A. CLEANING PROCEDURE

To clean properly the MD-400 series, the D/R tank on the front of the machine must be filled with RO water. Be sure the product water is fully closed by turning the handle (Right Side) on the front of the machine clockwise all of the way. To fill the tank with RO water without shutting down the system, the "FILL" stage of the program must be activated. To activate the fill stage, the product water line MUST be connected to the right side of the machine (see fig 8). Return to the MENU SCREEN and select the "D/R MODE" button. This will only access the D/R screens. The first screen that will appear is a warning indicating that dialysis MUST be completed prior to initiating the

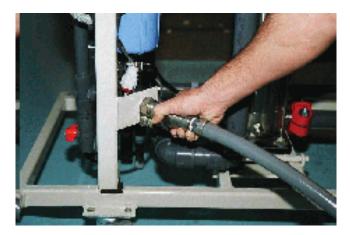


Fig 8

disinfection mode. If dialysis has been discontinued, press the "NEXT SCREEN" button. This will access the "D/R Fill Screen"

NOTE

If the D/R procedure is performed correctly, the procedure will log on the alarm log screen indicating that the conditions the machine will see during a D/R procedure have occurred. This is NOT an indication that the D/R procedure has been performed properly; only that the conditions that the machine will see during a D/R procedure have occurred.

B. D/R Tank Fill Procedure:

Close the valve located behind the pump



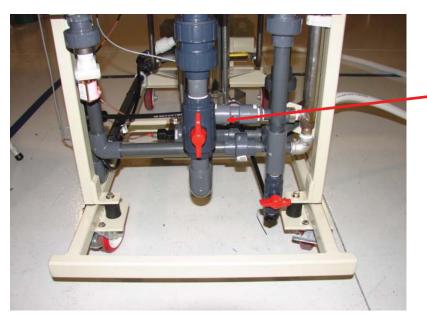
Normal Run Position



D/R Cleaning Position

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Press the "FILL" Button and the "POWER" button on the touch screen. This will access the D/R Fill program and begin to fill the D/R tank on the front of the machine. Open the D/R Tank Valve while the tank is filling



D/R Tank Valve

Once the tank is full, the system will automatically start the D/R program used to clean and disinfect the machine. When this occurs, the picture of the tank on this screen will change colors. The level in the tank will stop rising and will begin to fall about 2", then remain stationary. The level in the tank should be stationary and the water recirculating inside of the machine. If the water is rising and falling in the tank, check the Recirc/Rinse button. The RECIR Mode should be displayed. You will need to repeat this procedure when completely finished with Step 1 to perform Step 2.

NOTE

If the conductivity display fails to go full scale, then a problem exists such as an air leak or the RO pump is operating at too high a pressure (e.g., > 60 psi) during recirculation phase of the cleaning. Call Isopure if conductivity does not go to full scale.

Step 1 Procedure:

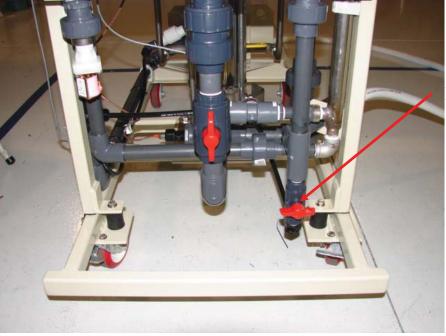
With the water recirculating inside of the machine and the tank on the front of the machine full of RO water, empty the entire contents of one (1) bottle of Step 1 (Pt No. CH 00401) into the tank located on the front of the machine. In the initial stage of the D/R recirculation phase, the product water conductivity display begins registering higher levels. Once chemical has passed through the machine, conductivity immediately goes full scale. This signifies that cleaning solution is now present on the product surfaces of the membranes.

Allow the solution to recirculate until the product water conductivity reaches full scale (100). Once the product water conductivity reaches full scale, check the pH of the solution in the tank. The target pH for Step 1 is 1-2. If the solution is within range, allow it to recirculate for 7-10 minutes and check the pH of the solution again. If the pH is greater than 2, add another ½ bottle of Step 1 and continue dwell time. After a dwell time of 7-10 minutes, check the pH of the solution again. If the pH is in the range of 1-2, add one bag (1) of Hydro*BLAST* Enhancer (Pt. No. CH30001). Allow the machine to recirculate for an additional 7-10 minutes. After the completion of the dwell time, press the "RECIRC" button. The button will change from "RECIRC" to "RINSE" and the tank on the front of the machine will begin to rise and fall. Continue the rinse procedure until the product water conductivity and the pH have returned to a normal range. Depending on the supply pH, this could take several minutes.

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Tank Drain Procedure:

Once the product water conductivity and the pH have returned to a normal range, the machine has completed the rinse out procedure. Next, drain the contents of the tank and perform the Step 2 procedure. Place the RO back in the RECIRC mode by pressing the "RINSE" button. (To expedite the tank drain procedure, stop the rinse procedure when the tank is at its lowest level) Turn the "POWER" button off. The RO will stop running. Press the "NEXT SCREEN" button to access the Tank Drain screen. Press the "TANK DRAIN" button, this will access the Tank Drain program, a box will appear in the upper right hand corner of the screen indicating that the tank drain program is activated. Open the valve located on the right hand side of the machine to drain the tank. Once the tank is completely empty usually indicated by a "gurgling" sound from the tank.



D/R Tank Drain Valve

The system will drain the remaining contents of the tank. Once the entire contents of the tank have been drained, press the "TANK DRAIN" button again and close the drain valve; the box in the upper right hand corner will disappear. Press the "D/R FILL SCREEN" button and return to the D/R tank fill screen. Be sure to close the tank drain valve located on the lower right side of the tank.

Repeat B - D/R Tank Fill Procedure for Step 2.

Step 2 Procedure:

With the water recirculating inside of the machine and the tank on the front of the machine full of RO water, empty the entire contents of one (1) bottle of Step 2 (Pt. No. CH 00402) into the tank located on the front of the machine. In the initial stage of the D/R recirculation phase, the product water conductivity display begins registering higher levels. Once chemical has passed through the machine, conductivity immediately

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goes full scale. This signifies that cleaning solution is now present on the product surfaces of the membranes.

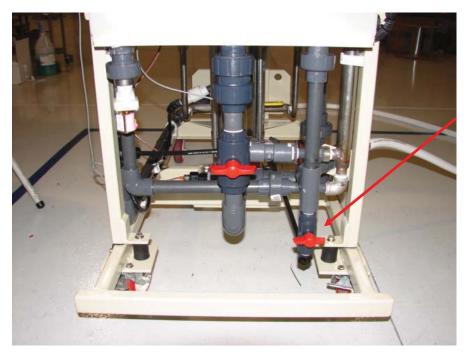
Allow to recirculate until the product water conductivity reaches full scale (100). Check the pH of the solution in the tank once the conductivity has reached full scale. The target pH for Step 2 is 10-12. If the solution is within range, allow to recirculate for 7-10 minutes. If the pH is less than 10, add another ½ bottle of Step 2 and continue dwell time. After the dwell time of 7-10 minutes, check the pH again. If the pH is in the range of 10-12, add one bag (1) of Hydro*BLAST* Enhancer (Pt. No. CH 30001). Allow the machine to recirculate for an additional 7-10 minutes, then press the "RECIRC" button. The button will change from "RECIRC" to "RINSE" and the tank on the front of the machine will begin to rise and fall. Continue the rinse procedure until the product water conductivity and the pH have returned to a normal range. Depending on the supply pH, this could take several minutes.

NOTE

It is common for water temperature to increase up to 20 F during the D/R procedure. This temperature increase, in addition to the cleaning agents will help disinfect the machine.

Tank Drain Procedure:

Once the product water conductivity and the pH have returned to a normal range, the machine has completed the rinse out procedure. Place the RO back in the RECIRC mode by pressing the "RINSE" button. (To expedite the tank drain procedure, stop the rinse procedure when the tank is at its lowest level) Turn the "POWER" button off. The RO will stop running. Press the "NEXT SCREEN" button to access the Tank Drain screen. Press the "TANK DRAIN" button, this will access the Tank Drain program, a box will appear in the upper right hand corner of the screen indicating that the tank drain program is activated. Open the valve located on the right hand side of the machine to drain the tank. Once the tank is completely empty usually indicated by a "gurgling" sound from the tank.



D/R Tank Drain Valve

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The system will drain the remaining contents of the tank. Once the entire contents of the tank have been drained, press the "TANK DRAIN" button again; the box in the upper right hand corner will disappear. Press the "D/R FILL SCREEN" button and return to the D/R tank fill screen. Be sure to close the tank drain and the D/R tank valve located underneath the D/R tank.

Press the "MAIN SCREEN" button to return to main screen and select the "RUN MODE" button to place the RO back to normal run mode.

NOTE

Isopure cannot guarantee membrane quality beyond a one-month (four weeks) storage period. If longer storage is required, then the RO should be taken out of storage, operated using pre-treated, carbon-filtered water for a few hours then returned to storage, after repeating a complete D/R procedure and place the machine back into storage solution. Isopure recommends that membrane function be tested and compared to its pre-storage state.

NOTE

THE FREQUENCY OF THE CLEANING PROCEDURE MUST BE DETERMINED BASED ON CONTINUOUS CULTURE RESULTS AND RECOMMENDATIONS FROM THE NEPHROLOGISTS ON STAFF. TYPICAL DISINFECTIONS CAN BE ONCE PER MONTH HOWEVER MORE FREQUENT DISINFECTIONS MY BE REQUIRED IF CULTRUE RESULTS WARRANT. LESS FREQUENT DISINFECTIONS MAY BE JUSTIFIED BASE ON CULTURE RESULTS AND RECOMMENDATIONS FROM THE NEPHROLOGISTS.

D/R CLEANING AND DISINFECTION LOG

Device Serial Number:							
Date							
<u> </u>							
Supply pH							
Supply Cond							
Temperature							
Pre-D/R							
Product Flow							
Product Cond.							
Feed psi							
Drain Flow							
Supply pH							
D/R Cleaning Procedure							
# Bottles of							
Step 1							
# Bottles of							
Step 2							
Other							
Chemicals							
Post D/R							
Product Flow							
Product Cond.							
Feed psi							
Drain Flow							
Comments:							
Signatura							