

Volume 16 Number 1 Winter 2021

# Respiratory Therapy™

The Journal of Pulmonary Technique





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#### REFERENCES

1. Volsko, T. Airway Clearance Therapy: Finding the Evidence. *Respiratory Care*. 2013; 58(10):1669-78.
2. O'Neill, K. et al. Airway Clearance, Mucoactive Therapies and Pulmonary Rehabilitation in Bronchiectasis. *Respirology* 2019; 24(3):227-237.
3. McShane, P et al. Concise Clinical Review: Non-Cystic Fibrosis Bronchiectasis. *Am J Respir Crit Care Med* 2013; 188(6):647-656.

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## Device Maker Chooses Company to Lead Sales Efforts

Dale Medical Products, Inc., (Dale) has been servicing customers for over 60 years with their value-based product solutions and support. Working closely with clinicians, Dale has pioneered many of the product categories within acute and post-acute/long-term patient care settings. As part of its continued growth strategy to service current and new customers, Dale has selected MedTech MedCare (MTMC) to lead Dale's sales efforts within the USA, effective January 1, 2021. Jack Moran, Managing Partner at MTMC stated "MTMC has developed an effective, efficient team of sales professionals representing leading brands nationwide. Dale's product portfolio is well aligned with MTMC's core competencies and we will be able to leverage their brand recognition in generating further market expansion for Dale." MTMC is recognized as the leader in national outsourced sales solutions, and understands the needs of today's manufacturers, supply chain and end-users. In partnership, their shared business model provides a solution that incorporates selling strategies related to clinical, financial, and operational outcomes. Their expansive team of sales executives understands the importance of delivering value-based solutions related to patient safety, readmission risks, impact of complications, patient outcomes and satisfaction. John Brezack, Dale's President, commented "Dale has been growing steadily for the entire history of the company. We have made the decision to focus on expanding our reach, and ultimately provide our products on a larger scale in order to support clinicians and improve patient outcomes and satisfaction." Dale Medical Products, Inc. was founded in 1961, in Sharon, Massachusetts as Baka Manufacturing Company. From a modest beginning in the home of David Kaplan, inventor of the Dale Abdominal Binder, the company has grown into an industry leader in the market niches it serves. Today, Dale resides in Franklin, Massachusetts where their corporate office and manufacturing facilities are located. Dale Medical Products, Inc. is an ISO 13485 registered company.

## Cancelled Events Open Doors for Webinar Education

COVID-19 has put many tradeshow and events on hold, but continuing to provide critical education is important to MGC Diagnostics. In the pre-COVID-19 environment, respiratory care professionals relied on these in-person events in order to gain insightful education in the field of cardiorespiratory diagnostics. Often, institutions such as the AARC or ACSM allowed these individuals to receive continuing education credits to keep their credentials active. With the cancellation of some in-person events, this opens the door for other educational possibilities.

MGC Diagnostics has always been dedicated to providing cardiorespiratory health solutions. They employ Respiratory

Therapists (RT's), Registered Pulmonary Function Technologists (RPFT) and exercise physiologists throughout the organization. From Sales to Training to Clinical Research, they strive to support the individuals working within the field and desire to support their abilities and contributing roles to their patients and community. As a regular sponsor of multiple awards and workshops at industry shows such as ATS and ERS, MGC Diagnostics recognizes the impact education has on the community.

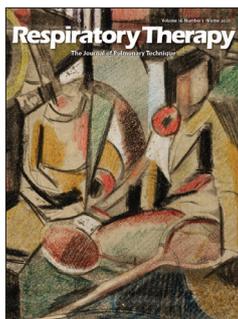
One of the hallmarks of their education portfolio has been a three-day Cardiorespiratory Diagnostics Seminar in which individuals gain insightful information regarding testing techniques, performance standards, quality assurance procedures and clinical applications for basic and advanced cardiorespiratory diagnostic testing. Participants have typically received 22 AARC accredited hours for attending this in-person event.

Offering webinars is a safe way to keep education active while social distancing. "We quickly realized we needed to find a way to continue to provide education with a renewed approach," said Courtney Beaton, Global Marketing Events & PR Manager for MGC Diagnostics, "With current events, these webinars provide essential education credits that are lacking at the moment and also educate individuals on important hot topics in the respiratory field."

Live Webinars and on-demand Webinars are offered regularly and can be found via their website ([www.mgcdiagnostics.com/events/webinars](http://www.mgcdiagnostics.com/events/webinars)).

## N95 Permission Granted

3B Medical announced receiving Emergency Use Authorization from the FDA to permit use of Lumin, a UVC system, on N95 respirators during the COVID-19 pandemic. Lumin was designed to clean CPAP accessories but is also used as a multi-purpose sanitizer. The announcement by the FDA allows Lumin to be used by healthcare workers employed in nursing homes, long term acute care, ambulatory, primary care, and clinics to allow N95 re-use to stop the spread of COVID-19 and help keep frontline healthcare workers safe. UVC was first reportedly used for N95 decontamination during the COVID-19 crisis by the University of Nebraska Medical Center. Since then the CDC recognized UVC as a potential means of decontaminating N95 respirators, if the proper wavelength and UVC irradiance dose were used. While FDA has approved other systems for hospital use, the approved systems are complicated, limited to large hospitals and/or extremely expensive. Lumin is the only N95 decontamination system formally recognized by FDA for killing SARS-CoV-2 that can be purchased for under \$300, and with a small enough footprint to be used safely in small offices and clinics, as well as in nursing homes. "The COVID-19 global pandemic requires novel approaches and thinking outside the box. We were starting to get inundated with calls from hospitals and nursing homes asking if Lumin was strong enough to kill SARS-CoV-2. Lumin's total output in a single 5 minute cycle ranges up to 2,400 mJ/cm<sup>2</sup>, which studies show is sufficient to kill almost any pathogen, including SARS-CoV-2. A lot of the calls coming into our office are from Fire and Rescue departments, nursing homes and smaller community hospitals, clinics and primary care physician offices trying to keep their workers safe. Lumin is likely the only device designed for home use that is powered high enough to repurpose for this use. We are very excited to have our device authorized by FDA for this application," said Alex Lucio, CEO of 3B Medical, Inc. N95 mask shortages have been widely reported throughout the country, and globally.



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## Table of Contents

### DEPARTMENTS

- 5 News
- 16 Company Profile
- 18 Ventilation Roundtable
- 20 Spotlight On Spirometry
- 21 Spotlight On Blood Gas

### ARTICLES

- 22 A Respiratory Care Department's Response to the Pandemic
- 24 Planned Intubation in Neonates
- 25 The Use of the VORTRAN GO<sub>2</sub>VENT
- 27 Prevalence of Excessive Daytime Sleepiness and Risk Factors of Obstructive Sleep Apnea Among Type 2 Diabetes Mellitus
- 40 Hospital to Home: NAVA Liberation Solved with the Vivo 65
- 44 Key Measure for Proper Airway Placement, Return of Spontaneous Circulation
- 45 Perspectives on 2020
- 48 High-Flow Nasal O<sub>2</sub> Therapy Used as an Alternative to CPAP
- 51 Vitalograph Cross Contamination Report for Bacterial Viral Filters
- 56 Evaluation of Harmonization Across Siemens Healthineers Blood Gas Systems
- 66 Using Telemedicine in the Care of Bronchiectasis Patients During the COVID-19 Era
- 69 Assessment of Automatic, Real-Time Pre-Analytical Quality Checks and Tools for Continuous Improvement
- 72 Improving Lung Health in Low- to Mid-Income Settings with Easy-On PC and EasyOne Devices
- 74 What Makes the MiniBox+ Different?
- 76 Effect of Nocturnal EPAP Titration to Abolish Tidal Expiratory Flow Limitation in COPD Patients

### Ventilation Stockpile Considered Inadequate

With the COVID-19 pandemic sweeping across its shores earlier this year, the US government in April announced orders for almost \$3 billion of ventilators for a national stockpile, meant to save Americans suffering from severe respiratory problems brought on by the disease. But of the 140,000 machines added since then by the government to the US Strategic National Stockpile, almost half were basic breathing devices that don't meet what medical specialists say are the minimum requirements for ventilators needed to treat Acute Respiratory Distress Syndrome, the main cause of death among COVID-19 patients. Only about 10% are full intensive care unit (ICU) ventilators of a type that doctors and ventilator specialists say they would normally use to intubate patients suffering from Acute Respiratory Distress Syndrome or ARDS. The remainder - or about 40% - are transport ventilators normally employed for shorter periods but are considered sophisticated enough to be used long enough for ARDS patients to recover. A September study by 22 ventilator specialists published in the official journal of the American College of Chest Physicians found half the models added to the stockpile were not suitable for treating ARDS. Many of the machines don't meet the requirements of ARDS patients and their presence in the stockpile gives "a false sense of security," Sajid Manzoor, director of adult respiratory therapy at The Johns Hopkins Hospital in Baltimore. "The COVID patients are so sick when they have ARDS. For the patients' benefit we really need to stick with the full ICU ventilators," he said. A spokeswoman for the Department of Health and Human Services (HHS), which is responsible for making purchases for the national stockpile, said that an interagency task force on ventilators made recommendations on which models and quantities to procure in March, a time of "extreme projections for respiratory care needs." With little known about COVID-19 at the time, the HHS "was preparing for the worst possible scenario," the spokeswoman said. HHS declined to share the medical advice it relied upon in setting its minimum requirements or in selecting devices. She added that the federal government has since adjusted its response as more clinical data has become available about the treatment of COVID-19. For instance, she said, the HHS is now procuring kits to provide alternatives to intubation, such

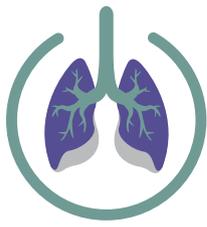
as plastic tubes that deliver oxygen into the nose. The United States is engulfed in a deadly escalation of the virus with more than 1.1 million new infections last week. The country has reported more than 268,000 coronavirus-related deaths in total since the pandemic began. There is currently no ventilator supply crisis in the United States as other treatments, including steroids, have reduced the need for intubation. HHS and manufacturers of the more basic devices said they can have a role in dealing with less acute cases of COVID.

### PulmOne's Complete PFT e-learning and certification program is approved

PulmOne announced the launch of MiniBox Academy, an innovative e-learning training and certification program approved by the AARC for 3.0 CEUs. The program is provided free of charge to all MiniBox/MiniBox+ customers. MiniBox Academy is a mobile-friendly platform accessible on computers, tablets, and smart phones. It consists of a comprehensive set of modules for independent, self-paced training of medical staff, to improve their PFT testing expertise, and ensure testing consistency, accuracy and reproducibility, as well as an outstanding patient experience. The self-paced syllabus includes 17 modules with topics such as: Respiratory System anatomy; introduction to all PFTs (FVC, lung volumes, DLCO, MVV, 6MWT, FeNO and more); optimal testing techniques for the MiniBox+ system. Most modules include how-to videos and knowledge quizzes. Upon completion of the entire set, each staff member receives a certificate of completion and 3 CEUs. For more information about the MiniBox+ visit [www.pulm-one.com](http://www.pulm-one.com)

### Inventing Therapies that Save Lives

Swedish-Canadian researcher Christer Sinderby is the man behind Getinge's patented *Neurally Adjusted Ventilatory Assist* (NAVA). Using the patient's own respiratory drive to control ventilator assistance, NAVA has elevated mechanical ventilation to an entirely new level and helped the tiniest premature baby in the world survive. "We are talking about the ECG of breathing," Christer says. "Using NAVA in mechanical ventilation is like adding ECG to a stethoscope when monitoring a heart. Both are based on electrical signals and more precise." The blowing of air has powered most of Christer Sinderby's life. In his



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youth, the talent for mastering the mighty sea breezes enabled him to compete with the best windsurfers in the world. As a scientist, the ability to control a few milliliters of air blown into a premature baby's tiny lungs has earned him and his wife Jennifer Beck respect in the entire medical world. Recently, NAVA played a major role in helping a premature baby in Japan, weighing only 258 grams at birth, survive. "It goes without saying that it is hard to sync a ventilator with rapid breaths of only 2-3 milliliters of air. We have managed to use the baby's own respiratory drive to achieve this synchronization," Christer explains. "The beauty of NAVA is that it can help all types of patients breathe; no matter if it is a tiny premature baby weighing a few hundred grams or an overweight 90-year old." NAVA has been used exclusively by Getinge since it was invented in the mid-1990s. Since 2003, Christer Sinderby is a scientist at the Keenan Research Centre for Biomedical Science, University of Toronto, Canada. "In principle, NAVA connects the patient's brain to the ventilator," Christer says. "The device uses the same electrical signal that activates the diaphragm to control the rhythm, depth and duration of our breathing. This means that the ventilator continuously is fully synchronized with the patient's own breathing efforts." The electrical discharge of the diaphragm is captured by a special Edi catheter; placed in the esophagus and also functions as a gastric feeding tube. "Since it is the patient's own physiological signal that control the tidal volume and respiratory pattern, NAVA promotes lung-protective spontaneous breathing and reduces the risk of blowing too much or too little air into the lungs. NAVA simply delivers what the patient wants." Christer adds: "With traditional mechanical

ventilation it is often easier to 'shut down' an uncomfortable patient with sedation than to finetune the ventilator to deliver the right tidal volume and frequency. This is what we want to avoid." Independent of air leakages, NAVA also facilitates non-invasive ventilation with nasal masks or prongs. A much more comfortable alternative than intubating the patient. Back in 1999, the innovation of NAVA was so remarkable that it was published in the prestigious *Nature Medicine*. "I think we are still the only researchers focusing on ventilator technology published there," Christer says. Christer Sinderby and Jennifer Beck are still dedicated to improve the abilities of Getinge's mechanical ventilators. "We focus on ventilation solutions that will be a reality in 5-10 years. Getinge's patience with the long-term scope that is a necessity in medical research has paved the way for a partnership with mutual respect for the corporate and scientific perspectives," Christer concludes.

### Company Earns Another Ventilation Industry Award

Dräger, an international leader in the fields of medical and safety technology, announced that Frost & Sullivan has recognized the company as a global technology innovation leader in the ventilation industry. Frost & Sullivan selected Dräger for its 2020 Global Technology Innovation Leadership Award due to the company's pioneering work to enhance patient safety and expedite recovery through innovative ventilator clinical protocols, continuous improvements in ventilation technology, and best-in-class services/support, training and continuing education. Furthermore, Dräger has significantly increased its ventilator production in 2020 to address the spike in demand driven by COVID-19. The COVID-19 pandemic has highlighted the essential need for ventilation in the treatment of critically ill patients, as well as the adverse events caused by the misuse of mechanical ventilators. During the pandemic, Frost & Sullivan analysts have been observing how the deployment of different types of ventilator models impact patient care. "We are honored to have been chosen by Frost & Sullivan for this prestigious award," said President and CEO for Dräger in North America, Lothar Thielen. "We would not be where we are today without our employees' dedication to continuous improvement in technology and services, and the support of our customers in helping us address their changing needs. Whether it is the ongoing challenges of value-based care, or the immediate needs presented by the current pandemic, we are proud to stand as a trusted partner to healthcare providers and their patients." Frost & Sullivan acknowledged Dräger in the following areas: **Ventilator technology:** "Compared to other competitors' products, Dräger's Evita ventilator models offer superior technology benefits for both patient safety and user flexibility." This includes invasive and non-invasive ventilation modes, advanced technologies that support lung protection and early weaning, and secured connectivity with other devices; **service and support:** "Dräger offers comprehensive and best-in-class services for healthcare providers with respect to ventilation along with digital solutions for connected care and data insights, which many competitors are striving to match." This includes device maintenance, IT consulting and system integration, user training, and network-based services and analysis of device data; **COVID-19:** "Dräger has upheld its guiding principle 'Technology for Life' during the COVID-19 pandemic, helping countries around the world to maintain the functionality of critical infrastructure as well as ensuring that the demand for ventilators is met across the globe by significantly increasing its production." Through its Intensive Care Online Network (ICON) emergency program, Dräger had made its ventilators available

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to hospitals in “hot spot” areas, along with online continuing education and a 24/7 real-time support. This is the third time in three consecutive evaluation cycles that Frost & Sullivan has recognized Dräger for best practices in ventilation therapy. In 2017, Dräger won the Frost & Sullivan North American Medical Ventilation Product Leadership Award, and in 2014 the Frost & Sullivan Best Practices Award in the Growth Excellence Leadership category for Mechanical Ventilation Equipment.

**Born too early with a 50/50 chance of survival—now she helps save other premature babies**

When Sabina Checketts holds her hand a certain way, the tiny scar on the back of it looks like a rocket ship. Checketts got the scar during the first few days of her life, during a tenuous struggle for survival, after she was born at 28 weeks—12 weeks prematurely. Her rocket ship scar, and a few other small ones, are marks left by lines inserted into her tiny, frail body to keep her alive. “I don’t point these out to parents,” Checketts says, “but to me they’re badges of honor, because I survived.” The parents she’s referring to are the parents of her patients. Thirty-three years after her early birth, Checketts now works as a neonatal doctor in London. Checketts decided to become a doctor at early age, when her mother routinely

pointed out a man walking down the street on his way to the hospital and said, “That’s the doctor who saved your life”. That experience motivates her to be a source of positivity for the families of the babies she treats. “When I talk to parents about the fact that I was premature, there always is a sense of surprise, I think a little bit even shock, you know. Oh, oh, and you’re a doctor,” Checketts says. “I think it’s a nice way to say to them that prematurity shouldn’t be a limit on what a child can do.” “I mean, the advances we’ve made in even just the last 10, 15, 20 years mean the outcomes are much better than they used to be.

And seeing me, who developed before that, as a newborn doctor, I give them a sense of hope and possibility, I think.” Today, she uses vastly improved technologies and techniques to create better outcomes for other premature babies—and more hope for their parents. As vulnerable premature babies fight to stay alive one of the most critical issues is something most people never think twice about—breathing. A pivotal advance in neonatal medicine—and one that has a major impact in adult critical care—has been the development of better ventilators. “One of the main challenges for premature babies is with ventilation,”

says Checketts. “Their lungs are quite stiff when they’re first born because they’re so immature. They’re very fragile.” The ventilator that helped Checketts survive was a far cry from what she sees today when she treats premature babies. “We’ve gone from a mode of ventilation where you were breathing for the baby to one now where we can breathe with the baby as well,” she says. One ventilation technique that breathes with the patient is called Neurally Adjusted Ventilatory Assist, or NAVA, developed by Getinge, a global leader in intensive care technology for both infants and adults. Before NAVA, ventilation technology had advanced to the point that a sensor in the breathing tube alerted when a baby was trying to breathe in, and the machine supplied

a breath. But there was lag time, resulting in the machine sometimes not supplying air when the lungs called for it, or forcing air into frail lungs that were not ready for it - a problem amplified by premature babies’ tendency to take short, rapid and uneven breaths. Sherry Courtney, a director of clinical research in neonatology, who has worked with premature babies since the 1980’s explains, “The diaphragm is a muscle. When it contracts, we’re going to breathe. When it relaxes, we’re going to exhale. So, NAVA senses the breathing using a catheter that goes down into the stomach and rests close to the diaphragm.” Courtney

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# Improving Critical Care in the ICU



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says she's observed many babies who switch to a NAVA-enabled ventilator almost immediately become more comfortable and less irritable. Their oxygen needs decrease, as do pressure and volume requirements. Babies can be more restful and concentrate energy on the single most important thing they can do during their premature stage — grow. "We have been switching in our unit more and more to NAVA because the babies seem to love it," Courtney says. NAVA is also approved for adults, and the features that make the technique successful for neonates translate well to adult patients. Adults on ventilators generally start with a functioning diaphragm, but it becomes weaker quickly. Getinge's Medical Director Miray Kärnekull says that advanced ventilator technologies like NAVA are used regularly in adult patients in Europe to keep patients' diaphragm muscles active. "It's really a groundbreaking technology", says Kärnekull. "NAVA gives the clinician a way to personalize not only the ventilation, but also the weaning process for adult patients". And in a very recent multicenter randomized controlled trial, results showed that patients with acute respiratory failure on NAVA spent significantly less time on the ventilator and experienced less extubation failure compared to conventional lung-protective mechanical ventilation.

### **New Ventilator Launched for Adult and Pediatric Patients**

Getinge has launched **Servo-air**, a high-performing ventilator intended for adult and pediatric patients in the United States. Servo-air includes both Invasive and Non-Invasive (NIV) ventilation modes, with Getinge's unique High Flow Therapy and Servo Compass options. Designed for mobility, Servo-air does not require wall-gas and utilizes "hot-swappable" battery technology to switch power sources without restarting the unit. The included software modes allow clinicians to adapt and personalize ventilation to the patient and situation. The COVID-19 health crisis has underscored the need for personalized ventilation for critically ill patients. As the number of coronavirus cases in the US increased, the demand for and pressure on the availability of ventilation machines was highlighted. That demand, coupled with the emergence of pop-up hospitals to treat the influx of patients, has made portable, easy to operate ventilators an increasingly important requirement. "At the start of the COVID-19 pandemic, Getinge responded by increasing our ventilator production by 160% to help offset the rapidly growing need for these machines. We are proud to introduce our latest model, which will create flexibility for hospitals, easy transportation for pop-up treatment centers and personalization in patient treatment," said Eric Honroth, President, Getinge North America. Servo-air will provide clinicians with a much-needed, mobile additional option. The high-performing ventilator is turbine-driven, which can be transferred intra-hospital with the patient, allowing the continuation of life-saving ventilatory support without having to switch devices. Servo-air also operates with intuitive start-up and personalization of settings. Additionally, the Servo Compass interface provides continuous monitoring and tools for supporting critical lung-protective strategies. As the patient's condition improves, Servo-air's Automode switches between controlled and supported ventilation depending on patient effort, providing a smoother patient transition to spontaneous breathing with less staff intervention, which is safe for the patient and is less burden on the medical center. For more than 50 years, Getinge has produced high-acuity ventilators such as the Servo-u and Servo-n, and technologies that help neonates and adults breathe including NAVA and NIV. Servo-air is a high acuity, versatile, intuitive and powerful ventilator that supports

the needs of critically-ill patients. To read more about our latest innovations and our full line of mechanical ventilatory support offerings, visit our website.

### **Wearable, Wireless Thermometer Launched**

Masimo announced the launch of the Radius T° Continuous Thermometer for consumers. Unlike spot-check, episodic thermometers, the wearable, wireless Radius T° measures body temperature continuously, seamlessly transmitting data and customizable temperature notifications to the user's smartphone – helping caregivers, such as parents, monitor loved ones' temperatures even while they sleep. Radius T° represents a paradigm shift in thermometry by making it continuous, wearable, and hassle-free. Traditional periodic and invasive methods depend on the user repeatedly conducting a series of steps that can interrupt daily activities, including sleep, and can miss body temperature trends and patterns. With a traditional thermometer, a person may only notice a spike in temperature hours after a spike has occurred, or may not even become aware of it if it is during sleep. By contrast, Radius T° continuously and seamlessly measures temperatures using a small, inconspicuous, wearable sensor that can be easily applied to anyone from children to elderly adults — with no action needed after initial application to the skin. Radius T° eliminates manual measurements while providing continuous insight into changes in the user's temperature and helps users understand which way their temperature is trending. In addition, Radius T° uses proprietary algorithms to provide body temperature measurements for users five years or older that approximate oral temperature, not just external skin temperature. Radius T° provides temperature measurements with laboratory accuracy within  $\pm 0.1^{\circ}\text{C}$ , whereas other oral thermometry solutions typically have laboratory accuracy within  $\pm 0.2^{\circ}\text{C}$ . Earlier this year, Masimo launched Radius T° as part of the Masimo SafetyNet™ remote patient management solution, for use both in hospitals and by patients at home. Dr. Neal Fleming, M.D., Ph.D., Vice Chair for Education in the Department of Anesthesiology and Pain Medicine at UC Davis Health, commenting on his experience using Radius T°, said, "Radius T° is noninvasive and convenient for patients. I do not have to interrupt their daily activities or their sleep and it provides me continuous trend data that is a powerful guide to patient care. It makes it easier for me to recognize possible changes in their symptoms." Flexible and slim, each disposable Radius T° sensor can be worn comfortably for up to eight days, and is water resistant during shower and exercise. Users are free to carry on with their daily activities and sleep, without interruption or hassle — all while Radius T° continuously collects temperature data. Using built-in Bluetooth, the sensor easily pairs with the Masimo Radius T° App on the user's smartphone, providing real-time temperature values with user-definable automatic notifications (for example, when temperature exceeds a certain user-selected threshold or if it spikes), as well as detailed historical trending data, revealing the baseline and fluctuation patterns unique to each person that can help users determine whether a rise in temperature warrants action. In addition, the user-friendly Masimo Radius T° App can support multiple family member profiles and can be easily set to schedule medication reminders. Joe Kiani, Founder and CEO of Masimo, said, "We're excited to expand our growing line of consumer solutions, which includes MightySat® and Masimo Sleep™, with the Radius T° Continuous Thermometer. For years, clinicians have trusted Masimo technology to monitor patients in the hospital. With Radius T° and our other consumer solutions, we're bringing our expertise and experience in accurately



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Additional sizes not shown.

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and reliably measuring physiological data from the hospital to the home.” Radius T° is not FDA 510(k) cleared. The device is marketed under the FDA’s Enforcement Policy for Clinical Electronic Thermometers During COVID-19. Radius T° is CE marked.

### **Ventilation Technology Breaks Ground for Adults and Premature Babies**

Born 12 weeks too early with a 50/50 chance at survival, Sabina Checketts has grown up to become a neonatal doctor herself, using new therapies and sophisticated technology to improve outcomes for premature babies. One such technique called NAVA, invented by Getinge, utilizes sensors to help babies on ventilators breathe more easily and naturally—and it’s increasingly being used on adults. And a new randomized study shows that NAVA can significantly shorten the time on the ventilator. Thirty-three years after her early birth, Checketts now works as a neonatal doctor in London. The ventilator that helped Checketts survive was a far cry from what she sees today when she treats premature babies. “We’ve gone from a mode of ventilation where you were breathing for the baby to one now where we can breathe with the baby as well,” she says. As vulnerable premature babies fight to stay alive one of the most critical issues is something most people never think twice about—breathing. A pivotal advance in neonatal medicine—and one that has a major impact in adult critical care—has been the development of better ventilators. One ventilation technique that breathes with the patient is called Neurally Adjusted Ventilatory Assist, or NAVA, developed by Getinge, a global leader in intensive care technology for both infants and adults. In most intensive care units 20% of patients consume 80% of ventilation resources, which may lead to increased complications and unwanted outcomes. NAVA, is also approved for adults, and the features that make the technique successful for neonates, translates well to adult patients. “NAVA is a way to do a little better job,” says Sherry Courtney, a director of clinical research in neonatology, who has worked with premature babies since the 1980’s. “The diaphragm is a muscle. When it contracts, we’re going to breathe. When it relaxes, we’re going to exhale. So, NAVA senses the breathing using a catheter that goes down into the stomach and rests close to the diaphragm.” Electrodes on the catheter sense contractions in the diaphragm, resulting in an almost instantaneous signal that the patient wants to breathe. Synchronously, the ventilator supplies air. And when the electrodes sense the end of diaphragmatic contractions, the ventilator allows exhalation. “NAVA just provides a little support, depending on the breath the patient can be breathing as the patient wishes,” says Courtney. Adults on ventilators generally start with a functioning diaphragm, but it will quickly become weaker if a machine breathes for them for too long. Getinge Medical Director Miray Kärnekull says that advanced ventilator technologies, like NAVA, are used regularly in adult patients in Europe to keep patients’ diaphragm muscles active. And in a very recent multicenter randomized controlled trial, results showed that patients with acute respiratory failure on NAVA spent significantly less time on the ventilator and experienced less extubation failure compared to conventional lung-protective mechanical ventilation. “In addition to helping maintain the diaphragm’s tone, the synchrony of a NAVA ventilator means patients don’t fight against the ventilator,” Miray Kärnekull continues. “To prevent that, adults usually need to be sedated. With NAVA, doctors can reduce sedatives, allowing for earlier weaning with fewer complications ... It’s really a groundbreaking technology”, says Kärnekull. “NAVA

gives the clinician a way to personalize not only the ventilation, but also the weaning process for adult patients.” These exciting advances have allowed physicians like Checketts to celebrate even more success stories. Checketts decided to become a doctor at early age, when her mother routinely pointed out a man walking down the street on his way to the hospital and said, “That’s the doctor who saved your life.” That experience motivates her to be a positive force in the families of the babies she treats. “When I talk to parents about the fact that I was premature, there’s always a sense of surprise, I think a little bit even shock, you know. Oh, oh, and you’re a doctor,” Checketts says. “I think it’s a nice way to say to them that prematurity shouldn’t be a limit on what a child can do. I mean, the advances we’ve made in even just the last 10, 15, 20 years mean the outcomes are much better than they used to be. And seeing me, who developed before that, as a newborn doctor, I give them a sense of hope and possibility, I think.”

### **Aerosolized Medications Are Back**

For the past six months, since the pandemic began, nebulizers have been removed from the arsenals of Emergency Medicine Physicians and Respiratory Therapists. The reason is that nebulized medications have been implicated in the spreading of viral particles into the environment. As specialties that often has to resort to improvisation in a pinch, we have come up with many inventive solutions. However, these are generally temporary and often expensive. For example, a CPAP mask with an attached viral filter costs about \$35 per treatment. Surprisingly, an MDI (metered-dose inhaler) with a spacer, (currently in short supply) costs \$100-\$150. AerosoLess Medical of South Florida has developed and recently released a new aerosol delivery device which allows us to again provide nebulized treatments. AerosoLess Medical is producing the SafetyNeb which is fitted with viral filters over the vent holes. These viral filters are designed to prevent exhaled pathogens from endangering Healthcare Workers. Additionally, the SafetyNeb uses an engineered Faceplate to create a tight seal with the patient’s face, which also provides a CPAP-like effect. With the SafetyNeb, practitioners can finally give aerosolized medications again. Look up [AerosoLessMedical.com](http://AerosoLessMedical.com) for more information or call 800-205-5913.

### **Device Maker Adds to its Team**

Mercury Medical, a medical device manufacturer focused on airway and respiratory healthcare markets, announces the appointment of Raymond L. Mundy to the newly created position, Executive Vice President – Sales and Marketing. Mundy will be responsible for the continued sales growth of Mercury’s products throughout the United States and the global marketplace. “We are excited to have Ray join the company at a time when, more than ever, the treatment of respiratory disease demands innovative new products and solutions. Ray is a 17-year veteran in our industry, with a diverse clinical and commercial background bringing a wealth of sales and operations expertise to our Company,” said CEO, John Gargaro, MD. Mundy joins Mercury from Medtronic plc including companies that were subsequently acquired by the firm, such as Covidien during his tenure. “I am very pleased to be joining Mercury Medical as their new Executive Vice President of Sales and Marketing. The opportunities that exist both at the company and the markets they serve are tremendous. There has never been a more critical time to ensure access to Mercury’s respiratory and airway management technologies,” said Mundy. Mercury Medical is a global provider of airway and respiratory medical device systems

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for healthcare providers bringing a legacy of innovation, high quality lower cost solutions, and better patient outcomes. The company distributes its products into 58 countries, into critical care, neonatal, anesthesia and EMS markets.

### Extracorporeal Life Support Refined Even More

Getinge is a world leading supplier of components to support Extracorporeal Life Support (ECLS)—a therapy that supports the function of lungs and/or a heart that have ceased working. Invented in the 1960's to facilitate heart bypass surgery, ECLS techniques and technologies have been refined to the point that they are used increasingly in Japan, Europe and, more recently, in the US. "For example, for pulmonary (lung) support, we take blood out of one of the big veins in the body," says David A. Kaufman, MD, Pulmonary & Critical Care Medicine at NYU School of Medicine in New York, US. "We then run it through a chamber where we are able to extract the carbon dioxide and put in a high concentration of oxygen. Then, that blood is injected back into another vein." ECLS is primarily a way to buy time and keep the blood oxygenated limiting the damage to the lungs in the most critical situations—like multi-organ failure—while doctors can figure out how to save the patient. The technique has potential in the case of trauma, while a patient awaits organ donations, or in the treatment of acute infectious disease, when long term utilization of a ventilator could cause damage. "There are times when a patient's lungs are in such bad shape that the force that a mechanical ventilator needs to apply to get any gas into the lungs is very high," Dr Kaufman says. "ECLS allows us to make sure that we're not adding to the damage that's already occurring from the patient's underlying disease." Getinge has a broad, high-end product portfolio

for short-term or prolonged ECLS that includes a choice of devices and consumables to provide individual and sufficient extracorporeal heart and lung support, such as centrifugal pumps, oxygenators, heater units, tubing sets, and catheters and *Continued on page 26...*

## COMPANY PROFILE

### Neotech

#### Describe your product(s) and its unique features.

Neotech offers a broad spectrum of unique, disposable products, including RAM Cannula®, NeoBar® ET Tube Holder, and EZCare™ Softouch trach ties. Our devices feature skin friendly materials such as hydrocolloid and NeoFoam. NeoFoam is so uniquely soft, you have to feel it to believe it. Neotech products are developed for neonatal and pediatric care.

Most recently, our NeoHug® Utility Device Holder has generated interest and excitement. It's a cute, colorful, and functional way to hold a variety of items in all areas of the hospital. It can be placed at the bedside or clipped on and IV pole to hold a suction tip, a pacifier, tape, tubing and more.

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

One product line, in particular, became critically important in 2020. Cell Wipe™ and Cell Shield is a simple system of an alcohol wipe to clean your mobile device and a crystal-clear plastic cover to help protect the device from cross contamination. Cell Wipe and Cell Shield are appropriate for all areas of the hospital.



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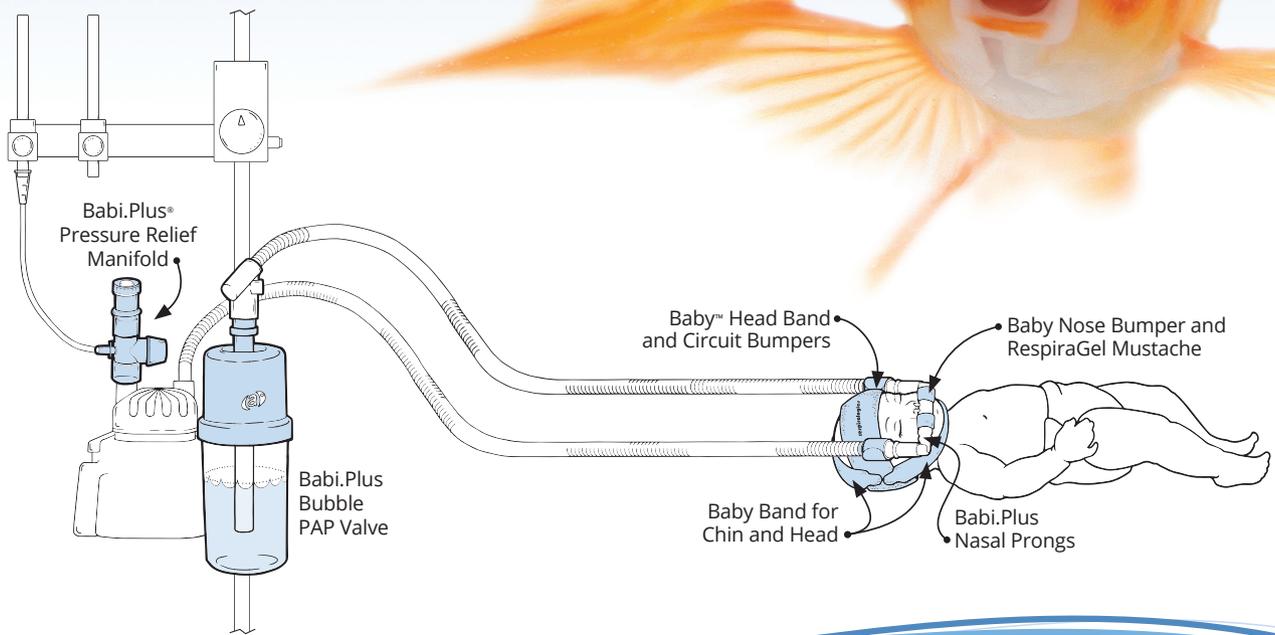
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**Discuss your R&D process, including clinical user input.**

Neotech has a 30-year history of working with clinicians to develop new and innovative technology. We have a robust engineering division that works directly with our team of clinical consultants and other end users to inform product design and critical features.

Inventors who bring their ideas to Neotech are never charged fees of any kind. We'll even help to secure patents.

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

We have a team of bedside clinicians who do training and in-servicing on our products, which has been an extremely successful program. We also offer a library of training videos for several products with more to come.

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

Newer and faster prototyping tools, such as 3D printers, have had a huge impact on product development. We have a few innovative respiratory products in the pipeline that will come to market much faster than in years past.

## VENTILATION ROUNDTABLE

### Breas

**What ventilation products does your company offer?**

Breas Medical offers the Vivo line of life support ventilators that includes Vivo 50 and Vivo 65.

**What are the new features?**

Our newest feature is our EveryWare by Breas remote monitoring software. EveryWare by Breas helps you manage your respiratory patients remotely with confidence. The web-based application connects Vivo 50 and Vivo 65 ventilators in the home to healthcare providers via the iLink, a 4G cellular modem, which sends the data to a securely hosted cloud platform.

The Dashboard presents demographic and compliance overviews. The Configurable Patient List uses extensive sorting, filters and functionality. Multiple devices per patient record streamlines workflow and reporting.

EveryWare is designed to improve patient outcomes and demonstrate compliance by generating a more insightful approach to the care of respiratory patients at home. Its aim is to help make a more productive use of healthcare resources and reduce secondary care admissions.

**Tell us about your company's current or recent R&D efforts.**

Breas continues our tradition to develop products that deliver leading edge innovations that can provide patient comfort and mobility needed to improve their quality of life while reducing the cost of care. This was our focus when we recently launched our EveryWare web-based remote monitoring software.

**Discuss the training and support services you offer.**

Last year Breas launched EducationbyBreas.com, a website focused on sharing world-wide knowledge and best practice in respiratory care. It features interviews with leading physicians,

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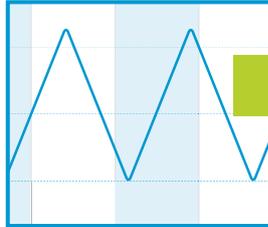


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Triangle waveform

**2** RespirTech bronchiectasis patients reported **62% reduction in hospitalizations** and a **14% reduction in antibiotic use** one year after initiating Philips InCourage vest therapy<sup>2</sup>



Outcomes

**3** “I was on antibiotics every month of the year for the last 40 years... **Since I’ve had the InCourage machine, I haven’t had to take antibiotics\* in over a year...**”

-Marjorie M., CA

\*Individual results may vary.



Patient results

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1. Milla CE, Hansen LG, Weber A, Warwick WJ. High frequency chest compression: effect of the third generation waveform. Biomed Instrum Technol 2004; 38:322-328. Note: 8 CF comparing triangular waveform vs. sine waveform technology.
2. Data from RespirTech’s bronchiectasis patient outcomes program. Methodology: As of 6/30/19, self-reported data from over 16,000 bronchiectasis patients.

white papers, peer-to-peer discussions and workshops. We also offer free webinars on respiratory topics for AARC CEU credits. Our clinical team is available for ventilator training and set up either remotely or in person. Breas offers remote service training following Breas terms and conditions. This training is provided at no charge for authorized service centers who are interested in servicing their own Vivo ventilators.

#### **Where are your products used? (ie, hospital, home, etc.)**

Our ventilators are designed to be used from Hospital to Home. Our core market focus is in the hospital sub-acute care, post-acute care institutions and the home care environment.

#### **What developments do you foresee for ventilation products and applications?**

Breas is dedicated to continuous products, services and solutions development for a better life. Innovation is central to our vision—we place great focus into ensuring every innovation will improve the experience for patients and make work more effective for clinicians. To keep our development on track, we have defined three core product values. These are the guiding principles that direct every activity and make sure we always lead the way in ventilation technology for people.

**Comfort** – Everything we do is motivated by a commitment to technology that harmonizes with the patient.

**Simplicity** – Simplicity is what happens when we design things around people.

**Communication** – Excellent care demands seamless communication between people and systems.

## **Ventec Life Systems**

#### **What ventilation products does your company offer?**

Ventec Life Systems created the first Multi-Function Ventilator, VOCSN, which seamlessly integrates five separate devices into one unified respiratory system. VOCSN integrates a critical care ventilator, oxygen concentrator that delivers the equivalent of 6 L/min, cough assist at the touch of a button without changing the patient's circuit, hospital grade suction that provides consistent high flows, and a high performance nebulizer that automatically syncs with the flows from the ventilator and turns off when the therapy is complete. VOCSN is fully customizable to meet the patient's needs, you can get all five therapies or just the mix of therapies needed. VOCSN works from hospital to home and for adult or pediatric patients above 5kg.

#### **What are the new features?**

The team at Ventec Life Systems is constantly enhancing VOCSN, most recently adding High Flow therapy and additional software features to improve clinician access and ease of use. VOCSN Multi-View is the first and only system to provide complete patient trending and monitoring for ventilator-dependent patients across multiple respiratory therapies and care environments, with remote cellular data transmission being added in 2021. Our team also made a number of customizations to support frontline medical professionals responding to COVID-19—more details are available at [www.VentecLife.com/COVID](http://www.VentecLife.com/COVID) or by calling 877-8VENTEC.

#### **Tell us about your company's current or recent R&D efforts.**

Ventec Life Systems is building on the integrated multi-therapy

delivery of VOCSN with Multi-View, which will include remote cellular data transmission in 2021. VOCSN Multi-View is designed to summarize patient data and create trend reports to facilitate actionable and informed treatment decisions and care plans, drive proactive interventions, control costs, and deliver seamless care across providers from hospital to home. The streamlined information is designed to provide decision makers with a comprehensive picture of the patient's respiratory wellbeing that has never before been possible.

#### **Discuss the training and support services you offer.**

Like many companies, Ventec Life Systems evolved our training and support in response to the COVID-19 pandemic. Because VOCSN V+Pro critical care ventilators are one of the go-to devices for the Strategic National Stockpile, we have added additional live training options via Zoom and expanded 1x1 clinical support available 24/7 by phone. Respiratory therapists can earn CEU credits for VOCSN training by signing up at [www.VentecLife.com/Training](http://www.VentecLife.com/Training). Ventec also offers comprehensive on-demand video training available for clinicians or caregivers to learn to use VOCSN.

#### **Where are your products used? (ie, hospital, home, etc.)**

VOCSN is a critical care ventilator suitable for use from hospital to home. Because VOCSN offers a comprehensive set of modes and settings to meet patient needs, VOCSN can be used across the care continuum for pediatric or adult patients above 5kg with invasive, non-invasive, or mouthpiece ventilation.

#### **What developments do you foresee for ventilation products and applications?**

Ventec Life Systems continues to define integrated respiratory care with upcoming enhancements to VOCSN, expanded access to integrated respiratory care in the home with HCPCS E0467, and integrated multi-therapy reporting with VOCSN Multi-View. We believe the integrated therapies of VOCSN combined with the integrated data and reporting capabilities with VOCSN Multi-View will provide medical professionals with important new insights to inform patient treatment plans.

## **SPOTLIGHT ON SPIROMETRY**

#### **Vitalograph Launches Integrated Online Training Service**

Vitalograph® announced today SpiroTutor™, a new online training website launching in the US. Vitalograph® is addressing the pervasive issue of affordable and timely training surrounding quality respiratory diagnostic testing and monitoring. Thus, SpiroTutor™ was developed to provide thorough and consistent training to clinicians of all skill levels online and on demand. Vitalograph® is working to break down the barriers to effective spirometry use by including this service with their products and thereby build confidence in the clinicians using our products to make a positive impact on the patients that they serve.

Through SpiroTutor™, Vitalograph® has the capability to provide training access to users 24/7, making training and maintaining critical skills sets easier and more convenient than ever. Furthermore, to ensure that clinicians are confident using their devices, Vitalograph® is providing a FREE enrolment with each new device purchased. Upon the completion of the training content, a manufacturer's certificate will be issued to the customer. Training content includes all Vitalograph diagnostic software, spirometers, respiratory monitors, and screeners.



Clinicians can access their free training by registering a new Vitalograph® device within 30 days of purchase at [www.vitalograph.com/warranty](http://www.vitalograph.com/warranty). Once registered, an invitation email will be sent with log in instructions to access SpiroTutor™ training content.

Vitalograph® is committed to enhancing the customer's clinical experience by providing this valuable resource to improve:

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**Quality** – Training improves accuracy, efficiency, and reliability. This novel tool can be used for initial training and annual competency review with a certificate to authenticate.

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Troy Pridgeon, Executive Vice President of Sales and Operations at Vitalograph® US commented:

“The development of this online service will help ensure that every Vitalograph® customer has timely access to product training from the start. Vitalograph® already manufactures market leading and award winning respiratory diagnostic products and this integrated service is going to make sure that all of our customers have access to resources that maximize efficient use.”

“We are happy to partner with Amanda Clark, President of Carolina Diagnostic Solutions, to build this resource and believe that this initiative further solidifies Vitalograph's position as an industry leader for respiratory diagnostics. Amanda brings more than two decades of clinical experience to make the content applicable to real life scenarios of use.”

Vitalograph is a world-leading provider of top quality respiratory diagnostic devices, clinical trial services and medical equipment servicing. With a pioneering heritage of excellence spanning over half a century, Vitalograph® continues to make valuable contributions to effective medical care and enhanced quality of life.

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the EasyOne Air can be used portably, where data is stored and the graph is displayed directly on the device. And thanks to proprietary TrueFlow ultrasound technology, all NDD devices are incredibly accurate and deliver a lifetime of robust, worry-free operation.

Effortless infection control is an inherent design feature of NDD products, as all elements in contact with patient breath are single-use and easily exchangeable. NDD also provides single-patient use inline filter solutions, providing additional COVID-19 protection when performing spirometry and DLCO tests. The company also provides spirometry training sessions. Visit [www.nddmed.com](http://www.nddmed.com) or contact [customerservice@nddmed.com](mailto:customerservice@nddmed.com).

### CPFS/D USB spirometer

When you need full-function spirometry and space is at a premium, the CPFS/D USB spirometer from MGC Diagnostics is a most fitting solution. This small, portable system is packed with technological advances and features to meet all of your testing and data management needs. The CPFS/D USB spirometer is compatible with desktop and laptop computers for maximum flexibility. It has incentive graphs for spirometry, which are ideal for pediatric populations. Powered by our Ascent cardiorespiratory diagnostic software, you can be assured it will do more than meet your testing and data management needs. MGC Diagnostics utilizes the preVent flow sensor with the CPFS/D USB—the same flow sensor used on our Platinum Elite plethysmographs and the Ultima CPET systems. This gives maximum infection control when used with a pulmonary function filter, cleaned between uses, or discarded. One flow sensor — one technology — one solution.

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# COVID-19: A Respiratory Care Department's Response to the Pandemic

Kenneth Miller MEd, MSRT, RRT-ACCS, NPS, AE-C, FAARC

In early 2020, many healthcare institutions were faced with the reality that everyday clinical practices would have to change secondary to the COVID pandemic. This was very evident in the respiratory management of the COVID patient. The cardinal question that arose was how to maximize patient outcomes and at the same time minimize the risk to the bedside clinicians who would be administering clinical interventions to the patient. Respiratory care departments were extremely affected by this since the virus is transmitted readily during many of the clinical interventions performed by their staff. Common everyday interventions such as aerosol therapy, mechanical ventilation, high flow oxygen administration, suctioning, to name of few, were indicated for the patients with COVID, but also placed the bedside respiratory care practitioner at higher risk of COVID exposure and increased transmission. Maximizing staff protection was not the only dilemma that respiratory care departments were faced with, but having enough equipment and other supplies to treat a tidal wave of patients that were predicted to fill their hospital's ICUs. To deal with these uncharted challenges, many respiratory care department's thrust in action to develop an action plan to address these dilemmas. Lehigh Valley Health Network (LVHN) received their first COVID patients in the middle of March and within a few weeks had many mechanically ventilated patients and full ICUs. In this article I will explain what steps the respiratory care department at LVHN took in attempting to maximize patient outcomes while minimizing bedside therapists' risk.

## The Daily Huddle

Starting in early March, at 0700 there was a daily multidisciplinary team phone call that discussed and assessed current clinical practices germane to the COVID patient population. This team included respiratory care leadership, departmental medical director, infection control, hospital administration, and ICU directors. During these daily discussions, topics like what practices changes needed to be implemented, what were current equipment par levels, what infection control practices needed to be instituted to maximize staff protection, and what was the current workload load and staffing resources. All updated information was placed in a staff folder to review and revised as needed. This was done every Monday-Friday and on weekends if an urgent issue needed to be addressed. This continued until early July.

Kenny Miller is an Educational Coordinator, Wellness Champion, Respiratory Care Services, LVHN.

## Ventilator Availability and Strategic Allocation of Them

The total number of ventilators that were available was determined by the department's respiratory educator and technology coordinator. The ventilators were then separated into different tiers based on the design and complexity of the ventilator. For example:

<b>Tier 1</b>
Extensive ventilator monitoring with complex pulmonary mechanics analysis
<b>Tier 2</b>
Moderate ventilator monitoring with modest pulmonary mechanics analysis
<b>Tier 3</b>
Minimal ventilator monitoring with the absent of pulmonary mechanics analysis

Twice a day ventilator load report was distributed to LVHN COVID leadership and other key clinical personnel. This report induced the number of total ventilators on patients, the number of COVID ventilated patients, patients that were on rescue interventions and patients who were in the weaning process.

Site Total	Types of Vents being used	R/O COVID	Confirmed COVID	EMCO/ Prone	Possible transition to different Ventilator
CC-48	40-G5 3-Galelio 2-V-60 2-C2 1-Drager	1	28	2/16 1 ECMO Not COVID	4
Muhl-16	14-G-5 1-C2 1-Galelio	1	12	0/5	0
LVH-S-1	1-C-1	1	0	0/0	0
LHV-P-7	4-BP 980 3-Drager	0	6	0/0	0
LVH-H-7	7-C-1	0	6	0/1	0
Total Network	79	3	52	2/22	4

Figure 1. Ventilator Load, April 14 0645

Figure 1 report allowed the COVID team to accurately know the number of available ventilators remaining available and the severity of ventilator workload. At our network's apex we had ninety-nine ventilated patients, sixty-six of them were COVID. The report also assisted with allocation of resources from one campus to another if regional surges were occurring. This report continues to be done a daily basis.

### Maximizing Staff Safety

All staff received formal education on how to properly put on and take off the appropriate personal protective equipment (PPE). All respiratory care bedside clinicians wear maximum protection (PPE) whenever they go into an aerosolizing room. Daily PPE inventory was conducted by the shift coordinator and required supplies were ordered as needed. An aerosolized generating sign was developed to alert any bedside clinical that there was an aerosolizing procedure in a COVID patient's room to reduce the risk of under protected transmission.



Figure 2. Aerosol generating NIV Procedure July 2020 B

Enhanced exhalation filtering was placed on all mechanical ventilators, non-invasive units and nebulizing devices to reduce viral transmission. To minimize viral transmission during high frequency percussive ventilation, which when utilized depends on the endotracheal cuff being partially deflated, a fiberglass box was constructed to be placed over the patient to trap exhaled gas. Department education and meetings were conducted via remote means and all staff was required to wear a face covering in the break rooms or during any live interactions.

### Final Thoughts

To combat a pandemic you need to take a proactive approach and not a reactive response. Multi-disciplinary communications are critical in order for every clinician to be well informed for ever-changing clinical practices policies and technology revisions. Focusing on maximizing patient outcomes and staff safety can be a difficult balancing act. Having a strategic pandemic plan and conducting daily communications can maximize a department's response to increasing patient volume and equipment needs. This strategic process will be re-defined and revised as other departmental challenges arise.

# Planned Intubation in Neonates

Shabih Manzar, MD

## Abstract

In clinical practice, a lack of proper preparation for neonatal intubation leads to increase risk of trauma and accidental extubation. In units where multiple providers are involved in intubation, errors can occur due to false expectations. We propose using a mnemonic of TUBE (Tube size and depth, Use of stylet or not, Blade size, Battery and Bulb, Equipment check), prior to the procedure.

## Keyword

Intubation, neonates, accidental, extubation

Unplanned extubations (UEs) in neonates are associated with worse outcomes and increased hospital costs.<sup>1</sup> Quality improvement initiative has shown to reduce UEs.<sup>2</sup> In studies reporting UEs, little focus is paid on the logistics of intubation. In clinical setting, intubations though are sought to be planned but are not. For example, in teaching institution, like ours, we noted that when our performers (residents and nurse practitioners) are called to intubate, the process is spilt between different providers (nurse, respiratory therapist (RT) and the performer). The performer expects the RT to check the prerequisites of intubation but many times either the tube size is not right, or the blade size is not appropriate. Some performers prefer stylet while others do not. Sometime the suction catheters are not attached and so on. Also, the depth of endotracheal tube (ETT) insertion is not pre-decided based on the calculations (weight-based or nasal septum-tragus measurement), which creates the risk for accidentally dislodgement.

To rectify these problems when multiple providers are involved in the process of neonatal intubation, we suggest that intubation should be a time out procedure with a checklist. We propose a TUBE mnemonic (Table).

## The procedure summary

The perform after performing adequate hand hygiene and disinfection procedure should say loud (using mnemonic TUBE):

**T: Tube size and depth** – “I am intubating baby X, who weighs 950 grams. I need ETT 2.5”, then ask for depth measurement (based on N-T length or weight), and says “I will secure/tape the ETT at 6.8 cm”

**U: Use stylet** – “I will use stylet”

**B: Blade size, battery/bulb check** – “I will use a size 0 blade”, ask to check for bulb/light

**E: Equipment check** (ask to check the bag & mask (appropriate size), working suction catheter, CO<sub>2</sub> detector, Stethoscope, O<sub>2</sub> source and saturation monitor, LMA).

Table 1

<b>T</b> (Tube size, Tube depth)	Tube size (2.5, 3.0 or 3.5)* Tube depth at lip* (estimated weight in kg + 6 = cm at lip OR (measure nasal septum to tragus length in cm + 1cm) = cm at lip *Follow NRP guidelines <sup>3</sup>
<b>U</b> (Use stylet)	Yes or No
<b>B</b> (Blade size, bulb)	1, 0, 00 (per NRP)*
<b>E</b> (Equipment)	Bag and mask, Oxygen source, Suction equipment, Stethoscope, Colorimetric CO <sub>2</sub> detector, Saturation monitor, Laryngeal Mask Airway (LMA), Securing tapes and adhesives

## References

- 1 Klugman D, Melton K, Maynard PO, et al. Assessment of an Unplanned Extubation Bundle to Reduce Unplanned Extubations in Critically Ill Neonates, Infants, and Children [published online ahead of print, 2020 Apr 13]. *JAMA Pediatr.* 2020;174(6):e200268. doi:10.1001/jamapediatrics.2020.0268
- 2 Hatch LD 3rd, Scott TA, Slaughter JC, et al. Outcomes, Resource Use, and Financial Costs of Unplanned Extubations in Preterm Infants. *Pediatrics.* 2020;145(6):e20192819. doi:10.1542/peds.2019-2819
- 3 Weiner GM, Zaichkin J, Kattwinkel J, eds. *Textbook of Neonatal Resuscitation, 7th edition.* Elk Grove Village, IL: American Academy of Pediatrics and American Heart Association; 2016

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# The Use of the VORTRAN GO<sub>2</sub>VENT During COVID-19

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. Participating in the interview is Dave Swift, RRT.

**Respiratory Therapy:** If a hospital is facing a ventilator shortage, what should they know about the GO<sub>2</sub>VENT?

**Dave Swift:** The GO<sub>2</sub>VENT is not intended to take the place of a full-spectrum critical care ventilator with all available modes. The GO<sub>2</sub>VENT can provide intermediate ventilatory support using its pressure controlled/pressure supported mode and the Airway Pressure Monitor/alarm module [APM-Plus]. With the addition of VORTRAN's new PEEP Valve, the GO<sub>2</sub>VENT can now provide a higher level of support for managing more patients in the ICU.

**RT:** What benefits does the GO<sub>2</sub>VENT have versus other ventilators?

**DS:** The GO<sub>2</sub>VENT is a cost-effective solution to a ventilator shortage as it is intuitive and easy to use/setup so that it does not require a huge investment in time or resources to become proficient in its use. Multiple units can be purchased for the cost of one annual scheduled p.m. on a critical care ventilator. Equipped with both inspiratory and expiratory HME/HEPA filters, it greatly reduces the risk to clinicians by virtually eliminating the dumping of exhaled contaminants into the clinical environment. It is portable so can be used transport and is very mobile. Since it is single-patient-use, no maintenance or cleaning is required. It can even be attached to a manifold, which can effectively power up to 7 GO<sub>2</sub>VENT units.

**RT:** Can the GO<sub>2</sub>VENT only be used in emergencies?

**DS:** The GO<sub>2</sub>VENT can be used in the majority of situations where mechanical ventilation is being initiated. This allows the clinicians to triage the patients as to whether they get a full-featured ventilator, are a short-term ventilatory candidate, or require ventilated transport until a critical care vent becomes available. It is FDA-cleared to support patients continuously for up to 30 days.

Dave Swift, RRT is a Respiratory Therapist who received his registration in 1983. For the last 38+ years he has worked in front line leadership roles as a charge RT/supervisor in Ottawa's tertiary trauma and referral hospital looking after neonates, trauma, general medicine, emergency, and critical care. He was the team lead in the (federal) National Office of the Healthcare Emergency Response Team, acting assistant manager of the Ottawa Hospital's endoscopy program, and an accreditor of respiratory therapy programs with CoARTE. In 2020 with the change in the Ottawa Hospital's leadership model, the charge RT positions were eliminated and he transitioned over to consulting. If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.

**RT:** Can the GO<sub>2</sub>VENT be used non-invasively?

**DS:** With an effectively sealed NIV mask, the GO<sub>2</sub>VENT can provide effective NIPPV in its pressure supported setting. Remember this is a pressure operated device so an effective seal is essential. Ecuador recently utilized it during a scarce resource event, on 120 patients with great success, while avoiding intubations with the negative outcomes from COVID in a majority of cases. The data from this study showing significant clinical benefits when used a non-invasive ventilator will be published in the near future.

**RT:** How has the GO<sub>2</sub>VENT been used during COVID-19?

**DS:** The GO<sub>2</sub>VENT has been used effectively both as a ventilator  
*Continued on page 26...*

**NEW!**

# GO<sub>2</sub>VENT

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*Interview...continued from page 25*

and NIPPV unit in many resource-challenged COVID stricken countries, such as Ecuador, Italy, and Mexico.

**RT:** What protections can the clinician have regarding airborne viruses when using the GO<sub>2</sub>VENT on an infected patient?

**DS:** The unit must have an HME filter on the patient connection port and a HEPA filter between the head of the unit and the modulator to greatly reduce or prevent release of airborne contaminants, protecting the most essential resource we have—our clinicians.

**RT:** What other devices or accessories do you recommend to get full functionality out of the GO<sub>2</sub>VENT?

**DS:** The Airway Pressure Monitor [VORTRAN APM-Plus] provides essential information to the clinician (PIP, PEEP, inspiratory time, respiratory rate and I:E ratio) and its alarm feature provides an extra layer of protection. It is an essential “must have” for critical care use of the GO<sub>2</sub>VENT. HEPA filters are another “must have” to safely use the GO<sub>2</sub>VENT and protect our clinicians. Additionally, the new VORTRAN PEEP Valve can be added to provide a higher level of support to treat more critical ill patients, including those experiencing ARDS symptoms.

*News...continued from page 16*

cannulae. During the COVID-19 outbreak, the ECLS therapy has provided support to acute care patients around the world in need of further life support than a ventilator can provide. “Globally, we have seen a rising demand for ECLS therapy related products and will continue to increase our production to help our customers save more lives”, says Lena Hagman, EVP Quality & Regulatory Compliance & Managing Director Cardiopulmonary at Getinge. “Getinge has increased production output of Heart Lung Support (HLS) Advanced Sets and Permanent Life Support (PLS) Sets this year by more than 30% at our production facility in Hechingen and 110% in Rastatt and we have ambitious plans for continued growth.” The significant investments at these manufacturing facilities in Germany, are primarily related to increased production capacity. This includes various production tools, assembly machinery, coating equipment but also significant headcount increase of production employees. “In the current health care environment, the US has also seen an increase in demand for ECLS therapy products for the acute care setting. Getinge investments in life-saving options have allowed us to meet the increased demands, such as the COVID-19 pandemic,” said Eric Honroth, Getinge President, North America. Honroth further states, “Vital equipment, such as ECLS therapy products allows the US to be prepared for future challenges.”

### **High-Frequency Oscillatory Ventilation in Infancy Shows No Lasting Benefit**

Children born before 29 weeks of gestation who were given high-frequency oscillatory ventilation (HFOV) within an hour of birth have a higher risk of asthma by age 16 to 19, according to a report in *The New England Journal of Medicine*. The team, led in part by Dr Anne Greenough, a professor of neonatology and clinical respiratory physiology at King’s College London, also found that, as young adults, the children born very prematurely tended to have substandard lung function. HFOV is designed to keep fragile lungs inflated by letting air pressure fluctuate slightly at 3 to 15 times per second. It was originally developed in Canada for neonatal intensive care units and for children. It is widely used in both populations as part of an attempt to avoid the lung damage from conventional mechanical ventilation. In 2014, a team led by Greenough found that children age 11 to 14 who had received HFOV as extremely premature infants had better lung function than babies who received conventional therapy. But when Greenough and her colleagues tested the children at age 16 to 19, “the use of HFOV in the neonatal period was not associated with superior respiratory or functional outcome.” In fact, 15% of the children who had received HFOV had received a diagnosis of asthma compared with only 3% who had received conventional ventilation therapy. “We were surprised that there were five times more young people diagnosed with asthma in the HFOV group as we saw no significant differences in asthma at 11-14 years,” said Greenough said. “During puberty, however, many children, particularly boys ‘grow out’ of asthma and this may have resulted in the changed findings.” However, both groups had similar scores on the primary outcome—forced expiratory flow at 75% of the expired vital capacity. The FEF-75 z score was -1.07 with conventional ventilation and -0.94 with HFOV. “The most important message is that despite the positive effect of puberty on lung function, the majority of these very prematurely born young adults had lung function below the lower limit of normal and they require long term follow-up to determine whether they will suffer premature onset of chronic pulmonary disease,” said Greenough.

*Continued on page 81...*

# Prevalence of Excessive Daytime Sleepiness and Risk Factors of Obstructive Sleep Apnea Among Type 2 Diabetes Mellitus

Joseph Boateng Makae

## Abstract

**Background:** Obstructive sleep apnea (OSA) is a breathing disorder of sleep that is gaining recognition in both developed and developing countries in recent years due to its associated morbidity and mortality worldwide. It contributes to the development of the cardiovascular disease, systemic hypertension and abnormalities in glucose metabolism. The relationship between OSA and Type 2 diabetes mellitus (T2DM) is bidirectional. The majority of studies on sleep-disordered breathing and T2DM have largely in developed countries hence, the need to explore the relationship between these conditions in developing countries like Ghana.

**Aim:** This study aimed to determine the prevalence of excessive daytime sleepiness and the risk of obstructive sleep apnea among Type 2 diabetes mellitus patients attending the Korle-Bu Teaching Hospital (KBTH).

**Methods:** This study was a cross-sectional study. Telephone interviews were conducted on Type 2 diabetes mellitus patients attending the National Diabetic Management and Research Centre at the KBTH. These interviews were conducted to complete two validated questionnaires; the STOP-BANG questionnaire and the Epworth Sleepiness Scale (ESS) questionnaire which was used to assess the risk of OSA and the prevalence of excessive daytime sleepiness respectively. Patients' demographic characteristics were also collected using a structured questionnaire and anthropometric measurement extracted from patients' folders. The data was analyzed using SPSS version 22.0.

**Results:** The prevalence rate of excessive daytime sleepiness was high, 73.3% among the 60 Type 2 Diabetes patients who took part in the study. By STOP-BANG scores, patients who were at high and medium risk for obstructive sleep apnea were 15.0% and 65.0% respectively. However, a minority of the respondents had a low risk for OSA representing 20.0%. Combining patients

with medium and high risk for OSA, the associated factors were found to be age > 55years, overweight, and obesity.

Finally, correlation showed a significant linear relationship between STOP-BANG and ESS scores ( $r = 0.44$ ;  $p < 0.01$ ). This showed that there is a likelihood of T2DM patients having obstructive sleep apnea if they have excessive daytime sleepiness.

**Conclusion:** The prevalence rate of excessive daytime sleepiness in T2DM patients was high as the compared lesser risk of obstructive sleep apnea. It can be concluded that there is a significant relationship between OSA and EDS in Type 2 Diabetes patients.

## Introduction Background

Obstructive Sleep Apnea (OSA) refers to a form of sleep-disordered breathing which is characterized by recurring episodes of partial or complete obstruction of the upper airway during sleep resulting in repeated arousal and lack of restful sleep. OSA is associated with increased morbidity and mortality in the community. Notable clinical presentations of OSA include excessive daytime sleepiness, loud snoring, and observed pauses in a breath when asleep at night. Other symptoms include altered mental status, fatigue, loss of memory, restless sleep, gasping during sleep, and severe morning headaches. All these manifestations are a result of the frequent interruption of quality sleep during the night. There is the induction of nocturnal hypoxemia, hypercapnia, and sleep fragmentation due to recurrent episodes of airway obstruction of such patients (Kim et al, 2019). Evidence from previous studies suggests that obstructive sleep apnea influences the development of abnormalities in glucose metabolism (Punjabi & Polotsky, 2005), hypertension (Peppard et al, 2000), and cardiovascular disease (Peker et al, 2006). Both hospital and population-based investigation of OSA has revealed that about 50% of patients with OSA also have Type 2 Diabetes Mellitus (T2DM) and as much as 50% of patients with Type 2 Diabetes Mellitus have moderate-to-severe OSA (Resnick et al, 2003; Foster et al, 2009).

Type 2 Diabetes Mellitus is a condition characterized by an elevated concentration of glucose in the bloodstream (Cho et al, 2018). This is due to a deficiency in the production of insulin by the islet of Langerhans of the pancreas (WHO, 2018) or the destruction of insulin produced. T2DM is a complex disease that can be inherited or acquired through genetic mutation and also through environmental factors (Bais, 2005). T2DM poses

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Joseph Boateng Makae – A young, visionary Respiratory Therapist, also a graduate from the University of Ghana, legon. Joseph is privileged to be part of the pioneers of the RT program in his country. He is currently practicing as an intern and the only Respiratory Therapist at the Komfo Ankye Teaching Hospital in Kumasi, one of the major busy cities in the country. Going forward, it is his dream to build his professional life and have an impact on the world around him. "All I care about is to put smiles on the faces of patients and people I come across daily. I know with dedication, hard work and determination, nothing shall be impossible for me."

macrovascular complications such as coronary artery disease and stroke (Yen, 2017) and also microvascular consequences that can affect the nervous system, kidney, and retina of the eye (Cho et al, 2018). Statistics show that there is a prevalence rate of 8.4% of diabetes mellitus globally and 3.8% in Ghana (IDF, 2017). Past studies investigating the relationship between OSA and T2DM have revealed a higher prevalence of OSA among T2DM patients even after adjusting for confounding variables like BMI and age.

### Problem Statement

The association between Obstructive Sleep Apnea (OSA) and Diabetes Mellitus (DM) has raised public health concerns worldwide. Notwithstanding, the relationship between these two conditions has not been well understood in developing countries. According to the International Diabetes Federation (IDF), the estimated number of diabetes cases at the outpatient care setting in Ghana was 518,400 in the year 2017 (Primary Care Diabetes Europe: Colophon, 2017). Most of these patients mostly go undiagnosed for OSA and hence management of their condition is problematic. The presence of OSA in DM worsens glycemic control and further contributes to DM-related cardiovascular complications. Despite the outstanding technological advancement to understand the bidirectional relationship between OSA and type 2 diabetes mellitus, few data are addressing the severity of the effect each condition has on the other (Moon et al, 2015).

A study conducted by Arosohn and colleagues in 2010 among 60 diabetes mellitus patients revealed that increasing severity of OSA was associated with poor glycemic control after adjusting for age, BMI, sex, race, number of diabetes medications, years of diabetes, total sleep, and physical exercise (Aronsohn et al, 2010). OSA and diabetes mellitus share common risk factors of age and obesity, which are also risk factors for cardiovascular disease. Predominantly, obesity is a prevalent risk factor. Studies have shown that a 10% increase in weight increases the risk of getting OSA by six-fold (Peppard, 2000). Hypoxaemia, evident in OSA has been shown to elevate inflammatory mediators in DM patients and this further worsens the condition of such patients. Even though OSA affects 24% of men and 9% of women, it is estimated that about 80-90% of patients are undiagnosed. (Young et al, 1997; Hussain et al, 2009). The public health burden of undiagnosed OSA cannot be underestimated due to its relationship with diabetes and cardiovascular diseases. Though, the implications OSA has on the management of T2DM has been elucidated in several studies (Hermans et al, 2009; Pillai et al, 2011) notwithstanding, OSA remains underdiagnosed and under-treated among individual populations with T2DM (West et al, 2006; Hermans et al, 2009; Pillai et al, 2011).

Additionally, the cost of management of DM is very high because of the comorbidities associated with it (Cho et al, 2018). It was therefore needful to investigate the risk of OSA and the prevalence of excessive daytime sleepiness in type 2 diabetes mellitus patients at the KorleBu Teaching Hospital using a questionnaire based approach.

### Significance of Study

Given the comorbidities and complications associated with diabetes mellitus, patients are advised to adhere to management protocols. Early identification of modifiable risk factors of DM is very relevant in the prevention of long-term cardiovascular risks associated with DM (Go et al, 2017). Information from this

study will help factor the treatment of OSA as part of the general management of T2DM. OSA is treatable using weight control and non-invasive ventilation with Continuous Positive Airway Pressure (CPAP) device in T2DM patients. The knowledge obtained from this research will also allow relevant stakeholders of health to put preventive measures in place to curb the burden T2DM poses considering its association with sleep-disordered breathing. In effect, there would be a conservation of resources in terms of healthcare delivery. Information from this study will also serve as a reference for further studies for researchers investigating similar research questions.

### Aim

This study aimed to determine the prevalence of excessive daytime sleepiness and the risk of obstructive sleep apnea among Type 2 Diabetes Mellitus patients attending the KorleBu Teaching Hospital (KBTH).

### Objectives

The objectives of these studies were to:

1. Determine the presence of risk factors for OSA among T2DM patients at the KBTH.
2. Determine the prevalence of EDS among T2DM patients at the KBTH.
3. To determine the relationship between obstructive sleep apnea, excessive daytime sleepiness, and T2DM.

### Literature Review

#### **Obstructive Sleep Apnea (OSA)**

OSA is a sleep disorder that is characterized by a temporal but repetitive cessation of airflow (apnea and hypopnea) in the upper airways during sleep usually resulting in the reduction of blood oxygen levels. In 2012, Valipour indicated that patients with this condition usually experience at least 15 apneas (complete cessation of breath during sleep) and hypopneas (partial cessation of breath during sleep) a night. Patient populations with OSA commonly present with symptoms such as excessive daytime sleepiness, morning headaches, a history of witnessed apneas or gasping, sleep disturbance, and cognitive dysfunction (Parati et al, 2012). Classical symptoms manifested in men with OSA are sleepiness, snoring and witnessed apneas (Arnardottir & Gislason, 2016). However, women with OSA usually present with different symptoms such as nightmares, fatigue, mood disturbances, insomnia and as such are seldom considered for evaluation of sleep-disordered breathing and hence diagnosis mostly missed in women (Basoglu & Tasbakan, 2017).

#### **Obstructive Sleep Apnea and Cardiovascular Disease**

A study done by Lurie in 2011, indicated that OSA is associated with an increased risk for cardiovascular diseases. According to WHO (2018), though OSA is not life-threatening, however, if left untreated it can result in detrimental cerebrovascular and cardiovascular problems including hypertension, ischemic heart disease, stroke and diabetes.

OSA is an important subject to consider in hypertensive patients. There is an estimated percentage prevalence of 30-70% of hypertension in OSA patients (Kaw, 2014) with about 30% of hypertensive patients with undiagnosed OSA (Kaw, 2014; Anh & Van, 2016). About 50% of hypertensive patients have accompanying OSA with current evidence supporting the claim that OSA is one of the most prevalent secondary causes of elevated blood pressure (BP) in patients with chronic

hypertension (Pedrosa et al, 2011). In normal healthy individuals, the physiological BP at night during sleep seems to decrease and is illustrated as a dipping pattern. However, in patients with OSA, this pattern is altered (non-dipping) considerably posing an adverse cardiovascular risk on such individuals (Endeshaw, White, Kutner, Ouslander, & Bliwise, 2009). The periodic stimulation of carotid baroreceptors during apneic events in OSA patients at night tends to increase the arterial blood pressure gradually. The elevation in the pressure eventually causes hypertension, increases vascular resistance and potentially generates congestive heart failure (CHF). Post apneic hyperventilation with stimulation of carotid baroreceptors usually causes an elevation in blood pressure, which can go up to 240/130 mmHg (Miglis, Muppidi, During, & Jaradeh, 2016). About two-thirds of patients will finally have diurnal hypertension (Mohsenin, 2014).

### Classification of Obstructive Sleep Apnea

The International Classification of Sleep Disorders (ICSD) classifies sleep-related breathing disorders into four (4) categories which are; obstructive sleep apnea (OSA) disorders, central sleep disorders, sleep-related hypoventilation disorders, and sleep-related hypoxemia disorder. Usually, more than one or even all these conditions could be present within the same patient, especially, OSA and central sleep apnea often co-exist in an exceedingly obese patient. Four primary contributors to OSA pathogenesis are identified and that they are a narrow, or collapsible upper airway causing “anatomical compromise” and “non-anatomical contributors which are; ineffective pharyngeal dilator muscle function during sleep, a coffee threshold for arousal to airway narrowing during sleep, and unstable control of breathing (Osman, Carter, Carberry, & Eckert, 2018). Each of those phenotypes may be a target during the therapeutic management of OSA.

### Risk Factors for OSA

The risk factors of OSA are gender, age, obesity, smoking, alcohol intake, stroke, coronary artery disease, hypertension, diabetes mellitus. Previously, OSA was highly recognized in men but recent studies show that OSA is not as rare in women as believed globally (Haqqee, Jordan, & Allen, 2017). OSA is more prevalent in men than women and increases with age and obesity (Franklin and Lindberg, 2012). Male gender from studies has shown to be an independent risk factor for developing the syndrome with a two to three-fold higher prevalence in men than women based on epidemiological studies (Kawada, 2016).

The male-to-female ratio is estimated to be 2:1 in a general population. Relevant explanations with male predominance in a general population include hormonal effects on the upper airway muscles, gender differences concerning body fat distribution and distinct pharyngeal anatomy and function (Fenik, Penzel, & Malhotra, 2019). However, the prevalence of OSA can be higher in postmenopausal women due to hormonal changes (Kendzierska et al, 2017). The pharyngeal anatomy gradually degenerates with aging in males, and the corresponding increase in upper airway malfunction with advanced age largely contributes to an increase in upper airway collapsibility (Carberry, Jordan, White, Wellman, & Eckert, 2016).

Snoring increases with age up to 50 to 60 years in both men and women presenting with OSA. Nonetheless, not all snoring is suggestive of sleep apnea (Ekbatani, Taavoni, & Haghani, 2012).

Snoring is a recurring event (with up to 40% prevalence in men and 20% prevalence in women) which occurs during sleep as a result of the vibration of the oropharyngeal structures and this signifies airflow resistance in the upper airway (Palou & AlonsoFernández, 2009). Snoring does not only create sleep deprivation and cause discomfort to the patient but frequent snoring is associated with a higher risk of cardiovascular disease (Javaheri, Omobomi, & Redline, 2019). Snoring occurs as a result of inflammation of the palate and a study by Grimbale in 2002, investigated that habitual snoring is a direct trigger of chronic insulin insensitivity.

Obesity as a risk factor of OSA is a major public health burden globally with increased morbidity or mortality. Obesity can be defined as having a body mass index (BMI) of at least 30 kg/m<sup>2</sup>. Obesity is the most relevant risk factor of OSA affecting about 70% of patients obese (Tuomilehto, Seppä, & Uusitupa, 2013). McPherson (2014), reports that overweight and obesity were estimated to cause 3.4 million deaths, 3.9% of years of life lost and 3.8% of disability-adjusted years in 2010 globally. The relationship between OSA and obesity has an enormous impact on the cardiovascular system than either condition on their own. According to WHO, there are about 1.6 billion adults who are overweight (BMI > 25 kg/m<sup>2</sup>) and 400 million obese (BMI > 30 kg/m<sup>2</sup>). Entirely, it has been estimated that about 20% of individuals in developed countries are obese and 1-2% morbidly obese ie BMI > 40 kg/m<sup>2</sup>. Even though obesity and overweight have raised public health concerns in western countries, low- and middle-income countries (LMICs) especially in urban areas and sub-Saharan African Countries like Ghana are facing a problem as the trend rises. Obesity is believed to incline OSA because of the mass loading in the upper airway regions (Marrone & Vicini, 2010). However, the controversy remains whether a definite measurement of body habitus, such as waist circumference and neck size better predicts OSA as compared with BMI alone. Peppard et al (2012), in his research, estimated that 58% of moderate to severe OSA cases are a result of a BMI ≥ of 25 kg/m<sup>2</sup> (Peppard et al, 2013). It has been previously investigated that a change in BMI affects the severity of OSA types (ie mild, moderate, and severe). To this end, as much as changes in BMI and OSA events are both closely related to increased cardiovascular risks, data on the effects of BMI on the severity of individual obstructive occurrence will give an understanding of the relationship between BMI and the overall severity of OSA (Leppänen, Kulkas, Mervaala, & Töyräs, 2018).

Cigarette smoking remains a serious public health problem and amounts to a large proportion of morbidity and mortality globally. Liao et al (2019), reports that in 2015 there were about 933.1 million people who smoke daily globally, and 6.4 million deaths (ie 11.5% of global deaths) were as a result of cigarette smoking worldwide. Smoking kills one in every 10 adults and causes 5 million deaths annually. Nicotine, the main stimulants in most cigarettes does not only make smoking cessation difficult but also causes withdrawal symptoms which are associated with poor quality of sleep and insomnia (Schnoll et al, 2011). Smoking has been shown to hurt sleep efficiency and sleep latency, contributing to insomnia, unrefreshing sleep and excessive daytime sleepiness, as demonstrated as Deleanu et al, (2012). The possible process describing the association between smoking and OSA include the inflammation of the upper airways and the impairment of the neuromuscular protective autonomic responses. Smoking conceivably leads to chronic inflammation of the upper airways by stimulating epithelium thickening,

cellular hyperplasia, edema and ciliary dysfunction (Hsu, Chiu, Chang, Chang, & Lane, 2019). There is a higher prevalence rate of smoking among patients with OSA ie 35% as compared to 18% without OSA (Kashyap, Hock, & Bowman, 2001). It is further hypothesized that smoking is perhaps an independent risk factor for OSA as the probability of current cigarette smokers with OSA is 2.5 times greater than nonsmokers and past smokers (OR = 2.5, CI = 1.3-4.7, p=0.0049), and a 2.8 times greater probability of having OSA than former smokers alone (OR=2.8, CI:1.4-5.4, p=0.0028) after elimination of different factors (Kashyap, Hock, & Bowman, 2001).

### Diabetes Mellitus (DM)

Diabetes mellitus (DM), commonly known as diabetes, is a metabolic disease that occurs as a result of the absence of insensitivity of the body to insulin. It is depicted by elevated levels of glucose in general circulation in the body (Cho et al, 2018). The pancreas is a relevant organ in the human body that assists in digestion. It performs both endocrine and exocrine functions hence its division into the endocrine portion (islets of Langerhans) and an exocrine portion (acinar and duct tissue). In performing its exocrine functions, it secretes pancreatic juice which contains enzymes needed for further digestion of useful metabolites in the body (Pandol, 2015). These secreted enzymes are amylase, lipase, chymotrypsin and trypsin (Chen, Xie, Shen, & Xia, 2018).

The endocrine portion of the pancreas produces and secretes five major hormones namely (glucagon, insulin, somatostatin, pancreatic polypeptide and ghrelin) responsible for glucose homeostasis. Notwithstanding, glucagon and insulin are the main hormones involved in controlling glucose homeostasis (Chen, Xie, Shen, & Xia, 2018). The pancreatic islets house three types of cells, namely, the alpha ( $\alpha$ )-cells, beta ( $\beta$ )-cells, and delta ( $\delta$ )-cells. The  $\alpha$ -cells of the pancreas are responsible for producing glucose in the bloodstream through the mechanism of hepatic glycogenolysis and gluconeogenesis (Quesada, Tudurí, Ripoll, & Nadal, 2008).

Conversely, the  $\beta$ -cells release insulin which aids in the removal of excess glucose from the blood into cells and also for storage in the liver as glycogen (Cernea and Dobreanu, 2013).  $\beta$ cells dysfunction impedes the secretion of insulin. Due to this, glucose homeostasis and tissue energy metabolism are affected by DM (Chen, Xie, Shen, & Xia, 2018).

### Types of DM

The onset of DM encompasses both environmental and genetic factors. The type and duration of the disease determine how severe the clinical signs and symptoms manifest (Kharroubi, 2015). The American Diabetes Association (ADA) in 2014 still considers the suggested classification of diabetes by the association in 1997 as the most recognized and adopted. ADA classifies DM as Type 1, Type 2 and Gestational Diabetes Mellitus. Kharroubi (2015), also includes two additional types, which are, mitochondrial diabetes and monogenic diabetes. Young adult patients may not ideally fit into a single class thereby making the classification difficult at times (ADA, 2014). OSA has been associated with type 2 diabetes mellitus.

### Type 2 DM

Type 2 Diabetes Mellitus (T2DM) is a complicated disorder that makes up approximately 90-95% of all DM cases (Kharroubi, 2015). In 2010, the estimated prevalence of T2DM globally

among adults was 285 million (6.4%) with this value expected to increase to around 439 million (7.7%) by 2030 (Shaw, Sicree, & Zimmet, 2010). The prevalence estimate rate of T2DM in Africa ranges from 0.3% to 17.9% (Wild et al, 2004) and adults are the most affected population when it comes to T2DM. Notwithstanding, there is an increase in the incidence among adolescents and children (Dabelea et al, 2014). The sequence from Normal Glucose Tolerance (NGT) to T2DM involves a series of stages which are Impaired Fasting Glucose (IFG) and Impaired Glucose Tolerance (IGT) usually called Prediabetes (D'Adamo & Caprio, 2011). Disturbance in the balance between glucose sensitivity and glucose secretion forms the bedrock in the development of T2DM. Chen et al, (2018) reported that the mechanism involved in the development of the disease is associated with insulin resistance, insulin hypersecretion and impaired function. Genetic and environmental factors play an important and complex role in the pathogenesis of T2DM because they contribute to the growth of insulin resistance in the muscle and liver in addition to  $\beta$ -cell dysfunction, the two (2) principal pathophysiological defects in T2DM (DeFronzo, 2009). Increased risk of morbidity and mortality and a decline in quality of life are associated with early onset of T2DM (Pinhas-Hamiel & Zeitler, 2007). Also, T2DM patients are predisposed to secondary obesity-complications such as metabolic syndrome, hypertension, nonalcoholic fatty liver disease and OSA all increasing cardiovascular risk (Pinhas-Hamiel & Zeitler, 2007).

### Pathogenesis of T2DM

The pathogenesis of T2DM is known to be progressive. A study conducted by Harrigan in 2007, shows that the principal mechanism for the development of T2DM is central (abdominal) obesity and insulin resistance however, it has also been established that insulin resistance and insulin secretion are the two ground laying effects involved in the development of T2DM (Bello et al, 2011). Evidence of insulin resistance playing a relevant role in the pathogenesis of the condition demonstrates that insulin resistance takes place 10-20 years before the onset of the disease and is the best predictor determining whether an individual would be diabetic or not in the later stages of life (Shulman, 2000). Obesity is identified as the most important factor of insulin resistance and it has been established that the important determining factor of insulin sensitivity is not the degree of obesity in itself but the distribution of fat to the central part of the body (Weiss et al, 2003). Fu et al (2013), also reported that it is usually associated with deterioration in energy metabolism which results in the accumulation of intracellular fat in various parts of the body such as the pancreatic islets, skeletal muscle and the liver.

The glucose production in the liver after an overnight fast is either increased or remains normal regardless of the presence of hyperinsulinemia in insulin resistance (Otero, Stafford, & McGuinness, 2014). This was attributed to the inability of insulin to balance glucose and uptake. Al Jobori et al (2018), state that, disruption in glycogen synthesis is an accepted distinctive and early impairment of insulin resistance in T2DM. The insensitivity to insulin in T2DM can be due to an impairment in insulin secretion and also a significant decrease in functional  $\beta$ -cells (Kahn, Hull, & Utzschneider, 2006). In situations of decreased insulin sensitivity, it very important for the pancreatic islets to secrete enough insulin to compensate for this impairment, through an increase in the amount of insulin secreted (hyperinsulinemia) due to improvement in the function of pre-existing  $\beta$ -cells and/or an increase in the  $\beta$ -cell mass.

This finally compensates for the decreased insulin sensitivity by restoring blood glucose levels to normal. Nonetheless, there is the likelihood of chronic insulin resistance progressing into T2DM if the  $\beta$ -cells are unable to secrete enough amounts of insulin to compensate for the impairment (Fu et al, 2013). The aftermath is elevated  $\beta$ -cell apoptosis and reduced  $\beta$ -cell mass and the dysfunction of  $\beta$ -cell characterizes T2DM development (Butler et al, 2003). Furthermore, the long stand subjection of the  $\beta$ -cell insulin secretion to increased quantities of fatty acids and glucose contributes to  $\beta$ -cell failure in the progression of T2DM (Fu et al, 2013).

### Obstructive Sleep Apnea And Type 2 Diabetes Mellitus

A large number of studies have shown that OSA has a close association with glucose intolerance, insulin resistance and type 2 diabetes (Pamidi & Tasali, 2012). Epidemiological studies according to Buxton et al, (2010) suggest that disturbed or short sleep has been associated with insulin resistance, glucose intolerance, reduced insulin sensitivity to glucose and increased risk of developing T2DM (Beihl, Liese, & Haffner, 2009; Chao et al, 2011; Chaput, Després, Bouchard, Astrup, & Tremblay, 2009; Tuomilehto et al, 2009). OSA is a common disorder that is often undiagnosed among diabetic patients in clinical practice. About 83% of patients with diabetes mellitus suffer from undiagnosed OSA which increases the severity of glucose tolerance (Pamidi & Tasali, 2012).

Poor concentration, fatigue, postprandial drowsiness and depression are some principal symptoms manifested in diabetic patients with OSA (Iyer & Iyer, 2008). There is repetitive stimulation of the sympathetic nervous in OSA patients and this is believed to be a result of intermittent hypoxia, recurrent arousals from sleep and sleep fragmentation. This recurrent stimulation leads to the release of stress hormones and catecholamines which are known to decrease glucose sensitivity and worsen glucose tolerance in DM patients (Iyer & Iyer, 2008). Furthermore, changes in somatotrophic and corticotrophic activity elevate levels of circulating adipocytes that alter glucose metabolism (Polotsky, Jun, & Punjabi, 2011). Habitual snoring in patients with OSA is a predictor of the onset of diabetes. According to JOO et al (2006), habitual snoring is consistent with reduced glucose tolerance, as investigated by abnormal oral glucose tolerance tests (OGTT) and elevated levels of HbA1c. Metabolic complications including type 2 diabetes mellitus, insulin resistance, hypertension and dyslipidemia are connected with visceral adiposity (Klein, 2010). Nocturia (frequent urination at night) is found to be increased in both

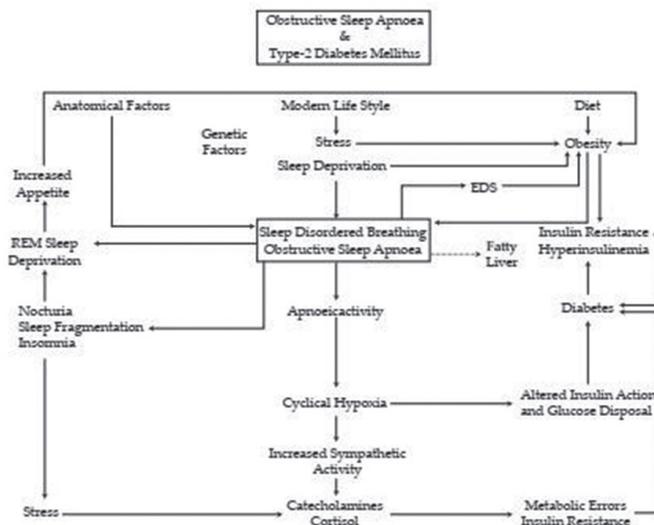
OSA and DM patients. This is a result of (1) the release of the atrial natriuretic peptide from the right atrium in patients with OSA (2) urinary tract infection and (3) hyperglycemia (Iyer & Iyer, 2008).

OSA prevalence is predicted to increase with age (Al-Abri, Al-Lawati, & Al-Zedjali, 2017) as well as blood glucose levels increasing with advanced age (Iyer & Iyer, 2017). Central adiposity is usually a peculiar character as individuals advance in age. The fat in the visceral regions of such individuals is metabolically active. An increase in body weight, recurrent upper airway collapsibility, decreased muscular endurance, decreased lung capacity, increased sleep fragmentation, decreased ventilatory control and decreased thyroid function are found to be the possible age-dependent risk factors for developing OSA in elderly patients (Iyer & Iyer, 2008).

### Common Risk Factors for Type 2 Diabetes Mellitus and Obstructive Sleep Apnea

Common risk factors for both T2DM AND OSA include:

1. Gender – male and postmenopausal females
2. Increase in the prevalence of OSA with advanced aging, the peak being 65 years for females (postmenopausal) and 55 years for males.
3. Metabolic syndrome – central obesity, dyslipidaemias (hypercholesterolemia), DM, hypertension.
4. Obesity
5. Cardiovascular morbidity and mortality.



**Figure 1.** A flow chart illustrating the close relationship between obstructive sleep apnea and type 2 diabetes mellitus and also the pathways taken by nocturnal events in a patient of obstructive sleep apnea resulting in the development of type 2 diabetes mellitus (Iyer & Iyer, 2008).

**Table 1.** Comparison of Type 2 Diabetes and Obstructive Sleep Apnea

Elements	Type 2 Diabetes Mellitus	Obstructive Sleep Apnea
Obesity	Often	Often
Sleep Disturbances	Usually Insomnia, Excessive daytime sleepiness, early awakenings may be associated with OSA	Snoring with excessive daytime sleepiness, sleep architecture disrupted. May have associated DM (OSA risk factor for DM)
Metabolic syndrome	Part of metabolic syndrome	A manifestation of metabolic syndrome
Family history	Yes	Yes
Post Prandial drowsiness	Yes	Yes
Lean subjects	Affected	Affected
Increasing prevalence with advancing age	Yes	Yes
Nocturia	Yes (glycosuria)	Yes (release of atrial natriuretic peptide)
Management of OSA	Rewarding for metabolic control	Rewarding and can prevent the development of DM in IGT

Table 1 expresses several similarities between type 2 diabetes mellitus and obstructive sleep apnea (Iyer & Iyer, 2006).

**Assessment and Diagnosis of Obstructive Sleep Apnea**  
Polysomnography (PSG) has been identified as the gold

standard for the diagnosis of OSA, but it's highly expensive, time-consuming, relatively inaccessible and requires trained personnel (Amra, Rahmati, Soltaninejad, & Feizi, 2018). However, various clinical models are developed over the years to effectively screen patients who are at high risk of developing OSA (Kushida et al, 2005; Ramachandran & Josephs, 2009; Manzar, 2015). The adoption of concise and precise screening tools can help medical doctors, respiratory therapists, sleep specialists and surgeons to help in the early recognition of OSA among different patient populations and also assist in the arrangement of PSG examination and OSA treatment strategies, especially in poor-resourced countries and sleep clinics where PSG is rare (Chiu et al, 2017). Validated screening tools like the STOP-Bang questionnaire (SBQ), the STOP questionnaire (STOP) and the Berlin questionnaire (BQ) are the most widely used for the detection of OSA. According to Johns (1991), the Epworth Sleepiness Scale (ESS), which was initially designed to assess the risk of excessive daytime sleepiness in patients has been also proposed to detect OSA.

The BQ developed in the year 1991, is used to determine risk factors for OSA. The Berlin questionnaire is one of the simplest, inexpensive and easily accessible tools used to screen OSA, according to a report from the Sleep in Primary Care Conference which took place in April 1996 at Berlin, Germany (Saleh et al, 2011; Netzer et al, 1999). It consists of 10 questions on the following three categories: snoring characteristic (category 1, items 1-5); daytime sleepiness or fatigue (category 2, items 6-9); medical history and anthropometric measurements like obesity and hypertension (category 3, item 10). Obesity is calculated as a Body Mass Index (BMI) using weight and height. This questionnaire groups patients into two categories or strata, that is, OSA high-risk and low-risk based on the responses provided (Karakoc et al, 2012). Patients are considered high risk for OSA when they show persistent symptoms (ie > 3-4 times a week) in at least two of the categories (Netzer, Stoohs, Netzer, Clark, & Strohl, 1999).

STOP-Bang questionnaire (SBQ) on the other hand was first developed in 2008 and used as a preoperative assessment tool to assess the risk of OSA in surgical patients (Chiu et al, 2017; Chung, 2008). Like the BQ, the SBQ is also a simple, convenient to use and self-reported screening tool for OSA. It consists of four subjective (STOP: Snoring, Tiredness, Observed apnea and high Blood Pressure) and four demographic items (Bang: BMI, age, neck circumference and gender) (Chung, 2008). This questionnaire was initially validated to screen OSA in surgical patient populations with a score of 5-8 classified as high risk for OSA (Chung, 2008). The sensitivity for the SBQ score  $\geq 3$  as the cut-off to predict any mild OSA (apnea-hypopnea index (AHI) >5), moderate-to-severe OSA (AHI >15) and severe OSA (AHI >30) was 83.9%, 92.9% and 100% respectively according to Chung (2008). The high sensitivity and simplicity of the SBQ has made it widely recognized and accepted in sleep clinics (Ong et al, 2010; Farney et al, 2011; & El-Sayed, 2012), preoperative clinics (Chung, 2008; Chung, 2012; & Nunes, 2014), the general population (Silva et al, 2011) and other unique populations (FIRAT et al, 2012 & Nicholl, 2013).

Excessive Daytime Sleepiness (EDS) is a very important symptom in various chronic sleep disorders including obstructive sleep apnea. The social and economic burden of sleep-related casualties are alarming and often unrecognized by both patients and clinicians (DINGES, 1995). The assessment

of EDS can be done both subjectively and objectively (Chung, 2000). Of the subjective method, the evaluation of excessive daytime sleepiness is done by the use of the Epworth Sleepiness Scale (ESS). The ESS is accepted to be in the comprehensive sleep assessment (Epstein et al, 2009) and it helps assist in the identifications of individual OSA patients with excessive daytime sleepiness because it can disrupt sleep (Johns, 1994). This is a self-administered, eight-item questionnaire use to estimate the extent of daytime sleepiness in adult patients (Johns, 1991). According to John (1991), the ESS asks patients to rate from a scale of 0-3 the likelihood of falling asleep in eight different circumstances (0 = would never doze; 1 = slight chance of dozing; 2 = moderate chance of dozing; and 3 = high chance of dozing). The ESS is currently the most widely recognized and easiest way of subjectively estimating daytime sleepiness amongst individuals presenting with OSA. Conversely, objective assessment of daytime sleepiness is done by the use of the Multiple Sleep Latency Test (MSLT) (Van den Hoed, 1981). With this method, the extent of daytime sleepiness can be assessed by how quickly a patient falls asleep (sleep latency) when given the chance to do so. The MSLT is cumbersome and less cost-effective, and as such only used to ascertain whether a simple objective scale like the ESS can suitably estimate mean sleep latency of the MSLT (Chung, 2000).

According to Chiu (2017), a suitable screening tool for detecting OSA in patients should consider sleep domains, feasibility and diagnostic accuracy. Regarding the assessment of sleep domains, the variables in the SBQ were developed based on OSA-related symptoms (ie snoring, fatigue during the daytime, cessation of breath during sleep, and hypertension) and clinical characteristics (ie age, gender, BMI, and neck circumference). Also considering feasibility, the SBQ is made up of four self-administered questions alongside four questions for demographic data and clinical characteristics (ie Age, BMI, neck circumference, and gender) (Chiu, 2017), with all responses rated as yes or no (Chung, 2008). Due to the short response time and few questions in the SBQ, there was a high response rate (91.2%-91.5%) based on past studies (Chung, 2008; Ong et al, 2010). Moreover, the SBQ has excellent sensitivity for determining OSA among diverse patient populations; notwithstanding, the substandard specificity of this questionnaire rendered its practicability limited in previous studies (Chiu, 2017). There is an early and accurate diagnosis of a good number of true-positive cases and thus minimizing medical costs and consequences of undiagnosed patients when a screening tool is highly sensitive (Chiu, 2017).

### **Management and Treatment of Obstructive Sleep Apnea**

Management and treatment of OSA improve the quality of life of patients by reducing the associated comorbidities of the disease. Positive Airway Pressure (PAP) therapies have been investigated as one of the most effective and relatively safe therapeutic methods of addressing OSA globally (Farrell & Richards, 2017). Farrell & Richards (2017), reports that, Continuous Positive Airway Pressure (CPAP), the primary treatment of sleep-disordered breathing like OSA is administered to the patient nasally, using both nasal prongs or nasal mask, or a full-face mask. CPAP is very effective when treating patients with moderate-severe OSA and affords a cost-effective use of resources in the healthcare setting of most developed countries (McDaid, 2009). The effect of CPAP on obesity, a risk factor of OSA and also a common finding in DM cannot be underestimated although the precise mechanism remains debatable.

The use of CPAP in the management of OSA has traditionally been recommended as an adjunct to aid in weight reduction, regardless of the inadequate evidence supporting this strategy (Joosten et al, 2017). The reverse has been established to be true. A post hoc evaluation of a randomized controlled trial (RCT) illustrated a mean weight gain of 0.3kg in patients using CPAP over 6 months while those who receive sham treatment had a mean weight reduction of 0.7kg (Quan, 2013). The mechanisms by which long-term use of CPAP can contribute to weight have recently been explained by Tachikawa et al, (2016). According to them, the use of CPAP leads to a very small decrease in basal metabolic rate without changing physical activity. Entirely, the discovery that prolonged use of CPAP contributes to weight gain emphasizes the relevance of combining weight loss and lifestyle modifications with CPAP treatments for all patients (Chirinos et al, 2014).

Bariatric surgery should be considered as a weight-loss strategy in obese patients with BMI >35 kg/m<sup>2</sup> with OSA and other obesity-related complications like arthritis, hypertension and diabetes or patients with BMI > 40 kg/m<sup>2</sup> without the aforementioned obesity-associated complications (Mechanick et al, 2008). This surgical procedure aids in caloric restriction, malabsorption, or both. The combination of weight-loss strategies and CPAP in the management of OSA significantly contributes to the quality of life than either alone in obese patients. In a randomized controlled trial of 136 patients, there was an improvement in blood pressure, lipids and insulin-sensitive with weight loss and/or CPAP than use of CPAP alone (Chirinos et al, 2014).

Surgical management of OSA is usually recommended as an alternative for patients who fail to benefit from the use of CPAP. The main relevance of surgical intervention is to address nasal obstruction, obstruction in the retropalatal, and retroglossal/hypopharyngeal regions, and in numerous patients where multiple levels of obstruction are identified (Randerath et al, 2011). A thorough physical examination is carried on patients who qualify for surgical intervention and this includes an examination of the nose/nasal cavity (ie for any external deformity, septal position or deviation, mucosal hypertrophy, nasal valve patency or collapse and nasal polyps), oral cavity (ie for trismus, tongue size/position, dental health), oropharyngeal region (ie for tonsil size, palatal/uvular elongation, modified mallampati score, and tonsil size), hypopharynx, larynx (ie true cord function and arytenoid location/dislocation) and neck for enlarged neck circumference (McNicholas, 2008). Recent evidence shows that effective management of OSA can attenuate the negative implications of untreated OSA and gradually slow the progression of associated comorbidities (Tasali & Ip, 2008; Patel et al, 2010; Kanagala et al, 2003; Fein et al, 2013). Two randomized controlled trials showed an improvement in the left ventricular ejection fraction as well as the overall quality of life in OSA patients with congestive heart failure (CHF) after 1-3 months of CPAP therapy (Kaneko et al, 2003; Mansfield et al, 2004). CPAP therapy was recommended as part of the guidelines of the 2010 Heart Failure Society of America Comprehensive Heart Failure (Heart Failure Society of America, 2010) and the 2013 American Heart Association Guidelines (AHA) (Yancy et al, 2013) for OSA patients with heart failure. Also, there is a significant improvement in the cardiovascular events of OSA patients with coronary artery disease after CPAP therapy. One

study confirmed a 36% reduction in the risk of fatal and nonfatal cardiovascular events in OSA patients undergoing CPAP therapy as compared to untreated patients, with this finding replicated in studies with prolonged follow-up durations (Cassar et al, 2007; Garcia-Rio et al, 2013; Marin et al, 2005; (Milleron, 2004). Additionally, there is an increasing body of evidence that the treatment of OSA with CPAP tends to lower fasting plasma glucose, postprandial glucose and glycosylated hemoglobin levels in diabetes patients (Tasali & Ip, 2008).

## Methodology

### Study Design

This study was a cross-sectional study involving type 2 diabetes mellitus patients at the National Diabetic Management and Research Centre (Diabetic Clinic) of the Korle-bu Teaching Hospital. This cross-sectional study sought to examine the relationship between suspected risk factors and the prevalence of a disease in diabetes mellitus patients.

### Study Site

The study was conducted at the Korle-Bu Teaching Hospital (KBTH) in the Accra Metropolis. This hospital is the largest premier government hospital in Ghana with about 2000 bed capacity. It serves as the leading tertiary referral center in Ghana. Three centers of excellence, the National Radiotherapy Oncology Centre, the National Cardiothoracic Center and the National Plastic and Reconstructive Centers can be found at the Korle-bu teaching hospital. The hospital has 17 clinical and diagnostic units with an average patient attendance of 1,500 and 250 patient admissions. The National Diabetic Management and Research Centre is the major referral center of diabetic patients at the KBTH. Patients have their usual diabetes clinical days from Mondays to Fridays with an average number of 70 patients reporting at the center each day.

### Participants

Participants were type-2 diabetes mellitus reporting at the center during clinical days. They were the ages of 30 years and above, confirmed type 2 diabetes mellitus patients at the clinic and signed an informed consent to partake in the study.

### Sampling Procedure

Participants were recruited based on convenient sampling. It was a convenient sampling of folders of patients attending the diabetic clinic each day based on the inclusion and exclusion criteria. 10-15 samples were collected over a 3-day period visit to the center. Additional information was obtained from participants via telephone call interviews.

### Sample Size Determination

The minimum sample size of participants for sampling is determined by the formula  $N = (Z^2(1-\alpha/2) P(1-P)) / d^2$

Where  $(1-\alpha/2)$ , is the standard normal variate at 5% type 1 error with a confidence interval of 95%.  $p$  is the expected proportion in population-based on recent surveys.

$d$  is the absolute error.

$p = 0.150$  (15.0%) from a study conducted on "The risk of obstructive sleep apnea, excessive daytime sleepiness and depressive symptoms in a Nigerian elderly population" (Fawale et al, 2016).

Therefore,

$$\frac{N = (1.96)^2 \times 0.150(1 - 0.150)^2}{0.05}$$

$N = 195.92 = 196$ . With the minimum sample size, 196 participants were to be recruited for the study but this number was reduced due to limitations imposed by the closure of universities and limited access to the study centre due to the COVID-19 pandemic. A sample size of 60 was selected to conduct a pilot study.

### Inclusion Criteria

1. Confirmed type 2 diabetes mellitus patients
2. Adult patients aged 30 years and above
3. Attendants and new referrals reporting at the diabetes clinic at Korle-bu.
4. Patients who consent to written or verbal consent.

### Exclusion Criteria

1. Children and adults aged below 30 years.
2. Pregnant women.
3. Patients who are mentally unstable and/or unable to communicate and cooperate.

### Sample Collection Procedure

During routine visits to the diabetes clinic, adult diabetes patients attending the clinic were selected for this study after authorization from relevant authorities of the National Diabetic Management and Research Centre and participants had given verbal consent over the telephone. The COVID-19 pandemic made it necessary for this research to be conducted using telephone call interview to administer questionnaires.

Specific demographic data including age and gender and level of education were obtained together with a background history of type 2 diabetes mellitus (ie the duration of disease and current treatment), diagnosis of hypertension or any other cardiovascular or pulmonary disease. Information regarding smoking status, use of caffeine, alcohol and psychoactive substance were also obtained.

Anthropometric measurements like height, weight, and blood pressure were extracted from patients' records. Body Mass Index (BMI) was computed from their height and weight. Two validated questionnaires were completed by interviewing participants by telephone. All 60 participants responded to the request for the telephone interview and the questionnaires were employed on these patients.

One of these questionnaires was the STOP-BANG QUESTIONNAIRE, which is a simple validated 8 item two-part instrument. The first part 'STOP' asks about symptoms of snoring, tiredness, observed apnea, and a history of high blood pressure. The second part includes a section where body mass index (BMI), age, neck circumference in (centimeters) and gender were documented. Neck circumference was however excluded from the questionnaire because of the inability to measure it directly on the patients due to restrictions imposed during the COVID-19 pandemic. A total score of 3 or above in a patient was considered as intermediate or high risk for obstructive sleep apnea.

### Scoring for STOP-BANG

**Low risk of OSA:** Yes to 0-2 questions.

**Intermediate risk of OSA:** Yes to 3-4 questions.

**High risk of OSA:** Yes to 5-8 questions

### However Intermediate risk becomes High risk if:

- Yes to 2 or more of STOP questions + Male gender.
- Yes to 2 or more of STOP questions + BMI > 35 kg/m<sup>2</sup>.
- Yes to 2 or more of STOP questions + neck circumference (>17 inches/43 cm in male, and 16 inches/41 cm in females).

The second questionnaire was the EPWORTH SLEEPINESS SCALE (ESS) QUESTIONNAIRE. This is also a validated 8 item instrument that measures the ease of falling asleep during the daytime under various circumstances as a measure of daytime hypersomnolence (Danilosio et al, 2017). The interpretation of the instrument is as follows:

1. 0-5: Good (likely getting restful sleep)
2. 6-10: Satisfactory (sleep could be improved but may not be to sleep apnea)
3. Above 10: Bad (likely to have excessive daytime sleepiness; suggestive of a sleep disorder possibly OSA).

### Data Management Plan

Data collected in this study was kept confidential in an encrypted personal computer for analysis. Data collected was also stored on an external drive for backup. This external drive was kept inaccessible to non-researchers and non-participants to ensure privacy. Hard copies were kept under lock and key. Information concerning the participants was made accessible to the researchers and participants only to ensure that issues of confidentiality with regards to the information obtained from participants are kept safe.

### Statistical Analysis

The data was analyzed using Statistical Package for Social Sciences (SPSS) version 22.0. Descriptive statistics such as pie chart, frequencies and percentages were used to analyze categorical and continuous variables. Correlation analysis was used to determine the relationship between OSA and EDS among T2DM patients, a comparison was made using chi-square and P-value of more than 0.05 was considered as significant in the analysis.

### Ethical Approval

Ethical clearance was sought from the Ethics and Protocol Review Committee of the School of Biomedical and Allied Health Sciences of the University of Ghana before the study. Approval was also sought from the National Diabetic Management and Research Centre at the Korle-Bu Teaching Hospital. The study was also explained to the participants giving them the option to accept or decline the opportunity to be involved in the study. The informed consent of participants was sought before the data was collected. Participation in this study was voluntary and participants were free to withdraw at any point. There was no risk associated with this study. However, much time was required from participants during the telephone call interview session.

### Dissemination of Results

Copies of the results were submitted to the School of Biomedical and Allied Health Sciences, Department of Respiratory Therapy as well as the School Library. The findings will also be published in peer-review journals.

## Results

### Introduction

This chapter focuses on data analysis and presentation of results. The topics covered are respondents' demographic information, observation of lifestyle of patients which includes smoking, alcohol intake, and BMI classification, to enable examination of risk factors of OSA or prevalence of excessive daytime sleepiness (EDS) among Type 2 Diabetes Mellitus patients, and the relationship between OSA, EDS and Type 2 Diabetes Mellitus. Primary data (questionnaire and interview guide) was employed for the analysis and SPSS was used to analyze and interpret findings.

### Socio-Demographic Data

#### Gender of Respondents

Out of a total of 60 patients surveyed, 14 of them equaling 23.3 percent, were male while 46 equaling 76.7 percent were female. Thus, more female patients were involved in the study compared to males.

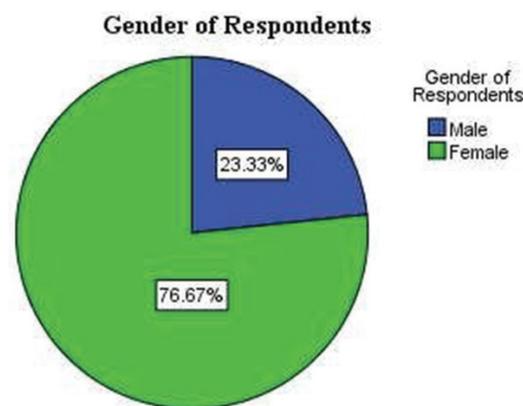


Figure 2.1 Gender of respondent

#### Age of Respondents

The mean age of patients in this study was  $59.8 \pm 10.4$  years with the mean age of females  $60.63 \pm 1.97$  and the mean age of males  $54.77 \pm 2.62$ . The patients were grouped into six (6) major age categories: 30-39, 40-49, 50-59, 60-69, 70-79 and 80 or above.

Table 2. Age groups of patients

Age Group (Years)	Frequency (N)	Percentage (%)	Mean Age	Standard Deviation
30 – 39	3	5.0	38.67	0.58
40 – 49	5	8.3	46.40	2.07
50 – 59	25	41.7	55.24	2.84
60 – 69	19	31.7	64.95	2.71
70 – 79	5	8.3	75.80	2.86
≥ 80	3	5.0	81.67	1.15
<b>Total</b>	<b>60</b>	<b>100.0</b>		

The findings in Table 2 show that most of the type 2 Diabetic patients interviewed were in the age categories of 50-59 and 60-69, equaling about 73.4 percent (41.7% and 31.7% respectively) among the interviewed patients. Very few patients represented the age groups 30-39, 40-49, 70-79 and 80 or above.

#### Educational Level of Patients

From the findings, 18 patients representing 30 percent of the respondents had no formal education. Out of the remaining 70

percent with formal educational background, 25 respondents, representing 41.7 percent were in the Basic level category. While 11 respondents representing 18.3 percent had Secondary level background and 6 respondents equaling 10 percent had tertiary educational level.

Table 3. Educational Level of Patients

Educational Level	Frequency (N)	Percentage (%)
No Formal Education	18	30.0
Basic Education	25	41.7
Secondary Education	11	18.3
Tertiary Education	6	10.0
<b>Total</b>	<b>60</b>	<b>100.0</b>

From the findings in table 2.2 above, the modal category for education variable was the Basic level. It could therefore be said that most patient who were interviewed for this study had basic level of education representing 41.7% out of the total sampled population.

#### Marital Status of Respondents

Out of the total 60 study participants interviewed, one patient, representing 1.7 percent was single. 47 patients, (78.3 percent) were identified as being in marital union while 12 patients (20 percent) who chose the 'others' option (were divorced or widowed).

#### Observation of Patients' Characteristics

This portion of the study focuses on lifestyle habits of patients which puts them at high risk for OSA as well as diabetic complications.

#### Lifestyle Habits of Patients

Specifically, on smoking of tobacco/cigarette, the majority of patients interviewed, 57 of them representing 95%, never engaged in smoking, whereas the remaining 5% (3 patients) smoked infrequently.

Considering alcohol intake majority, 60% of the patients (36 out of the 60 patients), never drank alcohol whereas 13.3% (8 patients) infrequently took alcohol and 16 out of the 60 respondents (17.7%) frequently took in alcohol.

#### Body Mass Index (BMI) of Respondents

Anthropometric measurements like height and weight were obtained from patients' records to aid computation of the Body Mass Index (BMI).

From the findings, as detailed in table 4, majority 35% of the patients were noticed to be overweight as their BMI fell within the range of 25.0-29.9 ( $\text{kg}/\text{m}^2$ ). 10 out of the 60 respondents were obese with their BMI greater or equal to  $30 \text{ kg}/\text{m}^2$  and 7 (11.7%) of the patients were underweight (BMI value  $< 18.5 \text{ kg}/\text{m}^2$ ). There were no morbidly obese patients (BMI  $> 35 \text{ kg}/\text{m}^2$ ) in this study.

Table 4. BMI of Respondents

BMI Category	Value ( $\text{kg}/\text{m}^2$ )	Frequency	Percentage (%)
Underweight	$< 18.5$	7	11.7
Normal	18.5-24.9	22	36.6
Overweight	25.0-29.9	21	35.0
Obese	$\geq 30.0$	10	16.7
<b>Total</b>		<b>60</b>	<b>100.0</b>

### Risk of OSA by STOP-BANG score

Information for assessing the risk of OSA was obtained from a validated questionnaire, the STOP-BANG questionnaire. This questionnaire addressed 8 attributes including snoring, tiredness, observation of choking/ceased breath/gasping in sleep, high blood pressure, BMI, age, neck size and gender. Neck circumference was scored as a “No” for all interviewed patients since majority of the them couldn’t give an accurate figure. Table 5 presents the scores of the patients.

**Table 5.** STOP-BANG Score of Patients

Scoring	Frequency	Percentage (%)
Yes to 0-2 questions	12	20.0
Yes to 3-4 questions	39	65.0
Yes to 5-8 questions	9	15.0
<b>Total</b>	<b>60</b>	<b>100.00</b>

Based on the scoring system of the STOP-BANG questionnaire and findings as shown in table 5, it indicates that the majority of the patients had intermediate risk for OSA with a few having high risk. Specifically, 39 out of 60 (65.0%) patients interviewed had Yes to 3-4 questions, hence were classified as patients with intermediate risk for OSA. Twelve patients (20.0%) had low risk for OSA whereas 9 patients (15.0%) had a high risk for OSA. Overall, including high and intermediate risk scores 48 patients (80.0%) had abnormal STOP-BANG score implying that they had moderate/severe risk for obstructive sleep apnea (OSA) whereas, 12 (20.0%) had a normal STOP-BANG scores signifying low risk for OSA. The mean score of patients with normal STOP-BANG score was  $1.17 \pm 0.58$  while that of patients with abnormal scores was  $3.71 \pm 0.80$ .

### Risk Factors for Medium-High STOP-BANG Scores in T2DM Patients

There were 38 patients (63.3%) aged 55 years and above who had abnormal STOP-BANG scores (moderate-to-severe risk for OSA) compared with 10 patients (16.7%) aged less than 55 years with abnormal scores.

**Table 6.** Body Mass Index (BMI) of Patients with Abnormal STOP-BANG

Body Mass Index (BMI)	Frequency (N)	Percentage (%)
Overweight	20	33.3%
Obese	10	16.7%

Table 6 shows that there were 20 patients (33.3%) who were overweight (BMI of 25.0-29.9 kg/m<sup>2</sup>) and also had medium-to-high risk for OSA. However, obese patients (BMI > 30 kg/m<sup>2</sup>) with medium-to-high risk for OSA formed 16.7% of participants.

**Table 7.** Patients scoring of the ‘STOP’ risk factors in the STOP-BANG questionnaire

Risk factor	Yes (%)	No (%)	Chi square	P-value
Snoring	50 (83.3%)	10 (16.7%)	11.76	0.02
Tiredness	53 (88.3%)	7 (11.7%)	13.45	< 0.001
Observed Apnea	13 (21.7%)	47 (78.3%)	4.22	0.07
P: High blood pressure	10 (16.7%)	50 (83.3%)	7.5	0.063

Table 7 above shows that majority of patients 50 (83.3%) snored and a few 10 (16.7%) had doctor-diagnosed high blood pressure based on the ‘STOP’ risk factor in the STOP-BANG questionnaire.

The presence of snoring and tiredness were significantly high in T2DM patients in the study with p-values 0.02 and < 0.001 respectively.

### Assessment of Excessive Daytime Sleepiness (EDS)

Under this section, ease of patients to fall asleep during the daytime under various circumstances as a measure of daytime hyper somnolence was determined using Epworth sleepiness scale (ESS).

Table 8 below shows the scores of patients on the ease of them falling asleep under various conditions.

**Table 8.** ESS Score of Patients

Scoring (Scale)	Frequency (N)	Percentage (%)
≤ 10	16	26.7
> 10	44	73.3
<b>Total</b>	<b>60</b>	<b>100.0</b>

Table 8 above indicates that 16 patients (26.7%) had a score ≤ 10 and 44 (73.3%) patients had an abnormal score of >10. This implies that the majority of the patients (73.3%) have excessive daytime sleepiness (EDS) while just over a quarter (26.7%) had no EDS. Patients with no EDS had a mean ESS score of  $8.63 \pm 1.02$  while patients with EDS had a mean ESS score of  $13.44 \pm 2.25$ .

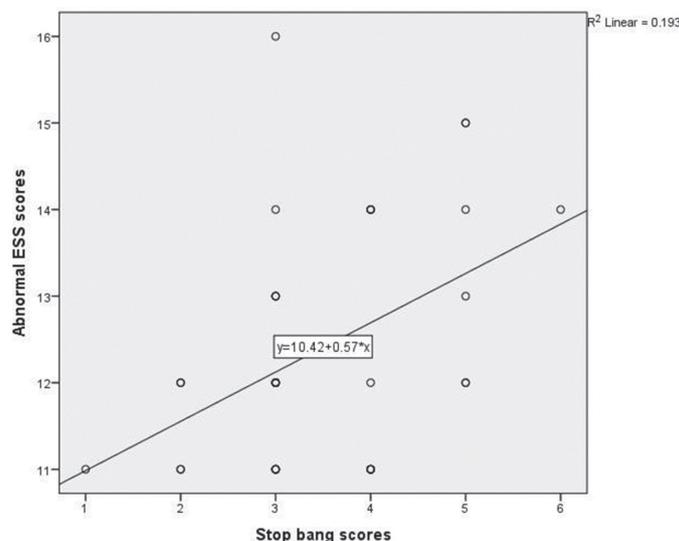
Additionally, comparing patients who answered ‘Yes’ to snoring, 37 out of 60 (61.70%) had abnormal ESS score and excessive daytime sleepiness (EDS), and 26 of them (70.3%) were females as shown in table 9 below.

**Table 9.** Gender of Patients with Both Snoring and Abnormal ESS score

Sex	Frequency (N)	Percentage (%)
Male	11	29.7%
Female	26	70.3%

### Relationship Between OSA And EDS

Figure 3 below shows the correlation between the STOP-BANG scores and the ESS scores amongst the 60 patients.



**Figure 3**

Correlation showed a significant linear relationship between the STOP-BANG and ESS scores of patients ( $r = 0.44$ ;  $p$ -value  $< 0.01$ ).

Additionally, comparing the mean difference of both patients with normal and abnormal STOP-BANG and ESS score in tables 10 and 11 below shows there is a significant difference between patient numbers, with significantly more T2DM patients with abnormal scores.

**Table 10.** Normal versus Abnormal STOP-BANG Scores

Stop-Bang Scores	Number of Patients	Mean Difference ( $X^2$ )	p-value
0-2	12	-2.250	$< 0.001$
3-8	48		

**Table 11.** Normal Versus Abnormal ESS Scores

ESS Score	Number of Patients	Mean Difference ( $X^2$ )	p-value
$\leq 10$	16	-3.393	$< 0.001$
$> 10$	44		

In Table 12, there was a significant difference between the mean ESS scores of patients with normal and abnormal STOP-BANG scores using the student T test ( $p$ -value  $< 0.001$ ), showing that T2DM patients with a high STOP-BANG score and medium-high risk of OSA were significantly more likely to have EDS. This supports the correlation between STOP-BANG and ESS scores in Type 2 diabetic patients demonstrated in Fig. 3.

**Table 12.** Comparison of ESS scores in patients with Normal (Low Risk) and Abnormal

	Mean ESS score Mean ( $\pm$ SD)	T-test	p-value of OSA
Low risk of OSA	8.4 (-2.159)	-6.37	$< 0.001$
Medium-High risk	11.8 (-1.884)		

## Discussion

### Introduction

Individual patients affected by OSA mostly suffer from diabetes, hypertension, dyslipidemia, metabolic syndrome and other related medical conditions (Lam et al, 2014; Drager et al, 2010 & Olufemi Adewole et al, 2009). There has been a scarcity of data in the sub-Saharan concerning OSA as compared to developed countries until recently (Mbata & Chukwuoka, 2012). This study did not employ the gold standard for the diagnosis of OSA since it mainly focused on the risk factors associated with OSA in T2DM patients. Since OSA and T2DM are associated with increased cardiovascular morbidity and mortality, it is comprehensible that the presence of both conditions results in synergistic risk factors (Greenberg & Rajan, 2015). This study, therefore, determined the prevalence of excessive daytime sleepiness and risk factors of obstructive sleep apnea among type 2 diabetes mellitus patients at the KorleBu Teaching Hospital in the Accra Metropolis, which further establishes an association between the conditions. This chapter discusses the findings about the study objectives and research aim.

### Prevalence of ESS and Risk Factors for OSA Among T2DM Patients

#### Age and Sex as Risk Factors for OSA Among T2DM Patients

In this study, the average age of T2DM patients was  $59.8 \pm 10.4$

years indicating that most patients were middle-aged adults, which is comparable to other works on adult T2DM populations (Akintunde, 2013). However, Wang (2019) reported an average age of  $63.5 \pm 11.6$  of T2DM patients in his study. In this study, there is a higher proportion (81.7%) of middle and older age groups (50-79 years) in comparison with the younger age group ( $\leq 49$  years) among the T2DM patients. There was a higher proportion of females (76.7%) in comparison with males (23.3%). The representation of females in this study was more than that of males possibly because females were more receptive to the interview than males. Age was a predictor of OSA in this study. The number of T2DM patients aged 55 years and above who had abnormal STOP-BANG scores (moderate-to-severe risk of OSA) made up 63.3% of patients in the study. However, a study conducted by Obaseki and colleagues (2014) in Nigeria, on the prevalence of OSA among a sample of 117 T2DM patients revealed a much lower proportion (25.1%) of moderate-to-severe OSA in T2DM patients. Aging causes an alteration in the upper airway muscles leading to greater upper airway collapsibility during sleep and predisposes them to the occurrence of OSA (Strollo et al, 2017).

#### BMI of Patients as Risk Factor for OSA

This study revealed 31.0% of participants take in alcohol (either infrequently and frequently) as well as 5.0% who smoke. The average BMI of  $25.7 \text{ kg/m}^2$  recorded in this study is lower than that of a study conducted by Obaseki et al (2014). This may be because the majority of the patients were more than 60 years of age in that study (Obaseki et al, 2014) as BMI increases with age (Zhang et al, 2015). The percentage of overweight and obese ( $\text{BMI} \geq 25 \text{ kg/m}^2$ ) was 51.7% which is lower than was observed in the Nigeria-based study (76%) conducted by Obaseki and colleagues. The proportion of Type 2 diabetes mellitus patients who had abnormal STOP-BANG scores (3-8) and were classified to have a moderate-to-severe risk for OSA was 80%. The average STOP-BANG score was  $3.71 \pm 0.81$  for such patients. The 'gold standard' for diagnosis of OSA is overnight Polysomnography. Notwithstanding, questionnaire-based screening tools can be used to assess patients who may have a high risk for obstructive sleep apnea. In this study, 15.0% of patients were at high risk for OSA and 20.0% were at low-risk OSA, however, the majority of patients (65.0%) had an intermediate risk for OSA. West et al, (2009) in a similar study of the prevalence of OSA in men with Type 2 diabetes found that 528 (56.2%) of the patients scored high risk for OSA while 362 (38.6%) were low risk. More patients were at high risk for OSA in their study probably because the sample population was solely male diabetic patients. Since the male gender is one of the predictors for OSA, this may explain the increased prevalence of high-risk patients for OSA in that study.

T2DM patients who were obese ( $\text{BMI} \geq 30.0 \text{ kg/m}^2$ ) and had a moderate-to-severe risk for OSA were 10 (16.7%). Also, overweight patients ( $\text{BMI} 25.0\text{-}29.9 \text{ kg/m}^2$ ) who had a moderate-to-severe risk for OSA were 20 (33.3%). Peppard et al, (2016) showed a strong relationship between an increase in BMI and risk of OSA. An increase in weight affects breathing in several ways. For example, the pharyngeal size and upper airway force of patients can be reduced as a result of increased adipose tissue in the upper airway or the muscle and this affects breathing during sleep (Oliven et al, 2016). Epidemiologic studies from around the world have consistently proven that BMI is the strongest predictor for obstructive sleep apnea (Akintunde, 2013). Though the neck circumference of patients in this study

was not measured, it is possible most overweight and obese T2DM who had abnormal STOP-BANG scores had large neck circumference.

### Prevalence of Excessive Daytime Sleepiness (EDS) Among T2DM Patients

Assessing the prevalence of excessive daytime sleepiness with the Epworth Sleepiness Scale (ESS) showed that the number of patients with a normal ESS score ( $\leq 10$ ) was 16 (26.7%). However, there was a significant number, 44 (73.3%) of T2DM patients with abnormal ESS scores and hence classified as having excessive daytime sleepiness (EDS). The mean ESS score for patients without EDS was  $8.63 \pm 1.02$  and that of subjects with EDS was  $13.44 \pm 2.25$ . Comparing the prevalence of EDS in this study to a similar study conducted by Obaseki and colleagues (2014), the latter showed a much lower prevalence of (22.0%) EDS among 117 T2DM patients that took part in the study in Nigeria. The reason for this low prevalence in that study was possibly due to a lower number of patients who reported as habitual snorers (35.0%). In this study, the number of patients who reported snoring and had abnormal ESS scores was 37 out of the 60 participants (61.6%) of which 11 (29.7%) were male and 26 (70.3%) were female.

### Relationship Between Excessive Daytime Sleepiness (EDS), Obstructive Sleep Apnea (OSA) and Type 2 Diabetes Mellitus (T2DM)

This study showed that 80% of T2DM patients had a moderate-to-high risk for OSA and 15.0% were at high-risk for OSA based on their STOP-BANG scores. Studies based on full polysomnography suggest that the prevalence of OSA in T2DM is higher than when using questionnaire-based screening tools to assess the risk of OSA (Obaseki et al, 2014). So in this study, patients with intermediate and high STOP-BANG scores were considered a medium-high risk for OSA. Comparing the mean ESS scores of T2DM patients who had low STOP-BANG scores (0-2) and medium-to-high STOP-BANG scores (3-8), it showed a significant difference between them in the ESS scores ( $p < 0.001$ ).

Correlation analysis (Fig.3) showed that there was a significant relationship between patients' ESS and STOP-BANG scores ( $p < 0.01$ ). Additionally, among T2DM patients interviewed in this study, there were significantly more patients with abnormal STOP-BANG scores and abnormal ESS scores ( $p < 0.001$ ), suggesting a significant association between T2DM, ESS AND OSA.

### Conclusion

In conclusion, this study showed that most patients with T2DM had a moderate or high risk for OSA. The prevalence of excessive daytime sleepiness was high in Type 2 diabetes mellitus patients based on this study, and it was a significant risk factor for patients with medium-high risk for OSA. The study further showed that older age, overweight, and obesity had an impact, increasing the risk of OSA in type 2 diabetes patients.

### Limitations

The limitations of this study were:

1. The sample size was smaller than the calculated sample size due to reduced access to patients and the need to conduct telephone interviews. This could have introduced sample bias.
2. An important parameter in the questionnaire (neck

circumference) was ignored in the study because restrictions on access to patients did not make it possible for it to be measured directly on the patients.

3. The use of telephone interviews made it very difficult to assess the true response of patients, or if there was a lack of understanding of questions. There was also in some cases the problem of the language barrier and the use of interpreters in translating the questions.

### Recommendations

The study recommendations are:

1. Recent studies have shown that sleep disorders impact on the development and management of diabetes so these important findings should be considered when managing diabetic patients.
2. The prevention or reduction of overweight and obese patients should be an important target in the treatment of T2DM as it puts them at increased risk of OSA.

Ambulant sleep studies like polygraph or full polysomnography should be conducted on T2DM patients found to have a significant risk of OSA and/or evidence of EDS, for corrective treatment with CPAP to be started.

### References

1. Akintunde, A. A. (2013). "Clustering of metabolic syndrome and obstructive sleep apnoea Syndrome Z among adult nigerians with systemic hypertension: Prevalence and clinical correlates". *International Journal of Cardiovascular Research*, 01(05).
2. Al Jobori, H., Daniele, G., Adams, J., Cersosimo, E., Solis-Herrera, C., Triplitt, C., & AbdulGhani, M. (2018). *The Journal of Clinical Endocrinology & Metabolism*, 103(4), 1402-1407.
3. Al-Abri, M., Al-Lawati, I., & Al-Zedjali, F. (2017). "Sleep pattern among young and middle aged Omani adults using actigraphy". *Sleep Medicine*, 40, e9.
4. Amra, B., Rahmati, B., Soltaninejad, F., & Feizi, A. (2018). *Oman Medical Journal*, 33(3), 184-192.
5. Anh, T. H., & Van, M. H. (2016). Ps 17-21 "effect of obstructive sleep apnea syndrome on essential hypertension". *Journal of Hypertension*, 34, e479.
6. Arnardottir, E. S., & Gislason, T. (2016). *Sleep Medicine Clinics*, 11(4), 421-434.
7. Aronsohn, R. S., Whitmore, H., Van Cauter, E., & Tasali, E. (2010). "Impact of untreated obstructive sleep apnea on glucose control in type 2 diabetes". *American Journal of Respiratory and Critical Care Medicine*, 181(5), 507-513.
8. Bais, R. (2005). *Clinical chemistry: Principles, procedures, correlations*, 5th ed. Michael L.Bishop, Edward P. Fody, and Larry Schoeff. Baltimore, MD: Lippincott Williams & Wilkins, 2005, 756 pp., \$76.95, hardcover. ISBN 0-7817-4611-6. *Clinical Chemistry*, 51(8), 1567-1567.
9. Basoglu, O. K., & Tasbakan, M. S. (2017). "Sleep and Breathing", 22(1), 241-249.
10. Beihl, D. A., Liese, A. D., & Haffner, S. M. (2009). "Annals of Epidemiology", 19(5), 351-357.
11. Bello, A., Adegoke, B., & Emmanuel, B. O. (2011). *International Journal of General Medicine*, 723.
12. Buxton, O. M., Pavlova, M., Reid, E. W., Wang, W., Simonson, D. C., & Adler, G. K. (2010). *Diabetes*, 59(9), 2126-2133.
13. Carberry, J. C., Jordan, A. S., White, D. P., Wellman, A., & Eckert, D. J. (2016). *Sleep*, 39(3), 511-521.
14. Cassar, A., Morgenthaler, T. I., Lennon, R. J., Rihal, C. S., & Lerman, A. (2007). *Journal of the American College of*

- Cardiology*, 50(14), 1310-1314.
15. Cernea, S., & Dobreanu, M. (2013). "Diabetes and beta cell function: From mechanisms to evaluation and clinical implications". *Biochemia Medica*, 266-280.
  16. Chao, C., Wu, J., Yang, Y., Shih, C., Wang, R., Lu, F., & Chang, C. (2011). *Metabolism*, 60(6), 799-804.
  17. Chaput, J., Després, J., Bouchard, C., Astrup, A., & Tremblay, A. (2009). "Sleep duration as a risk factor for the development of type 2 diabetes or impaired glucose tolerance: Analyses of the Quebec family study". *Sleep Medicine*, 10(8), 919-924.
  18. Chen, C., Xie, Z., Shen, Y., & Xia, S.F. (2018). *International Journal of Endocrinology*, 2018, 1-14.
  19. Chirinos, J. A., Gurubhagavatula, I., Teff, K., Rader, D. J., Wadden, T. A., Townsend, R., Foster, G. D., Maislin, G., Saif, H., Broderick, P., Chittams, J., Hanlon, A. L., & Pack, A. I. (2014). *New England Journal of Medicine*, 370(24), 2265-2275.
  20. Chiu, H., Chen, P., Chuang, L., Chen, N., Tu, Y., Hsieh, Y., & Guilleminault, C. (2017). *Sleep Medicine Reviews*, 36, 57-70.
  21. Cho, N., Shaw, J., Karuranga, S., Huang, Y., Da Rocha Fernandes, J., Ohlrogge, A., & Malanda, B. (2018). *Diabetes Research and Clinical Practice*, 138, 271-281.
  22. Chung, F., Subramanyam, R., Liao, P., Sasaki, E., Shapiro, C., & Sun, Y. (2012). *British Journal of Anaesthesia*, 108(5), 768-775.
  23. Chung, F., Yegneswaran, B., Liao, P., Chung, S. A., Vairavanathan, S., Islam, S., Khajehdehi, A., & Shapiro, C. M. (2008). *Anesthesiology*, 108(5), 812-821.
  24. Chung, K. (2000). "Use of the Epworth sleepiness scale in Chinese patients with obstructive sleep apnea and normal hospital employees". *Journal of Psychosomatic Research*, 49(5), 367-372.
  25. Cummings, K. M. (2010). *Behavioral and Social Science*.
  26. Dabelea, D., Mayer-Davis, E. J., Saydah, S., Imperatore, G., Linder, B., Divers, J., & Hamman, R. F. (2014). *JAMA*, 311(17), 1778.
  27. D'Adamo, E., & Caprio, S. (2011). *Diabetes Care*, 34(Supplement\_2), S161-S165.
  28. DeFronzo, R. A. (2009). *Diabetes*, 58(4), 773-795.

# Hospital to Home: NAVA Liberation Solved with the Vivo 65

Mark Marinello, MD

What happens when an infant cannot be weaned from the NAVA<sup>1</sup> to go home? This happened to a patient at the Pediatric Intensive Care Unit at VCU Health. An infant initially diagnosed with interstitial lung disease required high pressure ventilation that became difficult to wean over the following months. She was eventually transitioned to ventilation with NAVA. Early on, NAVA saved her life. According to Dr Mark Marinello, Medical Director of the Pediatric Intensive Care Unit, *“Had we not had that mode, I don’t know. She likely would have died of some kind of hospital-acquired infection because the only other way we were able to ventilate her—early in her life, was when she was sedated & paralyzed. Every time we would wake her up, she would just fight this ventilator and not be able to tolerate a rate, but she wasn’t strong enough to be on a CPAP or a no-rate mode...Slowly, day by day, month by month, over time she grew. She got bigger. We were able to wean off that sedation stuff. Clearly she got stronger.”*



She remained in the hospital for three years growing and developing, but not able to breathe without NAVA. *“We didn’t really understand why we couldn’t get this patient off of NAVA. Her diaphragm was clearly strong enough to trigger breaths.”* said Dr Mark Marinello. But various home ventilators they tried were not able to detect inhalation effort.

The clinical staff reached out to their colleagues around the world asking whether anyone else had this issue and how

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they could solve it. Finally, they heard about the Breas Vivo 65 ventilator from their respiratory therapy Director, Jennifer Reed, who had seen it at a local AARC conference. She heard about the sensitive trigger technology and wondered whether it would help this patient. The Vivo 65 uses a patented trigger technology called eSync™. Most home ventilators sense flow or pressure to trigger inspiration. eSync senses inspiration from airway gas flow velocity acceleration generated by the patient’s diaphragmatic inspiratory effort. It measures the level of energy of effort on a breath-by-breath basis and triggers accordingly.

The Vivo 65 was brought in and they slowly transitioned the patient over the course of several months to using the Vivo 65 until she transitioned to full time use. Transitions for an active four-year-old take time.

They move around causing leaks which can cause auto trigger asynchrony and alarms with traditional flow and pressure triggers. The eSync trigger works relatively independent of leaks as it looks for airway gas velocity accelerations that do not occur with the steady or slow gas velocities associated with leaks. According to Dr Marinello, *“There were times where she would have a big leak. And so the other (home) vents don’t tolerate that well. They alarm. They don’t work. They kick off. That’s a big deal, too, especially for kids, toddlers, infants.”*

Over 10 weeks, the PICU team worked on training her diaphragm off of NAVA. Once she was able to tolerate the Vivo 65 full time, she was able to go home with her parents 12 weeks later. Over those 12 weeks, the team learned how to use the 3 mode profiles offered by the Vivo 65. They created one mode for sleeping, one mode for her daily activities, and a “rescue” mode for when she became stressed or dyspneic. The parents were shown how to adjust the Vivo 65 using the three profiles. *“They understood what mode one, two, and three were for her easily, and they knew when she needed one versus the other... We could put in what we call the rescue mode that gave her a little bit more support if she got stressed or something and then a sleeping mode which when she was totally relaxed,”* explained Dr Marinello.

Since the first patient was weaned from NAVA to go home on the Vivo 65, the hospital has successfully transitioned a second long-term patient in the NICU who was approaching their first birthday and other than the NAVA was ready to go home. After failing on the other home ventilators, the patient was transitioned to the Vivo 65.



The patient was finally discharged at 15 months of age.

Before trying the Vivo 65, the pulmonologists and staff were skeptical that a home ventilator could offer something different. *“But,”* as Dr Marinello explained, *“I think it’s hard to deny—anybody who stood in front of this patient as we transitioned her from one vent to another could clearly see that there was a difference in her response.”*

## Reference

- 1 NAVA, Neurally Adjusted Ventilatory Assist is a lifesaving ventilation mode used exclusively on the SERVO (Getinge) critical care ventilator. A catheter to measure the electrical activity of the diaphragm (Edi) is inserted in the esophagus close to the patient’s diaphragm to sense the inspiratory effort and trigger ventilator breaths. It is often used on low birth weight, premature infants to facilitate patient-ventilator synchrony on a breath-by-breath basis. The weaning process from NAVA usually occurs spontaneously as the infant grows and improves their ability to initiate breaths on their own.

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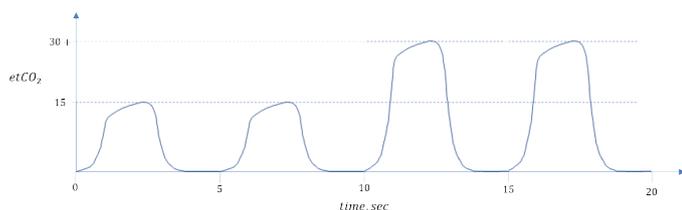
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# Key Measure for Proper Airway Placement, Return of Spontaneous Circulation, and Advanced Airway Displacement

John Zaleski, PhD, NREMT

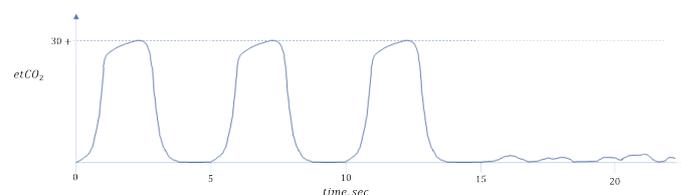
Emergency medical personnel, whether in the field or in the emergency department, are frequently faced with respiratory distress and failure and cardiac arrest. A key tool in monitoring and assessing cardiac and respiratory function, particularly when working with advanced airway placement, determining adequacy of chest compressions, and return of spontaneous circulation, is capnography, which provides immediate assessment of ventilation adequacy. The key measure obtained from capnography, End-tidal carbon dioxide, or  $etCO_2$ , is an indicator of active ventilation. In patients who are in cardiac arrest or who have an advanced airway (eg: supraglottic airways such as laryngeal mask airways and endotracheal tube intubation), the placement of the airway and its ability to transport air is directly discernible using end-tidal capnography. In patients who are in cardiac arrest, and for whom an advanced airway is in place, artificial positive-pressure ventilations are typically applied at the rate of eight-to-ten breaths per minute, or one breath every six-to-eight seconds. This contrasts slightly with non-intubated positive-pressure assisted ventilations, such as those using a bag-valve mask (BVM), in which, depending on the patient (ie, adult versus pediatric versus neonate) will be one breath every three-to-five seconds, or roughly twelve-to-twenty breaths per minute.<sup>1,2</sup> pp. 506-526 In the case of return of spontaneous circulation, end-tidal capnography may indicate values under fifteen mmHg, although experience has shown that this can vary widely. Capnography is also quite useful in guiding compressions in the case of cardiopulmonary resuscitation: in terms of providing feedback on effectiveness and rate of compression, which should be between one hundred and one hundred twenty compressions per minute. When a patient regains spontaneous circulation, a large increase to normal or elevated levels of end-tidal capnography are often seen as circulation begins to rid the body of excess carbon dioxide during exhalation and there is a return to normocapnia. This is illustrated in the plot of Figure 1.<sup>3,4,5</sup>



**Figure 1:** Capnography waveform typical of return of spontaneous circulation (ROSC) after cardiac arrest.

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The displacement of an advanced airway can result in little to no air entering or exiting the lungs, and in this case the capnography waveform is lost, as is shown in Figure 2.<sup>3,4,5</sup> It must also be noted that such an event may also be coincident with cardiac arrest, such as might be seen in a patient who is already intubated but lapses into asystole. Hence, capnography will indicate either the lack on effective ventilation that is due to displacement of the advanced airway, or the onset of cardiac arrest—both emergent events requiring immediate intervention.



**Figure 2:** Capnography waveform typical of displacement of an advanced airway.

In summary, real-time feedback is obtained on ventilation and placement of advanced airways, adequacy of chest compressions, and the possible dislodgement of the airway. These findings are critical to ensuring maintenance of life functions. Capnography is an essential link in establishing the adequacy of airway patency, breathing, and circulation—the ABCs of vital assessments that are key to life. Vital signs and medical device data capture has always been the essential foundation of Capsule's offerings, and with capnography, Capsule further underscores its commitment to patient safety.

## References

- 1 C. Newell, S. Grier and J. Soar, "Airway and ventilation management during cardiopulmonary resuscitation and after successful resuscitation," *Critical Care*, vol. 22, no. 190, 2018.
- 2 D. Limmer and M. F. O'Keefe, *Emergency Care* 13th ed., Pearson Education, 2016.
- 3 R. L. Duckworth, "How to Read and Interpret End-Tidal Capnography Waveforms," *JEMS*, vol. 42, no. 8, 2017.
- 4 B. Sullivan, "5 things to know about capnography," 8 July 2020. [Online]. Available: <https://www.ems1.com/ems-products/capnography/articles/5-things-to-know-about-capnography-Hr5ETRdXzCoU3fLH/>
- 5 B. Sullivan, "4 things paramedics need to know about capnography and heart failure," 17 October 2016. Available: <https://www.ems1.com/ems-products/capnography/articles/4-things-paramedics-need-to-know-about-capnography-and-heart-failure-IKcfyCmVA6dw5qz3/>

# Perspectives on 2020: A Year of New Challenges

Gail Sudderth, RRT

At the beginning of 2020, respiratory therapists from the United States and around the world began to face an unprecedented time, a global pandemic—a virus that is one the worst in recent times. In the US, some of the first reports, of what is now known as SARS-CoV-2 (COVID-19), and its catastrophic toll on the respiratory system occurred in the Pacific Northwest in the state of Washington. In early 2020, while speculation ran rampant, what was to come for both medical professionals and personal lives was unknown.

On March 18th, Carl Hinkson and Darryl Keefer, both respiratory therapists (RT) from the state of Washington shared what they saw and faced in the early stages of the pandemic (aarc.org). What they reported experiencing was beginning to be seen around the rest of the country, at first mainly in major cities and densely populated areas, with the early numbers spiking from the east and west coasts. Their patients were admitted with mild to moderate respiratory illness that very rapidly escalated to respiratory failure and did not respond to traditional pathways and standard treatments. That was just the beginning. Early on, healthcare practitioners knew they were facing an extraordinary, uphill battle.

When many other facilities were inundated with extremely ill patients, clinicians faced many unknowns and were called upon to make critical decisions quickly, often with very little information or direction. Since the initial presentation for these patients was a compromised respiratory system, which deteriorated very rapidly, respiratory therapists were on the front lines of the pandemic providing both supportive and critical care. Hospital leadership faced new challenges that increased the use of telemedicine, established new ways of procuring personal protective equipment (PPE), and led to creative solutions for increasing ICU beds and staff.

Now, with some experience to draw for decision-making when caring for patients diagnosed with COVID-19, reflection on the lessons learned has led to changes in standard processes and policies. This paper will not address the medical treatment interventions for this patient population, as this is being studied

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Gail Sudderth has been a registered RT for over 35 years. She has experience in multiple settings, with a primary focus on acute care and working with patients on mechanical ventilation. She provides education regularly and publishes articles on working with patients with tracheostomies and mechanical ventilation for both domestic and international audiences. She is a full-time clinical specialist with Passy-Muir, Inc.

and reported regularly, but rather will focus on the role of the respiratory therapist as part of the healthcare team, and how practice patterns may change going forward in regard to the RT's role, infection control practices, and the importance of self-care.

## Teamwork

Early in the pandemic, it became clear very quickly that “we are all in this together,” which meant teamwork was vital. It was an unprecedented time where the typical quality care and care plans to save lives had to be adjusted to meet extraordinary circumstances. Historically, clinicians worked more independently, and this led to an approach that was more like working in silos, with limited daily communication with one another regarding the plans of care. Now, during the pandemic, clinicians have found that quick decisions depend on continuous interdisciplinary communication amongst the team members.

At times, many practitioners have been forced to step out of their comfort zone, incorporating treatment strategies and circumventing problems that had not been a part of the normal routine prior to the pandemic. This pandemic called for co-treatment strategies, sharing responsibility for many procedures, learning and teaching new procedures, and keeping up with the latest discovery or research on direct care. More than at any other time, the members of the medical team and all staff within the facilities each have vital roles in assuring that patients receive the necessary treatments for recovery. It would have been difficult for any RT to imagine the sheer magnitude of what would be asked of them during the pandemic, but it is what they have been trained to do. When tough decisions have to be made, it has been comforting to know, that as part of a team, RTs have not been alone.

To many, social media has provided an outlet to release frustrations, to share concerns about the perception of roles during the pandemic. But looking on a more positive side of something that is overwhelmingly negative, respiratory therapists have been presented with a unique opportunity to cement their role as a valuable member of the team during and beyond this pandemic. Continuing teamwork, teaching others on the team, and learning from team members will enhance clinical practice. The opportunity to join a committee, participate in or design a quality improvement project, attend grand rounds, or even present a case study assists with developing the role of an RT on a team. Taking the time to mentor a new graduate or traveling RT and leading by example are options that may propel RTs to a level of recognition and participation that was not seen previously.

## Respiratory Therapists on the Front Lines

Respiratory therapists practice in all types of facilities, and whether they were working in an acute care facility in one of the hardest hit very populated areas in the US, smaller hospitals in rural areas, in rehabilitation centers, long-term acute care facilities, or skilled nursing facilities, all have been met with soaring patient admissions requiring respiratory care. It did not matter if the symptoms were mild or severe on admission, or if the patient was in recovery, it was established early on that most patients exposed to or diagnosed with SARS-CoV-19 (COVID-19) and would require some type of intervention by a respiratory therapist. When any patient has been compromised, maintaining an airway and assuring adequate oxygenation and ventilation has been the most important aspect of their care. While this is the training of a respiratory therapist, they have been asked to step up to one of the biggest challenges of their career.

In addition to the respiratory system compromise, this virus is airborne, which has added more layers to the challenge. Now, while respiratory therapists were caring for a record number of patients, they also had to assure that they were performing this care in the safest way possible, protecting themselves, other caregivers, the patient, and the environment. This care required that more personal protective equipment (PPE) be sought and used during the direct care of patients. Medical facilities developed COVID wards or floors with strict entrance and exit requirements. Therapists saw an unprecedented number of PPE being used. Initially, this led to a shortage of equipment. Ironically, companies that made other types of equipment started making PPE, and companies that previously made cars and other items not even related to medical care, began producing the much-needed mechanical ventilators. The level of patient compromise and the levels of this challenge caused many changes, even from unexpected directions.

Another consideration is that many of the therapies provided by respiratory therapists are aerosol generating procedures (AGP). AGPs are any procedure that potentially aerosolize the virus through breathing or coughing, among other functions. Bronchodilator therapy, bronchopulmonary hygiene, invasive and non-invasive mechanical ventilation are just a few of the therapies provided by the respiratory therapist which are all aerosol generating procedures (AGPs); therefore, it became critical to take a new look at how these therapies were delivered.

In discussions, many are already beginning statements with, “remember, before COVID, when ...?”

Historically, following a crisis or new discovery, our behavior changes, sometimes significantly. Even simple things, previously taken for granted, are looked at from a totally new perspective. In the field of healthcare, when a deficiency is identified that impacts safety, life, or limb; a discovery for a new treatment is made; or, in this case, a pandemic impacts care practices patterns, then a paradigm shift occurs and patterns change. For instance, while only a simple example, seasoned respiratory therapists will remember when gloves were not worn to draw blood gases; surgeons remember when there was no pre-procedure pause or boarding pass; and there was a time when *red rules*, rules that cannot be broken, did not exist. In the past, practices such as these developed because faulty practices were identified, and procedures were re-designed to meet the challenges and make delivery of care safer for the patient and the clinician who is providing the care.

As previously mentioned, the virus is airborne and almost every therapeutic intervention RTs administer or are involved in, is an AGP. Because of this, the standard practices were scrutinized and changed. For example, it was suggested early that patients should stay intubated longer instead of receiving a tracheostomy; nebulized medication was only delivered by metered dose inhaler; and, some procedures were not performed at all except in an emergency or in a very controlled situation with a limited number of clinicians. Eyes were opened to the amount of risk RTs and all healthcare practitioners were taking every day just by providing what had previously been considered routine care. As more and more cases were studied, procedures were reviewed, and practice changes were suggested. Then, when more information became available, practices were re-examined and more changes occurred.

The pandemic has had a big learning curve associated with it as previously unseen challenges were addressed. And, of course, since necessity is the mother of invention, a few changes included development of extubation tents or boxes, new methods for connecting ventilator circuitry, use of extra filters, and even practice changes. The use of PPE took on a whole new role in our practice and in the world—becoming a major area of need. The high use of PPE caused it to become scarce and new ways to conserve and safe ways to reuse some PPE were suggested. As the pandemic continues and new numbers are reached, how does healthcare move forward and how will what has been learned impact infection control procedures in regard to AGP and PPE practice patterns in the future?

## Self-care

It has often been said, in times of crisis people rise to the challenge and show incredible humanity, compassion and strength, and heroes emerge. In 2020, from the beginning of the COVID-19 pandemic—this has been no exception. Even on a “good” day, a healthcare worker has an incredibly challenging job, both physically and mentally. Clinicians have been faced with so many unknowns, but they stepped up and did what had to be done. Even under dire circumstances which included inadequate staffing, limited equipment, and low PPE access, many worked countless hours without relief due to the high numbers of patients who required constant attention.

Fears arose about going home to their families and spreading the virus to them. Although healthcare workers have faced losing patients, as it is an unfortunate reality of medical care, during the pandemic the amount of loss was inconceivable and the toll demoralizing. An unusual aspect of the pandemic is that loss became personal, as the virus took colleagues, family members, and friends.

This state of fear, loss, stress, and anxiety occurs so regularly that there often has been little to no time to just take time out for oneself to rest and regroup. When a shift ends, lockdown restrictions limited where someone could go. The ability to enjoy time away from work and to decompress was limited. Pride in the profession and knowing the amount of effort given only takes someone so far. Having time to regroup and relax is a key piece of providing best care to others.

Everyone knows how the airlines tell passengers in the safety talk to secure their own masks first, before helping others who may need it. This analogy presents a philosophy that all could adopt. It is not about being selfish, instead, it is a necessity. To

properly care for others, one must assure they are prepared and healthy—both mentally and physically—to do the work that is required to care for others. Some ways to enhance self-care and to help fellow RTs would be to consider organizing a weekly debrief with colleagues. During the debrief, not only would patient care be discussed but offering each other support and sharing what is needed personally to be a better provider would help others to get through the day and the pandemic. Each therapist needs to be sure to get enough rest and eat well. Activities such as meditation, reading a book, exercising, seeking out pastoral care or counselling and other self-help options will begin to balance life and work.

Since early 2020, the AARC (American Association for Respiratory Care) has been very actively supporting respiratory therapists around the country and sending letters to leaders in the US, including Vice President Pence, and to members of Congress, Health and Human Services, and the Surgeon General, asking for recognition of the contributions made by respiratory therapists. A letter from the chair of the AARC Board of Medical Advisors (BOMA) that was sent to the US Surgeon General shared the valuable contributions made by respiratory therapists as they provide a critical role in monitoring and assessing patient's respiratory needs on the front lines every day and contribute to the well-being of the nation in the face of COVID-19 (Papadakos, 2020).

As the holiday season begins, reports show that new spikes in cases are being seen all around the country. Whether this is a second wave, or a continuation of the first, has been debated. What is not up for debate is the role of the RT during this pandemic and the key part RTs play both on the team and in the care of patients with COVID-19. For best care, RTs must first take care of themselves, remembering to have team meetings, apply new knowledge, and being vigorous in the use of infection control procedures.

## References

- Papadakos, P. (2020) Letter to the surgeon general. Retrieved from <https://www.aarc.org/wp-content/uploads/2020/03/BOMA-letter-surgeon-general-032420.pdf>

# High-Flow Nasal O<sub>2</sub> Therapy Used as an Alternative to CPAP and NIMV to Improve Comfort and Relieve Distress

Robert DiBlasi RRT-NPS, FAARC

A premature infant on relatively high levels of CPAP following extubation in the NICU tolerated a heated high-flow nasal cannula (HFNC) better, resulting in reduced anxiety, lower respiratory distress, and improved gas exchange.

At birth, Baby Boy (BB) was a 25-week, 560-gram premature infant born at a community hospital following a complicated C-section delivery for intrauterine distress. He was transferred to a Level IV NICU for further care on day of life 20. Upon arrival, BB was intubated and placed on the Dräger Babylog® VN500 ventilator in Assist Control with Volume Guarantee mode.

Over the next several days, BB was weaned from mechanical ventilation and extubated to non-invasive ventilation using PC-CMV with the Dräger VN500. Within 24 hours, BB was reintubated for severe respiratory distress. Subsequent attempts to wean and extubate him from invasive ventilation over the next several weeks were unsuccessful due to increased WOB, severe agitation, hypercarbia, and increasing FiO<sub>2</sub> requirements.



On day of life 40, BB remained on the ventilator with severe BPD, mild pulmonary hypertension, small grade III/IV IVH, and mild tracheomalacia. He also had a surgical closure of a patent ductus arteriosus. Following a course of Dexamethasone, the PIP was 10-12 cmH<sub>2</sub>O on the PC-SIMV with VG mode with VT 7 mL/kg and PEEP 6, FiO<sub>2</sub> 0.35. There was a small audible endotracheal tube leak, minimal work of breathing, and a chest X-ray showed good bilateral inflation.

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The following day, BB was extubated to non-invasive PC-CMV 20/5, Ti: 0.4s, FiO<sub>2</sub>: 0.40. Initially, there was mild upper airway obstruction, stridor, grunting, nasal flaring, intercostal and substernal retractions, and occasional apneic episodes responding to intermittent tactile stimulation. There was some improvement in relieving the obstruction following administration of an 11.25 mg/0.5 mL racemic epinephrine nebulizer and by increasing PEEP to 6 cmH<sub>2</sub>O on non-invasive PC-CMV. Adjustments to PIP and breath rate were made to make BB comfortable over the next day. Initial Capillary Blood Gas (CBG) on non-invasive PC-CMV 24/6, FiO<sub>2</sub>: 0.50 was: pH: 7.33, PCO<sub>2</sub>: 56, HCO<sub>3</sub><sup>-</sup>: 32 and PO<sub>2</sub>: 50. A transcutaneous monitor was placed for continuous trending and non-invasive monitoring of gas exchange. The transcutaneous CO<sub>2</sub> (TcCO<sub>2</sub>) correlated well with the PCO<sub>2</sub>.

BB was weaned from non-invasive ventilation the next day and was placed on bubble nasal CPAP (BCPAP). An OG tube was placed and a weighted naso-duodenal tube remained in place. The CBG results on CPAP +8 cmH<sub>2</sub>O and FiO<sub>2</sub> 0.30-0.35 was: pH: 7.36, PCO<sub>2</sub>: 60, HCO<sub>3</sub><sup>-</sup>: 32 and PO<sub>2</sub>: 40. Shown (Figure 1) is BB chest X-ray.

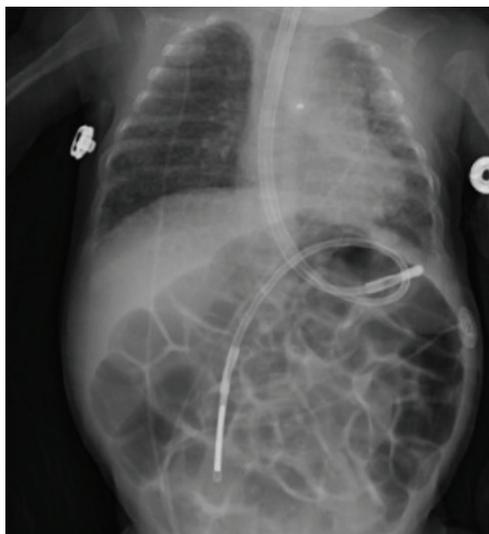
BB remained stable over the next day with minimal work of breathing and stable gas exchange. The next day, BB was placed on binasal short prongs secured with a head bonnet, alternating with a nasal mask every 4-6 hours following nasal inspection and suctioning. Upon being placed on the prongs with bonnet, BB became agitated and diaphoretic. PRN boluses of Morphine Sulfate and Ativan were administered to help reduce pain and anxiety.



**Figure 1**

The next morning, BB developed more pronounced respiratory distress with an increased respiratory rate (65-80 breaths/min), abdominal distension, diaphoresis, agitation, and crying. Based on increasing  $\text{FiO}_2$  requirements and  $\text{TcCO}_2$ , a CBG and chest X-ray were ordered.

Following transition to CPAP and bi-nasal short prongs with a bonnet fixation, CPAP 8  $\text{cmH}_2\text{O}$ , and  $\text{FiO}_2$ : 0.50, the CBG results showed pH: 7.26,  $\text{PCO}_2$ : 80,  $\text{HCO}_3^-$ : 36 and  $\text{PO}_2$ : 34 and chest X-ray shown in Figure 2.



**Figure 2**

Based on the progressive changes in respiratory distress and presence of increased gastric insufflation of gases, the OG tube was readjusted. There was no improvement in underlying work of breathing or gas exchange. BB appeared increasingly more agitated and diaphoretic.

Following rounds, the medical team discussed reintubating BB and options to have a tracheostomy tube placed for chronic ventilation for BPD. A respiratory therapist suggested a brief trial of heated high-flow oxygen therapy.

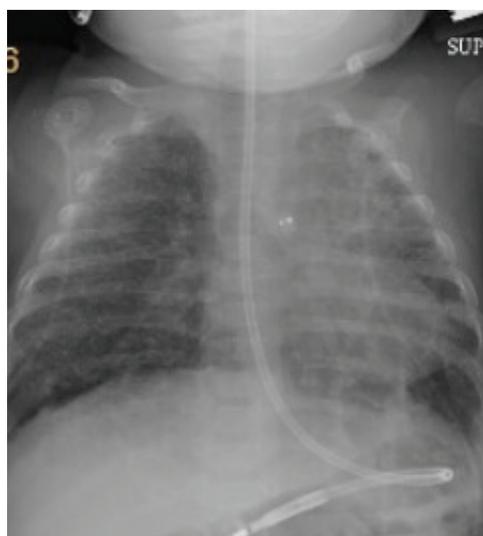
BB was removed from bubble CPAP and placed on HFNC with the Dräger Babylog VN500 ventilator at 8 L/min and  $\text{FiO}_2$  0.55.

Within 5 minutes of removing the bonnet and CPAP prongs and placing BB on HFNC, he appeared less diaphoretic and the respiratory rate decreased from 75 to low 50 breaths/min. There was nearly a 25 torr reduction in the  $\text{TcCO}_2$  levels following transition to HFNC. Also, there was reduced work of breathing and BB appeared more comfortable and was able to fall asleep. The  $\text{FiO}_2$  was able to be weaned over the next hour to 0.30 and the HFNC flow setting was able to be reduced to 6 L/min. There was less evidence of gastric insufflation and the OG tube was removed later that evening.

The next morning, a CBG and chest X-ray (Figure 3) were obtained. Overall, the medical team agreed that BB tolerated transitioning to HFNC very well.

pH: 7.26,  $\text{PCO}_2$ : 80,  $\text{HCO}_3^-$ : 36 and  $\text{PO}_2$ : 34

Over the next week, BB was slowly weaned from HFNC and discharged to the medical ward on room air.



**Figure 3**

## Conclusion

This represents a case where an infant on relatively high levels of CPAP tolerated HFNC better, with reduced anxiety and respiratory distress and improved gas exchange. Many clinicians remain skeptical about using HFNC and maintain that that this strategy provides less support than CPAP due to nasal leaks and variable pressure delivery. As such, this therapy is typically reserved for weaning patients from CPAP. However, some centers have found that HFNC may be better tolerated and as effective as CPAP prior to intubation and following extubation in the NICU.

A growing body of evidence supports that HFNC can be used safely and effectively as an alternative to non-invasive therapies in NICU for term and pre-term infants following extubation.<sup>1</sup> Unlike CPAP, the HFNC prongs are intended to occlude only 50% of the nasal airway opening. By increasing flows, HFNC provides increased  $\text{FiO}_2$  and pressure. Studies *in vitro*<sup>2</sup> and *in vivo*<sup>3,4</sup> have shown that increasing flow will provide end-expiratory pressure in the lungs that is similar to pressure provided by CPAP in infants.

The primary feature that sets HFNC apart from CPAP is that HFNC eliminates re-breathing of exhaled carbon dioxide from

the anatomic deadspace.<sup>2,5</sup> This effect may be more pronounced in infants—who have proportionally higher deadspace than adults, due to the relatively larger upper airway volumes and small tidal volumes.<sup>6</sup> By flushing deadspace from the nasopharynx, HFNC may reduce the inhaled carbon dioxide levels and improve effective alveolar minute ventilation, thus requiring infants to breathe at lower frequencies.<sup>2,5,7,8</sup> Also, HFNC has been shown to reduce rates of nasal trauma and reduce newborn infant pain scores, stress and pneumothorax when compared to CPAP and NIV.<sup>1</sup> HFNC could be considered as an alternative to CPAP and NIMV to improve comfort and distress.

## References

- 1 Wilkinson D, Andersen C, O'Donnell CPF, De Paoli AG, Manley BJ. High flow nasal cannula for respiratory support in preterm infants. *Cochrane Database Syst Rev* 2016;(2):CD006405
- 2 Nielsen KR, Ellington LE, Gray AJ, Stanberry LI, Smith LS, DiBlasi RM. Effect of high- flow nasal cannula on expiratory pressure and ventilation in infant, pediatric, and adult models. *Respir Care*. 2018;63(2):147-157.
- 3 Iyer NP, Mhanna MJ. Association between high-flow nasal cannula and end-expiratory esophageal pressures in premature infants. *Respir Care*. 2016;61(3):285-90.
- 4 Al-Alaiyan S, Dawoud M, Al-Hazzani F. Positive distending pressure produced by heated, humidified high flow nasal cannula as compared to nasal continuous positive airway pressure in premature infants. *J Neonatal Perinatal Med*. 2014;7(2):119-24.
- 5 Frizzola M, Miller TL, Rodriguez ME, Zhu Y, Rojas J, Heseck A, et al. High-flow nasal cannula: impact on oxygenation and ventilation in an acute lung injury model. *Pediatr Pulmonol*. 2011;46(1):67-74.
- 6 Numa AH, Newth CJ. Anatomic dead space in infants and children. *J Appl Physiol* 1996;80(5):1485-1489.
- 7 Möller W, Celik G, Feng S, Bartenstein P, Meyer G, Oliver E, et al. Nasal high flow clears anatomical dead space in upper airway models. *J Appl Physiol* 2015;118(12):1525- 1532.
- 8 Sivieri EM, Foglia EE, Abbasi S. Carbon dioxide washout during high flow nasal cannula versus nasal CPAP support: an in vitro study. *Pediatr Pulmonol* 2017;52(6):792-798.

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# Vitalograph Cross Contamination Report for Bacterial Viral Filters

## Abstract

The Vitalograph Bacterial Viral Filter (BVF) has been designed for use in pulmonary function testing to reduce the risk of cross-contamination and patient infection during testing.

Unlike barrier filters which trap expectorated matter whilst allowing viruses and bacteria to pass through, the Vitalograph BVF uses electrostatically charged material to trap expectorated matter plus bacteria and viruses. This creates a very effective protection against cross-contamination.

In addition to the hygiene benefits of using BVF, they also support productivity in pulmonary function testing by reducing the time spent cleaning and decontaminating the test equipment as the BVF is for single patient use only.

The manufacturers of the BVF barrier material, H&V (Hollingsworth and Vose) Technostat® 150 claim a BFE (Bacterial Filter Efficiency) of 99.99978% and VFE (Viral Filter Efficiency) of 99.99935%. The cross-contamination efficiency, ie serial patient usage of the test equipment, each with a new filter, would evidently be much higher.

Cross-contamination refers to the process by which bacteria or other micro-organisms are unintentionally transferred from one object to another, with harmful effects. The BVF prevents cross-contamination by means of reducing the amount of bioburden passing through the filter and then again back through a second filter to a level that is not detectable, based on the methods and materials used here.

This report summarises the work completed to verify that the Vitalograph BVF is effective in preventing cross-contamination. The Vitalograph BVF is a single patient use device and is to be used for pulmonary function testing only. The report confirms this by means of predicted calculations based on the filters manufactures specification, calculated using independent test lab results and demonstrated in another independent laboratory using a different protocol.

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This report is based on testing results by external agencies (Nelson Labs, Hollingsworth & Vose, Professor Colum Dunne). Calculations completed by Vitalograph Ltd.

This report concludes that the Vitalograph BVF is very effective in the prevention of cross contamination. The verification acceptance criteria for the report was met as all results generated for cross-contamination efficiency against bioburden for both theoretical and practical results were higher than 99.99999%.

## Verification Acceptance Criteria

The verification acceptance criteria for the report is that all results generated for cross-contamination efficiency against tested bioburden for both theoretical and practical results are equal to or higher than 99.99999%.

## Verification Units

The verifications units for the 4 different tests are as follows:

## Predicted Cross-Contamination Prevention – Technostat® Specification Data

N/A – This test was completed using the Specification Data supplied by the Manufacturer of the filter material H&V (Appendix 1).

## Calculated Cross-Contamination Prevention

(New BVF at >in vivo challenge level – see Appendices 2 & 3)

This test was completed using the following:

- BFE Test: 3 BVFs; part number 28552; LOT number 1829. (Appendix 2)
- VFE Test: 3 BVFs; part number 28552; LOT number 1829. (Appendix 3)

## Calculated Cross-Contamination Prevention

(BVF +7 Years at >in vivo challenge level – see Appendices 4 & 5)

This test was completed using the following:

- BFE Test: 3 BVFs; part number 28362 (supplied in PFT (Pulmonary Function Test) Kit part number 28372); LOT number 1026. (Appendix 4)
- VFE Test: 3 BVFs; part number 28362 (supplied in PFT (Pulmonary Function Test) Kit part number 28372); LOT number 1026. (Appendix 5)

## Demonstrated Laboratory Cross-Contamination Prevention

This test was completed using the following:

- BVF-BVF Test: 40 BVFs; part number 28554; LOT Number 1827
- BVF-Alpha Flow Head: 39 BVFs; part number 28554; LOT Number 1827

## Assessors

Data supplied by external agencies (Nelson Labs, Hollingsworth & Vose, Professor Colum Dunne)  
Calculations completed by Vitalograph Ltd.

## Equipment Used

### Predicted Cross-Contamination Prevention – Technostat® Specification Data

N/A – This test was completed using the Specification Data supplied by the Manufacturer of the filter material H&V. No equipment was needed for the calculations.

### Calculated Cross-Contamination Prevention – Nelson Labs, 2019 (New BVF)

N/A – This test was completed using the test results supplied by Nelson Labs. No equipment was needed for the calculations.

### Calculated Cross-Contamination Prevention – Nelson Labs, 2019 (+7 Years)

N/A – This test was completed using the test results supplied by Nelson Labs. No equipment was needed for the calculations.

### Laboratory Demonstrated Cross-Contamination Prevention – Professor Colum Dunne, University of Limerick, 2019

The Equipment used for the testing completed to determine the Laboratory Cross-Contamination Prevention can be split into the 2 tests completed:

#### BVF – BVF

- ♦ Transport swabs (101 x 16.5 mm; Ref: 80.625)
- ♦ Inoculation spreaders (Ref: 86.1569.005) from Startsted Ltd.
- ♦ Pre-set growth media plates namely plate count agar (PCA) and PBS (Phosphate Buffered Saline) Fannin Ltd.
- ♦ *Escherichia coli*, also known as *E. coli* (K12).
- ♦ 40 x Vitalograph Bacterial Viral Filters (BVFS) Part Number 28554, LOT Number 1827.
- ♦ 1 x 3 Litre Syringe: Part Number 36113; Equipment Number T2678.

#### BVF – Alpha Flow Head

- ♦ Transport swabs (101 x 16.5 mm; Ref: 80.625)
- ♦ Inoculation spreaders (Ref: 86.1569.005) from Startsted Ltd.
- ♦ Pre-set growth media plates namely plate count agar (PCA) and PBS (Phosphate Buffered Saline) Fannin Ltd.
- ♦ *Escherichia coli*, also known as *E. coli* (K12).
- ♦ 39 x Vitalograph Bacterial Viral Filters (BVFS) Part Number 28554, LOT Number 1827.
- ♦ 39 x Alpha Flowheads Part Number 61029 Job Number 14854.
- ♦ 1 x Alpha Touch Spirometer: Part Number 65502 Serial Number 26819.
- ♦ 1 x Silicone Twin-Tubing: Part Number 42172.
- ♦ 1 x PowerSAFE – Power lead for Alpha Spirometer: Part Number 41211.
- ♦ 1 x Calibrated 3 Litre Syringe: Part Number 36113; Equipment Number T2678.
- ♦ 1 x Touch Screen Stylus: Part Number 65813.

## Procedure

The Procedure for this test report can be split into 2 subsections. The subsections are as follows:

- The Cross-Contamination Prevention Procedure for the Predicted and Calculated methodologies
- The Laboratory Demonstrated Cross-Contamination Prevention Procedure

The Predicted Cross-Contamination Prevention Procedure was completed on the Technostat® filter Specification Data. The Calculated Cross-Contamination procedure was completed on the Nelson Labs test results from the testing of New BVFs and the Nelson Labs test results from testing +7 year old BVFs.

The calculation was firstly completed using the BFE and VFE values given in the Technostat® filter Specification Data sheet (see Appendix 1). This allowed for the efficiency of the Technostat® filters ability in preventing bacterial and viral cross-contamination to be predicted.

Vitalograph BVFs were then sent to Nelson Labs to be tested for BFE (see Appendix 2) and VFE (see Appendix 3). The testing was completed on 3 BVFs chosen at random from a batch. The lowest results attained for BFE and VFE was then used to calculate the BVFs' ability in preventing bacterial and viral cross-contamination.

To verify that the Vitalograph BVFs continue to function for the entirety of their shelf life, Vitalograph's BVFs that were over 7 years old were sent to Nelson Labs to be tested.

5 BVFs were chosen at random from a batch and sent, 3 BVFs were subsequently tested for BFE (see Appendix 4) and VFE (see Appendix 5).

The lowest results attained for BFE and VFE was then used to calculate the +7 years old BVFs ability in preventing bacterial and viral cross-contamination.

The BVFs were also tested by Professor Colum Dunne in the University of Limerick. The testing completed was to assess the Vitalograph BVFs ability to prevent bioburden cross-contamination in a laboratory setting. The parts were initially tested for its ability to prevent bioburden contamination passing through a BVF onto an Alpha Flow Head at determined Flowrates (BVF-Alpha Flow Head assemblies). The testing was then conducted using BVF- BVF assemblies.

The determined flowrates used were separated into 3 sets. The sets were as follows:

- Low - less than 55 L/min
- Medium - Between 55 L/min and 750 L/min
- High - Higher than 750 L/min

The highest flowrate the Alpha Spirometry device can test is 960 L/min. This flow rate is well in excess of what would be expected for a patient to exhale in a clinical setting. From the NHANES III reference paper, used to calculate predicted values for PEF, the highest flowrate used is for a 206cm, 30 year old Mexican American male at 13.79 L/s (827.4 L/min).

## Theoretical Cross-Contamination Prevention Calculation

$x$	= Let $x$ equal the efficiency of the filter.
$1 - x$	= This is the amount of bioburden to pass through each of the filters, as $x$ (the efficiency) is subtracted from the total amount of bioburden.
$(1 - x) \times (1 - x)$	= The amount of bioburden to pass through both the first and second filter is then calculated by multiplying the amount of bioburden to pass through the first filter by the amount of bioburden that will then pass through the second filter.
$1 - ((1 - x)^2)$	= The efficiency of the 2 filters being used in preventing cross-contamination can then be calculated by subtracting the amount of bioburden to pass through both the first and second filter from the total amount of bioburden.

## Demonstrated Cross-Contamination Prevention

The Vitalograph BVF was tested for bioburden cross-contamination prevention in a laboratory environment. The efficiency of the filter was tested to calibrated flowrates. This testing was completed to determine whether the Vitalograph BVF protects against cross-contamination at various flowrates. This was completed utilizing Alpha Flow Heads, an Alpha Touch Spirometer and a 3L Syringe to deliver defined volume and flow of air simulating use in practice.

### BVF-Alpha Flow Head

The BVF-Alpha Flow Head Methodology was split into 2 sub-sections: Flowrate Generation using the Alpha Touch Spirometer and 3 L Syringe and Microbial Testing.

#### Flowrate Generation

1. Alpha Touch was calibrated using the Calibrated 3 L Syringe.
2. In the Main Menu FVC was selected.
3. The Temperature was entered in degrees Celsius.
4. The required flowrates were divided into 3 bands: low flowrate (under 30 L/min), medium flowrate (between 55 L/min and 750 L/min) and high flowrate (over 750 L/min).
5. 5 BVFs were to be completed with a high flowrate, 29 BVFs with a medium flowrate and 5 BVFs with a low flowrate.
6. A stroke of the syringe was completed using the required speed/pressure to generate the desired flowrate.
7. The flowrate was displayed under PEF on the right of the display. This value was recorded.

#### Microbiology Testing

1. For each test, a BVF was placed in-line with an Alpha Flow Head.
2. In a microbiology containment hood, 1.0ml of  $1 \times 10^6$  CFU *E. coli* was introduced by sprayer into the BVF inlet.
3. Using the calibrated 3 L Syringe, air is directed through the inoculated BVF-Alpha Flowhead assembly.
4. The BVF-Alpha Flow Head is disassembled, and separated.
5. Alpha Flow Head Inlets, outlets and internal "insert filter" (Plastic Mesh Filter) were swabbed using diluent PBS (Phosphate Buffered Saline).
6. Each swab was vortexed to free microbial cells, and the suspensions diluted serially before being spread-plated onto the PCA.
7. Incubation was at 37 degrees C, aerobically.
8. Counts were performed at 24 hours.
9. This testing was performed a stipulated above.

### BVF-BVF

1. For each test, two BVFs were joined in-line using parafilm to create an airtight seal such that air flowing through the first BVF would not leak before entering the second BVF.
2. In a microbiology containment hood, 1.0ml of  $1 \times 10^6$  CFU *E. coli* was introduced by sprayer into the first BVF inlet.
3. Using the 3 L Syringe, air is directed through the inoculated BVF assembly.
4. The joined BVFs are disassembled, and using sterile scissors each BVF inlet, filter and outlet is separated.
5. Plastic inlets and outlets were swabbed using diluent PBS (Phosphate Buffered Saline).
6. Each swab was vortexed to free microbial cells, and the suspensions diluted serially before being spread-plated onto the PCA.

## Results

### Predicted Cross-Contamination Prevention - Technostat® Specification Data

The Technostat® Specification Data states that the BVF's Technostat® filter should have a BFE of 99.99978% and VFE of 99.99935%. This data allows for the cross-contamination efficiency of the filter to be calculated as follows:

#### Bacterial Cross-Contamination Prevention

99.99978%	= the % bacterial efficiency of the filter
0.9999978	= the bacterial efficiency of the filter in decimal
$1 - 0.9999978$ $2.2 \times 10^{-6}$	= the amount of bacteria to pass through the first filter
$(2.2 \times 10^{-6}) \times (2.2 \times 10^{-6})$	= the amount of bacteria to then pass through the second filter
$1 - (4.84 \times 10^{-12})$ 0.9999999999	= the bacterial efficiency of both the filters
<b>99.99999999%</b>	= the % bacterial efficiency of the filters in preventing Cross-Contamination

#### Viral Cross-Contamination Prevention

99.99935%	= the % viral efficiency of the filter
0.9999935	= the viral efficiency of the filter in decimal
$1 - 0.9999935$ $6.5 \times 10^{-6}$	= the amount of virus to pass through the first filter
$(6.5 \times 10^{-6}) \times (6.5 \times 10^{-6})$	= the amount of virus to then pass through the second filter
$1 - (4.225 \times 10^{-11})$ 0.9999999995	= the viral efficiency of both the filters
<b>99.99999995%</b>	= the % viral efficiency of the filters in preventing Cross-Contamination

### Theoretical Cross-Contamination Prevention – Nelson Labs Test Results (New BVF)

The efficiency of the filter was tested for both BFE and VFE by Nelson Labs (see Appendices 2 and 3 for details). The lowest BFE for the filters tested was 99.962%. The lowest VFE for the filters tested was 99.925%

### Bacterial Cross-Contamination Prevention

99.962%	=	the % bacterial efficiency of the filter
0.99962	=	the bacterial efficiency of the filter in decimal
$1 - 0.99962$ $3.8 \times 10^{-4}$	=	the amount of bacteria to pass through the first filter
$(3.8 \times 10^{-4}) \times (3.8 \times 10^{-4})$	=	the amount of bacteria to pass through the second filter
$1 - (1.444 \times 10^{-7})$ 0.999998556	=	the bacterial efficiency of both the filters
<b>99.99998556%</b>	=	the % bacterial efficiency of the filters in preventing Cross- Contamination

### Viral Cross-Contamination Prevention

99.925%	=	the % viral efficiency of the filter
0.99925	=	the viral efficiency of the filter in decimal
$1 - 0.99925$ $7.5 \times 10^{-4}$	=	the amount of virus to pass through the first filter
$(7.5 \times 10^{-4}) \times (7.5 \times 10^{-4})$	=	the amount of virus to then pass through the second filter
$1 - (5.625 \times 10^{-7})$ 0.999994375	=	the viral efficiency of both the filters
<b>99.99994375%</b>	=	the % viral efficiency of the filters in preventing Cross-Contamination

### Theoretical Cross-Contamination Prevention – Nelson Labs Test Results (+7 Years)

The efficiency of a filter that had exceeded its ‘Use by Date’ was tested for both BFE and VFE by Nelson Labs (see Appendices 4 and 5 for details). The lowest BFE for the filters tested was 99.9948%. The lowest VFE for the filters tested was 99.90%.

### Bacterial Cross-Contamination Prevention

99.9948%	=	the % bacterial efficiency of the filter
0.999948	=	the bacterial efficiency of the filter in decimal
$1 - 0.999948$ $5.2 \times 10^{-5}$	=	the amount of bacteria to pass through the first filter
$(5.2 \times 10^{-5}) \times (5.2 \times 10^{-5})$	=	the amount of bacteria to pass through the second filter
$1 - (2.704 \times 10^{-9})$ 0.999999973	=	the bacterial efficiency of both the filters
<b>99.99999973%</b>	=	the % bacterial efficiency of the filters in preventing Cross-Contamination

### Viral Cross-Contamination Prevention

99.90%	=	the % viral efficiency of the filter
0.9990	=	the viral efficiency of the filter in decimal
$1 - 0.9990$ $1 \times 10^{-3}$	=	the amount of virus to pass through the first filter
$(1 \times 10^{-3}) \times (1 \times 10^{-3})$	=	the amount of virus to then pass through the second filter
$1 - (1 \times 10^{-6})$ 0.999999	=	the viral efficiency of both the filters
<b>99.9999%</b>	=	the % viral efficiency of the filters in preventing Cross-Contamination

### Demonstrated Cross-Contamination Prevention

The cross-contamination prevention testing completed on the Vitalograph BVFs concluded that no bioburden was detected when a flowrate below 960L/min was used.

### BVF-Alpha Flow Head

No bioburden growth was observed from the Alpha Flowheads when tests were completed at low or medium flow rates. Of the tests performed, only two were positive. At flow rates at

or above 960L/min, two of the tests demonstrated levels of bioburden in the inlet of the Alpha Flow Head. This flow rate is well in excess of what would be expected for a patient to exhale in a clinical setting. From the NHANES III reference paper, used to calculate predicted values for PEF, the highest flowrate is for a 206cm, 30 year old Mexican American male at 13.79 L/s (827.4 L/min).

These results indicate that, when used at low, medium or high flow rates up to 960 L/min, any bioburden transfer allowed by the BVF to Alpha Flow Heads was below the level of detection based on the methods and materials used. From this we deduce that the BVF was effective in the prevention of bioburden transfer.

### BVF-BVF

The BVF-BVF assembly was a substitute model for BVF-Alpha Flow Head assembly. No growth was observed from any second BVF in the assemblies.

This indicated that any bioburden transfer allowed by the first BVF in assemblies to the second BVF was below the level of detection based on the methods and materials used.

### Conclusion

This report concludes that the Vitalograph BVF is effective in the prevention of cross-contamination. The verification acceptance criteria for the report was met as all results generated for cross-contamination efficiency against bioburden for both theoretical and practical results are equal to or higher than 99.9999%.

As can be seen the laboratory testing results generated corroborates well with the results theoretically calculated for cross-contamination efficiency.

### References

- NHANES III: Hankinson JL, Odencrantz JR, Fedan KB. Spirometric reference values from a sample of the general US population. *Am J Respir Crit Care Med* 1999; 159: 179-187.
- Study CDe 19/039 Calibrated Flow Bioburden testing of Vitalograph Alpha Flow Heads and Bacterial Viral Filters (BVF): Colum Dunne. 2019; 1-7
- Dickens, A. P., et al. (2020). “Accuracy of Vitalograph lung monitor as a screening test for COPD in primary care.” *NPJ Prim Care Respir Med* 30(1). 10.1038/s41533-019-0158-2.
- Fujita, M., et al. (2020). “Handheld flow meter improves COPD detectability regardless of using a conventional questionnaire: A split-sample validation study.” *Respirology* 25(2). 10.1111/resp.13602.
- ISO, 2019. Standards [Online]. Available at: <https://www.iso.org/standards.html> (Accessed 30 July 2020).
- US Department of Health and Human Services, Food and Drug Administration. Classification of Products as Drugs and Devices and Additional Product Classification Issues: Guidance for Industry and FDA Staff. Office of Combination Products, September 2017.
- US Department of Health and Human Services, Food and Drug Administration. Policy for Device Software Functions and Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff. Center for Devices and Radiological Health, September 2019.
- Vitalograph, 2019. Vitalograph Cross Contamination Report for Bacterial Viral Filters [Online]. Available at: <https://vitalograph.co.uk/downloads/view/284> (Accessed 30 July 2020).

# SpiroTutor™ Is Here



## Vitalograph Launches Integrated Online Training Service

SpiroTutor™ a new online training website launching in the US. SpiroTutor™ was developed to provide thorough and consistent Vitalograph device training of all skill levels online and on demand.

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# Evaluation of Harmonization Across Siemens Healthineers Blood Gas Systems and the Atellica CH 930 Clinical Chemistry System for Common Measurands

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## Introduction

Assessment and laboratory examinations are the primary method used by clinicians to evaluate a patient's condition and provide a diagnosis. The ability to perform laboratory tests quickly and receive accurate results allows for a more effective diagnosis, prognosis, and treatment plan. The development of point-of-care testing (POCT) has revolutionized the way in which patient biodata are sampled, analyzed, and reported. Convenient and easy-to-use POCT devices have combined portability with the accuracy of traditional laboratory analysis and instrumentation.<sup>1</sup> The turnaround time (TAT) from sample collection to test result has improved with POCT versus central laboratory testing, which allows for a quicker diagnosis and initiation of therapy.<sup>2</sup> TAT has been the primary driving force behind the implementation of POCT devices.<sup>3</sup> However, it is imperative that the POCT devices provide accurate results with minimal variability between portable and stationary devices, including those in the central laboratory. There are many types of POCT devices currently in existence and use, including blood gas analyzers, to name one category.

In the arena of blood gas analyzers, Siemens Healthineers offers the following platforms: the epoc<sup>®</sup> Blood Analysis System (for patient-side testing), RAPIDPoint<sup>®</sup> 500e Blood Gas System (designed for POC), RAPIDLab<sup>®</sup> 1265 Blood Gas System (clinical laboratory system), and RAPIDLab<sup>®</sup> 348EX Blood Gas System (designed for lower-volume testing sites). Siemens Healthineers recently introduced the Atellica<sup>®</sup> Chemistry (CH) 930 Analyzer, a high-throughput clinical chemistry system based in the central laboratory. The need for correlation and harmonization among these devices (e.g., POCT and central laboratory testing) at clinically relevant decision points is of utmost importance, specifically as a patient transitions between levels of care. Healthcare providers expect consistent results for the same patient sample when analyzed across various platforms and with different measurement procedures. A previously performed

study to determine correlation between Siemens Healthineers platforms and a clinical chemistry system found comparable results for the same patient sample.<sup>4</sup> Harmonization at medical decision levels (MDLs) was demonstrated between the platforms studied. Consistent and comparable results across platforms leave no room for misinterpretation and translate into confident diagnoses and appropriate treatments.

To further investigate harmonization across its most current clinical platforms, Siemens Healthineers conducted an internal study designed to assess the variability in results between the epoc, RAPIDPoint 500e, RAPIDLab 1265, RAPIDLab 348EX, and the Atellica CH 930 systems.

## Instrument Overview

A brief description of the blood gas systems and clinical chemistry system that were included in this study is provided below. It is important to understand the differences between these systems and what they offer to the diagnostic assessment, particularly when these instruments are being directly compared with one another.

### RAPIDPoint 500e Blood Gas System

Siemens Healthineers RAPIDPoint 500e system (Figure 1) is a point-of-care analyzer that measures pH, blood gases, electrolytes, glucose, lactate, and full CO-oximetry, providing patient results in just 60 seconds on a single sample of heparinized whole blood. The easy-to-use, cartridge-based technology offers heightened operational simplicity while leveraging Siemens Healthineers proprietary Integri-sense<sup>™</sup> Technology to enable robust accuracy from sample to sample and confidence in every result.

The measurement cartridge resides on the system for up to 28 days, and the variety of cartridge test sizes available accommodates low- to high-volume test sites, making the RAPIDPoint 500e system ideal for both point-of-care and laboratory settings. The sensors used in the RAPIDPoint 500e system are miniaturized and planar chip in design and represent an integral component of the RAPIDPoint measurement cartridge. The principal methodologies of the system include amperometry, potentiometry, and spectrophotometry.

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<sup>d</sup>Executive Director, Medavera, Inc., Springfield, Missouri. Product availability varies by country. RAPIDLab 348EX Blood Gas System is not available in the US. Atellica, epoc, RAPIDLab, RAPIDPoint, and all associated marks are trademarks of Siemens Healthcare Diagnostics Inc., or its affiliates. All other trademarks and brands are the property of their respective owners.



**Figure 1.** RAPIDPoint 500e Blood Gas System in an ICU.

### RAPIDLab 1265 Blood Gas System

The RAPIDLab 1265 analyzer (Figure 2) offers a similar comprehensive menu and quick turnaround time for busy clinicians. By combining the longevity of Ready Sensor® electrode technology with the efficiency and ease of cartridge-based reagents, the RAPIDLab 1265 system optimizes operational performance in medium- to high-volume testing sites.

The measurement module in the RAPIDLab 1265 system comprises individual sensors developed for selectivity to the analyte of choice. Ready Sensor electrodes are aligned in the measurement module of the RAPIDLab 1265 system and constantly maintained at 37°C for optimum performance. Minimal sample volume requirements, advanced automatic quality control, fast calibration times, and hands-free, bio-safe sampling help improve workflow wherever critical care testing is performed.



**Figure 2.** RAPIDLab 1265 Blood Gas System in the NICU.

### RAPIDLab 348EX Blood Gas System

Designed to deliver efficient critical care analysis in lower-volume testing sites, the RAPIDLab 348EX System (Figure 3) is a robust, cost-effective solution for smaller laboratories tasked with the challenge of performing faster-turnaround critical care tests. Fully automated operation supports low to medium throughput on an easy-to-use analyzer that is ready to generate accurate, on-demand results when clinicians need them, with a minimum of operator involvement.



**Figure 3.** RAPIDLab 348EX Blood Gas System in a laboratory.

### epoc Blood Analysis System

The epoc Blood Analysis System (Figure 4) is a handheld, wireless solution that provides blood gases, a basic metabolic panel, hematocrit and lactate test results at the patient bedside in less than 1 minute after sample introduction. By incorporating a full critical care menu, including creatinine and BUN, on a single room-temperature-stable test card, the epoc system delivers an efficient and easy-to-manage patient-side testing program for the hospital.



**Figure 4.** epoc Blood Analysis System at the patient-side.

### Atellica CH 930 Clinical Chemistry Analyzer

The Atellica CH 930 Analyzer (Figure 5) is the ideal solution for mid- to high-volume sample analysis within the laboratory, with the ability to perform up to 1800 tests per hour. The fully automated system offers an extensive menu and high throughput to meet the turnaround time demands of the busiest laboratories.



**Figure 5.** Atellica CH 930 Analyzer in the central laboratory.

## Materials and Methods

This study investigated the accuracy of whole blood analyte measurement across the full Siemens Healthineers blood gas analyzer portfolio compared to that of the RAPIDLab 1265 system and to plasma analyte measurement for common measurands on the Atellica CH 930 chemistry system.

Two of each blood gas system were set up on individual benches designated Bench #1 and Bench #2 and located in close proximity at the Siemens Healthineers Edgewater facility (Table 1).

**Table 1.** Blood gas analyzer bench setup.

Bench #1	Bench #2
RAPIDLab 1265 system #1	RAPIDLab 1265 system #2
RAPIDPoint 500e system #1	RAPIDPoint 500e system #2
RAPIDLab 348EX system (with chloride) #1	RAPIDLab 348EX system (with chloride) #2
RAPIDLab 348EX system (with ionized calcium) #1	RAPIDLab 348EX system (with ionized calcium) #2
epoc system #1	epoc system #2

Further whole blood testing on two additional epoc Blood Analysis Systems was performed at the Siemens Healthineers facility in Ottawa, Canada, for the BUN and creatinine measurands. One Atellica CH 930 Analyzer, located at the Siemens Healthineers Glasgow, Delaware, facility, was used for the plasma testing. The measurands tested on each Siemens Healthineers platform are identified in Table 2.

**Table 2.** Measurand by platform for comparisons.

Measurand	RL348EX	RP500e	epoc	RL1265	RL348EX	RP500e	epoc
	vs RL1265			vs Atellica CH 930			
pH	X	X	X				
pCO <sub>2</sub>	X	X	X				
pO <sub>2</sub>	X	X	X				
Na <sup>+</sup>	X	X	X	X	X	X	X
K <sup>+</sup>	X	X	X	X	X	X	X
Ca <sup>2+</sup>	X	X	X				
Cl <sup>-</sup>	X	X	X	X	X	X	X
Glu		X	X	X		X	X
Lac		X	X	X		X	X
Crea							X
BUN							X

The design of the study indicated a minimum of 40 samples, excluding outliers, and preferably 100 samples to be analyzed in duplicate for each measurand. Fresh whole blood was collected in lithium heparin tubes on each day of the study. Over the course of 16 days, samples were assayed across two of each blood gas analyzer—the RAPIDPoint 500e, RAPIDLab 1265, RAPIDLab 348EX, and epoc systems—in normal syringe mode. The first replicate of each sample was tested on Bench #1 on each blood gas system in random order; the second replicate of each sample was tested on Bench #2 on each blood gas system, also in random order. The samples were then centrifuged, and the resulting plasma removed and stored in a temperature control device at -20°C. The frozen plasma samples were subsequently thawed and tested on one Atellica CH 930 chemistry system. With three exceptions, only the first replicate was used for the analysis of the data. In the event that the results using the first replicate tested did not meet the study goal, the

second replicate was evaluated and reported. The performance of each system was verified daily with quality control materials, and the same lot numbers of reagents and sensors were used for each platform type throughout the testing process.

All measurement procedure comparisons were performed in accordance with the CLSI EP09c guideline.<sup>5</sup> Correlation statistics, including slope (m), intercept (b), and coefficient of determination (r<sup>2</sup>) as determined by Ordinary Deming, Weighted Deming, or Passing-Bablok regression analysis were calculated. Bias at a minimum of two MDLs was also calculated.

## Results

Measurement procedure comparison statistics for the epoc, RAPIDPoint 500e, and RAPIDLab 348EX blood gas systems (y) versus the RAPIDLab 1265 blood gas system (x) are summarized in Table 3. Scatter plots for each measurand with the identity line (y = x) are depicted in Figures 6 through 14.

**Table 3.** Summary statistics for the epoc, RAPIDPoint 500e, and RAPIDLab 348EX Blood Gas Systems vs the RAPIDLab 1265 Blood Gas System.

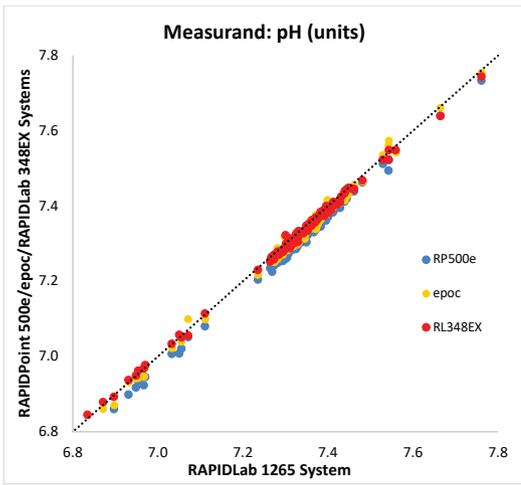
Comparison	Measurand	n	Slope	Intercept	r <sup>2</sup>	Regression	MDL	Bias
<b>epoc Blood Analysis System vs RAPIDLab 1265 Blood Gas System</b>	pH (units)	126	1.00	-0.013	0.994	Weighted Deming	7.3	-0.011
							7.5	-0.011
	pCO <sub>2</sub> (mmHg)	129	0.99	2.0	0.988	Weighted Deming	30	1.7
							50	1.5
	pO <sub>2</sub> (mmHg)	125	1.03	-3.4	0.999	Passing Bablok	50	-2.0
							200	2.1
	Na <sup>+</sup> (mmol/L)	131	1.05	-6.2	0.947	Passing Bablok	130	-0.1
							150	0.9
	K <sup>+</sup> (mmol/L)	114	1.02	-0.15	0.991	Weighted Deming	3.0	-0.09
							6.0	-0.02
	Ca <sup>2+</sup> (mmol/L)	129	1.10	-0.11	0.990	Passing Bablok	1.1	-0.01
							1.3	0.01
Cl <sup>-</sup> (mmol/L)	131	0.91	6.7	0.959	Ordinary Deming	90	-1	
						110	-3	
Glucose (mg/dL)	126	1.05	-2.8	0.996	Weighted Deming	45	-0.4	
						120	3.5	
						180	6.6	
Lactate (mmol/L)	124	0.95	0.02	0.966	Weighted Deming	1.3	-0.05	
						2.7	-0.13	
<b>RAPIDPoint 500e Blood Gas System vs RAPIDLab 1265 Blood Gas System</b>	pH (units)	127	1.03	-0.247	0.996	Passing Bablok	7.3	-0.025
							7.5	-0.019
	pCO <sub>2</sub> (mmHg)	130	0.92	3.8	0.968	Passing Bablok	30	1.4
							50	-0.3
	pO <sub>2</sub> (mmHg)	124	1.00	-2.5	0.998	Passing Bablok	50	-2.5
							200	-2.5
	Na <sup>+</sup> (mmol/L)	131	0.95	5.9	0.986	Weighted Deming	130	-0.1
							150	-1.0
	K <sup>+</sup> (mmol/L)	117	0.96	0.20	0.994	Weighted Deming	3.0	0.06
							6.0	-0.07
	Ca <sup>2+</sup> (mmol/L)	129	0.94	0.07	0.997	Ordinary Deming	1.1	0.01
							1.3	-0.01
Cl <sup>-</sup> (mmol/L)	131	0.92	5.1	0.977	Weighted Deming	90	-2	
						110	-3	
Glucose (mg/dL)	123	1.00	0.6	0.994	Ordinary Deming	45	1	
						120	1	
						180	1	
Lactate (mmol/L)	128	0.91	0.10	0.955	Passing Bablok	1.3	-0.02	
						2.7	-0.14	
<b>RAPIDLab 348EX Blood Gas System vs RAPIDLab 1265 Blood Gas System</b>	pH (units)	115	0.98	0.104	0.998	Passing Bablok	7.3	-0.006
							7.5	-0.009
	pCO <sub>2</sub> (mmHg)	119	1.01	1.9	0.993	Weighted Deming	30	2.2
							50	2.3
	pO <sub>2</sub> (mmHg)	114	1.02	-2.4	1.000	Weighted Deming	50	-1.4
							200	1.5
	Na <sup>+</sup> (mmol/L)	123	0.96	8.1	0.994	Weighted Deming	130	3.0
							150	2.3
	K <sup>+</sup> (mmol/L)	105	0.99	0.14	0.992	Weighted Deming	3.0	0.11
							6.0	0.08
	Ca <sup>2+</sup> (mmol/L)	103	1.12	-0.12	0.996	Weighted Deming	1.1	0.02
							1.3	0.05
Cl <sup>-</sup> (mmol/L)	122	0.94	4.5	0.962	Weighted Deming	90	-1	
						110	-2	

Measurement procedure comparison statistics for the aforementioned blood gas systems (y) versus the common measurands on the Atellica CH 930 chemistry analyzer (x) are

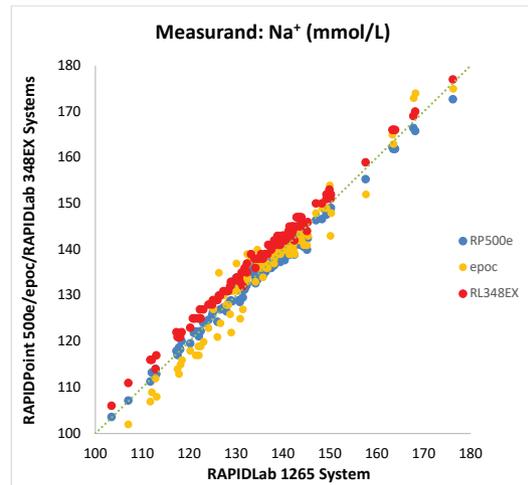
summarized in Table 4. Scatter plots for each measurand with the identity line (y = x) are depicted in Figures 15 through 21.

**Table 4.** Summary statistics for the epoc, RAPIDPoint 500e, RAPIDLab 1265, and RAPIDLab 348EX Blood Gas Systems vs the Atellica CH 930 Analyzer.

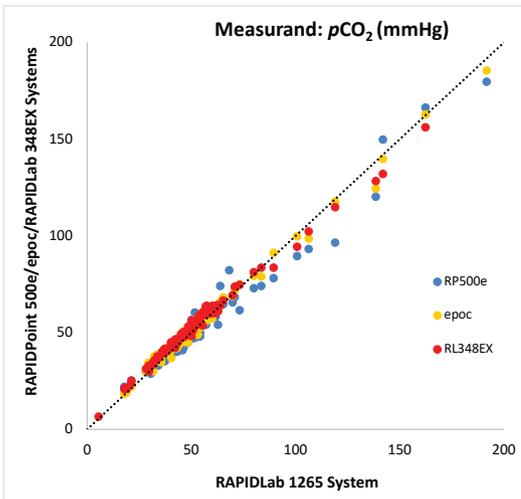
Comparison	Measurand	n	Slope	Intercept	r <sup>2</sup>	Regression	MDL	Bias
epoc Blood Analysis System vs Atellica CH 930 Analyzer	Na <sup>+</sup> (mmol/L)	131	1.08	-10.9	0.947	Passing Bablok	130	-0.8
							150	0.7
	K <sup>+</sup> (mmol/L)	123	1.02	-0.08	0.996	Weighted Deming	3.0	-0.02
							6.0	0.05
	Cl <sup>-</sup> (mmol/L)	132	0.88	11	0.976	Passing Bablok	90	0
							110	-2
	Glucose (mg/dL)	125	1.03	-2.1	0.998	Ordinary Deming	45	-0.9
							120	1.2
							180	2.8
	Lactate (mmol/L)	135	0.96	-0.02	0.971	Passing Bablok	1.3	-0.08
							2.7	-0.14
	BUN (mg/dL)	160	1.10	-1.0	0.992	Weighted Deming	6	0
							26	1
							50	4
Creatinine (mg/dL)	161	1.04	-0.04	0.996	Weighted Deming	0.6	-0.02	
						1.6	0.01	
						6.0	0.17	
RAPIDPoint 500e Blood Gas System vs Atellica CH 930 Analyzer	Na <sup>+</sup> (mmol/L)	131	0.99	0.8	0.976	Weighted Deming	130	-1.0
							150	-1.3
	K <sup>+</sup> (mmol/L)	122	0.95	0.29	0.997	Weighted Deming	3.0	0.14
							6.0	0.00
	Cl <sup>-</sup> (mmol/L)	128	0.93	5.9	0.990	Passing Bablok	90	-1
							110	-2
	Glucose (mg/dL)	125	1.02	-1.8	0.994	Weighted Deming	45	-1.1
120							0.1	
180							1.1	
Lactate (mmol/L)	137	0.81	0.32	0.956	Weighted Deming	1.3	0.07	
						2.7	-0.20	
RAPIDLab 1265 Blood Gas System vs Atellica CH 930 Analyzer	Na <sup>+</sup> (mmol/L)	132	1.02	-3.7	0.978	Ordinary Deming	130	-0.9
							150	-0.5
	K <sup>+</sup> (mmol/L)	113	1.00	0.07	0.994	Weighted Deming	3.0	0.07
							6.0	0.07
	Cl <sup>-</sup> (mmol/L)	130	1.00	1.3	0.960	Passing Bablok	90	1
							110	1
	Glucose (mg/dL)	126	1.00	-1.0	0.996	Passing Bablok	45	-1.0
120							-1.0	
180							-1.0	
Lactate (mmol/L)	137	0.90	0.24	0.979	Weighted Deming	1.3	0.10	
						2.7	-0.04	
RAPIDLab 348EX Blood Gas System vs Atellica CH 930 Analyzer	Na <sup>+</sup> (mmol/L)	121	1.00	2.0	0.984	Passing Bablok	130	2.0
							150	2.0
	K <sup>+</sup> (mmol/L)	105	0.99	0.22	0.994	Weighted Deming	3.0	0.18
							6.0	0.15
	Cl <sup>-</sup> (mmol/L)	121	0.92	7.4	0.988	Passing Bablok	90	0
110							-2	



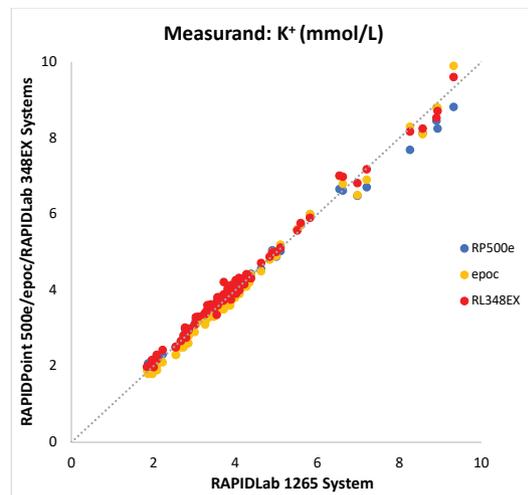
**Figure 6.** pH: RAPIDPoint 500e/epoc/RAPIDLab 348EX systems vs RAPIDLab 1265 system.



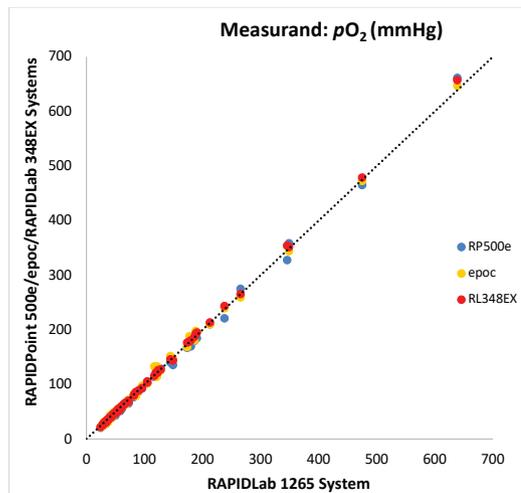
**Figure 9.** Na<sup>+</sup>: RAPIDPoint 500e/epoc/RAPIDLab 348EX systems vs RAPIDLab 1265 system.



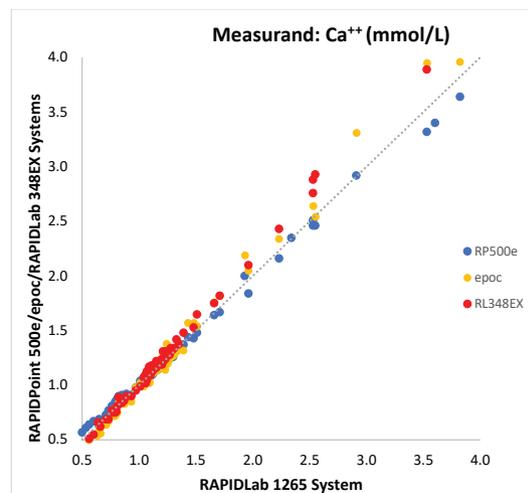
**Figure 7.** pCO<sub>2</sub>: RAPIDPoint 500e/epoc/RAPIDLab 348EX systems vs RAPIDLab 1265 system.



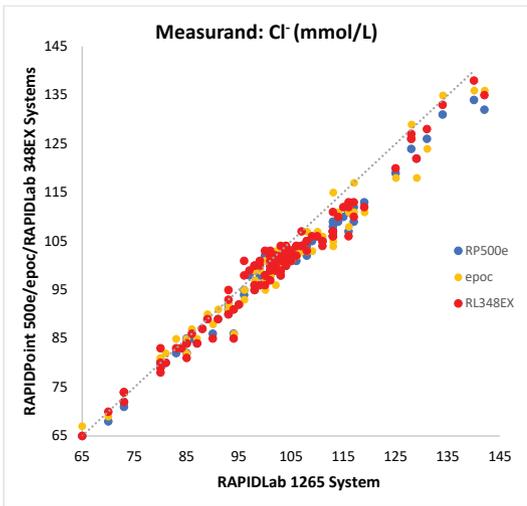
**Figure 10.** K<sup>+</sup>: RAPIDPoint 500e/epoc/RAPIDLab 348EX systems vs RAPIDLab 1265 system.



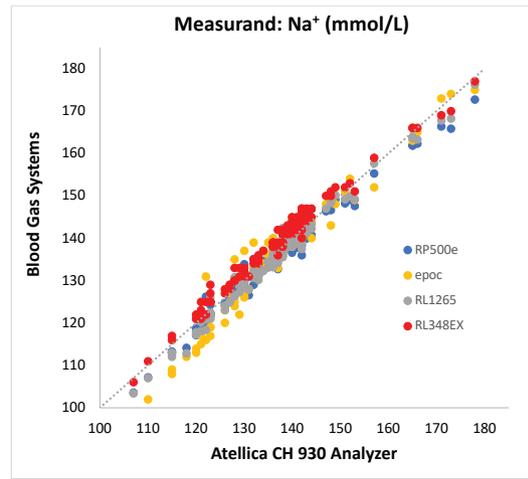
**Figure 8.** pO<sub>2</sub>: RAPIDPoint 500e/epoc/RAPIDLab 348EX systems vs RAPIDLab 1265 system.



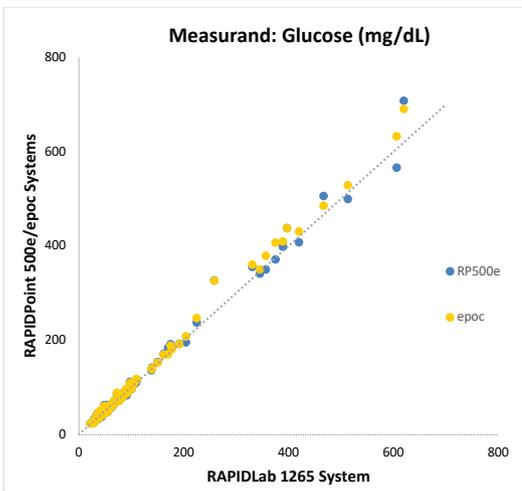
**Figure 11.** Ca<sup>++</sup>: RAPIDPoint 500e/epoc/RAPIDLab 348EX systems vs RAPIDLab 1265 system.



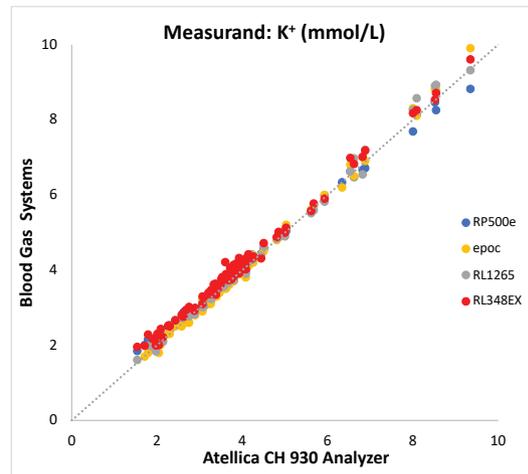
**Figure 12.** Cl<sup>-</sup>: RAPIDPoint 500e/epoc/RAPIDLab 348EX systems vs RAPIDLab 1265 system.



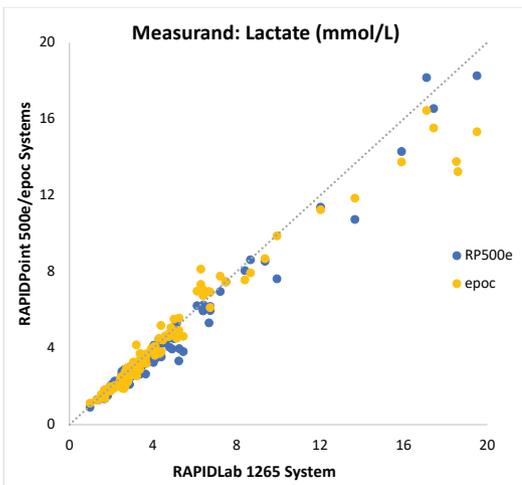
**Figure 15.** Na<sup>+</sup>: Blood gas systems vs Atellica CH 930 Analyzer.



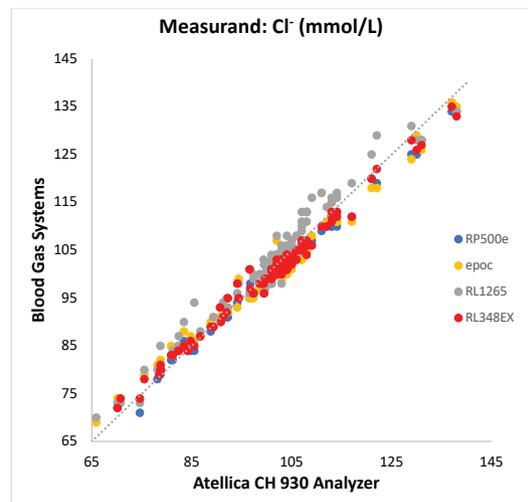
**Figure 13.** Glucose: RAPIDPoint 500e/epoc systems vs RAPIDLab 1265 system.



**Figure 16.** K<sup>+</sup>: Blood gas systems vs Atellica CH 930 Analyzer.



**Figure 14.** Lactate: RAPIDPoint 500e/epoc systems vs RAPIDLab 1265 system.



**Figure 17.** Cl<sup>-</sup>: Blood gas systems vs Atellica CH 930 Analyzer.

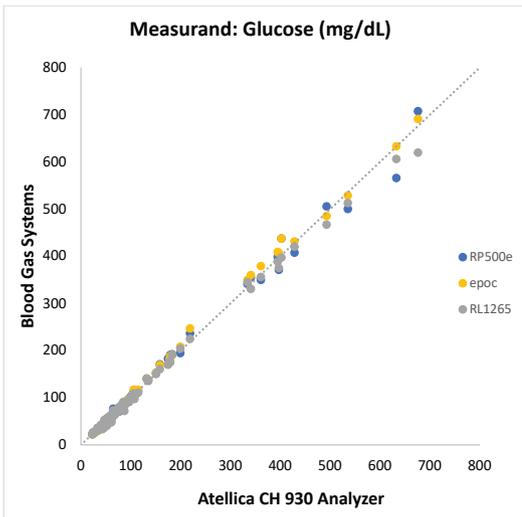


Figure 18. Glucose: Blood gas systems vs Atellica CH 930 Analyzer.

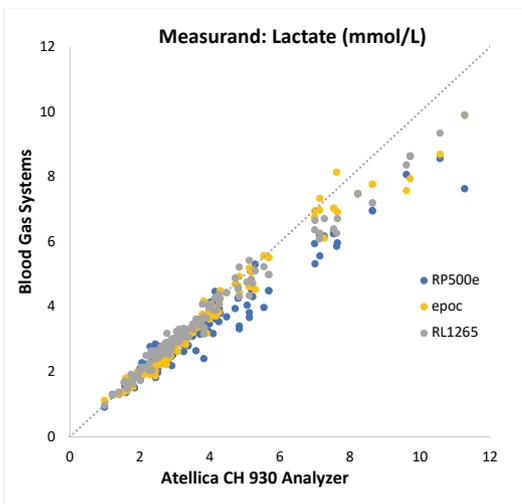


Figure 19. Lactate: Blood gas systems vs Atellica CH 930 Analyzer.

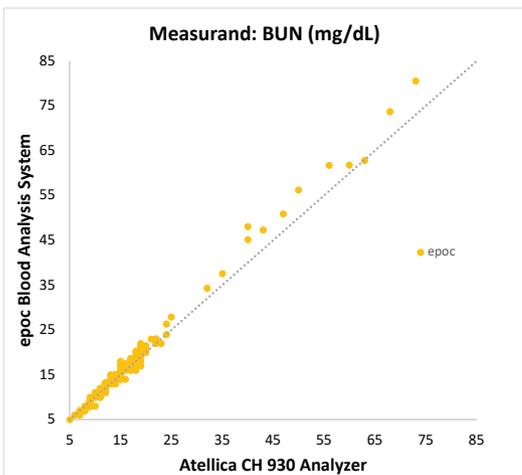


Figure 20. BUN: epoc Blood Analysis System vs Atellica CH 930 Analyzer.

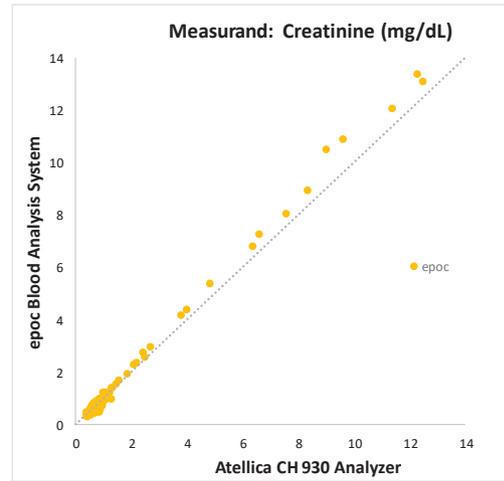


Figure 21. Creatinine: epoc Blood Analysis System vs Atellica CH 930 Analyzer.

### Discussion

The analysis outcome in terms of the slope and coefficient of determination ( $r^2$ ) is reported for each measurement procedure comparison. The desired slope across the common measuring interval is 0.90 to 1.10 for each comparison. The bias at the MDLs was also calculated for each comparison.

For blood gas system performance, the results of the study demonstrated that the desired outcome was obtained for all parameters, with the exception of ionized calcium on the RAPIDLab 348EX system vs RAPIDLab 1265 system, with a slope of 1.12. The coefficient of determination ( $r^2$ ) of 0.996 obtained for ionized calcium indicates that the regression model explains 99.6% of the variability in the response data. The software option available on the RAPIDLab 348EX system allows for the entry of the slope and intercept coefficients, thereby offering improved correlation of ionized calcium results compared to the RAPIDLab 1265 analyzer when the coefficients are applied.

For blood gas system performance versus the Atellica CH 930 Analyzer, the results of the study revealed that the desired outcome was obtained for the common measurands with the exception of chloride on the epoc system and lactate on the RAPIDPoint 500e system. The slope obtained for chloride (epoc system versus Atellica system) was 0.88, however, the coefficient of determination ( $r^2$ ) was 0.976, which suggests that the model explains 97.6% of the variability in the response data. Using the regression estimates for slope and intercept, the expected epoc system results for the biases and percent biases at the MDLs were calculated versus the Atellica analyzer. The percent biases at the two MDLs were 0.4% and -1.9%, indicating comparable performance on the two platforms at the MDLs. The slope obtained for lactate on the RAPIDPoint 500e system versus the Atellica analyzer was 0.81. The coefficient of determination was 0.956, which suggests that the model explains 95.6% of the variability in the response data. Using the regression estimates for slope and intercept, the expected RAPIDPoint 500e system results for the biases and percent biases at the MDLs were calculated versus the Atellica system. The percent biases at the two MDLs were 5.1% and -7.5%, indicating similar performance on the two platforms near the low end. A slope and offset may be applied in the RAPIDPoint 500e system software for improved correlation to the Atellica CH 930 Analyzer.

## Conclusions

Harmonization at clinically relevant medical decision levels was demonstrated for a true end-to-end solution across all of the Siemens Healthineers blood gas systems and the recently released Atellica CH 930 Analyzer for common analytes.

## References

1. De Koninck AS, De Decker K, Bocxlaer JV, et al. Analytical performance evaluation of four cartridge-type blood gas analyzers. *Clin Chem Lab Med.* 2012; 50(6):1083-91.
2. Krzych LJ, Wojnarowicz O, Ignacy P, et al. Be cautious during the interpretation of arterial blood gas analysis performed outside the intensive care unit. *ACTA Biochimica Polonic.* 2020; 67:1-6. [https://doi.org/10.18388/abp.2020\\_5178](https://doi.org/10.18388/abp.2020_5178).
3. Patel KP, Hay GW, Cheteri MK, et al. Hemoglobin test result variability and cost analysis of eight different analyzers during open heart surgery. *JECT.* 2007; 39:10-7.
4. LaRock K. Correlation between Siemens point-of-care and central laboratory blood gas systems and ADVIA 1800 Clinical Chemistry System for electrolytes and metabolites. Siemens Healthcare Diagnostics Inc., Norwood, MA, USA. 2015.
5. CLSI. Guideline EP09c: Measurement procedure comparison and bias estimation using patient samples, 3rd edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2018.

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Transforming care delivery for acute patients

[siemens-healthineers.us/bloodgas](https://siemens-healthineers.us/bloodgas)



Point your mobile phone camera at code to access Blood Gas Selection Checklist



RAPIDPoint® 500e Blood Gas System



RAPIDLab® 1200 System



epoc® Blood Analysis System



When lives are at stake and every second is crucial, how can you help ensure that your critical care teams make appropriate clinical decisions quickly?

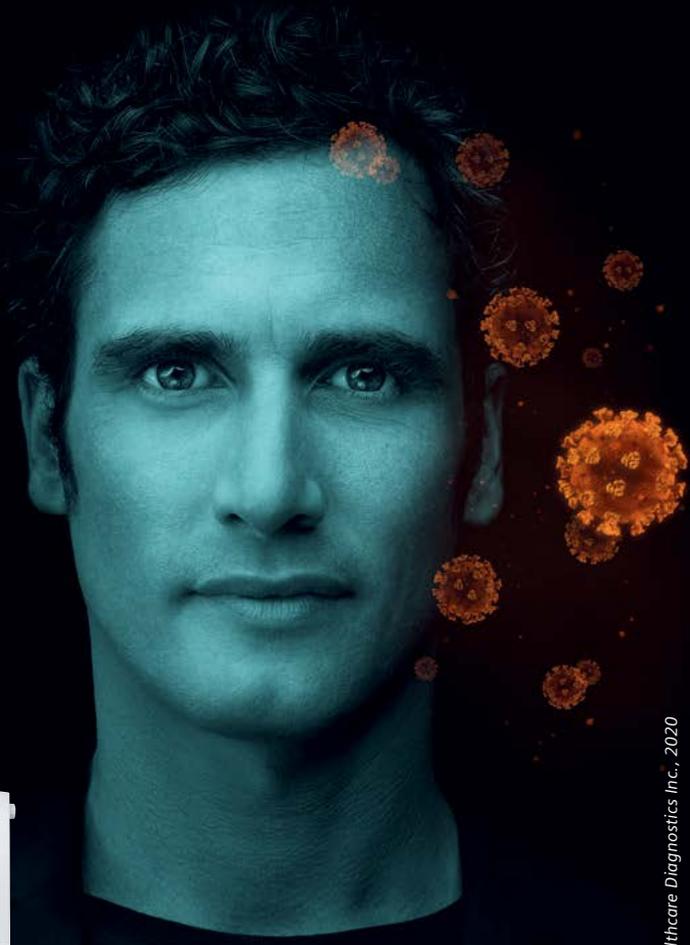
We stand by you and our partners with a highly focused commitment in the fight against the COVID-19 pandemic. Blood gas testing is important in supporting COVID-19 response efforts, and plays a critical role in managing infected patients by monitoring their respiratory status.

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# Using Telemedicine in the Care of Bronchiectasis Patients During the COVID-19 Era

Chris Campbell

## Introduction

The percentage of health visits via telemedicine continues to be well above the pre-pandemic baseline, while unfortunately patient visits to pulmonologists remain substantially below their baseline.<sup>1</sup> This highlights the continued need for health care professionals to find more and better ways to connect with patients during the pandemic. To discuss this topic, a select group of pulmonologists and healthcare law professionals participated in a virtual webinar panel to discuss the use of telemedicine in the care of bronchiectasis patients. In an expert discussion led by Karen Mullery, Hillrom Respiratory Health, the group shared perspectives and insights on caring for chronic bronchiectasis patients in a new, remote way during the era of COVID-19 and social distancing practices. Important points from the webinar are discussed below.

## Faculty

Ashwin Basavaraj, MD, FCCP, ATSF, Pulmonologist, Section Chief, Pulmonary, Critical Care & Sleep Medicine Bellevue Hospital Center. Assistant Prof., NYU Grossman School of Medicine

Patrick Flume, MD, Pulmonologist, Professor of Medicine and Pediatrics and Director of the Adult Cystic Fibrosis Center at the Medical University of South Carolina

Shyamsunder Subramanian, MD, FCCP, Pulmonologist, Section Chief, Specialty Clinics, Chief, Pulmonary/ Critical Care, Sutter Gould Medical Foundation

Kelly Custer, Esq., Senior Associate, Brown and Fortunato  
Cara Bachenheimer, Esq., Partner, Brown and Fortunato

## Moderator

Karen Mullery, Executive Marketing Director, Hillrom Respiratory Health

## Emerging CMS Policies on Telemedicine

**Bachenheimer:** Congress and the Centers for Medicare and Medicaid Services (CMS) have made tremendous policy changes to address the COVID-19 public health emergency, including expanding who can provide telehealth services, who can receive them, and what services can be delivered. In March, Congress passed the Coronavirus Preparedness and Response Supplemental Appropriations Act,<sup>2</sup> marking the first time the Department of Health and Human Services (HHS) has been given significantly more authority than under normal times to waive certain Medicare telehealth requirements. Specifically, Congress

expanded coverage to patients outside of rural areas and also to patients in their homes so they can receive telehealth services directly. In addition, Congress extended telemedicine coverage to new patients, increased funding for remote care technology, and passed the Coronavirus Aid, Relief, and Economic Security (CARES) Act (also in March),<sup>3</sup> which granted the authority to waive almost all statutory coverage restrictions that were previously applied to telehealth services.

On the regulatory side, CMS implemented policies to better ensure beneficiary access to telehealth.

Medicare pays for telehealth services at the same rate as in-office visits for all diagnoses. Physicians can also reduce or waive Medicare beneficiary cost sharing.

The federal government has issued a document with guidance for state Medicaid programs on how to expand their telehealth policies.<sup>4</sup>

**Custer:** These legislative and regulatory changes are important but would not have meaningfully expanded telehealth without the relaxation of HIPAA requirements by the Office of Civil Rights (OCR) at HHS. Previously, expensive IT programs were required to deliver telehealth, which was a barrier for tele-visits.

OCR temporarily relaxed the HIPAA requirements and created a new good faith standard for HIPAA compliance during tele-visits. Providers can now use readily available platforms like FaceTime®, Zoom®, and Skype® for tele-visits. Physicians and mid-level providers like NPs and PAs can see both new and established patients via telehealth and prescribe appropriate durable medical equipment. Providers can address any respiratory condition in the same manner as an in-office visit. A hospital-based physician can provide telehealth to hospital patients from the physician's own home, and the hospital can still bill for that service. CMS has waived its licensing requirement for tele-visits, but you still need to check with your state medical board and the state board where your patients are located to ensure you are meeting requirements.

The goal of expansion of telehealth is for providers to be able to treat patients identically, whether the visit is in person or via telehealth. Providers will not need to change any workflow when they're ordering diagnostic tests, establishing medical necessity, or performing any other required element of a visit. However, it may be worth double-checking EMR templates or other

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Chris Campbell is the Senior Editor of Respiratory Therapy.

shortcuts you use for documentation to make sure that they're up to par and will withstand future audits. The appropriate use of telehealth can help sustain your practice through this pandemic and help it grow into the future.

### **Panel Discussion: Telemedicine in the Care of Bronchiectasis Patients**

#### **Did you use telemedicine before the pandemic requirements for social distancing? How did you implement this new approach to seeing patients?**

**Flume:** We previously used telemedicine in our cystic fibrosis (CF) program but not our bronchiectasis clinic. Our institution has a large telehealth program, which was instrumental in helping us learn what we needed to do. The first step was quickly getting in touch with our patients. Our staff contacted patients to get them ready for telemedicine and to find out what their resources were. We also had to evaluate our resources (who had computers with webcams and speakers) and then had to find resources for those who didn't already have them.

**Subramanian:** Before the pandemic, our patients were seen in the clinic. It was a fast-evolving situation—we had to adapt quickly and decided early on that we would give iPads across the physician workforce, which happened within 3-4 days. We then had large-scale physician training to make sure everyone was comfortable with Canto® (the Epic-linked telemedicine platform) but simultaneously trained our physicians in WebEx®-based telemedicine. There was uniformity and a good amount of training on our end, and we needed to invest more in making sure that patients were up to speed with these new telehealth tools. Many of our patients, particularly the elderly, needed additional handholding. Our nursing staff served as patient advocates and patient educators who were on the phone with patients ahead of time, even if they didn't necessarily have appointments that day, to make sure they were prepared for tele-visits.

#### **Which video platform do you use for tele-visits?**

**Subramanian:** I like Canto because it's directly linked into Epic and completely HIPAA compliant. Even before COVID-19, many patients were using My Health Online, which makes it pretty easy to leverage that connectivity. An unanticipated issue was the sheer number of providers doing video visits at the same time and the amount of bandwidth that was required.

Part of the learning curve involved a lot of frozen video and video calls needing to be converted into telephone calls. We started to transition providers to home-based video visits, taking turns for outpatient-based specialties like endocrinology and rheumatology, and also for some of us in pulmonary and cardiology where if you weren't in the hospital that day, then preferably doing video visits from home. That helped quite a bit. We still fall back on using FaceTime through our iPad to connect to those patients who either don't have My Health Online or have issues understanding how to download the app.

#### **How are patients responding to telemedicine?**

**Basavaraj:** Most patients have been receptive. There's a sense of calm when they're talking to and connecting with their physicians and can see them using telemedicine. Patients were afraid to leave their homes and come into the offices; there was a sense of relief being able to safely talk to their physician. A few patients aren't as tech savvy, and their family members help them log on to telehealth, so they can talk to their physician. Other

patients are less inclined to use it and want to come to the office to get a physical exam and to see their physicians in person.

#### **How has telemedicine helped delivery of care and what are the drawbacks you've experienced?**

**Flume:** Patients struggle with the technology. If they don't have a camera, then it needs to be by telephone. Visits can end up being a little longer if you're trying to walk them through the technology, or the connectivity doesn't work. Some of the care we provide, like imaging or microbiology, needs to be in person.

Our patients come from all over the state and the area's surrounding states. Telemedicine has worked well here and probably works well for other centers like ours that have an extensive reach. It's helpful for patients because they don't have to travel and it offers convenience. Even if they lived locally and were coming in for a half-hour appointment, they lose a half a day doing that. For those who are still working and have parental responsibilities or have to travel long distances, it has been a real advantage. We probably see some patients more often than we would if we were asking them to drive down. It allows us to check in even for short visits to try to encourage adherence or answer questions regarding their care.

We've used the CF model in our bronchiectasis and NTM programs where we have different specialties working in the clinic—respiratory therapy, a dietician, a social worker, pharmacist, and psychologist.

Maintaining that team approach is not as easy in a telemedicine environment. In the beginning, we weren't all co-located and team communication was vital in terms of how we interact with patients. Now, we've moved to a model that allows the team to all be present in the clinic. We have half of our rooms dedicated to in-person visits and the other half are for virtual visits where we "room" or bring the patient onto the screen and then hand off among team members to talk with the patient who is at home while we're all here.

**Basavaraj:** One of the pros with telemedicine in this pandemic has been the patient comfort level. Patients were hesitant to come into the hospital or clinic for fear of getting sick. It was convenient on the patient side to talk with their doctor from home and even see their doctor via telehealth. They can ask their questions and tell their doctor how they're feeling and seek advice.

We already had telemedicine set up through Epic. Our emergency room providers and some outpatient internal medicine providers were utilizing telehealth before the pandemic. The technology was in place through our EMR, and it was a matter of training the rest of our providers who didn't take long to get up to speed.

How we approach the management of a patient with bronchiectasis has been a challenge. One drawback is the inability to examine the patient. Patients may complain of cough or shortness of breath, and we, as pulmonologists, want to listen for wheezing to decide whether they need inhalers or steroids. A challenge of telehealth is not being able to examine the patient, so that we can pinpoint the treatment they need.

Another drawback is that diagnostic studies (eg, chest x-ray, bloodwork) have been difficult to obtain, and the patients are fearful of coming to the hospital to obtain these diagnostic

studies. I don't obtain as many diagnostic studies as I normally would. I don't obtain as many CAT scans for patients to monitor their bronchiectasis now. Given the infection risk, obtaining sputum cultures or performing pulmonary function tests is more challenging.

### **How would you like to use telemedicine moving forward? What care needs to be performed in person?**

**Flume:** We were already discussing how to change care delivery, and the pandemic has been an accelerant. Our patients travel long distances. Our clinics are interdisciplinary but seeing multiple specialties in one clinic visit can be overwhelming,

so we started thinking about how to break it up using telemedicine. If insurance companies continue to pay for telemedicine, we envision a hybrid program with a combination of in-person visits and telemedicine,

coordinated in terms of those visits that we feel need to be done in the clinic and those that could be done with telemedicine. We may find that patients more often would be seen through telemedicine. For example, instead of seeing patients every 3 months in clinic, we'll see them twice a year in the clinic and six times overall during the year to keep checking in. Ultimately we can work toward better outcomes by reinforcing and monitoring the therapies we're prescribing.

**Subramanian:** COVID-19 provided the catalyst to catapult telemedicine to the next level. Within 30-40 days of adoption, our clinic volumes were almost back to pre-COVID-19 levels, except that now 90% of visits are tele-visits. One of the biggest changes with respect to the doctor-patient interaction is the frequency of contact. For example, I've had patients who have been seen three times within a month, first to discuss a complicated CT scan and then to discuss additional results at follow-up visits. Transitioning to home-based visits will extend the hours patients can be seen. Days will be longer, and patient visits shorter and more frequent.

**Basavaraj:** Telemedicine is here to stay, even past the pandemic. Patients enjoy seeing their physicians from home and using educational material they receive to practice airway clearance techniques at home.

### **What is the role of respiratory therapists and other auxiliary people in the office in the era of telemedicine? Is this a billable service?**

**Flume:** We adopted the CF model of care where the respiratory therapist is a core member of the team. We have respiratory therapists in our bronchiectasis and microbacteria clinics. The therapists' responsibilities are done in person or via telemedicine and include airway clearance instructions, aerosol therapies, oxygen supplementation, etc.

**Bachenheimer:** Unfortunately, respiratory therapists are not eligible practitioners to bill their services via telehealth. Although CMS has made a number of expansions, there are still restrictions on what telehealth services are billable.

### **Will the new ways of billing for telemedicine extend past the pandemic?**

**Bachenheimer:** Absolutely; however, there are some restrictions that have traditionally been in place but have been waived for the pandemic by Congress and CMS. Congress will have to pass

laws to continue those expansions, and there is already interest in this, so I expect it will happen as well.

### **Any final pearls of wisdom?**

**Flume:** Patients may be technologically challenged, so you need to have patience. Having a key platform you use is a good approach, but it's useful to have skills in other platforms in case you need to change. We use Doxy.me®, and if it's not working, then we can switch to FaceTime or Zoom. Being comfortable using different platforms is necessary.

**Subramanian:** Telemedicine will be a potential source of cost savings for payers in terms of reducing healthcare resource utilization. Most importantly, access will be greater—physicians will no longer be accessible only to a 30-40-mile radius; we have referrals coming in from far off places. Being able to diagnose obstructive airway disease in patients early on in the course and modify the illness trajectory could make a big difference. For physicians, there is a new etiquette on how these encounters should be handled. Some of the cues we usually have face-to-face—the hand shake, the smile, the physical interaction with the patient—are missing and there is a level of digital distancing that occurs because of this interface.

Education needs to be provided to physicians to make sure they understand how to modify their cues showing empathy and patient understanding.

### **References**

- 1 Mehrotra A, Chernew M, Linetsky D, et al. The Impact of the COVID-19 Pandemic on Outpatient Care: Visits Return to Prepandemic Levels, but Not for All Providers and Patients. <https://www.commonwealthfund.org/publications/2020/oct/impact-covid-19-pandemic-outpatient-care-visits-return-prepandemic-levels>.
- 2 Coronavirus Preparedness and Response Supplemental Appropriations Act, HR 748, 116th Cong. 2nd Sess (2020). Accessed August 28, 2020. <https://www.congress.gov/116/bills/hr6074/BILLS-116hr6074enr.pdf>
- 3 Coronavirus Aid, Relief, and Economic Security (CARES) Act, HR 748, 116th Cong. 2nd Sess (2020). Accessed August 28, 2020. <https://www.congress.gov/116/bills/hr748/BILLS-116hr748enr.pdf>
- 4 Centers for Medicare and Medicaid Services. State Medicaid & CHIP telehealth toolkit (COVID-19 Version). Accessed August 28, 2020. <https://www.medicare.gov/medicaid/benefits/downloads/medicaid-chip-telehealth-toolkit.pdf>

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# Assessment of Automatic, Real-Time Pre-Analytical Quality Checks and Tools for Continuous Improvement

## Summary

Review of point-of-care testing (POCT) data spanning three years at Derriford Hospital found that the GEM® Premier™ 5000 blood gas system with Intelligent Quality Management 2 (iQM®2) automatically identified pre-analytical errors in ~1% of samples. These errors may have gone undetected using traditional forms of quality control.

In addition, operator supervision, quality management and traceability reports from GEMweb® Plus 500 Custom Connectivity contributed to quality improvement efforts.

## Background

Derriford Hospital, a large teaching hospital in Plymouth, England and part of the University Hospitals Plymouth National Health Service Trust, serves as a major trauma

center for the Southwest region. Its intensive care unit (ICU) is one of the United Kingdom's busiest, admitting more than 1,700 patients per year. The hospital deploys 17 GEM Premier 5000 analyzers in the ICU and across other acute care departments.

Derriford Hospital supports the delivery of high-quality healthcare for acutely ill patients with POCT for its blood gas program. In addition to meeting high-volume demands, the challenge of managing hundreds of operators throughout the hospital required a solution that ensured proper management of the pre-analytical phase for every whole-blood sample, regardless of operator.<sup>1</sup>

The new IL GEM Premier 5000 blood gas analyzer was selected because of its simplicity and quality assurance technology, iQM2, which allowed them to meet the demands of their high-volume POCT environments. iQM2 provides real-time and automatic error detection, correction and documentation without operator intervention.<sup>2</sup> Pattern Recognition technology enables detection of errors originating from the pre-analytical phase (*e.g.*, micro-clots, microbubbles, air in sample, interferences).

“GEMweb Plus 500 Custom Connectivity empowers us with the information to continuously improve our quality of results and blood gas testing program, proactively.”

— Tony Cambridge, MSc, BSc  
Pathology Lead Biomedical Scientist in Blood Sciences and POCT Manager, Derriford Hospital



Derriford Hospital, Plymouth, England

Further, GEMweb Plus 500 Custom Connectivity allowed tracking of such errors by operator, analyzer and location. The sample handling and corrective action reports enhanced the POCT team's ability to identify trends associated with specific errors to continue to improve their blood gas testing program.

## The Challenge

### Detect and correct sample errors

Three years after implementing GEM Premier 5000 systems throughout acute care settings (ICU, Neonatal ICU (NICU), Central Delivery Suite, Cardiac Theaters, Cardiac ICU, High Dependency Unit (HDU), Emergency Department (ED), Maternity), the POC team sought to assess the efficacy of this new technology in terms of:

1. The ability of iQM2 to automatically detect and correct errors
2. The usefulness of the tools offered through GEMweb Plus 500 Custom Connectivity to set pre-analytical improvement targets for a vast network of operators

## Analysis

### A thorough review of thousands of clinical samples

Data from 249 GEM PAK cartridges from 17 GEM Premier 5000 systems was analyzed. In addition, reports from the GEMweb Plus 500 data management system were reviewed with managerial staff to determine how the information could be used to continuously monitor quality improvement initiatives.

17 analyzers	249 GEM PAKs	1,192 operators	47,528 clinical samples
>388 pre-analytical errors → ~1 in every 100 patient samples had pre-analytical errors			

Article submitted by Instrumentation Laboratory.

## Results

### Hundreds of errors detected, corrected automatically

iQM2 identified pre-analytical sources of error with real-time operator notification in ~1% of the 47,528 clinical samples analyzed. These errors may have gone undetected with traditional forms of quality control. Furthermore, iQM2 was able to automatically correct these errors in 100% of incidents, with no operator intervention required.

Pre-analytical sources of error	iQM2 detection
<b>Micro-clots</b>	<ul style="list-style-type: none"> <li>Detected: 216 (0.5%)</li> <li>Auto-correction: ~6 minutes with no operator intervention required</li> </ul>
<b>Interferences</b>	<ul style="list-style-type: none"> <li>Benzalkonium detection: 27 (0.06%)</li> <li>Other interferences (e.g., thiopental, methylene blue) detection: 99 (0.21%)</li> <li>Auto-correction: immediate with no operator intervention required</li> </ul>
<b>Transient/sample-specific</b>	<ul style="list-style-type: none"> <li>IntraSpect™ (during sample measurement) detection: 46 (0.10%)</li> </ul>

GEM Premier 5000 analyzers demonstrated sensor availability 99% of the time, maximizing uptime and system availability. Requiring no manual or hands-on troubleshooting, GEM Premier 5000 analyzers were predictable, reliable and enhanced the safety of clinical areas where testing occurred.

In addition, the team leveraged GEMweb Plus 500 Custom Connectivity reports (sample handling, sample aborts, sample count) to target pre-analytical training initiatives for 1,192 operators, since system implementation. These reports—particularly the Sample Handling Report—enabled greater collaboration with the clinical teams on data-driven quality initiatives.

Printed: 10/30/2019 11:43:42

### Sample Handling Report

From: 10/30/2019 23:59:59

Area: (All)  
Analyzer: (All)  
Operator: (All)  
Event: (All)

Operator ID	Last Name, First Name	Event Rate	Event	Analysis Date/Time	Area	Analyzer	Model	Serial Number
Operator ID: z10 Last Name, First Name: Buechelder, Vanesa Event Rate: 4 events for 224 samples (1.79%)			Micro Clot Detected	06/25/2019 14:47:30	CVOR 1	G5000 1	GEM® Premier 5000	16080388
			Absorbance Error	06/25/2019 14:13:32	CVOR 1	G5000 1	GEM® Premier 5000	16080388
				06/26/2019 14:37:11	OR 2	AACC-5	GEM® Premier 5000	17010537
				06/13/2019 14:57:46	OR 2	AACC-5	GEM® Premier 5000	17010537
Operator ID: z34 Last Name, First Name: Wadleigh, Oleta Event Rate: 4 events for 228 samples (1.75%)			Micro Clot Detected	06/28/2019 14:36:06	CVOR 1	G5000 1	GEM® Premier 5000	16080388
				06/28/2019 13:46:38	CVOR 1	G5000 1	GEM® Premier 5000	16080388
				06/28/2019 13:42:32	CVOR 1	G5000 1	GEM® Premier 5000	16080388
				06/28/2019 13:38:54	CVOR 1	G5000 1	GEM® Premier 5000	16080388
Operator ID: z01 Last Name, First Name: Andrew, Lorrinda Event Rate: 2 events for 203 samples (0.99%)			Micro Clot Detected	06/27/2019 13:37:40	CVOR 1	G5000 1	GEM® Premier 5000	16080388
				06/27/2019 13:34:01	CVOR 1	G5000 1	GEM® Premier 5000	16080388
Operator ID: z31 Last Name, First Name: Jeske, Chase Event Rate: 1 events for 145 samples (0.69%)			Micro Clot Detected	06/03/2019 15:18:08	OR 2	AACC-5	GEM® Premier 5000	17010537

### An additional clinical benefit—increased accuracy of Ca<sup>++</sup> and Na<sup>+</sup>

The ICU benefited from the accuracy of ionized calcium monitoring—core to the Continuous Renal Replacement Therapy program using citrate anticoagulation.<sup>3,4</sup> Additionally,

reliable sodium testing proved essential for management of severe hyponatremia in the ICU.<sup>5</sup>

### iQM2 and GEMweb Plus 500 helped improve quality

- Data analysis demonstrated the effectiveness of iQM2 in detecting common pre-analytical sources of error in ~1 out of every 100 patient samples that other systems may have missed.
- IntraSpect detected 46 errors that would have caused an erroneous result in other systems.<sup>4</sup>
- GEMweb Plus 500 Custom Connectivity reports enhanced the POCT team's ability to realize trends associated with specific errors, whether operator- or location-related, to improve the blood gas program.

### References

- Green S. The cost of poor blood specimen quality and errors in preanalytical processes. *Clin Biochem.* 2013;46:1175–9.
- Toffaletti JG, McDonnell EH, Ramanathan LV, *et al.* Validation of quality assessment system for blood gas and electrolyte testing. *Clin Chim Acta.* 2007;382:65–70.
- D'Orazio P, Visnick H, Balasubramanian S. Accuracy of commercial blood gas analyzers for monitoring ionized calcium at low concentrations. *Clin Chim Acta.* 2016;461:34–40.
- Feldkamp T, *et al.* Clinical deviations of ionized calcium measurements when using blood gas analyzers to monitor citrate dialysis. *Clin Lab.* 2016;62:2025–31.
- Cambridge T. Point of care in the ICU environment. Presented at MedLab Middle East 2019, February 4, 2019, Dubai, UAE.



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# Improving Lung Health in Low- to Mid-Income Settings with Easy-On PC and EasyOne Devices

Trishul Siddharthan, MD

Although COPD is a significant problem in the United States—more than 16 million diagnosed—over 90% of non-communicable chronic respiratory diseases occur in low- to middle-income countries, along with the vast majority of morbidity and mortality.

Dr Trishul Siddharthan, Assistant Professor in the department of Pulmonary Critical Care Medicine at Johns Hopkins, has dedicated his early career to building important research and clinical capacity to improve lung health in countries such as Uganda and Peru.

“The major problem is that when we only study these diseases in high-income settings, we don’t understand the different risk factors and profiles of disease” Trishul explains. In the United States and Europe, tobacco exposure and an underlying deficit in alpha-1 antitrypsin are well-known risk factors for COPD. However, in low- and middle-income settings the profile of risk that results in COPD is much broader, including in utero birth deficits, premature birth and chronic respiratory infections as children.

This work frequently puts Trishul and his team in roadless, rural environments—meaning that they need mobile equipment that can stand up to challenging conditions. To make this possible, Trishul decided to use the Easy-on PC and EasyOne Air devices from NDD Medical Technologies. The equipment is uniquely portable and extremely robust and reliable, making it possible for Trishul and his team to carry out their important work.

“Our conditions are really, really rough—tonnes of dust, areas without electricity, high humidity, high rain. We drop the equipment multiple times. So, we needed a technology that could be used over and over again in these conditions, that didn’t require calibration and was readily accessible. NDD’s Easy-On PC and EasyOne Air devices meet those needs as well as being, easy to use in the field, and very reliable.”

The NDD equipment employs proprietary TrueFlow ultrasound technology, which provides resistance-free, contact-free and calibration-free measurement. It is the only technology proven to require no calibration over its lifetime, as Trishul notes, “We do

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Dr Trishul Siddharthan is Assistant Professor, in the department of Pulmonary Critical Care Medicine at Johns Hopkins. He is committed to research into the prevalence, management and economic burden of non-communicable diseases in low- and middle-income countries.

checks, but frankly the calibration just doesn’t change. I can do thousands of spirometry tests with this equipment, drop them on the ground, put them on the back of a motorcycle without any problems.”



**Figure 1.** NDD’s EasyOne Air portable spirometer in action in Uganda

One particular risk factor that Trishul and his team has been looking at is biomass fuel exposure. Around 3 billion households use biomass such as dung, wood or charcoal to cook and heat their houses every day. This produces an enormous amount of household air pollution that can sometimes exceed the risk threshold of tobacco for COPD.

“I think we’re coming to a branch point within the research community, that perhaps COPD in lower income settings are different. The question now is whether or not they have a differential response to treatment.” Considering that the majority of morbidity and mortality occur in these settings, the significance of this is profound. As Trishul postulates, “Perhaps the treatments that we’re proposing in these settings don’t actually work and require us to rethink the entire histopathology of disease.”

Pulmonologists and spirometry are of course widely available in high income settings, but in low- and middle-income settings, an individual might have to drive hours for testing or treatment, and spend more money than a family will make in a year.

“It’s crazy to think there are entire regions of the world that don’t have access to diagnostics or treatment. One of the main reasons that COPD hasn’t been studied in these settings is due to this absence of diagnostic equipment. So, our main focus is to figure out how we can do spirometry in the field and make it available at the point of care. How do you identify cases in the field—places where there’s no roads? We’ve been operating in areas where spirometry has never been done and NDD’s equipment has helped to make this possible.”

In Uganda for instance, there are just three or four centres that have readily available access to spirometry for a population of 30 million people. Trishul and his team are now aiming to get equipment out to tertiary care centres and estimates that his team has performed between 12,000 to 13,000 spirometric measurements using the Easy-on PC spirometers and EasyOne Air instruments over the past five years.



**Figure 2.** Dr Trishul Siddharthan giving spirometry training in rural Nakaseke, Uganda

In addition to being extremely robust, NDD’s EasyOne spirometry and complete pulmonary function testing products are the most consistent and user-friendly lung function testing equipment on the market, helping clinicians to diagnose and treat lung disease with unmatched precision. “We’ve taken these things to places where they have never gone before and certainly weren’t designed for, and we haven’t had any issues”.

Trishul and his team are now looking to introduce important DLCO testing to his projects with NDD’s EasyOne Pro Lab devices. DLCO is a readily available test in high-income settings and has been shown in studies to be a powerful predictor of survival in patients with COPD<sup>1</sup>. It is used to pinpoint the type of respiratory disease when an obstruction or lung volume issues are predetermined. Even in high-income countries, over 50% of people living with COPD remain undiagnosed<sup>2</sup>; the combination of DLCO with spirometry is a particularly valuable tool in COPD.

“DLCO is a much more sensitive measure when it comes to lung disease and lung disease progression” Trishul explains. “There is currently no DLCO capability in the whole of Uganda, and we’re

starting to get that up and running at our sites. I think that will be a huge achievement.”

## References

- 1 Boutou AK et al. Lung function indices for predicting mortality in COPD. *European Respiratory Journal* 2013 42: 616-625.
- 2 Tilert T et al. Prevalence and factors associated with self-reported chronic obstructive pulmonary disease among adults aged 40-79: the National Health and Nutrition Examination Survey (NHANES) 2007–2012. *EC Pulmonol Respir Med.* 2018; 7(9): 650–662.

## What Makes the MiniBox+ Different From Other PFT Devices?

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. This interview is with Dr. Jeffrey Fredberg of the Department of Environmental Health at the Harvard TH Chan School of Public Health, and Dr. Kenneth Berger of the Division of Pulmonary Critical Care and Sleep Medicine at New York University's Grossman School of Medicine.

The MiniBox+ is a desktop plethysmography device for complete PFT testing, with cabinless and gasless Lung Volume Measurements (LVM), plus Spirometry and Diffusion Capacity (DLCO).

We asked two experts, Dr. Jeffrey Fredberg of the Department of Environmental Health at the Harvard TH Chan School of Public Health, and Dr. Kenneth Berger of the Division of Pulmonary Critical Care and Sleep Medicine at New York University's Grossman School of Medicine, to explain how the MiniBox+ works and how it compares to whole body plethysmography.

**Whole body plethysmography, or the body box, is considered the gold standard for lung volume measurements, yet it is not feasible and challenging for most pulmonologists and allergists. How do other methodologies compare to the body box for measuring lung volumes?**

**Professor Fredberg:** Five methods are recommended for measuring absolute lung volumes: whole body plethysmography, multi-breath helium dilution (He), nitrogen wash-out (N<sub>2</sub>), computerized tomography (CT), and chest radiography (CXR). Each of these techniques has pros and cons to the clinical user and the patient. CT and CXR are not utilized in pulmonary function laboratories and incur radiation exposure, while He and N<sub>2</sub> may underestimate lung volumes as gas may not fully distribute to poorly ventilated areas. Body plethysmography may overestimate lung volume relative to other measurements primarily in the setting of airflow obstruction and increased compliance of the extrathoracic airway. Several comparative studies have demonstrated differences between the gas-based techniques (He and N<sub>2</sub>) and plethysmography with coefficients of variation ranging between 8.8% and 23.7%.

Whole body plethysmography is simple in principle but inherently complex in practice because patients must sit inside a sealed booth and perform a complex respiratory maneuver against a closed shutter (i.e. an occluded airway). While gas dilution and gas wash-out techniques are well-established alternatives to plethysmography they require more time to demonstrate repeatability between maneuvers, especially in patients with obstructive airway diseases. Moreover, these gas

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Input on questions was provided by Cheryl Singer MS, Marketing Director, PulmOne USA. If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at [s.gold4@verizon.net](mailto:s.gold4@verizon.net).



MiniBox+ complete PFT device

based techniques correlate well with plethysmography only in normal subjects; underestimates of lung volumes occur in patients with airflow obstruction.

Investigators have explored alternative avenues to determine absolute lung volumes by other means, but with no success. Respiratory system impedance, even when extended to a wide range of forcing frequencies, has been shown to be inadequate to infer absolute lung volumes in the individual subject. Similarly, forced expiratory maneuvers have been shown to be inadequate. These failures may be attributable in part to the fact that the dynamics of gas distribution within the human lung are complex, and especially so in obstructive lung disease. Moreover, data interpretation in these approaches often rests upon fitting data to idealized mathematical models wherein there exists a wide range of TGV values that might fit the data equally well. When this happens, no useful determination of TGV can be inferred.

**How do lung volume measurements (or Total Lung Capacity, "TLC") with the MiniBox+ desktop device compare to whole body plethysmography?**

**Professor Fredberg:** Despite the simplicity of the measurement, TLC as measured by the MiniBox system is not significantly different from TLC measured by conventional whole body plethysmography. Moreover, the coefficient of variation for repeated measures is smaller. These observations validate the MiniBox method as a reliable method to measure absolute lung volumes.



MiniBox+ cabinless plethysmography

The National Heart Lung and Blood Institute, the American Thoracic Society, and the European Thoracic Society have encouraged innovation in technologies to measure absolute lung volumes so as to attain improved accuracy, ease of use, and rapidity of testing, and have recommended rigorous testing to ensure no substantial differences in results compared with standard techniques. In all sub-populations tested to date, the MiniBox performed in a manner that compares favorably with body plethysmography. Also, the day-to-day variability of TLC measurement is smaller than that of TLCs derived from helium dilution, CT imaging, or body plethysmography. Accordingly, data published to date establish the validity of the MiniBox for rapid, accurate, and repeatable determination of TLC in a heterogeneous population of healthy adults and those with respiratory system diseases.

#### **How does the MiniBox+ work?**

**Professor Fredberg:** The device sits on a desktop and comprises a flow-interruption valve connected to a rigid gas-filled container. TLC measurements are based on a series of short flow interruption events activated during the inhalation phase of the patient's normal breathing. These interruption events consist of rapid valve closures. Using these measurements together with data mining and machine-learning, the MiniBox measures for each interruption event the corresponding TLC, which is determined by the instantaneous lung volume during the interruption event plus the volume inhaled to TLC.

#### **How does the MiniBox+ lung volumes testing process compare to traditional whole body plethysmography?**

**Professor Berger:** Whole body plethysmography can be quite challenging for patients with disabilities or claustrophobic tendencies, who may find it difficult to be confined inside a closed chamber for an extended time. In addition, testing involves a complex respiratory maneuver. For technicians, testing accuracy requires a high level of training and proficiency.

The MiniBox+ testing technique is actually quite easy for patients. Since there is no chamber, they can sit comfortably next to the device and perform normal tidal breathing in a relaxed manner.

For the technician, a self-paced, online e-learning training program is provided by the manufacturer, suitable for all office staff. In addition, fully automatic lung volumes and DLCO, as well as automatically generated results, minimize technician bias.

**How does the MiniBox+ compare to the body box in terms of testing flow through times, particularly in light of the COVID PFT testing recommendations by ERS and ATS?**

**Professor Berger:** Lung volumes can be measured in roughly one minute, and complete PFT's in about 20 minutes.

With full mobility, the device can be easily moved into another clinic room during 15-minute air ventilation periods. The only downtime between patients is for a 5-minute disinfection wipe down.

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We'd like to thank Professors Fredberg and Berger for their informative responses. For further information about the MiniBox+ please visit [www.pulm-one.com](http://www.pulm-one.com).

# Effect of Nocturnal EPAP Titration to Abolish Tidal Expiratory Flow Limitation in COPD Patients With Chronic Hypercapnia

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## Abstract

**Background:** Tidal expiratory flow limitation (EFL<sub>T</sub>) promotes intrinsic PEEP (PEEPi) in patients with chronic obstructive pulmonary disease (COPD). Applying non-invasive ventilation (NIV) with an expiratory positive airway pressure (EPAP) matching PEEPi improves gas exchange, reduces work of breathing and ineffective efforts. We aimed to evaluate the effects of a novel NIV mode that continuously adjusts EPAP to the minimum level that abolishes EFL<sub>T</sub>.

**Methods:** This prospective, cross-over, open-label study randomized patients to one night of fixed-EPAP and one night of EFL<sub>T</sub>-abolishing-EPAP. The primary outcome was transcutaneous carbon dioxide pressure (*P*<sub>t</sub>CO<sub>2</sub>). Secondary outcomes were: peripheral oxygen saturation (SpO<sub>2</sub>), frequency of ineffective efforts, breathing patterns and oscillatory mechanics.

**Results:** We screened 36 patients and included 12 in the analysis (age 72 ± 8 years, FEV<sub>1</sub> 38 ± 14%Pred). The median EPAP did not differ between the EFL<sub>T</sub>-abolishing-EPAP and the fixed-EPAP night (median (IQR) = 7.0 (6.0, 8.8) cmH<sub>2</sub>O during night vs 7.5 (6.5, 10.5) cmH<sub>2</sub>O, *p* = 0.365). We found no differences in mean *P*<sub>t</sub>CO<sub>2</sub> (44.9 (41.6, 57.2) mmHg vs 54.5 (51.1, 59.0), *p* = 0.365), the percentage of night time with *P*<sub>t</sub>CO<sub>2</sub> > 45 mm Hg was lower (62(8,100)% vs 98(94,100)%, *p* = 0.031) and ineffective efforts were fewer (126(93,205) vs 261(205,351) events/hour, *p* = 0.003) during the EFL<sub>T</sub>-abolishing-EPAP than during the fixed-EPAP night. We found no differences in oxygen saturation and lung mechanics between nights.

**Conclusion:** An adaptive ventilation mode targeted to abolish EFL<sub>T</sub> has the potential to reduce hypercapnia and ineffective efforts in stable COPD patients receiving nocturnal NIV.

## Background

We have recently introduced a novel automatic ventilation mode that continuously titrates expiratory positive airway pressure (EPAP) to the lowest value that abolishes tidal expiratory flow limitation (EFL<sub>T</sub>).<sup>1</sup> This method, which uses the difference between inspiratory and expiratory reactance ( $\Delta X_{rs}$ ) measured by the forced oscillation technique (FOT)<sup>2,3</sup> to assess the

presence of EFL<sub>T</sub>, minimizes the neural respiratory drive and transdiaphragmatic pressure swings in COPD patients receiving non-invasive ventilation (NIV).<sup>4</sup>

We hypothesized that this adaptive ventilation mode would reduce hypercapnia during sleep in COPD patients with chronic hypercapnic respiratory failure. Moreover, since EFL<sub>T</sub> is associated with the development of intrinsic positive end-expiratory pressure (PEEPi) — which acts as an inspiratory threshold for the generation of inspiratory flows and can produce ineffective breath triggering<sup>5</sup> — we further hypothesized that the EFL<sub>T</sub>-abolishing respiratory support mode would reduce the triggering load imposed by PEEPi reducing the probability of ineffective efforts.

This pilot study aimed to evaluate the effects of a novel ventilation mode that automatically adjusts EPAP at the minimum level able to abolish EFL<sub>T</sub> compared to the standard fixed-EPAP mode in stable COPD patients receiving nocturnal NIV.

## Materials and methods

### Study design

In this prospective, randomized, cross-over, open-label pilot study, patients were studied in the hospital over two non-consecutive nights while using either fixed-EPAP or EFL<sub>T</sub>-abolishing-EPAP.

### Population

We enrolled moderate to severe COPD patients,<sup>6</sup> with FEV<sub>1</sub> ≤ 50%Pred, a history of more than 3 exacerbations per year or more than 1 hospitalization per year. Patients were well established on nocturnal NIV for chronic hypercapnic respiratory failure for longer than 6 months. Inclusion criteria were age below 85 years and presence of EFL<sub>T</sub> in the supine position at EPAP = 4 cmH<sub>2</sub>O.<sup>1</sup> Exclusion criteria were COPD exacerbation within the past two months, acute illness, or clinical instability.

### Outcomes

The primary outcome was *P*<sub>t</sub>CO<sub>2</sub>, expressed as mean overnight value and the percentage of night time spent in hypercapnia. Secondary outcomes were oxygen saturation, ineffective efforts, breathing pattern, and oscillatory mechanics. We hypothesized that mean *P*<sub>t</sub>CO<sub>2</sub> and the percentage of the night spent in hypercapnia would be lower during the EFL<sub>T</sub>-abolishing-EPAP than during the fixed-EPAP night.

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## Ventilation strategy

Pressure support NIV was delivered using a non-commercial version of BiPAP Synchrony Ventilator (Philips-Respironics) via an unvented facial mask (AMARA, Philips-Respironics). The ventilator measured  $EFL_T$  by FOT<sup>1,2,7</sup> and, in  $EFL_T$ -abolishing-EPAP mode, it continuously adjusted EPAP to the minimum level able to abolish  $EFL_T$ ,<sup>1</sup> with a minimum EPAP of 4 cmH<sub>2</sub>O and keeping the pressure support ( $\Delta P$ ) constant.

## Measurements

Full laboratory polysomnography (Alice5, Philips-Respironics) was performed according to the American Academy of Sleep Medicine recommendations.<sup>8</sup> During each study night, we recorded  $PtcCO_2$  and oxygen saturation ( $SpO_2$ ) (TOSCA, Radiometer) continuously. Airway opening pressure, flow and volume tracings were exported from the ventilator for offline analysis. We calculated the following parameters: mean  $PtcCO_2$  and  $SpO_2$ ; the percentage of night time spent in hypercapnia ( $PtcCO_2 > 45$  mm Hg) and with  $SpO_2 < 90\%$  (T90); mean tidal volume ( $V_T$ ), respiratory rate (RR), minute ventilation ( $V_E$ ), inspiratory resistance and reactance ( $R_{INSP}$  and  $X_{INSP}$ , respectively),  $\Delta Xrs$ , and the number of ineffective efforts (IE) per hour. We identified ineffective efforts by the presence of a positive deflection in expiratory flow without a concomitant breath delivered by the ventilator, as previously described.<sup>9</sup> At the end of the night, we asked the patients to report about their comfort on the ventilator.

## Statistical analysis

We compared parameters from the two nights using Wilcoxon signed-rank test. p-Values < 0.05 were considered statistically significant. Statistical analyses were performed using SigmaPlot v11 (Systat Software, Inc., San Jose, CA, USA).

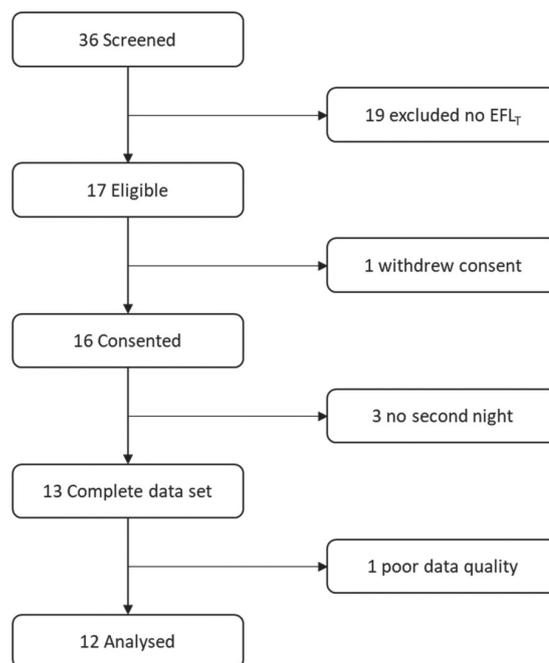
## Results

We screened thirty-six patients from April 2015 to April 2017. Of these patients, 19 did not satisfy the inclusion criteria as they did not present  $EFL_T$ , one withdrew consent after the screening, two did not perform the second night trial because they got acutely sick, one was excluded from the analysis because of poor data quality, and 12 were included in the analysis (Fig. 1). Table 1 reports the characteristics of the patients included in the analysis.

Some patients acknowledged the presence of the oscillations, but they got acclimated after just few minutes. No patients reported discomfort during the  $EFL_T$ -abolishing-EPAP night. We observed large within-night fluctuations in EPAP during the  $EFL_T$ -abolishing-EPAP night: the minimum within-night IQR was 1.8 cmH<sub>2</sub>O, the maximum within-night IQR was 8.8 cmH<sub>2</sub>O. Figure 2 shows the airway pressure and  $PtcCO_2$  of a representative patient during both nights.

The EPAP applied by the  $EFL_T$ -abolishing mode was not significantly different from the prescribed EPAP (median (IQR) 7.0 (6.0, 8.8) cmH<sub>2</sub>O during the  $EFL_T$ -abolishing-EPAP night vs 7.5 (6.5, 10.5) cmH<sub>2</sub>O during the fixed-EPAP night,  $p = 0.365$ ), despite its larger within-night variability.  $\Delta Xrs$  values clustered around the  $EFL_T$  threshold during the  $EFL_T$ -abolishing-EPAP night (Fig. 3).

Figure 4 shows gas exchange parameters during the  $EFL_T$ -abolishing-EPAP and the fixed-EPAP nights. The percentage of time spent in hypercapnia was lower (median (IQR)= 62 (8,



**Figure 1.** Study flow diagram.  $EFL_T$  tidal expiratory flow limitation

100)% vs. 98 (94, 100)%,  $p = 0.031$ ) during the  $EFL_T$ -abolishing-EPAP than during the fixed-EPAP night. We found no differences in mean  $PtcCO_2$  between the  $EFL_T$ -abolishing-EPAP and the fixed-EPAP night (44.9 (41.6, 57.2) mmHg vs 54.5 (51.1, 59.0), respectively;  $p = 0.365$ ). Mean  $SpO_2$  and T90 did not differ between nights.

The IE were fewer (126 (93, 205) vs. 261 (205, 351) events/hour,  $p = 0.003$ ) during the  $EFL_T$ -abolishing-EPAP than during the fixed-EPAP night. Additionally, mean  $V_T$  was lower ( $p = 0.029$ ), and RR was higher ( $p = 0.035$ ) during the  $EFL_T$ -abolishing-EPAP than during the fixed-EPAP night.  $V_E$ ,  $R_{INSP}$ , and  $X_{INSP}$  did not differ between nights, even if the statistical power was too low to exclude an effect of the ventilation mode on these variables (Table 2).

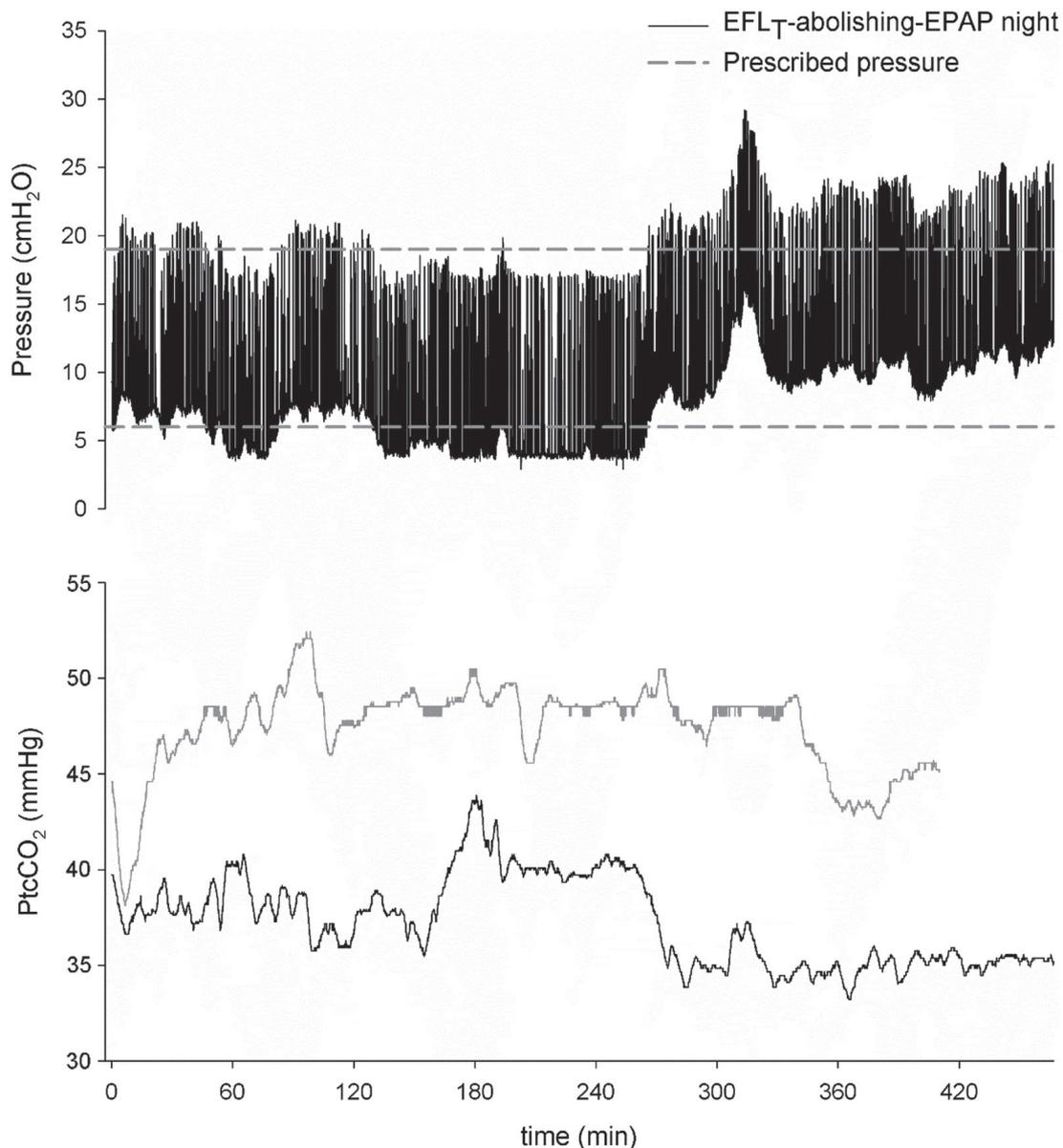
## Discussion

This is the first report of the nocturnal application of an adaptive NIV mode that continuously adjusts EPAP to the minimum level that abolishes  $EFL_T$  in hypercapnic COPD patients. This ventilation mode was well tolerated, reduced the frequency of ineffective efforts and the percentage of night time spent in hypercapnia. We found no differences in  $R_{INSP}$ ,  $X_{INSP}$ , and  $\Delta Xrs$  between the two modes. The median EPAP did not significantly differ between nights; however, on an individual basis, some patients received significantly different (either higher or lower)

**Table 1** Characteristics of study participants

N	12
Sex, %males	67%
Age, years	73 (66, 79)
BMI, kg/m <sup>2</sup>	29.2 (27.7, 32.9)
FEV1, % predicted	33 (25, 47)
FEV1/FVC, %	43 (32, 60)
Prescribed EPAP, cmH <sub>2</sub> O	7.5 (6.0, 9.0)

BMI body mass index, FEV1 forced expiratory volume in one second, FVC forced vital capacity, EPAP expiratory positive airway pressure



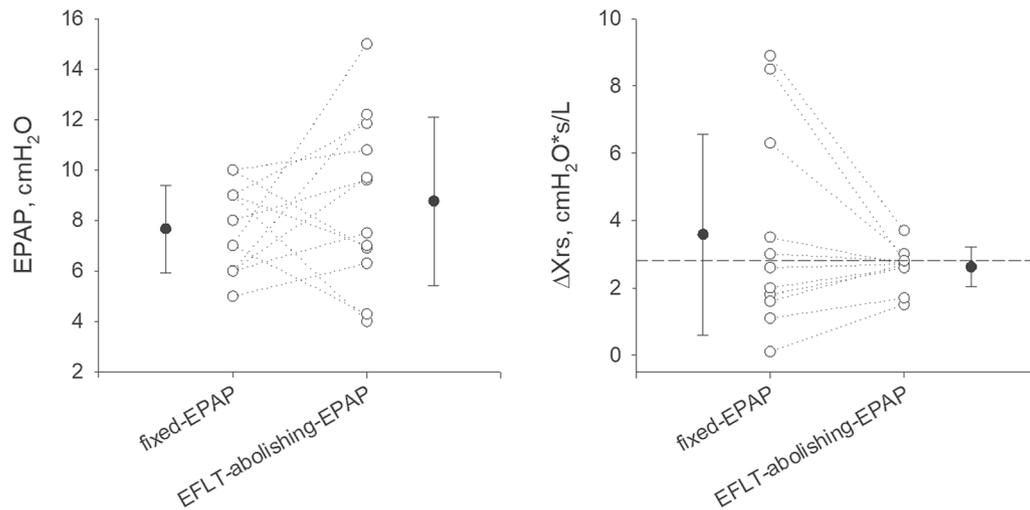
**Figure 2.** Representative pressure and  $P_{t\text{CO}_2}$  tracings for the  $EFL_T$ -abolishing-EPAP (black) and the fixed-EPAP nights (grey). During the fixed-EPAP night, EPAP and IPAP were kept constant at the prescribed values (horizontal dashed lines)

EPAP levels during the  $EFL_T$ -abolishing-EPAP and the fixed-EPAP nights. During the  $EFL_T$ -abolishing-EPAP night, the EPAP presented large fluctuations, suggesting that the ventilator automatically adapted the EPAP level to the changes in lung mechanics associated with changes in posture and sleep stage.

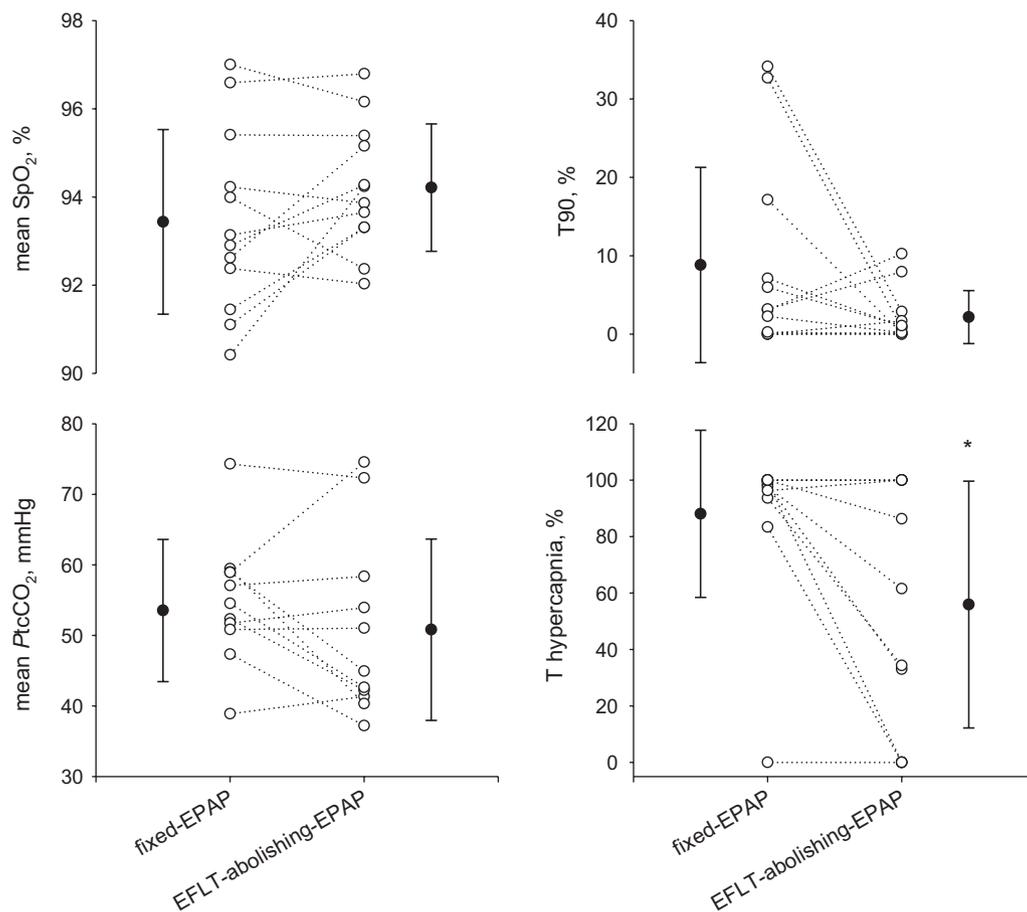
The individual responses to abolishing  $EFL_T$  were highly heterogeneous, and this heterogeneity may have contributed to the lack of statistically significant differences in gas exchange between nights. In several subjects, we noticed a clinically relevant improvement in either  $P_{t\text{CO}_2}$  or  $SpO_2$  during the  $EFL_T$ -abolishing-EPAP night. One patient presented a markedly higher mean  $P_{t\text{CO}_2}$  during the  $EFL_T$ -abolishing-EPAP than during the fixed-EPAP night. This patient was very flow-limited, received a median EPAP of 12 cmH<sub>2</sub>O during the  $EFL_T$ -abolishing-EPAP night vs 6 cmH<sub>2</sub>O during the fixed-EPAP night, and presented a much higher  $V_E$  during the  $EFL_T$ -abolishing-EPAP than during the fixed-EPAP night. We did not identify any parameter able to predict the gas exchange response of a given patient to the  $EFL_T$ -abolishing ventilation mode. Larger studies are needed to draw

conclusions about the clinical benefits of this novel adaptive mode and to identify phenotypes that may better benefit from it.

NIV is used in stable COPD patients with hypercapnic respiratory failure to reduce arterial partial pressure of CO<sub>2</sub>.<sup>10</sup> In our study improvements in  $P_{t\text{CO}_2}$  and in the percentage of night time spent in hypercapnia were not associated with increases in pressure support or  $V_E$ , highlighting the relevant role of EPAP in the control of hypercapnia in COPD patients. Titrating EPAP to abolish  $EFL_T$  may reduce CO<sub>2</sub> via several mechanisms:<sup>5,11,12</sup> (1) reducing work of breathing by improving patient-ventilator synchronization, (2) unloading the inspiratory muscles by counteracting the intrinsic PEEP, (3) reducing the ventilation-perfusion mismatch by eliminating choke-points. Moreover,  $EFL_T$  is highly variable within the same patient, e.g. it changes with body posture<sup>1</sup> and sleep stage. Therefore, an adaptive ventilation mode that continuously adjusts EPAP based on patient respiratory mechanics increases the time spent with the optimal EPAP compared with a fixed-EPAP mode, even if the average EPAP applied by the two ventilation modes is similar.



**Fig. 3** EPAP and tidal expiratory flow limitation index during the night with EFLT<sub>T</sub>-abolishing-EPAP vs. fixed-EPAP. Data are reported as individual values (open symbols dotted lines) and as mean  $\pm$  SD of all subjects (closed symbols). Dashed-line: tidal expiratory flow limitation threshold. EPAP: expiratory positive airway pressure.  $\Delta Xrs$ : difference between mean inspiratory and expiratory reactance (tidal expiratory flow limitation index).  $\Delta Xrs$  data for 11 subjects



**Fig. 4** Gas exchange during the night with EFLT<sub>T</sub>-abolishing-EPAP vs. fixed-EPAP. Data are reported as individual values (open symbols dotted lines) and as mean  $\pm$  SD of all subjects (closed symbols).  $SpO_2$ : peripheral oxygen saturation. T90: percentage of time spent with oxygen saturation  $SpO_2$  below 90%.  $PtcCO_2$ : transcutaneous partial pressure of carbon dioxide. T hypercapnia: percentage of time spent with a  $PtcCO_2 > 45$  mm Hg. T hypercapnia and  $\Delta Xrs$  data for 11 subjects. \* $p < 0.05$  between nights

This study has several limitations. Since it was a short-term study, we could not assess long-term effectiveness and safety. Moreover, this was a pilot study on a small number of patients. Ten to fifteen patients is the typical sample size for pilot studies. This number is not calculated on statistical bases, but it is

appropriate to assess the feasibility of a new method, inform possible improvements and collect preliminary data for larger clinical trials. The most reliable method for the assessment of ineffective efforts is to identify tidal swings in trans-diaphragmatic pressure (measured by gastric and oesophageal

**Table 2 Respiratory parameters and sleep quality during the night with fixed vs. EFL<sub>T</sub>-abolishing-EPAP**

	Fixed-EPAP	EFL <sub>T</sub> -abolishing-EPAP	p
<i>Gas exchange</i>			
mean PtcCO <sub>2</sub> , mmHg	54.5 (51.1, 59.0)	44.9 (41.6, 57.2)	0.365
<b>T hypercapnia, %</b>	<b>98 (94, 100)</b>	<b>62 (8, 100)</b>	<b>0.031</b>
Mean SpO <sub>2</sub> , %	93 (92, 95)	94 (93, 95)	0.204
T90, %	3 (0, 12)	1 (0, 2)	0.175
<i>Respiratory parameters</i>			
R <sub>INSP</sub> , cmH <sub>2</sub> O*s/L	9.7 (8.5, 12.0)	11.4 (9.3, 12.1)	0.577
X <sub>INSP</sub> , cmH <sub>2</sub> O*s/L	- 3.6 (- 4.1, - 2.3)	- 3.8 (- 3.9, - 2.9)	0.898
IPAP, cmH <sub>2</sub> O	15.7 (14.0, 17.1)	16.1 (14.3, 18.1)	0.638
<b>V<sub>T</sub>, mL</b>	<b>356 (252, 542)</b>	<b>272 (230, 395)</b>	<b>0.032</b>
<b>RR, bpm</b>	<b>16 (13, 18)</b>	<b>17 (14, 20)</b>	<b>0.019</b>
V <sub>E</sub> , L/min	5.3 (3.9, 6.4)	4.6 (3.8, 5.8)	0.123
<b>IE, n/h</b>	<b>261 (205, 351)</b>	<b>126 (93, 205)</b>	<b>0.003</b>

Data are reported as median (IQR)

Bold denotes a statistically significant difference between the fixed-EPAP and the EFL<sub>T</sub>-abolishing-EPAP nights (Wilcoxon signed-rank test, p < 0.05)

PtcCO<sub>2</sub> transcutaneous partial pressure of CO<sub>2</sub>, T hypercapnia percentage of time spent with a transcutaneous partial pressure of CO<sub>2</sub> > 45 mm Hg, SpO<sub>2</sub> peripheral oxygen saturation, T90 percentage of time spent with oxygen saturation SpO<sub>2</sub> below 90%, R<sub>INSP</sub> inspiratory resistance, X<sub>INSP</sub> inspiratory reactance, IPAP inspiratory positive airway pressure, V<sub>T</sub> tidal volume, RR respiratory rate, V<sub>E</sub> minute ventilation, IE ineffective efforts

\*p < 0.05 vs. fixed-EPAP

probes) that are not followed by an assisted breath. Our definition of ineffective efforts may have missed the efforts that did not generate any deflation in the flow signal, underestimating the actual number of events. However, we preferred not to measure the trans-diaphragmatic pressure because it could have disrupted sleep. We used PtcCO<sub>2</sub> and pulse oximetry as indicators of gas exchange. Arterial blood gas measurements would have been more precise; however, in the ordinary setting of polysomnography, it is not possible to have an invasive continuous measurement of arterial blood gasses. On the other hand, single blood gas measurements are not representative of the gas exchange during sleep, and multiple overnight assessments usually determine sleep disruption.

### Authors' contributions

EZ participated in data analysis and interpretation and prepared the first version of the manuscript. IM participated in the conception and design of the study, data collection, data analysis and interpretation. RP, LB and SC participated in the data collection and analysis. RT contributed to data analysis. FF participated in data analysis and interpretation and critically revised the manuscript. MV participated in the conception and design of the study, interpretation of the data and critically revised the manuscript. RLD participated in the conception and design of the study, data analysis, interpretation of the data and preparation of the manuscript. All authors read and approved the final manuscript.

### Funding

Politecnico di Milano University, Institution of EZ, IM, SC and RLD, owns a patent on the use of FOT for the detection of expiratory flow limitation licensed to Philips Respironics. Istituti Clinici Scientifici Maugeri received a free loan of part of the equipment used for this study and a research grant from Philips.

### Availability of data and materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

### Ethics approval and consent to participate

The study was approved by the ethics committee of ICS Maugeri (No. 897 CEC/2013) and written informed consent was obtained from all patients.

### References

- Milesi I, Porta R, Barbano L, Cacciatore S, Vitacca M, Dellacà RL. Automatic tailoring of the lowest PEEP to abolish tidal expiratory flow limitation in seated and supine COPD patients. *Respir Med.* 2019;155:13–8.
- Dellacà RL, Santus P, Aliverti A, Stevenson N, Centanni S, Macklem PT, et al. Detection of expiratory flow limitation in COPD using the forced oscillation technique. *Eur Respir J.* 2004;23:232–40.
- Zannin E, Chakrabarti B, Govoni L, Pompilio PP, Romano R, Calverley PMA, et al. Detection of expiratory flow limitation by forced oscillations during noninvasive ventilation. *Am J Respir Crit Care Med.* 2019;200:1063–5.
- Suh E-S, Pompilio P, Mandal S, Hill P, Kaltsakas G, Murphy PB, et al. Autotitrating external positive end-expiratory airway pressure to abolish expiratory flow limitation during tidal breathing in patients with severe chronic obstructive pulmonary disease: a physiological study. *Eur Respir J.* 2020. <https://doi.org/10.1183/13993003.02234-2019>.
- Fanfulla F, Taurino AE, Lupo NDA, Trentin R, D'Ambrosio C, Nava S. Effect of sleep on patient/ventilator asynchrony in patients undergoing chronic non-invasive mechanical ventilation. *Respir Med Respir Med.* 2007;101:1702–7.
- Vogelmeier CF, Criner GJ, Martinez FJ, Anzueto A, Barnes PJ, Bourbeau J, et al. Global strategy for the diagnosis, management, and prevention of chronic obstructive lung disease 2017 report. *Am J Respir Crit Care Med.* 2017;199(5):557–82.
- Dellacà RL, Rotger M, Aliverti A, Navajas D, Pedotti A, Farré R, et al. Non-invasive detection of expiratory flow limitation in COPD patients during nasal CPAP. *Eur Respir J.* 2006;27:983–91.
- American Academy of Sleep Medicine. The AASM manual for the scoring of sleep and associated events: Rules, terminology and technical specifications. Darien, IL, USA: American Academy of Sleep Medicine; 2007.
- Fanfulla F, Delmastro M, Berardinelli A, Lupo NDA, Nava S. Effects of different ventilator settings on sleep and inspiratory effort in patients with neuromuscular disease. *Am J Respir Crit Care Med.* 2005;172:619–24.
- Ergan B, Oczkowski S, Rochweg B, Carlucci A, Chatwin M, Clini E, et al. European Respiratory Society guidelines on long-term home non-invasive ventilation for management of COPD. *Eur Respir J.* 2019;54(3):1901003.
- Appendini L, Purro A, Patessio A, Zanaboni S, Carone M, Spada E, et al. Partitioning of inspiratory muscle workload and pressure assistance in ventilator-dependent COPD patients. *Am J Respir Crit Care Med.* 1996;154(5):1301–9.
- Elliott MW, Mulvey DA, Moxham J, Green M, Branthwaite MA. Inspiratory muscle effort during nasal intermittent positive pressure ventilation in patients with chronic obstructive airways disease. *Anaesthesia.* 2007;48:8–13.

News...continued from page 26

Asked whether the results should give doctors second thoughts about prescribing HFOV for preemies, Greenough noted, “We demonstrated no significant differences at 16-19 years in lung function, but did show significant advantages at 11-14 years of HFOV, I therefore I do not think they will have second thoughts about using HFOV for preemies—this would be likely if we had shown HFOV was associated with deleterious effects.”

### Screen COPD Patients With Sleep Problems for Mood Disorders

A study has shown a strong link between sleeping disturbances and depression in patients with chronic obstructive pulmonary disease. Adults with clinically stable COPD who reported sleep problems were significantly more likely to report depression or anxiety, poor self-efficacy, and poor health-related quality of life, compared with those not reporting sleep problems, according to the findings from a study of 245 patients. Sleep problems are common in patients with COPD and have been associated with poor COPD-related outcomes, wrote Sang Hee Lee, MD, of Wonkwang University Sanbon Hospital, Gunpo-si, South Korea, and colleagues. “However, there is a lack of research on factors associated with sleep disturbance in patients with COPD,” they wrote. In a prospective, multicenter, cross-sectional study published in the *Clinical Respiratory Journal*, the researchers enrolled 245 adults with COPD who completed the COPD and Asthma Impact Scale (CASIS) to determine sleep impairment. The CASIS was developed to measure sleep-related problems associated with respiratory disease, and scored on a scale of 1-100, with higher scores indicating greater sleep impairment. The average CASIS score was 40.9. The average age of the patients was 67 years, and 92% were men. Patients’ health-related quality of life, anxiety/depression, and self-efficacy were assessed using the St. George’s Respiratory Questionnaire (SGRQ), the 36-item Short-Form Health Survey (SF-36), Hospital Anxiety and Depression Scale (HADS), and the COPD Self-Efficacy Scale (CSES). The average scores on these measures were 36.0 for the SGRQ; 48.1 and 50.6, respectively, for the physical and mental components of the SF-36; 3.8 and 6.4, respectively, for the HADS-A and HADS-D measures of anxiety and depression; and 3.3 on the CSES. Worse sleep in these patients was associated with worse scores on measures of mood. In a multivariate analysis, higher scores on all four measures of health-related quality of life were significantly associated with higher CASIS scores ( $P = .006$  for SGRQ;  $P = .037$  for SF-36,  $P < .001$  for HADS, and  $P = .010$  for CSES). Although the CASIS did not allow for measurement of symptom severity and did not include many items related to breathing problems, the test “shows good internal consistency, test-retest reproducibility, and construct validity according to previous studies,” the researchers wrote. “The CASIS may be a good tool for evaluating sleep disturbances in COPD patients, and further study is needed,” they added. The study findings were limited by several factors including the cross-sectional study design, lack of data on obstructive sleep apnea, and lack of information on specific treatments such as at-home oxygen use or high-dose steroid use, the researchers noted. However, the results were strengthened by the use of a disease-specific sleep measure, and the study is the first known to include self-efficacy in relation to sleep quality in COPD patients, they reported. The results highlight the association between depression, poor quality of life, and self-efficacy in relation to poor sleep, and suggest that “Sleep quality could be improved by enhancing HRQL and self-efficacy,” the researchers said.

“Screening for mood disorder in patients with COPD is also needed,” they concluded.

### Dilated Blood Vessels in the Lung May Explain Low Oxygen Levels in Severe Cases of COVID-19

A new pilot study from the Icahn School of Medicine at Mount Sinai suggests that COVID-19 is causing significant dilation of the blood vessels of the lung, specifically the capillaries. This vasodilation is contributing to the very low oxygen levels seen in COVID-19 respiratory failure and also helps explain why the disease behaves differently than classic acute respiratory distress syndrome (ARDS). The study was published in the *American Journal of Respiratory and Critical Care Medicine*. In classical ARDS, pulmonary inflammation leads to leaky pulmonary blood vessels that flood the lungs with fluid, making the lungs stiff and impairing oxygenation. Many patients with COVID-19 pneumonia demonstrate severe hypoxemia that is markedly out of proportion to the degree of lung stiffness. This disconnect between gas exchange and lung mechanics in COVID-19 pneumonia has raised the question of whether the mechanisms of hypoxemia in COVID-19 differ from those in classical ARDS. The discovery was serendipitous. Researchers were initially assessing cerebral blood flow in mechanically ventilated COVID-19 patients with altered mental status to look for, among other things, abnormalities consistent with stroke. They used a robotic transcranial Doppler (TCD), the Lucid Robotic System by NovaSignal, to perform a “bubble study,” which is a non-invasive and painless ultrasound technique. “It is remarkable that a diagnostic machine used to study the brain could give us insight into the pathophysiology of a pulmonary disease. The benefit of using this particular system was that automated monitoring allowed providers to assess cerebral blood flow while minimizing the potential for exposure to COVID-19,” said Alexandra Reynolds, MD, Assistant Professor of Neurosurgery, and Neurology, at the Icahn School of Medicine at Mount Sinai and Director of TeleNeurocritical Care for the Mount Sinai Health System. During this study, agitated saline—saline with tiny microbubbles—is injected into the patient’s vein and TCD is used to determine if those microbubbles appear in the blood vessels of the brain. Under normal circumstances, these microbubbles would travel to the right side of the heart, enter the blood vessels of the lungs, and ultimately get filtered by the pulmonary capillaries, because the diameter of the microbubbles is bigger than the diameter of the pulmonary capillaries. If the microbubbles are detected in the blood vessels of the brain, it implies that either there is a hole in the heart, so that blood can travel from the right to the left side of the heart without going through the lungs, or that the capillaries in the lungs are abnormally dilated, allowing the microbubbles to pass through. In the pilot study, 18 mechanically ventilated patients with severe COVID-19 pneumonia underwent TCD with bubble study. Fifteen out of the 18 (83 percent) patients had detectable microbubbles, indicating the presence of abnormally dilated pulmonary blood vessels. The number of microbubbles detected by the TCD correlated with the severity of hypoxemia, indicating that the pulmonary vasodilations may explain the disproportionate hypoxemia seen in many patients with COVID-19 pneumonia. Previous studies have demonstrated that only 26 percent of patients with classical ARDS have microbubbles during a bubble study; furthermore, the number of these microbubbles does not correlate with the severity of hypoxemia, implying that pulmonary vascular dilations are not a major mechanism of hypoxemia in classical ARDS. “It is becoming more evident that the virus wreaks havoc on the pulmonary vasculature

in a variety of ways. If these findings are confirmed in larger studies, pulmonary microbubble transit may potentially serve as a marker of disease severity or even a surrogate endpoint in therapeutic trials for COVID-19 pneumonia. Future studies that investigate the use of pulmonary vascular constrictors in this patient population may be warranted,” says senior author Hooman Poor, MD, Assistant Professor of Medicine (Pulmonary, Critical Care and Sleep Medicine) at the Icahn School of Medicine at Mount Sinai and Director of Pulmonary Vascular Disease at the Mount Sinai – National Jewish Health Respiratory Institute. The pilot study has since expanded to collect data from approximately 80 patients, including those with less severe disease, and will evaluate the severity of microbubble transit and how it varies during the course of the disease.

### **Device Available for Clinical Trials**

Vitalograph announced that their most powerful ever In2itive e-Diary is now available for clinical trials in the USA. This next generation In2itive e-Diary combines in-clinic spirometry, home monitoring of respiratory endpoints, and eCOA data gathering functions in a robust, handheld medical device. New features include: large, high resolution touch screen with clear text, animated training module and live spirometry feedback making the device easy to use and promoting high quality and reliable data; alerts, reminders and workflows are fully customizable to fit study protocols; automatic end to end secure data transmission. Fully integrated GSM module allows automatic, secure, transmission of data to the study web portal for instant access enabling real-time insight into site and subject performance. The In2itive e-Diary is a fully validated class II medical device that meets or exceeds all technical requirements for cyber-security and data protection. Vitalograph is a world leading provider of outstanding quality cardio-respiratory diagnostic devices, clinical trial services and medical equipment servicing. With a pioneering heritage of excellence spanning half a century Vitalograph continues to make valuable contributions to effective medical care and enhanced quality of life.

### **Siemens Healthineers Obtains First FDA EUA for Semi-Quantitative Antibody Test**

Siemens Healthineers announced that it received FDA Emergency Use Authorization (EUA) for the SARS-CoV-2 IgG (COV2G) antibody test. This is the first antibody test authorized with a semi-quantitative detection claim and the fifth antibody test from the company to receive EUA that offers sensitivity and specificity of greater than 99 percent. The COV2G antibody test offers both a positive or negative result for IgG antibodies and reports a numerical result expressed as index value. The test also attained the CE-mark and is now broadly available globally. A positive or negative result for IgG antibodies provides insight into an individual's prior exposure to the SARS-CoV-2 virus. Importantly, a semi-quantitative result enables clinicians to gauge the level of IgG antibodies in a patient's blood sample. With this numerical value, clinicians can establish a baseline and be better equipped to assess changes of an individual's immune response to the SARS-CoV-2 virus. Comparison of numerical results will help determine how SARS-CoV-2 antibodies develop in an individual and persist over time. A semi-quantitative result is necessary to accurately establish the level of IgG that may be protective, and the Siemens Healthineers' COV2G assay is well positioned to support this global pursuit. When an individual is infected with the SARS-CoV-2 virus, unique antibodies will develop at different stages of the infection. Whereas the Siemens

Healthineers SARS-CoV-2 Total antibody test detects antibodies to IgM and IgG that are present both early and later during the immune response, the COV2G antibody test specifically detects IgG antibodies that persist, and are the basis for an individual's longer term immune response. The combination of these tests provides a complete picture of a patient's serological status for the most accurate results throughout his or her continuum of care. “Our high-quality antibody test helps clinicians assess the level of a person's immune response, which is an important tool to have at this stage of the pandemic,” said Deepak Nath, PhD, President of Laboratory Diagnostics for Siemens Healthineers. “Siemens Healthineers offers a robust portfolio of reliable tests to help support patient care and fight COVID-19.” Highly accurate antibody test results support key decision-making for individuals and communities. Antibody tests have multiple uses: As an adjunct to PCR tests to aid in clinical assessment; to help determine prior exposure to the virus, by detecting antibodies that may neutralize the virus; to potentially identify donors of convalescent plasma; for epidemiological purposes including establishing prevalence of disease in populations; to potentially help verify effectiveness of vaccines as they become available. Antibody tests from Siemens Healthineers are well-positioned to aid vaccine development efforts. The COV2G antibody test, and all SARS-CoV-2 antibody tests from Siemens Healthineers, detect antibodies to S1RBD. Multiple potential vaccines in development for SARS-CoV-2 include the spike protein, specifically S1RBD—a key protein on the surface of the SARS-CoV-2 virus—within their focus. Among the considerations for accelerated vaccine approval, according to most recent FDA guidance issued on June 30, validated serology testing in clinical trials may play a pivotal role in assessing surrogate endpoints such as immune response to a vaccine. This requires additional understanding of SARS-CoV-2 immunology and, specifically, vaccine immune responses that might be reasonably likely to predict protection against COVID-19 and post-marketing studies to affirm predicted efficacy. The COV2G test meets or exceeds FDA EUA requirements. The COV2G antibody test is available on an expansive installed base of analyzers installed in the U.S. and in countries that accept the CE mark worldwide. This includes the Atellica Solution and ADVIA Centaur XP and XPT families of analyzers. Comparable tests for Siemens Healthineers Dimension Vista and Dimension EXL systems also are being pursued. Siemens Healthineers has distinguished itself during the pandemic as a provider of quality antibody tests. For example, in a recent head-to-head evaluation of four commercial antibody tests conducted by Public Health England, in partnership with the University of Oxford, Siemens Healthineers' COV2T assay was the only test that met both sensitivity and specificity targets.



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<sup>1</sup> Huynh TT, Liesching TN, Cereda M, Lei Y, Frazer MJ, Nahouraii MR, Diette GB, Efficacy of Oscillation and Lung Expansion in Reducing Postoperative Pulmonary Complication, Journal of the American College of Surgeons (2019)

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