studies to optimize formulation, blending, and filling. The three INTO partners can also offer extensive consultancy services."I am very excited about the INTO initiative because it increases speed to market and reduces the complexity of formulation and process development. The three companies have a very good understanding of the critical aspects of development and manufacture of DPI products, therefore, adding significant value to our customers", explained Martti Hedman, CEO of DFE Pharma.

Babies of Pregnant Women Who Get RSV Vaccine Likely to Be Prescribed Fewer Antimicrobials

Babies born to moms who were vaccinated against respiratory syncytial virus (RSV) while pregnant appear to need fewer antimicrobial prescriptions than babies of unvaccinated moms, according to a study. To fight antimicrobial resistance, we need to use fewer antimicrobial drugs, the authors write in *Proceedings of the National Academy of Sciences* (PNAS). "In this study, an RSV vaccine was administered to pregnant women to prevent infection in their infants by the transfer of protective antibody to the infant," Kathryn M. Edwards, MD, a professor of pediatrics and the scientific director of the Vanderbilt Vaccine Research Program at Vanderbilt University School of Medicine in Nashville, Tennessee, said. Edwards was not involved in the study. "The authors investigated the impact of the vaccine on the use of antibiotics in infants during the first 90 days of life," Edwards added in an email. "They found that the use of antibiotics was less in infants born to mothers who received the RSV vaccine than in infants born to mothers who received placebo…They suggest that reducing RSV infection in infants will reduce respiratory infections that trigger antibiotic use." Senior author Ramanan Laxminarayan, PhD, MPH, director and senior fellow at the Center for Disease Dynamics, Economics, & Policy (CDDEP) in Washington, DC, and his colleagues conducted a secondary analysis of a double-blind, randomized controlled trial at 87 sites in 11 countries on several continents. In the original study, which was conducted between December 2015 and May 2018, 3005 maternal participants and 2978 infant participants received the experimental RSV F vaccine, and 1573 maternal participants and 1546 infants received a placebo shot. Baseline characteristics of mothers and infants were well balanced, according to the authors. In the current study, infants born to mothers who received the RSV vaccine were found to be 12.9% (95% CI, 1.3 - 23.1%) less likely to be prescribed antimicrobials during their first 3 months of life compared with infants whose mothers received placebo. Vaccine efficacy against antimicrobial prescriptions for acute lower respiratory tract infections was 16.9% (95% CI, 1.4 - 29.4%). During the first 3 months of life, for every 100 infants born, maternal vaccination prevented 3.6 courses of antimicrobials in high-income countries (20.2% of all antimicrobial prescribing), and 5.1 courses in low- and middle-income countries (10.9% of all antimicrobial prescribing). In addition to finding that lower respiratory tract infections accounted for 69%-73% of all antimicrobial prescribing prevented by maternal vaccination, the researchers found marked vaccine efficacy (71.3% [95% CI, 28.1 – 88.6%]) against acute otitis media-associated antimicrobial prescription in infants in high-income countries.

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Methodology: Phone surveys at regular intervals with bronchiectasis patients using the InCourage system. Data collection began 10/01/2013. As of 05/31/2021, the total cohort was 23,213 patients; 21,049 patients completed the baseline survey; 13,303 patients in 1-month cohort; 9,569 in 6-month cohort; 7,720 in 12-month cohort

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