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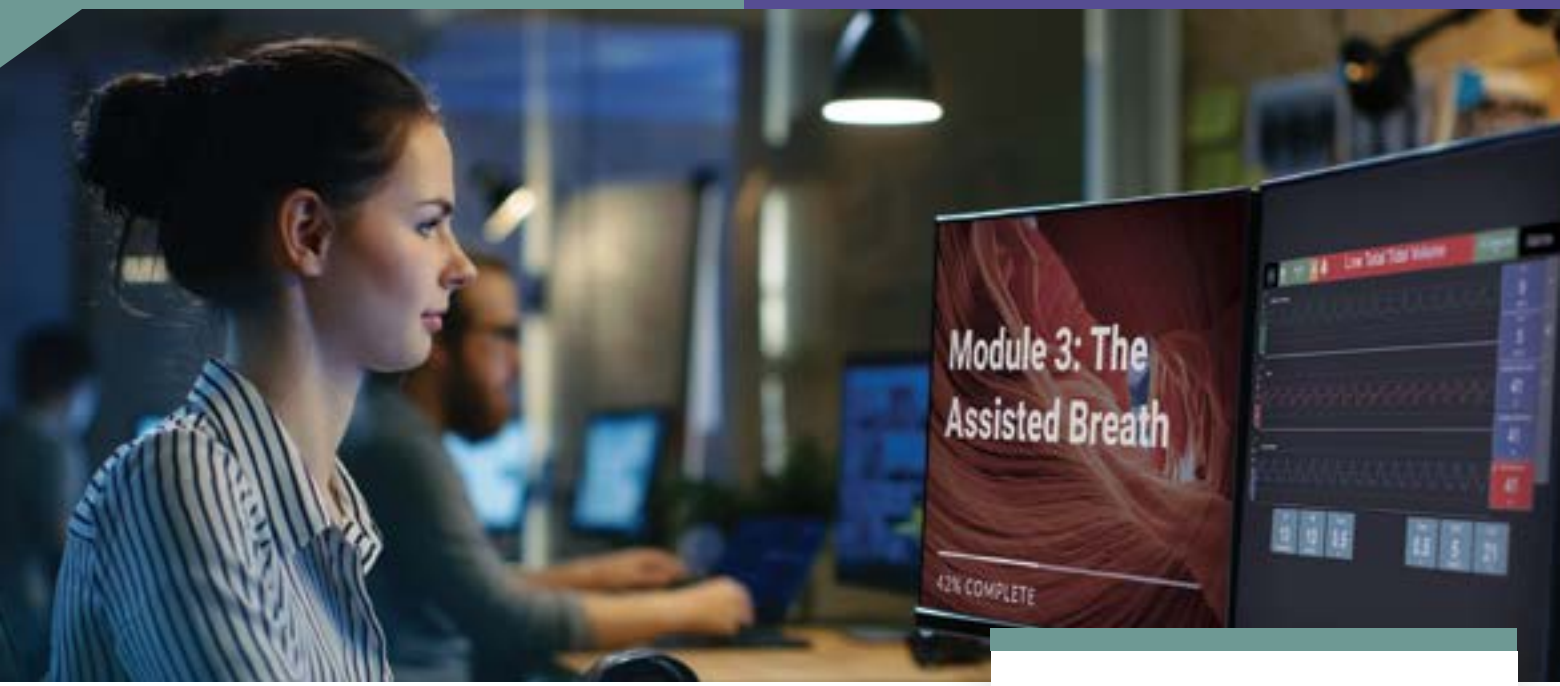

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Respiratory Therapy
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ISSN 2152-355X
Published four times each year by
Goldstein and Associates, Inc.
10940 Wilshire Blvd., Suite 600
Los Angeles, CA 90024 USA
Tel: 310-443-4109 · Fax: 310-443-4110
E-mail: s.gold4@verizon.net
Website: www.respiratorytherapy.ca

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■ Fall 2023

Vitalograph Reveals their Most Powerful, Versatile and Connected Handheld Spirometer Ever

The In2tive™ spirometer is a powerful and versatile portable respiratory diagnostic solution that enables detailed, point of-care spirometry testing wherever it is needed, all seamlessly connected to the hospital network. It features a 10,000-test subject memory, and also has a detachable flow head, which makes it easier to view data during testing while creating distance between subject and tester. In2itive allows for an elegant bi-directional flow of information via wireless or USB connection to the EMR as well.

The In2itive offers multiple spirometry testing options, such as FVC, SVC and bronchodilator responsiveness, all in compliance with ATS/ERS 2019 Guidelines. V-Core technology, comprising a core of air capillaries engineered from stainless steel, makes Vitalograph flow heads very accurate and stable (even at low flow rates) and extremely robust and long-lasting. No moving parts means there is little opportunity for breakages and makes them a practical and adaptable choice where frequent spirometry testing is required.

Troy Pridgeon, North America EVP Operations and Sales says: "The In2tive brings Vitalograph quality and test accuracy to a device that is much more powerful and more portable than ever before. It's rechargeable and lightweight and it has the largest screen of any handheld spirometer on the market. Its bi-directional EMR connectivity continuously synchronizes respiratory assessment needs and spirometry results, maximizing the efficiency of healthcare decisions, from anywhere within a healthcare setting."

Company Acquired

Werfen announced that it has successfully completed the acquisition of Immucor, Inc., after obtaining all necessary regulatory and antitrust approvals. Immucor is a privately held, US-based company, in the in vitro diagnostics (IVD) sector, with a solid global presence in the Transfusion and Transplant markets. "During our more than 50-year history, we have demonstrated our strong commitment to expand our IVD business through organic growth, complemented with highly strategic acquisitions," said Carlos Pascual, CEO of Werfen. The price of the acquisition was approximately US$2 billion, financed by a combination of cash on-hand and bank debt facilities, syndicated by 19 national and international entities, led by BBVA, BNP Paribas, CaixaBank and HSBC. As part of its credit management, Werfen plans to refinance part of the debt in the capital markets, as well as quickly reduce the level of indebtedness. Following the announcement of the acquisition, Standard & Poor's affirmed Werfen's investment grade rating (BBB-) with a stable outlook. With the integration of Immucor, Inc., Werfen expands its presence as a company of reference in the Specialized Diagnostics market and grows its portfolio of diagnostic solutions for hospitals and clinical laboratories. In addition, revenues will exceed €2.2 billion, and the Company will have seven technology centers and employ more than 7,000 people worldwide; with a direct presence in more than 30 countries and in more than 100 territories through distributors.

Siemens Healthineers launches Atellica CI Analyzer

The newest addition to the Siemens Healthineers Atellica in vitro diagnostics portfolio, the Atellica CI Analyzer for immunoassay and clinical chemistry testing, has received FDA clearance and is now available in many of the world's major markets. Labs operating at low to medium testing volumes will benefit from competitive advantages that the analyzer offers, including improved turnaround time predictability, advanced reporting functionality, and focused safety and security measures. Every lab, regardless of size, needs to tackle big challenges resulting from labor shortages—from producing test results reliably to enable predictable care, to protecting staff, securing data, and reaching environmental goals. The Atellica CI Analyzer makes it possible for both standalone labs and satellite labs of wider health networks to have the same reagents, consumables, and intelligent software as the company's flagship Atellica Solution—now condensed into a 1.9 square meters footprint ideal for smaller laboratories. "Workflow standardization and clinical equivalence are critical components of

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SIEMENS Healthineers

a successful laboratory operation within a health network. The Atellica CI Analyzer elevates laboratory operations to a new level of agility," said Sharon Bracken, head of Diagnostics for Siemens Healthineers. "Labs today need testing instrumentation and informatics that can easily keep pace with rapidly changing testing demands as they occur. This next-generation laboratory analyzer anticipates workflow bottlenecks, mitigates them proactively, and delivers insights based on data that help laboratory staff do their job more effectively and efficiently." CEO of Acibadem Labmed Clinic Laboratories and a Siemens Healthineers customer, Dr. Mustafa Serteser explains, "For mid- or low-volume sized laboratories, the Atellica CI Analyzer is a best-in-class approach. Preservation of space in the lab, staff allocation per analyzer, turnaround time, and cost-effective usage of reagents are important and addressed with this analyzer." The Atellica CI Analyzer is engineered thoughtfully with differentiating capabilities to leverage downtime and increase lab efficiency and profitability. Random access sampling, micro-volume aspiration, and automatic maintenance and quality control scheduling enable labs to deliver more predictable sample turnaround times. Chemistry and immunoassay engines run independently so throughput is not compromised if one of the two needs to stop. Beyond delivering patient results, labs must address reporting requirements, cybersecurity, and staff satisfaction goals. The Atellica CI Analyzer comes equipped with the Atellica Laboratory Evaluation Suite to deliver inspection-ready reports. This helps labs meet accreditation guidelines without the need for additional software and enables laboratory staff to refocus their time on other critical lab operations. User authentication, role-based authorizations, and audit trails are available for increased security. With a planned menu of more than 200 assays across 20 disease states, each lab in a health network can choose the best tests for its patient population to keep pace with demand and satisfy clinical needs of patients that may otherwise go unmet. More than 50 key assays can deliver results in under 14 minutes.

ResMed Acquires Somnoware

ResMed announced the acquisition of privately held Somnoware, a US leader in sleep and respiratory care diagnostics software. Somnoware software streamlines the processes of physicians as well as sleep and pulmonary function testing labs for diagnosing and evaluating a patient's sleep and respiratory care test results, ordering PAP treatment equipment, setting up appointments, tracking PAP compliance, and electronically providing this information directly into a patient's electronic health record—all from within the Somnoware platform. "We are thrilled to welcome the Somnoware team to ResMed," said ResMed Sleep & Respiratory Care President Lucile Blaise. "We're committed to driving wider adoption of Somnoware's open and interoperable platform to help more people with OSA or COPD get the diagnoses and treatment solutions they need. Improving patients' experience and health outcomes is our common goal." "We are very excited about this acquisition," said ResMed North America General Manager Bill Shoop. "Somnoware's offering has been well received in the marketplace and it naturally complements our ecosystem of digital solutions across the patient care pathway. Our team is excited to add Somnoware to our portfolio of solutions to help physicians, sleep labs, and HMEs drive greater efficiency and deliver better patient care." "I'm thrilled to join forces with ResMed and embark on a shared mission of guiding people toward better sleep and improved breathing. Our partnership will open new avenues to help physicians with the critical task of chronic care management," said Subath Kamalasan, Somnoware cofounder and CEO. "Together, we are committed to driving innovation and delivering solutions that improve the health of patients with sleep disorders and other chronic respiratory diseases." ResMed intends to retain all Somnoware staff, integrate its offerings into the ResMed brand and solution ecosystem, and maintain the open and device-agnostic nature of Somnoware's offerings so end users can keep interoperating with various testing solutions and place orders for treatment devices and accessories from any supplier. The transaction's financial terms are not material to ResMed's consolidated financial results and were not disclosed. Somnoware engaged Ziegler, a national boutique investment bank, as its financial advisor, and King & Spalding LLP as its legal advisor. DLA Piper served as ResMed's legal advisor.

Beyond Air Secures up to $40 Million Debt Financing

Beyond Air, Inc., a commercial stage medical device and biopharmaceutical company focused on developing inhaled nitric oxide (NO) for the treatment of patients with respiratory conditions, including serious lung infections and pulmonary hypertension, and, through its affiliate Beyond Cancer, Ltd., ultra-high concentration nitric oxide (UNO) for the treatment of solid tumors, announced securing a senior secured debt financing of up to $40 million from funds managed by Avenue Capital Group. The term loan provides Beyond Air with funding to support the ongoing commercial launch of LungFit PH and advance clinical development of the LungFit platform. Avenue Capital Group has agreed to provide the Company with up to $40 million of senior secured term loans funded across three tranches with $17.5 million fully funded at close. The facility has a four-year term from the funding of the first tranche. In

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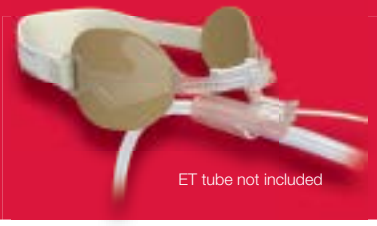

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addition to certain fees, the Company shall grant the lender warrants to purchase 233,843 shares of common stock. Upon Beyond Air meeting certain milestones, the remaining tranches of $10 million and $12.5 million will be made available, subject to the Company's discretion, until September 2024 and after April 2024, respectively. "This transaction immediately strengthens our balance sheet and allows us to continue ramping up our commercial efforts for LungFit PH. We are extremely pleased to have a strong partner in Avenue Capital, which has a strong track record in healthcare and a history with nitric oxide," commented Steve Lisi, Chairman and Chief Executive Officer of Beyond Air. "Additionally, this funding allows for the continued development of our clinical pipeline." Chad Norman, Senior Portfolio Manager at Avenue Capital Group, added, "We are impressed with Beyond Air's technology and its potential to improve the lives of patients who are in need of inhaled nitric oxide. We believe the Company's convenient, tankless solution is positioned to be a game changer for those living with chronic conditions."

Long COVID Devastates Patients' Careers and Quality of Life

A survey in Spain of the progress of individuals with long COVID reveals the tremendous toll that the condition has taken on their employment, quality of life, and social support network. The survey revealed that 46% of patients experience slight to significant difficulty performing their work, and that approximately 10% have lost their jobs. Data from the survey, which was conducted between October 2022 and January 2023, were presented at the XXIX National Congress of General and Family Medicine of the Spanish Society for General and Family Physicians. Survey responses were collected from 1122 individuals living in Spain whose symptoms of long COVID persisted during the abovementioned period. Participants already had experienced symptoms for several months. The survey elicited 942 valid responses, and nearly 80% were from women with an average age of 47 years. This profile reflects those of previous surveys conducted by the Spanish Society of General and Family Physicians. Nearly half (46%) of patients with long COVID were on leave at the time or were experiencing significant difficulty as they worked, compared with 15.6% who reported working under normal conditions, according to preliminary results from the follow-up survey. In addition, 9.5% of respondents lost their jobs due the illness, and under 3% had a permanent disability. One goal of the survey was to collect new data to stay up to date on how these patients have progressed from the beginning of the pandemic to now. During the conference, Pilar Rodríguez Ledo, MD, was elected president of the society for the next 4 years. She mentioned that studies like these that involve the progress of patients with long COVID "will provide us with very valuable information" that will help improve the health and the healthcare for these patients. To date, "many people impacted by long COVID continue to experience symptoms and some degree of functional disability that prevents them from resuming life as normal." It is therefore necessary to characterize the condition at the different waves of the pandemic by describing the symptoms and their severity, the age range of those affected, gender-based differences, and functional impact. Regarding quality of life and health status, the results of the survey show that on a scale of 0 to 10, the health of those who have been affected has worsened by an average of 4 points, while the degree of disability has increased by almost 6 points, compared with participants' situation before they got sick. A staggering statistic is that nearly 90% of respondents indicated that they experience worsening on physical (93.3%) and mental (87.8%) exertion.

Two New Devices Unveiled

The Hans Rudolph, inc. SmartLab Instrumentation System with Insight Software is a flexible system for measurement and analysis of respiratory signals in research applications. The base module can accept up to four sensor modules for measuring flow from pneumotachs and airway or other pressures or a voltage input from an external device. Optional inputs include an oximeter, CO2 sensor, temperature and humidity and digital I/O. The PC software provides real time graphs and calculations of many common respiratory parameters. Data can be saved for analysis or replayed. Custom software modules can be developed for special applications. Also new is the Hans Rudolph, inc. SmartLab Instrumentation System with Insight Software is a flexible system for measurement and analysis of respiratory signals in research applications. The base module can accept up to four sensor modules for measuring flow and pressures. Optional inputs include an oximeter, CO2 sensor, temperature and humidity and digital I/O.

CAIRE Expands Customer Service Support Network

CAIRE has announced the further expansion of its company's Authorized Service Center network with the addition of Quality Biomedical, a nationwide provider of fleet management services, and specialists in respiratory equipment maintenance and repair. Through this new agreement, the Boulder, CO-based company will support CAIRE customers with in-warranty and out-of-warranty repairs, which are critical to support the needs of home medical equipment (HME) providers and other major healthcare institutions, including hospitals, skilled nursing facilities,

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long-term acute care, and other providers across the country. In addition to stationary and portable oxygen concentrators, Quality Biomedical repairs Continuous Positive Airway Pressure (CPAP) and Bilevel Positive Airway Pressure (BiPAP) devices, ventilators, and more. Founded in 2004, Quality Biomedical has grown to a nationwide footprint of eight locations including: its headquarters in Boulder; Allentown, PA; Cartersville, GA; Dallas, TX; Fresno, CA; Fort Wayne, IN; Maryland Heights, MO; and Pinellas Park, FL. "We never forget there is a patient behind every piece of equipment. This is at the core of our values at Quality Biomedical," said Jim Worrell, Quality Biomedical Chief Commercial Officer. "We leverage our national footprint and advanced technology infrastructure to work more efficiently than the competition and create operational efficiency and reduced costs for our customers. It also helps us achieve a fast turnaround of customer's equipment so they can focus on what matters—patient care and service." Quality Biomedical runs 26 trucks serving 45 states with free pick-up and delivery. Customers who wish to ship defective equipment directly to any of the eight Quality Biomedical service centers should contact them directly to discuss the details of this option. "Quality Biomedical's commitment to excellent service and national footprint will make a meaningful impact on how HMEs and DMEs experience service and access updates throughout the repair process," said Lanier Hogan, CAIRE Global Technical Service Manager. "Working together, we can offer expanded customer support to providers as they navigate the ever-changing challenges of the healthcare environment." Quality Biomedical, joins Altra Services Professionals, Oxygen Sales & Service, Inc., ReOx Medical Services, and Repair Authority in supporting CAIRE equipment as part of the Authorized Service Center network in the United States. These sites complement CAIRE's new Global Service Headquarters in Canton, GA.

PAP Adherence Lowers ER Visits

People with heart failure and obstructive sleep apnea (OSA) can significantly reduce hospitalizations and ER visits as well as related costs by being adherent on positive airway pressure (PAP) therapy, according to two studies supported by ResMed and presented at SLEEP 2023. One retrospective study showed people with OSA and systolic heart failure and adherent to PAP had 24% fewer ER visits and incurred 40% lower costs related to hospitalizations and ER visits over 1 year ($3,500 vs. $5,879) compared to non-adherent patients. The study analyzed 1,472 people, exactly half adherent on PAP, half non-adherent. The second retrospective study showed people with OSA and diastolic heart failure and adherent to PAP had 36% fewer ER visits, 57% fewer hospitalizations, and incurred 18% lower related costs (an average $12,732 vs. $15,610) over 1 year. This study analyzed 1,926 people, again exactly half adherent on PAP, half non-adherent. It also found that converting a non-adherent PAP user in this study to an adherent one would save them an average 1.25 visits. The studies hold significant implications for managing heart failure patients, since 76% of them also have sleep apnea. "Since 3 out of 4 people with heart failure also have sleep apnea, these findings underscore the significant role PAP treatment plays in keeping people healthy and out of the hospital," said Fatima Sert Kuniyoshi, MSc, PhD, lead author and ResMed clinical research director. "I hope this leads to a greater emphasis on PAP prescription and monitoring for the sake of patients as well as the hospitals and ERs that would otherwise require added beds and resources to care for them." ResMed supported 10 abstracts presented this week at SLEEP 2023, including a global multi-study analysis that estimated over 200 million women worldwide have mild obstructive sleep apnea. That's equal to 13.4% of women ages 30-70 – or over 1 in 8. The study's abstract points out that while PAP treatment is beneficial in treating mild OSA, the key to optimizing health outcomes is first diagnosing it – particularly in women: "Females with OSA tend to be milder than their male counterparts, with lower AHIs, less oxygen desaturations, and different symptoms such as fatigue and insomnia. [Therefore], females with mild OSA are at risk of being underdiagnosed and undertreated." Overall, an estimated 936 million people worldwide have sleep apnea, ranging from mild (5-14 apneic events per hour) to severe (over 30 per hour).

Sanofi: Smoker's Lung Drug Benefit Was Swift and Sustained in Trial

The benefits of Sanofi and Regeneron's anti-inflammatory drug Dupixent set in quickly during a trial to treat "smoker's lung" and lasted for the duration of the 1-year study, French drugmaker Sanofi said. The company said it was discussing with major watchdogs across the world whether the trial results are substantial enough to support a regulatory review or whether that will require the results of another ongoing trial. It said in March in a brief summary of the late-stage trial that Dupixent was associated with a 30% reduction in acute exacerbations of the disease, which is also known as chronic obstructive pulmonary disease (COPD). This potentially added billions to the French drugmaker's growth prospects but also underscored a heavy reliance on its bestseller. Dupixent, approved to treat conditions including asthma and eczema, is

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being jointly developed with Regeneron. "Within two weeks we saw improvement in lung function and improvement in quality of life," said Naimish Patel, Sanofi head of global development for immunology and inflammation. "And this was also sustained, out to 52 weeks," he added.

Endobronchial Valves: Sustained Improvement in Emphysema

Patients with emphysema treated with one-way endobronchial values showed consistent improvement in lung function after 5 years compared with controls, based on data from 174 individuals.

One-way endobronchial valves demonstrated benefits for patients with severe emphysema over a 12-month period in the EMPROVE trial, according to Gerard J. Criner, MD, of Temple University, Philadelphia, and colleagues. Five-year results from the EMPROVE study were presented here in a poster session at the American Thoracic Society annual conference. The initial EMPROVE trial demonstrated safety and efficacy of the Spiration Valve System (SVS) over 12 months. However, data on the long-term benefits of one-way endobronchial values are limited, the researchers wrote. The valve was designed for use in selected areas of the bronchial airways and features a flexible umbrella that allows air and mucus to clear from treated airways while blocking inspired air flow to areas of the lungs affected by disease, the researchers explained in the poster. Criner and colleagues assessed 172 patients who were randomly assigned to treatment with a one-way valve system (113 patients) or a control group (59 patients). Participants were evaluated at 1, 3, 6, and 12 months, then annually for 5 years. The primary efficacy outcome was lung function, measured by forced expiratory volume per second (FEV_1). At five years, the FEV values improved by 0.1098 liters in the treatment group ($P < .001$). Treated patients and controls experienced decreased FEV at a rate of 0.0440 liters per year from baseline, a significant difference ($P < .001$). Assuming a steady rate of disease progression, "the treatment group gained approximately 2.5 years of FEV_1 improvement immediately following SVS treatment, which was maintained, compared to controls," the researchers noted in their abstract. Serious adverse events were assessed from 6 months to 5 years (352.7 patient-years) for treated patients and from 6 months to 2 years (72.9 patient-years) for controls. Overall, a total of 210 SAEs occurred in the treatment group and 35 occurred in controls, for rates of 0.60 and 0.48, respectively ($P = .201$). The most common SAEs in the treatment and control groups were COPD exacerbations, pneumothorax, and death. The results suggest that the FEV improvements seen in patients with severe emphysema after one-way endobronchial value placement compared with usual care are enduring after 5 years, with no significant changes in safety, the researchers concluded.

AI Platform Highlights Conference

Optellum, a medtech company that provides a ground-breaking AI platform to diagnose and treat early-stage lung cancer, attended this year's American Thoracic Society International Conference in conjunction with three prominent American healthcare institutions. Physicians from each of these institutions demonstrated how integrating Optellum Virtual Nodule Clinic into their clinical workflows offers benefits for both patients and providers. Dr Roger Kim and Dr Anil Vachani of Penn Medicine led a discussion called "Theoretical Net Benefit

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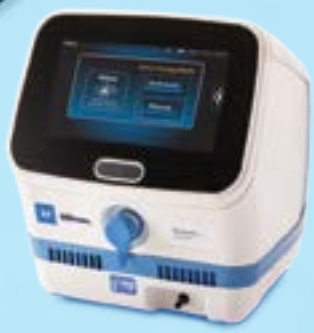

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of a Radiomics-Based Computer-Aided Diagnosis Tool for Risk Stratification of Pulmonary Nodules." The work at Vanderbilt Health demonstrates the cost-effectiveness of the AI platform, which was assigned CPT code 0721T in 2022 to facilitate health insurance claims for patients. Dr Vachani was the lead investigator for Optellum's FDA clearance, the first of its kind achieved in 2021, and his work with Dr Kim showing that clinical decision making is better if the AI tool is incorporated into radiology or pulmonology practice was published in Radiology in 2022. Optellum Virtual Nodule Clinic is in use at other leading hospitals in the US and being rolled-out in a government-funded widespread screening trial in the UK's National Health System (NHS). The company was named as one of the 150 most promising digital health companies of 2022 by CB Insights.

Masimo Announces Clearance of Radius VSM

Masimo announced that Radius VSM, a patient-worn, continuous multi-parameter vital signs monitor, has received FDA 510(k) clearance. Designed on a modular platform, Radius VSM allows clinicians to monitor a wide variety of physiological measurements, including Masimo SET pulse oximetry, noninvasive blood pressure, temperature, respiration rate, and electrocardiography (ECG). By combining the reliability and accuracy of larger bedside monitors with the comfort and freedom of a wearable device, Radius VSM allows ambulation and movement while ensuring patients remain continuously monitored. With its flexibility and expandability, Radius VSM can be easily scaled to match each patient's unique monitoring needs and level of acuity, across the continuum of care, and to accommodate surges in patient volume. Joe Kiani, Founder and CEO of Masimo, said, "Radius VSM's unique scalability, versatility, advanced connectivity, and broad range of accurate and automated continuous measurements—all in a wearable device that can be quickly and easily deployed anywhere in the hospital—make it a game-changing tool for clinicians everywhere. Doctors, nurses, and patients in Europe are already experiencing the advantages of Radius VSM and we are excited to share them with US hospitals now too." As a modular, wearable device, Radius VSM allows providers to equip any hospital bed with comprehensive monitoring, with the ability to quickly add or remove measurement technologies to match each monitoring scenario and offer more personalized care – without additional bedside equipment, network infrastructure, or any tethered connections. Radius VSM can operate as a self-contained device, with high-quality waveform and parameter trend data shown on its built-in multi-touch LED display, with visual and audible alarms and a built-in rechargeable battery. Or, Radius VSM can connect wirelessly to Masimo bedside monitors like Root and to the Masimo Hospital Automation™ platform, simplifying clinical workflows by automating patient data transfer to remote monitoring systems like Masimo Patient SafetyNet™ and electronic medical records (EMRs) – enabling its use as a part of a patient surveillance system and ensuring up-to-date physiological data is available to clinicians throughout the hospital. For example, integrating data from Radius VSM into Patient SafetyNet extends its reach across the hospital for clinicians remotely monitoring patients at centralized viewing stations, viewing continuous monitoring data on their Replica®-equipped smartphones, and benefiting from the workflow automation of the Halo ION patient scoring system—all regardless of where patients are in the hospital,

Continued on page 26…

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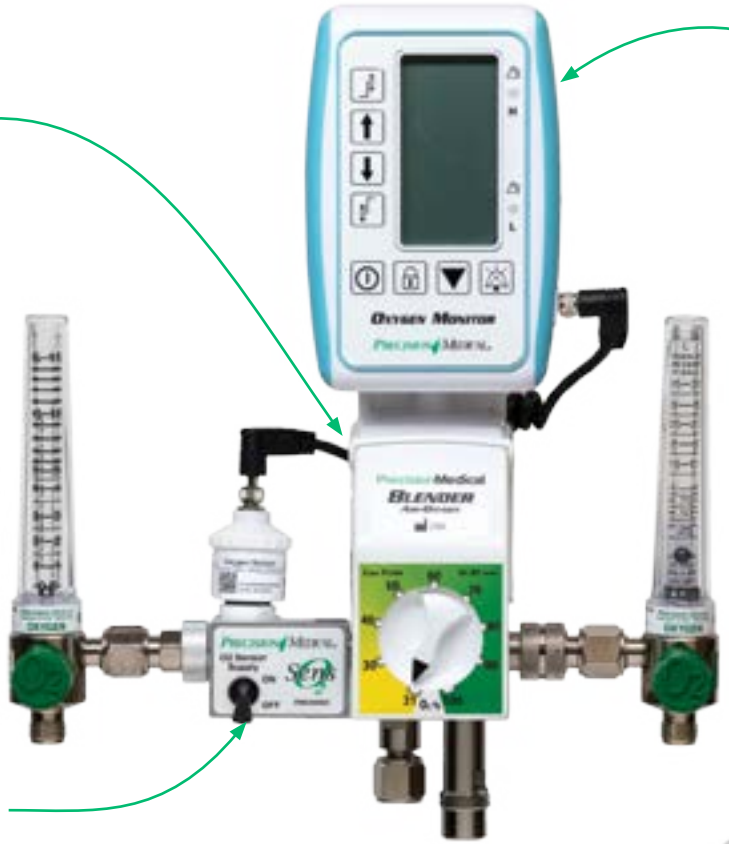

PM5300
Low-flow Air-O2 Blender
Precision Medical's low-flow and high-flow air-oxygen blenders offer unparalleled flexibility, safety, and value. Our innovative, modular systems can be configured to suit various clinical needs within minutes.

PM5900
Oxygen Monitor
Designed to accurately view oxygen concentrations, the monitor uses push buttons to easily set high and low alarms.

PM5300SO
SensO2 Oxygen Sensor Supply
Specifically designed for the Precision Medical line of blenders, attaches to the left primary outlet

1MFATP
Sensor Tee
Easily connects an oxygen sensor to any flowmeter

PM5950
AccuO2 Oxygen Analyzer
The AccuO2 Oxygen Analyzer is designed to accurately and reliably measure volume percent oxygen.*

**It is recommended that clinicians monitor or analyze the oxygen concentration given to patients.*

Mercury Medical

Booth 464

What products will you be presenting at AARC?

Mercury Medical will be displaying and demonstrating several innovative clinical solutions that meet the company's mission for dedication to delivering critical care technology that saves lives throughout the world. Such products include the first and only **Disposable Flow-Safe II+® BiLevel & CPAP system.** It is the only available disposable device in the global market that combines both BiLevel and CPAP in one complete single-patient use system with integrated manometer for verifying pressures. The lightweight disposable feature allows for easy CPAP or BiLevel CPAP therapy set-up and delivery during transport. Flow-Safe II+ is ideal for situations where backup BiLevel CPAP equipment is scarce or unavailable. Clinicians can now deliver BiLevel and CPAP therapy with just **ONE** disposable device.

Coupled with Flow-Safe II+, Mercury Medical will be showing **Flow-Safe II EZ®** CPAP & Nebulizer system with unparalleled advantages. Flow-Safe II EZ delivers consistent CPAP pressure while providing an integrated nebulizer using only one oxygen source. Additionally, it has an on/off switch that controls the nebulizer only, not the CPAP pressure. CPAP pressure is still controlled by the flow meter. Compared with other systems that require two O2 lines, Flow-Safe II EZ consumes less oxygen.

Also featured is the **Neo-Tee®** infant T-piece resuscitator product family, the first disposable T-piece and is celebrating over 10 years of success in the global market. The latest version is the **Neo-Tee®** with higher PEEP (orange knob). This Neo-Tee version offers approximately 8-10 cm H_2O PEEP with less flow, saving on oxygen consumption especially during transport. All Neo-Tees are **MR conditional** and **DEHP-Free.** Neo-Tee's sister product, **Resusa-Tee®** Adult/Child T-piece resuscitator will be displayed along-side Neo-Tee for those patients above 10 kg.

Delivering proper tidal volume at the proper pressure and rate are key elements for providing successful manual resuscitation. Mercury Medical will be featuring **the new, CPR-2+® adult small volume (1,000 mL) manual resuscitator with tidal volume markings, LiteSaver® Manometer and PEEP valve.** This is an award-winning manual resuscitator combination for any facility with a Protective Lung Strategy Program. The CPR-2+ adult small volume manual resuscitator with LiteSaver Manometer helps to reduce over inflation and breath stacking. This product is truly a "LiteSaver."

The Airtraq™ will also be featured which simplifies video laryngoscopy with its ETT channel guide aiding in safety and in reducing intubation time. The optional lightweight Wi-Fi camera facilitates video recording and auto recording options. The Airtraq is simple to use and makes intubation easy for non-expert and expert clinicians. Not only is Airtraq compact, portable, and affordable, it allows an indirect visualization of the upper airway and improves the success rate of tracheal intubation.

Are there any new products that you wish to emphasize?

In addition to the new, CPR-2+ adult small volume manual resuscitator with tidal volume markings, Mercury Medical will be showcasing BiWaze® Clear, a brand-new oscillating lung expansion (OLE) airway clearance system. The BiWaze Clear provides therapy to help treat and prevent atelectasis, remove retained secretions from deep in the lungs and reduce the work of breathing. BiWaze expands and clears the airways through a combination therapy in just 10 minutes! Alternating therapies of PEP and Oscillation combined with Aerogen nebulization enhance the therapy effectiveness by thinning and mobilizing mucus to the upper airways where it can be coughed or suctioned out. Based on a recent study, BiWaze Clear has shown to provide superior aerosol deposition to the lungs—five times more than the closest competitive system. BiWaze Clear is light weight, easy to use, transportable and is indicated to deliver therapy to adults and children over the age of 2 years in the acute care setting. A lithium-ion battery is included with each system. The device has been cleared by the FDA.

Discuss what educational/training materials you'll be offering.

Full product training will be provided at the booth by Mercury Medical Product Specialists. We will provide product information brochures and offer free samples of specific disposable products. The samples will be provided by fully trained Mercury Medical sales representatives who can answer your product questions and help fulfill your facility's clinical needs. Many training videos are available on the Mercury Medical website.

Why should AARC participants visit your display?

Mercury Medical is a leading manufacturer of respiratory products and is highlighting several key products that reduce costs, improve processes and improve patient outcomes.

Mercury Medical's innovation is evident with the introduction and unique concept of a disposable BiLevel and CPAP device. An alternative is when expensive equipment is not available at the right time. Additionally, Mercury Medical was the very first company to bring a completely disposable infant T-piece system to market and the latest Neo-Tee version with higher PEEP (orange knob) continues the trend of improving patient outcomes at an economical cost for the NICU, L&D, ED and transport.

With respect to NRP, Mercury Medical strives to create products that help clinicians meet industry guidelines. RT Directors, NICU Respiratory Specialists and nurses who visit our display will find resuscitation devices that meet NRP and AHA guideline requirements. For instance, the disposable Neo-Tee T-Piece Resuscitator offers more consistent inspiratory and expiratory pressure than other types of resuscitators. It is affordable for use at every NICU, L&D and ED bedside and transport. Furthermore, NRP recommends using a colorimetric CO_2 Detector on the OETT for intubated patients or supraglottic airway connector to ensure proper placement with rapid color change. Mercury Medical provides a solution for premature infants below 1 kg with the Neo-StatCO2 <Kg®—and it works for 24 hours. NRP also requires clinicians to use the right size mask for infants. With that in mind, Mercury Medical developed and introduced the anatomical silicone preemie masks to help solve the issues of masks covering the baby's eyes, or having to intubate when the smallest sizes are not available. These preemie masks are not only soft and flexible, but they are ergonomically designed which offers a tighter seal and reduction in mask leakage. The anatomical silicone preemie masks will also be exhibited in the Mercury Medical booth.

In summary, clinicians should visit the Mercury Medical display to get a first-hand view of our products and advantages.

MGC Diagnostics

Booth 517

What products will you be presenting at AARC?
MGC Diagnostics® is proud to present an impressive lineup of our latest products and technological innovations in the field of pulmonary function testing and gas exchange analysis.

As a leader in the industry, we'll be showcasing our advanced Pulmonary Function Testing systems, including the Platinum Elite™ body plethysmograph and the Ultima Series™ cardiorespiratory diagnostic systems. Both systems are equipped with our RTD™ real-time diffusion technology, which enables users to deliver clinically significant graphic data and immediate results. These tools are designed to streamline the diagnostic process and enhance the overall patient experience.

In addition to our Pulmonary Function Testing solutions, we're excited to showcase our Gas Exchange Testing systems. Among them, the Ultima CPX™ metabolic stress testing system and the Ultima™ CardiO2® gas exchange analysis system with integrated 12-Lead ECG stands out as powerful tools for comprehensive and accurate assessments. These advanced systems offer unparalleled insights into patients' respiratory health, assisting healthcare professionals in making informed decisions for optimal care.

We also invite you to explore our CPFS/D™ USB spirometer, a portable yet feature-rich spirometry device that empowers healthcare practitioners with flexibility and precision in respiratory testing. Additionally, we'll be presenting the Resmon PRO FULL V3 FOT (Forced Oscillation Technique) device, which offers valuable insights into lung function and airway resistance. MGC Diagnostics® is dedicated to respiratory healthcare, and our showcased products at AARC embody our commitment to innovation, accuracy, and patient well-being.

Are there any new products you wish to emphasize?
MGC Diagnostics is thrilled to present the much-anticipated release of Ascent™ cardiorespiratory diagnostic software for CPET testing. This groundbreaking software joins our Ascent™ pulmonary function software, creating a comprehensive, all-in-one solution for all your testing needs. Developed from the ground up, Ascent™ software stands at the forefront of technology, creating the most advanced testing software platform available. Designed to seamlessly integrate with today's hardware and with a vision for future innovations, Ascent™ software empowers users with an intuitive interface, guiding them through each step of the testing process, ensuring precise and effective patient outcomes.

Additionally, we are proud to introduce the all-new Meridian Series™ cardiorespiratory diagnostic systems, for exercise and metabolic testing. Engineered to deliver highly accurate results in a compact and efficient package, the Meridian Series is ideal for university settings, cath labs, and exercise labs. Keeping pace with the demands of modern labs, the Meridian Series offers versatile solutions to address your unique testing needs.

Our commitment to innovation and excellence shines through both the Ascent software and the Meridian Series. Join us to witness firsthand how these cutting-edge offerings are set to revolutionize cardiorespiratory diagnostics and enhance the overall quality of patient care.

Discuss educational/training materials you'll be offering.
Managing the MGC Diagnostics® exhibit will be our best-in-class clinical, sales and support experts, ready to not only answer your product questions but also provide personalized consultations to meet your unique clinical application and cardiorespiratory business needs.

Discover more about our highly anticipated Cardiorespiratory Diagnostics Seminars, scheduled to take place in Las Vegas in October 2023, and in Orlando in March 2024. These seminars are thoughtfully designed to provide participants with in-depth knowledge and practical insights into the latest advancements in cardiorespiratory diagnostics, equipping attendees with the tools to excel in their practice.

Why should AARC participants visit your display?
As a global leader in cardiorespiratory diagnostics, MGC Diagnostics® delivers diagnostic solutions for detection, classification, and management of cardiorespiratory patients worldwide. This singular focus guides our strategy and defines our commitment to customers, employees, and the cardiorespiratory industry. These attributes make us uniquely qualified to solve today's challenges and uncover solutions for tomorrow's opportunities. Through our comprehensive approach, we empower healthcare professionals worldwide to provide superior patient care and optimize treatment outcomes.

At MGC Diagnostics®, innovation and dedication converge to create a company that stands out in the industry. Visit us at AARC to discover how MGC Diagnostics® is shaping the future of healthcare through cutting-edge solutions and unwavering dedication.

Passy Muir

Booth 1026

What products will you be presenting at AARC?
Our full line of Passy-Muir Valves, adapters, and educational products.

Are there any new products you wish to emphasize?
PMV007 for ventilator use, **DigiSil**, **DB15** adapters.

Discuss educational/training materials you will be offering.
Newly updated **Pocket Guide**, as well as **Badge Buddies**, **Visual Use Guide**.

Why should AARC participants visit your display?
Meet our clinical specialists in person, engage in hands-on education, have your clinical questions answered, check out our full-range of PMVs, adapters and educational products.

Vitalograph

Booth 1020

What products will you be presenting at AARC?
Our complete range of diagnostic spirometers and new PFT solutions series, as well as recent additions to our complementary diagnostics offering, including FeNO and Oscillometry.

Are there any new products you wish to emphasize?
Respiratory muscle strength testing and spirometry in one portable device; V-Core range of handheld, portable and desktop diagnostic spirometers; new Vitalograph oscillometer and

VitaloPFT ROV+ — ideal for Diagnostic Hubs and point-of-care testing in any setting.

Why should AARC participants visit your display?
Meet our clinical specialists in person, engage in hands-on education, have your clinical questions answered, and check out our range of highly accurate respiratory diagnostic solutions.

Werfen

Booth 940

What products will you be presenting at AARC?
The GEM® Premier™ 5000 blood gas testing system from Werfen is the Intelligent Analyzer for point-of-care and centralized laboratory testing. Results for Arterial Blood Gas (ABG), Electrolytes, Glu, Lac, Hct, tHb, O_2Hb, COHb, HHb, MetHb, sO_2, tBili can be obtained from a single sample. Integrated Intelligent Quality Management 2 (iQM®2) — an active quality process control program designed to provide continuous monitoring of the analytical process, before, during, and after each sample measurement — assures real-time, automatic error detection, automatic correction and automatic documentation of all corrective actions. Maintenance-free, multi-use, self-contained GEM PAK cartridges incorporate all components needed for testing. GEM Premier 5000 with iQM2 is a complete solution for enhanced efficiency and patient care.

The GEM Premier ChemSTAT®, a whole-blood analyzer for rapid basic metabolic panel (BMP) testing is designed for the point of care. Delivering lab-quality results in <70 seconds, from venous or arterial samples, it has a menu designed for the ED, with a complete BMP panel — including Creatinine, BUN, tCO_2 Na^+, K^+, Ca^{++} Cl^-, Glu, Hct — plus Lac, pH and pCO_2. iQM ensures quality results with every sample. All-in-one, non-refrigerated GEM PAK cartridges simplify operations. GEM Premier ChemSTAT allows clinicians to focus on assessment of life-threatening conditions, for timely triage and enhanced patient management.

Discuss educational/training materials you'll be offering.
In blood gas testing, the most common errors occur within the preanalytical phase. To improve patient care and efficiency, Werfen has developed a new Preanalytical Training Package focused on increasing awareness about preanalytical errors and sample-handling best practices in blood-gas testing. Including an interactive learning module, quick guides for printing and placing near analyzers or patients, and a quality assessment for preanalytical training effectiveness and proof of competency for specific areas or operators.

What speakers or papers will you be featuring?
1) A peer-reviewed paper, co-authored by world-renowned quality control expert Dr. James Westgard and Werfen R&D Scientist, Jose Cervera, entitled "Intelligent Quality Management 2 with IntraSpect™ technology for quality control of GEM Premier 5000 blood gas analyzers — A novel application of the patient sample as its own control," published in *Practical Laboratory Medicine*, May 2022. Showcasing the excellent error detection performance of the GEM Premier 5000 and iQM2 with IntraSpect, a novel form of patient-based, real-time quality control (PBRTQC). iQM was originally validated by Dr Westgard, et al, 15 years ago when he published a seminal paper on the subject in Point of Care: The Journal of Near Patient Testing. Detecting errors during the patient sample measurement process addresses key risks in the total testing process to ensure optimal patient safety.
2) "Clinical Validation of a Novel Quality Management Solution for Blood Gas, Electrolytes, Metabolites and CO-Oximetry," a multi-center study focused on iQM2 published in the *Journal of Applied Laboratory Medicine*, November 2021. It is authored by leading experts in Point of Care and laboratory management from institutions in the US and UK:
   - James H. Nichols, PhD, DABCC, FAACC, Professor of Pathology, Microbiology and Immunology; Medical Director, Clinical Chemistry and Point-of-Care Testing, Vanderbilt University Medical Center, Nashville, TN
   - Tony Cambridge MSc., BSc. Lead Biomedical Scientist Pathology Management, Blood Sciences and Point of Care Testing, University Hospitals Plymouth NHS Trust, Plymouth, England
   - Neldis Sanchez, MBA, MT(NYS), Administrative Director for Ambulatory Laboratory Operations, Clinical Laboratories, NYU Langone Health, New York, NY
   - Debra H. Marshall, MBA, MA, RRT-NPS, RCP, Director, Adult Respiratory Care/Pulmonary Function Lab, Advocate Christ Medical Center, Oak Lawn, IL

This peer-reviewed clinical paper showcases the excellent performance of the GEM Premier 5000 with iQM2, including >6 sigma precision for all analytes and rapid error detection times in minutes vs hours or days, with traditional (intermittent) QC.

Why should AARC participants visit your display?
Visit our booth for a demonstration and to learn more about the GEM Premier 5000 and GEM Premier ChemSTAT systems and their positive impact on efficiency and patient care.

LungFit PH: Reactions from RTs on their Transition to and Use of this New System

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. This interview is with Heidi Dostal RRT-NPS, Lindsay Eddy RRT and Sarah Burda BSRT, RRT regarding the LungFit® PH system.

LungFit® PH is the most recent nitric oxide delivery device to become commercially available to treat neonates with hypoxic respiratory failure. Approved in June 2022 and with just over a year on the market, we asked a few respiratory therapists to share their transition from traditional cylinder-based systems and experience with the LungFit PH.

The LungFit PH is the first and only FDA-approved system that generates inhaled nitric oxide (iNO) from room air. The 3-in-1 integrated system generates, delivers, and monitors iNO and provides unlimited, on-demand iNO regardless of dose or flow, without the use of cylinders or cassettes.

Responses by Heidi Dostal RRT-NPS, Neonatal-Pediatric Advanced Practitioner, Bryan Health

Can you tell us about your career in respiratory care within the NICU?
I have been a respiratory therapist for 25 years, 15 years in NICU. Respiratory therapy (RT) is heavily involved with the care of NICU babies on respiratory support. We are also part of the neonatal transport team.

How did you find the transition from traditional cylinder-based systems to LungFit PH?
The transition to LungFit PH from the cylinder-based system was very smooth. The staff is good about letting the oncoming shift know when the NO_2 Smart Filter will need to be changed in report. The nursing staff is also good about letting us know when the last 30 minutes of the filter alarm goes off.

What are the advantages of the LungFit PH system compared to other systems on the market?
Our NICU is in a different building from the RT department, and you really had to plan ahead to make sure that we had enough tanks if we were running low. If you had a busy shift, it was easy for that to slip your mind. With the LungFit PH, we are getting into the habit of checking how many filters we have when we switch to a new filter. It is also easier to store the filters than the tanks, along with changing the filter vs tanks. The setup time is shorter for the LungFit PH system than the cylinder-based system.

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

How has LungFit PH improved NICU workflow?
The time that we would have spent getting the tanks to the NICU, changing the tank, and setup calibration, we can use that time to devote to patient care. Switching the filter is easy and fast.

What has been the initial response to LungFit from the NICU team?
We have had a positive response from the nursing staff, NNPs, and Neonatologists. Overall, there is less confusion about what needs to happen in order to manually ventilate a baby on nitric oxide (ie, which knob to turn, is the nitric oxide set where we need it, etc).

Responses by Lindsay Eddy RRT, Registered Respiratory Therapist, Northshore Edward-Elmhurst

Can you tell us about your career in respiratory care within the NICU?
I have been a NICU respiratory therapist (RT) for a little over a year now after years with adult and pediatric patients, and I love it. In Edward's NICU, respiratory therapists are very valued and work very closely with the NICU nurses and Neonatologists. I was very welcomed into the NICU and have thoroughly enjoyed my time learning and growing in our NICU. As a NICU RT we are responsible for maintaining airways, running ventilators, giving nebulizer treatments, as well as other respiratory treatments that may be ordered. And finally, we are responsible for setting up and running nitric oxide (NO) systems.

How did you find the transition from traditional cylinder-based systems to LungFit PH?
At first, I was nervous about the transition because a cylinder-based system was all I have ever known, and I was very comfortable with it. After setting up a LungFit unit on a patient and getting the system running I felt silly for being nervous. The LungFit system is extremely easy to use, and the setup was quick and seamless. I almost didn't believe it was on and running so quickly. I would say my transition from cylinder to LungFit was very smooth and I am happy with the switch.

What are the advantages of the LungFit PH system compared to other systems on the market?
The biggest advantage to the LungFit system is how quick and easy the system is to set up on patients. The delivery of NO is very fast with the LungFit PH. Aesthetically the LungFit system looks very new and is easy to transport. The screen display is easy to navigate and read, which is very helpful for all staff.

How has LungFit PH improved NICU workflow?
The LungFit PH has cut down the time from the physician order to delivery of NO dramatically, which is a huge asset. The nurses and doctors are very pleased with how fast we can set up and run the new nitric system. Timing is very important in NICU and when those patients need something, especially an inhaled gas, they usually need it rather promptly.

What has been the initial response to LungFit from the NICU team?
The initial response was as to be expected with anything new. The NICU team was excited about the new machine and loved the looks of it, but they were nervous about not having tanks and how effective the filters in the LungFit system would be. After using the system for a few days, the team expressed that they really liked the new machine and were happy about the transition. The bagging system was very easy for nursing to navigate and they were very happy about that.

Responses by Sarah Burda BSRT, RRT, Edward Hospital

Can you tell us about your career in respiratory care within the NICU?
I have worked in respiratory care since 1993. 30 years and have seen several changes. I haven't always worked within the NICU but I have been a supervisor and manager for 10 years and been involved in the monthly NICU meeting at my previous employer.

How did you find the transition from traditional cylinder-based systems to LungFit PH?
I find it incredibly easy to use compared to the cylinder-based system or the cassette-based system. It's quick and easy to exchange the filter.

What are the advantages of the LungFit PH system compared to other systems on the market?
Quick setup and delivery to the patient. Twelve hours before the filter needs to be changed. Easy to schedule the change of the filter.

How has LungFit PH improved NICU workflow?
Quick and easy setup for having the machine checked out, set up, and ready to go. It's like a grab and go system.

What has been the initial response to LungFit from the NICU team?
RNs were shocked at the machine when we brought it in. It's exciting to bring in a new piece of equipment. I am a little worried about bagging since I haven't needed to do that much. That is the only confusing part, otherwise the setup…easy! Weaning…easy! Showing the doctor or nurse what the patient is receiving…easy.

LungFit® PH | ALL YOU NEED IS AIR™

Unprecedented Speed to Care[1]

Generate and Deliver Nitric Oxide Within Seconds[1]

Visit us at AARC Congress booth #601 to learn more about unlimited, on-demand iNO from room air.

LungFitPH.com/AARC

INDICATIONS FOR USE

The nitric oxide from the LungFit PH System is indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilatory support and other appropriate agents. Refer to the full Prescribing Information within the LungFit PH System Operator's Manual before use.

Visit **www.LungFitPH.com** for full Important Safety Information.

Reference: 1. Data on file. Beyond Air Inc. 2021.

Beyond Air®

The Benefits of Remote Monitoring of Patients

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. This interview is with Alex Stenzler, the Chief Science Officer of Monitored Therapeutics (MTI), a remote health monitoring company. He is also the President of 12th Man Technologies, an R&D organization.

Give me some background on Monitored Therapeutics; why and how it started.
Monitored Therapeutics was started in 2011 following my departure as Vice President for Advanced Technologies from Viasys, Cardinal Health and CareFusion. In my role at these organizations, I had a real interest in improving the care of patients with respiratory diseases through the use of technology to remotely monitor and support patients, primarily with asthma and COPD. We had been working in collaboration with Battelle Memorial Institute in Ohio on this program until the program was closed in 2002. When we started Monitored, along with some of our former collaborators from Battelle and Michael Taylor, MTI 's CEO who I worked with at Viasys, we were building on concepts we had previously validated, so we felt we were on the right path.

What services does Monitored Therapeutics offer and what are its markets?
Monitored Therapeutics services three segments of the healthcare market. We have a clinical trials group that serves the pharmaceutical industry. Our solutions are utilized worldwide in studies monitoring lung function as an endpoint, as we manufacture one of the very few diagnostic spirometers that has been tested and certified for home use.

The second segment we serve is the disease specific monitoring needs of healthcare institutions. For example, we monitor pre and post lung transplant patients for a number of institutions such as the Cleveland Clinic and the Mayo Clinic, where we alert caregivers to sudden drops in lung function allowing them to intervene earlier. In other instances, we monitor patients with asthma, COPD, interstitial lung disease or cystic fibrosis.

The third segment brings our laboratory quality spirometry into the primary care space so that patients with lung disease can be diagnosed earlier and then managed with home monitoring, supported by educational materials.

Are there differentiating characteristics of your technologies?
While we have integrated more than 20 different physiologic monitoring devices, geolocation environmental data, and drug delivery devices, our primary differentiator is our technology associated with our monitoring of spirometry. There are a few special characteristics of our GoSpiro spirometer, which can collect hospital pulmonary laboratory diagnostic spirometry data from patients self-testing at home and from physician offices. It is the only turbine spirometer that can meet the low flow requirements defined by the ATS standards as it is a vertical turbine. Not all spirometers that are FDA cleared meet all the ATS standards. These standards also require that they not only pass waveform testing, but they are also able to measure flows down to 0.025 liters per second. While all FDA cleared spirometers can pass the waveform testing, no other turbine sold in the US can meet that low flow requirement. If physicians are using other turbine-based spirometers for monitoring patients at home, they may not be getting accurate measurements of FVC.

Another aspect of our unique solution is our avatar-assisted technology. The avatar, named Lisa, coaches patients through their spirometry measurements. Because the spirometer is Bluetooth connected in real time to the data collection platform, Lisa knows exactly where the patient is within the breathing maneuver and can coach the patient through the measurement. She knows whether the patient held their breath too long, didn't blast the air out, and if the patient has reached a plateau on exhalation. She encourages the patient to keep blowing until a plateau or 15 seconds of exhalation has been reached. She then reviews the measurement against all the ATS/ERS requirements and tells the patient if they did something wrong and how to correct the maneuver. The result is hospital quality data, captured remotely. Lisa also speaks 29 different languages, so patients can be coached in their native language. Our technology has enabled MTI to collect more than a million spirometry measurements that meet ATS criteria from patients self-testing at home.

How do you differentiate your company from others in the remote monitoring space?
There are several differentiating characteristics of MTI's remote monitoring solutions, namely our deep understanding and focus on lung function. The most significant differentiating capability as previously described, is our ability to get patients who are self-testing at home to consistently perform to ATS/ERS spirometry standards. We also have the capability to track medication use. Beyond that, we have embedded HIPAA compliant video conferencing on our data collection platform that enables a provider to chat with patients at home or watch them perform spirometry or other measurements remotely. Associated with our program are disease specific management

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

CarePlans, as well as a collection of ePRO data from either custom or validated questionnaires. The automated billing components of the platform for providers includes reports allowing for reimbursement under the available remote monitoring codes.

Can you get ATS repeatability and quality from patients self-testing at home?

ATS repeatability begins with assuring that each measurement that is collected meets the ATS/ERS performance standards. Once you have good quality measurements, it's far easier to meet the reproducibility requirements. Our avatar-assisted technology that coaches patients through each measurement and identifies and then corrects the patient for any errors, greatly enhances the likelihood of obtaining quality measurements, and therefore ATS repeatable results. From analyses of hundreds of thousands of measurements collected from patients at home, we have been able to get ATS/ERS grades of A or B from more than 90% of the testing sessions and when including acceptable Grade C's, the rate increases to 95%.

Tell me more about your disease specific and disease severity management platforms.

Not all respiratory diseases or conditions are the same and there are different levels of severity in each, which require unique programs to best manage their conditions. MTI has developed unique programs for each disease that are also scaled for level of severity. We call these CarePlans. They are a blend of objective physiologic measurements from a wide range of integrated devices and patient self-perception of their health and well-being.

The CarePlans automate patient engagement with medication and measurement reminders. We also send out CareTips which are brief pieces of information to help a patient better care for themselves. These tips can include information on nutrition, breathing exercises, clearing mucus, infection prevention, sleep, etcetera. We use CareTexts for single question patient checks. The platform can also check on other related aspects of these diseases that are not of pulmonary origin such as depression and anxiety using validated questionnaires.

The CarePlan platform can also send alerts to the patient, a family member or a healthcare provider upon physician set thresholds for either physiologic measurements or patient self-perception of their health. This fully automated platform enables management of a large population of patients with these conditions with a minimal number of healthcare personnel.

What do patients think of this level of digital engagement and has it had an impact on their health or healthcare?

We collected follow-up surveys with some groups of patients we have monitored. A high majority of these patients liked that they felt someone was watching over them. They also thought the frequency of communication from our platform was on target and they appreciated the educational material we sent. The majority responded that the program had a positive effect on managing their disease.

It's not always easy to find money in the budget to add new products and services. How does MTI assist in this solution?

There are two areas of need for a home monitoring program. First are how physicians acquire the technology to screen patients, and how do patients pay for the technology they use at home. Monitored Therapeutic has approached this problem with a two-pronged approach. For the PCP, who is concerned with investing thousands of dollars in equipment, we provide everything they need to perform tests for a low monthly fee that would be covered by the reimbursements from only 2-3 patients being screened per month. Fortunately for patients, the new Federal Remote Patient Monitoring (RPM) codes have enabled Monitored Therapeutics to provide the equipment and all of the associated services at no direct cost to the patient as it is reimbursed through CPT codes for RPM. This relieves both parties from the financial burden associated with diagnosis and monitoring.

Why do you think the primary care physician's office is the key to better care of patients with asthma and COPD?

There are at least 40 million people in the US with some form of pulmonary disease that should be seen by a physician at least once a year. To manage them according to the AMA, there are only 3,110 active pulmonologists, which equates to 12,862 patients for each pulmonologist. This is an unmanageable patient population for each specialist, particularly if they see patients every 6 months. Therefore, we believe that the answer to this problem is to enable diagnostic quality spirometry performed in the PCP office along with interpretation support. This moves the triage of pulmonary patients from the limited number of pulmonologists to the 135,000 family practice and internal medicine practices. Then the moderately severe and severe patients can appropriately be referred to pulmonologists, while the mild and moderate patients can be managed by the PCP with treatment support including monitoring.

What are the roadblocks to getting PCPs' participation in the early diagnosis of asthma or COPD?

PCP's face multiple obstacles to implement hospital laboratory quality spirometry testing in their offices. Without the certainty of being able to operate this level of testing, many are unwilling to invest in the thousands of dollars in equipment that they may not be able to use. Beyond that, very few PCP's would have a sufficient number of lung function tests to justify hiring a trained pulmonary lab technician to perform the testing. Also, the turnover of personnel in a PCP office is sufficiently high creating an undue burden of training replacement testing personnel. And lastly, most PCP's don't have adequate knowledge to interpret the test results.

The program for the PCP that MTI has created simplifies and addresses all of these challenges. MTI provides the solution for a monthly fee; testing only 2-3 patients a month provides sufficient reimbursement as pre and post bronchodilator testing more than covers that fee. Additionally, as our avatar Lisa I described earlier, coaches the patients through the measurements, staff members can collect accurate measurements with very little training. The demonstrated ability to collect hospital data with the avatar-assisted technology obviates both the need for highly trained personnel as well as the concern of personnel turnover.

The report generated for the PCP also includes an automated summary of the patient's lung function as well as providing a clinical impression based on the 2021 ATS/ERS interpretation strategies. Thus, the PCP is provided with sufficient information to diagnose and manage most patients or refer the patient to a pulmonologist for follow-up if required. The platform

then generates a billing invoice for PCP staff to use for reimbursement. This end-to-end solution enables the PCP to triage pulmonary patients, lowering the burden on the pulmonologists they refer to so they can focus on patients that really need to be seen. This can improve overall patient care and getting patients answers to their breathing concerns sooner than having to wait for a specialist appointment.

What are your thoughts on the future on remote monitoring of patients?

COVID made everyone from healthcare providers to patients recognize that remote care can improve the management of multiple conditions. While some services have returned to hospitals and clinics, we do not believe the transition to telehealthcare and remote monitoring will be reversed. The level of technological development that has occurred these past few years has been incredible. We are not at the end of telehealthcare, we are just at the beginning.

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even if they are on the move. Peter Pronovost, MD, PhD, FCCM, Chief Quality and Clinical Transformation Officer at University Hospitals, Ohio, and Clinical Professor of Anesthesiology and Perioperative Medicine at Case Western Reserve School of Medicine, said, "Radius VSM represents another radical transformation of care by Masimo, allowing clinicians to monitor based on patient acuity, not their location. With this new technology, not only can every bed have pulse oximetry monitoring, but if patient acuity increases, we can also easily scale up monitoring, even including ECG, without having to add new hardware or hardwire anything. With the staff shortages in hospitals and the high volume of patients, clinicians need the flexibility to put patients in any bed and ensure that that bed has the capability to monitor each patient appropriately. With Radius VSM, we will have enormous flexibility to manage patient risk across a hospital or, in our case, an entire health system: we can tailor what gets monitored to meet each patient's need, for truly personalized monitoring. And from a safety perspective, by allowing us to monitor patients based on their individual acuity and needs, linked to clinical protocols, we can significantly drive down the risk of possible harm in the hospital." Joan Carles Rueda, Deputy Director of Medical Technology at FGS Hospital de la Santa Creu i Sant Pau, Barcelona, Spain, where Radius VSM is already in use, said, "Radius VSM is a reliable solution that combines the advantages of a comprehensive monitoring platform with the autonomy of telemetry, giving the patient the safety and freedom to make their hospital stay more humanized. From a technical perspective, we had no doubt about the reliability of the solution as we have been working with Masimo for many years now. They provided the resources to ensure the proper operation of the technology, even evaluating our wireless network, and it has been working smoothly since the installation. We see the device design as an easy to maintain technology as it all is modular and plug and play." Thomas Callahan, MD, Principal Investigator and Director of the Inpatient Hospital Service for Cardiac Electrophysiology and Pacing, Cleveland Clinic, commented, "We are excited to have gained early experience with this next generation inpatient monitoring system at our center as part of the investigational study. What helps differentiate this technology from existing systems is high fidelity continuous ECG monitoring in a compact modular configuration and integration with high precision optical, electrical, and acoustic sensors for blood pressure, respiratory rate, pulse oximetry, and motion."

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Antiepithelial-derived Cytokines Need Targeting for Asthma

Use of antiepithelial-derived cytokines was of limited benefit for patients with severe asthma who had low eosinophil counts, as

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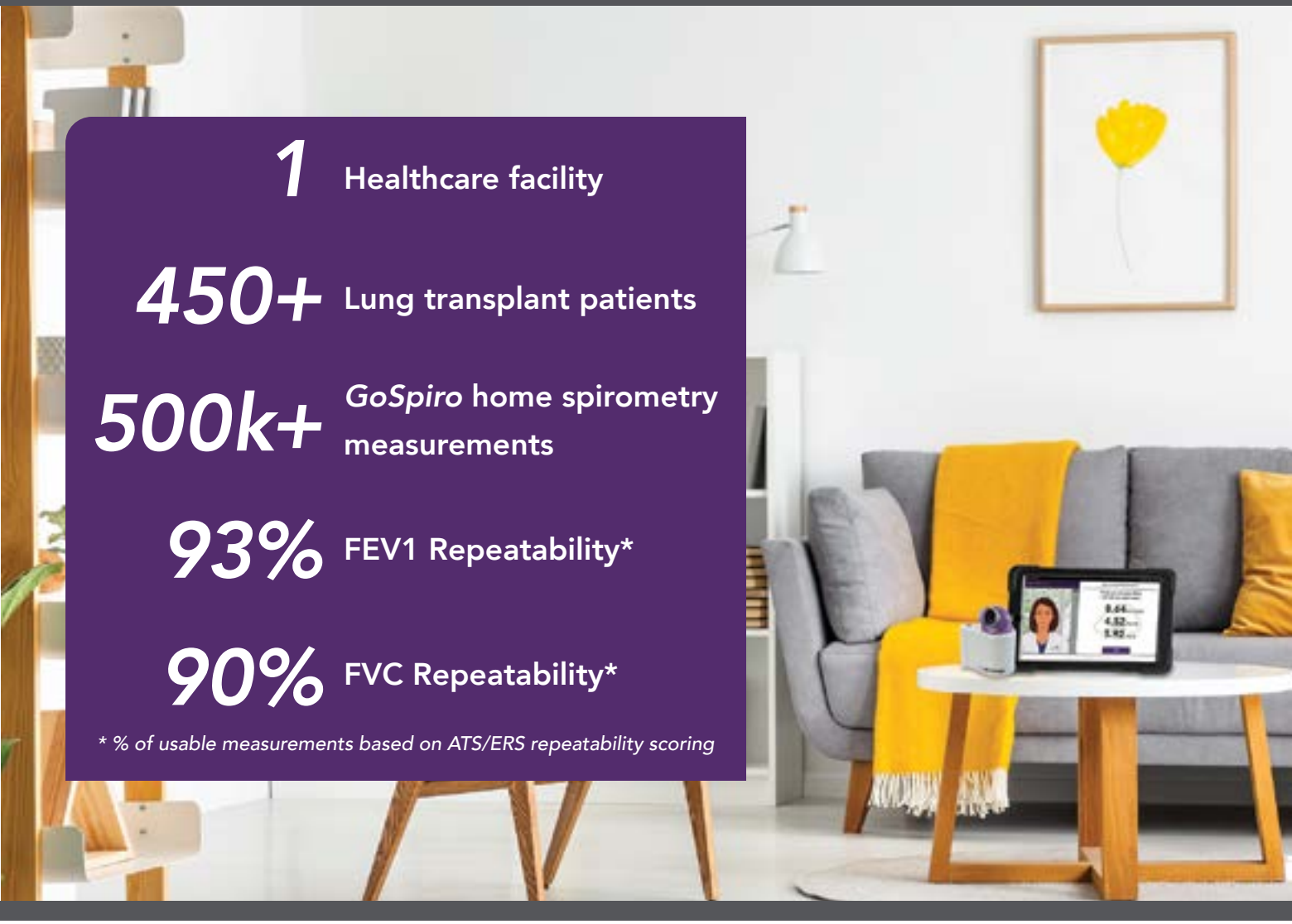

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20 Years Experience with Breas Ventilators

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. Participating in the interview is Stefano Nava, MD, University Hospital Sant' Orsola, Bologna, Italy.

Breas met with **Stefano Nava, MD,** a leading proponent and researcher of Noninvasive Ventilation who leads the respiratory and critical care unit at the University Hospital Sant' Orsola in Bologna, Italy. We spoke about his 20 years of experience with Breas ventilators and how he has seen NIV improve the quality of patient's lives. Here is an excerpt of the conversation:

Please tell us about yourself and your career as a physician, where you are working today, and so on, and your relationship with Breas?
Stefano Nava: I graduated from Pavia University, one of the oldest Italian universities. My career as a physician started in 1979 when I was attending the Respiratory Unit of the University of Pavia. Then when I graduated in 1982, my professor sent me for a three-year fellowship in Montreal, Canada at McGill University. McGill is very famous for pulmonary physiology and also mechanical ventilation. When I came back to my country, I first worked in a small hospital and then I moved to Pavia. And I spent some time in Belgium. Then I came back to Pavia. Then I took a sabbatical in Boston, and finally in 2010 I moved to the University of Bologna and I ran a busy unit.

At Bologna, we have a respiratory ward with 20 beds, including sleep studies, a very busy outpatient clinic and an eight-bed respiratory intensive care unit. My field of interest is obviously respiratory medicine, but with particular interest in respiratory insufficiency, chronic and acute. We studied various aspects of invasive and noninvasive mechanical ventilation, including sleep, respiratory mechanics and clinical outcomes. About 20 years ago I started my relationship with Breas working on different projects.

In those 20 years and in all the experience you have with Breas, how does Breas compare to other players in the ventilation market?
Stefano Nava: Well, Breas is one of those companies that are developing very good high-quality noninvasive and invasive ventilators.

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

I have a very good experience and relationship with the Breas team since the start. And it must also be said that even 20 years ago Breas were already quite innovative. They were reliable both in the ventilation systems and the quality of ventilation, and last, but not least … the patients were really satisfied with the Breas ventilator. When I think about the good old days, I remind myself how much a ventilator has been improved in 20 years — not only the shape, but in the monitoring system, in the algorithms. Twenty-five years ago we were pioneers of this kind of chronic application, and also acute application of mechanical ventilation in our patients.

What is your impression about Breas and the educational efforts they are doing, like for example, EducationbyBreas.com, or any other efforts?
Stefano Nava: Breas is a well-known company around the world. First of all, they manufacture a very good product. Second, because they advertise themselves quite well. They are always present in the major medical meetings, especially those devoted to home mechanical ventilation. They support events, I think, all over the world, educational events, and more, I would say, advanced events. But I'm part of a group that joins together periodically and discusses not only what should we do in the future, but also how to improve, I would say, the treasure of knowledge on mechanical ventilation with particular aims, at least to home care ventilation.

So altogether, with Breas and with all my other colleagues, they are all well-known colleagues with a lot of expertise in the field, we decided to do several initiatives. One is that we put together a website based on the Breas website where we try to explain the basics of home mechanical ventilation (including) our experience, for example, in the last few months with COVID. Some of us developed a booklet on How to Read Ventilator Waveforms and How to Apply NIV. So I think in this aspect, Breas is way ahead of most of the other companies.

In your experience, do the the Breas technologies and algorithms, that have been developed over the years for noninvasive ventilation, fulfill your expectations in the hospital and at home?
Stefano Nava: Well, I think the major feature that you want to ask from a ventilator that is going to follow the patient at home is reliability. The Breas ones in general are reliable. They match very well to the patient's demand. They improve tolerance and therefore we use this device when the patient is left alone at home. Otherwise, you can send the patient with a vent home, but

if the patient feels bad with this interaction with the ventilator, then after a while, and I saw this with so many of these patients, they leave the ventilator aside, and they don't use it.

Remember, the compliance to the ventilator is strongly dependent on how good the ventilator matches the patient demand. In this aspect, Breas ventilators are extremely good.

Thank you. Of course, you have your experience, or yourself, as an expert. But it's also important to look at your staff, your nursing staff or therapists. What is their view and their thoughts about the Breas ventilators?
Stefano Nava: Let me start not with nurses and respiratory therapists, but with medical students or fellows. Medical students, when they come to the hospital for the first time, they don't know a clue about ventilation. Nothing. They are looking at the ventilator like a monster, or something like that. Even fellows, first year fellows, they are exposed to night shift or something like that without a lot of experience, I found the ease-of-use to be extremely important in this situation. It is clear that a young student, a young fellow, needs to study. I mean, you can apply things, touching buttons, hoping that something is working. But when they know the basics of mechanical ventilation, what they are telling me is, "Oh, listen, this is quite easy to set. It is quite easy to understand how good the synchrony between the patient is and what I set on the ventilator." This is, I think, the strongest way to demonstrate, I would say, the appeal of the Breas ventilator.

…when they know the basics of mechanical ventilation, what they are telling me is, "Oh, listen, this is quite easy to set. It is quite easy to understand how good the synchrony between the patient is and what I set on the ventilator." This is, I think, the strongest way to demonstrate, I would say, the appeal of the Breas ventilator.

On the other side, nurses are happy because, if you set the alarms well, and as leak compensation is very good, they are not bothered too much, especially during the night hours because of leaks, unless the patient is agitated obviously. It's relatively easy to perform disinfection and to clean them when you change a ventilator from one patient to the other.

Concerning the respiratory therapists, when they receive an order to set the vent, they claim it is really easy to set, very understandable. I find that the ease-of-use also means they are easy to start ventilation and set the parameters that one wants to apply.

And I can tell that some of the other home care ventilators are very, very complicated, even to switch on. It is not easy to do that. And last, but not least, the screen is small. It's small as all the other home care ventilators, if they have a screen. Not all home care ventilators have a screen. The Breas traces are very clear and colored, so the screen resembles that of the ICU ventilators on a smaller scale.

If somebody would ask you, Professor Nava, we are considering to start using Breas Vivo ventilators in our practice, what would you tell them?
Stefano Nava: I would say "Go ahead, because the ventilators they sell are reliable," as I said before. I mean, reliability is the best thing. It never breaks. They are easy to use. We never receive major complaints from the patient. I think that having said all of this, I would say, "Really go for it." I worked with several ventilators, and I found that Breas, by far, the company is able to quickly respond to your questions. What does quickly respond mean? How fast you respond to a need of a clinician. That depends also on a home care provider obviously. But, for example, when you have some technical questions for example, how a specific algorithm is working, or you do not understand very well the mode of ventilation, or how the alarm or the numbers means, they very quickly respond.

Thank you. Thank you for the time. Thank you for this interview. I don't know if there is anything else.
Stefano Nava: If I can make a little story of a patient (a) COPD patient with emphysema, a young guy. At that point in time, he was 54, a former heavy smoker. He was facing once an acute exacerbation of COPD. So, he came to our unit. We had a Vivo ventilator available, so we wanted to ventilate him with NIV and the guy was really fighting. He said, "No. I don't want that. I don't want to be ventilated." So, we convinced him. We sedated him, applied NIV and after a while he got better and we weaned him from the ventilator.

So, six months later he came back. He needed once more NIV. So, at this point in time, he was more compliant, and the time of recovery was short. So we suggested since he was severely hypercapnic with a PaCO2 of 75mmHg, we said, "Why don't we think together to go home with this ventilator?" It was a Vivo ventilator. He said, "No way. No way. Absolutely no way. It's too demanding. Disrupt my family. I don't want my friends to see me if they come and visit me with a ventilator close to my bed. I don't want to disturb my wife. So, I don't want it."

Once more, three months later, he was admitted to another hospital. His wife called me. She was desperate. She said, "They want to intubate my husband. He doesn't want that. He wants to come to your unit because he thinks that you can manage with NIV. He doesn't want to be intubated." So, he refused. He wrote, "I don't want to be intubated." So, they discharged him, and they transferred him to our hospital. Well, once more, he underwent NIV, still with a Breas ventilator. At the end of the day, he asked, "Doc, could you please provide to me this vent that it can follow me at home?"

So, to make a long story short, he was so satisfied. Since, in the following three years, he was admitted only one time. Why was he admitted one time in three years, but he was admitted two times a year before? One of his daughters was an announcer at the local television. He invited me and other colleagues in the television program, explaining what NIV was and how good was life under NIV, and so forth. So, it was a big opportunity. The guy died a couple of years ago, but we strongly believe that we gave him five years of good quality of life, and this is what mattered.

We cannot treat emphysema. We cannot, I would say, definitely get rid of the disease. In this patient, we needed to improve the quality of life. Having two times a year an ICU admission deteriorates the quality of life a lot.

So this is just to say the journey of the patient, but he was, at one point in time, not convinced to be ventilated at home, and then with time he was very satisfied to go on television and tell the people how good it was. And he was asking, I remember, I want this ventilator.

Well, I have many patients, that they ask me, "Doc, please, I can't stand at home this vent. Please prescribe me a Vivo, like the one that was used when I was in the hospital." This is just to say that not all the ventilators are the same.

Well, that's an impressive patient story. And you are absolutely right. It's about the quality of life. It's not about life only.

Stefano Nava: Yeah. You know people are only concerned about improving the duration of life. That is good. But if you improve quality of life and you keep being admitted to the ICU, I don't know if it is a good quality of life or not. So, this patient was really impressive because he kept going for seven or eight years without major problems.

Yes, that's amazing. As you say, there are parts that can't be cured. Mechanical ventilation is not a cure. But it should help to buy time or to improve quality of life in these things, of course.

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indicated by data from a systematic review that included more than 2000 individuals. Several types of antiepithelial-derived cytokines (anti-EDCs) have been studied or approved for patients with severe asthma; however, "we understand very little about the effects for those who are not type 2," said Terence Ho, MD, of McMaster University, Hamilton, Ontario, Canada. The meta-analysis was needed because some clinical trials suggest benefits for patients with type-2 asthma (T2) and patients with non-T2 asthma, but data that compare outcomes are limited, Ho said. If one were to look at just one study, one might think that anti-EDCs would work equally for all patients with severe asthma, he noted. In a study presented at the American Thoracic Society (ATS) 2023 International Conference, Ho and colleagues identified 12 randomized, controlled trials that involved the use of anti-EDCs for a total of 2391 patients. The study population consisted of patients with T2 and non-T2 severe, uncontrolled asthma. T2 asthma was defined as asthma associated with eosinophil levels of ≥300 cells/uL; non-T2 asthma was defined as asthma associated with eosinophil counts of <300 cells/uL. The researchers used a random-effects pairwise analysis to evaluate outcomes in the different patient groups. Outcomes of interest were all-cause mortality, asthma exacerbation rate (AER), change in forced expiratory volume per second (FEV1), serious adverse events, change in blood, sputum, and/or submucosal eosinophil counts, fractioned exhaled nitric oxide (FeNO) level, and immunoglobulin E (IgE) level. Overall, anti-EDCs were associated with a reduced AER among patients with T2 asthma (risk ratio [RR], 0.33) with moderate certainty, but certainty was low for patients with non-T2 asthma (RR, 0.59). Anti-EDCs were significantly associated with improved lung function, as shown on FEV1, for patients with T2 asthma (mean difference with patients with non-T2 asthma: 218.5 mL vs 68.8 mL). Blood eosinophil counts, IgE level, and FeNO level were similarly reduced among both patient groups. The takeaway message for clinicians is not to presume that anti-EDCs will be equally effective for all patients with severe asthma, especially given the cost associated with these treatments, Ho said. More research on the use of anti-EDCs for patients with non-T2 asthma is needed, he said.

Dupilumab Curbs Acute COPD Exacerbations

Dupilumab significantly reduced exacerbations in adults with chronic obstructive pulmonary disease by approximately 30% compared with placebo, based on data from approximately 900 individuals. Chronic obstructive pulmonary disease (COPD) is associated with decreased lung function and increased risk of exacerbations, and previous studies of anti-interleukin-5 biologics have yielded mixed results, according to Surya Bhatt, MD, of the University of Alabama at Birmingham, and colleagues. Dupilumab, a fully human monoclonal antibody, is designed to target receptors for interleukin-4 and interleukin-13, known drivers of type 2 inflammation, the researchers said. In a study known as the BOREAS trial, simultaneously published in the *New England Journal of Medicine* and presented at the 2023 American Thoracic Society International Conference in Washington, DC, the researchers randomized 468 COPD patients to 300 mg of dupilumab and 471 to a subcutaneous placebo injection once every 2 weeks. The patients met criteria for type 2 inflammation, defined as blood eosinophil counts of at least 300 per microliter, and demonstrated an increased risk of exacerbations despite a history of triple inhaler therapy. The patients ranged in age from 40 to 80 years (mean age 65 years)

Continued on page 35…

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Benefits of Implementing an Airway Monitoring System at Children's Hospital of Illinois

In this feature, Neonatal Intensive Care interviews clinicians and healthcare providers about the actual application of specific products and therapies. this interview is with Dr Jawad Javed and Dr Ashley Fischer at OSF Healthcare Children's Hospital of Illinois.

For Dr Jawad Javed, Medical Director and Division Head of Neonatology at OSF Healthcare Children's Hospital of Illinois and Professor of Clinical Neonatology, improving monitoring of endotracheal tube (ETT) movement while implementing kangaroo care and improving unplanned extubation (UE) rates was a priority to ensure the safety of his facilities' patients. Located in Peoria, Illinois, the 60-bed neonatal intensive care unit (NICU) is a level four with the American Academy of Pediatrics' designation system. The comprehensive facility is set up with private rooms divided into neighborhoods, with each having between seven to ten rooms. Patients commonly range from 22 to 30 weeks' gestation, and while Javed and his team belonged to the Vermont Oxford Network of data-driven quality improvement, the global burden of UEs still impacts his facility.

I sat down with Javed and his colleagues — Dr Ashley Fischer, Quality Improvement Director and Associate Professor of Pediatrics, and John Sanford, Respiratory Therapist of Neonatology — to learn what it meant to integrate SonarMed™ airway monitoring system into their hospital for improving ETT monitoring, enhancing their kangaroo care offerings, and improving UE rates overall.

What were your team goals regarding unplanned extubations in your hospital?
Jawad Javed: The patients — it's why it's so important to for us to get a handle on our unplanned extubation rate and to ensure that we are doing more neuro-developmentally appropriate care.

Patient satisfaction for our parents was important — wanting to do kangaroo care and be involved. Having the confidence of holding their babies is a big thing. It didn't matter if they were preemies from 24 weeks up to term infants, whenever we used the device it worked efficiently for us. It gave parents confidence.

We presume that the ETT tended to move during critical moments, but there was no great way to measure and monitor if drifts occurred. There was no good way to determine if you're too high or too low, because the chest X -ray isn't always the most effective way to diagnose. We wanted to monitor these ETT movements in real time and that's what the SonarMed™ system was able to do for us — give us real-time information as to where that (ETT) tip is.

We pride ourselves on getting that mom-baby connection to start off quickly, so we get into kangaroo care positions early in life. We encourage families to hold their children; however, this does come with increased risk of potential of an unplanned extubations.

We want to provide safer care to improve our unplanned extubation rate and take that metric to the next level. These major interventions* we participated in brought our unplanned extubation rate down from 2.1 to roughly around 1.3 and 1.4 events per 100 ventilator days. We made great headway with our team and a team-based approach, but had a hard time breaking that threshold of below 1.0. **multiple UE bundle practices*

Were there any obstacles in launching this technology with your staff?
Jawad Javed: Medtronic did a nice job with our onboarding process, and this was a big challenge with COVID-19 and difficulties trying to bring personnel into the hospital.

We went through a champions course initially with our respiratory therapist and our clinical nurse educators to go through the device in a more meticulous fashion, and this education was conveyed to the staff. Medtronic spent time with our group to help the onboarding of all of our staff — a lot of the staff concerns would have been there otherwise.

Because of the great planning and education that was done by John (Lead RT and educator) and his group, our nurse educators, and the Medtronic support working with our staff one-on-one, it removed a lot of obstacles.

Did you do an evaluation of this device or how did you get this device adopted into your institution?
Jawad Javed: When I learned about the device, we started with the situation-background-assessment-recommendation (SBAR) process of understanding why we needed it and then spoke extensively about what this device had to offer. We sent it to our products committee, and it was really a matter of where the foundational funding would come from — the capital budget that exists within our unit and the device fit within that process.

I presented to our products committee and executive board. We spoke highly about what this could do for us and strongly

Abigail Scaggs is a Global Marketing Manager with Medtronic. If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net

SonarMed™ Airway Monitoring System.

believed in the science that existed within the device — it could be a game changer.

The actual purchasing part of it wasn't too bad once we got the approvals. But from a value-based approach, looking at the cost of an unplanned extubation in a premature infant, it becomes cost effective to invest. Additionally, our patient experiences of babies being able to bond quickly with kangaroo care — we try to get these small preemies into the parents' arms and support skin-to-skin bonding.

How does the SonarMed™ airway monitoring system support kangaroo care in your hospital?

Ashley Fischer: For me, it's families having skin-to-skin contact and performing kangaroo care confidently. But for the mothers — to feel more comfortable holding their child — is valuable. Over the last six to ten months, we still have been doing our kangaroo care and have been able to optimize that a little bit more for patients.

John Sanford: We've embraced the thought of having parents participate in kangaroo care or skin-to-skin care. We encourage this on daily rounds. We always do a patient assessment to see how the patient's doing and if they are able to tolerate getting the baby into the parents' arms. We facilitate that as much as we can. We don't have too many limitations to keep the baby in the isolette, and even if they're on high-frequency ventilation, that doesn't automatically disqualify them from kangaroo care. But it is a little intimidating when getting the baby out. Making sure we keep the ETT in the proper place can be tense, stressful. Parents pick up on that, and they know when the caregivers are watching more closely.

When we're using the SonarMed™ device during those movements, it reassures us quite a bit and eases that tension while it's in place. While the parents are holding the baby, we tend to turn the monitor towards the parent, and they, too, can watch as that ETT migrates up and down.

It helps parents relax a bit more if the baby moves a little. For parents that have seen an unplanned extubation, it's terrifying for them, so it's really heartbreaking to hear parents not wanting to participate in kangaroo care after they've had one of those episodes. It's nice to have this monitor to help reassure them that the tube is where it should be and we're watching.

They can feel that sense of security now with that monitor in line. Parents are more apt to participate in kangaroo care if they can keep an eye on that airway.

How has using the SonarMed™ airway monitoring device impacted the number of X-rays and your suctioning practice?

John Sanford: Actually, having the device has cut down on repeated ETT movement orders as it's this dance that we sometimes do with the X-rays. Hopefully we're cutting down on the number of X-rays that we're getting because we can look at the monitor and see where the tube is then decide whether we need to adjust tape position or not. †

You're adding those encounters more every time you tape and re-tape, either with something slipping out or the tape failing, so you decrease the number of times you're moving those in and out.

Ashley Fischer: We're not doing routine monitoring with X-rays for ETT placement — it's just really needed if there's a clinical change.

John Sanford: Our suctioning procedures have changed with the device. We use safe suction distance measurements for every baby that's intubated, so we've got to add more length to get down to the tip of the airway (with the inline sensor). We do that calculation and post it for the nurses, which also gets passed into a report for the RTs. The device displays a percent of occlusion in the airway, so we have a frequency that we go in and assess for our patients if they need to be suctioned. In between, if we notice the monitor is alarming and showing a percent of occlusion as well as if it was to the point where we can see if our baby was desaturating or having a bradycardic component, we go in and do additional suctioning.

Sometimes we may pass on deep suctioning of our patient because it isn't necessary. A nice feature on the monitor is listening to breath sounds without putting a stethoscope on the baby's chest. If we turn that feature on and the breath sounds are clear, heart rate, and stats we're doing fine with everything else stable, we may differ away from the invasive suctioning to another point of care.

What sets off the alarm and how do you adjust it to avoid it becoming a nuisance alarm?

Ashley Fischer: When we were learning about the SonarMed™ device as we trialed it for a day on a patient in a private room, the nurse was asking me what the alarm sounded like, right then the alarm went off and the patient was experiencing occlusion. The patient then started coughing with hacking noises, and we realized we should try suctioning.

Abigail Scaggs: There are three main alarms that you can set specific to a patient, and we provide some guidance around those levels:

- Movement of the tip of the ETT
- Specific severity of obstructions
- Circumference around the tip of the tube

How did you tackle your unplanned extubation goals?

Jawad Javed: We trialed different things, and a lot of collaborative efforts in our quality work with our respiratory therapist (RT) and nursing colleagues. We did a full audit of the bundled measures for a root cause analysis of all UE events.

Ashley Fischer: Before implementing SonarMed™, we've been able to reduce our unplanned extubation rate to 1.5 per 100 ventilator days for the last six months and we've noticed the bedside staff realizes how much movement has occurred with the ETT.

This allows more focus on watching the ETT tip during movement when we're conducting X-rays during transport. By ensuring everybody in the unit had a uniform way of doing their X-rays, ensuring heads were midline and straight, but that it is held in a proper position. Then working with our peripherally inserted central catheter (PICC) line positioning during that same time. We are able to work with our radiologists to annotate the X-ray exactly where that ETT tip was.

We did more education with our fittings and ensuring they had optimal fit during X-ray. All those things made some difference, and we dropped it to about 1.4, but you can see in

SonarMed System in use at Children's of IL on neonate during kangaroo care.

April to June of 2020, we had three outliers as the result of a couple of really big feisty babies that were difficult to control and monitor.

How do you do choose which patient goes on the SonarMed™ device? Is there a certain patient population or patient criteria to help you choose which babies go on the device?

John Sanford: We have five monitors, and we've quickly outpaced those five monitors. We're in the process of getting additional monitors. But a tough decision. We don't have a priority to the patients; if there's a monitor that's available, it goes to an intubated patient. We have five monitors right now on our unit. We try to push the monitors towards a patient that has already had an unplanned extubation or a patient that has a tenuous airway. We don't want any repeat offenders.

Even some of the bigger neonates that we noticed have strong and purposeful movements with their hands — something that has worried us or caught our attention — we may try to steer the monitor towards that patient.

What would your message be to those considering this type of airway monitoring technology?

Jawad Javed: For the NICU, we did what we could do with our team-based quality approach. We tried different modalities to bring that unplanned extubation rate down as best as we could. We made headway — going from 2.1 to 1.4 and 1.3 — but it was a tremendous amount of work from our amazing staff and crew. Taking it to the next level was a game changer for us to get below the 1.0 mark.

My message is that the technology is a potential game changer for the area of unplanned extubations — if you really want to make a significant dent. Now we're looking at other populations in the PICU as there's a lot of interest to try to get a handle on these because of the cost burden that exists there.

What are your team goals for the future with this airway monitoring device?

Jawad Javed: For me, honestly, the patient care is always first and foremost. To see what the families are doing around kangaroo care is incredible. When you work so hard to move a metric number even a few points, it's so much effort. To provide this kind of device moves that bar to a different level to support the team's efforts while watching that cultural transformation — it's astounding.

It's great to be able to utilize this. We started a neonatal fellowship program in our institution, so getting our fellows to work on the research aspects of this device is going be very fascinating over the coming months and years — to see how much we can push the folds of the metrics and what we can get off of this device while pushing towards a zero unplanned extubation rate.

Footnotes

†The SonarMed™ Airway Monitoring System should not be used as the sole basis for diagnosis or therapy and is intended only as an adjunct in patient assessment.

††This testimonial is based on one facility's experience. Experiences vary.

News…continued from page 30

and had physician-diagnosed COPD for at least 12 months. Approximately two thirds were men, and 84% were White. The study population overall had an average of 2.3 moderate or severe COPD exacerbations in the past year, and 30% were current smokers. The primary outcome was the annualized rate of COPD exacerbations, which was 0.78 in the dupilumab group vs. 1.10 in the placebo group, (rate ratio 0.70, $P < .001$). Secondary endpoints included change in prebronchodilator forced expiratory volume in 1 second (FEV1). This change was significantly greater from baseline to 12 weeks in the dupilumab group compared with the placebo group (mean of 0.160 L vs. 0.077 L, $P < .001$); this difference continued at 52 weeks. Other secondary endpoints examined quality of life using St. George's Respiratory Questionnaire (SGRQ) and the Evaluating Respiratory Symptoms in COPD (E-RS: COPD). On these measures, lower scores indicated better quality of life and less severe symptoms, respectively. SGRQ total scores improved by 4 or more points in 51.5% of dupilumab patients and 43.1% of placebo patients, and the least squares mean difference in the dupilumab group vs. the placebo group from baseline to 52 weeks was -3.4 ($P = .002$). The least squares mean difference in E-RS: COPD total score from baseline to 52 weeks in dupilumab patients vs. placebo patients was -1.1 ($P = .001$).

Sublingual Immunotherapy Stops Onset and Worsening of Asthma

The EfficAPSI study showed with real-world data that sublingual immunotherapy (SLIT), or "desensitization," reduces the risks for asthma onset and the worsening of asthma symptoms for patients with allergic rhinitis. The research was presented at the 18th French-language allergy conference in Paris. These results confirm that allergen immunotherapy (AIT), or "desensitization," is indeed an etiologic treatment of this allergic condition. SLIT encompasses personalized solutions created for an individual specifically for allergies to dust mites, grass, birch, cats, and so on. These preparations are commonly used by allergy specialists when establishing an AIT treatment plan. The pharmacoepidemiologic EfficAPSI study is the largest retrospective, real-world, longitudinal cohort study ever carried out regarding liquid SLIT using data stored in the French National Health Data System (SNDS). The primary objective of the study was to evaluate the real-world impact of liquid SLIT on the onset and worsening of asthma for patients with allergic rhinitis and to evaluate the impact of sublingual treatments on public health. A cohort analysis of patients treated with SLIT and control patients treated for allergic rhinitis with or without treatment for asthma was carried out. The patients treated with SLIT for at least 2 consecutive years were anonymously selected from the SNDS using the Stallergenes Greer prescription database. In all, 99,538 patients who received SLIT were compared with 333,082 control patients (those who had received treatment for allergic rhinitis without taking SLIT). Participants were stratified according to their treatment history for asthma and were paired using a propensity score to minimize comparison bias.

Tests Clear Recalled Philips Sleep Apnea Machines of Health Risks: Company

Dutch medical devices maker Philips said that independent tests have shown that the use of its respiratory devices involved in a major global recall did not cause health risks for patients. Philips said "rigorous testing" by external parties on the range

Continued on page 59…

How Mobile Ventilators Can Help Patients Transition From Hospital to Home

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. This interview is with Megan Carpenter, Vice President of Ventilation Sales, React Health, makers of an exciting new ventilator called V*Home.

Respiratory Therapy: We recently had an opportunity to sit down with Megan Carpenter, Vice President of Ventilation Sales for React Health, Inc. Her team has spent the past several months developing an exciting new ventilator called V*Home. Megan, can you describe the benefits this new product offers?
Megan: It would be my pleasure. Here at React Health, we sought out to develop a ventilator that's optimal for treating the patients that we serve. The V*Home ventilator is compact and the easy-to-transport design supports patient's changing needs across a range of care environments, making it an ideal ventilator to transition patients from hospital to home.

RT: That sounds like a very considerate approach.
Megan: We certainly try to keep the needs and concerns of our patients and clinicians in mind to create consistency in therapy across the continuum of care. In order to make that transition as seamless as possible, most features and functions that patients and caregivers become comfortable with in the hospital remain similar in the home. We really wanted to do everything we could to reduce the complexity of care for patients suffering from respiratory disease, while easing their transition to home ventilation.

RT: Tell us more about V*Home. What methods of ventilation is it compatible with?
Megan: V*Home is compatible with invasive, non-invasive, and mouthpiece ventilation. Additionally, we offer the added benefit of High Flow Therapy. As you know, High Flow therapy has been used in the acute space for many years. Now with the introduction of the V*Home ventilator High Flow therapy is also available for patients at home. NIV (non-invasive ventilation) and High Flow Therapy have been proven to improve quality of life and reduce exacerbations; we're excited to be able to offer the therapies in complement within the homecare setting.

RT: How exciting, I know HFT has long been desired in the homecare market. Is the V*Home intended for adult patients?
Megan: Great question. Like all the ventilators in our portfolio, V*Home is safe for use with both adults and pediatric patients weighing greater than 5 kilograms.

RT: I see, and what else can you tell us about it?
Megan: Well, in the development of the V*Home, we included patient-centric features and a high level of customization specifically related to Ventilator synchrony. Additionally, the V*Home's intuitive Volume Targeting mode is responsive to changing ventilatory needs, while keeping the patient comfortable in the homecare environment.

Also, it was designed with an interface that is user-friendly for clinicians and patients alike, making it easy to find and adjust settings as needed. We maintained that theme of an easy-to-use platform with our plug-n-play connectivity with the optional React DataLink, which is powered by and connected directly to the V*Home. This allows clinical care teams to quickly and easily view trend reports, track compliance with prescribed therapy, and make informed treatment decisions. React DataLink also includes a GPS function, which has been something our DME partners have been asking for to track the financial investment they have in their product.

RT: It sounds like you're bringing a really versatile product to the market, and one that seems to prioritize the needs and concerns of your patients and clinicians.
Megan: Thank you. We certainly pushed ourselves to address patient and caregiver needs. We developed the V*Home with a mindset of 'What if it were me, or one of my loved ones, who needed to rely on this ventilator?' I'm very proud of what we're able to offer.

RT: And how can people interested in V*Home learn more about it?
Megan: Absolutely. Our Clinical Team would be thrilled to speak with potential customers to help them learn more about V*Home. I would encourage people to contact their React Health representative, visit reacthealth.com, email ventec-info@reacthealth.com, or call 844-698-6276.

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

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V-Home

VC-Pro

V-Pro

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- **High Flow Therapy**, with flow rates of 4 - 60 L/min
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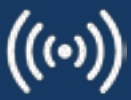
- **Portability,** with compact, lightweight design and up to 9 hours of battery life
- **User Friendly** smartphone style touchscreen interface

Invasive and Non-invasive

HFT

High Flow Therapy



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MADE IN AMERICA

Transcutaneous Monitoring in the NICU: Enabling Proactive Ventilator Management for Quality Patient Care

Dr Shaili Amatya, MD, FAAP, Jennifer Erkinger, MS, RRT-NPS, AE-C, C-NPT, and Ann Donnelly, MS, RRT-NPS

Dr Shaili Amatya, Jennifer Erkinger, and Ann Donnelly from Penn State Children's Hospital discuss the important role of continuous transcutaneous CO_2 monitoring for reducing painful events and proactively managing ventilation in the NICU. The following has been adapted from its original presentation for clarity and brevity.

Introduction

Our team at the Penn State Children's Hospital level IV NICU comprises a large group of people. We are neonatologists, neonatal perinatal medicine fellows, neonatal advanced practice providers, pediatric residents, bedside neonatal nurses, respiratory therapists, speech therapists, pharmacists, and dieticians.

Ventilation Modalities for Neonates in the Penn State Children's Hospital NICU

As seen in Figure 1, our NICU saw 63 very low birth weight (VLBW) patients in 2021, 11 of whom were younger than 26 weeks gestational age. Our guideline is to manage these small babies on gentle ventilation using high-frequency jet ventilators, and the 52 other patients who were more than 26 weeks at gestation were managed on mechanical ventilators.

For conventional mechanical ventilation, our unit utilizes volume-targeted or volume-guaranteed ventilation. For the babies treated with ventilatory support, once they are able to wean to a noninvasive support, we tend to use noninvasive NAVA, or neurally adjusted ventilatory assist. Once stable, they're placed on bubble CPAP, which is our primary mode of continuous positive airway pressure that we provide for our patients. As you can see, we have a lot of respiratory support changes that happen during the hospital stay.

Monitoring Gas Exchange in the NICU

Arterial blood gas (ABG) measurements are the gold standard assessment of gas exchange when monitoring patients in the NICU. However, ABGs are invasive, painful, and only offer a point-in-time measurement. And in some of our tiny patients, there is a lot of blood sampling that is done during their NICU stay.

Shaili Amatya is a Neonatologist and Assistant Professor with Penn State College of Medicine. Jennifer Erkinger is a Pediatric Clinical Specialist, Respiratory Therapist, and Neonatal ECMO Coordinator. Ann Donnelly is a Respiratory Clinical Research Expert and Pediatric Respiratory Therapist.

Penn State Children's Level IV NICU: By the Numbers

The Facility

- 56 beds
  - 18 open beds
  - 4 twin rooms
  - 1 triplet room
  - 27 single family rooms
- 800+ admissions per year
- 13 neonatologists
- 130 staff nurses
- 35 dedicated respiratory therapists

VLBW Admissions (less than 1500 g)

- 2021 | 63 VLBW patients
- 2022 | 72 VLBW patients

Oxygen is monitored noninvasively by pulse oximetry (SpO_2). For carbon dioxide monitoring, we have a few devices that we use for our patients:

End-tidal CO_2 ($etCO_2$) monitor

- CO_2 levels measured at the end of exhaled breaths
- NOTE: Although usually used in the pediatric population, we do use it in our NICU, but it is limited because it is only useful in intubated patients.

Figure 1. Ventilation modalities used for very low birth weight neonates in the Penn State Children's Hospital NICU.

How Does Transcutaneous CO_2 Monitoring Work?

Transcutaneous CO_2 technology warms the skin at the measurement site to encourage blood flow and the diffusion of gas across the skin. The recommendation for the sensor temperature is 41°C, which allows for this gas to be diffused. A thin electrolyte layer is confined to the sensor surface with a CO_2-permeable membrane, which maintains contact with the skin during monitoring.

CO_2 diffuses through the membrane and into the measurement electrode, where the sensor measures CO_2 by the change in the pH of the electrolyte solution, utilizing a Stow-Severinghaus electrode. This value is then translated into an estimation of arterial CO_2.

Transcutaneous CO_2 ($tcPCO_2$) monitor

- Measures $PaCO_2$ that diffuses through the skin
- Device is placed on the baby's abdomen or forehead

Colorimetric CO_2 detector

- A qualitative assessment of CO_2 detected in the exhaled breath
- Often used during resuscitative measures

CO_2 and the Neonatal Brain

In a term baby, the brain vasculature is fragile but developed. Because of this, autoregulation is present in infants who are more than 36 weeks gestational age. The cerebral blood flow (CBF) remains relatively stable during fluctuations of the partial pressure of CO_2, which leads to a decreased risk of bleeding or hemorrhage.[1]

Preterm babies, on the other hand, have underdeveloped vasculature and an absence of this autoregulation. Preterm babies don't have the ability to maintain CBF, which can become uncontrolled due to changes in the CO_2 levels. As a result, there is an increased risk of hemorrhage.[2]

"$PaCO_2$ is the most potent acute regulator of CBF," researchers wrote in a 2014 study in the Journal of Pediatrics.[3] There are two extremes of pCO_2 levels that we want to avoid. Hypocarbia, in which CO_2 levels are less than 35 mmHg, can lead to cerebral vasoconstriction and decreased CBF. Hypercarbia, in which CO_2 levels are more than 55 mmHg, can lead to cerebral vasodilation and an increase in CBF.

This unstable blood pressure and flow can lead to complications, including intraventricular hemorrhage (IVH). IVH is a bleed in the ventricles of the brain, a common condition in neonates that presents the risk for long-term consequences. We would like to be at a safe range of CO_2 to prevent this dangerous complication, amongst others.

How Transcutaneous CO_2 Monitoring is Used in Penn State's NICU

In Ventilated & Non-Ventilated Patients | Transcutaneous monitoring has helped us to identify rapid changes in lung compliance within the first few hours of life. This allows us to be able to see the changes and make timely ventilator adjustments. With transcutaneous monitoring, we're able to avoid prolonged hypocarbia and hypercarbia, and minimize fluctuations in CO_2 and cerebral blood flow.

Transcutaneous CO_2 monitoring is also feasible with both invasive ventilation and non-intubated patients (which is most of our patients in the NICU). This differs from $etCO_2$ monitoring, which is infeasible for non-intubated patients. We have also been able to use it for postoperative CO_2 monitoring.

To Reduce Blood Draws | By utilizing transcutaneous monitoring, we have been able to minimize the need for repeated blood sampling, while also being able to trend pCO_2 over a period of time.

During Transports | We have found transcutaneous CO_2 monitoring to be reliable during transport of ventilated newborns.

In one case, a very sick baby on an oscillatory ventilator was being transferred to the Penn State Children's Hospital NICU from an outside facility. However, we were not able to take the oscillator in the helicopter transport with us. What we were able to do was once we transitioned the baby to the transport ventilator, we hooked up the transcutaneous CO_2 monitor. This allowed us to manage the ventilator settings in real time by monitoring the transcutaneous CO_2 continuously. Time is of concern during these transports since we're not able to do blood sampling to find out what the blood gas analysis is. So, transcutaneous monitoring is very helpful in allowing us to perform safe transports and manage ventilation better with the continuous measurement of CO_2 to guide us.

Advantages of Transcutaneous CO_2 Monitoring

Transcutaneous CO_2 monitoring is preferred over end-tidal monitoring here in the NICU—again, with the reason that $etCO_2$ monitoring can only be used in intubated patients. In our NICU, we tend to use uncuffed endotracheal tubes because we want to prevent tracheal injury in some of these delicate patients. However, this inadvertently leads to esophageal mixing and causes false $etCO_2$ readings. End-tidal measurement also encounters dead space; this is very significant for our fragile patients, as this can lead to false measurements.[4]

$EtCO_2$ also cannot be used with high-frequency oscillatory ventilators or high-frequency jet ventilators; modes of ventilation that are very much used in extremely preterm patients in our NICU.

Compare that with transcutaneous CO_2 monitoring, which we have been able to use for both intubated and non-intubated patients, and the use of which has increased as more and more

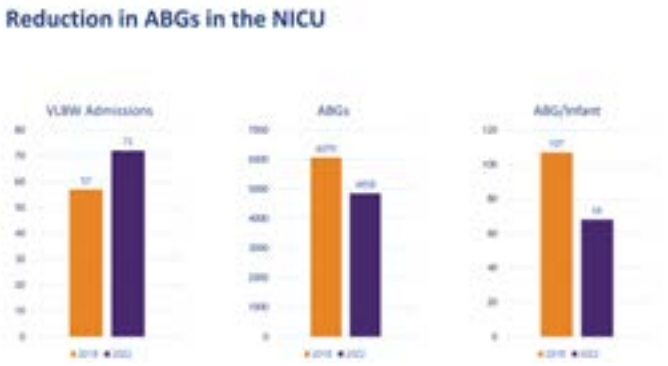

Figure 2. Number of total ABGs, as well as ABGs per infant, taken in the Penn State Children's Hospital NICU before (2018) and after (2022) the implementation of transcutaneous CO2 monitoring.

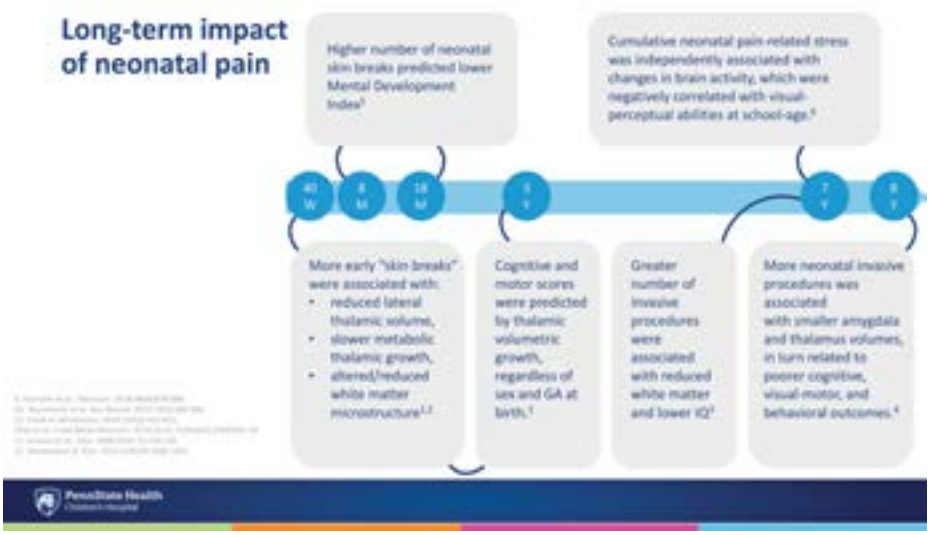

Figure 3. Timeline of the long-term impacts of neonatal pain and early skin breaks, from 40 weeks to 8 years of age.

preterm patients are managed with noninvasive ventilation. When compared to end-tidal monitoring, transcutaneous monitoring has been shown to be equally as accurate in patients with normal respiratory function and more accurate in patients with shunt or ventilation-perfusion inequalities.[5]

Transcutaneous monitoring also helps to prevent excessive blood draws from neonatal patients.[6] The average neonate has about 85 to 105 ml/kg of total blood volume.[7] And out of that, we use about 0.3 ml of blood per blood gas analysis. That's a lot if you think cumulatively of how many blood draws we need to do.

Studies have shown that about 13 to 18 ml/kg of blood loss happens during blood sampling or testing in these patients. Add that to the normal physiological fall in the hemoglobin, and these babies are at high risk of having anemia and requiring blood transfusion, which happens in about 20 to 50% of these patients.[7] Because of this, many institutions are trying to limit unnecessary blood draws and waste, which is something we do in our own NICU.

Impact of Implementing Transcutaneous CO_2 Monitoring in the NICU

As seen in Figure 2, despite an increase in patients in 2022 as compared to 2018, the implementation of transcutaneous CO_2 monitoring contributed to a 36% decrease in blood gas draws per patient in the Penn State Children's Hospital NICU.

How can NICUs reduce painful events?

1. Bundle routine medical interventions with other care procedures to reduce bedside disruption.
2. Utilize noninvasive monitoring wherever applicable, such as transcutaneous monitoring.
3. Anticipate testing procedures to reduce the frequency of blood sampling.
4. Use handheld devices capable of performing several analyses from a single blood sample.
5. Consider using peripheral arterial and central venous catheters in babies who require more than 3 or 4 heel sticks per day.[16]

Why Reducing Pain in the NICU is Important

Another thing that we saw with the use of transcutaneous monitoring was a reduction in painful procedures for our preterm patients. Preterm infants endure 643 procedures in the first four weeks of life for an average of 23 events per day. Over the span of their stay, the average pain exposure is thought to be between 10 and 18 events per day.[8] One of these procedures is blood sampling, which is an important test done in the first week of life in preterm infants for blood gas analysis.

Several studies show how this exposure to pain can have long-term impacts for these neonates. As displayed in Figure 3, neonatal pain, largely driven by blood draws, has consistently been shown to negatively affect neurologic and developmental outcomes, even extending into school age.[9,10,11,12,13]

As a neonatologist, this makes a significant impact on how we manage our premature infants, because we want to make sure that they have a good quality of life and have better neurodevelopmental outcomes down the road.

Less Invasive Care with Noninvasive Monitoring

With noninvasive monitoring modalities, such as transcutaneous O_2, CO_2, glucose, and bilirubin monitoring, and even near infrared spectroscopy (NIRS), we can avoid the need for blood sampling. In the Penn State Children's Hospital NICU, we use pulse oximetry for noninvasive O_2 monitoring, NIRS for some of our sicker patients to avoid blood sampling, and also consider noninvasive therapeutic approaches to provide analgesia to newborns.[16]

Implementing transcutaneous monitoring helps to reduce painful events in the NICU by reducing the need for repeated blood sampling.[6] As a result, there is a reduction of blood loss, which in turn will reduce neonatal anemia, reduce transfusion rates, and overall reduce the number of painful events.

Factors that Impact the Accuracy of Transcutaneous Monitoring

There are some factors that may affect the correlation between transcutaneous monitoring and blood gas values. Hypoperfusion of the skin at the measurement site caused by low cardiac index, presence of circulatory centralization, hypothermia, use

of vasoactive drugs, and arterial occlusive disease may limit accuracy. Skin breakdown, scarring, and edema can prevent adequate diffusion of CO_2 through the skin, also leading to inaccurate measurements.

Additionally, inadequate sensor temperatures, poor sensor application, incorrect measurement sites, and pressure on the sensor could lead to a lack of correlation between transcutaneous monitoring and blood gas values.

In patients with a shunt, the transcutaneous CO_2 sensor and the blood sampling site should be on the same side of the shunt. For example, if the patient has a large patent ductus arteriosus (PDA) causing a left-to-right shunt, the measurement will be inaccurate if the sensor is placed on the right side.

Case Studies: Transcutaneous Monitoring in the Penn State Children's Hospital NICU

In the Penn State Children's Hospital NICU, transcutaneous monitoring is standard of care for all patients who require continuous monitoring. For example, if they're being transitioned from one ventilator to another, if they're transitioning from invasive ventilation to noninvasive ventilation, or if we see that they still have a large scale of changes in their ventilatory status, we use transcutaneous CO_2 monitoring to guide our management.

Case Study 1 | 26 weeks GA, 366 g, transcutaneous monitoring to reduce ABGs and maintain safe CO_2 levels in an extremely low birth weight baby

The baby in our first example had severe fetal growth restriction, with a gestational age of 26 weeks and a birth weight of just 366 g.

The baby was placed on the high-frequency jet ventilator and needed frequent changes, which does happen with these extremely small babies. The transcutaneous sensor was placed on the forehead due to limited surface area on the rest of the body and it correlated pretty well, with the average correlation being ±1.9 mmHg (shown in Figure 4). 113 blood gases were drawn in the first 172 days of life. Once the arterial blood gases began correlating with the transcutaneous monitor, we used transcutaneous monitoring to guide our management rather than frequently repeating the blood gases.

These tiny patients are particularly sensitive to small changes in CO_2 levels, and we saw that the transcutaneous CO_2 measurement had a steep fall to 16 mmHg. Now at this point, as a clinical provider, we questioned: Is the perfusion okay?

Figure 4. Correlation between CO_2 levels measured with transcutaneous monitoring and blood gas analysis.

Is this picking up well? We followed up with an arterial blood gas, which did show that it correlated pretty well, enabling us to change our ventilation management and bring this infant to a normal level again. Examples of correlation seen across 4 separate blood gases are presented in Figure 4.

Case Study 2 | 25 weeks GA, 820 g, transcutaneous monitoring to guide ongoing ventilatory decision-making

At birth, day-of-life 0, this neonate was intubated in the delivery room and placed on a high-frequency jet ventilator as per our guidelines. The first 24 hours were critical, as the baby required 7 blood gas analyses, not just to maintain ventilation, but also to monitor electrolytes and other parameters.

By day-of-life 7, the baby was stable and we were able to extubate to noninvasive NAVA, or neurally adjusted ventilatory assist. Then, by day-of-life 20, the baby had respiratory failure that required reintubation, which does happen with these tiny babies. And again, we did a couple of blood gases to make sure that the transcutaneous monitor was correlating. On day-of-life 25, the support changed to invasive NAVA. And on day-of-life 29, the baby was able to be extubated to noninvasive NAVA. We attempted on day-of-life 33 to see if the baby would tolerate being on bubble CPAP, but the baby did not. So again, the next day required the noninvasive NAVA. On day-of-life 40, we attempted bubble CPAP, but by the next day the baby needed the noninvasive NAVA again.

Once we found that the transcutaneous monitoring and the CO_2 arterial gases were correlating well, we did not use arterial gases in the last 3 weeks to guide our management, despite making multiple ventilatory changes. And the correlation with the transcutaneous monitor was good at ±4.5 mmHg, allowing us to accurately trend the CO_2 to guide our ventilatory management.

Case Study 3 | 40 weeks GA, transcutaneous monitoring to accurately monitor entire patient course

This case study is of a patient who was transferred from an outside hospital to Penn State Children's Hospital. This was a term gestation at 40 weeks and 3 days, and the diagnosis for this baby was idiopathic persistent pulmonary hypertension. This baby, being critically ill, was transferred to the NICU and started on the oscillator with nitric oxide because of the pulmonary hypertension. We placed the transcutaneous monitor on the right abdomen and immediately the transcutaneous monitor was reading pretty high, with values around 100 and 109 mmHg.

An echocardiogram was performed after admission, which showed that there was significantly depressed left and right ventricular heart function and that the patient was in cardiogenic shock. At that point, because of the hypertension, the baby was placed on milrinone, dobutamine, and epinephrine, and the decision was made to start venoarterial extracorporeal membrane oxygenation (VA ECMO).
The moment the baby was placed on the VA ECMO, the transcutaneous reading came down pretty nicely to values around 37, 42, and 48 mmHg, which was maintained during the use of VA ECMO. Once the baby was able to successfully come off ECMO, we continued the transcutaneous monitoring. This continued to correlate and show us the ventilatory status even after we were able to extubate the baby and transition to noninvasive support.

Summary

In summary, transcutaneous CO_2 monitoring enables timely management of ventilation status in patients in the NICU. Used with proper technique, it can provide comparable monitoring to blood gas analysis, and is comparable to end-tidal CO_2 measurement in intubated patients, with the advantage of being compatible with non-intubated patients as well. Transcutaneous CO_2 monitoring can enable ventilator management and prevent blood losses and painful procedures in the NICU.

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Balancing Brain & Lung Protection in the NICU with Transcutaneous CO_2 Monitoring

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The very same ventilatory support that can help keep CO_2 within safe ranges for brain protection can also damage the lungs without careful consideration. Failing to deliver enough volume can result in derecruitment and atelectasis. Delivering too much risks overdistension and volutrauma.

In this way, the brain and the lungs are in constant tension – what protects one can harm the other. To prioritize lung protection and avoid potentially harmful airway pressures, respiratory teams may employ a strategy of permissive hypercapnia, which can help keep plateau pressures within a safe range, but could put the brain at risk. Prioritizing the brain may require increased ventilator settings that damage the lungs. In these scenarios continuous visibility to CO_2 can be a powerful, even vital, tool to balance both priorities.

Continuous CO_2 monitoring can be a valuable tool when care teams employ permissive hypercapnia, as it can allow them to keep a close eye on how the patient is responding and to react quickly to unexpected changes or spikes.

From Paper Charts and Automatic Control Processes to Patient-based, Real-time Quality Control—the Evolution of Statistical Quality Control Continues

Chris Campbell

Today's medical school graduates must seem bewildered at the quaintness of old-school paper charts and hand-written data that were the norm decades ago.

Statistical quality control—known as SQC—has changed rapidly over the years, with new technology and informatics replacing the slow pace of writing data on a paper chart.

But while this technology is the latest way to do things, is it the "ultimate" form of SQC?

That's what a new paper sought to discuss. The paper, titled "The most purely patient-based quality control: a novel application of the patient sample as its own control," was authored by James O. Westgard, Professor Emeritus, Department of Pathology and Laboratory Medicine, University of Wisconsin School of Medical and Public Health, and President, Westgard QC, Inc.; Sten Westgard, Director of Client Services and Technology for Westgard QC, Inc.; and Jose Cevera, R&D Manager, Werfen.

Together, the authors detailed how SQC has changed over the years, but also how it's come "full circle" in important ways, to bring patients more completely into the data equation.

"Today's automatic control processes represent the latest, but not the ultimate, form of quality control (QC)," the authors write. "The dawn of SQC was patient-based. When Stanley Levey and Elmer Jennings introduced their control chart (now known as the Levey-Jennings Chart), they were plotting the results, not of commercial controls—which did not yet exist—but instead, those of patient duplicates. Early QC involved repeated patient samples and pooled patient samples, until the economics of commercial controls made them practical and ubiquitous. QC appears to be coming full circle with the rise of interest in patient-based, real-time quality control (PBRTQC). There is a profusion of recent scientific literature on PBRTQC and its lofty aspirations to replace the use of commercial controls entirely."

The authors cite the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) as having given this type of approach an "official blessing," with a formal committee dedicated to its promotion.

The federation has stated that "PBRTQC will become the mainstay of QC in laboratories, once the profession sees the advantages of this form of process control, and manufacturers and middleware vendors provide the onboard capability."[1]

The author write that point-of-care testing (POCT) would be a welcome place for this process due to "high error rates."

"A recent survey asked point-of-care (POC) clinicians to identify the 'practices and wants' most helpful for improving the quality of POCT.[2] The most popular request was for more manufacturer-integrated quality and function checks. That is, better QC," the authors write. "To address the needs of today's POC users, manufacturers should provide more integrated controls and a more complete system for monitoring all potential failure modes. These capabilities would reduce the need for operator training and supervision of operations. No longer the stuff of fiction, these automatic control systems have been advancing in significant ways. A POC blood gas testing system with enhanced patient-based quality system capabilities has been developed and recently validated by Nichols et al at four different institutions.[3] The study used the average detection time (ADT) validation methodology developed by Westgard et al, approximately 15 years ago.[4] Notably, it found that the ADT for each test is much faster using newer technologies versus traditional SQC practices. This improved performance has been demonstrated in two additional studies, one by Toffaletti et al (four institutions), and one by Mion et al (two institutions).[5,6] The blood gas system's PBRTQC capability incorporates software to monitor the response curves of individual tests, allowing detection of transient errors caused by microclots, microbubbles, or other events that disturb the sensor response during sample data acquisition.

What could be more patient-based than a thorough, individual QC check on each sample?"

The authors write about the need to personalize the QC check that's made possible new technology that monitors the "measurement-response curve of each patient sample for patient-based analysis. Monitoring of the measurement-response curve directly detects potential problems for each patient sample within each measurement cycle."

Collecting these readings makes it easier to inspect them and to spot errors, which are "events occurring during the sample measurement, due to sample preparation and preparation," the authors write.

Chris Campbell is the Senior Editor of Respiratory Therapy.

"Such errors are random in nature and may not produce a recognizable signal before or after the sample measurement—making them typically undetectable by traditional QC," said the authors. "Microclots and microbubbles are particular problems for systems that utilize whole blood samples and particularly difficult to monitor via traditional, liquid control methods.[7]"

PBRTQC comes in many forms, including keeping track of the measurement-response curve, said the authors. IntraSpect technology is a unique component of Intelligent Quality Management 2 (iQM®2) in the GEM® Premier™ 5000 system, that monitors in real-time applications during the measurement cycle.

"Along with automation of traditional SQC, and extensive system function checks, IntraSpect technology is an excellent example of a manufacturer's implementation of a PBRTQC technique," the authors wrote.

IntraSpect records 15 sensors readings in the final 15 seconds of each patient sample measurement, and then analyzes them to "fit the sample response to a regression model that characterizes the observed sample output and estimates the value of the measurement. This regression model can also identify abnormal sensor responses by comparing the response curve to a compiled library of standard response curves established from the data of normal patient samples. Unusual sensor responses are identified by the shape of the response curve and/or by regression coefficients outside of acceptable limits."

The authors wrapped up their paper by saying PBRTQC capabilities are a leap forward in detecting mistakes.

"Demonstrating that these capabilities actually detect errors is the ultimate proof of this new technology," the authors wrote, adding that about half of the errors discovered "could only be detected by this new technology."

"The individualized, patient-based technique of IntraSpect provides the truest of real-time QC, scrutinizing the measurement response curve of each patient sample, which greatly exceeds the speed of population statistics, in most PBRTQC applications," the authors added.

"For years, laboratory medicine has promised more personalized care. In QC, at least, that promise is now fulfilled."

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What is Global Lung Function Initiative or GLI Network

The interview below was adapted from the exhale podcast, their guest was Brendan Cooper, Consultant Clinical Scientist & Hon. Professor of Respiratory & Sleep Physiology. The Global Lung Function Initiative (GLI) Network was established as a result of international collaboration, and altruism between researchers, clinicians and industry partners. The ongoing success of the GLI relies on network members continuing to work together to further improve how lung function is reported and interpreted across all age groups around the world.

Narrator: Welcome to the Exhale podcast, a candid conversation about current matters relating to respiratory diagnostic and lung health. Today's hosts are Mark Russell, Marketing Communications Manager, and Troy Pridgeon, Executive Vice President of Sales and Operations for Vitalograph in North America, a global leader in respiratory diagnostics. We interviewed Brendan Cooper, a clinical scientist and professor in respiratory and sleep physiology. He leads one of the largest lung function departments in Europe. In our discussion, we explore the global lung function initiative, also known as the GLI network.

Host 1: Well, Brendan, welcome to our podcast.

Brendan Cooper: Hi. Thank you very much indeed for inviting me.

Host 1: Well, please give us a little background on yourself, education, experience, and what your current responsibilities are.

Brendan Cooper: Okay. Well, you've heard of the Beatles, and I happen to come from the same town as the Beatles - city as the Beatles - Liverpool, one of the greatest cities on the planet, and basically the city which populated most of America, I think. Not something they're going to repeat. But I educated there. I went to the University of Sheffield to do physiology and zoology as a bachelor's degree. And then from there moved up to Newcastle upon Tyne in the northeast of the UK, where I worked as a physiological measurement technician. Wow, that's a big word. At the Freeman Hospital, which is a big cardiothoracic center in the northeast. Before I did my master's there, I became a senior technician in those days. Then I got into research in a big way at the University of Newcastle, and actually, my PhD is on protein metabolism and human pregnancy.

Not a lot of lung function in that bit, but it did give me very broad understanding of science and medicine, and physiology, and a whole host of other things. And so, from there, I went on and worked as the head of the lung function service at Nottingham City Hospital with Anne Tattersfield. And then moved, actually just 20 years ago this month, to the Queen Elizabeth Hospital in Birmingham, part of university hospitals in Birmingham, where I am currently the honoree Professor of Respiratory and Sleep Physiology and a consultant clinical scientist in respiratory and sleep physiology. I have many of the strings to my bow, which will probably use up the whole of the podcast. So, I think I'll just stop there.

Host 2: Well, that's a great introduction and background. We certainly appreciate you joining us today. And of course, we are a respiratory diagnostic company ourselves. So, today's podcast is all about GLI, and was hoping we could just start from the beginning and have you give us a sense of what is the Global Lung Function Initiative or GLI network?

Brendan Cooper: Okay. So, I am currently a co-chair of the GLI, but I've come into this all a little bit late. The GLI is the Global Lung Function Initiative or GLI network, as we now call it. And it was initiative to obtain better reference values for lung function testing. It was originally founded by Philip Quanjer, Janet Stocks, Graham Hall, and others. Philip Quanjer, particularly, because he was a very, very smart scientist and medic who had done a lot of his own research on reference values. But being the generous man that he was, decided to share this globally and was very patient with a lot of other people. Over the space of about two decades, this organization has helped to improve lung function reference values and their interpretation. It's made up of leading respiratory physiologists and physicians with an interest in physiology from Europe, UK, North America, Australia, Asia Pacific. The whole globe, hence the global part.

And it's got ambitions really to constantly improve the reference values because our patients get sick, but before they get sick, they have changes in their lung function. And we want to test

Brendan is a clinical scientist and professor in respiratory and sleep physiology and leads one of the largest lung function departments in Europe. He was elected as Head of ERS Assembly 9, Chairman of Association for Respiratory Technology & Physiology, then its first President and now he is first President of the Academy for Healthcare Science. He enjoys leading professional standards of quality and promoting science with innovation in respiratory physiology. Brendan has published 160+ peer-reviewed papers on his scientific work which underpins his research experience.

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people to see whether they are normal or whether they are abnormal. And it's defining normality, which has been the problem, because then we know how to spend our resources on people that need further testing and follow-up and care, are those people that are just aging a bit, and actually, you're okay. So, there's a lot of work going on. We've covered most of the key lung function tests: spirometry, lung volumes, gas transfer, but work is ongoing with multiple breast washouts, FeNO measurements, and cardiopulmonary exercise testing reference values as well. So it's a very vibrant and exciting project.

Host 1: So, why is it important to use GLI reference values for routine lung function testing?

Brendan Cooper: Okay, I think I've probably already started to answer this, but it's needed to detect evidence of disease by finding out what's abnormal. But you need to define what's normal. So, we use reference ranges. For example, in blood tests, it's very common. You go to the doctor, you get your blood taken, and then the values come back, and then it shows what's outside the normal range as to what's abnormal. And then that fits a clinical picture along with the history and imaging and everything else. But how we define normal has changed over the history of the last a hundred years, in terms of respiratory physiology. We now understand that part of normal comes from our nature, comes from our genetics. But another side of it is influenced by nurture, that what genetic pressures or evolutionary pressures happen to our genetics in the way that we will grow healthily or be malnourished and not grow as well as we would've done if we'd had a different environment.

So, people with the same genetics may have these different evolutionary pressures, and hence, we get different development and growth. And so, we get a range of normality. And what we're trying to do is to figure out: can we get a single equation that will describe normality? Previous reference ranges and values have many problems. They had small numbers, they had different types of populations were studied, they had very questionable quality of data, some of them, poor spirometry calibration or unreliable measurements made. And then, the populations were measured with different and mixed ethnicity. But what GLI has tried to do is to use the best quality data that was published and available in large numbers. So, for example, spirometry, 97,000 individuals' values were used to define those reference values. Transfer factor, 12,000, lung volumes, 12,000, whereas in some of the other previously used reference values, there may have been barely a thousand or a couple of thousand subjects involved. So, we've improved the sharpness of that tool for defining normality.

Host 2: So, it sounds to me like the GLI is a predictive set, but it is more adaptive or complex, I suppose you would say. What is the future of the GLI initiative? Is that going to continue to grow those parameters or that understanding of what is normal?

Brendan Cooper: Yeah, it's actually just coming into a very exciting time for GLI, in that, partly as a result of worldwide events and societies, Black Lives Matter was a particular catalyst around the world that made people think very differently about how we deal with ethnicity and race. And just before Christmas just gone, 2022, GLI Global was published as the new race-neutral spirometry reference equations. And this was a huge step forward because we'd always had the dilemma in that the process of GLI takes published normal data from studies around the world, but it was dependent upon the populations that were studied in those particular papers. GLI has no control over that, that's all that was published. And the data was donated to GLI to perform part of the large equation. Now, the problem with that is that you get biased samples, you get whole ethnic groups that are never measured or are never represented.

So, we always had this difficulty that we could provide reference values for whites, but not necessarily good ones for people from Asia, South or North Asia, Africa, African-Americans, different ethnicities. So, this step forward is absolutely huge because we're producing a single equation that it is unnecessary to know ethnicity. It's a very bold move and it's a very different move, and it isn't always going to be met with a lot of satisfaction by certain professionals, but it's something that we have to do. The GLI Global fits all races. It's got slightly wider Zed scores — or sorry, you guys say Z-scores — and residual standard deviations for whites, but a more inclusive and independent set of values in terms of racial mix.

The other exciting project is we are looking at a South American project where the data collection is complete, and we can add the whole population of many South American countries. And the key message there seems to be an association with altitude, in otherwise healthy individuals. So they have evolved altitude matters affected their lung growth. That's another environmental pressure on the genetics. And then, finally, there's a big project we have to do, which is the implementation for GLI Global and also adding GLI Global for more than spirometry, for all the tests involved. So, as you can imagine, that's going to be quite a project in the years ahead, but it has many impacts on our clinical services, and it's generating many questions as well. It's something that GLI is working on quite a lot going forward.

Host 1: Well, let's talk about GLI for all ages. Can you touch upon the age equation and what does that mean for diagnostic consistency?

Brendan Cooper: Yeah, so for example, the spirometry reference values from GLI cover from the age of three to 90 years. And GLI Global covers, as we've mentioned already, all races and ethnicities. So, that really gives it a consistency. But prior to, for example, in pediatric respiratory physiology, there used to be a very difficult set of data used in the UK, particularly, where there was this sort of referred to as the "adolescent dog leg" in the data, in that there was a set of reference values for children under a certain age or height, and then there was a second graph or gradient above that age. And so, literally overnight, a child could have a birthday and suddenly switch from one graph to another and gain half a liter in FEV-1, which clinically made absolutely no sense. Whereas now, with GLI Global and the fact that we're covering from three to 90 years of age, there's a much more smoothed-out clinically relevant set of equations that applies to all populations. So, that's really helped with all age equations and diagnostic consistency.

Host 2: That's good to know. Well, what are the challenges involved in developing and improving your reference values for lung function tests?

Brendan Cooper: Well, quite a lot of challenges for us, actually. Obviously, once you produce your GLI equation, and we've found that since 2012 and onwards, or in fact before, is implementing it into all countries, and we're going to have this issue with GLI Global as well because there are the practicalities that have to be

taken into account. For example, manufacturers, like yourselves, provide the software to predict the predicted equations, but they have to be put into the software, loaded up onto every device in the world that you have sold, and then has to be checked and double-checked during procurement to make sure that there aren't any errors in it for each individual site. So, that implementation becomes quite a complex procedure from the manufacturer down to the person buying a new spirometer in a clinic or wherever. Another challenge, I think, is collecting data on all populations.

So, even though GLI Global is representing an ethnicity-free equation, we still need to collect data from lots of other ethnic groups and keep adding that data so that we get a better and better and better overall equation that does fit people from all backgrounds. We are also, not struggling, but facing the challenges of tackling the genetics and the statistics informing these reference equations. Maybe in years to come, when I'm long off the scene, reference values may have genetic markers that really help selection of the data for a particular gene factor, you know, gene expression in certain people that will predict how big they're going to grow, how big their lungs are going to be. Obviously, that's complicated by... It depends on the environment they grow up in. We're looking also to sequential reference equations. So, what we do at the minute, for an individual, it's a snapshot.

You are this age, this height, this sex, and this is your FEV-1 reference range. We want to do reference equations about sequential changes in the lungs over time, and that will be very interesting, obviously, in following patients who have conditions where they're deteriorating. You can imagine the trajectory of the sick patients compared to their reference range will help to better define when they're descending rapidly or treatment is either improving or at least stabilizing the decline.

And finally, to do all this extra work, particularly to get the information from the populations around the world, we need to be looking for funding from big organizations like the World Health Organization or something like the Bill Gates Foundation or similar because these are big, almost altruistic projects. They're not sexy to the journals, particularly, you know, it's: "Oh, you've got a whole load more data and you've published a few more equations." But it's something that is so fundamental to humankind that we understand where's normal and where abnormal is. In other words, in defining how big a health problem we have and how much resource we need to give to treating it, I think it becomes absolutely fundamental. And we've struggled to get that funding and struggled to engage with these organizations, but we never give up.

Host 1: So, how's the GLI network working with the European Respiratory Society and European Lung Foundation moving forward? And are you also involved with the ATS, over here at the States?

Brendan Cooper: Yep. Well, because Philip Quanjer was from the Netherlands and was very, very involved with the ERS early on, indeed, he won an ERS award quite early on, which I'm very proud to have also won along with him many years later. The ERS have always been very supportive of the work. And about five years ago, the GLI, needing to expand, we'd done spirometry and now we wanted to look at the other tests, lung volumes and gas transfer. So, we went to the ERS, and they have what they refer to as the CRC, and gave us funding for over five years to be able to pay for this work to be done. So the collection of data, the analysis, the costs for meetings and teleconferences, and things like that. And they continued to support us. Now, ATS, early on, were also part of that call-out for help and kind of withdrew.

We're not quite sure why, but they said they weren't able to fund this project particularly, I think the rules changed about funding things. It wasn't a malicious thing, it was just the way things went. And so, they kind of dropped out of it. But at all times we've been looking for help, and it's great to hear that in the last three to six months, ATS have shown an interest in getting back involved with GLI. That's absolutely fantastic. We're going to have meetings at the ATS with the GLI and ERS to see what we can do to work together because if ERS has been carrying the burden for the last five years, maybe ATS can help us carry the burden a bit further and maybe even connect us with these people we need to connect with for this global altruistic project as well.

So, it's all very hopeful for the future. The European Lung Foundation, which is the charity that runs alongside the ERS, have also been very supportive with their Healthy Lungs for Life, which collects data around Europe. So, it's been an ongoing project there. So, yes, there's lots of links with the ERS, but so have there been with the ATS, and I think the success of GLI is in that we all work together across all the continents, all over the world.

Host 2: I agree. So, are you going to be attending the ATS in Washington, D.C. this year?

Brendan Cooper: Well, unfortunately, I'm not, but some of the team, Sanja Stanojevic, will be coming down from Canada, so she will definitely be there. And I find it quite hard to get across the pond these days. But yeah, we will have a presence there. So, it's going to continue. It's going to carry on.

Host 2: Well, Brendan, thank you so much. We really enjoyed having you here today. That's great insights and a lot of very interesting answers. How can our listeners learn more about the GLI network?

Brendan Cooper: The GLI website, for mainly cost purposes, has been incorporated into the ERS website. It's not a political move, it was just somewhere that we could keep that information. And if you go on that website, you can look out for new publications, obviously, in all the leading respiratory journals, you know, the American Journals and the ERJ, these publications and articles are coming out on a regular basis and will be doing as each of the projects comes to fruition. So, quite honestly, Google GLI or Google Global Lung Initiative because sometimes you get some very weird responses. And read a lot more. There's a lot out there. We're continuing to have the link with the ERS, in terms of the website, but would be more than happy to continue that with the ATS, but there's discussions to be had in Washington, D.C., I think.

Host 1: Well, Brendan, thank you again for being on our podcast. This has been very informative, and hopefully, we can extend our communication with the GLI network over here with ATS and get more of a comprehensive of what is going on in today's lung function testing.

Brendan Cooper: Yep. I think Europe and America are coming a lot closer for a lot of other reasons at the moment, and GLI wouldn't be another bad one.

Host 1: Exactly. Well, thanks again.

Brendan Cooper: Okay, thank you.

Narrator: You reached the end of another episode of The Exhale podcast. Don't forget to follow us for upcoming new episodes, and please take our survey to help provide good content for the future. Thank you for listening, and we look forward to you joining us again on the Exhale Podcast, brought to you by Vitalograph.

From 2014 to 2022: Update for the Prevention of Ventilator Associated Pneumonia and Events

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. Participating in the interview is Tracy Cook with Saxe Healthcare Communications.

Tracy Cook: Hello, everyone, and welcome to our webinar. My name is Tracy Cook with Saxe Healthcare Communications, and I'd like to show our audience how they can send in questions throughout the webinar. Our speaker will try to answer as many questions as possible. At the end of the presentation. Please type your questions into the questions box. I'd like to introduce our moderator, Lisa Wall. Lisa has over 30 years experience in acute and chronic respiratory care and health organization management. She is currently a respiratory care manager at Highland Hospital in Rochester, New York. In her current role, Lisa works with multidisciplinary discharge transitions teams to develop COPD pathway in order to decrease hospital readmissions associated with that state. In 2023, Lisa was awarded a leadership fellowship in quality improvement by University of Rochester Medical Center. Lisa, welcome.

Lisa Wall: Thank you, Tracy, for the kind introduction. The title of our webinar today is From 2014 to 2022, Update on Ventilator Pneumonia and Ventilator Associated Events. Speaking on this critical topic is a leading expert and colleague, Linda Greene. Ms Greene was director of infection prevention at the University of Rochester Highland Hospital until May of 2022. Currently, she is an independent consultant for acute and long-term care. She has over 30 years experience in infection prevention. She has authored and co-authored several peer review publications in nursing and infection prevention journals, textbook chapters, and implementation guides. Linda was the 2017 APIC, Association of Professionals in Infection Control and Epidemiology, president. Linda was the APIC representative to the SHEA Compendium sections on ventilator associated events and surgical site infections. She has served on several advisory panels, public reporting of HAIs, and has received several awards in infection prevention, leadership, and nursing.

Linda has lectured extensively at the state, national, and international level. In 2022, she was awarded the prestigious APIC Carol DeMille given annually to an infection preventionist who has demonstrated extraordinary leadership and visionary thinking. Our speaker has disclosed the following relationships. Continuing education for nurses and respiratory therapists. A link to obtain credit will be available at the end of the webinar. This educational activity is approved for one contact hour for nurses and RTs, and support for this educational activity is provided by Dale Medical Products Incorporated. Now I will turn the presentation over to Linda.

Linda Greene: Thank you so much, Lisa. It's really a pleasure to join the webinar today, and I have worked with Lisa for a long period of time, so I'm so thrilled that she is the moderator today. At this point, we'll get started. So the first thing is in terms of learning objectives, we're going to identify the essential elements for prevention of ventilator associated events, including ventilator associated pneumonia based on the 2022 guidelines. I'm also going to list strategies to incorporate these elements into routine practice, and I'm going to discuss the challenges and barriers to implementation of best practices, and we will go through those because, again, there are many challenges and barriers. So let's talk about the evolution of this, and really the first VAP Compendium was published in 2008, so it goes back several years.

And about 2011 to 2013, we began developing the new VAE definition, and I was on that panel, and really it was an arduous task because looking at a very different definition really required a great deal of work. There was a multidisciplinary team. Many people were involved in that. By 2014, we were able to, and I was fortunate enough to be on an interdisciplinary team with renowned experts in the field. And I think it's so important because when we came out with the compendium, it isn't just one area of expertise. We had respiratory therapy. We were represented by nursing, ANA, APIC, SHEA, pulmonology, Infectious Disease Association, CDC. So it truly, truly was an interdisciplinary process, but when we came out with the 2014 compendium, we now had the new definition of VAE. And then in 2022, there was an update to the compendium, which I'm going to talk about today.

Now, clearly the target date for the update was 2020, but with COVID, we know that that had to be delayed, so very happy to have worked on that for 2022. So let's talk about a little bit of that background and the new definition, because I think there's always a starting point when we talk about it. So part of it was taking really a 30,000 foot view and not just looking at pneumonia. And so the new definitions really include criteria for ventilator associated conditions called VACs, infection related ventilator associated complications called IVACs. So in other words, you could develop another infection which might be a complication of being on the ventilator, and then possible pneumonia. And what we do know is that the literature shows us that approximately 5% to 10% of mechanically ventilated

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patients develop VAEs, but when we think of ventilator associated pneumonia, and we think of other complications of mechanical ventilation, they're detrimental to patients, and they do increase costs. And when you look at the attributable mortality of ventilator associated pneumonia, it's estimated to be approximately 10%, but it can vary for different types of patients.

So in terms of background, we know this, that patients on mechanical ventilation are at risk for a variety of serious complications in addition to pneumonia, and they include respiratory distress, pneumothorax, pulmonary embolism, lobar atelectasis, and pulmonary edema. And so in 2013 when the new definitions were released by the CDC, they were designed to make surveillance more objective and to expand surveillance from VAP alone to include additional serious complications. And I want to really hone in on the idea of objective definitions, and when we talk about some of those challenges, we want to keep that in mind. The other thing is, and there's been recent reports in the literature that we need to look more broadly at things, other areas like catheter associated urinary tract infections, and look at some of those non-infectious complications, because really what we're talking about is patient safety as well as infections, and I think the VAE definition was an excellent start to that.

So the shift is really important because the quality improvement initiative should ideally focus on identifying and preventing objective morbid complications, and most of those are unambiguously associated with poor outcomes. So by broadening the scope of this surveillance, we acknowledge, as I said earlier, that both infectious and non-infectious complications can arise in ventilated patients, and we really should be considering that in designing programs. So I love this particular slide because when we put patient safety first and foremost, and we look at ventilator harm, what we're really looking at is all of those types of things. Certainly we're still going to look at pneumonia, but we're looking at morbidity. We're looking at more mortality. We're looking at infectious complications. What about immobility, atelectasis, and cost, and length of stay? So many of these things really all go back to ventilator harm.

So let's look at VAP or VAP pneumonia in general and one of the problems, and I was at the first meeting when we were coming up with a new definition. I will tell you that this is a real, real challenge because people were looking at outcomes related to VAP surveillance. The problem with the definition is that there were a lot of questions or ambiguous definitions when you were interpreting it. So this is a very nice slide by Dr Mike Klompas in 2010, but it points out where the problems are. So they took three infection preventionists, and they looked at the consistency in looking at ventilator associated pneumonias, and they found a wide degree of ambiguity that definitions did not necessarily meet. So the way I interpreted it, you may not, and I remember being at that first meeting, and I have to chuckle because there was a pulmonologist that said, "Well, the problem with this is you have to fire the IPs, because obviously some of them don't know what they're doing," but that's not the real issue.

The real issue is that we know that when we look at chest X-rays that the interpretation can be very vague. It may say, "Possible pneumonia. Could be atelectasis. Could be these, something else." And so we really had to come up with a new definition, and then moving on as we did the 2022 update, we really needed to look -at all of the elements and some of the things that had changed since that time. And again, as I said, I think it's extremely important that we realized that this was a true multidisciplinary effort, and having so many experts from various backgrounds really made this a very robust paper.

So I'm going to look at the starting point, and I think we need to realize that there are many risks. So let's look at the risks, first of all, in VAE. Well, we know that deep and prolonged sedation is a risk, and some of the mandatory modes of ventilation are risk. High tidal volume they've talked about, aspiration. I'll get into oral care with chlorhexidine, which is what Dr Klompas calls one of the thorniest issues right now. Excess fluid balance. So all of those things come to play when we're looking at VAE. But going back to that very big picture, and one of the things I want us all to think about when we're taking care of patients on the ventilator, and I know I've worked with Lisa on things, is what are our prevention goals? When we look at the big picture, what is it we want to do?

Well, first and foremost, we want to avoid intubation. If it's necessary, we want to get that patient off the ventilator as soon as possible. While they are on the ventilator, we want to avoid aspiration. We want to maintain nutrition, and we want to maintain muscle strength, and these are just some of the things we can think about in terms of our prevention goals. So in 2014, when we look at the updates on essential practices, and I want to talk about the word essential practices. What does that basically means? Well, it means that some of the data do show improvement in outcomes. It also means that the benefit outweigh the risks, and we always have to think of that.

We might have practices that have risks, but the benefits definitely outweigh the risks, and so in 2014, we said, "Avoid innovation if possible, and use non-invasive positive pressure ventilation whenever feasible," and it had a fairly high quality of evidence, and that really hasn't changed, but what has changed and I think is really significant is there is an added recommendation for high flow nasal oxygen and non-invasive positive pressure ventilation. So I will say that the high flow really, really came into existence and is used more often now with COVID than I have seen it used in the past. So who are the patients at risk for innovation anyways? Well, we know if you have acute or chronic hyperbaric respiratory acidosis, acute cardiogenic pulmonary edema, acute hypoxemic, respiratory failure, moderate to severe respiratory distress, tachypnea, accessory muscle use, abdominal paradox, and neuromuscular diseases, and respiratory muscle fatigue, all of those patients are at risk for intubation, and I'm sure most of us do know that.

But one of the things that was very interesting, and that was the addition of high flow nasal cannula, and it really, as I said earlier, it has gained popularity during COVID, but there are several meta-analysis reviews on the impact of these modalities. And so certainly one of the things I will say with the compendium is our references. There was just rigorous review of references looking at meta-analysis and things like that, and high flow certainly was an important thing. The other thing that changed, and really some of these aren't so much changes as it's an improvement to what we previously talked about. So I always want us to think about the word, improvements. So we look at it, we see what's going on, and then we say, "Wow, there's more to this."

So in 2014, we said, "We managed ventilated patients without sedatives whenever possible." And we talked about interrupting sedation once a day for patients without contraindications and assessing the readiness to extubate once a day by the SBTs and SATs, but one of the things that moved forward is we really put into that, and I should say the experts, because certainly that is not my area of expertise, but to use multimodal strategies other than benzodiazepines, and use a protocol to minimize sedation and implement a ventilator liberation protocol, and I'll talk a little bit about that, because you might say, "Well, you're pretty much saying the same thing," but let's get into that a little more.

Well, in order to minimize sedation, we know that deep and sustained sedation is associated with adverse events, and when we talk about those, we know it's mortality, prolonged medical ventilation, and the risk for VAEs. And so one of the things that the potential strategies to minimize sedation include nurse-driven protocols for light sedation, daily sedative interruptions, and the spontaneous awakening trials, and managing agitation and examples, analgesics for pain, and reassurance for anxiety, and many of those types of things. But if the patient is ventilated, what do we want to do? We want to minimize sedation. We want to avoid benzodiazepines in favor of other agents, but the two things that really we are looking at and are somewhat I would say of a change is the protocol to minimize sedation and implement a ventilator liberation protocol.

So what do I mean by that and why is that important? Well, oftentimes the SAT and the SBTs would be physician driven, and it depends on which intensivist is covering the unit. It was really kind of at the discretion of the intensivist, and one of the things that is really important is acutely hospitalized adults who've been mechanically ventilated for more than 24 hours are managed with a ventilator liberation protocol rather than no protocol. So in other words, it's not, "Well, let's just put this person on." Let's have a standardized protocol. And physician-led protocols can actually lead to lack of standardization. So if you leave it up to individual physicians, you're not standardized, but the important thing is, and for those of you who are respiratory therapists, once the protocol is in place, so if you have a standardized ventilation liberation protocol, it can be managed by respiratory therapy. It can also be managed by nursing.

And I know when I gave a talk on this to some of my APIC colleagues, I reached out to Dr Klompas, who was lead author and just a wealth of information. And I said, "What are the two things that you think are most important?" And he said, "The standardized ventilation protocol, having it standardized, having the same protocol no matter who's on, to have those clearly standardized." And then the other thing that I will get into was toothbrushing. So we felt those were very, very important, and we'll talk about that as we move on.

So what is the ventilator liberation protocol anyways? Well, it suggests that they be managed by a protocol. And what we found and what the evidence shows us is that with physician-led ventilator management, there's a wide variation, and when you initiate SATs, SBTs, but with the ventilator liberation protocols, they're often led by respiratory therapy or nurses. They're sometimes computer driven, and they have been designed to standardize and enhance identification of patient readiness and liberation from mechanical ventilation. So in other words, what we've learned over the past several years is the more we're standardized, the more we're protocolized. We certainly can do individual things, but the more that those things are in place, the better the chance that we're going to achieve the goals.

So when I think of all of you who are listening, I would just ask you to think about your own practices. Do you have a sedation policy? Is it standardized? Do you have a true ventilator liberation protocol or policy? How is it instituted? Who monitors it? How are you sure that you're really doing it? And most importantly, how engaged are your intensivists and your respiratory therapist? And I think that's really, really important. As an infection preventionist, which is my background, one of the things that being on the VAE Task Force has really opened my eyes that we are truly need to work in our disciplinary. No one of us alone can do it, and if our intensivists, our respiratory therapists, our nurses, our infection preventionists are all rowing in sync, we can truly achieve better patient outcomes. So I love this bundle.

This was published by Critical Care Medicine, and it really kind of just shines a light, and that was published in 2018. Clinical Practice Guidelines for Prevention and Management of Pain, Agitation, Sedation, Delirium, and so they call it PADIS Guidelines, and it can be implemented through the liberation bundle. So when we think about this, we think about assessing, preventing, and managing pain, looking at both SATs and SBTs, having the right choice of analgesia, preventing delirium, assessing, preventing, and managing that delirium, which is very, very important, the early mobility and the exercise. And I thought what really was very nice in this particular one is family engagement and empowerment, and we think of a patient being on a ventilator and being sedated, but that family engagement and empowerment is also extremely important, and I think we all know this. So this is a sample protocol for liberating patients from mechanical ventilation.

You have your timeframe. You look at their [inaudible 00:23:42]. You look at PEEP, FiO2, and you can look at all these, but having an algorithm really does help, and then putting that algorithm as part of standard care is an important step in all of this, and although your liberation protocols may be somewhat different, having that standard protocol with the goal being getting the patient off the ventilator as soon as possible, and I think that's really important. So I'm going to move on to a really I will say a bit of a controversial issue, or as I heard a talk by Dr Klompas, a thorny issue is in 2014, we still had perform oral care with Chlorhexidine, but in 2022, and looking at the evidence, looking at some of the studies, provide that daily oral care with toothbrushing without chlorhexidine.

Now, one of the important things in my background is nursing. I know many infection preventionists come from different backgrounds, but in my nursing background, I'm thinking that something as basic as oral care and nursing care can really make a difference in patient outcomes. Many of you know there's been just a ton of literature on toothbrushing, and it is associated with significantly lower VAP rates, shorter duration of mechanical ventilation, and shorter ICU length of stay. And I think that's so critically important. I've talked to colleagues, and it's very interesting. I've talked to some colleagues that have been even in an ICU for one reason or other, and they're saying that many of the ICUs are still giving you the little sponge things to wipe out your mouth. And particularly with ventilated patients, the question is, is the daily toothbrushing instituted as much as possible?

Whoops, excuse me. Okay, here we go. So what happens? Well, dental plaque accumulates rapidly in the mouths of critically ill patients, and because you're in a hospital, there is a significant shift in the microbial community. So we know our microorganisms, multi-drug resistant microorganisms, many of those, they live in the hospital. There really is a shift, and colonization with possible pathogens certainly is a leading cause of VAP. So toothbrushing has been found to be an important intervention. Now, people have asked, "Well, how do I do toothbrushing with a ventilated patient?" There are several online procedures. Many of those talk about using a small toothbrush followed by suctioning or a suction toothbrush, but a very, very important strategy because our mouth is very dirty, and we're colonized with multiple microorganisms, particularly when we're in an ICU.

So what about oral care? Well, first of all, we wrote this article in 2014, and it was the reappraisal of routine oral care with chlorhexidine gluconate for patients receiving mechanical ventilation. So this is a little older article, almost 10 years old, but there certainly was some emphasis even at that time looking at that, and one of the things that is extremely important is if you're looking at the use of chlorhexidine, and you're saying, "Well, the literature shows it is a decrease in VAP," but you don't have a really consistent or good VAP definition, you're really talking about apples and oranges sometimes, because the definition was so not consistent, so to speak. So we did find at that time that in cardiac surgery, that seems to be the one area where chlorhexidine is used and has shown better outcomes, and the reason for that may be shorter ventilation in many of these patients. I'm not saying all cardiac patients, but when we look at some of our cardiac patients, we know that they are extubated in short periods of time, so I'm not sure really about that.

But in the discussion and what we were looking at is CHG was definitely associated with a high risk of mortality and non-cardiac surgery patients, and there are several meta-analysis to look at that. The effectiveness of CHG of different strengths, preparations, or frequency was inconclusive, and there was no evidence for an association between CHG and reductions in duration of ventilation, duration of ICU stay, or antibiotic exposures, or oral health issues. Now, one would say, "Well, why does Chlorhexidine... Why do you say not to use it? Maybe it doesn't work, but why would we not use it?" Well, certainly when you look at other outcomes, when you look at mortality, when you look at other types of potentials, it did seem that there was a slight increase in mortality to those that use CHG, and oral mucosal lesions are common adverse events with chlorhexidine.

So first of all, we know chlorhexidine works well on intact skin, but we've got our mucosal there. They found mucosal lesions. The other thing that they found oftentimes, which may have led to some adverse outcomes in mortality, was micro aspiration of the CHG. Now, one of the questions that often comes up is there's still a number of studies that show a positive effect of CHG, and there are some studies that do show that. Most of the studies that the team looked at, particularly related to this, were open label studies. In other words, people were using CHG. They were looking at outcomes, but when they randomized it, they found poorer outcomes in the CHG group. Still an issue that many people certainly are dealing with. It's still used quite a bit, but that is the evidence behind it, and when you look at not only VAE, but you begin to look at mortality and some of those other outcomes, CHG really was associated with it.

This is a nice single study retrospective study. They had 82,274 patients, low level exposure to chlorhexidine oral care was associated with increased risk of death, and the association was stronger among patients even in those with a lower risk of death, so that was that. So the data kind of argue against the indiscriminate, widespread use of chlorhexidine oral care in hospitalized patient without a proven benefit. So I'm going to move on right now to the discussion on nutrition, and this is interesting as well.

So in 2014, we looked at initiation of parenteral nutrition in critically ill patients within 48 hours of ICU admission with an increased risk of nosocomial or healthcare associated infections and mortality with initiating parental nutrition, especially on or after day eight. So we do know that. We know that parenteral nutrition is associated with bloodstream infections, central line infections, and so we certainly addressed that or the compendium addressed it in 2014, but in 2022, the recommendation was to provide early enteral nutrition rather than parenteral nutrition.

So in other words, we're going to do [inaudible 00:33:16] nutrition, the tube feedings. That's where we would like to go, except in maybe some unique circumstances. And we really looked at some of the meta-analysis where they said, "Well, maybe all patients should get post pyloric feedings." Did not really seem reasonable. Enteral nutrition certainly was the standard of care, but what we did put in there, and I know I researched that area in particular, is that you should consider post pyloric feedings in certain patients that are very high risk for aspirations, so patients with swallowing, patients with stroke or neurological conditions.

You may want to consider the post Pyloric feedings rather than a parenteral nutrition. But when you look at the risk and benefits, we're still recommending early enteral nutrition unless you fall into one of those high risk groups. Now, early trach. Early tracheostomy, and this was interesting, but in 2014, early tracheostomy was generally not recommended. They said that it really had no impact on ventilator associated pneumonia rates or the average duration of mechanical ventilation, but in 2022 it was added as a special consideration. So this is an area where in certain groups it may very well be a benefit to go to early tracheostomy, and some of the data shows a meta-analysis of like 17 randomized trials suggest that early tracheostomy within seven days of intubation may be associated with a 40% decrease in VAP rates, less time on mechanical ventilation, and fewer ICU days.

It did not though reflect mortality, but what was put in the compendium basically was that decision maker should integrate these potential benefits with each patient's values and preferences. So in other words, we really have to look at that. It would be an individual decision, but something that you may want to look at. Now, preventing aspiration, as I said earlier, recommend enteral versus post pyloric feeding in most circumstances, and again, patients who are at high risk for aspiration, stroke, and there are a number of patients who have severe gastric reflux, so we want to look at those again, and then certain neurological conditions as well. Now, the physical conditioning, that's another thing. We know that, but early exercise and mobilization programs may shorten duration of mechanical ventilation, reduce ICU length of stay, lower your VAP rates, increase the rate of return to independent

function. And we really want to think about those things in these ventilated patients because we certainly want them to return, if indeed they were in the beginning, to independent function.

So there isn't any consistent association between that, but it's certainly there are some financial modeling that suggests that early mobility programs might be cost saving. Now, I love this. This particular diagram comes to us, this progressive mobility diagram, from AHRQ Agency for Healthcare Research and Quality. And I know many organizations have different levels, but again, they look at that. They have different levels that they look at in terms of PEEP and all of those types of things, and so you can see where you look at your RASS scales, you see what level they're at, and it's really called a progressive mobility continuum, and I think it is very, very helpful.

So another recommendation in 2014 was to utilize endotracheal tubes with subglottic secretion moderate drainage ports for patients expected to require greater than 48 or 72 hours of mechanical ventilation, and what they did in 2022 was really reclassify this as an additional approach, and I think there are many reasons, and one of the things is that depending on how long the patient is going to be ventilated, if you have to put in a new tube, many of those types of things. So that's just considered an adequate device approach, and not recommended was oral care with chlorhexidine, so we know that, probiotics, polyurethane endotracheal tube cuffs, tapered endotracheal tube cuffs, automated control of endotracheal tube, and frequent endotracheal cuff pressure monitoring. None of those are recommended.

So many of the changes that we have seen really focus on new evidence. They focus on standardization and development of protocols, and the other thing I think is really important is that we look at this idea of recognition of synergistic effects. So if you do one thing, it may impact other things as well. So we have a lot of barriers to rigorous adherence. Uptake by hospitals typically has been what we would call heterogeneous. We need more studies on preventability, and we need some of the major barriers to greater adoption of surveillance and prevention include ongoing misunderstanding or the lack of sympathy for the purposeful differences between VAE and VAP. Now, I'm going to say that again because ventilator associated events encompass all of those, and again, looking beyond just the pneumonia. And the other thing that has been a barrier is that there are not regulatory mandates.

So we do know that many hospitals are monitoring that. Many states have initiatives, a lot of compelling hospitals to prevent VAE, but it is not a mandate like many other things are. So again, I talked about CHG, peptic ulcer prophylaxis, which was in the very early guidelines, and lack of standardized protocols for weaning. So those are some of the challenges. Well, I'd like to use this because I think it's incredibly important. It's one of the strategies, it's called the 4Es Model, and they highlight this. There are many models, but I love the 4Es Model because I think it really speaks to what we need to do. We need to engage the team, develop your local champions, use these peer networks. We need to educate and have the materials, so we know what to do. We need to execute, improve our processes, standardize, build our bundles, and then monitor outcomes and review our cases, and I think if you're tracking VAE, it's really, really important to review your cases and say, "Is something wrong here? What's going on, and what can we learn?"

And oftentimes I look at these more as what you would call a mini root cause analysis. So other strategies including nursing tools, developing interdisciplinary rounding tools with respiratory therapy, changing any changes in the past 24 hours, how the patient is responding, looking at all of those patient specific factors. Those are important as well. And then in terms of standardizing mobility, this was a really nice organization of things from John Hopkins, and they used an eight step approach, which looks at prioritizing it, making goals, mitigating any barriers, having local interdisciplinary roles. Oftentimes there are barriers because there's not the resources in ICUs. Education and training, workflow integration, and giving feedback, all of those again.

Now I'm going to speak for just a couple of minutes on some of the special populations before we end in about five minutes or so, but avoid intubation if possible because continuous CPAP ventilation, many of those things, high-flow, those are things. Success rates though as preterm neonates are greatest for those delivered above 28 weeks gestation, but they have found that many premature neonates can successfully be supported with non-invasive positive pressure ventilation and managing them without sedation. Caffeine therapy within 72 hours after birth to facilitate expedition, assess the readiness to extubate, take your steps for unplanned extubation, CPAP in post-extubation period, and again, we're back to the regular oral care. And in pediatric patients, avoid intubation and reintubation, avoid fluid overload, regular oral care, elevate that head of the bed, and use your cuffed endotracheal tubes.

So some of the key points, and I'm just going to talk for a moment about non-ventilator healthcare associated pneumonia before we end and open it up to questions in about five minutes here, but one of the things that the compendium addressed, and I want to highlight this. This is really not the crux of our webinar today webinar, but I think it's something that we all should be thinking of. Non-ventilator hospital associated pneumonia is one of the common and morbid healthcare associated infections, but unfortunately, it's not tracked. It's not reported, and many hospitals don't actively have initiatives to prevent it, and so there has been a national call to action. They've launched a national healthcare conversation about non-ventilator associated pneumonia, adding prevention measures, and some of those are many things that we talked about, the toothbrushing, the preventing aspiration.

They really have wanted to challenge healthcare systems and insurers to implement and support it, and they really want to encourage researchers to develop new strategies, so when we talk about post surgery aspiration, many things like that, and oftentimes you'll find some hospitals have done an amazing job, but others really haven't attacked this non-VHAP. And so it's important. It was addressed here. I think we're going to see more and more coming out on it, and hopefully we'll be able to see what that's going to entail.

So just a couple things, elevating the head of the bed or have patients in a chair for meals, some of the basic nursing things. And I think that's one thing I love about the VAE Compendium is it's talking about some of those basic strategies that many of us have known for years. So again, when we talk about mouth care, poor oral care, increased bacterial counts, reduced salivary flow, and the interesting thing, within 24 to 48 hours, these pathogens become colonized. The patient begins to have those as part of

their flora, and if they aspirate at that time, it certainly can cause pneumonia. So I'm just going to talk for a minute or so before we end about the infection prevention team, what you can do if you're an infection preventionist. Monitor, internally report patient outcomes, assist with monitoring of adherence rates, communicate your outcomes to key organizational stakeholders. Be sure you give feedback to frontline providers. Make sure you give feedback to respiratory therapy are so incredibly important, and reporting this data back to providers and leaders can really, really help.

So compliance, an increasing number of centers now have quality collaboratives showing how multiple measures can reduce VAE and VAE rates. And in conclusion, what we really want to do, and I know I've gone through that quickly, but that's just a high level overview, but what we really want to do is reduce VAE, because it is an important aspect of patient safety, and if we have that coordinated interdisciplinary approach, which is so necessary for success. So again, no one of us does it alone. We do it together, and I am happy to turn this back to our moderator. Lisa, thank you so much, and I'll let Lisa moderate the questions.

Lisa Wall: Thank you, Linda, for such an informative session. Before we get to questions, I'd like to inform our viewers how to obtain their continuing education credit for this session. As a reminder, this educational activity is approved for one contact hour. To obtain your continuing education credits, you log into www.saxetesting.com/p. You will need to register at the site, complete the evaluation, and upon successful completion, you will be able to print your certificate of completion. And again, many thanks to Dale Medical Products Incorporated for supporting this educational activity.

Now we will get to our questions. Oh, I'm sorry. An archive on demand version of this webinar will be available on www.perspectivesinnursing.org. An [inaudible 00:49:48] will be sent to all registrants when it is available, and the on-demand version is accredited for CEs. We will now begin our questions. I do you have a few, Linda. Is there a found benefit to bolus feeds rather than continuous feeds in relation to aspiration risk?

Linda Greene: I have seen that many people do use bolus feeds. I think it really depends. I wouldn't say that necessarily I would classify it as best practices, but it does make some logical sense. However, sometimes the bolus feeds certainly can cause regurgitation, so that's one of those that you have to look at the benefit and the risk, and sometimes the two are not, so it really does depend. I would say that it's a sound improvement.

Lisa Wall: Second question, "How often is considered too frequent for cuff pressure monitoring?"

Linda Greene: I really can't answer that. Certainly you don't want to. I think the recommendations are not to do it. I would not give you an example of a hour. Lisa, I don't know if you have encountered that in your respiratory therapy or not, and what the standard is that you are used to.

Lisa Wall: Well, someone else mentioned in the questions that at their facility, they check the cuff pressures Q shift, and that is what we are doing also because we have to balance it against injuries that can occur due to high cuff pressure. So we are still doing Q shift with two shifts twice a day.

Linda Greene: Yeah, I think to that question, I think it's a good question, and I would say I probably would not do it any more frequently than that, and in some cases, they probably do it less frequently.

Lisa Wall: Excellent. Third question, "Could you please comment on if we could implement one single change to get the best outcome for reducing VAP? What would that change be?"

Linda Greene: Do you mean overall VAE, or VAP, or overall VAE, I'm thinking?

Lisa Wall: The question says, "For reducing VAP"

Linda Greene: Okay, for reducing VAP in general, if I were to do one thing consistently, I'm looking at really continuing, because if you get the patient off the ventilator sooner, you reduce VAP. So I would say the one thing is making sure that your protocols are consistent. We talked about the liberation protocol, making sure that they're standardized, that we're using them among patients consistently, but I'll use the two interventions because I also think that the tooth brushing at least every shift is important. So I think those two recommendations are probably the two things that could make the biggest difference, so to speak.

Lisa Wall: Okay. Another question, "What is a real realistic benchmark for VAE?"

Linda Greene: Well, the realistic benchmark, it's really hard to put a realistic benchmark for VAE, because it looks at standardized infection ratios. And right now, I know there is some publications out there. The CDC does an annual report on VAE rates, and I think you start... Obviously, your realistic benchmark should be a standardized infection ratio. It should be less than one, and so what I always look at with benchmarks is I pull the most recent CDC publicized data. I look at where the organization is, and then I decide where I want to be in terms of a benchmark, and using your benchmarks, looking at the CDC data, where it is, and move from there. So I can't say it's a specific benchmark, but clearly I would want my standardized infection ratio to be below one, and then I would look at the CDC data to see where the average is, and my goal would be to continually reduce that.

Lisa Wall: Excellent. Another question, "When toothbrushing was used, did it make a difference and were they using regular toothpaste?"

Linda Greene: Some institutions did use a toothpaste, but the most important thing was the friction of the rubbing, and as I said earlier in some of the meta-analysis that were blinded, that they found that toothbrushing really did make a difference. There's no doubt about it, and I think that's some of our most compelling data right now, and it's something that has been ignored in many, many cases in intensive care units.

Lisa Wall: Okay. Here's another question, "How should non-unavoidable VAEs be handled? My trauma ICU has done many [inaudible 00:56:06] for IVAC, but these conditions are based on patients that have severe pulmonary contusions that we expect to blossom over 48 hours or so."

Linda Greene: How should it be handled? There are many

patients that are going to be at risk for VAE. There's no doubt about it, but I always think within some of those risks, there is an opportunity to look at those and to ask yourself, first of all, "Did we follow all the protocols?" That's number one, did we really follow all of our protocols? Were there protocols missing? And so I like to not only look at outcomes. I like to look at processes. What's the connection between the processes of care? Am I doing everything I can in terms of processes, and if my patient still gets a VE, then maybe it was unpreventable, but what I found over my years in infection prevention is we always like to say, "Well, these are non-preventable."

And if I'm following my bundles 100%, if I'm following everything, if everything that could possibly be implemented is done, then I could say, "They're non-preventable," but what some experts have shown is even in those cases where you might say they're not preventable, there are opportunities for improvement. So I always look for the opportunity to do a better job, and not every time will it be prevented, but oftentimes you will find some gems there that you could do something better.

Lisa Wall: Excellent. Thank you, Linda. I think that we are out of time as far as the questions. We had some great ones. I do want to thank everyone for attending this webinar, and I will turn the presentation over to Tracy for some concluding remarks.

Tracy Cook: Thanks, Lisa, and thank you, Linda, for such a great presentation. We would like to talk about our survey. Immediately upon the conclusion of this webinar, you will be presented with an online survey. Please keep your web browser open, and we appreciate your feedback, as well as for the CE certificate of completion, in one hour following the conclusion of this webinar, you'll receive an email with instructions and this link to obtain your CE credits. You can go to www.saxetesting.com/p and then add another back slash. It should work. If you're having issues, you can also try using the Chrome browser to access your CE credits. Again, we'd like to thank everyone for attending, and we hope you have a great rest of your day.

News…continued from page 59
of DreamStation machines used to treat sleep apnoea showed positive results, confirming preliminary results released last year. "We are very pleased with these results, it is very important for patients to know that the use of the devices did not lead to a health risk", Philips Chief Executive Roy Jakobs said. "It proves we have worked with a safe product, even though it might degrade." Amsterdam-based Philips has been grappling with the fallout of the global recall in June 2021 of millions of respirators used to treat sleep apnea over worries that foam used in the machines could become toxic.

Masimo Announces FDA Clearance of the Rad-G with Temperature

Masimo announced that the Rad-G with Temperature has received FDA 510(k) clearance. Rad-G with Temperature is a rugged, versatile, handheld monitor that provides clinically proven SET® pulse oximetry, respiration rate from the pleth (RRp®), and other important parameters alongside non-contact infrared clinical thermometry. With its long-lasting rechargeable battery, robust rubber casing, light weight, and the added convenience of integrated noninvasive forehead thermometry, Rad-G with Temperature makes it easier for care teams to quickly measure vital signs using a single, compact, portable device and make informed decisions anywhere patient assessment is needed. Rad-G with Temperature is designed for use in a variety of settings, including physicians' offices, outpatient services, urgent care facilities, wellness clinics, and in first-responder scenarios, both indoors and in the field. Joe Kiani, Founder and CEO of Masimo, said, "With Rad-G, we set out to create an accessible, high-quality care solution that could be used in a multitude of care settings to serve the five billion people on our planet that to date have not had access to pulse oximetry, let alone SET pulse oximetry. With the addition of temperature measurements, Rad-G is more versatile than ever, streamlining the assessment of multiple key vital signs. Having a product that is light, small, multifunctional, and 'accurate when you need it most' is crucial, and Rad-G was designed to be just that. With this FDA clearance, Rad-G with Temperature can now be deployed across the US, in addition to many other parts of the world, helping support clinicians in almost any care scenario." The infrared thermometry offered by Rad-G with Temperature provides a host of benefits. Rad-G's thermometer is non-contact and does not require probe covers or other disposable accessories. Its integration into the Rad-G platform eliminates the need for clinicians to locate a separate clinical thermometer to take body temperature measurements and ensures that many people can be seamlessly and efficiently screened for temperature, with one-touch operation, alongside oxygen saturation, respiration rate, and more, in the same session, using a single device. Designed from the start to maximize portability and battery life, Rad-G's rechargeable battery provides an impressive 24 hours of operational use between charges—allowing clinicians to work in transport, emergency, and other challenging scenarios with confidence that the device will continue to function hour after hour. First developed in partnership with The Bill & Melinda Gates Foundation as a spot-check device for use in pneumonia screening, Rad-G with Temperature originally launched outside the US. Since its introduction in Europe, more than 100 global customers have adopted the device to help them assess patient status in a variety of care settings. Among other care scenarios, the National Health Service (NHS) England, which provides the majority of

Continued on page 76…

Nonin Model 7500 Pulse Oximeter Tabletop Pulse Oximeter Classroom Session

In this feature, Respiratory Therapy interviews clinicians, companies and healthcare providers about the actual application of specific products and therapies. Participating in the interview is the Nonin Medical, Inc. product marketing team.

Thank you for taking time to review this walk through of the Nonin Model 7500 Tabletop Pulse Oximeter. Nonin is excited to bring this product demo to you, so you can see firsthand how the Model 7500 works. Specifically, we will highlight the features that make this a great device in the home care market.

This Model 7500 Classroom was developed to showcase the operation of the device in a demo format. We cover troubleshooting tips, FAQs, and walk through a few key device settings.

Nonin Model 7500 Tabletop Pulse Oximeter Product Overview

To begin, I would like to highlight the indications for use, taken directly from the operator's manual. The Model 7500 is intended for spot checking and continuous monitoring of patients during motion and non-motion conditions, and for patients that are well or poorly perfused.

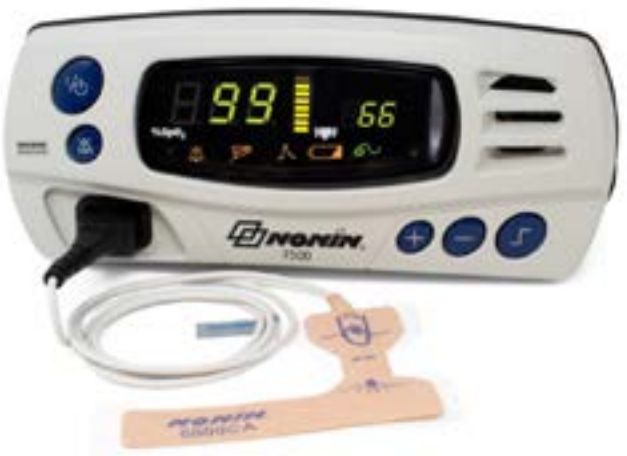

Figure 1. Model 7500 with a 6000CA cloth disposable sensor.

Now let's take a closer look at what sets the Model 7500 apart from other competitive devices. In homecare, durability and alarm setting options are critical. Nonin supports the Model 7500 with an industry-leading three-year warranty, highlighting our commitment to device durability. The Model 7500 is built for the repeated and heavy use that you often see in homecare settings. Nonin offers this device with both standard and Nonin Hybrid Averaging™ alarm settings. This gives the user a way to minimize any non-actionable alarms for long-term patients. Additionally, the Model 7500 boasts a battery life of 16 hours, four times longer than leading competitors.[1] This is intended to help mitigate the risk of losing patient data in the instance of a power outage.

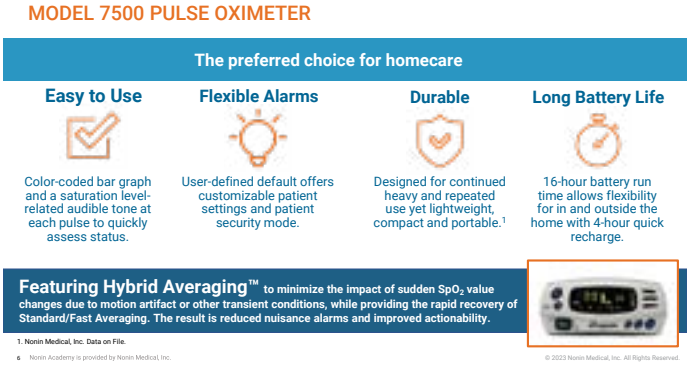

Figure 2. Model 7500 Key Features and Benefits.

The Model 7500 was designed for patients that require continuous monitoring. Examples of this can include patients with chronic respiratory diseases who need long-term home monitoring, patients in need of short-term respiratory monitoring in a hospital setting, or low-weight infants who need to be monitored in a hospital Neonatal Intensive Care Unit (NICU) setting and then further monitored when they are discharged. Because of this, we have a very large sensor selection. Nonin offers reusable and single use sensors, in sizes that range from neonate to large adult. Additionally, Nonin sensors are compatible across our tabletop or handheld pulse oximeters. Some homecare patients use a Nonin Model 7500 tabletop and a Nonin PalmSAT® 2500 handheld pulse oximeter, so those sensors can be interchanged across the devices.

Before we get into the demo slides, I want to point out Nonin's new Hybrid Averaging™ feature. Hybrid Averaging uses beat by beat averaging, which utilizes a four-beat average on the saturation and an eight-beat average on the desaturation. This is intended to reduce non-actionable alarms. It can be especially important in situations that include motion, for example when you're monitoring a crying, kicking baby.

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

Tabletop Pulse Oximeter: Model 7500 Product Demo

The next series of slides walk you through important features of the Model 7500 and how to update commonly needed settings.

Important Model 7500 Screen Display Icons

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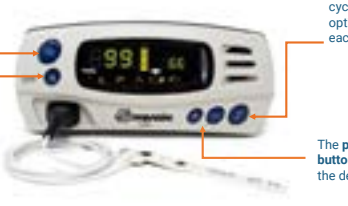
Important Model 7500 Panel Buttons



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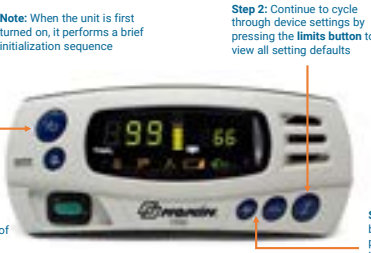
Changing the Default Settings



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Clearing Settings

Note: Clearing settings returns the device to factory defaults

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Selecting Hybrid Averaging

Note: Once Step 3 has been completed, your Model 7500 device will be set to Hybrid Averaging Mode

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Locking a Setting via Patient Security Mode

18 Nonin Academy is provided by Nonin Medical, Inc.

Turning off Patient Security Mode

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Data Collection and Download

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Please note that the data collection and download feature requires the additional purchase of a serial download cable.

Tabletop Pulse Oximeter: Model 7500 Frequently Asked Questions

Where can I find warranty information for the Model 7500?
The 7500 has a 3-year warranty and it is listed on page 35 of the Operators Manual.

What is the battery run time of the 7500?
It is 16 hours and can be found on page 35 of the Operators Manual under Internal Power.

What is a E04 Error code and how can it be resolved?
This indicates that the unit is not full charged. To resolve, plug the unit into the AC Power supply.

If I see an Error code, how do I resolve?
Contact Tech support to resolve all Error codes, except for Error code E04.

Tabletop Pulse Oximeter: Model 7500 Training Resources

You can find additional product training tools, informational materials, and links to product support on the Model 7500 training website: nonin.com/7500-Training-Resources.

We hope this was a helpful overview of the Nonin Model 7500 Tabletop Pulse Oximeter. If you're interested in watching the recorded live demo of this session, you can find the recorded version on the Model 7500 training website nonin.com/7500-Training-Resources

References

1 Competitive comparison information is being made against the Masimo Rad-97. See https://www.masimo.com/products/continuous/rad97/.

Thinking Beyond Lung Protection

The Diaphragm in Critical Care – Ventilator Induced Diaphragmatic Dysfunction

Edwin Coombs, MA, RRT-NPS, ACCS, FAARC

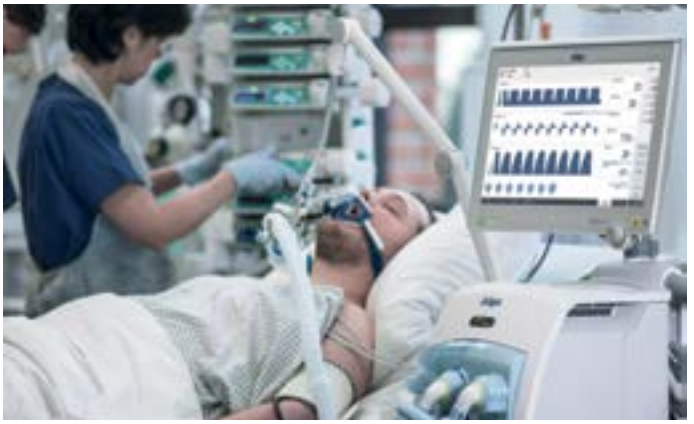
Background

Although mechanical ventilation is a life-saving intervention, complications from mechanical ventilation occur frequently, which can result in an extended length of stay in a hospital. Patients who undergo prolonged mechanical ventilation (greater than four days) suffer from high rates of mortality, morbidity, and commonly experience functional disability due to weakness after their ICU stay.

The human body breathes approximately 20,000 times per day. As the core breathing muscle, the diaphragm contracts every 3-5 seconds. However, patients undergoing mechanical ventilation often cannot utilize their diaphragm to inspire, thus the diaphragm becomes inactive and essentially passive. Under normal physiologic conditions, the diaphragm should be contracting during the inspiratory phase of breathing. When the diaphragm becomes inactive during mechanical ventilation the muscle atrophies rapidly and massively. The diaphragm loses up to 50% of its muscle fibers in only 18-69 hours of mechanical ventilation.[1]

The use of controlled mechanical ventilation results in a major reduction of diaphragmatic contractile force and atrophy of diaphragm muscle fibers, a condition commonly referred to as "Ventilator-Induced Diaphragmatic Dysfunction" (VIDD). VIDD is a leading contributor to weaning difficulties and increased mortality rates.[2]

Patients with VIDD are more likely to experience higher rates of primary and secondary weaning failure, increased days on mechanical ventilation, and longer ICU stays.[3] Evidence suggests that diaphragmatic dysfunction, which develops during critical illness, also poses a significant obstacle to recovery. This is especially critical as the diaphragm plays a crucial role during liberation from mechanical ventilation.[4]



Edwin Coombs is the Director of Marketing, Intensive Care at Dräger.

As the core respiratory muscle, our diaphragm plays an important role in respiration. A matter of great concern lies in patients who undergo mechanical ventilation while their diaphragm remains inactive.

Although current clinical practices address the avoidance of complications as patients improve and heal, there are limited opportunities for active exercise during the initial phase of stabilization and treatment. Unfortunately, this delay in intervention may prove to be detrimental as diaphragmatic muscle loss occurs during the first 18-48 hours of mechanical ventilation5. Recognizing the criticality of early intervention becomes imperative in addressing this issue.

Patient & Financial Impact

From as early as the 2000s, Mercat et al. estimated that Medicare would face significant financial strain due to rapid growth in the aging population and increased resource utilization associated with prolonged mechanical ventilation (PMV). Approximately one third of patients >65 years of age require ventilation for more than 14-21 days. The economic burden was projected to cost $64 billion in USA alone, and consume 2/3 of mechanical ventilation resources.[6]

This state of persistent critical illness leads to a higher degree of mortality and morbidity. Since acute brain dysfunction frequently occurs during acute illness, patients who do survive remain at high risk for long-term brain dysfunction which is also associated with increased mortality and other adverse outcomes such as prolonged hospitalizations and increased healthcare costs. Therefore, interventions to prevent or treat acute or long-term brain dysfunction should be implemented during the initial phase of care.[7]

One model suggested a projected growth in the USA for prolonged mechanical ventilation that results in annualized increases of more than 2, 3, and 6 million mechanical ventilation

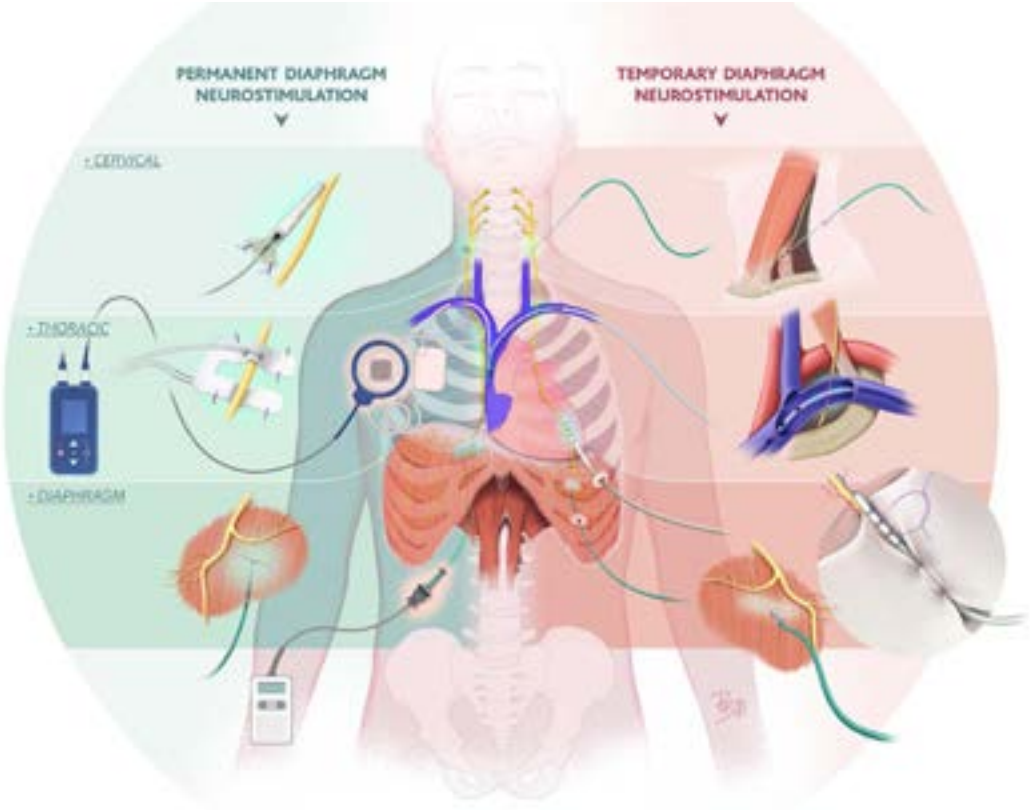


Diagram credited to Pierre Bourcier/ARCCM-March 2023

and ICU days. Such growth requires intense planning efforts and a renewed focus on the efficacy of health care delivery.[8]

The advancement in the understanding of lung physiology and pathophysiology has brought about an evolution in clinical practices. The emphasis has increased on minimizing ventilator-induced lung injury and related sequalae.

Recognizing the significance of avoiding intubation when possible has resulted in the increased use of non-invasive ventilation during initial treatment. In situations in which an invasive ventilation is required, the focus is on early weaning which involves measures such as minimizing sedation and facilitating spontaneous breathing trials.

Despite reservations due to resource allocation, patient risk, or caregiver injury, additional measures such as early ambulation programs and physical therapy protocols have also been employed with varied success rates.

The Diaphragm in Respiratory Research Today

The diaphragm is comprised of a peripheral muscle and a central tendinous portion. The phrenic nerve, which connects the brain and diaphragm, originates in the C3-C5 cervical region, and innervates each side to stimulate spontaneous breathing efforts. Recently, many researchers worldwide have been investigating neurostimulation of the diaphragm.

In the past, the primary focus was rehabilitating diaphragm weakness in patients recovering from critical illness. Currently, the emphasis has shifted towards preventing diaphragmatic weakness and atrophy while optimizing lung-protective ventilation. Efforts are also being made to also explore potential cardiac and brain effects related to diaphragm stimulation Although diaphragm stimulation has been well-established for patients with high spinal cord injury and central alveolar hypoventilation, a less invasive approach for critically ill patients as a supplement to mechanical ventilation shows promise but requires further study.[9] To that end, one recent single-center study has shown that non-invasive phrenic nerve stimulation can be safely performed in awake and anesthetized individuals. It was feasible and effective in stimulating the diaphragm, and diaphragm contractility could be well controlled indicated by diaphragm stimulation-induced scalable tidal volumes with minimum positive airway pressures.[10]

Potential Physiological Benefits of Diaphragm Stimulation

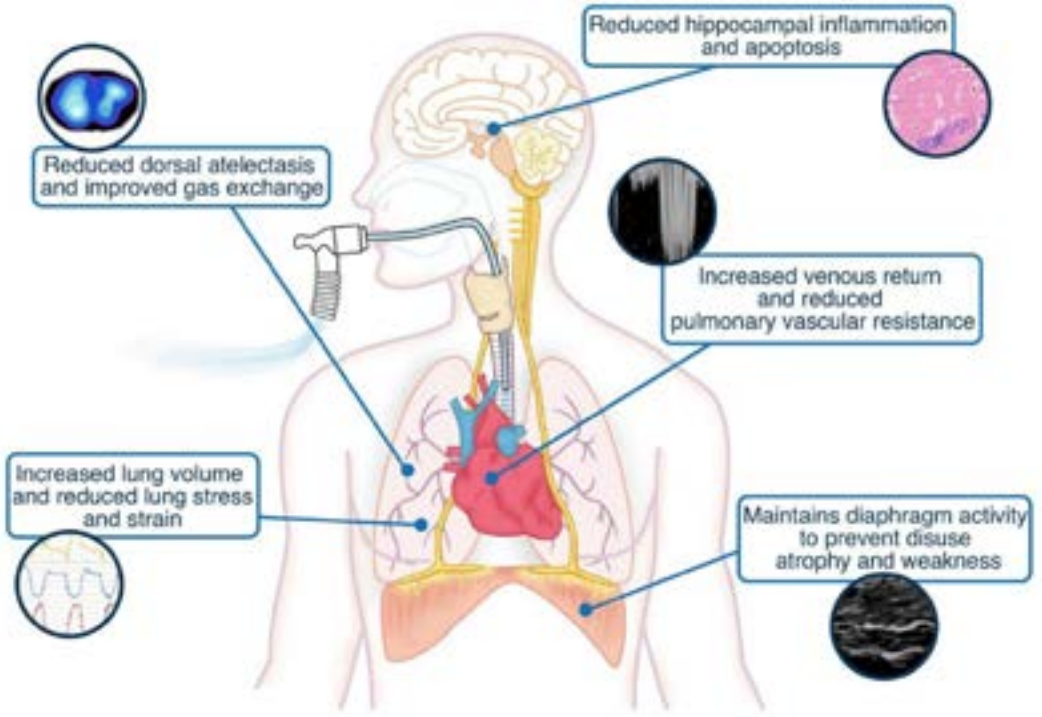
A recent review paper by Morris & Dres & Goligher summarizes the potential benefits of diaphragm stimulation.[11]

Respiratory Mechanics

"In the absence of diaphragmatic contractions, posterior lung regions become atelectatic and anterior lung regions are relatively overdistended."[9] Early data showed a dose dependent increase in alveolar homogeneity, reduced atelectasis, and improved oxygenation upon phrenic nerve stimulation.[11] Therefore, phrenic nerve stimulation might reduce lung stress and strain during mechanical ventilation and have positive effects on ventilator-induced lung injury.[9]

Cardiovascular Function

The effects of an active diaphragm on venous return to the heart are well understood, and it has been hypothesized that phrenic nerve stimulation may protect certain cardiovascular functions.[9]



Morris, Idunn. Dres, M. Goligher, E. "Phrenic nerve stimulation to protect the diaphragm, lung, and brain during mechanical ventilation," Intensive Care Medicine, June 10, 2022, DOI: 10.1007/s00134-022-06760-8

Diaphragm – Brain Effects

A recent phenomenon was described as ventilator-associated brain injury (VABI). Early data showed that phrenic nerve stimulation was associated with a dose-dependent reduction in hippocampal apoptosis and inflammation.[12]

While much research remains to be done, VIDD remains a causal factor that leads to life threatening complications during mechanical ventilation and financial strain to healthcare systems. With early intervention to prevent disuse atrophy, the potential for more positive outcomes is promising.

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Deflating the Cuff With Passy Muir Valve Use: Impact on Respiratory Function and Mechanical Ventilation Considerations

Kristin A King, PhD, CCC-SLP

The Passy Muir® Valve (PMV) is a device that allows patients with tracheostomies to communicate and breathe more naturally. When used in conjunction with mechanical ventilation, the PMV offers several advantages, such as improved speech, reduced respiratory complications, and enhanced patient comfort. To maximize the benefits of PMV use in patients receiving mechanical ventilation, proper usage of the PMV involves deflating the cuff to optimize respiratory function and patient safety. The reasons behind deflating the cuff while using the PMV and its impact on respiratory function are related to how the Valve functions. Having a comprehensive understanding of cuff deflation and its effects on improving speech and respiratory efficiency in patients with tracheostomies is critical to improved care with mechanical ventilation and during the weaning process.

The Passy Muir Valve is a no-leak, bias-closed position Valve which opens during inspiration and closes at the end of inspiration, redirecting airflow up and out the mouth and nose during exhalation. It is this change in direction of airflow that restores a more typical respiratory process by re-engaging the upper airway. This reengagement has been shown in the literature to improve lung recruitment and function[1-3]; psychological well-being;[4-5] and multiple benefits related to restoring sensation, communication, swallowing, and secretion management.[6-7]

Cuff Deflation for Passy Muir Valve Use

Enhanced Speech and Communication

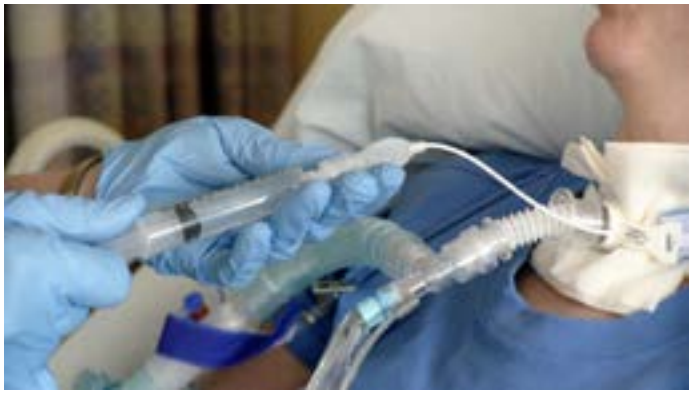
Deflating the cuff while using the PMV is essential for speech production. The PMV enables exhaled air to pass through the vocal folds resulting in voice production. This restoration of speech ability not only enhances communication but also improves the overall quality of life for patients with tracheostomies.[4] When considering restoration of speech and communication, one should also consider that doing so allows them to participate in their care and be engaged in the decision-making process. A study published in 2016 reported that medical errors are the third leading cause of death in the United States and that communication barriers and breakdowns are the leading cause of medical errors and adverse events.[8] So while restoring communication enhances quality of life, handoff communication and the patient's ability to communicate potentially have a significant impact on patient safety. Deflating the cuff and using a Valve provides the opportunity for a patient to access their voice. It also has been shown to improve both diagnostic and treatment interventions because of the patient's improved ability to participate.

Reduction of Aspiration Risk and Improved Swallow Function

A primary consideration for healthcare professionals is the impact of cuff management on swallowing and airway protection. Deflating the cuff during PMV use has been shown to help to reduce the risk of aspiration.[9] While trachlore™ (information spread by word of mouth, not supported by research, but commonly thought or done) would present that keeping the cuff inflated prevents aspiration, this is not accurate. Aspiration occurs when foreign substances, such as liquids or food particles, pass the vocal folds and enter the airway and lungs. As the cuff is located below the vocal folds, it cannot prevent aspiration. A cuff also cannot stop aspirated material from moving into the lung fields as the airway is dynamic with the walls of the trachea moving during respiration and allowing microaspiration even with an inflated cuff. Additionally, an inflated cuff, if not properly managed, has actually been shown to impair swallowing and airway protection.[10] By deflating the cuff and using the Passy Muir Valve, swallowing pressures that assist with airway protection are restored and assist with preventing substances from entering the airway, mitigating aspiration risk.

Cuff deflation also contributes to improved swallowing function. The presence of a fully inflated cuff can interfere with the natural swallowing mechanism. By deflating the cuff, patients can restore sensation, improve swallowing function, and restore the more normal pressurized system. Pressure assists with driving a bolus through the oral cavity, pharyngeal area, and esophageal sphincter. A tracheostomy tube with an inflated cuff reduces pressures throughout the swallowing system, including having a reduction in subglottic pressure.[11] By deflating the cuff and using a Valve, the swallowing reflex and experience allow for better control over the process, reducing the risk of complications.

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.



Deflating the cuff for a patient on mechanical ventilation prior to placing a Passy-Muir Valve in-line.

Impact on Respiratory Function

Cuff deflation during PMV use decreases airway resistance, allowing for more efficient airflow to the upper airway. A fully inflated cuff may create an obstruction in the airway, leading to increased work of breathing and is a contraindication for Valve use. By deflating the cuff, patients experience less resistance to airflow, resulting in improved respiratory function by re-engaging the upper airway. When the cuff is deflated and a Valve is used while on mechanical ventilation, research has shown that there is actually improved lung recruitment, increased diaphragmatic function, and overall improved respiratory mechanics as compared to mechanical ventilation with an inflated cuff.[3]

Improved lung recruitment was described as occurring because with the Valve in-line with mechanical ventilation, more normal respiratory pressures occurred allowing for improved ventilation of the alveoli. The research study by Sutt et al. (2016) also demonstrated that there were increased lung volumes in the patients with a Passy Muir Valve as compared to those patients with an inflated cuff. Cuff deflation in conjunction with Valve use facilitates better lung volume and ventilation.[3] When the cuff is deflated and a Valve is used, patients can achieve a more natural breathing pattern, allowing for deeper inhalations and more effective exhalations. This enhanced ventilation helps prevent atelectasis and promotes lung expansion.

They also found that these positive effects of improved lung recruitment and pressures continued for a period of time after removal of the Valve. By improving respiratory pressures and reengaging the upper airway, use of the PMV with the cuff deflated encourages the engagement of respiratory muscles. Breathing through an open airway, restoring pressures, and producing speech with the PMV requires increased respiratory effort, leading to improved strength and endurance of respiratory muscles.

Conclusion

Numerous research studies have investigated the benefits of cuff deflation for Passy Muir Valve use and its impact on respiratory function.[1-11] A study by Suiter et al. (2003) found that cuff deflation with PMV resulted in significant improvements in the penetration-aspiration scaled score during swallow studies. Even speech clarity and respiratory function in patients with tracheostomies have been indicated in numerous studies. In conclusion, deflating the cuff for Passy Muir Valve use is crucial for restoring speech, reducing aspiration risk, and improving respiratory function in patients with tracheostomies. The use of the PMV with cuff deflation leads to enhanced speech and communication, decreased airway resistance, improved respiratory muscle function, and better lung volume and ventilation. Clinical evidence supports the positive impact of cuff deflation, emphasizing the importance of incorporating this practice into the management of patients with tracheostomies with use of the PMV. Healthcare professionals should be aware of these benefits and encourage proper cuff deflation to optimize the respiratory function and overall well-being of their patients.

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BiWaze® Cough System – a Bench Study Evaluation and Comparison of Cough Efficiency

Patrik Malone RRT and Robert DiBlasi RRT-NPS, FAARC

Introduction

An effective cough relies on the ability to take a slow deep breath followed by the generation of high intrathoracic pressure to promote dynamic airway compression and increase expiratory airflow velocity to remove mucus and other foreign debris.[1] When a person is unable to cough effectively due to muscle weakness or lung disease, techniques are required to either augment or assist

their ability to cough. A common respiratory therapy for an ineffective cough is called Mechanical Insufflation - Exsufflation or MIE therapy. MIE therapy devices mimic a person's natural cough with a simulated cough. A typical simulated cough cycle includes applying a positive pressure or **insufflation** to inflate the lungs, quickly followed by negative pressure or **exsufflation** to remove the air and mucus from the lungs, and a timed pause for the patient to rest before the next cough cycle. MIE therapy can be used with pediatric to adult patients in the Intensive Care, Acute Care, and home care environments.

The general thought is that when MIE therapy is combined with High Frequency Oscillations (HFO), it could enhance lung volume on inhalation, recruit collapsed airways and alveoli and improve cough efficiency. HFO superimposes small compressions in pulmonary pressure and flow similar to chest physiotherapy intended to assist in mobilizing secretions from peripheral airways to larger conducting airways so that they can be coughed up and expectorated.[2] However, there is not a lot of clinical evidence to support the efficacy of MIE therapy with HFO for airway clearance.

Many patients that receive MIE therapy for airway clearance also require noninvasive or invasive mechanical ventilation. It is common clinical practice to disconnect patients from the ventilator in order to receive MIE therapy.

The abrupt disruption in ventilation can result in acute lung deflation due to transient loss of Positive Inspiratory Pressure (PIP) and Positive End-Expiratory Pressure (PEEP). Repeated disconnection from mechanical ventilation and acute deflation has been shown to result in sustained changes in altered lung mechanics, hypoxia, alveolar de-recruitment, reduced lung volume, increased pulmonary edema and injury, and hemodynamic instability.[3] Additionally, studies in critically ill subjects have shown that by applying a negative pressure with suctioning to the lungs, which is commonly done in combination with MIE therapy, can produce a marked reduction in lung volume and associated changes in arterial oxygenation.[4,5]

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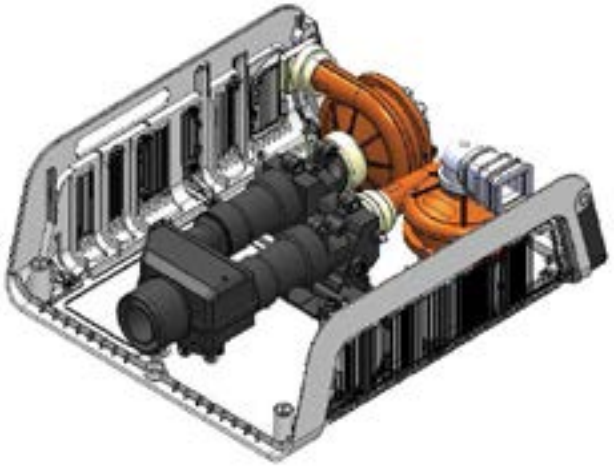
New Technology

ABM Respiratory Care has an innovative MIE device called, BiWaze® Cough System. BiWaze Cough has a unique two blower design unlike other MIE devices. The two blowers are dedicated to driving and separating the inhaled and exhaled airflow.

BiWaze Cough is lightweight (9 lbs.) with a built-in lithium ion battery. It can deliver MIE therapy along with HFO to assist with breaking down and mobilizing retained secretions. BiWaze Cough is designed to prevent lung volume loss and derecruitment by applying a positive pressure during the pause or 'rest' phase between insufflation and exsufflation. The Positive Airway Pressure (PAP) during the pause phase (aka PAP on Pause) feature provides a distending pressure to stabilize the lung volume immediately after a planned disconnection from a ventilator and during exsufflation or suctioning. The PAP on Pause could allow for improved lung mechanics, gas exchange, and lung protection. By maintaining airway pressure similar to PEEP, airways are stented open following exsufflation. PAP on Pause is designed to increase expiratory lung volume and generate a larger inspiratory capacity which could have a beneficial effect on improved cough efficiency. Additionally, PAP on Pause applied between cough cycles could prevent airway



BiWaze Cough two blower design

collapse, reduce airway resistance and allow better recovery of retained pulmonary secretions.

Study Method

We conducted studies in vitro to evaluate the effects of BiWaze Cough on flow and pressure within a mechanical lung model during assisted cough maneuvers at different MIE Insufflation Pressure (IP) and Expiratory Pressure (EP) settings both with and without PAP on Pause and HFO.

In addition to testing BiWaze Cough, we wanted to compare performance to a widely used MIE device, the CoughAssist T70 (Philips Respironics, Pittsburgh, PA). The CoughAssist T70 also provides HFO to facilitate mobilization of airway secretions but it does not provide PAP on Pause.

Measurements were taken using a digitally controlled, high-fidelity breathing simulator (ASL 5000; IngMar Medical, Pittsburgh, PA), which uses a screw-drive-controlled piston and mathematical modeling to simulate disease specific pulmonary mechanics. Inspiratory and expiratory resistance, linear and non-linear pulmonary compliance, and chest wall mechanics can be set independently by the user. An adult passive patient model was used to evaluate the performance of each MIE device. The adult lung model was configured with normal pulmonary compliance and increased resistance to mimic airway obstruction from retained secretions. A passive chest wall model (no active breathing efforts) was used to ensure synchrony and isolation of the assisted cough device performance measurements independent of patient spontaneous efforts. The ASL 5000 was configured with an intrinsic lung resistance of 25 $cmH_2O/L/s$, a lung compliance of 100 mL/cmH_2O, and an uncompensated residual volume (residual volume, RV) of 1.5 L. MIE therapy was delivered to the ASL 5000 lung model using a 7.0 endotracheal tube and a 15mm adaptor. Each MIE device was equipped with a bacterial filter, patient circuit and evaluated for leaks prior to testing. The ASL 5000 data output array provided measurements of airway pressure, alveolar pressure, cough flow acceleration (maximum change of slope in velocity of the exp. flow curve), Peak Cough Flow (PCF, maximum negative value of the slope for the expiratory flow curve, aka Peak Expiratory Flow), as shown in Figure 1.

Additional calculations were included to evaluate cough efficiency based on the lung model measurements. The Transairway Pressure gradient (ΔP) or driving pressure of a cough is based on the change in intrathoracic pressure at peak lung inflation followed by rapid expulsion and pressure release at the airway opening that generates high Peak Expiratory Flows (PEF) during a cough. This Transairway Pressure was calculated by taking the absolute difference between alveolar pressure and airway pressure (Palv-Paw) at IP and EP, respectively. The difference or 'bias' between Peak Cough Flow and Peak Inspiratory Flow (ΔPCF-PIF) was calculated based on prior findings that greater increases in this value have been shown to correlate with greater mucus displacement from peripheral airways.[6,7] Descriptive statistics were calculated as mean values for 20 breaths at each testing condition.

We acquired raw data from the lung model and reconstructed the airway and alveolar pressure and flow over time to illustrate HFO waveforms and describe differences in oscillatory output generated by the HFO modality with both MIE devices.

Test Results

Waveform Analysis

BiWaze Cough delivers a controlled gradient to reach target alveolar pressures which results in a constant square inhalation flow pattern and lower inspiratory flows (Figure 2). The expiratory flow profile with BiWaze Cough (Figure 2) shows a brief compression and release in the expiratory flow and

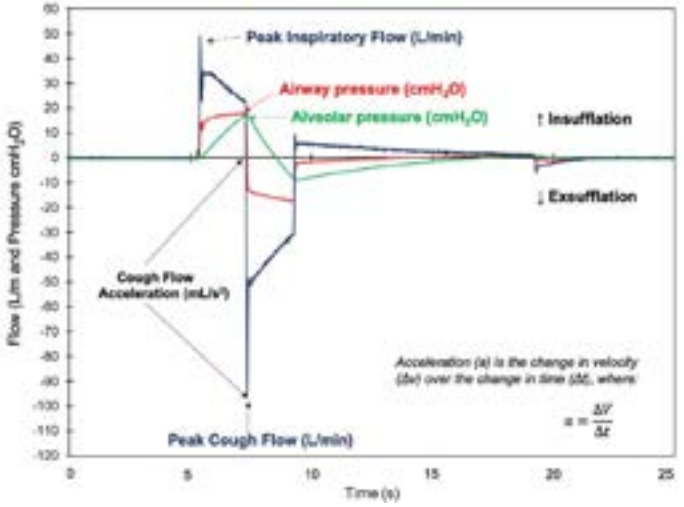


Figure 1. Pressure and flow measurements obtained from the ASL mechanical lung model

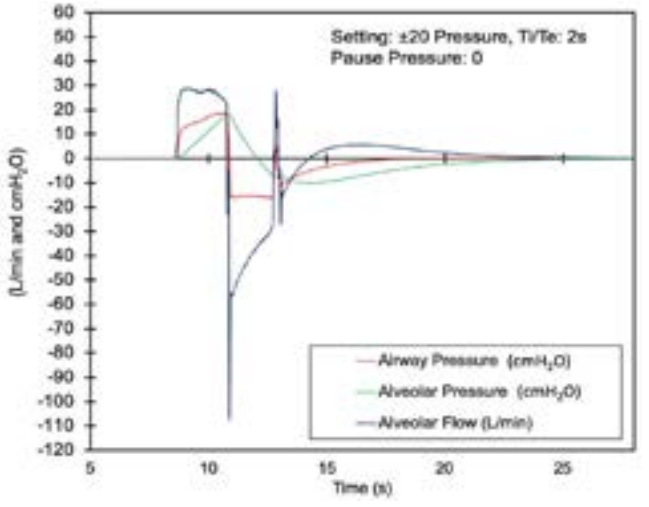


Figure 2. Pressure and flow waveforms of BiWaze Cough (PAP on Pause at 0 cmH_2O)

pressure waveform at the end of the cough cycle that may be representative of valve closure or flow being dispersed with the dual flow control of (two blower design) BiWaze Cough.

CoughAssist T70 on the other hand provides a rapid onset inspiratory pressure resulting in a decelerating flow waveform (Figure 3) and higher inspiratory flow. BiWaze Cough showed immediate and sustained airway pressure decay to -15 cmH_2O upon cough initiation; whereas CoughAssist T70 has a less aggressive algorithm with initial airway pressure decay to -12 cmH_2O and achieves -15 cmH_2O just prior to the completion of the cough cycle (Figure 3).

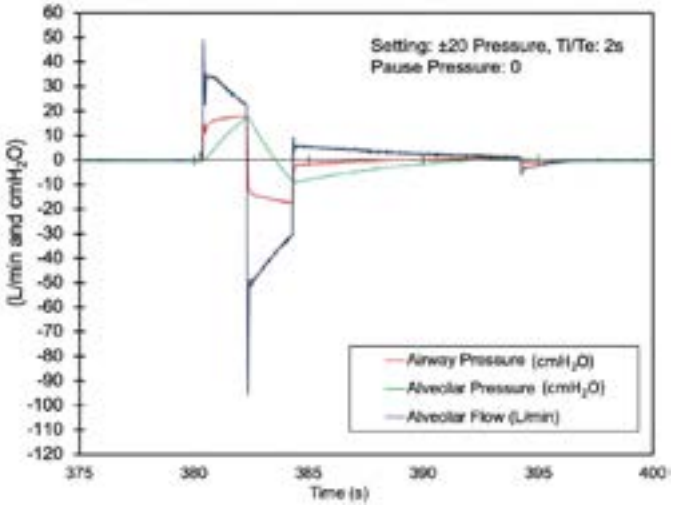


Figure 3. Pressure and flow waveforms of CoughAssist T70

Measured Lung Parameters and Cough Efficiency

The lung model measurements obtained at different IP/EP with BiWaze Cough and CoughAssist T70 are shown in Table 1. The differences in the slope of the EP profile with BiWaze Cough resulted in higher observed Transairway Pressure, Flow Acceleration and Peak Cough Flow (PCF) (Table 1). The combined lower PIF and higher PCF with BiWaze Cough showed greater differences in ΔPCF-PIF at all settings than CoughAssist T70.

MIE Device	IP/EP	PIF (L/min)	PCF (L/min)	ΔPCF-PIF (L/min)	Flow Accel. (mL/s²)	Trans-airway Pressure (cmH_2O)
BiWaze	±20	30	106	76	72	32
T70	±20	43	89	46	43	31
BiWaze	±30	48	156	108	101	47
T70	±30	55	124	69	58	46
BiWaze	±40	62	186	123	146	65
T70	±40	69	173	104	92	63

Table 1. Effects of BiWaze Cough and CoughAssist T70 on cough efficiency at similar IP and EP settings (no PAP on Pause pressure).

The application of PAP on Pause at 5 and 10 cmH_2O maintained similar cough efficiency values as BiWaze Cough without PAP on Pause (see Table 2).

IP/EP	Pause Pressure (cmH_2O)	PIF (L/min)	PCF (L/min)	ΔPCF-PIF (L/min)	Flow Accel. (mL/s²)	Trans-airway Pressure (cmH_2O)
±20	5	34	107	73	70	31
±20	10	31	109	77	71	31
±30	5	44	159	115	103	48
±30	10	48	158	111	102	47
±40	5	62	186	124	118	65
±40	10	66	186	119	159	61

Table 2. Effects of BiWaze Cough on cough efficiency with different insufflation, exsufflation and PAP on Pause pressures.

In a series of multiple MIE therapy cycles with BiWaze Cough, airway pressures, alveolar pressures, and volumes were observed with and without PAP on Pause (Figure 4.1 and 4.2). The top graph in Figure 4.1 and 4.2 represents airway pressure (orange) and alveolar pressure (yellow). The bottom graph in Figure 4.1 and 4.2 represents volumes (orange) and baseline lung volume (white).

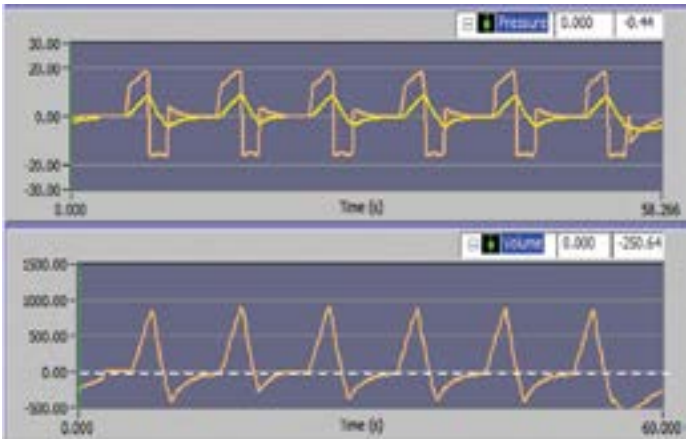


Figure 4.1. IP/EP 20 cmH_2O with no PAP on Pause. The Expiratory Reserve Volume (ERV) is 0 mL above lung Residual Volume (RV), which predisposes patients to alveolar collapse following each cough maneuver.

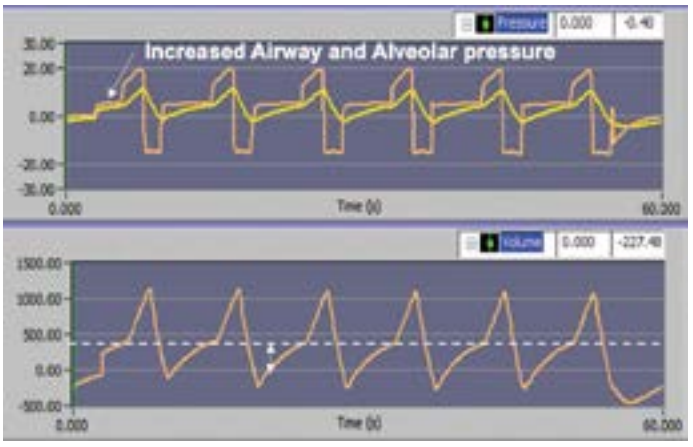


Figure 4.2. IP/EP 20 cmH_2O with PAP on Pause of 5 cmH_2O. By placing the PAP on Pause pressure at 5 cmH_2O, alveolar and airway pressure is increased at baseline and there was a 450% increase in ERV which would equate to an increase in the Functional Residual Capacity (FRC). Once the PAP on Pause pressure is applied initially in the first breath, it is maintained throughout all coughs with effective Cough Peak Flow (CPF).

The volume above residual volume (1.5 L) in the lung model, or ERV, that contributes to the FRC is visible in Figure 4.2.

The ERV was 0 mL with no PAP on Pause and increased to ~400 ml above RV due to the addition of PAP on Pause of 5 cmH_2O. The increased inspiratory airway and alveolar pressures in Figure 4.2 demonstrate that applying a PAP on Pause of 5 cmH_2O, resulted in a nearly 4-fold increase in ERV. This increase in ERV is translated to an increase in FRC or end-expiratory lung volume in a human lung.

Application of HFO with MIE therapy

Descriptive waveform analysis of the High Frequency Oscillation (HFO) feature applied to cough cycles with BiWaze Cough and CoughAssist T70 are shown in Figure 5 displaying pressures and flow and Figure 6 with the flows removed in order to visualize the effects of HFO on airway and alveolar pressures.

The BiWaze Cough generated consistent oscillatory power throughout the cough cycle (IP + EP) and at greater oscillatory flow and airway pressure force than CoughAssist T70. Moreover, the oscillations in airway pressure and flow generated in the lung model were not only lower with CoughAssist T70 but were highly variable throughout the cough cycle. Pressure transmission and oscillatory amplitude was briefly reached at the end of the inspiratory and expiratory phases with CoughAssist T70. The greater oscillatory output with BiWaze Cough resulted in greater transmission of flow and oscillations in the alveolar pressure waveform that were not apparent with the CoughAssist T70 (Figure 6).

Adding PAP on Pause with BiWaze Cough resulted in incremental 'stairstep' increases in airway pressure oscillations on inhalation that resulted in greater transmission of flow and pressure during the MIE cough maneuver (Figure 7). Increases in the PAP on Pause pressure from 5-10 cmH_2O showed greater pressure transmission of the oscillations to the distal alveolar compartment (Figure 7).

There is currently insufficient evidence to indicate whether differences in MIE device performance in bench models could translate to clinically meaningful differences in outcomes in patients. Very few studies have investigated the physiologic effects of MIE in critically ill patients, much less compare different devices. Nonetheless, our bench data show unique differences in flow and pressure delivery between BiWaze Cough and CoughAssist T70 that could generate interest for future research.

Discussion

This is the first study to evaluate MIE performance between BiWaze Cough and the widely used CoughAssist T70. The BiWaze Cough showed greater Peak Cough Flow (PCF) and lower Peak

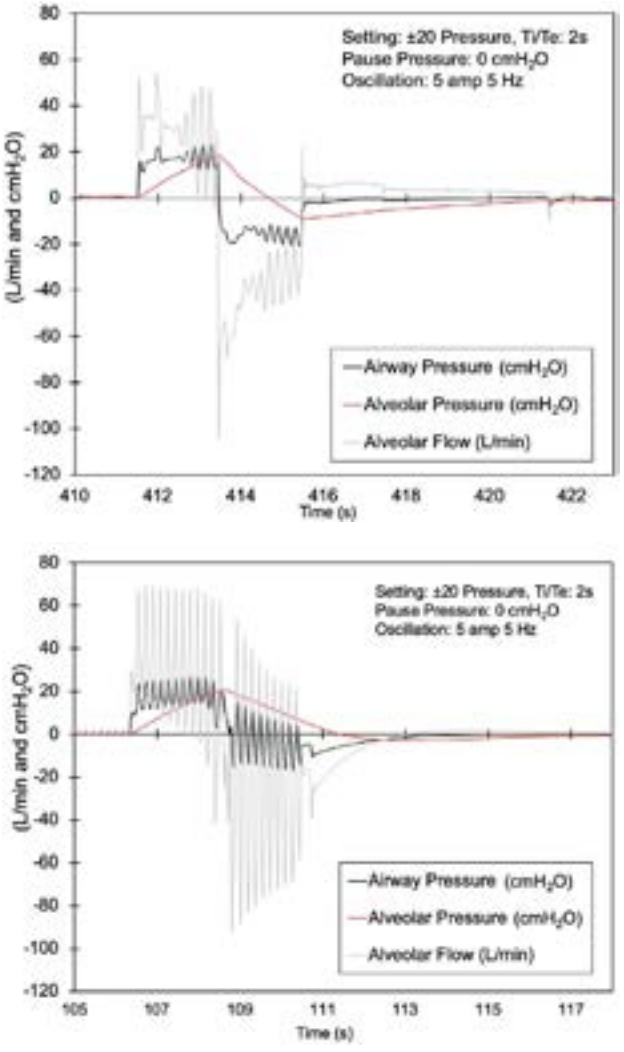


Figure 5. Pressure and flow waveforms of CoughAssist T70 (top) and BiWaze Cough (bottom) with (no PAP on Pause).

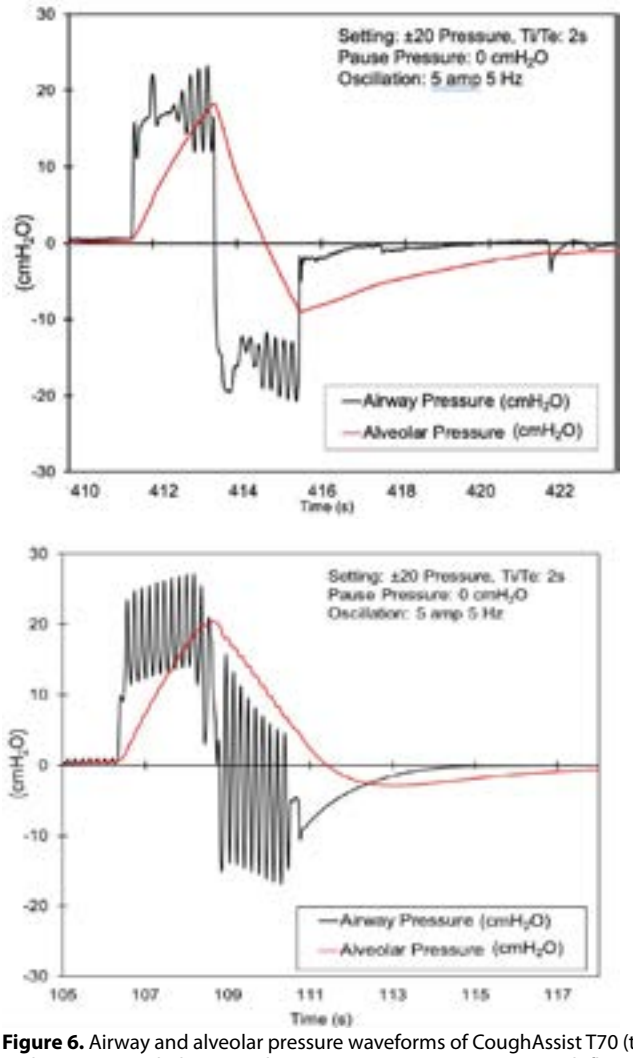


Figure 6. Airway and alveolar pressure waveforms of CoughAssist T70 (top) and BiWaze Cough (bottom) showing HFO (no PAP on Pause) with flow data removed.

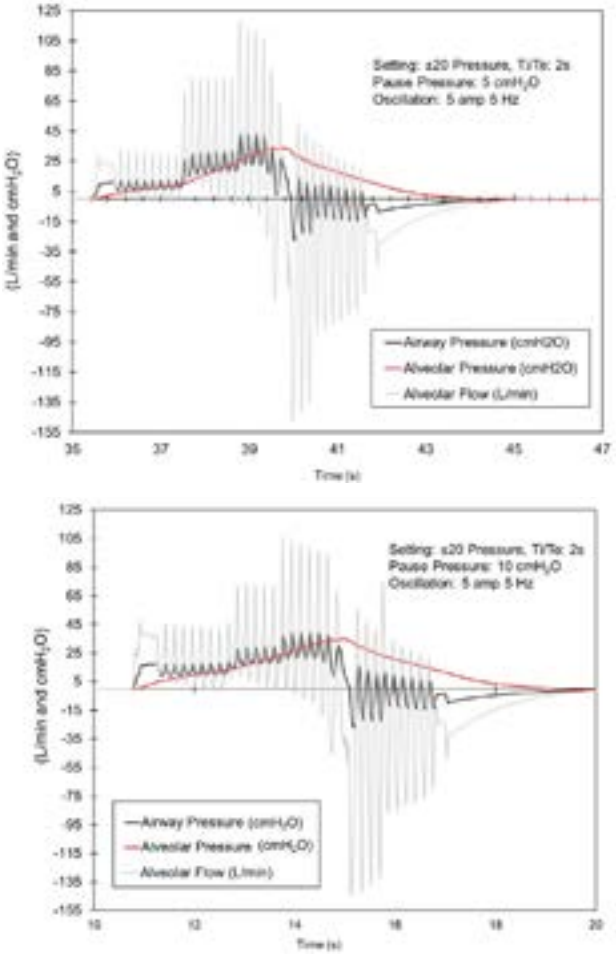


Figure 7. Pressure and flow waveforms for BiWaze Cough HFO with PAP on Pause of 5 cmH_2O (top) and 10 cmH_2O (bottom).

Inspiratory Flow (PIF) that resulted in higher flow acceleration and ΔPCF-PIF compared to CoughAssist T70 at identical MIE therapy settings. The PAP on Pause feature with BiWaze Cough provided similar increases in PCF as well as increases in Functional Residual Capacity (FRC) or end-expiratory volume than without PAP on Pause. The BiWaze Cough's High Frequency Oscillations (HFO) feature controlled by the dual blower system resulted in greater lung transmission of pressure and flow than with the single blower system of the CoughAssist T70.

During a cough cycle, there is a rapid increase in positive pressure during inhalation that is followed immediately by a rapid airway depressurization. During a physiologic cough the intrathoracic pressure gradient has been shown to range from 30 to 160 cmH_2O in order to generate high cough flows necessary for airway clearance.[8,9] In our model, similar Transairway pressures were generated that ranged within 1-3 cmH_2O between the two MIE devices. However, the BiWaze Cough was shown to result in greater increases in PCF in the lung model. Unlike the CoughAssist T70, BiWaze Cough had a expiratory airway pressure plateau that was sustained over the initial 2/3 of the exsufflation which may explain why PCF and acceleration of gas during EP were higher with BiWaze Cough. This pressure profile compares well to the rapid deceleration in pressure followed by plateau that has been previously described in subjects with voluntary cough.[10] Interestingly, following the initial 2/3 of the cough cycle, the BiWaze Cough produced a distinct positive pressure inflection and expiratory flow interruption during exsufflation. This is reminiscent of the characteristic partial glottic closure that is typically observed in a voluntary cough.[11] The reflex, first described by Williams in 1841[12] and then extensively studied by Korpas and his colleagues[13] in the 1960s, is referred to as Expiratory Reflex (ER). The ER consists of a glottal closure and forced expiration followed by glottal opening and expulsive airflow, in response to irritation (mechanical or chemical) of the vocal folds or trachea. It is believed that the initial cough reflex and ER that occurs later in the cough phase have quite different functions: cough will clear the lower airways of debris including mucus, while the ER will prevent aspiration of expectorated material into the lungs.[14] In one study, the ER was referred to as "coughing peals" which were shown to achieve similar mechanical effects as voluntary cough (without ER) but were achieved in a much shorter duration when ER was present.[15] BiWaze Cough may provide realistic mechanisms that could improve upon cough efficiency, especially in intubated patients who are unable to perform glottal closure due to physical and mechanical limitations of the endotracheal tube bypassing the vocal cords.

Reduced Peak Cough Flow (PCF) can be due to a number of mechanisms including reduced respiratory muscle strength, lack of coordination of glottic closure and opening, airway obstruction and, age and activity related changes.[11] Generally, PCF > 160 L/min is sufficient to eliminate airway debris and secretions during spontaneous cough.[17-18] In clinical practice, cough efficacy with mucus expectoration may require higher PCF in weak or impaired inspiratory and/or expiratory muscles. MIE therapy attempts to increase PCF in patients with impaired cough to assist with airway clearance. The BiWaze Cough achieved values that coincided with this requirement (~160 L/min) when IP/EP settings >20 cmH_2O; whereas CoughAssist T70 did not. The higher PCF resulted in nearly two-fold greater increases in linear air flow velocities (acceleration) with BiWaze Cough. Increased kinetic energy enhances the removal of mucus adhering to the airway through shearing.[12] The ability to generate high flow velocities needed to expel secretions forward with BiWaze Cough's Transairway Pressure could contribute to improved cough efficiency by enhancing the rheological interaction between flowing gas and mucus in the airways.[8]

Our findings showed BiWaze Cough generated large differences in ΔPCF-PIF based on how each of the devices provide IP and EP during MIE assisted cough maneuvers. BiWaze Cough was shown to deliver a controlled gradient to reach target alveolar pressure which resulted in a constant flow square inhalation flow pattern and generation of lower inspiratory flow delivery with Inspiratory Pressure (IP). The physiologic use of linear flows during inhalation is common prior to initiating a nautral cough in humans.[9] The peak flow increase at the onset of IP with CoughAssist T70 based on the preset pressure control level generated higher inspiratory flows. As mentioned previously, high kinetic energy from high velocity gas affects movement of secretions within the airways. As such, there could be some benefit for applying linear inspiratory flows over a longer inspiratory time in order to reduce airflow velocities and prevent dislodgement and displacement of airway secretions into the distal airways prior to MIE cough maneuver.

In airway clearance studies with mechanical ventilation, when PIF >PEF, an inspiratory flow bias may lead to increased risk of embedding pulmonary secretions.[7]

The flow bias difference (PEF – PIF) between the peak flows that may affect mucus transport by this mechanism include inspiratory-expiratory air velocity, viscosity of mucus, and thickness of the mucus layer.[12] One animal study reported mucus displacement only occurred once an average PEF-PIF difference of 34 L/min was obtained.[19]

MIE is commonly applied with fast insufflation-exsufflation pressures to achieve high Peak Expiratory Flow (PEF) in order to assist airway clearance.[20-21] Very little attention is given to the fact that long inspiratory times (>1 sec.) are needed in order to fill lung regions that have long time constants due to high resistance from mucus impaction or the fact that high Peak Inspiratory Flow (PIF) may impair secretion removal.[21] Volpe et al.[21] showed in a MIE study *in vitro* that the PEF – PIF difference and MI-E pressure gradient were significantly correlated with mucus displacement, whereas the PEF was not. The PEF-PIF difference observed from these prior studies is identical to the PCF-PIF difference (ΔPCF-PIF) generated in our studies and is likely to be a key determinant for secretion clearance with MIE that can be used to infer the efficacy of airway clearance techniques in critical care patients in the future.

Investigators have reported that MIE maneuvers could be optimized by applying slow lung insufflation, which could reduce the PIF and, consequently, increase the expiratory flow bias (ΔPCF-PIF) to improve cough efficiency by setting EP>IP.[20] We demonstrated that BiWaze Cough was shown to generate lower inspiratory flows and greater PCF than CoughAssist T70 that did not rely upon having to set separate IP and EP settings. Our findings with BiWaze

Cough showed large differences in ΔPCF-PIF that coincided with values of PEF-PIF differences (>34 L/min) that have been shown to be effective for removing airway secretions. The BiWaze Cough may provide major benefits for improving MIE efficacy with assisted cough maneuvers.

There are several concerns regarding use of the MIE therapy in critically ill patients which include risk of deterioration, large airway collapse during exsufflation with high negative pressures, and loss of Functional Residual Capacity (FRC) with prolonged exsufflation time. In a recent review, this limitation was addressed as a major concern that has not been investigated properly; could the use of high EP reduce the end-expiratory volume leading to hypoxemia and lung injury or, on the contrary, does it cause airway collapse that would prevent this from happening.[20] In addition to the MIE therapy itself, critically ill patients with repeated disconnection from the ventilator for MIE therapy and suctioning following therapy, the lungs are exposed to rapidly changing conditions, and it could take some time for patients to stabilize upon return to a mechanical ventilator or noninvasive support. An additional feature of BiWaze Cough that is not found in CoughAssist T70 is the option to set PAP on Pause. We showed in a mechanical lung model of airway obstruction that small increases in PAP on Pause could translate to large increases in Expiratory Reserve Volume (ERV) that could stabilize end-expiratory lung volumes and Functional Residual Capacity (FRC) in patients with poor pulmonary compliance following disconnection from ventilatory support. This could have a profound impact on patient stabilization and ability to tolerate MIE therapy following disconnection from positive pressure or suctioning or reducing airway collapse when using high Expiratory Pressure (EP) with MIE therapy.

We provided some descriptive waveform analysis using both BiWaze Cough and CoughAssist T70 High Frequency Oscillations (HFO) while being applied to MIE therapy.

The BiWaze Cough showed consistent airway pressure and flow oscillations throughout the entire cough cycle. The CoughAssist T70 had lower amplitude pressure and flow oscillations that were highly variable when compared to BiWaze Cough. The ability to provide MIE therapy combined with PAP on Pause and effective HFO represents an exciting novel development in airway clearance with BiWaze Cough.

In summary, based on measurements in a simulated lung model, the BiWaze Cough is effective in maximizing Peak Cough Flow (PCF) and airflow velocity within a standard range of pressure and time settings. Application of PAP on Pause and effective HFO (due to the dual blower design) are two features that are likely to result in more effective airway clearance and improved FRC with BiWaze Cough. These developments in MIE technology present greater options for clinicians providing bedside airway clearance therapy in patients with weak or ineffective cough.

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It's Time to Get Serious About Incidental Lung Cancer Detection

Ryan Hennen

Lung cancer is the leading cause of cancer deaths worldwide, with approximately 1.8 million people dying from this disease each year. Most patients are diagnosed after symptoms have appeared and the disease has progressed to an advanced stage (Stage III or IV), which explains the current worldwide five-year survival rate of just 20 percent. In contrast, the survival rate for small lung tumors that are treated at Stage 1A is as high as 90 percent. This significant difference highlights a critical need for diagnosis and treatment of lung cancer at the earliest possible stage.

One of best opportunities to diagnose more small, pre-symptomatic lung cancers earlier is presented by the two million patients in the United States every year[1] who have a *lung nodule identified incidentally* during chest CT scans ordered for other reasons, such as during an ER visit or after a cardiac event.

Current care guidelines mandate follow-up over one to two years to determine whether a nodule is cancerous. However, more than 60 percent of these patients do not receive guideline-recommended follow-up[2], severely limiting opportunities for early intervention and treatment. Patients who do receive recommended follow-up often require multiple imaging scans and biopsies, and sometimes unnecessary invasive procedures such as surgical biopsies and lung resections, before arriving at a definite diagnosis.

Several factors contribute to this situation:

1. **Broken care workflows.** As noted earlier, a patient may receive a chest CT scan for any number of reasons unrelated to a lung issue. During their review of the scan, the radiologist notes that there is a lung nodule present and recommends follow-up by the patient's primary-care physician (PCP). However, at that moment, this is a secondary and non-urgent issue for this patient, so therefore the care team may not alert appropriate care team for nodule management. Also possible: the PCP assesses the radiology report as non-critical and does not inform the patient. It's important to note that there are Standard of Care and legal liability issues associated with both scenarios.

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A clinician and a research scientist evaluate a scan using Optellum's Virtual Nodule Clinic, which helps physicians identify and track at-risk patients so that they can biopsy suspicious lesions early and start treatments sooner to improve the outcome of patients' care.

2. **Incidental screening diagnoses may not receive the attention they merit.** Regionally, doctors may be aware that a significant percentage of the local population has completely benign lung nodules. And it's true: 95 percent of these modules will stay benign. So, when the patient's PCP is informed of an incidental diagnosis, they can be hesitant to prescribe a care path that involves a course of six-month CT scans — which are expensive and may unnecessarily alarm the patient.
3. **The high cost of chasing down a definitive diagnosis.** It is widely accepted that nearly one-third of all CT scans that include part of the lungs describe an incidentally detected lung nodule. Managing these nodule patients can present enormous resource challenges in scheduling appropriate follow-up care. The larger the healthcare network, the greater the challenge.
4. **Low ROI.** Implementing a nodule tracking workflow without automation to properly manage patients is costly and has a low ROI. Most hospitals are therefore reluctant to implement a program to diligently review radiology report findings of all scans. A high prevalence of incidental nodules combined with increasing CT scan utilization exacerbates this problem. Clinical teams are already very busy, so allocating resources to track benign nodules with conventional manual processes that require additional full-time employees is a low priority

Scale up: the cost-benefit equation is changing

Recent advances in artificial intelligence (AI) are changing the calculus of these decisions. For example, the Optellum AI-powered platform applies natural-language processing (NLP) automation to instantly read and grade any radiology report, and then to identify and track patients who should be assigned special care. Additionally, the system assigns a Lung Cancer Prediction score to the nodules of interest, which stratifies patients and assists with accurate diagnosis. This, in turn, supports better clinical decision making.

The potent combination of NLP-powered case-note analysis and AI-assisted diagnostic tools represent a viable solution for many healthcare systems, enabling the treatment of more early-stage lung cancers without increasing the workload of clinical teams. And, by arriving at the right diagnosis sooner, hospitals can also minimize unnecessary invasive biopsies. The potential for better outcomes with this integrated AI-assisted approach has warranted both FDA clearance and a CPT code from CMS to help accelerate adoption across more healthcare systems.

Is AI-assisted lung cancer diagnosis right for your hospital?

Given the importance of early diagnosis, hospitals should implement a plan for tracking and managing incidental lung nodules — to avoid reputational risk and save the lives of more patients. As you assess your course of action, your clinical teams should ask these questions:

1. Last year, how many nodules were identified incidentally at your healthcare system?
2. Were they all tracked and what procedures are in place to recommend a care pathway?
3. How many patients were lost to follow up?
4. In 2023, if we were to track and treat significantly more nodules appropriately, could we do this without adding resources and staff?

If you cannot find any of the above information easily, it's time to re-evaluate your approach. It's quite likely you have a serious issue that needs to be addressed.

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healthcare in England, uses the technology to support primary care assessments of unwell children in physician's offices across the country. In a survey of 109 NHS England clinicians whose primary care facilities were using more than 4,000 Rad-G with Temperature devices, 85% of respondents scored Rad-G with Temperature as "Quite Easy" or "Very Easy" to use. SpO_2 and PR monitoring on Rad-G is provided using clinically proven Masimo SET Measure-through Motion and Low Perfusion pulse oximetry, which has been shown in over 100 independent and objective studies to outperform other technologies. SET is estimated to be used on more than 200 million patients a year and is the primary pulse oximetry at 9 of the 10 hospitals that top the 2022-23 *US News and World Report* Best Hospitals Honor Roll. With Masimo SET® technology in Rad-G, clinicians have access to accurate pulse oximetry measurements in the palm of the hand. In addition to temperature measurements and Masimo SET® oxygen saturation (SpO_2) and pulse rate (PR), the same SpO_2 sensor can be used to monitor respiration rate from the plethysmograph, with RRp. Difficulty breathing and fever are generally considered two of the earliest signs of patient deterioration, and Masimo believes that the availability of RRp and thermometry on Rad-G may play a role in assisting clinicians and public health officials as they seek to combat numerous types of illnesses, including pneumonia and other respiratory viruses. Rad-G with Temperature can be used with a variety of reusable and single-patient use sensors. The universal direct-connect Rad-G reusable sensor, indicated for monitoring adult, pediatric, and infant patients, helps to eliminate the need to stock and carry multiple sensor types, increasing the device's versatility and ease of use, especially in more challenging field environments. Rad-G with Temperature is also compatible with the vast portfolio of Masimo single-patient-use adhesive sensors — including Masimo RD SET sensors, which offer best-in-class accuracy specifications of 1.5% in conditions of motion and no motion — ensuring clinicians can customize their setup based on the unique needs of each care setting. In addition, Rad-G is designed to work reliably on all people, regardless of skin tone, from neonates and babies to elderly patients.

Vitalograph Announces US Sales Agreement with NIOX

Vitalograph announced a US sales agreement with NIOX , the world-leading point-of-care fractional exhaled nitric oxide (FeNO) testing device. "At Vitalograph, we constantly work to push the boundaries of innovation through our high-quality medical devices. Our devices are found in healthcare and occupational health settings worldwide, where they are used to aid in the diagnosis and management of respiratory conditions," said a news release. Executive Vice President of Vitalograph's Sales and Operations for North America, Troy Pridgeon, said: "This is a very convenient and beneficial opportunity to bundle the NIOX FeNO testing products into our own portfolio of spirometers and screening devices. Vitalograph is proud to include this important testing tool as an option to further enhance the range and sophistication of our available solutions." Physicians worldwide use the market-leading NIOX products to help improve asthma diagnosis and management. NIOX accurately assesses airway inflammation at the point-of-care, helping improve patient outcomes. NIOX's Senior Vice President, Americas and Research Business, Tom Scaccia, said: "NIOX is the gold standard point-of-care FeNO testing device and an accurate, reliable, and straightforward technology trusted by thousands of healthcare professionals

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Proper Tracheostomy Training is Necessary to Prevent Adverse Events

Nicole DePalma, MS, CCC-SLP

The number of tracheostomy procedures has increased, with more than 100,000 adults receiving a tracheostomy in the United States each year (Mehta, AB, et al. 2019). In the past, tracheostomy care was seen as a "low incidence" skill outside of the intensive care unit. However, the increasing use has led to higher numbers of tracheostomy outside the ICU. These patients are now found in settings that care providers are unaccustomed including step down units, rehabilitation units, skilled nursing facilitates, or in the general community. Tracheostomy skills were often taught anecdotally rather than through a standardized training at schools since it was a low incidence skill. This can lead to variability in experience and training.

If clinicians are not properly trained, this can result in potentially preventable adverse events. Patients with tracheostomy can be classified as high-risk patients, having a high potential for injury if they do not receive inadequate care. UK reports adverse events occurring in 20-30% of hospitalized patients with tracheostomy (McGrath BA, Thomas AN., 2010). Complications can include unplanned decannulations, tracheostomy tube blockage, tube displacement, uncontrolled bleeding/hemorrhage. This can lead to life-threatening situations, permanent harm or death.

Adequate training is a necessary step to preventing adverse events. Tracheostomy webinars are a simple way to get started with a clinician's educational needs. Hands on training with simulation devices are also critical for educating staff and family members and have been shown to be effective tools for hands on learning without causing harm to a patient.

Tracheostomy Courses

An individual clinician may be interested in improving their knowledge to provide better care and enable themselves to be more suitable for the job market by taking courses on

tracheostomy care. A facility may also want their staff to gain more knowledge of tracheostomy to provide better care for their patients and reduce costs associated with inadequate care. Courses that provide certificates after the course for completion can determine if the staff member completed that course.

Tracheostomy Education provides online courses of a variety of topics such as tracheostomy care, mechanical ventilation, tracheostomy tube, dysphagia, treatments, communication. Templates are also available to download for patient and staff education. You can also find a multi-disciplinary community for question and answer. Certificates of completion are provided so that facilities can be sure their staff has completed each webinar. These may be used for competencies.

Tracheostomy simulation devices are another great tool for education of staff and can include manikins that simulate real life. The Clearview Tracheostomy Trainer is available with a free clinical scenarios download. It is the only model that shows the dynamic functional interactions between the endotracheal/tracheostomy tube and the patient in various clinical scenarios. The model includes an epiglottis, intubatable vocal cords with a functional "voice box," 360-degree transparent trachea, stoma, bronchial bifurcation, and realistic functional lungs. The transparent trachea/stoma is replaceable and conversion to a pediatric trachea can be accomplished with the removal of a screw.

Nicole DePalma, MS, CCC-SLP received her BA at Georgetown University and subsequently earned her MS at NY Medical College in Speech-Language Pathology. She is the co-owner of Tracheostomy Education, an all inclusive resource for tracheostomy education for respiratory care practitioners, doctors, nurses, speech-language pathologists and other clinicians. She has presented tracheostomy-related courses at conferences and universities throughout the nation. Nicole also owns NDoscopy Dysphagia Specialists, partnering with hospitals, subacute facilities, and skilled nursing facilities in the greater New York City area to provide Flexible Endoscopic Evaluation of Swallowing (FEES) and provide consulting for interdisciplinary tracheostomy team development. No relevant financial or nonfinancial relationships exist.

Tracheostomy Simulation Device

The Clearview Tracheostomy Trainer can demonstrate the functional interactions between the tracheostomy and the patient in various clinical scenarios to provide learners with confidence in tracheostomy management. The transparent trachea/stoma can accommodate any brand of tracheostomy tube or endotracheal tube and visually demonstrates the function of the cuff including subglottic secretion aspiration. The lungs can also function to either replicate spontaneous breathing or inflate with positive pressure mechanical ventilation. Additionally, this product can demonstrate the application of a speaking valve with its built-in "voice box." With the tracheostomy cuff deflated and the speaking valve attached, an auditory cue that simulates speech through the vocal cords will sound with exhalation. A removable chest plate allows direct visualization of the cuff and trachea interface.

Simulation training for patients with tracheostomy can include tracheostomy care such as cleaning the inner cannula, stoma care, suctioning, cuff inflation/deflation, cuff management, changing a tracheostomy tube, and speaking valves.

Emergency situations can also be trained such as airway obstruction or accidental removal of the tracheostomy tube. There can be a displaced tube scenario where the tube is occluded with tape and placed under the chest flap of the manikin. The airway can be partially blocked for a difficult reinsertion. The goal would be for the clinician to recognize that the tube is not in the airway and to critically think.

Sample educational objectives can include checking the respiratory rate, placing a pulse oximeter, providing oxygen to a patient with tracheostomy. The patient with a cuffed tracheostomy tube will mostly breathe through the tracheostomy tube and therefore the oxygen should be placed at the site of the tracheostomy tube. If the patient is in distress, oxygen can be placed on both the tracheostomy site and the upper airway (mouth/nose).

In order to determine competency, a simulation training may utilize pre and post-testing to determine if the training improved retention of key skills. Patients and family members may also benefit from simulation training prior to discharging from the facility.

With the uprise in tracheostomy patients sent to locations outside of the hospital, tracheostomy training is important for staff to be aware of the unique needs of these patients. Many staff were not trained in tracheostomy care in schools. Given the lack of accessible, low-cost tracheostomy care training available to providers, tracheostomyeducation.com's online courses combined with hands on training with a Clearview Tracheostomy Trainer, is a great way to bridge the gap in learning about tracheostomy care and improving the safety, care and lives of those with tracheostomy.

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Minimizing Dosage Interruptions During Inhaled Nitric Oxide Delivery

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Abstract

Background: Inhaled nitric oxide (iNO) selectively dilates pulmonary capillaries close to alveoli participating in gas exchange and decreases intrapulmonary shunting to improve V/Q (ventilation/perfusion) matching.[1] An FDA-cleared nitric oxide delivery system (NODS) is essential to the delivery of inhaled pulmonary vasodilators to achieve and maintain continuous delivery of the prescribed dosage. Abrupt discontinuation of pulmonary vasodilators or unintended dosage changes may lead to worsening oxygenation or increased pulmonary artery pressures, i.e., rebound pulmonary hypertension syndrome.[2] Device behavior between monitoring and delivery is important in how delivery systems respond to external exposures. This study evaluated if the delivered dose of iNO in a dual channel design NODS was affected by monitoring conditions without a single channel feedback loop design.

Methods: This prospective original research study evaluated nitric oxide delivery responses of a dual channel design nitric oxide delivery system (NODS) when exposed to pre-determined monitoring variables. Multiple nitric oxide dose and flow combination ranges were utilized in this study and measured over time. Verification of drug delivery was confirmed by the monitoring system of an independent NODS device not participating in drug delivery.

Results: When a dual channel design NODS was exposed to multiple monitoring variables, nitric oxide delivery was uninterrupted across all dosage and flow combinations being independently verified. Nitric oxide delivery remained unchanged during sample line occlusion, sample line disconnection, low and high calibrations, interruption of a pre-use checkout performance test, and sensor failure.

Conclusion: In a dual channel design NODS, accurate and precise dosing of nitric oxide was not affected by monitoring and could potentially avoid interruptions to therapy while maintaining stable drug delivery.

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Introduction

Described as a biological messenger, nitric oxide (NO) has known endogenous properties that relax vascular tissue and inhibits platelet aggregation and platelet adhesion. Cyclic GMP (cGMP) is synthesized from the nucleotide GTP using the enzyme guanylyl cyclase (Figure 1) and serves as the second messenger for nitric oxide.[3] Clinically, inhaled nitric oxide (iNO) selectively dilates pulmonary capillaries close to alveoli participating in gas exchange, and decreases intrapulmonary shunting to improve V/Q (ventilation/perfusion) matching.[1] Being rapidly scavenged by hemoglobin in pulmonary capillaries with minimal systemic side effects,[4] iNO has a historical safety record as a therapy used in neonatal intensive care units to increase oxygenation and decrease the need for Extracorporeal Membrane Oxygenation (ECMO) since the 1990s leading to it being labeled molecule of the year in 1992.[5] An FDA-cleared nitric oxide delivery system (NODS) is vital in the delivery of this inhaled pulmonary vasodilator to achieve and maintain constant delivery of the prescribed dosage,[6] as abrupt discontinuation of pulmonary vasodilators or unintended dosage changes may lead to worsening oxygenation or increased pulmonary artery pressures.[2]

Nitric oxide delivery systems add iNO into breathing systems and then utilize a monitoring system to visualize what is being delivered to the patient.[6] These monitoring systems use a sample line that pulls back a continuous gas sample.[6] As with many sampling devices found in healthcare, sample lines can be exposed to several elements within the breathing circuit, such as moisture/condensation, patient secretions, and nebulized aerosol medications. The behavior between the monitoring and delivery systems is essential in how the NODS responds to these external sample line exposures.[6] In NODS with a single-channel design, monitoring and delivery are within a single-channel communication loop, whereas a dual-channel design allows drug delivery to be independent of monitoring. Even though communication occurs between the two channels, the delivery computer and monitoring computer function independently in a dual-channel system[2] (Figure 2). With a dual-channel design for a NODS, we hypothesized that external exposures would not affect the continuous delivery of the inhaled pulmonary vasodilator, thus potentially minimizing or reducing interruptions of the intended prescribed dosage to the patient.

Methods

Testing methods used in this study included exposing the monitoring system to various conditions with different pre-

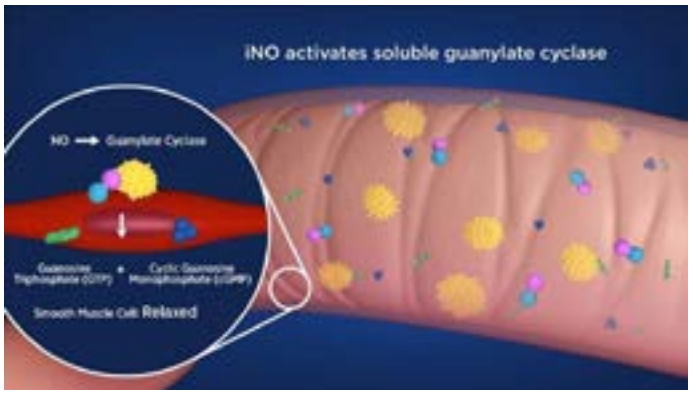

Figure 1. Illustration of how nitric oxide causes pulmonary vasodilation in the smooth muscle cell, with consent.[2]

determined dosages of iNO and multiple breathing circuit flow ranges to test how the prescribed dosage of iNO over time is affected by monitoring in a dual channel design. For purposes of this testing, Device A was the delivery system with a dosage set. At the same time, Device B had no dose set and was used strictly for independent monitoring purposes to verify the delivery of Device A.

Assessing a dual channel design's delivery response to various external conditions was performed utilizing INOmax DS_{IR} Plus delivery systems manufactured by Mallinckrodt Pharmaceuticals.[2] The nitric oxide dose ranges set on Device A included **5, 10, 20, 40,** and **80ppm** and were assessed in combination with flow ranges of **2, 5, 10, 20,** and **40 LPM** using a Precision Flow Hi-VNI breathing system by Vapotherm.[7] To initiate testing, two INOmax DS_{IR} Plus systems were calibrated (both low and high range calibrations), and a pre-use checkout procedure was performed on each device to verify that all equipment was operational. The time frames for the external variable exposure were **30 seconds, 45 seconds,** and **1 minute** (Figures 4, 5, 6). An additional 3-minute interval was used during calibration testing. At these time intervals, the nitric oxide measurements were recorded. All device response behavior to monitoring was independently verified using the monitoring system of a second calibrated INOmax DS_{IR} Plus (Device B) with no dosage set.

Test 1. Sample Line Occlusion

This test allowed the user to determine how the delivered dosage of iNO was affected by conditions that may result in a sample line occlusion. In hospitals, medical device sample lines can be physically occluded by other equipment found in a patient's room, such as the ventilator, non-invasive delivery system, and patient bedding, to name a few. In addition, condensation from heated, humidified breathing circuits can also cause an internal sample line occlusion. Finally, when patients require nebulized medication concomitantly with iNO, the sample line removes a portion of that aerosolized medication into the sampling system at a rate of 230 ml/min, which can potentially cause sample line occlusion to occur. After setting the assigned dosage and flow combination, a sample line filter block occlusion was created on Device A. At the pre-defined time intervals after occlusion, the monitored values on Device B were recorded.

Test. 2 Sample Line Disconnection

During troubleshooting, a sample line may need to be replaced while using a NODS. During this time, the sample line is removed from the NODS and the patient breathing circuit; the patient

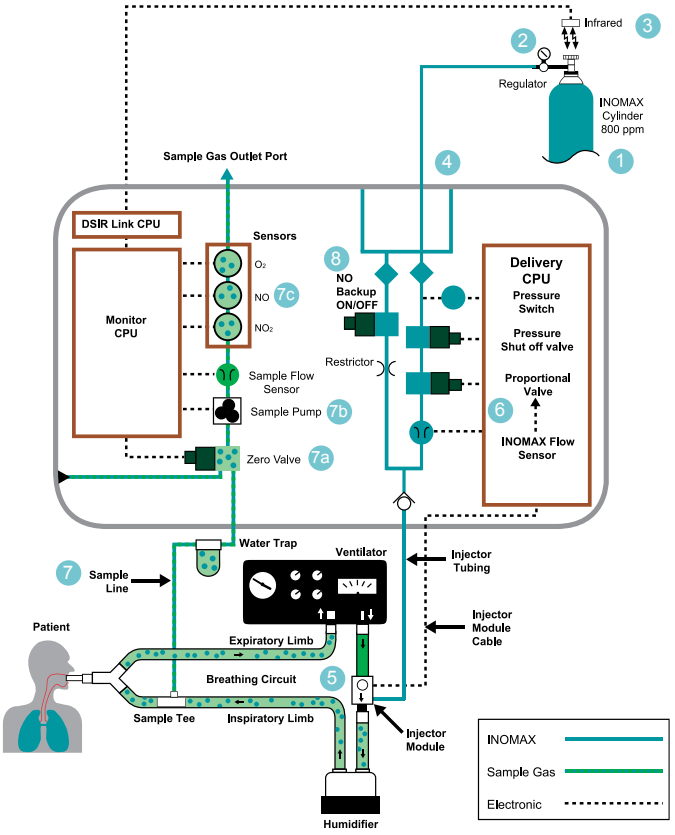

Figure 2. Displays the INOmax DS_{IR} Plus separation of delivery and monitoring computers in a dual channel design NODS, with consent.[2]

breathing circuit is then capped off until it can be replaced with a new sample line. Sometimes a backup sample line is close by in a storage or small parts bin; however, the user may need to leave the delivery system to go to a storage supply room in another part of the hospital to obtain a backup sample line when not nearby. For this last part of the test, the sample line was removed from Device A and the patient breathing circuit for the pre-determined time frames while a dose was set. Device B's monitored values of the delivered dosage during sample line disconnection were then recorded.

Test 3. Device Calibrations

The following testing series involved initiating calibrations while a nitric oxide dosage was set to determine how the delivered dosage was affected by the calibration process. Only a calibrated NODS must be used on a patient, and as with many medical devices, calibrations are often used for conditioning and troubleshooting. For this testing, the dose was set on Device A, and Device B was used for independent monitoring without a dose set. First, a manual low calibration was performed on Device A, while Device B monitored how the delivered dosage of nitric oxide was affected by the low range calibration. The delivery system used for this test has automated low calibrations; however, the user can initiate a low range manual calibration, which was performed during this testing.

Similarly, the next test included performing a high range calibration on Device A while a dose was set and verifying the dosage delivery with Device B's monitoring system. The delivery system being used in this test requires a high calibration every 30 days or as needed for troubleshooting and can be performed while on a patient.[2] The high range calibration was initiated

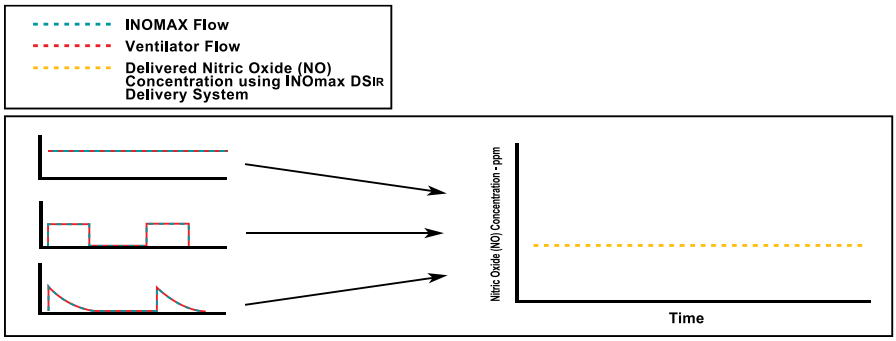

Figure 3. Displays the delivered NO concentration with variable breathing circuit flow patterns, with consent.[2]

using the test gas of 45 ppm of nitric oxide (NO) supplied by the manufacturer. During the high calibration, the delivery of Device A was monitored using Device B. The next part of the high range calibration test included creating a failed high NO calibration by removing the water trap bottle from Device A and then exiting the high range calibration to observe how the delivery was affected by a failed high range calibration for the pre-determined times chosen.

Test 4. Pre-use Checkout Performance Test

Nitric oxide delivery systems should have a pre-use procedure performed by the user to verify that the delivery system is calibrated and functional before use. During this time, a performance test is used to verify that the delivery system is functional and accurate before placing the device on a patient by verifying a dose of 40 ppm at 10 LPM of flow. For this reason, this part of the dual channel design test included performing the pre-use procedure and interrupting the sample line on Device A during the performance check to evaluate if delivery was affected by this monitoring interruption using Device B to monitor the performance check values during the pre-use checkout procedure.

Test 5. Sensor Failure

Although not common, monitoring sensors do have the potential for failure. When a sensor cannot be recovered by a two-point low range calibration followed by high range calibration, the failed sensor will need to be replaced. This part of the test was essential to determine how a delivered dose of nitric oxide was affected by a failed sensor. While a dose was set for this testing, the NO sensor was removed from Device A's monitoring system. To change a NO sensor while on a patient scenario, the NO sensor can be installed while the NO high-range calibration screen is displayed. The rear sensor cover of this delivery system was removed by turning two-panel screws counterclockwise, and the NO sensor was removed to initiate a sensor failure. At this time, the dose being delivered on Device A was independently verified with Device B's monitoring system to evaluate if and how the delivery was affected by a failed NO sensor while a dose was set.

Secondary Delivery Confirmation

In addition to using two monitoring systems for dosage verification, the delivery system used for this testing had a secondary delivery confirmation that allowed the user to utilize a graphic in the menu option to visualize delivery accuracy. This feature was found under the *Settings* option. Here the user could verify if the delivery channel was performing within specifications. The calculated delivery graphic assists in quick troubleshooting by letting the user know if the delivery system is performing within ±20% accuracy of the set dose of nitric oxide independent of the monitoring system.

Results

Table 1. Baseline dosage and flow combinations over time for Devices A & B

Device A 5 LPM				Device B 5 LPM			
	30 sec	45 sec	1 minute		30 sec	45 sec	1 minute
5ppm	4	3.7	4.3	5ppm	4.3	3.9	4.1
10ppm	8.1	8.1	8.2	10ppm	8.3	8.4	8.5
20ppm	17	17	17	20ppm	17	17	18
40ppm	35	35	35	40ppm	35	35	36
80ppm	72	72	72	80ppm	72	72	72
Device A 10 LPM				Device B 10 LPM			
	30 sec	45 sec	1 minute		30 sec	45 sec	1 minute
5ppm	4.6	4.7	4.3	5ppm	4.9	4.9	4.5
10ppm	8.5	8.6	8.6	10ppm	8.8	8.9	8.9
20ppm	17	17	18	20ppm	18	18	18
40ppm	35	37	37	40ppm	36	38	38
80 ppm	78	74	74	80ppm	79	74	75
Device A 20 LPM				Device B 20 LPM			
	30 sec	45 sec	1 minute		30 sec	45 sec	1 minute
5ppm	5.2	5.3	5.1	5ppm	5.5	5.3	5.1
10ppm	9	8.8	8.8	10ppm	9.3	9.1	9.9
20ppm	18	18	18	20ppm	18	18	18
40ppm	37	37	37	40ppm	37	38	38
80 ppm	75	76	76	80ppm	76	76	77
Device A 40 LPM				Device B 40 LPM			
	30 sec	45 sec	1 minute		30 sec	45 sec	1 minute
5ppm	5.3	5.2	4.9	5ppm	5.3	5.1	5
10ppm	9.2	9.1	9.2	10ppm	9.5	9.5	9.4
20ppm	18	18	19	20ppm	19	19	19
40ppm	38	38	38	40ppm	38	39	38
80 ppm	76	77	77	80ppm	77	77	77

Delivery confirmation collected pre-testing showed no baseline statistically significant differences between Device A and

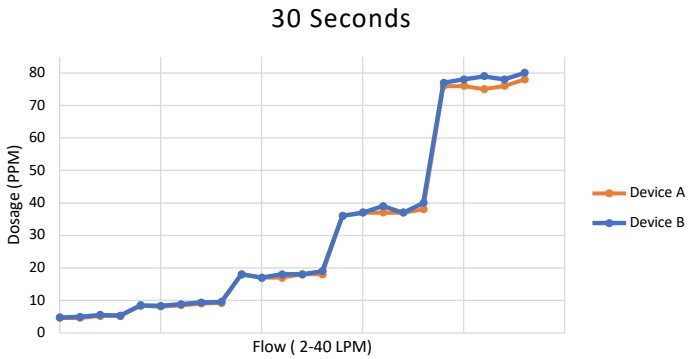

Figure 4. Dose and flow over 30 Seconds

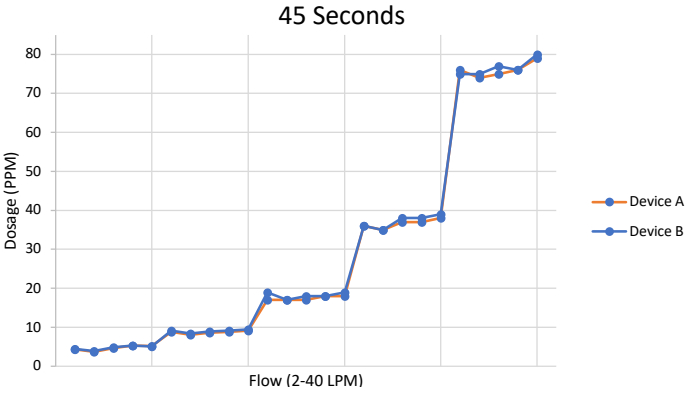

Figure 5. Dose and flow over 45 seconds

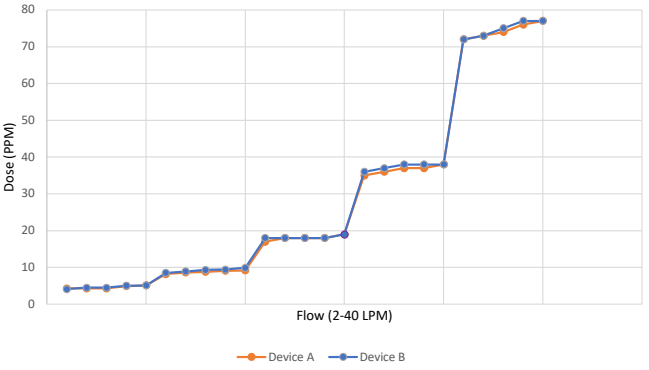

Figure 6. Dose and flow over 1 minute

Device B for monitoring values during delivery (Table 1). Upon introducing the first two variables on Device A of a sample line occlusion (Figure 7) and sample line disconnection (Figure 8), Device B data verified that delivery was unchanged over time in the dual channel system. During multiple monitoring interruptions, the delivered nitric oxide dosage remained within ±20% of the set dose throughout testing.

For the variable of low range calibrations (Figure 9) and high range calibrations (Figure 10) with monitoring interruption, the data shows no change in the delivered dosage of iNO during the three-minute durations of both calibration tests. Additionally, during a sensor failure, data results showed that the delivered dosage of inhaled nitric oxide in the dual channel system was unchanged and remained within ±20% of the set dose.

The data for interruption of monitoring during a pre-use checkout (Figure 11) showed that performance delivery was

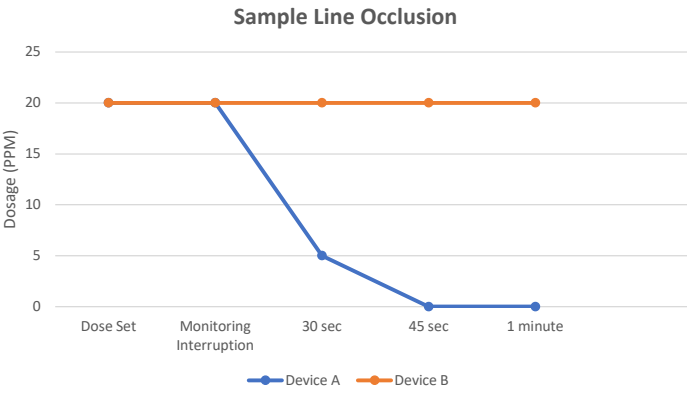

Figure 7. Sample line occlusion

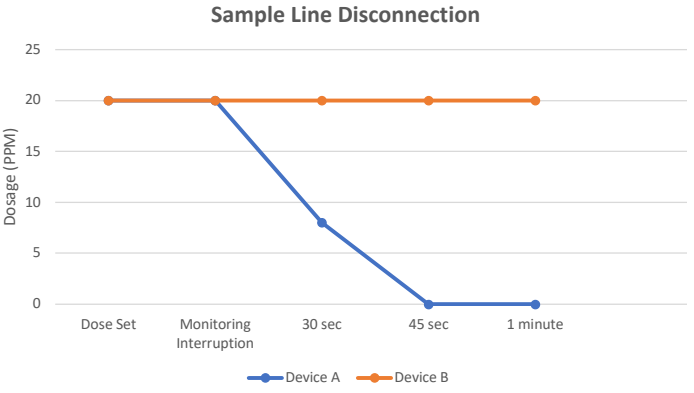

Figure 8. Sample line disconnection

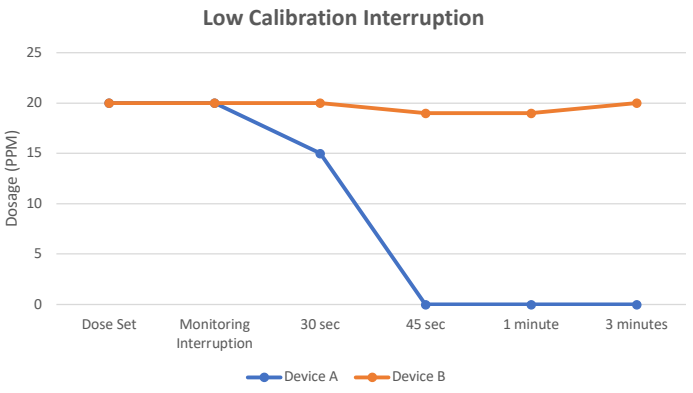

Figure 9. Low calibration interruption

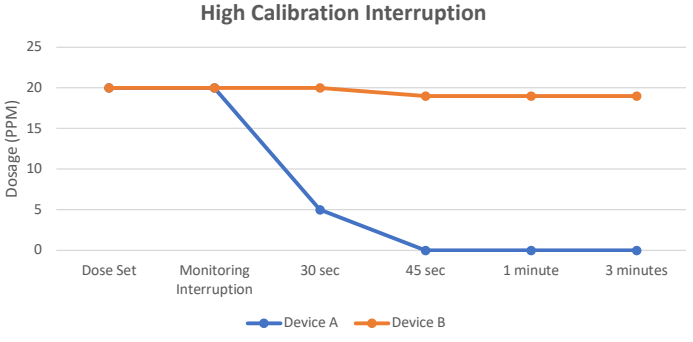

Figure 10. High calibration interruption

unaffected at a dose of 40ppm and a flow of 10 LPM. Delivery of nitric oxide during the pre-use checkout was not interrupted by monitoring. During the removal of the nitric oxide sensor for

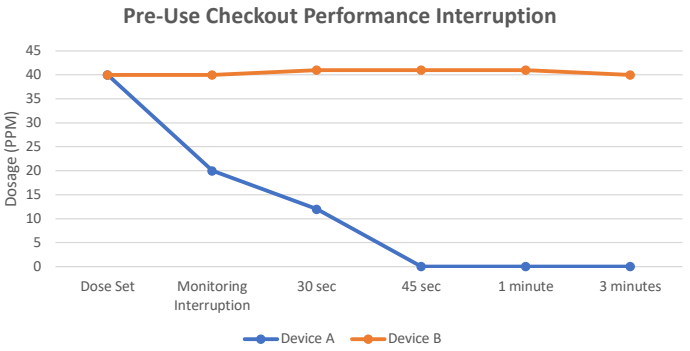

Figure 11. Pre-use checkout performance test interruption

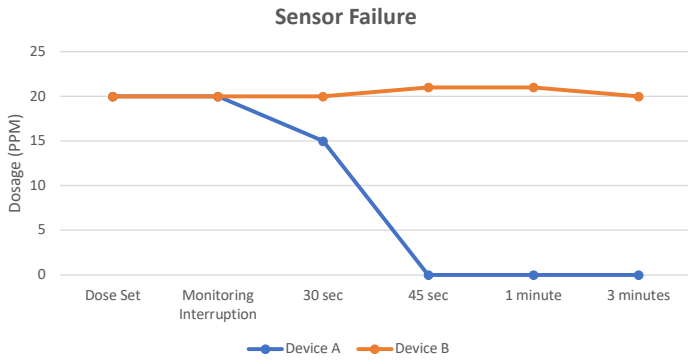

Figure 12. Sensor failure during delivery

sensor failure (Figure 12), the data showed from Device B that the delivery system of Device A was unaffected and continued to deliver a steady set dosage within ±20 percent for the dual channel design. Additional results collected from the calculated delivery graph in the settings menu of Device A confirmed that delivery for all tests remained within ±20 of the set dose during all variable factors.

Discussion

The clinical relevance of this study was to test monitoring variables that could potentially result in interruptions to the delivery of iNO if it were potentially on a patient. Inhaled nitric oxide has minimal systemic side effects due to it being a selective pulmonary vasodilator that is rapidly scavenged by hemoglobin.[9] This also means that the drug's short half-life justifies the importance of minimizing or eliminating delivery interruptions to the patient. Abrupt discontinuation, inability to achieve the desired dose, or inconsistent dosing could lead to rebound pulmonary hypertension or hemodynamic compromise.[10]

One of the limitations of this study was that it was performed in a controlled lab setting. Another limitation of this study is that no comparisons were made directly with a single-channel delivery system. The primary focus was to see how the delivery channel of a dual-channel NODS responded to pre-defined variables. Lastly, this test was performed with a fixed flow breathing system to control the total flows across a broad range of settings for the testing requirements.

For additional follow-up testing, clinicians should evaluate the performance of NODS amongst different types of validated breathing systems used within their healthcare system to test the accuracy and reliability of its performance. For further studies, a comparison of a dual-channel delivery system to a single channel feedback loop delivery system could be performed. To build upon this testing, one could expand the study to do additional repeated testing with other types of equipment frequently used in combination with NODS such as conventional ventilators, non-invasive ventilation systems, high flow breathing systems, high frequency jet ventilation systems, high frequency oscillatory ventilation systems, transport breathing systems, and circle anesthesia breathing systems. This thorough evaluation of delivery channel interruptions in NODS with flow and dose combinations could be a valuable tool in the decision-making process of determining the best fit equipment to meet the needs of one's healthcare system and patients.

Conclusion

Multiple tests of various flow and dosage combinations were performed with the dual channel design NODS to evaluate delivery behavior in response to monitoring exposure variables. Across all nitric oxide dosage and flow combinations being independently verified, the delivered dosage remained unchanged due to the synchronized proportional delivery (Figure 3) that was independent of monitoring. In a dual channel design NODS, accurate and precise dosing of nitric oxide was not affected by monitoring and could potentially help to avoid interruptions to therapy while maintaining stable drug delivery.

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Lung Volumes by Body Plethysmography: Technical Considerations

Understanding some of the technical issues with measurement of lung volumes helps the clinician obtain accurate and consistent results.

Ralph Cook, RRT, RPFT, BA

As previous articles have stated, body plethysmography continues to be the gold standard for the measurement of lung volumes and the valuable information these volumes provide in identifying lung disease. However, there are a couple of technical questions that are asked regularly:

1. Should I perform airway resistance within the same maneuver as my lung volumes?
2. Should I perform a vital capacity within my lung volume maneuvers?

While the ATS/ERS has technical standards for measuring lung volumes, and reportedly will be issuing an update later this year, guidance on performing airway resistance measurements has been lacking. Many articles have been written throughout the years on the value of airway resistance, but how to perform the maneuver has been left more to the manufacturers of the equipment.

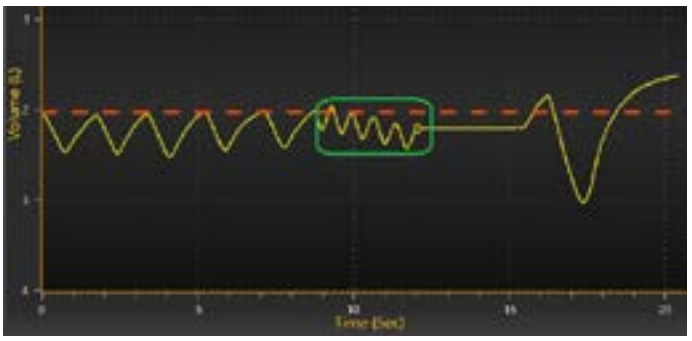
Many years ago, lung volumes and airway resistance (Raw) measurements were performed separately with the MGC Diagnostics body box system AND there were two distinct CPT codes for reimbursement. However, a competitor decided to combine the two maneuvers into one effort to save time; thus, MGC had to offer that option as well. As time passed, the insurance providers saw that only one maneuver was being performed and eliminated reimbursement for both lung volumes and Raw; effectively reducing reimbursement slightly. Now there is one combined CPT Code (94726) for both maneuvers.

From a technical point of view there are several reasons to separate lung volume measurements from Raw efforts. The first has to do with the breathing (panting) frequencies at which the efforts are performed. The ATS/ERS standards recommend performing the closed shutter efforts (lung volumes) with "a series of gentle pants at a frequency between 0.5 and 1.0 Hz". This frequency calls for one complete effort every one to two seconds. For the sake of simplicity, having patients "pant" once per second seems easier to remember.

When performing Raw maneuvers, the patient is instructed to perform open shutter panting before closing the shutter as instructed above. In North America and several other areas of the world, most operators use a panting frequency of approximately 1.5-2 Hz (90-120 per minute). This is 1.5 to 2 open shutter pant efforts every second for approximately 2-3 seconds. This means that once the subject has performed enough acceptable open shutter efforts and the shutter closes for lung volumes, the subject is asked to slow down their breathing to once per second. For many subjects this is not easily done. If the subject continues to close shutter pant at a frequency greater than 1.5 Hz, ATS/ERS states this may lead to errors. However, using the built-in metronome in the MGC Diagnostics Ascent software helps guide the clinician and subject to the preferred breathing frequency.

Another reason to consider not doing combined lung volumes and Raw is that we are trying to measure Functional Residual Capacity (FRC) during the closed shutter panting maneuver. However, if the subject is performing open shutter panting before closing the shutter, the subject more than likely is not at FRC when the shutter closes. This means we are measuring something other than FRC. The software will compensate for the difference between true FRC and where the shutter closed. The MGC Diagnostics software calls this the "Switch-In" value, but now we are asking the software to make another calculation to correct for testing methodology.

During open shutter panting many subjects, especially those with COPD, tend to "stack" their breaths and slowly increase the volume in their lungs. It is easier for these subjects to inhale than exhale. So with each pant effort they exhale slightly less than they inhaled, which builds up the volume in the lungs. This can be illustrated with the following graph.



The above graph shows a combined FRC/Raw effort. The first five breaths are normal tidal breathing to establish the subject's

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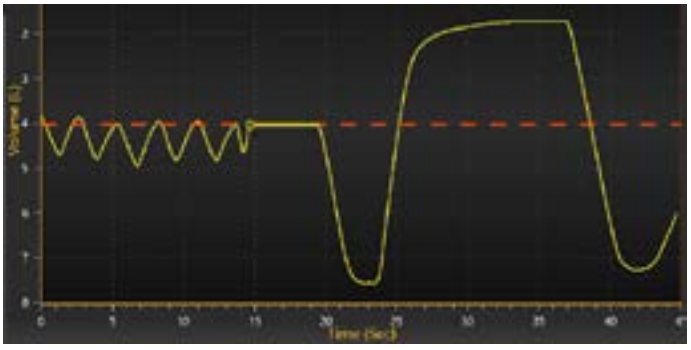
FRC, indicated by the horizontal red dotted line. The area in the green box displays the open shutter panting. The round dot at the end of the panting is where the shutter closed to measure FRC. While this subject had "normal" PFT values, you can see that where the shutter closed is not at the subject's true FRC. The difference between the dot and the red dotted line is the Switch-In value and the software must compensate for this difference. In subjects with COPD, the Switch-In volume could be several hundred mls. This is not to say that the measured FRC will be incorrect; however, it adds another level of complexity to the maneuver.



When comparing the combined maneuver to one that measures FRC only, you can see in the graph above that where the shutter closed (yellow dot) is very close to the subject's FRC; thus, the software has very little if any compensation to account for.

Performing the FRC as a separate maneuver will usually provide for more consistent and repeatable FRC measurements. Again, I am not emphasizing that doing a combined maneuver is wrong or will give inaccurate results. But measuring FRC separately helps to simplify the maneuvers for the subject, keeps the subject from having to pant at two different frequencies, and eliminates compensation by the software.

Another technical aspect of performing FRC measurements in the body box is adding a vital capacity measurement at the end of each closed shutter maneuver. This is called a linked maneuver. The ATS/ERS recommends that the closed shutter panting be followed by an ERV maneuver, then a slow IVC maneuver, OR, an IC maneuver followed by a slow EVC maneuver. From personal experience, the first thing the subject wants to do after 3-4 seconds of closed shutter panting is take a breath in—so let them. As soon as the shutter reopens have them take a deep breath in to TLC (IC maneuver), then slowly exhale out to RV. A cautionary note here is that if the subject has a severe obstructive defect, they may not be able to get all the way back out to RV once they have inhaled to TLC. However, doing the exhaled maneuver slowly will typically overcome this issue.

Using the linked maneuver will also give you more consistent and repeatable TLC values. While measuring FRC and RV is important, the ATS/ERS strategy for interpreting lung volumes begins with looking at the TLC. Determining if the TLC is less than or greater than the Lower Limit of Normal (LLN) or Upper Limit of Normal (ULN) determines which path to take in the interpretation flow chart.

Performing an SVC maneuver separate from the plethysmograph efforts can be used to calculate lung volumes; however, this may not give optimum results because the maneuvers are performed under different conditions. Performing accurate linked maneuvers will essentially ensure that your TLC values are accurate.

To illustrate this, below is a chart with different FRC and IC values. This presumes that TLC is calculated using FRC + IC. Even if the measured FRC values are inconsistent, the measured TLC will be consistent and accurate if the subject fully inhales to TLC (IC maneuver). This is because the lungs are obviously a fixed volume. Regardless of your starting point (FRC), when the subject fully inhales to TLC, combining the two values (FRC + IC) will accurately reflect the subject's TLC.

	FRC	IC	TLC
Effort #1	3.00L	2.00L	5.00L
Effort #2	2.50L	2.50L	5.00L
Effort #3	3.50L	1.50L	5.00L

In Effort #1, the subject performed a good FRC effort with a full inhalation after. The resulting FRC + IC calculated a TLC of 5.00 liters.

In Effort #2, the subject exhaled beyond FRC slightly before the shutter closed, thus the measured FRC was smaller than the first effort. However, because of this the subject could inhale more and have a larger IC. Adding the smaller FRC but larger IC still gives you a TLC of 5.00 liters.

Effort #3 shows that the subject did not exhale to true FRC before the shutter closed, which gave them a larger measured FRC. With that came a smaller IC because the starting point for IC was higher. Again, combining these two values will give you a TLC of 5.00 liters as well.

While not ideal, a variable FRC value linked to a proper IC will accurately calculate the subject's TLC. If the above subject was able, additional efforts should be performed until at least three repeatable FRC values that agree within 5% were obtained, with the mean value reported. The software should, if needed, allow you to take a separate SVC value (if it's the largest) combined with the average IC/ERV from the plethysmograph maneuvers to calculate TLC and RV. With these values, negotiating the ATS/ERS interpretive flow chart on lung volumes should lead to a more accurate decision on the subject's lung health.

While performing lung volume measurements with the MGC Diagnostics Platinum Elite body box can be faster and more accurate than dilutional methods, technical considerations, as in all pulmonary function tests must be evaluated. Software, regardless of manufacturer and test, will usually give you options for performing PFTs. An important aspect is ensuring that all clinicians in your lab are performing tests in the same consistent manner as reflected in your policies and procedures. This is especially true if any of your patients have serial testing and you are comparing test results to other test sessions. By following the ATS/ERS Technical Standards as well as the recommendations from your manufacturer, you can ensure that the values obtained and reported are correct, and the physician has the best data to diagnose and treat their patients.

BiWaze® Clear System – Evaluation of Aerosol Delivery In Vitro

Robert DiBlasi RRT-NPS, FAARC, Niko Kontoudios RRT and Rebecca Engberg RN

Introduction

An issue when caring for patients with a respiratory condition is when excess mucus production surpasses the normal capacity of the body to clear it from the airways, it leads to blockage, collapsed lungs and impaired respiratory function.[1] To address this issue, oscillating lung expansion (OLE) therapy is used to mobilize and remove mucus, helping to reinflate partially or fully collapsed lungs.[2,3] OLE therapy can be administered noninvasively using a face mask, mouthpiece, or trach adapter. It combines various treatments for airway clearance, including positive expiratory pressure, high-frequency oscillations, and therapeutic aerosol delivery.

Positive expiratory pressure increases airflow to the collapsed lung regions and increases functional residual capacity.[4] High-frequency oscillations generate small pressure bursts, known as "micro coughs," which increase airflow velocity, shear mucus, and facilitate its mobilization from the peripheral airways.[2,3] During OLE therapy, aerosol medication is also delivered to reduce inflammation, bronchoconstriction, and thin secretions.

In the past, there were concerns about the effectiveness of OLE therapy due to low aerosol deposition caused by limitations in older device designs. The aim of this in vitro study was to compare the aerosol medication delivery efficiency of the two newest OLE systems during simulated therapy.

New Technology

The BiWaze® Clear System (ABM Respiratory Care, USA) is an innovative OLE system that has recently obtained FDA 510k Clearance. BiWaze Clear has a unique two- blower design precisely engineered to drive and separate the inhaled and exhaled airflow. BiWaze Clear has a proprietary Dual Lumen Breathing Circuit which includes a coaxial bacterial/viral filter, coaxial breathing tube, handset, Aerogen® Solo nebulizer (Aerogen, Ireland), and a patient interface. The Aerogen Solo nebulizer is electronically powered and controlled by the BiWaze Clear through the Aerogen power cable provided with the BiWaze Clear system.

Aerosol delivery with BiWaze Clear was compared to the Volara (Baxter-Hillrom, USA), which received FDA clearance in 2020. The Volara uses a single-limb breathing circuit which includes a standard filter, standard breathing tube, handset with an integrated expiratory leak valve, and a Sidestream jet nebulizer (Philips Respironics, USA) which is driven from an internal motor generating compressed air through the nebulizer and into the handset for therapy.

Figure 1. BiWaze Clear Control Unit and BiWaze Clear Dual Lumen Breathing Circuit

While both systems provide OLE therapy, they use different abbreviations for the treatment phase names. BiWaze Clear calls positive expiratory pressure PEP, while Volara calls it CPEP. BiWaze Clear calls high-frequency oscillations OSC, while Volara calls it CHFO.

Study Method

Scintigraphy (gamma) imaging was used to quantify inhaled aerosol deposition to the upper airways and lungs as well as residual losses to the OLE systems' components, nebulizer, and fugitive aerosol transmission to the atmosphere. The OLE systems were programmed with the same settings to complete a typical 10 minute therapy. The PEP/CPEP phase was set to a typical setting of 10 cm H_2O and the nebulizer was set to run throughout the therapy.

The OSC/CHFO phase was set to a typical setting of 20 cm H_2O with a frequency of 4 Hz and the nebulizer was set to run throughout the therapy.

A spontaneous breathing adult lung model, ALS 5000 (Ingmar Medical, USA,) was configured with 12 breaths/ min frequency, tidal volume of 700 mL, compliance of 100 mL/cm H_2O and resistance of 10 cm H_2O/L/s. A 3D-printed adult upper airway nasotracheal (NT) cast was attached to a simulated trachea and lung model. Each OLE system's proprietary handset was attached to the mouthpiece and inserted into the oral opening of the upper airway model, and the nostrils were covered to minimize the leak from the nose (see Figure 2). A filter was

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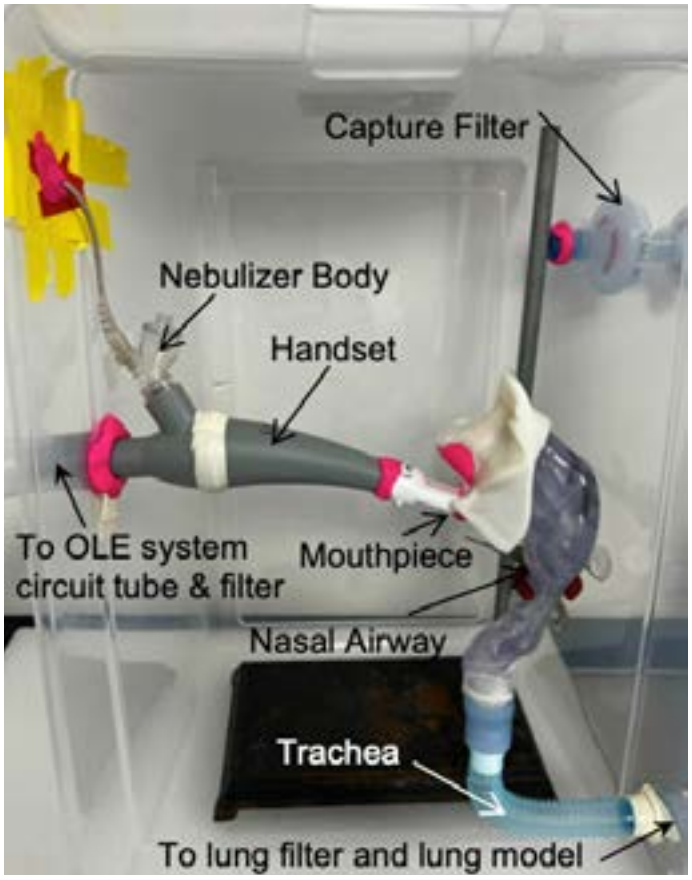

Figure 2. Experiment setup

attached between the tracheal outlet and the lung model to capture inhaled aerosol at the distal trachea and quantify the inhaled lung dose. The handset, nebulizer, mouthpiece, nasal airway, and trachea were placed into a sealed plethysmograph box (see Figure 2). A filter was attached to a vacuum toward the top of the plethysmograph box to capture fugitive aerosols that leaked out of the OLE system during therapy.

Technetium (99mTc) pertechnetate (RLS Bio, USA), a nonabsorbable radiopharmaceutical particulate, was mixed with 2.5 mL normal saline and nebulized as a radio-tagged aerosol to be a surrogate for inhaled medication. The deposited aerosols were quantified with a SPECT gamma camera, GE Starcam XCT (GE Healthcare, USA) by scanning the following regions of interest (ROI):

1) OLE system components (i.e., bacterial/viral filter, breathing circuit, nebulizer, handset, mouthpiece)
2) Nasopharyngeal and tracheal airways
3) Lung (filter)
4) Plethysmograph and filter (fugitive aerosol)

A 20 µCi dose of 99mTc was confirmed with a dosimeter. The radioaerosol solution was placed into the nebulizer, then scanned with the dosimeter and gamma camera to correlate the loading dose (µCi) to gamma camera counts (µCi/ct.). A timer was started to correct for radio decay over time. The 99mTc loaded nebulizer was inserted into the handset within the sealed plethysmograph box. The radioaerosol solution (2.5 mL) was nebulized to completion with BiWaze Clear using the Aerogen Solo. The Volara with the Sidestream was noted to have a volume of liquid remaining in the nebulizer reservoir after the typical 10 minute therapy, so the therapy was continued for 5 more minutes

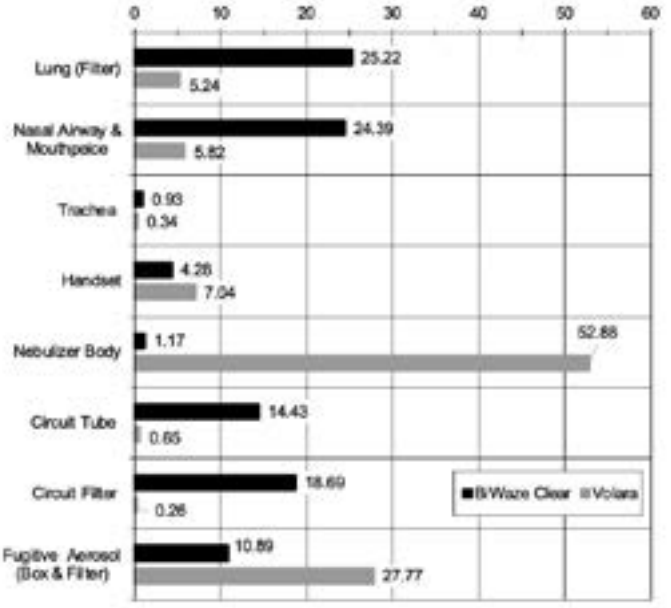

Table 1. Percent of Regional Aerosol Deposition for BiWaze Clear and Volara with the setting of PEP/CPEP 10 cm H_2O

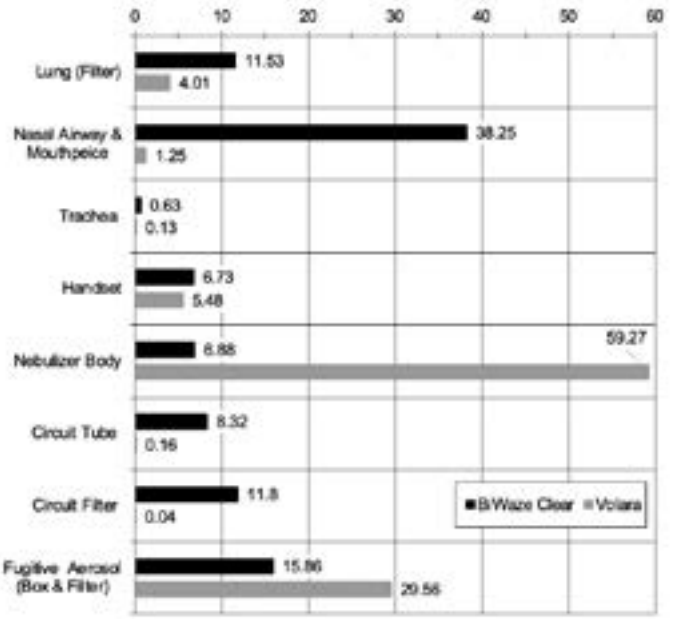

Table 2. Percent of Regional Aerosol Deposition for BiWaze Clear and Volara with the setting of OSC/CHFO 20 cm H_2O at 4 Hz

for a total therapy time of 15 minutes and no liquid remained in the reservoir.

After the completion of therapy, the experimental set-up was kept enclosed within the sealed plethysmograph box for five minutes, enabling the capture of fugitive aerosols within the chamber filter. Each component was carefully disconnected in series, and individual ROIs were scanned with the gamma camera to quantify deposited radioaerosol. The fugitive aerosols were calculated as the sum of radiation counts deposited within the plethysmograph box and outlet vacuum filter. The radiation counts at each ROI was converted to dose (µCi) based on the calibration conversion factor and adjusted for radioactive decay. A mass balance was calculated, and activity counts detected in each ROI were expressed as a percentage (%) of the total sum of the counts. Also, images were acquired to illustrate the spatial

distribution of radioaerosol deposited within the respective ROIs using low energy, high-resolution function with a 256x256 pixel/ count matrix. The digital color spectrum was selected, with red showing the highest pixel/ count activity (aka hotspots) and green, blue, and black illustrating progressively lower activity levels, respectively.

Test Results

The mass balance of deposited radioaerosol droplets within the different ROIs of both BiWaze Clear and Volara after OLE therapy, are shown in Tables 1 and 2, respectively.

The corresponding gamma camera images illustrating the aerosol deposition with different regions of interest for both BiWaze Clear and Volara are shown in Figures 3 and 4, respectively.

BiWaze Clear and Volara had greater inhaled lung deposition with PEP/CPEP than OSC/CHFO therapy phases. The BiWaze Clear showed a 5-fold greater lung deposition with PEP and a 3-fold greater lung deposition with OSC therapy than Volara. Increased nasal airway deposition naturally led to an increase in lung delivery efficiency with BiWaze Clear. The residual nebulizer losses were high (>50%) with the Volara and low with BiWaze Clear (<7%) for both therapy phases of OLE therapy. The depositional losses within the BiWaze Clear Dual Lumen Breathing Circuit (closed circuit design) coincided with a lower concentration of fugitive aerosol released to the atmosphere than Volara. The Volara had low deposition in the lung filter and single- limb breathing circuit (open circuit design), with about 1/3 of the aerosol dispersed through their proprietary handset's expiratory leak valve as fugitive aerosols.

Discussion

The administration of aerosols during OLE therapy remains prevalent in patients receiving airway clearance in both the hospital and home healthcare settings. This is the first in vitro study to evaluate aerosol delivery with the BiWaze Clear and Volara systems. The major finding of these experiments demonstrates that BiWaze Clear has a higher medication delivery efficiency of inhaled aerosol than Volara.

We attribute these findings to multiple factors which include the use of the Aerogen Solo's vibrating mesh nebulizer which has an aerosol output 2 to 3 times greater than a jet nebulizer, with a documented low residual medication volume in the nebulizer following therapy (<0.2 mL).[5] BiWaze Clear's Dual Lumen Breathing Circuit is a coaxial, closed circuit and has been optimized to prevent aerosol retention, minimize expiratory medication losses, and increase the availability of small particles for inhalation. It has been suggested that bi-directional (transitional) flows through a valveless handset could result in high impactive losses and reduced aerosol delivery with an OLE system. However, this was not the case with BiWaze Clear, which had only 4-6% loss of radio-tagged aerosol. The BiWaze Clear's handset may prevent aerosol waste to the circuit by holding some of the small, exhaled particles and those continuously generated by the nebulizer on exhalation to remain within the handset chamber, serving as a reservoir to increase the concentration of inhaled particles during subsequent breaths. Furthermore, the BiWaze Clear Dual Lumen Breathing Circuit's bacterial/viral coaxial filter sufficiently captured exhaled aerosols and prevented high fugitive aerosol losses.

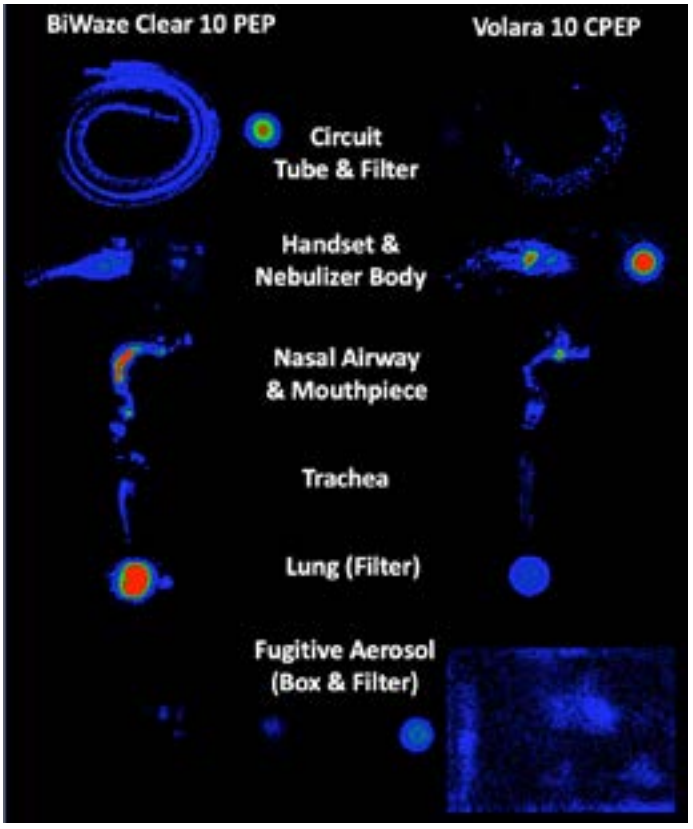

Figure 3. Gamma camera images showing aerosol deposition at different regions of interest for BiWaze Clear and Volara with the setting of PEP/CPEP 10 cm H_2O

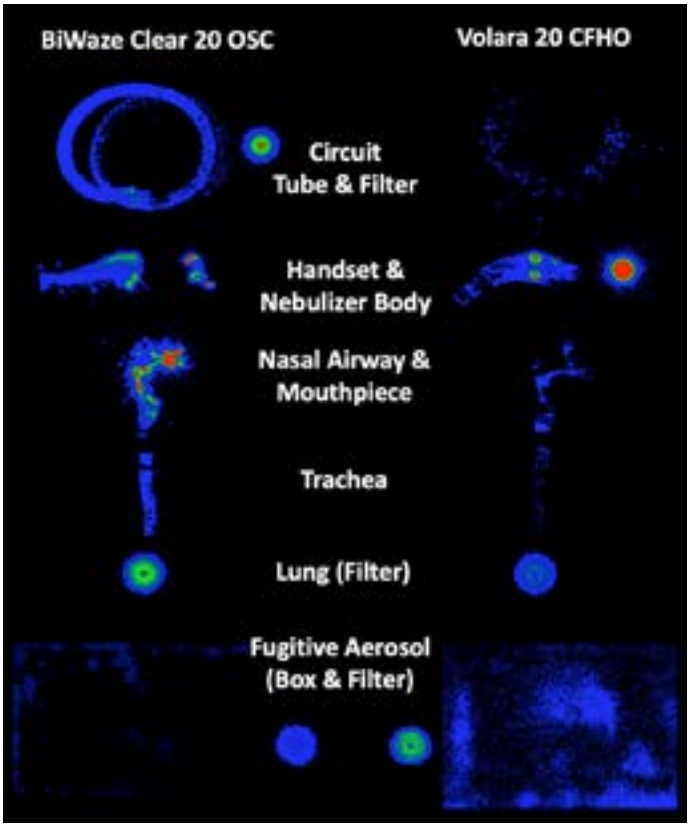

Figure 4. Gamma camera images showing aerosol deposition at different regions of interest for BiWaze Clear and Volara with the setting of OSC/CHFO 20 cm H_2O at 4 Hz

In a previous study, Li et al. showed that an inhaled dose with a gas-powered jet nebulizer and aerosol mask alone was as high as 10%, but when the same nebulizer was placed into a predicate OLE system, the MetaNeb (Baxter- Hillrom, USA) proprietary circuit, consisting of a venturi and entrainment port, the inhaled dose was reduced to 2% during the high-frequency oscillation (CHFO) therapy phase.[6] They speculated that MetaNeb's handset design increases the impact-related loss of larger aerosol particles. The Volara showed a similar low inhaled dose (4%) as the MetaNeb study when applying CHFO. The MetaNeb and Volara OLE systems share several common features: they use jet nebulizers, apply aerosol through a single-limb circuit, and apply a manifold leak (aka exhalation valve) into the handset to eliminate carbon dioxide.

We identified a leak manifold in the Volara handset that produced fugitive aerosols, resulting in a 2-fold increase compared to the closed breathing circuit of the BiWaze Clear system. The fugitive losses in Volara significantly impacted medication delivery. Even after extending the nebulizer's runtime by 5 minutes beyond the manufacturer's recommended treatment time, the residual losses within Volara's nebulizer (50-60%) remained the primary factor affecting delivery efficiency.

Conclusion

In conclusion, our study found that BiWaze Clear's aerosol efficiency was superior to Volara. BiWaze Clear delivered a 5-fold greater aerosol deposition with PEP therapy and a 3-fold greater aerosol deposition with OSC therapy to the patient's lungs compared to Volara. Additionally, the fugitive aerosols generated by Volara were 2-fold greater than those produced by BiWaze Clear.

Short-term physiologic studies designed to evaluate the effectiveness of aerosol therapy on secretion removal with BiWaze Clear and other forms of airway clearance are underway.

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to help manage their patient's asthma. A US sales agreement with Vitalograph furthers our goal of ensuring that the millions of asthma patients in the US have access to this important device." NIOX products are used to improve asthma patient outcomes and are indicated for use in those aged 7 years and older in the US. NIOX technology is based on the discovery that patients with Type 2 airway inflammation (previously known as allergic or eosinophilic inflammation) have elevated levels of nitric oxide in their exhaled breath. Corticosteroid therapy has been proven to reduce airway inflammation and FeNO levels. Research has shown that up to 84% of asthma patients have Type 2 airway inflammation, which is particularly associated with exacerbations. By measuring the concentration of FeNO, NIOX enables clinicians to evaluate airway inflammation in asthma patients, aiding diagnosis and reducing exacerbations.

Study Finds Masimo PVi Reliably Predicted Fluid Responsiveness in Young Children Undergoing Neurosurgery

Masimo announced the findings of a prospective study published in *Pediatrics International* in which Dr. Ya-Fei Liu and colleagues at Peking University First Hospital in Beijing evaluated the ability of noninvasive, continuous Masimo PVi, alongside other dynamic parameters, to predict fluid responsiveness in children 1-3 years old who were undergoing major neurosurgery. The researchers concluded, "Volume-based PVi and ΔVpeak [respiratory variation in aortic blood flow peak velocity] showed acceptable reliabilities for fluid responsiveness prediction in young children undergoing major neurosurgery, while pressure-based SVV [stroke volume variation] using FloTrac/Vigileo, Ea_{dyn} [dynamic arterial elastance], and PPV [pulse pressure variation] [did] not." Noting that dynamic variables have been shown to predict fluid responsiveness more accurately than static variables, and the critical importance of optimizing fluid administration in pediatric surgical patients, the researchers sought to evaluate and compare the performance of a variety of dynamic variables in such a scenario. The parameters evaluated were noninvasive, continuous PVi (pleth variability index, obtained from the photoplethysmographic waveform measured by fingertip pulse oximetry sensors and, in this study, the Masimo Radical-7 Pulse CO-Oximeter), ΔVpeak (obtained intermittently by Doppler echocardiography), SVV (measured by the Edwards Lifesciences FloTrac/Vigileo system), PPV (obtained from the peripheral arterial pressure waveform), and Ea_{dyn} (an index of arterial load). The researchers enrolled 60 patients, aged 1-3, who were undergoing major neurosurgery with mechanical ventilation set at a fixed tidal volume of 8 ml/kg. Following induction of anesthesia, during a hemodynamically stable period, the patients were administered 10 ml/kg of Ringer's lactate solution, over 10 minutes; all variables were measured before and within five minutes of fluid loading. Patients with an increase in cardiac index (CI) of 10% or more were identified as a fluid responder. (CI was defined as stroke volume index multiplied by heart rate.) The researchers identified 26 of the 60 patients as fluid responders. They found that baseline PVi showed "fair diagnostic accuracy" for CI-fluid responsiveness, with an area under the receiver operating characteristic curve (AUROC) of 0.775, $p < 0.001$. A baseline PVi cutoff value of 15% predicted CI-fluid responsiveness with 77% sensitivity and 68% specificity. Baseline ΔVpeak was an "excellent predictor" of a CI increase, with AUROC of 0.982, $p < 0.001$, and a cutoff value of 9.6%. However, ΔVpeak, which is dependent on the timing

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of echocardiograms, can only be obtained intermittently; the authors also note, as a practical drawback, that the limited availability of echocardiographic professionals "decreases its wide use in routine clinical settings." The researchers found the other methods were either "poor" or "were not" predictors. The researchers concluded, "Volume-based PVI and ΔVpeak showed acceptable reliabilities to predict fluid responsiveness, defined by a CI increase, after anesthesia induction in mechanically ventilated young children undergoing major neurosurgery. However, pressure-based FloTrac/Vigileo-derived SVV, Ea_{dyn}, PI, PPV, and SVIc were not or [were] poorly reliable predictors. PVi's noninvasiveness, continuity and acceptable predictability for fluid responsiveness could make it a potential aid in evaluating hemodynamic status, facilitating fluid administration, and developing optimal fluid management protocols in young children undergoing neurosurgery." Joe Kiani, Founder and CEO of Masimo, said, "From its inception, Masimo has focused on developing technologies that improve outcomes for the very youngest and most fragile of patients. This latest study on PVi—the second we are reporting on just this week!—adds to the body of evidence that PVi can help clinicians predict fluid responsiveness." In the US, PVi is FDA 510(k) cleared as a noninvasive dynamic indicator of fluid responsiveness in select populations of mechanically ventilated adult patients. Accuracy of PVi in predicting fluid responsiveness is variable and influenced by numerous patient, procedure and device related factors. PVi measures the variation in the plethysmography amplitude but does not provide measurements of stroke volume or cardiac output. Fluid management decisions should be based on a complete assessment of the patient's condition and should not be based solely on PVi.

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Combining decades of scientific expertise and experience in respiratory diagnostics, Vitalograph and Morgan Scientific have come together to create the most advanced series of Pulmonary Function Testing systems. The state-of-the-art innovative Pulmonary Function Testing (PFT) hardware from Vitalograph, combined with the most comprehensive enterprise PFT software, ComPAS2 from Morgan Scientific will revolutionize Pulmonary Function Testing as we know it. For clinicians, this means having an accurate and reliable point-of-care and laboratory testing system. Ease of testing for both clinician and patient is a hallmark of the new products, with pressure-less gas delivery and instant test quality feedback, resulting in research-grade accuracy and repeatability. Clinicians can be assured that results meet stringent regulatory standards and also meet the new gas pathway directive. The Vitalograph Morgan PFT range is designed to grow with your clinic and respond to the complex respiratory diagnostic needs of all secondary care health facilities. The ComPAS2 software allows seamless workflow integrations that work with the dynamics of each unique setting, be it with a single device, a mult-device lab, or a complex hospital system with numerous departments. The ComPAS2 Task Manager makes interpreting and billing for a PFT as easy as answering an email, with its inbox design and integrated billing interface. ComPAS2 and its Task Manager, coupled with Vitalograph's expertise in respiratory diagnostic hardware, enables you carry out complete respiratory diagnostics, wherever they are needed. Commenting on the partnership Vitalograph CEO, Frank Keane said: "We are delighted to bring together our combined respiratory diagnostic expertise to create what we believe is the world's most comprehensive PFT range. Our vision is to have a real impact on the effective management of respiratory diseases and ultimately improve patients' lives." While Gareth Morgan, President from Morgan Scientific added, "Morgan Scientific working in partnership with Vitalograph is an ideal alliance. Our two family-owned companies have a combined legacy summing more than 100 years of providing the highest quality pulmonary diagnostic solutions to the world. What we have been able to accomplish with regard to new software and hardware innovations, amidst the challenges of a pandemic, is simply amazing and speaks to the strength of the relationship. I have never been more excited about what we have to offer and how it will help to reset the gold standard in the industry. Furthermore, we couldn't be more aligned with our approach to customer care and truly listening to our users."

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