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## Home PAP devices in COVID-19 infected patients

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### DISCLOSURE STATEMENT

The authors report no conflicts of interest.

Given that the COVID-19 pandemic is affecting millions of people, many patients on positive airway pressure (PAP) therapy are affected. As current PAP systems are open and do not filter expired air, there is a theoretical concern, supported by experimental data of plausibility, that viruses can be shed from the patients into the local environment. This may endanger those around the patients in homes or healthcare facilities. However, both in countries where ventilator devices have been traditionally readily available, and in resource poor conditions, demands can exceed supply, needing consideration of using positive pressure devices at least as bridging therapy to formal invasive ventilation. The United States Food and Drug Administration recently allowed such use during the COVID-19 crisis: <https://www.fda.gov/medical-devices/letters-health-care-providers/ventilator-supply-mitigation-strategies-letter-health-care-providers>.

Humans produce exhaled breath particles (EBPs) during various breath activities, such as normal breathing, coughing, talking, and sneezing.<sup>1</sup> EBP concentrations do not differ significantly between the volume control and pressure control modes of the ventilation settings in the mechanically ventilated patients.<sup>1</sup> The EBPs concentrations in patients with high PEEP (> 5 cmH<sub>2</sub>O) are higher than those in patients with low PEEP (< 5 cmH<sub>2</sub>O).<sup>1</sup> Thus, the risk of environmental contamination from droplet-based mechanisms seems real, and relevant to viral and bacterial infections.

Bacterial/viral filters are designed to trap over 99.99% of relevant particles.<sup>2</sup> They typically consist of a housing which incorporates a hydrophobic glass fiber filter and a media made of corrugated hygroscopic paper. An example of specifications is tidal volume: 150- 500 ml, flow rate resistance: of 5, 13, and 28 mm H<sub>2</sub>O at 30, 60 and 90 liters/minute, bacterial filtration: >99.9999%, viral filtration: 99.9999%, ([https://www.accessdata.fda.gov/cdrh\\_docs/pdf10/K102483.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf10/K102483.pdf)). The maximum duration of use is usually 24 hours, but they could be replaced more frequently if necessary.

We designed elements of a circuit that we believe will be helpful in reducing viral shedding in COVID-19 patients on PAP devices. The elements of the circuit were described previously as Enhanced Expiratory Rebreathing Space (EERS), used to stabilize carbon dioxide fluctuations and thus to aid in the management of central and complex sleep apnea.<sup>3</sup> The fundamental idea is to vent exhaled air away from the patient and impose a filter before the air can exit the system. The air going to the patient passes a filter, but more importantly, the air leaving the system passes through the same viral and bacterial filter. We believe that versions of this design can also be used in hospital settings in patients requiring respiratory support when volume ventilators are not available. However, home bilevel and CPAP systems differ by model and manufacturer and are not designed to be used as life-support ventilators. Repurposing home units for this use may be problematic, especially if high flow oxygen is added to the circuit of some devices (David Rapoport, personal communication).

The circuit consists of:

Non-venting full-face mask (to reduce leaks at the face)<sup>4</sup>

Safety valve (this is integrated in some masks allowing the patient to breath in case there is a power failure)<sup>5</sup>

In-line HME (heat moisture exchanger – which would need to be replaced daily) or viral filter<sup>6</sup>

Tubing connected to a whisper swivel type valve; also called leak valve by some manufacturers<sup>7</sup>

Tubing connected to the PAP device.

An alternative approach is to use a non-rebreathing valve following the filter. A non-rebreathing valve prevents any CO<sub>2</sub> retention,<sup>8</sup> which can occur even in some conventional PAP set-ups, though less so when exhalation ports are in the mask design at the nose/mouth itself. The main difference of such a configuration compared to what we propose is that the exhalation port of the valve is a large leak port, which could compromise pressure ventilation at low settings and reduced the effective pressure at the mask, or interfere with sensing by the device which drives switching between inspiratory and expiratory support. There is data that such undesirable effects are small,<sup>8</sup> but direct comparisons with our proposed configuration are not available.

If necessary, standard adaptors can be added that will allow oxygen or metered dose inhalers to be added to the circuit. Close collaboration with experienced respiratory therapists is recommended to source the components mentioned above. The main manufacturers of PAP units and/or supplies are ResMed, Philips, Fisher & Paykel, Becton Dickinson, Invacare, DeVilbiss-Drive, and Hans Rudolph. When components are not available from usual channels, online-retailers might have components in stock.

Figure 1 shows an example of such a circuit with off the shelf components that could be used. Other manufacturers' components with similar functions could also be used. One of the authors has used this type of circuit for over 15 years and, in his experience, there is not more than a 1-2 mm Hg increase in measured mainstream end-tidal CO<sub>2</sub><sup>3</sup>

There is obviously still a danger that virus will be shed if there is any leak at the patient/mask interface, or when the patient is repositioned, mask changed or when the patient eats or drinks. It is strongly recommended that in the hospital setting anyone attending the patient wear full PPE, that if possible the patient be in a negative pressure room, and consideration of adding a HEPA filter system in the room. The patient will breathe through the in-line filter and thus may re-inhale pathogens. The only way to reduce this is to change filters more frequently.

Additional measures such as full head masks, bed tents, etc. may be considered for the safety of the healthcare professionals in contact with the COVID-19 patients. Further, this may be considered in the future for other infectious agents (influenza, measles, herpes zoster, etc.).

In the home setting, it may be difficult to protect family members and other domestic contacts. It might be most prudent for a patient with severe OSA and COVID-19 infection to be monitored and treated in a healthcare facility, where PPE and adequate precautions are hopefully more readily available. Patients with persistent cough and dyspnea may have difficulty tolerating PAP. Milder disease may be conservatively managed perhaps by short-term supplemental oxygen or simply with positional therapy.

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4. Most vented masks can be easily modified to become non-vented by blocking the holes in the mask with a putty like product, such as Mack's ear putty. There are also some native non-venting masks (available from major PAP manufacturers):  
Philips: <https://www.usa.philips.com/healthcare/solutions/hospital-respiratory-care/hospital-respiratory-patient-interface-masks>  
Fisher Paykel: <https://www.fphcare.com/us/products/nivairo-rt045/>  
ResMed: <https://www.resmed.com/us/en/healthcare-professional/products/masks.html>
5. Integrated safety valves examples:  
Fisher Paykel: <https://www.fphcare.com/us/products/nivairo-rt045/>; also available to add to circuit.
6. <https://www.4mdmedical.com/main-flow-bacterial-viral-filter.html> (example)

7. <https://www.vitalitymedical.com/respironics-whisper-swivel-ii-exhalation-valve.html>
8. Ferguson GT, Gilmartin M. CO2 rebreathing during BiPAP ventilatory assistance. Am J Respir Crit Care Med 1995;151:1126-35.

Accepted Paper

Figure 1

