

**Mar Cor Purification
MILLENNIUM HX® REVERSE OSMOSIS UNIT
Operation and Maintenance Manual**



Trademarks

MILLENIUM HX[®] is a registered trademark of Mar Cor Purification

MINNCARE[®] HD is a registered trademark of Medivators Inc.

Viton[®] is a registered trademark of E.I. Du Pont De Nemours And Company

Liqui-Clean[™] and Biosan[™] are registered trademarks of GE Osmonics, Inc.

Memstor[™] is a trademark of King Lee Technologies

This page intentionally left blank.

TABLE OF CONTENTS

<u>CHAPTER 1: GENERAL INFORMATION</u>	<u>1-1</u>
1.1 The Manual	1-3
1.2 General Notes, Cautions and Warnings	1-3
1.3 Applications	1-7
1.4 Intended Use	1-7
1.5 Contraindications	1-7
1.6 Environmental Considerations	1-8
1.6.1 Power	1-8
1.6.2 Water	1-8
1.6.3 Drain	1-8
1.6.4 Water Purity	1-9
1.6.5 Temperature	1-9
<u>CHAPTER 2: INSTALLATION AND INITIAL SYSTEM START-UP</u>	<u>2-1</u>
2.1 Installation Considerations	2-3
2.2 Installation Procedures	2-3
2.3 Product Water AAMI Analysis Procedure	2-13
<u>CHAPTER 3: SYSTEM OPERATION</u>	<u>3-1</u>
3.1 Daily Start-Up	3-3
3.2 Shut-Down Procedure	3-6
3.3 Disinfection Indications	3-7
3.3.1 Heat Disinfection Procedure (Single Heat)	3-8
3.4 System Storage	3-11
3.4.1 Storage Heat Procedure	3-12
<u>CHAPTER 4: SCREEN OPERATION AND SPECIFICATIONS</u>	<u>4-1</u>
4.1 Theory of Operation	4-3

4.2 Fluid Components.....	4-3
4.2.1 Solenoid Valves.....	4-4
4.2.2 Check Valves	4-4
4.2.3 High-Pressure Pump (HPP)	4-5
4.2.4 Level Switches (L1, L2 and L3).....	4-5
4.2.5 RO Membrane Assembly (ROMA)	4-5
4.2.6 Feed Port	4-5
4.2.7 Product Port.....	4-5
4.2.8 Waste Port	4-5
4.2.9 Product Return Port	4-5
4.2.10 RO Feed Water Conductivity Sensor (WP1)	4-6
4.2.11 Product Water Conductivity Sensor (WP2)	4-6
4.2.12 RO Feed Water Pressure Sensor (PT1)	4-6
4.2.13 Pump Outlet Pressure Sensor (PT2).....	4-6
4.2.14 Product Water Pressure Sensor (PT3)	4-6
4.2.15 Pressure Regulator (PR)	4-6
4.3 System Operation Controls.....	4-7
4.4 Alarm Screens	4-20
4.5 Optional Equipment.....	4-22
4.5.1 Pretreatment Cart.....	4-22
4.5.2 Carbon Filter Tanks	4-22
4.5.3 Carbon Block	4-22
4.5.4 Softeners	4-23
4.5.5 Dealkalizers.....	4-23
4.6 Specifications	4-24
4.6.1 RO Feed Water Requirements	4-24
4.6.2 Flow Rates	4-25
4.6.3 Electrical Requirements	4-25
4.6.4 Dimensions	4-25
4.6.5 Membrane Performance Characteristics.....	4-25
4.6.6 Environmental Requirement	4-26
4.6.7 Approvals.....	4-26
4.7 Disposal	4-26
4.8 Electromagnetic Interference	4-27
4.9 Service Assistance.....	4-31
4.10 Return Materials Authorization (RMA) Procedure.....	4-31
4.11 Symbols and Abbreviations	4-32

CHAPTER 5: ROUTINE MAINTENANCE5-1

5.1 Routine Maintenance.....	5-3
5.1.1 Per Treatment Day Maintenance	5-4
5.1.2 Weekly Maintenance.....	5-4
5.1.3 Monthly Maintenance	5-5
5.1.4 Quarterly Maintenance	5-5
5.1.5 Annual Maintenance	5-6
5.1.6 As Required	5-6
5.2 Specific Maintenance Procedures and Instructions	5-7
5.2.1 Leak Repair	5-7
5.2.2 Conductivity/Temperature Sensor Verification.....	5-9
5.2.3 Membrane Replacement	5-10
5.3 Cleaning Indications.....	5-12
5.3.1 Cleaning Procedure	5-13
5.4 Chemical Sanitization Procedure.....	5-19
5.5 Product Water Microbiological Testing	5-25
5.5.1 Product Water Culture Procedure.....	5-25
5.5.2 Endotoxin Testing Procedure.....	5-27
5.6 Chemical Storage Procedure.....	5-28
5.7 Auto Run.....	5-30

CHAPTER 6: TROUBLESHOOTING.....6-1

6.1 RO Fails to Run	6-3
6.2 RO Feed Pressure Alarm.....	6-3
6.3 Product Water Quality Alarm	6-4
6.4 This Unit Must Stand Upright Alarm.....	6-4
6.5 Product Water High Temperature	6-5
6.6 RO Feed Water Quality Alarm.....	6-5
6.7 Pump Pressure Alarm.....	6-6
6.8 Product Pressure High Alarm	6-6
6.9 Service Required Component Failure Detected	6-7
6.10 Product Flow Too Low	6-8
6.11 Product Flow Too High	6-9
6.12 Leaks.....	6-9

6.13 Low Percent Rejection.....	6-10
6.14 TDS/μS Value High	6-11
CHAPTER 7: DRAWINGS.....	7-1
7.1 Component Identification	7-3
7.1.1 Front View	7-3
7.1.2 Rear View.....	7-4
7.1.3 Electrical Right Side View	7-5
7.1.4 Electrical Left Side View	7-6
7.1.5 Membrane Assembly.....	7-7
7.1.6 Top Hydraulic View	7-8
7.1.7 Center Hydraulic View	7-9
7.1.8 Main Manifold	7-10
7.1.9 Lower Hydraulic View	7-11
7.1.10 Tank View	7-12
7.2 Flow Schematics	7-13
7.2.1 Run Mode	7-13
7.2.2 Divert to Drain.....	7-14
7.2.3 Heat/Chemical Purge.....	7-15
7.2.4 Heat/Chemical Recirculation	7-16
7.3 Electrical Diagram.....	7-17
7.4 Maintenance Schedule	7-18
CHAPTER 8: SPARE PARTS.....	8-1
8.1 Spare Parts List	8-3

Millenium HX RO System

CHAPTER 1: GENERAL INFORMATION

This page intentionally left blank.

1.1 The Manual

This manual has been prepared to provide the operator with information and instructions regarding the installation, use, maintenance and troubleshooting of the Mar Cor Purification Millenium HX Reverse Osmosis System.

CAUTION:

When used as a medical device, Federal law restricts this device to sale by or on the order of a physician. Per CFR 801.109 (b)(1).

The manual has been written in narrative form supplemented with schematics and drawings for clarification. The operator can perform most procedures mentioned in this manual. Any exceptions will be clearly identified by a qualifying statement.

1.2 General Notes, Cautions and Warnings

Words in **BOLD CAPITAL** letters are used to identify labels on the device and key safety or qualifying statements. A list of all symbols and abbreviations is located at the end of this chapter. This safety summary does not contain all of the safety statements in the manual. Other safety statements are included within the manual text and are enhanced and defined as follows:

NOTE:

Statements that provide further clarification.

CAUTION:

Statements identifying conditions or practices that could result in equipment or other property damage.

WARNING:

Statements identifying conditions or practices that could result in personal injury or loss of life.

WARNING:

Read this manual prior to operating or servicing this device. This manual must be read and understood and no deviations from the procedures shall be made. Keep this and other associated manuals for future reference and for new operators or qualified service personnel. A note sheet is provided at the end of each chapter for operators to make notations that may be valuable to other users.

WARNING:

Only chemicals listed in the manual may be used with the Millenium HX RO. Other chemicals may not be compatible with the materials of construction. When using chemical cleaners or sanitizers, ensure the system is properly rinsed prior to use for dialysis.

WARNING:

The selection of water treatment equipment for dialysis is the responsibility of the user and the product water should be tested periodically in accordance with AAMI and CSA standards.

WARNING:

This device will reach temperatures up to 180°F (82°C). Only appropriate heat resistant materials can be used for fluid pathways that are disinfected with hot water.

WARNING:

After installation and subsequent use, if any device in the water treatment system is changed or replaced, the user should conduct appropriate tests to ensure that the revised system meets the initial design criteria.

WARNING:

The product water quality is proportional to the RO feed water quality. The product water may not meet quality limits if RO feed water quality deteriorates significantly. The user is responsible for monitoring the RO feed water quality.

WARNING:

Carbon cannot be regenerated and must be replaced with new beds when exhausted or contaminated.

WARNING:

A suitable carbon filter should always be present as pretreatment for the RO in order to prevent chlorine/chloramine damage to the thin film RO membrane and harm to the patient. Mar Cor Purification strongly recommends the use of two carbon devices, used in a series configuration.

WARNING:

This RO can only operate in the vertical position. This machine has been equipped with a sensor that will prevent operation of the unit while lying horizontal. Damage to equipment may result if operated in the horizontal position.

WARNING:

Some settings are user adjustable. Entering the SETTINGS screen and/or adjusting any settings should only be done by properly trained personnel and according to facility policies and procedures.

WARNING:

Do not attempt to tamper with or perform any unauthorized modifications to the device including programming changes. Any unauthorized work on the device could cause damage to the equipment or harm to personnel if any safety features are circumvented.

WARNING:

While a water treatment system may produce water of sufficient quality to meet the requirements of AAMI and CSA standards, distribution of the water may degrade its quality to the point where it no longer meets the requirements of the above mentioned standards if the distribution system is not maintained appropriately.

WARNING:

DO NOT REMOVE COVERS OR PANELS: To avoid electrical shock hazard, do not remove covers or panels when power is supplied to the device. Do not operate the device when covers or panels are removed.

WARNING:

Connect this device to a proper ground connection in accordance with the National Electrical Code. **DO NOT** under any circumstances remove the ground wire or ground prong from any power plug. **DO NOT** use an extension cord with this equipment. Keep the surface under the RO free of water.

WARNING:

During operation of the equipment, position the RO so there is access to the power switch located on the back of the machine.

WARNING:

Do not, under any circumstances, remove any Caution, Warning or any other descriptive labels from the devices until the conditions warranting the label are eliminated.

WARNING:

To avoid fire or explosion, do not operate this device in an explosive environment or near flammable products.

WARNING:

Do not remove the back panel of the RO during operation. System is under pressure during operation. Only remove panel when RO is turned OFF.

WARNING:

To avoid physical and/or equipment harm, move the RO by using both handles at all times.

CAUTION:

Do not cover or enclose the RO during operation to ensure the unit properly dissipates heat.

CAUTION:

The input water quality to the RO must meet the National Primary Drinking Water Standards of the United States Environmental Protection Agency (EPA) or Canadian Federal and Provincial guidelines governing drinking water in Canada. If the input water does not meet these standards, the RO may not produce water that meets AAMI and CSA standards.

NOTE:

Use proper wiring and connection methods to satisfy hospital electrical codes.

NOTE:

Use proper water and drain connections to prevent contamination of the RO and danger to the patient. The Product/Return Ports are male quick disconnect to prevent mix up of connection ports.

NOTE:

The Millenium HX RO's hot water disinfection process is effective in reducing at least 99.9% of an introduced bacteria load of *Pseudomonas aeruginosa* under normal operation conditions.

NOTE:

Clean the HMI display screen as necessary with an alcohol based fluid and a soft towel as required to maintain the screen's cleanliness.

NOTE:

This device does not supply hot water to disinfect hemodialysis machines.

1.3 Applications

The Millenium HX Reverse Osmosis (RO) System is designed to purify water by forcing water through a semi-permeable RO membrane. Water purified by reverse osmosis has had approximately 95% of the dissolved inorganic contaminants and approximately 99% of all microorganisms, pyrogens, particulates and organics with a molecular weight greater than 300 removed. The quality of the purified water, referred to as product water or permeate, depends on the quality of the RO feed water and normally is equal to or exceeds standards set forth by AAMI and CSA for water treatment equipment hemodialysis applications. Refer to Technote 103 for AAMI and CSA Product Water Quality Standards.

1.4 Intended Use

The Mar Cor Purification Millenium HX Portable Reverse Osmosis Water Purification System is intended to be used as dialysis accessory to produce water through reverse osmosis for use with hemodialysis equipment.

The Millenium HX can be connected to hemodialysis equipment used in hospitals, clinics and in home environments, in conjunction with the appropriate pre and post treatment units, as a part of a water treatment system designed to meet current AAMI and Federal (US.) Standards.

1.5 Contraindications

WARNING:

This system is not designed, sold, or intended for use in producing water for injection.

Mar Cor Purification systems are not intended to be used outside of the device specifications and limitations, as outlined in this manual and other related material. If this equipment is used in a manner not specified by the operating instructions, the protection provided by the equipment may be impaired.

1.6 Environmental Considerations

Prior to the installation of the Millenium HX RO, it will be necessary to provide utilities and create an environment suitable for the trouble free operation of the RO and its accessories.

WARNING:

Ordinary pipe dope must be avoided since it may leach objectionable and potentially dangerous impurities into the water.

CAUTION:

It is necessary to keep the RO from freezing to prevent serious damage to the RO.

CAUTION:

The use of mobile telephones or communication equipment in the vicinity of the Millenium HX could adversely influence the performance of the machine. See specification in Section 4.8.

CAUTION:

Millenium HX needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Operators and Service Manuals.

1.6.1 Power

The RO operates on 115/230 VAC single-phase power. Histories of power failure, power surges, and low line voltages should be noted and reported to the manufacturer or their agent as they may create adverse conditions for the operation of equipment.

1.6.2 Water

Reverse osmosis systems require a reliable water source (rapid pressure fluctuation of greater than 10 PSI should be avoided to prevent damage). The RO needs a minimum of 20 PSI pressure at a minimum flow of 1.5 gallons per minute. It is important that water is flowing at the design flow rate when testing water pressure rather than reading static pressure. Inlet water must contain less than 0.1 ppm free chlorine.

1.6.3 Drain

A drain outlet is required for the RO. The drain must have a minimum capacity of 2 gallons per RO per minute of continuous flow for as long as and as often as the RO is operating.

1.6.4 Water Purity

Plumbing materials can significantly contribute to the contamination of the water. Metallic pipes (with the exception of 316 stainless steel) must be eliminated once the purification process has begun. Schedule 40 or 80 PVC pipes, polypropylene, PVDF, and other FDA recommended materials are suitable for most grades of purified water. Care must also be exercised in the choice of a thread sealant.

1.6.5 Temperature

The RO is normally connected to a cold water supply. The performance specifications of the RO are based on 77°F (25°C) RO feed water temperature. The Millenium HX contains a VFD motor that will increase the pump speed when operating on cold water helping to increasing the amount of product water produced.

NOTES:

Millenium HX RO System

**CHAPTER 2:
INSTALLATION AND
INITIAL SYSTEM START-UP**

This page intentionally left blank.

2.1 Installation Considerations

1. Select a location for the RO near the required utilities and dialysis equipment.
2. The RO requires 115 or 230 VAC for operation depending on model.
3. The RO requires nominally 1.5 GPM water at 20 PSI. Warmer RO feed water (greater than 77°F (25°C)) will produce more permeate (product water), and will consume more water. Inadequate RO feed water flow and pressure may cause the RO to shut down due to low pressure. The water may also require some pretreatment to ensure maximum performance and suitability. Mar Cor Purification recommends that RO feed water be chlorine/chloramine free and solids above 5 microns in size to be filtered out.
4. A free flowing drain with a minimum capacity of 2 GPM is required for the RO.
5. Back flow prevention may be required in accordance with local codes.
6. Special connections may be needed to connect to the facility water supply. Connections vary with different facilities.

2.2 Installation Procedures

CAUTION:

If a carbon tank is present on the Millenium HX RO, the carbon tank must be completely rinsed of all carbon fines and ash before connecting to the RO. Otherwise, irreparable damage to the TF membrane and RO internals will result (refer to Carbon Tank O&M Manual).

WARNING:

The Millenium HX RO is stored with Storage Solution from the factory. Follow all Material Safety Data Sheet (MSDS) guidelines that are included with the RO.

CAUTION:

Supply water with a pH above 8.5 and containing chloramines will adversely affect the operation of the RO membrane.

CAUTION:

Any pre-treatment device supplying water to the RO must be ready for use prior to operating the RO.

NOTE:

The Product Water and the Product Return connections on the RO are a male quick disconnect fitting. All other quick disconnect fittings on the cabinet are female disconnects to prevent cross connection. In addition, the RO fittings are color coded. Green is RO feed water, red is RO waste water and the RO product and return connectors are white.

1. Unpack the RO and inspect the contents for the following;
 - Millenium HX RO
 - Manual (this document)
 - Hose Kit
 - Y-Connector with adapter hose and sample port
 - Power Cord
 - Chemical Bottle
 - AAMI analysis kit
2. Inspect the RO for damage. When removing the RO from the packaging, you should use 2 people to lift out of the box.

NOTE:

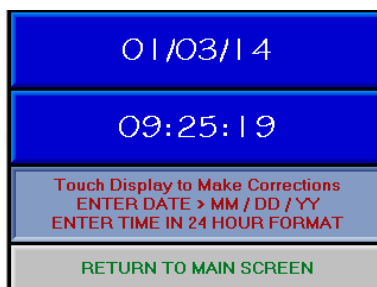
If using pre-treatment equipment, refer to the specific O&M manual for proper placement and hose connections.

3. Connect the RO feed inlet hose connector to the water supply, and the QD end to the "Feed" connection on the RO. This is a green quick disconnect fitting on the RO.
4. Connect the waste water line to the red "Waste" QD fitting on the back of the RO and route to drain in accordance with the local plumbing code.
5. Assemble the product line. Take the two ¼" silicone lines from the hose kit. Place hose clamps over the tubing and install the Y connection. Secure the hose clamps to secure the line on the Y connection. On the product side of the line, cut the silicone tubing a few inches back from the Y connector. Place the hose clamps on the tubing ends. Install the sample port and secure the hose clamps. Connect the product line between the Product and the Return connector on the back of the RO. The Y connector will be connected to the mating item on the dialysis machine. Do not connect the Y connector to the hemodialysis machine until the completion of this installation procedure.

6. Plug the power cord into a 115 VAC (230 VAC) grounded outlet and reset the GFCI if necessary (60 Hz RO only). Do not use an extension cord or an ungrounded adapter.
7. Turn the water supply to the RO ON.
8. Turn ON the power module switch located on the rear of the RO. The touch screen will illuminate and read PLEASE WAIT as the RO starts up. Once the startup is complete, navigate to the MAIN Screen by pressing EXIT if necessary.



9. Verify the time and date on the RO. If they need to be adjusted, touch in the area of the time and date and follow the on screen instructions to adjust. The time does not automatically adjust for day light savings.

**NOTE:**


The RO is ready for initial startup.

NOTE:


The RO SETTINGS have been set at the factory. It may be necessary to adjust the Product Quality Alarm set point and the Membrane Performance Monitor Setting to allow the RO to operate without interruption.

10. Press the RUN button.



11. The RO will start in a flush and divert mode where the product water is diverted to the internal tank. The machine will operate in this flush mode for a user specific time (adjustable from 30-300 seconds) indicated on the run screen. The RO will not come out of divert mode until the flush is complete and the TDS/ μ S is below the alarm set point. The  symbol in the lower right hand side of the display indicates the machine is in divert mode. If water quality does not improve as the RO is operating, the RO may shutdown because of product water quality. If this occurs, clear the alarm screen and press RUN again.



12. After the RO startup flush is complete and the product water is below the alarm set point, the divert valve will open and start supplying product water through the product water line. The  symbol in the lower right hand side of the display indicates the machine is supplying water to the product water line.



13. Let the RO run for 15 minutes or until the percent rejection and TDS/ μ S values have stabilized.

WARNING:

Ensure that TDS/ μ S and membrane performance (% rejection) are normal for the regions water quality. Consult your facility physician. An appropriate AAMI analysis and bacteria/Endotoxin test meeting AAMI or CSA requirements of the product water must be obtained and interpreted before using the RO unit for hemodialysis treatment, refer to Section 2.3 "Product Water AAMI Analysis Procedure" and Section 5.5.1 "Product Water Culture Procedure".

14. Once the RO has achieved a steady state, note the percent rejection, and product TDS/ μ S (Run Screen), and the Combined Pump Feed Water Condition TDS/ μ S (V-1 screen). You will need these values when setting the operating parameters in the SETTINGS screen.
15. After a minimum of 30 minutes of run time, perform a Single Heat disinfection of the RO (steps 17 through 25).
16. From the RUN screen, press and hold the STOP button for 2 seconds. The RO will continue to operate for 60 seconds in a flush mode. When in flush, the RO RUN button is not visible until the process is complete.

NOTE:

When in stop flush, the message STOP FLUSH ACTIVE is visible on the screen indicating that the RO is flushing the membrane with low TDS/ μ S water.



17. Press and hold the blue banner at the top of the screen that states PRESS AND HOLD FOR CLEANING MODES to enter the Chemical or Heating Operations selection screen.



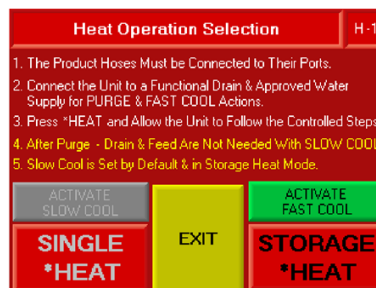
18. Review the instructions on the screen and press and hold the HEAT PROCESS SELECT button.



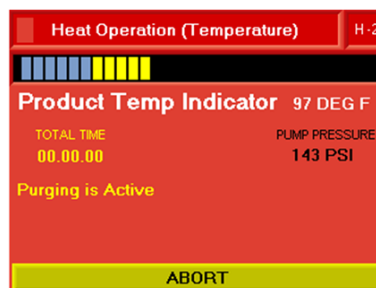
WARNING:

During heat disinfection, the RO heats the internal water to approximately 176°F (80°C). To avoid injury, do not touch the RO connections during the heat cycle.

19. Press the ACTIVATE FAST COOL cooling method. Default cooling method is Slow Cool. Review the instruction on the display. Verify all instructions have been completed. Once verified, press and hold the SINGLE HEAT button.

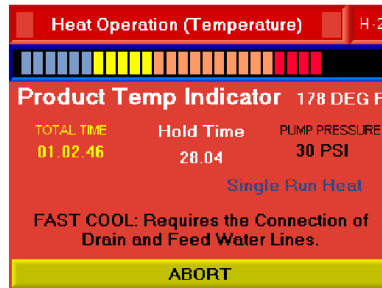


20. The machine starts to purge, filling the internal tank to the proper level with product quality water.

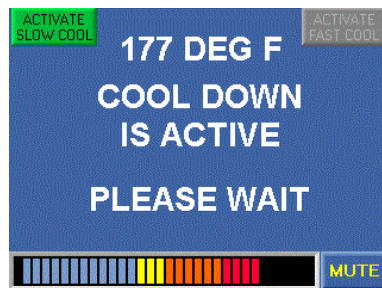


21. Once the purge process is complete, the RO's internal water is circulated and heated to a target temperature of 176°F (80°C).

22. Once the target temperature is achieved, the system will maintain the temperature for 30 minutes by automatically cycling the heater modules ON/OFF.



23. After the system is held at the target temperature for 30 minutes, the RO enters cool down. With ACTIVATE FAST COOL selected, the inlet solenoid cycles to introduce small amounts of RO feed water to slowly reduce the RO's temperature.



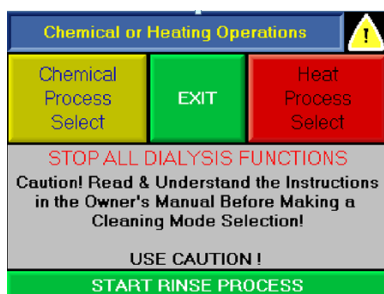
24. After the RO reaches 120°F (49°C), the RO will enter a POST HEAT RINSE. This will further cool and rinse the RO for a minimum of 5 additional minutes.



25. After the POST HEAT RINSE is complete, the RO is ready for normal use. Press the EXIT button to return to the CHEMICAL OR HEATING OPERATIONS screen.



26. Press EXIT to return to the Main Screen.



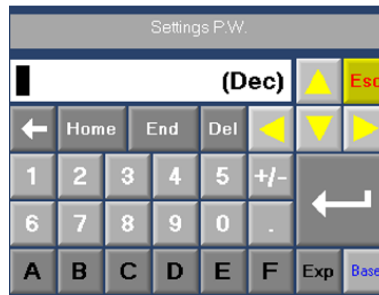
NOTE:


Entering the SETTINGS screen and adjusting any setting should only be done by properly trained personnel and according to facility policies and procedures.

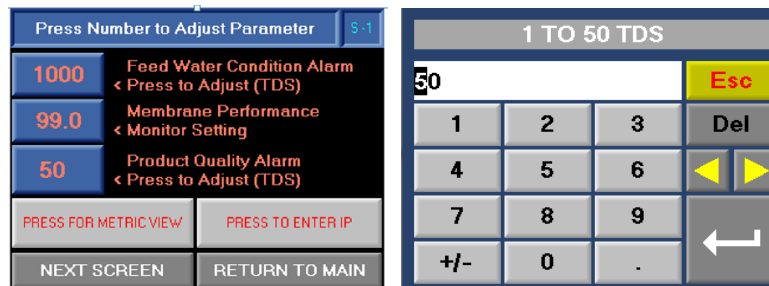
27. From the Main Screen, press SETTINGS.




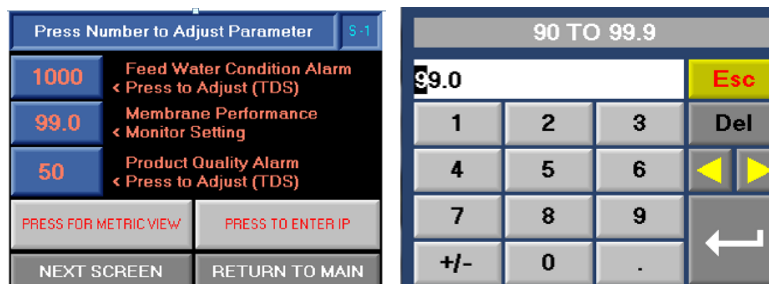
28. Enter a value of 999 and press  to access the alarm set point screens.




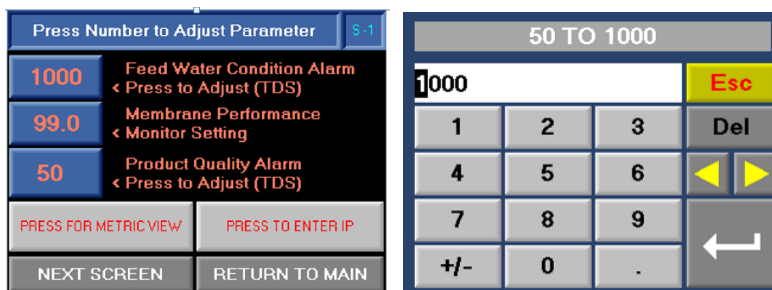
29. Press the PRODUCT QUALITY ALARM. Once in the set point screen, set the alarm set point per facility protocol or if no protocol exists, set at two times the steady state operating TDS (μ S). Once complete, press .



30. Press MEMBRANE PERFORMANCE and input the operational % Rejection noted in step 14. Once complete, press .



31. Press the Feed Water Condition Alarm. Set the RO feed water quality alarm 50 TDS/100 μ S above the steady state Combined Pump Feed Water Condition noted in step 14. If the Combined Pump Feed Water Condition is greater than or within 50 TDS/100 μ S of the alarm limits of 1000 TDS/2000 μ S, disable the alarm to prevent nuisance alarms. To disable the alarm, set the TDS setting to 1001 or conductivity setting to 2001 μ S. Once complete, press .



32. Press RETURN TO MAIN.
33. The RO product may be used in conjunction with hemodialysis treatment equipment only after obtaining test results, which validate compliance with accepted standards.
- AAMI or CSA Product Water Panel
 - Microbiological Culture (colony count) results
 - Endotoxin (pyrogen) level testing
34. **The Millenium HX RO is now ready for use.**

2.3 Product Water AAMI Analysis Procedure

In order to ensure that the RO is performing at or above AAMI (Association for the Advancement of Medical Instrumentation) or CSA (Canadian Standards Association) Standards, it is necessary to perform a Water Quality Analysis test. For new units, the RO must be operated (rinsed to drain) for at least 30 minutes after readings have stabilized before taking a sample to ensure that the membranes are free of preservative or other contaminants, which would invalidate the test.

WARNING:

There are many documented clinical risks in using less than AAMI/CSA Standard product water (refer to Technote 103, "Hemodialysis Water Quality Standards").

NOTE:

Follow the procedures recommended by your water quality testing laboratory if they vary from the following steps.

NOTE:

Using the provided sample container, laboratory turn-around time for results is 7-10 days after receipt of sample at lab. If faster service is required, expedite shipping (overnight courier) and/or expedite the sample test results. Call Customer Service with a Purchase Order PRIOR to sending the sample.

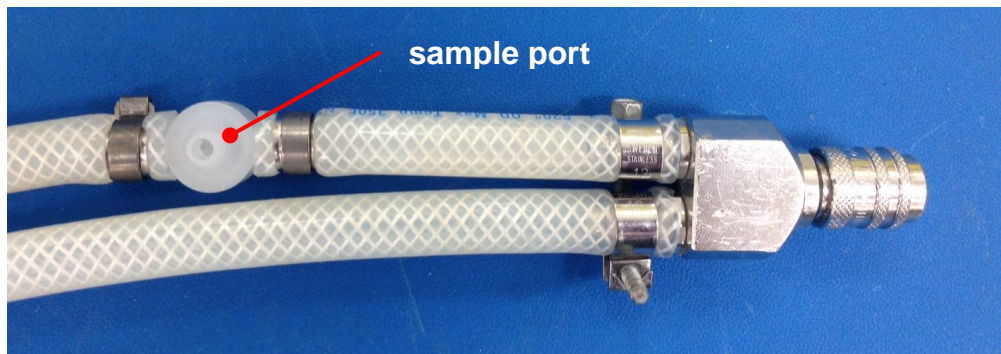
NOTE:

Total chlorine must be measured on-site. Tests for chlorine/chloramine (total chlorine) are not typically reported on the AAMI Analysis. Chlorine and chloramine dissipate from the water sample over time and reported results will be inaccurate.

Materials Required:

- Water Sampling Kit
 - Sterile Gauze
 - Tape
 - Syringe (two required – 30 mL minimum)
 - Container (such as a small bucket)
1. Ensure that all pre-RO devices are operating correctly and their performance verified by the appropriate testing.
 2. Connect the RO to the required utilities (RO feed water, drain, and power).

3. Operate the RO with product line connected between the product and return ports on the RO and waste flow to drain for at least 15 minutes (minimum 30 minutes for new machine or after membrane replacement), after the product water quality has stabilized and before drawing the water sample.
4. Using alcohol, wipe the sample port and allow to air dry. Using aseptic technique, insert the male luer end of the first sterile/pyrogen free syringe into the port, withdraw the syringe plunger to the maximum sample volume. Remove and discard the syringe.



5. Using the second sterile/pyrogen free syringe draw a sample by inserting the male luer end into the port and withdraw the appropriate sample as required for your laboratory. Aseptically transfer the sample to the lab supplied container and cap the specimen container immediately.
6. Label the specimen appropriately with:
 - Test to be performed - "AAMI"
 - Sample source - product water/RO, machine serial number and room location
 - Time and date sample obtained
 - Person who obtained specimen
 - Any other pertinent information or procedures your facility or lab requires
7. Fill out the laboratory requisition form. Ensure the requisition form has, at a minimum, information to identify the facility or location of the RO, the serial number or facility equipment number to ensure which RO was tested and the name, phone number and address of whom to contact.
8. Place the bottle and the completed requisition in the pre-addressed mailer and mail it directly to the laboratory.

NOTES:

This page intentionally left blank.

Millenium HX RO System

CHAPTER 3: SYSTEM OPERATION

This page intentionally left blank.

3.1 Daily Start-Up

WARNING:

Verification of the absence of all sanitizers, cleaners, disinfectants and chlorine/chloramines must be performed before RO product water is used for any patient related uses. At a minimum, carbon pretreatment should be used to remove chlorine/chloramine. Chlorine/chloramine tests should be conducted after the RO has operated for a minimum of 15 minutes.

CAUTION:

Any pre-treatment device supplying water to the RO must be ready for use prior to operating the RO.

1. Connect the RO unit to the required utilities (RO feed water, drain line, product line and power).

WARNING:

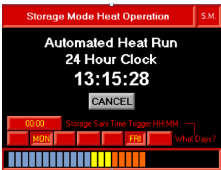
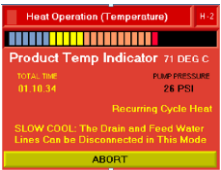
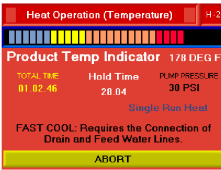




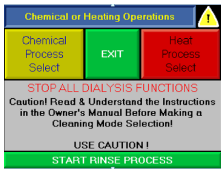

If blending hot and cold water, an appropriate blending valve must be used and the temperature of the incoming water supply must be continuously monitored. The system is equipped with a high product water temperature alarm that will activate above 105°F (41°C).

NOTE:

Systems with blending valves usually have thermometers installed in the plumbing. Hand held thermometers or the displayed Product Water Temperature (V-1 screen) may also be used. The water temperature has a significant effect on the flow rate of the RO membrane (refer to Technote 113, "Temperature Correction Factor") and on the evaluation of the membrane needing to be cleaned. RO feed water temperature blending assemblies can be used on portable RO.


2. Ensure that all the valves in the water supply line to the RO are open.
3. Turn ON the main power module located on the rear of the RO (if not already on).

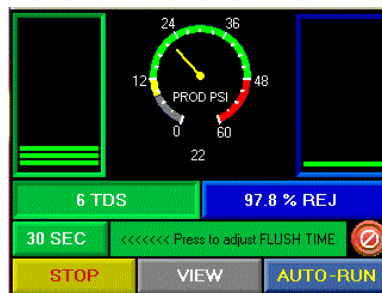
4. The screen that will appear will depend on how the RO was left after its last use. Use the table below to navigate the RO to the Main Screen.


Follow directions to the left of the displayed screen in chart below until you reach the Main Screen.			
Directions	Displayed Screen		
Press CANCEL or ABORT.			
Connect to RO feed water and drain (if not already connected). Press ACTIVATE FAST COOL if not already grayed out.			
Connect to RO feed water and drain (if not already connected). Press START. If button says RINSING no further action is required in this screen.			
Press EXIT.			
Proceed to next step.			

5. Press the RUN button.



6. The RO will start in a flush and divert mode where the product water is diverted internally to the storage tank. The machine will operate in this flush for the specified time indicated on the RUN screen. The RO will not come out of divert mode until the flush is complete and the water quality is below the alarm set point. The  symbol in the lower right hand side of the display indicates the machine is in divert mode.



7. After the RO startup flush is complete and the product water is below the alarm set point, the divert valve will open and start supplying product water through the product water line. The  symbol in the lower right hand side of the display indicates the machine is supplying water to the product water line.



8. Let RO run for 15 minutes from when the start button was pressed to ensure pre-RO devices are flushed. Test pre-RO devices to ensure they are operating within specifications.

9. Record data on a daily log sheet.

WARNING:

The RO should not be placed in service until data on the log sheets meet the minimum standards set at your facility.

10. The Millenium HX RO is now ready for connection to the dialysis machine (if not already connected).

3.2 Shut-Down Procedure

1. From the RUN screen, press and hold the STOP pushbutton for 2 seconds. The RO will continue to operate for 60 seconds in a shutdown flush. When in shutdown flush, the RUN button is not visible until the process is complete. The RO may be heat disinfected at this time.



NOTE:

If the RO is going to be off line for an extended period of time, Mar Cor Purification recommends that the RO be setup for storage heat disinfection. Refer to Section 3.4.1 "Storage Heat Procedure". The operator can also perform a single heat. Refer to Section 3.3.1 "Heat Disinfection Procedure (Single Heat)".

2. Turn off the inlet water supply.
3. Disconnect from the utilities and store the RO.

3.3 Disinfection Indications

DETERMINATION OF MICROBIAL CULTURING AND DISINFECTION FREQUENCY IS THE RESPONSIBILITY OF THE OPERATING FACILITY. The following is recommended for critical applications where bacteria and endotoxins are a major concern, such as for Hemodialysis.

Disinfection should occur when bacterial growth is above the limits set by the facility or when within 50% of the maximum allowable level. Routine disinfection at lower CFU counts will inhibit colonization of bacteria in the system and the distribution plumbing.

Rapid re-growth of bacteria following disinfection or excessively high colony counts, i.e., TNTC, may indicate a need for more aggressive intervention. Strategies such as increased frequency of disinfection/sanitization may be employed.

NOTE:

At a minimum, cultures should be taken prior to disinfection. To determine effectiveness, cultures can be taken pre and post disinfection.

3.3.1 Heat Disinfection Procedure (Single Heat)

Materials Required:

- Cleaning/disinfection log

NOTE:

Read and understand instructions before beginning procedure.

1. Connect the water inlet line to the water supply. Connect the waste line to a functional drain. Ensure that the product line is connected between the product and return ports on the RO. Turn the RO and water supply on.

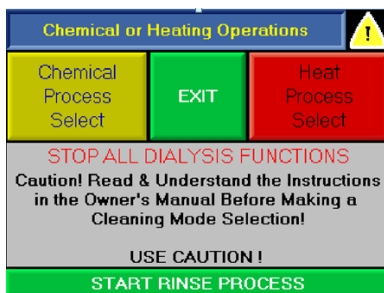
CAUTION:

Water to be used must be chlorine free or damage to the RO membrane may result.

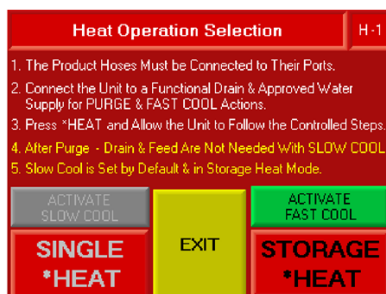
2. Press and hold the blue banner on the top of the Main Screen that says PRESS AND HOLD FOR CLEANING MODES.



3. Press and hold the HEAT PROCESS SELECT button.

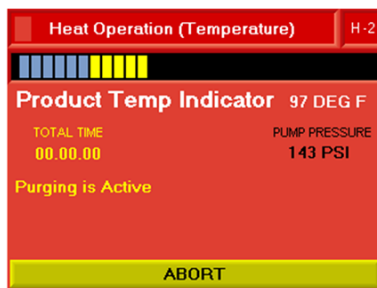


4. Follow the direction on the screen, then press and hold the SINGLE HEAT button. The ACTIVATE SLOW COOL is grayed out and set by default and the RO will cool down by convection, in addition it can be disconnected from the RO feed supply and drain after the completion of the purge step. If ACTIVATE FAST COOL is pressed the button will turn gray and the RO will introduce small amounts of RO feed water to cool the RO so it will be required to be connected to the RO feed supply and drain. A grayed out cooling method button means that the process will occur when cooling begins.

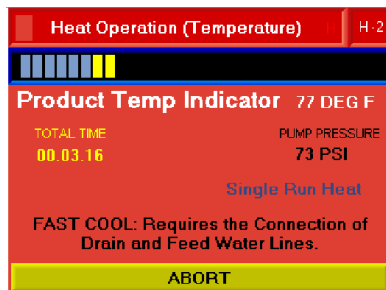

WARNING:

During heat disinfection, the RO heats the internal water to approximately 176°F (80°C). To avoid injury, do not touch the RO connections during the heat cycle.

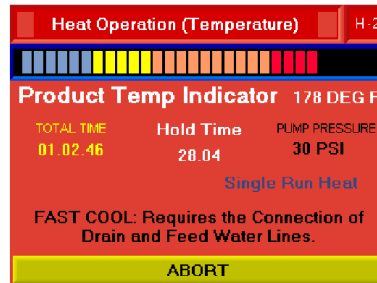
5. The machine starts to purge, filling the internal tank to the proper level with product quality water.



6. Once the purge is complete, the system starts to heat to 176°F (80°C). The RO will indicate the heat process selected and the cooling method that was activated.



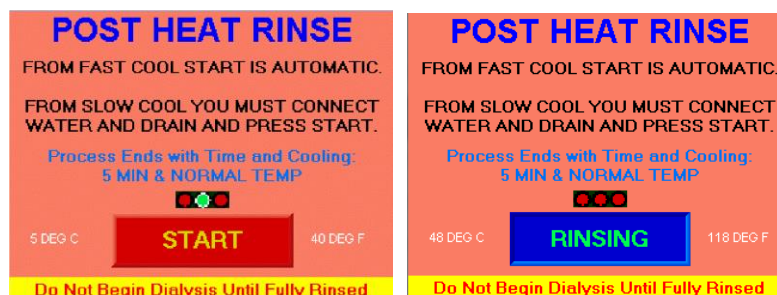
7. Once the product water temp reaches 176°F (80°C), the heaters cycle ON/OFF maintaining the system at temperature for 30 minutes. The hold timer will count down displaying the amount of heat hold time left in the cycle.



8. After the hold time is complete, the RO cools by convection or by introducing small amounts of RO feed water. This is dependent on the cooling method you have activated. When in Cool Down the operator can toggle between fast cool and slow cool. When the ACTIVATE SLOW COOL or ACTIVATE FAST COOL is grayed out, that indicates it is operating in that mode. To change, press the green screen button and it will change cooling mode to the one selected.



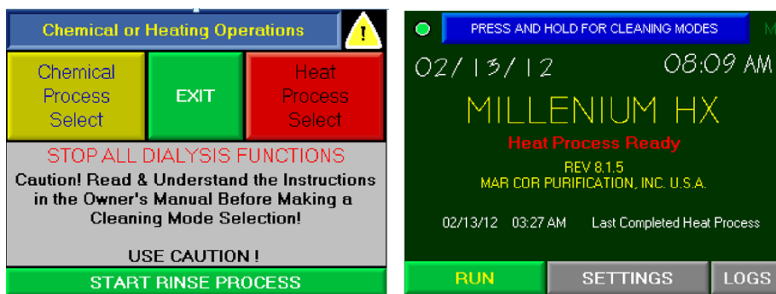
9. After the system cools to a temperature of 120°F (49°C), the screen moves to a POST HEAT RINSE screen. If the RO is in Fast Cool and water and drain are supplied, the machine will automatically start in POST HEAT RINSE. If the RO is in Slow Cool, the operator must connect the RO feed water and drain and press START to begin the post heat rinse.



10. After the POST HEAT RINSE is complete, the next screen shows that the heat process completed successfully. Press EXIT to move to the next screen.



11. Press EXIT to move to the Main Screen from the Chemical or Heating Operations selection screen.



NOTE:

To further verify that the heat process was completed, press the LOGS button on the Main Screen to confirm completion.

3.4 System Storage

This storage procedure has been established to store Millenium HX RO's. It is not recommended that a unit be dormant longer than 72 hours without disinfecting. An RO that has been left unused for more than 72 hours risks the possibility of colonizing bacteria and exceeding acceptable limits. A longer dormant period without disinfection is the responsibility of the operating facility. RO's to be stored should first be disinfected with one of the procedures in this manual. The RO should be stored in a location that would avoid freezing and excessive heat.

CAUTION:

MINNCARE HD is not acceptable for RO storage.

3.4.1 Storage Heat Procedure

Materials Required:

- Cleaning/disinfection log

NOTE:

Read and understand instructions before beginning procedure.

1. Connect the water inlet line to the water supply. Connect the waste line to a functional drain. Ensure that the product line is connected between the product and return ports on the RO. Turn the RO and water supply on.

CAUTION:

Water to be used must be chlorine free or damage to the RO membrane may result.

NOTE:

You can leave the RO in STORAGE HEAT for 30 days. If you require longer storage, you will need to connect the RO to utilities and flush the system for 15 minutes prior to putting the RO back into STORAGE HEAT.

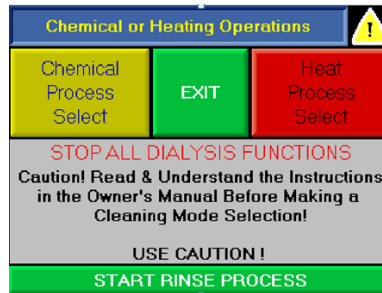
2. Press and hold the blue banner on the top of the Main Screen that says PRESS AND HOLD FOR CLEANING MODES.



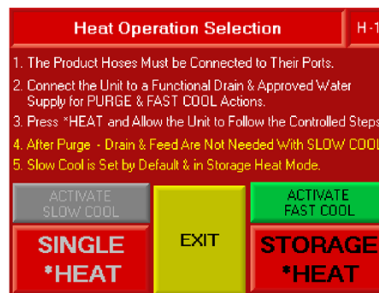
3. Press and hold the HEAT PROCESS SELECT button.

WARNING:

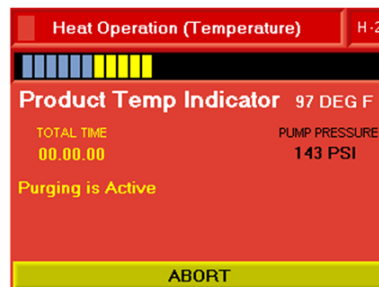
During heat disinfection, the RO heats the internal water to approximately 176°F (80°C). To avoid injury, do not touch the RO connections during the heat process.



4. Follow the direction on the screen then press and hold the STORAGE HEAT button. For STORAGE HEAT, the cooling method must be SLOW COOL.



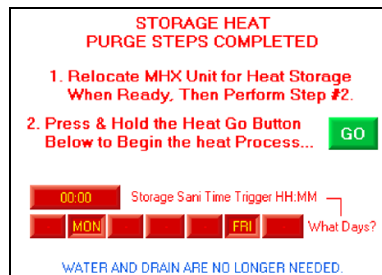
5. The machine starts to purge filling the internal tank to the proper level with product quality water.



6. Once the purge is complete, the RO will display the screen below. The operator can adjust the timing of the storage heat. To select the days of the week to disinfect, touch the appropriate day. If the day of the week is visible, the RO will heat disinfect on that day. To adjust the time of day the disinfection process starts, press the Storage Sani Time Trigger. This is a 24 hour clock.

NOTE:

The drain and RO feed water may now be disconnected (will not be needed again until process is canceled or aborted). If relocating, turn power off using the power switch and disconnect power cord from outlet. When located in new location, plug power cord into electrical outlet and turn the power switch on, the RO will return to the screen below.

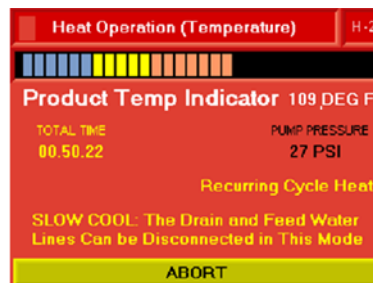


7. When GO is pressed the RO will immediately start a heat disinfection regardless of the current time or day of the week.

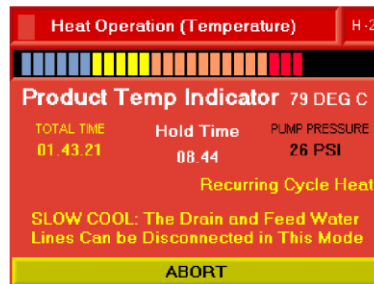
NOTE:

If the RO is turned off, unplugged, or power is disrupted at any point after GO is pressed and before the storage heat process is canceled or aborted, a new heat disinfection will be started when power is restored and the RO will continue to operate as described in the steps below.

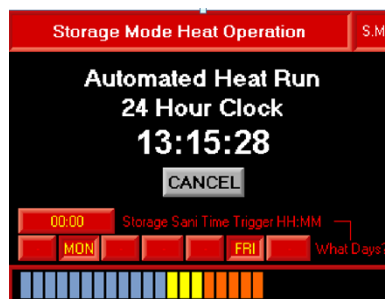
8. The RO will indicate the product water temp and total heat time.



9. Once the product water temp reaches 176°F (80°C), the heaters cycle ON/OFF maintaining the system at temperature for 30 minutes. The hold timer will count down displaying the amount of heat hold time left in the process.



10. After the hold time is complete, the RO cools by convection. In addition, the screen will display a 24 hour clock and the operator can adjust the days of the week to disinfect or adjust the time of day the disinfection process starts. The RO will perform heat disinfections (return to step 8) when the Storage Sani Time Trigger is equal to the current time displayed on the clock and the current day is visible on the screen.



11. The RO will repeat steps 8-10 until the operator presses CANCEL or ABORT on the screens shown in steps 8-10 above.

12. Once the CANCEL or ABORT button is pressed, the RO will exit from the Storage Heat and display one of the following screens depending on the product water temp.

NOTE:

The RO may be powered off, unplugged and relocated to a location where a drain and RO feed water are available. When power is returned the RO will continue to operate as described in the steps below.

- a. **If the RO is above 120°F (49°C):** the RO will enter a slow cool process. If the drain and RO feed water lines are connected, a FAST COOL can be activated by pressing the green button. When 120°F (49°C) is reached, the RO will proceed to the POST HEAT RINSE below.



- b. **If the RO is at or below 120°F (49°C):** the RO will enter the POST HEAT RINSE screen.

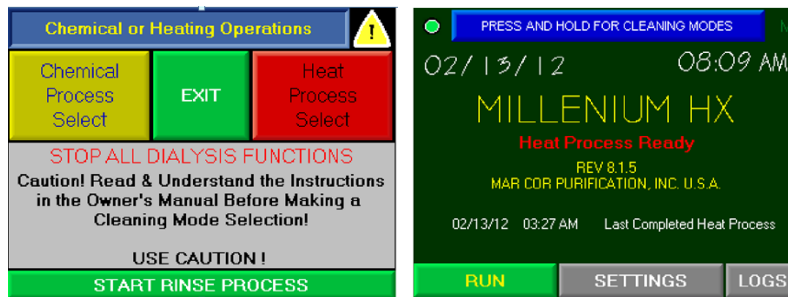


13. Connect the RO to water and drain (if not already connected) and press START to begin the post heat rinse.

14. After the POST HEAT RINSE is complete, the next screen shows that the heat process completed successfully. Press EXIT to move to the next screen.



15. Press EXIT to move to the Main Screen from the Chemical or Heating Operations selection screen.



NOTE:

To further verify that the heat process was completed, press the LOGS button on the Main Screen to confirm completion.

NOTES:

Millenium HX RO System

CHAPTER 4: SCREEN OPERATION AND SPECIFICATIONS

This page intentionally left blank.

4.1 Theory of Operation

The Millenium HX Portable Reverse Osmosis system (RO) is a fully cabinetized unit that purifies a given feed water (by way of reverse osmosis) for use in hemodialysis applications. The RO possesses monitoring for RO feed water pressure, RO feed water quality, pump outlet pressure, product water pressure, product water temperature, product water quality and membrane performance (percent rejection). The RO pump provides the pressure required to push water through the RO membrane. The fluid controls provide a means of managing flow rates and pressures. The following paragraphs detail the function of these fluid control components, which are used within the RO.

4.2 Fluid Components

The Millenium HX product water wetted components consist of the following materials.

Component	Material
Product Tubing	Nylon
RO Membrane Housing	304/316 SS
Plastic Fittings	Acetal or Polypropylene, Buna-N, 316 SS
O-rings/Gaskets	Viton [®] , & EPDM
Check Valve	316 Stainless Steel, Hastelloy, Viton [®]
Manifold Blocks	Acetal
Product Hose	Silicone
End Caps	Polypropylene
Solenoid Valves	300 & 400 SS, Glass filled Nylon, Silicon, 316SS, Viton [®] , Polypropylene
Pressure Transducer	316/316L Stainless Steel
Conductivity Probe	PTFE, 316 Stainless Steel, ABS
Element	Polyamide, Polysulfone, Vinyl

4.2.1 Solenoid Valves

Solenoids located inside the Millenium HX at various locations are used to direct fluid flow during the different operations steps during the operation of the RO.

- SV1 - Inlet water solenoid. It is used to control the RO feed water flow into the RO.
- SV2 - Located on the waste side of the membrane. During normal operation, this valve remains closed. During the heat disinfection and chemical processes, this valve opens to maintain the system at the required pressure during the process. In addition, it is open during the start and stop flushes. This valve also has an orifice hole to allow controlled flow of water through when valve is closed.
- SV3 - Product Divert Solenoid. During system startup, this valve will remain closed during the startup flush time and will not open until the RO is producing product water below the water quality set point. During the heat disinfection and chemical modes, this valve cycles to direct fluid throughout the system to ensure a proper disinfection/cleaning.
- SV4 - Pump Isolation Solenoid. Controls the pump's source of feed water. The feed source will be from the internal tank or from the RO feed.
- SV5 - Product Water Return Solenoid Valve. This valve provides backpressure during normal operation of the RO allowing it to supply product water at a pressure of approximately 30 PSI. During heat and chemical modes, this valve is open allowing full flow for proper operation.

4.2.2 Check Valves

- CK1 - Located on the waste side of the membrane and prevents the backflow of fluid into the membrane.
- CK2 - Located on the drain line and prevents the backflow of drain fluid into the system.
- CK3 - Located between the RO feed line and the drain line. It allows fluid from the waste line to be used to feed the pump during low pressure operations.
- CK4 - Located in the product water line prior to the RO's internal tank and prevents backflow of the tank water into the product water.
- CK5 - Located in the tank outlet to the pump and prevents RO feed water from being fed into the internal tank.
- CK6 - Located on the tank drain and prevents the tank from over pressurizing.

FC - Located in the feed line of the RO and prevents the backflow of water to the RO feed supply.

VV1 - Tank vent valve that allows the tank to vent and intake air but not water.

4.2.3 High-Pressure Pump (HPP)

Provides a boost of the inlet water pressure to the RO Membrane. The RO pump pressure is displayed on the HMI on a simulated 0 to 300 PSI gauge. The typical pump pressure setting is between 160-180 PSI.

4.2.4 Level Switches (L1, L2 and L3)

The level switches sense the water level in the tank during operation.

4.2.5 RO Membrane Assembly (ROMA)

There is a single membrane included in the Millenium HX RO. This assembly includes the membrane housing, end caps, O-rings, and a membrane that can provide a minimum of 750 gallons per day of product water at 77°F (25°C).

4.2.6 Feed Port

The Feed Port is located on the rear of the RO and is a quick-disconnect port for the introduction of water in to the RO. The port has a check valve that closes when there is no line connected to the fitting.

4.2.7 Product Port

The Product Port is located on the rear of the RO and is a quick-disconnect port for the output of product water. The port has a check valve that closes when there is no line connected to the fitting.

4.2.8 Waste Port

The Waste Port is located on the rear of the RO and is a quick-disconnect port for the output of concentrate or waste fluid to the drain. The port has a check valve that closes when there is no line connected to the fitting.

4.2.9 Product Return Port

The Return Port is located on the rear of the RO and is a quick disconnect port for the return of product water to the unit. The port has a check valve that closes when there is no line connected to the fitting.

4.2.10 RO Feed Water Conductivity Sensor (WP1)

This sensor monitors the quality of the inlet water to the pump. Inlet water quality can be viewed from screen V-1 during normal operation and the value is compared to the product water quality reading to calculate the percent rejection, viewed from the run screen. This sensor is temperature compensated.

4.2.11 Product Water Conductivity Sensor (WP2)

This sensor monitors the quality and temperature of the water after it exits the membrane. Product water quality can be viewed from the run screen during normal operation and the value is compared to the inlet water quality reading to calculate the percent rejection, also viewed from the run screen. Temperature can be viewed from screen V-1. This sensor is temperature compensated.

4.2.12 RO Feed Water Pressure Sensor (PT1)

This sensor monitors the incoming water pressure to the RO machine and will shut down the machine if there is low or high RO feed water pressure. The feed water pressure is viewed from screen V-1.

4.2.13 Pump Outlet Pressure Sensor (PT2)

This sensor is part of the pressure control system and monitors the output of the pump and will shut down the RO if an over-pressure or under-pressure condition is sensed. The pump outlet pressure is viewed from screen V-2.

4.2.14 Product Water Pressure Sensor (PT3)


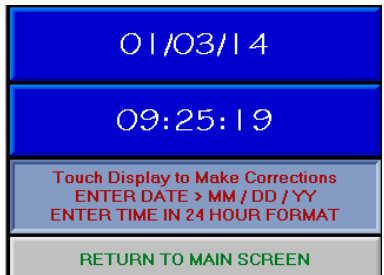
This sensor monitors the product water pressure and will shut down the RO if an overpressure condition is detected. The product water pressure is viewed from the run screen.



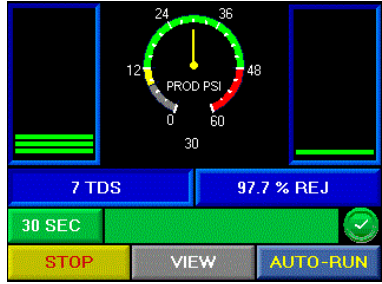
4.2.15 Pressure Regulator (PR)

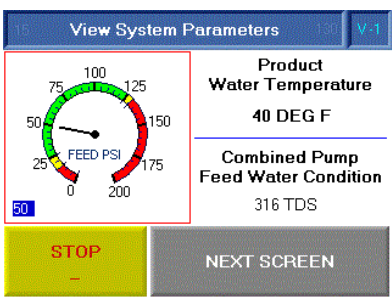
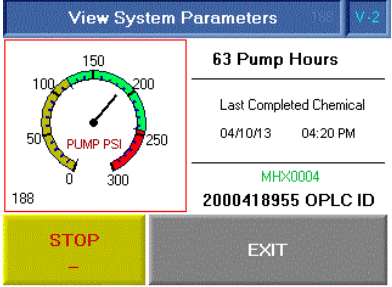

This regulator controls the incoming feed pressure to the RO.

4.3 System Operation Controls

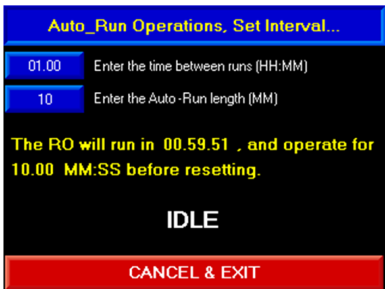

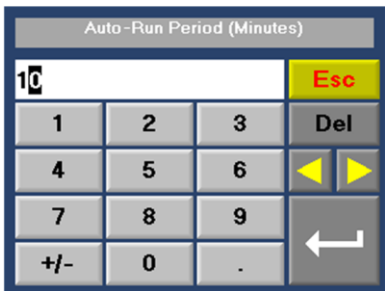
The Millenium HX system is controlled by a Programmable Logic Controller (OPLC) with an integrated operating panel that sends and receives signals to and from various components and sensors in the system. The user can set and view different parameters on the Human Machine Interface (HMI) display on the front of the RO. In this section, an overview of the operation of the OPLC controller is provided to help the user gain familiarity with the RO and basic system parameters.

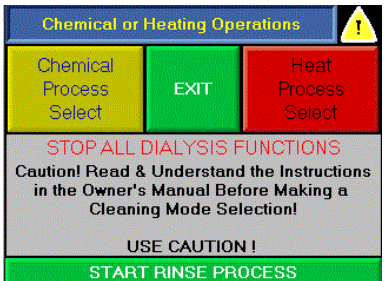
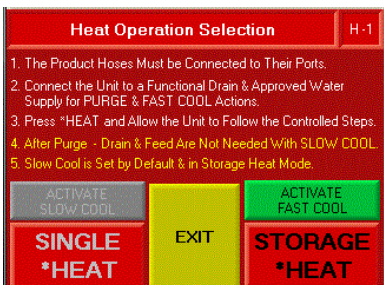
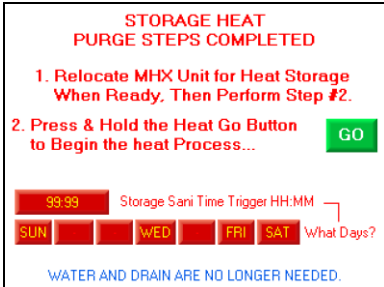
Screen Title: Main	Screen Description:
 <p>Figure 1</p>  <p>Figure 2</p>	<p>MAIN SCREEN</p> <p>Refer to Figure 1, from this screen, the operator can press RUN, SETTINGS, LOGS or PRESS AND HOLD FOR CLEANING MODES. If the RO is set to display in metric units, the letter M will be visible in the upper right hand corner of the screen.</p> <p>In addition, this screen displays the current date, time and date/time of the Last Completed Heat Process. This could represent a Storage Heat or Single Heat disinfection.</p> <p>The current date and time may be adjusted by pressing the area of the time and date and following the on screen instructions to adjust (Figure 2). The time does not automatically adjust for day light savings.</p> <p>PRESS AND HOLD FOR CLEANING MODES</p> <p>This allows the operator to enter the Chemical or Heating Operations selection screen.</p> <p>RUN</p> <p>Pressing this button will start the RO and produce water for dialysis.</p> <p>SETTINGS</p> <p>Pressing this button will allow an operator to enter the settings screens with a password. See settings section in this chapter for more information.</p> <p>LOGS</p> <p>Pressing this button will allow the operator to view the events that have taken place as part of the logging system. For a list of logged events, refer to page 4-10 in this chapter.</p> <p>ETHERNET</p> <p>There is an indicator located in the upper left corner of the screen. When the indicator is green, the RO is connected to an operable Ethernet connection. If the indicator is red, the RO is not connected to the network. Ethernet connection is not required to operate the RO.</p>

Screen Title: Run	Screen Description:
 <p>Figure 1</p>  <p>Figure 2</p>  <p>Figure 3</p>	<p>RUN SCREEN</p> <p>During Flush (Figure 1)</p> <p>This screen is viewed once the RUN button is pressed. Upon startup, the RO performs a flush, which is shown in the 2nd banner. The flush time is user adjustable from 30 to 300 seconds. The operator can also view the product water pressure (0-60 PSI), TDS/μS value and % Rejection (% REJ). These values are displayed in number form as well as graphically for a quick visual indication of the parameters value or state (Figure 1 and 2).</p> <p>NOTE: Adjustment of any setting should only be done by properly trained personnel and according to facility policies and procedures.</p> <p>Service Unit Soon Indicator (Figure 2)</p> <p>The % rejection reading provides the operator a means for evaluating membrane performance. The % rejection is calculated based on a comparison of RO feed water quality and product water quality. If the membrane performance decreases by 5% from the original membrane performance setting, a SERVICE UNIT SOON message will be display indicating that the RO membrane should be cleaned or evaluated. The RO will not alarm or shutdown as a result of this indicator being activated. In addition, this message is received if the membrane displayed % rejection increases by 3% from the performance setting indicating that there could be a problem with the conductivity probes.</p> <p>The Product Water TDS/μS reading indicates the quality of the RO's product water read in TDS or μS. It is temperature compensated to adjust the value of the display with changing water temperature for improved accuracy.</p> <p>There is an indicator on the screen that shows the state of the divert valve (lower right of screen). When the indicator is red, the divert valve is closed. When there is a green indicator with a check mark, the divert valve is open allowing product water to flow through the product line.</p> <p>After Flush (Figure 3)</p> <p>This screen is viewed once the flush time has completed. The operator can view the product water pressure (0-60 PSI), TDS/μS value and % Rejection. These values are displayed in number form as well as graphically for a quick visual indication of the parameters value or state (Figure 1 and 2).</p> <p>The operator can STOP the RO, VIEW additional screens or enter AUTO-RUN.</p>



<p>Screen Title: Run</p>  <p>The screenshot shows the 'View System Parameters' screen (V-1). It features a 'FEED PSI' gauge with a scale from 0 to 200, a needle pointing to approximately 50, and the number '50' displayed in the bottom left corner. To the right of the gauge, the text reads: 'Product Water Temperature 40 DEG F' and 'Combined Pump Feed Water Condition 316 TDS'. At the bottom, there are two buttons: a yellow 'STOP' button and a grey 'NEXT SCREEN' button.</p>	<p>Screen Description:</p> <p>RUN SCREEN V-1</p> <p>This screen is viewed if the operator presses the VIEW button in the previous screen. The operator can view the Product Water Temperature in F or C, Combined Pump Feed Water Condition in TDS or μS and the feed water pressure on a scale of 0-200 PSI (also shown numerically in lower left corner of gauge).</p> <p>NOTE: The RO feed water can mix with some recycle water depending on feed water pressure.</p> <p>The operator can STOP the RO or proceed to the next screen.</p>
 <p>The screenshot shows the 'View System Parameters' screen (V-2). It features a 'PUMP PSI' gauge with a scale from 0 to 300, a needle pointing to approximately 188, and the number '188' displayed in the bottom left corner. To the right of the gauge, the text reads: '63 Pump Hours', 'Last Completed Chemical 04/10/13 04:20 PM', 'MHX0004', and '2000418955 OPLC ID'. At the bottom, there are two buttons: a yellow 'STOP' button and a grey 'EXIT' button.</p>	<p>RUN SCREEN V-2</p> <p>This screen is viewed if the operator presses the NEXT SCREEN button on the previous screen. This screen displays the number of hours the pump has operated, date and time of the last completed chemical, pump pressure and the identification number of the OPLC.</p> <p>The Pump Pressure Gauge reads the pump pressure from 0 to 300 PSI (also shown numerically in lower left corner of gauge).</p> <p>The operator can STOP the RO or EXIT returning to Run Screen.</p>
 <p>The screenshot shows the 'MAIN SCREEN STOP FLUSH' screen. It has a green background with white and red text. At the top, it says 'PRESS AND HOLD FOR CLEANING MODES'. Below that, it shows the date '02/08/12' and time '04:44 PM'. The main text reads 'MILLENNIUM HX' in large letters, followed by 'Heat Process Ready' in red. Below that, it says 'REV 8.1.4' and 'MAR COR PURIFICATION, INC. U.S.A.'. At the bottom, it shows '02/08/12 03:15 PM' and 'Last Completed Heat Process'. A red bar at the bottom left says 'STOP FLUSH ACTIVE'. At the bottom right, there are two buttons: 'SETTINGS' and 'LOGS'.</p>	<p>MAIN SCREEN STOP FLUSH</p> <p>If the STOP button is pressed and held for 2 seconds from any of the run screens, the RO will enter a stop flush. During the shutdown, a 60 second low pressure membrane flush is performed. Once complete, the RO pump stops running and the RUN button reappears.</p>


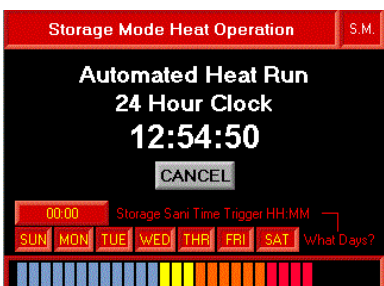
Screen Title: Logs	Screen Description:																												
<div><div>EXIT LOG REVIEW</div><table><tr><th>DATE</th><th>TIME</th><th>EVENT</th><th>463</th></tr><tr><td>11/13/09</td><td>10:47</td><td>REPAIR / SERVICE</td><td></td></tr><tr><td>11/13/09</td><td>10:47</td><td>STOP BUTTON PRESSED</td><td></td></tr><tr><td>11/13/09</td><td>12:33</td><td>REPAIR / SERVICE</td><td></td></tr><tr><td>11/13/09</td><td>12:33</td><td>REPAIR / SERVICE</td><td></td></tr><tr><td>11/13/09</td><td>12:33</td><td>AC POWER CYCLED</td><td></td></tr><tr><td colspan="2">UP</td><td colspan="2">DOWN</td></tr></table></div>	DATE	TIME	EVENT	463	11/13/09	10:47	REPAIR / SERVICE		11/13/09	10:47	STOP BUTTON PRESSED		11/13/09	12:33	REPAIR / SERVICE		11/13/09	12:33	REPAIR / SERVICE		11/13/09	12:33	AC POWER CYCLED		UP		DOWN		<div><div>LOG SCREEN</div><p>The operator can enter the Log Screen by pressing the LOGS button from the Main Screen. This screen logs events performed by the RO system. The following items can be logged. The log can contain error codes numbers, which aide in troubleshooting.</p><ul style="list-style-type: none">• Low Product Water Quality• Product High PSI• Pump Pressure Alarm• High Cond Feed Water• Feed PSI Problem• High Temperature• Heat Hold Complete• AC Power Cycled• Run Button Pressed• Stop Button Pressed• Chem Clean Selected• Heat Process Started• Heat Process Failed• Abort @ Hot Machine• Tip Over Warning• Abort Button Pressed• Sleep Heat Triggered• PCOM• Repair/Service• Failure to Rinse Chemical• Calibration Entered• Auto-Run Entered• Exit Auto-Run• Rinse Activation• Exit Rinse• Chem was Sensed• Heat Rinse Started• Heat Rinse Complete</div>
DATE	TIME	EVENT	463																										
11/13/09	10:47	REPAIR / SERVICE																											
11/13/09	10:47	STOP BUTTON PRESSED																											
11/13/09	12:33	REPAIR / SERVICE																											
11/13/09	12:33	REPAIR / SERVICE																											
11/13/09	12:33	AC POWER CYCLED																											
UP		DOWN																											

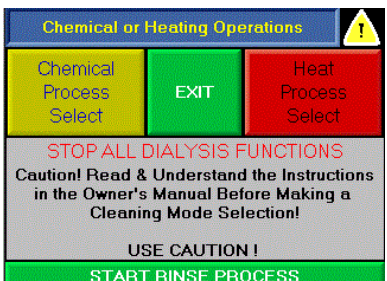
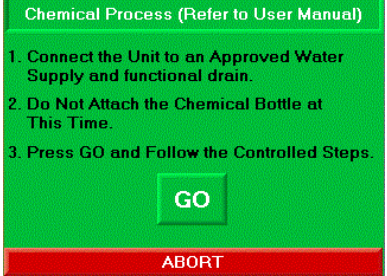


Screen Title: Auto Run	Screen Description:
<div data-bbox="235 310 618 596">  <p>Figure 1</p> </div> <div data-bbox="235 674 618 961">  <p>Figure 2</p> </div> <div data-bbox="235 1039 618 1327">  <p>Figure 3</p> </div>	<p>AUTO RUN</p> <p>When AUTO-RUN is pressed and held from the run screen, the operator enters the Auto Run Screen (Figure 1). The operator can set the RO to run for up to 59 minutes (Figure 3) at specified time intervals (1 minute up to 99 hours and 59 minutes) (Figure 2). To enter the times, press the box indicating the time. When the RO is running in this mode, the IDLE indicator is replaced with OPERATING. To exit, press the CANCEL & EXIT banner.</p> <p>When the RO is OPERATING in auto run, water is circulated through the product line at low pressure.</p> <p>When CANCEL & EXIT is pressed, the RO will return to the run screen in a startup flush and divert for the set time.</p>




Screen Titles: Heat Disinfect	Screen Description:
 <p>The screen displays a banner at the top with a yellow warning triangle. Below the banner are three buttons: 'Chemical Process Select' (yellow), 'EXIT' (green), and 'Heat Process Select' (red). Below these buttons is a gray box with the text: 'STOP ALL DIALYSIS FUNCTIONS', 'Caution! Read & Understand the Instructions in the Owner's Manual Before Making a Cleaning Mode Selection!', 'USE CAUTION!', and 'START RINSE PROCESS' (green button).</p>	<p>CHEMICAL OR HEATING OPERATIONS SELECTION SCREEN</p> <p>The operator can only enter the chemical/heating process screens from the Main Screen. The operator must hold the banner at the top of the Main Screen for 2 seconds to enter this screen.</p> <p>The operator can press the CHEMICAL PROCESS SELECT, EXIT, HEAT PROCESS SELECT or START RINSE PROCESS. If the operator presses EXIT, the screen returns to the Main Screen.</p> <p>The START RINSE PROCESS can be used to place the RO into a rinsing process allowing the RO to rinse.</p>
 <p>The screen displays a red banner at the top with the text 'Heat Operation Selection' and 'H-1'. Below the banner are five numbered steps: 1. The Product Hoses Must be Connected to Their Ports. 2. Connect the Unit to a Functional Drain & Approved Water Supply for PURGE & FAST COOL Actions. 3. Press *HEAT and Allow the Unit to Follow the Controlled Steps. 4. After Purge - Drain & Feed Are Not Needed With SLOW COOL. 5. Slow Cool is Set by Default & in Storage Heat Mode. Below the steps are five buttons: 'ACTIVATE SLOW COOL' (gray), 'EXIT' (yellow), 'ACTIVATE FAST COOL' (green), 'SINGLE *HEAT' (red), and 'STORAGE *HEAT' (red).</p> <p>Figure 1</p>  <p>The screen displays a red banner at the top with the text 'STORAGE HEAT PURGE STEPS COMPLETED'. Below the banner are two numbered steps: 1. Relocate MHX Unit for Heat Storage When Ready. Then Perform Step #2. 2. Press & Hold the Heat Go Button to Begin the heat Process... Below the steps are a green 'GO' button, a digital clock showing '99:99', a date display showing 'SUN', 'WED', 'FRI', 'SAT', and a text prompt 'What Days?'. At the bottom, it says 'WATER AND DRAIN ARE NO LONGER NEEDED'.</p> <p>Figure 2</p>	<p>HEAT SCREEN 1</p> <p>Figure 1 is reached when the HEAT PROCESS SELECT button is pressed and held from the previous screen. The operator can now pick the cooling method used (Slow Cool is selected as default).</p> <p>Slow Cool: Allows the RO to cool by convection without the need for water and drain to be connected after the heat purge is completed.</p> <p>Fast Cool: Utilizes small amounts of feed water to cool the RO. Water and drain must remain connected to the RO. Cannot be used with Storage Heat function.</p> <p>Once the cooling method is picked, the operator may now pick their heat process.</p> <p>SINGLE HEAT: When this button is pressed, the RO will immediately perform a single hot water disinfection. Figure 2 is not displayed during a single heat process.</p> <p>STORAGE HEAT: When this button is pressed, the RO will immediately perform a heat purge and then display Figure 2. The RO can now be turned off and disconnected from power and moved. Once in new location, reconnect to electrical power and turn the RO on (Figure 2 will again be displayed). Once GO is pressed, the RO will immediately start a heat disinfection and will disinfect again on the specific days at the specific time selected from the scheduling screen (a visible day indicates that the RO will disinfect on that day).</p> <p>NOTE: Cooling method selected will be indicated with a grayed out button. Example if the ACTIVATE SLOW COOL button is grayed out, the slow cool cooling method is active.</p>


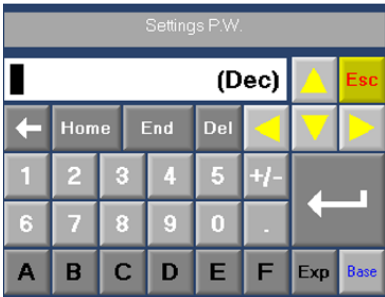
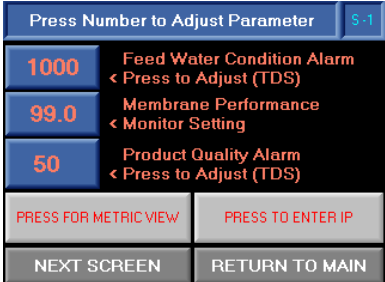
Screen Titles: Heat Disinfect	Screen Description:
 <p>Figure 1</p>  <p>Figure 2</p>  <p>Figure 3</p>	<p>HEAT SCREEN 2</p> <p>Figure 1 shows the screen while the RO is purging for the heat process. The Single Heat and Storage Heat purge processes are identical. Information available is the product temperature (displayed numerically and graphically), pump pressure, total time of the process and a message in yellow indicating that purging is active.</p> <p>Figure 2 shows the screen while the RO is heating up to target temperature of 176°F (80°C). The RO indicates the heat process selected (Recurring Storage Heat) and the cooling method active (SLOW COOL: The Drain and Feed Water Lines Can be Disconnected in This Mode). Other information available is the product temperature (displayed numerically and graphically), pump pressure and total time of the process. This process is the same for Storage Heat and Single Heat.</p> <p>Figure 3 shows the screen while the RO is in heat hold. This is where the temperature is held at 176°F (80°C) for 30 minutes. The Hold Time counter counts down from 30 minutes to zero before exiting the heat screen. The screen shows the heat process selected (Single Run Heat) and the cooling method active (FAST COOL: Requires the Connection of Drain and Feed Water Lines). Other information available is the product temperature (displayed numerically and graphically), pump pressure and total time of the process. This process is the same for Storage Heat and Single Heat</p> <p>The operator can ABORT the heat process. If the temperature is above 120°F (49°C), the RO will proceed to the cool down screens. If below 120°F (49°C), the RO will proceed to the post heat rinse.</p>
	<p>COOL DOWN SCREEN</p> <p>After the hold time is complete during a single heat, the RO will begin a cool down process. In SLOW COOL, the unit will cool by convection. In FAST COOL, the inlet solenoid valve (SV1) opens and closes allowing small amounts of cooler feed water to enter the machine. The cool down process is active until the product water temperature falls below 120°F (49°C). If in STORAGE HEAT, this screen is only displayed if the process is canceled or aborted and the temperature is above 120°F (49°C).</p> <p>When Cool Down is active, the operator can toggle between Fast Cool and Slow Cool. When the ACTIVATE SLOW COOL or ACTIVATE FAST COOL is gray, that indicates it is in that mode. To change, press the green button and it will change cooling mode. Fast Cool requires feed water and drain connections.</p>

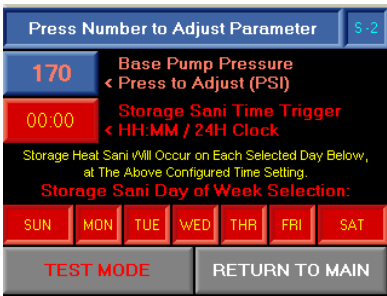
Screen Titles: Heat Disinfect	Screen Description:
 <p>Figure 1</p>	<p>POST HEAT RINSE Figure 1</p> <p>After the completion of a heat process and cooling below 120°F (49°C), the RO automatically advances to the Post Heat Rinse screen. The RO operates in this mode cooling and rinsing the RO product water below 105°F (41°C). Figure 1 is shown if the cooling method is set to Slow Cool. The operator must connect water and drain and press the START button to initiate the rinse process (Figure 2). If START is pressed and there is no water available a LOW FEED PRESSURE message (not shown) appears.</p> <p>Figure 2</p> <p>Figure 2 is shown after the cool down screen if the cooling method is set to Fast Cool or the START button is pressed in Figure 1. The RINSING indicator shows that the machine is in the process of rinsing.</p> <p>There are 3 indicator lights above the START/RINSING box that show when the process is complete. The left indicator when green indicates that the 5 minute rinse process is complete; the middle indicator shows when the product water temperature is below 105°F (41°C) and the final indicator shows when the bottom float (LS3) has been satisfied indicating the tank level is low.</p> <p>Figure 3</p> <p>If during the heat disinfection process, an error is detected, you will receive the ERROR MODE POST HEAT RINSE screen. To exit from this screen for troubleshooting, hold your finger on the screen in a blank area for 10 seconds. The START button does not work when you receive the ERROR MODE screen.</p>
 <p>Figure 2</p>	<p>HEAT SCREEN 3</p> <p>Once the post heat rinse is complete, the RO displays HEAT HOLD PROCESS COMPLETED PRESS EXIT TO RETURN TO NORMAL USE.</p> <p>The operator presses EXIT to return to the Chemical or Heating Operations selection screen.</p>

Screen Titles: Heat Disinfect	Screen Description:
	<p>HEAT SCREEN 4</p> <p>During heat disinfection, if the hold process does not successfully complete, the display screen will warn the operator of a FAILURE TO COMPLETE HEAT HOLD PROCESS.</p> <p>The operator presses EXIT to return to the Chemical or Heating Operations selection screen.</p> <p>The logs may contain additional information on why the heat disinfection did not successfully complete (see page 4-10).</p>
	<p>S.M. (Storage Mode Heat Operations)</p> <p>After a successful STORAGE HEAT disinfection, a countdown timer is visible in addition to the current disinfection schedule after the heat hold is complete. The schedule can be adjusted from this screen. If the day of the week indicator is visible, the RO will heat disinfect at the specified time on that day. The settable time is in a 24 hour clock format. If CANCEL is pressed, the screen will advance to the Cool Down Screen if water temperature is above 120°F (49°C) or Post Heat Rinse screen if below 120°F (49°C).</p>

Screen Titles: Chem Process	Screen Description:
 <p>The screen displays a banner at the top with the title "Chemical or Heating Operations" and a warning icon. Below the banner are three buttons: "Chemical Process Select" (yellow), "EXIT" (green), and "Heat Process Select" (red). Below these buttons is a grey box with the text "STOP ALL DIALYSIS FUNCTIONS Caution! Read & Understand the Instructions in the Owner's Manual Before Making a Cleaning Mode Selection! USE CAUTION!". At the bottom is a green button labeled "START RINSE PROCESS".</p>	<p>CHEMICAL OR HEATING OPERATIONS SELECTION SCREEN</p> <p>The operator can only enter the Chemical or Heating Operations selection screen from the Main Screen. The operator must hold the banner at the top of the Main Screen for 2 seconds to enter this screen.</p> <p>The operator can press the CHEMICAL PROCESS SELECT, EXIT, HEAT PROCESS SELECT or START RINSE PROCESS. If the operator presses EXIT, the screen returns to the Main Screen.</p>
 <p>The screen displays the title "Chemical Process (Refer to User Manual)". Below the title are three numbered instructions: 1. Connect the Unit to an Approved Water Supply and functional drain. 2. Do Not Attach the Chemical Bottle at This Time. 3. Press GO and Follow the Controlled Steps. Below the instructions are two buttons: "GO" (green) and "ABORT" (red).</p>	<p>CHEM GO SCREEN</p> <p>This screen provides the operator instructions for getting the RO ready for a chemical cleaning or sanitization.</p> <p>Operator presses GO to proceed with purge process.</p> <p>The operator can press ABORT and return to the Chemical or Heating Operation selection screen.</p>
 <p>The screen displays the title "Chemical Process". Below the title is a large yellow box with the text "MACHINE PURGE IS ACTIVE" in green. At the bottom is a red button labeled "ABORT".</p>	<p>CHEM PURGE SCREEN</p> <p>During the MACHINE PURGE IS ACTIVE screen, the RO is draining and refilling the internal tank to the correct water level with product water for the chemical process.</p> <p>The operator can press ABORT and return to the Chemical or Heating Operation selection screen.</p>
 <p>The screen displays the title "Chemical Process (Refer to User Manual)". Below the title are three numbered instructions: 1. CONNECT THE PREPARED CHEMICAL BOTTLE. 2. THE DRAIN AND FEED WATER SUPPLIES ARE NOT NEEDED DURING THIS STEP. 3. ENTER A CHEMICAL APPLICATION TIME OR RUN WITH THE FACTORY TIME, THEN PRESS START. Below the instructions are two buttons: "START" (green) and "ABORT" (red). To the right of the buttons are two displays: "336 TDS FEED" and "4 TDS PROD". Below these displays is a large digital clock showing "01:00" and "01:00:00 HH:MM:SS". Below the clock is the text "Enter Chemical Process Time".</p>	<p>CHEM START SCREEN</p> <p>This screen provides the operator instructions for connecting the chemical bottle and has an adjustable timer for the chemical process. This timer is settable between 36-60 minutes.</p> <p>The operator can initiate the chemical process by pressing the START button. A countdown clock indicates where the RO is in its process. The feed and product conductivity are displayed to show that chemical is being introduced into the RO.</p> <p>If the operator does not connect the chemical bottle or does not add chemical to the bottle prior to pressing START, the RO will sound an audible alarm and the ABORT button will flash after a delay. To clear the alarm, the operator will need to identify the issue. Once chemical is sensed, the alarm will clear after approximately a 3 minute delay.</p> <p>The operator can press ABORT and return to the Chemical or Heating Operation selection screen.</p>


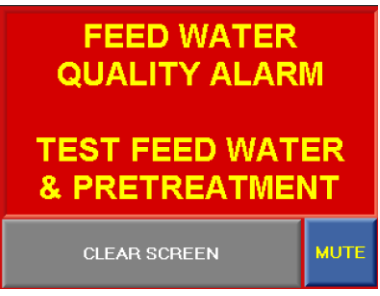


Screen Titles: Chem Process	Screen Description:
	<p>CHEM COMPLETE SCREEN</p> <p>This screen provides the operator instructions for removal of the chemical bottle and setting up for the rinse process after the chemical application process is complete.</p> <p>The operator presses CONTINUE or ABORT.</p>
 <p>Figure 1</p>  <p>Figure 2</p>	<p>CHEM RINSE SCREEN</p> <p>Refer to Figure 1, this screen will initiate the rinse process. The operator presses the START RINSE NOW button and the display provides the operator with a status of the rinsing process. The RO feed and product conductivity is displayed showing the status of rinsing the RO. Once the RO completes 30 rinse steps, the EXIT button appears (Figure 2) and the operator can exit to the Chemical or Heating Operations selection screen. If exit button is not pressed, the RO will continue to rinse until a total of 50 rinses are completed. If this occurs, the RO will automatically return to the Chemical or Heating Operations selection screen.</p> <p>If rinse is entered from the Chemical or Heating Operations selection screen by pressing the START RINSE PROCESS button (chemical or heat disinfection not performed), the EXIT button appears immediately allowing the operator to exit the rinse process.</p>

Screen Titles: Settings	Screen Description:
 <p>The screenshot shows the Main Screen of the Millenium HX RO System. It displays the date 02/13/12, time 08:09 AM, and the status 'Heat Process Ready'. Below this, it shows 'REV 8.1.5' and 'MAR COR PURIFICATION, INC. U.S.A.'. At the bottom, it indicates '02/13/12 03:27 AM Last Completed Heat Process'. There are three buttons at the bottom: 'RUN' (green), 'SETTINGS' (grey), and 'LOGS' (grey).</p>	<p>MAIN</p> <p>The operator can only enter the SETTINGS screens from the Main Screen.</p>
 <p>The screenshot shows the 'Settings P.W.' screen. It features a numeric keypad with buttons for numbers 1-9, 0, and a decimal point. There are also buttons for 'Home', 'End', 'Del', '+/-', and a left arrow. At the bottom, there are buttons for 'A', 'B', 'C', 'D', 'E', 'F', 'Exp', and 'Base'. The screen also has a 'Settings P.W.' title bar and a 'Dec' button.</p>	<p>PASSWORD</p> <p>To enter the settings screen, the operator must enter a pass code. The passcode is 999.</p> <p>NOTE: Entering the SETTINGS screen and adjusting any setting should only be done by properly trained personnel and according to facility policies and procedures.</p>
 <p>The screenshot shows the 'Settings S-1' screen. It has a title bar 'Press Number to Adjust Parameter' and a 'S-1' button. Below the title bar, there are three rows of settings: '1000 Feed Water Condition Alarm < Press to Adjust (TDS)', '99.0 Membrane Performance < Monitor Setting', and '50 Product Quality Alarm < Press to Adjust (TDS)'. At the bottom, there are four buttons: 'PRESS FOR METRIC VIEW', 'PRESS TO ENTER IP', 'NEXT SCREEN', and 'RETURN TO MAIN'.</p>	<p>SETTINGS S-1</p> <p>From this screen, the operator can adjust the Feed Water Condition Alarm, Membrane Performance and the Product Quality Alarm.</p> <p>Feed Water Condition Alarm is user adjustable between 50-1000 TDS (100-2000 μS). If incoming RO feed water quality is greater than 1000 TDS (2000 μS), the alarm can be disabled by setting the Feed Water Condition alarm to 1001 (2001).</p> <p>Membrane Performance is user adjustable from 90-99.9%. This should be set at the time of installation. Refer to the Installation Guidelines in Chapter 2.</p> <p>Product Quality Alarm is user adjustable from 1-50 TDS (1-100 μS).</p> <p>The operator can also toggle between US and metric readings (PRESS FOR METRIC VIEW), enter IP data (PRESS TO ENTER IP), advance to NEXT SCREEN or return to the Main Screen by pressing RETURN TO MAIN.</p>

Screen Titles: Settings	Screen Description:
	<p>SETTINGS S-2</p> <p>From this screen, the operator can adjust the Base Pump Pressure, the Storage Sani Time Trigger and the Storage Sani Day of Week Selection.</p> <p>Base Pump Pressure is user adjustable from 100-200 PSI.</p> <p>Storage Heat is user settable. The user may select the time to start the heat disinfection (Storage Sani Time Trigger) and the days of the week for the heat disinfection (Storage Sani Day of Week Selection). If the day is visible, the RO will heat disinfect at the specified time on that day.</p> <p>The operator can return to the Main Screen by pressing RETURN TO MAIN.</p> <p>The TEST MODE is password protected and intended for trained personnel use only.</p>

4.4 Alarm Screens

Screen Titles: Alarms	Screen Description:
 <p>SERVICE REQUIRED</p> <p>COMPONENT FAILURE DETECTED</p> <p>CLEAR SCREEN</p>	<p>This screen is displayed indicating that a component within the RO has failed along with a possible error code. Refer to Section 6.9 "Service Required Component Failure Detected" for the error code list.</p>
 <p>DANGER !</p> <p>THIS UNIT MUST STAND UPRIGHT</p> <p>CLEAR SCREEN</p>	<p>This device has a tilt sensor to prevent operation in a horizontal orientation. If the device is placed on its side, operation of the device ceases and it cannot be started until the RO is placed in an upright position.</p>
 <p>PRODUCT WATER HIGH TEMPERATURE</p> <p>STOP DIALYSIS</p> <p>CLEAR SCREEN MUTE</p>	<p>This device has a product water temperature sensor that is integral to the conductivity probe. If the product water temperature exceeds 105°F (41°C), the RO will shut down and cannot be restarted in run until the product water sensor is stable below 105°F (41°C).</p>
 <p>PUMP PRESSURE ALARM</p> <p>SERVICE REQUIRED</p> <p>CLEAR SCREEN MUTE</p>	<p>This device has a pressure transducer that monitors the pump outlet pressure. If pump pressure exceeds 240 PSI, or is 20 PSI below the target pressure, the RO will shut down. The pressure alarm settings are not user adjustable.</p> <p>During the heat process, pump pressure is monitored and if the pressure goes outside of a factory set range, the Pump Pressure Alarm will sound. These settings are not user settable.</p>

Screen Titles: Alarms	Screen Description:
 <p>PRODUCT WATER QUALITY ALARM</p> <p>STOP DIALYSIS</p> <p>CLEAR SCREEN MUTE</p>	<p>This device, when running normally, continuously monitors product quality. If the product water quality reading increases to the user settable alarm set point (between 1-50 TDS or 1-100 μS), the RO will stop and display the alarm screen.</p>
 <p>FEED WATER QUALITY ALARM</p> <p>TEST FEED WATER & PRETREATMENT</p> <p>CLEAR SCREEN MUTE</p>	<p>This device monitors the RO feed water during normal operation. If the RO feed water quality reading unexpectedly increases above the user adjustable set point (50-1000 TDS or 100-2000 μS), the alarm screen will be displayed. In some areas, RO feed water quality normally exceeds 1000 TDS (2000 μS). This alarm can be disabled in these areas by setting the alarm set point at 1001 TDS/2001 μS.</p>
 <p>PRODUCT PRESSURE HIGH ALARM</p> <p>TEST PRODUCT & DRAIN CONNECTIONS</p> <p>CLEAR SCREEN</p>	<p>This device monitors the product pressure. If the product water pressure exceeds 60 PSI, the RO will shut down. During normal operation, if the dialysis machine is not drawing water, the fluid path is directed into the internal tank through a check valve. This alarm could indicate that the RO has been connected incorrectly or external pressure is being applied.</p>
 <p>FEED PRESSURE ALARM</p> <p>PLEASE CORRECT CONDITION</p> <p>CLEAR SCREEN MUTE</p>	<p>This device monitors the RO feed pressure and will alarm if the pressure is too high or low. This alarm is factory set and cannot be user adjusted. The low limit is 15 PSI and the high limit is 130 PSI.</p>

4.5 Optional Equipment

Mar Cor Purification offers a number of optional items to adapt the equipment to meet specific needs. Options are available to improve portability and to improve the quality of the feed water to the RO. Frequently requested options are briefly described in the following paragraphs. If more information is needed or if other options are desired, please consult Mar Cor Purification.

4.5.1 Pretreatment Cart

Holds the Millenium HX and RO feed water treatment equipment. The cart will hold 2 carbon block filters or any combination of two or three of the following tank sizes: .25 c.f., .44 c.f., .50 c.f., or .85 c.f..

4.5.2 Carbon Filter Tanks

Removes chlorine/chloramine from the RO feed water, preventing damage to the RO membrane and injury to patients. The filter incorporates a bed of granular activated carbon. Three sizes of carbon tanks come in semi-automatic control valve and exchange head styles.

4.5.3 Carbon Block

Can be used to remove chlorine/chloramine from the RO feed water preventing damage to the RO membrane and injury to patients. These filters mount directly to the pretreatment carts.

WARNING:

Carbon cannot be regenerated and must be replaced with new beds when exhausted or contaminated.

WARNING:

A suitable carbon filter should always be present as pretreatment for the Millenium HX RO in order to prevent chlorine/chloramine damage to the thin film membrane and harm to the patient. Mar Cor Purification strongly recommends the use of two carbon devices, used in a series configuration.

4.5.4 Softeners

Remove calcium, magnesium, and other scale producing contaminants from the RO feed water. Their removal prevents the build-up of scale on the membrane surface. A control valve drives the regeneration of the softener and will remove the hardness ions with a brine solution and rinse the ion exchange bed afterwards. The control valve is normally governed by a semi-automatic time clock. There are three sizes of softener tanks available.

4.5.5 Dealkalizers

Are used to lower the pH of alkaline RO feed water. Water with pH levels above 8.5 with chloramines present can reduce the performance of the carbon filters and thin-film membranes. A control valve drives the regeneration rinsing of the dealkalizer. The control valve is normally governed by a semi-automatic time clock. There are three sizes of dealkalizer tanks available.

4.6 Specifications

4.6.1 RO Feed Water Requirements

CAUTION:

The RO feed water quality to the RO must meet the National Primary Drinking Water Standards of the United States Environmental Protection Agency (EPA) or Canadian Federal and Provincial guidelines governing drinking water in Canada. If the RO feed water does not meet these standards, the machine may not produce water that meets AAMI and CSA standards.

	<u>Minimum</u>	<u>Maximum</u>
Input Flow Rate	1.5 GPM	N/A
Temperature (Water)	4°C (40°F)	32°C (90°F)
Maximum Feed Silt Density Index	N/A	SDI 5
Free Chlorine	N/A	0.1 ppm

NOTE:

Operating at lower temperatures may make it impossible for the Millenium HX RO to produce adequate product water for the dialysis machine.

	<u>Minimum</u>	<u>Maximum</u>
pH (Continuous) TF Membrane	2.0	11.0
pH (Cleaning) TF Membrane	1.0	12.0
Pressure, Dynamic ¹	20 PSI	130 PSI

CAUTION:

Feed water hardness levels ≥ 10 GPG should have a water softener or other means of preventing or periodically removing scale. If no water softener is used with the portable RO, it may be necessary to perform more frequent acid cleanings or periodically replace the membranes in accordance with the instructions in this manual. The amount of hardness in the feed water will determine the frequency of membrane cleaning and or membrane replacement. If operating without a softener, more frequent AAMI testing should be performed to assure the product water meets current AAMI water specifications.

¹ Pressure fluctuations of 10 PSI or greater should be avoided to prevent water hammer damage

4.6.2 Flow Rates

Product Flow based on the following conditions:

New Membrane

Operating Pressure:	170 PSI (+/- 10 PSI)
Product Back Pressure:	1 PSI
Feed Water Temperature:	77°F (25°C)
Product Flow:	0.52 GPM/1.97 LPM
Waste Flow:	0.52 GPM/1.97 LPM

Membrane flux may vary $\pm 20\%$

4.6.3 Electrical Requirements

Motor	1/3 HP
Voltage	115 ~/230 ~
Amperage	6/3
Hertz	60/50
Phase	single

4.6.4 Dimensions

Height	25 ½ inches
Depth	23 inches
Width	8 ½ inches
Weight (Dry)	<75 Lbs

4.6.5 Membrane Performance Characteristics

Rejection Rate (TF Membrane): 95% minimum (Mar Cor test lab conditions)

NOTE:

Rejection rate will vary depending on the quality of the water supplied to the RO. Cleaner feed water may result in rejection rates lower than that seen by the RO manufacturer.

4.6.6 Environmental Requirement

	<u>Minimum</u>	<u>Maximum</u>
Ambient Temperature	4°C (39°F)	32°C (90°F)
Storage Temperature	2°C (36°F)	32°C (90°F)
Altitude	N/A	10,000 feet

CAUTION:

This equipment must not be allowed to freeze. Irreparable harm to various components, including RO membrane, may result.

NOTE:

The user/operator should recognize that moisture can be caused by condensation and is not necessarily an equipment leak. This equipment will function in the presence of condensation.

4.6.7 Approvals

The Millenium HX is listed by ETL as certified. This medical equipment has been tested and demonstrated compliance with the following standards:

- CAN/CSA Standard C22.2 No. 61010-1, second edition, including Amendment 1
- UL 61010-1

4.7 Disposal

Disposal of this product or parts must be carried out according with local disposal codes.

4.8 Electromagnetic Interference

The Millenium HX has been tested and demonstrated compliance with the following standard:


- IEC 60601-1-2: 2001 + a1:2004, Class B for Emissions, Immunity for Non-Life-Supporting Equipment.
- IEC 61000-3-2:2006
- IEC 61000-3-3:1995 + A1:2001 + A2:2006

This equipment can generate, uses and can radiate radio frequency energy and if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device
- Increase the separation between the equipment
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) is connected
- Consult the field service technician or manufacturer for help

Guidance and manufacturer's declaration - electromagnetic emissions		
The Millenium HX is intended for use in the electromagnetic environment specified below. The customer or the user of the Millenium HX should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Millenium HX uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	The Millenium HX is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration - electromagnetic immunity			
The Millenium HX is intended for use in the electromagnetic environment specified below. The customer or the user of the Millenium HX should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical transient/burst fast IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The Millenium HX is intended for use in the electromagnetic environment specified below. The customer or the user of the Millenium HX should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 Vrms</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Millenium HX, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p>$d = 1.2\sqrt{P}$</p> <p>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m)</p> <p>Field strengths from fixed RF Transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Millenium HX is used exceeds the applicable RF compliance level above, the Millenium HX should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Millenium HX.</p>			
<p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Recommended separation distances between portable and mobile RF communications equipment and the Millenium HX

The Millenium HX is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Millenium HX can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Millenium HX as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter <u>W</u>	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $D = 1.2\sqrt{P}$	80 MHz to 800 MHz $D = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $D = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at the maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

4.9 Service Assistance

If service assistance is required, please take the following steps:

1. Consult the troubleshooting section of this manual (Chapter 6). If the problem cannot be identified and corrected by any of the procedures found in that section, then
2. Contact your Facility Equipment Technician. If the technician is unable to help, then
3. Call Mar Cor Purification Technical Support Department at (800) 633-3080. Technicians are available for all calls between 7:00 a.m. and 7:00 p.m. CST, Monday through Friday. Technicians are also available at other times for **emergency calls only**. Product consultants will be on hand to discuss the problem with you and endeavor to rectify it over the phone. If the problem appears to be of a more serious nature, you will be given instructions regarding the action to be taken. Prior to making the phone call, you must be prepared to answer two questions:
 - a. What RO do you have; Millenium HX?
 - b. What is the serial number of your RO?

RO SERIAL NUMBER: _____

4. In addition, for **Non-Emergency** issues, you may e-mail techserv@mcpur.com and a Technician will respond, generally within one working day.

4.10 Return Materials Authorization (RMA) Procedure




If you wish to return materials for warranty evaluation and/or credit, please have your original sales order, invoice, and device serial number or material list number, if applicable, available when you call Mar Cor Purification. Call Mar Cor Purification at (800) 633-3080 and request Technical Support. A representative will provide instructions and a return material authorization number, **which needs to be clearly written on the outside of the box used to ship your materials**. All equipment must be shipped with the freight prepaid by the customer. Call our Customer Service Center with any questions or issues concerning freight claims and a representative will discuss your situation.

All materials to be returned must be rendered into a non-hazardous condition prior to shipping.

4.11 Symbols and Abbreviations

ASTM	American Society for Testing and Materials
AAMI	Association for the Advancement of Medical Instrumentation
C	Celsius
CSA	Canadian Standards Association
cc	Cubic Centimeters
cf	Cubic Foot (feet)
cfu/ml	Colony Forming Units per milliliter
cm	Centimeters
DI	Deionization
EMC	Electromagnetic Compatibility
F	Fahrenheit
FDA	Food and Drug Administration
Ft.	Foot (feet)
GPD	Gallons Per Day
GPM	Gallons Per Minute
gr	Grains
GAC	Granular Activated Carbon
HMI	Human Machine Interface
Hz	Hertz
HP	Horse Power
IEC	International Electrotechnical Commission
Kohm	One Thousand Ohms

Lbs.	Pounds
LPD	Liters Per Day
LPM	Liters Per Minute
m	Meter
mg/L	Milligrams Per Liter
ml	Milliliters
MNPT	Male National Pipe Thread
MSDS	Material Safety Data Sheet
mw	Molecular Weight
NaCl	Sodium Chloride
N/A	Not Applicable
NPT	National Pipe Thread
NSF	National Sanitation Foundation
OPLC	Operating Panel & Programmable Logic Controller
PA	Polyamide
P/N	Part Number
PPE	Personal Protective Equipment
ppm	Parts Per Million
PSI	Pounds Per Square Inch
PVC	Polyvinyl Chloride
QD	Quick Disconnect
RO	Reverse Osmosis
ROMA	Reverse Osmosis Membrane Assembly

TF	Thin Film
TDS	Total Dissolved Solids
TNTC	Too Numerous To Count
UL	Underwriters Laboratory
VAC	Volts Alternating Current
WFI	Water for Injection
WT	Weight
~	Volts Alternating Current
μS	microsiemens
	Caution Risk of Danger. Consult the Operation and Maintenance manual for instructions
	Protective Earth Terminal
	ME EQUIPMENT and ME SYSTEMS that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment shall be labeled with this symbol

Millenium HX RO System

CHAPTER 5: ROUTINE MAINTENANCE

This page intentionally left blank.

5.1 Routine Maintenance

The Millenium HX has been designed to operate with a minimum of operator attention. Like all mechanical systems, they will operate longer and with less trouble when operator maintenance is performed regularly. Operator maintenance on a Mar Cor Purification reverse osmosis system is limited to maintaining performance logs, cleaning and disinfection and replacement of damaged or failed parts. The maintenance procedures have been categorized by their frequency of action and are as follows:

WARNING:

Prior to performing any electrical maintenance, unplug the RO power cord from the wall receptacle.

WARNING:

Do not perform maintenance while RO is being used for patient treatment.

WARNING:

If maintenance instructions are not followed, the RO may not produce water that meet the requirements of AAMI and CSA.

NOTE:

The first part of this section provides the timelines and simple instructions for maintenance of your RO. The specific instructions and procedures for the more complex maintenance items are provided in the second part of this section.

5.1.1 Per Treatment Day Maintenance

1. Test and record the hardness level of the RO feed water in the pretreatment log, if necessary.
2. Observe and record salt level in the brine tank (for systems with a water softener).
3. Observe and record the chlorine/chloramine concentrations in the pretreatment log. Follow the instructions included with each test kit.

WARNING:

If multiple treatments are performed in one day, the chlorine/chloramine testing is to be performed and recorded before each treatment.

WARNING:

Take corrective action or contact your local service representative if any optional pretreatment device fails to provide adequate treatment of RO feed water before continuing with the use of the RO.

4. If you are using cartridge pre-filters with your RO, observe and record the pre-filter inlet and outlet pressure gauges on the operation log. The difference in the pressure values will help measure the condition of the filter cartridge. When the pressure differential (delta P) increases 8 PSI above the clean, initial delta P, the cartridges need to be changed (or sooner if the pre-filter core appears soiled). To change the pre-filter, the water supply must be turned off. The pre-filter inlet and outlet gauges should read zero PSI. The pre-filter bowl can now be removed by rotating it clockwise (as viewed from above). Remove the old filter, install the new filter and re-install the filter bowl.
5. Observe and record the percent rejection and TDS/ μ S water quality readings in the operation log. These readings can be taken from the various screens.

5.1.2 Weekly Maintenance

1. Disinfect/Sanitize the system, if needed. Refer to the disinfection procedure in Section 3.3 or the sanitization procedure in Section 5.4.

NOTE:

Low pH chemical cleaning should be performed as a method to remove transitional metals from the RO membrane prior to chemical sanitization.

5.1.3 Monthly Maintenance

1. Take a product water culture to test for bacteria colony forming units count. Refer to the product water culture procedure in this chapter. Disinfect if results are above the limits set by the facility or when results reach with 50% of the maximum allowable level.
2. Visually inspect the pre-filter core if you are using cartridge pre-filtration.

NOTE:

Recorded log data may be used to analyze the operating performance of the RO, such as decreasing rejection or increasing TDS/ μ S, which indicates a need for service.

5.1.4 Quarterly Maintenance

1. Verify the TDS/ μ S and percent rejection readings with an independent monitoring device. TDS readings are to be calculated using the following equation: $TDS = 0.5 \times \text{conductivity } (\mu S/cm)$. % rejection is calculated using the following equation: $\% \text{ Rejection} = 100(1 - \text{Product TDS} / \text{RO feed TDS})$. Readings should be within $\pm 10\%$ or ± 2 TDS (whichever is greater) of the RO's readings. If verifying conductivity, no conversion is required. Machine reading can be mixed with some recycle water depending on feed water pressure. Feed water pressure should be above 35 PSI to make this comparison.
2. Check the quick-disconnect fittings and lines. They should seat securely and fluid should shut off when they are disconnected. Inspect O-rings for any nicks or cuts.

5.1.5 Annual Maintenance

1. An AAMI or CSA Water Quality Analysis of the product water should be conducted at least yearly. (Refer to the “Water Quality Analysis Procedure” in Chapter Two.)

Test RO feed water (tap water). Test for:

- a. Iron presence (critical when a PAA based sanitizer is used)
- b. pH alteration
- c. Chlorine/chloramines shifts
- d. Hardness fluctuations

CAUTION:

If RO feed water changes in its constituents, the pretreatment components may need to be reassessed for proper capacity.

2. Check the tubing and fittings for leaks or wear.
3. Check all pre RO devices for correct operation.

5.1.6 As Required

1. Low pH chemical cleaning
 - a. Should be performed if the rejection rate has decreased by more than 5% from the initial value.
 - b. Should be performed if sufficient output flow is not obtained.
 - c. Should be performed as a preventive measure when a softener is not used.
 - d. Should be performed as a method to remove transitional metals from the RO membrane prior to chemical sanitization.
2. High pH chemical cleaning
 - a. Should be performed if organic fouling is suspected.
 - b. Should be performed if the rejection rate has decreased by more than 5% from the initial value and low pH cleaning has not helped to improve product water flow.
3. Chemically sanitize the RO with MINNCARE HD. Refer to the Chemical Sanitization Procedure in this chapter.

5.2 Specific Maintenance Procedures and Instructions

5.2.1 Leak Repair

General information: Any leak from any part of the system should be corrected as soon as possible. Left unattended, leaks can cause secondary damage necessitating expensive repairs.

NOTE:

Use FDA/NSF approved silicone sealant on all threaded connections.

Threaded Connections

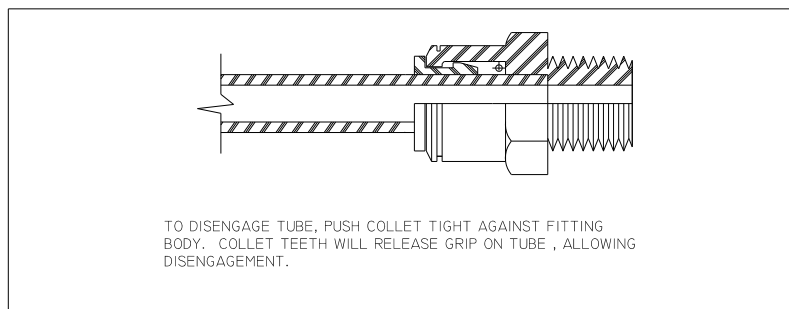
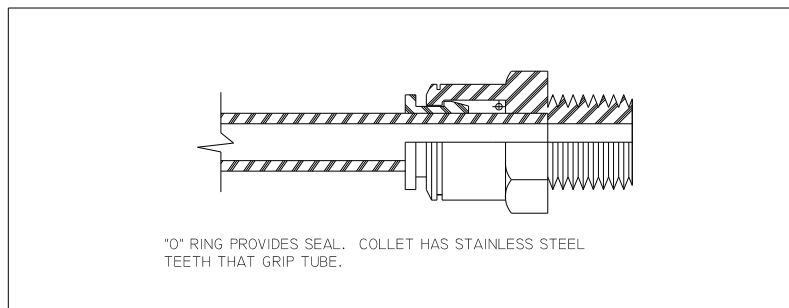
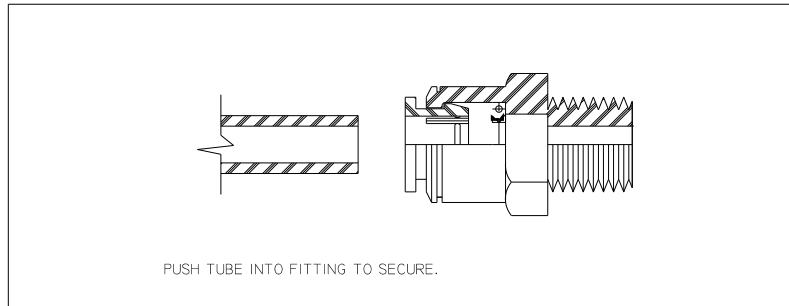
1. Prior to performing maintenance on any threaded fitting, release the pressure in the piping/tubing system, i.e., turn off the pump, open a drain port, etc.
2. Remove the connecting tubing.
3. Re-tape the pipe threads with 2 or 3 wraps of PTFE tape, if required. (It is not necessary to remove the old PTFE tape, although it may be advisable to do so if it is in very bad shape).
4. Insert the threaded fitting into the opening and hand tighten. Be careful to avoid cross threading. Tighten using a wrench, only if necessary, about one-half turn.
5. Reconnect piping, pressurize, and inspect for leaks.
6. If the leak is still present, de-pressurize system and tighten the fitting an additional quarter-turn. Excessive tightening can crack threaded fittings. Pressurize the system and inspect for leaks.
7. If the leak continues, it may be necessary to replace the fitting.

Barbed Connections

1. Prior to performing maintenance on any fitting, release the pressure in system, i.e., turn off pumps, open a drain port, etc.
2. Remove the hose from the barbed connection by loosening its clamp. If permanent clamp device is used, it may be necessary to cut the tubing behind the barb.
3. If reusing the barbed connection, ensure there is no damage to the barb connection. Slide clamp onto hose and reinsert barbed fitting into hose and tighten the clamp.
4. Reconnect and pressurize system and inspect for leaks. If leak continues, it may be necessary to replace the fitting.

Tubing Connections:

NOTE: IF THE FITTING LEAKS, CHECK FOR IMPROPER TUBE INSERTION OR TUBE ROUTING THAT MAY CONTRIBUTE TO LEAKAGE. INTERNAL COMPONENT REPLACEMENTS ARE NOT AVAILABLE. LOCKING CLIPS NOT REQUIRED.



NOTE: SOME "PUSH-IN" FITTINGS HAVE DUAL O-RINGS.

"PUSH-IN" FITTING INSTRUCTIONS

1. Prior to performing maintenance on any tube fitting, relieve pressure in the tubing system; i.e., turn off the pump, open a drain port, etc.
2. Remove the red locking clip (if applicable).
3. Push the collar in towards the body of fitting. This releases the 'gripper' that holds the tube in place.
4. Hold the collar in while gently pulling the tube away from the fitting.
5. Remove the gripper collar by pulling straight out. Reach into the opening with a small, blunt (non-scratching) probe and remove the O-ring(s). Inspect the collar to insure that all grippers are intact.
6. Rinse the O-ring with warm running water to remove any debris and set aside to dry on a clean paper towel.
7. Clean the inside of the fitting with a wet cotton swab or paper towel to remove any debris. Be sure not to leave any cotton fibers from the swab or towel inside the fitting.
8. Lubricate the O-ring(s) sparingly with silicone O-ring lubricant and place the O-ring back inside the fitting.
9. Replace the gripper collar.
10. With a sharp utility knife, cut off approximately ½" of tube. Carefully cut the tube as square (perpendicular to the length) as possible. Inspect remaining tubing for marks/scratches and replace/repair as necessary.
11. Place the tube in the fitting opening and push firmly until the tube seats fully into the socket.
12. Pull back on the tubing to seat the grippers and re-install the locking clip (if applicable) between the body of the fitting and the collar (flat side towards the body).
13. Re-pressurize the system (if applicable) and inspect for leaks.
14. If the leak is not resolved, replace the entire tube fitting or tube.

5.2.2 Conductivity/Temperature Sensor Verification

1. Log the product TDS/μS, RO feed water TDS/μS and the product water temperature after the RO has run for 15 minutes.

2. Draw a product water sample and use an independent meter to read the conductivity ($\mu\text{S}/\text{cm}$) and temperature. Readings should be within $\pm 10\%$ or $\pm 2 \text{ TDS}/4 \mu\text{S}$ (whichever is greater). TDS readings are to be calculated using the following equation: $\text{TDS} = 0.5 \times \text{conductivity } (\mu\text{S}/\text{cm})$. Temperature should read within $\pm 10\%$. If verifying conductivity, no conversion is necessary.
3. Draw a RO feed water sample and use an independent meter to read the TDS/conductivity. Readings should be within $\pm 10\%$ or $\pm 2 \text{ TDS}/4 \mu\text{S}$ (whichever is greater). TDS readings are to be calculated using the following equation: $\text{TDS} = 0.5 \times \text{conductivity } (\mu\text{S}/\text{cm})$. If verifying, conductivity no conversion is necessary. Machine reading can be mixed with some recycle water depending on feed water pressure. Feed water pressure should be above 35 PSI to make this comparison.

WARNING:

Ensure that TDS/ μS and membrane performance (% rejection) are normal for the regions water quality. Consult your facility physician. An appropriate AAMI analysis and bacteria/Endotoxin test meeting AAMI or CSA requirements of the product water must be obtained and interpreted before using the RO unit for hemodialysis treatment, refer to Section 2.3 "Product Water AAMI Analysis Procedure" and Section 5.5.1 "Product Water Culture Procedure".

5.2.3 Membrane Replacement**WARNING:**

Only perform this procedure when the RO is OFF and disconnected from feed water.

1. Remove the rear access door by removing the 4 screws that keep the door in place.
2. Remove the membrane assembly by pulling the housing straight out from the cabinet.
3. Remove the end caps from housing.
4. Remove the membrane from the housing. Discard membrane.
5. Install new membrane into housing. The membrane can be installed from either direction. If only one end cap was removed, install the membrane with the capped side of the permeate tube towards the bottom end cap.
6. Install the bottom end cap into the housing. The end cap is installed into the membrane permeate tube that is capped.

7. Install the top end cap into the housing. Ensure that the holes located on the side of the top and bottom end caps are located on the same side.
8. Install the membrane assembly into the RO.
9. Install the rear access door and secure the 4 screws that keep the door in place.
10. Start the RO and verify proper operation. Allow the RO to operate for 1 hour.
11. Perform a single heat disinfection of the RO.
12. Verify the RO is operating with proper flows and pressures and set the product water alarm limit and the membrane performance set point to new readings.
13. Draw sample of product water and submit for AAMI testing.

WARNING:

Ensure that TDS/ μ S and membrane performance (% rejection) are normal for the regions water quality. Consult your facility physician. An appropriate AAMI analysis and bacteria/Endotoxin test meeting AAMI or CSA requirements of the product water must be obtained and interpreted before using the RO unit for hemodialysis treatment, refer to Section 2.3 "Product Water AAMI Analysis Procedure" and Section 5.5.1 "Product Water Culture Procedure".

14. The RO is ready for use.

5.3 Cleaning Indications

Foulants such as minerals, silt and organic substances may collect on the RO membrane surface and cause the RO membrane to foul and diminish in its function. Many of these foulants are prevented by proper selection of pretreatment equipment, while others are treatable only with more sophisticated designs. Regardless of the foulant, it is essential to clean the membrane promptly once cleaning is indicated (typically loss of flow or decreasing rejection). The longer a foulant is allowed to remain in contact with the RO membrane, the more difficult it will be to remove. In severe cases, repeated cleanings may be required.

NOTE:

Some foulants CANNOT be removed with cleaning and membrane performance may not be fully restored. Observe the appearance of the cleaning solution before discarding it. If the solution is heavily soiled, repeat the cleaning procedure with fresh solution of the same type (high or low pH).

Routine cleaning of the RO membranes in conjunction with regular disinfection/sanitization will keep bacteria counts at a minimum and the RO membrane performance at its best. Cleaning removes the silt, organic and mineral deposits that collect on the RO membrane surface, which if left untreated, encourages bacterial growth and will eventually impair the RO membrane's ability to perform. Sanitization/disinfection kills most of the bacteria that may be present in the system but it does not remove the biofilm from the membrane.

There are a variety of indications for cleaning membranes. The most common is a reduced product flow rate. Remember that a reduction in inlet water temperature can also result in a reduced flow rate. Refer to Technote 113, "Temperature Correction Factors", to determine the reduction in flow that can be attributed to reduced water temperature. Clean the membranes whenever the % rejection drops by 5%. A loss in the membrane performance (percent rejection) or increase in TDS/ μ S of the product water may also be an indication to clean the membranes. If the current cleaning schedule is not effectively maintaining acceptable readings, more frequent cleaning may be required.

CAUTION:

Membranes that have not been cleaned for a long time may actually incur damage during cleaning as perforations are exposed that were masked by accumulations of foulant. Regular maintenance cleaning is the best assurance of long membrane service.

5.3.1 Cleaning Procedure

There are two types of cleaners available, a low pH cleaner (Calcium/Iron removal) and a high pH cleaner (Silt/Organics removal). Mar Cor Purification provides these cleaners in liquid form. The low pH cleaner attacks mineral scale deposits such as calcium, magnesium and iron build-up. The high pH cleaner will remove accumulated silt and organic matter from the RO membrane. Typically, the low pH cleaner should be used first followed by the high pH cleaner. There may be specific fouling/scaling situations where it will be advantageous to reverse this order of cleaning.

WARNING:

The cleaning solution is an irritant to eyes and skin. It is recommended that protective gloves and eye protection be worn when handling the cleaner. Always follow recommendations found in the Material Safety Data Sheet and any applicable OSHA standards for the chemical being used.

WARNING:

Label machine with appropriate warning signs such as "DO NOT USE/CONTAINS CLEANER" to prevent use of the RO until it is properly rinsed.

CAUTION:

The different cleaners must not be mixed together. For typical cleaning processes, Mar Cor Purification recommends using the low pH cleaner first, thoroughly rinse the system, and then use the high pH cleaner.

CAUTION:

Biosan™ is not intended for use in hemodialysis machines.

NOTE:

Follow the procedures recommended by cleaning solution manufacturer if they vary from the following steps.

NOTE:

Disposal – Water contaminated with this product may be sent to a sanitary sewer treatment facility, in accordance with any local agreement, a permitted waste treatment facility or discharged under a permit. Product (cleaners) as is – Incinerate or land dispose in approved land fill.

Storage – Keep containers closed when not in use. Do not freeze. If frozen, thaw and mix completely prior to use.

Materials Required:

- High and Low pH cleaner
 - Liqui-Clean™ 103 – (Low pH liquid) – P/N 1228653 (1 gal.)
 - Liqui-Clean™ 511 – (High pH liquid) – P/N 1228791 (1 gal.)
- Chemical Bottle– Provided with the RO (P/N 3026770)
- pH test strips - (P/N 3026658)
- **“DO NOT USE”** warning labels (not provided by Mar Cor Purification)
- Cleaning/Disinfect log sheets
- Current log sheets for water quality comparison

Read and understand instructions on cleaner container before beginning procedure.

1. Connect the water inlet line to the water supply. Connect the waste line to a functional drain. Ensure that the product line is connected between the product and return ports on the RO. Turn the RO and water supply on. Disconnect the dialysis machine from the product line if connected.
2. On the Main Screen, press RUN.



3. Establish a pre-cleaning % rejection, TDS/μS and pH; record on the cleaning disinfect log sheet. Fill your chemical tank with the proper amount of RO water. Refer to the label on the chemical bottle. Once readings are recorded, press and hold the STOP button to stop the RO.
4. Add the cleaner, as specified on the labeling, to chemical bottle. Do not connect the bottle at this time.

CAUTION:

Water to be used must be chlorine free or damage to the RO membrane may result.

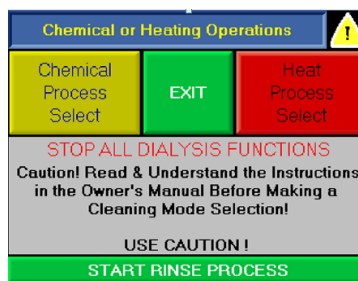
WARNING:

Label machine with appropriate warning signs such as "DO NOT USE/CONTAINS CLEANER" to prevent use of the RO until it is properly rinsed.

5. Press and hold the blue banner on the top of the Main Screen that says PRESS AND HOLD FOR CLEANING MODES.



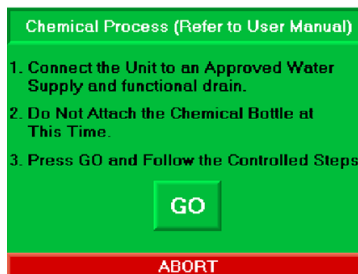
6. Press and hold the CHEMICAL PROCESS SELECT button.



7. Follow the on screen instructions and press GO.

NOTE:

Do not connect the chemical bottle at this time.



8. The machine starts to purge filling the internal tank to the proper level with product water. Once this is complete, proceed to step 9.



9. Connect the chemical bottle. Remove the product line from the return port and connect to the bottle. Connect the remaining line on the chemical bottle to the return port. At this time the operator can adjust the chemical time. It is factory set for 1 hour but is adjustable between 36 to 60 minutes. Follow the on screen instructions and press START. The RO will re-circulate the cleaner for the selected time. Verify that during the chemical process, the FEED and PROD TDS/conductivity readings increase indicating that chemical is being distributed through the RO.

CAUTION:

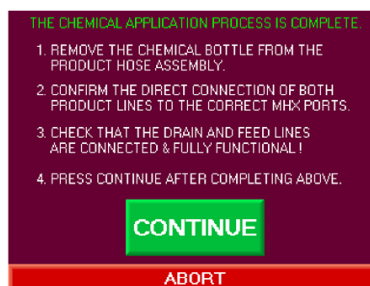
The program is designed to rinse the RO at the completion of the chemical process. Do not try to bypass the operation of the machine. It is the responsibility of the end user to ensure the RO has been rinsed of all chemicals prior to use for dialysis.

CAUTION:

If the operator does not add chemical to the bottle or if the bottle is not properly connected, the machine will sound an audible alarm and the ABORT button will flash. To clear the alarm, the operator will need to identify the issue. Do not add chemical to the bottle while it is connected to the machine. Prior to adding any chemical, remove bottle from the product line. When the problem is rectified, the alarm will clear after approximately a 3 minute delay.



10. After the chemical process is complete, perform the on screen instructions and press CONTINUE.



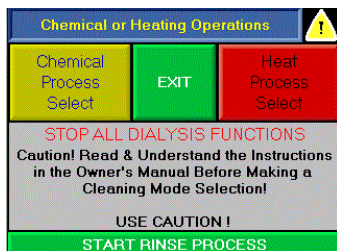
11. The RO is ready for rinsing. Press START RINSE NOW. The RO will begin a flush process to remove the residual chemical. Verify that the FEED and PROD TDS/conductivity readings decrease as the rinse process is performed. Do not connect any fittings to the Y connector.



12. The RO will operate in a rinse mode where the internal tank is being filled and drained rinsing the RO.
13. After 30 STEPS (i.e. rinses) are complete, the EXIT button will be visible indicating that the operator can exit. If the EXIT button is not pressed, the RO will continue to flush for a total of 50 STEPS. If the operator presses EXIT or allows the RO to complete all of the rinse steps, the RO will return to the Chemical or Heating Operations selection screen.



14. Press EXIT.



15. Press RUN from the Main Screen. Rinse for an additional 15 minutes or until the % rejection and TDS/ μ S monitors' displays normalize, e.g., 'usual' % rejection and 'usual' TDS/ μ S reading. Refer to your operating log for 'usual' readings and compare to the pre-cleaning values.



16. Test the product water for post-cleaning pH and compare it to the pre-cleaning pH level. The values should be within 1 pH unit of the pre-cleaning pH. If it is not, continue rinsing until equalization of the value occurs.
17. Press and hold the STOP button to turn off the RO pump.
18. Remove the **“DO NOT USE/CONTAINS CLEANER”** warning label.

NOTE:

The Millenium HX must be disinfected by heat or sanitized with MINNCARE HD after the cleaning procedure.

19. **The Millenium HX system is now ready for use.**

5.4 Chemical Sanitization Procedure

NOTE:

Chemical disinfection is not required for Millenium HX units. Heat disinfection is the preferred method to maintain bacterial control.

WARNING:

Always wear rubber gloves, apron and facemask. Use proper ventilation during disinfection and rinse-out. **DO NOT BREATHE FUMES OR ALLOW MINNCARE HD TO COME IN CONTACT WITH SKIN OR EYES.** Always follow recommendations found in the Material Safety Data Sheet and any applicable OSHA standards for the chemical being used.

WARNING:

Label machine with appropriate warning signs such as “DO NOT USE/CONTAINS SANITIZER” to prevent use of the RO until it is properly rinsed.

CAUTION:

The different cleaners/sanitizers must not be mixed together.

NOTE:**MINNCARE HD STORAGE AND DISPOSAL:**

Do not contaminate water or food by storage or disposal.

STORAGE:

Store in shipping carton. Do not expose to direct sunlight. Maintain temperature below 75°F (24°C). Avoid contact with combustible materials. Avoid contamination from any source, including metals, dust, etc. Such contamination may cause rapid decomposition, generation of large quantities of oxygen gas and high pressure. Store in original closed container. **NEVER TAMPER WITH VENT.**

DISPOSAL:

Waste resulting from the use of this product may be disposed of on-site by dilution in a sanitary sewer or at an approved waste disposal facility.

CONTAINER DISPOSAL:

Triple rinse empty container with water, then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill; incinerate; or if allowed by state and local authorities by burning. If burned, stay clear of the smoke.

Materials Required:

- MINNCARE HD Disinfectant (select one)
 - 4 x 1 Qts P/N 3029765
 - 6 x90 mL P/N 3031105
- MINNCARE HD Residual Test Strips P/N 3029795
- Chemical Bottle (Provided with the RO) P/N 3026770
- **"DO NOT USE"** warning labels (not provided by Mar Cor Purification)
- Cleaning/Disinfect log sheets
- Current log sheets for water quality comparison
- PPE

NOTE:

Read and understand instructions before beginning procedure.

CAUTION:

MINNCARE HD is corrosive to most metals other than stainless steel. The Millenium HX uses only compatible materials. MINNCARE HD contains oxidizing agents that are potentially damaging to thin film (polyamide) membranes. It is imperative that all the precautions and instructions are followed correctly. Failure to comply with these instructions, which incorporate instructions from the membrane manufacturer, will jeopardize the system's performance and warranty.

1. Connect the water inlet line to the water supply. Connect the waste line to a functional drain. Ensure that the product line is connected between the product and return ports on the RO. Turn the RO and water supply on. Disconnect the dialysis machine from the product line if connected.
2. Prepare the sanitizer by adding RO water and the amount of sanitizer as specified on the labeling of the chemical bottle. Do not connect the bottle at this time.

CAUTION:

Water to be used must be chlorine free or damage to the RO membrane may result.

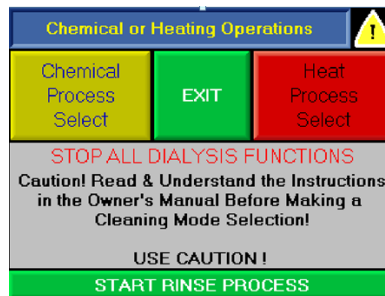
WARNING:

Label machine with appropriate warning signs such as "DO NOT USE CONTAINS SANITIZER" to prevent use of the RO until it is properly rinsed.

3. Press and hold the blue banner on the top of the Main Screen that says PRESS AND HOLD FOR CLEANING MODES.



4. Press and hold the CHEMICAL PROCESS SELECT button.



5. Perform the on screen instructions and press GO.

NOTE:

Do not connect the chemical bottle at this time.



6. The machine starts to purge filling the internal tank to the proper level with product quality water. Once the purge is complete, proceed to step 7.



7. Remove the product line from the return port and connect to the bottle. Connect the remaining line on the chemical bottle to the return port. At this time, the operator can adjust the chemical time. It is factory set for 1 hour but is adjustable between 36 to 60 minutes. Follow the on screen instructions and press START. The RO will recirculate the sanitizer for the selected time. Verify that during the chemical process, the FEED and product PROD TDS/conductivity increase indicating that chemical is being distributed through the RO.

CAUTION:

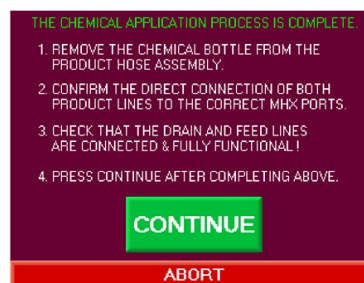
The program is designed to rinse the RO at the completion of the chemical process. Do not try to bypass the operation of the machine. It is the responsibility of the end user to ensure the RO has been rinsed of all chemicals prior to use for dialysis.

CAUTION:

If the operator does not add chemical to the bottle or if the bottle is not properly connected the machine will sound an audible alarm and the ABORT button will flash. To clear the alarm, the operator will need to identify the issue. Do not add chemical to the bottle while it is connected to the machine. Prior to adding any chemical, remove bottle from the product line. When the problem is rectified, the alarm will clear after approximately a 3 minute delay.



8. After the chemical process is complete, perform the on screen instructions and press CONTINUE.



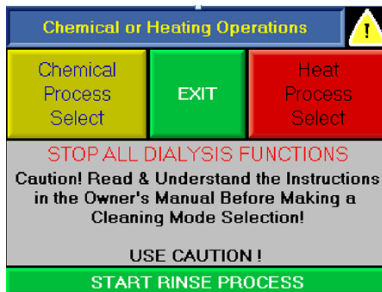
9. The RO is ready for rinsing. Press START RINSE NOW. The RO will begin a flush process to remove the residual sanitizer. Verify that the feed and TDS/conductivity readings decrease as the rinse process is performed. Do not connect any fittings to the Y connector.



10. The RO will operate in a rinse mode where the internal tank is being filled and drained rinsing the RO.
11. After 30 STEPS (i.e. rinses) are complete, the EXIT button will be visible indicating that the operator can EXIT. If the exit button is not pressed, the RO will continue to flush for a total of 50 STEPS. If the operator presses EXIT or allows the RO to complete all of the rinse steps, the RO will return to the Chemical or Heating Operations selection screen.



12. Press EXIT.



13. Press RUN from the Main Screen. Rinse for an additional 15 minutes or until the % rejection and TDS/ μ S monitors' displays normalize, e.g., 'usual' % rejection and 'usual' TDS/ μ S reading. Refer to your operating log for 'usual' readings and compare to the pre sanitizing values.



14. Test the product water with the residual test strips. Continue to rinse until the product water results confirm there is no residual sanitizer in the RO.
15. Press and hold the STOP button to turn off the RO pump.
16. Waste resulting from the use of this product may be disposed of on-site by dilution in a sanitary sewer or at an approved waste disposal facility.
17. Remove the “**DO NOT USE/CONTAINS SANITIZER**” warning label.
18. **The Millenium HX system is now ready for use.**

5.5 Product Water Microbiological Testing

Product water must meet the AAMI and CSA Standards for both bacteria (AAMI 100 CFU max level (or lower if required by national legislation or regulations)) / 50 CFU action level (typically the limit will be 50% of the maximum allowable level) and endotoxin levels (AAMI and CSA 0.25 EU max (or lower if required by national legislation or regulations)) / 0.125 EU action level (typically at 50% of the maximum allowable level).

5.5.1 Product Water Culture Procedure

Materials Required:

- Bucket or similar container
- Sterile syringe (30 mL minimum – 2 required)
- Sterile specimen (your lab may require).

LAB CONSIDERATIONS:

- Consult your lab to find out what type of sterile container to use and how much product (RO) water is required to perform the test and any other specific requirements of the laboratory.
- Make certain that your laboratory is informed of the correct procedure for performing a product water culture. A "spread plate method", NOT a "calibrated loop" technique, should be used with typtone glucose extract agar (TGEA), Reasoners 2A (R2A) or other media that can be demonstrated to provide equivalent results. Blood or chocolate agar shall not be used.
- If tested incorrectly, the results may be inaccurate. The sample should be assayed within 4 hours of obtaining it or be immediately refrigerated and assayed within 24 hours of collection on a regular schedule.
- Obtain the samples wearing long sleeves and a mask to prevent contamination of samples; use a "mid-stream", "clean catch", type procedure.

NOTES:

Follow facility protocols (gloves, mask, etc.) for collection of samples.

This procedure assumes the RO is connected to power and water and is running in normal operating condition.

1. Turn on the RO unit. Allow the RO unit to run for 15 minutes.

2. Using alcohol, wipe the sample port and allow to air dry. Using aseptic technique, insert the male luer end of the first sterile/pyrogen free syringe into the port, withdraw the syringe plunger to the maximum sample volume. Remove and discard the syringe.
3. Using the second sterile/pyrogen free syringe draw a sample by inserting the male luer end into the port and withdraw the appropriate sample as required for your laboratory. Aseptically transfer the sample to the lab supplied container, cap the specimen container immediately.
4. Label the specimen appropriately with:
 - Test to be performed - "culture/colony count"
 - Sample source - product water/RO, machine serial number and room location
 - Time and date sample obtained
 - Person who obtained specimen
 - Any other pertinent information or procedures your facility or lab requires
5. The samples should be assayed within 4 hours of collection or refrigerated immediately and assayed within a 24-hour period.

5.5.2 Endotoxin Testing Procedure

Due to the nature of endotoxin testing, it is recommended to consult with a laboratory or test kit instructions for appropriate procedures.

Materials Required:

- Bucket or similar container
 - Sterile syringe (30 mL minimum – 2 required)
 - Sterile specimen, your lab may require.
1. Turn on the RO. Allow the RO to run for 10-15 minutes.
 2. Using alcohol, wipe the sample port and allow to air dry. Using aseptic technique, insert the male luer end of the first sterile/pyrogen free syringe into the port, withdraw the syringe plunger to the maximum sample volume. Remove and discard the syringe.
 3. Using the second sterile/pyrogen free syringe draw a sample by inserting the male luer end into the port and withdraw the appropriate sample as required for your laboratory. Aseptically transfer the sample to the lab supplied container, cap the specimen container immediately.
 4. Label the specimen appropriately with:
 - Test to be performed - "endotoxin"
 - Sample source - product water/RO, machine serial number and room location
 - Time and date sample obtained
 - Person who obtained specimen
 - Any other pertinent information or procedures your facility or lab requires
 5. The samples should be assayed within 4 hours of collection or refrigerated immediately and assayed within a 24-hour period.

5.6 Chemical Storage Procedure

WARNING:

It is recommended that PPE attire such as gloves (latex/vinyl) and eye protection be worn when handling the storage solution. Always follow recommendations found in the Material Safety Data Sheet and any applicable OSHA standards for the chemical being used.

1. Mix 0.25lbs of Memstor™ to 630mL of warm tap water. The warm water helps dissolve the Memstor into solution.
2. Follow direction in section 5.3.1, step 4 through step 9
3. After the chemical process is complete, do not rinse the RO after the storage solution has been circulated in the RO.
4. Turn the RO off by turning the main power switch on the rear of the RO to OFF. Label the machine with appropriate warning labels and the date it was stored.
5. Coil the hoses and power cord and cover the RO with a large plastic bag to protect the RO from dust.

CAUTION:

The Millenium HX may be stored in Memstor for up to 90 days. After 90 days, if longer storage is needed, the RO must be rinsed and re-packed with Memstor solution.

WARNING:

After storage, the RO must be completely rinsed of Memstor and a bacterial culture performed and interpreted before use. Perform AAMI or CSA analysis if it has been one month or more since last done.

START UP AFTER STORAGE

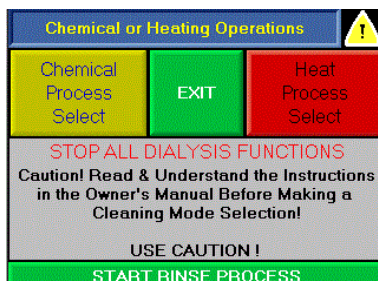
6. Connect the RO inlet hose connector to the inlet cold water supply and the QD end to the FEED connection on the RO.

NOTE:

If using pre-treatment equipment, refer to the device manual for proper placement and connections.

7. Connect the waste water line to the "Waste" QD connection on the back of the RO and to the drain in accordance with the local plumbing code.
8. Connect the "Product" line between the Product and Return QD's on the RO. Do connect any fittings to the Y connector.

9. Plug the power cord into a 115 VAC (230 VAC) grounded outlet and reset the GFCI if necessary (60 Hz RO only). Do not use an extension cord or an un-grounded adapter.
10. Turn on the water supply to the RO.
11. Turn on the main power module power switch. The touch screen will illuminate. Press START RINSE PROCESS to rinse RO. Allow the RO to rinse for 30 steps.



12. Press EXIT to enter the Chemical or Heating Operations selection screen after the rinse is complete.



13. Complete a SINGLE HEAT disinfection. Refer to Chapter 3, Section 3.3.1 "Heat Disinfection Procedure (Single Heat)".

5.7 Auto Run

1. From the Run Screen press and hold AUTO-RUN.



2. When AUTO-RUN is pressed, the operator can set the RO to run for up to 59 minutes at specified time intervals (1 minute up to 99 hours and 59 minutes). To enter time, press the box indicating the time. When the RO is running, the IDLE indicator is replaced with OPERATING. To exit, press the CANCEL & EXIT banner. When pressed, the RO will exit back into the normal run screen starting in a startup flush with product water diverted to drain.

Auto_Run Operations, Set Interval...

01.00	Enter the time between runs (HH:MM)
10	Enter the Auto-Run length (MM)

The RO will run in 00.59.51 , and operate for 10.00 MM:SS before resetting.

IDLE

CANCEL & EXIT

Millenium HX RO System

CHAPTER 6: TROUBLESHOOTING

This page intentionally left blank.

6.1 RO Fails to Run

- 1. Power off (Screen Dark).**
 - a. Check power cord (plugged in).
 - b. Verify that line and equipment voltages are compatible.
 - c. Check outlet and circuit breaker/fuse panel for power with voltmeter.
 - d. Check the two fuses at power cord entry module above main power switch.
 - e. Check GFCI (reset if necessary).
- 2. Power switch inoperative.**
 - a. Check switch with voltmeter.
 - b. Replace switch if necessary.
- 3. Pump/Motor inoperative.**
 - a. Verify that voltage supply is correct at pump controller.
 - b. Cycle the main power switch (5 seconds off).
 - c. Verify the amber light in the motor controller is lit and not flashing.
 - d. Verify incoming water pressure meets minimum requirements.
 - e. Check the pump power feed cable at both ends for a secure fit.
 - f. Verify the voltage supply switch on the Power Distribution PCB is correctly set.

6.2 RO Feed Pressure Alarm



- 1. Feed Pressure shut down in normal run and during purge process.**
 - a. Verify the dynamic supply pressure to the RO. Pressure needs to be a minimum of 15 PSI and a maximum of 130 PSI with appropriate flow.
 - b. Correct incoming RO feed water pressure.

6.3 Product Water Quality Alarm



1. **Product Quality Shutdown during normal run.**
 - a. The Product water Quality set point is adjustable from 1 to 50 TDS (1-100 μ S). Verify that your set point is correctly set.

6.4 This Unit Must Stand Upright Alarm



1. **This Unit Must Stand Upright shutdown.**
 - a. Verify the Unit is in the upright position.
 - b. With the unit disconnected from electricity, verify that the tilt sensor is closed using an ohmmeter when in the upright position. If faulty, replace tilt sensor.

6.5 Product Water High Temperature



1. **Machine shutdown during normal run.**
 - a. This will activate when the product water temperature is above 105°F. Verify the water temperature with a handheld instrument.

6.6 RO Feed Water Quality Alarm



1. **Machine shutdown during normal run.**
 - a. This is a user adjustable setting between 50 and 1000 TDS (100-2000 μ S). Verify incoming RO feed water TDS/ μ S and compare against the set point. Adjust set point if necessary.
 - b. If operating in a region where RO feed water TDS is typically greater than 1000 TDS (2000 μ S), this alarm can be disabled to allow operation. Set the set point to 1001 TDS (2001 μ S) to disable this alarm.

6.7 Pump Pressure Alarm



This alarm is active at all times as a high and low pressure watch. If this alarm is triggered, the pump will shut down. The levels at which the alarm will activate are based on the mode, water temperature, and pump pressure set points. The alarm set points can not be changed.

- 1. Pump shut down during normal run or chemical.**
 - a. The RO is designed to operate at higher pressures when operating on cold water. Verify the current set point vs. the operating pressure of the pump to see if the pump is producing pressures at or above the alarm set point.
 - b. Check the waste flow path for obstructions

6.8 Product Pressure High Alarm



This function is active during all operations of the Millenium HX and if triggered will stop the pump and sound an alarm. This set point is set in the code at 60 PSI.

- 1. Pump Shutdown during operation.**
 - a. Verify that the lines are connected correctly.

6.9 Service Required Component Failure Detected



The OPLC monitors various signals during operation to detect a failure of components. This is active while the RO is running. Below are the error codes. Have this code ready when you contact Technical Support.

Error Code List	
Code	Error Description
8	RO Feed quality probe error, out of range, quality PCB circuit error, Fuse F5 Open
9	Product quality probe error, out of range, quality PCB circuit error, Fuse F5 Open
41	Product temperature probe error, out of range, quality PCB circuit error, Fuse F5 Open
51	High product pressure during chemical (SV5 or SV3 may be faulty)
62	Major drop in water temperature during heat hold phase
71	Solenoid valve 4 error, tank filling, tank draining or flow problem
72	Pump fault during dialysis, chemical or cooling mode
79	Pump high pressure condition
95	Low product production in any disinfection/cleaning
108	RO Feed pressure transducer PS1 fault/error, Fuse F5 Open
147	Pump fault during the heat process
165	Pump pressure transducer PS2 fault/error, Fuse F5 Open
167	Product pressure transducer PS3 fault/error, Fuse F5 Open
170	Tank filling error, level switch error, water flow path error
184	Tanks level sensor error, tank level error during heat purge, tank thermal protection switch trigger, analog component error
194	Membrane door or membrane incorrectly secured/installed
333	Thermal safety switch circuit opened
444	Tank level sensor sequence error

6.10 Product Flow Too Low

Low water temperatures, fouled membrane elements, or inadequate pump pressure can cause low product flow. A partial blockage of the RO feed stream (dirty pre-filter) can also result in low product water flow by causing the pump to draw a strong vacuum. Similarly, an obstruction (such as a defective check valve) in the product flow path may cause reduced flow.

1. **Low RO feed water temperature.**
 - a. Verify product production with Technote 113, "Temperature Correction".
 - b. Install or adjust temperature blending valve.
2. **Membrane fouled or scaled.**
 - a. Review trend analysis logs.
 - b. Clean membrane with low and or high pH cleaners.
 - c. If flow is not recoverable, replace membrane.
3. **Check softener pretreatment for brackish (high salt) water.**
 - a. Check inlet water for high conductivity.
 - b. Check water softener for proper function.
 - c. Regenerate softener.
 - d. Check supply water for hardness and conductivity.
4. **RO Feed water fouling membrane (change in RO feed water).**
 - a. Check for change in RO feed water quality.
 - b. Check with city water department.

6.11 Product Flow Too High

1. **Rejection Satisfactory**
 - a. **Quick disconnect tubing connections not in correct port.**
 1. Verify QD connections.
2. **Rejection Unsatisfactory**
 - a. **Waste flow too low.**
 1. Check waste flow rate.
 2. Check for blockage or kink in waste line.
 3. Quick disconnect not connected completely.
 - b. **High pH and chlorines in RO feed water.**
 1. Check RO feed water for pH higher than 8.5 and the presence of chloramines.
 2. Check pH reduction equipment if applicable.
 3. Contact Mar Cor Purification.
 - c. **Membrane internal seals damaged, dirty, or dislodged.**
 1. Disassemble the membrane assembly, clean and inspect O-rings and seals.
 - d. **Membrane oxidized (exposed to oxidant).**
 1. Verify condition of carbon pretreatment equipment.
 2. Overexposure to MINNCARE HD.
 - e. **Membrane damaged (or ruptured).**
 1. Check for high product pressure.
 2. Check for product line being back pressured.
 - f. **Normal membrane rejection decline (over time).**
 1. Perform AAMI/CSA water lab analysis.
 2. Replace membrane if indicated by analysis.

6.12 Leaks

General information: Any leak from any part of the system should be corrected as soon as possible. Left unattended, leaks can cause secondary damage necessitating expensive repairs.

Refer to Section 5.2.1 "Leak Repair".

6.13 Low Percent Rejection

The overall membrane performance can be affected by a number of factors. Poor rejection performance, as well as, high TDS/ μ S can result from fouled membrane, low pump pressure, inadequate waste flow, or RO feed water problems. The recommended first step for any 'membrane performance' question is to confirm the rejection percentage and product TDS/ μ S with a hand-held meter. If the product water quality is poor, investigate the membrane. However, if the water quality tests 'normal', investigate the monitoring circuits.

1. **Disinfectant or cleaner left in RO.**
 - a. Check for presence of disinfectant or cleaner; rinse as necessary.
2. **Waste flow too low.**
 - a. Check for obstruction or kink in waste line.
3. **Product flow too high.**
 - a. See Section 6.11.
4. **Membrane scaled or fouled.**
 - a. Verify condition of softener pretreatment equipment.
 - b. See membrane cleaning procedure in this manual.
5. **Erroneous meter readout.**
 - a. Verify water quality with independent meter and check conductivity probe connection.
6. **Membrane failure.**
 - a. Replace membrane.
7. **Change in RO feed water TDS/ μ S.**
 - a. Verify RO feed and product water quality with independent meter.
 - b. Softener problem, rinsing out high levels of salt.
8. **Normal membrane rejection decline (over time).**
 - a. Perform AAMI / CSA water lab analysis.
 - b. Replace membrane if indicated by analysis.

6.14 TDS/ μ S Value High

The overall membrane performance can be affected by a number of factors. Poor rejection performance, as well as, high TDS/ μ S can result from fouled membranes, low pump pressure, inadequate waste flow, or RO feed water problems. The recommended first step for any 'membrane performance' question is to confirm the rejection percentage and product TDS/ μ S with a hand-held meter. If the product water quality is poor, investigate the membrane. However, if the water quality tests 'normal', investigate the monitoring circuits.

- 1. Disinfectant or cleaner left in RO unit.**
 - a. Check for presence of disinfectant or cleaner; rinse as necessary.
- 2. Waste flow too low.**
 - a. Measure and compare to original data.
- 3. Product flow too high.**
 - a. See Section 6.11.
- 4. Membrane scaled or fouled.**
 - a. Verify condition of softener pretreatment equipment.
 - b. See membrane cleaning procedure in this manual.
- 5. Erroneous meter readout.**
 - a. Verify water quality with independent meter.
 - b. TDS/ μ S water probe wire disconnected or loose.
 - c. Verify incoming voltage.
- 6. Membrane failure.**
 - a. Replace membrane.
- 7. Change in RO feed water TDS/ μ S.**
 - a. Verify feed and product water quality with independent meter.
 - b. Communicate with municipal water plant.
 - c. Softener problem, rinsing out high levels of salt.
- 8. Normal membrane rejection decline (over time).**
 - a. Perform AAMI / CSA water lab analysis.
 1. Replace membrane if indicated by analysis.

NOTES:

Millenium HX RO System

CHAPTER 7: DRAWINGS

This page intentionally left blank.

7.1 Component Identification

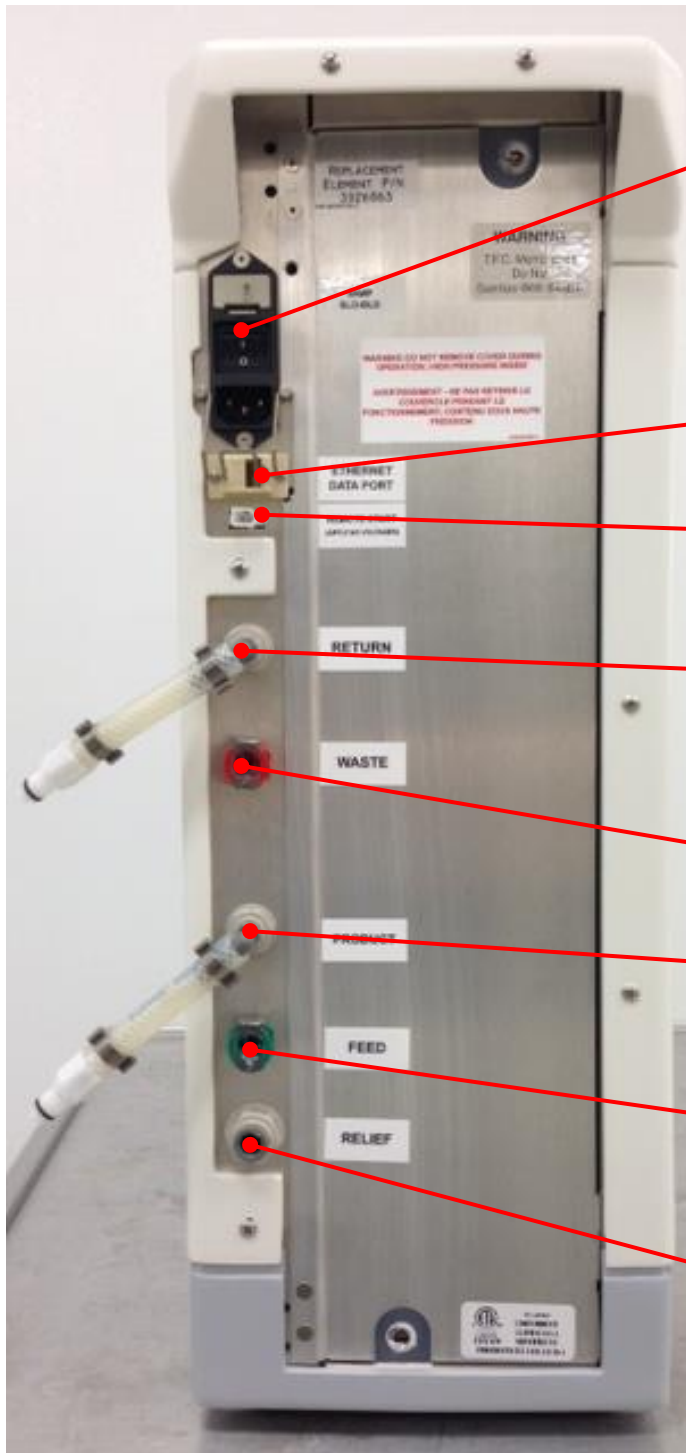
7.1.1 Front View



OPLC Touch Screen:

Operating panel and programmable logic controller.

7.1.2 Rear View



Power Inlet Module:

Power cable connects here. Also includes power switch and incoming power fuse holder. Two identical fuses are housed here depending on model.
(2x 6A SLO BLO 115VAC)
(2x 3A SLO BLO 230VAC)

Communications Port:

Used to connect to a network.

Remote Start/Stop:

Used to remotely start/stop the RO machine.

Return Port:

Product hose connects here. Unused product water returns to tank for later use.

Waste Port

Drain hose connects here.

Product Port

Product hose connects here. Product water is sent to dialysis machine.

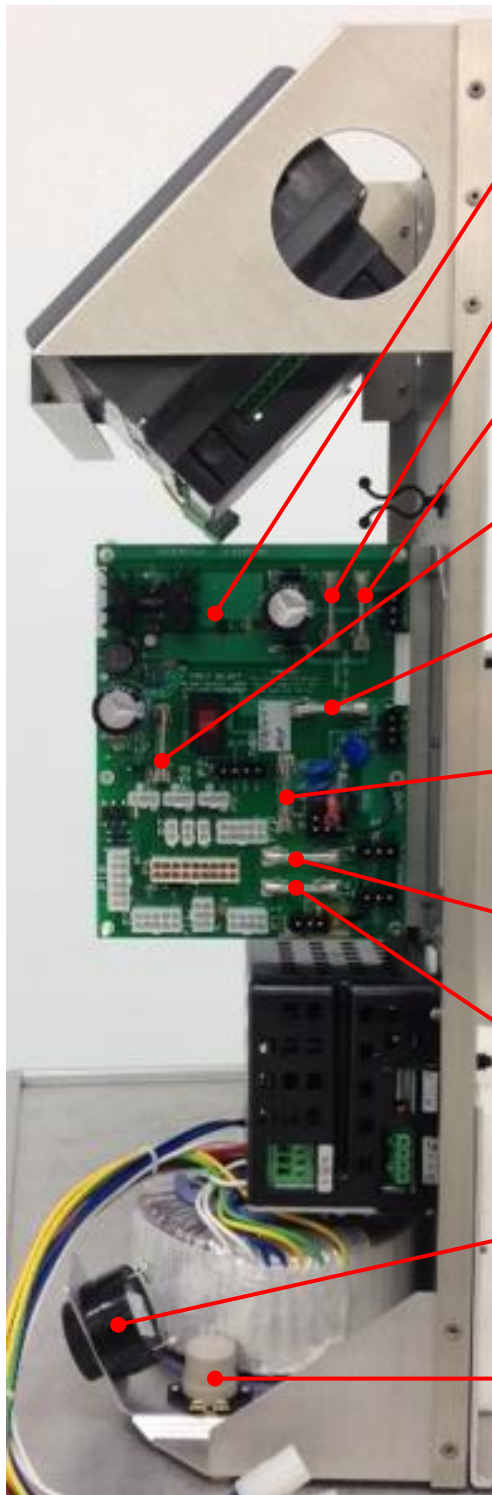
Feed Port

Pre-treated water source connects here.

Pressure Relief Port

Water exits RO here if tank pressurizes (something is wrong if this happens).

7.1.3 Electrical Right Side View



Power Distribution PCB

Distribution board used to connect the electrical components together.

Fuse 3:

30VAC power fuse.
(3A/Slo Blo)

Fuse 2:

30VAC power fuse.
(3A/Slo Blo)

Fuse 4:

24VDC power fuse.
(2.5A/Slo Blo)

Fuse 1:

Input power fuse.
(10A/Fast Blo 115 VAC)
(5A/Fast Blo 230 VAC)

Fuse 6:

Heater power fuse.
(6A/Fast Blo 115 VAC)
(3A/Fast Blo 230 VAC)

Fuse 7:

Pump controller power fuse.
(4A/Slo Blo)

Fuse 5:

24VAC power fuse.
(1.5A/Slo Blo)

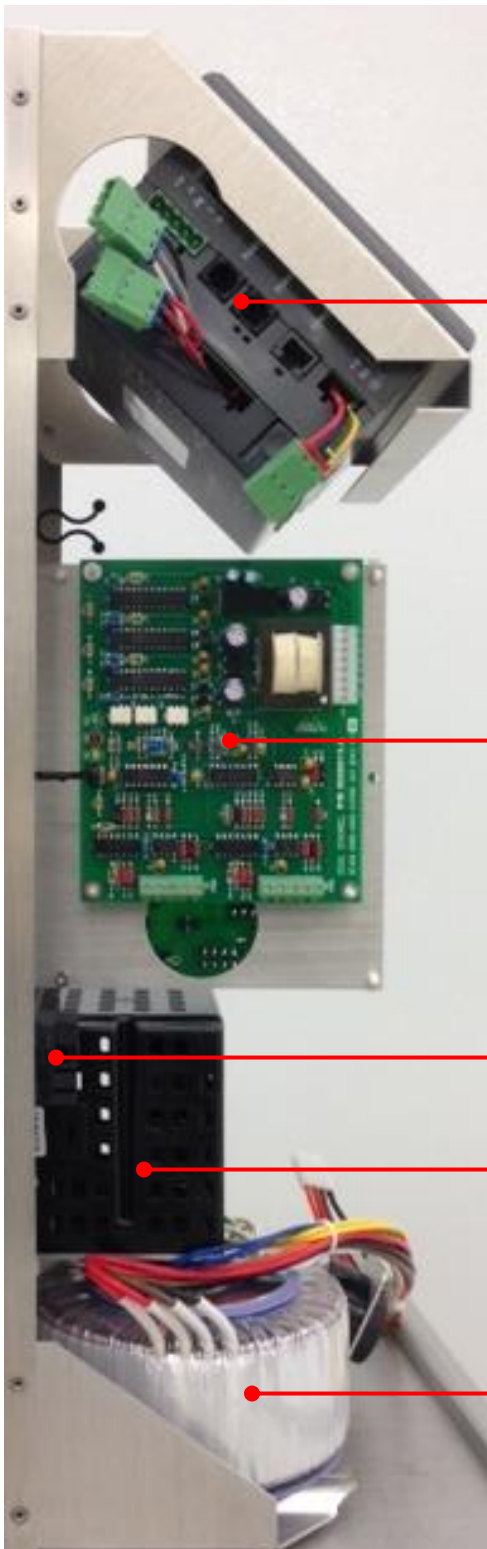
Alarm Horn

Horn for alarms and
screen touches.

Tilt Sensor

Senses if the machine is in
the upright position.

7.1.4 Electrical Left Side View



OPLC Touch Screen:

Operating panel and programmable logic controller.

Water Quality PCB:

Measures the water quality from the feed and product water quality sensors.

Heater Power Relay:

Switches the heaters on and off.

Pump Controller:

Controls the pump motor speed.

Transformer:

Transforms facility power to power needed by different devices within the RO.

7.1.5 Membrane Assembly



Top End Cap:

Caps the outlet side of the membrane.
Inserted on the top of the membrane (open
end of membrane permeate tube).

Membrane Housing:

SS housing to hold the RO element.

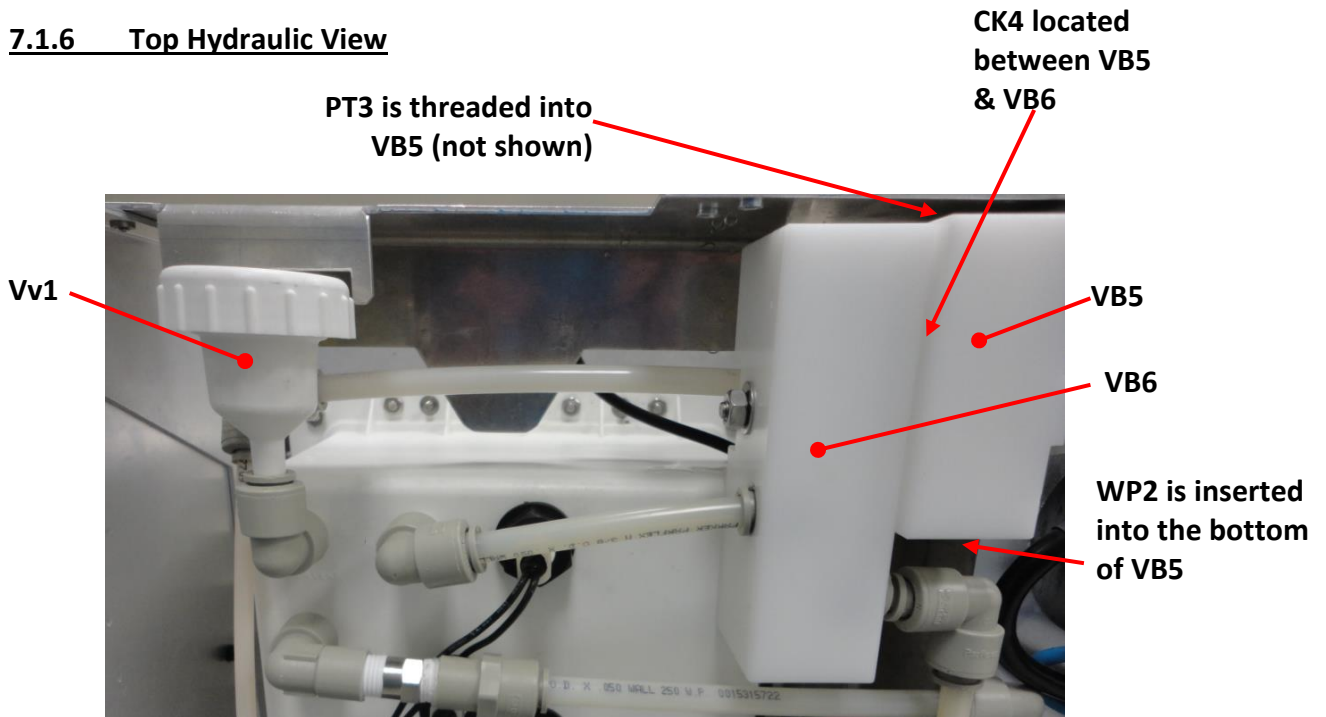
Membrane:

Reverse osmosis element used to purify the
source water.

Bottom End Cap:

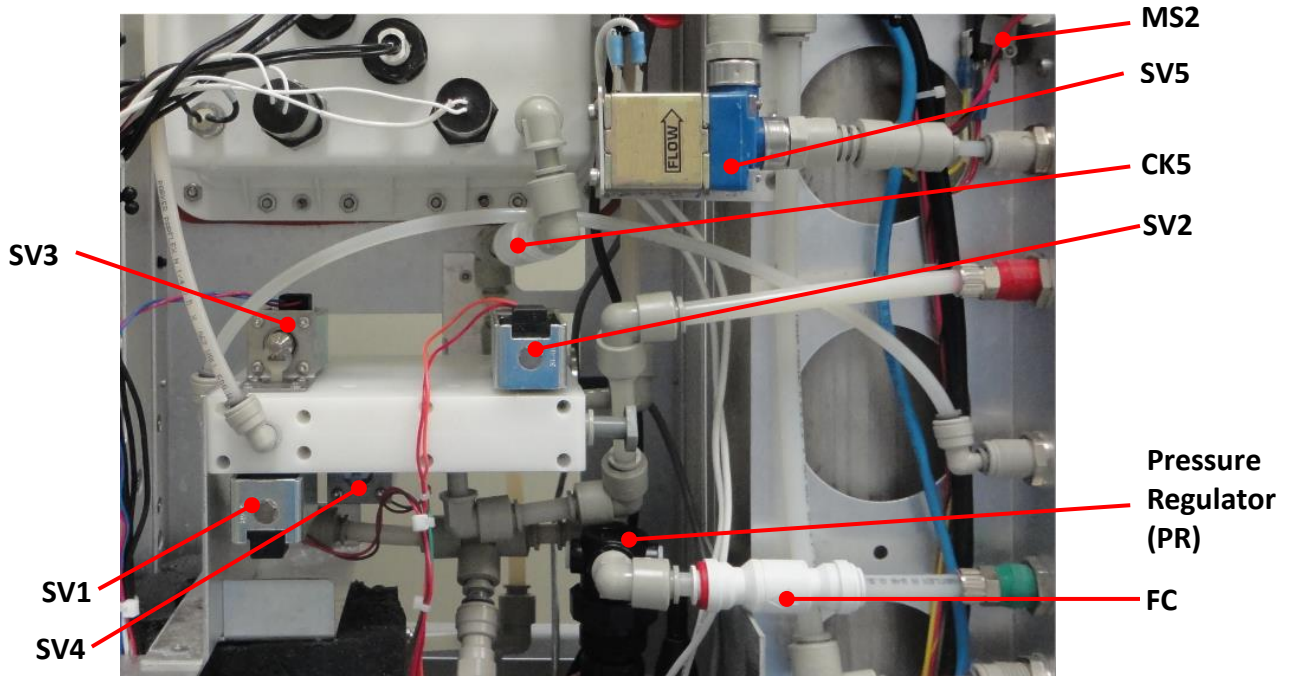
Caps the inlet side of the membrane. Inserted
on the bottom of the membrane (plugged end of
permeate tube).

7.1.6 Top Hydraulic View



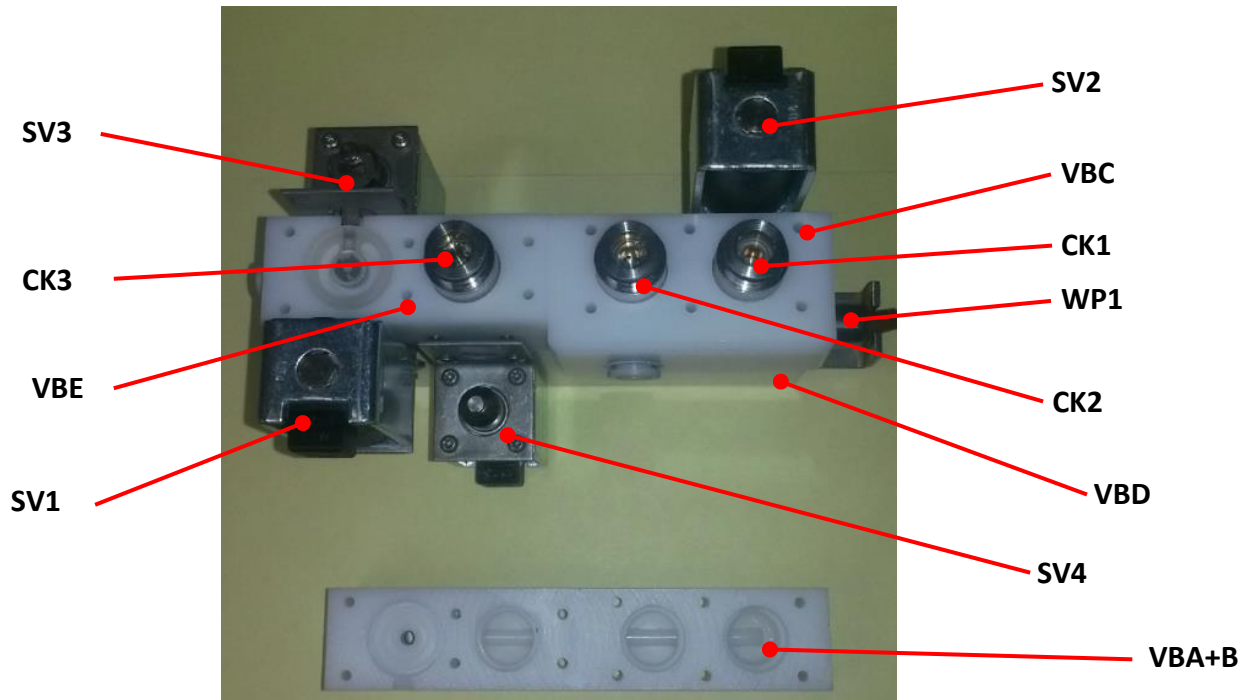
Part	Description
VB5	Valve body 5. Provides flow paths for product water.
VB6	Valve body 6. Provides flow paths for diverted and returned product water.
CK4	Check valve 4. Product divert check valve. Prevents backflow of tank and return water into the product water.
PT3	Pressure transducer 3. Product water pressure transducer. Senses the pressure of the product water.
WP2	Product water conductivity sensor. Monitors the quality and temperature of the product water.
Vv1	Vent valve. Allows air to vent from the tank but not water.

7.1.7 Center Hydraulic View



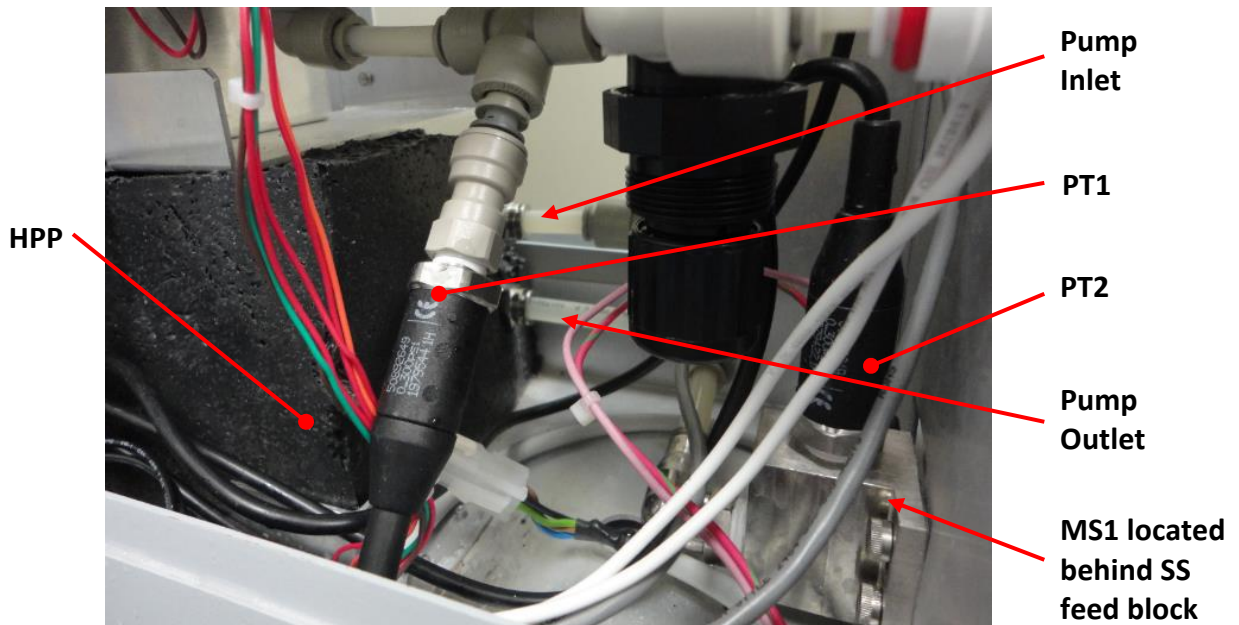
Part	Description
SV1	See next page for description.
SV2	See next page for description.
SV3	See next page for description.
SV4	See next page for description.
SV5	Solenoid valve 5. Product water return solenoid valve. Provides backpressure on the product water line. Opens during cleaning/sanitizing/disinfecting modes.
CK5	Check valve 5. Prevents RO feed water from entering the tank.
FC	Feed check valve. Prevents back flow of water to the RO feed supply.
MS2	Membrane switch 2. Ensures membrane door is present and properly secured.
PR	Pressure Regulator. Controls the incoming feed pressure

7.1.8 Main Manifold



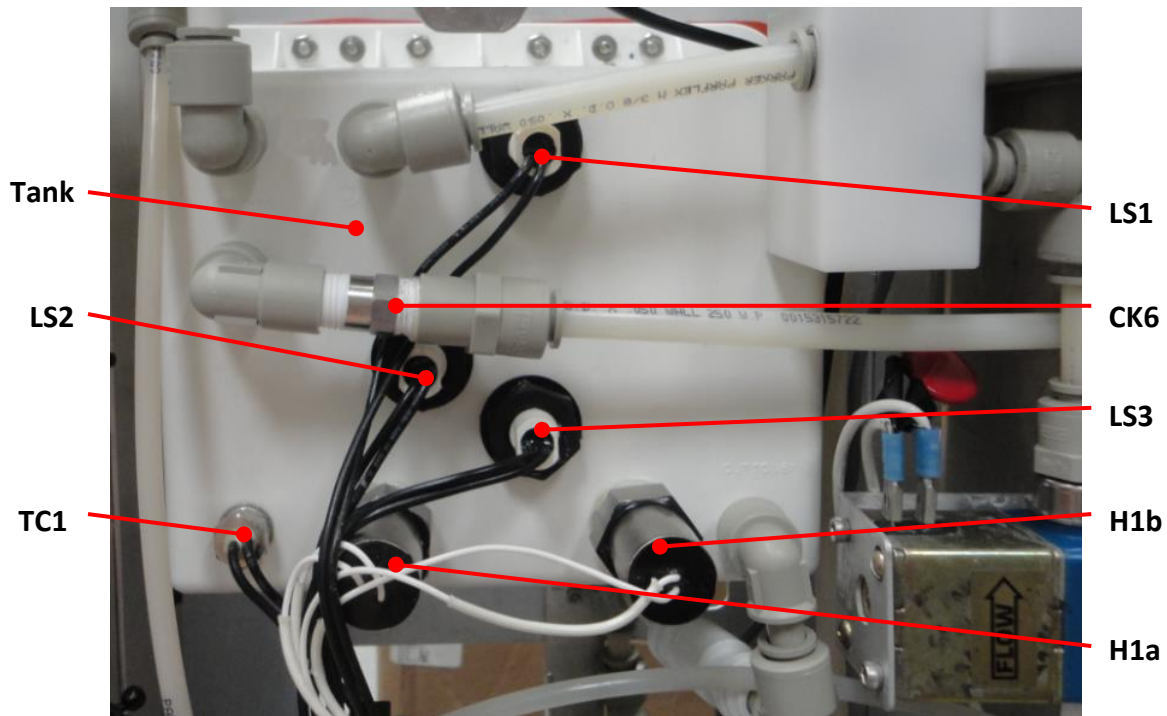
Part	Description
VBA+B	Valve body A+B. Provides internal flow paths for drain, recycle and product water and contains parts of CK1, CK2, CK3 and SV3.
VBC	Valve body C. Provides flow paths for the waste water and contains parts of CK1, CK2 and SV2.
VBD	Valve body D. Provides flow paths for waste water and feed water and contains the feed conductivity probe WP1. It contains parts of SV1, SV4 and SV2.
VBE	Valve body E. Provides flow paths for waste and product water it contains parts of SV1, SV3, SV4 and CK3.
SV1	Solenoid valve 1. Inlet water solenoid valve. Opens to allow supplied water to enter the RO.
SV2	Solenoid valve 2. Concentrate water solenoid valve. Closed during run mode. Has orifice hole to allow controlled flow of water through when valve is closed.
SV3	Solenoid valve 3. Product divert solenoid valve. Opens to supply product water to the dialysis machine. Stays closed for flush or if product water quality is above the set point.
SV4	Solenoid valve 4. Pump isolation solenoid valve. Controls the source of the pump feed water between the internal tank and RO feed water.
CK1	Check valve 1. Concentrate water check valve. Prevents backflow of water into the membrane.
CK2	Check valve 2. Waste water check valve. Prevents backflow of waste water into the RO.
CK3	Check valve 3. Recycle water check valve. Allows concentrate water to feed the pump during low feed pressure conditions.
WP1	Feed water conductivity sensor. Monitors the quality of the feed water.

7.1.9 Lower Hydraulic View



Part	Description
PT1	Pressure transducer 1. RO feed water pressure transducer. Senses the pressure of the incoming RO feed water.
PT2	Pressure transducer 2. Pump pressure transducer. Senses the pressure of the water coming out of the pump.
MS1	Membrane switch 1. Ensures membrane is present and in proper position.
HPP	High pressure pump. Contains the pump and motor. Boosts RO feed water to the desired pressure.
Pump Inlet	Water enters the pump here.
Pump Outlet	Water exits the pump here.

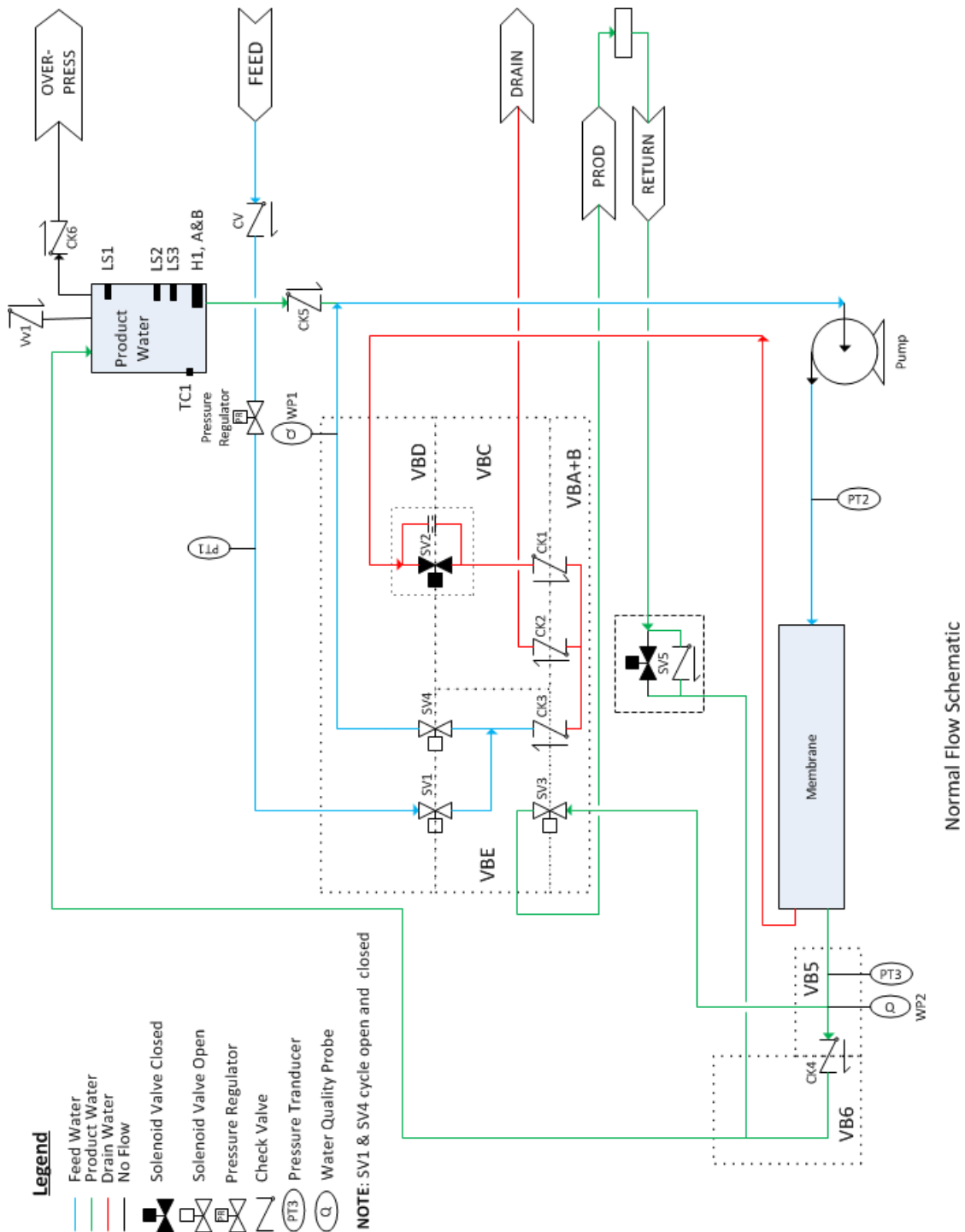
7.1.10 Tank View



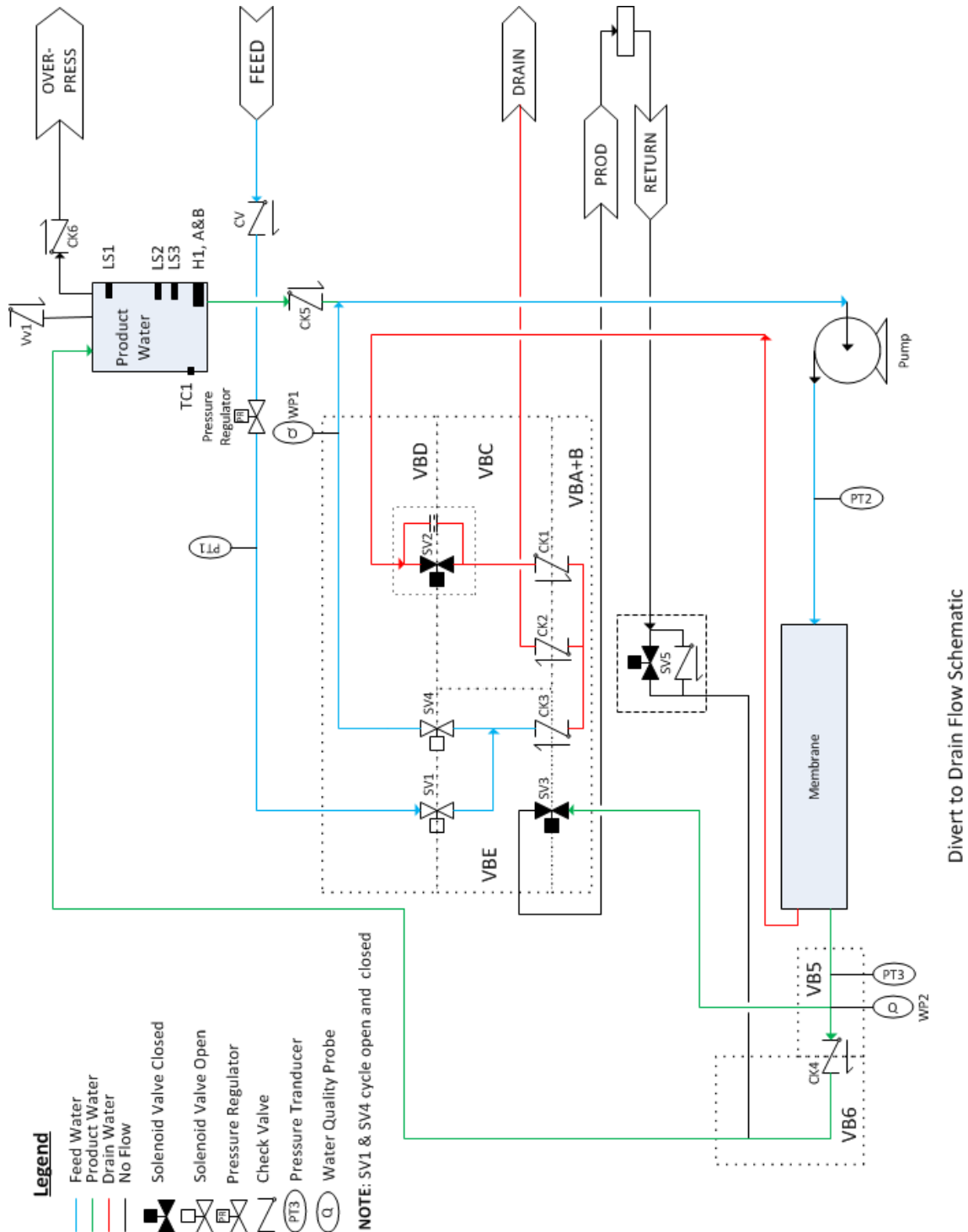
Part	Description
Tank	Tank that holds product water for cleaning, disinfection, and sanitization as well as reuse during the run mode.
LS1	Level switch 1. Senses the water level in the upper part of the tank.
LS2	Level switch 2. Senses water level in the middle of the tank.
LS3	Level switch 3. Senses the water level in the lower part of the tank.
CK6	Check valve 6. Prevents tank from over pressurizing.
TC1	Temp control thermostat. Turns heaters off to prevent damage due to excessive heat.
H1(a&b)	Heater elements. Heats the tank water for heat disinfection processes.

7.2 Flow Schematics

7.2.1 Run Mode

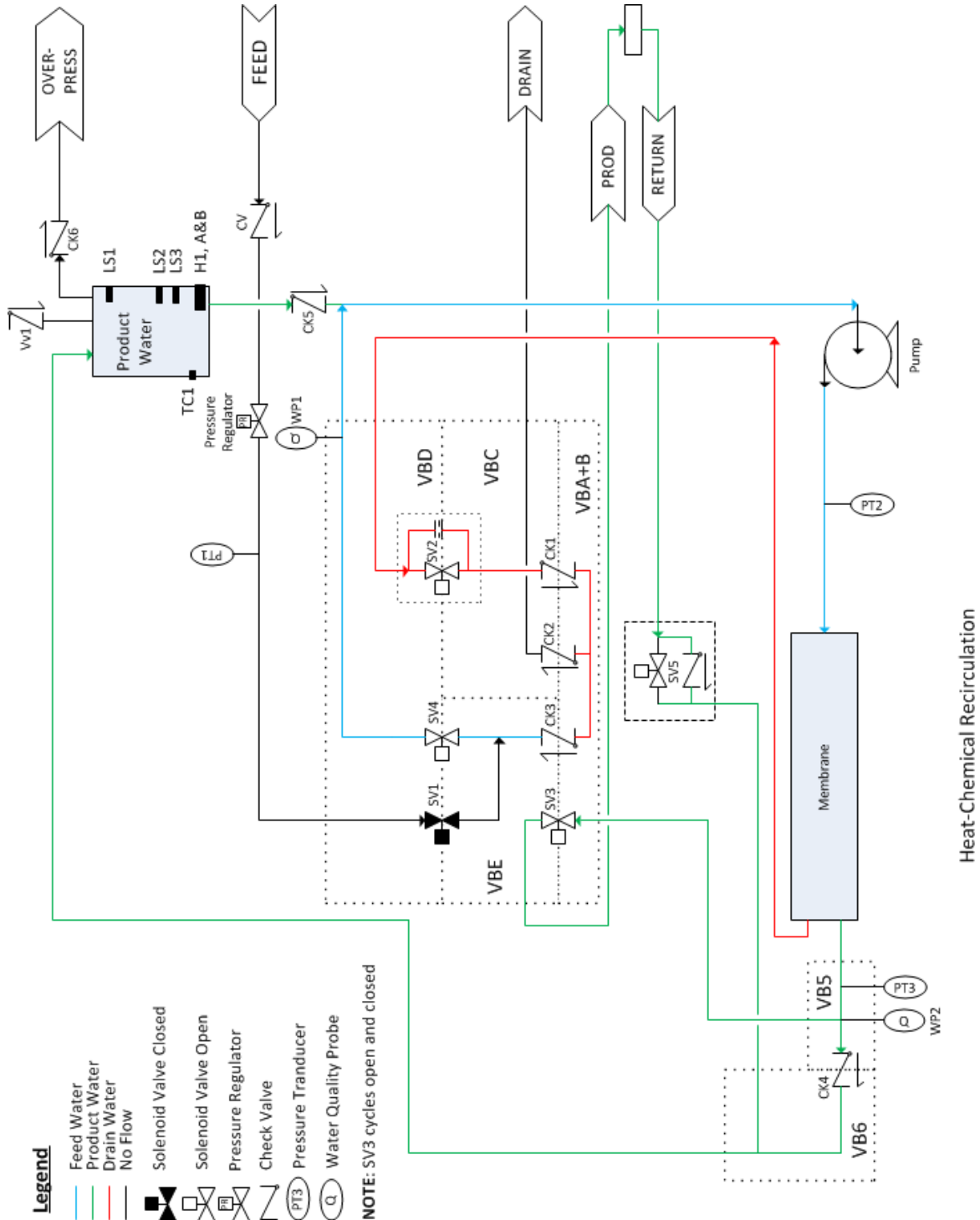


7.2.2 Divert to Drain

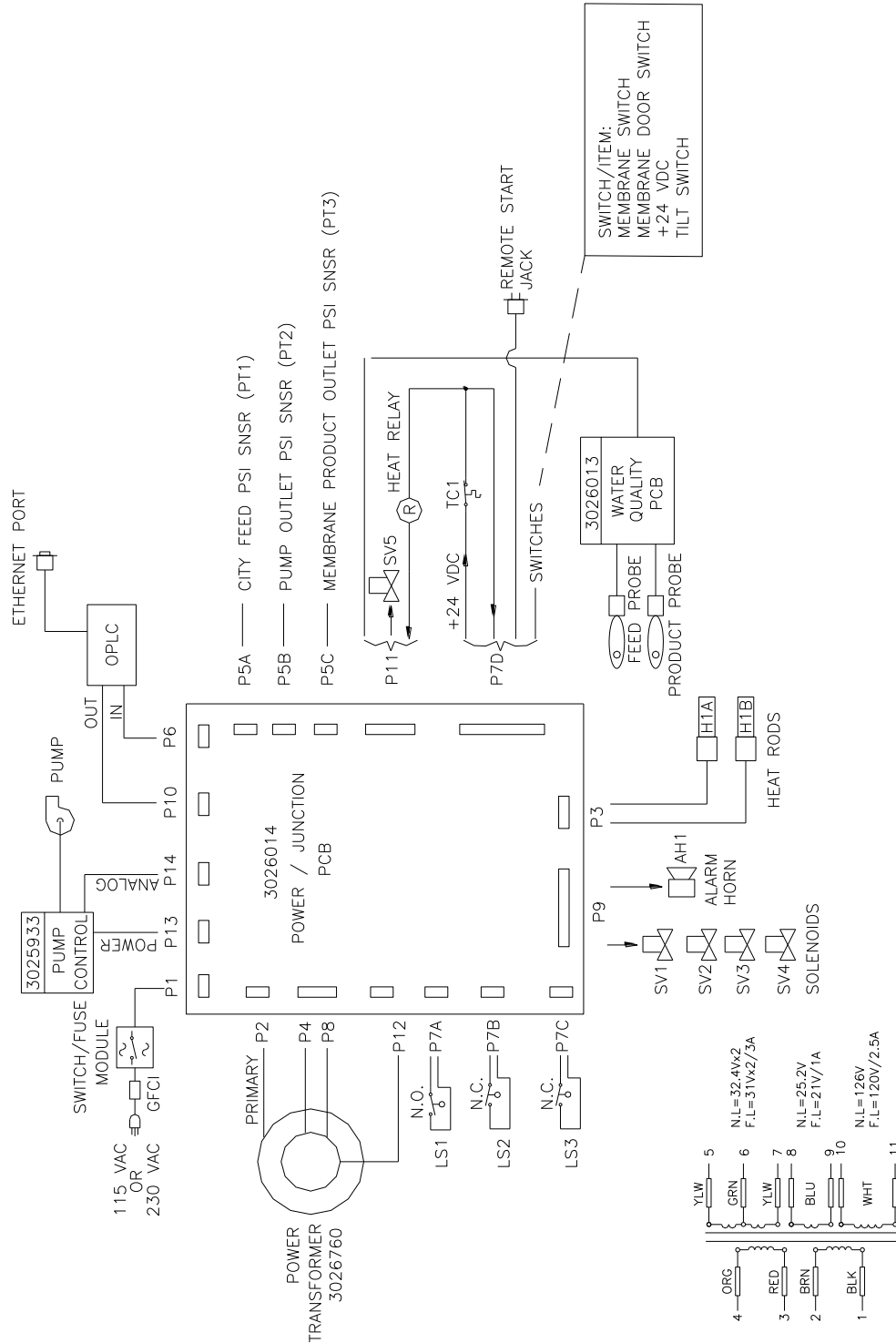


Divert to Drain Flow Schematic

7.2.4 Heat/Chemical Recirculation



7.3 Electrical Diagram



7.4 Maintenance Schedule

	As Required	Per Treatment Day	Weekly	Monthly	Quarterly	Annually
Record hardness (if applicable)		X				
Verify salt level (if applicable)		X				
Record chlorine/chloramine levels (per treatment)		X				
Record % rejection/water quality		X				
Record pre-filter pressures		X				
Disinfect the system (minimum)			X			
Bacteria/Endotoxin test				X		
Visually inspect pre-filter				X		
Clean RO membrane	X					
Sanitize RO with MINNCARE HD	X					
Verify TDS/μS and % Rejection					X	
inspect the QD fittings and lines					X	
AAMI/CSA water quality testing						X
RO Feed Water Test						X
Inspect tubing and fittings for leaks or wear						X
Inspect all pre RO devices for correct operation						X

NOTES:

This page intentionally left blank.

Millenium HX RO System

CHAPTER 8: SPARE PARTS

This page intentionally left blank.

8.1 Spare Parts List

NOTE:

Part numbers are subject to change and should be verified when ordering spare parts.

P/N	DESCRIPTION
<u>ELECTRICAL</u>	
ME21094	FUSE, 10A, FAST BLO, 250V
ME20114	FUSE, 3A, SLO BLO, 250V
1243700	FUSE, 2.5A, SLO BLO, 250V
3025641	FUSE, 1A, FAST BLO, 250V
3025642	FUSE, 6A, FAST BLO, 250V
ME21078	FUSE, 4A, SLO BLO, 250V
250-13-133	FUSE, 6A, SLO BLO, 250V
3025643	FUSE, 5A, FAST BLO, 250V
3025644	FUSE, 3A, FAST BLO, 250V
ME21165	FUSE, 1.5A SLO BLO
ME21077	FUSE, 1A SLO BLO
3026760	TRANSFORMER, 120/240 VAC
3028351	PROGRAMABLE LOGIC CONTROLLER
3030223	VFD PUMP/MOTOR ONLY
3030224	VDF CONTROLLER W/CABLE
3026013	PCB, QUALITY BOARD
3026014	PCB, POWER DISTRIBUTION BOARD
3026015	TILT SWITCH
250-07-336	RELAY, POWER
3029714	ALARM HORN
3027106	INLET POWER MODULE
3026011	CONTACT SWITCH
3025877	THERMAL SWITCH
3025839	HEATERS 115 VAC
3025842	HEATERS 230 VAC
3027823	PROBE, CONDUCTIVITY

MEMBRANE ASSEMBLY

3026761	HOUSING
3028365	MEMBRANE
3025866	MEMBRANE END CAP TOP
3025865	MEMBRANE END CAP BOTTOM
OS1114311*	O-RING, VITON®, 110
ME41593*	O-RING, EPDM, 210
1270003*	O-RING, EPDM, 342

*Recommended Spare Part

P/N	DESCRIPTION
<u>VALVE/FITTINGS/O-RINGS</u>	
WTW508004001	SOLENOID VALVE MAGNET SINGLE ACTION SV1, SV2, AND SV3 (NOT TO BE USED FOR SV4)
3030687	SOLENOID VALVE MAGNET SINGLE ACTION SV4 (MARKED WITH RED DOT)
3030164	VALVE SEAL, SV2
WTW50900001	VALVE SEAL, SV1/SV3/SV4
3028122	SOLENOID VALVE 5 (SV5)
3027847	TANK (ASSEMBLED)
3025950*	O-RING, VITON®, 014
375-83-002	O-RING, BUNA-N, 3/8" SF FITTINGS
347-63-995	O-RING, BUNA-A, ¼ FLOW QD
3025853	QUALITY PROBE RING VB1
374-06-104*	STRAIGHT, SPEED-FIT, 3/8 X 3/8 MNPT
374-10-108*	STRAIGHT, SPEED-FIT, 3/8 X 1/4 FNPT
374-06-108*	STRAIGHT, SPEED-FIT, 3/8 X 1/4 MNPT
OS1164298*	ELBOW, SPEED-FIT, 3/8 X 3/8
374-04-104*	ELBOW, SPEED-FIT, 3/8 X 3/8 MNPT
374-08-108*	ELBOW, SPEED-FIT, 3/8 X 1/4 FNPT
347-62-013*	COUPLING INSERT, 3/8 MNPT, WHITE
374-14-104*	TEE, SPEED-FIT, 3/8
3030199	REGULATOR, PSI, 5-125 PSI

***Recommended Spare Part**

P/N	DESCRIPTION
3026762	CHECK VALVE, 1/4 NPT, 316, 3#
3032681	CHECK VALVE, PVDF, 1/3#
3030816	CHECK VALVE, 316, 25#
3030815	CHECK VALVE, 316, NO SPRING
ME40605	GARDEN HOSE THREAD, (FEMALE)
ME40095	RUBBER WASHER FOR GARDEN HOSE THREAD
3027389*	QUICK-DISCONNECT (FEMALE) FOR FEED PORT, GREEN
ME40561*	SPEED-FIT, FOR RELIEF AND WASTE PORT
ME40677	SPEED-FIT, FOR PRODUCT/RETURN PORTS
ME42082*	QUICK-DISCONNECT (MALE) FOR FEED HOSE, GREEN
3030935	ELBOW CONNECTOR FOR WASTE HOSE
3027822*	VALVE, SAMPLE PORT
W900000097	Y – CONNECTOR
WT300HOSE	Y – FITTING CONNECTOR HOSE TO DIALYSIS MACHINE
3028694	HOSE, PRODUCT/RETURN 3”
3027077*	TUBE, NYLON, 3/8, INTERNAL
3027821*	HOSE, SILICONE, 1/4, FOR PRODUCT HOSE
ME60370*	HOSE, PVC, 3/8, BRAIDED

*Recommended Spare Part

P/N	DESCRIPTION
------------	--------------------

<u>CLEANERS/DISINFECTANTS</u>	
--------------------------------------	--

1228653	CLEANER, LIQUI-CLEAN™ 103,1GAL., LOW PH, LIQUID
1228791	CLEANER, LIQUI-CLEAN™ 511,1GAL., HIGH PH, LIQUID
3029765	MINNCARE HD DISINFECTANT(4 x 1 QUARTS)
3031105	MINNCARE HD DISINFECTANT (6 X 90 MI)

<u>TESTS</u>	
---------------------	--

185-40-031	HARDNESS TEST KIT
ME14604	SILT DENSITY INDEX (SDI) TEST KIT
3024671	TOTAL CHLORINE TEST KIT
3029795	MINNCARE HD RESIDUAL TEST STRIPS
3026658	pH TEST STRIPS
ME70001	WATER TEST KIT, AAMI STANDARDS

<u>OPTIONAL</u>	
------------------------	--

ME40695	FILTER, 1 MICRON, 9 7/8"
ME40696	FILTER, 5 MICRON, 9 7/8"
ME40694	O-RING, PRE-FILTER (9 7/8")

NOTES:

This page intentionally left blank.

