

pNeuton mini NEO Ventilator

This procedure outlines a validation testing method used to verify proper operation of the **pNeuton mini NEO** Ventilator. The Operational Verification should be performed prior to using the ventilator with each patient application.

Ventilator Setup

The following equipment is needed:

- 1. **pNeuton mini neo** Ventilator with breathing circuit (Airon # 58031 or 58201)
- 2. Oxygen analyzer
- 3. Watch, a timer or stop 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 (PINSP) to 20 cm H₂O
 - d. Continuous Flow (VINSP) to 8 L/min
 - e. Inspiratory Time (T₁) to 0.4 sec
 - f. Expiratory Time (T_E) to 2.0 sec
 - g. Oxygen (F_1O_2) to 60%
 - h. High Pressure Alarm (PALARM) to 30 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 (55 psi <u>+</u> 15 psi each gas) and turn on both gases.

NOTE: The ventilator will begin operation at the above settings when the oxygen and air are 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 20 cm H_2O and drop to 0 cm H_2O .	20 ± 3 cm H ₂ O	Pass / Fail
Count the respiratory rate with a stopwatch. Measure the number of breaths in one minute.	25 ± 5 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 ₂ O. The alarm should activate with each breath. Turn High Pressure Alarm back to 30 cm H ₂ O post test.	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.

Tested by:

Date:

