Mount Sinai Health System Emergency Ventilator Sharing Protocol and Instructions for Use

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

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Preamble

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.

Intended Use

Allow one standard mechanical ventilator to be used to ventilate two patients simultaneously during the COVID-19 pandemic, with individual adjustment of volume and pressure for each patient.

DISCLAIMER

This shared ventilator protocol has been trialed in only a limited number of patients. The protocol was designed and tested in the Mount Sinai 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. Initial testing with fully consented human subjects confirmed the valves perform as expected.

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 positive.
2. Patients should have initial similar lung compliances and levels of ventilatory support.
3. Patients should require similar levels of positive end-expiratory pressure (PEEP).
4. 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. Attached to either end of the T-piece is an adjustable flow valve (similar to commercially available plumbing equipment), followed by a unidirectional valve, and then the inspiratory limb of the breathing circuit. Near the patient, a standard spirometry sensor is placed in-line between the endotracheal tube (ETT) elbow and the wye connector of the breathing circuit. The sensor is connected to the gas analyzer-spirometry module of a physiologic monitoring system. At the start of each expiratory limb, one unidirectional valve is placed between the circuit wye connection and the tubing. The end of the expiratory limbs are joined with a T-piece. Due to the nature of the COVID pandemic, bacterial/viral (B/V) filters are 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.

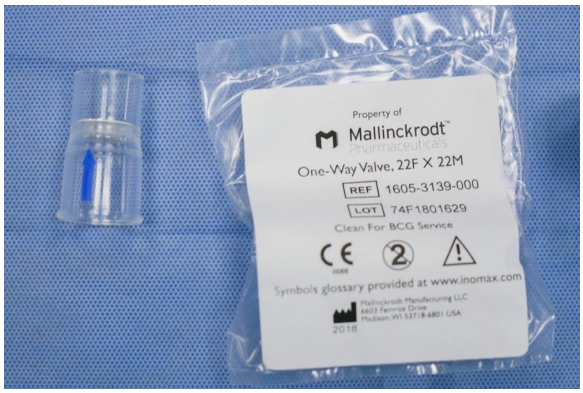
Improvements over other solutions

1. Adjustable flow valves allow the pressure and volume delivered to each patient to be customized 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.

Parts List

1. 2x adjustable flow valves, such as:
    a. 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.**
    b. ¾” PVC plumbing valves
    c. Custom-made, 3D printed, adjustable valves, **pictured below**
2. 4x in-line, unidirectional (“check”) valves for inspiratory and expiratory limbs (Mallinckrodt One-way valve, 22mm F x 22mm M). These **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 ID female-to-female adapter (clear Mallinckrodt Universal Cuff Adapter). **Only necessary if using valves 1a) or 1b) above.**
   These 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
5. 2x ventilator circuits
6. 2x yellow spirometry sensor and tubing (GE D-lite++ patient spirometry set; GE part number 2102497-002- 3 meter length tubing)
7. 3x Bacterial/Viral (B/V) filters (placed near ETT and in expiratory limb)
8. 2x Heat and Moisture Exchanger Filters (HME Filter)
9. Spirometry module/monitor (GE Carescape Respiratory Module)
10. Thread seal tape, such as Teflon plumbing tape, to improve the seal between connections
11. Electrical tape, to reinforce connections and help prevent circuit disconnects

Figure 1A. 3D printed adjustable flow control valve. Part 1c, listed above



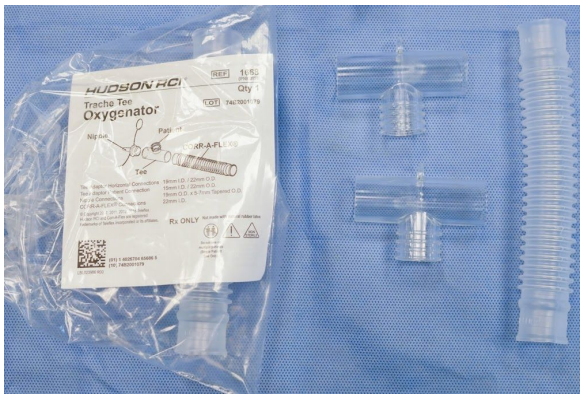


Figure 1B. Part #2 and #3, listed above.

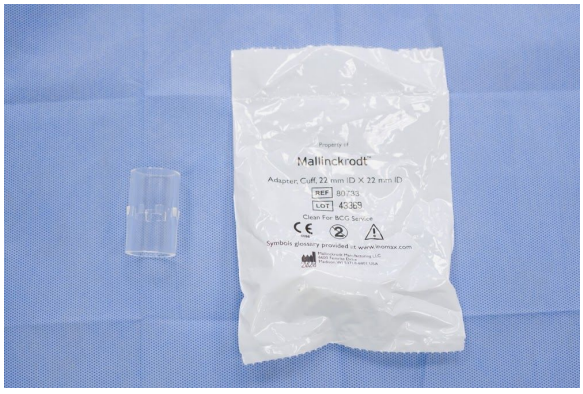


Figure 1C. Part #4, listed above.

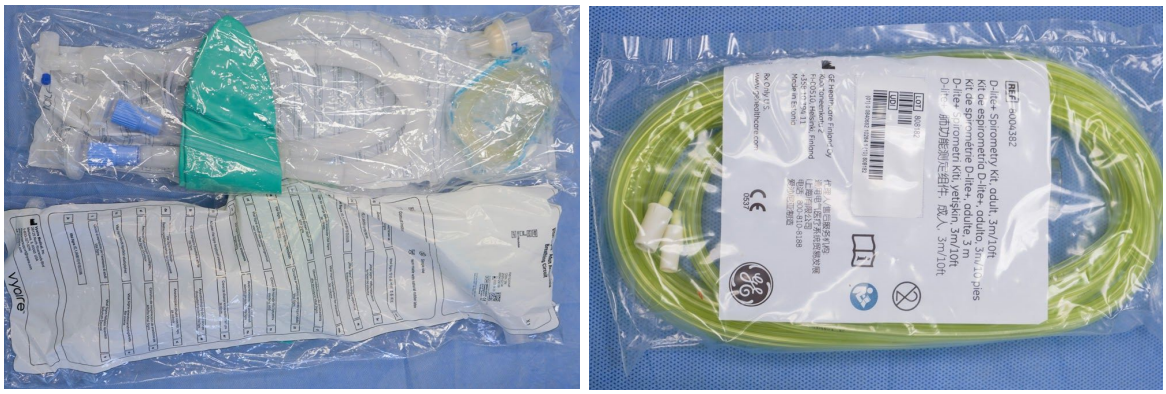
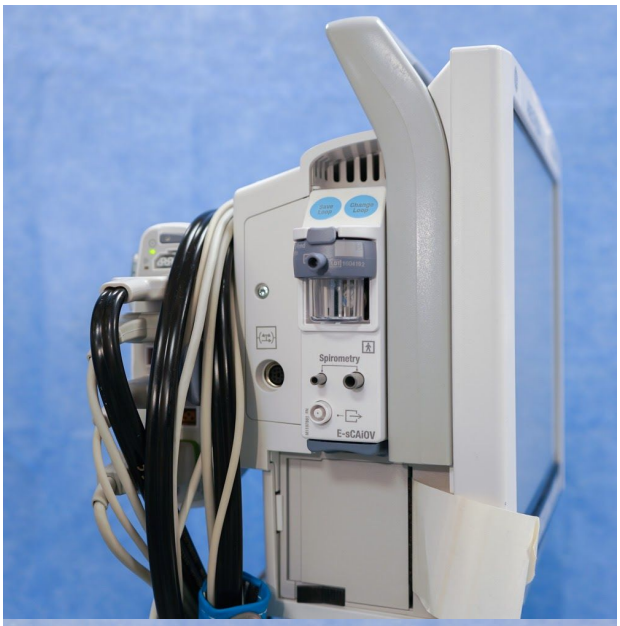
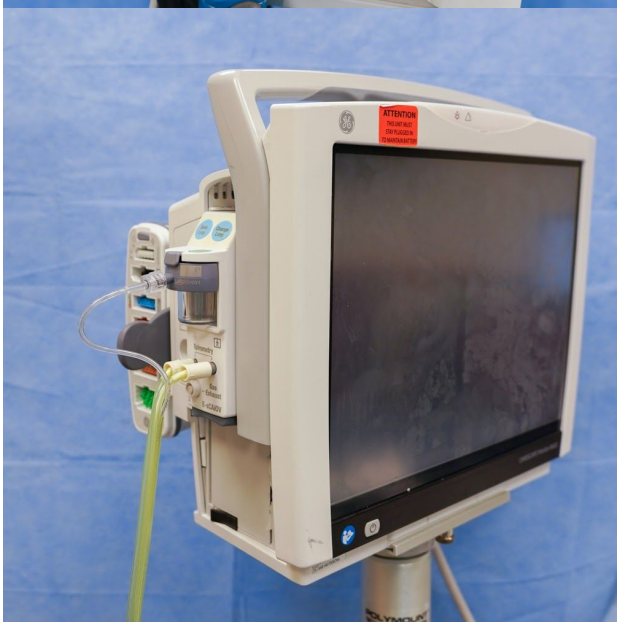


Figure 1D. Part #5 and #6, listed above.





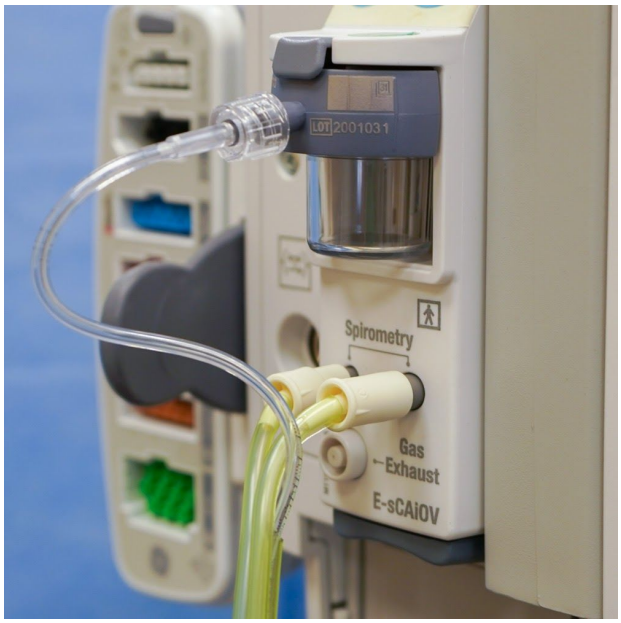


Figure 1E - Part #9, listed above. GE Carescape Respiratory Module installed in a GE transport monitor. This is a key feature for any split ventilation design, as it allows for the monitoring and titration of each patient's ventilation.

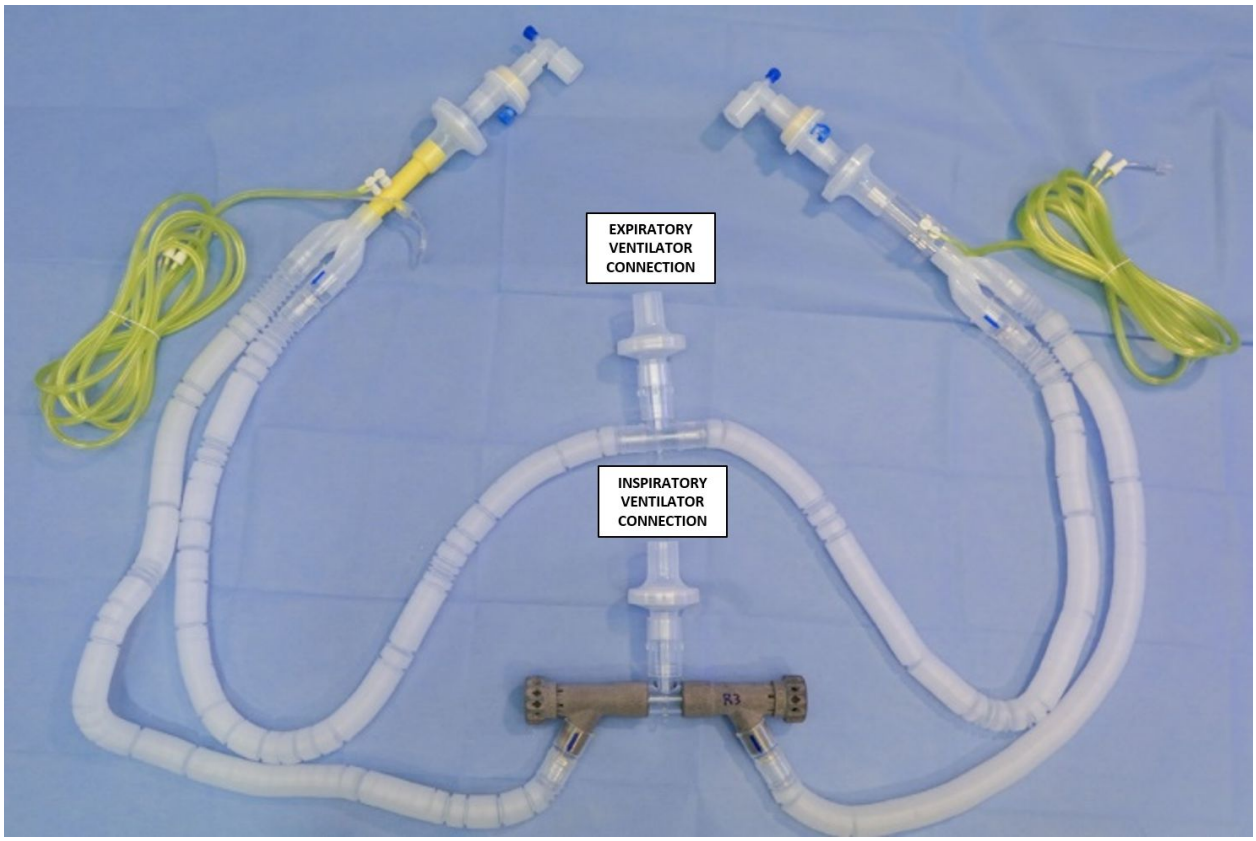


Figure 2 - All assembled parts.

Circuit Assembly

Preparation

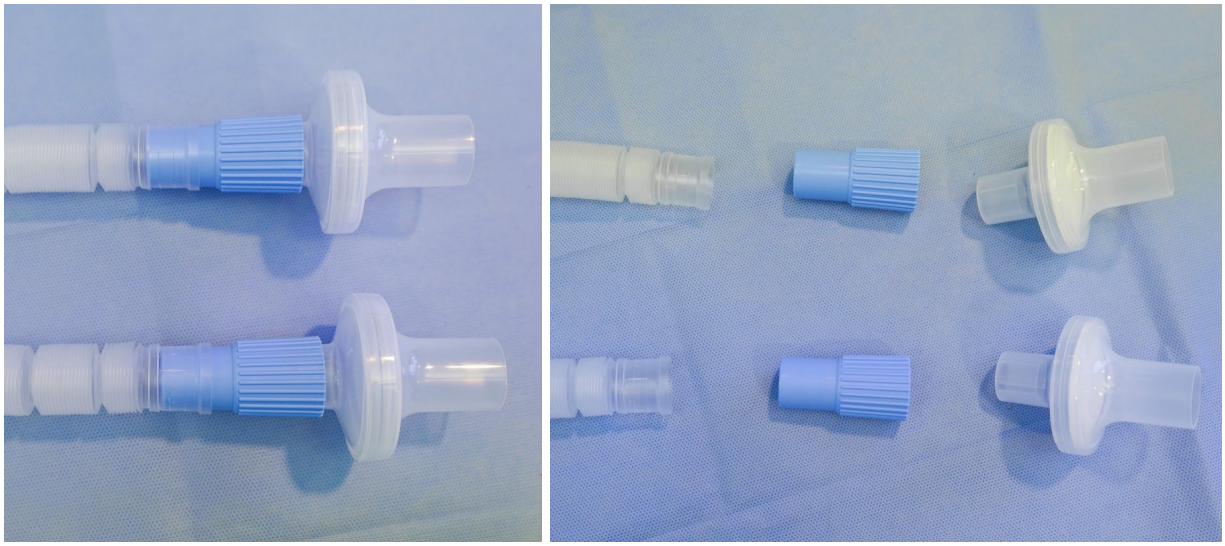


Figure 3A - The ventilator ends of the anesthesia breathing circuit.
At the end of the anesthesia circuits, detach and set aside the blue connectors and bacterial/viral (B/V) filters.

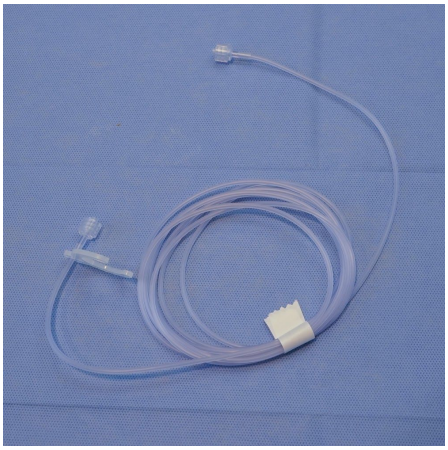


Figure 3B - The end tidal CO_2 tubing included with the anesthesia breathing circuit.
Detach and set aside this tubing.

Ventilator inspiratory connection → Bacterial/Viral filter → 22mm ID female-to-female adapter → 22mm T- piece. To each side of T piece: → adjustable flow valve → one way valve → inspiratory limb of circuit → circuit wye connector

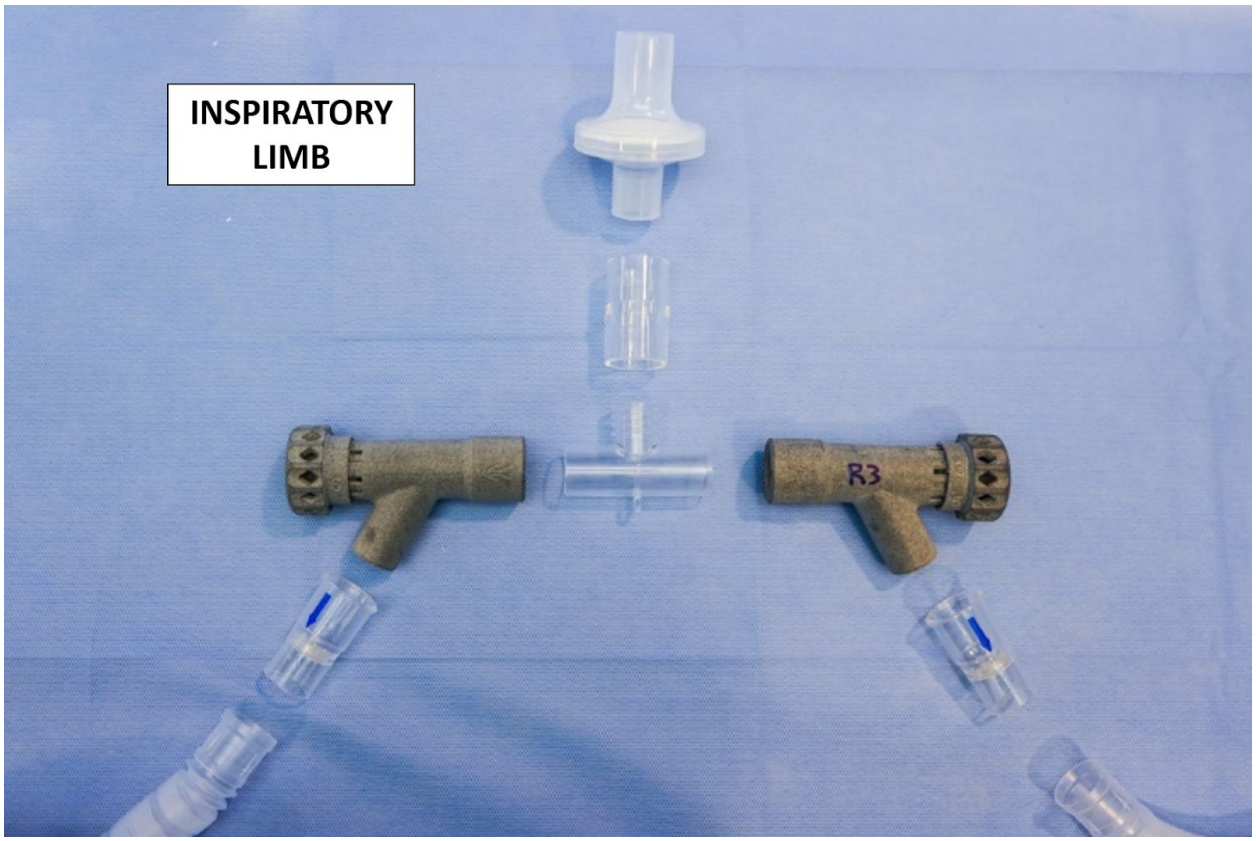


Figure 4 - Components of the **inspiratory limb**. The filter (top center) attaches to the ventilator inspiratory connection, while the one way valves (with blue arrows) connect to the inspiratory limb of the breathing circuit.

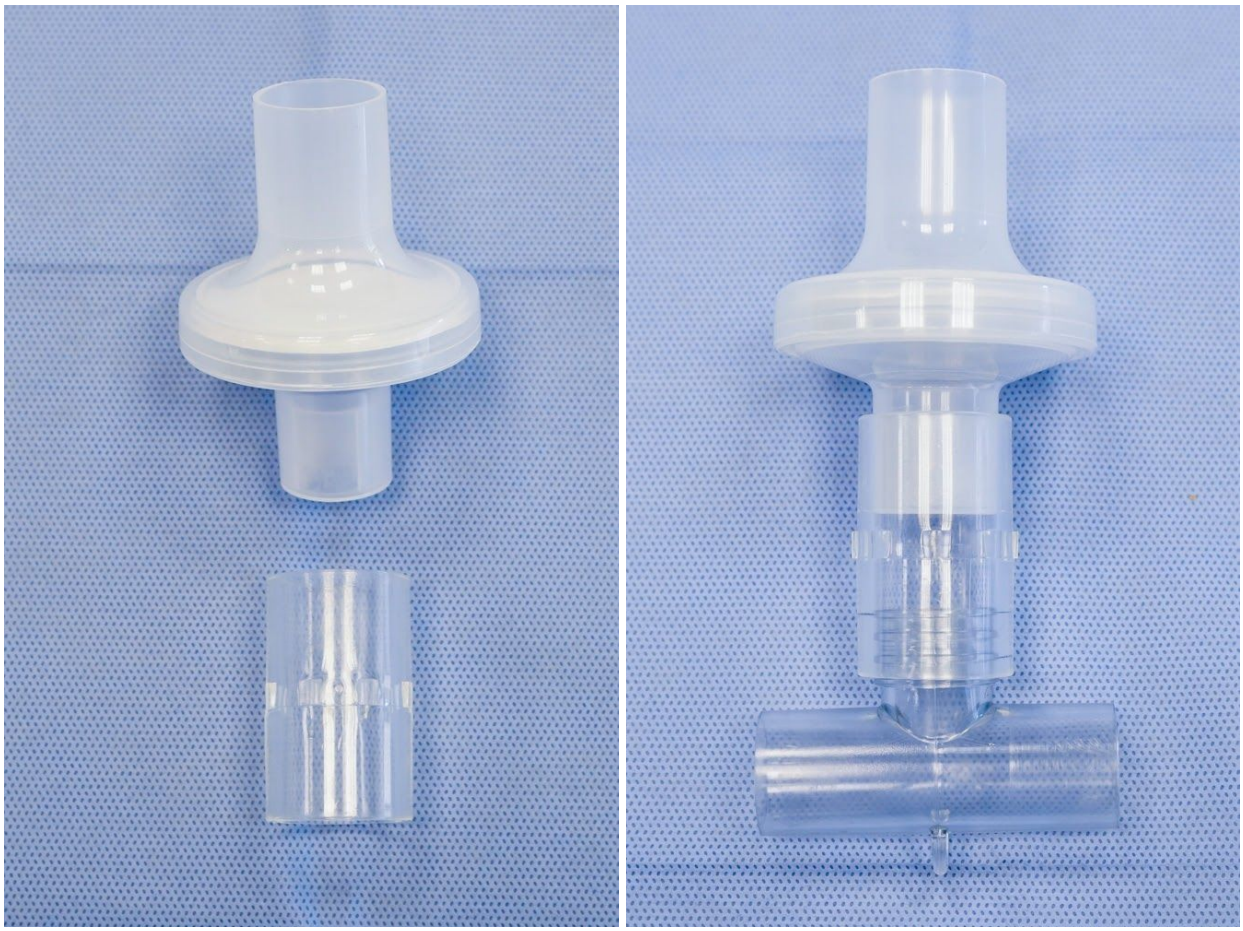


Figure 5 - Partially assembled **inspiratory** limb. The ventilator inspiratory port is connected to a filter, then a 22mm ID connector, and then the T-piece.

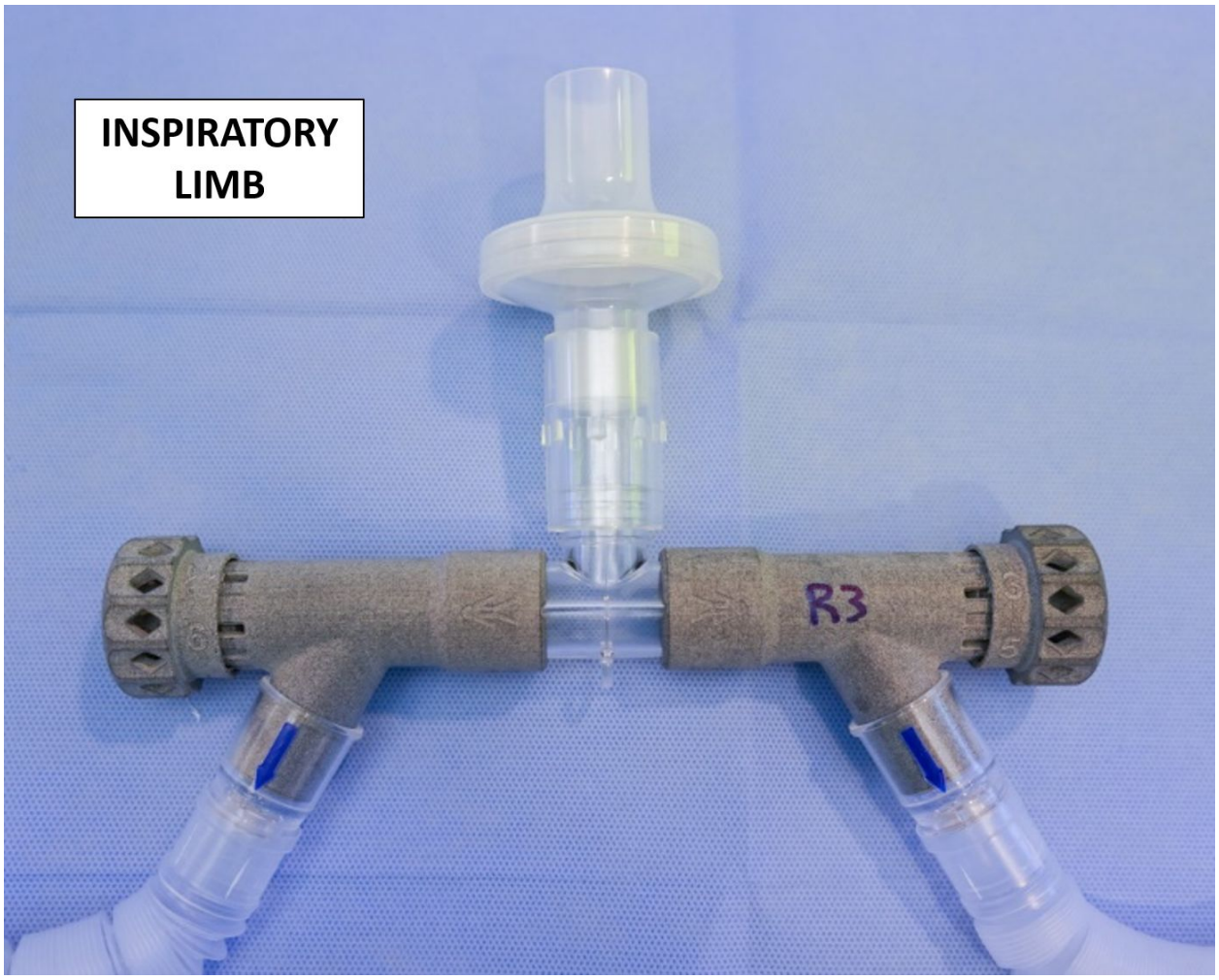


Figure 6 - Both adjustable flow valves have now been attached. One way valves have been inserted between the adjustable flow valves and the inspiratory limb of each patient circuit. Note that the blue arrows on the one way valves indicate air flow.

ETT → elbow connector → heat and moisture exchange filter (HMEF) → bacterial/viral (BV) filter → yellow spirometry tubing → circuit wye → one way valve on expiratory limb. **Make one for each patient.**

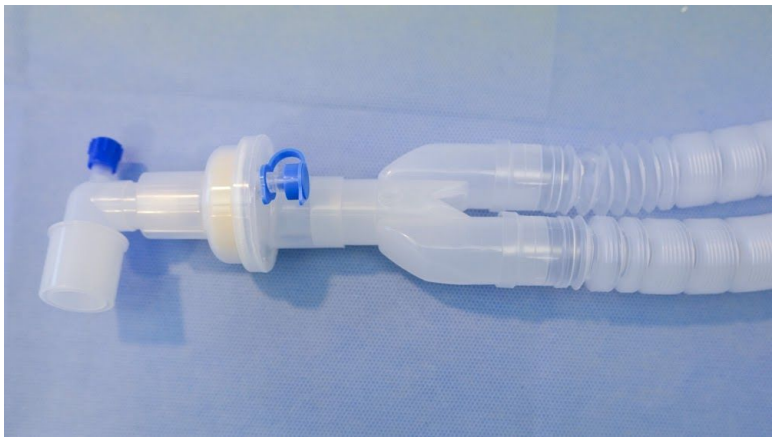


Figure 7A - The patient end of the anesthesia breathing circuit.

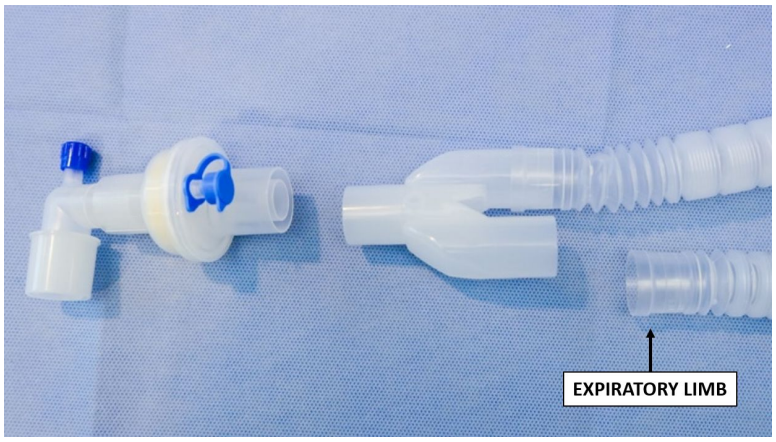


Figure 7B - partly disassembled. Separate the expiratory limb and the HMEF from the circuit wye.

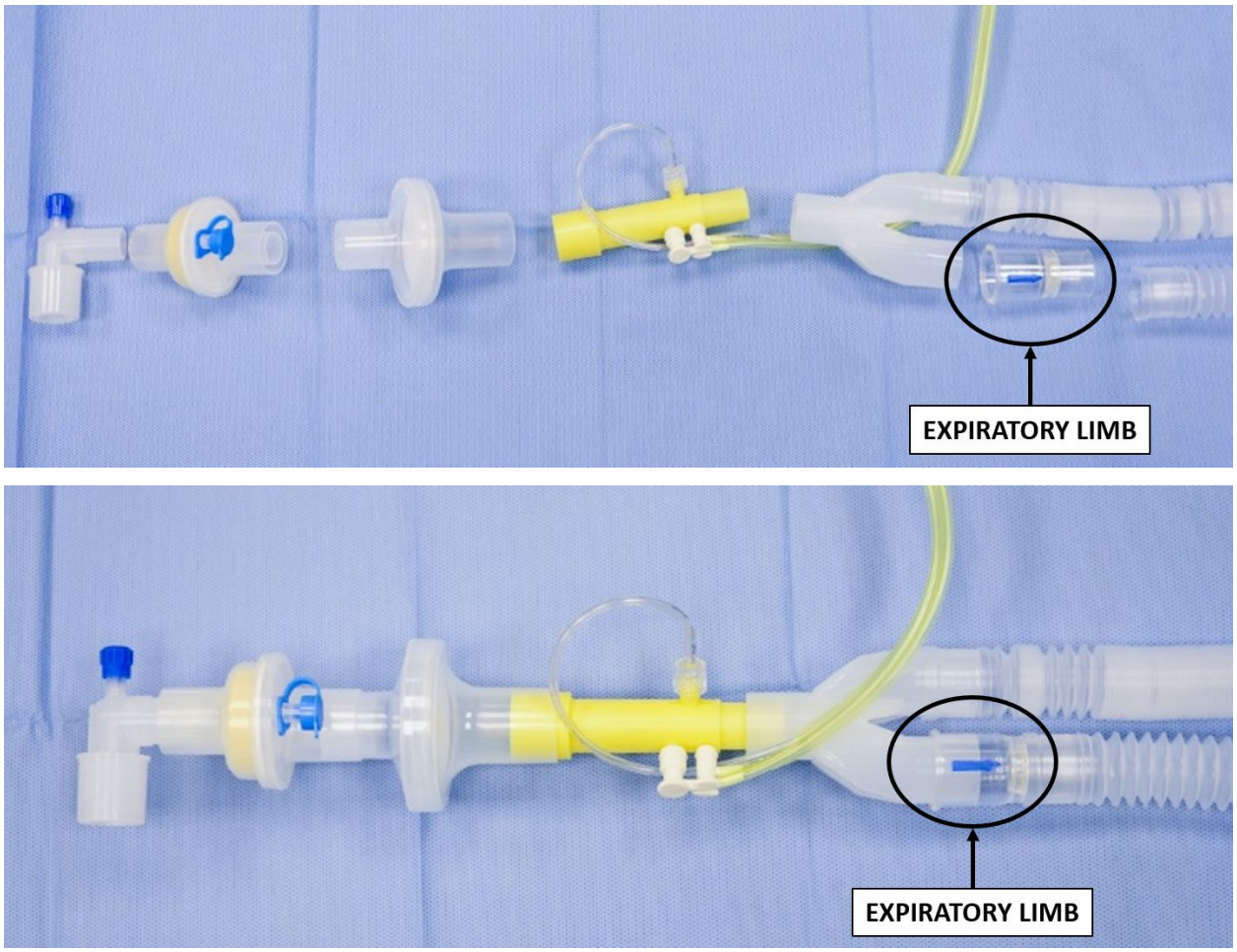


Figure 7C - Fully disassembled and assembled patient connection with (left to right): elbow, HMEF, B/V filter, spirometry tubing, circuit wye connector, and one-way valve on the expiratory limb. One set of these is necessary for each patient. **NOTE:** the HMEF needs to be most proximal to the patient. This prevents the viral filter from absorbing excessive moisture, losing effectiveness, and causing obstruction.

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

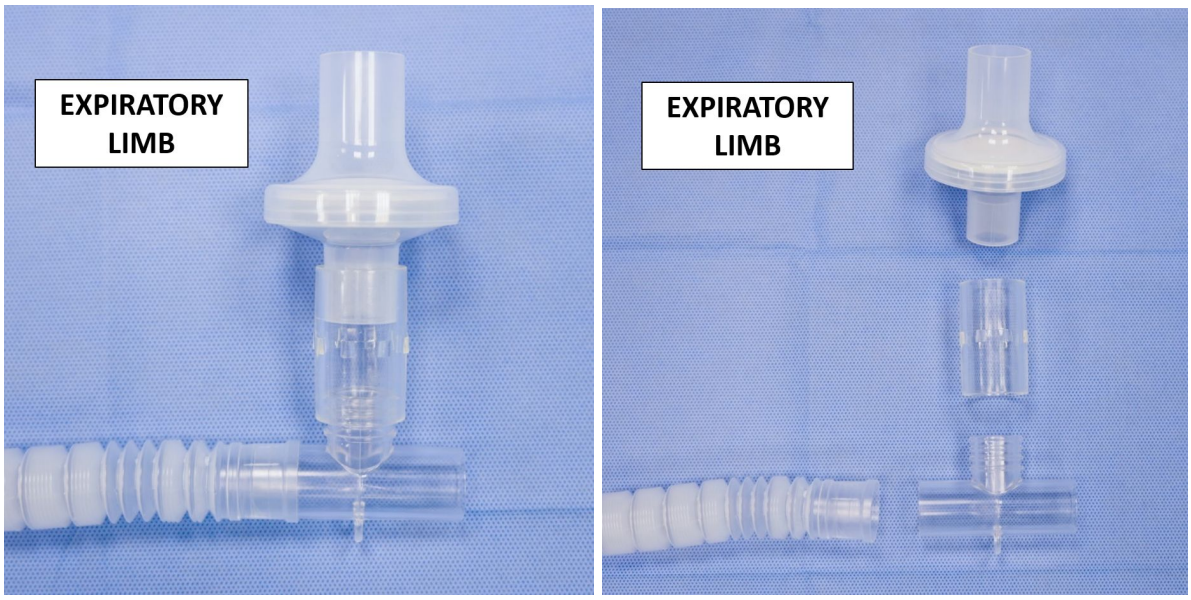


Figure 8 - Components of the expiratory limb, one side only. **NOTE: B/V filter is not needed if the ventilator already has a B/V filter in place at the expiratory connection, such as with the Puritan Bennett 840 ventilator.**

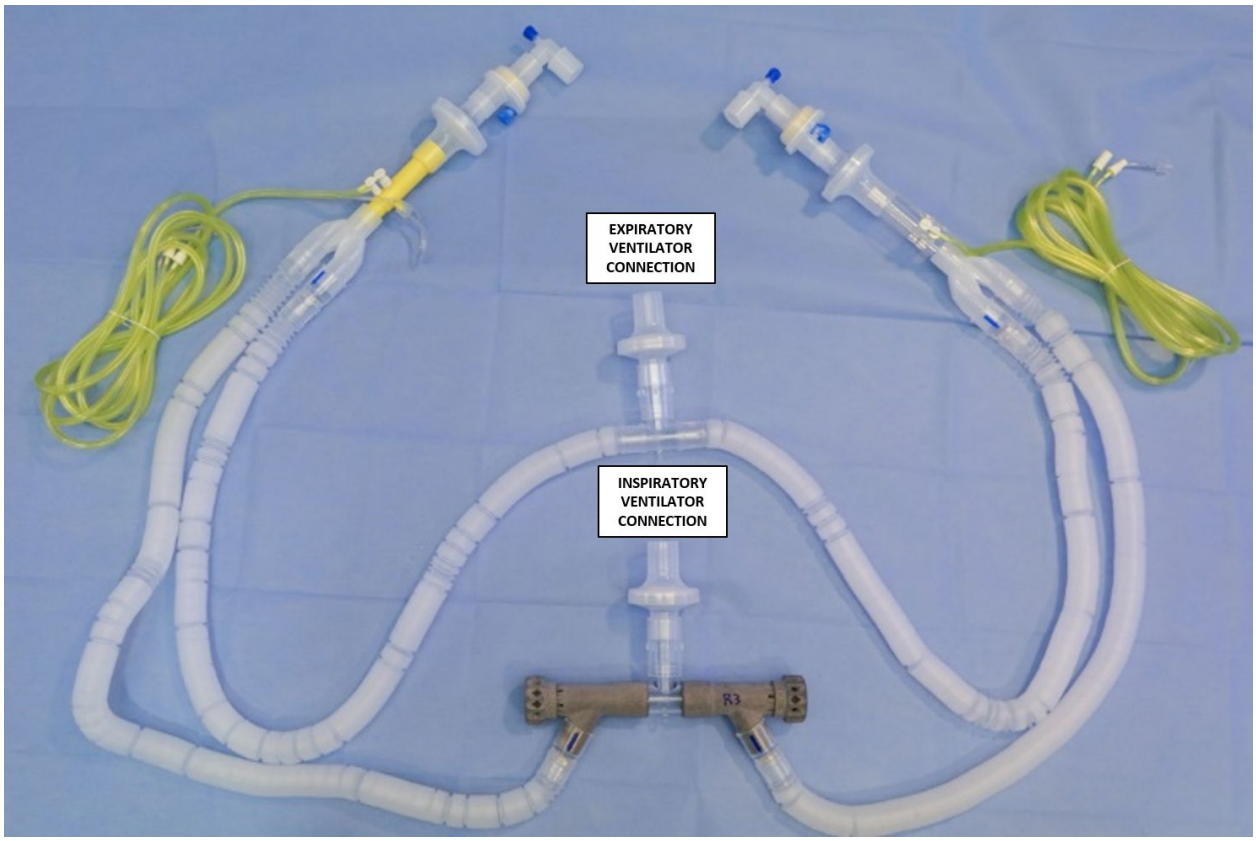


Figure 9 - All assembled parts of final setup

Placeholder.

Figure 8 - Final assembled dual patient limbs connected to a GE Aisys Anesthesia Machine (also was tested with a Puritan Bennett 840 ventilator).

Instructions for Use

As part of overall preparation for utilizing split ventilation, ensure the following:

1. There is one manual resuscitation bag per patient in the room at all times
2. There are additional "kits" or pieces for each patient in case components of the circuit such as the one-way valves need to be replaced while split ventilation is in use.
3. Patients are clearly labeled as “Patient A” and “Patient B”

Preparation

1. The split ventilation circuit should be fully assembled before connection to patients, including flow control valves, one-way valves, and T connectors prior to initiation.
2. The ventilator to be used should be turned on, and system checks should be performed while attached to a single circuit as would be done in standard practice. If the system check is performed with the dual circuit, many ventilators will error. The purpose of this test is to confirm the integrity of the ventilator.
3. Prior to initiating mechanical ventilation, and while not attached to the ventilator, the adjustable flow valves should be closed, then completely opened to full stop (2 turns).
4. Patients will be co-located in the same ICU room, connected to separate ventilators, and to separate physiologic monitors.
5. The patients should be paralyzed, sedated, and hemodynamically stable.
6. The patients should each be placed on Pressure Control Ventilation on their own ventilators with the same Respiratory Rate, PEEP, Inspiratory time, and FiO_2 prior to initiating split ventilation. Adjust driving pressure as needed for each patient to ensure that they are receiving tidal volumes of 4-6 cc/kg ideal body weight and a minute ventilation similar to their previous ventilator settings. After 30 minutes obtain an arterial blood gas (ABG) from each patient to confirm adequate oxygenation and ventilation. Adjust the ventilator and reconfirm with an arterial blood gas if necessary. **Record the driving pressure and tidal volume for each patient, from the individual physiologic monitors via spirometry sensor and tubing, as this will be the patient’s target pressure and target tidal volume while on split ventilation. Take note of the patient with the higher driving pressure. The patient with higher driving pressure is Patient A.**
7. **Patient B will be the patient with the lower driving pressure.**
8. If a third ventilator is available to start split ventilation,that is preferred. If not, **the ventilator connected to Patient A will be used for split ventilation. If you only have two ventilators, you should use Patient A’s ventilator for split ventilation.**

9. Make sure the ventilator to be used is placed between the two patients and that the patients are close enough together to connect without stretching or kinking the circuit.

Initiation

1. The patients should be connected to the split ventilation circuit sequentially: Patient A first, followed by Patient B.
2. - With both valves set at the predetermined fully open position, and the circuit for Patient B capped, clamp Patient A's endotracheal tube and disconnect Patient A from their individual ventilator and attach Patient A to the split ventilation circuit and initiate ventilation. The portion of the circuit for Patient B should be capped at the patient end. Adjust the driving pressure on the ventilator to deliver 4-6 cc/kg tidal volumes to **Patient A.**
3. Adjust the driving pressure on the ventilator to deliver 4-6 cc/kg tidal volumes to **Patient A. Observe the delivered tidal volume on Patient A's monitor and confirm they match the desired set tidal volume.**
4. Once the ventilator has been attached to patient Patient A and the settings have been adjusted, attach patient B to the second limb of the circuit, by clamping Patient B's endotracheal tube (ETT - check if defined). Patient B will likely be receiving tidal volumes and driving pressures in excess of the target values obtained on a single ventilator. In this case, slowly close the flow control valve to Patient B by rotating in a counterclockwise direction until tidal volumes for **Patient B (the patient with the lower driving pressure)** are at their baseline values of 4-6 cc/kg ideal body weight. **Expect to see minimal change in delivered tidal volume to patient B until the valve has been closed approximately 1 ½ turns. Most adjustment will occur in the last ½ turn (90 degrees)**
5. After 30 minutes an ABG should be obtained from each patient to confirm appropriate oxygenation and gas exchange.

Management

1. If Patient A is being hypoventilated, first attempt to increase the driving pressure on the ventilator to increase Patient A's tidal volumes as long as they are within the range of 4-8 cc/kg ideal body weight. If this is sufficient to correct Patient A's minute ventilation, once again, slowly close the flow control valve to Patient B by rotating in a counterclockwise direction until tidal volumes for **Patient B (the patient with the lower driving pressure)** are at their baseline values of 4-6 cc/kg ideal body weight.
2. Again an ABG should be obtained 30 minutes after the change.

3. If patient A requires further increases in minute ventilation the respiratory rate can be increased while the driving pressure to Patient B is decreased as long as Patient B's tidal volumes remain greater than 4cc/kg ideal body weight.
4. If Patient B is being hypoventilated, slowly open the flow control valve to Patient B by rotating in a clockwise direction until tidal volumes for **Patient B (the patient with the lower driving pressure)** are at their baseline values of 4-8 cc/kg ideal body weight.
5. If patient B requires further increases in minute ventilation the respiratory rate can be increased while the driving pressure to Patient A is decreased as long as Patient A's tidal volumes remain greater than 4cc/kg ideal body weight.
6. If either patient is being hyperventilated, adjust flow to that patient by turning the valve clockwise by
7. until the desired new lower tidal volume is achieved as long as it is greater than 4 cc/kg ideal body weight.
8. After 30 minutes draw an arterial blood gas to confirm that oxygenation and ventilation have improved.
9. Thereafter the patients should remain closely monitored, with arterial blood gases drawn at frequent intervals to determine the appropriateness of ventilation.

Example

Patient A is 170 cm and has IBW of 80 kg. The driving pressure on their ventilator 16 cm•H_2O. Their desired tidal volume is 6 ml/kg = 480 ml.

Patient B is 150 cm and has IBW of 46 kg. The driving pressure on their ventilator is 14 cm•H_2O. Their desired tidal volume is 6 ml/kg = 276 ml**.**

The ventilator used for split ventilation should be set to a driving pressure of 16 cm•H_2O.

When split ventilation is initiated, **Patient B** will be over-ventilated. Quickly turn the valve clockwise until **Patient B**'s spirometry reads less than 250 ml tidal volume. Slowly open the valve counterclockwise until the expired tidal volume of Patient B is ~322 ml.

Check that **Patient A** is getting ~ 480 ml of tidal volume. If getting more than that amount, slowly close the valve clockwise. If getting less, slowly open the valve counterclockwise.

After 30 minutes, an arterial blood gas shows that **Patient B** is acidotic, with a pH of 7.2. Slowly open the valve counterclockwise for Patient A until a higher tidal volume is achieved.

Monitoring

Clinicians should continuously monitor each patient for adequacy of ventilation using in-line spirometry that measures expired tidal volume, peak airway pressure, PEEP, and lung 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., SpO_2 or $EtCO_2$) demand additional investigation. Routine sampling of arterial blood 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 adjustable flow valves in the expiratory limb as a method of controlling PEEP - this has been shown to fail in the simulation lab. See Appendix A for details.** Permissive respiratory acidosis is tolerated. Lung injury results from prolonged exposure to FiO_2 > 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, SpO_2, 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.**

1. Make sure both patients are stable
2. Have tubing clamp and circuit cap available (red caps from respiratory blue circuit or green plug for anesthesia check)
3. Have individual ventilator for patient to be removed from the split circuit available, tested, and set with correct ventilator settings for patient. With a clean circuit
4. Turn on the ventilator that will be used for the patient about to be removed from the split ventilator. Perform a system check if needed and set the ventilator with the desired ventilation parameters for the patient to be removed.
5. In rapid sequence, (1) Close the control valve for patient to be removed (2) Clamp ETT of patient to be removed (3) cap split circuit at spirometry tubing piece (make sure to maintain the B/V and HME Filter on ETT for protection)
6. Connect patient to their individual ventilator
7. Confirm ventilation of pt removed and patient who remains connected
8. Observe patients for 5-10 minutes and check ABG to confirm adequacy of ventilation
9. At this point, the split circuit can be exchanged for a single circuit for the remaining patient

Emergency Disconnect

Additional ventilators, either portable or otherwise, and/or manual resuscitation bag, should be immediately available in case of an emergency, in addition to staff that are familiar with troubleshooting this novel design.

1. Call for additional ventilator emergently
2. Close valve for patient needing to be emergently removed from split setup

3. Clamp ETT of patient needing to be removed, and option to cap or plug split circuit at Wye connection (keep spirometry piece as well as B/V filter in place)
4. Attach patient's ETT (preferably still with B/V filter and spirometry in place) to manual resuscitation bag
5. Confirm ventilation of patient removed using spirometry and continue supporting with manual bagging until arrival of additional ventilator
6. Set up newly arrived independent ventilator to patient's parameters and perform system check
7. Connect patient to newly arrive independent ventilator
8. Check ABG to confirm adequacy of ventilation on independent ventilator

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. Due to the fact that pressure control is the recommended mode of ventilation, it is important to pay special attention to the tidal volume and minute ventilation alarms. This section details the alarm configuration by machine.

Alarm Configuration Strategy

Independent physiologic monitors should be used for each patient. It is likely that the ICU space was not originally designed for multiple patients in one room, so care must be taken to identify patients properly amongst the entire care team. While staff may have varying comfort levels in altering this system, everyone involved in their clinical care should be vigilant and monitor key ventilatory parameters.

Given the volume of additional information needed to manage the split ventilator system, having the target respiratory parameters posted in a readily accessible manner can improve patient safety. Suggested parameters include: Target TV range, Target MV range, Valve Closure Amount, and last arterial blood gas.

As per unit standard, verify that alarms are audible from outside the ICU room. Standard monitors, such as SpO_2, EKG, and blood pressure should all be active as per unit standard, and preferably visible from outside the room. Standard ventilation alarms, such as FiO_2 and $EtCO_2$, should all be active and easily visible.

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 pressure seen by the split ventilator will be approximately the sum of the peak airway pressures of each individual patient. Setting the pressure alarm on the ventilator at this sum plus 5 cmH2O will generally be appropriate. Peak pressures greater than this could indicate circuit obstruction.

Individual Patient Spirometry Alarms

Individual patient spirometry alarms should be set with the same alarm parameters as if the patient were on a single ventilator, as per institutional standards/guidelines.

MINUTE VENTILATION ALARMS: Currently the minute ventilation alarm exhibits a 30-second delay before an audible alarm begins.

TIDAL VOLUME ALARMS: There is no tidal volume alarm present.

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Appendix A - Comments on PEEP

Customized PEEP can be delivered to patients by attaching an adjustable flow 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 CO2, due to a decrease in minute ventilation. This would necessitate an increased driving pressure, and thus a further adjustment to decrease flow to the other vented patient (patient B). **Due to the complex nature of adjusting customized PEEP with adjustable flow valves, we strongly advise against it at this time.**

Appendix B - Notes on Tidal Volume Measurement

In the absence of individual spirometry, it is possible to get an **estimate** of individual tidal volumes.

- If only one patient (**Patient A**) has spirometry, then the tidal volume of **Patient B** will be approximately the **total tidal volume - Patient A tidal volume**.
- If neither patient has spirometer (**not recommended)**, then the tidal volumes can be estimated as follows:
    1. Record tidal volume reported by the vent as being delivered to both patients. This is the **total tidal volume**.
    2. Clamp the ETT of one patient (**Patient A**) for 2-3 breaths and record the tidal volume reported by the vent. This will be the tidal volume of **Patient B**. **Make sure to unclamp the ETT after 2-3 breaths.**
    3. Subtract the volume of Patient B from the total volume (**Total TV - Patient B TV)**. This will be the approximate volume of **Patient A.**
    4. **Remember** that the ventilator does not measure dead space. You will need to estimate and subtract the dead space of the second circuit.

Appendix C - Assembly Instructions Using Commercially-Available Plumbing Valves

During project inception, commercially-available ¾" brass plumbing valves were used for prototyping. They have an internal diameter (ID) of approximately 22 mm, and can fit onto 22mm ventilator tubing with thread seal tape and appropriate adapters. It is important to note that most will have lubricant inside, which must be removed or otherwise cleaned to ensure compatibility with ventilator use.

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). These **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). **These 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). **These 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. Thread seal tape, such as Teflon plumbing tape (required for metal joints)
12. Electrical tape

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 thread seal tape, i.e. 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.

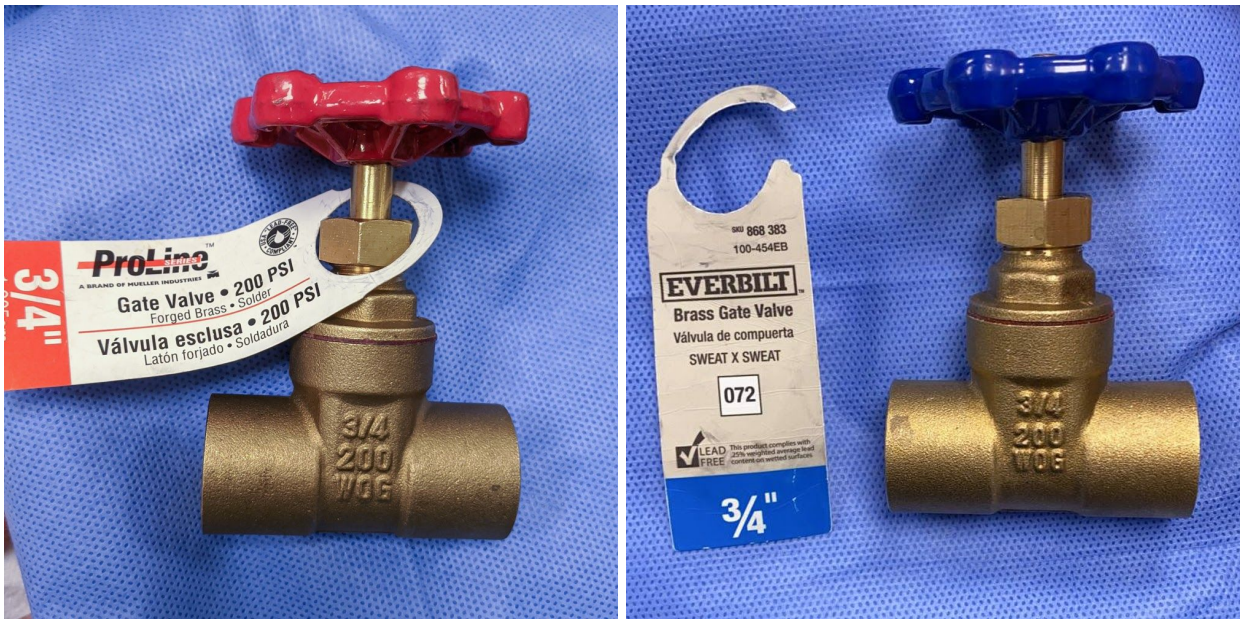

Figure 1A - Part #1, listed below. Example ¾" brass gate valves with solder/sweat connections. PVC alternatives exist but are not readily available.

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

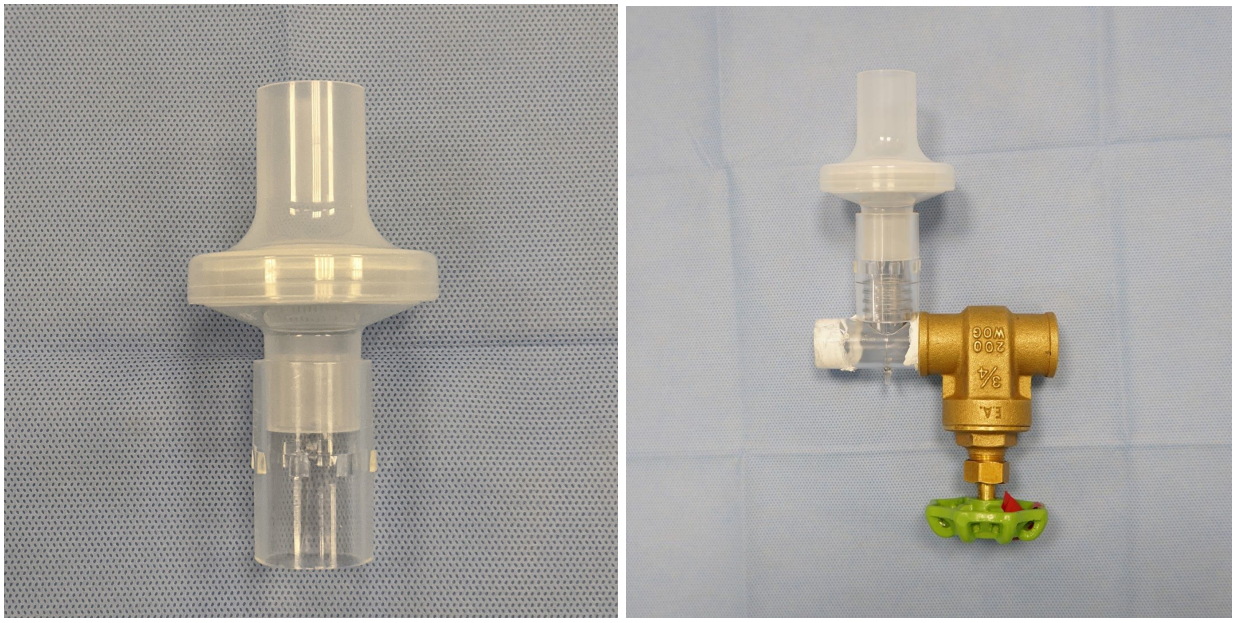

Figure 3 - Partially assembled inspiratory limb. Gate valve has been attached to one limb of the T-piece using thread seal tape for snug fit. Filter on the T-piece stem will connect to the ventilator inspiratory port.

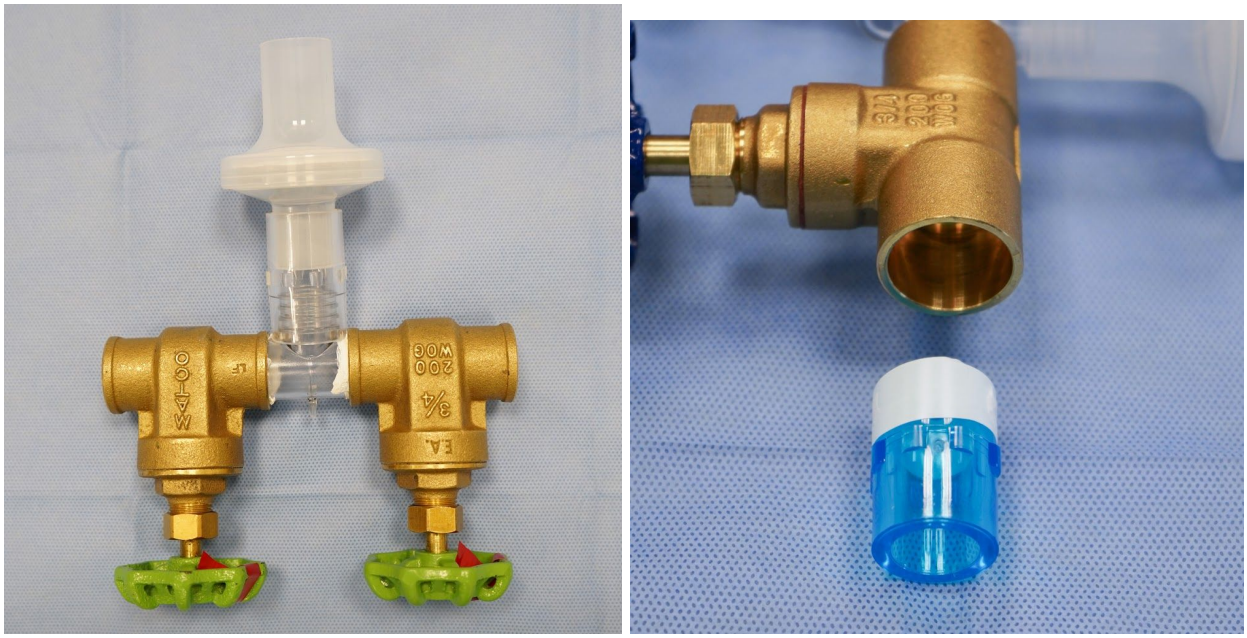

Figure 4 - both gate check valves have now been installed. 22 mm OD blue male-male adapter with thread sealtape ready to be inserted into the gate check valve.

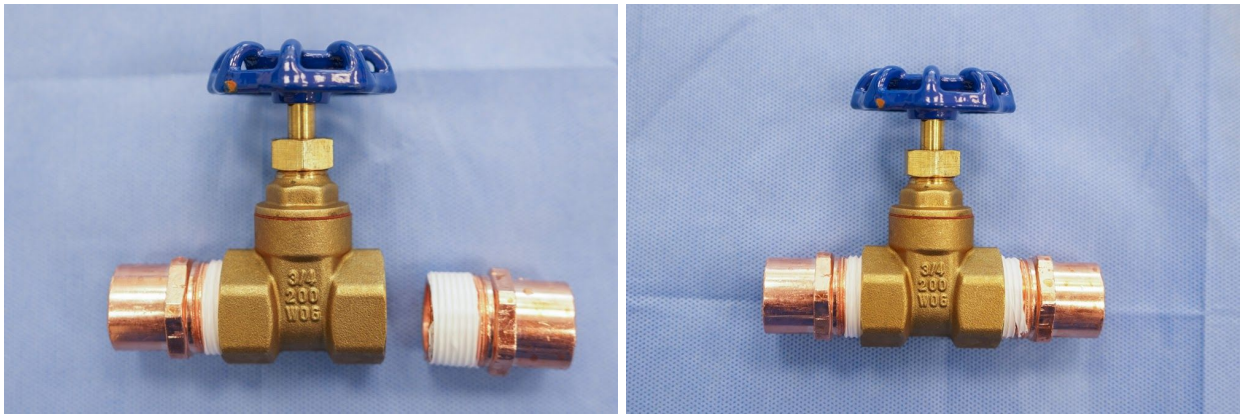

Figure 5 - Alternatively, ¾" lead free brass gate valves with threaded connections can be used for the inspiratory limb. If a threaded connection is used, an additional ¾" thread-to-sweat connection on both sides is needed. Thread seal tape is used once again to create a proper seal between the threaded brass gate valve and the copper connection. The 22 mm OD blue male-male adapter with thread seal tape 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 (on right side) used to provide structural support, and colored labeling tape has been added to the valve on the right to indicate orientation.

The Patient Connection and Expiratory Limb portions are the same as described previously.

Version History

1.0 - March 26 2020. Initial version.

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 - March 28, 2020. 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 - April 1, 2020. 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.

1.4 - April 2, 2020. Update pictures and instruction to show 3D printed valves. Move original pictures and assembly instructions to Appendix B. Add suggested steps for initiation of split ventilation.

2.0 - April 9, 2020. major revision to match Instructions For Use submitted to FDA for EUA. Also includes some updates to pictures.

2.0.1 -April 17, 2020. add acknowledgement of Sinai BioDesign team (Anthony Costa)