

WaterPAP™

Positive Airway Pressure Device

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed physician.

<u>Indications:</u> WaterPAP[™] is a single patient use positive end expiratory pressure setup for use with infant patients weighing <10 kg in hospital environments to increase end lung pressure above atmospheric in constant flow conditions.

<u>Contraindications:</u> The WaterPAP $^{\text{m}}$ device is contraindicated in individuals not requiring elevated lung pressure therapy. WaterPAP $^{\text{m}}$ is not intended to be used during Magnetic Resonance Imaging.

<u>Warnings:</u> Positive Airway Pressure (PAP) may have an adverse effect on patient cardiopulmonary status.

- Always use the corrugated tube with diffuser supplied with WaterPAP™.
- Always use a pressure gauge to measure the delivered pressure proximal to the patient's airway.
- Flow rate increases result in higher then intended pressures being delivered with the use of this device. See FIG 1 below.

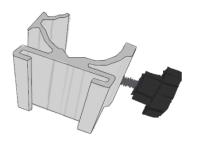


This data was generated using a standard 10mm heated ventilator circuit. Results may vary depending on the type and length of the circuit being used.

The graph represents how increasing the flow rate can cause unintended increases in PAP pressures when using the WaterPAP™ device with a standard 10mm heated infant breathing circuit.

- Be advised that excessive pressure may be generated as a result of condensation of water when humidified gas is used.
- Follow the humidifier instructions with regard to condensation accumulation in the tubing and its affect on pressure.
- Clinical staff should check infant patient every 2-3 hours.
- WaterPAP™ is intended to be used by medical personnel qualified to manage instrumentation that
 provide respiratory assistance and or pulmonary ventilation for infants.
- WaterPAP™ is a single patient use device. Do not wash, sterilize or reuse.

<u>Precautions:</u> Use WaterPAP[™] only at flow rates from 4-12 L/min. The water level may change over time and needs to be monitored to make sure the surface of the water is maintained at the 0 cm level. Evaporation or condensation of water may occur during operation of this device. Changes in water level directly affect the delivered PAP pressures. Always monitor water level and adjust as required. Use only sterile water to fill the WaterPAP[™] chamber.



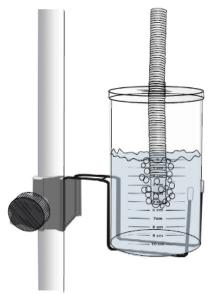
Attach the Pole Clamp to the IV pole



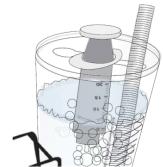
Slide the stainless steel bracket into the pole clamp



Fill the canister with water to the 0 cm line



Attach the 10mm corrugated tube with air diffuser to the expiratory limb of the continuous flow breathing circuit. Insert the tube through the center hole to the desired depth with the flow rate on. Slide the tube sideways into the notch that secures the tube in position. The depth the tube is submerged in cm = positive airway pressure in cmH2O. Verify the pressure with an inline pressure gauge and adjust the depth as needed. Apply the protective cover to the top of the canister.



Maintain the water level to the 0 level. Water level may be adjusted by inserting a syringe through the center hole into the water for aspiration.

Dispose of WaterPAP™ as per your institutional guidelines for medical waste, in accordance with local, state, and federal regulations.

Specifications:

Pressure Range:	0-10cmH2O Positive Pressure
Flow Rate Range:	4-12 L/min
Pressure Accuracy:	+/- 1 cmH2O
Storage Temperature:	12 - 140°F (-11 - 60°C)
Materials:	TENITE™ Propionate, CYROLITE™ polypropylene/ethylene-octene polymer

Ordering Information:

WP-7700A	WaterPAP™ Setup, includes 0-10cm Graduated Canister, 10mm Corrugated Tube with Air Diffuser, Tube Support Top & Protective Lid	Box of 9
WP-7700		Case of 36
CP-2203	Pole Clamp	Each
CP-2204	Bracket	Each
WP-7704	Bracket with Tube Guide	Each
WP-7705	WaterPAP™ Starter Kit, includes Four Setups, One Pole Clamp & One Bracket with Tube Guide	Each
WP-7707A	Pressure Relief Valve	Box of 9
WP-7707	riessuie kellei valve	Case of 36

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