Mount Sinai Health System Emergency Ventilator Sharing Protocol

The protocol described in this document is a work in progress and is subject to revision

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Protocol Developed By:
Martin Chen MD
Anjan Shah MD
Ronak Shah MD
George Zhou MD
Erica Kane MD, MPH
Garrett Burnett MD
Chang Park MD
Daniel Katz MD
Shams Ranginwala MBA, RRT-NPS, CPFT
Matthew Levin MD

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Table of Contents

Purpose

This document describes the implementation of a shared (also referred to herein as *split*) ventilator protocol for the Mount Sinai Health System (MSHS). It would be utilized when enacting Crisis Standards of Care at hospitals within the MSHS, when rescuable patients who require mechanical ventilation would otherwise be denied ventilation due to lack of available ventilators. **This protocol poses significant risks to both patients sharing a single ventilator and does not in any way reflect the normal standard of care within the MSHS.** It has been developed in response to the unique situation caused by the COVID-19 Crisis in New York City. Each patient should be mechanically ventilated individually, unless the supply of ventilators is completely exhausted and the patient would otherwise be expected to die.

DISCLAIMER: This shared ventilator protocol has not yet been trialed in patients. The study was designed and conducted in the Department of Anesthesiology, Perioperative and Pain Medicine's high-fidelity human patient simulator laboratory using two CAE HPS Anesthesia Simulator Mannequin Systems (CAE Healthcare, Sarasota, Florida). The parameters were determined experimentally.

Patient selection

Criteria for split ventilation will likely be adaptive given the emergent circumstances, but if possible the following criteria should be satisfied:

1. Both patients are Covid-19 patients, in order to avoid infection.
2. Patients should be paired according to ideal body weight.
3. Patients should have initial similar lung compliances and levels of ventilatory support
4. Patients should require similar levels of PEEP.
5. Patients should be predicted to require mechanical ventilation with paralysis for > 72 hours.

Design Overview

The ventilator breathing circuit is split using standard T-pieces and connectors. On the inspiratory limb, two standard ¾" brass lead-free gate valves (normally used in plumbing applications) are placed in-line on either side of a T-piece, and one unidirectional valve between the valve and circuit tubing on each of the inspiratory limbs. The connections on the ¾" valve have an internal diameter (ID) of approximately 22 mm. On each of the expiratory limbs of the two circuits, one unidirectional valve is placed between the circuit tubing and Wye connection. Near the patient, a standard spirometry sensor is placed in-line between the endotracheal tube elbow and the wye connector of the breathing circuit. The sensor is connected to the gas analyzer-spirometry module of a portable or stationary physiologic monitoring system. Due to the nature of the pandemic, a bacterial/viral (B/V) filter is placed between the elbow and the endotracheal tube, and additional B/V filters are placed between the circuit and the inspiratory and expiratory connection ports on the ventilator.

Improvements over other solutions

1. The ¾" gate valves allow the pressure and volume delivered to each patient to be adjusted and titrated to account for the potentially different lung compliance (stiffness) of each patient.
2. The use of appropriately placed spirometry sensors enables more accurate measurement of the delivered tidal volume and pressures for each patient individually. Spirometry and gas analysis data can be displayed on a wall-mounted or portable monitor, provided that a spirometry-gas analyzer module can be installed in the physiologic monitoring system.
3. The unidirectional valves in both the inspiratory and expiratory limbs prevent reverse flow of gas in the circuits.

The ¾" valves used are brass, lead-free standard plumbing valves that are certified for use in domestic water supply applications. These brass valves are heavy, so ensure that the connections are gas-tight using teflon tape and secure the valves to the ventilator.

DISCLAIMER: The use of these valves for a medical application is not approved in any way and is a significant deviation from standard of care. The valves MUST be cleaned to remove obvious manufacturing contaminants such as oil, grease, dirt, etc. Our protocol was to clean by hand using soap and a brush, then place through a steam sterilization cycle. As per CDC guidelines, peracetic acid and hydrogen peroxide should be avoided due to the issue of brass corrosion.

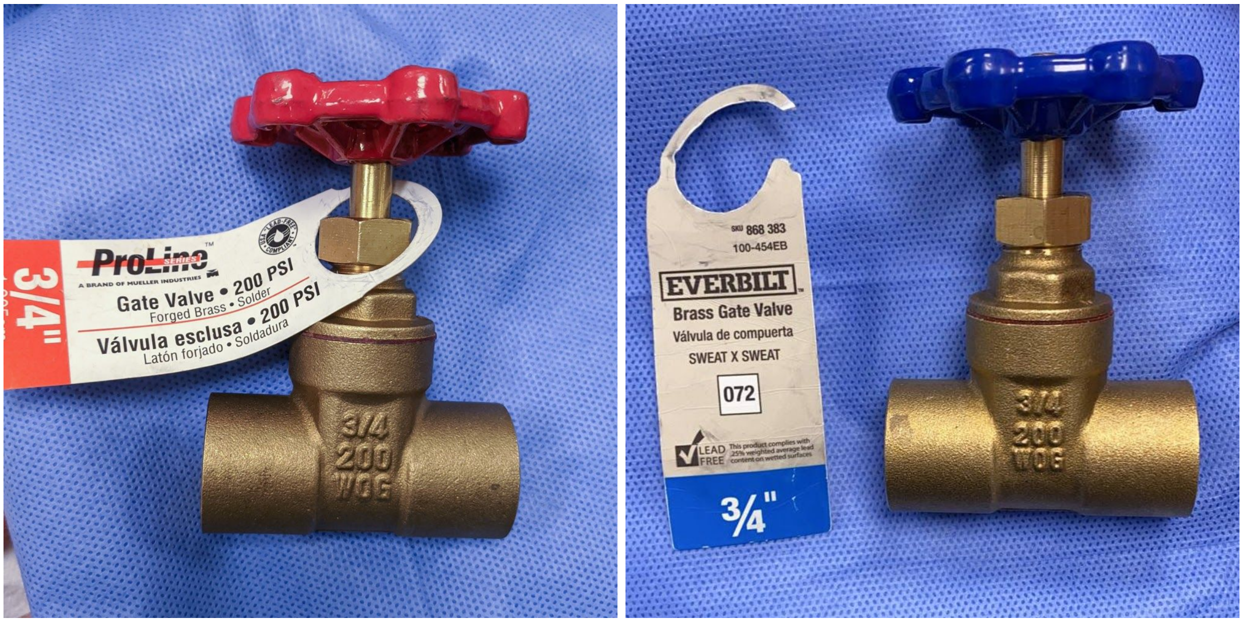

Figure 1A - Part #1, listed below. Example ¾” brass gate valves with solder/sweat connections. PVC alternatives exist but are not readily available.

Parts List

1. 2x ¾” ID lead-free brass gate valves with “sweat” or “solder” connections for the inspiratory limbs. **These should be available from Home Depot, Lowes, or any plumbing supply store.**
2. 4x in-line, unidirectional (“check”) valves for inspiratory and expiratory limbs (Mallinckrodt One-way valve, 22mm F x 22mm M). **Can be replaced with a 3D printed check valve, specifications are on GitHub:** https://github.com/acoastalfog/sinai-ventilator-components
3. 2x T-pieces, 15mm ID/22mm OD to 2x 19mm ID/22mm OD (Hudson RCI Trache Tee Oxygenator)
4. 2x 22mm OD, 15 mm ID both ends (male-to-male) adapter (blue Airlife Intubation Adapter 001820); 4x total needed if installing 2x additional valves for PEEP customization, see **Appendix A. Can be replaced with a 3D printed 22mm OD adapter, specifications are on GitHub labeled as adapter_v1.3_smallMaleMale:** https://github.com/acoastalfog/sinai-ventilator-components
5. 2x 22mm ID female-to-female adapter (clear Mallinckrodt Universal Cuff Adapter). **Can be replaced with a 3D printed 22mm ID adapter, specifications are on GitHub labeled as adapter_v1.3_largeFemaleFemale:** https://github.com/acoastalfog/sinai-ventilator-components

6. 2x ventilator circuits
7. 2x yellow spirometry sensor and tubing (GE D-lite++ patient spirometry set; GE part number 2102497-002- 3 meter length tubing)
8. 3x Bacterial/Viral (B/V) filters (placed near ETT and in expiratory limb)
9. 2x Heat and Moisture Exchanger Filters (HME Filter)
10. Spirometry module/monitor (GE Carescape Respiratory Module)
11. Teflon plumbing threadseal tape (required for metal joints)
12. Electrical tape

Figure 1B. Part #2 and #3, listed above.

Figure 1C. Part #3 and #4, listed above.

Figure 1D. Part #6 and #7, listed above.

Figure 1E. All parts needed for the dual circuit. Note brass gate valves in upper left.

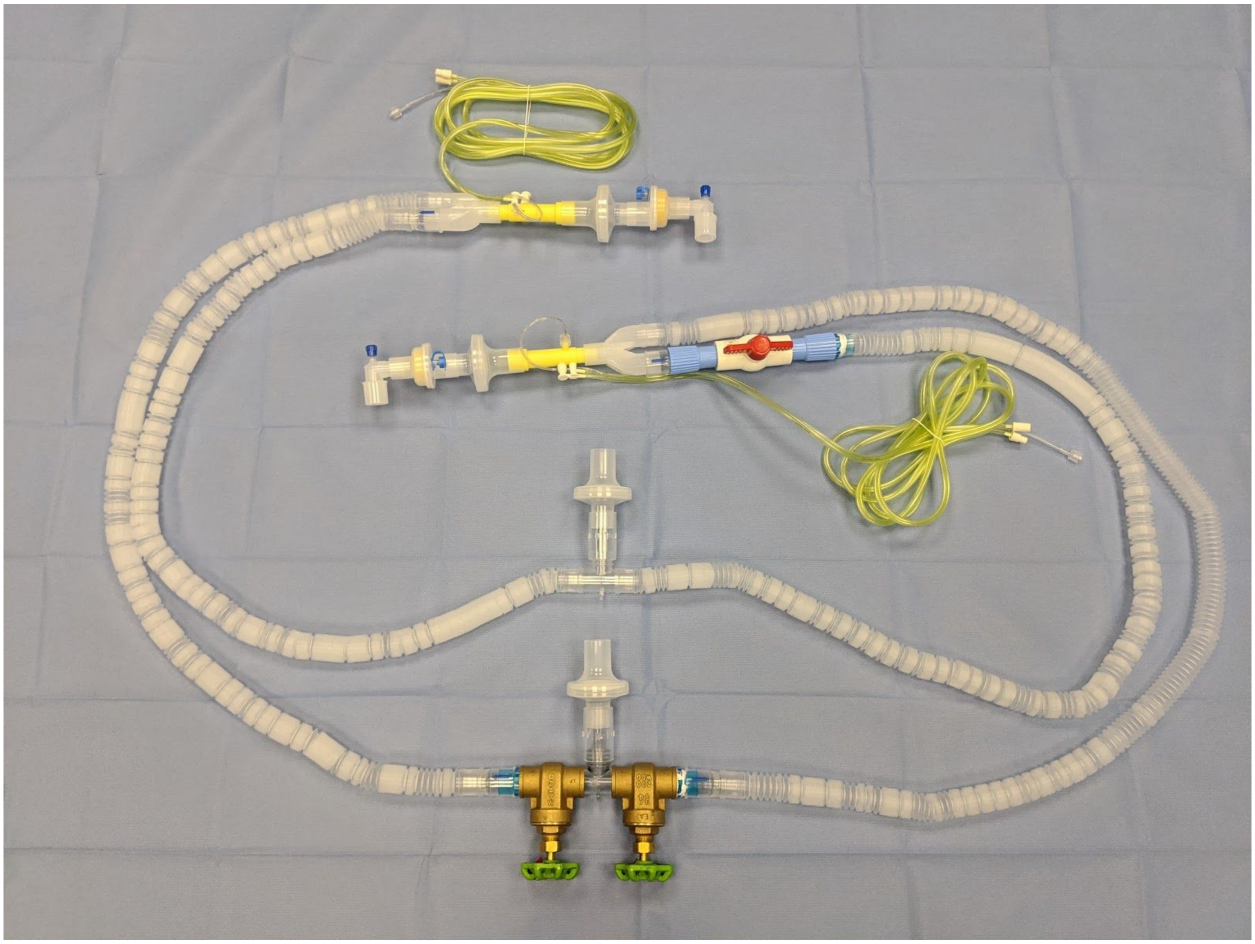

Figure 2 - All assembled parts. The circuit on the right contains an extra valve (red handle) on the expiratory limb for increasing PEEP (see Appendix A).

Circuit Assembly

Inspiratory limb: Vent Inspiratory connection → Bacterial/Viral filter (optional) → 22mm ID female-to-female adapter → 22mm T- piece* with distal limbs wrapped with teflon tape, then to each side of T piece: → ¾" brass gate valve → 22mm OD male-to-male adapter wrapped with teflon → one way valve → inspiratory limb of circuit → wye piece

***Wrap T-piece -to- brass valve connection with electrical tape to ensure gas-tight seal and to prevent disconnection**

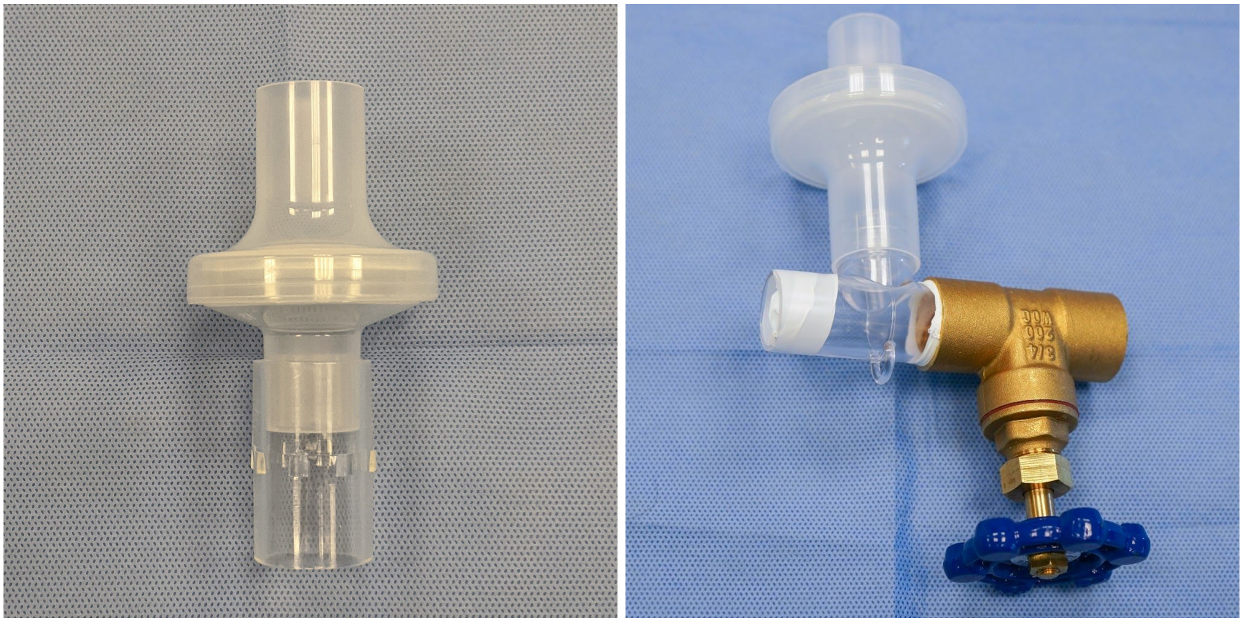

Figure 3 - Partially assembled inspiratory limb. Gate valve has been attached to one limb of the T-piece using Teflon tape for snug fit. Filter on the T-piece stem will connect to the ventilator inspiratory port.

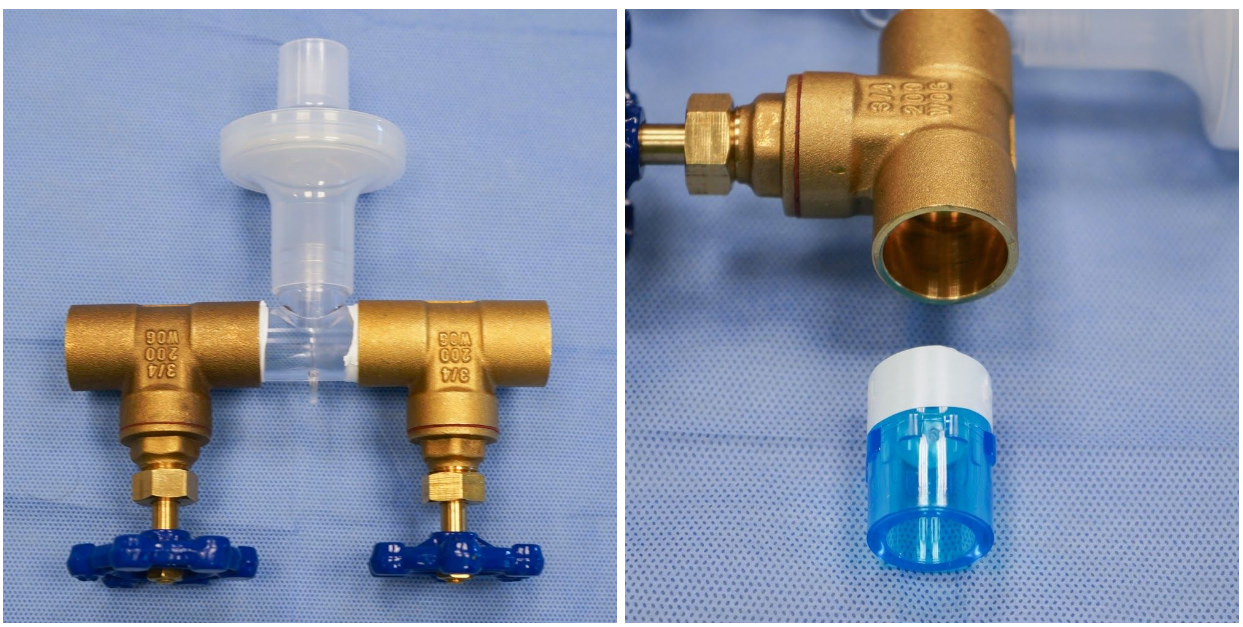

Figure 4 - both gate check valves have now been installed. 22 mm OD blue male-male adapter with teflon tape ready to be inserted into the gate check valve.

Figure 5 - Alternatively, ¾" lead free brass gate valves with threaded connections can be used for the inspiratory limb. If a threaded connection is used, an additional ¾" thread-to-sweat connection on both sides is needed. Teflon tape is used once again to create a proper seal between the threaded brass gate valve and the copper connection. The 22 mm OD blue male-male adapter with teflon would then be inserted into the smooth "sweat" connection on both sides.

Figure 6 - The 22mm OD blue adapters are connected to one way valves, then to the inspiratory limb of the breathing circuit. The gate check valves have been rotated with knobs facing upwards to optimize circuit ergonomics, decrease torque on the vent, and minimize the chance of circuit disconnect. These gate check valves are heavy, so it is important to keep the entire assembly close to the inspiratory port of the ventilator.

Figure 7 - Assembled Inspiratory Gate Check Valves. Note: red electrical tape used to provide structural support, and colored labeling tape has been added to the valve on the right to indicate orientation.

Patient Connection: ETT -> elbow connector → HME filter → Viral filter → yellow spirometry sensor → patient wye → one way valve on expiratory limb. **Make one for each patient.**

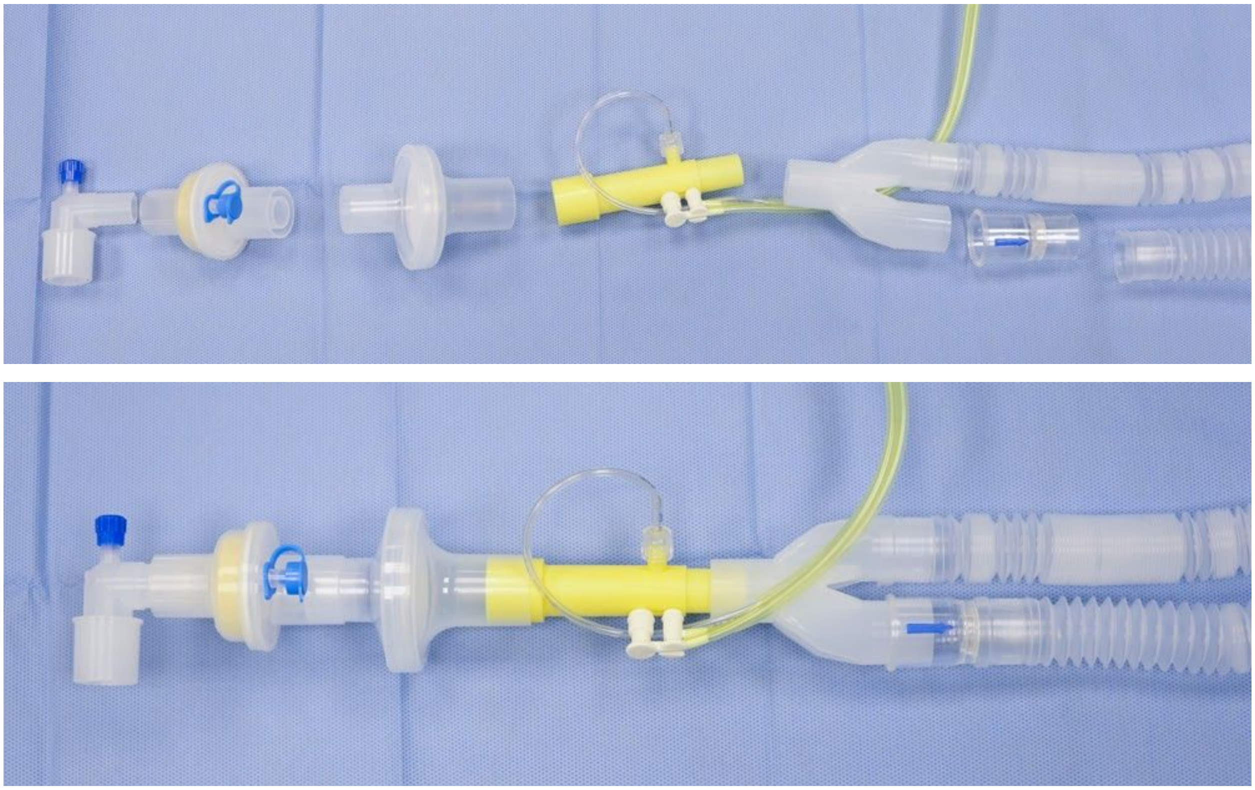

Figure 8 - Disassembled and assembled patient connection with (left to right): elbow, HME filter, Bacterial/Viral filter, spirometry tubing, circuit wye connector, and one-way valve on the expiratory limb. Note that one of these is necessary for each patient. Note: the HME filter needs to be most proximal to the patient.

Expiratory limb: Patient wye → one way valve → expiratory circuit tubing → 22mm T-piece → 22mm ID female-to-female adapter → B/V filter → Vent expiratory return connection

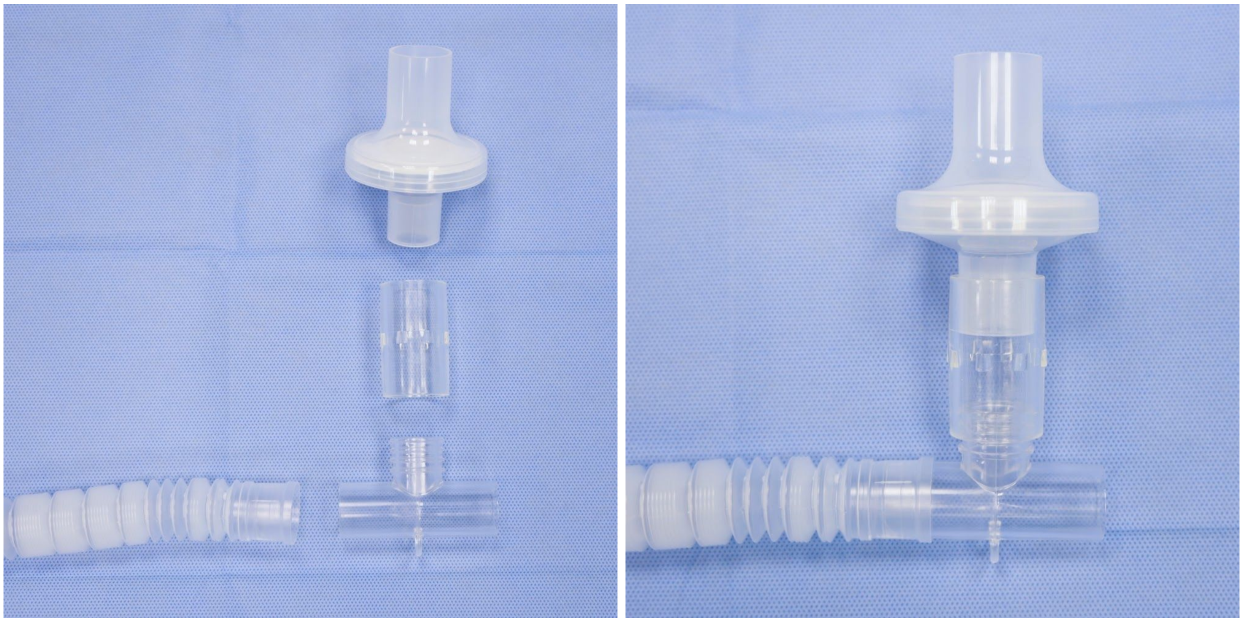

Figure 9 - Components of the expiratory limb, one side only. Note: B/V filter is not needed if the ventilator already has a B/V filter in place at the expiratory connection, such as with the Puritan Bennett 840 ventilator.

Figure 10 - Final assembled dual patient limbs connected to a Puritan Bennett 840 ventilator.

Figure 11 - GE Carescape Respiratory Module installed in a GE transport monitor. Monitoring of ventilation is key.

Using the Dual-Patient Ventilation Setup

Initiation

The ventilator and circuit should be prepared, and usual system checks should be run. **Prior to initiating mechanical ventilation the ¾" brass gate valves should be closed completely and then turned one revolution (360 degrees) open.** We have found that these valves provide **variable, but not linear, resistance** to inspiratory flow that is useful when the valves are opened **in the range of 120-360 degrees from the fully closed position**, although **this may vary depending on manufacturer and should be validated before use.** Many ventilators will give an error alert during the leak test. In this case double-check all connections and consider re-running the circuit test with only one circuit attached. The tidal volume estimated by the ventilator may be inaccurate during two circuit ventilation, necessitating individual tidal volume assessment by spirometry.

Management

Split ventilation, as described in this document, should be exclusively used for paralyzed patients ventilated in assist control pressure control mode. Paralysis is important to avoid rapid changes in lung compliance that could affect ventilation of the other patient and the system described herein has only been validated under these conditions. Pressure control should be optimized with the average best PEEP for both patients (Use clinical judgement on the appropriate PEEP that both patients can tolerate) and an initial driving pressure and inspiratory time on the ventilator which provides 4-6cc/kg ideal body weight **to the least compliant patient** (patient A). **Thereafter the driving pressure for the more compliant patient (patient B) should be decreased by turning the ¾" brass gate valve slowly clockwise until tidal volumes for patient B decrease and are also in the 4-6cc/kg ideal body weight range, to avoid further lung injury from volutrauma and/or barotrauma.** These parameters were determined experimentally in our anesthesia high-fidelity human patient simulator laboratory using two CAE HPS Anesthesia Simulator mannequin systems (CAE Healthcare, Sarasota, Florida) connected to the dual circuit and a Puritan-Bennett 840 series ventilator. **We further confirmed these results using an anesthesia workstation mechanical ventilator (GE Aisys, Louisville, KY). With the GE Aisys ventilator, despite low fresh gas flow rates (1 liter/minute), the ventilatory parameters for both high-fidelity simulators remained the same (including tidal volume and peak airway pressures).**

Monitoring

Ideally, clinicians should continuously monitor each patient for adequacy of ventilation using in-line spirometry that measures inspired (and expired) tidal volume, peak airway pressure, and total thoracic compliance. Continuous monitoring is preferred for patient safety and to limit unnecessary exposure of staff due to circuit disconnects. If continuous spirometry is unavailable, these parameters should be assessed and recorded at least every 4 hours for each patient, or when continuously monitored vital signs (i.e., SpO2) demand additional investigation. Routine sampling of arterial blood for gases should be analyzed to ensure adequacy of ventilation and gas exchange, as available. It is not expected that ventilation for both patients can be optimized. **Both patients will receive the same PEEP and FiO_2. Do not attempt to use gate-check valves in the expiratory limb as a method of controlling PEEP, this has been shown in the simulation lab to not work. See Appendix A for details. Respiratory acidosis is tolerated.** Lung injury results from prolonged exposure to FiO2 > 60% (24 hours on 100% FiO_2 will begin to cause injury), and from PIP > 30-35 cmH_2O (volutrauma), but not carbon dioxide or acidosis toxicity. The presence or absence of acidosis is immaterial and permissive hypercapnia is the norm when using smaller tidal volumes < **6 ml/kg**.

EKG, BP, SpO2, and other routine monitoring should continue as per ICU standards.

Discontinuation

Split ventilation should be discontinued immediately upon availability of enough ventilators to ventilate each patient independently, or in the event that ventilator weaning is to be attempted and prior to the discontinuation of deep sedation and paralysis. **It should also be discontinued if either patient does not tolerate split ventilation.** Additional ventilators, either portable or otherwise, should be immediately available in case of an emergency.

Alarm Parameters

Due to the unique nature of this ventilator setup, it is crucial to monitor each patient's ventilatory parameters in addition to the ventilator, with alarms tailored to each patient and group of co-ventilated patients. This section details the alarm configuration by machine:

Ventilator Alarms

Tidal Volume Alarm: This must be set up appropriately to ensure that a kink in any limb of the circuit, a circuit disconnect, or a change in patient physiologic parameters is quickly identified. The alarms should be configured so that the minimum tidal volume is equal to the expected tidal volume of Patient A + Patient B minus 20%, and the maximum tidal volume is the expected volume plus 20%.

Pressure Alarms: The peak airway pressure alarm, generally set at 40cm H2O, is appropriate for this setup. Peak pressures > 40cm H2O could indicate circuit obstruction, most likely at the level of the gate valves.

Sample Alarm Configuration

	Patient 1 (IBW 70kg)	**Patient 2 (IBW 70kg)**	**Ventilator**
Tidal Volume Minimum (4cc/kg)-10%	252cc	252cc	**504cc**
Tidal Volume Max (4cc/kg)+10%	308cc	308cc	**616cc**
Minute Ventilation Min (4cc/kg * 20/min) - 20%	**4.5L/min**	**4.5L/min**	**9L/min**

IBW= Ideal Body Weight

Verify that alarms are audible. Standard monitors, such as SpO2, EKG, and blood pressure should all be active as per unit standard, and preferably visible from outside the room. FiO2 and EtCO2 alarms should all be active and easily visible.

Respiratory Module/Spirometry Alarms

References:

1. Smith R, Brown J. Simultaneous ventilation of two healthy subjects with a single ventilator. *Resuscitation*. 2009;80(9):1087. doi:10.1016/j.resuscitation.2009.05.018
2. Amato M, Meade M, Slutsky A, et al. Driving pressure and survival in the acute respiratory distress syndrome. *N Engl J Med*. 2015;372(8):747-755. doi:10.1056/NEJMsa1410639
3. Branson R, Blakeman T, Robinson B, Johannigman J. Use of a single ventilator to support 4 patients: laboratory evaluation of a limited concept. *Respir Care*. 2012;57(3):399-403. doi:10.4187/respcare.01236
4. Carvalho P, Thompson WH, Riggs R, Carvalho C, Charan NB. Management of bronchopleural fistula with a variable-resistance valve and a single ventilator. Chest. 1997 May;111(5):1452-4. PMID: 9149613
5. Charan NB, **Carvalho** CG, Hawk P, Crowley JJ, **Carvalho** P. Independent lung ventilation with a single ventilator using a variable resistance valve. **Chest**. **1995** Jan;107(1):256-60. PMID: 7813287
6. Neyman G, Irvin CB. A single ventilator for multiple simulated patients to meet disaster surge. Acad Emerg Med. 2006 Nov;13(11):1246-9. Epub 2006 Aug 2. PMID: 16885402
7. Rutala WM, Weber DJ. Guidelines for Disinfection and Sterilization in Healthcare Facilities. Centers for Disease Control. 2008. 1-158.

Appendix A

Customized PEEP can be delivered to patients by attaching a valve to the expiratory limb, provided that a one way valve is present on the inspiratory limb. Used in this way, the valve will only provide resistance to expiratory flow, allowing one patient to see increased PEEP, but does not truly increase PEEP in the traditional sense. When attempting to customize PEEP for patient A, as resistance is increased, tidal volumes for the patient decrease, and there is an increase in end tidal CO_2, likely due to a decrease in minute ventilation. This would necessitate the need to increase driving pressure as well, and thus would need to further adjust the valve to decrease the flow for the other vented patient (patient B). Due to the complex nature of adjusting customized PEEP, we strongly advise against it.

Figure 12. Pressure and flow graphs from spirometry monitoring, from high fidelity simulation mannequins. Left, patient ventilated with all valves open. Right, patient with partial closure of a gate check valve, producing a characteristically downsloping expiratory pressure tracing, rather than the expected flat tracing.

An experiment with two additional ¾" brass valves attached to the expiratory limb of each patient was performed to determine if individualized PEEP could be delivered to each patient using these valves. The results showed that incrementally closing the ¾" valve in the expiratory limb of patient **A until almost fully closed (while keeping the valve on patient B wide open), resulted in no significant increase in PEEP to Patient A (from baseline intrinsic system PEEP of 7cm H_2O to an increase of 8 cm total), and in fact led to additional negative events:**

- **Rise in observed end- tidal CO_2 on monitor of patient A**
- **Gradual overall decrease in total system volume with decrease in observed tidal volume of patient B.**

Therefore, we do NOT recommend using gate check valves for PEEP.

Version History:

1.0 - Initial version March 26 2020

1.1 - March 27, 2020 Clarify that gate valves cannot be used in the expiratory limb. Add Appendix A with details of why this is not advised. Add Disclaimer. Clarify that respiratory acidosis is tolerated and not inherently dangerous.

1.2 - Add disclaimer regarding the brass valves. Make disclaimer text Red. Update pictures with higher resolution. Clarify language in Appendix A. Add suggested Alarm Parameters and results of alarm testing.

1.3 - Update text and pictures to show one way valves in all limbs, reduced connector parts. Add table of contents. Lock editing down to named users. Allow viewers with the shared link to comment only. Add link outs to GitHub for printed one-way valves.