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1 - Kacmarek RM, Villar J, Parrilla D, et al. Intensive Care Med. 2020 Dec;46(12):2327-2337.

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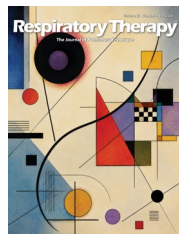
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News

■ Fall 2026

Mercury Medical Joins Sarnova

Mercury Medical has joined forces with Sarnova, a leader in health and safety products, services and technology. Sarnova is the parent company of Bound Tree Medical, which serves EMS and first responders, and Tri-anim Health Services, a specialty distributor of respiratory, anesthesia, airway management, and critical care markets. The addition of Mercury Medical products strengthens Sarnova's commitment to delivering comprehensive portfolio solutions for its customers. There are no immediate changes in how you interact with Mercury Medical, the company said in a statement.

Early-Life Respiratory Infection Burden Linked to Higher Childhood Atopic Dermatitis Risk

Children with a high burden of infections through age 3 showed a greater risk of developing atopic dermatitis (AD) in a large Danish cohort study. Researchers used data from 663 children in the Danish Copenhagen Prospective Studies on Asthma in Childhood (COPSAC2010) birth cohort, monitored from birth to age 10 years between November 2008 and November 2010. Researchers replicated the COPSAC2010 findings in 707 children from the US VDAART cohort followed to age 6 years. Parents recorded daily infections including common cold, acute otitis media, tonsillitis, pneumonia, gastroenteritis, and fever in COPSAC2010 through age 3; VDAART monitored cold, respiratory infection, otitis media, and fever. The primary outcomes were AD diagnosis through age 10 years in COPSAC2010 and physician-diagnosed AD through age 6 years in VDAART. In the Danish cohort, children with more infection episodes (upper vs lower tertile: adjusted odds ratio [AOR], 1.63; $P = .02$) and infection days (upper vs lower tertile: AOR, 1.80; $P < .001$) had an increased risk for AD. Each additional infection episode was associated with a modest increase in the risk for AD (AOR, 1.02; $P = .03$), demonstrating a dose-response relationship. Respiratory infection subtypes and otitis media were strongly linked to an AD diagnosis: upper vs lower

tertiles for common colds (AOR, 1.71; $P = .01$), tonsillitis (AOR, 1.61; $P = .03$), pneumonia (AOR, 1.73; $P = .01$), and acute otitis media (AOR, 1.98; $P = .002$). In the US cohort, children in the upper vs lower infection episode tertile had an increased risk for AD (odds ratio [OR], 1.76; $P = .01$), and each infection episode raised the odds (OR, 1.03; $P = .002$). "Early common infection burden, and in particular upper respiratory infections, were associated with AD in childhood," the authors of the study wrote. "These findings suggest a long-term relationship between early respiratory infections and AD that has previously been unclear due to inconsistent findings in previous studies," they added. The study was led by Nicklas Brustad, MD, PhD, Herlev and Gentofte Hospital, University of Copenhagen, Copenhagen, Denmark, and was published online on July 29 in *JAMA Dermatology*.

Asthma With Preserved Ratio Impaired Spirometry Raises Exacerbation Risk

Patients with asthma and preserved ratio impaired spirometry (PRISm) experienced severe acute exacerbations more than twice as often as those with normal lung function. This exacerbation burden was comparable to that seen in patients with obstructive ventilatory defects, despite the absence of overt airflow obstruction. Researchers conducted a retrospective analysis of 1411 adult patients with asthma in Japan. Based on spirometry, patients were categorized into control (normal % forced expiratory volume in 1 second [FEV1] and preserved FEV1/forced vital capacity [FVC], $n=1102$), PRISm (reduced %FEV1 with preserved FEV1/FVC, $n=133$), and airflow obstruction (reduced %FEV1 and reduced FEV1/FVC, $n=176$). Primary outcomes included the frequency of severe acute exacerbations (defined as events requiring emergency room visits, hospitalization, or systemic corticosteroid treatment for ≥ 3 days) assessed over the 2 years preceding enrollment, along with clinical characteristics and treatment patterns. Severe acute exacerbations occurred in 40% of the PRISm group



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compared with 24% of the control group and 30% of the airflow obstruction group. Compared with the control group, patients with PRISm had higher BMI (adjusted odds ratio [aOR], 1.08; $P = .003$), longer asthma duration (aOR, 1.02; $P = .030$), and more than double the odds of severe acute exacerbations (aOR, 2.31; $P < .001$). Compared with the airflow obstruction group, patients in the PRISm group had higher BMI (aOR, 1.15; $P < .001$) and shorter asthma duration (aOR, 0.97; $P = .003$), while the frequency of severe acute exacerbations did not differ significantly (aOR, 1.39; $P = .267$). Obesity (BMI ≥ 25) was present in 43% of the PRISm group, significantly higher than in the control (28%) and airflow obstruction (24%) groups ($P = .001$). “Our study identifies asthma with coexisting PRISm as a clinically important phenotype characterized by increased exacerbation burden,” the authors wrote. “Recognition of asthma with coexisting PRISm may have potential clinical implications for identifying patients who may benefit from closer monitoring and more proactive optimization of management.” The study was led by Masako To, Department of Laboratory Medicine, Dokkyo Medical University, Saitama Medical Center in Koshigaya, Japan. It was published online on July 17 in *Journal of Asthma and Allergy*.

Where AI Is Leading and Lagging in Pulmonary and Critical Care

AI offers real promise in the fields of pulmonary medicine and critical care, experts shared, but also features hype, uneven maturity, and some considerable barriers to implementation. Despite these challenges, AI technology is advancing rapidly across these fields. Applications in radiology still outpace the rest, accounting for about 76% of the approximately 1400 AI medical devices cleared by the FDA. Within pulmonology, AI is changing

or poised to transform diagnostics in general and for chronic obstructive pulmonary disease (COPD), interstitial lung disease (ILD), and pulmonary hypertension (PH) in particular. “Pulmonary medicine is particularly ripe for this because we deal with a lot of physiological data,” Shirin Shafazand, MD, MS, professor of clinical medicine in the Division of Pulmonary, Critical Care, and Sleep Medicine at the University of Miami Miller School of Medicine in Miami, said during a panel presentation on AI at the American Thoracic Society (ATS) 2026 International Conference. “We deal with a lot of images, complex patients, and patients that require long-term follow-up management. Wearables are coming into play right now, and there is a shortage of pulmonary specialists, so there is potential for these tools as they mature to actually have benefit for many populations. Hopefully,” said Shafazand, who also leads the Office of AI in Medical Education at University of Miami. One current limitation is that most FDA-approved AI technology has a narrow focus. Machine learning algorithms focus on specific indications such as triage and detection of lung nodules, pulmonary emboli, or pneumothorax, for example. Therefore, unlike humans, AI cannot yet read an entire x-ray for different abnormalities, Shafazand said. “Although that is coming, and many radiologists are excited about that possibility.” For COPD detection, AI is able to accurately predict whether the condition is present or not. Deep learning models yielded a pooled sensitivity of 0.87, specificity of 0.88, and an area under the curve (AUC) of 0.93 for this binary classification in a January 2026 systematic review and meta-analysis. However, the analysis of 56 studies with 886,753 participants also showed that accurate staging remains a challenge for AI in COPD, Shafazand said. Combining wearable monitors with AI technology could reduce emergency department (ED) visits, Shafazand added. The dual



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strategy predicted COPD exacerbations about 7 days in advance by combining oximetry, heart rate, genomics, and environmental data, a 2025 review revealed. AI models that integrated these data achieved an AUC of 0.80 or more, lowered ED visits by up to 98%, and reduced readmission rates by 25%-48%. In another study, AI outperformed both senior and junior pulmonologists when presented with the same pulmonary function test (PFT) and clinical data for 50 patients. Results from the AI model trained on European Respiratory Society guidelines were contrasted with interpretation from 120 pulmonologists. The study included a choice of nine diagnostic categories, including COPD. Pulmonologists made correct diagnoses in 45% of the cases (range, 24%-62%). In contrast, the AI-based software correctly diagnosed 82% of all cases ($P < .0001$). One caveat is that AI technology has evolved rapidly since the study was published in 2019. A more recent study, published in 2023, revealed that when pulmonologists used AI assistance to interpret PFT results, they outperformed AI alone in terms of accurate diagnoses.

Steroid Abuse in Men Tied to Subtle Changes in Breathing Parameters During Sleep

Recreational androgen abuse in men was associated with a significant but modest increase in indices of sleep-disordered breathing, with the most pronounced changes observed at approximately 3 months after cycle cessation rather than during active abuse. Sleep architecture was largely preserved aside from a modest reduction in deep sleep, and subjective sleep quality did not worsen. Researchers in Netherlands conducted a prospective cohort study to evaluate effects of supraphysiologic androgen abuse on sleep-disordered breathing, sleep architecture,

and subjective sleep quality in men. They included 23 men aged 18 years or older who planned to initiate a self-administered androgen cycle lasting at least 6 weeks, with a cumulative weekly androgen dose of at least 250 mg. Participants were evaluated at three timepoints: before the initiation of the cycle, at approximately 8 weeks during the cycle, and at approximately 3 months after cycle cessation. Sleep was monitored using an ambulatory sleep diagnostic device,

and subjective sleep experiences were assessed at each visit using validated questionnaires. The primary outcome was a longitudinal change in the peripheral arterial tone-derived apnoea-hypopnoea index (pAHI) across three timepoints; secondary outcomes included changes in the peripheral arterial tone-derived respiratory distress index (pRDI) and oxygen desaturation index (pODI), sleep architecture, and other parameters. During active androgen abuse, the pRDI increased significantly by 3.0 events per hour ($P = .035$), but no significant increases were observed in the pAHI or pODI. At approximately 3 months after cycle cessation, the pAHI increased significantly by 2.7 events per hour ($P = .029$), the pRDI increased by 4.4 events per hour ($P = .003$), and the pODI increased by 3.0 events per hour ($P = .021$) compared with baseline. Sleep architecture was largely preserved; however, the proportion of deep sleep decreased

modestly during the androgen cycle ($P = .022$); the average heart rate also increased by 4 beats/min during the cycle ($P = .017$). No significant changes were observed in subjective sleep experience scores. “[The study] findings suggest that androgen abuse may subtly influence sleep-disordered breathing parameters, but are unlikely to translate into overt or clinically meaningful sleep apnea

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in most androgen abusers,” the authors wrote. This study was led by Tijs Johannes Verdegaal, Elisabeth-TweeSteden Hospital, Tilburg, Netherlands. It was published online on July 20, 2026, in the *Journal of Endocrinological Investigation*.

Persistent Airflow Limitation Linked to Severe Exacerbation Risk in Asthma

Patients with asthma who had persistent airflow limitation (PAL) experienced severe exacerbations more than twice as often as those without PAL and faced a nearly twofold higher annual incidence of these events. The risk escalated with increasing severity of airflow obstruction, with the most advanced stage showing more than triple the risk compared with patients without PAL. A multicenter cohort study combined retrospective data from two tertiary hospitals in South Korea (January 2013–December 2019) with data from a prospective cohort (April 2018–August 2023), enrolling a total of 849 adult patients with physician-diagnosed asthma. PAL was defined as postbronchodilator forced expiratory volume in 1 second (FEV1)/forced vital capacity (FVC) ratio < 0.70 at baseline spirometry; severity was graded using the STaging of Airflow obstruction by Ratio classification (STAR stage), ranging from stage 0 (no PAL) to stage 4 (FEV1/FVC < 0.40). Primary outcomes included the annual incidence of subsequent moderate-to-severe acute exacerbations and time-to-first severe exacerbation; secondary outcomes assessed longitudinal lung function decline through repeated spirometric measurements over a mean follow-up of approximately 4 years. Overall, 75.4% of patients had PAL at baseline; during follow-up, PAL was associated with a significantly higher incidence of severe exacerbations (13.0%

vs 5.7%; $P = .046$) and a 1.77-fold higher annual incidence rate ($P = .014$). The risk for severe exacerbations was approximately 1.8-fold, 1.7-fold, and 2.3-fold higher with STAR stage 1, 2, and 4 PAL compared with stage 0 PAL. In time-to-event analysis, STAR stage 4 was associated with a more than threefold higher risk for severe exacerbations compared with stage 0 (adjusted hazard ratio [HR], 3.32; 95% CI, 1.60-6.89). Annual FEV1 decline was slower in the PAL group than in the non-PAL group (–28.1 mL/year vs –42.5

mL/year; $P = .028$), but within patients with PAL, STAR stage 4 demonstrated the most pronounced declines in both FEV1 and FVC, likely reflecting higher smoking intensity and more frequent severe exacerbations in this subgroup. “The presence and severity of PAL convey important prognostic information beyond cross-sectional lung function, underscoring its role as a longitudinal risk phenotype. Assessing PAL and its severity may therefore aid risk stratification and prognostication in clinical practice,” wrote the authors of the study. The study was led by Jung-Kyu Lee, Division of Pulmonary and Critical Care Medicine, Department of Internal Medicine, Seoul Metropolitan Government-Seoul National University Boramae Medical Center, Seoul National University College of Medicine, Seoul, South Korea. It was published online on July 9 in *Journal of Asthma and Allergy*.

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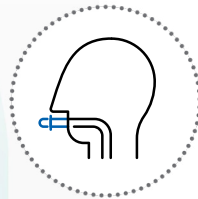
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patients with pulmonary arterial hypertension (PAH, World Health Organization Group 1). The OLE study is a non-placebo-controlled trial and was designed to evaluate the long-term safety, tolerability, and effectiveness of TPIP over 24 months in patients who completed the lead-in TPIP PAH studies. “These data from our ongoing OLE study with TPIP represent an important milestone in our efforts to fully harness the potential of treprostinil and provide meaningful benefit to patients with pulmonary arterial hypertension,” said Gene Sullivan, M.D., Chief Product Strategy Officer of Inmed. “In this analysis, TPIP demonstrated sustained improvement across all efficacy endpoints and was well tolerated with no newly identified safety signals, and notably, patients who switched from placebo to TPIP in the OLE study achieved similar clinical benefit. These data, coupled with the statistically significant and clinically meaningful results from our Phase 2b randomized study, demonstrate TPIP’s potential to become the prostanoid of choice for PAH patients, and we remain excited to be advancing our Phase 3 PALM-PAH study.” Results for secondary efficacy endpoints demonstrated sustained improvement with TPIP in six-minute walk distance (6MWD), N-terminal fragment pro-B-type natriuretic peptide (NT-proBNP) concentration, and World Health Organization (WHO) Functional Class, as well as a clinically meaningful improvement in REVEAL Lite 2.0 score at Month 12. Patients in the Placebo Crossed group (N=31) showed similar outcomes to patients in the TPIP Continued group (N=60) across all efficacy measures at Month 12. The results at Month 12 were as follows: Mean improvement from baseline for 6MWD was +55.7 meters for the TPIP Continued group and +54.1 meters for the Placebo Crossed group; NT-proBNP concentration was reduced by approximately 60% in both groups with geometric mean ratios [GMR] to

baseline of 0.40 and 0.41 in TPIP Continued and Placebo Crossed, respectively; WHO Functional Class I or II was achieved in 78.3% of TPIP Continued group and 80.6% of Placebo Crossed group patients, and more than 25% of patients across both groups achieved WHO Functional Class I; and mean REVEAL Lite 2.0 score improved 2.0-points from baseline for the TPIP Continued group and 1.4-points from baseline for the Placebo Crossed group. Approximately 65% of all patients achieved Refined Low Risk status, which is associated with a less than 5% estimated risk of mortality at three years and an approximately 7% risk of clinical worsening at one year. “Pulmonary arterial hypertension is one of the most devastating diseases we face as clinicians, and these results from the ongoing TPIP OLE study give us genuine reason for optimism,” said Dr. Raymond Benza, M.D., F.A.C.C., FAHA, FACP, Phase 2b PAH study Steering Committee Member, George M. and Linda H. Kaufman Academic Chair of Cardiology, Sentara Health. “The REVEAL Lite 2.0 risk score provides a powerful, non-invasive way to track disease trajectory. Previous REVEAL Lite 2.0 validation showed that a 1-point score improvement reduces risk of mortality by 23% and reduces the risk of clinical worsening by 21%. Here we saw that patients on TPIP averaged a greater than 1-point improvement from baseline, which is really meaningful for patients. Sustained improvements of this magnitude, alongside gains in exercise capacity and Functional Class, provide a strong clinical rationale to advance this therapy into Phase 3 development.” Results for the primary endpoint of safety & tolerability showed that once-daily TPIP therapy was generally well tolerated with no newly identified safety signals at doses up to 1,280 µg through Month 12. Of the 91 patients in the study, treatment-emergent adverse events (TEAEs) occurred in 89.0% of patients; serious TEAEs were observed in

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18.7% of patients; and severe TEAEs were observed in 16.5% of patients in the study. TEAEs leading to study discontinuation were experienced by 7.7% of patients. There were four deaths, none of which were considered related to TPIP treatment. The most common TEAEs through Month 12 occurring in 5.0% or more of all patients were headache (28.6%), cough (15.4%), nasopharyngitis (14.3%), diarrhea (11.0%), upper respiratory tract infection (9.9%), bronchitis (7.7%), dizziness (6.6%), epistaxis (6.6%), nausea (6.6%), anemia (5.5%), influenza (5.5%), and pneumonia (5.5%). The 12-Month OLE findings support the continued clinical development of TPIP and the recent initiation of PALM-PAH, a Phase 3, randomized, double-blind, placebo-controlled trial evaluating once-daily TPIP in patients with PAH over 24 weeks. The primary endpoint of PALM-PAH is change in 6MWD, with additional assessments of safety, tolerability, and overall efficacy. Insmed plans to publish the 12-Month results from this OLE study in the future. Topline results from the Phase 2b study of TPIP in patients with PAH were previously reported in June 2025.

Can Early Metformin Treatment Prevent Long COVID Symptoms?

A 14-day course of metformin during acute COVID did not definitively prevent long-term symptoms at 6 months. However, relatively fewer long COVID cases were diagnosed, with no major safety signals. In a quadruple-blinded, randomized controlled platform trial (ACTIV-6) of repurposed treatments for COVID, researchers assessed whether early metformin reduced long-term symptoms in patients with mild-to-moderate disease. They included 2983

patients aged 30 years or older who tested positive for SARS-CoV-2 infection within 10 days and had at least two symptoms for up to 7 days; the median age of the patients was 47 years, and 63.4% were women. Patients were randomly assigned to receive either metformin or a matching placebo for 14 days, with the metformin dose starting at 500 mg once daily and increasing to 500 mg in the morning and 1000 mg in the evening. The primary outcome was

mortality or COVID-related symptoms at day 180. Secondary outcomes included symptoms at days 90 and 120, clinician-diagnosed long COVID, and symptom burden. The analysis used a statistical measure called the posterior probability of efficacy (PPE), and a threshold of 0.975 was required to declare metformin effective for the primary outcome. At day 180, 2.3% of patients receiving metformin and 3.0% of those receiving placebo reported COVID-related symptoms, with a statistically nonsignificant difference in risk. No deaths occurred. The PPE for preventing the primary outcome was 0.83, indicating that the trial did not meet its prespecified threshold for efficacy. At day 180, 0.56% of the patients receiving metformin and 1.17% of those receiving placebo had clinician-diagnosed long COVID, corresponding to nearly half the relative risk (although the finding was of borderline significance). The

absolute risk difference between the metformin and placebo groups was not significant. "While a low event rate makes it challenging to evaluate therapeutics, it is encouraging that the proportion of participants reporting new clinician diagnosis of long COVID at 6 months was low," the authors of the study wrote.

Continued on page 46...



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AARC PREVIEW

Bio-Med Devices

Booth 925

What products will you be presenting at AARC?

- TV-100 Transport Ventilator
- Crossvent Ventilators
- OxyMinder® Pro Oxygen & Pressure Monitor
- OxyMinder® Oxygen Monitor
- Bio-Med Devices Air/Oxygen Blenders

Are there any new or featured products to highlight?

Our featured product is the **OxyMinder® Pro**, our touchscreen oxygen and pressure monitor designed for use with Bio-Med Devices Air/Oxygen Blenders. The OxyMinder® Pro continuously monitors both oxygen concentration and pressure, allows users to set high and low alarm limits, and helps simplify patient monitoring with an intuitive touchscreen interface.

What educational or training materials will you offer?

We will have our full line of product brochures available for attendees, along with a scrolling informational presentation detailing our offerings. Throughout the conference, our clinical team will provide live product demonstrations and in-service training on our ventilators, and on the OxyMinder® Pro. We are also working on an online CEU program covering High Frequency Jet Ventilation (HFJV) used in conjunction with conventional ventilation.

Will you feature any speakers or presentations?

Our clinical specialists, Mike Smith and Mike MacGregor, will be at the booth throughout the conference providing product education, clinical insights, and answering questions about our ventilation solutions.

Why should attendees visit your booth?

Attendees will have the opportunity to speak directly with our experienced clinical team and receive hands-on demonstrations of our products. We'll have two fully operational ventilator setups running on test lungs, including a Crossvent paired with a Bunnell Jet Ventilator, allowing visitors to see the systems in action. Visitors can also enter our raffle to win a pair of Apple AirPods.

Will you offer promotions, giveaways, or incentives?

Yes. Visitors can enter our booth raffle for a chance to win a pair of Apple AirPods.

Will there be live demonstrations or hands-on experiences?

Yes. Our team will be conducting live demonstrations throughout the conference, giving attendees the opportunity to see our ventilators in operation, ask questions, and gain hands-on experience with our products.

Who is the ideal attendee for your booth?

Our booth is ideal for:

- Respiratory Therapists (RRTs)
- Neonatal and Pediatric Clinicians
- ICU and NICU Clinical Staff
- Transport Teams
- Biomedical Engineers and Technicians
- Hospital Purchasing and Materials Management

- Clinical Educators and Department Leaders
- Distributors and OEM Partners

Will you present any new clinical data or outcomes?

We will not be presenting new clinical data. Instead, our focus will be on product education, clinical applications, and demonstrating how our ventilation and oxygen delivery solutions support patient care across neonatal, pediatric, transport, and critical care environments.

How can attendees connect with your team?

Attendees can visit our booth to speak with our sales and clinical teams, take product information and educational resources, or connect with us online at www.biomeddevices.com. Our team will also be available throughout the conference to schedule follow-up demonstrations and answer any additional questions.

Breas Medical, Inc.

Booth 525

What products will you be presenting at AARC?

- Vivo 45LS life support ventilator
- Vivo 2 bilevel
- Clearo cough assist
- NEW — Apto Full Face and Nasal Masks, pending 501(k) Clearance

Are there any new or featured products to highlight?

- NEW — Apto Full Face and Nasal Masks (pending 510(k) clearance) support sound sleep with a flexible endoskeleton and no hard plastic offering premium softness and a confident, comfortable fit.
- Vivo 45LS has been reimaged with the most significant upgrade to the Vivo 45LS since its launch, featuring powerful enhancements and capabilities that elevate performance and usability.
- Attendees can also experience the Clearo® cough assist system through a hands-on demonstration. The booth will feature a Clearo station where visitors can program the TreatRepeat® feature using the handheld remote and listen to the audible alert with Synchrony Beep®.

What educational or training materials will you offer?

Printed product literature and educational resources will be available in the booth. Additional materials, including webinars, white papers, and clinical presentations, can be accessed through Education by Breas® (educationbybreas.com), our online educational portal. Product information and resources are also available at breas.us.

Why should attendees visit your booth?

The booth offers hands-on demonstrations of the Vivo 45LS®, Vivo 2®, and Clearo®, as well as a fitting station for the the Apto Full and Nasal Masks (pending 510(k) clearance), providing attendees with an opportunity to evaluate key features and applications firsthand.

Will you offer promotions, giveaways, or incentives?

Attendees are encouraged to visit the booth and speak with their Breas representative for details.

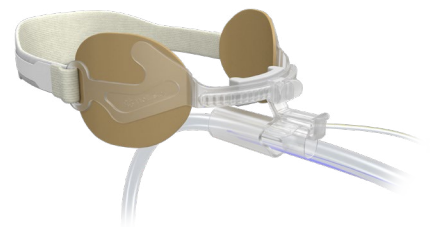


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Shown: AnchorFast Guard™
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Will there be live demonstrations or hands-on experiences?

Yes. Attendees are welcome to visit our mask fitting station to trial the Apto Full and Nasal Masks (pending 510(k) clearance). This hands-on experience allows participants to evaluate the comfort and fit of the masks and experience the benefits of their unique, patented endoskeleton design firsthand.

Additionally, hands-on demonstrations of the Vivo 45LS, Vivo 2, and Clearo will be available throughout the event. Attendees can explore product features firsthand, including the TreatRepeat® and Synchrony Beep® functions on the Clearo® cough assist.

Who is the ideal attendee for your booth?

The ideal attendee is any healthcare professional seeking a more comfortable mask for their patient, or information on ventilation and airway clearance solutions.

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Supporting the Most Vulnerable

Advancing pediatric home monitoring with elevated solutions

For families caring for a child with a respiratory condition, every moment matters.

A drop in oxygen saturation may be the first sign of clinical deterioration, and early recognition can mitigate escalation or unnecessary hospitalizations.¹ At the same time, parents want their children to live as normally as possible, going for walks, playing at home, and sleeping soundly without the constant shadow of worry.

Pulse oximetry has become a cornerstone of pediatric respiratory care in both clinical and home care settings. This noninvasive, immediate measure of blood oxygen saturation (SpO₂) and pulse rate allows caregivers and clinicians to act quickly when changes occur.

Yet monitoring children at home presents challenges. Devices not designed for pediatric patients may not be suited for smaller bodies, can trigger nuisance alarms, and add stress for families already under pressure.² These issues often translate into frequent calls to Durable Medical Equipment (DME) and Home Medical Equipment (HME) providers, increasing service demands and eroding caregiver trust.

That is why an increasing number of DME and HME providers are turning to Nonin Medical's Model 7500 tabletop pulse oximeter, paired with 6000C disposable cloth sensors. Together, these solutions deliver the accuracy,^{3,4} portability, and ease of use that pediatric home care demands.

The clinical imperative for pediatric oximetry at home

Clinical guidelines from leading organizations like the American Academy of Pediatrics (AAP) and the American Thoracic Society (ATS) recommend pulse oximetry as a standard tool for managing both acute and chronic pediatric conditions.^{4,5}

These range from bronchiolitis and pneumonia to bronchopulmonary dysplasia, pulmonary hypertension, and sleep-related breathing disorders.

Studies show that accurate oximetry helps detect hypoxemia early, supports timely access to oxygen therapy, and supports better triage decisions in outpatient care.^{6,7}

At home, pulse oximetry extends those same benefits into daily life. For families, it confirms that therapy plans—whether supplemental oxygen, ventilatory support, or careful observation—are being safely implemented outside the hospital.

The challenges of at-home monitoring

Monitoring a child in a controlled hospital ward is one thing; doing so in the unpredictability of daily home life is another. Parents and caregivers are tasked with balancing clinical vigilance with everyday routines, and they need devices that can adapt to those realities.

Examples of common challenges in pediatric home care include:

- **Motion and activity:** Infants wriggle, toddlers wander, and children play, all of which can generate motion artifacts that mimic dangerous desaturations.⁸
- **Small anatomy:** Generic or adult pulse oximeters are not sized for children and may not be indicated for use in pediatric patients.
- **Alarm fatigue:** When alarms trigger too frequently without clinical cause, caregivers may begin to ignore them—risking delayed responses when true desaturation occurs.
- **Usability:** Devices must be intuitive enough for non-clinicians to operate correctly and trust fully.

Research confirms these issues. Infants monitored at home with non-optimized devices experience high rates of false alarms, increasing caregiver stress and reducing confidence.^{2,9} Parents themselves cite nuisance alarms and unreliable readings as major barriers to effective monitoring.²

For DME and HME providers, these challenges underscore the importance of selecting equipment designed specifically for pediatric patients. Technology that reduces false alarms, strengthens caregiver confidence, and minimizes service calls helps support patient management while delivering the best care possible in a cost-effective way.



The Nonin Model 7500: Built for confidence

Nonin's Model 7500 tabletop pulse oximeter is recognized for its accuracy in pediatric home care.³ Weighing just two pounds and small enough to fit neatly on a nightstand or tabletop, it combines that clinical-grade accuracy with features tailored to the realities of home use.



Accuracy Without Compromise

Many pulse oximeters tend to overestimate oxygen saturation in patients with darker skin pigmentation.⁹ The Model 7500 features Nonin PureSAT[®] signal processing, delivering accurate measurements in motion and low perfusion, helping clinicians make more informed decisions.³

Proven Durability

Both families and providers value equipment that can withstand daily use. The Model 7500 has durability that lasts. Since 2014, fewer than 4% of units required repairs after their three-year warranty expired.³ This reliability reduces costly service calls for providers and ensures families are not left without monitoring.

Easy To Use

Clear, color-coded bar graphs and audible indicators make readings easy to interpret at a glance, while customizable alarms adapt to patient needs. The intuitive interface reduces training time and supports both families and providers.

Long Battery Life

The Model 7500 supports uninterrupted, portable monitoring outside the home or during power outages. With up to 16 hours of runtime with a four-hour recharge, the device lasts four times longer than leading competitors like the Masimo Rad-97.¹⁰

Fewer False Alarms³

One of the most important innovations in the Model 7500 is Hybrid Averaging[™], a feature designed specifically to reduce nuisance alarms, which may result in fewer callbacks.³

By smoothing out transient SpO₂ changes caused by motion while still responding quickly to true desaturations, Hybrid Averaging helps parents and clinicians focus on what matters—real events that demand action.

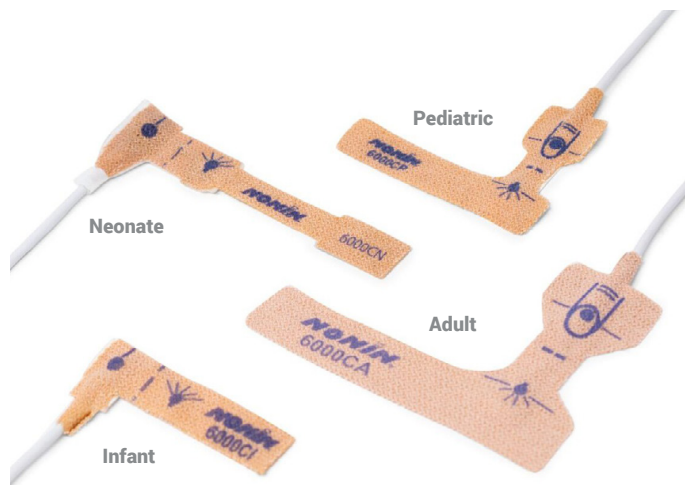


6000C Disposable Sensors: Designed for comfort and accuracy

Accurate oximetry depends not only on the device but also on the sensor. Standard adult sensors are not suitable for small, active patients and may contribute to false alarms and caregiver frustration.² The 6000C Series disposable cloth sensors from Nonin Medical are engineered for pediatric use, with dedicated pediatric, infant, and neonatal sizes that help support both comfort and accuracy.

Key benefits of the 6000C sensors for at-home pediatric monitoring include:

- **Breathable, stretchable cloth** for comfort during extended monitoring
- **Tear-resistant material for secure placement**, even with active infants and children
- **Comprehensive sizing** from neonate to adult patients
- **PureLight[®] LEDs with PureSAT[®] processing** for consistent accuracy³



Impact where it matters most

The Model 7500 tabletop pulse oximeter with 6000C disposable cloth sensors from Nonin Medical delivers measurable value for families and providers, empowering caregivers to act quickly while giving children the freedom to live more fully.

Peace of mind at home

- Accurate readings, even when children are in motion³
- Alarms families can trust, not ignore
- Comfortable, secure sensors designed for pediatric patients

Confidence in the field

- Devices that minimize service calls and training time
- Fewer frustrated families and more satisfied customers
- A reputation for delivering technology that works in real-world home settings

Value beyond the clinic

While clinical performance is essential, DME and HME providers also need solutions that support their business objectives. The Model 7500 tabletop oximeter and 6000C sensors deliver value across the board.

- **Total cost of ownership:** fewer repairs, fewer service calls, and longer device lifespans.
- **Industry-leading warranty** with three years of coverage, compared to one year from leading competitors, which minimizes risk and replacement costs.¹⁰
- **Higher customer satisfaction** thanks to intuitive and comfortable equipment that families trust.
- **More efficient support** through Nonin's dedicated product team, helping resolve issues quickly and reduce provider burden.

Nonin Medical solutions safeguard clinical outcomes while strengthening the provider-patient relationship that DME and HME professionals depend on.

Raising the standard in pediatric home monitoring

Pulse oximetry is more than a number on a screen—it is a lifeline for children with respiratory conditions and a reassurance for the families who care for them. But not all devices are created with pediatric patients in mind.

The Nonin Model 7500 pulse oximeter, paired with 6000C disposable sensors, combines clinical accuracy and pediatric-specific usability to meet the unique demands of pediatric home care.^{3,4}

When caring for the most vulnerable, accuracy is essential—and when it comes to at-home care, ease of use becomes just as critical. With Nonin Medical, providers can deliver both.

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Continued on page 21...



Data you can trust.

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Nonin Model 7500 Pulse Oximeter
with Hybrid Averaging™
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Easy to use
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Fewer false
alarms¹

nonin.com/products/7500

¹ Nonin Medical, Inc. Data on File.

Beyond Air LungFit® PH: Bedside Nitric Oxide Generation and the Evolution of Inhaled NO Delivery in Neonatal Respiratory Care

The Editors of Respiratory Therapy

Persistent pulmonary hypertension of the newborn (PPHN) and hypoxic respiratory failure remain among the most serious respiratory challenges encountered in neonatal intensive care. In affected infants, elevated pulmonary vascular resistance impairs pulmonary blood flow and oxygenation, often resulting in severe hypoxemia despite aggressive ventilatory support. Over the past several decades, inhaled nitric oxide (iNO) therapy has become an established component of treatment for term and near-term neonates with hypoxic respiratory failure associated with pulmonary hypertension.

The physiologic role of inhaled nitric oxide is well understood within neonatal respiratory care. Delivered directly into the pulmonary circulation, nitric oxide functions as a selective pulmonary vasodilator, improving ventilation-perfusion matching while minimizing systemic hypotension. In clinical practice, successful iNO therapy depends not only on patient selection and ventilatory management, but also on the consistent and uninterrupted delivery of nitric oxide at the bedside.

Traditionally, inhaled nitric oxide systems have relied upon high-pressure gas cylinders as the source of nitric oxide delivery. While clinically effective, cylinder-based systems introduce logistical and operational considerations that extend beyond patient physiology alone. Hospitals must manage cylinder storage, replacement, transport, inventory control, and system continuity, particularly in high-acuity environments such as the NICU where uninterrupted respiratory support is critical.

The LungFit® PH system from Beyond Air approaches inhaled nitric oxide delivery through a different model. Rather than relying on high-pressure, compressed gas cylinders, the system generates nitric oxide from ambient room air at the bedside. This distinction is operationally significant because it shifts nitric oxide therapy from a supply-dependent gas delivery model toward an on-demand generation system integrated into the environment where it is needed.

From a clinical standpoint, the relevance of this approach lies in the continuity and accessibility of inhaled nitric oxide therapy. In neonatal respiratory care, maintaining consistent pulmonary vasodilator delivery is an important operational consideration during therapy administration. By generating nitric oxide continuously at the bedside, the LungFit PH system is designed to remove dependency on cylinder replacement logistics and simplify aspects of therapy management.

Equally important is the system's integrated monitoring capability. Inhaled nitric oxide delivery requires careful monitoring not only

of nitric oxide concentration itself, but also nitrogen dioxide (NO₂) levels and oxygen concentration within the delivered gas mixture. Excessive NO₂ exposure may pose safety concerns, particularly in vulnerable neonatal populations with fragile lung tissue and evolving respiratory pathology. The unique design of the LungFit PH device allows for a variable concentration of Nitric Oxide to be produced on demand further reducing the risk of excessive NO₂ exposure to both patient and care provider.

The LungFit PH system incorporates integrated monitoring and alarm systems intended to support real-time awareness of delivered therapy conditions. This monitoring structure is clinically relevant because inhaled nitric oxide therapy functions within a narrow therapeutic and safety framework where both under-delivery and excessive byproduct exposure may influence patient management decisions.

In neonatal respiratory care, bedside respiratory technology is increasingly evaluated not solely on therapeutic capability, but also on workflow integration, situational awareness, and operational reliability. NICU environments are characterized by continuous monitoring demands, multiple respiratory support modalities, and rapidly changing patient conditions. Systems that simplify respiratory care logistics while maintaining therapy continuity may help reduce operational complexity in high-acuity settings.

The relevance of LungFit PH is therefore not limited to nitric oxide therapy itself—which remains an established clinical intervention—but extends to the infrastructure through which that therapy is delivered. By generating nitric oxide on demand from room air, the system represents a shift in how inhaled nitric oxide support may be integrated into neonatal respiratory care operations.

This distinction may be particularly meaningful in settings where nitric oxide utilization varies significantly, where rapid therapy initiation is important, or where transportation and storage of compressed gas cylinders present operational challenges. In these environments, bedside nitric oxide generation may offer workflow advantages while preserving the physiologic goals of selective pulmonary vasodilation and oxygenation support.

It is important to note that LungFit PH does not alter the fundamental therapeutic principles of inhaled nitric oxide therapy. Clinical management of hypoxic respiratory failure, ventilatory support strategies, oxygenation targets, and pulmonary hypertension treatment protocols remain dependent on clinician judgment and institutional practice standards. Rather, the

system's relevance lies in the method of nitric oxide generation and delivery infrastructure surrounding established neonatal care practices.

From a broader respiratory care perspective, the system aligns with ongoing trends toward integrated bedside technology, simplified device logistics, and enhanced continuity of critical respiratory therapies. As NICUs continue to emphasize stability, rapid intervention, and workflow efficiency, technologies that reduce dependency on external supply chains while maintaining therapeutic consistency may become increasingly relevant within neonatal practice.

In summary, the Beyond Air LungFit® PH system is clinically relevant within neonatal respiratory care for its ability to generate inhaled nitric oxide directly from room air at the bedside. By reducing reliance on traditional compressed gas infrastructure and supporting uninterrupted nitric oxide therapy, the system reflects an evolving approach to the operational delivery of pulmonary vasodilator support in the NICU environment.

Supporting the Most Vulnerable...continued from page 19
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10 Compared directly to the Masimo Rad-97 Tabletop. See <https://www.masimo.com/products/continuous/rad97/>

LungFit® PH

ALL YOU NEED IS AIR®

The first and only FDA approved system that **generates unlimited iNO from room air.**

Ease of Use

Initiate iNO therapy quickly & simply

Cost Control

Competitive pricing and predictable consumption

Sustainable

Clean iNO generation without tanks or chemicals

Reliable Support

Customer-centric iNO delivery



Discover the future of **tankless Nitric Oxide today!**

Indication for Use: The LungFit® PH System is indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term neonates with hypoxic respiratory failure associated with pulmonary hypertension. Refer to full Prescribing Information in the Operator's Manual before use.

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O₂ (%)

21

NO (ppm)

0.0

NO (ppm)

20

MAIN SYSTEM

Backup System

NO Flow Release

NO Flow Location

Beyond Air

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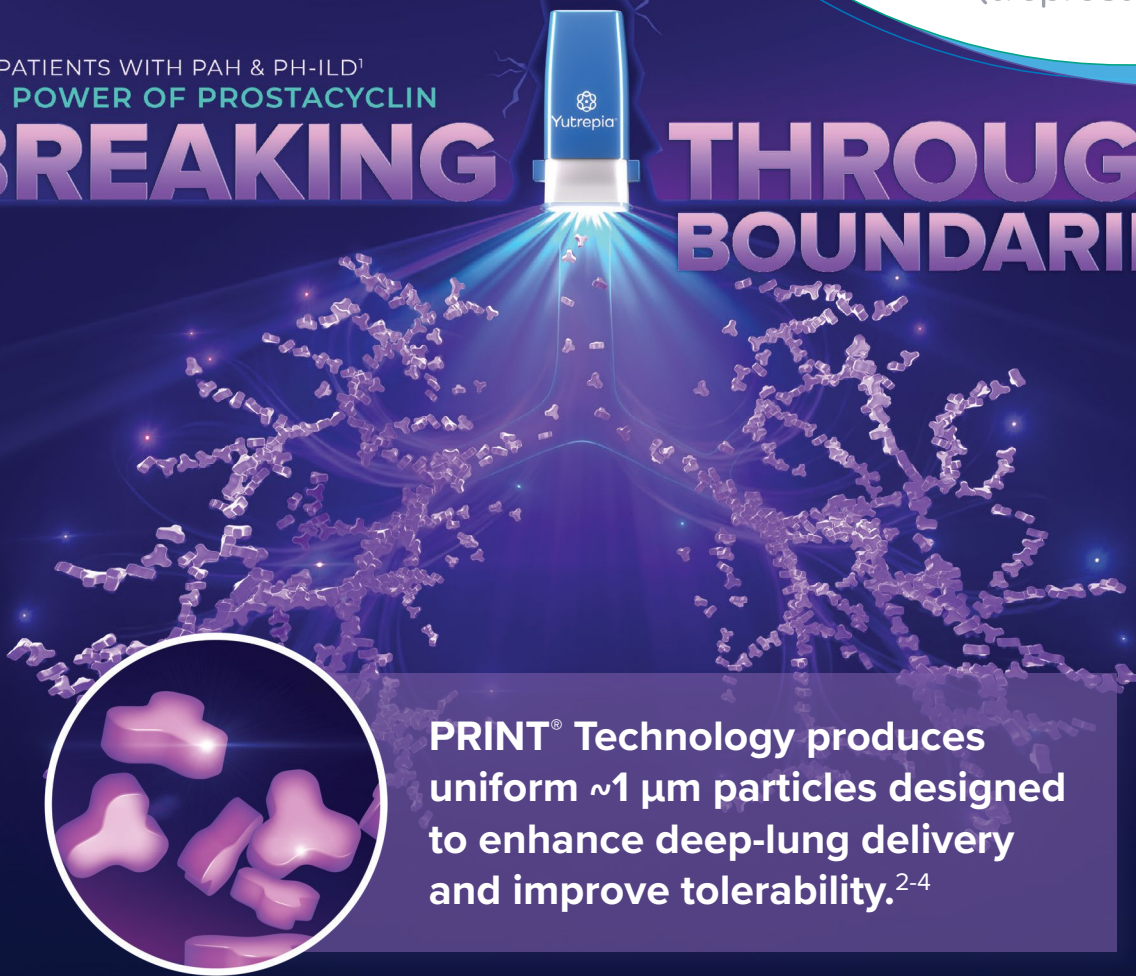
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PRINT[®] Technology produces uniform ~1 µm particles designed to enhance deep-lung delivery and improve tolerability.²⁻⁴

INDICATION

YUTREPIA[®] (treprostinil) is a prostacyclin mimetic indicated for the treatment of:

- Pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability. Studies establishing effectiveness predominately included patients with NYHA Functional Class III symptoms and etiologies of idiopathic or heritable PAH (56%) or PAH associated with connective tissue diseases (33%).
- Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability. The study establishing effectiveness predominately included patients with etiologies of idiopathic interstitial pneumonia (IIP) (45%) inclusive of idiopathic pulmonary fibrosis (IPF), combined pulmonary fibrosis and emphysema (CPFE) (25%), and WHO Group 3 connective tissue disease (22%).

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- Treprostinil is a pulmonary and systemic vasodilator. In patients with low systemic arterial pressure, treatment with treprostinil may produce symptomatic hypotension.
- Treprostinil inhibits platelet aggregation and increases the risk of bleeding.
- Co-administration of a cytochrome P450 (CYP) 2C8 enzyme inhibitor (e.g., gemfibrozil) may increase exposure (both C_{max} and AUC) to treprostinil. Co-administration of a CYP2C8 enzyme inducer (e.g., rifampin) may decrease exposure to treprostinil. Increased exposure is likely to increase adverse events associated with treprostinil administration, whereas decreased exposure is likely to reduce clinical effectiveness.

Please see Brief Summary of Prescribing Information on following page. For more information about YUTREPIA, including Full Prescribing Information and Instructions for Use, please visit www.YUTREPIAhcp.com.



References: 1. YUTREPIA. Prescribing information. Liquidia Technologies, Inc; 2025. 2. Hill NS, Feldman JP, Sahay S, et al; INSPIRE study investigators. INSPIRE: safety and tolerability of inhaled Yutrepia (treprostinil) in pulmonary arterial hypertension (PAH). *Pulm Circ.* 2022;12(3):e12119. doi:10.1002/pul2.12119 3. Garcia A, Mack P, Williams S, Fromen C, et al. Microfabricated engineered particle systems for respiratory drug delivery and other pharmaceutical applications. *J Drug Deliv.* 2012;2012:941243. doi:10.1155/2012/941243 4. Roscigno RF, Vaughn T, Parsley E, Hunt T, et al. Comparative bioavailability of inhaled treprostinil administered as LIQ861 and Tyvaso[®] in healthy subjects. *Vascul Pharmacol.* 2021;138:106840. doi:10.1016/j.vph.2021.106840

BRIEF SUMMARY OF PRESCRIBING INFORMATION FOR YUTREPIA® (treprostinil) inhalation powder, for oral inhalation

SEE PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

INDICATIONS AND USAGE

YUTREPIA® is a prostacyclin mimetic indicated for the treatment of:

- Pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability. Studies establishing effectiveness predominately included patients with NYHA Functional Class III symptoms and etiologies of idiopathic or heritable PAH (56%) or PAH associated with connective tissue diseases (33%).

The effects diminish over the minimum recommended dosing interval of 4 hours; treatment timing can be adjusted for planned activities.

While there are long-term data on use of treprostinil by other routes of administration, nearly all controlled clinical experience with inhaled treprostinil has been on a background of bosentan (an endothelin receptor antagonist) or sildenafil (a phosphodiesterase type 5 inhibitor). The controlled clinical experience was limited to 12 weeks in duration.

- Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability. The study establishing effectiveness predominately included patients with etiologies of idiopathic interstitial pneumonia (IIP) (45%) inclusive of idiopathic pulmonary fibrosis (IPF), combined pulmonary fibrosis and emphysema (CPFE) (25%), and WHO Group 3 connective tissue disease (22%).

DOSAGE AND ADMINISTRATION

Please see Full Prescribing Information for complete information.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Risk of Symptomatic Hypotension: Treprostinil is a pulmonary and systemic vasodilator. In patients with low systemic arterial pressure, treatment with treprostinil may produce symptomatic hypotension.

Risk of Bleeding: Treprostinil inhibits platelet aggregation and increases the risk of bleeding.

Effect of Other Drugs on Treprostinil: Co-administration of a cytochrome P450 (CYP) 2C8 enzyme inhibitor (e.g., gemfibrozil) may increase exposure (both C_{max} and AUC) to treprostinil. Co-administration of a CYP2C8 enzyme inducer (e.g., rifampin) may decrease exposure to treprostinil. Increased exposure is likely to increase adverse events associated with treprostinil administration, whereas decreased exposure is likely to reduce clinical effectiveness.

Bronchospasm: Like other inhaled prostaglandins, YUTREPIA may cause acute bronchospasm. Patients with asthma or chronic obstructive pulmonary disease (COPD), or other bronchial hyperreactivity, are at increased risk for bronchospasm. Ensure that such patients are treated optimally for reactive airway disease prior to and during treatment with YUTREPIA.

ADVERSE REACTIONS

Clinical Trials Experience: The safety and tolerability of YUTREPIA was evaluated in an open label study (INSPIRE) of 121 patients with PAH (WHO Group 1 and NYHA Functional Class II [80 patients] and Class III [41 patients]) followed for up to 2 months.

Adverse Reactions Occurring in ≥4% of Patients in the INSPIRE Study

Adverse Reaction	Transition ^a ; n=55	Add-On ^b ; n=66
	n (%)	n (%)
Cough	15 (27)	36 (55)
Headache	14 (25)	18 (27)
Throat Irritation	5 (9)	14 (21)
Dizziness	6 (11)	7 (11)
Diarrhea	3 (6)	8 (12)
Chest Discomfort	5 (9)	5 (8)
Nausea	4 (7)	5 (8)
Dyspnea	3 (6)	3 (5)
Flushing	1 (2)	5 (8)
Oropharyngeal Pain	1 (2)	4 (6)

^aTransition: Patients were on stable doses of treprostinil inhalation solution for at least 3 months prior to enrollment in the study and transitioned to treatment with YUTREPIA.

^bAdd-on: Patients were prostacyclin-naïve and were taking no more than 2 approved oral PAH therapies for at least 3 months at time of enrollment and addition of treatment with YUTREPIA.

The adverse reactions in the INSPIRE study were consistent with those observed in previous studies of inhaled treprostinil.

Adverse Reactions Identified in Post-Marketing Experience:

Angioedema has been identified during the post-approval use of treprostinil inhalation solution.

DRUG INTERACTIONS

Effect of Cytochrome P450 Inhibitors and Inducers: Co-administration of an oral formulation of treprostinil (treprostinil diolamine) with the CYP2C8 enzyme inhibitor gemfibrozil increases exposure (both C_{max} and AUC) to treprostinil. Co-administration of the CYP2C8 enzyme inducer rifampin decreases exposure to treprostinil. It is unclear if the safety and efficacy of treprostinil by the inhalation route are altered by inhibitors or inducers of CYP2C8.

Effect of Other Drugs on Treprostinil: Co-administration of treprostinil (oral or subcutaneous) with acetaminophen (4 g/day), warfarin (25 mg/day), or fluconazole (200 mg/day) did not affect the pharmacokinetics of treprostinil. Treprostinil did not affect the pharmacokinetics or pharmacodynamics of warfarin.

USE IN SPECIFIC POPULATIONS

Pregnancy – Risk Summary: Limited case reports of treprostinil use in pregnant women are insufficient to inform a drug-associated risk of adverse developmental outcomes. However, there are risks to the mother and the fetus associated with pulmonary arterial hypertension. In animal studies, no adverse reproductive and developmental effects were seen for treprostinil at >9 and >145 times the human exposure when based on C_{max} and AUC, respectively, following a single YUTREPIA dose of 79.5 mcg. The estimated background risk of major birth defects and miscarriage for the indicated populations is unknown.

Lactation – Risk Summary: There are no data on the presence of treprostinil in human milk, the effects on the breastfed infant, or the effects on milk production.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use: Placebo-controlled clinical studies of treprostinil inhalation solution did not include sufficient numbers of patients aged 65 years and over to determine whether they respond differently from younger patients. The open-label INSPIRE study in PAH patients included 28 patients aged 65 and over in which no age-related differences were noted. In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of hepatic, renal, or cardiac dysfunction, and of concomitant diseases or other drug therapy.

Patients with Hepatic Insufficiency: Plasma clearance of treprostinil, delivered subcutaneously, was reduced up to 80% in subjects with mild-to-moderate hepatic insufficiency. Uptitrate slowly when treating patients with hepatic insufficiency because of the risk of an increase in systemic exposure which may lead to an increase in dose-dependent adverse effects. Treprostinil has not been studied in patients with severe hepatic insufficiency.

Patients with Renal Insufficiency: No dose adjustments are required in patients with renal impairment. Treprostinil is not cleared by dialysis.

OVERDOSAGE

In general, symptoms of overdose with treprostinil include flushing, headache, hypotension, nausea, vomiting, and diarrhea. Provide general supportive care until the symptoms of overdose have resolved.

PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Instructions for Use). Train patients in the administration process for YUTREPIA, including dosing, inhaler preparation, administration, cleaning, and maintenance, according to the instructions for use. To avoid potential interruptions in drug delivery because of equipment malfunction, patients should have access to a back-up. In the event that a scheduled dose is missed, take another dose as soon as possible.

Taking Steps Towards Recovery: Mobilizing Patients on Advanced Respiratory Support with the New UPS Battery Designed for Better Respiratory Care

Emory University Hospital Respiratory Therapy Department

In this feature, Respiratory Therapy interviews clinicians on a game-changing innovation in the medical field: UPS battery system purpose-built for patients on advanced respiratory support. Designed to deliver uninterrupted power, unmatched mobility, and peace of mind, this breakthrough allows clinicians to safely mobilize patients without compromising life-sustaining equipment. Participating in the interview are Soumaya Osen PhD, MHA, RRT, RRT-NPS, RRT-ACCS, Respiratory Clinical Specialist, Ryan P. Echols MBA, RRT-ACCS, Emory University Division Director of Respiratory Care, EKG, & Pulmonary Lab services, Darcy Crayton, MS, RRT, Assist. Director-Respiratory Care Division at Emory University Hospital Atlanta-Georgia, Dorothy H. Bendah, Clinical Manager-Respiratory Therapy, Zopec Medical

Please tell us about your hospital and the critical care you provide.

We are a large academic medical center in the Southeast of the US. We provide the highest quality of care to very complex medical conditions and diseases, such as infectious diseases, brain and neuro programs, cancer, orthopedics care (bone and spine), pediatrics, kidney, ophthalmology (eyes), comprehensive women healthcare services, geriatrics care, and transplantation including but not limited to lung, heart, liver, kidneys, and bone marrow. In addition, our academic medical center is one of nation's leading research universities with the goal of saving lives and strengthening partnerships.

How did you get to know about Zopec medical?

During the Covid-19 pandemic, we began ambulating patients on heated high flow oxygen because some battery powered devices offered the heated high flow software; however, we did not have the ability to heat the high flow during ambulation because the heaters did not include batteries. We were looking for a battery that supports the heaters. Some patients did not tolerate the cold high flow of oxygen, and we had to use a combination of a high flow oxygen via mask and a nasal cannula under the mask.

While in the process of looking for a battery that can be used with heaters, our respiratory department director, Ryan Echols, received a communication from Strong Huang, the founder and CEO of Zopec Battery. Ryan contacted Strong, and the trial-and-error process was initiated with different battery designs.

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 challenges have you experienced while transporting patients?

For our academic medical center, transporting patients while on heated high flow oxygen was challenging if the device did not include a battery with at least 60 minutes run time to account for round-trip transports. We are a large academic medical center with large buildings and bridges connecting the buildings.

In addition, the best way to transport patients on heated high flow oxygen is being able to run the device and heat the flow that is delivered to the patient. Heated high flow nasal cannula is not a non-rebreather mask. Heated high flow nasal cannula provides CPAP. If the patients are taken off the heated high flow nasal cannula when they are not ready, their lungs will de-recruit. Some patients might end up needing escalation of care to non-invasive mechanical ventilation or invasive mechanical ventilation when transported without heated high flow oxygen.

Having the ability to transport patients on heated high flow oxygen is extremely imperative to provide the safest care for our patients

What solutions were you considering for patient transport?

We were looking for a battery that can support the heated high flow oxygen devices and can heat the flow delivered to the patient during transport for 90 minutes.

How has the use of the UPS 90 Pure positively impacted patient safety in the hospital?

The first battery we purchased from Zopec Medical was the T60 with 60 minutes run time. Our respiratory care department director, Ryan, assistant director, Darcy, equipment supervisor, Tryon, and I, respiratory clinical specialist, collaborated with Strong Huang Founder and CEO at Zopec Medical to continue to improve the original 60 minutes battery (T60) until the UPS 90 Pure design met our patients' needs. UPS 90 Pure includes:

- 90 minutes run time
- Two outlets to plug electric cords
- Ability to zip tie the electric cords for better securements
- Two USB ports to connect devices that include USB connections
- Alarm system that alerts the clinicians when the battery is starting to run low
- Integrated mounting for easy transport
- Powering Airvo 2, Airvo 3, and ventilator heaters.

How does the 90 minutes run time meet your needs?

The 90 minutes run time met our patients' transports needs, and our mobility program needs. It allowed us to safely transport our patients who are on heated high flow oxygen back and forth between the buildings. It also allowed us to mobilize our patients and take them outside the hospital buildings for a breath of fresh air while keeping them on heated high flow oxygen.

Can you provide examples of how the UPS 90 Pure facilitates seamless transport?

We have dedicated Airvos on poles for transports. They are mounted on poles with three or four E cylinders and Zopec UPS 90 Pure. We have a high number of patients transports including patients who are on heated high flow oxygen. The UPS 90 Pure battery allows us to transport our patients who are on heated high flow oxygen safely as long as the round trip does not exceed 90 minutes.

We transfer the patients from the Airvo at the bedside to the transport Airvo. When we arrive at the transport destination, procedural area, imaging, etc. we plug the oxygen and battery to the wall to preserve the oxygen cylinders and the battery power.

We change the oxygen cylinders if they are below 1500 psi before leaving to the patient's room. With Zopec UPS 90 Pure we know we can safely transport the patients round trip up to 90 minutes.

Can you share the usability experience with UPS 90 Pure?

We use it for intra-hospital transports and for our mobility program when the patients are on heated high flow oxygen. UPS 90 Pure met our patients' needs.

How has Zopec shown commitment and responsiveness to the hospital's needs?

Strong Huang is very caring and collaborative. He listens to our needs. We were the first hospital to Trial Zopec batteries and start using them. With every model, we found what our needs are and asked Strong if he can improve the next model. After trial, the UPS 90 Pure was born with extra outlets, USB ports, and zip ties to secure cords. It meets our needs to transport and mobilize patients safely. Patient mobility is extremely crucial to optimize care, provide in hospital rehabilitation, and reduce ICU and hospital length of stay.

How does the investment in the Zopec UPS 90 Pure compare to other options used in the hospital?

Since there are not too many options available in the market for heated high flow oxygen with batteries run time of 90 minutes, and the need to have heated high flow oxygen devices that allow the delivery of inhaled medications during mobility and transports, Zopec UPS 90 Pure is the best option at this time.

It also allows the ventilators' heaters to heat when active humidity is in use. Mobilizing the patients while they are on the ventilators is part of the mobility programs and the ABCDEF Bundle.

UPS 90 Pure Battery System

Powering Safe Patient Mobility

- ✓ Ultra-light UPS (Uninterruptible Power Supply) Battery designed to provide **100% relative humidity during mobility**
- ✓ **Ambulates patients for 90 minutes** of heated high flow oxygen (F&P AirVo2, Telesair Bonhawa & more)
- ✓ **80 minutes of high flow or ventilation support** with MR850, FP950, H900, and Neptune respiratory humidifiers
- ✓ **Supports safe outdoor mobility**, giving critical care patients sun while **reducing delirium risk**
- ✓ Enables **faster healing, stronger rehab, and shorter hospital stays**
- ✓ **Supports mobility programs** before and after surgery
- ✓ Proven in hospitals to improve outcome and **prevent readmission**



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Inhaled Therapy Protocol — From the Emergency Department to Hospitalization

César Cinesi, Consuelo Alcalde, Ricardo Felipe Gil, María José Córcoles
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The administration of inhaled medication is common practice in the treatment of both chronic and acute lung diseases. The use of this technique allows the rapid and selective delivery of medication to the respiratory tract, reducing the prevalence of side effects.

There are different ways of administering inhaled medication, either through pressurized metered dose inhalers (MDI) or

nebulizers (ultrasonic, pneumatic/jet and vibrating mesh (VMN)). The method of administration determines the amount of drug that is deposited in the airways, while the inhalation technique developed by the patient and the anatomy of the airway also play a fundamental role.

Within nebulizers there are different types with varying characteristics:

NEBULIZER TYPE	JET/PNEUMATIC	ULTRASONIC	AEROGEN SOLO A-VMN™
OVERVIEW	Require a generating source (oxygen, air or compressor) at 6-8 l/min to nebulize the drug from the reservoir. They convert a liquid into small droplets (atomization), using the force of a pressurized gas.	Generate the aerosol by means of high-frequency vibrations through an ultrasonic generating unit formed by a piezoelectric crystal connected to an alternating electric current. They do not require additional flow.	Palladium vibrating mesh (does not heat or degrade the drug) that, when connected to a controller, vibrates at 128 thousand times per second producing an aerosol with a consistent particle size. No additional flow needed. If required, a flow of 1-6 l/min oxygen can be added in spontaneous breathing. Unique closed-circuit nebulization system.
AVERAGE PARTICLE SIZE	Not very consistent. The size of the particles depends on the solution (density, viscosity and surface tension) as well as the velocity and flow of the gas. The higher the flow, the smaller the size.	Consistent at first (0.5-3µm) but as soon as the volume of medication to be nebulized decreases, the particle size increases.	Consistent aerosol particle size (1-5 µm).
FLOW	Fast and turbulent.	Depends on the design and frequency of the ultrasonic waves.	Slow and laminar.
RESIDUAL VOLUME	Variable according to type and dilution. In some cases, reaching 4ml of the solution. Requires cleaning.	About 0.5 to 1 ml.	<0.1 ml for a 3ml dose. No cleaning required.
FUGITIVE EMISSIONS	Loss to the environment during the expiratory phase of between 60-70% of the dose given to the nebulizer (nominal dose).	Depends on the design and frequency of the ultrasonic waves.	It mitigates fugitive emissions by not adding flow and can be managed in a closed circuit. Spontaneous accessories reduce emissions (valved face mask, mouthpiece that connects to filter).
IN-LINE NEBULIZATION WITH VENTILATORY CIRCUIT	Circuit needs to be broken every time after each nebulisation.	Not compatible with a ventilator circuit.	Closed circuit nebulization without additional flow. Integrated into the world's leading ventilator manufacturers.
SOUND	Noisy.	Less noisy than jet nebulizers.	Silent.
TIME	15-20 min. Requires multiple steps and increased workflow.	N/A	5-10 min (0.38 ml/min). Ease of use and reduces workflow.
MEDICATIONS	Not suitable for nebulizing suspensions.	Nebulize large volumes but not appropriate for proteins and peptides, as they can heat and degrade the drug.	Suitable for solutions, suspensions, proteins and peptides. They may not nebulize crystallising medications.
PATIENT POPULATION	Pediatric and adult patients.	Not in < 3 years.	Neonatal, pediatric and adult patients.
DURATION	Use per patient. Depends on the manufacturer, cleanliness and number of uses.	N/A	28 days at 4 nebulizations per day. It accompanies the patient on their care pathway.

Inhaled Therapy Protocol – Emergency Department (ED):

In the emergency ventilatory unit, the inhaled therapy system is performed with an MDI and spacer chamber for spontaneously breathing patients unless there is an indication for nebulization. The indications for using nebulization as inhalation therapy are as follows:

- If after proper instruction and demonstration, the patient is unable to use an MDI with a spacer.
- Inspiratory vital capacity is less than 10.5 ml/kg.
- The inspiratory flow is less than 30 l/min.
- Pause in respiration less than four seconds.
- In patients with recurrent episodes of acute bronchial obstruction that compromise their ability to use inhalers.
- Patients with non-invasive or invasive respiratory support.

Nebulizations in the emergency ventilatory unit are performed through a vibrating mesh device (Aerogen Solo A-VMN™ and USB controller, Aerogen Ltd, Galway, Ireland). Therefore, treatment for the clinical scenarios is as follows:

Clinical scenario	Inhaled therapy
Spontaneously breathing patients (without respiratory support) with vital capacity greater than 10.5 ml/kg and inspiratory flow greater than 30 l/min	MDI with spacer
Spontaneously breathing patients (without respiratory support) with a vital capacity of less than 10.5 ml/kg or inspiratory flow of less than 30 l/min	Aerogen Solo A-VMN™
Patients undergoing non-invasive ventilation (NIV)	Aerogen Solo A-VMN™
Patients undergoing high flow nasal cannula (HFNC)	Aerogen Solo A-VMN™
Patients undergoing mechanical ventilation	Aerogen Solo A-VMN™

The drugs authorized in the hospital's protocol under medical prescription will be used. The Aerogen Solo A-VMN™ is approved to nebulize prescription inhaled medications that have been approved for use with a general-purpose nebulizer, as indicated in the table below.

Name	Class
Salbutamol	Short acting beta2 agonist
Ipratropium bromide	Anticholinergic
Salbutamol/ipratropium bromide	Short acting beta2 agonist and Anticholinergic
Dornase-Alfa (DNase)	Mucolytic Enzyme
Sodium chloride 0.9% (normal saline)	Diluent
Hypertonic Saline	Mucoactive agent
Colistin	Antibiotic

1. General procedure for using the MDI with a spacer:

- 1) Prepare the necessary material.
- 2) Follow the general recommendations for individual protection.
- 3) Perform hand hygiene according to the 5 moments of the World Health Organization. Use of gloves only when indicated.
- 4) Inform the patient of the procedure to be performed.
- 5) Uncover, and shake the inhaler vigorously.
- 6) Adapt the inhaler to the chamber.
- 7) Set the camera horizontally or upwards.
- 8) Place the mouthpiece of the chamber in the mouth, sealing the lips well, avoiding gaps on the sides and without covering it with your teeth or tongue.
- 9) Remove all the air slowly through the nozzle.

- 10) When the patient's chest is empty, press the inhaler.
- 11) Instruct the patient to start the inspiration slowly and once the end of the inspiration is reached, hold breath for 5-10 seconds.
- 12) Instruct the patient to initiate expiration slowly.
- 13) Perform the same procedure once again to empty the chamber completely.
- 14) Leave a minute of separation between actuations, shaking the inhaler before each actuation.
- 15) Instruct the patient to perform a mouthwash.

2. General procedure for the use of the Aerogen Solo A-VMN™

- 1) Prepare the necessary material.
- 2) Follow the general recommendations for personal protection (use of PPE according to current regulations), including prior hand hygiene.
- 3) Verify the physical integrity of the Aerogen Solo A-VMN™ and connection to the Aerogen USB controller.
- 4) Inform the patient of the procedure to be performed.
- 5) The patient will be placed in a position as upright as possible, with the back straight supported. In bedridden patients, it will be placed in the Fowler or semi-Fowler position.
- 6) Connect the nebulizer chamber to the controller using the controller cable. Check that the controller is operational and configured in the appropriate cycle: 30 min. mode or continuous mode depending on volume and prescription. Verify the connection of the Aerogen Solo A-VMN™ to the corresponding respiratory modality (spontaneous breathing, HFNC, NIV, mechanical ventilation)
- 7) Fill the nebulization chamber with the appropriate volume: 6 mL maximum. This nebulizer allows the administration of drugs without the need to disconnect the circuit. The position of the nebulizer chamber must allow the liquid to be in contact with the vibrating mesh. Optimal positions:



- 8) Turn on the aerosol generator (press the blue on/off button). Check that the 30 min green indicator light comes on and the aerosol is visible. The device is programmed to turn off after 30 minutes even if the drug nebulization ends earlier (2ml is nebulized in approximately 7 minutes).
- 9) Place the controller in the specific place for the controller (cleaning according to the center's protocol). The Aerogen Solo A-VMN™ does not require cleaning (single patient use). Minimize disconnections from the respiratory circuit.

3. Specific procedure for the use of the Aerogen Solo A-VMN™ and Aerogen Ultra in spontaneous breathing:

- 1) Connect the mouthpiece or valved facemask to the patient depending on the patient's clinical situation. If using the mouthpiece, instruct the patient to seal the mouthpiece with the lips without leaving gaps.



- 2) If the patient requires supplemental oxygen, connect the oxygen source between with a flow between 1-6 l/min.
- 3) Connect an antiviral/antibacterial filter to the back of the mouthpiece for airborne or droplet transmission pathologies.
- 4) At the end, remove the nebulization system and rinse with sterile water. Shake off excess fluid and allow to air dry. Each device is single patient use.

4. Specific procedure for the use of Aerogen Solo A-VMN™ with NIV:

- 1) Connect the nebulization system t-piece between the mask and the exhalation port. Avoid condensation or increased resistance.



- 2) Make sure that the position of the nebulization chamber allows for correct nebulization.
- 3) Once the nebulization is complete or if the nebulization has lasted a maximum of 30 minutes, maintain or remove the nebulizer as directed (to avoid a prolonged increase in dead space).
- 4) Do not remove turn off humidification for nebulisation.
- 5) Do not modify parameters systematically. Monitor pressures, volumes, and alarms. Set alarms if necessary.
- 6) Monitor saturation, ventilator adaptation, and clinical response.

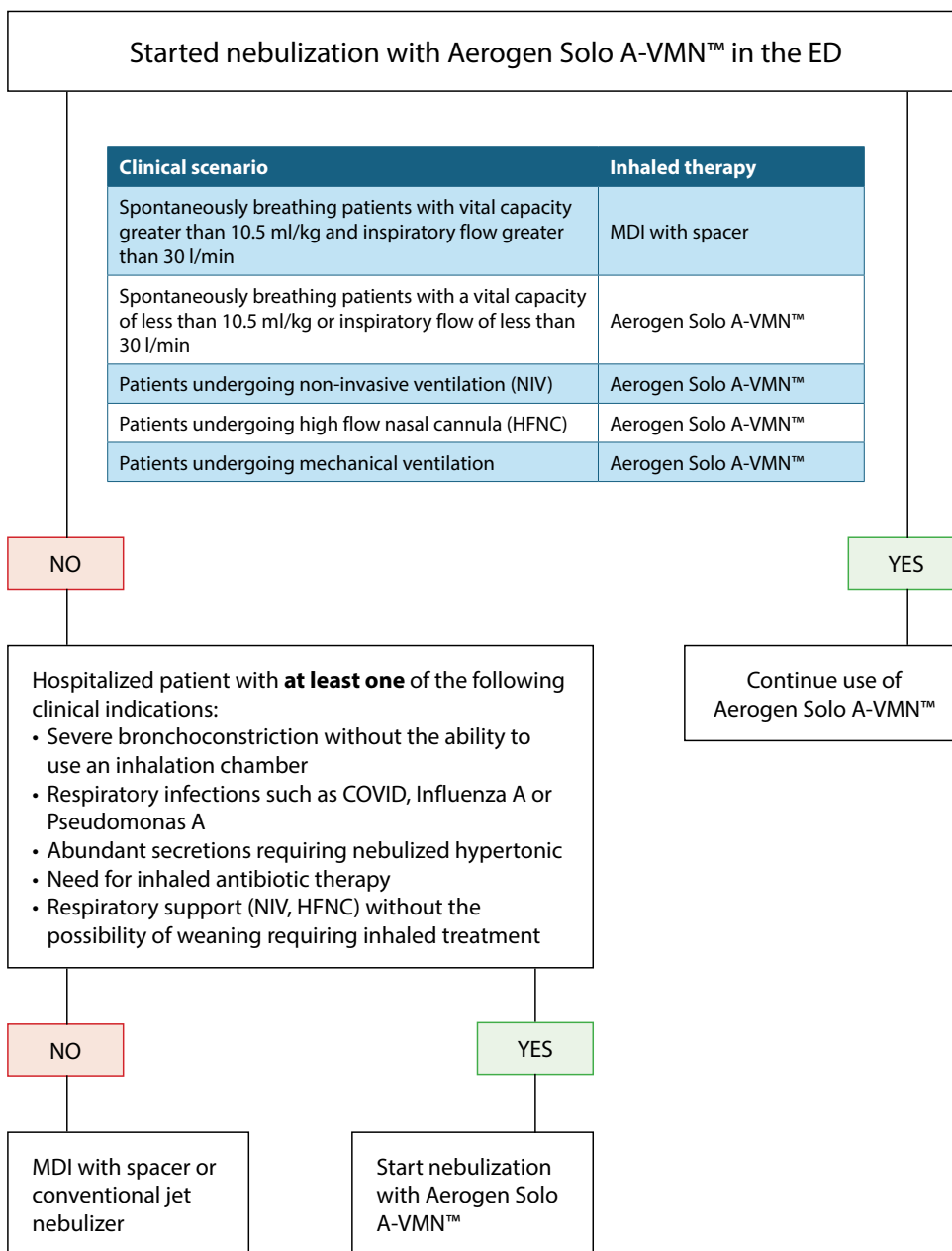
5. Specific procedure for the use of the Aerogen Solo A-VMN™ with HFNC and mechanical ventilation:

- 1) Connect the T-piece of the nebulization system on the dry side of the humidifier:



- 2) If using with the Airvo-2 or Airvo-3 HFNC systems, connect the nebulization chamber to the connection port.
- 3) Make sure that the position of the nebulization chamber allows for correct nebulization.
- 4) Once the nebulization is finished, the nebulizer can be maintained in the same position, mainly in situations of risk of aerosol transmission.

Inpatient requiring inhaled treatment



Inhaled Therapy Protocol — Hospitalization:

The objective is to ensure continuity of care, safety and efficacy of inhaled treatment using the Aerogen system (Aerogen Solo A-VMN™ and USB Controller, Aerogen Ltd, Galway, Ireland) in hospitalized adult patients, including those with NIV or HFNC, who have started nebulization in the Emergency Department or require its use during hospitalization. Upon admission to the pneumology department or intermediate respiratory care unit, it must be ensured that the patient continues to receive the active nebulized treatment, duly documented in his or her medical history. As far as possible, the nebulization system previously used will be maintained. Adjustments in respiratory support will be made according to medical indication.

Hospitalized adult patients who are candidates for nebulization with vibrating mesh (Aerogen Solo A-VMN™ and USB Controller, Aerogen Ltd, Galway, Ireland) are as follows:

1. Patients who have started nebulization in the emergency department.
2. Patients who have not started nebulization in the emergency department have:
 - Severe bronchoconstriction requiring management with inhaled bronchodilators that are not capable of conscious inhalation with an inhalation chamber and requiring more effective nebulization than with conventional jet nebulizer.
 - Patients with respiratory infections that require reduced environmental dispersion during nebulization (covid, influenza A, pseudomonas A.)
 - Respiratory infections that require treatment with inhaled antibiotic therapy.
 - Abundant secretions with difficulty in their elimination and requiring nebulization with hypertonic saline.
 - Patients undergoing respiratory support therapy, either with mechanical ventilation or HFNC, which can't be withdrawn for the administration of treatment with an MDI or a conventional jet nebulizer.
 - Patients undergoing mechanical ventilation via a tracheostomy tube who meet the above conditions.

The contraindications and precautions to be taken into account are the following:

- ☒ Known hypersensitivity to the drug.
- ☒ Clinical deterioration during nebulization.
- ☒ Special caution in patients with:
 - Hemodynamic instability
 - Risk of barotrauma
 - Tachyarrhythmias

The criteria for stopping inhaled therapy are as follows:

- ☒ Clinical improvement.
- ☒ Lack of response
- ☒ Adverse effects
- ☒ Medical indication

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- 3 Lin, H-L., Fink, J.B. & Ge, H. (2021) 'Aerosol delivery via invasive ventilation: a narrative review', *Annals of Translational Medicine*, 9(7), p. 588. doi: 10.21037/atm-20-5665.
- 4 Li, J. et al. (2023) 'Aerosol therapy in adult critically ill patients: a consensus statement regarding aerosol administration strategies during various modes of respiratory support', *Annals of Intensive Care*, 13(1), p. 63. doi: 10.1186/s13613-023-01147-4
- 5 O'Toole, C., Joyce, M., McGrath, J., O'Sullivan, A., Byrne, M. & MacLoughlin, R. (2021) 'Fugitive aerosols in the intensive care unit: a narrative review', *Annals of Translational Medicine*, 9(7), p. 592. doi: 10.21037/atm-20-2280
- 6 Aerogen Solo Instruction for Use.

Aerogen[®]

In a study of patients in an emergency department requiring treatment with an aerosolized bronchodilator:¹



85%

of patients achieved symptom control with one 2.5 mg albuterol dose¹



37-minute

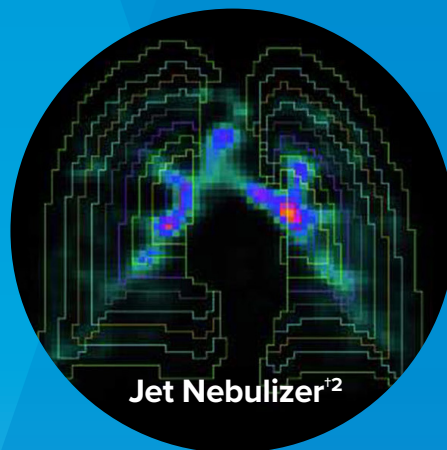
median reduction in ED length of stay per patient with Aerogen Ultra versus jet nebulizer¹



30%

higher discharge rate with Aerogen Ultra versus jet nebulizer¹

Aerogen Ultra delivers **6X** more aerosol when compared to jet nebulizers.¹²



LOWER DEPOSITION

HIGHER DEPOSITION

¹ Representative scintigraphy images of aerosol deposition in healthy male subjects during spontaneous breathing; between-group difference: 34.1% vs. 5.2%; p<0.001.

¹ Dunne RB, Shortt S. Comparison of bronchodilator administration with vibrating mesh nebulizer and standard jet nebulizer in the emergency department Am J Emerg Med. 2018;36(4):641-646.

² Dugernier J, Hesse M, Vanbever R, et al. SPECT-CT comparison of lung deposition using a system combining a vibrating-mesh nebulizer with a valved holding chamber and a conventional jet nebulizer: a randomized cross-over study. Pharm Res. 2017;34(2):290-300.

Expanding Access to Pulmonary Function Testing: Why Decentralized Spirometry is Becoming a Clinical Necessity

The Editors of Respiratory Therapy

Pulmonary function testing has long served as a foundational tool in respiratory medicine, yet many healthcare systems are struggling to keep pace with the growing demand for diagnostic access. Across both hospital systems and outpatient networks, pulmonary function laboratories are experiencing increasing scheduling pressure driven by rising chronic respiratory disease prevalence and expanding demand for earlier diagnosis and longitudinal monitoring.

For many providers, the challenge is no longer whether spirometry is valuable, but how to deliver it efficiently and consistently in environments where access to traditional testing infrastructure is limited. Long scheduling delays, centralized testing bottlenecks, and limited respiratory staffing have created barriers that affect both patient throughput and timely clinical decision-making.

This issue has become particularly relevant as integrated delivery networks and outpatient respiratory programs increasingly shift toward more decentralized care models. Health systems are placing greater emphasis on expanding diagnostic capabilities beyond the centralized pulmonary function laboratory to improve access, reduce delays, and support earlier intervention.

However, expanding access alone may not fully address the need for meaningful diagnostic data equivalent to a hospital laboratory if testing quality varies substantially across locations, operators, or patient populations. As respiratory testing moves beyond highly controlled environments, maintaining consistency in how maneuvers are performed becomes increasingly important.

As healthcare systems explore more scalable approaches to respiratory diagnostics, attention is increasingly shifting toward technologies and workflows designed to support more consistent testing processes across care settings. For respiratory therapists and pulmonary teams, this transition introduces both opportunity and operational complexity. Ensuring acceptable test quality outside highly controlled lab environments requires attention to patient coaching, procedural standardization, and repeatability. Historically, variability in patient coaching, operator experience, and testing technique have represented meaningful barriers to broader deployment of spirometry beyond specialized respiratory settings.

Avatar-assisted and digitally guided spirometry platforms represent one emerging strategy aimed at supporting more standardized patient interaction. These technologies are increasingly designed not simply to expand testing availability, but to help reduce variability in how testing is performed across different operators and care environments while reducing dependence on highly specialized staffing resources for every testing encounter. The timing of this shift is significant. In this environment, technologies that support workflow expansion without proportionally increasing staffing requirements are attracting considerable attention.

From an operational standpoint, decentralized testing models may also help address one of the most persistent frustrations facing providers today: delayed access to diagnostic information. When spirometry can be performed closer to the point of care, clinicians may gain earlier insight into a patient's respiratory status, more clearly identify patients who need referral to a pulmonologist or hospital laboratory for further testing, and better monitor treatment response and disease progression. This therefore has implications not only for outpatient management, but also for referral efficiency and overall patient flow.

Importantly, decentralized respiratory diagnostics do not eliminate the need for pulmonary laboratories or respiratory expertise, but focuses those resources on patients who require higher levels of need. They reflect an evolving care model in which spirometry testing may increasingly occur across a broader range of clinical environments, supported by digital tools that help standardize workflow and patient interaction.

Ultimately, the growing interest in decentralized spirometry reflects a larger shift occurring throughout healthcare: the movement of diagnostic capability closer to the patient. In respiratory care, where early identification and ongoing monitoring are central to disease management, expanding access to reliable testing may become an increasingly important component of both clinical quality and operational efficiency.

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Nasal Hygiene: The Missing Component of Airway Clearance

Why upstream airway management deserves greater attention in respiratory care

Every respiratory therapist has cared for patients whose secretions remain difficult to mobilize despite appropriate humidification, airway clearance therapy, and respiratory support. When secretion management becomes challenging, attention naturally turns to the lungs. Yet one of the airway's most important clearance mechanisms begins well before inspired air reaches the trachea or bronchi.

The nasal cavity serves as the respiratory system's first line of defense. Before air reaches the lower respiratory tract, it is filtered, warmed, humidified, and conditioned by the nasal passages. The nose also supports mucociliary clearance, regulates airflow resistance, and exposes inspired air to endogenous nitric oxide (NO) produced within the paranasal sinuses. Together, these functions help preserve airway integrity while reducing the physiologic burden placed on the lower respiratory tract.

For respiratory therapists (RTs), this raises an important question: Could optimizing nasal function improve the effectiveness of downstream airway clearance strategies?

Airway Clearance Starts Earlier Than We Think

Airway clearance is often discussed in the context of the bronchi and lungs, but mucociliary transport begins much earlier. The nasal epithelium contains ciliated cells and mucus-producing goblet cells that continuously trap inhaled particles, allergens, bacteria, and viruses. Coordinated ciliary activity transports this material toward the nasopharynx, where it is swallowed and eliminated through normal gastrointestinal defenses.

When nasal tissues become dehydrated, inflamed, or chronically obstructed, mucus viscosity increases and ciliary function slows. Secretions become more difficult to mobilize, normal clearance declines, and inhaled contaminants remain in contact with the mucosa longer. While these changes are often viewed as sinonasal concerns, they also increase the burden placed on downstream airway defenses.

For RTs who routinely assess secretion quality below the glottis, the condition of the nasal airway deserves similar consideration.

Nasal Obstruction Affects More Than Airflow

Persistent nasal obstruction frequently shifts patients toward chronic mouth breathing, bypassing many of the protective functions of the nose.

Unlike the nasal passages, the oral cavity provides minimal filtration or humidification of inspired air. Chronic oral breathing contributes to drying of upper-airway tissues, reduced mucosal hydration, and impaired mucociliary transport. Patients receiving supplemental oxygen, noninvasive ventilation, CPAP, or high-flow nasal oxygen may be particularly susceptible to these effects because continuous airflow can further increase mucosal drying, especially when mouth leak is present.

The result is often a cycle in which nasal obstruction promotes mouth breathing, mouth breathing further dries the airway, and airway dryness contributes to patient discomfort, secretion retention, and reduced tolerance of respiratory therapies.

Although correcting lower-airway pathology remains the primary objective of respiratory care, identifying upper-airway dysfunction may remove barriers that limit therapeutic success.

Humidification Begins in the Nose

Respiratory therapists routinely optimize inspired gas humidity to preserve secretion mobility within the lower respiratory tract. The same physiologic principle applies to the nasal cavity.

Healthy nasal mucus is essential for efficient mucociliary transport. Dehydration, inflammation, environmental irritants, and chronic disease increase mucus viscosity and reduce ciliary efficiency, slowing clearance of inhaled particles and microorganisms. Supporting hydration throughout the airway—not only below the glottis—helps preserve one of the body's primary airway defense mechanisms.

Considering airway hydration from this upstream perspective broadens the concept of airway clearance without changing its fundamental goals.

Biofilms and Airway Hygiene

Upper-airway biofilms are receiving increasing attention as contributors to persistent respiratory disease.

Biofilms are structured microbial communities that adhere to mucosal surfaces within a protective extracellular matrix. Once established, they become substantially more resistant to antibiotics and host immune responses than free-floating bacteria. Biofilms have been implicated in chronic rhinosinusitis and other persistent upper-airway conditions.

Rather than attempting to sterilize the airway, emerging strategies focus on reducing conditions that favor biofilm development while preserving the normal microbial community.

Among these approaches, xylitol has attracted attention because laboratory and clinical studies suggest it interferes with bacterial adhesion and early biofilm development without acting as a traditional antibiotic. By reducing opportunities for biofilm maturation, xylitol may help support normal mucosal defenses while minimizing disruption of beneficial commensal organisms.

This distinction is increasingly relevant as respiratory care shifts toward preserving healthy airway physiology in addition to treating established disease.

Nasal Hygiene as a Supportive Airway Clearance Strategy

Routine nasal hygiene has long been incorporated into postoperative sinonasal care and the management of chronic rhinosinusitis. Saline irrigation remains the standard approach because it hydrates mucosal surfaces, removes mucus, reduces crusting, and supports mucociliary transport.

Xylitol-containing nasal irrigations and sprays have emerged as an adjunctive option. Clinical studies have reported improvements in patient-reported sinonasal symptoms while also demonstrating enhanced nasal nitric oxide expression and support of mucociliary function compared with saline alone in selected patient populations.

Although larger clinical trials are warranted, current evidence suggests that maintaining nasal hygiene may complement broader airway clearance strategies, particularly in patients with chronic sinonasal disease, persistent mouth breathing, or upper-airway dryness that interferes with respiratory therapy.

Clinical Implications for Respiratory Therapists

Respiratory therapists are uniquely positioned to recognize factors that compromise airway clearance beyond the lungs. Routine assessment already includes secretion characteristics, humidification, patient comfort, and therapy adherence. Expanding this assessment to include chronic nasal obstruction, habitual mouth breathing, persistent nasal dryness, or impaired nasal airflow may identify contributors to therapy failure that otherwise go unrecognized.

For patients struggling with CPAP tolerance, recurrent respiratory infections, or excessive secretion burden, collaboration with otolaryngologists, primary care providers, dental professionals, and certified orofacial myofunctional therapists may provide opportunities to address upstream contributors to respiratory dysfunction.

As respiratory care continues to evolve toward prevention, chronic disease management, and interdisciplinary care, recognizing the nose as an integral component of airway clearance represents a logical extension of established respiratory principles rather than a departure from them.

Conclusion

Airway clearance does not begin in the bronchi—it begins with the first breath through the nose.

The nasal cavity conditions inspired air, supports mucociliary transport, and contributes to innate immune defense before inhaled particles ever reach the lower respiratory tract. When these functions are compromised, downstream respiratory therapies may be asked to compensate for dysfunction that originated much earlier in the airway.

For respiratory therapists, incorporating nasal assessment and evidence-based nasal hygiene into a comprehensive airway management strategy offers an opportunity to strengthen the body's natural defense mechanisms while supporting the effectiveness of established respiratory interventions. As evidence continues to evolve, thinking “upstream” may become an increasingly important component of optimizing respiratory health.

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Living Healthcare



Restoring Voice After Tracheostomy: A Team-Based, Patient-Centered Approach

Carmin Bartow, MS, CCC-SLP

The Clinical Significance of Restoring Communication

A tracheostomy tube alters normal airflow through the larynx, resulting in an inability to produce audible voice. Patients with tracheostomies frequently report frustration, fear, anxiety, isolation, and a loss of control related to their inability to speak (Foster, 2010; Tolotti et al., 2018). Qualitative studies describe communication loss after a surgical airway as one of the most distressing aspects of critical illness, with patients expressing feelings of helplessness, panic, and despair when they are unable to make their needs known (Freeman-Sanderson et al., 2018; Volpato et al., 2025).

Restoring verbal communication is therefore a critical component of patient-centered tracheostomy care. The ability to speak has been associated with significant improvements in patient-reported self-esteem, particularly related to being understood by others (Freeman-Sanderson, 2016). Verbal communication allows patients to more fully express their thoughts, emotions, and care needs, which in turn enhances patient satisfaction and overall quality of life (Morris et al., 2015). Improved patient-reported quality of life has also been demonstrated in individuals with tracheostomies receiving mechanical ventilation when verbal communication is restored (Pandian et al., 2020), highlighting the importance of prioritizing verbal communication whenever clinically feasible.

From Rationale to Practice: Implementing Effective Communication Strategies

Implementing effective patient communication requires a coordinated, multidisciplinary approach. Communication assessment and intervention are primarily within the scope of practice of the speech-language pathologist; however, respiratory therapists, nursing, and physicians also play essential roles in airway management, ventilation, and determining physiologic readiness for communication strategies. Early communication intervention is critical, and patients may require a combination of non-verbal strategies, such as augmentative and alternative communication (AAC), and verbal communication approaches. AAC strategies may include writing tools, communication boards, gesture systems, and electronic communication aids. When verbal communication is not yet possible, AAC should be implemented promptly to ensure access to communication while airway- and ventilation-based strategies are evaluated.

Whenever possible, verbal communication should be prioritized, as it represents the most natural form of interaction. Restoring

airflow to the upper airway not only enables voice but also provides important physiologic benefits, including improved secretion management and swallowing (O'Connor et al. 2019; Tang et al. 2025). Upper airway airflow can be reestablished using strategies such as leak speech, speaking valves, and Above Cuff Vocalization (ACV), helping patients regain their voice as early as clinically appropriate.

Restoring Voice: Clinical Options and Considerations

Leak Speech

Leak speech occurs when airflow passes around the tracheostomy tube and through the vocal folds during exhalation, which may be possible with a cuffless tube or a deflated cuff, provided there is adequate airway patency and sufficient space between the tube and tracheal wall.

When audible voice is produced under these conditions, it is referred to as leak speech. Voice quality is often weak or low in volume, but leak speech may provide an early opportunity for verbal communication in select patients. Tracheostomy tubes with an optimized inner-to-outer diameter ratio, such as the Tracoe Twist Plus, can help facilitate airflow around the tube and support voicing potential.

Speaking Valves

Speaking valves are devices that attach to the 15 mm connector of a tracheostomy tube. They permit inhalation through the tube and, during exhalation, the valve redirects airflow around the tracheostomy tube, through the larynx, restoring audible voice. To utilize a speaking valve, patients must have a cuffless tracheostomy tube or completely deflated cuff.

Several categories of speaking valves are available to meet varying patient needs:

- A fully occlusive speaking valve redirects all exhaled airflow through the upper airway to support phonation.
- An adjustable speaking valve can be fully closed to direct all exhaled airflow through the upper airway, or it can be opened or partially opened to reduce expiratory resistance and potentially minimize air trapping (e.g., Tracoe Phon Assist Speaking Valve).
- Speaking valves with integrated heat and moisture exchangers (HME) provide both speech and humidification in a single system (e.g., DualCare Speaking Valve + HME).

Tracoe Phon Assist Speaking Valve

Phon Assist is an adjustable-resistance speaking valve designed for spontaneously breathing patients. It features adjustable side

Carmin Bartow is a speech pathologist and tracheostomy clinical educator with Atos Medical.

openings that allow clinicians to tailor expiratory resistance based on individual patient needs, patient tolerance, and clinical decision-making.

- When fully closed, all exhaled airflow is directed through the upper airway.
- When partially or fully open, a portion of exhaled airflow is directed through the upper airway to support phonation, while remaining airflow exits through the valve, reducing resistance and potentially minimizing air trapping for some patients.



Figure 1. Tracoe Phon Assist Speaking valve

DualCare Speaking Valve + HME

The Freevent DualCare system combines a speaking valve and an HME in a two-part design. Patients can easily switch between speaking mode and HME mode with a simple twist, without changing devices. This integrated approach supports both communication and airway humidification.



Figure 2. DualCare Speaking Valve + HME

Tracoe TrachPhone HME

TrachPhone is an HME with an integrated push-to-speak valve, offering an alternative method of voice restoration while maintaining humidification.



Figure 3. TrachPhone HME

To learn more about speaking valves:
Enhancing Communication with Tracheostomy Speaking Valves — Atos Medical (<https://www.atosmedical.us/professionals/tracheostomy/enhancing-communication-with-tracheostomy-speaking-valves>)

Above Cuff Vocalization (ACV)

Above Cuff Vocalization (ACV) is a voicing technique used for patients requiring an inflated tracheostomy cuff during mechanical ventilation. A tracheostomy tube with a subglottic suction port (e.g., Tracoe Twist Plus Extract) is required. Air or oxygen is introduced through the subglottic port, directing airflow into the upper airway to restore voice.



Figure 4. Tracoe Twist Plus Extract Tracheostomy Tube

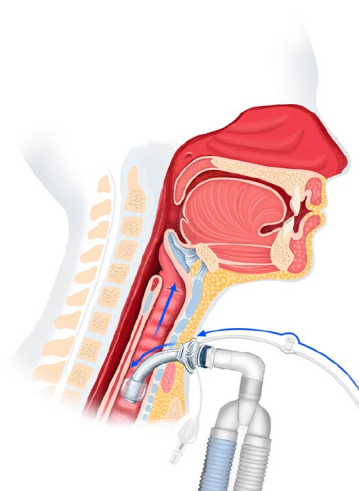


Figure 5. Above Cuff Vocalization Airflow Pathway. Illustration showing airflow during ACV. The blue arrows indicate the flow of air introduced through the subglottic suction channel, above the cuff and into the upper airway to enable phonation.

General clinical considerations for ACV

- ACV implementation typically involves close collaboration between respiratory therapy and speech-language pathology.
- Preparation: Clear secretions from above the cuff before starting, explain the procedure to the patient and caregivers, ensure appropriate positioning, and connect appropriate tubing for ACV delivery.
- Airflow management: Deliver airflow through the subglottic suction line. Start with low flow (approximately 1 L/min) and adjust based on patient tolerance, keeping flows below 10 L/min. (Petosic et al. 2021; Gajic et al. 2024)
- Monitoring: Observe vital signs, patient comfort, and voicing ability throughout the procedure. Discontinue ACV if there are significant changes in status or discomfort.
- ACV should be individualized for each patient, balancing communication goals with safety and comfort.

To learn more about ACV:

Above Cuff Vocalization (ACV) — Atos Medical (<https://www.atosmedical.us/professionals/tracheostomy/above-cuff-vocalization-acv>)

Clinical Implications and Key Takeaways

Loss of verbal communication is one of the most distressing consequences of a tracheostomy, with profound effects on emotional well-being and quality of life. Although AAC strategies are essential when speech is not immediately possible, restoring verbal communication should be prioritized whenever clinically appropriate. Respiratory therapists, speech-language pathologists, and their multidisciplinary colleagues play a critical role in actively advocating for, assessing, and implementing verbal communication strategies including leak speech, speaking valves, and above-cuff vocalization to ensure timely, patient-centered care, promote patient engagement, and optimize both clinical and psychosocial outcomes.

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Underutilization of Airway Resistance

This article explores the use of airway resistance testing for improving the diagnosis and management of obstructive diseases.

Ralph Cook, BA, RRT, RPFT

Plethysmography as a pulmonary diagnostic tool has been in use for many years. Starting in the '50s plethysmographs (also called "body boxes") were used as research tools. As refinements improved the design, electronics, and usability of plethysmographs, they are now the majority of systems purchased by pulmonary function laboratories.

Plethysmography is widely recognized for rapid and accurate lung volume measurement, directly measuring FRCpleth, then calculating Total Lung Capacity and Residual Volume. However, the use of this diagnostic tool for the measurement of airway resistance (R_{aw}) is underutilized in many labs. In discussions with pulmonary function technologists, many report that R_{aw} is not routinely measured, or that results are recorded but receive little attention in the interpretation. Many readily admit that their physicians were not trained on airway resistance and do not know how to interpret the results. Increased airway resistance is the primary finding in Obstructive Airways Disease and may be caused by bronchospasm, compression or consolidative filling. "Spirometry is considered the gold standard method to measure air flow limitation. However, since air flow limitation occurs in part due to increased airway resistance, it makes sense that measuring airway resistance directly may provide additional information."¹

Airway resistance is the pressure difference per unit flow as gas flows into or out of the lungs.² Conceptually, R_{aw} reflects how much work (driving pressure) is required to move air back and forth. Airflow results when the driving pressure overcomes resistance and inertance. As the pressure required increases, ventilation becomes more difficult. In healthy subjects, the upper airways and trachea account for approximately 80% of resistance, while the smaller airways contribute only about 20% of total resistance to flow. Along with R_{aw} , plethysmography provides airway conductance (G_{aw}), which is the reciprocal of R_{aw} and is the flow generated per unit of pressure drop. As R_{aw} increases (pressure), G_{aw} (flow) decreases. When G_{aw} is normalized to the lung volume at which it was measured, specific conductance (sG_{aw}) can be calculated. This adjustment facilitates comparison because lung volume influences resistance measurements. When a subject has increased lung volumes, such as FRC, airway resistance may decrease and airway conductance may increase because the large and medium airways can become slightly distended, allowing for air to move more easily. This is one of the reasons COPD

patients hyperinflate. It is a compensatory mechanism to make breathing easier.

R_{aw} provides a relatively effort-independent assessment of airway caliber. Similar to how a larger garden hose will allow more water to move through it, a larger airway permits more air to move through it for any given pressure gradient. Most of the resistance in the airways is created by the walls of the airway. Friction of the gas molecules against the walls of the airways requires more pressure to move the air.

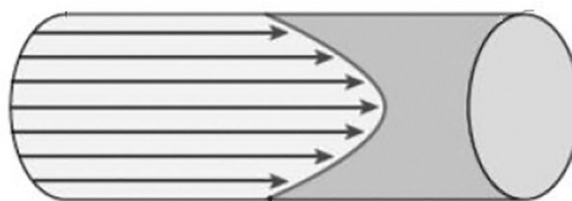


Figure 1. Resistance to Airflow.

Poiseuille's Law says that flow rate is proportional to the 4th power of a pipe's radius. Based on this relationship, one might expect a majority of airway resistance would come from the smaller airways. However, the sheer number of smaller airways at each generation, and their total cross-sectional area more than compensates for their smaller diameter. In addition, all of the inspired and exhaled gas must traverse the upper airways, whereas each peripheral airway conducts flow only to its associated lung units. As a result, the upper airways contribute the largest proportion of total resistance.

Airways resistance can detect significant changes in airway caliber during bronchodilator and bronchoprovocation trials which might not be reflected in spirometry. This may help explain a patient's perceived response in the absence of spirometry changes. "Patients with suspected reversible airways obstruction sometimes report subjective benefit after bronchodilator treatment despite no objective spirometric improvement."³ Flows determined by spirometry inherently incorporate driving pressure and therefore:

1. Are effort dependent
2. Are insensitive to early obstructive changes, especially in a young, motivated subject
3. Reflect true obstruction only after significant compromise of airway radius, well beyond the development of symptoms
4. Appear less abnormal in mild-to-moderate disease when

Ralph Cook, BA, RRT, RPFT, is the Director of Marketing Education at MGC Diagnostics and has over 40 years of experience in respiratory care and pulmonary function testing.

Spirometry	Pred	Baseline	+1.5 cmH ₂ O/L/s	% Change Pre 2021	% Change Post 2021	+4.0 cmH ₂ O/L/s	% Change Pre 2021	% Change Post 2021
FVC	4.88	4.64	4.58	-1	-1	4.59	-1	-1
FEV1	3.84	3.31	3.19	-4	-3	3.19	-4	-3
FEV1/FVC	79.00	72.00	70.00	-3	-3	69.00	-3	-4
Airway Mechanics								
Raw	1.95	3.31	4.82	46		6.66	101	
sRaw	4.76	11.89	19.93	68		26.10	120	
Gaw	1.03	0.30	0.21	-30		0.15	-50	
sGaw	0.25	0.08	0.05	-38		0.04	-50	

Table 1. Fixed External Resistance.

patients can increase expiratory effort (e.g., strong respiratory musculature and/or high elastic recoil)

To illustrate how airway resistance values can significantly change the way you perceive test results, two studies are summarized below.

Fixed External Resistance

In the first example, a relatively healthy 70 year old subject with asthma performed spirometry and airways resistance before and after the addition of external fixed resistors. The added resistance provides a known, quantifiable change in total airway resistance (Table 1).

With the addition of 1.5 cmH₂O/L/s of resistance (which doubles the typical subjects' baseline resistance), spirometry values did not change significantly. In contrast, the airway resistance increased by 46% and the specific conductance (flow) decreased by 38%. Both of these are significant changes with a mild resistor addition. Adding 4 cmH₂O/L/s again had no significant impact to the spirometry values, yet had a 101% increase for Raw over the baseline values, and a 50% decrease in sGaw. An additional resistance of 4 cmH₂O/L/s would be perceivable to most individuals and would meaningfully increase the work of breathing.

Case Studies

A second example involves a 16 year old male hockey player who complained of shortness of breath and dyspnea on exertion. The patient demonstrated moderate diffuse bronchospasm and mild diaphragmatic tenderness. Pulmonary function studies yielded the following results (Table 2).

In this case, the post bronchodilator spirometry values showed no significant response. Plethysmography however, showed all values returning to normal and having a dramatic change post

bronchodilator. With a 10% change or greater to FVC or FEV1 considered a significant bronchodilator response, had this patient been tested with spirometry only, a prescription for an inhaler may not have been clinically justified, and a home bronchodilator trial might not have been initiated.

Based on the results of the plethysmograph values, the physician was able to make a diagnosis of reversible airways obstruction and prescribe an appropriate regimen, including inhaled bronchodilators and anti-inflammatory medication. A follow-up visit three months later revealed normal prebronchodilator measurements.

In 1994, an abstract that was presented at the American College of Chest Physicians reported that spirometry before and after bronchodilator identified 264 patients out of 879 as having reversible airways disease based on the guidelines at the time (12% and >200 mL). In the same cohort, plethysmography identified 447 responders.

Similarly, Smith and colleagues found that spirometry alone failed to find bronchodilator reversibility in 15% of patients with suspected reversible airway obstruction and clinical responses to bronchodilator, but that these patients could be identified by additional plethysmographic measurements.³

Bronchial Provocation

While not used routinely, plethysmography can also be a valuable tool when performing bronchial provocation testing, such as methacholine challenge, cold air, or exercise. The purpose of a challenge test is to identify the level of airway hyperreactivity — if any. The provocation concentration causing a 40% drop in sGaw was found to be more sensitive than a 20% drop in FEV1 at detecting bronchial constriction.⁴ Combining spirometry with plethysmography can significantly increase the sensitivity of the test.

Spirometry	Pred	Baseline	%Pred		Post BD Actual	Post %Pred	Post %Change
FVC	5.54	4.69	85		4.73	85	1
FEV1	4.79	3.13	65		3.40	71	6
FEV1/FVC	82	67			72		6
Airway Mechanics							
Raw	1.51	7.17	474		0.96	63	-87
Gaw	0.66	0.14	21		1.04	158	643
sGaw	0.19	0.02	11		0.25	131	1150

Table 2. Bronchodilator Response.

Summary

Airway mechanics can be more sensitive to airway narrowing and bronchoconstriction than spirometry and reflect different physiologic processes that are not captured by FEV1 alone. They also have the advantage of being relatively effort independent. When used in addition to spirometry, these values (Raw, Gaw, sGaw) can provide earlier detection and better differentiation of the causes of airflow impairment as well as the presence of concurrent processes. Since resistance in the airways plays a part in air flow limitation, measuring these parameters significantly adds relevant information needed to make a clinical decision.

As with all diagnostic tests, we must first ask ourselves: “What clinical question are we trying to answer?” and then select the most appropriate tests. Not every patient will require airways resistance testing. But this information should challenge all of us to carefully consider the tests we are using to both diagnose and manage asthma.⁵

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Respiratory Therapy Technology Insight

OxyMinder® Pro: Advancing Bubble CPAP Through Patient-Level Oxygen and Pressure Monitoring

The Editors of Respiratory Therapy

Bubble Continuous Positive Airway Pressure (Bubble CPAP) has been a mainstay of neonatal respiratory care for decades. Its simplicity, effectiveness, and ability to support spontaneous breathing while avoiding invasive mechanical ventilation have made it one of the most widely used respiratory support modalities for premature and low-birth-weight infants.

While the basic principles of Bubble CPAP have remained remarkably consistent, expectations for monitoring the therapy have evolved. Today's neonatal clinicians are increasingly focused not only on prescribing respiratory support, but also on verifying that the intended therapy is actually being delivered to the patient.

This shift has created interest in technologies capable of monitoring oxygen concentration and CPAP pressure at the patient interface rather than relying exclusively on system settings.

Looking Beyond System Settings

Traditional Bubble CPAP systems establish oxygen concentration using an air/oxygen blender while pressure is generated by the depth of the expiratory limb within the water column. These settings define the intended therapy, but they cannot independently confirm that the infant continues to receive those same parameters throughout treatment.

Normal clinical events—including interface leaks, condensation within the circuit, loose tubing connections, patient movement, or displacement of nasal prongs—can influence the oxygen concentration and pressure ultimately delivered to the patient.

Although experienced clinicians recognize these variables, many changes may not become apparent until physiologic signs such as oxygen desaturation, increased work of breathing, or bradycardia begin to develop.

The clinical objective, therefore, is straightforward: verify the therapy before the patient demonstrates signs that therapy has changed.

A Patient-Centered Monitoring Philosophy

BioMed Devices approached this challenge from a different perspective.

Rather than concentrating on the performance of the Bubble CPAP system itself, the OxyMinder® Pro focuses on monitoring the therapy delivered to the patient.

The system continuously measures both oxygen concentration (FiO₂) and delivered CPAP pressure near the patient interface, providing clinicians with real-time confirmation that prescribed respiratory support is reaching the infant as intended.

This patient-centered approach reflects an important evolution in respiratory monitoring. Ultimately, the infant responds to delivered oxygen concentration and delivered pressure—not simply to blender settings or theoretical pressure generated by water depth.

Continuous Awareness Throughout Therapy

One of the defining characteristics of the OxyMinder Pro is continuous monitoring.

Instead of relying on periodic equipment checks or visual inspection alone, clinicians receive ongoing measurements of both delivered oxygen concentration and delivered pressure throughout Bubble CPAP therapy.

Continuous monitoring allows caregivers to recognize subtle changes that might otherwise go unnoticed during routine patient care.

This additional layer of information can be particularly valuable in busy neonatal intensive care units where multiple patients require frequent assessment.

Intelligent Alarm Technology

A key feature of the OxyMinder Pro is its integrated alarm system.

Should delivered oxygen concentration or CPAP pressure move outside clinician-defined limits, the system immediately alerts caregivers.

Pressure loss resulting from circuit leaks, loose tubing, displaced interfaces, or other interruptions may therefore be recognized before secondary physiologic consequences become evident.

Rather than waiting for declining oxygen saturation or increasing respiratory distress, clinicians receive earlier notification that the delivered therapy has changed.

This proactive approach complements traditional bedside assessment and supports earlier clinical intervention when equipment performance or patient interface conditions change.

Designed for Clinical Integration

BioMed Devices recognized that new monitoring technology must integrate easily into existing NICU workflows.

The OxyMinder Pro is designed to retrofit onto existing Bubble CPAP systems, allowing facilities to expand monitoring capabilities without replacing current equipment. This approach minimizes capital investment while preserving familiar clinical workflows.

Additional engineering features include a bright color touchscreen display optimized for NICU environments, real-time in-use calibration capability that supports uninterrupted therapy, and BioMed Devices' patented Auto-Purge Technology, designed to help reduce the potential for backflow contamination within the hospital's air and oxygen supplies.

Collectively, these features reflect an emphasis on both clinical performance and practical bedside usability.

Supporting Precision in Neonatal Respiratory Care

As neonatal respiratory care continues to advance, clinicians are placing greater emphasis on precision, consistency, and early recognition of changes in respiratory support.

Patient-level monitoring represents a logical extension of that philosophy.

By continuously verifying delivered oxygen concentration and CPAP pressure, technologies such as the OxyMinder Pro provide clinicians with additional information regarding the therapy the infant is actually receiving. This capability complements existing Bubble CPAP systems while supporting lung-protective respiratory care strategies that seek to minimize unnecessary fluctuations in oxygen delivery and airway pressure.

Technology Insight

Innovation in respiratory care is often measured not by changing the therapy itself, but by improving how that therapy is monitored.

The BioMed Devices OxyMinder® Pro represents this type of innovation. Rather than altering the proven principles of Bubble CPAP, it enhances clinicians' ability to verify delivered oxygen concentration and pressure continuously at the patient interface.

As neonatal intensive care units continue to pursue greater precision in respiratory support, patient-level monitoring technologies are likely to play an increasingly important role in helping clinicians ensure that the therapy prescribed is the therapy delivered.

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Habit Score Tied to Improved Inhaled Drug Adherence in Cystic Fibrosis

Habit formation was one of the strongest factors associated with adherence to inhaled medicines among adults with cystic fibrosis in the elexacaftor/tezacaftor/ivacaftor (ETI) era. Additionally, age, socioeconomic status, neurodivergence, and regimen complexity were also independently linked. Researchers conducted a cross-sectional observational study using electronically captured nebuliser data to identify factors associated with adherence to inhaled medicines among adults with cystic fibrosis in the ETI period. They included 214 individuals aged 16 years or older who were eligible for inhaled therapy at a UK adult cystic fibrosis centre between July 2023 and August 2024. Overall, 25 factors were assessed across four categories: demographic, socioeconomic, health-related, and treatment-specific psychological factors including habit formation, which was ranked from 1-5 on a Likert scale (with 1 indicating "strongly disagree" and 5 indicating "strongly agree"). The outcome was mean daily percent adherence to inhaled medicines over 12 months, with missing adherence data conservatively imputed. Adherence data were classified as complete (covering all 12 months), incomplete (> 3 months within the 12-month study period), or missing (no adherence data across either 12-month period). Individuals with the strongest habit of taking inhaled medicines had a mean adherence of 41.7% compared with 11.7% in those with low/absent habit. Each one-level increase in habit score was associated with a 9.73 percentage point increase in adherence ($P < .001$). Likewise, higher socioeconomic status was linked to increased adherence, with each one-level increase in socioeconomic status associated with a 2.85 percentage point increase in adherence ($P = .020$). Adults aged 16-18 years had significantly lower adherence than those in the 19- to 25-year reference group (-15.88 percentage points; $P = .011$). Likewise, complex treatment regimen (> 3 prescribed doses per day, $P = .014$) and neurodivergence were also associated with higher adherence. "Habit formation may continue to support adherence among adults on ETI and may also benefit 'the 10%' who are ineligible for ETI or other CFTRm [cystic fibrosis transmembrane conductance regulatory protein modulator] therapy," the authors wrote.

Dupilumab Reduces Asthma Exacerbations in Children With Allergen Sensitization

Dupilumab reduced severe exacerbations of asthma, levels of total serum immunoglobulin E (IgE), and improved lung function and asthma control in children with uncontrolled moderate-to-severe type 2 asthma with monoallergen or multiallergen sensitization. Researchers conducted a post hoc analysis of the VOYAGE trial to assess whether dupilumab was effective in children aged 6-11 years with moderate-to-severe asthma regardless of allergen sensitization status; participants were randomly assigned to receive 100 or 200 mg dupilumab every 2 weeks or a matching placebo. They included 336 children with moderate-to-severe type 2 asthma, defined as having blood eosinophil counts ≥ 150 cells/ μ L or fractional exhaled nitric oxide levels ≥ 20 ppb and known status for allergen sensitization and IgE levels at baseline. Children were stratified into three groups based on total serum IgE levels and perennial allergen-specific IgE levels: non-sensitized, monoallergen-sensitized, and multiallergen-sensitized. The primary endpoint was severe exacerbation of asthma, defined as a deterioration in asthma control, resulting in treatment with systemic glucocorticoids, hospitalization, or an emergency department visit requiring systemic glucocorticoids; an additional endpoint was change in

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Introducing OxyMinder® Pro

Oxygen & Pressure Monitor for Bubble CPAP



Designed to deliver real-time monitoring of both Oxygen and Pressure Levels during Oxygen Therapy & Bubble-CPAP Therapy

Key Product Features:

- ✓ **User-Friendly Display:** Enhances ease-of-use with a bright, easy-to-read, color, touchscreen display – ideal for low-light NICU and PICU environments.
- ✓ **Seamless and Cost-Effective Integration:** As an option, the OxyMinder® Pro easily retrofits onto your existing blenders, eliminating the need to replace entire fleets and reducing capital costs.
- ✓ **In-Use Calibration:** The only blender monitoring system that offers real-time calibration capability without disconnecting the therapy from the patient or taking the device out of service – ensures uninterrupted therapy.
- ✓ **Auto-Purge Technology:** Unique to the OxyMinder® Pro, this patented feature promotes safer respiratory care and treatment efficacy by eliminating backflow contamination from occurring when the blender is left connected.

✓ **OxyMinder® Pro keeps clinicians informed, helping safeguard patients health risks related to:**

- Excessive oxygen exposure (O₂ toxicity) ● Insufficient CPAP pressure support ● Inadequate oxygen delivery to the patient
- Device malfunction or unintended disconnection ● Acute Respiratory Distress Syndrome (ARDS)



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The Metric Mirage: Why Reclassifying Airway Complications Fails Our Patients and Fuels Antimicrobial Resistance

Hamid Khosrowshahi, Jerry Gentile, Stanley John

Healthcare-associated infections (HAIs) remain a primary, unyielding focus of the Department of Health and Human Services (HHS). Yet, for the past decade, the critical care community's response to ventilator complications has focused more on bureaucratic reclassification than on physical infection prevention. When a mechanical vulnerability allows an unmanaged, 800 to 1,500 cc daily¹ column of colonized pharyngeal secretions to migrate past an endotracheal tube cuff, the biological consequence is absolute.

Today, roughly 50% of all antibiotics prescribed in the intensive care unit (ICU) are deployed strictly to treat or control ventilator-associated respiratory complications after the fact.² This massive reactive chemical treatment cycle is a primary driver of ICU antimicrobial resistance (AMR), a global crisis where critical, ventilator-associated pathogens regularly exhibit resistance rates exceeding 70% to last-resort therapies in high-acuity settings,³ contributing to nearly five million deaths associated with drug-resistant infections annually.⁴ Furthermore, we must acknowledge a critical clinical trajectory: a profound majority of devastating ICU Sepsis cases directly originate from preventable Ventilator-Associated Pneumonia (VAP). We cannot prescribe our way out of a mechanical plumbing failure; we must prevent the infection from occurring in the first place.

Why must we confront this crisis now? Because the administrative frameworks the industry has relied on for over a decade are officially fracturing. As exposed in detail within this issue's companion feature article, *"The Structural Blindspot: How Behavioral Checklist Mandates Hijack Mechanical Source Control in Ventilator-Associated Pneumonia (VAP) Guidelines,"* our current standard guidelines are built on vulnerable methodological assumptions. The companion article provides a vital, long-overdue forensic audit, illustrating how guideline committees have relied on historical, non-reproducible data and inflated denominators to artificially elevate free "behavioral checklists" over sound mechanical safety engineering. To truly protect patient safety, clinicians must read the companion audit to understand how deeply flawed paradigms have dictated bedside care.

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This forensic unmasking arrives at a critical historical juncture. In 2013, the Centers for Disease Control and Prevention (CDC) fundamentally shifted surveillance paradigms, moving away from traditional VAP metrics to automated Ventilator-Associated Events (VAE) and Infection-Related Ventilator-Associated Complications (IVAC).⁵ Rather than clarifying clinical reality, this administrative transition introduced deep confusion regarding the true incidence of VAP at the bedside. By relying on automated triggers like shifts in PEEP or FiO₂, VAE algorithms capture non-infectious complications, such as fluid overload or atelectasis, obscuring biological infection behind a smokescreen of physiological data.⁶

This administrative transition did not eliminate the underlying biological pathology; it merely hid the physical etiology inside an electronic database. Hospitals could comfortably claim "Zero VAP" on paper while continuing to bill payers for the exact same pulmonary infections under reclassified codes.

The failure of this administrative transition has now been laid bare by the surveillance complex's own architects. Leading epidemiologists have recently conceded that legacy surveillance paradigms failed to drive true clinical improvements at the bedside, prompting a desperate industry pivot toward tracking a new metric: Hospital-Onset Sepsis (HOS).⁷ By highlighting the limits of traditional device-associated tracking, recent analyses confirm that decades of behavioral checklists were blind to the broader, systemic sepsis crisis.

This continuous shifting of goalposts toward automated, EHR-based sepsis metrics mirrors the quiet retreat of historic safety organizations. For nearly twenty years, the Institute for Healthcare Improvement (IHI) anchored hospital protocols around behavioral checklists that ignored the physical reality of the patient's airway. Every single one of those highly publicized, historic "near-zero VAP" success stories actually involved the concurrent use of Subglottic Secretion Drainage (SSD). Yet, SSD was completely omitted from the written bundle protocols, acting as the hidden lynchpin that was truly responsible for the zero-rate claims.

Their recent actions speak louder than any administrative defense: the IHI quietly updated its digital archive, removing historical VAP success stories and promotional toolkits from its website. Today, they host only basic, static informational overviews, a silent retreat standing as a de facto acknowledgment that behavioral checklists cannot override the gravity-driven fluid dynamics of the intubated airway.

We must replace the metric mirage with mechanical source control. The definitive, Level-1 evidence to achieve this already exists. The landmark Mastrogianni (2023) systematic review of 38 bundle implementation studies confirmed that the most successful clinical protocols heavily rely on the active mechanical evacuation of the subglottic space via SSD.⁸

By ignoring this mechanical safeguard to chase minor procurement savings, hospitals do not just trigger acute infection costs; they sentence survivors to the devastating, invisible trajectory of Post-Intensive Care Syndrome (PICS). The resulting ICU Sepsis cascade leaves discharged patients to suffer from profound cognitive decline, severe delirium, and permanent physical disabilities. It is time for clinicians, regulatory bodies, and healthcare payers to look beyond the administrative safety shield of behavioral checklists. We must mandate mechanical source control, re-evaluate our flawed guidelines, and finally honor the absolute foundational principle of patient safety: First, do no harm.

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pre- and post-bronchodilator percent-predicted forced expiratory volume in 1 second (ppFEV₁). Patients who received dupilumab had significantly lower annual rates of severe exacerbations than those who received placebo in both the monoallergen-sensitized (rate reduction, 75.1%; $P = .0376$) and multiallergen-sensitized (rate reduction, 59.6%; $P = .0004$) groups. At week 52, dupilumab significantly improved pre-bronchodilator ppFEV₁ in the monoallergen-sensitized compared with the placebo (least squares mean difference [LSMD], 10.1 percentage points; $P = .001$) and multiallergen-sensitized (LSMD, 9.0; $P < .001$) groups. Significant improvements in post-bronchodilator ppFEV₁ were seen with dupilumab vs placebo in children with monoallergen sensitization ($P = .01$). Dupilumab significantly improved asthma control in children with monoallergen sensitization and multiallergen sensitization compared with placebo and reduced total serum IgE levels across all sensitization subgroups at week 52. "In children with moderate-to-severe asthma, dupilumab demonstrated significant efficacy in allergen-sensitized patients, while non-sensitized patients had less pronounced yet numerically greater improvements. This study extends our knowledge of dupilumab efficacy by patient allergen sensitization status," the authors wrote.

Masimo Receives Clearance for AI-Enabled Opioid-Induced Respiratory Depression Detection

Masimo, a Danaher company and a specialty diagnostics solutions innovator of pulse oximetry and other patient monitoring solutions, today announced FDA 510(k) clearance for an opioid-induced respiratory depression detection capability integrated into the Radius VSM wearable continuous patient monitor. Enabled by Masimo's next-generation *smartSET* pulse oximetry sensor platform, the new feature uses advanced pattern recognition that analyzes continuous physiologic data to help clinicians identify early signs of respiratory compromise in hospital patients receiving opioid therapy. This clearance represents the first implementation of Masimo's OIRD detection capability in a hospital monitoring solution. By combining the trusted signal quality of best-in-class Masimo SET with AI-enabled analysis, *smartSET* features like OIRD detection are expanding the role of pulse oximetry from monitoring patient status to surfacing actionable insights. Translating continuous data into earlier clinical awareness supports faster, more informed decisions when time matters most, such as when a patient's condition is rapidly worsening. To accelerate the potential impact of such technology on how patient care is delivered throughout the hospital, Masimo is developing additional pattern-recognition algorithms for the *smartSET* platform. "Opioid-Induced Respiratory Depression remains a critical patient-safety concern," said Dr. Basil Matta, Chief Medical Officer at Masimo. "With OIRD detection, Masimo is bringing advanced pattern recognition to continuous, wearable monitoring to help clinicians identify earlier changes in a patient's respiratory status that may not be apparent through traditional approaches. This capability reflects our ongoing focus on working closely with clinicians to address complex patient-safety challenges with meaningful innovation. OIRD detection on Radius VSM will help expand continuous monitoring from simple measurement to meaningful insight, supporting safer care throughout the hospital." Building on industry-leading RD SET sensor technology, *smartSET* is engineered to unlock the value of continuous parameter insights by analyzing complex physiological patterns and relationships rather than relying on individual parameters alone. Its design also allows for future integration into additional hospital monitoring solutions, extending its transformative impact across care environments

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Understanding Your Breathing Tests: A Plain Language Reference to Pulmonary Function Tests for Pulmonary Hypertension Patients and Caregivers

Seth Hall MBA, RRT, RRT-ACCS, RRT-NPS

Why Did My Doctor Order Breathing Tests?

If you have pulmonary hypertension (PH), you may have been through several tests already such as blood work, a six-minute walk down a hallway, or a heart scan. At some point, your care team might ask you to breathe into a machine to test your lungs.

Those breathing tests are called pulmonary (lung) function tests, or PFTs. This guide explains what they measure and why they matter when you have PH. It also walks through the numbers you see on your report.

PFTs do not find PH on their own. What they do is help your team answer a few questions. How open are your airways? How much and how fast is air moving in and out of your lungs? How well does oxygen move from your lungs into your blood?¹

Spirometry and PFTs: What Is the Difference?

Sometimes the words spirometry or PFTs are used when referring to lung tests. PFT is the general term for all the breathing tests. Spirometry is just one of them. A full PFT visit usually has three parts:

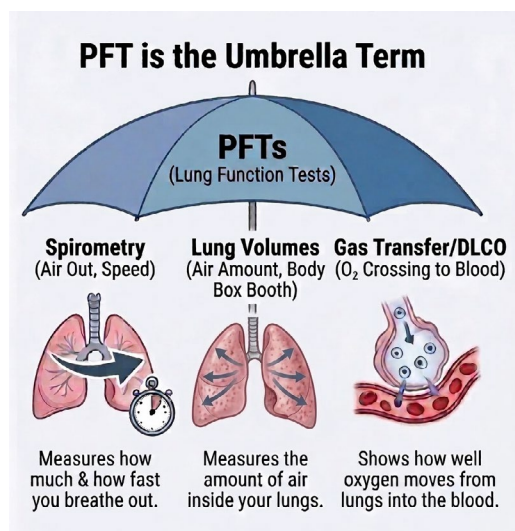


Figure 1. PFT is the umbrella term. Spirometry is one test under it

- **Spirometry** measures how much air you can breathe out, and how fast. A respiratory therapist coaches you to take a deep breath and push the air out.²
- **Lung volumes** measure the amount of air inside your lungs. This part is often done in a clear booth called a body box.³
- **DLCO** measures how well gas moves from your lungs into your blood. You breathe in a safe gas, hold your breath for about ten seconds, and let it out.⁴

If your doctor says you are going to get PFTs, spirometry is part of it. The full set usually includes lung volumes and DLCO as well.

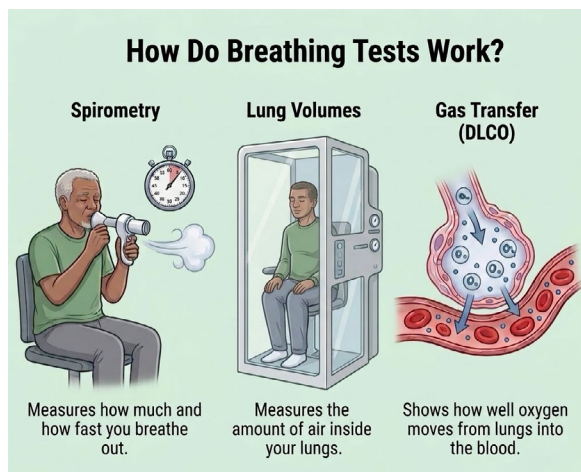


Figure 2. Understanding the different breathing tests

The Numbers on Your Report

- **FVC:** The total amount of air you can breathe out after filling your lungs. Think of it as your internal air tank.
- **FEV1:** How much air comes out in the first second. This shows how open your airways are.
- **FEV1/FVC ratio:** How much of your air comes out fast. A low number can point to narrow airways. A normal number with a small air tank can point to stiff lungs.
- **TLC:** The largest amount of air your lungs can hold.
- **DLCO:** How well oxygen moves from your lungs into your blood. PH affects the small blood vessels in the lungs, so this is often the number your PH team watches closely over time.⁵
- **Percent predicted:** Next to each result is a percentage. It compares you with a healthy person of your age, height, and sex. As a rough guide, a value around 80 percent or higher is often considered close to normal, but there is no single cutoff that

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fits everyone. Your care team looks at the full picture, and your own change over time usually tells them more than any single number.⁶

Your Breathing Test Report: What the Numbers Mean

Key Term & Icon	Plain Language Explanation
FVC (Full Tank) 	Total air you can blow out (full tank).
FEV1 (First Second) 	Air you blow out in the first second.
FEV1/FVC Ratio (Speed) 	How much comes out quickly.
TLC (Total Lung Size) 	The largest amount of air your lungs can hold.
DLCO (Oxygen Move) 	How well oxygen moves into to your blood.
Percent Predicted (Comparison) 	How your results compare to what's expected for someone like you.

Figure 3. A plain language guide to the terms on your report

What PFTs Often Show in PH

In some kinds of PH, spirometry can look normal. That catches many people off guard. Your airways might move air just fine. The real trouble sits deeper, in the tiny blood vessels of the lungs, where the vessels have become narrow and stiff. DLCO is the test that picks this up. Many people with PH have a low DLCO while the rest of their report looks fine.⁷

If you have PH along with a lung disease that scars the lungs (PH-ILD), the pattern usually looks different. Scarring makes the lungs small and stiff, so FVC and TLC are often low. DLCO tends to fall even further than the smaller lung size would explain. That gap is one of the clues that PH may be present too.⁸ This is why your team may repeat PFTs from time to time. Changes in these numbers, such as DLCO, help your team see how you are doing over time and whether your plan needs to change.

What the Test Feels Like

PFTs are safe, but they take real effort. You will breathe out hard and repeat the same steps a few times. You might feel a little dizzy or tired, or you might cough. All of that is normal. Your respiratory therapist repeats the steps because the results have to match to be trusted, not because you did anything wrong.² A few things that help:

- Ask your team ahead of time whether to take or hold any medicine, such as inhalers, before the test.
- Do not eat a big meal right before testing and skip hard exercise that day.
- Wear loose clothes that do not squeeze your chest.
- If you use oxygen, do not change it on your own. Tell the care team, and they will follow your provider’s plan.
- Give it your best effort. The numbers are only as good as the breaths behind them.

What Should I Expect?



Preparation Checklist

- ☒ Ask about medicines/ inhalers before the test 
- ☒ Skip big meals and hard exercise 
- ☒ Wear loose clothes 
- ☒ Tell the team if you use oxygen 
- ☒ Give your best effort. It helps get the best results 

You might feel tired, dizzy, or cough. This is normal.

Figure 4. What to expect on test day, and how to prepare

Questions to Ask About Your Results

- How do these results compare with my last test? Am I stable, better, or lower?
- What is my DLCO, and what does it tell you about my PH?
- Do my results point to an airway problem, a lung size problem, or a gas transfer problem?
- Do these results change my treatment plan or my oxygen?
- When should I have PFTs again?

What to Remember

Spirometry is one test. PFTs are the whole set. For people with PH, DLCO is very useful, because it looks straight at the job your lung blood vessels might be struggling with: moving oxygen into your blood. If one number is flagged, or the report is hard to make sense of, that is okay. Bring your questions to your PH team and ask them to show you how your results are changing over time. These tests are there to help your team take good care of you.

**This reference is for learning only. It does not replace advice from your own care team. Always talk about your results, your medicine, and your oxygen with your PH care providers.*

**Figures in this guide used AI generation to assist with plain language visualization of key messaging for patients and caregivers then verified for medical accuracy.*

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as part of Masimo's broader connected ecosystem. Radius VSM is a wearable, tetherless, modular vital signs monitor designed to support continuous assessment of patient status throughout the hospital, with the ability to tailor monitoring to meet each patient's needs. The addition of *smartSET*-powered analysis and OIRD detection to Radius VSM expands the platform's ability to assist clinicians in spotting changes in patient condition and helps bring advanced physiological insight to more care areas. The OIRD feature includes visual alarms, which alert clinicians to changes in a patient's condition and escalate as OIRD risk increases. The alarms are presented on the device's display and can be relayed to remote and centralized monitoring stations.

Positive Airway Pressure Therapy May Reduce Pulmonary Arterial Pressures in Obstructive Sleep Apnea

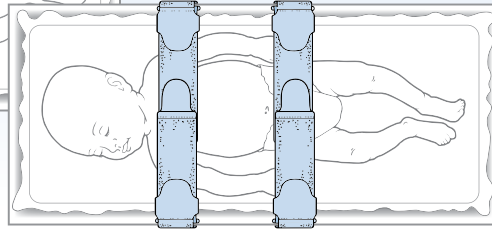
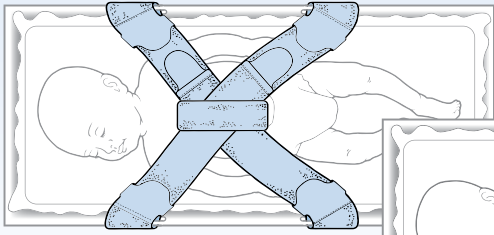
In patients with predominantly severe obstructive sleep apnea (OSA) or obesity hypoventilation syndrome (OHS), treatment with positive airway pressure (PAP) therapy was associated with clinically meaningful reductions in pulmonary arterial pressures, especially among those with established pulmonary hypertension. Researchers conducted a systematic review and meta-analysis of 23 studies (20 observational studies and three randomized controlled trials) to examine whether PAP therapy alters mean and systolic pulmonary arterial pressures in patients with OSA or OHS, including those with preexisting pulmonary hypertension. Overall, 733 patients (mean age, 55.9 years; 64% male), including 518 with OSA and 215 with OSA or OHS, underwent PAP therapy; pretreatment and posttreatment pulmonary arterial pressure measurements were available for 718 patients. The primary outcome was the absolute change in pulmonary arterial pressure, measured in mm Hg, after PAP therapy. OSA is marked by repeated partial or complete upper airway collapse during sleep, causing intermittent hypoxemia, arousals, and large intrathoracic pressure swings; OHS was defined as obesity with sleep-disordered breathing plus daytime hypercapnia. Among all patients, use of PAP therapy was associated with a mean reduction of 5.96 mm Hg in pulmonary arterial pressure across all measurement methods, including mean and systolic pulmonary arterial pressures ($P < .0001$). Among patients with pulmonary hypertension at baseline, use of PAP therapy was associated with a mean reduction in pulmonary arterial pressure of 11.41 mm Hg ($P < .00001$). “[Our] finding highlights the need for assessing patients with severe forms of OSA or OHS for PH [pulmonary hypertension] and assessing treatment response over time,” the authors of the study wrote.

Company to Present at ATS 2026

Insmid Incorporated, a people-first global biopharmaceutical company striving to deliver first- and best-in-class therapies to transform the lives of patients facing serious diseases, announced that it will present six abstracts from across its respiratory portfolio and pipeline at the American Thoracic Society International Conference 2026 (ATS 2026), taking place May 17–20 in Orlando, Florida. Notably, data will be presented from the Phase 3b ENCORE study evaluating ARIKAYCE (amikacin liposome inhalation suspension) with multidrug therapy (azithromycin 250 mg + ethambutol 15 mg/kg) once-daily versus placebo with multidrug therapy once-daily in diagnosed adult patients with a new occurrence of *Mycobacterium avium* complex (MAC) lung infection who had not received antibiotics. Additional presentations include a post-hoc analysis from the Phase 3 ASPEN trial of BRINSUPRI (brensocaticib), real-world experience data in patients with non-cystic fibrosis bronchiectasis (NCFB), a

Continued on page 56...

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A Novel High Flow Nasal Interface (HFNI) Cannula Designed to Improve Comfort and Safety

Alex Stenzler, Ben Dadacay, Steve Han

Inhaled oxygen has been used as a therapeutic agent since the late eighteenth century and was used to treat acute hypoxemia as early as 1887.¹ It is currently administered to increase the alveolar partial pressure of oxygen (PO_2) to treat abnormal ventilation-perfusion mismatching. In nonintubated patients with acute hypoxemic respiratory failure (AHRF), the oxygenation effect of supplemental oxygen using standard masks or nasal cannulas may be limited if the patient's inspiratory flow rate exceeds the flow of delivered oxygen, resulting in entrainment of ambient air.

The High Flow Nasal Cannula (HFNC) is a newer mode of delivering supplemental oxygen at high flows (40–60 L/min) that enables meeting the patient's high inspiratory flow to deliver a high FIO_2 . The gas is also heated and humidified to minimize mucosal injury and patient discomfort, somewhat overcoming the key problems of past use of high flow rates.

Since its recent entry into clinical practice, the HFNC has proven clinically successful. In a trial of patients with AHRF, HFNC (compared with either standard oxygen therapy or noninvasive ventilation) was associated with reduced mortality risk, higher ventilator-free days, and reduced risk of intubation in the subset of patients with moderate or severe hypoxemia ($PaO_2:FIO_2 < 200$ mmHg).² Other clinical trials have found that HFNC can prevent post-extubation respiratory failure.³ Because of its apparent clinical benefit, considerable attention has been devoted to developing cannulas and high flow delivery systems to improve its clinical application.

While nasal cannulas are generally safe and effective, they can still be uncomfortable, especially with prolonged use. Common complaints include nasal irritation, sneezing, dry or bleeding nasal passages from the physical prong contact and the continuous oxygen flow, as well as from the ear irritation or friction where the plastic tubing rests.

However, one of the more concerning aspects of existing HFNC designs, is that therapists need to “estimate” the percent occlusion of the nares when selecting the appropriate size cannula for a specific patient.⁴ If a patient keeps their mouth closed when treated with a HFNC, the only pathway out of the lungs is around the cannula prongs that are blocking the nostrils. If the area around the cannula is too small, then the increased resistance can generate an elevated end-expiratory

pressure, a form of PEEP, which can result in a negative cardiac performance from over-distention of the lungs.

Most manufacturers therefore recommend that cannulas are selected for patients where the prong is only 50 percent of the diameter of the nostril. However, besides being just an estimate, any cause of nasal passage narrowing as a result of inflammation, nasal discharge, or mucus accumulation, can change the level of PEEP without the therapist or bedside nurse being aware of the effect. Additionally, nasal passages naturally alternate their resistance, a process called “the nasal cycle”, whereby the erectile tissue (turbinates) inside the nose alternately swells and shrinks, causing resistance and airflow to shift between the nostrils roughly every 2 to 6 hours. And even simply adjusting the location of the prongs within the nose can affect the level of PEEP generated by the high flows. For these reasons, the use of HFNC is frequently limited to environments with more highly trained personnel.

New Novel Design

To address the comfort and potential safety aspects that may be associated with conventional HFNC's, a novel cannula interface was designed that keeps the prongs outside of the nose and seals the nostrils with nasal pillows, similar to those used for nasal CPAP. The pillows act like an extension of the nostrils with the nasal prongs situated within the pillows. This transfers the patient's usual nasal irritation to the pillow. Nasal pillows are typically used for nasal CPAP and are sufficiently comfortable so that patients can easily sleep through the night while the CPAP devices deliver 20 to 120 LPM through them.

An additional benefit is that the angle of the design keeps the pillows and prongs off the patient's upper lip, eliminating another area of discomfort. Further comfort is enabled with a split head strap between the crown and back of the head, eliminating irritation from tubing contacting the top of the patient's ear.

Author information is found at the end of this article.



Figure 1. The nasal pillows are lifted off the upper lip and the split head strap doesn't rest on the patient's ears.

To solve the uncertain unintended PEEP associated with nostril size estimation and conventional HFNC nasal prongs, there are multiple fixed gas exit ports on the back of the nasal pillows that provide the openings for excess flow, as well as serve as the exhalation pathway for the patient.



Figure 2. Gas exit ports

Since the ports do not change resistance, the PEEP generated does not change as patient nasal resistance changes, or with changes in the patient's lung compliance.

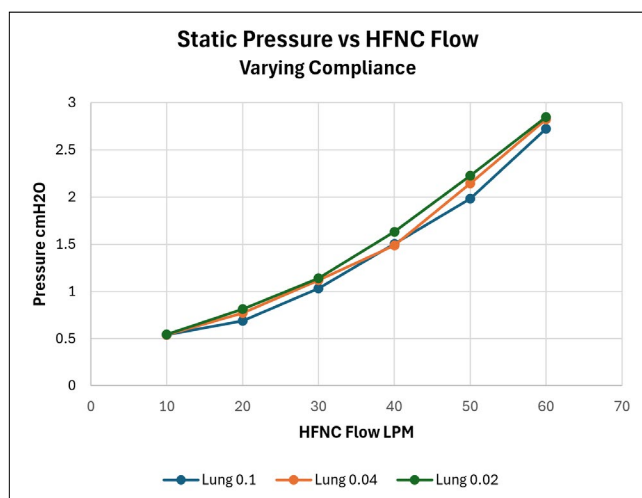


Figure 3. Static pressure at flow ranges from 10 to 60 LPM at three compliances

The high flows entering the upper airway from the pillows generate significant mixing to enhance CO₂ clearance. A computational fluid dynamics (CFD) analysis of the flow in an NIH model of the upper airway is shown in Figure 4.

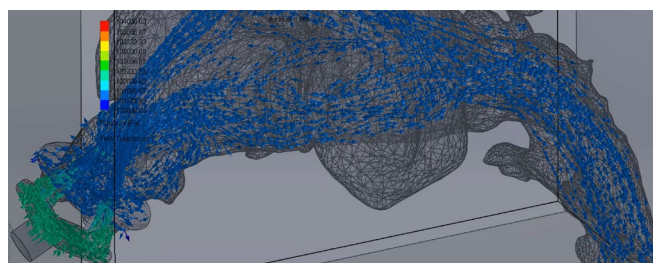


Figure 4. CFD analysis of flow in the upper airway

Other general benefits of this design include expandable wings that allow for different nasal septum width without having to stock multiple sizes of prongs, and easily exchangeable pillows to adapt to a wide range of nostril sizes. The high flow gas source enters the HFNI from the center, which can swivel so that it can conveniently come from either side of the patient's bed.

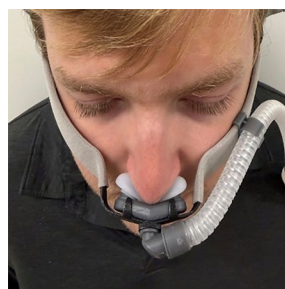


Figure 5a



Figure 5b



Figure 5c

Figure 5a shows the swivel gas entry for enabling placement from either side of the patient's bed. Figures 5b and 5c show the adjustment of the spacing to meet three different septum width of patients with a single device. Easily swappable silicone pillows for three different nostril sizes.

Discussion

Clinicians are constantly identifying more patients that might benefit from the use of High Flow Nasal Cannulas. However, due to the unpredictability of increasing distending pressure, better trained personnel are required to supervise the use of the devices. Described here is a new High Flow Nasal Interface that extends patients' nostrils with silicone pillows and moves the nasal prongs to within the pillows. The addition of gas exit ports on the pillows eliminates the need to estimate the area around the nasal prongs, removing the concern with elevated end expiratory pressure.

Conclusion

A novel HFNI as described in this paper can address many of the concerns with HFNCs, broadening where the benefits of this therapy might be applied. The increased comfort, wider addressable patient population, and better safety profile can improve the care of patients who require higher oxygen concentrations at higher flows.

Patent Pending

About the authors

Alex Stenzler is the president of 12th Man Technologies, Inc. He was a Registered Pulmonary Function Technologist and has been working in the field of pulmonary function testing since 1968. He spent half of his career managing Respiratory Care Departments, COPD Clinics and Pulmonary Function Laboratories, or teaching pulmonary function technology as an Assistant Professor at the State University of New York at Stony Brook and twelve years at the Graduate School of Adelphi University. He has been the PI for two NIH and one DARPA grant and has extensive research experience. He has co-authored 28 peer-reviewed papers and one book chapter on pulmonary function testing. He holds 70 patents, most of which are related to pulmonary medicine. Alex is a member of the Editorial Advisory Board for Respiratory Therapy.

Ben Dadacay, BS is a Staff Design Engineer for Inneo Lab in California. He has designed several products in the healthcare space.

Steve Han, BSME is Vice President Product Development for Inneo Lab in California. He has developed dozens of infusion and respiratory products during his more than 28 years working for 12th Man Technologies, CareFusion, Cardinal Health, Viasys, Medtronic, and Johnsons and Johnsons. He holds more than 40 US patents.

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pharmacokinetic analysis of investigational treprostinil palmitil inhalation powder (TPIP), and data highlighting disease burden in pulmonary hypertension associated with interstitial lung disease (PH-ILD). “At Inmed, our work in respiratory disease is guided by the experiences of people living with serious and rare pulmonary conditions, where meaningful treatment advances are still urgently needed,” said Martina Flammer, M.D., MBA, Chief Medical Officer of Inmed. “The research we’re presenting at ATS 2026 reflects the strength of Inmed’s respiratory portfolio and pipeline, and our unwavering commitment to patients. Additionally, we’re honored to present the Phase 3b ENCORE study findings as a late breaker, which will highlight compelling evidence of ARIKAYCE’s potential use earlier in the treatment journey for patients living with *Mycobacterium avium* complex lung disease.”

Study Finds That When Patients Decline, Respiratory Changes Often Come First

As research has shown, early respiratory compromise can signal rapid patient deterioration — often before obvious warning signs appear. A study published in *Respiratory Care* highlights that respiratory decline may progress quickly and can lead to respiratory failure if not recognized and addressed early. In busy clinical environments where possible changes in respiratory status can be subtle and nurses are managing multiple patients at once, continuous monitoring that indicates possible changes in respiratory status can help support timely escalation of care — playing a critical role in patient safety and helping clinicians improve outcomes.

New Post-Surgical Compression Bra Launched

The Dale Post-Surgical Compression Bra offers the compression and support patients need following breast and thoracic surgeries. Soft, seamless, breathable fabric stretches to accommodate edema without binding or irritating sensitive tissue. Tabs to secure drainage bulbs directly to the bra. Multi-directional stretch provides uniform coverage over a patient’s chest and back. Front hook & loop closures facilitate inspection of the surgical site and dressing changes. Detachable straps allow for ease of application for caregivers and patients with limited arm movement. Provides maximum comfort throughout recovery, even while sleeping. Can be used to hold surgical dressings in place without tape. Not made with natural rubber latex.

Company Granted Breakthrough Device Designation

Airiver Medical, a clinical stage company developing technologies to help patients who suffer from certain respiratory tract conditions, was granted designation as a Breakthrough Device from the US Food and Drug Administration (FDA) for its Airiver Pulmonary Drug Coated Balloon (DCB) to treat central airway stenosis. The FDA Center for Devices and Radiological Health (CDRH) granted Airiver Medical the Breakthrough Device Designation to expedite development of its Pulmonary Drug Coated Balloon (DCB) for patient access because it has a reasonable chance of providing more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions than the current standard of care. “Receiving this designation is extremely meaningful for us because with it, patients and health care providers may gain more timely access to our novel DCB technology, with the potential to provide safer and more effective treatment,” said Mitchell Erickson, Director of Research and Development for Airiver Medical. “The Airiver DCB has the potential to fill a gap that currently exists, as there is no optimal

Continued on page 70...



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The Structural Blindspot: How Behavioral Checklist Mandates Hijack Mechanical Source Control in Ventilator-Associated Pneumonia (VAP) Guidelines

Hamid Khosrowshahi, Jerry Gentile, Stanley John

Abstract

Background

Clinical guidelines extensively emphasize behavioral checklist interventions, specifically Head of Bed (HOB) elevation and daily oral care with toothbrushing, as primary practices to mitigate Ventilator-Associated Pneumonia (VAP). Concurrently, these frameworks have shifted mechanical engineering controls, such as Subglottic Secretion Drainage (SSD), to secondary or optional statuses.

Objectives

This forensic literature audit examines the structural and data integrity of Ventilator-Associated Pneumonia (VAP) frameworks. Specifically, it investigates whether the documented clinical efficacy of behavioral checklists has been systematically co-opted from baseline data cohorts where mechanical source control (SSD) was actively present but uncredited as a confounding variable.

Methods

A comparative analysis was conducted on the evolution of critical care surveillance metrics, tracing the transition from Ventilator-Associated Pneumonia (VAP) to the 2013 Ventilator-Associated Event (VAE) paradigm.¹ We audited the structural methodology of the 2022 SHEA/IDSA/APIC guidelines,² the 2024 Klompas³ toothbrushing meta-analysis, Pileggi 2018,⁴ and modern systematic reviews (Leone 2026, Martelli 2026)^{5,6} alongside the CHEST 2025⁷ administrative guidelines critique.

Results

The audit identifies four distinct methodological and data-reporting discrepancies in current guidelines:

- **The Hydrodynamic Variable & Pathogenesis:** Standard guidelines frequently treat the oral cavity as a static surface, underemphasizing the 800 to 1,500 cc of secretions generated daily.⁸ Established pathogenesis data (Bonten 1994)⁹ indicates that approximately 80% of VAP cases originate from the microaspiration of these pooled subglottic secretions.
- **Single-Study Staging Thresholds:** The elevation of HOB compliance to a primary mandatory baseline within early surveillance blueprints (Klompas 2009)¹⁰ traces back to a

single randomized controlled trial with a limited sample size (Drakulovic 1999; n=86).¹¹

- **Inconsistent Variable Compounding:** Current meta-analyses championing independent toothbrushing mortality benefits (Klompas 2024)³ rely heavily on an inflated study denominator containing 8,709 non-ventilated ward patients. Concurrently, these analyses rely on datasets where toothbrushing was actively compounded with chlorhexidine, despite separate guideline recommendations advising against chlorhexidine usage and classic trials (Munro 2009)¹² showing no independent benefit for toothbrushing.
- **Omission of Baseline Mechanical Controls:** Influential systematic reviews (Pileggi 2018, Martelli 2026)^{4,6} attribute positive airway outcomes entirely to behavioral bundles, omitting the baseline equipment variable of the underlying trials, such as Lorente 2012,¹³ where mechanical source-control was actively running in the background but went uncredited. This clinical blindspot directly validates the global perspective of Leone 2026,⁵ who warns that the modern shift toward checklist-driven surveillance has systematically marginalized necessary physical engineering controls. Specifically, the Zhao 2020 (Cochrane)¹⁴ and Sozkes 2021¹⁵ meta-analyses, which serve as the primary empirical justification used by the 2022 SHEA guidelines² to mandate daily oral care with toothbrushing as an essential practice, heavily incorporate the data from Lorente 2012¹³ while failing to disclose or control for this critical confounding variable: 87.7% of the patients in both the intervention and control cohorts of the Lorente trial (n=436) was intubated with an SSD endotracheal tube active in the background, systematically co-opting the therapeutic signal of mechanical source control and misattributing the VAP reduction entirely to behavioral toothbrushing.

Conclusion

HOB elevation and oral hygiene serve as important supportive clinical measures, but their efficacy remains physically dependent on mechanical fluid evacuation. Decoupling behavioral checklists from their mechanical prerequisites satisfies administrative reporting metrics but leaves the physical airway vulnerable to VAP. SSD warrants re-evaluation as an essential engineering foundation of airway safety.

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Introduction: The Checklist Paradigm in Airway Management

Critical care medicine has increasingly relied on standardized, behavioral checklist protocols to manage complex, hydrodynamic Ventilator-Associated Pneumonia (VAP) risks. Over the past two decades, national and international guidelines have steadily elevated interventions such as intensive oral care, toothbrushing, and head-of-bed (HOB) elevation to primary positions within safety bundles. As observed in the comprehensive historical review by Leone et al. (2026),⁵ the evolution of preventive strategies has steadily favored behavioral process compliance over physical, device-based engineering controls.

To establish an objective baseline: HOB elevation, oral hygiene, and mechanical toothbrushing are highly valuable, common-sense clinical practices that represent standard patient care. Their utility in reducing oral bioburden and preventing gross gastric macro-aspiration is well-documented.

However, a forensic audit of the literature trail reveals a recurring reporting pattern: published clinical outcomes frequently attribute systemic success to these behavioral interventions while omitting the baseline mechanical engineering controls running concurrently in the background. When guidelines isolate behavioral checklists from their physical prerequisites, they risk substituting administrative process metrics for objective, anatomically grounded source control.

To expose how these biases became institutionalized, we must examine the very foundation of modern VAP prevention literature. Below, Table 1 provides a direct forensic auditing comparison. This table is structurally designed to challenge the highly influential Table 1 from Klompas’s landmark 2009¹⁰ analysis. That 2009 table became an academic blueprint for evaluating prevention measures, frequently prioritizing behavioral bundles while marginalizing mechanical controls. By comparing the original “Headline Claims” summarized in that paper against the primary data tables and patient cohort sizes (n) of the cited studies, the systemic reporting flaws that have compromised clinical guidelines for nearly two decades are laid bare.

Analytical Commentary: The forensic data shown in Table 1 illustrates a structural bias in the evolution of VAP prevention guidelines. By analyzing the lineage of these studies, a pattern emerges: the elevation of behavioral interventions, such as Head-of-Bed (HOB) positioning, at the direct expense of proven mechanical source control. The institutional “bundle” mandate was anchored by studies like Drakulovic (1999).¹¹ Despite the small sample size (n=86) and the fact that it studied HOB

positioning rather than mechanical airway drainage, it was used to establish the “essential” baseline. In contrast, the historical omission of SSD benefits, such as the classification of the Bouza (2008)²⁰ study as “Not Significant” and the length-of-stay metrics reported in the Dezfulian (2005)²¹ meta-analysis, effectively steered the industry away from a high-value mechanical technology in favor of the behavioral “bundle” model.

Hydrodynamic Reality and Pathogenesis: The Fluid Burden

An evaluation of behavioral oral interventions requires analyzing the baseline physiology of the human airway. As detailed in *Guyton and Hall Textbook of Medical Physiology*,⁸ the adult oral cavity produces between 800 to 1,500 cc of salivary secretions every 24 hours. In an intubated patient, the presence of an endotracheal tube compromises natural protective mechanisms, including functional swallowing, glottic closure, and effective coughing mechanisms.

The pathogenesis of ventilator-associated pulmonary complications follows a specific mechanical trajectory. The landmark data established by Bonten et al. (1994)⁹ outlines an 80/20 distribution in airway contamination pathways:

- **The 80% Mechanical Vector:** Approximately 80% of documented pulmonary infections develop via the continuous, gravity-driven microaspiration of colonized secretions pooling in the subglottic space directly above the endotracheal tube cuff.
- **The 20% Alternative Vectors:** The remaining 20% originate from hematogenous seeding, translocation, or acute gastric macro-aspiration.

The oral cavity functions as a continuous secretion generator. Mechanical toothbrushing represents a periodic, transient disruption of surface plaque. Once the procedure is completed, salivary production continues uninterrupted for the remainder of the 24-hour cycle. Consequently, surface interventions do not arrest the fluid volume vector itself.

The Gravitational Vector and the Staging of HOB Guidelines

Elevating the Head of Bed (HOB) to 30°–45° is widely implemented to minimize gastric reflux. However, when evaluated against the daily 800–1,500 cc oral secretion volume, physical principles dictate an additional outcome (see Figure 1).

Positioning an intubated patient upright directs un-swallowed, contaminated salivary secretions downward into the posterior pharynx. This fluid pools directly above the endotracheal tube cuff,

Table 1. Forensic Audit of the Klompas 2009 Literature Lineage

Study	Intervention	# of Patients	Klompas’s Reported Impact	Actual/Factual Outcome
Drakulovic 1999 ¹¹	HOB Elevation	86	Essential: The bedrock of the VAP bundle	HOB Study: Methodological limitations; reported a 78% VAP reduction
Van Nieuwenhoven 2006 ¹⁶	HOB Elevation	221	Included: Used to validate bundle logic	HOB Study: Strongly refutes Drakulovic’s claims
Valles 1995 ¹⁷	Continuous SSD	153	37% VAP reduction	43.4% VAP reduction; superior mechanical control
Smulders 2002 ¹⁸	Intermittent SSD	150	Minimized	Significant reduction (75%) in colonization and infection
Lorente 2007 ¹⁹	Intermittent SSD	280	Minimized	Significant reduction (64%)
Bouza 2008 ²⁰	Continuous SSD	690	NS (Not Significant)	Significant (p=0.04) for patients 48h
Dezfulian 2005 ²¹	Meta-analysis	896	Zero impact on length of stay	~2 days reduction in ventilation; ~2 days reduction in ICU

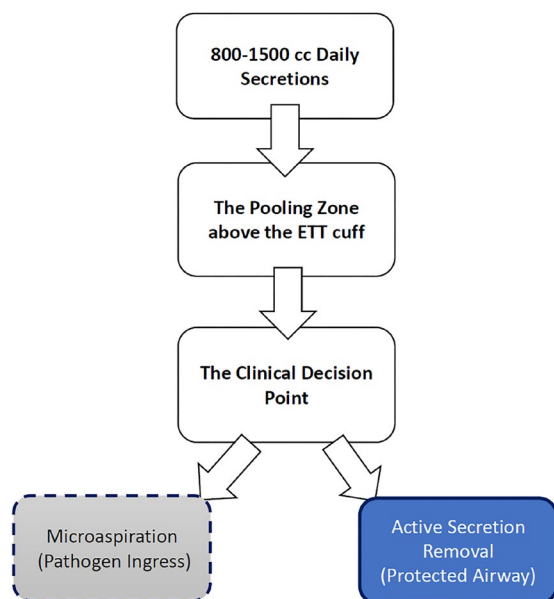


Figure 1. The Gravity Trap: Anatomy of Airway Failure.

creating a localized hydrostatic column. Because standard cuffs do not form a perfectly fluid-tight seal against the irregular mucosal walls of the trachea, positive pressure ventilation and capillary action facilitate the microaspiration of this colonized fluid into the lower respiratory tract.

HOB elevation shifts the fluid transit path but does not evacuate the volume. Without active mechanical extraction via Subglottic Secretion Drainage (SSD) to intercept this pool, the biological threat to the lower respiratory tract persists.

When we contrast these behavioral risk-reduction strategies against the mechanical reality of the airway, the systemic error becomes clear: we have been focused on managing the consequences of aspiration rather than stopping the source. The following visual taxonomy (Figure 2) categorizes these interventions to highlight this fundamental failure.

The Silence on Harvard-Funded Research

Perhaps the most striking indicator of the “VAE-first” bias is the institutional silence regarding Branch-Elliman et al. (2015).²² This Harvard-funded cost-benefit decision model, which evaluated 120 different intervention combinations, identified SSD as an essential component of all optimal VAP prevention strategies. Despite these robust cost-effectiveness conclusions across all tested parameters, subsequent consensus guidelines have ignored these findings and

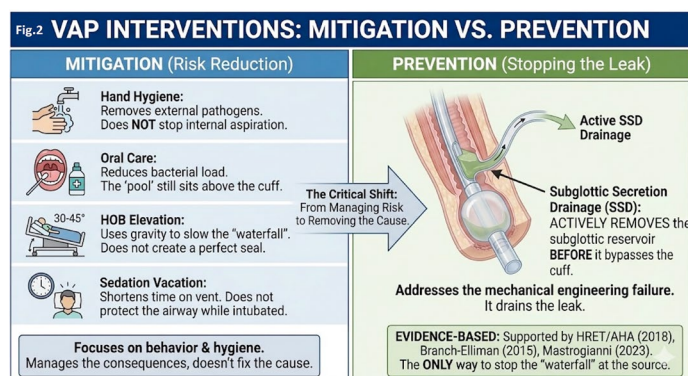


Figure 2. VAP Interventions: Mitigation versus Prevention.

downgraded the intervention. Furthermore, the participation of co-author Michael Howell in both the 2014 SHEA²⁴ guidelines and the 2015 Harvard study²² creates a profound paradox: the data existed to support SSD as a “Zero Harm” standard, yet that reality was systematically sidelined to accommodate the VAP-to-VAE surveillance transition.

Methodological Origins of HOB Dogma: Drakulovic 1999 vs. Van Nieuwenhoven 2006

The historical elevation of HOB compliance to a primary mandatory status, relative to mechanical controls, is traceable to early surveillance design models, specifically Klompas’s 2009 “Paradox”¹⁰ paper. This framework established HOB elevation as a foundational recommendation, relying primarily on the randomized controlled trial by Drakulovic et al. (1999) (n=86).¹¹ Although Klompas (2009)¹⁰ explicitly cited Van Nieuwenhoven et al. (2006)¹⁶ in his review, the profound methodological criticisms raised by the latter were systematically sidelined in the resulting guideline models. A forensic audit of the Drakulovic 1999¹¹ data reveals:

- **Control-Group Protocol Variation:** Drakulovic¹¹ utilized a 0° supine control position protocol and administered enteral nutrition strategies that may have accelerated retrograde fluid flow, influencing the control cohort’s comparative VAP rate, contrary to standard clinical care (10°–15°). Furthermore, Van Nieuwenhoven et al. (2006)¹⁶ exposed that Drakulovic¹¹ aggressively administered anti-gastric and enteral feeding solutions to these completely flat control patients, physically accelerating the retrograde flow of gastric contents and saliva upward toward the airway, thereby artificially inflating the control cohort’s VAP rate.
- **Workplace Unsustainability:** Van Nieuwenhoven’s¹⁶ larger, multi-center randomized trial (n=221) demonstrated that maintaining a 45° angle is clinically unsustainable in daily practice due to patient slipping and nursing workflows. When compared against standard care (10°), forcing HOB elevation resulted in 0% difference in VAP rates.

Despite this clear refutation, Klompas¹⁰ used these early surveillance blueprints to lock HOB elevation into national guidelines as a mandatory metric, establishing a historical precedent of prioritizing low-cost behavioral compliance over specialized mechanical engineering.

The Surveillance Paradigm Shift and Historical Content Modifications

The repositioning of mechanical source control within clinical guidelines corresponds with structural changes in how healthcare facilities track and report airway complications.

The VAP-to-VAE Surveillance Transition

In 2013, under guidance from the US Department of Health and Human Services (HHS) and its National Action Plan to Eliminate Health Care-Associated Infections (HAIs), the Centers for Disease Control and Prevention (CDC) shifted surveillance tracking from Ventilator-Associated Pneumonia (VAP) to the Ventilator-Associated Event (VAE) model.¹

This transition substituted subjective clinical and microbiological criteria with automated, electronic algorithms tracking changes in PEEP and FiO₂. Commenting on this shift, Leone et al. (2026)⁵ observe that the VAE paradigm has effectively isolated surveillance metrics from clinical biological reality. While the automated criteria

minimized inter-observer variability and lowered reported “paper rates,” they rendered the electronic surveillance system structurally blind to the physical process of subglottic fluid migration and localized tissue infection.

Content Modification Trends in Safety Organizations

For two decades, numerous publications and institutional reports cited the Institute for Healthcare Improvement (IHI) Ventilator Care Bundle²⁶ as the primary driver behind reported ‘near-zero’ Ventilator-Associated Pneumonia (VAP) rates. A retrospective examination of these success stories, however, indicates that these outcomes were consistently achieved in environments where mechanical source control, specifically Subglottic Secretion Drainage (SSD), was utilized, a finding supported by Mastrogianni et al. (2023)²⁵ and Pileggi et al. (2018).⁴

Following an extensive re-evaluation of the clinical evidence, the IHI removed its legacy VAP bundle documentation and associated success stories from its platform in December 2023 (Lorente 2024).²⁹ Despite this formal retraction, the reliance on these original, behavioral-only bundles remains pervasive, with approximately 75% of hospitals globally continuing to apply them. There is an urgent need to modernize these protocols by formally incorporating mechanical interventions, such as SSD, as essential rather than optional components of airway protection.

Methodological Double Standards: Rigorous Device Criteria vs. Lax Checklist Mandates

The clinical downgrading of mechanical interventions within official guidelines frequently relies on an asymmetrical application of epidemiological standards. Guideline architects apply an isolated, single-variable standard to physical hardware, demanding that a mechanical device independently demonstrate a reduction in all-cause ICU mortality to maintain an “essential” safety recommendation. Conversely, behavioral checklist interventions are fast-tracked and mandated using deeply flawed, highly compounded, and non-ventilated datasets.

The Asymmetrical Mortality Standard for Devices

A critical inconsistency exists in the evidentiary standards applied to medical devices versus behavioral interventions within current guidelines. For example, the expert panel justifying the SHEA 2022² guidelines downgraded Subglottic Secretion Drainage (SSD) from an essential to an optional practice, citing a lack of significant impact on mortality as the primary rationale. However, this rigorous mortality standard is applied asymmetrically. The same guidelines elevated mechanical toothbrushing to “essential” status based largely on systematic reviews by Zhao¹⁴ and Sozkes.¹⁵ These reviews relied on Randomized Controlled Trials (RCTs) that utilized Chlorhexidine (CHX) and featured historical data, such as the study by Lorente et al. (2012),¹³ which achieved an active SSD implementation rate of **87.7%** across its study population. It is inherently contradictory to leverage outcomes derived from SSD and CHX to justify the promotion of toothbrushing, particularly when the SHEA 2022² guidelines do not recommend the use of CHX at all. This analytical friction is underscored by previous evaluations (Klompas, 2017)³⁰ regarding the variable benefits of oropharyngeal decontamination, which questioned the broad use of antiseptics. Ultimately, the guidelines demand a mortality-based evidentiary threshold for mechanical source control devices that is not applied to the behavioral interventions they continue to prioritize.

Denominator Inflation, Variable Compounding, and the Munro 2009 Omission

This rigid mortality standard contrasts sharply with the methodology utilized by Klompas et al. (2024)³ to endorse universal hospital toothbrushing mandates, claiming an ICU mortality benefit. A forensic audit of the underlying data structure reveals a massive epidemiological mismatch built on variable compounding, denominator inflation, and active data co-option:

- **Denominator Inflation:** To establish statistical significance for the mortality signal, the meta-analysis incorporated data from 8,709 awake, non-ventilated ward patients into the primary study denominator (Figure 3). These patients maintain intact airway reflexes, meaning they do not experience the subglottic secretions pooling typical of intubated patients. When these non-ventilated populations are separated from the analytical cohort, the reported ICU mortality benefit shifts significantly. Furthermore, these flawed metrics are not merely academic errors; they are actively used as marketing tactics by industry stakeholders to promote “bundle” products to hospital systems, despite the absence of a proven, independent mechanical link to patient survival.
- **The Chlorhexidine Variable Compounding:** The foundational data supporting current VAP prevention guidelines suffers from significant “variable compounding,” particularly regarding the historic use of oral chlorhexidine (CHX). Guideline panels have frequently cited systematic reviews, such as those by Zhao¹⁴ and Sozkes,¹⁵ to justify elevating interventions like toothbrushing to “essential” status. However, these reviews are heavily reliant on RCTs that utilized CHX as an adjunct. This bias persists in recent literature; for example, the Klompas (2024)³ meta-analysis relies on a study pool where 11 out of 15 included RCTs actively compounded the effect of toothbrushing with CHX or other antiseptic agents. This creates a methodological complexity: while the current SHEA 2022² guidelines do not recommend the use of CHX due to concerns over efficacy and potential mortality risks (Klompas, 2017),³⁰ the evidence base used to build the current bundle recommendations remains inextricably tied to its application. By failing to account for this variable compounding, the guidelines grant “essential” status to behavioral interventions based on outcomes that may have been driven by an antiseptic that the panel itself now deems unsupported.
- **The Munro 2009 Baseline Filter:** The flaw of compounding these variables is proven by classic critical care literature. In the definitive randomized controlled trial by Munro et al. (2009) (n=192)¹² investigators isolated mechanical toothbrushing from chlorhexidine. The Munro data demonstrated that while topical chlorhexidine significantly reduced VAP scores on day 3, mechanical toothbrushing provided absolutely zero independent statistical benefit in reducing VAP incidence (see Figure 3).

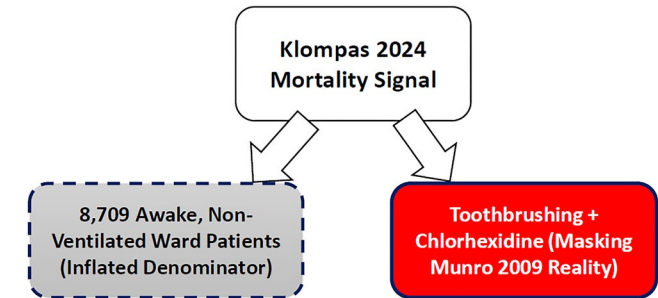


Figure 3. Denominator Inflation: Diluting the Mortality Signal.

Data Co-Optation of Lorente 2012: To inflate the “success” of oral hygiene, Klompas heavily utilized the data from Lorente et al. (2012)¹³ (randomizing n=436 patients). Yet, Klompas³ failed to disclose or control for the fact that while the trial protocol mandated mechanical source control, actual procedural realization showed that **87.7%** of those patients were intubated with an active Subglottic Secretion Drainage (SSD) endotracheal tube.

By absorbing datasets where toothbrushing was merely a passive passenger next to strong chemical antiseptics and active mechanical drainage, the 2024³ framework incorporated external procedural variables, influencing the outcomes of the administrative toothbrushing evaluation.

Documented Data Omissions: Exposing the Clinical Guideline Double Standard

The elevation of behavioral checklists within respiratory guidelines frequently relies on secondary literature that purports to provide objective, aggregate proof of bundle efficacy. However, a structural audit of these systematic reviews reveals that they do not evaluate clinical interventions in isolation from institutional bias; rather, they serve as closed-loop validation mechanisms designed to defend a specific administrative paradigm. This systemic bias is perfectly exemplified by the highly cited meta-analysis of Pileggi et al. (2018).⁴

The Pileggi 2018 Bundle Evaluation and the IHI Filter

Rather than evaluating the mechanical or physiological drivers of VAP reduction independently, Pileggi et al. (2018)⁴ anchored their entire scientific premise to the behavioral framework established by the Institute for Healthcare Improvement (IHI).²⁶ To preserve the structural homogeneity of their checklist narrative, the investigators used a strict screening mechanism. According to the study’s PRISMA flow chart, Pileggi et al.⁴ reviewed 94 potentially appropriate studies in detail but systematically excluded 18 trials explicitly because the “intervention implemented was not specific of IHI’s bundle approach.” This structural filter established a restricted study pool, ensuring that aggregate statistical outcomes aligned with the evaluation of checklist strategies.

The Omitted Mechanical Variable & Methodological Discrepancies in Guideline Leadership

By building a meta-analysis that functioned exclusively as an operational proxy for the IHI bundle, Pileggi et al. (2018)⁴ inherited the identical flaw that contaminated the IHI narrative for two decades: the variable erasure of downstream mechanical engineering.

Multiple primary trials analyzed in the Pileggi dataset, specifically Marra (2010),³¹ Hawe (2009),³² DeBose (2010),³³ Pérez (2014),³⁴ and De Luca (2017),³⁵ utilized endotracheal tubes equipped with Subglottic Secretion Drainage (SSD) as a baseline equipment standard. Yet, this physical variable was completely unaccounted for in Pileggi’s final bundle analysis.

The significance of this omission is laid bare by a direct mismatch in academic reporting:

1. In July 2018, Dr. Michael Klompas co-authored a prominent editorial in *Critical Care Medicine* titled “Rethinking Ventilator Bundles,”³⁶ specifically written to validate and accompany the Pileggi 2018⁴ meta-analysis.
2. In this editorial, the bundle’s “mortality benefit” was celebrated as the ultimate justification for maintaining the “essential”

status of behavioral bundles.

3. Yet, in the 2022 SHEA guidelines,² Klompas personally led the reclassification of SSD, downgrading it to an “Additional/Optional” practice because it supposedly lacked an independent, unconfounded mortality benefit in individual RCTs.

This illustrates a methodological inconsistency: bundle-level outcomes derived from trials utilizing active SSD were used to support behavioral recommendations, while individual device evaluations required unconfounded mortality endpoints to maintain essential status.

The Lorente 2012, Zhao 2020, and Sozkes 2021 Reporting Gaps

This systemic omission of baseline mechanical variables persists in contemporary reviews. In Martelli et al. (2026),⁶ a systematic review evaluating surface oral care, as well as the Zhao 2020 (Cochrane)¹⁴ and Sozkes 2021¹⁵ meta-analyses, the authors rely heavily on historical trial data, most notably the study by Lorente et al. (2012),¹³ to support the clinical value of intensive oral care and toothbrushing.

However, the synthesis omits a foundational technical parameter: in the Lorente 2012 trial (n=436),¹³ the evaluated patient cohort in both the toothbrushing and control arms was intubated using endotracheal tubes equipped with active SSD (Figure 4). By evaluating oral hygiene as an isolated variable, contemporary literature reviews celebrate surface decontamination while remaining structurally detached from the hydrostatic fluid collection occurring simultaneously at the balloon cuff, thereby co-opting the clinical success of physical source control to mandate a behavioral toothbrush.

The Surveillance Escape Hatch: From VAE to Hospital-Onset Sepsis (HOS)

The systematic retreat from physical airway pathogenesis to administrative checklists relies on a shifting series of surveillance metrics engineered to protect institutional budgets rather than patient biology.

The Algorithmic Blindspot: Leone 2026 and the VAE Shift

As documented by Leone et al. (2026),⁵ the CDC’s 2013¹ transition from Ventilator-Associated Pneumonia (VAP) to Ventilator-Associated Events (VAE) effectively isolated surveillance tracking from clinical reality. By replacing biological and microbiological markers of parenchymal tissue infection with automated electronic ventilator algorithms (such as changes in PEEP and FiO₂, the VAE paradigm lowered reported “paper rates” of VAP while remaining structurally blind to the physical migration of subglottic secretions past the endotracheal tube cuff. Leone et al. (2026)⁵ observe that while this algorithmic approach satisfied administrative reporting requirements, it left the physiological airway vulnerable to unmonitored fluid migration.

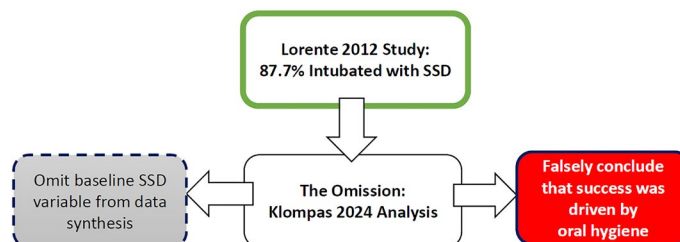


Figure 4. Analytical Omission: Misattributing Clinical Success.

The Underreporting Culture: Serrano-Mayorga & Reyes (2025)

The real-world consequence of this definitional decoupling is exposed in the CHEST (2025)⁷ editorial by Serrano-Mayorga and Reyes. Because clinical VAP is classified as a preventable complication, diagnosing it carries severe reputational and financial consequences. The authors document a pervasive “underreporting culture” where clinicians and hospitals hesitate to report airway infections to avoid commercial insurance claim rejections and institutional grading penalties. This financial risk may inadvertently incentivize administrative recording practices that favor automated VAE categories over clinical diagnoses.

As Serrano-Mayorga and Reyes (2025)⁷ emphasize, the systemic focus on “preventability” has created an underreporting culture that prioritizes avoiding financial and reputational penalties over actual patient safety. This is compounded by the fact that the very bundles used to “prevent” VAP, and which serve as the basis for these reporting metrics, have been shown to have no significant association with decreased VAP rates.

Shifting the Goalposts: The Pivot to Hospital-Onset Sepsis (HOS)

To bypass the widespread clinical failure and unpopularity of the VAE metric, surveillance architects are currently pivoting to a new automated EHR metric: Hospital-Onset Sepsis (HOS). This shift offers a final administrative escape hatch:

- **Administrative Expansion as an Exit Strategy:** The recent push by Manzoor/Klompas (2025)²⁷ to pivot surveillance metrics from device-associated infections (like VAP/VAE) to broader “Hospital-Onset Sepsis” broadens the tracking framework. By shifting the scope of accountable events, the reporting metrics alter the visibility of device-specific failures that were previously tied to stringent, albeit flawed, VAP/VAE performance metrics.
- **Empirical Admission of Surveillance Failure:** The shift is implicitly justified by data within the same research, which reveals that of all hospital-onset sepsis cases stemming from pneumonia, only 34.9% were officially classified as ventilator-associated (Manzoor 2025 and Page 2021).^{27,28} Co-authored by the very architects of legacy tracking frameworks, this data mathematically demonstrates that traditional device-associated tracking (like VAP/VAE metrics) misses over 65% of those severe, life-threatening respiratory infection drivers, letting them escape legacy surveillance.²⁸ This empirical finding proves that legacy surveillance frameworks focused narrowly on mechanical ventilation codes completely fail to capture the broader reality of hospital-acquired respiratory morbidity, rendering the previous device-centric framework obsolete.
- **Evidentiary Dilution:** By moving surveillance targets toward broader, more ambiguous categories, institutions insulate themselves from the specific punitive consequences of VAP reporting. This “shifting of the goalposts” avoids addressing the mechanical inadequacies of ICU care protocols by simply expanding the diagnostic framework, thereby hindering progress and delaying solutions for device-associated complications.

No amount of behavioral compliance, metric shifting, or broad-spectrum sepsis categorization can alter the physical laws of gravity and fluid dynamics. As demonstrated by the 64% VAP reduction observed in the Lorente et al. (2007)¹⁹ study, successful source control is achieved through mechanical intervention, not administrative surveillance. Until clinical guidelines reject these surveillance escape hatches and mandate continuous

mechanical evacuation via SSD, “zero harm” will remain an administrative illusion.

Conclusion: Reclaiming Engineering Over Checklists

VAP cannot be brushed away with a toothbrush or avoided simply by tilting a bed. While HOB elevation and oral care are valuable, common-sense supportive measures, elevating them to “essential” standalone status while downgrading mechanical controls is an epidemiological oversight driven by administrative convenience.

The 2013 shift to the VAE paradigm¹ allowed the medical industry to satisfy federal mandates on paper, but it did so by turning a blind eye to the biological reality of the airway. The clinical data utilized to evaluate SSD involves distinct evaluative standards: guidelines demand un-powered, all-cause mortality signals to downgrade a mechanical device, yet lower the bar to mandate a toothbrush using heavily inflated, non-ventilated ward data and trials that co-opted chlorhexidine benefits while ignoring classic standalone trials like Munro 2009.¹² Most importantly, the industry continuously co-opts the clinical success of trials like Lorente 2012,¹³ where toothbrushing was evaluated against a backdrop where 87.7% of patients had active SSD, to promote oral hygiene while erasing the mechanical device that made the outcome possible, all while ignoring dedicated SSD trials like Lorente 2007.¹⁹

When you elevate a bed or brush a patient’s teeth without continuous subglottic drainage, gravity and fluid dynamics simply deliver a cleaner biofilm straight down to pool at the balloon cuff. Influenced by current reporting penalties in the CHEST 2025 editorial,⁷ healthcare systems frequently default to administrative process metrics rather than physical engineering controls. To restore data integrity to respiratory medicine and ensure true patient safety, the clinical community must look past the administrative illusion of the checklist and recognize that Subglottic Secretion Drainage serves as the baseline engineering foundation that underpins all other airway interventions.

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Conflict of interest

Hamid Khosrowshahi is employed by Flosure Technologies, a manufacturer of an FDA-cleared automated subglottic suction pump. The authors report no involvement in the manufacture or sales of subglottic secretion drainage (SSD) endotracheal tubes.

Hamid Khosrowshahi performed the conceptualization, original research, and writing of the manuscript. Jerry Gentile and Stanley John contributed to the review, editing, and final approval of the manuscript.

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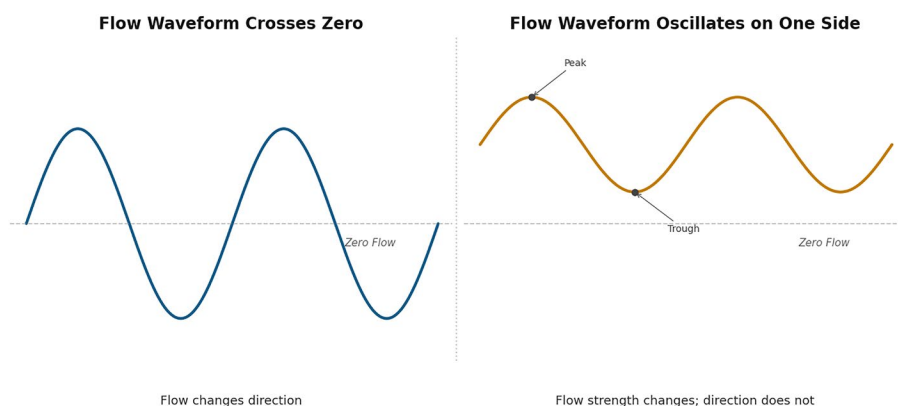
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When Flow Oscillations Don't Cross Zero

Distinguishing a change in flow strength from a true change in flow direction

Leah Noaeill, MBA and Vinay Joshi, BTech, MBA

When you watch an oscillatory flow waveform dance across the screen, it is easy to be dazzled by the amplitude. Rapid-fire oscillations that look like a vigorous tug-of-war between inspiratory flow and expiratory flow. But here is the question that separates a pretty waveform from a clinically meaningful one: Did the flow actually cross zero?



That distinction matters when we are thinking about secretion movement. Secretions do not respond to the appearance of a wave; they respond to the push created by airflow over time. A stronger pulse on the same side of zero is just a change in strength which may modulate the push in that same direction, but it does not automatically create an opposing pull.

Figure 1. Crossing zero indicates a change in flow direction. Remaining on one side of zero indicates that flow is changing in strength, but not direction.

Watch the zero line as reference point

Flow on one side of that line moves in one direction; flow on the other side moves in the opposite direction. Positive and negative conventions can vary by device or display, so the practical bedside question is simple: does the waveform cross zero?

If it does, the oscillation includes a true reversal. Otherwise, the trace may still look dynamic, but the flow remains directionally consistent. This is why “higher versus lower” flow should not be read as “expiratory versus inspiratory” flow unless the waveform changes sides.

Analyze the Momentum

For secretion clearance, the more useful mental model is a tug of war around zero. Expiratory and inspiratory components compete, but the winner is not decided by peak flow alone. It is decided by how high the flow rises on each side of zero and how long it stays there. A brief high spike may matter less than a lower flow that persists to keep pushing secretions in one direction.

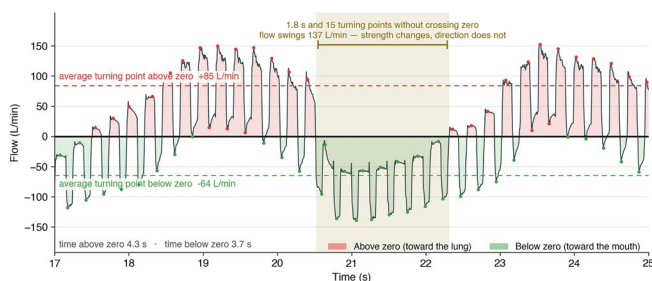


Figure 2. Flow above zero (red) travels toward the lung, flow below zero (green) toward the mouth. Dots mark the turning points of each oscillation.

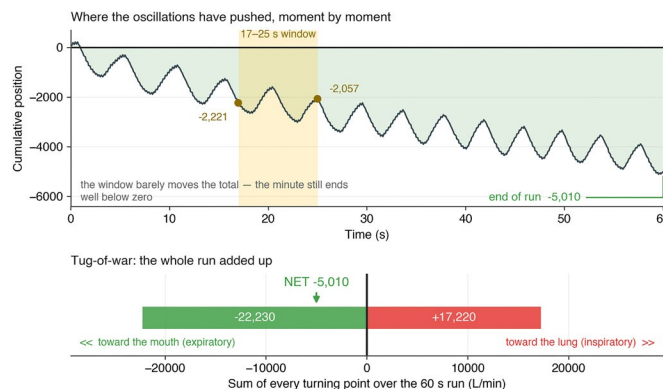


Figure 3. The same 60 seconds recording. Above: every turning point added in sequence, so the line falls whenever the expiratory side is winning. Below: the whole minute as a single contest.

This framing avoids overemphasizing baseline or bias flow while still preserving the essential physiology. A baseline can shift where oscillations sit relative to zero, but the secretion-relevant question is simpler: over the observed interval, which side kept pushing longer and stronger?

The takeaway is concise: do not equate a changing oscillatory waveform with changing direction. First ask whether the trace crosses zero. Then ask which side of zero carries more sustained flow. In the movement of secretions, the tug of war is won by the side that combines enough height with enough time

At the patient side

Find zero, then ask whether the waveform crosses it. If it does not, the oscillation is changing the strength of the flow, not its direction. If it does, the reversals themselves are not the finding. Use tools such as cumulative position and tug-of-war views to answer the question that matters for secretion movement: which side did flow stay on longer and stronger? Where those two answers disagree, as they do here, only adding them up across the whole recording will tell you which one won

Sometimes the waveform reveals its true story only from the right reference point.

¹Pulmonary Research Institute for Systems & Metrics (PRISM), Founding Members

Author Affiliations & Disclosures

Leah Noaeill, MBA, and Vinay Joshi, B.Tech, MBA, are Founding Members of the Pulmonary Research Institute for Systems & Metrics (PRISM), a voluntary, precompetitive forum focused on respiratory device performance measurement. Leah Noaeill is Vice President, Marketing & Clinical Affairs at ABM Respiratory Care. Vinay Joshi is Founder & Chief Technology Officer at ABM Respiratory Care. ABM Respiratory Care is a manufacturer of respiratory therapy systems. The authors participated in this work in their individual capacities as PRISM members.

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Clinical Toolbox: Managing Voice, Swallowing, and Respiratory Changes for Patients with Tracheostomies and Mechanical Ventilation

Kristin A King, PhD, CCC-SLP

Tracheotomy, the surgical creation of an opening through the neck into the trachea, is a critical intervention for patients requiring long-term mechanical ventilation, airway protection, and secretion management. While lifesaving, a tracheostomy introduces significant changes to the physiology of voice production, swallowing, and respiration. These changes often pose challenges for patients and clinicians tasked with managing the patients' complex needs.

An integrated, multidisciplinary toolbox is essential for assessing, monitoring, and rehabilitating voice, swallowing, and respiratory functions in this patient population. Considering the needs of these patients and the medical professionals who treat them, below is a discussion related to some of the primary tools available to clinicians, including speech-language pathologists (SLP), respiratory therapists (RT), nurses, and physicians, to address changes secondary to a tracheostomy and to optimize patient outcomes.

First, a significant amount of research reports that patients with tracheostomies have the best outcomes when followed by a multidisciplinary team.¹⁻² The lack of standardized care and the associated complications have led to a surge in the development of multidisciplinary tracheostomy teams. For a team to function well and provide the best evidence-based care, it must also have the appropriate tools for evaluation and intervention.

Multidisciplinary Team Roles

A tracheostomy team ("trach team") is a dedicated multidisciplinary group of medical professionals who specialize in tracheostomy practice. Trach teams are institution-specific, and there is not a "typical" model. However, most teams have common goals such as:

- Standardizing tracheostomy practice
- Providing safe and high-quality tracheostomy care
- Establishing an optimal means of communication for all patients with tracheostomy tubes
- Delivering ongoing education and support to patients, caregivers,

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- and staff regarding tracheostomy management
- Delivering cost-effective care to patients with tracheostomy
- Avoiding poor outcomes and adverse events related to tracheostomy
- Improving the quality of life for patients with tracheostomy

For the team to function well and provide the best evidence-based care for patients, they must be equipped with both training and equipment that address patients' needs. Multidisciplinary collaboration improves patient safety, facilitates comprehensive care, and enhances outcomes in tracheostomy management.³ Each clinician brings a unique perspective, and communication between team members ensures that tools and techniques are used effectively and appropriately

Voice and Communication Tools

Patients with tracheostomies and inflated cuffs have impaired communication and voicing due to a lack of airflow through the upper airway and through the vocal folds for voice generation. As patients' rights include access to effective communication and, therefore, participation in their healthcare, clinicians must have tools that help restore patients' voices and enable functional communication. Research has also shown that access to their voice and communication reduces the risk of ICU delirium and has significant psychological benefits for patients.⁴⁻⁵ Ideally, the form of communication provided to a patient is the primary form they used prior to injury or illness—e.g., if they were verbal, then they are provided access to their voice.

Clinical Application Communication

Speaking Valves (e.g., Passy-Muir® Tracheostomy & Ventilator Swallowing and Speaking Valve)

One of the most effective tools for restoring vocal communication in patients with tracheostomies is the speaking valve. The Passy-Muir Tracheostomy & Ventilator Swallowing and Speaking Valve (PMV™) is the only bias-closed, no-leak speaking Valve, which allows air to be inhaled through the tracheostomy tube but redirects 100% of exhaled air out through the vocal folds, enabling phonation and many other evidence-based benefits. Use of a no-leak speaking valve has been shown in research to restore verbal communication, improve swallowing, enhance secretion management, and normalize subglottic pressure.⁶

Electrolarynx and AAC Devices

For patients who cannot tolerate speaking valves due to significant vocal fold damage or upper airway obstruction, alternative methods like electrolarynx devices or augmentative



Figure 1. A Passy-Muir Heat Moisture Exchanger assists a patient with inhaling warm, humidified air.



Figure 2. The Passy-Muir Airway Protection Filter (APF15) for use on the tracheostomy hub (non-vent).

and alternative communication (AAC) tools (e.g., communication boards, tablet-based apps) can facilitate communication.⁷ An electrolarynx, with proper placement, can be used to generate sound during the mouthing of speech, while communication boards and communication-based apps may provide ready access to basic wants and needs and text-to-speech or the use of icons. In determining a mode of communication, the clinician must consider cognitive ability, motor skills, and patient preferences.

Cuff Management and Leak Speech

Some patients may achieve phonation through “leak speech” when the tracheostomy cuff is partially deflated or the tracheostomy tube is fenestrated. A small amount of air escapes around the tube and through the vocal folds, allowing for some voicing, although the quality may be variable.⁸ This technique also requires appropriate ventilator management for the best voice production while maintaining appropriate ventilatory support.

Above the Cuff Vocalization (ACV)

ACV is a method for restoring airflow through the vocal folds and allowing for some vocalization. With this technique, a special tracheostomy tube with a subglottic port (a small opening above the cuff of the tracheostomy tube) is placed for the patient; the cuff is NOT deflated for this technique, and oxygen tubing is connected to provide airflow out the port to the upper airway and vocal folds. While this technique does allow for some vocalization, the voice quality is variable but audible and may be better than mouthing attempts.⁸

Swallowing Rehabilitation Tools

Swallowing Therapy Tools

Respiratory Muscle Strength Training (RMST)

Expiratory and Inspiratory Muscle Training (EMT/IMT) has been proven beneficial for respiratory and swallowing muscle strengthening, particularly in neurogenic populations and more recently in patients with tracheostomies.^{5,9-11}

Neuromuscular Electrical Stimulation (NMES)

Recent studies suggest NMES may be effective for improving swallowing in select patients and may even shorten wean times for mechanical ventilation, although evidence remains mixed.¹²⁻¹³

Lingual Strengthening Interventions

With the high incidence of dysphagia in patients with

tracheostomies, swallowing therapy may include lingual strengthening tasks. Lingual strength has been linked to pharyngeal residue and pressure generation.¹⁴⁻¹⁵ Patients with tracheostomies have a loss of pressure due to the “hole” in their system, and they are at risk of increased pharyngeal residue and poor airway protection secondary to the loss of pressure. Addressing lingual strengthening for patients with dysphagia and tracheostomies may be key to lessening the risk of aspiration and enhancing decannulation potential.

Swallow Maneuvers and Exercises

Interventions like the supraglottic swallow maneuver and effortful swallow are commonly used to enhance airway protection and swallowing function.¹⁶⁻¹⁷

Respiratory Management Tools

Cuff Pressure Manometers

Manometers are tools used to maintain appropriate cuff pressures, which is crucial for airway management and to reduce the risk of tracheal injury. The optimal range is reported to be 20–30 cmH₂O, but ideally for patients with tracheostomies, pressure between 20–25 cmH₂O should be considered.¹⁸⁻¹⁹ Research has shown that pressure above 25 cmH₂O may start to impair swallow function.²⁰

Humidification Systems

Because a tracheostomy bypasses natural humidification, artificial humidifiers (e.g., heat and moisture exchangers (HME) or heated humidifiers) are essential for maintaining mucociliary function and decreasing suctioning requirements.²¹⁻²² It also has been suggested that the use of humidification may even provide cost savings for the patient and facility.²² Humidification may be provided for a patient both on and off mechanical ventilation. When using a humidifier, a speaking Valve may be in place as long as the humidification does not have a medicated aerosol treatment included. Another option for patients with a tracheostomy is to use a heat and moisture exchanger; however, HMEs would not be effective with a speaking valve in place if airflow does not pass through the valve during exhalation.

Viral and Bacterial Filter

Previously, available filters for tracheostomies had been intended for use with ventilators, anesthesia machines, and open-flow systems where filtration of inspired and/or expired gases was desired. These filters are often developed in combination with a heat and moisture exchanger component to allow the provision of both filtering and humidification for patients on mechanical ventilation. However, it is a large device that is not designed or intended for placement directly on a tracheostomy tube hub. And while HME devices are designed for placement on the hub, the HME design is for humidification and has little to no filtration capability. However, the Passy-Muir Tracheostomy Viral & Bacterial Airway Protection Filter (PM-APF15) is a filter available for use directly on tracheostomy tube hubs and intended for both pediatric and adult patients.

Suctioning Equipment

Critical for managing secretions, suctioning must be performed with proper technique to avoid hypoxia or mucosal injury.²³

Mechanical Insufflation-Exsufflation Devices

A non-invasive technology used to clear secretions by simulating coughs. It can be used with patients on mechanical ventilation without disrupting ventilatory support and may be safer than the standard invasive catheter suctioning.²⁴

Capnography and Pulse Oximetry

Used for continuous monitoring of respiratory status and to detect early signs of deterioration, capnography is recognized as a tool for monitoring patient safety.²⁵⁻²⁶

Patient and Caregiver Education

Training in tracheostomy care, speaking valve use, and emergency response is critical. Providing written materials, demonstrations, and return demonstrations improves confidence and safety in home settings. Being familiar with educational tools and materials is essential for providing appropriate support to patients and families, especially after discharge from a medical setting.

Tracheostomy T.O.M./Pocket T.O.M./P.A.M. (Passy-Muir, Inc)

These educational tracheostomy observation models display an anatomical representation of a tracheostomy tube placement and may be used to assist with demonstrating basic functions impacted by a tracheostomy. Use of the models also allow placement of a speaking valve on a mannikin prior to patient placement. These tools may be used for training clinical professionals, caregivers, and patients.

Emerging Tools and Innovations

High-Flow Oxygen Therapy via Tracheostomy

Recent evidence supports the use of high-flow systems with patients following tracheostomies to improve oxygenation and secretion clearance.²⁷

AAC and Wearable Tech Innovations

Eye-tracking devices and voice synthesis technologies are increasingly used in patients with severe speech impairments or progressive conditions.⁷

Telehealth and Remote Monitoring

These tools are now being applied for remote monitoring of respiratory parameters and for delivering therapy services, especially in outpatient or rural settings.²⁸

Conclusion

Patients with tracheostomies face complex challenges involving voice, swallowing, and respiration. A multidisciplinary toolbox of evidence-based tools and techniques—including speaking valves, swallowing rehabilitation, secretion management systems, and AAC devices—enables clinicians to effectively address these challenges. Through collaborative care, ongoing assessment, and technological integration, clinicians can improve both safety and quality of life for individuals with tracheostomies.

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treatment of recurrent airway stenosis available as part of today's treatment paradigm." The first patient was enrolled and treated in Airiver Medical's pivotal clinical trial by Dr. Ashli O'Rourke, professor and director of laryngology at the Medical University of South Carolina. Airiver Medical received investigational device exemption (IDE) approval from the FDA to begin this U.S. pivotal clinical trial that will enroll up to 200 patients suffering from central airway stenosis to assess the safety and efficacy of the Airiver DCB. The technology combines standard balloon dilation to open the respiratory tract with proprietary drug delivery designed to maintain symptom relief and prevent recurrence. The proprietary coating allows for localized paclitaxel delivery to the stenosis, while limiting levels in the surrounding healthy tissue. The study is testing the Airiver DCB against standard of care bare balloon dilation. The study, if successful, will serve as the basis for Airiver Medical's regulatory submission to the FDA and eventual commercialization of the Airiver Pulmonary DCB in the US. "Central airway stenosis is a debilitating condition with no minimally invasive, long-lasting treatment," said Dr. O'Rourke. "This technology has the potential to provide a life-changing treatment option. That's why I'm thrilled to treat the first patient in this potentially groundbreaking clinical trial." Central airway stenosis, otherwise defined as airway narrowing, is often associated with prolonged intubation, tracheostomy, stenting, tuberculosis or lung transplant. There are approximately 100,000 tracheo-bronchial stenting and dilation procedures performed annually in the United States. The Airiver DCB is an investigational device for treating benign central airway stenosis. The Airiver DCB has not received marketing authorization from the FDA and is not available for sale in the United States.

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