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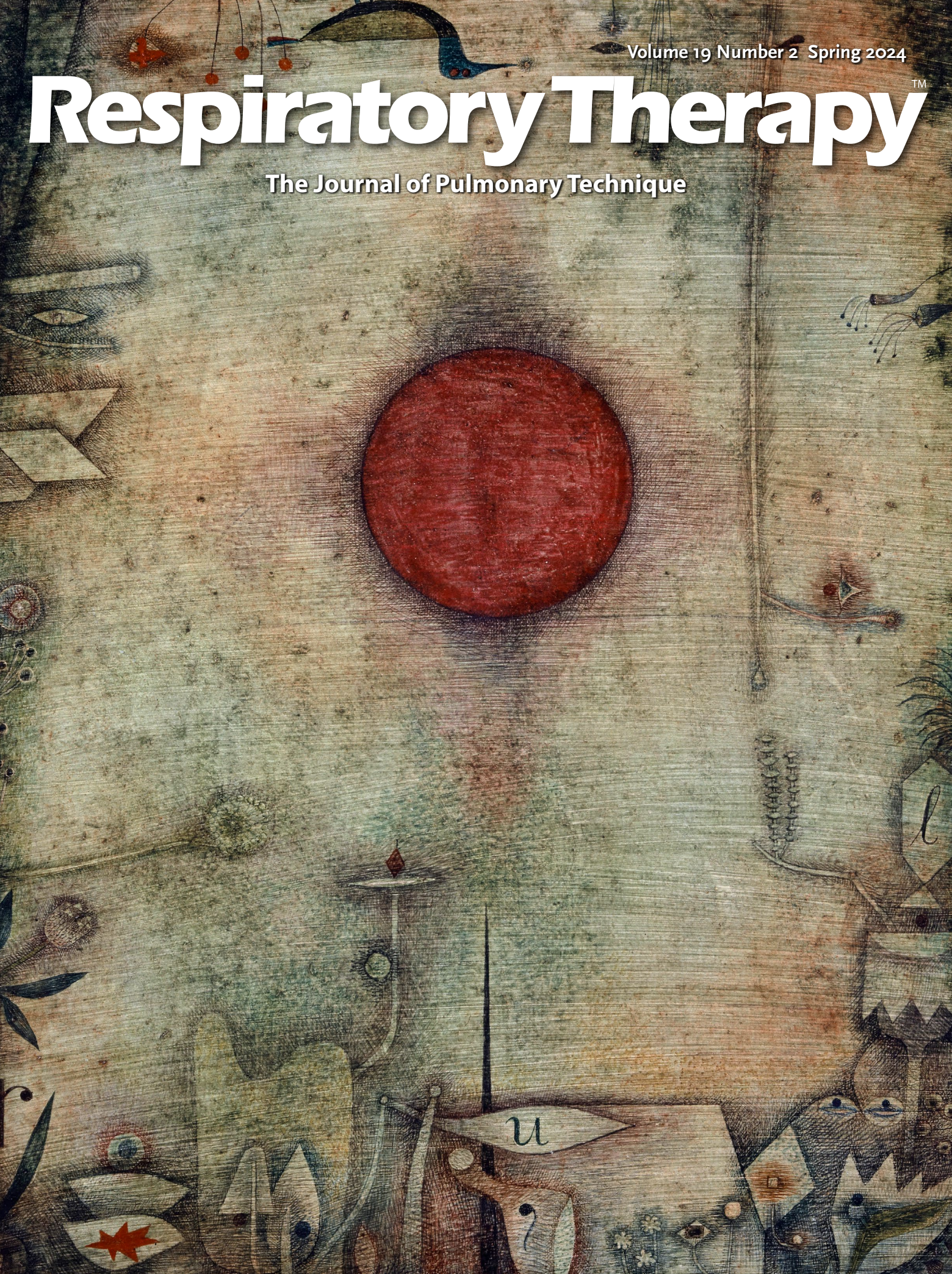
Respiratory Therapy™

The Journal of Pulmonary Technique



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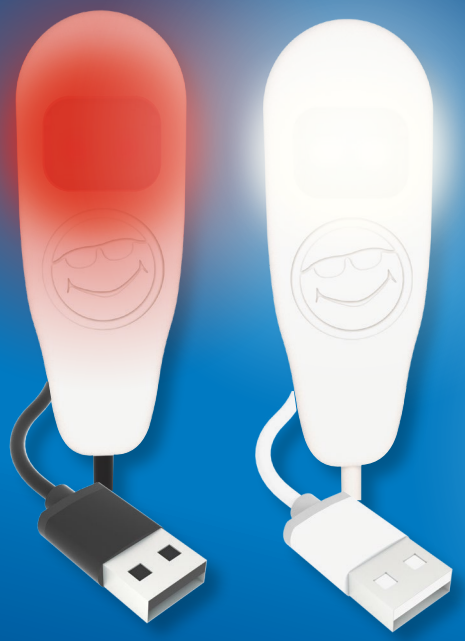

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Respiratory Therapy™
The Journal of Pulmonary Technique

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Spring 2024

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News

■ Spring 2024

Spirometer Receives Approval from China's NMPA

Monitored Therapeutics, Inc. (MTI), a Remote Patient Monitoring company, announced the approval of its GoSpiro spirometer by China's FDA equivalent, NMPA. MTI has partnered with Shenzhen based Spiritumtec Ltd, a Chinese company with a history of producing high-quality respiratory products to manufacture and market the GoSpiro in China. The founders of Spiritumtec have previously worked for VIASYS Healthcare alongside of the founders of MTI, building a strong long-term relationship. The version of the GoSpiro approved for sale in China will be manufactured by Spiritumtec under a licensing agreement with MTI. "The approval of the GoSpiro in China will amplify MTI's reach for supporting clinical trials for the pharmaceutical industry in China where there is a great need for validated spirometers for home monitoring," said Alex Stenzler, Chief Science Officer for MTI. "The manufacturing line in China will increase the production capabilities of spirometers to supplement MTI's production needs in the US." Monitored Therapeutics is a digital health company built to empower providers with end-to-end solutions to easily evaluate, monitor, and care for their patients. Our solutions focus on the respiratory care continuum—not just a portion of it—so providers can deliver the best care for patients no matter where they are in their healthcare journey and how it evolves. The company's mission is to improve the quality of life of respiratory patients by increasing patient engagement, promoting drug adherence while simultaneously reducing healthcare costs.

Pulse Oximetry Device Measures Accurately on Both Black and White People Even During Low Perfusion: Study

Masimo announced the findings of a retrospective, peer-reviewed study published in the *Journal of Clinical Monitoring and Computing* in which Dr Vikrant Sharma, along with Dr Steven J. Barker, Dr William C. Wilson, and colleagues at Masimo performed a focused analysis of previously published data to evaluate the impact of low perfusion on the performance of Masimo SET pulse oximetry across a variety of skin pigmentations. The analysis demonstrated that Masimo RD SET sensors accurately measured oxygen saturation (SpO_2) for both Black and White subjects when perfusion index (Pi) was normal *and* when Pi was low—adding to the body of evidence that Masimo SET pulse oximetry delivers

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accurate values across the skin tone range, with no clinically significant difference in accuracy or bias, even in challenging conditions. In a study published in 2023, Drs Barker and Wilson analyzed Masimo laboratory data obtained from self-identified Black and White volunteer subjects to evaluate differences in Masimo pulse oximetry accuracy and bias on the basis of skin tone. To do so, they reviewed more than 7,000 paired data samples (collected between 2015 and 2021) from 75 subjects (39 Black and 36 White) and found no clinically significant difference in accuracy or bias. For this newly published study, noting that low peripheral perfusion is a "recognized confounder of conventional pulse oximetry" and in light of concerns that low perfusion combined with dark skin pigmentation might decrease pulse oximetry's accuracy, the investigators sought to determine whether accuracy on Black or White subjects was impacted by a subject's perfusion index (Pi) with Masimo SET pulse oximetry. To that end, they abstracted Pi values from their dataset, and divided them into "low perfusion" (Pi ≤ 1) and "normal perfusion" (Pi > 1) groups. They then performed statistical analyses to determine bias (the mean difference between SpO_2 and arterial oxygen saturation [SaO_2]), precision (the standard deviation of the difference), and accuracy (root-mean-square error, or A_{RMS}[*]). The researchers found that in the normal perfusion group, comparing SpO_2 to SaO_2 values, there was overall bias and precision of +0.18% ± 1.34%, with accuracy of 1.37% A_{RMS}. For the subset of Black subjects, there was bias and precision of -0.26% ± 1.37%, and for White subjects, -0.12% ± 1.31%. In the low perfusion group, there was overall bias and precision of 0.48% ± 1.59%, with accuracy of 1.64% A_{RMS}. For Black subjects, bias and precision were 0.19% ± 1.53%, and for White subjects, 0.91% ± 1.57%. Based on their analysis, the authors concluded, "Masimo SET pulse oximeters with RD SET sensors are accurate

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1. DiBlasi, R, et al. (2023). BiWaze Clear Aerosol Comparison White Paper. Seattle Childrens Hospital and Research Institute. https://abmrc.com/wp-content/uploads/2023/07/BiWaze-Clear-Aerosol-Comparison-White-Paper.pdf

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for individuals of both Black and White races when Pi is normal, as well as during conditions when Pi is low. The A_{RMS} for all conditions studied is well within FDA standards. This study was conducted in healthy volunteers during well-controlled laboratory desaturations, and results could vary under certain challenging clinical conditions." However, the authors noted that controlling conditions in the laboratory setting helps "minimize confounders that are present in clinical scenarios, allowing for greater focus on the topics of skin tone and Pi. Indeed, abnormal hemoglobin species (e.g., carboxyhemoglobin and methemoglobin) [known clinical SpO_2 confounders] were measured and reported in the earlier paper by Barker and Wilson, and the values were similar (statistically the same) between Black and White groups. Also, one can only ethically conduct desaturation studies using healthy volunteer subjects in a safe setting."

Conference Comes Back to America

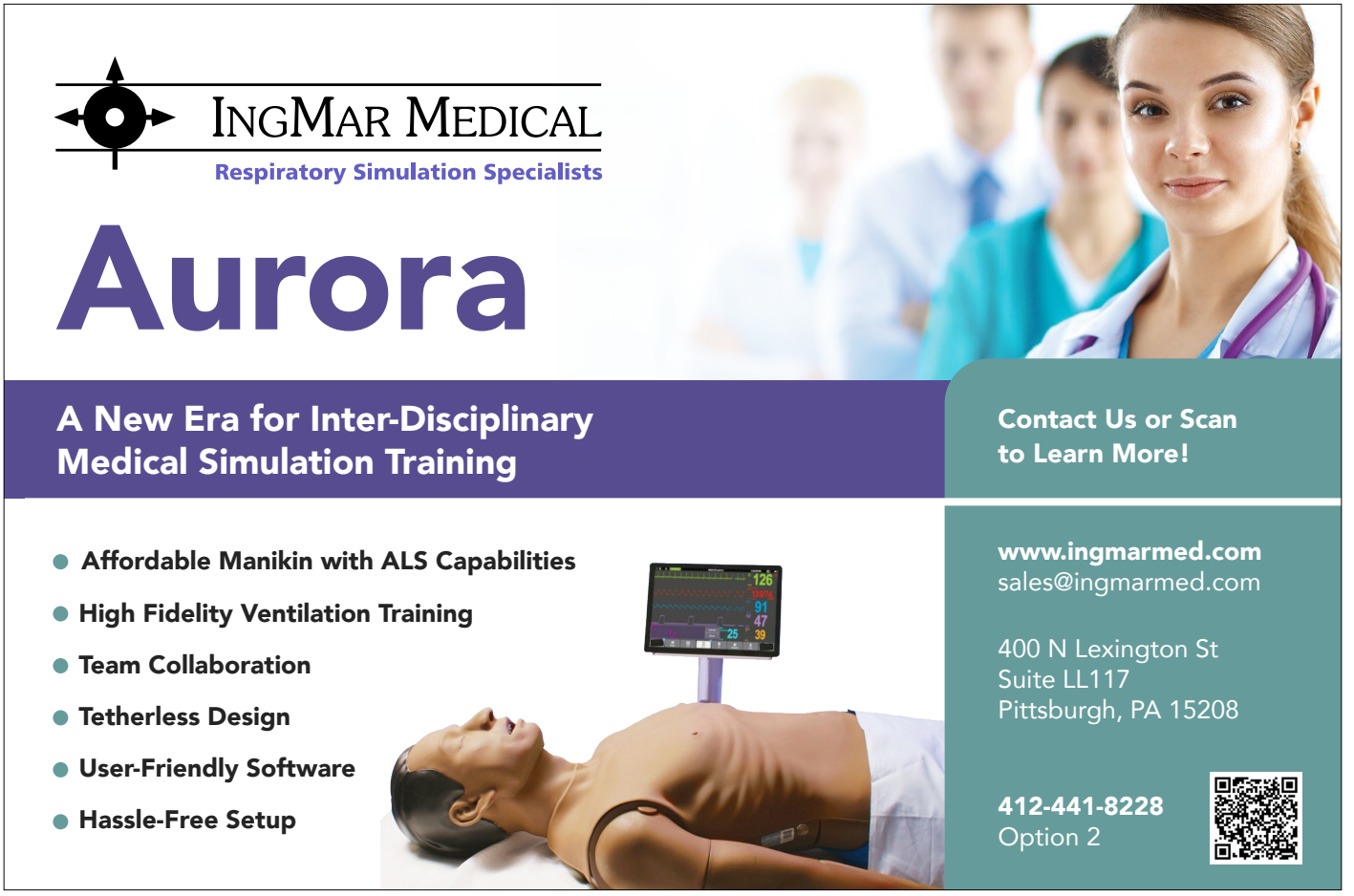
ECO PHYSICS, INC. will exhibit at the International Association of Breath Research's (IABR) International Conference for Breath Research. This year the show will take place in Indianapolis, Indiana-the heartland of America. This is the first time in twelve years the show will be held in the USA, from June 3-6, 2024. The International Congress for Breath Research represents an opportunity for experts to learn and exchange the latest breakthroughs and emerging topics on breath research with peers around the world. More than 150 guests from academics, basic sciences, medicine, industrial companies, and laboratories are expected to attend. ECO PHYSICS, INC. will be presenting and exhibiting the Analyzer CLD 88 Series {pictured below} for exhaled nitric oxide research measurements. ECO PHYSICS, INC. offers a broad range of nitric oxide (NOx) analyzers for medical research & indoor, ambient, tropospheric, and stratospheric monitoring. The principle of chemiluminescence detection (CLD) is an extremely selective method for measuring NO precisely, with high linearity over a wide concentration range and with remarkably high reproducibility. ECO PHYSICS, INC. is the sole North American distributor of ECO PHYSICS AG and ECO MEDICS AG nitric oxide measurement devices.

Device Maker Welcomes New CEO

React Health, a leading US sleep, respiratory and cardio-pulmonary device manufacturer, distributor, and diagnostic services provider, is excited to announce the appointment of Bill Shoop as its Chief Executive Officer. Bill brings two decades of invaluable experience in the healthcare industry, with his most recent role being Vice President and General Manager of ResMed North America. In his previous capacity at ResMed, Shoop demonstrated his exceptional leadership skills and played a pivotal role in the company's success. Now as React Health's CEO, he is poised to bring his wealth of knowledge and expertise to lead the company to even greater success. Bill shared his enthusiasm for the new role, saying "I am extremely excited about the opportunity to join this experienced and talented team. I believe React Health is very well positioned to help the industry and continue to advance our mission of delivering innovative solutions that positively impact patients' lives and the people that care for them." React Health is confident that Bill's strategic vision and leadership will contribute to the company's continued growth and success. "Bill is a proven executive with a successful record of building strong and diverse teams. He is a passionate leader who delivers results", said Sean Heyniger, React Health Board Member. Bill Shoop officially assumed his role as CEO of React Health effective February 1, 2024.

Five Bold Predictions for Long COVID in 2024

#1: We'll gain a better understanding of each long COVID phenotype This past year, a wide breadth of research began showing that long COVID can be defined by a number of different disease phenotypes that present a range of symptoms. Researchers identified four clinical phenotypes: Chronic fatigue-like syndrome, headache, and memory loss; respiratory syndrome, which includes cough and difficulty breathing; chronic pain; and neurosensorial syndrome, which causes an altered sense of taste and smell. Identifying specific diagnostic criteria for each phenotype would lead to better health outcomes for patients instead of treating them as if it were a "one-size-fits-all disease." #2: Monoclonal antibodies may change the game We're starting to have a better understanding that what's been called "viral persistence" as a main cause of long COVID may potentially be treated with monoclonal antibodies. These are antibodies produced by cloning unique white blood cells to target the circulating spike proteins in the blood that hang out in viral reservoirs and cause the immune system to react as if it's still fighting acute COVID-19. Smaller-scale studies have already shown promising results. A January 2024 study published in *The American Journal of Emergency Medicine* followed three patients who completely recovered from long COVID after taking monoclonal antibodies. "Remission occurred despite dissimilar past histories, sex, age, and illness duration," wrote the study authors. Larger clinical trials are underway at the University of California, San Francisco, California, to test targeted monoclonal antibodies. If the results of the larger study show that monoclonal antibodies are beneficial, then it could be a game changer for a large swath of patients around the world. #3: Paxlovid could prove effective for long COVID The US Food and Drug Administration granted approval for Paxlovid for the treatment of mild to moderate COVID-19 in adults at a high risk for severe disease. The medication is made up of two drugs packaged together. The first, *nirmatrelvir*, works by blocking a key enzyme required for virus replication. The second, *ritonavir*, is an antiviral that's been used in patients with HIV and helps boost levels of antivirals in the body. In a large-scale trial headed up by Putrino and his team, the oral antiviral is being studied for use in the post-viral stage in patients who test negative for acute COVID-19 but have persisting symptoms of long COVID. Similar to monoclonal antibodies, the idea is to quell viral persistence. If patients have long COVID because they can't clear SAR-CoV-2 from their bodies, Paxlovid could help. But unlike monoclonal antibodies that quash the virus, Paxlovid stops the virus from replicating. It's a different mechanism with the same end goal. It's been a controversial treatment because it's life-changing for some patients and ineffective for others. In addition, it can cause a range of side effects such as diarrhea, nausea, vomiting, and an impaired sense of taste. The goal of the trial is to see which patients with long COVID are most likely to benefit from the treatment. #4: Anti-inflammatories like metformin could prove useful Many of the inflammatory markers persistent in patients with long COVID were similarly present in patients with autoimmune diseases like rheumatoid arthritis, according to a July 2023 study published in *JAMA*. The hope is that anti-inflammatory medications may be used to reduce inflammation causing long COVID symptoms. But drugs used to treat rheumatoid arthritis like abatacept and infliximabcan also have serious side effects, including increased risk for infection, flu-like symptoms, and burning of the skin. Still, other anti-inflammatories that could work don't have as many side



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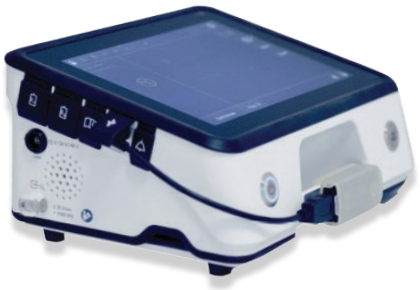

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[1] As of January 24, 2024, the Triology series ventilators have been discontinued and are not for sale in the United States.

[2] The LUISA ventilator is authorized for distribution in the USA, EU, Japan, Israel, UK and Australia, among others.

effects. For example, a study published in *The Lancet Infectious Diseases* found that the diabetes drug metformin reduced a patient's risk for long COVID up to 40% when the drug was taken during the acute stage. Metformin, compared to other anti-inflammatories (also known as immune modulators), is an inexpensive and widely available drug with relatively few side effects compared with other medications. #5: Serotonin levels — and selective serotonin reuptake inhibitors (SSRIs) — may be keys to unlocking long COVID One of the most groundbreaking studies of the year came last November. A study published in the journal *Cell* found lower circulating serotonin levels in patents with long COVID than in those who did not have the condition. The study also found that the SSRI fluoxetine improved cognitive function in rat models infected with the virus. Researchers found that the reduction in serotonin levels was partially caused by the body's inability to absorb tryptophan, an amino acid that's a precursor to serotonin. Overactivated blood platelets may also have played a role. If patients show an improvement in symptoms, then the next step is looking into whether SSRIs boost serotonin levels in patients and, as a result, reduce their symptoms.

Philips' US Sales Of Sleep Apnea Devices Face Years-long Halt After FDA Deal

Dutch health technology company Philips will not sell new devices to treat sleep apnea in the US in the coming years as it works to comply with a settlement with the Food and Drug Administration (FDA) announced. The agreement followed the recall of millions of breathing devices and ventilators used to treat sleep apnea in 2021 because of concerns that foam used to reduce noise from the devices could degrade and become toxic, carrying potential cancer risks. Philips said it had reached what is known as a consent decree that spells out the improvements it needs to make at its Respironics plants in the US. Until the conditions are met, no new Respironics devices will be sold in the US, the company said. Philips shares were down in Amsterdam, after news of the agreement, which ING analyst Marc Hesselink said was "very punitive." "We believe it will be very difficult for Philips to recover its US Respironics market position," Hesselink said in a note. Citi analyst Mathieu Chevrier said he had previously assumed Philips would return to the U.S. market from July, but Monday's announcement delays the timeline, and is likely a positive for rival ResMed. Shares of ResMed rose nearly 2% in early US trading. The decree is being finalized and will be submitted to the relevant U.S. court for approval. It was not clear how long that would take. CEO Roy Jakobs declined to give details on the conditions that Philips will have to meet, but as a general indication said it on average takes between five and seven years to comply with consent decrees in the medical equipment industry. Philips said the costs of the agreement led to a provision of 363 million euros ($393.5 million) in the fourth quarter of last year, and were expected to be about 1% of total revenues in 2024.

High and Low Body Mass Indices Promote Respiratory Symptoms

Individuals with either high or low body mass index (BMI) showed an increased risk for respiratory symptoms and diseases than those with BMI in the normal range. The researchers reviewed data from the National Health and Nutrition Examination Survey (NHANES) from 2003 to 2012; the study population included 12,719 adults older than 40 years with data on respiratory symptoms; 51% were female, and 53.3% were non-Hispanic White individuals. The study sought to assess the correlation between BMI and respiratory symptoms (cough, wheezing, and dyspnea), chronic obstructive pulmonary disease (COPD), and asthma in unadjusted and adjusted models based on sex, race, marital status, poverty-income ratio (PIR), education level, and smoking status. In a logistic regression and curve fitting analysis, BMI showed a U-shaped relationship with respiratory symptoms, asthma, and COPD, with increased risk in individuals with high or low BMI than those with BMIs in the middle quartiles. In a stratified analysis by race, the risk for cough was significantly higher among non-Hispanic Black individuals than other races ($P < .0001$), and a higher BMI was associated with an increased risk for COPD in non-Hispanic Black individuals (odds ratio, 1.053; $P < .0001$). The researchers found no significant impact of biological sex on the relationship between BMI and respiratory symptoms, COPD, or asthma. The results support previous studies showing that a BMI that is too low can be detrimental to health. "These results suggest that the risk of small airway obstruction in underweight individuals deserves more attention and that excessive wasting may also affect the prognosis of patients with COPD," the researchers wrote. The lead author on the study was Yuefeng Sun of Shandong University of Traditional Chinese Medicine, Jinan, China.

Notice Issued for Ventilators

Valued Customers, Bunnell Incorporated hereby announces the Model 203 LifePulse High Frequency Jet Ventilator will be rendered obsolete as of July 1, 2026. The aging ventilators have been used in the critical care of neonates for 36 years. Bunnell intends to service and support these neonatal ventilators until the date of obsolescence. Hospitals are encouraged to migrate to the newer Model 204 LifePulse High Frequency Jet Ventilator, which has been on the market since 2017. The Model 204 LifePulse HFJV provides the same therapy and utilizes the same disposables. Model 203 ventilators may be traded in towards the purchase of the Model 204 LifePulse HFJV. To learn more about the enhanced features of the new LifePulse High Frequency Jet Ventilator Model 204, visit www.bunl.com. For inquiries call 800-800-4358 or email info@bunl.com.

Masimo Announces Reinstatement of Import Ban on Infringing Apple Watches

Masimo, a global leader in innovative noninvasive monitoring technologies, welcomes the Federal Circuit's ruling to lift the temporary stay on the import ban of certain Apple Watch models. This decision reinstates the US International Trade Commission's import ban and cease and desist order on Apple watches that were found to infringe Masimo's patented pulse oximetry technology. "The Federal Circuit's decision to lift the temporary stay is a victory for the integrity of the American patent system and the safety of people relying on pulse oximetry," said Joe Kiani, Founder and CEO of Masimo. "It affirms that even the largest and most powerful companies must respect the intellectual rights of American inventors and must deal with the consequences when they are caught infringing others' patents." Masimo has previously made available a study showing that Apple Watch's pulse oximetry missed over 90% of potentially life-threatening events. The Apple Watch pulse oximeter was not cleared by the United States Food and Drug Administration for medical use. On the other hand, the Masimo W1 health watch was recently cleared by the FDA for its indicated medical uses, including continuous pulse oximetry. Masimo's pulse oximetry technology is used on over 200 million patients in hospitals

Continued on page 29…

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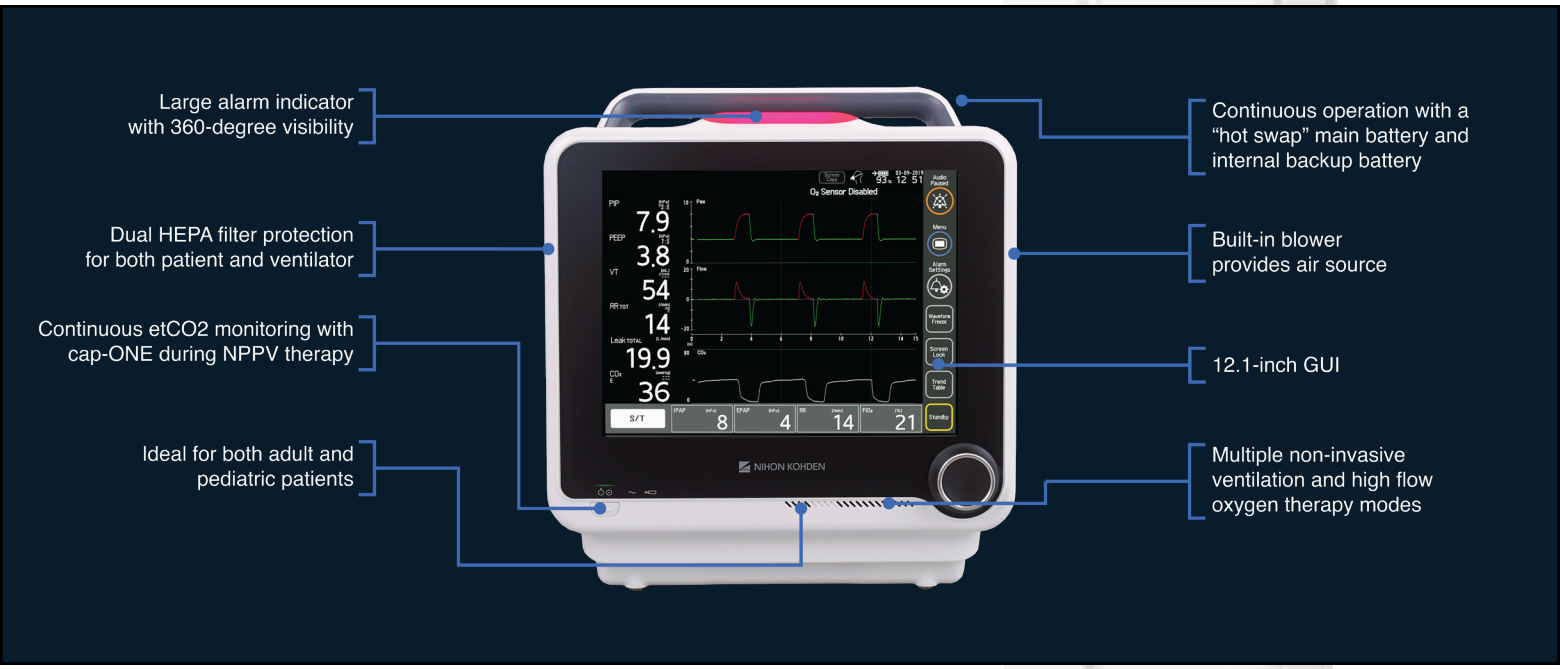

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MKT-01261 [A]

Hemodynamic Monitoring: Are We Keeping Our Patients Safe?

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. Participating in the interview is Angela Craig, nurse specialist at Cookeville Regional Medical Center.

Tracy Cook: Hello everyone and welcome to our webinar. My name is Tracy Cook and I'm with Saxe Healthcare Communications. I'd like to show our audience how you can send in questions throughout our webinar. Our speaker will try and answer as many as possible at the end of the presentation. Please submit your text questions and comments using the question panel and you can download today's handout in the handout section of the GoTo Webinar control panel. I'd like to introduce our moderator, Heather Davenport. Heather has been a critical care nurse for over 23 years. She is currently the cardiovascular clinical nurse educator at Cookeville Regional Medical Center. She works with CVICU and cardiac stepdown and cardiac outpatient procedure units. Additionally, Heather provides clinical education for staff in all aspects of medical and surgical cardiac care, Impella, IABP, CRRT, arrhythmia, and hemodynamics in multiple modalities and technologies. Heather is also the president of her local AACN chapter. Heather, welcome.

Heather Davenport: Thank you, Tracy. I appreciate that kind introduction. The title of our webinar today is Hemodynamic Monitoring: Are We Keeping Our Patients Safe? Speaking on this very timely topic is my colleague and one of the experts on the topic of hemodynamic monitoring, Angela Craig. Angela is a clinical nurse specialist. She's been a clinical nurse specialist for over 25 years and is PRN at Cookeville Regional Medical Center. She has spoken on hemodynamics at the local, state, and national level. She speaks around the country on stroke volume-based hemodynamic monitoring and fluid management.

Disclosures. The speaker disclosed the following relevant financial relationships. She's a medical science liaison with Baxter Medical Affairs and she's an independent consultant. Non-financial relationship with the Sepsis Alliance Advisory Board. Continuing education for nurses and respiratory therapists. This activity has been approved for one contact hour of continuing education. At the end of this webinar, you can obtain those continuing education credits. The URL will be provided at the conclusion of this webinar. The accreditation statements are listed below. This activity is supported by an education grant from Dale Medical Products. And with that, Angela, thank you so much for joining us today and we'll turn the presentation over to you.

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

Angela Craig: I thank you, Heather. Heather and I have worked together for quite some time and is a wonderful friend, so I'm super excited she can moderate today. Well, hello. Good morning, good afternoon, depending on where you are in the country. And today, we are going to talk about Hemodynamic Monitoring: Are We Keeping Our Patients Safe? And know this is a point that is very near and dear to our hearts. We want to do everything we can to keep our patients safe. So today, the objectives will be to discuss the importance of leveling and zeroing of a pressurized line. We're going to talk about some infection prevention strategies and techniques with an arterial line as well as a central line, and we're going to discuss potential clinical errors that are associated with hemodynamic monitoring and what we can do to prevent these errors.

So we are going to get right to it. We're going to start first by talking about the importance of leveling and zeroing a pressurized line. Now we know that there are factors that affect arterial pressure monitoring. And we're going to start with priming of tubing and components. We're going to then talk about proper leveling, proper zeroing, and then talk about a square wave test. So when we think about priming of tubing and components, I want to just go back. And I know that this topic may seem very basic, but I will tell you that I know years ago when I was trained, I really wasn't taught the right way initially on how to do all these things. So I try really hard and I have tried over the years to really educate the new nurses coming on and we have a lot of new nurses to make sure they understand also the why and the rationale behind why we do what we do.

So the first thing I want to mention is that we really should prime our line before we add pressure. So whenever we're priming that pressure tubing, making sure that we prime before we add pressure. Now why is that? What is the rationale? Well, priming that tubing under pressure, what it does is it increases turbulence and it can cause air bubbles to enter that tubing. And we know that in any pressurized line, we really don't want to have those extra bubbles. We don't want to have any air in that line. I will tell you that, gosh, when I graduated years ago, my first nurse job was in the ICU, and we just would just put that pressure bag on, pump it up, and then when we would pull our tubing to allow the fluid to go through, it would just fly through. Right? But I've realized over the years that we always thought that saved time, but the reality is that's not the safest, best way to do that. So always prime before you add pressure.

The other thing is really to ensure that the air is out of that bag

prior to priming. Now, there are multiple ways of doing this and I'm not going to go into all those methods, but just whatever you do, you want to make sure that that air is out of that bag before you prime. Now our rationale behind that is evacuating air from that flush bag will help prevent air from being flushed to the patient if the bag runs out of normal saline solution. Now I, one time, was in a meeting, and all of a sudden, we heard a code called and what we found out was that that patient, the fluid had run out of the bag and air had gotten into that line and that patient coded. So it can be significant. That's why it's really important also when you ensure the air is out of that bag, also as you're doing your checks before and when you start every shift, making sure there is an adequate amount of solution in that flush bag.

Also, filling the drip chamber halfway prevents air bubbles from entering the tubing. It allows the nurse to see that the solution is flowing during a manual flush of that invasive line. So that is really good because how many of you have had where you have too much fluid in that flush chamber and you can't see when you're pulling the tab or squeezing, whatever technology you have, you can't see that coming down. So you really want only about half of that filled so you can know and be able to troubleshoot with that. Next is just something to mention along with that is you really want to make sure your line is stabilized, and I'm going to give you some suggestions for stabilization of a line with an arterial line as well as stabilization of a line with a central line. So this is just one example how you can try to stabilize your arterial line. It's really important that that arm is stabilized. We also want protection against that arterial line.

I also want to focus, point out here on this area. You can see that it's very well-stabilized with the dressing. You can also see there is a patch here at the center, the insertion site, and that is a chlorhexidine-impregnated patch, and so that or sponge. So that is really important to help with infection prevention. Also, I wanted to show you, here, you can see that it's stabilized over on the end here, taped down. The other thing I want to mention, and I'm hoping you can see my cursor, that you can see here, I just want to remind everybody that wherever this stopcock is facing this little tab here, that means it's off. So right now, this is off to the patient, and you can see here that there is a cap.

Now it's important when we first have a cap that comes with the packaging, it is a vented cap and it's totally okay to prime your line. In fact, you want to prime it with that vented cap so you can keep that vented cap on and you can prime your line. However, once that line is primed, you want to remove the vented cap and put something like what is on here, which is a non-vented cap. Once again, that is a safety mechanism for infection prevention. And then you can see the stabilization device. That just helps keep the patient's arm in the appropriate setting so that you can get a good waveform. It's really important that you have a good waveform and that it's not sensitive to position.

Now let's talk next about proper leveling. So you want to level that stopcock to the phlebostatic axis. So let's talk through that. How can we determine what phlebostatic axis is? So it's determined by, if you think about drawing an imaginary vertical line from the fourth intercostal space at the sternal border to the right side of the chest, and you can see that's with A. And then

a secondary imaginary line is drawn horizontally at the level of the midpoint between the anterior and posterior surfaces of the chest. So you can see the anterior and posterior surfaces of the chest, think about where the middle of that is and draw a line in there. And then your phlebostatic axis is located at the intersection of point A and B. So right about there. And it is really important that we level to that appropriate area.

Now the reason why it's important that we level to the appropriate area is that when the transducer is aligned mid-chest, the effects of hydrostatic pressure on the transducer are zero. So the displayed pressures will then be accurate. Now one thing I want to share with you is that you can see here the patient is flat. However, just know, studies have shown that it doesn't matter what level the patient is at as long as you are leveled and zeroed to the phlebostatic axis. So even though you're going to see this patient is flat. Most of our patients are not flat, right? A lot of them, we want up at 30 degrees at least, and so you would level to that patient's. Wherever they're at, in their bed. Now, for every inch the transducer is below mid-chest level, the weight of that fluid on the transducer diaphragm will add two millimeters of mercury to the true pressure. So that is why one of the reasons why it's so important that we level in zero to that so we get an accurate reading.

And then in the opposite direction, for every inch that the transducer is above the mid-chest level, the displayed pressure will be about two millimeters of mercury less than actual pressure. And I will tell you that I've gone into a room before as I'm rounding, and one time, I noticed a patient wasn't up 30 degrees and I asked the nurse, "Is there a reason why this patient can't have their head of the bed up 30 degrees?" And she said, "Well, their blood pressure is low," so she wanted to keep their head down a little bit. So I walked in the room and I noticed that it wasn't leveled correctly, so I re-leveled it, I got it to where it was correct, and lo and behold, the patient's pressure was just fine. I lifted the head of the bed up 30 degrees and I came out, and then we had a discussion with the nurse about, "Hey, just so you know, that patient actually wasn't leveled appropriately." So really making sure these new nurses know where proper and appropriate leveling is because that may make a difference in the patient.

Now there are two different devices I'm showing you here. One is on a pole. What I find in the hospital that I'm affiliated with, Cookeville Regional, it seems like in my CVICU, everybody likes a pole mounting. And in my ICU, they like more leveling it to phlebostatic axis on the patient. So these are just some options for you. So it's important to notice all these stopcocks align, and so this is what you would level the phlebostatic axis. So you'll have to move this up and down on the pole when you have position changes with the patient. Over here, is just this is an arm device where you can place it on the arm so that this levels to phlebostatic axis. I've seen it taped to phlebostatic axis on the gown. You definitely don't want to have any pressure on the patient. So this is just a really nice device as well.

Now, proper zeroing, when we zero on our monitor, it's important that we turn the stopcock. You can see here, the stopcock would turn off to the patient. So if this is to the patient, we would move this stopcock down to the patient, we would open this to air, and then we would push zero on the cardiac monitor to zero the line. And then if you also have a hemodynamic monitor to that device, you would zero it on the hemodynamic monitor as well. And remember, the rationale behind zeroing is that zeroing negates the effects of atmospheric pressure. Okay? And then the last item I want to mention is this square wave test. So we expect when we do a square wave test.

So let me explain what a square wave test is. Sometimes people call it something different, but basically what you're doing is you're instilling whether you have the pull tab to instill the saline from the bag into the pressurized line or whether you have the squeeze technology. Just doing that rapidly, you should see a rapid upswing where you then see a nice square wave followed by one to two oscillations before returning to baseline. And that should be what is expected and that is here in figure A. Now notice that in figure B, if I did a square wave test and I saw whatever was in B or C, I know I need to do some work on my arterial line, right? If it's overdamped, that means there's less than one oscillation before returning to baseline.

And this underestimates your systolic blood pressure and overestimates the diastolic. If it's under damped, you can see in figure C where you have greater than two oscillations before returning to baseline. It overestimates systolic it underestimates diastolic. So basically, if you don't have a good square wave test, you need to think about what you need to do if it's overdamped or underdamped, what we can do to work on getting that corrected so that you can know you have accurate readings on your arterial waveform. Now this is extremely important if you're using arterial-based hemodynamic monitoring, right? Because we want to really make sure if we're going to be making decisions based on the hemodynamics off the arterial line, you need to make sure that the waveform is correct.

So let's talk about that overdamped waveform. What can cause an overdamped waveform? Well, bubbles in the system, loose connections, no or low fluid in the system, low pressure in the system. There could be a kink in that catheter, there could be blood in the line or the transducer. So based on those causes, you want to make sure that you flush that line, you make sure those connections are nice and tight. You make sure there is enough solution in that system. If you need to change bags, you need to do that. If there's a kink in the catheter, try to unkink that. All of those things are causes for this overdamped waveform. As far as the underdamped waveform, remember the underdamped waveform consists of that over-response, which is seen as an exaggerated narrow artificial peak tracing. And we know what that causes, that results in that systolic blood pressure that's reported as falsely high and diastolic as falsely low.

So some causes of that would be presence of small bubbles. There could be pressure tubing that is too long. I don't know about you, but sometimes in the OR, they like to add extension tubings to your pressurized line. So when they come back to the ICU, it's probably good if you can remove the extra extensions, especially if you notice an underdamped waveform. There could be a defective transducer and you might see this because of hyperdynamic circulation, patients who have a very high cardiac output as well as patients who are tachycardic or those are some reasons why we might be hyperdynamic. And then tachycardia can also sometimes overshoot those values. Now I think a good just basic standard of care should be if you have an arterial line, you should always have that connected where you can see a waveform, right? This is just a basic

safeguard. If you're not connected to a monitor, you cannot know if there are changes to that waveform, and I think you're at risk if you don't have that connected.

Next, we're going to talk about infection prevention techniques with an arterial line and with a central line. Now, central line-associated bloodstream infections can come from four routes of catheter contamination. One is skin pathogens at the insertion site, one is intraluminal contamination when that catheter hub is manipulated, one is... Sorry, I have a terrible time saying this word, you guys. Homogeneously. Thank you. Sorry, just being real with you. Homogeneously from a secondary blood infection that develops from another focus of infection or the contamination infusate that contaminates into the catheter. And so that would be your contaminated injectable flushes, which hopefully that doesn't happen a lot, but it could.

So let's look at this a little closer. When you look here... And by the way, this was released from the New England Journal of Medicine. I really liked this picture. This is a fairly recent publication, and it talks about catheter contamination at the insertion site. So at the insertion site, this would be done by hospital staff. And what happens is there's extraluminal spread of the infection and you can see right around this area, hence why it's really important to put some kind of a patch or a sponge or something that has chlorhexidine infusion in there. Notice it says increased skin microorganism density under the dressing without frequent decontamination, and that can be done by hospital staff.

Secondly, there is catheter hub manipulation, and that's done by hospital staff as well. So this causes intraluminal spread. Now, one thing I want to mention, and one thing that the hospital that I'm still PRN at does well is anytime we manipulate a central line, we consider that we have to use all the same rules as inserting a central line. And we'll talk about that in a few minutes, but I think that's really important that if you are going to manipulate a catheter, you've got to use all the same safeguards that you do when you're inserting. All right. The third is catheter contamination by a secondary infection. So this is that intraluminal spread. And you can see here where the bacteria stick to the biofilm and they adhere to the internal lumen of the catheter and you can see the biofilm, the bacteria, and the catheter lumen. And then last but not least is contaminated infusates. So where you'll have intraluminal spread because you have contamination in the infusate and it contaminates through that intraluminal spread.

Now, hot off the press, or at least in the last few months, I believe it says 2022, but I believe it came out to the public maybe in 2023, but this was a 2022 update. But it's the SHEA, the IDSA, and the APIC practice recommendations for strategies to prevent central line-associated bloodstream infections in acute care hospitals. And this is the 2022 update. And I'm going to go over all of these in detail because I noticed as I was reading them, I'm like, "Oh, that? I don't think I knew," or, "Hey, this is something that we need to probably work on." So we're going to talk through the summary of recommendations to prevent CLABSI and it's split up before insertion and after insertion. We're going to go over those individually. So let's start first by before insertion. Before we even insert a catheter, we want to provide easy access to an evidence-based list of indications for CVC use to minimize unnecessary CVC placement.

So there should be a definite thought process for why we need a central line, central line-associated bloodstream infections, and by the way, CLABSI, that's what that stands for. Central line associated bloodstream infections, and I'm going to probably just say CLABSI from here on out, but it's important not to over-utilize central lines, right? So we need to know, "Hey, do we really need that central line?" Next would be to require education and competency assessment of HCP involved in insertion, care, and maintenance of CVCs about CLABSI prevention. So it's not enough just to train the nurses. The people who are inserting these, they need to have mandatory, required education. I threw in the mandatory. I think it's important that we have required education for these providers. Now this quality of evidence was moderate.

Also, we should be bathing our ICU patients that are greater than two months of age with a chlorhexidine preparation on a daily basis. I remember one day, I was doing competencies with my staff and I had them just... I said, "Let's all be real. Raise your hands. Are you doing a daily chlorhexidine bath?" And I was sad to see that not every nurse raised their hand. And we then had a discussion about how this is not optional. This is a basic infection prevention technique that is so important that we do for all of our patients. Some people would say, "Well, we don't like how it feels on the patient." Okay. It doesn't matter what our personal preferences are. This is a high quality of evidence. It should be what we do for every intensive care unit patient greater than two months. So this goes for those pediatric patients as well.

All right, at insertion, in ICU and non-ICU settings. So it doesn't matter. Hospital-wide, a facility should have a process in place such as a checklist to ensure adherence to infection prevention practices at the time the CVC is inserted. Now what I did was I added a central line that we use at Cookeville Regional Medical Center. I was going to take off the name of the hospital, but they deserve credit for developing this. And so it's required by Tennessee State Law for us that we do some very important CLABSI prevention strategies. So notice it says, "Prior to insertion, we want to educate the patient and/or family on central line infection prevention." So we've got a sheet, it's straight from the CDC that you can hand out to patients and families, and they let you just use, straight up, that document for your patients and families, and it has a place for location.

But what I wanted to mention, it talks about the insertion site, it talks about infection prevention education, and mind you, this is the paper version, but we also have imported this electronically. It was just easier for me to show you a paper version for this presentation. Now it's important that notice it says multi-lumen, PA introducer, PICC lines or vascath. So any of those are considered a line type that we need to make sure we utilize the CLABSI bundle for. And is this a line over wire? And then is the procedure elective emergent or are repositioning? I think I mentioned to you guys earlier that even repositioning needs to be treated like an insertion, right? So we put that right on there.

Now for the insertion, the provider or whoever is inserting has to clean their hands, and we literally watched to see did they do that. Now if they did not, somebody needs to speak up. There needs to be a culture in your institution to where you can speak up and say to the provider, "Hey, did you wash your hands?" And I remember one day, I did this, and it was with my infection prevention doctor and I said, "Hey, doctor, did you happen to

wash your hands? And he said, "I did, Angela, but I will wash it again for you." So try to keep it light, but make sure if you don't see that, that you encourage that behavior. Also, did they use chlorhexidine? Yes or no? If they did not, you need them to speak up. There needs to be that culture where you could speak up. A large body drape, and that means from the top of their head to the bottom of their feet, no more of these three-quarter drapes. It is a full-body drape. You need to make sure that is used on every patient who's getting a central line.

And then also, a mask for the inserter. A mask, sterile gown, hair cover, and sterile gloves need to be used all for the inserter. If you're helping to insert, then definitely you need to have the full barrier as well. Now anybody in the room should have a mask on. All right? Also, and I probably should have marked out, biopatch, I apologize, it should say chlorhexidine-impregnated sponge. That's just what they use at this institution placed on insertion. The sterile field needs to be maintained. So as you're in that room, you're really monitoring to make sure that sterile field is maintained. And then you document the timeout. So we want to treat this just like a surgical procedure, timeout, right? Patient, are we doing the right thing? And then documenting why we don't use this subclavian if for some reason another site is used, and then, of course, the names.

Next is at insertion, perform hand hygiene prior to catheter insertion or manipulation. That's very important. That was on our checklist as well. And then also, the subclavian site is the preferred site to reduce infectious complications when that catheter is placed in the ICU setting. I want to mention that I've been called the guardian of the groins before. I know that sounds corny. But because I couldn't stand whenever we place a groin catheter. So really making sure if, for some reason, there were times when we could not prevent that, the patient absolutely had to have that line. So then making sure we're monitoring that site, that we get that line out as soon as possible. Another thing that's a moderate quality of evidence is using an all-inclusive catheter cart or kit. So I'm going to show you an example of a line cart that our practice council did in the intensive care unit.

You can see here, the team developed a line cart and it is beautiful. We just wheel this right to the room wherever we're having the procedure done. These little areas down here can open up and it allows for a larger table. You guys know bedside space is hard to come by in a ICU room many times. And then you can see a very organized drawer system. We treat this line cart very similar with our code blue carts. We mark what we use, and then we have our people come up from supply and they exchange out the drawers. It's a fabulous system. This has been a nice addition. Really good job done by the practice council to initiate this. And it has everything you can think of in all these doors. I didn't take a picture of all the doors, but anything related to any line insertion, and not only a central line, but also the arterial lines as well.

Another thing that is a high quality of evidence is to use ultrasound guidance for catheter insertion. So I think it's important that we just move on to ultrasound guidance. Also mentions use maximum sterile barrier precautions during that CVC insertion. And we went through what those maximum barrier precautions were on the checklist a little bit earlier. Also, it says to use an alcoholic chlorhexidine antiseptic for skin preparation. It's really important that our skin is prepped with chlorhexidine. I remember one day, when a doctor came to the room to place the line, and I remember handing them a chlorhexidine stick and I said, "And don't forget, it's illegal if you don't use this." And later, he called me and he said, "Angela, why is that illegal?" I said, "Well, that is the skin prep of choice. That's in the guidelines. You have to use that." Originally, he said, "Don't say things if it's not true," or implied that he did not realize the importance of chlorhexidine. I said, "Oh, no, no, no. I will send you some evidence."

And so he got a chlorhexidine folder loaded with all kinds of articles about why it's so important for skin antisepsis, right? We have to prep that skin well. Next, after insertion, we want to ensure appropriate nurse-to-patient ratio and limit the use of float nurses in the ICU. That's difficult to do to limit float nurses in the ICU right now. There is definitely a nursing shortage, but I think the point of this is that making sure if any nurse is caring for a central line in the ICU that they know how important it is to take care of that line and be so meticulous with that line care. For non-tunneled CVCs in adults and children, we will change that transparent dressing and perform site care with a chlorhexidine-based antiseptic at least every seven days or immediately if that dressing is soiled, is loose or damp. Change gauze dressings every two days or earlier if the dressing is soiled, loose or damp.

So you have the ability to have a transparent dressing onto where you can assess that site and only change that dressing every seven days as long as it's nice and if the edges are adhered to the skin so that it's not loose and we don't want any dampness or soil. We also want to disinfect catheter hubs, needleless connectors, and injection ports before you access that catheter. It is so important that we are not just going straight to the hub without having cleansing of that catheter hub before we utilize it. And then we also want to remove non-essential catheters. There should be a process in place where you're evaluating your patients that are in the ICUs, do we need to keep that central line? If not, let's try to remove it. And then also, routine replacement of administration sets not use for blood or blood products or lipid formulations can be performed at intervals up to seven days. And then I wanted to mention also performing surveillance for CLABSIs in ICU and non-ICU settings. That is really important.

Now I wanted to share with you just a sample document of daily assessments of central lines. So putting a label of a patient who has a central line, looking at the location, the line location, and the question you would ask, "Is the line still necessary?" And some of the rationales for keeping it would be if they're on pressers, if they're on TPN, if they have lipids going, if there are certain antibiotics that have a pH that might be caustic to the veins that might be appropriate. Looking at the dressing, "Is it dry and intact? Is there a chlorhexidine-impregnated sponge in place? Are dressings changed and dated within seven days? And are all IV tubings dated and timed? Is there any redness or swelling at the site? And do we need education for this patient or family?" Making sure that education sheet is in the chart. So this is just a great example of some good assessments that you could do in your ICUs daily.

Now there are other practice recommendations that I just want to mention just in general. We talked about what insertion before and after insertion, but there are also some additional approaches that are mentioned here using antiseptic or antimicrobial-impregnated CVCs as well as using antimicrobial

lock therapy for long-term CVCs, using recombinant tissue plasma activation factor once weekly after hemodialysis in patients undergoing hemodialysis through a CVC. And I will tell you these additional approaches, a lot of these were things that made me pause and think we may need to work on some of these items. Also, utilizing infusion or vascular access teams for reducing CLABSI rates, using antimicrobial ointments for hemodialysis catheter insertion sites, and then using an antiseptic containing hub, connector cap, port protector to cover connectors. So those are really nice if you're able to use that and get that in your supply scan.

Now, approaches that should not be considered to be a routine part of CLABSI prevention. It says, "Do not use antimicrobial prophylaxis for short-term or tunnel catheter insertion or while catheters are in place and do not routinely replace CVCs or arterial catheters." I'm not going to list all the other unresolved issues, but you can read those if you want to download this presentation. But there are still some unresolved issues that this team has mentioned there. Now lastly, we're going to talk about some potential clinical errors that are associated with hemodynamic monitoring and what we can do to prevent those errors. So we talked about preventing potential clinical errors with our central lines, with our arterial lines, and we talked about priming of the tubing and components, making sure that we prime before we add pressure and so there's less chance of air in that line. We talked about proper leveling, that will help us make sure that we have appropriate reliability on our readings.

And then also we talked about proper zeroing to have more accuracy is so important. We also talked about doing a square wave test, that should be done at the beginning of every shift when you start and you're working with your arterial line or your central line, making sure that that is accurate so that you have reliability of readings for your central lines and your arterial lines. Now in summary, let's talk about CLABSI prevention. It's a must. It is absolutely a must. It's up to us and our unit culture to make a difference. I want to pause here for a moment and talk about unit culture. You can make a difference in your unit's culture. It is important that you speak up. There needs to be that culture of safety to where you can speak up. If something is not right regarding a central line or an arterial line, speak up. We need to have that culture of safety. I cannot mention that enough.

And also, you're there for the patient. So it's not just about if you notice a colleague is having poor practice, you need to talk to them about it because it's about the patient. Often I say, "This is about the patient, it's not personal. I really like everybody I work with, but at the same time, it's my responsibility as a nurse to speak up when I think something's not correct." We also want to utilize our standards and our guidelines to help change the culture and your unit's practice. Guidelines are a great go-to. In fact, you can say, "You know what? It's not me. It's what the guidelines say." So then we can impact that. We also want to utilize those checklists for preventions of CLABSI. Checklists, help train those novice nurses as well as reference for seasoned nurses, right? It is important that we utilize the knowledge and the references and the resources that we have so that we make good decisions.

We should also have an annual competency that is done in real time to get immediate feedback. I want to mention one of the things we do at the hospital I work at, and I'm PRN, but I still have to annually go in and change a central line dressing. What we do, it's in our health stream system and whatever educational system you have to where they assign me to do a central line insertion checklist or a central line insertion. It is complete with a checklist. So I can print that off, I can then... There are certain people in my unit that can sign me off, and I know I'm a clinical nurse specialist, but that doesn't mean that I do it right every time. So that's why it's important that I get checked off as well. And so I go in a room and I do all the appropriate things, and I have one of the nurses that can check me off, check me off as well.

And I think that's important because we do this all the time and we can talk about it or we can do little practices on a dummy arm or a dummy chest, but I think it's important to see it in real time and get that feedback from somebody who's a leader in your unit. So determining who those leaders are, making sure they're able to check you off and take that really seriously, right? Don't just say, "Yeah, you're in there doing that. I'm watching from the door," right? You should go in there and take this really seriously. And then remember, when using pressurized lines, make sure you are safe. Keep those lines stable and secure. Keep the lines leveled and zeroed and make sure you prime before you add pressure. And always check a square wave test and document. And actually, before I hand this over to you, Heather, I'm just going to go back. Since I have a few minutes, I'm going to go back here to this slide just real quick and you can stay online. That's fine. And let's talk really quickly about these unresolved issues since I have a few more minutes.

The unresolved issues, and this might get your mind going to what are some things we need to do to move forward, but routine use of needleless connectors as a CLABSI prevention strategy before an assessment of risk, benefits, and education regarding proper use. Surveillance of other types of catheters like peripheral arterial or peripheral venous catheters, standard non-antimicrobial transparent dressings and CLABSI risk. So I don't recommend you do that. These are the things that are unresolved. The impact of using chlorhexidine-based products on bacterial resistance to chlorhexidine, that's something we're thinking about as well as sutureless securement. So we're not quite there yet. Impact of silver zeolite-impregnated umbilical catheters in preterm infants. And then the necessity of mechanical disinfection of a catheter hub, needleless connectors and injection ports before accessing the catheter when antiseptic containing caps are being used. So those are all some unresolved issues that hopefully they're going to work on and maybe we'll get a future explanation. So since I had time, I wanted to go over that as well. But we've talked about the summary, and now I'm going to hand it back over to you, Heather, and thank you.

Heather Davenport: Awesome. Thank you so much, Angela. Amazing information. So I'm going to quickly go over how you can obtain your CEs for this presentation. Continuing Education for Nurses and Respiratory Therapists. The activity has been approved for one contact hour. You can obtain those continuing education credits by logging on to www.saxetesting.com/p. You'll need to register on the test site and complete the evaluation form. Upon successful submission, you'll be able to print your certificate of completion. And this activity is supported by an education grant from Dale Medical Products. An archive version. The archive and on-demand version will be available at www.perspectivesinnursing.org. The on-demand version will be accredited for continuing education also. All right. Now let's get to some questions here. Bear with me just a moment. All right, so

we did have several questions come in. Our first question is from Ryan. He says, "My understanding is that A-lines around digits like the thumb were contraindicated because of the potential for edema and circulatory compromise. What are your thoughts?"

Angela Craig: Yeah, so arterial lines around the thumb, I personally have not seen that as far as on this area. What I've really seen is more based here in the radial area. So just to be real with you, Ryan, do some research on that. I think you have to think also common sense-wise. For instance, I don't want an IV catheter in a digit if I don't have to have it, because there's more risk. So if you can get it in those larger vessels, I think that's going to be where you have better blood flow. I think that makes more sense. And maybe I'm misunderstanding a part of that. Feel free to re-chat in if there's other questions too. And, Heather, feel free to speak up on what your experience has been if you've seen one of these as well.

Heather Davenport: Sure. Ryan, maybe you're referring to... All right, let me find my camera here. So when we put the A-line in, and then we take the tubing and wrap it around the thumb, just secure it at that loop, I know over years of experience, sometimes that can be too tight if the line is in too long or in an extended amount of time and the patient does develop edema because they're critically ill. I think, Ryan, that's something you just have to monitor, do a good assessment of the skin and continue the site assessment. If it starts looking like it's causing damage, a deep tissue injury or something like that, then perhaps when you redress the site, you can loop that tubing in a different manner to keep the skin looking okay and prevent any other issues.

Angela Craig: Sounds great.

Heather Davenport: All right. Great question. All right, so this one is a little bit longer. This is from John. He said, "You mentioned the cap on the valve has a hole. The unit where we draw our blood gases has a hole and some nurses don't have the cap, others do. I agree. Infection control is a must. I'm wondering, have you ever seen an infection developed from not changing the cap?" In my years, I haven't seen that occur, but I'm not there every day. What are your thoughts on this?

Angela Craig: Okay. So great question, John. I think what you need to do is we always want to just go with best practice. I've seen a lot of CLABSIs in my time and we've done a drill-down. So it's hard to know really always what causes it. So you always want to do what's best practice. Best practice would be not having a line that has a cap that is vented, right? So whether or not it has caused an infection, it could. It's like one of those things where people will say, "Well, let's not change something if it's not caused a problem." Well, the reality is if it could cause a problem, we want to prevent the chance of error.

So I'm not sure that I've seen that specifically, but I always educate. You want to change that out and you want to definitely put a fresh cap. And I know we keep extra individual caps, if your department or unit doesn't have extra sterile caps, I think they're very economical and you definitely want to have a stash of those so that... Especially if one drops on the floor, people aren't prone to them cleaning them and trying to put them back on. As well as when you take that cap off, when you take it off to open to air when you're zeroing in that, you want to make sure that you're not touching the end piece on that. So you may need to just replace it with a fresh one. So those are just more best practices. I don't know that I've actually seen one as that being the primary cause, but I do know that you never want any chance of any any bacteria to migrate into that line.

Heather Davenport: Absolutely. All right, next questions comes from Leah. Do you recommend the same infection prevention strategies for arterial lines? I'll assume she's comparing that to a central venous catheter.

Angela Craig: Yeah. So I have seen an article that talks about the arterial line typically doesn't have as many infections, but you know what? At our institution and, Heather, where you work, where we both work, definitely we try to treat our arterial lines very similar to our regular central lines. Now, notice that... I don't know if you noticed when I read they were talking about that some areas that they haven't put definite information about regarding arterial lines, but we try to treat it the same. So we use a smaller, or you can use the regular size, a chlorhexidine-impregnated sponge right at that site. We don't want there to be any infection. Technically, it's a vascular access cath, right? So it could get infected. There's always that risk. So we do treat ours very similarly. Yeah, we treat it similar. I don't know that we actually do a whole time out for an arterial line there, but we definitely try to treat it similar and use some of the same techniques.

Heather Davenport: Yes, absolutely agreed. All right. The next question, how are some of the ways that you recommend to remove the air from the normal saline bag when setting up the pressurized line?

Angela Craig: So this question came up.

Heather Davenport: This is always entertaining.

Angela Craig: I know, right? If I had my supplies, I could show you. So, all right. So I think the method that's probably best, if you can keep it contained, there are ways where you can have the bag down, and then you can pull the tab... Boy, this is hard to do without my stuff. Pull the tab to where the saline comes up, and then you can flip it, and then to where you get all the air out. You can squeeze the bag, the air comes up through the little... This is hard to explain. So you can do it all enclosed. I've seen people also puncture and remove, squeeze it out, but you have to be so careful that you don't contaminate that puncture site. But I've done that multiple times, but that's not a closed system, so there's risk there. So probably the better method, and Heather, you can speak to this, probably the better method is the closed system. But what are your thoughts, Heather?

Heather Davenport: So I would agree the closed system is just that it's a closed system. It's going to decrease the chance of introducing any bacteria into the closed system. In full transparency, I'm the one that wipes off the injection port and uses a needle to squeeze the air out because I make a tremendous mess. Again, in just full transparency.

Angela Craig: So, no. Let's talk about that because I failed to mention that method too. So you can add... And I would change

your terminology from needle to a blunt-tip. Okay? So you can do a blunt-tip needle in the port where... It's the port where you can add... Yeah, just the medication port or whatever. You can put a blunt-tip, you can then squeeze that bag, and then you can pull that out. But, yes, actually cleansing that site. So squeeze that bag, get all that air out. That's a great method too, Heather. Thank you.

Heather Davenport: All right.

Angela Craig: I think that's a much better one than pressing then puncturing it, pulling it out, squeezing it, and putting it back in. I think that is more risk for air and contamination.

Heather Davenport: And I think coordination comes a lot into play with the puncture, and the squeeze, and that sort of stuff. All right. Let's see. Let me click through a couple of these questions. What is your policy and procedure for PICU and NICU for bathing a patient? John, at our facility, we don't have those types of units. Angela, I don't know if you have any information to add to that question.

Angela Craig: So the guideline did say for greater than two months that you should do a chlorhexidine bath. Now here I'll speak to... And when you say NICU and PICU, I'm thinking you're talking about the PICU and NICU. Sometimes NICU is neurointensive care units. So when it comes to the intensive care units, making sure they have a chlorhexidine scrub on their skin if they're greater than two months of age. Now you can go to those guidelines, they're listed on my slides, and so bring that to your practice counsel if you don't currently do that on anybody two months or greater than two months of age.

Heather Davenport: Okay. We've got Tom for just a few more questions. This one, is there recommendation as to how often the line should be zeroed?

Angela Craig: So I need to probably go back to the references to see when that is. Usually, I would zero it at the beginning of my shift. I would then zero it. If I have position changes, I leveled and zeroed and did that together. I would have to go back and really read what it says as far as for sure. But you definitely want to make sure it's leveled and zeroed anytime you've had a position change. Heather, any comments on that?

Heather Davenport: Speaking of leveling and zeroing, are there any tools or tips or tricks for leveling appropriately? "Hey, let me just eyeball this and make sure that it's level"?

Angela Craig: Yeah, yeah. I always got made fun of because I carried in my pocket, my lab coat, a little lever that I bought at the area Ace Hardware store, right? It was just a little one, and then I put on the side a little string that you could easily clean off. And I would go in that room and I would actually level it. Now, people are like, "Oh, yeah, eyeballed it." Nowhere in the literature have I read, "Eyeball your line," right? There are things like laser levels that can fit right on that pole where right next to those lines, and you can laser level. That's a great method.

I've seen the big old wooden levels, carpenter levels in a unit before. Back in the ICU I worked in when I first started, we would carry those around. Now you want to make sure you clean it, but there's definitely ways you can do that. But I recommend that definitely you don't just eyeball, that you really should level that. And as far as the timing between that, just making sure too, when you're in there, you want to make sure what you're seeing is accurate. So you want to make sure it's leveled and appropriate.

Heather Davenport: Okay.

Angela Craig: And by the way, whoever asked that question, you're welcome to email me privately and I can go back through my resources to tell you exactly what the recommendations would say for how often you do that.

Heather Davenport: Okay. Another question. What is your hospital policy on how frequent RNs should document site assessments on a central venous line? We are currently doing Q4 hours with our head to toe in ICU, but we're seeing that Q12 is a standard. What are your thoughts?

Angela Craig: I don't think in the guidelines it mentioned specifically. Our nurses have to do it every shift for sure, an assessment. I love the idea of more frequent. I mean, really, if you're putting medications to that, you should be looking at that because it's just like an regular IV site. You need to be assessing that frequently to making sure there's no extravasation, making sure there's no redness, that the site looks good, that it hasn't, all of a sudden, started bleeding. So that's a great question. I just consider that as part of your two-hour... We do assessments every two hours in our ICU, sometimes every hour, depending on the patient. And I just think that's part of that automatic assessment.

Heather Davenport: Sure, absolutely. Interesting question. What do you do if the patient's allergic to chlorhexidine?

Angela Craig: Oh, my goodness. I call my infection prevention nurse and say, "What do I do?" That's a great question. And you guys, it's interesting. There really has not been a lot, at least in my practice, I haven't seen that many patients who are allergic to it. So if you do obviously have an allergy, you can't do that. So you are going to need to do a good soap and water scrub, right? And there may be an alternative, I'm just not sure what that alternative would be. So seriously, my go-to would be call my infection prevention nurse and have dialogue with her. They usually have a pager if they're not in their office, to where you can have that dialogue, because we want to do everything we can to prevent an infection. So good question. Obviously, you can't use it, even though it's a guidelines document that they're allergic though. Make sure it's documented. So that if that patient does develop an infection, you can have something to go back to and say why you couldn't do that.

Heather Davenport: Yes, absolutely. All right. This will be our last question before we wrap up. At our facility, we change our art lines every four days. Would you recommend that be changed to every seven days instead?

Angela Craig: Oh, wow. I've never been to a facility where we had routine change out times for arterial lines. And I would just ask the question, is this based off of evidence? And is there evidence that supports changing that out every four days? In the evidence that I've read, central lines... Let's take arterial lines off the table for a second. Central lines, they say they recommend that we don't just automatically change those out. Back in the day, we did it. You probably remember, Heather. Back in the day,

we used to do it every seven days or every 14 days or whatever. That's no longer recommended.

So when you think about an arterial line where blood flow is more brisk, and I've seen the evidence that says less chance of infection, I'm not sure why that practice would be in place and I would definitely challenge you to challenge that. I'm not sure that that is best practice. And I don't know if you're talking about adults versus peds or NICU. Typically, my practice has been with adults, so I've not seen that. And that, for me, as a clinical nurse specialist, I would probably question that if I saw that in my institution and I would look for the literature to support that. If it's not supported, try to change it. That'll save on workload too for you guys.

Heather Davenport: Yes, absolutely. Absolutely. Awesome. Great questions. Thank you so much for your participation, and I want to turn it back over to Tracy.

Tracy Cook: Thank you, Heather, and thank you, Angela, for such a great presentation. We'd like to thank everyone for attending today's webinar. Immediately, upon the conclusion of this webinar, you'll be presented with an online survey. Please keep your web browser open and we appreciate your feedback. For your CE, certificate of completion, in one hour following the conclusion of this webinar, you will receive an email with instructions with this link to obtain your CE credits. That's www.saxetesting.com/p. And this ends today's session. We hope you have a great rest of your day. Thank you.

Here is the link to watch the webinar
https://www.perspectivesinnursing.org/hemo-monitoring

Fundamental Ventilation Training With RespiSim eLearning

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. Participating in the interview is Justina Gerard MBA, RRT, Director of Product Management at IngMar Medical, LLC.

Liz Bolen: Hello everyone. Thank you so much for coming and welcome to our webinar. I see we got a lot of people in the chat from Ohio to New York to California to Canada. Thanks so much for your engagement and again, welcome to our webinar today, Fundamental Ventilation Training with RespiSim eLearning. My name is Liz Bolen and I'm the Director of Sales and Marketing here at IngMar Medical. I will be one of your hosts today and to tell you a bit about myself, I have a sales and marketing background in the healthcare industry and I've been with IngMar Medical for a little over five years now. I definitely know a lot more than I ever thought I would about the lungs and I am very thankful for the people that take care of them. Speaking of, right to the next to me is Justina Gerard. She's one of our main hosts today and I'll let her introduce herself.

Justina Gerard: Hello everyone and thank you for joining with us. My name is Justina. I am our Director of Customer Experience here at IngMar Medical. I've been with IngMar for approximately four years. I am a respiratory therapist by trade and have been a respiratory therapist for probably 11 years now. But I can say working at IngMar, I've learned so much more than I ever thought I would know about the lungs and the best practice for simulation. So speaking of, that's what we're here for today, so I'm going to hand it back over to Liz.

Liz Bolen: Awesome, thank you. All right, a little bit about this webinar. Today's webinar will be about 45 minutes, which does include time at the end for questions and discussion. Speaking of, if you have a question or comment, we definitely want to hear from you. The audio is muted for everyone during the presentation, but please do type your comments and questions into the chat. Our friendly moderator, Greg is there to respond. He's already chatting with some of you. Soon after the completion of today's webinar, you will receive an email with a link to the webinar recording. That way you can share it with your colleagues or anyone who may have missed the webinar or you can save it for your own reference. You can also access any of our webinars at the support section of our website. Also, after the webinar is complete, a survey will be emailed to you and please do take a quick minute or so to take that survey. It does help us understand how we can improve your webinar experiences going forward and what kind of topics you would like to see in the future.

One final announcement here, you will also receive this free resource. We're super excited about this. It's called the How to Create Fundamental Patient Ventilator Interactions. And this resource is just a PDF with all of the background information for the two live simulations that we're running today and we really hope that you'll use this resource for inspiration for your own simulations moving forward. Just a quick disclaimer about our scenarios in general, they are meant for educational practice only and are not meant to replace policies or protocols established by medical professionals. Please always refer to your organization's policies and procedures for best clinical practice.

So I want to do a quick overview of IngMar Medical for anyone who may be new to us. We were founded in 1993, so we're coming up on 30 years here. And we're located in Pittsburgh, Pennsylvania in the United States. We are the global leader in respiratory simulation. Our vision at IngMar Medical is a world where medical errors and adverse events for patients supported by respiratory devices are eliminated. And the way that we do that is through our mission. So we provide lung simulation solutions that help respiratory researchers and engineers test and develop their new products. And we also provide lung simulation solutions that help educators train clinicians to achieve the highest level of patient care.

Okay, so what is on the agenda for today? Well, first up, we're going to discuss some of the ways that you can implement simulation into all levels of learning. So self-study, all the way to that immersive hands-on training. Justina is going to walk us through some ways that you can implement simulation. Next up, I'm really excited to tell you about our brand new lung simulation solution, RespiSim eLearning. Now this new solution was designed for clinicians and educators who want to provide that fundamental ventilation training to both remote and on-site learners at an affordable cost. That's the most exciting part. Then you will be able to interact with us as we run two live simulations with our brand new RespiSim virtual ventilator. Can't wait to show you that. And then of course we'll wrap up with time at the end for question, discussion, and answer. All right, let's get into the content. Justina.

Justina has been with IngMar Medical since December 2018. Justina is a Respiratory Therapist, and while she does not work with patients, IngMar Medical gives her the ability to lead projects that relate to empowering the simulation community to reach their fullest potential. Her passion is improving the care that we provide to patients along with finding fun ways to help clinicians reach their fullest potential when it comes to patient care. If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.

Justina Gerard: Awesome, thank you so much for that, Liz. So over the past few years, restrictions around social distancing forced institutions to become more inventive when looking for ways to teach so our customers came to us. We knew that they valued on-site training, but they have had to adapt to a more of a hybrid model of teaching. This left them asking for ways to provide a remote learning experience. So we started to think, how can us at IngMar really help our educators to provide experiential learning for all levels of learning in both remote and on-site environment? Well, you're looking at our answer right here. A training experience saturated with experiential learning through simulation, appropriately challenging for each level of learning. For example, as we move from the foundational eLearning environment, through the hands-on simulation, and finally we get to those real-world clinical experiences. We can gradually increase our learner's knowledge, providing a variety of learning experiences to ensure that they're retaining the fundamentals they need to become those successful clinicians that we all want to train with.

So at a minimum, we know traditional programs offer at least a classroom dictation, low fidelity training with a review of equipment, possibly using a mannequin to perform intubation techniques, maybe some assessment, and maybe even using a test lung to interact with a ventilator. While those are all terrific options, I will speak for myself as a learner. When I got to the clinical experience, I felt like that girl over there on the right-hand side. I was a little lost, I was confused, and I didn't feel confident as a clinician when I went out to take care of my first patient. So let's discuss the ways that we can help our learners lessen that feeling of being lost or overwhelmed when it comes time for that first clinical experience. Here you can see that we've filled in the gaps with additional opportunities for simulation experiences that you can implement, leading to a more confident clinician. So we all want to be like that girl over there on the right now. So let's review the types of simulation experiences that you can provide at each level of learning.

Liz Bolen: Awesome.

Justina Gerard: So our first level is eLearning. So eLearning enables learners to practice in a self-paced environment. This can be done via webinars, websites, or even for today's purpose, through e-courses on a learning management system. This allows for learning in a space that is comfortable for your learners so they can start to familiarize themselves with these foundational concepts. Now that your learners have had some self-study time, they feel a little bit more prepared, they can come to class and start really understanding those fundamental concepts. Remember, classroom dictation is what you as instructors already provide to your learners every day. We can now begin to reinforce those fundamental topics versus this being the first time they're seeing them. So again, we're just starting to get our learners a little bit more comfortable in giving them multiple opportunities to see these topics over and over.

Liz Bolen: Makes sense.

Justina Gerard: The next level of learning is using virtual training techniques. Compared to self-study with eLearning or passive classroom dictation, this level starts with more interactive training experiences. Virtual training techniques allow us to provide interactive hands-on experiences without the hassle of hardware such as ventilators or test lungs. Remember back a couple years ago, getting access to a ventilator was nearly impossible and some programs still haven't even received their ventilators back or if they have, they've been broken, they're not in the shape that they should have been. So now we're able to perform bench simulations with both remote and onsite learners via a virtual ventilator software.

Up next we have our low fidelity training. So remember I did mention this as being probably a part of your current curriculum already. At this level you may begin to offer some hands-on or low fidelity training with a task type trainer. For example, we could be using a test to get some hands-on experience with modes of ventilation and seeing basic patient ventilator interactions. Next, we have medium fidelity training. So think about all those topics we already learned with our low fidelity, even our onsite. Now we're going to add the concept of assessment and this is going to allow us to look at the bigger patient picture so now learners can interact with the ventilator and a patient monitor. So we're starting to teach that whole big concept. It's not just the ventilator, it's not just the patient monitor. We're starting to bring the things together.

And finally, this gets us to our last topic before we go onsite to train with real humans, and that is our high fidelity training. We're able to provide fully immersive hands-on simulation and most importantly in a safe environment. This will be our last key level before sending those learners out for their first patient experience.

Liz Bolen: Nice.

Justina Gerard: So now we feel we have a more rounded experience for our learners. We've given them multiple opportunities for deliberate practice to solidify those fundamental knowledge in ensuring what we're all concerned mostly about, higher patient care. I'd like to now hand the presentation over to Liz who will introduce our brand new solution for the first levels of learning that our represented here in teal, RespiSim eLearning.

Liz Bolen: Awesome. Yeah, I would definitely want to take the more solidified approach here with all of those steps than just a couple of steps. It looks a lot better there and I'm super excited to tell you about the levels covered in teal here under RespiSim eLearning. So for people who are familiar with IngMar, you've known that for nearly 30 years, our lung simulation solutions have been highly regarded as the most realistic and versatile simulators available when it comes to mechanical ventilation training. And of course, empowering educators to better prepare clinicians for the most complex mechanical ventilation challenges is always going to be a part of our identity. We love our respiratory nerds. But RespiSim eLearning does mark the beginning of a new chapter at IngMar Medical because this solution was designed to help support training objectives of a much wider range of clinicians and educators who have adopted hybrid and remote teaching modalities.

So a little bit about eLearning and what it includes. It is a subscription-based eLearning environment. So each person would get a license that allows them access to our RespiSim learning management system. So our LMS with those self-study eLearning courses focused on mechanical ventilation concepts and the RespiSim virtual ventilator software. So now with these two items together, we have honestly the most exciting thing

about it, the affordable, highly realistic ventilation training for the entire healthcare community. We really hope that this subscription is going to strengthen learners' understanding of key mechanical ventilation concepts, which of course is only going to pave the way for more effective simulation outcomes and again, ultimately better patient care.

I'm going to focus a little bit more on the virtual ventilator software portion of the subscription because that is what we're going to show you up next with our live simulations. So with this virtual ventilator, learners can now experience that high fidelity patient ventilator interaction in a virtual environment. So like Justina said, having the hardware of the test lung and the ventilator, that's of course great and does offer that high level of fidelity, but you can still have high fidelity in a remote environment. And the way that we're able to do that is with the ASL 5,000 lung modeling technology. Our customers have come to rely and depend upon the accuracy of the ASL 5,000 and the types of patients that it can simulate on real ventilators.

But now we take that same lung modeling technology, use it on a virtual ventilator, and now you have a whole world opened up to you as far as self-study and new virtual training options. So you can use the ventilator for waveform analysis, you can view the monitored and live data indistinguishable from a real patient on both of those, and you have three modes of ventilation to start practicing with. We really hope that the virtual ventilator, along with the LMS will reinforce and supplement the learning that you already have in your own curriculum.

Okay, so let's get into the good part where we're simulating with our virtual ventilator. So to help me prepare, this is what we're going to do. We're going to have a case scenario. We have two case scenarios prepared for you. Justina will read to you a little bit about your patient. She's going to give us the initial ventilator settings that the patient is on and she's going to tell us a little bit about the patient's lung mechanics, so asthma or ARDS for example. Then you're going to see us pull up both of these software platforms. So we'll open up our RespiSim software, which is going to help us create our patient and their lung mechanics such as asthma.

And then we'll open up the virtual ventilator to set our initial ventilator settings and begin ventilation. We'll show you what the interaction is between the patient and our virtual ventilator and we'll put you in the learner's point of view. So we'll pop a poll up and it's your chance to get interactive and engage with us, put you in the hot seat like you do to your learners. Throw a poll up and ask what would you do in this case to adjust the ventilator settings? So after you guys submit the poll, we'll adjust the settings for you, view the changes in real time and debrief on what we learned. Okay, let's get into it. Scenario number one.

Justina Gerard: Awesome. Thank you so much, Liz. Okay, our case scenario number one is a patient with a severe, who is, excuse me, a severe asthmatic. She was intubated due to decreased level of consciousness and the inability to protect her airway. She is status post intubation right now and just placed on these settings per the MD's recommendation, her ideal body weight is 60 kilos. So we'll start to remember some of these settings as we move over into RespiSim and our virtual ventilator. So she's currently in assist control and pressure, a respiratory rate of 26. PIP we're going to try to target six milliliters per kilogram. Remembering she is 60 kilograms, so we're going to be looking for something around 360 milliliters. Her I-time is 0.9, PEEP of five and 40%.

The current lung model we will be running is severe asthma. Her resistance, excuse me, is going to be 10, compliance of 22. The underlying respiratory rate of this patient is going to be 30. However, we know she was just intubated and still on paralytic, so her muscle pressures, that diaphragm movement is going to be set to zero. So we will have an apneic patient. Awesome. So let me go ahead and pull up the software for us and then we can get started.

All right, perfect. So the first thing I'm going to show you is our RespiSim software and just from the instructor's perspective, I'm going to make some changes very simply and easily. Real quick, we're going to go from our normal regular effort and we're going to find that severe asthma patient lung model. All right, asthma, severe adult. And just to revise, or excuse me, just to review, our resistance is 10, our compliance is 22, our muscle pressure is 20, but I'm going to go ahead and make that patient apneic. So now you're going to see those waveform lines of our patients stop moving and then this is our underlying rate for our lung model of 30 and the neural I-time of 0.6, but those won't apply because our patient is apneic.

I'm going to come over here to our virtual ventilator. I'm just going to expand that so it's easier to see. Then the next thing I'm going to do is start putting in those initial settings just like your learner would. I'm going to go from AC volume to AC pressure and hit apply, and then I'm going to start making my changes to my ventilator. So remember she was on a rate of 26. She was on, we were trying to target a PIP of six milliliters per kilogram. Because I'm not really sure what that's going to look like right now, I'm just going to go ahead and set a PIP that I think is still pretty safe for her lungs, but I also think might help ventilator her so I'm going to try at 27. I'm going to make changes if that's too high or too low. My I-time remember was 0.9 for this patient, PEEP of five, we were at 40%.

And then our slope, I'm just going to take that back down to 0.25 because that's more normal for our pressure control mode. But again, we can always adjust anytime once we see how the patient's interacting. So I'm going to go ahead and start ventilation and what we're going to see is now our patient is going to be interacting with the ventilator. So with that PIP of 27, I'm getting my tidal volumes of right around 245. So those are a little bit low, but I'm kind of concerned about going higher on the peak inspiratory pressure right now. I would actually rather figure out what solutions we have for this patient to maximize their safety. So Liz, I'm going to go ahead and open up the poll and we can see what options we have.

Liz Bolen: All righty my attendees, we have a poll launched for you. Now we have an asthmatic patient. What would you do to ensure patient safety here? Would you, based on what you're seeing on the ventilator, would you change the mode of ventilation? Would you decrease the I-time? Or would you decrease the respiratory rate? I'll give you cue the, what was it? The Jeopardy music in your head and just give you a little time here. And I hope that you could see how fun and interactive engaging this could be for your learners in a remote or onsite. Whether you're projecting this on a screen or sharing it via Zoom or Teams, it's very simple to create some interactions. You create

a problem on the ventilator for your learners to solve and you can put a poll up like this to get some engagement.

So it looks like about half of you have already participated. I'll give you a couple more seconds before we close the poll. We have quite a ray of answers coming in. All right, I'm going to end the poll and share the results. It does look like most people would like to decrease the respiratory rate. Now for instructors too, Justina, I'm sure they would kind of take a look at what their learners are submitting for answers and it could be a powerful moment for teaching or pulling out why you would maybe want to make one of these adjustments, excuse me, versus the other.

Justina Gerard: Exactly, yeah. These are all teaching moments and the joy of this is it's remote, so we're not concerned about time. I could be at home, my instructor, I could be watching this on their screen just like you guys are doing right now. So there's a lot of different options with this platform. All right, before I take the respiratory rate down, I'm just going to have us remind ourselves of some of these settings. So we're making sure we're maintaining our patient. Our minute ventilation is six and our tidal volume is 245. Those are the ones that are kind of the most important to me right now that I'm going to be focusing on. So I'm going to go ahead and let's try a rate of 16, seems like a more normal number. But we're going to be making sure that our tidal volume is more appropriate at that six milliliters per kilogram.

So looking for something right around 360-ish. And then we want to make sure that we're still maintaining that minute ventilation around the six to seven liters per minute. So once our patient normalizes, let's take a look and see where we fall. I don't know Liz, I'm pretty happy with the way that looks. We have a really smart group here with us today.

Liz Bolen: Yeah, attendees hit the nail on the head here. So we are hitting right around 360 milliliters for our tidal volume and right around six liters per minute for our minute ventilation. So congratulations, you all passed case scenario one. Let us prepare you for case scenario two.

Justina Gerard: Awesome.

Liz Bolen: Actually, I forgot we need to debrief first.

Justina Gerard: Yep, we're going to debrief first. All right.

Liz Bolen: So let's talk about what interaction we just saw on the ventilator and the interaction that we suggested to make the patient a little bit more safe.

Justina Gerard: Exactly. So our goal here was patient safety. The patient ventilator interaction that we were seeing was a high resistive load. So that was that auto-PEEP that we were seeing or that inability to return the baseline and the flow. So the reason we, or I guess the reason we did what we did was to try to decrease that auto-PEEP. So we took that respiratory rate down but we were still able to maintain that minute ventilation because we saw that increase in tidal volume. So awesome job guys, you did great.

Liz Bolen: Okay, here we go. Case two of the day.

Justina Gerard: All right, so case scenario number two, you start your daily rounds and walk into your patient's room who is recovering from severe ARDS. Oh, excuse me. His condition has been improving and he's been leaning back towards normalized settings. He's still on a mild sedative, but has been waking more. His current ventilator settings are AC and volume, a respiratory rate of 18, a tidal volume of 450 milliliters, I-time of 1.0, five of PEEP and 40%. You will notice that we're really no longer on those ARDSnet protocol settings. So we do think our patient is definitely getting better. That's what I'm seeing from the high level, looking at this patient. The lung model I am going to run is severe ARDS. The resistance on this lung model is 20, the compliance is 29, my muscle pressure is 5.5, indicating that my patient is still a little bit weak. His respiratory rate is 30, so he might be a little agitated at this point in time and that normal I-time is 0.6.

Liz Bolen: All right, okay, let's create our patient and get into the virtual ventilator.

Justina Gerard: Awesome. So I'm just going to come back to RespiSim. I made no changes since the last time we were here. We're still running that asthma severe lung model. Now I'm going to activate the ARDS severe lung model. Just as a refresher, our resistance is 20, our compliance is 29, that muscle pressure is 5.5. I am going to leave the respiratory rate at 30 and then the normal I-time of 0.6. And what you'll see on the RespiSim side is that our patient is spontaneously breathing. And go ahead and open up our virtual ventilator. So if you remember for this case, my patient was in volume control, so I'm going to go ahead and switch the volume, hit apply. I'm going to go ahead and change my respiratory rate to the 26 that I had. Oh, excuse me, I'm sorry, that was not 26, that was 18. I am remembering my old case for some reason, my tidal volume of 450. If I can get my clicker correct.

Technology always does that to you when you're displaying things. 1.0. I am going to put my flow right around 60 liters typically that's where we kind of let off, but we'll make it sure that we're maintaining our tidal volume. Five of peep and 40%. So I'm going to go ahead and start ventilation. All right, perfect. So before we really start analyzing what's going on, I just want to make sure that my peak inspiratory pressures of my patient are within normal range. I want to make sure that I'm achieving my tidal volume. I'm doing everything from my perspective that I can see on the live data side, but my patient doesn't look real great on the ventilator right now.

Liz Bolen: All right. So here we go, back in the hot seat. I'm going to launch the poll here for our ARDS patient. Now, what would you do to ensure patient safety here? Would you change the mode of ventilation? Decrease the inspiratory time? Or decrease the tidal volume? Again, cue the jeopardy music. We also have a very heavy rainstorm here in Pittsburgh right now, so we have relaxing rain in the background for you to critically think and make your treatment decision. Looks like there's a lot of confident people out there, the answers are flying in on the poll.

Justina Gerard: And that's a pretty split room here. Almost 1/3, 1/3, and 1/3.

Liz Bolen: Yep.

Justina Gerard: This is going to be a hard one. We're at a tie right now, guys.

Liz Bolen: Over half has participated as well. Very engaged group today which I'm enjoying.

Justina Gerard: Yes.

Liz Bolen: All right. We're at about 65% participation, I cannot complain about that. I'm going to end the poll and show you just how split this room is right now. Here is the results. So we have about 32% change the mode, 39% wins at decrease the I-time and 29% at decrease the tidal volume. So again, a lot of opportunities here for a good discussion, but let's stop sharing the poll and we'll let Justina take it away and show us what happens.

Justina Gerard: Yeah, awesome. So right now we're at the I-time of 1.0. Let's go ahead and try, let's try 0.75. I'm just kind of taking a guess here. Now, we can always adjust up and down based upon what we're seeing in the ventilator waveforms as well. So that's just something we always consider when we're making changes to the ventilator. Now, one thing I did note whenever I took down that I-time is that we did lose our tidal volume here as well. So our patient's not getting the demand that they need based upon the ventilator settings that we have. Now, this ventilator does both manipulate I-time and flow. I know some traditional ventilators on the market right now do not do that. But this is a great learning experience, because your learners may encounter a ventilator that has both settings, and to understand that I-time and flow interact, and we have to make sure they're in sync with each other to meet our patient's demand or to meet the demand that we're giving to the patient. So I'm just going to go ahead and keep adjusting.

Liz Bolen: And you'll see just when the ventilator is normalizing as well, you might see some alarm flashing going on. It is important to note that this virtual ventilator has alarms. You can set alarm limits, you can set the volume wherever it needs to be, but like a ventilator, it will flash, it will alarm, and you can set alarm limits. So very good to see that. And what are we thinking that the patient looks like now on the ventilator?

Justina Gerard: Patient looks good. I did see we had that little blip there. Let's just let it run for a moment and make sure we don't see that again. But if we don't, I'm looking pretty happy with this. Yep, I think we're good. We've normalized out our settings. Awesome, let's go ahead and switch to debrief.

Liz Bolen: Sounds good. Nice job, crew. Okay, so name that interaction. So Justina, tell us what our goal was here, what we saw, and why we did what we did.

Justina Gerard: So our goal this time around was actually comfort because the patient was spontaneously breathing. We wanted to make sure that they were in sync with the ventilator. So we had a failed trigger, that was where we were missing out. So we saw that there was a little blip, but the ventilator wasn't actually triggering. We decreased the I-time and it allowed the inspiratory effort to be effective in triggering. So great job, crew, that was amazing.

Liz Bolen: Cool. We really hope that you enjoyed those live interactions. It was really great to have a good group and be so engaged and got to see our virtual ventilator and actually one of the use cases and one of the ways that you can use it with your learners, put you in the hot seat this time though. Thank you so much. It is time for Q and A. I hope that you've been chatting with Greg along the way or submitting any questions, but please do submit your questions and comments now in the chat panel. You can either put it in the chat or there is a function called Q and A, you can put them there as well. We will definitely address as many questions as we can live and any that we don't, we will connect with you offline. But please do, questions about the scenarios, questions about RespiSim eLearning subscription. Any comments that you have, please do share and this is the time.

All right, so I do see a, well first of all, we have a shout-out for the Snowball mic. I absolutely love that. Yes, this orange ball right here is the Snowball microphone. It is probably one of the best microphones out there. Anyone who is teaching live and wants a good solid microphone, the Snowball microphone is always good. I love that that was a shout-out for that. And thanks for everyone for saying hello. So it looks like we have a question here. Are there modes other than AC and CPAP and pressure control?

Justina Gerard: So for this iteration of the virtual ventilator, we kept the foundational modes of ventilation. We do hope to add additional modes of ventilation in the future, but for right now, those are the three modes of ventilation that we have to offer.

Liz Bolen: Great. Okay, so if someone put in the same resistance, compliance, and muscle pressure to their existing LLEAP platform, for example, will it work in the same way?

Justina Gerard: Yeah. Hi, Alex, nice to talk to you again. But yeah, it should, there's no reason why. The only thing I would caution is every ventilator algorithm is a little bit different. So just because you see a specific interaction on our virtual ventilator, there might be a little tweaking necessary to your ventilator to see the exact interaction that you're looking for. Remember, some of those flow sensors are internal, some of them are external and some of them just fix problems all on their own. So that would be the only thing I would caution.

Liz Bolen: And depending on what you're using now, obviously as a LLEAP user, you're probably using the ASL 5,000 Lung Solution, so you are good to go. But we have the lung parameters there as well, so resistance, compliance, muscle pressure, you can set those on any test lung that you may have. But yeah, anyone who's using the ASL already out there, those will work wonderfully and you'll just have to tinker with the ventilator interaction to see what you would like. Information on whether we have pediatric and neonatal scenarios with the platform.

Justina Gerard: So right now we have pediatric neonatal child lung models built into RespiSim already. Those lung models can be used with the virtual ventilator, however it is not tested. So we would kind of consider that beta tested at this point in time, but we haven't validated that those interactions are exactly perfect. The physiology that runs the virtual ventilator has only been validated for the adult patient. However, I've tested a few of those lung models and I don't see any reason why they wouldn't interact appropriately.

Liz Bolen: Yep. So I did open up RespiSim here. I'm just showing once you go into the library, you're able to select the patient population to help filter neonatal, infant, child, adolescent. So we absolutely have plenty of models to run for pediatric and neonatal scenarios. Angela says, I thought I was seeing flow dyssynchrony during case two. As changing the flow pattern or

flow rate was not an option, I would've changed to a variable mode. Can you show the failed trigger? I didn't see that.

Justina Gerard: Yeah, there was a slight missed trigger. There was actually a decent amount of patient ventilator dyssynchrony in general. So let me go ahead and take us back down to our, I believe we were at 60 liters, yeah. And then our I time was 1.0. Now if we remember back to our neural I-time of our patient, our patient was set at a neural I-time of 0.6. So basically our patient is saying, I only really need 0.6 seconds of an I-time. And then right here we have our missed trigger where we have that deflection where our patient's trying to trigger and they're not getting it.

Some of that could also be caused by the fact that our patient's actually expiring whenever we're still delivering that breath. So that's why changing the flow, excuse me, changing the I-time and increasing the flow was able to give us what we were looking for. Now Angela, I will say on the session we ran this morning, changing to a different mode of ventilation was also one of the popular choices as well. So definitely different options that we can do to make sure that we're achieving the most in this situation, the most comfortable option for our patient.

Liz Bolen: Awesome. Let me pull up more questions. Remind us, Justine, of the three modes that can be used in the virtual ventilator, they're right here.

Justina Gerard: Yeah, the assist control and volume, assist control and pressure, and CPAP and pressure support. And I do want to point out that a portion of RespiSim eLearning does give you access to our LMS and that within the LMS we have SEVA courses and SEVA courses will really allow you to understand the fundamental taxonomy of mechanical ventilation. And that's why we chose to introduce these first three modes of ventilation because we really wanted to focus on getting the foundations, understanding what basic, I say basic like it's simple, it's not, but understanding what these types of modes of ventilation do, how they interact with each other and how different patients can look on them. So that's the reason why we kind of chose these first three modes of ventilation.

Liz Bolen: I do have a question here for how much is a subscription for the faculty slash school and individual students. I am going to pull up the website really quickly for anyone who wants to learn a little bit more in general, please head to ingmarmed.com. If you head to our products tab and go down to RespiSim eLearning, it'll take you to this product page here. And what's really exciting about it is it affordable and it is a subscription-based item. So you are able to purchase it right from our website via credit card. And to answer your question, I believe it was David, you would choose the number of users that you would have. So the total number of instructors and students. So let's say one to five and then the number of years that you would want. So a yearly subscription or there are definitely cost savings with a three year, but just to give you an idea between one to five users, it's $999 a year.

So that is all available for you on the website to check out. Again, ingmarmed.com, head to the product tab, scroll down to RespiSim eLearning and you'll find out a lot more about cost and plenty of FAQs. I did also see a question here about the virtual ventilator is what the student sees, do they see the patient we are building or do they only see the patient presentation? That is a great answer, or question. And the answer is actually kind of a mixed bag. It depends on what you want to do. I'm going to open up the FAQs underneath the webpage here. And that's actually one of the first questions that we had thought that people might ask, what options do I have for running RespiSim eLearning with my learners? So if you pop into here and open up this resource, it's called a use cases resource, and it will tell you all about the ways that you can use RespiSim eLearning. One of those ways is going to be as you suggested in which you have the learner and the instructor both creating the patient and seeing the interactions.

So you do have that option and we do have resources for your learners to understand how to quickly create a patient. It's just a basic use tutorial video on our resource page so that way they can come in here for self-study for example, or with group bench simulations. They can come in, create their patient and see the interactions on the ventilator on their own. That could be self-study as well with our LMS. But there are other ways to run it. For example, the instructor leads and the learner interacts. So this is where either onsite or remote, you have everyone operating from one shared instance of the virtual ventilator. So for example, here's our instructor.

If this student on the left here makes a change to the virtual ventilator settings, that's going to reflect for the teacher and for the learner. So it's a very good kind of controlled experience. And you also have the ability for, like I said, learners to have their own instances, a shared instance, or self-study on their own. So it kind of depends whether you want to enable your learners to create their own patients within RespiSim and interact on the virtual ventilator. Or you can kind of lead the way and just demonstrate and share your screen. So up to you. But we'd love to hear about how you all decide to use this subscription. Let's see, however many questions we have. Thanks so much for being so engaging and asking these great questions. I hope that I'm answering them clearly enough for you.

Okay, I'm going to give a couple more minutes here for any final questions or anything that I can show you here on the web page or the virtual ventilator or RespiSim, please let me know and I will. But in the meantime, thanks so much. I just want to say thanks for spending this time with us today and learning more about and the ways that you can implement into your existing curriculum to provide some really powerful experiential learning experiences. Please visit ingmarmed.com, learn more about RespiSim eLearning and all of the technology that we showcased today. You will receive the recording to this webinar as well as a resource.

So we have How to Create Fundamental Patient Ventilator Interactions. It's a PDF that's coming your way soon and it just has the ventilator settings and parameter settings to recreate the scenarios we showed today. And you'll also get a link to a survey. Please fill out the survey. It's really short and it just provides us with feedback on how we can improve and what topics to showcase in the future. And of course, we're always here to help reach out to us sales@ingmarmed.com. And thank you again. I hope you have a wonderful day.

Justina Gerard: Yeah, thank you so much. This is great.

Hi Amy. I'm not sure if you're still on, we were just reading back through our chat and realized we missed one of the questions.

The question was, do you have anything with hemodynamic monitoring, like respiratory rate, heart rate, capnograph, SpO2 in conjunction to use with the ventilator platform? And would it respond in real time? So yeah, there is a patient monitor application. I believe Liz had kind of showed or you know what? It was on one of our slides where we kind of showed the patient monitor next to the ventilator. You can use that with a real ventilator. You can also use that with the virtual ventilator. It would give you a capnograph, it would give real-time data, so both the waveforms and the live output data. And then you also are able to input X-rays, vital signs, images that you would like, anything that would be more relevant to the case that you are presenting. And this is going to allow you to have the opportunity to have more of that immersive experience as immersive as possible, but even in the remote environment and take it into your hands-on experience as well.

Liz Bolen: Awesome. Thanks again so much for the engagement. Have a great day.

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a year and has been proven to help save babies' eyesight in the neonatal ICU, detect critical congenital heart defects in newborns, and save the lives of patients in post-surgical wards who are taking opioids.

New Study Finds Significant Correlation Between Masimo ORi and Arterial Partial Pressure of Oxygen During One-Lung Ventilation

Masimo announced the findings of a retrospective study published in the Journal of Anesthesia in which Dr Yu Jeong Bang and colleagues at the Samsung Medical Center, Sungkyunkwan University School of Medicine, in Seoul, South Korea, investigated the association of Masimo ORi and the arterial partial pressure of oxygen (PaO_2) in 554 patients who underwent non-cardiac thoracic surgery during one-lung ventilation (OLV), making this study the largest to date on ORi. The researchers found that ORi values "were significantly correlated with PaO_2 measured simultaneously" and that ORi "could provide useful information on arterial oxygenation even during one-lung ventilation." Noninvasive, continuous Masimo ORi provides continuous, real-time insight into the oxygenation of hemoglobin in the moderate hyperoxic range (PaO_2 > 100 and ≤ 250 mmHg) to be used alongside arterial blood gas analyses, which have the drawbacks of being invasive, intermittent, and delayed. ORi is trended continuously with SpO_2 as a unit-less index between 0.00 and 1.00 to extend the visibility of the patient oxygenation beyond SpO_2 under supplemental oxygen. By convention, SpO_2 is limited to an upper limit of 100%, but oxygenation is not limited and can rise into hyperoxia (higher than normal oxygenation state) when supplemental oxygen is administered. ORi provides clinicians with additional visibility, as a complement to SpO_2 monitoring with Masimo SET pulse oximetry, into when oxygenation is increased into, or decreased out of, moderate hyperoxia, in real time. Noting the importance of striving to prevent hyperoxemia and hypoxemia especially during surgery requiring OLV, because of the risk of pulmonary complications, the researchers sought to evaluate a noninvasive, continuous method of predicting imminent over- or under-oxygenation to overcome the drawbacks of invasive blood gas analysis alone, using Masimo ORi. To evaluate ORi's performance, they analyzed data collected from 554 patients who underwent non-cardiac elective thoracic surgery requiring OLV between January 1 and December 31, 2022 at a tertiary hospital in South Korea. During anesthesia, ORi was monitored using Masimo RD rainbow SET® Pulse CO-Oximetry sensors, and blood gas analysis was performed 15 minutes after OLV was initiated. The researchers' primary endpoint was the association between simultaneous ORi and PaO_2 values. They also sought to identify risk factors for PaO_2 < 150 mmHg, based on their clinical experience that most patients with PaO_2 > 150 mmHg in this scenario rarely show hypoxemia. The researchers found a linear correlation between ORi and PaO_2 measured simultaneously. Using linear regression analysis, they found there was a statistically significant positive relationship between ORi and PaO_2 measured 15 minutes after OLV initiation (r^2 = 0.5752, p < 0.001). Using receiver-operated curve (ROC) analysis, they identified an optimal cut-off ORi value of 0.27 to detect PaO_2 ≥ 150 mmHg during OLV (area under the ROC curve of 0.96, 95% confidence interval of 0.94 – 0.98, sensitivity 0.909, specificity 0.932). Of the 11 potential predictors for PaO_2 < 150 mmHg identified by the researchers, ORi was highly predictive (odds ratio 0.001, p < 0.001). The researchers concluded, "ORi values

Continued on page 35…

Saving Money and Saving Lives, One Mask at a Time

Ann Hewitt, RN, BSN, MM

In 2014, Don St. Peter was diagnosed with sleep apnea. An apparently healthy and vital man in his early 50s, his only symptom was snoring, and he didn't seem to be at any particular risk of cardiac complications. Like many people, Mr. St. Peter found the prescribed CPAP mask uncomfortable and intrusive, and he abandoned it a few months after he was diagnosed. A year later, Mr. St. Peter had a heart attack and died in his sleep.

Unfortunately, this story is relatively common. What is not common is the impact it had on Mr. St. Peter's daughter, Kristina Weaver. Kristina was a sleep technologist at the time, and she was the one who had performed the sleep study on her dad. Kristina knew she had an ability to change the health trajectory of health for other people's parents. To honor her dad's memory, Kristina spearheaded the Sleep Mask Fit Clinic at the Sleep Lab at Parrish Medical Center in Cocoa, FL, in order to make it easier for patients to comply with wearing their prescribed sleep masks. The Fit Clinic was inaugurated in 2015, shortly after her father's death.

At that time, reusable sleep masks were the default option for patients in many centers, and storing an inventory of multiple sizes, brands and configurations of masks was not unusual. Kristina and her colleagues instituted the daytime Fit Clinic so that patients who had been prescribed a CPAP mask could evaluate as many options as necessary to find one they could wear faithfully. The staff would clean and low level disinfect the masks and accessories after each trial fitting, and re-use them again and again.

Not long before Mr. St. Peter died, the Joint Commission decreed that reusable devices used in sleep centers were semi-critical devices and could no longer be cleaned and disinfected with a low-level disinfectant, even if it was EPA approved. Going forward, referencing the Spaulding Classification for risk and level of reprocessing, reusable devices would need to be high-level disinfected as an infection prevention measure. High-level disinfection (HLD) is used for semi-critical devices, those which might touch non-intact skin or mucous membranes. Semi-critical devices include flexible endoscopes and anesthesia equipment, along with respiratory tubing and face masks. The options for high-level disinfection, or HLD, were historically based on chemicals such as glutaraldehyde or orthophthalaldehyde (OPA).

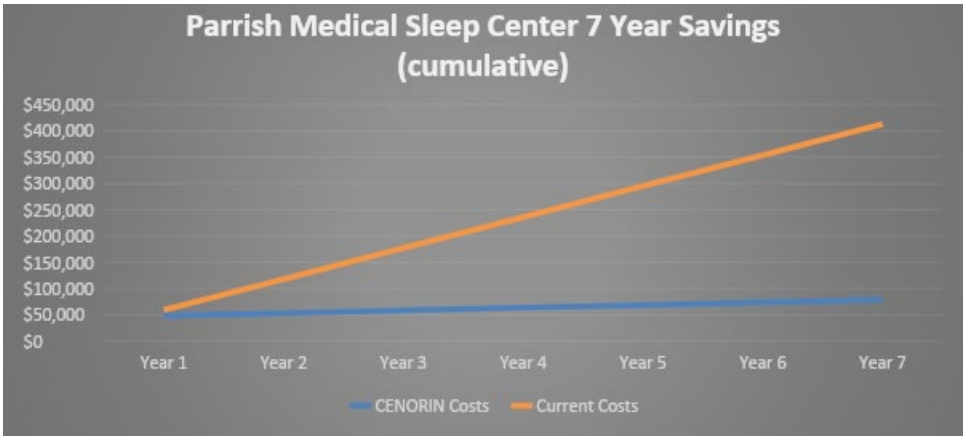
For many facilities, the burdens to incorporate chemical HLD were unappealing. The chemicals are dangerous to work with. OSHA requires PPE, an eye wash station and a ventilation hood when working with glutaraldehyde. Chemicals need a lot of storage space. State and local regulations on disposal would have to be followed. Most sleep centers, whether hospital based or stand-alone, decided the easiest course of action was to switch to single-use devices, so they could avoid dealing with the consequences of HLD with chemicals.

For Kristina, motivated as she was by her mission to prevent other families from suffering the devastating and preventable loss of a parent at a young age, switching to single use devices (SUDs) wasn't an option. She intuitively recognized that there would be significant ongoing costs to purchasing, storing and disposing single use products in a never-ending cycle. More important, she realized that the success of the Sleep Mask Fit Clinic depended on patients being able to try on as many masks as they needed to find the right fit. If the Sleep Clinic had to discard each single-use mask that was used in the fit clinic, it would quickly go bankrupt.

Kristina and Michele Roberge, the former Sleep Lab Manager at Parrish Medical Center, investigated alternatives, with the goal that their selection must be both cost-effective and completely safe for patients and their staff. They wanted to mitigate the perceived drawbacks of SUDs: the single use devices would be more expensive in the long run, their disposal clogs up the waste stream and is bad for the environment, and managing the logistics of device procurement, storage, opening and disposing was going to require time that they didn't have.

Their research led them to thermal high-level disinfection, a discovery that seemed to check all the boxes they had defined: 1) it was must be non-toxic; 2) must be easy to operate; 3) must be compatible with the materials in their reusable supplies; 4) must meet the expectations of The Joint Commission; and 5) must be so cost-effective that they could continue to run the Fit Clinic at no charge to their patients.

With a clinical background and over 30 years of infection prevention experience in industry, Ann Hewitt has a comprehensive perspective on medical device reprocessing. She has been an invited speaker at national and international meetings on reprocessing, a member of the AAMI ST91 working group and a SME for numerous publications and education programs. Ann is currently the Vice President of Sales & Marketing for Cenorin, LLC.



Cumulative savings of over $300,000 in six years.

"This gives us the ability to help more patients get comfortable on CPAP by offering a variety of different masks."

"I always tell patients, 'There is no reason that you should be uncomfortable on a CPAP mask. We will figure out something that works for you, and we'll keep trialing until we get it right,'" said Michele. "An automated cleaning and high-level disinfection system gives us the ability to help more patients by offering a variety of different masks."

The Parrish Sleep Center initially purchased an Olympic pasteurizer and used it until it wore out a few years later. By that time, Olympic had been purchased by a larger company and was no longer selling or servicing their products, so Parrish had no choice but to purchase from a different company if they wanted to continue offering the Sleep Mask Fit Clinic. The hospital administration was skeptical of their commitment to replacing their old unit with another thermal disinfection system, but Kristina and Michele were confident that chemical-free high-level disinfection was their best option.

They knew they would need to make a persuasive financial case to their administration. With that in mind, they went to Materials Management to get costs on their current inventory of reusable devices. Materials Management was also able to provide the costs of the individual SUDs that were comparable to their reusable devices.

The Sleep Center would pay for their new thermal HLD system in less than a year

The two of them dug into their ongoing purchase history and patient load to do an accurate analysis of their current costs. The Sleep Center was processing each device 15 times before discarding it, so they used 15 as the number of replacement SUDs they would need for each purchase of reusable devices they had been making. The ROI impact stared them right in the face: their anticipated cost savings would be so substantial that the Sleep Center at Parrish Medical Center would pay for a new thermal high-level disinfection system in less than a year, even without including any labor savings or any soft costs. It was an oranges-to-oranges comparison. Their administration agreed with the recommendation to purchase a new system.

Before they could purchase, however, they faced a second obstacle: overcoming the clinical concerns of their Infection Preventionist. Kristina and Michele reviewed manufacturer reprocessing recommendations for every mask they used to ensure they knew how many reprocessing cycles were allowed before discarding. They also had to document that the new system would meet all the manufacturers' guidelines for high-level disinfection. Once their Infection Preventionist was on board, they were ready to research their options.

Kristina and Michele's research led them to the only system that has received 510(k) clearance from the FDA for thermal high-level disinfection: they selected the 610 Thermal High-Level Disinfection System from CENORIN as their replacement. The entire Sleep Center staff was delighted to realize that the automated cleaning cycle would eliminate the labor they had previously devoted to cleaning their reusable devices before placement in their previous machine.

But labor savings and cost savings weren't the only benefit. Their ability to support the Fit Clinic continued to expand, due to the number of options Parrish could now afford to offer. "We had countless patients coming to us after they'd had a home study and then purchased the first mask they tried when they went to the DME," said Michele Roberge. "It was multiple patients a week, coming in saying, 'This is terrible, it's so uncomfortable.'" Knowing that good fit is critical to compliance, Parrish has placed an intense focus on getting the patient into the right set-up. Michelle went on to say, "We earned a reputation among both the primary care doctors and the DMEs in our area for being able to supply patients with the proper fit. The DME tells the patient, 'We'll call Parrish Sleep Center — you can go there to figure out what mask you want, and then we'll do the exchange for you.' Without our thermal high-level disinfection capability, Parrish Sleep Center would not be able to provide this level of service and clinical support. It would just be a testing center."

Kristina expanded on these observations, saying, "When we look at the big picture, daytime fittings create brand awareness and drive volume. We've become a one-stop shop; the word has gotten out that our patients are compliant. For us, these daytime fittings opened up a whole new set of referrals as we became known for providing proper fit. Our compliance levels are above 80%, when the national average is between 50 and 60%." Research backs up the compliance benefits of providing a proper fitting and titration.

Parrish Sleep Center's ability to support this increased volume is entirely based on the cost savings of reprocessing reusable devices instead of using single use devices. Kristina estimates that in the first five years of offering the daytime Fit Clinic, their business increased 540%. She attributes at least half that growth to their ability to offer treatment from beginning to end and supporting compliance with their patients. She celebrates the fact that their fit clinic has created life-long patients because Parrish will offer mask fittings to any patient in their lifetime who want to trial new masks.

Parrish Sleep Center calculated that it took only eight months to hit break-even on its new CENORIN 610 Thermal High-Level Disinfection System. After that, the savings all dropped to the bottom line. Kristina summarized her thoughts: "Our top three benefits are 1) immediate cost savings; 2) better quality patient outcomes from our person-centered care; and 3) brand awareness and increased referrals flowing from that better person-centered care." Eduardo Hernandez, the new Sleep Manager at Parrish Sleep Center, reported that one of the reasons he appreciates the opportunity to be a part of the Parrish Sleep Center team is the capacity to provide education and other support to the community. Without the positive financial impact created by the 610 Thermal High-Level Disinfection System, Eduardo said, "We wouldn't be able to fund activities such as the fit clinic and community education efforts that other facilities might bill for. It is a privilege to work in an environment that consistently puts the patient first."

When asked if she would recommend thermal HLD as a viable option for other sleep centers, Kristina said, "Yes, definitely. We are able to meet the demands of The Joint Commission for infection control while saving a lot of money and being environmentally conscious."

Eduardo added, "We have built-in peace of mind with the 610. On a day when we are fully booked for sleep studies and fittings, we can still get slammed with patients who don't have an appointment. We are able to accommodate them all because we can reprocess our masks and have inventory available no matter how busy we get."

Thermal high-level disinfection is providing improved patient outcomes, improved financial management, and improved staff morale at Parrish Sleep Center. Who would have guessed that "getting into hot water" would be such a profitable thing to do? Kristina summarized their experience by saying, "When we think of the cost of disposable masks and even the impact on our environment, having an option like we have with our thermal high-level disinfection is a game changer." Her dad would be proud of the legacy she's created in his memory.

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A Review of the 2023 American Association for Respiratory Care International Congress: From a Perspective of a First Time Attendee Undergraduate Student

Introduction

In the fall of 2023, the opportunity presented itself to attend the American Association for Respiratory Care (AARC) International Congress. Being a senior in my undergraduate program at Texas State University, my experience in attending professional conferences was limited to a smaller, but well organized, state conference hosted by the Texas Society for Respiratory Care. Despite my limited experience, I jumped at the opportunity to attend the AARC Congress in Nashville, Tennessee. From my perspective, Congress provided a unique opportunity to engage with the latest advancements in the field of respiratory care, network with professionals, and gain valuable insight into various career paths. All of which are invaluable to a person set to graduate into the profession in just a few short months.

Personally, I hoped to develop a broader understanding of careers within the profession and was excited to look for opportunities to network with potential employers. Looking at the conference guide, my expectations for the days ahead revolved around shuffling between lecture presentations and abstract/poster presentations and looking for the best ways to work my way into meet and greets among established respiratory care professionals. Although all of this came to fruition, there was also so much more in store than was originally anticipated.

Experience

From the moment of arrival, it was easy to tell that attending the conference was the right decision. The energy and enthusiasm between workers at the check-in and small talk among the attendees was infectious. Even the host site, the Gaylord Opryland Resort & Convention Center, provided impressive amenities that proved the conference spared no expense. There was a positive energy to the conference that repeatedly not only made me proud to be a respiratory therapist, but also excited about the possibilities of pursuing an advanced degree, namely a master's degree in respiratory care.

As the week's activities started, I was impressed with the lecture and research presentations. I made it a point to attend lecture presentations and open forum research poster presentations.

Meagan Ramos is currently a senior in the Bachelor of Science in Respiratory Care (BSRC) program at Texas State University. She is also currently dual-enrolled in the Master of Science in Respiratory Care (MSRC) Program where she has elected to specialize in the area Clinical Specialist. Meagan will graduate from the BSRC program in May of 2024 and the MSRC program in August of 2025.

Meagan Ramos

All of which were well presented and provided a lot of valuable content. The open forum research poster presentations were some of my favorite lectures attended for the week. It was great to see every day respiratory therapists take initiative within their workplace and initiate patient research to improve patient care at their hospitals. I was particularly impressed with the content presented involving the neonatal and pediatric areas of clinical practice, since this is my primary area of interest.

Without a doubt, my favorite part of the conference was the exhibit hall. The volume of exhibitors was initially overwhelming yet exciting at the same time. It was awesome to see the most up-to-date advances within the field of respiratory care on full display. There was also a variety of employers on site, giving information on their respective hospitals and healthcare companies. While exploring the exhibit hall I gained insight on new areas of interest including vascular access, extracorporeal membrane oxygenation (ECMO), and new technology involving actigraphy watches used for sleep diagnostics. Up to this point, my understanding of the role of a respiratory therapist was limited to primarily inpatient care and diagnostic / rehabilitation services. It was encouraging to see therapists working in a variety of areas and present those areas in the conference exhibit hall. Similarly, it was interesting to observe the credentials of many of the therapists working in the exhibit hall. Not only did many of the therapists hold advanced credentials offered by the National Board for Respiratory Care, but I also observed many of the exhibitors held a master's degree level education. This was a welcomed sight, verifying the advancement of the field of respiratory therapy.

Networking

One of the most significant advantages to attending Congress for the first time is the opportunity to network with peers, mentors, and potential employers. The conference hosted social events, receptions, and networking sessions specifically designed to facilitate interactions between attendees. Informal settings such as this allowed me to engage in meaningful conversations, seek advice from seasoned professionals, and have the opportunity to build relationships beyond the conference. The exhibit hall gave me the opportunity to speak with future employers such as The Mayo Clinic and different companies offering certifications to respiratory therapists such as vascular access and ECMO training. Not only did I have the opportunity to connect with various companies, I also got the chance to speak with therapists and develop an understanding of the variety of positions that are possible in this career field. While expanding my knowledge on all things respiratory, I also got the unique experience to be able to get to know and connect more with my current undergraduate faculty. Although the AARC Congress offered remarkable learning opportunities, one of my favorite parts of this experience was having the luxury of spending time with faculty members outside the classroom.

Outlook

Attending the conference was extremely motivating to me. Upon returning, I immediately enrolled in the Master of Science Program in Respiratory Care program at Texas State University. I also reached out to contacts I made at the conference to express my desire to work at their respective hospitals upon graduation. Long term goals include exploring a career in ECMO services along with pursuing a career in education at the undergraduate school level and research topics in the areas of pediatric intensive care medicine.

Conclusion

Attending the AARC Congress was a transformative experience that offered immeasurable opportunities for learning, networking, and professional development. What I found was a pleasant surprise of fellow respiratory enthusiasts who were not only inviting to a future therapist, but also helpful in providing insight to a career yet to come. I look forward to attending many more conferences hosted by the AARC for years to come.

News…continued from page 29

during one-lung ventilation were significantly correlated with PaO_2 measured simultaneously. Therefore, the ORi monitor can provide useful information for estimating the PaO_2 value even during one-lung ventilation." In the US, ORi has been granted a De Novo by the FDA to be used in patients undergoing surgery as an adjunct to SpO_2 for increased monitoring resolution of elevated hemoglobin oxygen saturation levels (e.g., due to administration of supplemental oxygen). The ORi feature is indicated for the monitoring of hemoglobin oxygen saturation levels in patients 18 years and older (adults and transitional adolescents) on supplemental oxygen during no-motion conditions perioperatively in hospital environments.

CHLA Testimonial – New UPS Battery Designed for Better Respiratory Care

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. Participating in the interview are Russelle Cazares, MHA, RRT-NPS, Associate Director, Cary Sodetani, BS, RRT-NPS, Clinical Supervisor, and Daniel Villareal, MBA, RRT-NPS, Clinical Practice Leader at Children's Hospital Los Angeles, Los Angeles, CA.

Please tell us about Children's Hospital Los Angeles and the critical care you provide.
Children's Hospital Los Angeles (CHLA) is a free standing, non-profit, academic, acute care organization. Founded in 1901, CHLA is a world leader in pediatric and adolescent health. CHLA is one of America's premier teaching hospitals, affiliated with the University of Southern California's Keck School of Medicine since 1932. It is one of the nation's leading pediatric hospitals, consistently ranked in the Top 10 Nationally by the United States News and World Report.

Can you identify challenges you encountered during critical care transport and the subsequent patient issues that arose?
The Heated High Flow Nasal Cannula (HHFNC) systems that we have in the hospital did not have a reliable transport battery. We would transport patients from the Emergency Department to the floors without heat and humidity, which poses a patient safety risk because it can cause irritation, bleeding, and dryness of the nares. We used the Tripp-lite Uninterruptible Power Supply (UPS) battery as a backup for the HHFNC and the High Frequency Oscillatory Ventilation (HFOV).

What solutions were you looking for?
We were looking for a new UPS battery to replace the Tripp-lite battery, that would power the HHFNC during transport. In addition, we wanted a smaller and lighter backup battery in case of electrical failures.

Having found Zopec Medical and their UPS 90 Pure battery, how has it positively impacted patient safety in your hospital?
The Zopec battery has had a significant positive impact on our concern regarding patient safety and transport. Prior to implementing the Zopec battery, we were using the Tripp-lite battery, which was bulky, heavy, and had short runtimes. These issues were not only affecting our patients, but also our staff members who had to manage the 45 lbs. Tripp-lite battery. For patient transport, the previous battery was not ideal for equipment that needed to be mobile. Additionally, as the Tripp-lite battery aged, the battery became so unreliable that it would die mid-transport with patients on the F&P Airvo™ 2. This became a patient safety issue.

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

What are your assessments of the Zopec UPS 90 Pure battery runtimes and how well does it meet your hospital's needs?
The runtimes of the Zopec battery have consistently met, and sometimes even exceeded, the requirements of our patients being transported to different locations of care. It is reassuring to know that life support equipment being used during transport will continue to function effectively.

CHLA tested the Zopec battery on several types of equipment, the most impressive was on the HFOV. The test was done solely with the battery running the ventilator on high settings to see how long the battery would last. The UPS 90 Pure ran for almost 2.5 hours.

Can you provide examples of how the Zopec UPS 90 Pure battery facilitates seamless transport?
The most frequent use of the Zopec battery at our hospital is for the F&P Airvo™ 2. The Tripp-lite battery we formerly used was close to 45 lbs. The Zopec battery is only about 6 lbs. The F&P Airvo™ 2 unit can be easily moved throughout the hospital and we can confidently transport patients for longer.

Patients who require transportation from the Emergency Department can be transported without any interruption in the type of care being provided. This means that if a patient is receiving a specific therapy, such as the HHFNC using a Zopec battery, they will continue to receive that therapy during transport. Similarly, if a patient requires HHFNC and is started on the Zopec battery, they can be transported on that same device without any interruption.

Has the Zopec UPS 90 Pure battery been effective in preventing power failures in your hospital?
We have not experienced such an emergency at this time. However, we do have weekly testing of the hospital generators where the power inhouse shifts toward the backup generators and there is a momentary cutoff of electrical power during the changeover. The Zopec battery has flawlessly maintained a steady flow of electrical power to our equipment.

We also conduct regular power surge testing. To ensure uninterrupted power supply to our critical equipment, the Zopec battery is installed on devices that require battery backup, such as our HHFNC and HFOV fleet. This ensures critical patients receive continuous therapy without any interruptions.

Can you share the usability experiences with the Zopec UPS 90 Pure battery and how it has improved these processes?
The Zopec battery is much lighter than the one we used previously, which makes it easier to manage. The extended battery life enables staff to transport longer with confidence.

In which ways has Zopec Medical shown commitment to continuous improvement and responsiveness to your hospital's needs?
Zopec Medical has been very generous and responsive to our needs, from trial evaluations to mounting solutions for our equipment. Each time we recommend a solution to improve our staff workflow, they have been willing and able to produce a solution immediately.

Overall, how does the investment of the Zopec UPS 90 Pure battery compare to other solutions and what specific value does it bring to your hospital?
It was an easy decision to make the change over to the Zopec battery, where it has received positive evaluations from our staff. Its portability, low footprint for storage, and reliability gives our staff the confidence to transport patients without concern that the battery will fail mid-transport. Also, it's great to have a light and maneuverable battery that easily attaches to equipment.

UPS 90 PURE

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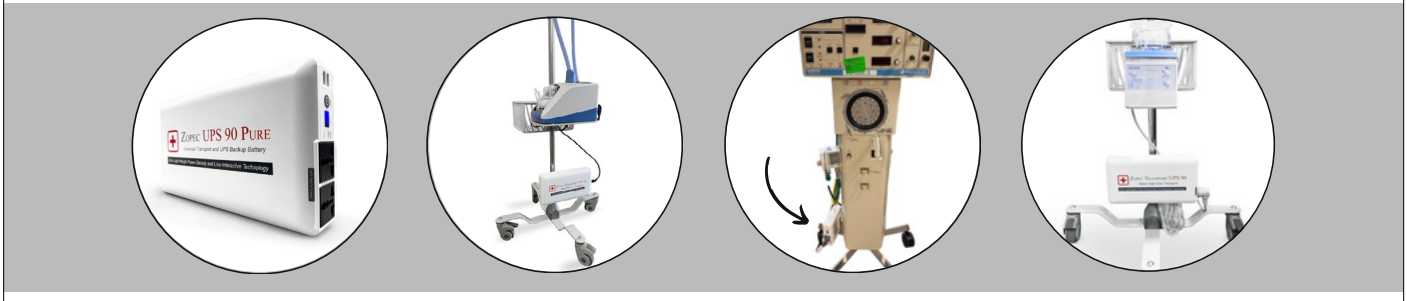

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Indication

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If They Don't Breathe It In…

Phil Lake, PhD and Kevin McCarthy, RPFT

Submaximal inhalation error (SIE) is listed as the first entry in the 2012 NIOSH booklet, "Spirometry Quality Assurance: Common Errors and Their Impact on Test Results",[1] citing "submaximal inhalation causes underreporting of true spirometry results. An incomplete inhalation is a frequent and serious problem that occurs in spirometry testing." A 2015 letter to the editor of Respiratory Care[2] called for recognition of this error in training programs for spirometry operators and requested spirometry manufacturers develop software to detect this error and provide feedback to alert operators.

SIE is impossible to quantify unless a FIVC is measured immediately after the FVC. The 2019 ATS/ERS spirometry task force felt SIE was more common than most doctors and spirometry operators believed and the collection of the FIVC was added to the forced spirometry maneuver to allow objective evaluation of full inflation.[7]

A review of the guidance given about coaching to full inflation in every ATS/ERS spirometry standard[3-7] reveals little or no guidance was given on the technique of coaching to full inflation until the 2019 set of standards. If the forced exhalation starts before full inflation is reached, satisfying the start-of-forced exhalation acceptability criteria still leaves the reported FEV1 understating the true value. For this reason, the 2019 ATS/ERS task force updating the spirometry standards added a fourth phase to the forced vital capacity maneuver. Upon completing the forced exhalation, the patient is now coached to rapidly inhale back to full inflation (see Figure 1, below).

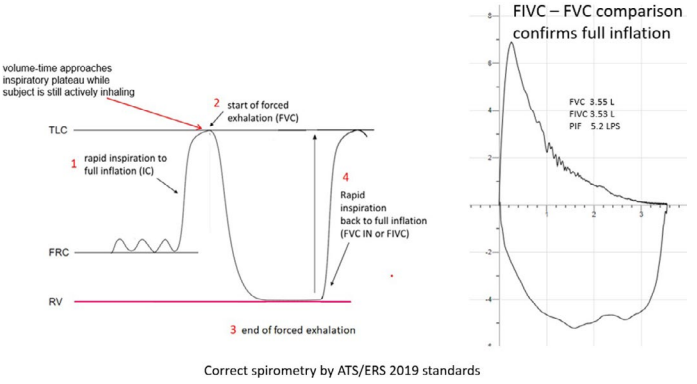

Figure 1. The four phases of spirometry

Comparison of the volume of a truly maximal forced inspiratory vital capacity (FIVC) with the FVC can objectively confirm the patient was at, or close to, full inflation when the forced exhalation began. If that comparison demonstrates that the measurement did not start from full inflation ((FIVC – FVC)/FVC >0.05 or FIVC – FVC > 0.100 L, whichever is greater), both the FVC and FEV1 are considered unacceptable, even if all other acceptability criteria are met and repeatability is demonstrated.

Proper timing of the command to start the forced exhalation is more difficult than most believe. Evaluating the patient's face and simultaneously assessing when the volume-time tracing is approaching full inflation is difficult to do and sometimes results in a pause before the operator gives the command to BLOW. During this pause, the patient will often leak a small volume of air into the spirometer. The back-extrapolated volume (BEV) is the volume exhaled before maximum flow is achieved. If the BEV is too large, the FEV1 is unacceptable. Operators sometimes give the command to blow while the patient is still inspiring and easily meet the BEV acceptability criterion. If the coaching is delivered in a consistent manner, the lung volume from which the forced exhalation starts is similar and repeatability of the largest FEV1 and FVC from multiple efforts in a measurement can be achieved. Absence of BEV errors and demonstration of repeatability is thought to guarantee the quality of the effort is good. Unfortunately, this is not the case.

It is important to remember that the 2019 ATS/ERS spirometry standards now give us a new lens through which to view

Phil Lake, PhD, Director, Respiratory Solutions, Clario. Phil Lake has been working to interpret lung function test data within respiratory drug development for the last 24 years. He was involved in one of the first trials to adopt a central spirometry review and has spent much of his career looking into spirometry data variability and plausibility to understand why studies fail and how aberrant data can be generated. He Joined ERT/Clario in 2017 after acting as an advisor for several centralised spirometry vendors and has been championing a more holistic approach considering active management of lung function data, study design modifications and a focus on data plausibility to reduce the incidence and impact of problematic spirometry data.

Kevin McCarthy, RPFT, Director, Respiratory Science, Clario. Kevin McCarthy has been working in the field of lung function testing for 50 years. Most of his career was spent managing the Pulmonary Function Laboratories at Cleveland Clinic. A former member of the ATS PFT Committee, he was on the ATS/ERS Task Forces that updated the standards for both spirometry and lung volume measurements. He began working for Clario assessing the quality of lung function measurements and now works on minimizing lung function data variability in clinical trials.

spirometry quality. Because experienced operators are accustomed to looking at spirometry quality through the lens of the 2005 ATS/ERS spirometry standards, they are surprised to find measurements that meet acceptability and repeatability criteria are now being called unacceptable because the FIVC that followed the forced exhalation showed the forced exhalation started too early.

Perhaps doubting that a new standard that assigns an unacceptable rating to a spirometry measurement that meets all previous standards for acceptability and repeatability. Some chose to satisfy the new standard by modifying the technique for measuring the FIVC. Rather than instruct and coach the patient to inhale the FIVC as rapidly as possible, some have instructed the patient to inhale slowly and coached them to stop the inhalation when the real-time flow-volume curve showed the inspired volume approaching the lung volume the forced exhalation started from. Others manually terminate the collection of the FIVC, also trying for a match of FVC and FIVC. Examples of these are shown below.

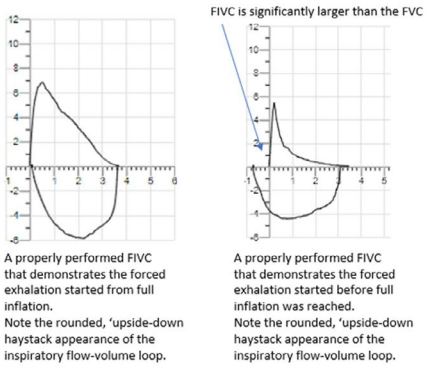

Figure 2. Using the FIVC after the forced exhalation to confirm full inflation.

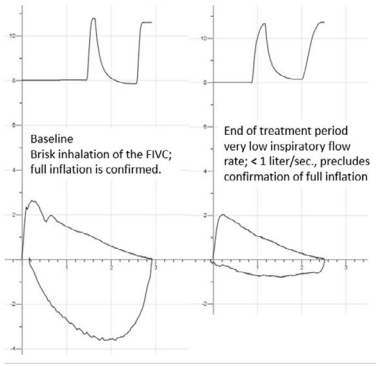

Figure 3. The FIVC must be inhaled as rapidly as possible. Slow inspiration is not acceptable. Operators can easily give the command to stop the inspiration when the FIVC matches the starting volume of the forced exhalation on the flow-volume loop

All operators should compare their technique with the guidance given in the 2019 ATS/ERS standards. It is likely that when you begin to incorporate simultaneous feedback from the patient and the volume-time tracing, you may experience an increase in the number of BEV, or hesitant start, errors. With practice though, you will develop a sense of timing that integrates the feedback from the patient and the spirometer and results in perfect timing of when to give the command to BLOW. You may be tempted to revert to your old method of coaching and failing to adopt the new practice of coaching a proper FIVC at the end of the forced

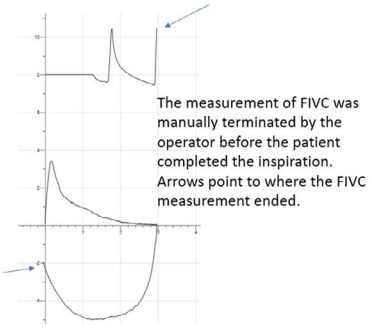

Figure 4. Unacceptable manual termination the FIVC measurement

exhalation. If you do, you will be perpetuating a spirometry quality problem that can cause variability of spirometry results that provide misleading information to the doctor treating the patient.

Spirometry in clinical trials

Clinical trials offer a unique view of spirometry quality. Clinical trials often utilize sites across the globe. Large numbers of measurements from a variety of sites contribute to the clinical trial spirometry data. From the trial's sponsor's point of view, there is a dynamic tension between recruiting as many sites and patients as possible to achieve the critical number of patients estimated to accurately determine the drug effect and maintaining high data quality. When the 2019 ATS/ERS Spirometry standards were published, there was a reluctance among spirometry operators at clinical sites to embrace a new standard that would possibly result in more measurements being rate Unacceptable for inclusion in the study.

An analysis of an ongoing asthma study that utilized strict adherence to the 2019 guidelines saw a dramatic improvement in the variability of the FEV1.[8] When compared to a comparable asthma study utilizing ATS/ERS 2005 guidelines that did not require verification of full inflation, the benefits were striking. The variability of FEV1 in two baseline spirometry measurements done 30 minutes apart fell from 83mL to 49mL, a reduction of 41%. The coefficient of variability of the FEV1 on therapy fell from 8.3% to 4.6%, a 46% reduction. The number of patients showing a FEV1 coefficient of variability exceeding 15% fell by 89%. Establishing a more precise baseline and reducing spirometry variability associated with measurement technique both aid in a more accurate characterization of the treatment effect. In that study, 12.8% of the measurements that met the ATS/ERS acceptability and repeatability criteria, failed the full inflation standard. 54% of the operators from 48% of the sites contributed at least one measurements that showed significant SIE.

Some sponsors demanded that the requirement to demonstrate full inflation as an acceptability criterion be loosened, concerned that study recruitment and data points would be in jeopardy if the new standard were strictly enforced. Some sponsors allowed measurements with no adequate or absent FIVC to be allowed if the repeatability of the largest FVC was demonstrated. The result was that these studies saw the same level of FEV1 variability that was seen in studies that utilized the ATS/ERS 2005 guidelines.

In three asthma studies utilizing the 2019 guidelines we found that SIE was common.[9] In these 3 asthma studies, 13.2% of all measurements meeting FEV1 and FVC acceptability and

repeatability criteria demonstrated the forced exhalation started before full inflation was reached. 69% of the operators from 81% of the sites submitted at least one measurement that met ATS/ERS acceptability and repeatability criteria but started at a lung volume below full inflation. In these studies, the forced exhalation started, on average, 0.270L ± 0.151L before full inflation. This amount can be larger than the expected treatment effect in most clinical trials for asthma medications. In each of the three asthma studies the maximum volume below full inflation that a measurement started from was more than a liter below full inflation. Small numbers of measurements with such large measurement errors can undermine a clinical trial by canceling out the effect of many accurate measurements.

The impact of SIE in clinical trials is variable and highly dependent on when the measurement occurs. Remembering that SIE always underestimates lung function, it can result in an inappropriately low baseline value. If this occurs in the treatment group, it can overestimate the treatment effect but if it occurs in the placebo group, it can result in raising the bar the treatment group must pass to show the drug is effective. If the measurement with SIE occurs in during the treatment period, it can underestimate the drug effect in the treatment group. It is safe to say that it is necessary to avoid SIE in clinical trials.

We examined the impact of incorporating the FIVC maneuver on the total number of efforts required to achieve an acceptable measurement[10] and found that there appeared to be a learning curve for both operators and patients, in terms of the number of efforts and the time required for the measurement session that diminished after the third measurement session. More work is required to determine if this effect diminishes as the use of the ATS/ERS 2019 standards becomes more commonplace.

Summary

Submaximal inhalation error is an underappreciated spirometry error—in terms of both frequency and magnitude. The impact of SIE in clinical trials and clinical medicine can be large. Clinicians use spirometry for diagnostic and treatment decisions and need accurate data, free from preventable technical issues. We want to increase the awareness of this problem and present a simple solution—spirometry operators should evaluate their technique in the light of the guidance give in the 2019 ATS/ERS Spirometry Standards and modify and practice their technique to collect the highest quality data possible. You should adopt the proper measurement of the FIVC and evaluate full inflation after each effort.

Remember this: if they don't breathe it in, they can't blow it out.

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OLE Therapy Moves to a New Level of Performance at Oklahoma Heart Hospital With the Volara System

Oklahoma Heart Hospital, the first dedicated heart hospital in Oklahoma, is on a mission to provide the greatest possible care. And as the first all digital heart hospital in the nation,[1] they understand how to evaluate and incorporate new tech no logy to deliver on that mission. The hospital's locations specialize in cardiovascular and pulmonary care, treating a variety of post operative thoracic surgery patients in the ICU and interventional units.

Overview

The hospital used the **MetaNeb** System to provide Oscillation and Lung Expansion (OLE) therapy since 2014. As those units began to reach end of service, leadership realized they had to explore other options. Their Baxter representative introduced them to the **Volara** System, the next generation to deliver OLE therapy.

"We had a great clinical evaluation period where we were able to look at some clinical results and get some good feedback from our therapists on the machine and the interface," says Justin Rowley, Respiratory Therapy Manager at Oklahoma Heart Hospital. "Being able to show the outcomes and the great versatility was key in being able to get the approval to move to the **Volara** System."

The Transition

"Transitioning to a new system is no easy task. It was a breath of fresh air at the time, in the middle of COVID," Justin says. "This is a big interface to bring into a respiratory department for what it can do and what it could replace. That requires a lot of work and qualifications to support that this is the direction we want to go. Working through those processes, having our Baxter representative there who worked closely with our biomed manager, and getting more units in here when we made the decision to move was critical."

The Performance

Moving to the **Volara** System opened up better ways for Justin and his team to deliver the therapy their patients needed. The **Volara** System has several attributes that help Justin's team treat patients, such as:

- the digital interface on the electromechanical **Volara** System versus the pneumatic MetaNeb System, and
- the ability to select manual or automatic modes to deliver precise pressure

Provided by Baxter.

HIGHLIGHTS

Facility
Oklahoma Heart Hospital Oklahoma City, OK

Profile
- 141-bed heart hospital on two campuses
- 60+ clinics statewide

Partner
Justin Rowley, Respiratory Therapy Manager

Reported Impact
- Expanded clinical treatment options
- Provided versatility to treat specific patient needs
- Helped reduce time on ventilator and ICU length of stay
- Utilization of myVolara App

Customizable Care

"It's been very beneficial for our therapists to use the manual mode and adjust to the patient, giving more or less pressure as clinically indicated," says Justin. "And the automatic mode gives physicians the ability to provide a standardized treatment for a specific patient population. It's customizable, so you can go in and make a custom care plan, identifiable by room number or patient name."

"As a heart hospital, we see some patients with heart and valve anomalies, or younger patients in that population that sometimes may require more pressure," he says. "Being able to go into the clinical menu and make that happen is a big improvement from the **MetaNeb** System."

Versatility

With its versatility and portability, the **Volara** System is helping the team deliver therapy where it's needed. "The nice versatility of the machine is it can go anywhere in the hospital," says Justin, "although our primary use and protocols are in the ICU and

It frees up the clinician to focus more on the patient. You're not focusing so much on the operation of the machine. That's a huge advantage to the patient and therefore, the outcome. You have adjustability and versatility in giving the patient what they actually need to have the desired outcome.
–Justin Rowley
Respiratory Therapy Manager

interventional step-down units. We have larger suites or rooms in our ICU, so sometimes the patient is sitting by the window, or they're in a recliner away from the bed. We can still provide that treatment anywhere in the room."

One example of how the **Volara** System is helping the team deliver therapy is in the ICU, where postoperative patients recover on a ventilator. Justin says, "We see a lot of lobular-specific atelectasis due to manual compression of the lung or patients having thick, retained secretions from being in surgery with dry anesthesia gases in their airways for three hours. Those secretions are sticky and hard to move and it plugs off the lung."

"We use either medication or normal saline in the nebulizer and are able to get those secretions moving with hyperinflation and oscillations," he says. "Within two or three treatments, we're seeing significant chest X-ray improvements off the ventilator. That's now a standard course for many of our postoperative heart patients. Before, we weren't able to get really deep into the airways to actively engage those secretions. Adding that modality with the **Volara** System has been a valuable addition to our immediate postoperative phase for lung function."

Accessible Information

Another way the **Volara** System is helping therapists treat patients is by providing easy access to the information they need. "With the **Volara** System, you get a summary about the treatment, an average of your pressures, a total time for all modalities—CPEP, CHFO and your nebulizer. Having that information that the **Volara** System provides is a vast improvement over the **MetaNeb** System as far as pressure delivery."

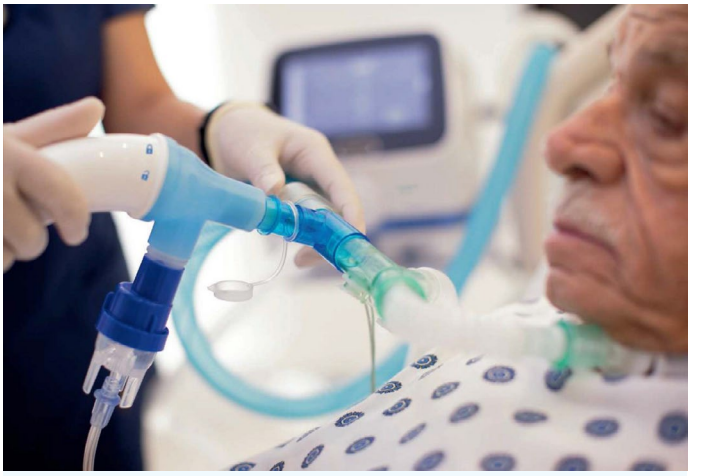
Ultimately, for Justin and Oklahoma Heart Hospital, transitioning to the **Volara** System came down to two main considerations:

Patient outcomes

"The most important consideration is the outcomes we saw on patients treated with the **Volara** System," he says. "Going through a good clinical evaluation and being able to see the results—that"s confirmation it"s benefitting the patient."

Ease of use

Close behind that is the ease of use for the respiratory therapists. "When you have staff that are confident and comfortable using an interface, that alone is going to provide a better therapy to the patient," he says. "They're going to be more focused on the patient and what is going on clinically—the pressures and vital signs—instead of just operating the machine."



We've had top patient satisfaction awards for 20 years, and it's because we like to offer the best of what's out there to our patients.
–Justin Rowley, Respiratory Therapy Manager

Technology That Works For People

Any well-designed tool or technology is developed to allow people to do what they do best. In a hospital, that's to make it easier for clinicians to provide the best therapy and care for patients. At Oklahoma Heart Hospital, the **Volara** System helping the respiratory team to deliver on their mission.

For more information, contact your Baxter Sales Representative, call us 1-800-426-4224 or email us at cfs_customer _service@baxter.com.

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Case Study Looks at Home Monitoring of Lung Mechanics by Oscillometry Amid COVID-19

Chris Campbell

Home isn't just where the heart it — it's also where healing sometimes needs to take place. COVID-19 sort of brought that message home, so to speak, because at different times during the pandemic people have had limited access to in-person medical care. For example, many health-care facilities were shut down due to severe COVID-19 outbreaks as the condition spread like wildfire between patients and staff. Some patients actually prefer to be healing at home as opposed to a hospital — the problem, of course, is ensuring they are receiving proper care.

That's where home monitoring through the latest advances in technology comes in. A new case study looks at home monitoring of lung function for a patients struggling due to COVID-19 allowed for some "unique" evaluation opportunities.

The case study was conducted by Veneroni C, Perissin R, Di Marco F, et al., entitled Home monitoring of lung mechanics by oscillometry before, during and after severe COVID-19 disease: a case study. The study was approved by the ethics committee of Politecnico di Milano University.

In a letter about the study written by Chiara Veneroni, who designed the project, the goal was to study the benefits of home monitoring amid the "overload" of the health-care system due to COVID-19.

"Together with variables related to COVID-19 infection,[1] home-based lung imaging[2] and lung mechanics[3,4] were used to monitor COVID-19 and chronic respiratory patients during limited access to traditional care," the study author wrote. "Home-monitoring respiratory-specific variables may provide important information about patient health status and clinical course."

The letter also said that the home monitoring of patients with respiratory comorbidities need to be studied due to COVID-19's long-term impact on lung function.

"Spirometry was successfully used at home during the pandemic;[4] however, testing requires guidance, is difficult in naïve patients, prone to erroneous results[5] and may release contaminated aerosols. Oscillometry allows noninvasive monitoring of respiratory resistance (mainly reflecting airway resistance) and reactance (primarily related to peripheral airway and lung volume recruitment/derecruitment) during spontaneous breathing.[6] Moreover, oscillometry is suitable for home-monitoring and provides accurate results and high patient adherence."[7]

The Case Study

Veneroni outlined in the letter how oscillometry measurements were documented over a one-year period for a patient at the start, during and amid the recovery period for COVID-19.

The items that made this clinical case interesting and unique to the international scientific community is that the patient is a professional in respiratory medicine who had the chance to have an Oscillometer (Resmon Pro Full) available at home.

He had been lecturing from home during the COVID lockdown period, collecting FOT measurements and, after contracting COVID, continued the weekly testing DURING and AFTER, along with other respiratory parameters.

What makes the clinical study unique and interesting is that the FOT results were available for about 6 months months before the onset of Covid-19, and were added to the study to complete the 12 months monitoring.

The patient chosen for the study was 59 years old, Caucasian and male. The patient had a history of being a heavy smoker up until the year 2005, and takes medication (metformin) for type-2 diabetes. By all accounts, the patient exercised and led a "normal" life.

"As he is a clinical and commercial expert in the field of lung physiopathology, his diffusing capacity of the lungs for carbon monoxide (DLCO), spirometry (forced expiratory volume in 1 s (FEV1) 102% predicted; forced vital capacity (FVC) 108% pred; FEV1/FVC ratio 94% pred), oscillometry (figure 1) and lung volumes (vital capacity (VC) 108% pred; inspiratory capacity (IC) 103% pred) measurements for months before the onset of COVID-19 were available," said the letter about the case study.

The patient was diagnosed with COVID-19 in October 2020 and by November, "demonstrated diffuse bilateral B-lines compatible with COVID-19 interstitial pneumonia," said the letter about the study. "The disease severity was 'severe' per World Health Organization classification. However, the patient was apprehensive about attending a busy hospital and opted for home-treatment, including oxygen by portable concentrator (up to 2–3 L·min−1 for 24/24 h), azithromycin and low-molecular-weight heparin."

Chris Campbell is the Senior Editor of Respiratory Therapy.

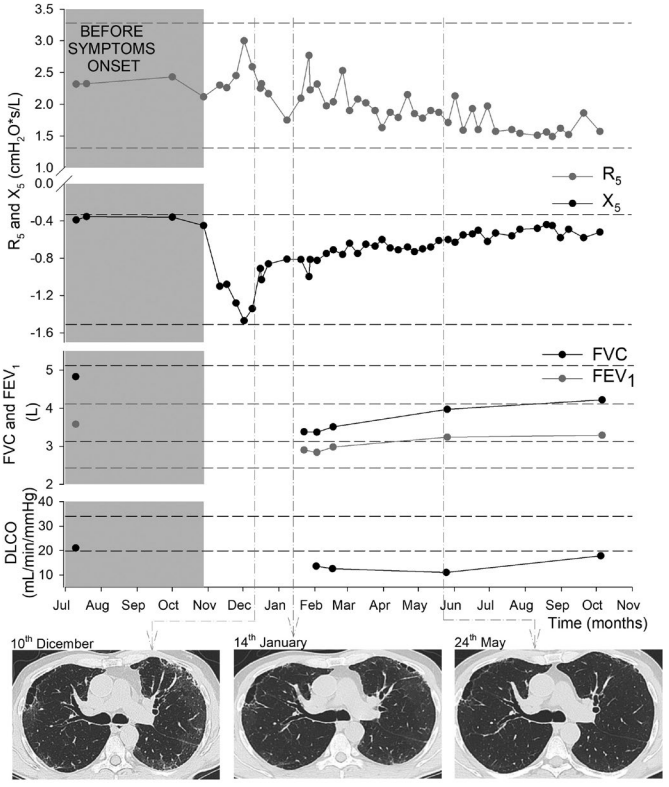

Figure 1. Respiratory resistance (R_5), respiratory resistance (X_5), forced vital capacity (FVC), forced expired volume in 1 s (FEV_1) and diffusing capacity of the lungs for carbon monoxide (D_{LCO}) data over 15 months. Spirometry and D_{LCO} data were not recorded during the acute phase of the disease. Upper (ULN) and lower limits of normality (LLN) are reported. b) Images from computed tomography scans.

The study detailed how the patient did weekly oscillometry tests and then in December a "chest computed tomography (CT) scan demonstrated bilateral paraseptal emphysematous lesions (most likely pre-existing and due to prolonged exposure to cigarette smoke) and bilateral diffuse ground-glass opacities," said the case study letter.

The patient received various treatments and medications based on these results and subsequent measurements over the course of the year the case study looked at.

The Findings

The case study letter described the "unique" evaluation opportunities of home monitoring.

"Our results show that home longitudinal monitoring of lung function by oscillometry allowed a unique evaluation of the mechanical properties of the lung before, during and after COVID-19 interstitial pneumonia, including the long recovery phase. Despite not exceeding the lower limit of normality, X5 decreased >400% from baseline values. The wide range of normality provided by existing oscillometry reference equations, together with fast improvement after commencement of steroid treatment, may explain the normal X5 values found in several severe COVID-19 patients.[9] Spirometry results were also within the range of normality, despite being worse than pre-COVID values. These data underline that alterations in lung mechanics are difficult to detect when only considering the lower limit of normality. Conversely, monitoring longitudinal changes may provide a more sensitive tool for evaluating disease evolution and the impact of treatments. Oscillometry can facilitate longitudinal monitoring, as it allows measurements in dyspnoeic patients and when spirometry is difficult or not indicated (any forced or maximal manoeuvre during the acute pathology)."

The case study letter also described how the studying the home monitoring results made it easier to track changes in the patients.

"Measurements were performed in standardised conditions and with the same set-up. However, changes in the patient's breathing patterns may have influenced oscillometry parameters. Additionally, the clinical care that the patient agreed to did not follow standardised protocols, as he refused hospitalisation and steroid administration was delayed. Finally, because of the observational design of the study, causality could not be inferred. Despite these limitations, our study shows that longitudinal assessment of respiratory mechanics by oscillometry at home allowed changes in lung function to be tracked in a patient with severe interstitial COVID-19 pneumonia when limited monitoring data were available."

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The Utilization of Venous-Venous Extracorporeal Membrane Oxygenator as a Recuse Therapy in Refractory Asthma

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

Introduction

A of 2022, approximately 262 million people worldwide were affected by asthma and approximately 461,000 people died from the disease. Mortality due to bronchial asthma has gradually declined since the introduction of inhaled corticosteroids in the late 1980s, but it has plateaued since 2006.[1] Refractory status asthmaticus is defined as asthma that is intractable to conventional therapies. It accounts for a mortality rate of 1.5 per 100,000 patients diagnosed with bronchial asthma.[2] Patients suffering from asthma exacerbation may present with an array of signs and symptoms. Dyspnea, chest tightness, cough and wheezing are common symptoms, but there is broad heterogeneity in the presentation of asthmatic patients. The features that characterize acute severe asthma are agitation, drowsiness or signs of confusion, significant breathlessness at rest, with the patient talking in words, not sentences, tachypnea of more than 30 breaths per minute, increased work of breathing noted using accessory respiratory muscles, tachycardia of >120 beats per minute, and pulsus paradoxus.[3] Chest radiographs often reveal hyper-inflation, air-bronchograms and a flattened diaphragm.[4] Arterial blood gas results often show a slight respiratory acidosis and in severe cases a pH <7.20. Typically, hypoxemia in not an issue in the common asthma attack, however in the refractory attack there is ventilation perfusion mismatching leading to mild to moderate hypoxemia.[4]

Conventional Management

The pharmacological therapy of acute severe asthma should consist of a short acting beta agonist, ipratropium bromide, systemic corticosteroids and supplemental oxygen therapy, high dose inhaled corticosteroids, and β_2 adrenergic receptor agonists such as epinephrine or terbutaline.[5] Continuous beta agonist therapy should be instituted and administered for a minimum of twenty fours or until unwanted side effects occur. Methylxanthines and leukotriene modulators may also be considered despite limited evidence for their efficacy.[6] A mixture of helium (70-80%) and oxygen (20-30%) can be used for severe asthma exacerbations that are unresponsive to standard therapy or in patients with an upper airway obstruction component in patients who do not exhibit moderate to severe hypoxemia. Heliox mixtures less than 70% are not effective in reducing airway flow turbulence.[7] A trial of non-invasive ventilation or high flow oxygen may be beneficial for a low-risk intubation in the group of patients unresponsive to medical therapy. Intubation and invasive mechanical ventilation are indicated if the respiratory failure is progressing and is unlikely to be reversed by addition pharmacological therapy. Venous-venous extracorporeal membrane oxygenation (V-V ECMO) should be considered in patients who remain severely acidotic and hypercapnic, require high airway pressure via the ventilator, and have moderate to severe hypoxemia despite conventional therapy.[8]

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Ventilator Management

Ventilator management of asthma is directed at improving gas exchange without contributing to air trapping and causing ventilator-induced trauma. A low tidal volume, low rate and an extended expiratory time is set. Airway pressure target goals are to maintain an alveolar distending pressure <30 cm/H_2O and a driving pressure <15 cm/H_2O. Measurements of auto-peep, airway resistance, and assessment of ventilator waveforms should be performed at each ventilator assessment and post therapeutic interventions. The utilization of an esophageal balloon for transpulmonary monitoring or performing a slow flow pressure volume tool should be considered to determine optimal PEEP for airway stenting and accurate driving pressures in a high resistance airway disease. Permissive hypercapnia should be attempted to reduce the need for a high minute ventilation delivery that can be injurious to the lung. When these mechanical ventilation goals cannot be achieved secondary to high driving pressure required and the inability to remove CO_2 and provide adequate oxygenation saturation then V-V ECMO is indicated.[9]

Veno-venous (VV) ECMO

VV ECMO is used for patients requiring respiratory support only, where cardiac function is adequate. Blood is drained from the superior vena cava via an internal jugular venous cannula or inferior vena cava via a femoral venous cannula. The blood is pumped to an oxygenator and carbon dioxide is swept off via a liter flow back into the venous system via a femoral venous cannula. A double-lumen cannula, inserted in the internal jugular vein, can be used for venous drainage and return. VV ECMO can provide full or partial extracorporeal pulmonary support with blood flow up to 6 L/min. ECMO, however, is not without its adverse effects. While V-V ECMO has been associated with successful outcomes, it is not without risks. The most common risks that may occur with ECMO include bleeding, blood clotting disorder, infection, limb ischemia, seizures, and CVA.[10]

Table 1. V-V ECMO Asthma Population

Patient #	Age/G	/E	Vent Mode/settings	V-V ECMO LOS	ECMO settings	Ext time from decannulation	Heliox
1	51/M		PCMV 4 cc/kg	7	100/ 5 lpm	120 hrs	Y
2	28/M		CMV 4 cc/kg	8	100/9 lpm	70 hrs	Y
3	49/M		PCMV 5 cc/kg	5	100/4.5 lpm	42 hrs	Y
4	31/F	E	CMV 5 cc/kg	15	80/3 lpm	NA	Y
5	18/M		CMV 4 cc/kg	8	80/4 lpm	209 hrs	Y
6	31/F		PCMV 4 cc/kg/IBW	9	100/1.5 lpm	42 hrs	Y
7	57/F		CMV 5 cc/kg/IBW	8	100/1 lpm	250 hrs	Y
8	42/F		PCMV 6 cc/kg/IBW	7	70%/2 lpm	72 hrs	Y

Denotes:
All received continuous Proventil
Heliox administration >70%
PEEP settings were guided by transpulmonary E -2 to 2 cm
PEEP range 8-16 cm
Patient 4 and 5 developed barotrauma prior to cannulation
Patient 7 required tracheostomy

V-V ECMO has been historically utilized in patient populations associated with refractory hypoxemia, air leaks, and organ transplantation. In the literature, V-V ECMO providing full blood oxygenation, CO2 elimination and combined with lung protective ventilation has benefited from major technological advances in the last two decades. In 2009, favorable outcomes were reported in patients who received ECMO during the influenza A (H1N1) pandemic.[11] The Conventional Ventilator Support vs Extracorporeal Membrane Oxygenation for Severe Acute Respiratory Failure (CESAR) trial showed that transfer to an ECMO center was associated with fewer deaths or severe disabilities at 6 months compared with conventional mechanical ventilation (37% vs 53%; p 0 = 0.03), although 6 month mortality was not significantly reduced (37% vs 45%; p = 0.07).[12] The more recent ECMO to Rescue Lung Injury in Severe ARDS (EOLIA) trial showed a non-statistically significant reduction in 60-day mortality with ECMO (35% vs 46%; p = 0.09).[13] More recently during the COVID-19 pandemic early and effective ECMO intervention in critical ill COVID-19 patients might be a valuable strategy in critical care settings to increase their odds of survival.[14] Based this robust evidence of V-V ECMO improving gas exchange, while minimizing ventilator induced injury by the utilization of resting parameters, make this an attractive strategy for refractory asthma management.

V-V ECMO and Ventilator Management

ECMO should be considered as a prompt treatment in patients with status asthmaticus whose gas exchange cannot be satisfactorily maintained by conventional therapy for providing adequate gas change and preventing lung injury from the ventilation.

Typically, the ventilator and clinical criteria to consider implementing ECMO in the asthma patient population is the following:

- $PaCO_2$ >90 torr with a pH <7.20
- PaO_2 <60 torr with a FIO_2 >70% (Heliox not an option based on high FIO_2)
- An alveolar distending pressure <30 cm/H_2O and a driving pressure <15 cm/H_2O
- Refractory to conventional management: Continuous beta-agonist therapy, Heliox via the ventilator, paralytic administration, and other adjunct therapies
- Hemodynamic instability
- Ventilator induced trauma denoted by a pneumothorax or pneumomediastinum

When the patient meets this criterion, they should be assessed for ECMO cannulation to improve the chance of survival and minimize ventilator induced injury. If ECMO is not available at the current setting the patient is hospitalized at, rapid transfer to an ECMO center should be considered.

Once ECMO is employed the patient should be placed on rest ventilator settings. ECMO CO_2 removal should be done over a few hours to prevent a rapid shift in acid-base status. To rapid CO_2 removal could result in hemodynamic and cerebral instability.[15] Recommended rest ventilator settings are pressure control mode (PCV) with a driving pressure of 10 cm/H_2O, PEEP 10-14 cm/H_2O, rate 10 bpm, and an I/E ratio 1:4, with a FIO_2 25-30%. This low FIO_2 administration allows ventilation with Heliox administration at a therapeutic level of 70% or greater. Oxygenation and ventilation targets are regulated by the ECMO oxygenator and sweep gas flow. Target acid-base balance is to maintain a pH >7.30 and a SpO_2 >88%. Conventional asthma clinical management should be continued including continuous beta-agonist therapy, good pulmonary hygiene, and appropriate sedation. Ventilator waveform assessment should be focused on the recognition of improving or deteriorating pulmonary mechanics, especially airway resistance and auto-peep values. Prudent hemodynamic monitoring is critical to recognize tachycardia or dysrhythmias from high doses of beta-agonist delivery. Routine nursing and general care should be continued during ECMO to reduce pressure injures, secondary infections, delirium, and increased muscle weakness.

Case Study Review

From January 1 2021 to November 2023 timeframe, we placed eight status asthmaticus patients with refractory gas exchange on V-V ECMO. Seven of the eight patients were management on V-V ECMO until the patient's asthma exacerbation was controlled and progressed to both ECMO and ventilator liberation.
One patient expired secondary to multi-system organ failure unrelated to asthma.

All asthmatic patients receive mechanical ventilation via pressure or volume target modes to achieve an exhaled tidal volume between 4-5 cc/kg/IBW and PEEP was set via either

a pressure/volume tool or via transpulmonary monitoring. V-V ECMO parameters we set to achieve a SpO_2 >88% and a pH >7.25. There were no additional occurrences of additional VILI post ECMO intervention. And all patients receive pharmacological paralytics, Heliox, and continuous beta-agonist therapy for the first forty hours of mechanical ventilation and ECMO support (Table 1).

Conclusion

Fortunately, only a small percentage of asthma exacerbations escalate to a refractory status. However, these events can be life threatening and increase the chance of asthma morbidity. V-V ECMO provides a rescue intervention that can provide life-saving support until the patient is clinical stable and airway spasm controlled. It also reduces the risk of additional airway or lung parenchyma damage that can occur via traditional mechanical ventilation strategies.

Based on our clinical experiences V-V ECMO along with lung protective ventilation can provide a safe management of the status asthmaticus with refractory gas exchange. It should be part of any treatment arsenal that cares for the severe asthmatic patient population.

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The Benefits of Using NAVA-PAP in Premature Neonates With Apnea of Prematurity

Chris Campbell

Effectively managing apnea of prematurity can be a challenge for clinicians especially when treating the smallest of these patients. When less invasive therapeutic options fail to provide adequate support, intubation and mechanical ventilation is their only option. Avoiding intubation in these patients is challenging.

According to a recent study out of two US hospitals, these neonates "clinically deteriorate because continuous positive airway pressure (CPAP) provides inadequate support during apnea."

And so the study authors conducted a prospective, two-center, observational study of preterm neonates using neurally adjusted ventilatory assist (NAVA) which, according to the authors, "provides proportional ventilator support from the electrical activity of the diaphragm. When the NAVA level is 0 cmH_2O/mcV (NAVA-PAP), patients receive CPAP when breathing and backup ventilation when apneic. This study evaluates NAVA-PAP and time spent in backup ventilation."

The study ended up concluding that the neonates suppported with NAVA-PAP exhibited fewer CSEs PAP and spent little time on backup ventilation.

The study authors, Alison Protain, Kimberly Firestone, Saima Hussain and Daniel Lubarsky, looked at preterm patients admitted to the NICUs of ProMedica Ebeid Children's Hospital and Akron Children's Hospital during the period between August 2019 and February 2020.

In all, 28 patients were studied and the gestational age was 25 ± 1.8 weeks and a study age of 28 ± 23 days. "The number of CSEs was 4 ± 4.39/24 h. The patients were on NAVA-PAP for approximately 90%/min, switched to backup mode 2.5 ± 1.1 times/min, and spent 10.6 ± 7.2% in backup," the authors wrote.

The study said that premature neonates are "vulnerable" to the impacts of AOP, with consequences including bradycardia and desaturation[1]—something dangerous for such "fragile" patients.

"Caffeine citrate and continuous positive airway pressure (CPAP) are commonly used therapeutic modalities that demonstrate significant benefits,[2-4]" the authors wrote in their study, entitled Evaluation of NAVA-PAP in premature neonates with apnea of prematurity: minimal backup ventilation and clinically significant events. "Unfortunately, increasing respiratory support may be required for the smallest and most fragile premature neonates. Non-invasive respiratory strategies have shown promise, with synchronization of nasal ventilation showing further improvement for respiratory stability,[5] although intubation and mechanical ventilation may be needed for severe apnea.[2,3,6]

The Benefits of NAVA-PAP

NAVA-PAP, according to the study authors, is a sort of next line of defence for such tiny patients struggling to breathe.

"Neurally adjusted ventilatory assist (NAVA) provides support in synchrony with the respiratory efforts of a patient based on the detected electrical activity of the diaphragm (Edi)," the authors wrote. "It is delivered with the Servo-I/U/N ventilator (Getinge, Sweden) using NAVA software. The NAVA level is a proportionality factor that converts the Edi signal into a pressure above the positive end-expiratory pressure (PEEP) supporting each spontaneous breath. If no Edi signal is detected for a predetermined amount of time (apnea time), the ventilator switches into pressure control ventilation until the patient breathes spontaneously again, which provides a minimum rate."[7]

Data was downloaded after 24 hours and the CSEs were documented. There was also a paired t-test used to analyze the data. In all, more than 40,000 data points were collected from the 28 patients.

In the discussion part of the study, the authors said a priority is reducing the need for intubation through the application of non-invasive ventilation strategies.[8]

The authors said CPAP is still the "gold standard" but there are some preterm neonates who will "require increased respiratory support.[6,9,10]

"Non-invasive respiratory support subsequently evolved with options such as nasal intermittent positive pressure ventilation (NIPPV) to augment lung inflation and respiratory muscle unloading.[11] The flow-triggered synchronized mode of NIPPV was also found to have beneficial effects on reducing apnea and desaturations compared with CPAP and NIPPV,"[12] the authors wrote.

NAVA stands out for its benefits, the authors said.

Chris Campbell is the Senior Editor of Respiratory Therapy.

"NAVA, a novel mode of ventilation, changed the paradigm by providing synchronized ventilation in which the patient controls both timing and degree of ventilatory assistance. Several studies have demonstrated decreased PIPs, oxygen requirement, and apnea in preterm neonates receiving NAVA ventilation compared with those receiving traditional synchronized intermittent mechanical ventilation (SIMV) and pressure control ventilation."[13-16]

"NAVA-PAP is the only non-invasive mode that delivers CPAP while breathing and backup ventilation when the patient is apneic," the authors added. "Utilizing NAVA-PAP as a strategy in neonates with AOP while on CPAP was recently studied and demonstrated significant benefits in reducing CSEs.[1] This approach offers the advantage of reducing CSEs while minimizing exposure to non-invasive ventilation."

The study concluded by saying that the data show a dramatic reduction in the time spent on backup ventilation.

"Compared with CPAP, some data suggest that NIV NAVA in neonates may reduce the need for intubation, facilitate early extubation, and decrease extubation failures.[17-19] NIV NAVA has also been shown to decrease the number of CSEs compared with non-synchronous, non-invasive ventilation,[20]" the authors wrote. "NAVA-PAP is the only non-invasive mode that delivers CPAP while breathing and backup ventilation when the patient is apneic."

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Dispelling Misconceptions: Improving Use of the Passy Muir Valve In-line With Mechanical Ventilation

Rachel O'Hare, RRT

The Passy Muir Tracheostomy & Ventilator Swallowing and Speaking Valve (PMV) was developed by a patient for patients for use in-line with mechanical ventilation. Several decades ago, David Muir became ventilator-dependent with his tracheostomy tube. As a young man, he became frustrated with his difficulty communicating with those around him. So, he used his engineering background to develop the speaking valve. Since then, a lot of research has occurred with the Valve, and it has been shown to provide a means of effective communication both on and off mechanical ventilation. To further the understanding of how and why to use a Valve in-line with mechanical ventilation, this overview discusses common misconceptions and introduces considerations for addressing them.

Most Common Misconception: The Valve Cannot be Used In-line with Mechanical Ventilation

The PMV is the only speaking valve that can be used in-line with mechanical ventilation. This is due to the patented biasclosed, no-leak design. As a one-way, bias-closed valve, the resting position of the diaphragm on the PMV is closed. When the patient inhales through the PMV, the diaphragm opens allowing airflow to pass through the Valve, then when inhalation is complete, the diaphragm automatically returns to the resting closed state, without the expiratory effort of the patient. The diaphragm remains closed throughout exhalation preventing airflow leaking back through the tracheostomy tube. This no-leak design, allows the PMV to be used in-line with mechanical ventilation without interfering with flow from the ventilator and ensuring all of the patient's volume is exhaled through the upper airway, providing full breath support to assist with various functions such as speech, cough, throat clear, swallowing, and more.

Research has been conducted for many years which investigated the PMV in-line with mechanical ventilation. This research has shown that the Valve is a safe and effective means of providing access to communication while the patient is receiving mechanical support.[1] Additional benefits shown in the research include improved secretion management, normal pressures associated with swallowing, improved diaphragm mobility, improved lung recruitment, and positive airway pressures.[2-5]

Example of placement for the PMV®007 (Aqua Color™) in-line with the ventilator circuitry.

Additional Common Misconceptions

1) The Valve will not work with the ventilators we use in our facility.

The PMV can be used with positive pressure mechanical ventilation, and since the modern approach to mechanical ventilation is positive pressure, the Valve can be used in-line with any ventilator. When the Valve is in-line, the ventilator delivers the breath; the Valve will open during the inspiratory phase, allowing the flow to pass through, then at the end of the inspiratory phase the Valve will automatically close, redirecting the expiratory volume to the upper airway during exhalation. This means that none of the patient's expiratory volume is returning to the ventilator. Therefore, when the patient is no longer exhaling through the circuit to the ventilator, it becomes essential to manage the ventilator on the expiratory side adjusting alarms and flow as necessary.

2) When the cuff is deflated, I cannot adequately ventilate my patient.

When working with Invasive Ventilation (IV), typically a sealed system is preferred which requires an inflated cuff. A ventilator is a machine that sends variations of flow through a circuit, and

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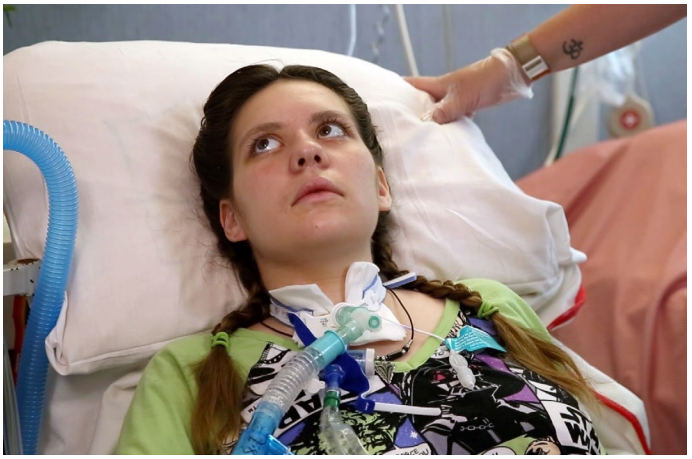
that flow is always going to take the path of least resistance. The primary purpose of the cuff is to seal the system and ensure that all airflow is moving solely through the artificial airway and the ventilator circuit. If we want to direct and control the flow into the lungs, we create a sealed system. Having this sealed system, the ventilator can obtain precise measurements of pressure and volume. To place the Valve in-line, one must deflate the cuff; essentially, introducing a large leak into the ventilatory system, and flow is no longer moving solely through the artificial airway and circuit. However, it is possible to provide adequate ventilation for a patient with the cuff deflated. To do so, one must take into account the leaking system and direct the ventilator to compensate for the leak or at times manually compensate for the leak. Most ventilators are equipped to ventilate with a small leak and will compensate accordingly. However, with a larger leak, it is often necessary to provide compensation by managing the ventilator settings. One option is to place the ventilator into non-invasive mode ventilation (NIV) because the ventilator is more adept at measuring, managing, and compensating for the leak in NIV, and it can often help with alarm management. But when it comes to mechanical ventilation and cuff deflation, consider the following:

1) There are three types of parameters are on a ventilator: set parameters, measured parameters, and calculated parameters. The flow from the ventilator is controlled by the parameters set and these set parameters will be consistently delivered to the patients even when the cuff is deflated. In other words, the ventilator will always do what it is told to do. Therefore, the ventilator will continually provide support to patients regardless of cuff deflation and Valve placement.
2) Pressure is only generated when flow becomes obstructed or there is resistance to it. When the cuff is deflated, there is less resistance to flow. When there is less resistance, there is less pressure which affects the pressure measurements on the vent. Therefore, to compensate for these changes in pressure, the amount of flow the ventilator is using is adjusted.
3) Volume can move around the tracheostomy tube and into the upper airway. Now, the volume the vent is delivering is no longer exclusively moving through the circuit which impacts the volume measurements on the ventilator. To compensate, consider adjusting the amount of volume the ventilator is delivering—primarily, compensating for the leak that has been created with cuff deflation.

3) I cannot place the Valve because my patient is not in a weaning mode of ventilation, and/or they are not ready to be placed in a weaning mode.

The patient does not have to be weaning or weaned from mechanical ventilation to use the Valve. Full ventilatory support with the PMV in-line may be provided as long as the patient is stable on the ventilator. Three conventional modes of mechanical ventilation that work well with the PMV include continuous mandatory ventilation (CMV) or assist control (AC), synchronized intermittent mandatory ventilation (SIMV) or a spontaneous mode such as continuous positive airway pressure (CPAP). However, the mode is not as important as the patient's stability on the ventilator, consider the settings such as positive end-expiratory pressure (PEEP) and fraction of inspired oxygen (FiO_2) as well as measured parameters such as peak inspiratory pressure (PIP). Typically, a PEEP of 10 or less and FiO_2 of 0.50 (50%) or less with a reasonable PIP indicate the patient may be ready for assessment for Valve use.



Using the PMV®007 (Aqua Color™) in-line with mechanical ventilation to communicate with staff.

It is important to consider early intervention and restore more normal function of the aerodigestive system as soon as possible. Early intervention is key and includes the possibility of Valve use as early as 48-72 hours after the tracheotomy or upon physician's order. With early intervention, research has shown earlier communication and reduced negative impacts from psychological effects due to loss of voice.[6] It should be noted that recent research has investigated Valve placement as early as 24 hours after a percutaneous tracheotomy procedure and found no adverse effects.[7]

Research also has shown that placing a PMV in-line with mechanical ventilation facilitates lung recruitment including increasing end-expiratory lung impedance or PEEP and increasing end-expiratory lung volume. The increase in PEEP was sustained for at least 15 minutes after the Valve was removed and with the increased end-expiratory lung volume there was a decrease in end-tidal CO_2 as well as the patients' respiratory rates.[2-4] With improved lung recruitment, patients may maintain stable respiratory function on minimal settings as well as transition to T-piece or trach collar trials earlier.

Summary

The Passy Muir Valve was originally designed to be used in-line with mechanical ventilation and may be used with patients who require full ventilatory support. It also may be placed in-line with any mechanical ventilator, regardless of make or model. Managing the ventilator requires adjusting for the leak that was created by cuff deflation and loss of expiratory volume moving through the upper airway. To help the mechanical ventilator compensate for the leak, it may be necessary to place the vent in a non-invasive mode of ventilation. It is important to restore normal function of the aerodigestive system as early as possible.

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LungFit PH: Transforming iNO Assumptions and Possibilities

Shelly Brown, MBA, RRT-NPS


Shelly Brown, MBA, RRT-NPS

Tell us about your background.
I've spent the last 34 years as a respiratory therapist (RT) in clinical settings that include neonatal, pediatric, and adult populations. My experience with inhaled nitric oxide (iNO) predates a commercialized delivery system and I've had the benefit of using many of the systems currently on the market.

Later in my career, I learned the business side of nitric oxide purchasing as the Director of Respiratory Care for Baptist Health in Arkansas, overseeing the operations and management of respiratory care departments across 10 hospitals. There, I experienced the frustrations of iNO contracting and cost management firsthand.

This background has given me an appreciation for the day-to-day challenges of an RT and a breadth and depth of understanding for the business decisions hospitals are faced with.

You previously worked at Baptist Health in Arkansas as the Director of Respiratory Care, why did you choose Beyond Air and LungFit PH?
When I discovered Beyond Air (at that time AIT Therapeutics) at the AARC meeting in 2018, I was instantly intrigued by their sign, "Ask Me About Tankless Nitric Oxide," and had a brief conversation about their product. At the 2019 AARC meeting, I sought them out to learn more about their ionizing technology and the benefits the Lung Fit PH could bring to the NICU. I was frustrated with the control that cylinder-based systems had on the market and saw (1) the value of being able to generate iNO from room air and (2) the positive impact it would have on operational efficiency and pricing.

In early 2020 I participated in a pilot study with Beyond Air related to nitric oxide therapy for COVID-19 patients using their LungFit PRO system. Seeing and experiencing the ease of delivering nitric oxide using a device that doesn't rely on tanks cemented my appreciation for the technology and company.

In 2022, I joined the Beyond Air team as a Clinical Specialist for their FDA-approved LungFit PH device. The reasons are wide-ranging and include:

The LungFit PH device is safe, easy to use, quick to set up, and completely tankless with no cartridges.

The opportunity to develop a partnership with RT departments, show them I understand the frustrations of their work, and build trust to help them navigate delivery of iNO therapy.

Beyond Air's extensive research for nitric oxide therapeutic use outside of PPHN and the potential for commercialization of other devices in the future.

How is LungFit PH changing the expectations for contracting, operations, and inventory management?
Beyond Air has set out to redefine the iNO experience, from demo to delivery. Currently, hospitals are faced with hidden contracting and operations obstacles, we've worked to create a customer experience that's more transparent.

Our agreements are straight-forward
Respiratory departments don't have to worry about stringent cost control measures; our competitive offering allows the flexibility to deliver therapy without micromanaging budget.

We've eliminated cylinder and cassette supply demands
Respiratory therapists can shift their focus from device management to delivering therapy. Additionally, LungFit PH consumables can easily be stored at the point of care. No bulky cylinder management or inconvenient storage requirements.

How have you seen the industry transform over the past 34 years?
The use of surfactants, new modes of ventilation, and iNO have benefited newborns all over the world. Advances with non-invasive ventilation have also greatly enhanced care in the NICU. It is so rewarding to see how these advancements in neonatal care have benefited these tiny babies as they begin their life journey.

However, while clinical care is advancing, a lot of outdated assumptions exist in our industry about what to expect from your iNO supplier and devices.

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

Assumption 1: iNO is cost prohibitive

iNO is an expensive line item in a hospital's budget. I found many contract structures require estimating an entire year's worth of use, penalize you for exceeding anticipated use, have unanticipated costs, lock you into long-term contracts, and limit competition, including new/advanced technology. It's not transparent and it's not a partnership.

Beyond Air's straight-forward partnership model ensures you have everything you need, without the worries of constant cost management. We're not looking to lock our customers into multi-year agreements that prohibit them from accessing new advances in technology.

Assumption 2: iNO use should be left to Level 3 & 4 NICUs

In instances that a state doesn't regulate what's allowed by NICU level, iNO has been limited to Level 3 & 4 NICUs due to cost, staff proficiency, and the demands of cylinder management. LungFit PH is easy to handle and initiate iNO therapy, so the healthcare teams in smaller NICUs and birthing centers can confidently initiate therapy. This means mom and baby can be kept together.

Assumption 3: A hospital can only contract with one iNO supplier

iNO is one of the few drugs where hospitals are forced to choose just one supplier. That's bad for the healthcare system and bad for the patient. Beyond Air recognizes the value in having the flexibility to use more than one iNO supplier and that technology is always advancing, we won't contractually obligate you to have us as your sole supplier.

Where do you see opportunity to have an impact on an RT's day to day?

Speed to care has so many benefits when managing these fragile lives. LungFit is quick and easy to set up at the bedside, generates and delivers iNO from room air within seconds, and can be stored with all accessories at the point of care.

Storage and handling requirements place a significant burden on RT teams, including monitoring, management, and storage. I worked with one hospital who estimates they dedicate ~2000 hours annually to RT and tech staff time for cylinder management.

LungFit PH is easy to use. The complicated and time-consuming setup process required by cylinder and cassette-based systems has been eliminated.

Where do you see the future of iNO treatment?

I see NICUs that don't currently provide iNO adding it to their treatment protocol so they can treat or initiate treatment prior to transport. This has the added benefit of keeping moms and babies together and, hopefully, avoiding transport.

I also see iNO becoming accessible to patients without significant expense or stress on RT staff. RTs can stop spending so much time managing system use and reallocate it to delivering more care.

What has the response been from customers using the LungFit PH?

I've found the ease of use and the speed to treatment has helped many RTs overcome their anxiety around iNO. This, in turn, has helped them spend more time on patient care rather than device management and setup.

A Vizient Innovative Technology Contract Partner

LungFit® PH | ALL YOU NEED IS AIR™

Unprecedented Speed to Care. No Cylinders, No Cassettes.[1]

- Generate and deliver iNO within seconds[1]
- Unlimited, on-demand iNO regardless of dose or flow[2]
- Simplified contracting and savings

Schedule a demo and say goodbye to iNO cylinders. LungFitPH.com/Speed

INDICATIONS FOR USE

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

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

Reference: 1. Data on file. Beyond Air Inc. 2021. **2.** LungFit PH System Operator's Manual. Garden City, NY: Beyond Air Inc. 2022.

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Beyond Air®

Nellcor™ Pulse Oximetry Performance in Challenging Conditions

Clark R. Baker, BS and Scott McGonigle, MEng

Background

Pulse oximetry noninvasively measures blood oxygenation by estimating the fraction of hemoglobin bound to oxygen in pulsing arterial blood (SpO_2). This parameter primarily reflects oxygen transfer from the lungs to tissues via the blood and provides an early indication of oxygenation issues. Pulse oximetry is quantitative, accurate, continuous, and convenient.[1] Today, pulse oximetry is considered a standard of care and is often relied upon to ensure patient safety.[2,3]

Pulse oximetry performance and reliability is necessary across patients with diverse demographics and challenging physiological conditions and co-morbidities. Common challenging conditions for pulse oximetry include low sensor-site perfusion and motion artifact. Low perfusion is often encountered in patients with sepsis, shock, and other vascular conditions, and motion artifact can occur in a variety of circumstances, ranging from the involuntary movement of a neonate to a hospitalized adult eating lunch.[3-5] These conditions can occur in all care settings (ED, OR, ICU, GCF, L&D, NICU, etc.), and can impact clinical workflow due to difficult sensor placements and nuisance alarms. A pulse oximeter that can accurately measure pulse rate and SpO_2 is necessary in cases in which a patient presents with one or more conditions that make pulse oximetry challenging, both to ensure patient safety and to maintain efficient clinical workflow.

The purpose of this paper is to review key literature examining Nellcor™ pulse oximetry performance in challenging clinical conditions. Key technical features important in challenging clinical conditions include pulse rate accuracy, SpO_2 accuracy, and alarm management.

Low Sensor-Site Perfusion

Patients with low sensor-site perfusion have a smaller pulse amplitude, due to vasoconstriction or hypotension, that can result in artifact and inaccurate readings.[3]

Low sensor-site perfusion is common in patients with peripheral vascular disease, sepsis, hypothermia, or shock, making pulse oximetry more challenging.[3,5] To evaluate pulse oximetry performance during low sensor- site perfusion, both clinical studies and healthy volunteer studies have been performed. While controlled volunteer studies often create low sensor-site perfusion using cold temperatures or partial arterial occlusion, prospective clinical studies have focused on critically ill patients and transport conditions in which low perfusion occurs.

Clark R. Baker and Scott McGonigle are with Research and Development, Patient Monitoring, Medtronic.

Healthy Volunteer Pulse Oximetry Low Perfusion Studies

Oximetry performance during low sensor-site perfusion has also been evaluated in volunteer studies of diverse designs, using reproducible protocols and distinct challenges, such as cold or occlusion, to represent non-ideal pulse oximetry conditions. In this section, we summarize the results of several healthy volunteer pulse oximetry studies.

Study 1

In one prospective study, 18 anesthetized volunteers underwent induced apnea, along with reduced finger perfusion by compressing the axillary artery.[6] Circulatory delay was evaluated using Nellcor™ pulse oximetry monitors connected to Nellcor™ pulse oximetry digit (MAXA) and forehead (MAXFAST) sensors. The forehead is a uniquely robust pulse oximetry site, for which the Nellcor™ MAXFAST pulse oximetry sensor was designed. Because forehead arterial supply also feeds the brain, this site is not susceptible to vasoconstriction.[7] However, because veins in the head lack one-way valves, the forehead may be prone to venous pulsation, particularly if the head is below the heart (Trendelenberg) or the patient condition or surgical procedure impedes venous return.[5] The primary mitigation is proper headband application to provide ample pressure to restrict venous pulsation, with secondary mitigation in the monitor's signal processing that was designed for such conditions.

In their low perfusion study, Sugino et al found that, as hypothesized, axillary compression induced a modest incremental circulatory delay for digit SpO_2 relative to forehead SpO_2 (6.3±4.9 seconds), whereas the response at both sensor sites was essentially equal before axillary compression.[6] Therefore, the forehead sensor demonstrated reduced time to detect the changes caused by induced apnea.

Study 2

In another prospective, healthy volunteer, low perfusion study, Addison et al performed a cold-room (13°C) motion hypoxia study with 12 volunteers of varied skin pigmentation.[8] This study was conducted and sponsored by Medtronic. The study demonstrated excellent pulse rate accuracy versus ECG (1.6 per minute) on the non- motion digits using Nellcor™ pulse oximetry, indicating that during reduced perfusion with no motion, the pulse oximeter is accurate.

Table 1. Response times (seconds) of pulse oximeters during hypoxic challenge in healthy volunteers.

Site and Monitor:	Forehead Nellcor™ MAXFAST	Earlobe Masimo	Finger Mean of 4 vendors	p-value
Normothermia	41±14 sec	60±16 sec	130±44 sec	p<0.001
Hypothermia	40±11 sec	60±36 sec	215±67 sec	p<0.001
Hypothermia + glyceryl trinitrate	22±11 sec	33±14 sec	188±77 sec	p<0.001

Study 3

In contrast to studies using a cold room or axillary artery compression to simulate low perfusion, MacLeod et al used a mild hypothermia model (water mattress 14°C, core temperature 36°C) to induce vasoconstriction.[9] In this prospective study of 10 volunteers, the mean finger circulatory delay was 215 seconds relative to co-oximeter with blood drawn from a radial artery catheter, while head sites demonstrated a fraction of this delay.[9] Out of 6 pulse oximeter sensor types evaluated (forehead, ear, and finger sensors), a statistical test of rank order found that the Nellcor™ MAXFAST sensor ranked first in response time in 28 of the 30 hypoxic challenges, and the four digit sensors showed equivalent digit circulatory delay, confirming that this delay is a function of physiology.[9] Table 1 shows the response times to hypoxic challenge (3 minutes at 11% FiO_2).[9]

Study 4

Although circulatory delay due to low sensor-site perfusion may not be readily apparent, a pulse oximeter cannot monitor a drop in oxygenation at the lungs (e.g. apnea) until blood reaches the sensor site. To evaluate the performance of Nellcor™ pulse oximetry during low perfusion, the data from 12 Medtronic-internal motion hypoxia studies performed with room temperature 13-15°C were retrospectively pooled and analyzed.[10]

Among 369 forehead-digit sensor pairings (114 healthy volunteers), we observed an incremental circulatory delay for non-motion digit SpO_2 relative to forehead SpO_2 of 74±19 seconds. In response to cold, digit pulse signal amplitude varied by over an order of magnitude across the volunteer pool, as well as compared to normothermic studies on different dates (example: 4.18% in normal conditions and 0.11% in cold room). In this retrospective analysis, we found that digits with the smallest pulses had up to a two-minute circulatory delay compared to forehead pulse oximetry.[10]

Study 5

The Nellcor™ MAXFAST forehead sensor provides robust, accurate and timely oximetry monitoring with appropriate headband application. Table 2 shows the results of an 11-volunteer Medtronic-internal room- air study in Trendelenberg position, creating a venous pulsation challenge at the forehead.[11] It shows the bias and posting of the Nellcor™ MAXFAST sensor compared to the mean of four digits with Nellcor™ MAXA sensors. With the headband, the Nellcor™ MAXFAST sensor provided reasonable SpO_2 accuracy for tilts down to 20 degrees. However, without the headband, bias ± precision relative to digits at -20 degrees tilt was 6.40±8.38.[11]

Clinical Pulse Oximetry Low Perfusion Studies

Pulse oximetry performance during low sensor-site perfusion has been evaluated across multiple clinical settings. In this section, we summarize the results of several clinical studies that examined pulse oximetry performance.

Study 1

In a prospective study performed at a large university- affiliated medical center, Schallom et al measured SpO_2 accuracy in 30 critically ill surgical/trauma patients, versus co-oximeter.[5] Table 3 summarizes results for Nellcor™ pulse oximetry with OxiMax™ technology, which found that Nellcor™ pulse oximetry has low mean error and precision, particularly when using the Nellcor™ MAXFAST sensor.

Study 2

In a separate prospective clinical study, 52 patients were evaluated with Nellcor™ and Masimo pulse oximetry monitors, using both sensors on the same hand, with randomized digit selection, during ambulance transport in cold weather (Vienna, Austria, October-November).[12] Twenty patients had blood pressure ≤ 100/60. The incidence of "malfunctions" (no reading) was 0.13 and 0.21 per patient for Nellcor™ and Masimo pulse oximetry, respectively, which was statistically equivalent. Root-mean-square difference (RMSD) between the two oximeters was 1.69% SpO_2 and 4.48 BPM, implying acceptable accuracy and performance for both monitors. Overall, a systematic review of pulse oximetry accuracy in adult patients with low site perfusion at digit and forehead sensor sites concluded that "Oximeters are accurate in poorly perfused patients, especially newer oximeter models."[3]

Study 3

Consider the following case report, which exemplifies the robustness of the forehead site: A coronary artery bypass graft (CABG) surgery was performed in 2002 on a 106 Kg dark-pigmented patient.[13] As seen in Figure 1, the combination of the Nellcor™ MAXFAST sensor and Nellcor™ pulse oximetry with OxiMax™ technology provided the earliest indication that the

Table 2. Bias, precision, and posting of the Nellcor™ MAXFAST sensor in Trendelenberg position with and without a headband.

Patient Position	SpO_2 Bias vs finger	SpO_2 Posting %
0 degrees, with headband	1.09±1.85	100%
-10 degrees, with headband	-0.17±2.30	100%
-15 degrees, with headband	-0.59±3.07	100%
-20 degrees, with headband	-1.28±3.61	100%
-20 degrees, without headband	-6.40±8.38	97%
-20 degrees, re-apply headband	-1.39±3.75	96%
Back to 0 degrees, with headband	0.05±1.85	100%

Table 3. Nellcor™ pulse oximetry performance in critically ill surgical/trauma patients.

Site	Forehead	Digit	Digit
Monitor	Nellcor™	Nellcor™	Philips
Technology	OxiMax™	OxiMax™	OxiMax™
Sensor	MAXFAST	MAXA	MAXA
Measurements	89	89	89
Measurement failures	1 (1%)	6 (7%)	9 (10%)
Mean error ± precision	-1.39±1.28	-2.61±3.61	-3.84±6.91
R^2 versus catheter	0.834	0.433	0.254

patient's heart had been restarted. Pulse amplitudes (normally 0.5 – 2.0% for the forehead) were 0.04%, increasing to 0.06% when pulse beeps became regular. When blood pressure display resumed, pulse pressure was still only 3 mm Hg, compared to normal pulse pressure of 40 mm Hg. This example is consistent with the high sensitivity and accuracy of Nellcor™ pulse oximetry across multiple clinical studies.[5,6,8,9,12]

Motion Artifact

A second key challenge for pulse oximetry is motion artifact, which occurs in all areas of care. In a review of pulse oximetry and the effect of motion, Petterson et al recognized that the invention of pulse oximetry was based on two principles:[14]

1. The light absorbance of oxygenated hemoglobin is different from that of reduced hemoglobin at the two wavelengths used in pulse oximetry (red and infrared).
2. The absorbances at both wavelengths have a pulsatile, or oscillating (AC) component, which is the result of the volume change, normally from arterial blood, occurring between the emitter and the detector of the sensor.

Petterson et al then enumerate the following implicit assumptions:[14]

1. All the hemoglobin present is either oxyhemoglobin or reduced hemoglobin.
2. There are no other absorbers between the emitter and detector other than those present during the empirical calibration. The absorption characteristics of these "other absorbers" are the same as during the empirical calibration.
3. All the blood that "pulsates" is arterial blood.

Motion artifact violates the second and third assumptions, both through the movement of venous blood and by modulating non-blood tissue and its physio-optics.

Squeezing a fingertip visibly changes its optical characteristics, resulting in modulations that are much larger than those caused by arterial pulses. Pulse oximetry studies focused on motion artifact are often healthy volunteer studies, with heterogeneous methods and results.

Healthy Volunteer Pulse Oximetry Motion Studies

Healthy volunteer studies have evaluated oximeter performance during motion artifact, often including low sensor-site perfusion as part of the study design. Table 4 summarizes several pulse oximetry motion studies on digit sensors and illustrates the heterogeneity of both the study designs and the results. One common feature is that all adult studies included controlled hypoxia. In one study, Townsend et al noted, "All new generation pulse oximeters tested performed well to within 20 mmHg of total brachial artery occlusion, mimicking poor perfusion. Only the Nellcor™ 595 [with OxiMax™ technology] with finger sensor met all predefined criteria for accuracy during movement."[15]

One important aspect of healthy volunteer studies examining pulse oximetry accuracy relates to the type of motion utilized in the study. While some studies utilize mechanical, repetitive movement to estimate the accuracy of pulse oximetry

Figure 1. Nellcor™ pulse oximetry during coronary artery bypass graft surgery.

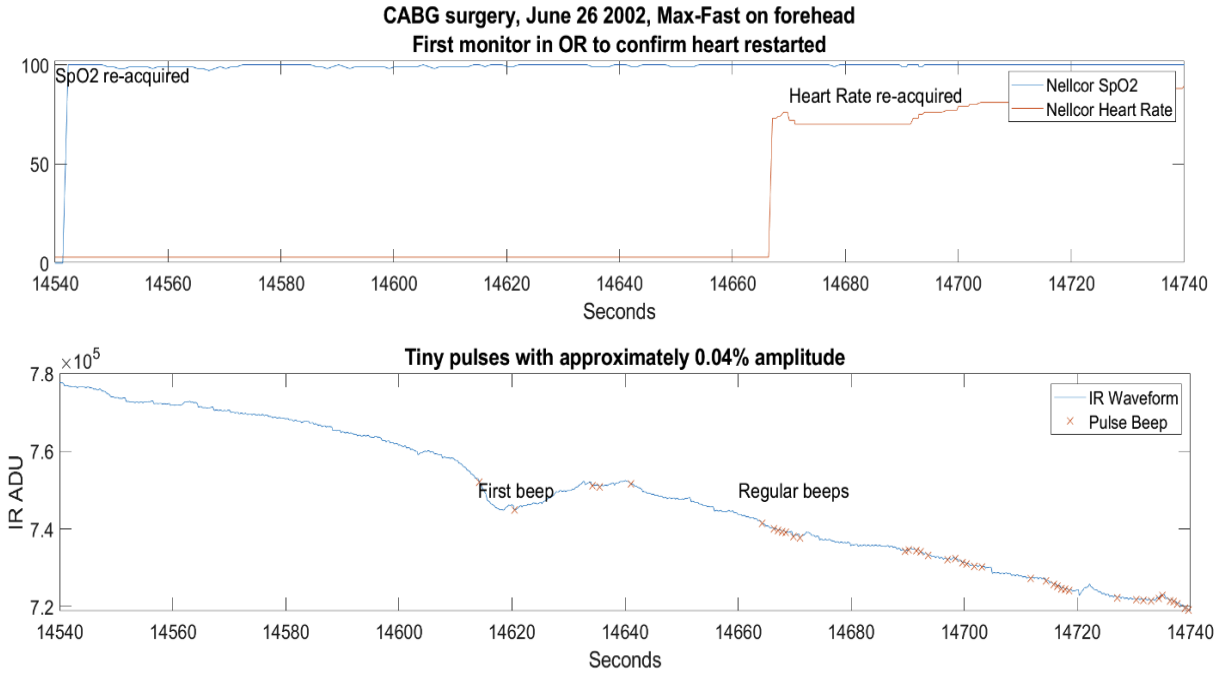

Table 4. Summary of health volunteer pulse oximetry study designs and results.

Study Design	Population	Vendor	SpO_2 or Pulse Rate reference and results		Conclusions	Reference
20 body turns Room air	18 children Ages 6-10		**SpO_2 change during turn**	**ECG**	Both Nellcor™ and Masimo pulse oximeters report accurate heart rates, but Nellcor™ pulse oximetry had more stable SpO_2	Townshend 2006[15]
		Nellcor™	0.07±0.98[a]	1.11±4.08[a]		
		Nellcor™ forehead	-0.74±2.33	-0.46±7.40		
		Masimo	-0.04±2.25	0.53±8.94		
Voluntary motion + cool room (16-18°C)	10 adults		**Within 7% of non-motion digits**	**Within 10% of non-motion digits**	Using a performance index, both SpO_2 and HR measurements were not significantly different between Nellcor™ and Masimo pulse oximetry. Masimo had no dropouts.	Shah 2012[16]
		Nellcor™	73.1%[b]	60.3%[c]		
		Masimo	98.5%[b]	88.5%[c]		
Periodic and aperiodic voluntary motion + cold room (13°C)	12 adults		**ECG**		Across 5 types of voluntary motion, Nellcor™ pulse oximetry reported pulse rate error > 25 BPM 3.4% of the time, compared to Masimo, which exceeded the error threshold 27.6% of the time. The HR reported by Nellcor™ pulse oximetry was significantly superior to Masimo.	Addison 2013[8]
		Nellcor™	RMSD = 8.6			
		Masimo	RMSD = 25.2			
Motion + hypoxia, normal room temperature (28°C) Low perfusion categorized as Masimo PI<2% on non-motion hand	10 adults		**SpO_2 vs co-oximeter RMSD (95% CI)**		All pulse oximetry performed well during normal perfusion with motion, but only Nellcor™ and Nihon Kohden pulse oximetry performed well during low perfusion with motion	Louie 2018[17]
			Low perfusion	**Normal perfusion**		
		Masimo, non-motion hand	2.2 (1.9-2.6)	1.1 (1.0-1.3)		
		Masimo	7.4 (5.4-9.3)	3.1 (2.0-4.2)		
		Nellcor™	5.1 (3.5-6.8)	3.4 (2.5-4.3)		
		Nihon Kohden OxyPal Neo	2.3 (1.8-2.7)	2.2 (1.7-2.8)		
		Philips Intellivue MP5	7.8 (5.4-10.2)	4.0 (2.4-5.6)		
Voluntary motion + cold room (13-15°C)	115 adults 244 motion digits & 248 non-motion digits	Nellcor™	**SpO_2 Reference: Mean of non-motion digits**		Nellcor™ pulse oximetry is very consistent during low perfusion and has more variability during episodes of motion artifact with low perfusion.	Internal Medtronic studies[10]
			Low perfusion	**Low perfusion + motion**		
			RMSD=1.64	RMSD=7.68		

[a]Precision calculated from the 95% limits of agreement

[b]Difference between Nellcor™ and Masimo not statistically significant

[c]Difference between Nellcor™ and Masimo not statistically significant

during motion, these results are not reflective of real-world conditions, in which patient movement is not mechanical, but random and unpredictable.[8] Pulse oximetry algorithms may be better equipped to adjust pulse rate and SpO_2 values measured during mechanical motion, making the results of these studies appear accurate, but in reality may be less applicable to real world conditions. In contrast, the healthy volunteer studies in which random motion is utilized generate data more reflective of real-world patient monitoring circumstances.[8] Importantly, out of the five pulse oximetry with motion studies summarized in Table 4, one prospective volunteer study sponsored by Masimo found equivalence between Nellcor™ and Masimo pulse oximetry performance,[16] two prospective volunteer studies concluded that Nellcor™ pulse oximetry provides superior SpO_2 measurements compared to Masimo,[15,17] and two Medtronic-internal studies, one prospective and one retrospective, concluded that Nellcor™ pulse oximetry has high accuracy in heart rate measurements, including superiority to Masimo in one study.[8,10] Together, these findings from a broad

Table 5. Performance of Nellcor™ and Masimo pulse oximetry in newborns.

	Nellcor™ pulse oximetry	Masimo pulse oximetry
Stable SpO_2 reading achieved	60 / 60 (100%)	55 / 60 (92%)
Mean time to stable reading	15 seconds	27 seconds
Median time to stable reading	8.5 seconds	12 seconds
False bradycardia compared to ECG	0 / 55 (0%)	18 / 55 (35%)

set of studies highlight that Nellcor™ pulse oximetry is accurate and reliable during motion.

Clinical Pulse Oximetry Motion Studies

Motion is to be expected in L&D and the NICU.[4] In a single-center prospective clinical study independent of manufacturers, Khoury et al monitored sixty newborns (55 with ECG, mean age 4 minutes) delivered by C-Section with Nellcor™ pulse oximetry with Nellcor™ MAXN sensors and Masimo Radical-7 with M-LNCS Neo sensors.[1] SpO_2 readings were defined as stable when consistent for at least three beats, as well as consistent with clinical appearance and ECG, if available. Nellcor™ pulse oximetry had a shorter time to stable reading and no false bradycardia episodes, as seen in Table 5.[1]

For adult and pediatric patients, motion artifact is typically episodic restlessness, such as scratching or tapping, rather than continuous motion.[4] This still creates the possibility of false alarms that can interrupt clinical workflow. Nellcor™ pulse oximetry system with OxiMax™ technology includes Nellcor™ SatSeconds alarm management, to suppress audible alarms that are too shallow or transient (in combination) to result in interventions. After comparing Nellcor™ pulse oximeter alarms with and without Nellcor™ SatSeconds, Brostowicz concluded that "application of an integrated alarm system at 50 SatSeconds reduces the clinically insignificant pulse oximetry alarms by 40% and allows for a new alarm management feature to aid caregivers to respond to potentially clinically relevant alarms."[18]

Conclusion

The truly challenging patients are the "corner cases" in the patient population that interrupt clinical workflow with difficult sensor placements and nuisance alarms. For example, a sensor on the oversized dark-pigmented foot of a NICU patient who frequently vasoconstricts during neonatal abstinence syndrome may pose a triple challenge to the pulse oximeter, and the scenario in which a patient presents more than one challenge for pulse oximetry is quite realistic.

Nellcor™ pulse oximetry is consistently tested, using over 2,000 unique test conditions (infrared and red signal levels, pulse amplitude, SpO_2 and pulse rate) representing a full range of physiological conditions. Nellcor™ pulse oximetry can often acquire saturation and pulse rate for test points having a pulse amplitude of 0.03%, which is very difficult to create in a volunteer study, given that normothermic pulse amplitudes typically range from 0.5-2.0% on forehead and > 2% on digit sites. For low signals (e.g. dark pigment or thick sensor site), our systems can typically acquire pulses with amplitudes under 100 pico-amperes, which is 1000-fold smaller than the average pulse amplitude. Our extensive internal clinical data evaluation, along with independent clinical studies of Nellcor™ pulse oximetry performance, provide evidence that Nellcor™ pulse oximetry can provide reliable pulse rate and oxygen saturation readings in challenging monitoring conditions.[1,5,6,8-11,15]

Nellcor™ pulse oximetry with OxiMax™ technology demonstrates strong monitoring performance for patients with low sensor-site perfusion, and Nellcor™ pulse oximetry offers the Nellcor™ SpO_2 forehead sensor (MAXFAST) and headband as an alternative to a digit sensor. Nellcor™ pulse oximetry with OxiMax™ technology has a record of accurate, reliable monitoring during motion and low perfusion, as well as reducing nuisance alarms, which combined, can limit consequent disruption to clinical workflow while providing the critical information needed to support decision-making for patient care, even in the most challenging patient conditions.[1,4,5,8,15,17,18]

The Nellcor™ pulse oximetry monitoring system should not be used as the sole basis for diagnosis or therapy and is intended only as an adjunct in patient assessment.

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Practical Use of Transcutaneous CO_2 Monitoring in the NICU

Anne M Geistkemper, MSc, RRT, RRT-NPS

Summary
Anne M Geistkemper, MSc, RRT, RRT-NPS discusses the practical applications of transcutaneous CO_2 monitoring in the NICU, its integration into neonatal care practices, and the evolution of this technology's adoption in the Rush University Children's Hospital NICU.

The following has been adapted from its original presentation for clarity and brevity.

Rush University Children's Hospital NICU: An Overview

- Part of a large teaching hospital
- 60-bed level III NICU
- 700 admissions per year | 17% are very low birth weight (VLBW) infants
- Unit comprised of neonatologists, fellows, advanced practice providers (physician assistants and nurse practitioners), nurses, respiratory therapists, and ancillary staff

Why Use Transcutaneous CO_2 Monitoring in the NICU?

The NICU admission process is fairly invasive for infants: lights, sounds, sticking for lab tests. So, the less invasive we can be within the NICU, the better. If we can introduce something that minimizes invasiveness, especially in those first 72 hours of a neonate's life, it's a valuable addition to our care regimen. Transcutaneous CO_2 monitoring, because it's noninvasive, is one such addition.

Transcutaneous monitoring provides continuous, real-time measurements of CO_2, allowing us to closely observe changes and trends. This becomes crucial when considering hypercapnia (elevated CO_2 levels) and hypocapnia (low CO_2 levels). Research has demonstrated that both hypercapnia and hypocapnia heighten the likelihood of injury to the brain, including intraventricular hemorrhage (IVH).[1] Because of this risk, we want to make sure that we're closely monitoring CO_2 to maintain levels within a safe range. Transcutaneous monitoring facilitates continuous monitoring of CO_2, providing greater visibility to support its effective management.

Clinical Applications of Transcutaneous Monitoring for Neonates

Reducing Iatrogenic Blood Loss

The most common reason for blood sampling is arterial blood gases (ABGs), which account for about 47% of neonatal blood samples.[2] One study found that neonates lost approximately a third of their blood volume within the first month of life, which is significant especially if you consider micro-preemies.[3] This blood loss can have implications for things like anemia and infection.[4]

At Rush, we're frequently getting labs, especially in the first 36 to 72 hours of life, as we strive to stabilize neonates and adjust ventilator settings in a timely fashion. If we can reduce the frequency of these blood gases, while also improving the monitoring of ventilation, that's ideal—something that transcutaneous monitoring can help us accomplish by providing continuous visibility into CO_2.

Continuous Monitoring on Mechanical Ventilation

Titrating mechanical ventilation is important for neonates due to their immature respiratory system. This is especially vital during the "honeymoon period," a well-known concept in the NICU, particularly for micro-preemies. It refers to the period following their birth, often after they've been given a surfactant, where settings are titrated down to minimize support. However, they can abruptly exit this honeymoon phase due to a large cytokine release, requiring prompt adjustment of settings to ensure adequate ventilation.

Because a neonate's status can constantly change, frequent adjustments are often needed. In these cases, having the option to continuously monitor CO_2 can be extremely beneficial. Instead of depending on scheduled blood gas draws to drive care decisions, continuous transcutaneous monitoring can offer greater visibility for enhanced titration support. The goal is to decrease our use of the ventilator while ensuring proper gas exchange; transcutaneous technology can give us continuous visibility into ventilatory status to help support this goal.

Continuous Monitoring on High-Frequency Oscillatory Ventilation

High-frequency oscillatory ventilation is highly effective in removing CO_2, but consequently, there's the potential for rapid fluctuations. We want to prevent these fluctuations as they can impact an infant's cerebral blood flow, which can put their brain

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at risk for injury, including IVH.[1] The use of transcutaneous monitoring is helpful because we can closely monitor CO_2 and catch these fluctuations, allowing for proactive management of levels in real time.

Reducing Neonatal Pain

Research has shown that in newborn infants, a high number of early-life skin breaks correlate with worse mental development when examined at both 8 and 18 months.[5] Furthermore, more frequent invasive procedures early in life have been associated with decreased white matter at 7 years old.[6]

We're drawing labs, we're getting gases, and maybe even placing lines. What can we do to help reduce the frequency of painful stimuli?

To minimize pain, we can employ noninvasive methods like transcutaneous CO_2 monitoring. This approach offers continuous CO_2-level visibility, helping to reduce the need for frequent heel sticks. There are also some developmentally appropriate strategies that can help reduce pain and stimuli. This includes swaddling, prone positioning, kangaroo care, or utilizing anesthetic cream or short-acting systemic analgesia for skin-breaking procedures.

Managing Specific Disease Processes

Table 1 outlines recommended CO_2 targets for neonates based on their specific disease process, as well as recommended interventions for neonates experiencing severe hypocapnia or severe hypercapnia. The use of transcutaneous CO_2 monitoring is valuable as we address the unique needs of each patient, providing enhanced titration support to maintain CO_2 levels within the targeted range.

When effectively managing CO_2, observing a reduction in CO_2 levels throughout making adjustments to ventilator settings is important. Transcutaneous monitoring provides instant visualization of the impact of our titrations. We can see the changes happening, and that can help guide effective titrations and drive care.

Special Considerations

Edema

Edema can lead to altered capillary hemodynamics and cause an increase in the blood-skin barrier due to excess fluid. As a result, transcutaneous readings can be inaccurate, making it important to avoid edematous areas when monitoring. Avoiding areas of edema can be challenging, particularly for infants who are fluid-overloaded. In these cases, however, we can still leverage transcutaneous monitoring to track the trend of CO_2 over time rather than using it for precise values.

Premature Skin

For neonates, especially in 22- and 23-weekers, the skin is thin and fragile, something we want to make sure we consider when using our transcutaneous monitor. To prioritize skin integrity, we should ensure the sensor is at the appropriate temperature (41°C) and that we're not leaving it on for too long (no more than 8 hours at a time). While the transcutaneous monitor will automatically apply appropriate settings, it is crucial to be aware of this consideration, so you can promptly identify deviations and take action if needed.

Note It is recommended that the site time be evaluated and adjusted more frequently on premature skin to reduce the risk of skin injury.

Shunting and Low Perfusion

Correct sensor placement is crucial for patients with a shunt. As per AARC Clinical Practice Guidelines, it is recommended to place the transcutaneous sensor on the same side as a shunt.[7] In

Table 1. Recommended CO_2 targets for neonates based on disease process and recommended titrations of ventilatory settings for severe hypocapnic and severe hypercapnic infants

SEVERE HYPOCAPNIA (30 mmHg)	NORMOCAPNIA (45 mmHg)	PERMISSIVE HYPERCAPNIA (65 mmHg)	SEVERE HYPERCAPNIA
CONSIDER: ↓ Respiratory Rate (RR) ↓ Tidal Volume (VT) ↓ Peak Inspiratory Pressure (PIP) ↓ Amplitude (HFOV) ↑ I:E Ratio (increase inspiratory time)	**Transient Tachypnea of Newborn (TTN)** • Assess & maintain normal ventilation • Follow institutional protocol & best practices **Respiratory Distress Syndrome (RDS)** • Assess & maintain normal ventilation • Follow institutional protocol & best practices **Persistent Pulmonary Hypertension of Newborn (PPHN)** • Routine use of TCM to assess and maintain normal ventilation because hypercapnia and acidosis increase pulmonary vascular resistance (PVR)	**Congenital Diaphragmatic Hernia (CDH)** • Allow permissive hypercapnia (PCO_2 45-65 mmHg) • PCO_2 > 60mmHg is associated with decreased survival[11-13] **Bronchopulmonary Dysplasia (BPD)** • Allow permissive hypercapnia (PCO_2 50-55mmHg) as long as pH remains in normal range • In severe disease, PCO_2 up to 70mmHg may be tolerated[14] **Meconium Aspiration Syndrome (MAS)** • Allow permissive hypercapnia (PCO_2 50-55mmHg) as long as pH remains in normal range	**CONSIDER:** ↑ Respiratory Rate (RR) ↑ Tidal Volume (VT) ↑ Peak Inspiratory Pressure (PIP) ↑ Amplitude (HFOV) ↓ I:E Ratio (decrease inspiratory time)

these cases, arterial sampling should also be done on the same side, as having these two monitoring methods aligned will allow for an accurate correlation.

Low perfusion may cause transcutaneous CO_2 values to be falsely high. In this situation, similar to the case of edema, it may be more helpful to utilize the monitor to trend CO_2 in order to observe patterns and track progress during care.

Hypothermia

Hypothermia is something we see often in NICUs, especially with hypoxic-ischemic encephalopathy (HIE) or post-cardiac arrest patients undergoing cooling therapy. HIE, hypovolemia, reduced myocardial contractility, and bradycardia can all lead to decreased cardiac output. Consequently, if the region experiences hypoperfusion, it is important to note that the correlation between the transcutaneous and arterial CO_2 may be poor. In this situation, establishing a correlation between the two values, rather than focusing on the exact values, becomes more clinically valuable. Again, this can be used for tracking the trend in CO_2 throughout care.

AARC Clinical Practice Guidelines

The AARC Clinical Practice Guidelines (shown in part in Figure 1) provides recommendations for the effective use of transcutaneous CO_2 monitoring in clinical care.[7] If you're not fully utilizing your transcutaneous monitors, haven't developed guidelines or implemented it into any protocols, or don't have devices at all, the AARC Clinical Practice Guidelines can guide you. I encourage you to develop a process for your NICU. It can be difficult to get started, but aligning with the AARC guidelines is going to create a standard practice. By adopting this approach, you can foster growth within your team, encouraging increased utilization of the technology. We have a great opportunity especially as respiratory therapists, to help drive care in an efficient, noninvasive manner.

TCM 3.0 SETTING

TCM may be performed by trained personnel in a variety of settings that include, but are not limited to hospitals, extended care facilities, and patient transport. It is utilized in the following specific clinical settings to determine the presence of hypoventilation or respiratory depression:

- **3.1** Mechanical ventilation, including conventional modes of ventilation, high-frequency ventilation, steady state high frequency jet ventilation, and noninvasive ventilation.

TCM 4.0 INDICATIONS

The use of TCM is indicated in patients who either lack arterial access or have the need for continuous monitoring of oxygen and carbon dioxide with minimal blood draws. TCM allows the assessment of:

- **4.1** adequacy of oygenation and/or ventilation
- **4.2** response to diagnostic and therapeutic interventions, as evidenced by $PtcO_2$ and/or $PtcCO_2$ values
  - **4.2.1** Weaning and extubation decisions may be made based on $PtcCO_2$ measurement alone.

Figure 1. 2012 AARC Clinical Practice Guidelines for Transcutaneous Monitoring of Carbon Dioxide and Oxygen[7]

Benefits of Transcutaneous CO_2 Monitoring in the NICU

Transcutaneous CO_2 monitoring offers a noninvasive method to continuously analyze CO_2 levels in all modes of ventilation. With continuous monitoring, we're able to get real-time values for instant visualization of a patient's response to care strategies. This newer technology preserves skin integrity for delicate patients and helps reduce the need for frequent blood draws.

Additional benefits of transcutaneous CO_2 monitoring in the NICU:

- Provides accurate measurements
- Compatible with any ventilation strategy
- Supported by AARC guidelines
- Supports cost reductions
- Supports neuroprotective care
- Simplifies workflows
- Enables lung-protective ventilation strategies

Tips for Selecting a Monitoring Site

Choosing the ideal site for transcutaneous monitoring depends on your patient. The main determinant for location is perfusion, so the sensor is often placed on the thighs. This is a particularly good choice when swaddling, as there's less of a risk of the sensor falling off. However, in a 22-, 23-, 24-weeker, you might not have the real estate available in these areas, given the presence of a peripheral intravenous line (PIV) and/or other lines they may have.

In the past, we utilized the upper chest and thigh areas at our institution, but encountered challenges in achieving good correlation with these sites. In discussion with the manufacturer, we were advised to try the forehead. While some caregivers initially had concerns, once everyone embraced the idea, we saw remarkable improvements.

In most scenarios, the forehead is well-perfused, making it a great location for monitoring. For us, we keep our preemies midline for 72 hours, which also means there's typically nothing obstructing this area. And when they are being repositioned, we don't have to worry about the sensor as much, and whether there will be pressure placed on it. It's an easy-access area where we found much better correlation, and for my staff, it was less stressful to manage the sensor and troubleshoot appropriately. If you're not using the forehead yet, I challenge you to try it.

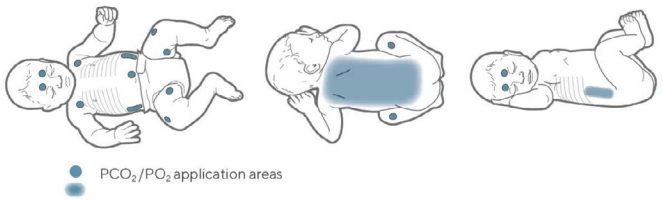

Figure 2. Recommended sensor sites for transcutaneous monitoring include the thorax, the abdomen, the back, the area low on the forehead, the temples, and the inner or anterior aspect of the thigh.

Using Contact Gel: How Transcutaneous Monitoring Use Transformed at Rush

Our facility got by without using contact gel with our transcutaneous sensors for a long time. However, we were having correlation issues. We were experiencing frequent sensor errors and doing a lot of troubleshooting.

We learned from our clinical specialist that by using normal saline in place of contact gel, it meant that we were putting salt on an electrode—no wonder our membranes were struggling. When we replaced the saline with contact gel, we found our sensors were providing much better correlation. In addition, it was more cost-effective because our machines required less maintenance and troubleshooting, and we didn't have to replace membranes as frequently.

Table 2. Five S's of troubleshooting a transcutaneous monitoring device: sample, site, seal, sensor, and status.

Sample	Site	Seal	Sensor	Status
Record the tcPCO2 value when you draw the sample, not when results are read. Verify proper lab draw technique and operation of blood gas analyzer.	Check for external pressure on the sensor. Check perfusion at measurement site. Sampling site and sensor should be on same side of shunt.	Verify attachment ring is secure on the skin. Use 1-2 drops of Contact Gel during application. Ensure sensor is clipped into the ring.	Verify correct sensor temperature. Check the quality of the sensor membrane. Check when the sensor was last calibrated.	Shock, sepsis, and edema can impact the local perfusion. Consider the effect of vasoactive medications. Decreased perfusion may cause falsely high tcPCO2.

Present day, our correlation has improved significantly, and I attribute that to using contact gel, as well as using the forehead as a monitoring site. Before, we owned 6 devices and had an average of about 3-4 in use. Now, while we still own 6, we are renting additional units because our usage has increased after gaining the trust of not only the RTs, but also complete medical teams. If you are struggling with usage, I encourage you to reach out to your vendor's support team to see if there is any education to help you along the way.

The Five S's: Troubleshooting Tips for Your Transcutaneous Monitoring System

When it comes to troubleshooting your transcutaneous monitoring device, I like to refer to the Five S's: sample, site, seal, sensor, and status. When you're trying to figure out why your transcutaneous readings aren't correlating as well as you'd like, figuring out which issue you're dealing with can help you troubleshoot appropriately.

Integrating Transcutaneous Monitoring Into NICU Protocols

At Rush, we implemented transcutaneous monitoring within our unit protocols, not only to increase the usage of the devices that we bought, but also to showcase its value and get everybody on the unit more comfortable with the technology.

If you don't have protocols in your unit yet, that's okay. You can use the AARC Clinical Practice Guidelines to start utilizing the technology and building trust. If you do have protocols, there are simple ways to implement the usage of transcutaneous monitoring in your unit, just by adding it to your existing processes.

NICU Conventional Ventilation Protocol

As part of our NICU conventional ventilation protocol, patients who are born at less than 35 weeks get a transcutaneous sensor placed on them for the first 72 hours of life, which allows us to start trending our gases with our $tcPCO_2$. Because there is a high volume of gases and labs being drawn in the first 24 to 36 hours, we're able to lay a good foundation for our correlation. This protocol also gets everybody more comfortable with transcutaneous monitoring in the NICU.

High-Frequency Jet Ventilator Protocol

As part of our care goals for our high-frequency jet ventilator protocol, any patient who goes on a jet ventilator must have a transcutaneous monitor.

Other Cases to Integrate Transcutaneous CO_2 Monitoring

Other cases where we use transcutaneous monitoring are BPD and noninvasive ventilation (NIV). While we don't necessarily have these protocolized yet, we still utilize transcutaneous monitoring to continuously monitor ventilation in these patients.

Bronchopulmonary Dysplasia (BPD)

Although gases are not frequently obtained from patients with BPD, their status can change quickly. These patients are often sweaty, which can make finding the proper transcutaneous sensor placement difficult. However, transcutaneous monitoring is a useful tool for this population, providing continuous CO_2 visualization when gas sampling is infrequent.

Noninvasive Ventilation (NIV)

Patients on noninvasive mechanical ventilation are often teetering on the verge of needing an escalation of care, perhaps requiring intubation. Or, they may have just been extubated, and there is uncertainty about their ability to thrive. To be able to have constant CO_2 monitoring in these cases is helpful in guiding our management strategies.

Summary

Transcutaneous monitoring provides clinicians with a noninvasive method to monitor CO_2. This isn't just beneficial for patients in terms of lessening pain; it has the potential to yield benefits for your hospital in terms of cost-effectiveness by supporting the reduction of blood draws. And importantly, as a respiratory therapist, it offers valuable insights into the efficacy of ventilation strategies, which helps guide care.

The more you use transcutaneous monitoring, the more comfortable you're going to be and hopefully the better you'll become at it. In the Rush University Children's Hospital NICU, we already had active protocols, so we took the opportunity to integrate transcutaneous monitoring. This not only got our staff more comfortable using it, but also allowed our bedside caregivers to begin to trust the technology and rely on it during care.

As we continue utilizing transcutaneous CO_2 monitoring, keeping up with current research remains valuable. However, actively engaging with other facilities, who are utilizing devices even more than we are, has also proven significant for our hospital. If you're looking to embrace this technology, or increase its usage, consider reaching out to your colleagues at other hospitals to gain valuable insights on successful implementation. This has played a vital role in our adoption of transcutaneous monitoring in the NICU, and our progress towards utilizing its fullest potential for our patients.

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Recurrent Upper Respiratory Tract Infections in Early Childhood: A Newly Defined Clinical Condition

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Introduction

Recurrent respiratory tract infections (RRTIs) represent a widespread childhood medical condition that poses significant challenges to pediatric healthcare providers. These infections affect a substantial proportion of infants and children aged 1–6 years, accounting for up to 25% of cases.[1,2] During early childhood, RRTIs often trigger medical consultations and emergency room visits, significantly impacting the well-being of affected children and their families, and frequently resulting in school absences.[3]

Moreover, RRTIs impose a substantial burden on public health, necessitating recurrent medical assessments, frequent antibiotic treatments and, in some cases, hospitalizations.[1,4,5] Several risk factors may contribute to the development of RRTIs, including early exposure to infectious agents, immune system immaturity, indoor and outdoor pollution, secondhand smoke exposure, atopy and allergy, and low socio-economic status.[1,6]

Despite the clinical significance of RRTIs, the scientific community lacks consensus on its definition.[3,5,7,8] Moreover, some children exclusively experience recurrent upper respiratory tract infections (R-URTIs), but the number of infections required to classify them as recurrent remains unknown. The differentiation between RRTIs and R-URTIs could be speculated considering that that both the risk factors associated with these two conditions and their clinical burden may differ.[9–12] Therefore, we postulated that the incidence and specific risk factors of R-URTI may warrant its classification as a distinct clinical entity.

For this purpose, we initiated a prospective cohort study in a primary care setting. Our main objectives were to estimate the actual prevalence of URTIs in preschool children aged 0–5 years. Subsequently, we aimed to identify the actual prevalence and potential risk factors for R-URTI events in children without underlying predisposing conditions. Finally, we sought to propose a practical definition for R-URTI based on these findings.

Materials and methods

This prospective, observational cohort study was performed between October 2019 and February 2020 in a primary care setting in Lombardy, Italy.

Study population

This study was performed involving a convenience sample of 69 family pediatricians working for national public health system and providing free medical care, and who were member of the Italian Primary Care Pediatrics Society (SICuPP), Lombardy section, joined the study as volunteers. Children aged 0–5 years cared by involved family pediatricians were considered eligible for the study. Children with prematurity (gestational age < 37 weeks), congenital abnormalities of the respiratory tract, congenital or acquired immunodeficiency, cystic fibrosis, cardiovascular, renal or hematological diseases were excluded. Medical history was collected using a specific questionnaire during the first medical visit, and the exclusion of comorbidities aimed at ensuring a homogenous study population, in order to investigate the impact of respiratory infections in an otherwise healthy cohort, minimizing confounding factors related to other diseases.

Study protocol

At recruitment, the family pediatrician completed a case report form (CRF) for each enrolled child which included socio-demographic information about each child. Furthermore, information on the gestational age, type of childbirth and early feeding (breastfeeding, formula, mixed feeding), number and type of vaccinations, exposure to passive smoking, number of siblings, parental age, attendance in the community, active or

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familiar history of allergies were collected. Further information on data collection is reported in the Supplementary Material.

Parents of enrolled children were instructed to contact the pediatrician in case of fever (defined as an axillary temperature > 38 °C) or flu-like symptoms.[13] A full clinical examination was then conducted and, if an URTI was diagnosed, another CRF was filled with the specific diagnosis, as previously described in other studies conducted on an analogue cohort.[14,15] Based on the site infection, rhinitis, rhinosinusitis, pharyngotonsillitis, acute otitis media and laryngitis were considered as potential diagnosis of URTI.[16-18] Each child was followed from the day of recruitment up to March 30, 2021. Due to the occurrence of the COVID-19 outbreak, only months from October 2019 to February 2020 (corresponding to autumn and winter months) could be used for this purpose. In March 2020 Lombardy experienced one of the first and deadliest COVID-19 outbreaks in the world, forcing Health Authorities to a national lockdown.[19]

Statistical analysis

The recruited population was divided into 3 groups: children aged < 1 year, 1–2 and 3–5 years. Incidence rates of URTIs were computed for each age group to estimate the expected likelihood of experiencing a URTI episode in any given week. For each child, if symptoms were present for four or more days out of seven in a week, that week was deemed "affected by URTI." The overall incidence rate of URTI for each age group was calculated as the total number of URTI episodes divided by the total number of weeks of observation per child. This calculation considered the possibility that some subjects transitioned between age groups during the observation period, thus contributing to the incidence rate for both age categories. Subsequently, for each child, we estimated the probability of experiencing a URTI in any given week using the binomial distribution. A R-URTI was defined as a subject who had a number of URTI episodes for which the cumulative probability of that number (or a higher number) of URTIs was less than 10% ($p = 0.10$). The probability of URTIs occurring at least "$x = k$" times in n weeks was determined using the formula: *"P(URTI ≥ x = k) = 1 - Σ[n!/(x!(n-x)!) * p^x * (1–p)^(n-x)] < 0.10"* (p = probability of URTI in one week, x = number of weeks with URTIs, k = threshold number for R-URTI, n = number of weeks of exposure).

The association between each independent variable and the development of an R-URTI was assessed. Associations were evaluated using the Chi-square test or Fisher's exact test when expected frequencies were low ($p = 0.05$).

Table 1 Minimum events required to define R-URTI, categorized by observational period and age

N. of weeks of observation	< 1 years	1–2 years	3–5 years
3–5	2	2	2
6	2	3	2
7	3	3	2
8–12	3	3	3
13–14	3	4	3
15–16	4	4	3
17–19	4	4	4
20–21	4	5	4

Results

A total of 483 children participated in our study. The frequency of URTIs, taking into account both the number of cases and the cumulative weeks of observation across all children in various age groups, was as follows: (1) children aged < 1 year: 133 cases/1658 weeks, with a mean of 8.02 cases per 100 weeks per person; (2) children aged 1–2 years: 282 cases/3025 weeks, with a mean of 9.32 cases per 100 weeks per person; (3) children aged 3–5 years: 191 cases/2750 weeks, with a mean of 6.95 cases per 100 weeks per person.

The calculated incidence rates were 8.02%, 9.32%, and 6.95% for the < 1 year, 1–2 years, and 3–5 years age groups, respectively. Table 1 provides a summary of the minimum number of URTIs required to classify a child as affected by R-URTIs, taking into account different observation periods between the first and the last episode and specific for the different age groups.

When considering the entire population, 44 out of 483 children (9.1%) met the criteria for a R-URTI. Among infants (age < 1 year), there were 122 participants, of whom 12 developed R-URTI (9.84%). In the 1–2 years age group, which had 219 participants, 14 children were affected by R-URTI (6.39%). In the 3–5 years age group, consisting of 186 children, 18 presented with R-URTI (9.68%). These percentages account for the fact that 44 children transitioned from one age group to the next during the observation period.

Moreover, when considering possible significant risk factors associated with the occurrence of R-URTIs, community placement was found to be more related in children aged 1–2 years old (OR 14.45, $p = 0.005$); in cases of community placement since more than three months, this association was still significant (OR 7.58 $p = 0.023$), as well as subgroups including the size of the class (more than 10 children per class, OR 10.84, $p = 0.019$) and having meals at school (OR 8.55, $p = 0.033$). These factors were not confirmed to be significant in children aged > 2 years old.

Moreover, our data showed that patients aged 1–2 years old with inhalant allergy present an increased risk of developing RRTIs (OR 16.25, $p = 0.023$). No statistically significant association either between the development of R-URTIs and family history of allergies was found in any of the three groups. Type of feeding, gestational age at birth, number of siblings, parental age, vaccinations and passive smoke were not found to be associated with an increased or reduced risk of R-URTI in any group. Associations with specific risk factors for each age group are reported in the Supplementary Material.

Discussion

This study identified a subset of children who manifest recurrent upper respiratory infections without involving the lower airways and, for the first time, attempts to provide a new clinical and epidemiology definition of R-URTI.

In 2021, an Italian intersociety consensus proposed the following classification of RRTIs after a review of scientific literature: (1) 1–3 years, 6 or more respiratory tract infections in a year, of which 1 has to be severe pneumonia or 2 mild cases of pneumonia confirmed by clinical or radiological criteria; (2) 3–6 years, 5 or more respiratory tract infections in a year, including at least either 1 episode of severe pneumonia or 2 mild ones (confirmed by clinical or radiological criteria); (3) 6–12

years, 3 or more respiratory tract infections (including either 1 severe or 2 mild pneumoniae, as previously stated).[10] Children with chronic diseases such as cystic fibrosis, primary ciliary dyskinesia, bronchiectasis, cardiorespiratory malformations, or neuromuscular disorders are excluded from this definition. Specific definitions have also been provided for particular respiratory diseases. For instance, acute otitis media is considered recurrent if it occurs more than three times in six months (or four times in one year).[20] Although classifications are relevant for clinical practice, they may not characterize those children who present several episodes of URTIs but do not fit any specific existing definition. Furthermore, it is important to point out that some of the studies included to join this definition of RRTIs were conducted even decades ago, when circulation of infectious agents, available preventive measures and environmental exposure were significantly different.[10]

Our findings also provide an estimate of the R-URTI in children aged 0–5 years old that rages from 5 to 10%. This discovery represents a pivotal aspect of our research, highlighting the substantial burden of upper RRTIs in young children. This study did not identify specific risk factors for R-URTI. This finding has at least two implications: (1) it suggests that R-URTI might affect potentially all children regardless of their family or clinical history; (2) the frequency of URTI events may be the most crucial criterion to consider in definition of R-URTI.

Assessing the frequency of URTIs may be a challenge for the clinician. Indeed, the observation and duration of URTI events can be highly heterogeneous, influenced by factors such as parental reporting accuracy, the unpredictable nature of URTIs, and the diverse manifestations of these infections. Moreover, the considerable variability in URTI episodes further complicates the task of assessing frequency.

To address these challenges, our study introduced a practical and dynamic tool for categorizing patients between the ages of one month and five years as having upper RRTIs. The dynamic observation period reported in our thresholds, ranging from 3 to 21 weeks, may allow pediatricians to early identify cases of R-URTI. Overall, we suggest the diagnosis of R-URTI in otherwise wellbeing children up to 5 years of age experiencing at least 4 URTI episodes lasting four days or more within a six-month period. The episodes must be separated from each other by a period of well-being. New studies should test the validity of this new definition.

Our study has inherent limitations, notably the narrow time frame from October 2019 to February 2020 for data collection. Unfortunately, the COVID-19 pandemic's unprecedented outbreak in Lombardy, Italy, led to nationwide lockdowns, school closures, and disruptions to healthcare services, rendering data collection beyond February 2020 unfeasible.[21,22] Consequently, our study did not account for lower respiratory infections, which would have provided a more comprehensive understanding of RRTIs in children, as well as other possible risk factors such as the mode of delivery. Moreover, we have not included in our data possible ENT evaluations or anatomical anomalies that may predispose to the development of URTIs.

On the other hand, the stratification of results by age group not only enriches data interpretation but also facilitates age-specific clinical decision-making. This stratification provides clinicians with an additional tool to diagnose the single patient with R-URTI based on the number of weeks between the first and last episode of URTI during the first 5 years of life, regardless of the duration of the observation period.

In this study, we emphasized the importance of considering the frequency of URTI events as a central criterion for defining and addressing R-URTI in clinical practice. This differentiation may offer a specific understanding of pediatric RRTIs, advocating for a more nuanced approach to their management and prevention.

Conclusions

In this study, we observed a significant prevalence of R-URTI in children aged 0–5 years, with estimates ranging from 5 to 10%. To address the lack of a consensus on its definition, we proposed a practical and dynamic definition of R-URTI, suggesting that children within this age group experiencing a minimum of four episodes within a six-month period could be classified as having R-URTI. This clinical entity not only underscores the substantial burden of URTI in young children but also offers a specific criterion for clinicians to identify and manage cases of R-URTI, facilitating a more nuanced approach to its early diagnosis. Further research is needed to validate this proposed definition and enhance our understanding of recurrent infections in children without specific risk factors.

Abbreviations

R-URTI Recurrent upper respiratory tract infection RRTI Recurrent respiratory tract infection SICuPP Italian Primary Care Paediatrics Society

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Author contributions

Conceptualization, C.M. and P.M.; methodology, G.P.M, A.C., and M.P.; validation, G.P.M., and C.M.; formal analysis, A.C., M.G., and G.C.; investigation, A.C., C.M.,

R.B., and M.P.; resources, M.G. and R.B.; data curation, R.C., G.P.M., and A.C.; writing A.C. and G.P.M.; P.M. and C.M. supervised the findings of this work and revised the manuscript. All authors have read and agreed to the published version of the manuscript.

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Data availability

Data and consents are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate

All methods were performed in accordance with the ethical standards as laid down in the Declaration of Helsinki and its later amendments or comparable ethical standards. Written informed consent to participate was obtained. The study was conducted in accordance with the Declaration of Helsinki and was approved in September 2019 by the Ethics Committee of the IRCCS Ca' Granda Ospedale Maggiore Policlinico Foundation, Milan, Italy.

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