

SOP #: 809.01

Title: SOP - Use and Maintenance of the Hydropac AWS-2500 Pouch Machine and HYP-2527 Wall Mounted Proportioner

Approvals:
Attending Veterinarian

Coordinator

Approvals:

Date:

Date:

1. Purpose

1.1 To describe the proper application and use of Hydropac® Pouches.

2. Responsibility

2.1 The procedure outlined in this policy is limited to use by authorized employees at FIU

3. Definitions

3.1 FIU – Florida International University

4. Guidelines

4.1 Autoclaved or even chlorinated water bottles will quickly produce very high microbial levels in 2-3 days due to regurgitation of air that carries into the bottle saliva and nutrients. The Hydropac valve is a one-way valve that does not allow organic material to back up into the pouches. Chlorination with 1-5 ppm to sterilize the Manifold unit, all of its components as well as the inside surfaces of the film and any air that enters the pouch will ensure that the water in the pouch is sterile.

4.2 Preparation of Chlorine Solution Using the Proportioner for Hydropac Pouches

4.2.1 The Water Treatment Proportioner is used for the injection of diluted chlorine, acidifying or injection of other chemical additives into the water system during the

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- Hydropac water filled Pouch production process. The Proportioner is self- operating during the Pouch production process and the additive rate set at desired concentration levels.
- 4.2.2 The chlorine solution is essential in maintaining the sterility of the final product.

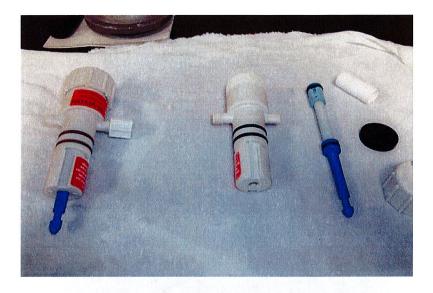
 Chlorine to a final concentration of 5 to 10 ppm is added prior to the filling process to compliment the sterility achieved by R/O water and UV light sterilization

4.2.3 Materials used:

- 4.2.3.1 Use <u>5.25</u>, <u>6.0</u> or <u>8.5</u> % sodium hyperchlorite solution (Clorox) with no fragrance added.
- 4.2.3.2 Dilution tank on the MINI Manifold
- 4.2.3.3 Personal protection equipment, i.e. gloves and scrubs

4.2.4 Procedure:

- 4.2.4.1 Before adding stock solution, make sure that the Dilution Tank drain valve is closed.
- 4.2.4.2 Partially fill Dilution tank with R/O water by opening the valve from the R/O water intake to the Dilution tank.
- 4.2.4.3 To achieve an approximately a final concentration of 5 ppm chlorine, measure and add to the dilution tank approximately:
 - 4.2.4.3.1 5.25% Clorox use 21 ml Clorox or 0.7 ounces added to the tank.
 - 4.2.4.3.2 6 % Clorox use 18 ml Clorox or 0.6 ounces added to the tank.
 - 4.2.4.3.3 8.5% Clorox use 10 ml Clorox or 0.3 ounces added to the tank.
- 4.2.4.4 Complete filling the tank to the top. Close the valve from the water intake.
- 4.2.4.5 If it is necessary to achieve a 10 ppm final chlorine concentration in the pouches, the quantity of Clorox that is added to the Dilution tank is doubled.
- 4.2.4.6 Move the blue stem from Proportioner Pump in a back and forth direction to manually pump solution through the clear tubing of the Dilution Tank.
- 4.2.4.7 Reassemble Proportioner Pump back into the Proportioner and secure the pump by twisting clockwise. Slowly rotate the main water source.
- 4.2.4.8 Listen for the Proportioner Pump to start making a clicking sound. Look for fluid flow in the clear tube.



Assembled Pump

Disassembled Pump

- 4.2.4.9 Verify that the pump has been primed by testing the water for chlorine by testing a water sample with a Chlorine Strip.
 - 4.2.4.9.1 Chlorine Testing verifies that proper concentration of Chlorine in the pouches or at the valve located prior to entering the Hydropac 2500 machine.

4.2.4.9.1.1 Materials:

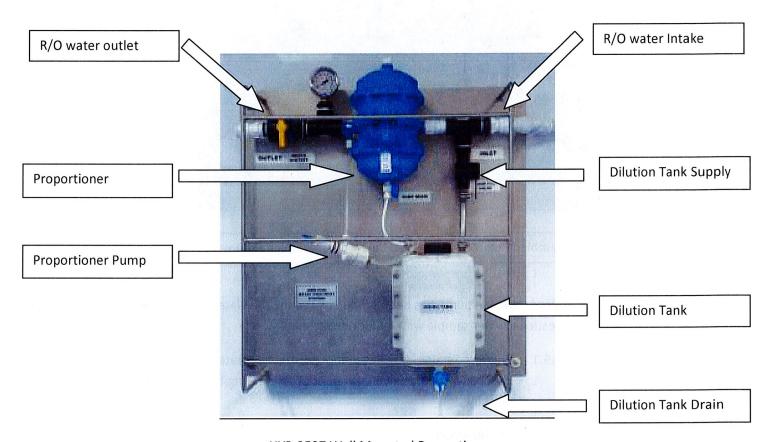
4.2.4.9.1.1.1 Chlorine Test Sample

4.2.4.9.1.1.2 Chlorine dip Sticks (Purchased from Pool store)

4.2.4.9.1.1.3 Personal protection equipment, i.e.gloves and lab coat

4.2.4.9.1.2 Follow directions on dips strips

4.2.4.9.1.3 Sample range for most applications is 5-10 PPM of Free Chlorine.

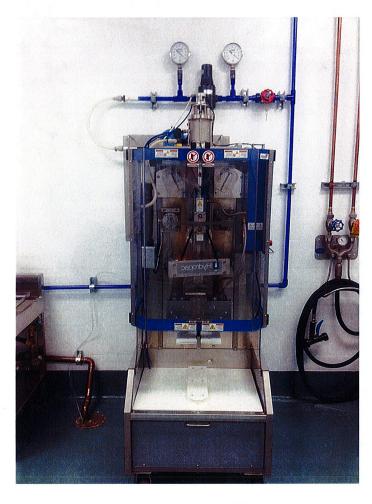


HYP-2527 Wall Mounted Proportioner

4.3 Preparation and Use of Hydropac AWS-2500

- 4.3.1 Connect with a dedicated hose the water intake from Hydropac AWS-2500 to the water outlet from HYP-2527 Wall Mounted Proportioner.
- 4.3.2 Follow the instruction in the Quick Start Manual that is placed on the back of the machine.
- 4.3.3 Plug the machine into the outlet and turn on the main power switch and wait for the red light to come on and then rotate the key to the run position.
- 4.3.4 Follow on screen commands. Go through the check list menu making sure the machine is in operating order.
- 4.3.5 After the machine warmed up, input the type of pouches (small 237 ml or large 384 ml) and the quantity of pouches that are desired.
- 4.3.6 After the pouches are being created, inspect them to ensure that the seals are strong and secure by applying pressure to the pouch.

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Hydropac AWS-2500

- 4.3.7 When one tote is full, the machine will automatically switch to the next empty tote.
 - 4.3.7.1 The Tote Container conveniently stores and protects 20 water filled Pouches during Pouch production. However, the Totes will hold 30 water filled Pouches if evenly distributed and arranged inside of the container. Totes weigh 2.72 lbs (1.24 kg) empty, 20 lbs. (9.1 kg) with 30 filled 8 ounce (237 ml) Pouches and 30 lbs. (13.6 kg) with 30 filled 13 ounce (384 ml) Pouches. Pouch lid flaps interlock when closing. 3/8" (9.5 mm) diameter reinforced locking tab hole for optional locking.
 - 4.3.7.2 The Totes easily stack when full. Stack only 3 high on a Tote Transport Cart. Do not stack Totes more than 5 high when filled with pouches. When empty, Totes efficiently nest inside one another to provide the most efficient use of available space. Empty Tote containers can be stacked 25 high.



Mobile Tote Transport Cart

4.4 Preparation of Water Pouches for Quality Control (QC) Testing

- 4.4.1 To outline the procedure to properly collect a representative number of samples to insure the microbial status of each lot of pouches produced.
- 4.4.2 Materials
 - 4.4.2.1 Test pouches from each production run.
 - 4.4.2.2 Personal safety equipment, i.e. gloves, mask, lab coat

4.4.3 Procedure

- 4.4.3.1 Each time the Water pouching machine is set up to fill pouches a batch number and date should be assigned.
- 4.4.3.2 Quality control will be conducted to insure that the batch of water produced in any given session is free of microorganisms.
- 4.4.3.3 To properly sample different portions of each water load a sample bag is taken at the start, the middle and the end of the pouch filling operation. Example: In a pouch collection of 600 pouches the technician should collect a pouch marked #1 from the beginning of the batch, pouch #2 at 300 pouches and pouch #3 at 600 for testing.
- 4.4.3.4 Each LOT is placed on hold until the QC testing is completed.

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4.4.4 Longevity of pouch storage is no more than 3 months. This would be consistent with packaged consumables, such as fortified diets. However, based on the chlorine as well as microbiological testing using the Heterophilic Plate Count, the shelf life could be extended by the Director of OLAR.

4.5 <u>Use of Hydropac Silicone Patch</u>

4.5.1 The Hydropac Silicone patch is designed to allow the injection of chemicals or drugs compatible with the Hydropac pouch and valve into a pre-filled Hydropac pouch.
 This is accomplished by the insertion of needle mounted on a syringe into the Hydropac silicone patch once the patch has been attached to the Hydropac pouch.

4.5.2 Materials:

- 4.5.2.1 Patch for Hydropac Silicone pouches (1000 per carton) HYP-5303
- 4.5.2.2 Sterile disposable syringe, 1 or 3 cc
- 4.5.2.3 Sterile needle 25 or 21 gauge
- 4.5.2.4 Hydropac pouches filled with Small or Large (8 or 13 ounces) (237 or 384 ml) of facility water
- 4.5.2.5 Personal protection equipment, i.e. gloves and lab coat
- 4.5.3 Before applying the patch onto the surface of the pouch insure that the pouch is clean dry and free of any foreign matter. The surface can and may be disinfected with chlorine-based compounds, as well as Alcohol based agents. Note: Always place silicone patch on a seamless portion of the pouch. Patches will not seal properly on a seam. In addition, pouch surface must be absolutely dry for patch to adhere properly.
- 4.5.4 Remove a strip of silicone patches (20 per strip) from its plastic envelope. Gently Peel away one silicone patch off the paper backing by bending the backing material slightly. Place and press the self-adhesive patch in a location that allows the insertion of the needle used to inject the substance into the pouch.

5. References

5.1 LabProducts Hydropac and proportioner manuals.