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| Step 1: Driving Circuit Leak Test | | |
| Setup:   1. Connect the inspiratory and expiratory limbs of the Cerebrus system to the corresponding inspiratory and expiratory ports of the driving ventilator 2. Occlude the patient Y of each secondary circuit | Performance:   1. Perform a standard low P leak test using an anesthetic gas machine | PASS   * Leak < 500 mL |
| Step 2: Secondary Circuit Leak Test | | |
| Setup:   1. Connect test lungs to the end of each secondary circuit\* 2. Set driving ventilator to initial system setup up parameters 3. Begin ventilation on test lungs   \* *Anesthetic gas machine (AGM) breathing bags can be used as test lungs*\* | Performance   1. Allow the test lungs inflate and deflate 2. Allow 2 minutes of ventilation 3. Note the total volume returned to the ventilator 4. Allow the lungs to ventilate for an additional 2 minutes | PASS   * Each test lung visually inflates and deflates with each respiratory cycle of the driving ventilator * Volume return to the ventilator remains constant for 2 minutes after the total volume was noted |
| Step 3: Fresh Gas Flow Check | | |
| Setup:   1. Ensure the fresh gas flows to each secondary circuit is attached 2. Set each fresh gas flow to 4 L/min | Performance   1. With each fresh gas flow set to 4 L/min allow 2 minutes of ventilation 2. After 2 minutes note the total volume returned to the ventilator 3. Change the fresh gas flow on Lung A to 10 L/min while holding lung B at 4 L/min 4. Ventilate for 2 minutes 5. Note the total volume returned to the ventilator 6. Note any change in the observed inflation in Lung A 7. Return fresh gas flow on Lung A to 4 L/min 8. Repeat steps (III – VII) with lung B set to 10 L/min and lung A held at 4 L/min | PASS (all conditions must be met)   * breath-delivery bag inflates and deflates with each respiratory cycle of the driving ventilator * Increased volume returned to driving ventilator AND increased lung expansion of Lung A following Step VI * Increased volume returned to driving ventilator AND increased lung inflation of Lung B following Step VIII |
| Step 4: Secondary Circuit Independence | | |
| Setup:   1. Set driving ventilator to initial system setup up parameters 2. Set fresh gas flow to 4 L/min 3. Begin ventilation on test lungs | Performance:   1. Allow system to ventilate for 2 minutes 2. Measure the tidal volume or visually observe the approximate inflation of each lung 3. Decrease the compliance in Lung A 4. Ventilate for 1 min 5. Measure the tidal volume lung B or visually observe the approximate inflation of Lung B 6. Return the compliance of Lung A to baseline 7. Repeat steps (III – VI) using Lung B | PASS   * No major changes in measured tidal volume or observed inflation of lung B when lung A compliance is decreased   AND   * No major changes in measured tidal volumes or observed inflation of lung A when lung B compliance is decreased |
| Step 5: Manometer Check | | |
| Setup:   1. Set driving ventilator to initial system setup parameters 2. Ensure manometer is installed into the sampling port of the HME filter distal to the patient Y 3. Ensure each secondary circuit is attached to a test lung 4. Ensure the PEEP valves on each secondary expiratory limb is set to 5 cm H2O 5. Set fresh gas flow rates for each secondary circuit is set to 4 L/min | Performance:   1. Note the nadir (lowest reading) on the manometer 2. Note the zenith (highest reading) on the manometer | PASS   * Zenith (peak inspiratory pressure) occurs with each inspiration   + Peak inspiratory pressure does not equal the driving pressure of the ventilator * Nadir occurs at end expiration (PEEP) and the manometer reads at least 5 cm H2O\*   \*PEEP may be higher than 5 cm H2O due to intrinsic PEEP generated by the constant fresh gas flow. Higher fresh gas flow rates lead to higher intrinsic PEEP\* |
| Step 6: Disconnect Alarm | | |
| Setup:   1. Set driving ventilator to initial system setup up parameters 2. Set fresh gas flow to 4 L/min for each secondary circuit 3. Begin ventilation on test lungs | Performance:   1. Allow lungs to ventilate for 2 minutes to reach steady state 2. Set volume alarms according to instructions on ALARM SETTING 3. Disconnect Lung A 4. Reconnect Lung A 5. Disconnect Lung B 6. Reconnect Lung B | PASS   * Disconnect of Lung A results in low volume alarm   AND   * Disconnect of Lung B results in low volume alarm |
| Step 7: Pop-Off Valve Integrity AND Occlusion Alarm | | |
| Setup:   1. Set driving ventilator to initial system setup up parameters 2. Set fresh gas flow to 8 L/min for each secondary circuit 3. Begin ventilation on test lungs | Performance:   1. Allow lungs to ventilate for 2 minutes to reach steady state 2. Set volume alarms according to instructions on “Alarm Settings” 3. Clamp Lung A distal to secondary circuit Y 4. Note peak pressure on Lung A as measured by inline manometer 5. Unclamp Lung A 6. Allow lungs to ventilate until volume alarm ceases 7. Clamp Lung B distal to secondary circuit Y 8. Note peak pressure on Lung B as measured by inline manometer 9. Unclamp Lung A 10. Allow lungs to ventilate until volume alarm ceases | PASS   * Clamping of Lung A results in: * Low volume alarm * Peak inspiratory pressure as measured by inline manometer = 45 cm H2O   AND   * Clamping of Lung B results in: * Low volume alarm * Peak inspiratory pressure as measured by inline manometer = 45 cm H2O |