

Operational Verification Procedure pNeuton mini Ventilator

Thank you for your purchase. This procedure outlines a validation testing method used to verify proper operation of the **pNeuton mini** Ventilator. It must be performed prior to using the ventilator for the first time in a health care facility. If the ventilator fails to pass any of the following tests do not apply it to patients. Call Airon Corporation Customer Support at 888-448-1238.

Ventilator Setup

The following equipment is needed:

- 1. **pNeuton mini** Ventilator with breathing circuit (Airon # 58031 # 58250)
- 2. Oxygen analyzer
- 3. Watch

When ready:

- 1. Attach breathing circuit to ventilator following instructions in the Operators Manual.
- 2. Set the controls as follows:
 - a. **Mode** control to IMV + CPAP
 - b. **PEEP / CPAP** to off
 - c. **Peak Pressure (P**_{INSP}) to 30 cm H_2O
 - d. Continuous Flow (VINSP) to 8 L/min
 - e. Inspiratory Time (T_I) to 0.6 sec
 - f. Expiratory Time (T_E) to 2.0 sec
 - g. Oxygen (F₁O₂) to 60%
 - h. High Pressure Alarm (P_{ALARM}) to 40 cm H₂O
- 3. Occlude the patient connection or place a cap over the patient connection to seal the circuit.
- 4. Attach Oxygen and Air Input on side panel of the ventilator to high-pressure gas sources and turn on both gases.

NOTE: The ventilator will begin operation at the above settings when the oxygen is turned on. The alarm will sound. You may press the "Reset / Silence" button to silence the alarm.

Operational Verification

Verification Step	Acceptable Range	Result
Observe the pressure gauge. It should rise to 30 cm H_2O and drop to 0 cm H_2O .	$30 \pm 3 \text{ cm H}_2\text{O}$	Pass / Fail
Count the respiratory rate with a stopwatch. Measure the number of breaths in one minute.	23 ± 3 breaths per minute	Pass / Fail
Attach an oxygen analyzer to the output of the expiratory valve. Using a calibrated oxygen analyzer measure the oxygen percentage.	60% <u>+</u> 3%	Pass / Fail
Set the High Pressure alarm to 20 cm H_2O . The alarm should activate with each breath.	Visual and audible alarm	Pass / Fail
Remove the patient connection cap and allow the breathing circuit to remain open. Using a stopwatch, measure the time until the alarm sounds.	10 ± 2 seconds	Pass / Fail
Disconnect one gas input with the remaining gas source connected to Air or Oxygen gas source. Verify the Low Gas Supply alarm activates.	Visual and audible alarm	Pass / Fail

If the ventilator has passed all the above steps it is ready for clinical use. Please fill out the Product Registration Card and return it to Airon Corporation. Thank you.



Tested by: _

Airon

__ Date:

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