Quick and Easy Conversion of Vented Nebulizer and Oxygen Masks into CPAP-like Aerosol Filtration Masks Using the SafetyFilta™ and SafetyFit™ Devices

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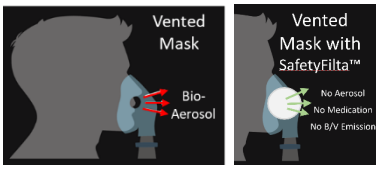
BSME, BSAE, MSME, Six Sigma Black Belt

Inventor of SafetyFilta, SafetyFit, SafetyNeb, SafetyO2

Our patented ***SafetyFilta™*** and ***SafetyFit™*** devices are innovative solutions that enable aerosol filtration for most respiratory treatments. While our award-winning devices – SafetyNeb™ and SafetyO2™ – were developed specifically for the Emergency Medical Services (EMS) market, the ***SafetyFilta™*** and ***SafetyFit™*** devices are easy to apply in all therapeutic settings to fit most masks and patients. These products were all designed to protect healthcare providers by drastically reducing two sources of potentially dangerous aerosols:

1. bioaerosol pathogen contaminants exhaled via breath, speech, & cough droplets; and
2. fugitive emissions of aerosolized medications.



Nebulized medications often trigger coughing reflexes, greatly increasing the risk of contaminating the surrounding environment with patients' pathogens, especially in confined spaces. By filtering out these potentially dangerous aerosols, healthcare providers can safely resume the use of aerosolized medications as the main weapons against respiratory diseases such as asthma, bronchitis, and COPD exacerbations. Analogously, with oxygen treatments – medium concentration and non-rebreather – where the aerosol mist is not readily visible, the SafetyFilta™ and SafetyFit™ devices reduce the risk of bioaerosol spread.

Our EMS devices have been independently tested for efficacy and effectiveness with results published in PubMed Central (MC) National Library of Medicine (NIH) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8335408/ through the American College of Emergency Physicians Research Forum. The abstract is included for convenience in Appendix A below. A more general discussion of these results was published in The Journal of Pulmonary Technique, Respiratory Therapy, Spring 21 issue, attached as Appendix B.

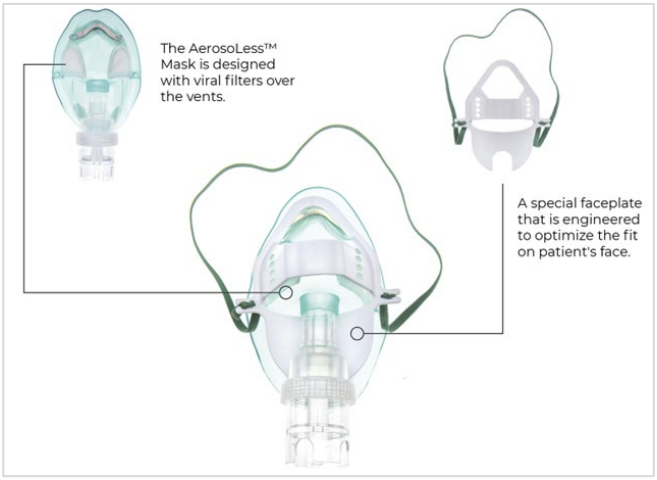
The studies concluded that our solutions **"...did provide profound control of fugitive aerosolized particle emissions during nebulizer applications. "** and **"...confirmed that use of the SafetyNeb™ can drastically reduce the presence of environmental bioaerosols during treatment. This effectively eliminates the risk of bioaerosol-contaminated fugitive emissions to the healthcare professionals who risk their lives each day to treat others.... The unique design of the SafetyNeb™ drastically reduces the ability of pathogens contained in patients' exhaled breath and coughs to escape into the environment."** Additional studies published in the Critical Care Medicine Journal, January 2022 Volume 50, attached as Appendix C, and Annals of Emergency Medicine, Volume 78 August 2021, attached as Appendix D, assert that the **"...specially designed nebulizer mask modified with expiratory-port filters and sealing faceplates to minimize bio-aerosol spread... indicate a much safer approach to treating COVID-19 patients and all others requiring nebulization."**

Our EMS devices have been field tested with nearly 50,000 mask procedures performed since 2021 and with exceptional user feedback. They are sold directly by us, as well as through many distributors including Medline, Bound Tree and Henry Schein. All our products have been researched, designed, and manufactured at our FDA-listed facility in South Florida under GMP regulations. Since 2003 our facility has been supplying medical and dental professionals with innovative disposable products that have won multiple prestigious awards.

One key to the success of our respiratory devices is our selection of filtration media meeting the most stringent requirements while providing low airflow resistance for easier breathing. The filtration media has been independently tested by Nelson Labs to confirm that at 3.2 micron mean particle size the filter media yields more than 99.9970% efficiency protection for viral particles and more than 99.9992% efficiency protection for bacterial particles at high flow with minimal pressure drop. Refer to Appendix E for additional details on the filtration media.

Why Our EMS Solutions Are Effective

The SafetyNeb™ and SafetyO2™ devices are constructed using standard vented nebulizer and non-rebreather oxygen masks. These low-cost masks are modified and retrofitted with 1) expiratory-port filters and 2) a sealing faceplate to minimize bioaerosol spread. The expiratory-port filters are attached directly and permanently to the masks. In the case of the nebulizer masks, the vented ports are enlarged to provide sufficient air flow through the filters and in the case of the oxygen masks the filters are mounted over the non-rebreather ports with a patent pending cover that maintains the integrity of the non-rebreather valves.



Fitted with our high efficacy filters, these masks prevent exhaled pathogens from endangering first responders. The faceplate mounted over the mask creates a CPAP-like seal with the patient's face and improves oxygenation

Design Limitations of Our EMS Solutions

Since a minimum filter size is required to permit the needed air flow and compensate for degradation in filter effectiveness caused by nebulizer aerosols clogging the filters, the largest possible mask size (Adult Long) is used in the fabrication of SafetyNeb™ and SafetyO2™ devices. Smaller size masks do not have sufficient 'real estate' (available surface area) to enable the direct welding of the required filter size. This filter size limitation dictates an upper limit to the duration of use with medications.

Since large size masks are utilized, the fit for individuals with smaller faces can result in gaps around facial features, most predominantly the chin and nose bridge. SafetyNeb™ and SafetyO2™ masks are therefore fitted with nose and chin pads to close those gaps. These added pads increase cost and are still susceptible to leakage in some individuals due to varying facial features. Additionally, these masks are unsuitable for paediatric patients since the nose and chin pads are not sufficient to close these gaps in the case of children.

Furthermore, basic vented nebulizer and non-rebreather oxygen masks are low-cost masks which are susceptible to leakage around facial features due to the materials used in these masks, as well as to their inexpensive construction. These standard masks utilize a single elastic strap to secure the mask to the face. Tightening this single strap leads to mask buckling at the attachment points for the strap, further exacerbating leakage. To counteract this effect, an innovative faceplate is available for use with the SafetyNeb™ and SafetyO2™ devices that pushes the masks against the facial features to assure a substantially better fit and to evenly distribute the elastic force along the interface of the mask with the face. The faceplate's own elastic strap provides enhanced control in fitting the mask securely to the patient's facial features, and drastically reduces leakage at the mask-to-face interface.

While the SafetyNeb™ and SafetyO2™ are effective devices, the large mask size, predefined faceplate shape, and permanently mounted filters limit their usability to certain treatments and therapeutic settings.

Universal Solution for Respiratory Therapies

The ***SafetyFilta™*** device is a stick-on filter that allows for the conversion of **any size vented mask** into a filtered mask in a few simple steps. The SafetyFilta™ device solves the problem of the 'real-estate' (available surface area) restriction and curvature issues by mounting and conforming to the mask exhalation vents without filter size restrictions. Any size masks (including pediatric masks) can now be converted into filtered masks. Healthcare providers can now select the ideal size mask for each individual patient, and **quickly and easily** convert the selected mask into a filtered mask. The ***SafetyFilta™*** device is available in various models and configurations that provide additional flexibility depending on required treatment duration and frequency.

The ***SafetyFilta™-NEB*** device is optimized for vented nebulizer masks. In this configuration, each SafetyFilta™-NEB device comes with an accompanying non-filtered stick-on port seal for closing the secondary mask exhalation vent port. This configuration allows for an 18-minute treatment of 6cc of medication (two doses) at oxygen/air flow rate of 6-8L/min.

To apply the ***SafetyFilta™ device***, the healthcare provider: 1) removes the protective cover of the filter sticker; 2) aligns the SafetyFilta™-NEB device port with the mask exhalation port and presses the filter to attach; 3) removes the protective cover of the port seal sticker; 4) aligns the port seal sticker with the secondary mask port and pushes the cover to attach and seal the port.

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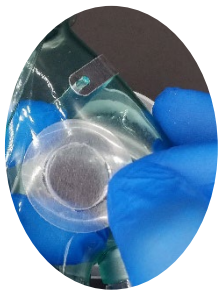
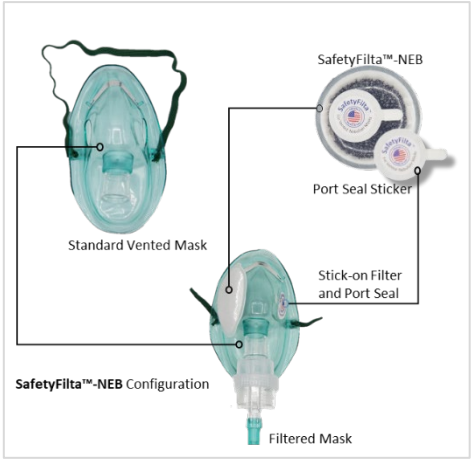
4. 

The used SafetyFilta™ device can be removed from the mask using the pull-tab and replaced with a new – non-saturated – SafetyFilta™-NEB device. This allows for extended usage of the mask when multiple treatments are to be administered.

An alternative configuration provides for two SafetyFilta™ devices to be mounted on a single mask – one SafetyFilta™ device on each vented mask port – thereby increasing the treatment duration of the mask as required for continuous nebulizer treatments.

The SafetyFilta™-NEB-DF configuration allows a 45-minute treatment of 12cc of medication at oxygen/air flow rate of 6-8L/min. (As a side note, since the SafetyFilta™ device can be fabricated to accommodate even larger filter configurations, there is opportunity to address specialized applications where extended duration respiratory treatments are required.)

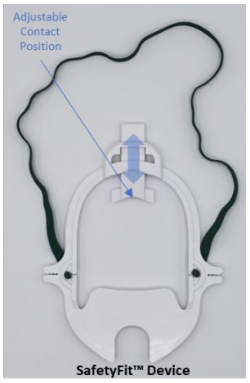


Similarly, the ***SafetyFilta™-O2*** device fits any standard oxygen mask over its non-rebreather ports with or without the rubber diaphragm valve. Unlike the ***SafetyFilta™-NEB*** device, the usage duration limitation does not apply since there is no medicinal aerosol to degrade the filter performance.

The SafetyFilta™-MP and SafetyFilta™-BA models are SafetyFilta™ devices optimized for reducing bioaerosol emissions through the exhalation tubes of mouthpiece and breath-actuated nebulizers. These devices simply snap onto the ends of the exhalation tubes to collect the aerosol.

Further Reducing Aerosol Emissions with the SafetyFit™ Adjustable Faceplate

When additional protection is required***,*** the ***SafetyFit™*** adjustable faceplate works in conjunction with the SafetyFilta™ device to further reduce aerosol emissions. By conforming standard respiratory masks to face contours, the SafetyFit™ adjustable faceplate improves mask fit thereby ***reducing potential contour gap microleakage***. The SafetyFit™ adjustable faceplate device works with any size mask to create a CPAP-like seal to the patient's face.



The SafetyFilta™ and SafetyFit™ devices also work with pediatric-size masks in single and dual filter configurations.

Together, the SafetyFilta™ and SafetyFit™ devices offer the ultimate in flexibility to healthcare providers: they increase efficacy, reduce costs, and allow for the re-use of masks on the same patient over an extended period of treatments.


Pediatric Mask in the SafetyFilta™-NEB configuration


Pediatric Mask with the SafetyFit™ device in the SafetyFilta™-NEB configuration

Important consideration: SafetyFilta™ and SafetyFit™ devices should only be used as additional protective devices in conjunction with other PPE, and in accordance with clinical guidelines. The user should watch for any leakage and reposition the mask and tighten the elastic to eliminate any such leakage. The patient should be instructed not to speak or move the mask once it has been attached, so as to maintain optimal seal. The patient's breathing should be monitored.

Appendix A

PubMed Central (MC) National Library of Medicine (NIH)

American College of Emergency Physicians Research Forum

Title: SAFER DELIVERY OF AEROSOLIZED MEDICATIONS WHEN DEALING WITH COVID-19 AND OTHER CONTAGIOUS AIRBORNE VIRUSES

Authors: Paul Pepe, Steven Rios, Leslie Leal, Juan Cardona, Michael McNally, James Roach, Peter Antevy

Abstract Body

BACKGROUND: Nebulizer treatments for ill patients with chronic lung disease, reactive airways and other respiratory emergencies have been implicated in aerosolized spread of highly- contagious airborne viruses, including COVID-19. Considering the increased risk of aerosolized spread of viruses within confined ambulance compartments, this study specifically evaluated a specially-designed nebulizer mask modified with expiratory-port filters and a sealing faceplates to minimize bio-aerosol spread.

METHODS: Recognizing that fugitive aerosol emissions (such as those that would possibly carry COVID-19) typically range from 0.5 to1.5 micron (µ), a six-port (0.3–10µ) Kanomax 3889^{R} particle measurement (PM) counter was placed 78 cm from each of 15 rotating adult volunteers (non-patient, beardless) including 7 women and 8 men, ages 18-59 with a mean age of 39 years. The subjects were each sitting upright on a stretcher within a closed standard ambulance compartment. Assigned to one of three rotating fleet ambulances, subjects used the EMS agency's usual jet-nebulizers with a conventional mask (CM) and then returned on another day to receive jet-nebulization with the aerosol-controlling mask (ACM) or vice versa (ACM first day, CM next day). After documenting baseline ambient PMs (PM_{amb}) within the compartment, the Kanomax operator quickly brought in a subject, closed the door, and waited 5 minutes before making a pre-nebulization PM (preNeb-PM). Jet-nebulizers (using H_20 solutions) were then applied (either by CM or ACM as described) for 5 min with immediate post-nebulization measurements (Post1) and two successive measurements (Post2/Post 3), all five minutes apart.

RESULTS: Following the 5 min nebulization, mean CM PMs ($Post1_{CM}$) were 152.2-fold larger than mean ACM PMs ($Post\ 1_{ACM}$) measurements (p=0.001) and respectively remained 49.6-fold (p=0.005) and 7.2-fold (p=0.006) larger at Post2 and Post3 readings. PM_{amb} and preNeb-PM were all similar (NSD) for both ACM and CM approaches when examining all studied particle sizes (0.5, 1.0, and 3.0 µ) including 1µ preNeb-PMs, measuring 6,977K for ACM approaches and 5,683 for CM use, respectively (NSD). While mean $Post1_{ACM}$ 1µ PMs decreased (-31.7%) from pre-Neb-PM readings (6,977 to 4,662; p=0.002), counterpart $Post1_{CM}$ 1µ measurements rose 14,500.09% (from 5,683 to 70,949.93; p=0.002) with corresponding significant elevations for 0.5µ (p=0.001) and 3µ (p=0.002) particle sizes using conventional masks. Of additional note, though applied for just five minutes, ACMs were uniformly well-tolerated.

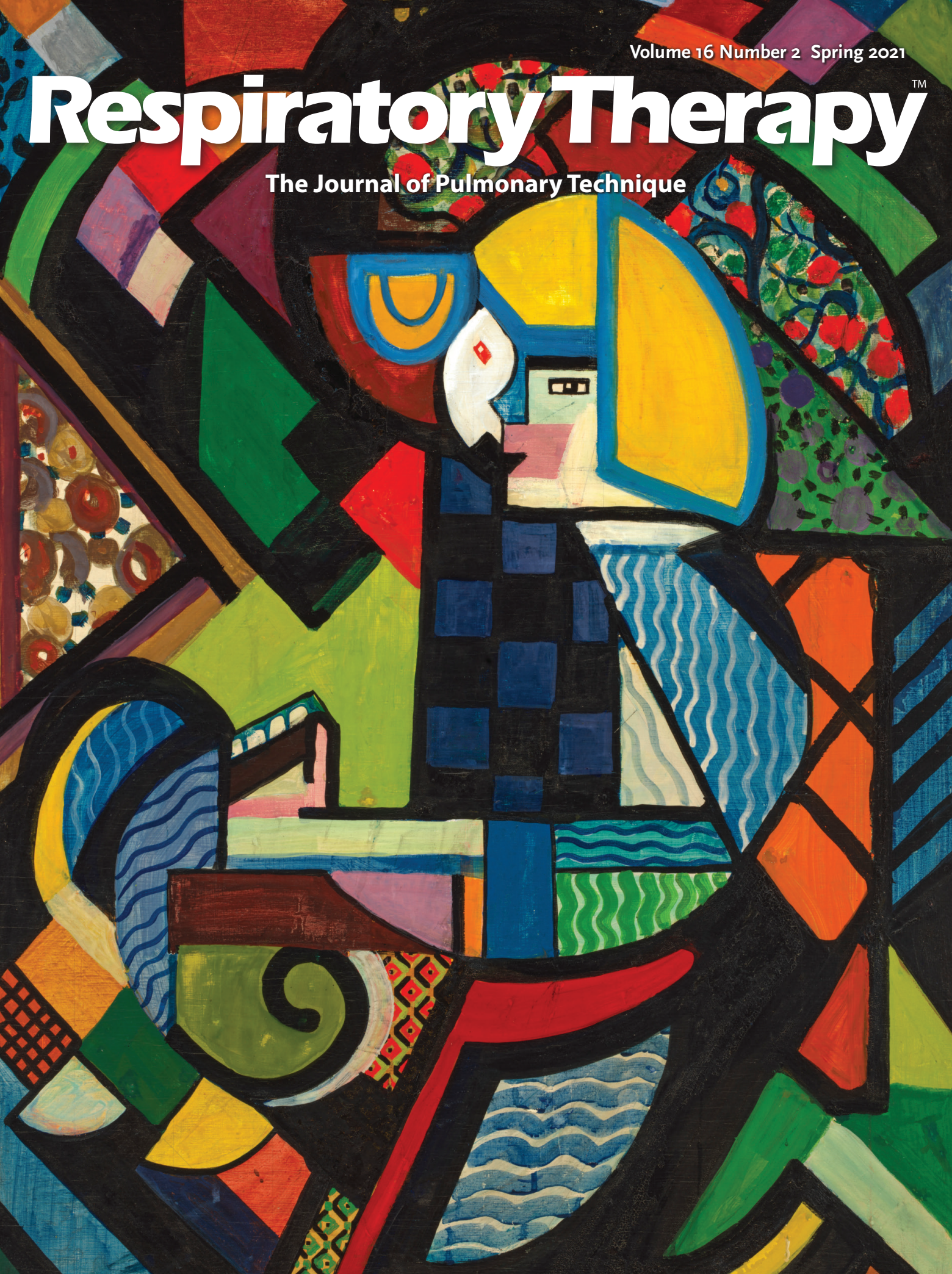
CONCLUSION: Compared to conventional methods, a modified mask system designed specifically to limit aerosolization of inhaled solutions did provide profound control of fugitive aerosolized particle emissions during nebulizer applications. The findings indicate a much safer approach to treating COVID-19 patients and all others requiring nebulization.

Appendix B

Volume 16 Number 2 Spring 2021

Respiratory Therapy™

The Journal of Pulmonary Technique



Safe Delivery of Aerosolized Medications in the Age of COVID

Peter Antevy, MD

Early in the COVID pandemic, aerosolized medications were removed from all of the ambulances across my EMS agencies. The sick, asthmatic or elderly patient suffering from COPD unfortunately could not receive the gold standard treatment of nebulized medications for fear of transmitting COVID-19 to the treating paramedics in the small confines of an ambulance. In order to protect the EMS professionals on the front lines, the decision was made by me that all nebulizations had to stop until further notice. For similar safety reasons, the avoidance of nebulization treatments also became common in hospitals and urgent care centers.

Now, one year later, protocols across the country do not allow for aerosolized medications. With all of the media attention, even the lay person has become familiar with various aspects of the SARS-CoV-2 virus and its primary mechanisms of spread: respiratory droplets and aerosols. These have become household terms and now carry a negative connotation, but it's not the aerosol itself that is concerning. It is the viruses that attach to them for a free ride and ultimately travel to the depths of the airways that pose a danger to others in the same confined space, such as paramedics in ambulances, or healthcare professionals in emergency departments and intensive care units across the country.

An aerosol is simply defined as a fine mist that is suspended in air. Due to their optimal delivery to the depths of the lungs, aerosolized medications are some of our main weapons against respiratory diseases such as asthma, bronchitis and COPD exacerbations. Once an aerosol combines with living organisms such as viruses or bacteria it becomes a *bioaerosol*, a process that occurs when the patient coughs, sneezes, speaks or simply breathes out.

The bad reputation aerosolized medications have received is linked to their suspension in the environment from minutes to hours depending on their size and the surrounding conditions.[1,2,8] When treating patients with aerosolized medications, up to 50% of the intended treatment is not inhaled by the patient, instead a large number of particles are released into the surrounding atmosphere. These un-inhaled aerosols are called *fugitive emissions*. Scientists believe that through the mechanism of bioaerosols combining with fugitive medication aerosols, COVID-19 has spread and infected others nearby.[3,4,10] This is the main reason healthcare professionals have stopped using aerosolized medications.[5]

The particles produced by aerosolized treatments range from 1-5 microns in size,[6,8] compared to the 0.06-0.14 micron size range of the SARS-CoV-2 virus.[7] One study showed the size of fugitive emissions ranging between 0.86-1.4 microns across all nebulizer combinations.[8] Vibrating mesh nebulizers (VMN) are reported to generate smaller micron size distributions than those generated by jet nebulizers, improving medication delivery, but due to their smaller size, lighter particles are reported to remain suspended longer in in the air.[8]

Experiments with a human patient simulator have shown that significant quantities of exhaled droplets exit through the side vents of a typical facemask.[9] The risk of exposure to these exhaled droplets being accompanied by COVID-laden bioaerosols has led healthcare workers to take extra protective measures if within 0.8 meters of patients with febrile respiratory illnesses of unknown etiology, even in isolation rooms under negative pressure.[10]

The avoidance of nebulized medications — a mainstay of respiratory therapy — has made the standard treatment of shortness of breath particularly challenging during the pandemic. Some practitioners have adopted the use of breath-actuated nebulizers (BANs) as a safer option since they produce less aerosols and increase the concentration of medication delivered. However, breath-actuated nebulizers do NOT reduce fugitive bioaerosols. As all respiratory therapists know, the first thing that a "tight" asthmatic or COPD patient does when bronchodilators open up their airways, is cough! Further, the work of breathing and respiratory rate are both increased due to the patient's dyspnea, and lung compliance is decreased. The combination of dyspnea and coughing are forceful mechanisms which expel bioaerosols into the air and increase the risk to front line healthcare personnel.

Researchers have confirmed that viruses are contained in the patients' exhaled breath.[4,11] Practitioners treating patients with shortness of breath should be keenly aware of this and should

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take the necessary precautions. Common sense suggests that the best way of minimizing bioaerosols is to filter the patient's exhaled breath.[9] CPAP creates a tight seal, and when used in conjunction with a filter, provides significant aerosol reduction. However, this modality is uncomfortable and expensive. VMNs and breath-actuated nebulizers produce less aerosols but do not have a means for the containment of bioaerosols. The solution we sought out provided aerosol delivery while simultaneously preventing the release of patient-expelled pathogens into the immediate atmosphere.

Such a mask was recently introduced into the medical device market and after conducting a validation study, we've added a new type of nebulizer back into our respiratory distress tool kit. The SafetyNeb™ is a new product that uses high efficiency filters and a CPAP-like seal that allows for safer aerosol delivery, even in confined spaces. Now, instead of reverting to archaic methods for treating bronchospasm such as terbutaline and intramuscular epinephrine, we can resume the use of modern nebulized and targeted medications while dealing effectively with the problem of fugitive bioaerosols.

Our data has confirmed that use of the SafetyNeb™ can drastically reduce the presence of environmental bioaerosols during treatment. This effectively eliminates the risk of bioaerosol-contaminated fugitive emissions to the healthcare professionals who risk their lives each and every day to treat others. This type of innovation will undoubtedly be effective for the next superbug which many experts fear will not wait another century to develop.

As we move past the current COVID-19 pandemic into the future, medical professionals will continue to be confronted with patients presenting with cough, fever and shortness of breath due to unknown causes. Safety will always take priority, but it shouldn't be at the expense of quality of care. A mask that can filter out over 99% of exhaled bioaerosols allows us to strike the perfect balance between safety and quality of care so we can get back to the work we are here to do.

The author of this article pays tribute to our Frontline Workers, especially our Respiratory Therapists, EMTs and nurses for their dedication, tenacity, and bravery as they approach each patient with care and compassion despite the dangers of viral transmission. See "Lost on the Frontline".

References

1 Long C.M., Suh H.H., Catalano P.J., Koutrakis P. Using time-and size-resolved particulate data to quantify indoor penetration and deposition behavior. Environ. Sci. Technol. 2001;35:2089–2099. doi: 10.1021/es001477d.
2 Nazaroff W.W. Indoor particle dynamics. Indoor Air. 2004;14:175–183. doi:10.1111/j.1600-0668.2004.00286.x.
3 Somogyi R., Vesely A.E., Azami T., Preiss D., Fisher J., Correia J., Fowler R.A. Dispersal of respiratory droplets with open vs closed oxygen delivery masks: Implications for the transmission of severe acute respiratory syndrome. Chest. 2004;125:1155–1157. doi: 10.1378/chest.125.3.1155.
4 Fabian P, McDevitt JJ, DeHaan WH. Influenza virus in human exhaled breath: an observational study. PLoS ONE. 2008;3:e2691.
5 CDC Infection Control Precautions for Aerosol-Generating Procedures on Patients Who have Suspected Severe Acute Respiratory Syndrome (SARS) [(accessed on 18 August 2018)]; Available online: https://stacks.cdc.gov/view/cdc/25034.
6 ICRP Human Respiratory Tract Model for Radiological Protection. Ann. ICRP. 1994;24:1–3. doi: 10.1016/0146-6453(94)90004-3.
7 Zhu N, Zhang D, Wang W, et al. A novel coronavirus from patients with pneumonia in China, 2019. N Engl J Med. 2020;382(8):727–733. doi: 10.1056/NEJMoa2001017.
8 James A. McGrath,1,* Andrew O'Sullivan,2 Gavin Bennett,2 Ciarraí O'Toole,1 Mary Joyce,2 Miriam A. Byrne,1 and Ronan MacLoughlin2 Investigation of the Quantity of Exhaled Aerosols Released into the Environment during Nebulisation Pharmaceutics. 2019 Feb; 11(2): 75.
9 Hui D.S., Hall S.D., Chan M.T.V., Chow B.K., Tsou J.Y., Joynt G.M., Sullivan C.E., Sung J.J.Y. Noninvasive Positive-Pressure Ventilation: An Experimental Model to Assess Air and Particle Dispersion. Chest. 2006;130:730–740. doi: 10.1378/chest.130.3.730.
10 Hui D.S., Chow B.K., Ng S.S., Chu L.C.Y., Hall S.D., Gin T., Chan M.T.V. Exhaled Air Dispersion Distances During Noninvasive Ventilation via Different Respironics Face Masks. Chest. 2009;136:998–1005. doi: 10.1378/chest.09-0434.
11 Jones RM, Brosseau LM. Aerosol transmission of infectious disease. J Occup Environ Med 2015; 57:501.
12 Wittgen B.P., Kunst P.W., Perkins W.R., Lee J.K., Postmus P.E. Assessing a system to capture stray aerosol during inhalation of nebulized liposomal cisplatin. J. Aerosol Med. 2006;19:385–391. doi: 10.1089/jam.2006.19.385.

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appreciate and welcome this support from NIH/NIAID, which follows our signing of a Patent and Biological Materials License Agreement providing GeoVax with access to key NIAID patent rights, and which provides GeoVax with nonexclusive rights to develop, manufacture and commercialize our COVID-19 vaccine. While we continue to advance our COVID-19 vaccine program, we remain in discussions and negotiations related to additional funding support that will further accelerate our progress into clinical testing and supply chain preparation. We anticipate that additional vaccines, such as ours will be necessary against COVID-19, as well as potentially new strains and variants, requiring broader immune response, strong durability, exquisite safety within various cohort populations and minimal refrigeration for distribution and supply throughout the world. These attributes represent the focus of our overall 'COVID-X' vaccine program (think 'COVID-20, -21', etc.)."

Company Signs Distribution Agreement

Dräger, an international leader in the fields of medical and safety technology, today announced that it has entered into an agreement with Breas Medical, a global medical device company delivering respiratory care solutions throughout the continuum of care. Together, they will provide long-term acute care (LTAC) and skilled nursing facilities (SNF) in the US access to both Dräger and Breas Medical mechanical ventilator technologies. Both Dräger and Breas Medical offer solutions specifically designed to address the challenges faced by many LTACs and SNFs, most notably the complexity and costs associated with caring for chronically ill patients after requiring mechanical ventilation following intensive care. This new agreement with Breas Medical, effective January 6, 2021, will extend the reach of high-quality ventilation, along with the company's unparalled service and support, into these and other non-acute settings. "In an effort to reduce costs, the care of stable but chronically ill patients is increasingly being pushed from the hospital out to extended care settings with many of these patients relying on mechanical ventilation," said Dräger Senior Vice President of Sales, Hospital Solutions, Steve Menet. "Administrators at these alternative care facilities continue to deliver quality care with limited resources. This distribution agreement with Breas Medical offers a more comprehensive solution with the combined goals of positively impacting patient and financial outcomes." "Quality and patient comfort are Breas' top priority; we put great focus into these core values using innovation in all of our devices. This agreement with Dräger will improve the experience for patients, operators and clinicians while creating more effective access and support for Breas ventilators in the LTAC and SNF markets," said Chris Southerland, General Manager of Commercial Operations, Americas Region at Breas Medical. "Dräger is known throughout the healthcare industry and respiratory community for its state-of-the art mechanical ventilation technology. We are proud to partner with Dräger in their efforts to care for more clinically complex patients."

AerosoLess Medical Has Introduced a New Nebulizer Mask

According to a recent estimate, more than 2,900 US healthcare workers have died in the COVID-19 Pandemic since March 2020. The gravity of the pandemic has heightened awareness of the necessity of preventing patients' pathogens from infecting front-line medical personnel. In the case of nebulizers, which are the recommended treatment protocol for medical conditions

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no longer. *Respir Med.* 2020;166:105940.
31 Nicolini A, Cardini F, Landucci N, Lanata S, Ferrari-Bravo M, Barlascini C. Effectiveness of treatment with high-frequency chest wall oscillation in patients with bronchiectasis. *BMC Pulm Med.* 2013;13:21.
32 Barto TL, Maselli DJ, Daignault S, et al. Real-life experience with high-frequency chest wall oscillation vest therapy in adults with non-cystic fibrosis bronchiectasis. *Therapeutic advances in respiratory disease.* 2020;14:1753466620932508.
33 Gruffydd-Jones K, Keeley D, Knowles V, et al. Primary care implications of the British Thoracic Society Guidelines for bronchiectasis in adults 2019. *NPJ primary care respiratory medicine.* 2019;29(1):24.
34 Martinez-Garcia MA, Maiz L, Olveira C, et al. Spanish Guidelines on the Evaluation and Diagnosis of Bronchiectasis in Adults. *Arch Bronconeumol.* 2018;54(2):79-87.
35 Polverino E, Goeminne PC, McDonnell MJ, et al. European Respiratory Society guidelines for the management of adult bronchiectasis. *Eur Respir J.* 2017;50(3).
36 WHO. World Health Organization: Clinical management of severe acute respiratory infection when novel coronavirus (2019-nCoV) infection is suspected. *Interim Guidance.* 2020(WHO/nCoV/Clinical/2020.3):January 28, 2020.
37 Web site https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-07Jan2021.aspx, accesed January 23, 2020.
38 Rumback M. In a 90-day trial of HFCC/HFCWO, COPD patients electing to continue therapy experienced significant improvements in dyspnea, exercise tolerance and quality of life. *Chest.* 2001;120(4):250S.
39 van der Schans CP. Conventional chest physical therapy for obstructive lung disease. *Respir Care.* 2007;52(9):1198-1206; discussion 1206-1199.
40 Farag T, EL-Syed M. Utility of vest high frequency chest wall oscillation device versus flutter device in acute exacerbation of chronic obstructive pulmonary disease. *Int J Res Med Sci.* 2018;6(1):1-9.
41 Chakravorty I, Chahal K, Austin G. A pilot study of the impact of high-frequency chest wall oscillation in chronic obstructive pulmonary disease patients with mucus hypersecretion. *International journal of chronic obstructive pulmonary disease.* 2011;6:693-699.

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where patients present with shortness of breath, the pandemic has compromised physicians' options in treating their patients. Nebulizers are being underused due to concerns that they facilitate the spreading of patient-generated viral particles into the environment.

AerosoLess Medical is producing the SafetyNeb, an aerosol delivery device fitted with water-resistant viral filters over its vent holes. These highly effective viral filters are designed to prevent both patient exhaled pathogens and fugitive emissions from entering into the environment and thereby endangering Healthcare Workers. In addition to the viral filters, the SafetyNeb uses patent-pending technology to create a CPAP-like tight seal with the patient's face. Unlike other devices which were designed primarily for optimizing the delivery of aerosolized medications, the AerosoLess SafetyNeb was designed from the very beginning with the utmost focus on protecting the safety of healthcare personnel without compromising medication delivery. The unique design of the SafetyNeb drastically reduces the ability of pathogens contained in patients' exhaled breath and coughs to escape into the environment.

Siemens Healthineers IL-6 Test Receives Emergency Use Authorization

The US Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for Siemens Healthineers' laboratory-based IL-6 assay to measure the presence of Interleukin-6 (IL-6) in human serum or plasma. IL-6 is an indicator of potential severe inflammatory response in patients with confirmed SARS-CoV-2 infection. This simple blood test may be used to assist in identifying a severe inflammatory immune response in patients confirmed to have COVID-19, to aid in determining the risk of needing intubation with mechanical ventilation, in conjunction with clinical findings and the results of other laboratory testing. Emergency use of this test is limited to authorized laboratories. Approximately five percent of COVID-19 patients develop a systemic dysregulated cytokine response known as cytokine storm. IL-6 is a type of cytokine (intercellular messenger molecule) that plays a central role in the immune response to infection and can evoke many different actions when it is released. It is substantially elevated in patients presenting with cytokine storm. Cytokine release is a normal part of the body's immune response when fighting off a virus. However, a severe immune response can cause overproduction of cytokines leading to potential wide-scale cellular and organ damage, and ultimately death. IL-6 levels were found to be higher in COVID-19 patients with severe disease. "The Siemens Healthineers' IL-6 assay is an important tool for the care of hospitalized COVID-19 patients. This assay expands Siemens Healthineers' already comprehensive portfolio of tests available to aid in fighting the COVID-19 pandemic," said Deepak Nath, PhD, President of Laboratory Diagnostics, Siemens Healthineers. Siemens Healthineers' IL-6 assay is currently available across the US on the ADVIA Centaur Immunoassay Systems, the largest installed base of instruments in the US, with a time-to-result of 18 minutes. The IL-6 assay is also available outside the US with the CE mark on the ADVIA Centaur Systems, Atellica IM Analyzer and IMMULITE Systems. Siemens Healthineers has distinguished itself as a provider of quality assays to aid the COVID-19 pandemic. In addition to antibody, antigen, and molecular SARS-CoV-2 tests, Siemens Healthineers offers a broad diagnostics portfolio to aid in the prognosis, treatment and follow-up of COVID-19 patients. The company's broad and

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Appendix C

RESEARCH SNAPSHOT THEATER: PROCEDURES, ADULT AND PEDIATRIC

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VACUUM EXTRACTION OF AN OBSTRUCTING CLOT IN MASSIVE PULMONARY HEMORRHAGE USING A MECONIUM ASPIRATOR

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INTRODUCTION: Massive hemoptysis can cause life-threatening ventilation obstruction, especially if clots form in the trachea. These can be managed like an obstructing food bolus with bronchoscopy suction, basket retrieval, or removal via Magill forceps. In this case, we describe vacuum extraction with a meconium aspirator to relieve complete airway obstruction.

DESCRIPTION: A 53 year-old male with tricuspid endocarditis and septic pulmonary emboli was intubated for respiratory failure. On day two he developed blood-streaked secretions that progressed to frank blood with clots. He began to desaturate and exhibit high peak pressures on volume cycled mechanical ventilation, with exhaled tidal volumes of 50 mL. Bag-valve-mask ventilation was started, but manual breaths required significant force. Attempts to pass a suction catheter down the endotracheal tube (ETT) were unsuccessful. Bronchoscopy revealed a clot obstructing the lumen of the ETT. The patient was rapidly extubated and re-intubated by the ICU team. However, the clot did not come out with the ETT. Significant resistance to manual ventilation remained. The bronchoscope was re-introduced and a large clot was visualized overlying the carina and intermittently protruding into the ETT causing complete obstruction in a ball-valve manner. A meconium aspirator was attached to the ETT and connected to wall suction. Suction was engaged by occluding the side hold of the meconium aspirator and the clot was removed with the ETT en bloc. The patient was intubated again, and bag-valve-mask ventilation was easily performed. Repeat bronchoscopy demonstrated non-occlusive clot at the carina originating from an occluded right upper lobe bronchus; there was no ongoing bleeding. The patient went to IR for selective right sided bronchial artery embolization. The remaining clot was subsequently removed from the right mainstem via bronchoscopy with cryotherapy.

DISCUSSION: Vacuum extraction of an occlusive airway clot using a meconium aspirator attached to an ETT proved to be quick, safe, and effective in reversing complete airway obstruction. This technique has previously been described to successfully remove obstructing food boluses, thick emesis, and copious airway secretions. To our knowledge, there are no reports of this technique being used in an adult intensive care unit.

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CONTROLLING POTENTIALLY INFECTIOUS FUGITIVE BIOAEROSOL EMISSIONS DURING NEBULIZER TREATMENTS

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INTRODUCTION: Nebulizer treatments can create aerosolized spread of highly-contagious airborne viruses (eg, COVID-19). With increased risk of aerosolized spread within confined ambulance compartments, this study specifically evaluated a specially-designed nebulizer mask modified with expiratory-port filters and a sealing faceplate to minimize fugitive bio-aerosol emissions (FBAE).

METHODS: As FBAE carrying contagious viruses typically range from 0.5 to 1.5 micron (μ), a 6-port (0.3–10μ) *Kanomax 3889* particle measurement (PM) counter was placed 78 cm from each of 15 rotating adult volunteers (non-patients; beardless; 7 women, 8 men; ages 18-59 yrs) sitting upright in one of 3 rotating fleet ambulances using the EMS agency's usual jet-nebulizers on day 1 with either a conventional mask (CM) or an aerosol-controlling mask (ACM). Each person returned on another day using the other mask as indicated. Ambient ambulance PMs (PM_{amb}) were sampled before subjects entered. After re-closing the door and waiting 5 mins, a pre-nebulization PM (preNeb-PM) was made. Jet-nebulizers (using H_2O solutions) were then applied (either by CM or ACM) for 5 min followed by post-neb PMs (Post1) and 2 successive PMs (Post2/Post 3), all 5 mins apart, with masks remaining in place.

RESULTS: After "treatment", mean 1μ CM PMs ($Post1_{CM}$) were 152.2-fold larger (p=0.001) than mean 1μ ACM PMs ($Post1_{ACM}$), remaining 49.6-fold (p=0.005) and 7.2-fold (p=0.006) larger at Post2 and Post3 readings. PM_{amb} and preNeb-PM were all similar (NSD) for both ACM and CM across all PM sizes (0.5, 1.0, 3.0 μ) including 1μ ACM preNeb-PMs of 6,977/cf vs. 5.683/cf for CM preNeb-PMs (NSD). While mean 1μ $Post1_{ACM}$ readings decreased (-31.7%) from ACM pre-Neb-PM (6,977 to 4,662/cf; p=0.002), the 1μ $Post1_{CM}$ readings rose 14,500.1% (5,683 to 700,549.93/cf; p=0.002) with corresponding elevations for 0.5μ (p=0.001) and 3μ (p=0.002) particles using CM. Of additional note, ACMs were uniformly well-tolerated over the 15 mins being worn.

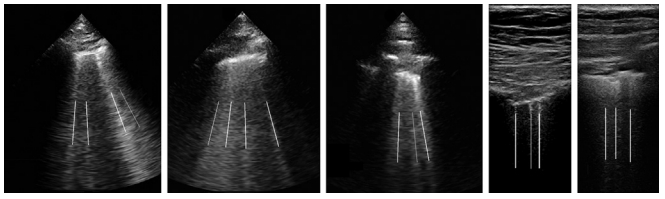
CONCLUSION: Compared to conventional methods, a modified mask system designed specifically to limit aerosolization of inhaled solutions did provide profound control of fugitive aerosolized particle emissions during nebulizer applications. The findings indicate a much safer approach to treating COVID-19 patients and all others requiring nebulization.

Appendix D

collection were performed on days 3, 5, 7 or 12+/- 1 day for admitted patients. All clips with 2 or more B-lines were included (N=80), as well as a random selection of 70 clips with 1 or fewer B-lines. B-line count for inclusion was based on visual rating by two researchers with POCUS training. A POCUS fellowship trained emergency physician visually assessed each clip frame and counted the maximum number of B-lines per clip. This was compared to automatic counts by the commercially available Lumify TM Lung B-lines Quantification software by intraclass correlation coefficient (ICC) and Cohen's weighted kappa.

Results: Of the 899 total clips,150 clips from 30 unique subjects and 44 overall exams were used for analysis, with 100 clips from patients with confirmed COVID by PCR. The average maximum B-line count by algorithm was 1.52 +/- 1.24, and that by expert was 1.60 +/- 1.35 (ns). The ICC between algorithm and expert was 0.87 (95% CI 0.83-0.91), with a weighted kappa of 0.64 (95% CI 0.48-0.81), indicating substantial agreement. Average of maximum B-line counts, ICC and weighted kappa between algorithm and expert were comparable for COVID+ and COVID- subgroups as well as between transducer types. For COVID + subgroup, the average of maximum B-line counts was 1.73 +/- 1.28 for algorithm and 1.78 +/- 1.37 for expert, with weighted kappa 0.67 (95% CI 0.50-0.84), and ICC 0.87 (95% CI 0.83 to 0.91).

Conclusion: An automated algorithm developed on non-COVID patients can accurately distinguish and quantify B-lines in clips from patients with COVID-19, with substantial agreement to expert visual rating.



20 Safer Delivery of Aerosolized Medications When Dealing With COVID-19 and Other Contagious Airborne Viruses

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Study Objective: Nebulizer treatments for ill patients with chronic lung disease, reactive airways and other respiratory emergencies have been implicated in aerosolized spread of highly contagious airborne viruses, including COVID-19. Considering the increased risk of aerosolized spread of viruses within confined ambulance compartments, this study specifically evaluated a specially designed nebulizer mask modified with expiratory-port filters and sealing faceplates to minimize bio-aerosol spread.

Methods: Recognizing that fugitive aerosol emissions (such as those that would possibly carry COVID-19) typically range from 0.5 to1.5 micron (μ), a six-port (0.3–10μ) Kanomax 3889 R particle measurement (PM) counter was placed 78 cm from each of 15 rotating adult volunteers (non-patient, beardless) including 7 women and 8 men, ages 18-59 with a mean age of 39 years. The subjects were each sitting upright on a stretcher within a closed standard ambulance compartment. Assigned to one of three rotating fleet ambulances, subjects used the EMS agency's usual jet-nebulizers with a conventional mask (CM) and then returned on another day to receive jet-nebulization with the aerosol-controlling mask (ACM) or vice versa (ACM first day, CM next day). After documenting baseline ambient PMs (PM amb) within the compartment, the Kanomax operator quickly brought in a subject, closed the door, and waited 5 minutes before making a pre-nebulization PM (preNeb-PM). Jet-nebulizers (using H 2 0 solutions) were then applied (either by CM or ACM as described) for 5 min with immediate post-nebulization measurements (Post1) and two successive measurements (Post2/Post 3), all five minutes apart.

Results: Following the 5-min nebulization, mean CM PMs (Post1 cm) were 152.2-fold larger than mean ACM PMs (Post1 ACM) measurements (p=0.001) and respectively remained 49.6-fold (p=0.005) and 7.2-fold (p=0.006) larger at Post2 and Post3 readings. PM amb and preNeb-PM were all similar (NSD) for both ACM and CM approaches when examining all studied particle sizes (0.5, 1.0, and 3.0 μ) including 1μ preNeb-PMs, measuring 6,977 for ACM approaches and 5,683 for CM use, respectively (NSD). While mean Post1 ACM 1μ PMs decreased (-31.7%) from pre-Neb-PM readings (6,977 to 4,662; p=0.002), counterpart Post1 CM 1μ measurements rose 14,500.09% (from 5,683 to 709,549.93; p=0.002) with corresponding significant elevations for 0.5μ (p=0.001) and 3μ (p=0.002) particle sizes using conventional masks. Of additional note, though applied for just five minutes, ACMs were uniformly well tolerated.

Conclusion: Compared to conventional methods, a modified mask system designed specifically to limit aerosolization of inhaled solutions did provide profound control of fugitive aerosolized particle emissions during nebulizer applications. The findings indicate a much safer approach to treating COVID-19 patients and all others requiring nebulization.

21 Lung Ultrasound Versus Chest X-Ray for the Radiographic Diagnosis of COVID-19 Pneumonia in a High Prevalence Population

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Study Objectives: The viral illness severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), more commonly known as coronavirus 2019 (COVID-19), has become a global pandemic infecting over 160 million individuals worldwide. Symptoms are often vague, and physical exam findings have proven unreliable as indicators of infection. Therefore, diagnosis typically relies on imaging or nasopharyngeal swabs. The objective of this study was to compare point-of-care lung ultrasound (LUS) with chest x-ray (CXR) to determine which is the more accurate diagnostic imaging modality for diagnosing COVID-19 pneumonia.

Methods: This was a single-center, prospective, observational study at an urban university hospital with >105,000 patient visits annually. Patients >18 years old, who presented to the emergency department with signs and symptoms of COVID-19, were eligible for enrollment. Each patient received a LUS, performed by an emergency medicine resident or attending physician, using a portable, handheld ultrasound and a portable AP CXR after the LUS was completed. High-risk patients or those with an abnormal imaging finding underwent a non-contrast-enhanced computed tomography (NCCT) as the diagnostic standard. The primary outcome was the sensitivity and specificity of LUS and of CXR at identifying COVID-19 pneumonia against NCCT as the reference standard. Using a power analysis of 80%, our sample size calculation of 98 patients was based on previous data demonstrating a 20% difference in sensitivities between LUS and CXR at diagnosing pneumonia. Data are presented as proportions with 95% confidence intervals (CIs). Data analysis included the chi-square and t tests.

Results: 143 consecutive patients with signs and symptoms of COVID-19 were approached and enrolled. 27 patients were considered low-risk by the attending per emergency department guidelines, and 6 patients were admitted for alternate diagnoses without advanced imaging. 110 patients underwent LUS, CXR, and NCCT. 99 LUS and 73 CXRs were interpreted as positive. 81 NCCT were interpreted as positive providing a prevalence of COVID-19 pneumonia of 75% (95% CI 66.0-83.2) in our study population. Sensitivity of LUS was 97.6% (95% CI 91.6-99.7) vs 69.9% (95% CI 58.8-79.5) for CXR. Specificity was 33.3% (95% CI 16.5-54.0) for LUS and 44.4% (95% CI 25.5-64.7) for CXR. LUS positive and negative likelihood ratios were 1.46 (95% CI 1.12-1.92) and 0.0723 (95% CI 0.01-0.31), respectively vs 1.26 (95% CI 0.87-1.81) and 0.67 (95% CI 0.39-1.16) for CXR. PPV and NPV for LUS were 81.8% (95% CI 72.8-88.9) and 81.8% (95% CI 48.2-97.7) compared to 79.5% (95% CI 68.4-88.0) and 32.4% (95% CI 18.0-49.8) for CXR.

Appendix E

SafetyFilta™, SafetyNeb™, and SafetyO$_2$™

Filter Media Performance

Tests Performed by Nelson Labs

Material Composition			
Filter Media		Blended Synthetic Fiber	
Laminate Scrim		Polypropylene	
Overall Thickness		1.1 mm	
Filter Specifications			
NaCl Efficiency at 32 LPM	> 99.5%	TSI8130 NaCl 0.1 micron particle size	
Pressure Drop at 32 LPM	1.6mm H_2O	TSI8130 NaCl 0.1 micron particle size	
BFE Efficiency	> 99.9992%	Mil-M-36954C	at 3.2 micron mean particle size
VFE Efficiency	>99.9970%	Mil-M-36954C	at 3.2 micron mean particle size
Air Permeability	>125 CFM	ASTM D373	