Mount Sinai Health System Emergency Ventilator Sharing Protocol

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

Version 1.2
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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. The connections on the ¾" valve have an internal diameter (ID) of approximately 22 mm. On the expiratory limb, two unidirectional valves are placed on two sides of another T-piece. 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 the 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 are available, but were not tested due issues with valve performance.

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. 2x in-line, unidirectional valves for breathing circuit’s expiratory limbs (Mallinckrodt One-way valve, 22mm F x 22mm M)
3. 2x T-pieces, 15mm ID/22mm OD to 2x 19mm ID/22mm OD (Hudson RCI Trache Tee Oxygenator)
4. 4x 22mm OD, 15 mm ID both ends (male-to-male) adapter (blue Airlife Intubation Adapter 001820)
5. 2x 22mm ID female-to-female adapter (clear Mallinckrodt Universal Cuff Adapter)
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. 2x 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

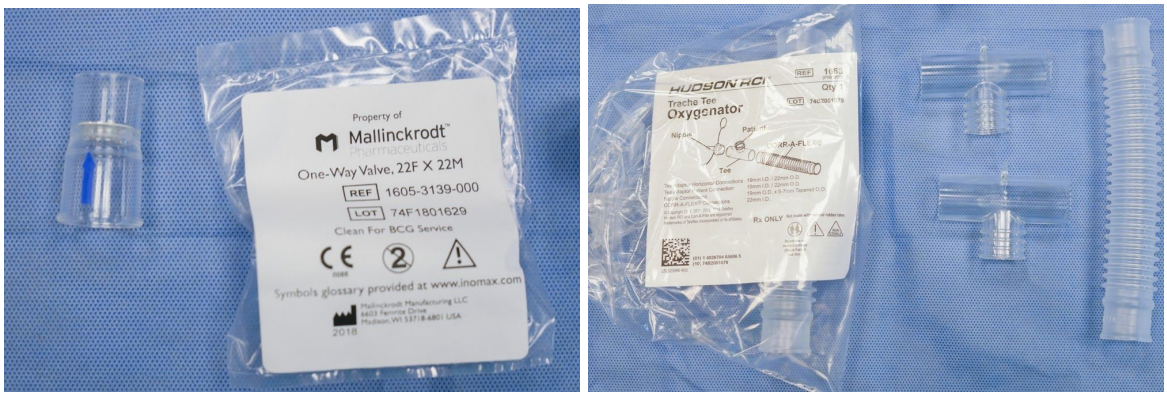

Figure 1B. Part #2 and #3, listed above.

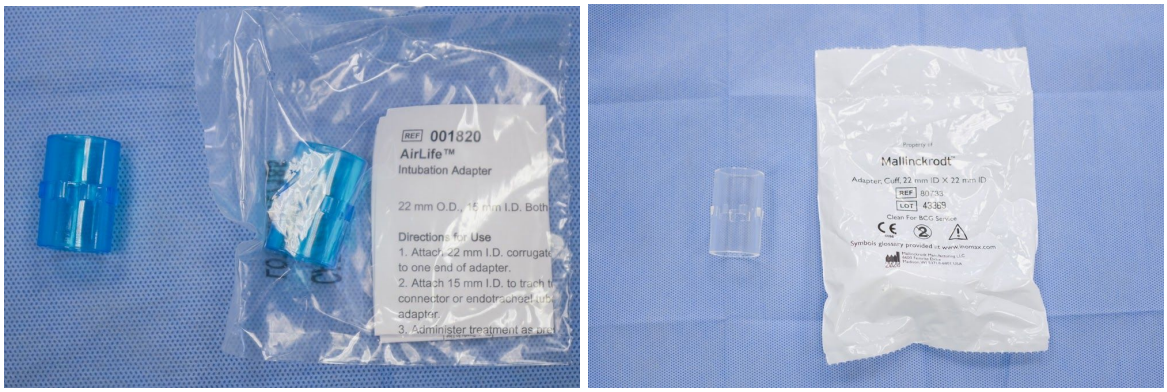

Figure 1C. Part #3 and #4, listed above.

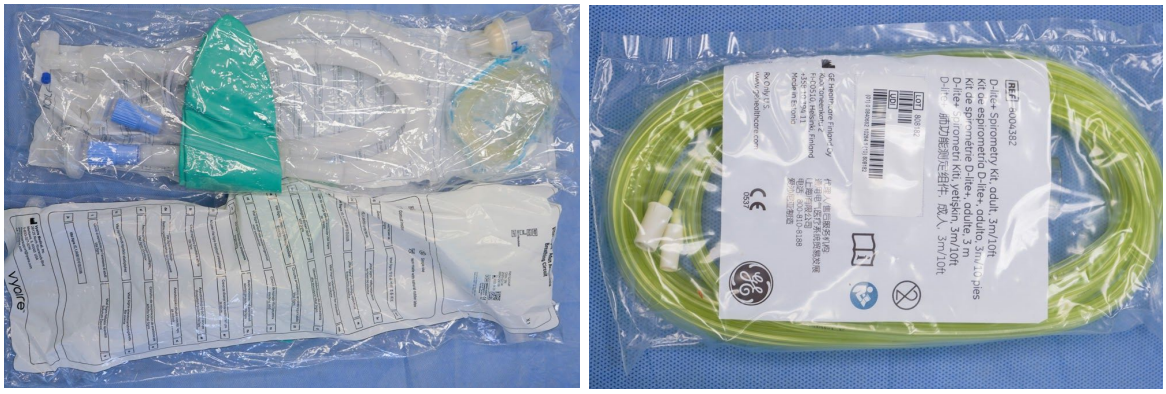

Figure 1D. Part #6 and #7, listed above.

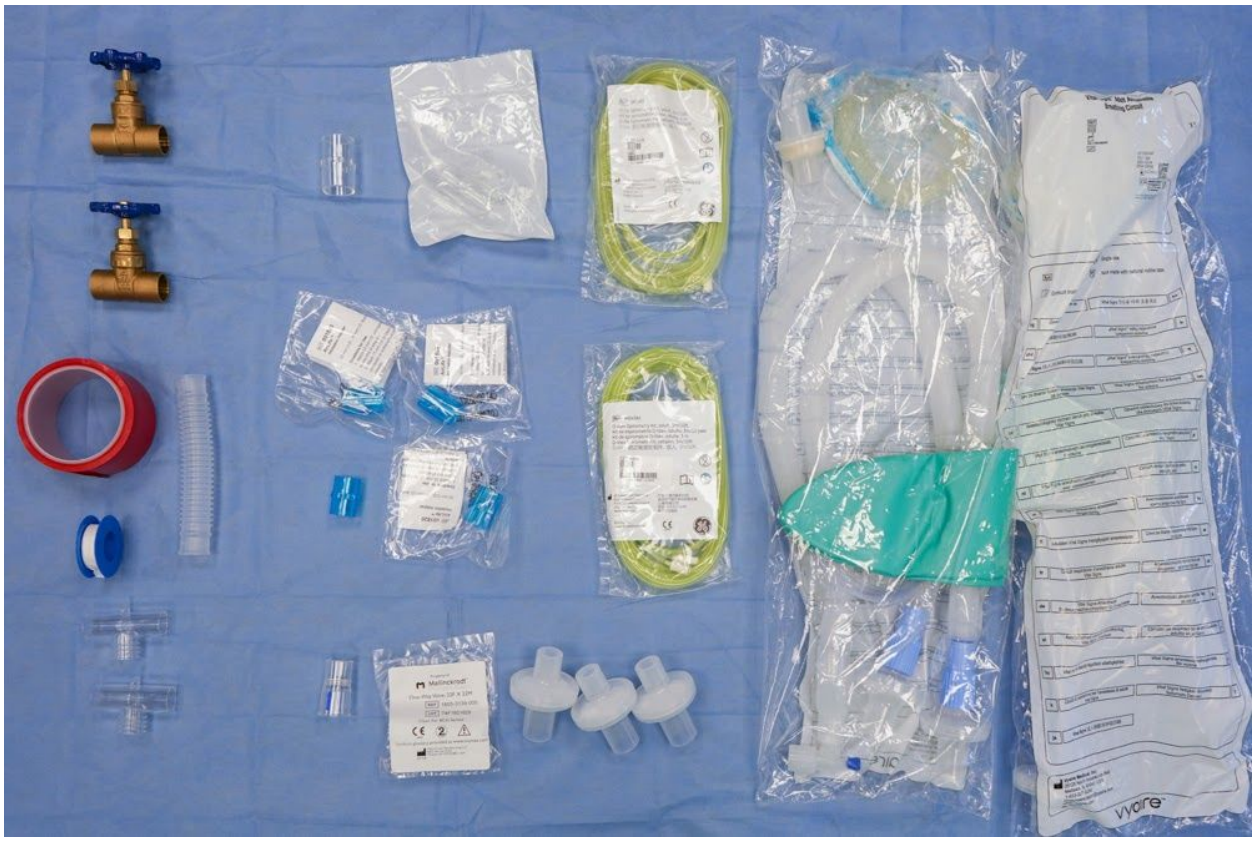

Figure 1E. All parts needed for the dual circuit. Note brass gate valves in upper left.

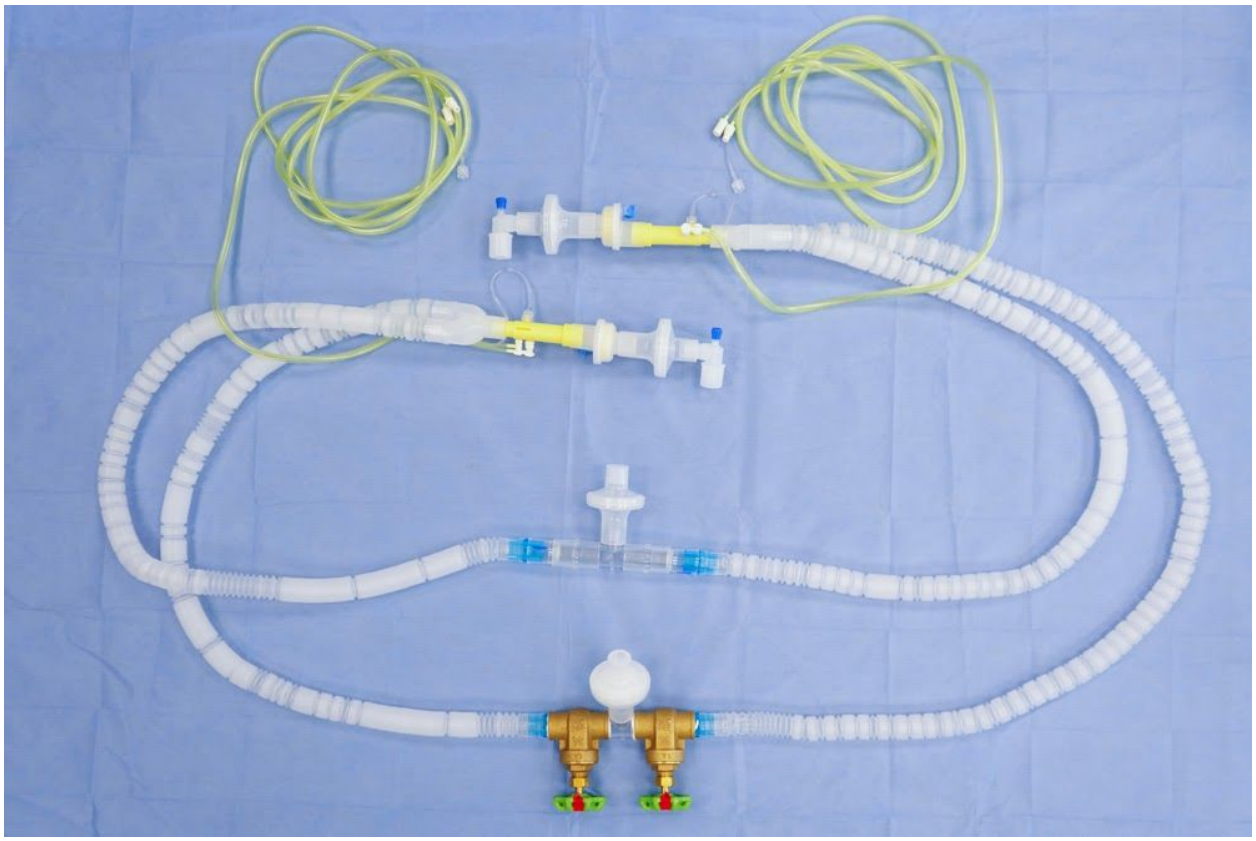

Figure 2 - All assembled parts.

Circuit Assembly

Inspiratory limb: Vent Inspiratory connection → Viral filter (optional) → 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 → 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**

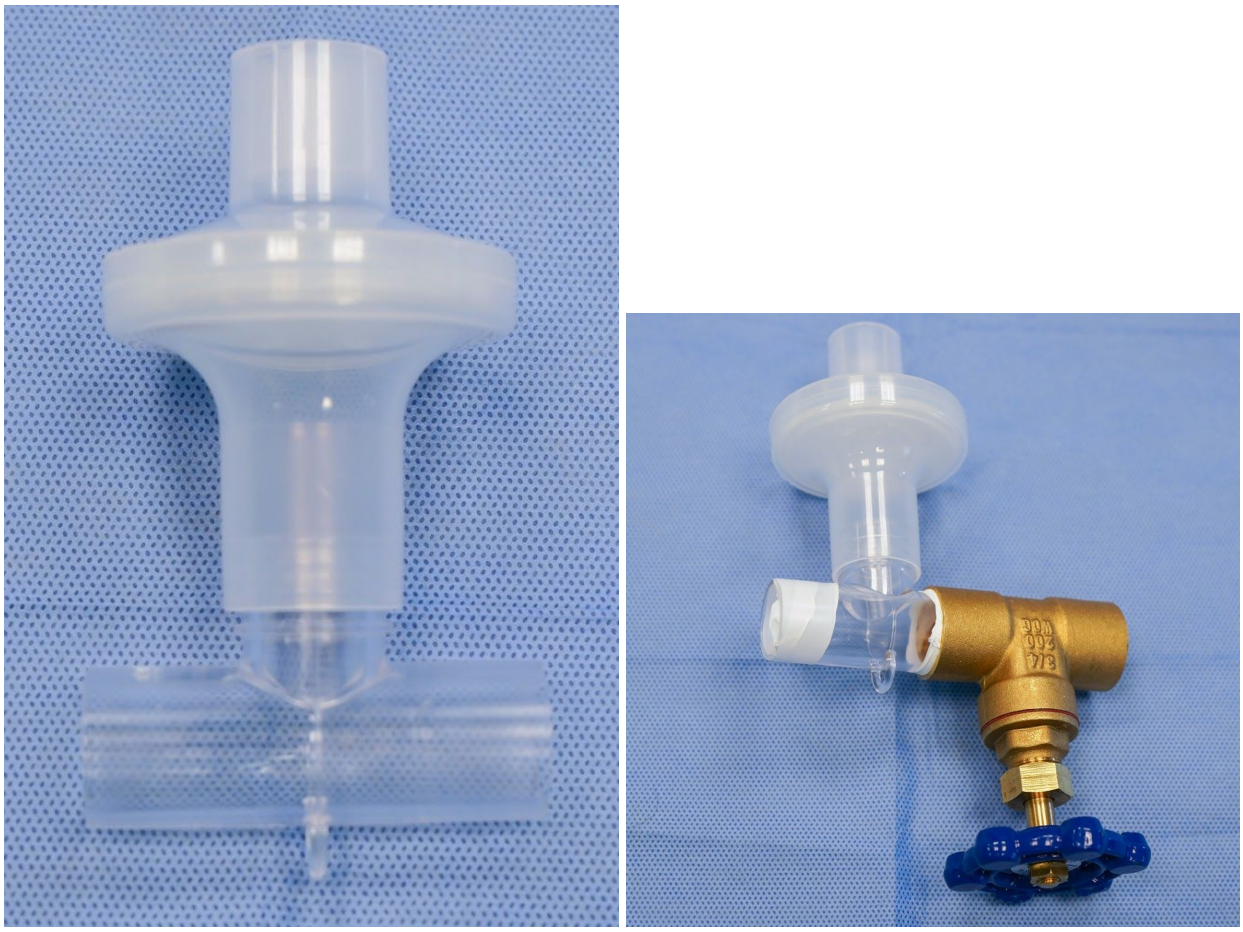

Figure 3 - Partially assembled inspiratory limb. Gate valve has been attached to one limb of the T-piece using Teflon tape for snug fit. Filter on the T-piece stem will connect to the ventilator inspiratory port.

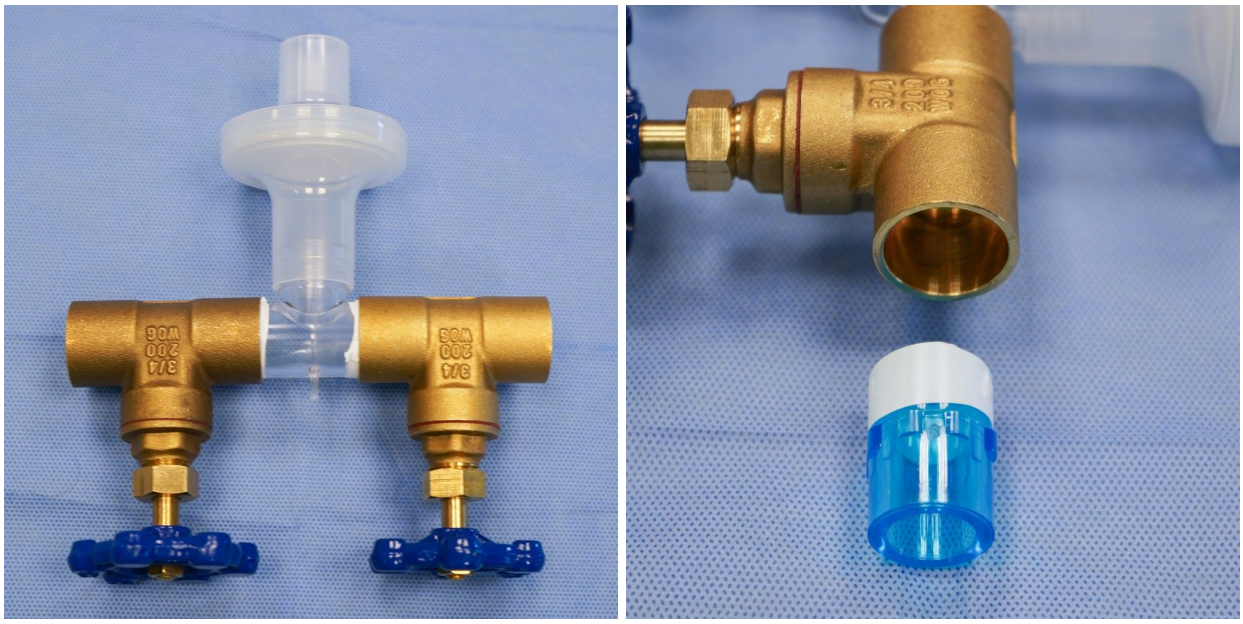

Figure 4 - both gate check valves have now been installed. 22 mm OD blue male-male adapter with teflon tape ready to be inserted into the gate check valve.

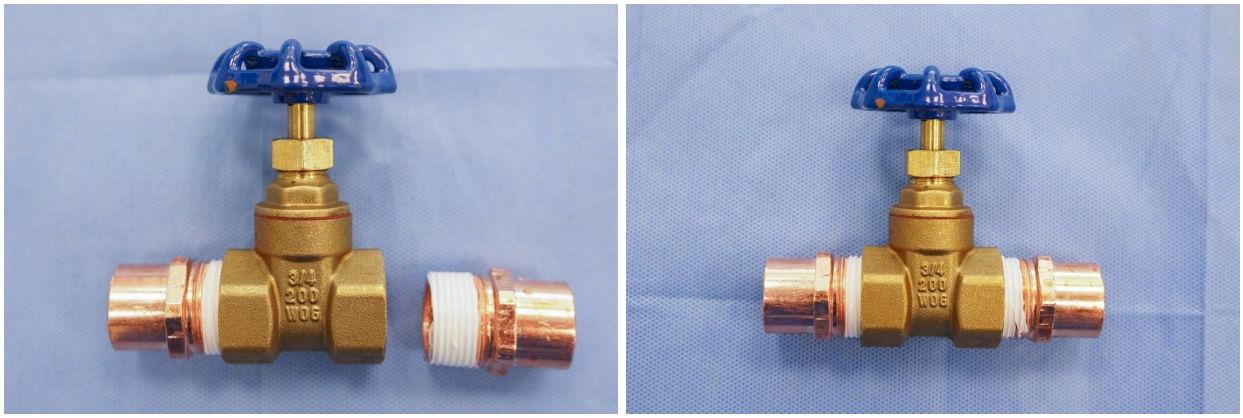

Figure 5 - Alternatively, ¾" lead free brass gate valves with thread connections can be used for the inspiratory limb. If a threaded connection is used, an additional ¾" thread-to-sweat connection on both sides is needed. Teflon tape is used once again to create a proper seal between the threaded brass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

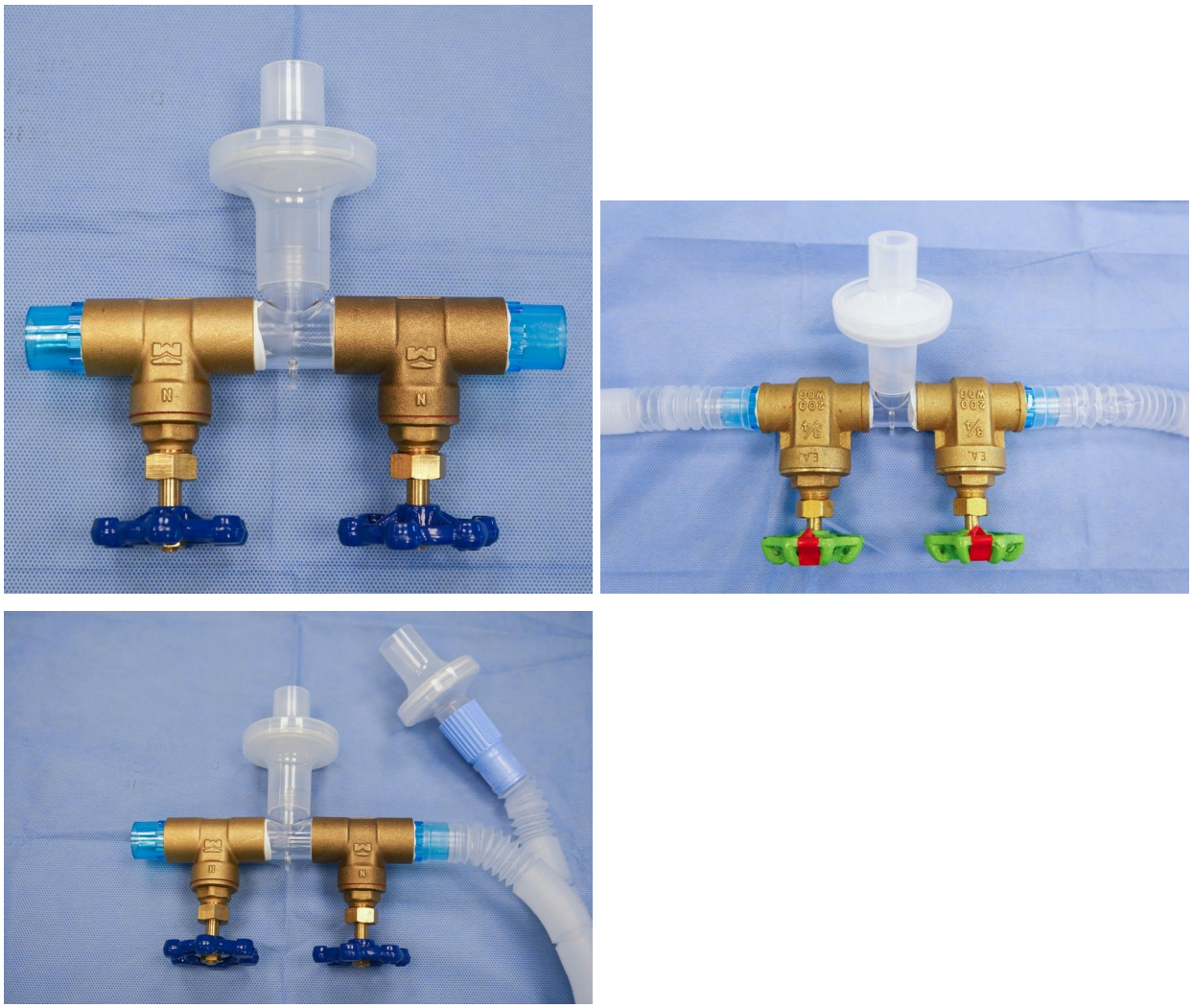

Figure 6 - inspiratory limb of breathing circuit is connected to 22 mm OD blue male-male adapter. With this particular circuit, the included B/V filter and blue connector can be optionally disconnected or rearranged to optimize circuit ergonomics and minimize circuit leaks. It is important to keep the connection to the inspiratory port of the ventilator short, due to the weight of the gate check valves.

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 → Viral filter → HME filter → yellow spirometry sensor →patient wye. **Make one for each patient.**

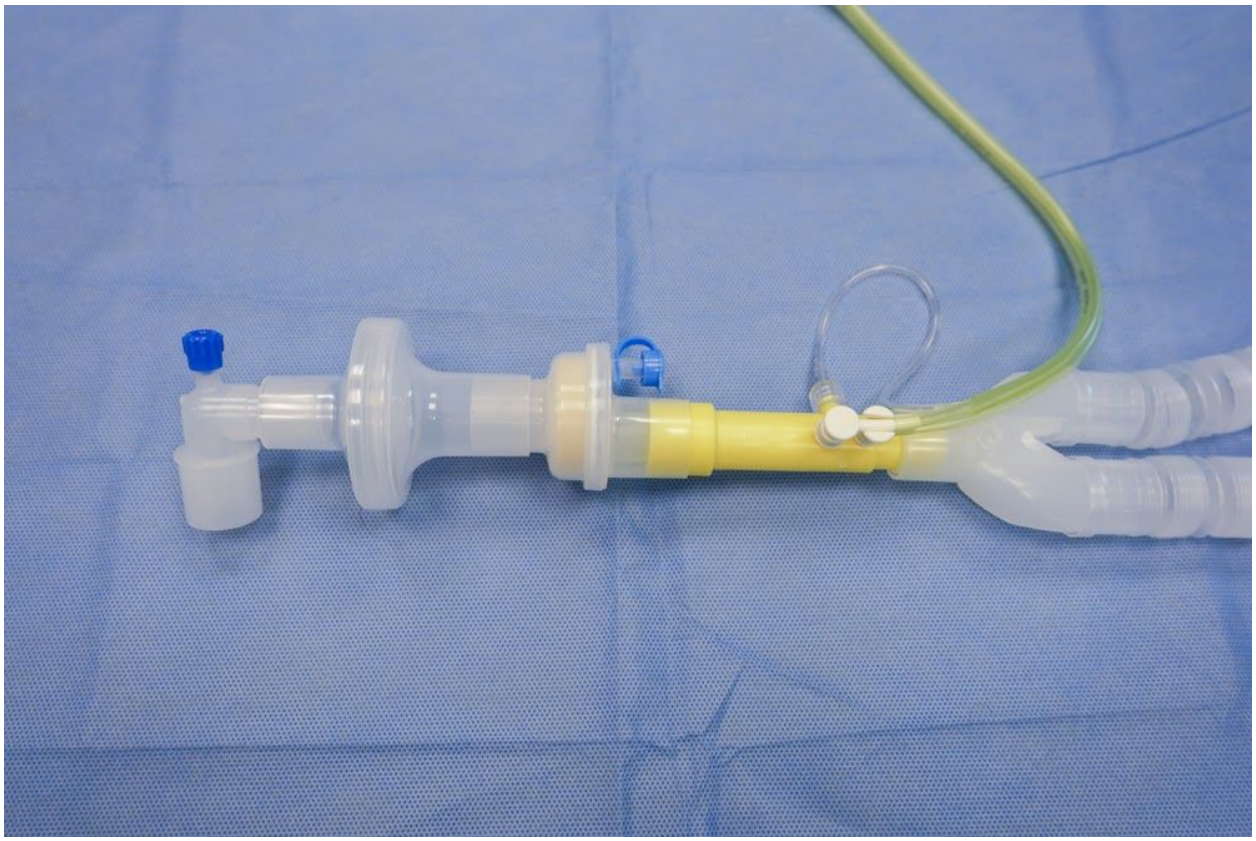

Figure 8 - Assembled patient connection with (left to right): elbow, Bacterial/Viral filter, HME filter, spirometry tubing, and circuit wye connector. Note that one of these is necessary for each patient.

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

Figure 9 - Components of Expiratory Limb.

Figure 10 - Assembled expiratory limb, one side only.

Figure 11 - Final assembled expiratory limb with one-way valves. Note that the ventilator pictured above (Puritan Bennett 840) has a large B/V filter already in place, and the smaller B/V filter was not needed.

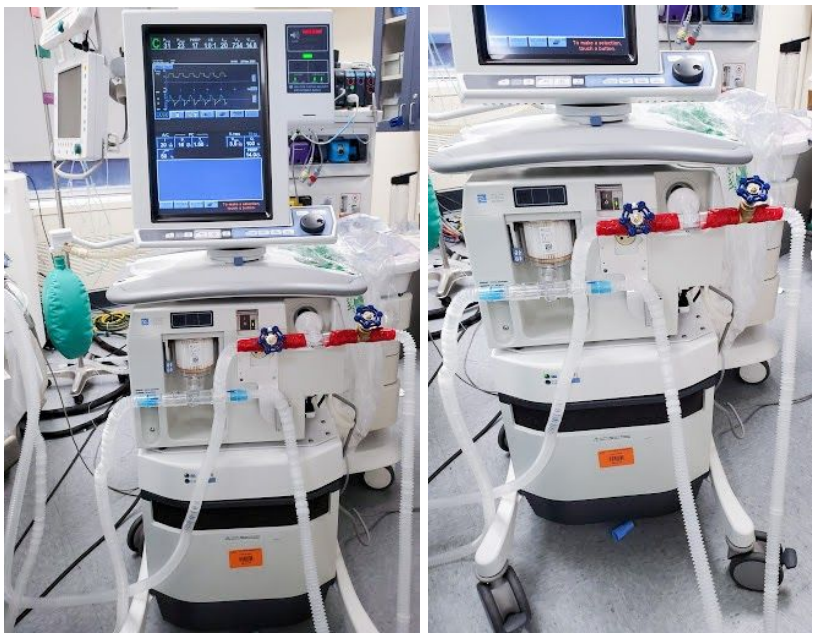

Figure 12 - Final assembled dual patient limbs connected to ventilator, in this instance a Puritan Bennett 840.

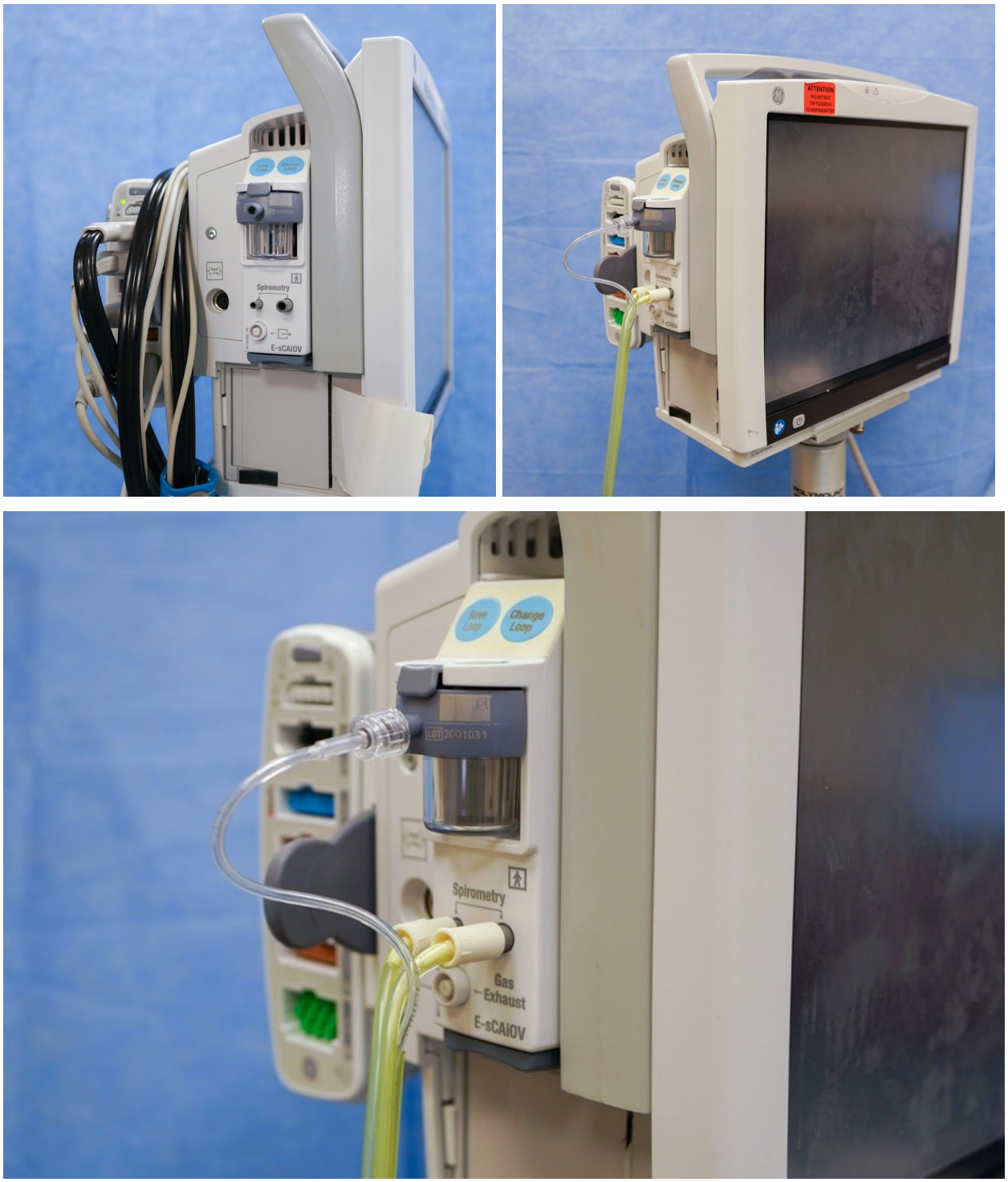

Figure 13 - GE Carescape Respiratory Module installed in a GE transport monitor

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 not been fully tested in the simulation lab. 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:

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Appendix A

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.

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.