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Repurposing bi-level ventilators for use with intubated patients while minimizing risk to health care workers during insufficient supply of conventional ventilation for patients with COVID-19

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Mount Sinai Health System

Current Working Protocol – Subject to Revision

This current working protocol is subject to revision. It is expected this document will be updated and re- released as additional experience is accumulated.

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This protocol is shared with our health care colleagues to increase knowledge about potential solutions to increase the capacity and access to mechanical ventilation during the COVID-19 crisis. Icahn School of Medicine does not warrant the contents or effectiveness of the protocol, and the use and implementation of this protocol should be first reviewed and evaluated with each hospital’s medical staff.

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1. EXECUTIVE SUMMARY

The available supply of invasive mechanical ventilators is inadequate to fulfill the anticipated demand for these devices in a COVID-19 pandemic. These devices are required to support patients who present with acute hypoxemic respiratory failure secondary to viral infection. The recent development of approaches to modify invasive ventilators to support two patients may extend the supply of devices available to treat selected patients, yet it is unlikely to completely meet demand.

There is an abundant supply of non-invasive bi-level ventilators that are typically used to treat sleep disordered breathing. These devices can be modified to provide safe and monitored ventilation to patients with acute hypoxemic respiratory failure; the availability of these devices for repurposing is such that supply will be sufficient to better position hospitals to meet the anticipated ventilation device demand during the COVID-19 pandemic.

Experience accumulated from a long history of non-invasive ventilation by mask and anecdotal use of these systems with intubated patients suggests that these devices can provide adequate ventilation in a crisis. We have determined that bi-level ventilators intended for non-invasive use can deliver adequate ventilator pressures to support most patients with acute hypoxemic respiratory failure. Virus aerosolization and subsequent exposure of healthcare workers to the virus is a significant risk associated with use of non-invasive ventilators in the setting of COVID-19. This risk is mitigated by replacing the porous mask interface with a closed circuit delivering tidal volume via an endotracheal tube and by use of expiratory port filters. The ResMed VPAP ST device can be modified to add monitoring devices to allow for precise measurement and display of inspired oxygen concentration, tidal volume delivery, and expired carbon dioxide levels so that the adequacy of ventilation support can be assessed continuously from outside of the patient's room.

Taken together, we have developed a protocol that is capable of ventilating and monitoring patients with acute respiratory failure and mitigates the significant potential risks of exposure. This device has been tested in the Simulation HELPS Center at Mount Sinai, and the protocol has been validated in a clinical setting. We suggest that this system to repurpose noninvasive ventilators for invasive support of COVID-19 patients with acute hypoxemic respiratory failure can be utilized in the situation in which there is an insufficient supply of conventional respiratory ventilators.

2. KEY PROTOCOL RISKS & SAFETY FEATURES

The primary potential risks of the repurposed ResMED VPAP ST ventilator (VPAP ST) protocol are the risk of respiratory contamination from aerosolization, limitation of high oxygen delivery and delayed detection of hypoventilation and hyperventilation as described in [Table 1](#).

Table 1: Potential Risks and Mitigation Strategies

Risk	Risk Mitigation
Respiratory contamination from aerosolization, increasing risk to health care workers, if unmodified circuits are used.	Intubation with delivery of ventilation through an endotracheal tube is expected to reduce the amount of exhaled gas vented into the room other than by the ventilator circuit to near-zero. The ventilator circuit components and configuration are designed to capture and filter all gas exhaled by the patient with non-invasive single limb circuits.
Limitation of high O ₂ delivery imposed by the circuitry	Modifications of the circuit are intended to maximize inspired O ₂ levels if needed. Saturation monitoring will be used and patients will be switched to conventional respirators if needed (i.e. low O ₂ saturation despite maximal settings) if such ventilators are available.
Delayed detection of hypoventilation	Monitoring, including use of saturation monitoring and of capnography where available. Alarms to alert hospital personnel to circuit disconnection will be added as available, but are not a standard part of these devices.
Delayed detection of hyperventilation	Non-invasive ventilators are not likely to deliver sufficient ventilation to hyper ventilate at maximal settings. Monitoring of end-tidal CO ₂ , if available, may suggest hyperventilation but should be confirmed by an ABG. Turning down the rate or level of ventilator support (IPAP-EPAP) will reduce minute ventilation.

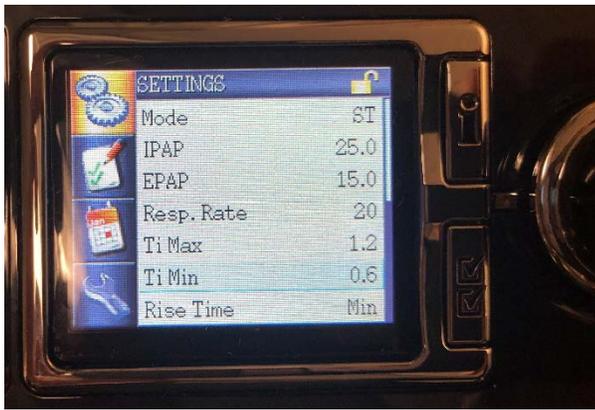
3. EQUIPMENT & SUPPLIES

Specific equipment required may vary depending on supplies and equipment available.

1. ResMed VPAP ST (alternate bi-level devices would be acceptable)
2. Oxygen feed port (w/ 20' oxygen tubing, capped) [CareFusion 004204]
3. Second Oxygen port (w/ 20' oxygen tubing, capped) [CareFusion 004204]
4. Ventilation tubing
 - a. Standard “leak-port” tubing (including from multiple manufacturers) is preferable
 - b. Must include required exhalation ports (e.g. Fisher Paykel RT 219 or Phillips Respironics 1073228)
5. Inline heated humidifier (if available)
6. Exhalation port device with high resistance
 - a. With attached filter (e.g. Filta-Guard 1944000)
7. Gas sampling adaptor for CO₂ and flow monitoring (e.g. D-Lite Spirometry Kit 889560)
8. HME (inline moisture exchanger) if inline heated humidifier is unavailable (e.g. Covidien 353US908)
9. Endotracheal tube

4. SETTING UP VPAP ST AND CIRCUIT

Step 1: Set up VPAP ST device by plugging it in, turning it on and holding down the “turn knob” and “double check” buttons together for 3 seconds to enter Clinical Mode



Step 2: Connect antimicrobial filter

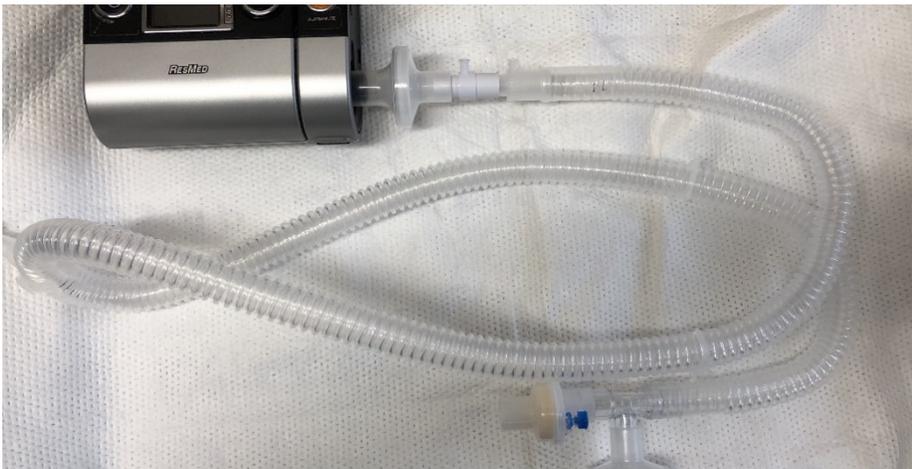


Steps 3 and 4: Connect BOTH inline O₂ feed ports (with 20' oxygen tubing) at VPAP ST outlet

- One tube is kept capped and in reserve for adding high O₂
- One tube is connected to 15 L/min source of O₂ (e.g. wall)

**Step 5: Connect VPAP ST tubing circuit**

- Preferably standard circuit with exhalation port (e.g. Fisher Paykel RT 219 or Phillips 1065832)
 - If needed any standard ventilator tubing can be used, but an exhalation port device must be added if it is not included
- Circuit **MUST** include exhalation “leak-port”
 - If using standard respiratory tubing, can add standalone exhalation port (e.g. Fisher Paykel RT017 or Philips 1065775)

**Step 6 (optional): When available, add inline heated humidifier if available (e.g. Fisher Paykel stand-alone humidifier)**

Not pictured

Step 7: Verify that the exhalation port device with high resistance is present and can accept a viral filter

- This should be near the patient, e.g. at end of tubing.
- Attach viral filter after exhalation port (so it can be changed when wet or clogged)

**Step 8: If available, attach gas sampling adaptor for CO₂ and flow monitoring**

- This is for monitoring only and does not affect system performance



Step 9: Use inline heat and moisture exchanger (**HME**) if heated humidification via reservoir is unavailable



Step 10: Set to Bilevel ST mode. Suggested default settings at a glance (refer to Step 12 for details):

- ST mode
- Smart Start OFF
- IPAP 25
- EPAP 15
- Backup Rate 20 or 5 less than patient's spontaneous rate.
- Set TiMax to 1.2 seconds and TiMin to 0.6 seconds
 - These may need to be adjusted if patient RR is greater than Backup Rate (see Clinician Guide)
- Rise time: min

SAFETY CHECK: If available, connect a “test lung” to the end of circuit and verify that it inflates when setting VPAP ST to IPAP 25, EPAP 15, Resp Rate 25.



Step 11: Attach setup above to ET tube and patient

- The cuff on ET tube should be inflated.

Step 12: Initiate ventilation

1. Set Mode: ST (do not use CPAP, S or T modes)
2. Set IPAP: Start at 25 (likely will need max = 25 cmH20)
3. EPAP 15
 - a. Do not increase EPAP if ventilation is needed, can use high EPAP if PEEP (oxygenation) alone is needed
 - b. NOTE: Increasing EPAP alone without increasing IPAP will reduce ventilation
4. Check Tidal Volume (TV) read out (on VPAP ST screen or gas sampling/flow monitor if available)
 - a. Calculate what TV is 6 cc/kg (IBW) for patient (usually 300-400 cc)
 - b. If TV is over goal, IPAP can be reduced (or EPAP raised if additional support for oxygenation is needed). If TV is under goal, IPAP should be increased (if not already at maximum of 25 cmH20). Refer to clinical guide for details.
5. Set Respiratory Rate:
 - a. Initially 5 less than patient breathing (no less than 15, can be as high as 25-30, but level of FiO₂ attained may worsen with increasing rates)
 - b. Check FiO₂ via gas sampling/flow monitor if available

*****If the patient's ventilation needs cannot be met by the above IPAP/EPAP and RR settings, an alternate ventilator should be considered *****

1. Set TiMax to 1.2 seconds and TiMin to 0.6 seconds
2. Set Rise Time: Min
3. Set Trigger: Low
4. Set Cycle: Low

*****IMPORTANT: Disconnecting the VPAP ST circuit is an aerosol-generating procedure. Anyone present for this procedure must wear appropriate PPE, including eye protection and an N95 or equivalent respirator.**

5. PATIENT SELECTION

This mode of ventilation is expected to be similar to pressure control ventilation. Patients who meet the following criteria will be eligible for treatment with this mode of ventilation:

1. Patients with milder respiratory failure who still need ventilator support.

OR

2. All patients if there is no other ventilator available. It is likely to work best in those with higher lung compliance (appears to be relatively frequent in many COVID-19 patients).

OR

3. Patients being weaned from mechanical ventilation as they stabilize and improve may benefit equally from this ventilator and thus free up more advanced ventilators.

NOTE:

- Patients with need for high levels of FiO₂ may be eligible, but second O₂ input port or further modifications of the leak circuit will be required. Simplest modification to increase delivered FIO₂ is to utilize the second oxygen bleed in (see circuit) with an additional 15 L/min O₂ (up to 30 L/min O₂ total for two ports). In order to prevent backup of oxygen into the VPAP ST blower:

Do not increase bleed-in of oxygen to a level that produces FiO₂ > 95% at the endotracheal tube.

- Because of dyspnea and risk of patient self extubation, it is expected many patients may require sedation or even paralysis. While this likely will improve efficacy of mechanical ventilation, it carries an added risk in these patients due to the lack of alarms and backups available with these ventilators. Due to the lack of alternative, this is a risk that may be unavoidable and must be mitigated by minimizing sedation and paralysis, and maximizing supervision by staff of the patient. However, if an alarm for disconnect can be provided (eg via a separate pressure monitor, or using the existing monitoring port for volume, Co₂, etc and existing software connections) this alarm is highly desirable and should be set.

6. MONITORING & SUPPORT DURING USE OF VPAP ST

The VPAP ST was not intended to be a life support device and thus has no safety alarms. Because of this, close observation of the patient is critical and there should be added caution with sedation and neuromuscular blockade

Due to the highly contagious nature of COVID-19 and the risk of infection with close contact, it is unlikely there will be a healthcare worker in the room to monitor the patient. To mitigate risk of infection of healthcare workers, these patients will be monitored from outside the room whenever possible after initial stabilization post-intubation using telemetry (where available). Frequent spot checks will be performed if telemetry equipment is limited. Spot checks should include

1. Monitoring of O₂ sat via continuous pulse-oximetry
2. End tidal CO₂ and respiratory rate (low or high), when available
3. Tidal volume, FiO₂ and flow monitoring via telemetry equipped with spirometry module (e.g. GE Carescape monitor with D-fend Pro + spirometry module)
 - a. **If this module is used, alarms can be introduced**

7. CARING FOR PATIENTS USING VPAP ST

Managing Shift Changes

Each time there is a shift change for staff caring for patients being treated with a VPAP ST, outgoing and incoming staff should review key safety elements, including the following:

- Location of this protocol
 - Must be available at the patient's bedside at all times
- State of sedation and paralysis of the patients
 - If there is no spontaneous respiratory effort, added supervision is needed.
- Circuit configuration, including how to reconnect if ever dislodged or disconnected.
- Whether or not there is availability of acute airway and respiratory backup support devices, including location of bag valve mask and rescue ventilator nearby (if available)
- Inspection of expiratory filter and replacement if wet (this will increase resistance and reduce CO₂ venting)

Key Considerations to Take into Account Before Making Changes to Settings:

- Higher pressures (both IPAP and EPAP) will increase the leak through the expiratory port. This may lower the FiO₂ due to added entrainment of room air.
 - Increase bleed into the circuit of O₂ from second port if this occurs (if not already at max).
 - Check FiO₂ with gas sampling/flow monitor, if available.
 - If FiO₂ is already at 100% and saturations are inadequate, escalation of ventilator strategy may be needed.
 - Further increase in FiO₂ requires modification of circuit to reduce leak flow.
- IF THE EXHALATION LEAK PORT IS MODIFIED, pressures in the circuit to below an average pressure of 10-15 may drop the leak flow below 15 L/min (minimum to prevent CO₂ rebreathing) and cause hypercapnia.
 - This will not happen with the commercially available unmodified expiratory port unless there is blockage of the port or any attached filter as by secretions. Promptly examine port and filter for patency if patient experiences increasing hypercapnia.

If possible, a standard ventilator should be available for use in case the patient cannot be maintained on the repurposed VPAP ST (bilevel). It is understood, however, that a standard ventilator is not likely to be present as the primary purpose of this protocol is to deal with limited availability of standard ventilators.

8. ADMINISTRATIVE AND ETHICAL CONSIDERATIONS

Hospital administration must approve this protocol before use, acknowledging the unique ethical considerations.

This protocol is only appropriate for consideration when (i) crisis standards have been instituted, (ii) there are not enough ventilators to meet demand for ventilation of intubated patients with a reasonable probability that intubation/ventilation will be lifesaving.

Ethically, it must be recognized that the conversion of ventilators meant for non-invasive ventilation to use with intubated patients is not the usual standard of care, but in the setting of a mass crisis, such as the COVID19 pandemic, the number of potentially rescuable patients may exceed the number of ventilators to support them. Initial experience with the repurposed non-invasive ventilators indicates that the proposed use of these devices as outlined above offers the best chance at saving the most lives in the current pandemic climate. The use of the repurposed non-invasive ventilators should be discontinued as soon as a sufficient supply of ventilators becomes available.