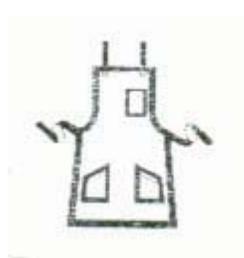
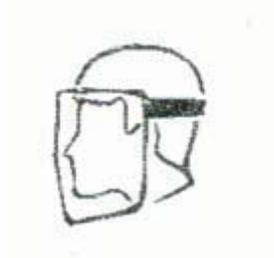


D. Membrane Disinfection/Rejuvenation (D/R):

WARNING: ALWAYS WEAR PROTECTIVE EYE GOGGLES AND CLOTHING WHEN APPLYING RO CLEANING AGENTS. UPON CONTACT WITH EYES OR SKIN, IMMEDIATELY WASH WITH TAP WATER AND CALL A PHYSICIAN.



WARNING: ALL D/R CHEMICALS ARE POTENTIALLY DAMAGING TO THE HUMAN BODY; THE OPERATOR SHOULD WEAR PROTECTIVE EYE GOGGLES DURING THE CLEANING PROCEDURE AND AVOID CONTACT OF CHEMICALS WITH MOUTH AND SKIN

CAUTION: NEVER STORE STERILANTS OF ANY TYPE IN THE D/R JUG. THE JUG'S HANDLE IS VENTED TO ATMOSPHERE AND ITS CAP IS NOT AIR-TIGHT, SPILLAGE MAY OCCUR.

CAUTION: ISOPURE IS NOT RESPONSIBLE FOR MISAPPLICATION OF CHEMICALS OR ABUSE OF THE RO MACHINE THROUGH USE OF NON-SPECIFIED CLEANING CHEMICALS.

**NOTE: THE FOLLOWING STEPS WILL BE REPEATED TWICE.
STEP 1 MUST ALWAYS BE DONE FIRST.**

Cleaning of the RO membrane-element, i.e. the removal of scale and bio-growth (bacterial slime), is recommended weekly for the MD100, since it is most often used in situations where the supply water is neither clarified nor softened. Cleaning should clearly occur whenever the RO product water flow rate has declined by 10% or its conductivity has increased by 50% (i.e., **The 10/50 Rule**). If the user adheres to these simple recommendations, complete recovery of the RO membrane-element can be expected following the routine maintenance described below. An indeterminately long lifetime for the membrane-element can also be anticipated. If on the other hand, the user habitually allows a marked decline in product water formation rate before cleaning, then complete recovery may not occur following these procedures. It should also be noted that a reversible decrease in product water formation rate may accompany a decline in supply water temperature or a reduction in RO membrane (pump outlet of feed) pressure. Both the temperature of supply water and RO pump outlet (feed) pressure should be checked before initiating cleaning. It should be noted that bacteria slime contamination of the RO

membranes can occur without any change in product water formation rate or quality. Thus, where the dialysis application is concerned, the user should clean the machine at a frequency independent of changes in product water formation rate or quality, specifically to maintain a sanitary state for the product water. The user must adhere to recommendations set-forth here and under Long Term Machine Storage (VI. E) to satisfy the warranty conditions.

Membrane cleaning is accomplished using first, an **acidic** **escailer** and bactericidal solution (**STEP 1 Solution** for the RO machines of < 3,600 gpd product water generation rates) to remove scaling due to calcium/magnesium carbonates and to kill bacteria and, second an **alkaline degreaser** solution (**STEP II SOLUTION** for RO machines of <3,600 gpd product water generation rates) to additionally kill bacteria and to remove bacterial biofilm and naturally occurring oils and organics. This involves the use of four (4) ounce volumes of each solution, differing in the extreme in pH. These solutions are pre-packaged and available through Isopure; they are provided in labeled bottles to minimize confusion. The target concentration of the **acidic** **escailer** throughout the hydraulic system of the machine is a **pH of 1.0-2.0 units**. The target concentration of the **alkaline degreaser** is a **pH of 11.0-12.0 units**. Application of the basic solution before the acidic solution may cause hardening of scale already on the RO membranes, rendering them irreversibly damaged. This sequence must be avoided. Both acid and base treatments are usually required to obtain full recovery of the RO membrane-elements, as there is usually a combination of problems (i.e., scale and bacterial slime). Other cleaning agents for more specific membrane problems are also available through Isopure.

NOTE: AS IN THE ALPHABET, “A” COMES BEFORE “B” IN THE ACID-BASE CLEANING SEQUENCE.

The RO membrane is poorly permeable to both the acidic **escailer** and the alkaline degreaser. Therefore, because of the osmotic pressure of these solutions, each causes “backflow” (product-side to feed-side) of product water contained in the membrane envelope to enhance removal of scalants and foulants: The rate of “back-flow”, however, is markedly increased by adding either the STEP 1 or the STEP 2 solution to a pre-mixed solution of **HydroBLAST enhancer (Pt #: CH30002)** prepared in RO product water. To develop the HydroBLAST solution, simply **add and thoroughly dissolve, 100 grams** of HydroBLAST granular to one (1) liter of RO product previously placed in the D/R cleaning Jug.

Sustaining the above indicated target pH levels is very important to achieving clean membranes. Thus, if the pH of fluid sampled from the D/R Jug at five minutes into the STEP1 (Pt #: CH00101) recirculation period has risen to >2.0 units, a partial or total second bottle of STEP 1 should be added to the Jug. Sometimes, scale is so abundant that the first bottle of acid is buffered before complete de-scaling occurs. A similar problem can occur with STEP 2 administration. If the pH at five minutes into recirculation of STEP 2 declines to < 11.0 units, a partial or total second bottle of STEP 2 Solution may be required. The goal here, whether cleaning with the

escailer or degreaser, is to sustain the target pH of the respective cleaning agent for at least 15 minutes of recirculation.

CAUTION: DO NOT DEVIATE FROM THE PROCEDURES AS OUTLINED BELOW. TO DO SO, MAY RESULT IN DAMAGE TO THE RO MEMBRANES.

1700-□ D/R Jug Fill

- A. While the RO is running and generating quality Product Water, fill the D/R Jug with one (1) liter of Product Water. The level in the jug should be about halfway between the two disconnect fittings.

NOTE: IF THE RO IS NOT RUNNING
a. Turn the RO on.
b. Wait for the Product Water Quality to fall below the set point.

NOTE: IF THE D/R PROCEDURE IS BEING INITIATED BECAUSE THE PRODUCT WATER QUALITY WILL NOT FALL BELOW THE SET POINT, TURN THE MACHINE OFF. OPEN THE DRAIN VALVE AND USE THE DRAIN WATER. THIS WILL PROVIDE TREATED SUPPLY WATER.

- B. With the Jug Filled, add 100 grams of HydroBLAST Enhancer.
- C. Thoroughly mix contents of D/R Jug by shaking Jug.

1700-□ D/R Machine Setup

- A. **Switch** the Power Switch to the OFF position.
- B. **Close** the RO Supply Valve.
- C. **Open** the Drain Valve to depressurize the RO.
- D. **Close** the Drain Valve.
- E. **Disconnect** the Product line from the Dialysis Connector and attach it to the Product D/R port. (See fig 10)
- F. **Attach** the Jug to the two D/R Ports on the back of the machine.
- G. **Open** the Recirc. Valve.



Fig 10

3. Recirculation Phase

- A. **Add** one (1) bottle of the Chemical Solution by pouring it into the D/R Jug.

Step	Chemical Solution
1	Acid
2	Base

1700-☐ **Switch** the Power switch on.

NOTE: DURING THIS PHASE THE PUMP INLET, PUMP OUTLET, AND PRODUCT PRESSURE GAUGES WILL READ LESS THAN 10 PSI. THIS IS NORMAL.

1700-☐ Did the Yellow Light come on?

Yes - Continue

No - Turn Machine Off

Make sure the Product line is connected

Try Again

Still no light, call an Isopure Representative.

- D. About 2-3 minutes into recirculation, check pH of D/R Jug contents. If the pH is not within the target pH range, add an additional bottle of the appropriate chemical.

Step	pH Range
1	1.0 – 2.0
2	11.0 – 12.0

Recheck pH after 2-3 more minutes of recirculation. Continue this repetitive action of acid addition, waiting and remeasuring pH, until pH is in target range for that Chemical.

NOTE: THE LEVEL IN THE D/R JUG MAY RISE AND THEN FALL AS THE CHEMICAL SOLUTION CIRCULATES THROUGH THE RO. THIS IS NORMAL AND IS PART OF THE HydroBLAST™.

CAUTION: MAXIMUM EXPOSURE TIME FOR THE MEMBRANES AT EITHER EXTREME IN pH DURING RECIRCULATION IS 30 MINUTES. TO CONTINUE LONGER WITHOUT RINSING CLEANING AGENT FROM SYSTEM BEFORE REPEATING EXPOSURE TO A GIVEN CLEANING AGENT MAY IRREPARABLY DAMAGE THE RO MEMBRANES.

1700-□ D/R Rinse Phase

- A. **Close** the D/R Rinse Valve located on the back of the machine.
- B. **Close** the Recirc. Valve and then open it ¼ turn.
- C. **Open** the RO Supply Valve.
- D. The D/R Jug will begin filling and then stop.
- E. If the Pump Outlet Pressure Gauge registers more than 150 psi, reduce the pressure until it is at or below 150 psi.
- F. **Observe** the Product Conductivity Monitor. Once it declines to below threshold and reaches its usual minimal value, **CHECK** pH of D/R Jug. This should be the pH of the Supply Water.

NOTE: THIS PHASE TAKES APPROXIMATELY 15-30 MINUTES.

NOTE: DURING THIS PHASE THERE WILL BE A FEED PRESSURE, AND SOME PRODUCT FLOW. THE PUMP INLET PRESSURE WILL STILL READ LESS THAN 10 PSI.

NOTE: IF AT ANY TIME THE JUG BEGINS TO OVERFLOW, TURN THE RO OFF.

- E. When the D/R Jug pH is that of Supply Water, simply switch the RO off.

1700-□ Return to Service

CAUTION: BOTH D/R JUG pH AND PRODUCT CONDUCTIVITY SHOULD BE WITHIN ACCEPTABLE LIMITS BEFORE RETURNING THE RO MACHINE TO SERVICE.

- A. The D/R procedure is now complete.
- B. Remove the D/R Jug and discard the contents down a drain.
- C. Open the Rinse Valve.
- D. Close the RO Supply Valve.
- E. Open the Drain Valve. (Relieve any pressure).
- F. Close the Drain Valve.
- G. Disconnect the Product Line from the Product D/R Port.
- H. 1. The RO is now ready for Step 2. Simply repeat steps 1-5 for the Base.

1700-□ The RO is ready for Service.

WARNING: BEFORE RETURNING THE RO TO SERVICE RUN THE RO AND FILL THE D/R JUG WITH PRODUCT WATER.

Alternative Cleaning Procedure Using Step 1 and Step 2 Cleaner.

Because of the extreme importance of the machine cleaning and disinfecting process, an alternative cleaning procedure is included. This process should be utilized if the D/R tank which connects to the back of the machine is misplaced or not available or if the above procedure is confusing. Both procedures achieve the same results when properly done.

To maintain cleanliness, membranes should be operated daily for at least three (3) hours. Cleaning/disinfection should be performed at least every two weeks, after any 72 hour period during which the RO has not been used, after parts replacement or repair work is performed where the integrity of the product side of the RO has been breached, when product water endotoxin units reach 1.0 EU/ml or greater, or when bacterial counts reach 50 cfu/ml or greater.

In normal operation, the membrane in reverse osmosis elements can become fouled by minerals, biological matter, and grime. These deposits build up during operation until they cause loss in water output or salt rejection or both. Membranes should be cleaned whenever the water output rate drops by 10 percent from its initial flow rate, or when salt content in the product water rises noticeably.

It should be noted that the water output rate will drop if the feed-water temperature drops; this is normal and does not indicate membrane fouling. Also, a change in water output or salt passage may be due to a drop in feed-water pressure. If such adjustments are needed, the element may not require cleaning.

During this procedure, carefully read and follow all warnings and cautions.

EQUIPMENT NEEDED:

Examination gloves; eye protection; 2.5 Gallon Cleaning/Disinfection Jug; 1 Long Cleaning Port Hose; 1 Short Cleaning Port Hose; 110 ml 1N HCl; 110 ml 1N NaOH; pH test strips; alcohol swabs; paper towels; watch or clock.

ACTION:

1. Place the free end of the Product Water Line in the drain, turn the RO ON and let it be rinsing.
2. Place several paper towels or something similar on the floor near the right rear corner of the machine. This will serve to protect the area from spillage of the cleaning solutions.

WARNING! Wear protective clothing and handle the cleaning solutions carefully.

Preparing acid solution:

3. Place the 2.5 gallon Cleaning/Disinfection Jug on the paper towels and fill it to the 8-Liter mark with RO water. Add 110 ml 1N HCl to the water in the jug.

CAUTION: The external Water Supply Valve and the Disinfect Valve must remain closed during the disinfection process. Opening the valves may cause disinfectant to overflow the Jug.

4. Turn the RO machine OFF and CLOSE the Water Supply Valve.
5. OPEN the Drain Valve to relieve the internal water pressures, then CLOSE the valve.
6. CLOSE the Disinfect Valve and make sure all gauges read '0'. If they do not, OPEN the Disinfect Valve and repeat steps 4 through 6.
7. **Refer to Figure 1** Connect the Long Cleaning Port Hose to the Upper Disinfection Port on the back of the RO making sure the connector 'SNAPS' on. Put the free end in the drain.

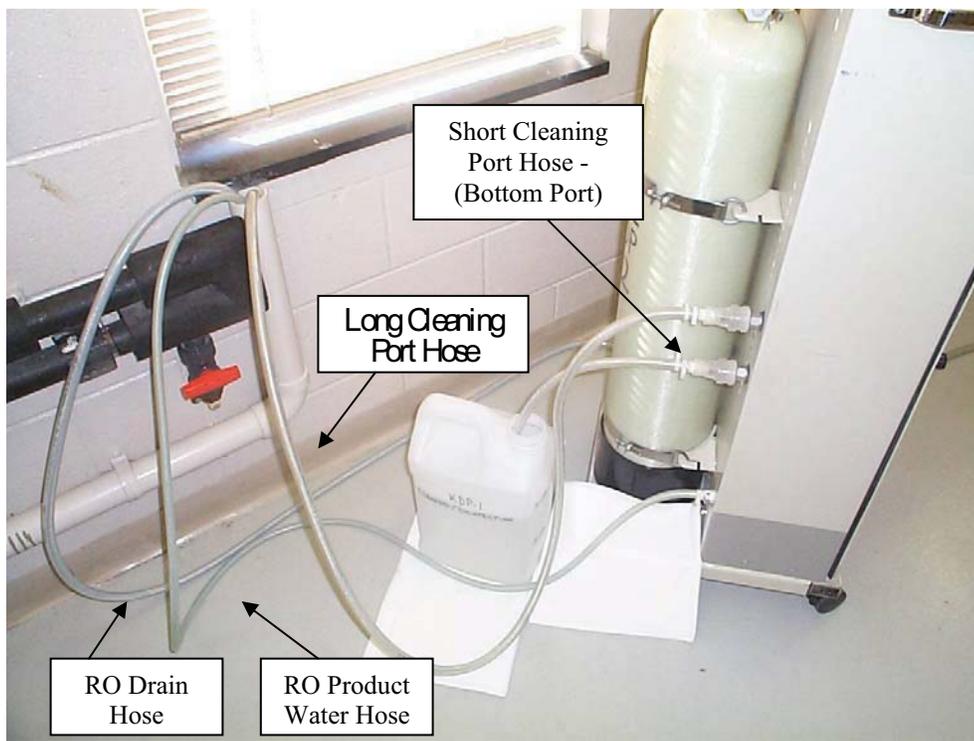


Figure 1

8. Connect the Short Cleaning Port Hose to the Lower Disinfection Port on the back of the RO making sure the connector 'SNAPS' on. Put the free end in the Cleaning/Disinfection Jug making sure that its free end is under the surface of the disinfectant solution.
9. Turn ON the RO and when the level of the solution in the jug reaches the 4 liter mark, turn the machine OFF.
10. **Refer to Figure 2** Remove the free ends of both the Product Water Line and the Long Cleaning Port Hose from the drain and place them in the jug under the surface of the disinfection solution.

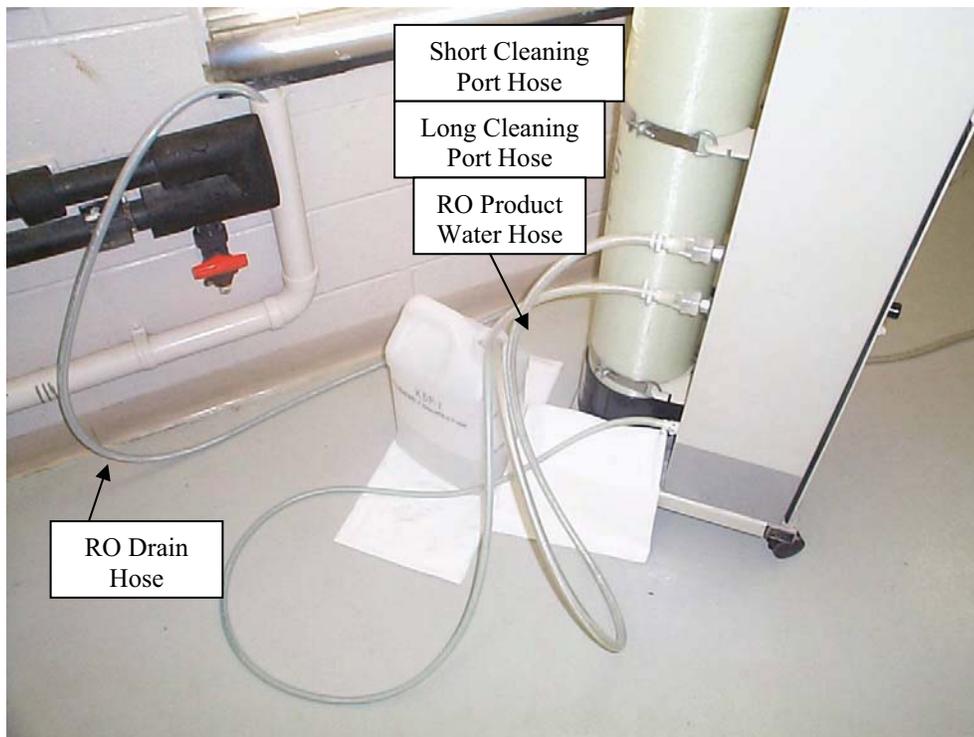


Figure 2

11. Turn the RO ON and insure that after two or three minutes a High Conductivity alarm sounds. Turn the Water Quality alarm OFF and allow the machine to run for 30 minutes.

12. After thirty minutes, turn the RO OFF, disconnect both hoses from the Disinfection Ports, and carefully allow them to drain back into the jug.
13. Remove the end of the Product Water line from the jug and place it in the drain.
14. OPEN the Water Supply Valve.
15. OPEN the Disinfect Valve.
16. Turn the RO ON, turn the High Conductivity alarm ON, and rinse the machine for **15** minutes. Do not mute the Poor Water Quality alarm. It should go off by itself after two or three minutes. If it does not, cleaning solution is not being rinsed.
17. While the machine is rinsing, discard the used solution inside of the Cleaning/Disinfection Jug and flush the discarded solution down the drain with plenty of tap water.
18. When the 15-minute rinse is complete, rinse the jug with RO water and prepare the base solution.

WARNING! Wear protective clothing and handle the cleaning solutions carefully.

Preparing the Base Solution:

19. After the 15 minute rinse, place the Cleaning/Disinfection Jug on the paper towels and fill it to the 8-Liter mark with RO water. Add 110 ml of 1N NaOH to the water in the Cleaning Jug.
20. Repeat steps 4 through 18 using the base solution, and then proceed to the next step.
21. Turn the RO ON, turn the High Conductivity alarm ON, and rinse the machine for **30** minutes. Do not mute the Poor Water Quality alarm. It should go off by itself after two or three minutes. If it does not, cleaning solution is not being rinsed.
22. After the 30 minute rinse, hold a strip of pH Test Paper under the stream of water coming from the Product Water Line. Compare the strip to the color chart on the container and if the test indicates the pH is less than 9, continue to the next step.

If the pH is 9 or greater, continue rinsing and testing every five minutes until it is less than 9.

23. Thoroughly wipe the dialysis machine's Supply Line with an alcohol swab and connect it to the RO.

24. Thoroughly rinse the Disinfection Jug with purified water.

25. Return the machine to service and document the disinfection.

E. Long-Term Machine Storage:

Storage in Bacteriostatic High pH/HydroBLAST Solution: Anytime the MD-100 is to be placed in storage for a period of up to 7 days, it should first be disinfected and rejuvenated, such as is achieved with sequential STEP 1/STEP2 treatments of the RO module (See Membrane Disinfection/Rejuvenation, Section VI.D.1). For storage periods > than 7 days, it is recommended that the operator complete the cleaning procedure outlined above and then load the machine's hydraulic system with 10% HydroBLAST solution (100 grams per liter of RO product water in D/R Jug). While this solution is recirculating, the pH is adjusted upward to 10.5-11.0 units, using the STEP 2 Solution. The machine is then turned off and the Jug detached.

After loading the MD-100 with high pH HydroBLAST solution, the D/R Jug is detached from the machine and its contents (containing residual chemical) discarded