

## Operational Verification Procedure MACS CPAP System

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

## Device Setup

The following equipment is needed:

- MACS CPAP Device with Airon patient breathing circuit (PN 58001, 58006, 58011, 58021 or 58051)
- 2. High pressure oxygen hose with pressure regulated oxygen supply
- 3. Test lung, (1 L rigid wall, Airon Part #21002 suggested)

## When ready:

- 1. Attach breathing circuit to device following instructions in the Operators Manual.
- 2. Attach the test lung to the patient side of the breathing circuit.
- 3. With the device set up as described above, adjust the controls as follows:
  - a. Oxygen % to 65%
  - b. CPAP to 10 cm H<sub>2</sub>O.
- 4. Attach Oxygen Input on rear panel of the device to a high pressure oxygen source (55 psi <u>+</u> 15 psi) and turn on the oxygen.

NOTE: The unit will begin operation at the above settings when the oxygen is turned on.

## Operational Verification

Verification Step	Acceptable Range	Result
Expand the test lung at a rate of approximately 10 breaths per minute to simulate spontaneous breathing. Ensure that the pressure gauge returns to $10 \pm 2$ cm $H_2O$ after each breath.	10 ± 2 cm H₂O	Pass / Fail
Switch the oxygen toggle to 100%. Expand the test lung at a rate of approximately 10 breaths per minute and ensure the pressure gauge returns to $10 \pm 2$ cm H <sub>2</sub> O after each breath.	10 ± 2 cm H₂O	Pass / Fail
Turn the CPAP knob to the off position. Ensure the pressure gauge points inside the off range and flow stops.	Off	Pass / Fail

When the device has passed the Operational Verification procedure it is ready for clinical use
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Tested by:	Date:	
		Airon

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