**gVent Validation Testing**

Prior to connecting a patient to the ventilator a simple verification test should be complete to confirm no faults in the system. For a patient being maintained on this device for mechanical ventilation, a ventilator check should be completed regularly. Although there is no verified national standard, regular ventilation checks in the ICU are recommended to occur every 4 hours by the Society of Critical Care medicine (1). Further testing of our device specifically is needed to determine if we would need ventilation checks at a higher frequency than the recommended standard.

To conduct a validation test the following would be checked prior to connecting a patient to the ventilator:

1. Validate and calibrate pressure settings
   1. Our design currently has an external water column for visualization of pressures generated by the water column inside the canister, as well as a manometer placed near the top of the internal column.
   2. Simply cross comparing the pressure readouts of these two devices provides a means of cross comparing that the pressure within the canister is that which is expected.
   3. By connecting an in-line manometer to the circuit after the valves and more proximal to the patient, we could confirm the discrepancy between intended pressures as indicated on the ventilator manometer and those more proximal to the patient subject to resistance of the circuit.
   4. Although not currently included due to delays in supply, a pressure sensor will be enclosed with our flow sensor.
   5. The pressure sensor would be calibrated ahead of each use by turning off source flow, opening all out flow ports, and then closing all outflow ports to create a depressurized and closed circuit. We would then occlude the patient port and zero the pressure sensor.
2. Verify volume delivered
   1. Final designs are inclusive of a flow sensor that would be calibrated and enable us to have ongoing feedback about volume of gas flow. Given delays in supply we do not yet have the flow sensor to incorporate into our working model and so propose the alternative means of verifying the delivered volume of gas.
   2. The flow sensor would be calibrated ahead of each use by turning off source flow, opening all out flow ports, and then closing all outflow ports to create depressurized and closed circuit with zero flow. We would then occlude the patient port and zero the flow sensor.
3. Verify pressure release mechanism
   1. As designed, the system is inherently pressure limited and so the point at which this bubbling begins indicates the maximum pressure it could administer, as limited by the weight of the upper column.
   2. To confirm this inherent safety mechanism is limited to a pressure of 40cm of H2O, occlude patient outflow and pressurize the system to a point where bubbling occurs in the canister.
   3. Hold pressure here and confirm that 1) alarm sounds when exceeding a pressure of 40cm H20 and 2) excess pressure is being released through bubbling.
4. Verify low pressure alarm
   1. Turn main source flow off, and open the patient port on inspiratory phase to depressurize the gravity chamber. Set Ventilator to pause on expiratory phase. Adjust PEEP Valve to 25 cmH20. Turn Dead Space Washout Flow to 10L/min.
   2. Occlude patient port and pressurize system to 25 cmH20.
   3. Set Low Pressure Alarm to 10 cmH20.
   4. Slowly adjust PEEP Valve down in increments of 5 cmH20 until alarm sounds.
   5. Verify that the PEEP Valve is set to 10 cmH20 (or within a 10% error) as the PEEP represents the only pressure in the system in this setting, and we have set the alarm to sound at a threshold of 10cm H20.
5. Verify low and high minute ventilation alarms
   1. Once a flow sensor is included in the design we will be able to detect tidal volumes, combined with the respiratory rate this will provide us with the minute ventilation.
   2. Inclusive in our code is an alarm to sound when the minute ventilation is above or below the parameters set for the specific patient, roughly a minimum would be to alarm at half the desired minute ventilation and a high would alarm at approximately double the patient’s desired minute ventilation.
6. Circuit Leak Test
   1. Occlude patient port, then pressurize the system to 40 cmH20. Turn off Source Flow (and once added, Dead Space Washout Flow). Observe the pressure chamber for 5 minutes to ensure no gross loss of volume. Ensure during this time, flow measurement remains at 0 L/min. Open the patient port and resume source gas flow.
7. Mechanical Ventilation in Adult Patients with Acute Respiratory Distress Syndrome - *Am J Respir Crit Care Med. 2017 May 1;195(9):1253-1263*