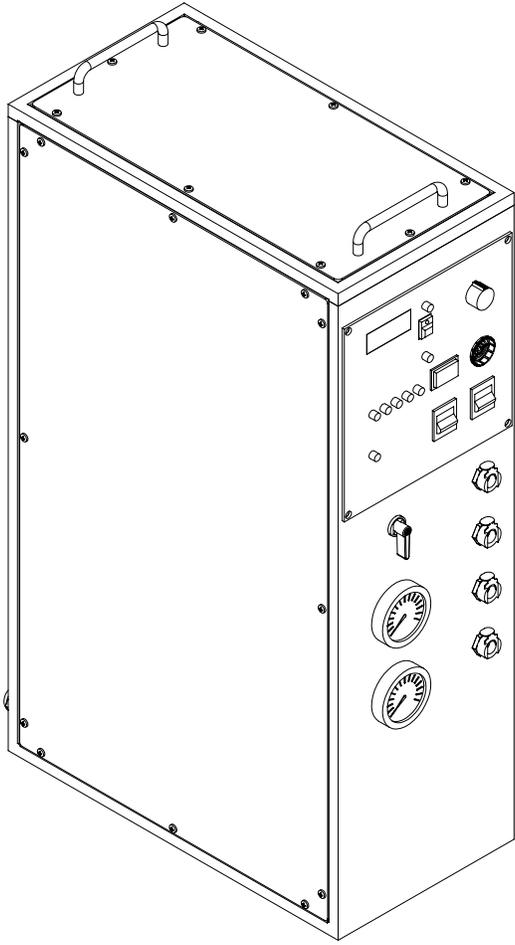


GE OSMONICS MILLENIUM™ REVERSE OSMOSIS UNIT

Operation and Maintenance Manual



SUPERCEDES P/N 14693 REV. D

MILLENNIUM REVERSE OSMOSIS UNIT
Installation, Operation and Maintenance Manual

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Millenium RO System

CHAPTER ONE:
GENERAL INFORMATION



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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 GE Osmonics Millenium™ 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 Safety Summary

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. See Technote 120 for a glossary of relevant terms.

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.

READ THIS MANUAL:

Prior to operating or servicing this device, this manual must be read and understood. 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.

USE PROPER POWER CONNECTIONS:

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

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.

SHOCK HAZARD:

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(s) free of water.

DEVICE LABELING:

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.

DO NOT OPERATE IN A FLAMMABLE ATMOSPHERE:

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

1.3 Applications

The Millenium™ 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 ions and approximately 99% of most other contaminants removed. The quality of the purified water, referred to as product water or permeate, depends on the quality of the feed water and normally is equal to or exceeds AAMI standards. Such water is suitable for hemodialysis applications.

1.4 Contraindications**WARNING:**

GE Osmonics systems are not designed, sold, or intended for use in producing water for injection

Furthermore, GE Osmonics systems are not intended to be used outside of the device specifications and limitations, as outlined in this manual and other related materials.

1.5 Environmental Considerations

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

POWER:

The Millenium™ operates on 115 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.

WATER:

Reverse osmosis systems require a reliable water source. The Millenium™ RO needs a minimum of 30-PSI pressure at a minimum flow of 2 gallons per minute. It is important that water is flowing at the design flow rate when testing water pressure rather than reading static pressure.

DRAIN:

A drain outlet is required by the RO system. 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.

TEMPERATURE:

The Millenium™ RO is normally connected to a cold water supply. The performance specifications of the RO are based on 77°F (25°C) feed temperature. Each degree Fahrenheit the feed water temperature falls, the RO product flow decreases approximately 1.5%, and each degree Celsius drop, the product flow is reduced by 3% (See Technote 113 for the “Temperature Correction Factors” chart). In climates where the winter water temperature drops significantly below 77°F it may be necessary to temper (heat) the water.

WARNING:

The temperature of the tempered water should be monitored closely with a thermometer as high temperatures can damage the RO membranes and possibly harm the patient. Refer to the inlet water requirements (Section 1.10.1) for the maximum operating temperature for the Millenium™ RO.

CAUTION:

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

NOISE:

The RO unit does not generate significant noise levels. Hard walls may reflect noise and will make the RO seem louder.



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. Teflon tape is suitable for all threaded connections in this system.

WARNING:

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

1.6 Theory of Operation

The Millenium™ 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 Millenium™ RO possesses monitoring for pressure, product water quality and membrane performance (percent rejection). The RO pump provides the pressure required to push water through the RO membranes. 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.

1.7 Fluid Components

Inlet Solenoid:

Located inside the Millenium™ RO at the inlet, and serves to shut off the water supply to the system, until it is actuated when the Inlet water valve switch is placed in the ON position.

Pressure Adjust Regulator:

Used to adjust the product pressure. The pressure is displayed on the product pressure gauge, on the front of the RO.

Inlet Water Check Valve:

Prevents back-flow of disinfectants or cleaning agents.

Inlet Water Sensor:

Monitors the quality of the inlet water. Inlet quality is compared to the outlet (product) water quality and is displayed as "percent rejection" on the front panel.

High-Pressure Pump:

Provides up to a 200 PSI boost of the inlet water to the Reverse Osmosis Membrane Assembly (ROMA). The RO pump pressure is displayed on a 0 to 300 PSI gauge mounted outside the RO, above the product pressure gauge. The pressure is factory set at 190 PSI.

Reverse Osmosis Membrane Assemblies (ROMAs):

Two are included in the Millenium™ RO. A ROMA is an assembly that includes the membrane housing, end caps, fittings, and a membrane. Depending on the model, thin film membrane ROs can either provide up to 500 or 750 gallons per day of product water, depending on membrane type, condition, and water temperature.

Waste Flow:

The Waste Flow is controlled by a length of 1/8" tubing. The length of the tube is factory determined to correctly govern the wastewater flow to drain.

Operate/Flush Valve:

The Operate/Flush Valve on the front panel is used to flush the membrane surface of rejected contaminants, and to accelerate the rinse out of cleaners or disinfectants from the RO. Some pump noise (chattering) is normal in the flush position. The RO is in "flush" from the full open (flush) to just before the fully closed (operate) position.

CAUTION:

Excessive "chattering" may be eliminated by slowly moving the valve from the full flush position towards "OPERATE".

Product Water Pressure:

Product Water Pressure is read on a 0 to 100 PSI gauge on the front panel. Product pressures will register only when the product is back pressured (product hose removed from fitting or connected to dialysis unit).

Product Recirculation Check Valve:

Prevents over-pressuring of the product supply. When the product pressure exceeds the set point of the pressure regulator, the product recirculation check valve opens. Excess product water is then recirculated back to the inlet water flow.

Product Water Sensor:

The Product Water Sensor is used in conjunction with the inlet water sensor by the percent-rejection circuitry to calculate the membrane rejection rate. The rate of rejection is displayed from 70% - 99% in a 5 LED array on the front panel.

Product Check Valve:

The Product Check Valve is used to prevent anything from flowing backward into the product side of the RO membranes.

CAUTION:

Back-flow pressure into the product line can cause damage to the membranes.

Total Dissolved Solids (TDS) Sensor:

Samples the product water quality via the sensor probe, and the final quality of the product water is indicated on a digital display on the front panel as TDS in mg/L and ppm. The monitor is temperature compensated to adjust the display value to changing water temperature.

Disinfect Inlet Port:

The Disinfect Inlet Port is a quick-disconnect valve that allows access to the inlet water side of the pump. The port is used when cleaners or disinfectants are introduced to the RO. The valve can also be used to obtain feed water samples for testing feed water for chlorine/chloramine, pH and hardness levels.

WARNING:

Water from this port is NOT RO product water and should not be used for dialysis solutions.

Disinfect Switch:

The Disinfect Switch is used to introduce disinfectants and cleaners into the RO. For safety, this switch must be held continuously to operate.

CAUTION:

When drawing disinfectants or cleaning solutions, do not allow the RO to draw air. This may cause irreparable damage to the RO pump.

1.8 Monitors and Controls

Inlet Water Valve Switch:

The Inlet Water Valve Switch is mounted on the control panel. The switch is used to energize a solenoid, pressurizing the system with feed water.

RO Pump Power Switch:

The RO Pump Power Switch is mounted on the control panel. The switch is used to energize the RO pump/motor. The inlet water switch must be ON for the pump/motor to operate.

Disinfect Switch:

The Disinfect Switch is mounted on the front panel. This switch is used to introduce disinfectant or cleaning agents into the RO through the disinfect port.

Pressure Adjust Regulator:

The Pressure Adjust Regulator inside the RO is used to set the maximum product pressure needed to supply a dialysis machine. Adjusting this regulator will also result in small adjustments in the pump pressure.

Product Pressure Gauge:

The Product Pressure Gauge reads the product pressure from 0 to 100 PSI. Product pressure will read zero when the product line is not connected to a dialysis unit and the product hose is connected to the product fitting and the valve is open.

Pump Pressure Gauge:

The Pump Pressure Gauge reads the pump pressure from 0 to 300 PSI. It is used for monitoring during operation and when adjusting the pump pressure, and is located on the front of the RO.

Operate/Flush Valve:

The Operate/Flush Valve is a 1/4-turn ball valve. When in the operate mode, the valve is in the closed position. When the valve is turned at any point towards flush, the valve is open. The closer to the flush point, the more the valve is open. When in flush, the valve bypasses the waste flow tube.

Disinfect Port:

The Disinfect Port is a quick-disconnection port for the introduction of disinfectant or cleaning agents. The port has a check valve that closes when there is no hose connected to the fitting.

Feed Port:

The Feed Port is a quick-disconnection port for the introduction of feed water to the RO. The port has a check valve that closes when there is no hose connected to the fitting.

Product Port:

The Product Port is a quick-disconnection port for the output of purified product water. The port has a check valve that closes when there is no hose connected to the fitting.

Waste Port:

The Waste Port is a quick-disconnection port for the output of concentrate or waste to the drain. The port has a check valve that closes when there is no hose connected to the fitting.

Percent Rejection Display:

The Percent Rejection Display is a 5 LED array that indicates how the RO membranes are performing. The lights correspond to 99%, 95%, 90%, 85%, and >70% rejection. The 99% light, when illuminated, indicates a need to evaluate the RO system performance. RO units do not normally perform in excess of 99%; verify this reading with an independent meter and take corrective action if indicated. Some RO membranes will achieve this level of performance under optimum conditions.

Product Water Total Dissolved Solids (TDS):

The Product Water Total Dissolved Solids (TDS) digital display indicates product water purity in mg/L (ppm). It is temperature compensated to adjust the value of the display with changing water temperature for better accuracy.

Less Than 0.5 mg/L Check System Lamp:

The Less Than 0.5 mg/L Check System lamp illuminates when the TDS reading is 0.5 mg/L or less. This indicates a need to evaluate the RO system performance. RO units do not normally have this low product TDS. Verify this reading with an independent meter and take corrective action if indicated. RO membranes may achieve this level of performance under optimum conditions (good feed water).

Alarm Set:

The Alarm Set switch allows the operator to set the TDS levels at which the alarm will sound. The alarm should be set at twice the initial TDS reading. If the set point is exceeded, an audible alarm will sound.

Alarm Mute:

The Alarm Mute switch will mute the audible alarm for 30 - 45 seconds. A red indicator lamp is displayed on the switch when the mute switch has been pressed.

1.9 Optional Equipment

GE Osmonics 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 feedwater 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 the factory.

Pretreatment Cart holds the Millenium™ RO and feedwater treatment equipment. The cart has a bracket that provides for the attachment of prefilter cartridge housings. The cart will hold any combination of two or three of the following tank sizes, .25 c.f., .47 c.f., or .60 c.f..

Carbon Filter Tanks remove chlorine/chloramine from the 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.

WARNING:

Carbon is not regenerated and must be replaced when exhausted.

WARNING:

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

Softeners remove calcium, magnesium, and other scale producing contaminants from the 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.

Dealkalizers are used to lower the pH of alkaline 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.

1.10 Specifications:
1.10.1 Input Water Requirements

	<u>Minimum</u>	<u>Maximum</u>
Input flow Rate	2.0 GPM	N/A
Temperature (water)	1.7°C (35°F)	32°C (90°F)

NOTE:

Operating at lower temperatures may make it impossible for the Millenium™ to produce adequate permeate for the dialysis machine.

pH (operating) TF Membranes	4.0	11.0
pH w/chloramines present (operating) TF Membranes	4.0	8.5
pH (cleaning) TF Membranes	2.0	11.0
Pressure, dynamic	30 PSI	100 PSI

1.10.2 Flow Rates

Product Flow based on the following conditions:

New Membranes

Operating Pressure:	190 PSI
Product Pressure:	1 PSI
Feed Water Temperature:	77°F (25°C)

<u>GPM</u>	<u>LPM</u>	<u>GPD</u>	<u>LPD</u>
.34	1.31	500	1892.5
.52	1.97	750	2839.1

Membrane flux may vary ±15%

Waste Flow: .84 GPM (3.2 LPM) (±10%)

1.10.3 Electrical Requirements

Motor	1/3 HP
Voltage	115 VAC / 230 VAC
Hertz	60 / 50
Amps	8 / 5
Phase	single



1.10.4 Dimensions

	<u>Vertical Cabinet</u>	<u>Horizontal Cabinet</u>
Height	25 ½ inches	8 inches
Depth	15 inches	15 inches
Width	8 inches	25½ inches
Weight – Operating – 55 lbs.		

1.10.5 Membrane Performance Characteristics

Salt rejection (TF Membranes):	95% minimum at initial testing at factory.
Test Solution:	Inlet water 1000 PPM NaCl
Conductivity:	2000 micro mhos-cm
Operating Pressure:	190 PSI, ± 10 PSI
Product Back pressure:	0 PSI

1.10.6 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 membranes 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.

1.11 Disposal

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

1.12 Electromagnetic Interference

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.

1.13 Service Assistance

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

Consult the “Troubleshooting” section of this manual (Chapter Five). If the problem cannot be identified and corrected by any of the procedures found in that section, then...

Contact your Facility Equipment Technician. If the technician is unable to help then...

Call GE Osmonics Technical Service Department at (800) 633-3080 or (206) 395-2200. Technicians are available for all calls between 7:00 a.m. and 4:30 p.m. PST, 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:

1. What RO do you have, i.e. Millenium™
2. What is the serial number of your RO? (Label, found on back of RO.)

RO SERIAL NUMBER: _____



1.14 Return Goods Authorization (RGA) Procedure

If you wish to return goods for, warranty evaluation and/or credit please have your original sales order, invoice and device serial number available when you call GE Osmonics. Call GE Osmonics at (800)-633-3080 and request Technical Service. A GE Osmonics Technical Service representative will provide instructions and a return authorization number, which needs to be clearly written on the outside of the box used to ship your materials. All equipment must be shipped to GE Osmonics 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.



1.15 Symbols and Abbreviations

“RENALIN®”	Refers to Peracetic Acid and Peroxide-based Compounds, such as Renalin®, Minncare™, Peracidin™ (20% peroxide, 4% Peracetic Acid)
ASTM	American Society for Testing and Materials
AAMI	Association for the Advancement of Medical Instrumentation
CA	Cellulose Acetate
C	Celsius
CSA	Canadian Standards Association
cc	Cubic Centimeters
cf	Cubic Foot (feet)
cfu/ml.	Colony Forming Units per milliliter
cm	Centimeters
DI	Deionization
F	Fahrenheit
FDA	Food and Drug Administration
Ft	Foot (feet)
GPD	Gallons Per Day
GPM	Gallons Per Minute
GHT	Garden Hose Thread
gr	Grains
GAC	Granular Activated Carbon
HZ	Hertz
HP	Horse Power
lbs.	Pounds
LED	Light Emitting Diode
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
Megohm/cm	Million Ohms/Centimeter
mw	Molecular Weight
NaCl	Sodium Chloride
N/A	Not Applicable
NPT	National Pipe Thread
NSF	National Sanitation Foundation
PA	Polyamide
P/N	Part Number
ppm	Parts Per Million
psi	Pounds Per Square Inch
PVC	Polyvinyl Chloride
QD	Quick Disconnect
RO	Reverse Osmosis
ROMA	Reverse Osmosis Membrane Assembly
TB	Terminal Barrier Strip (Main): “TB1” (Example: “TB1-9” refers to the terminal marked number 9 on the Main Terminal Barrier Strip)
TF	Thin Film
TDS	Total Dissolved Solids
UL	Underwriters Laboratory
VAC	Volts Alternating Current
WFI	Water for Injection
WT	Weight
~	Volts Alternating Current



NOTES:



Millenium RO System

CHAPTER 2: INSTALLATION GUIDELINES AND INITIAL SYSTEM START-UP



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2.1 Installation Considerations

1. Select a location for the Millenium™ near the required utilities and dialysis equipment.
2. The RO unit requires 115 VAC power for operation and consumes 8 amps of current (the 230 VAC model consumes 5 amps).
3. The RO unit requires nominally 2 GPM water at 30 PSI. Warmer feed water (up to 25°) will produce more permeate, and will consume more water. The water may also require some pretreatment to ensure maximum performance and suitability. GE Osmonics recommends that feed water be chlorine/chloramine free and solids above 5 microns in size be filtered out.
4. A drain with a minimum capacity of 2 GPM is required for the RO unit.
5. Back flow prevention may be required in accordance with local codes.
6. Special connections may be needed to connect to water supply. Connections vary with different facilities.

2.2 Installation Procedures:

CAUTION:

If a carbon tank is present on the RO system, the carbon tank must be completely rinsed of all carbon fines and ash before connecting to the RO unit. Otherwise, irreparable damage to the TF membrane will result (refer to Carbon Manual).

WARNING:

The Millenium™ RO is stored with 1 wt.% sodium metabisulfite from the factory. Follow all Material Safety Data Sheet (MSDS) guidelines that are included with the RO.

NOTE:

For initial start-up, the large removable panel must be removed to allow access to the pump and regulator for adjustments as well as to remove shipping materials. The panel is held on with twelve stainless steel screws. Use caution any time a panel is removed from the Millenium™.

1. Connect the Millenium™ RO inlet tubing GHT (garden hose thread) connector to the inlet cold water supply, and the QD (quick-disconnect) end to the “Feed” connection on the front panel.
2. Connect the waste water line to the waste QD connection on the front of the RO, and to the drain in accordance with the local plumbing code. Making this connection allows the waste flow by opening a check valve; disconnecting closes it.
3. Connect the product line QD connector to the product fitting on the front panel. Connecting together the male and female fittings (hose to RO) opens a check

valve allowing product flow. When the hose is disconnected, the product flow is stopped.

4. Make sure that the inlet water valve switch and the RO pump power switch are in the OFF position. Plug the power cord into a 115 VAC (230 VAC) grounded outlet. Do not use an extension cord or an adapter.
5. Turn the water supply to the RO on.
6. Turn the operate/flush valve to the flush position.
7. Turn the inlet water valve switch on. Water will start to fill the RO. Allow the RO to rinse to drain for five minutes after water begins to flow from the drain line. The pump pressure gauge should indicate some pressure.
8. Turn the RO pump power switch on.

NOTE:

The operate/flush valve may need to be rotated part way towards the operate position if the pump makes excessive noise.

9. Slowly turn the operate/flush valve to the operate position. Pump pressure should not exceed 200 PSI. If 200 PSI is exceeded, adjust pump pressure on pump head located inside the cabinet. See instructions in Figure 1 below:

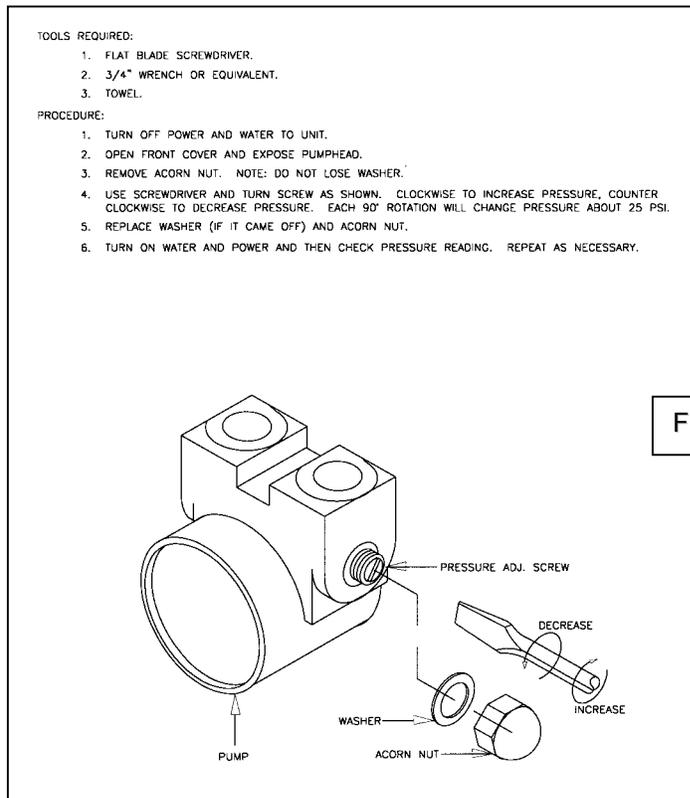


Figure 1

10. Let the RO run for an additional 15 minutes or until the percent rejection and TDS values have stabilized.

WARNING:

Ensure that TDS and membrane performance (% rejection) are normal for the regions water quality. Consult your facility physician. An AAMI analysis and bacteria test of the product water must be obtained and interpreted before using the RO unit for hemodialysis treatment (refer to the Product Water Analysis procedure and the Product Water Culture Procedure).

11. Set the product water TDS alarm limit switch as prescribed by the physician. The switch is normally set to twice the initial TDS reading (or “next higher” setting) at start-up.

WARNING:

The TDS alarm limit should not be moved from this setting unless instructed by a physician.

12. After a minimum of 3 hours run time, disinfect and rinse the RO unit with an approved disinfectant before using for hemodialysis treatment (refer to the Formaldehyde and ‘RENALIN®’-type disinfection procedures in chapter four).

CAUTION:

New RO units with thin film membranes must be rinsed to drain with normal pressures for a minimum of three (3) hours before exposure to disinfectants.

WARNING:

After disinfection, the product water must be verified free of residual disinfectant.

13. The RO product may be used in conjunction with hemodialysis treatment equipment only after obtaining test results which validate compliance with excepted standards.

- AAMI Product Water Panel
- Microbiological Culture (colony count) results
- Endotoxin (pyrogen) level testing (if applicable)

14. **The Millenium™ RO is now ready for use.**

2.3 Product Water Analysis Procedure:

In order to ensure that the RO is performing at or above AAMI (Association for the Advancement of Medical Instrumentation) Standards, it is necessary to perform an AAMI Water Quality Analysis test. For new units, the RO must be operated (rinsed to drain) for at least two hours 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 Standard product water (refer to Technote 103, "AAMI Hemodialysis Water Quality Standards").

NOTE:

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

Materials Required: Produce water sampling kit, sterile gauze, tape, and container (such as a small bucket).

1. Ensure that all pre-RO devices are operating correctly and are performance verified by the appropriate testing.
2. Connect the RO unit to the required utilities (feed water, drain, power).
3. Operate the RO unit with product and waste flows to drain for at least 15 minutes after the product water quality has stabilized before drawing the water sample.
4. Hold the product line over the container and run product water for 60 seconds.
5. Aseptically remove the lid from the sample bottle and rinse the bottle twice with RO product water.
6. Fill the bottle completely with RO product water and cap it immediately.
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 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.

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.

NOTES:



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Millenium RO System

CHAPTER 3: SYSTEM OPERATION



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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.

1. Connect the RO unit to the required utilities (feed water, drain, and power).
2. Ensure that all the valves in the water supply line to the RO are open.
3. Ensure that all pre-RO devices have been flushed and tested and are operating within their specifications.
4. Ensure that the product rinse line is connected to the RO, with the other end in a drain.
5. Move the inlet water valve switch to the open position. When water flows to drain, the RO pump power switch can be moved to the on position.
6. The "Percent Rejection" monitor should indicate 95% rejection within 2 minutes of start-up. It is normal for rejection to drop off until membranes have rinsed up to optimum quality.
7. The TDS monitor should stabilize within 2 minutes of start-up. The TDS during this time may be higher than the alarm set point. The audible alarm may be muted at this time by pressing the alarm mute switch. The alarm mute switch will silence the audible alarm for 30 - 45 seconds each time the switch is used.

WARNING:

When the RO is used for dialysis service, a test for disinfectant residual **MUST** be performed.

8. Record data on a daily log sheet.

WARNING:

Any data that does not meet minimum standards set at your facility must be reported to the medical director. The RO should not be placed in service until readings are acceptable.

9. The Millenium™ RO is now ready for connection to the dialysis machine.

3.2 Shut Down Procedure

1. Turn off the RO pump power switch.
2. Turn off the inlet water valve switch.
3. Turn off the inlet water supply.



4. Briefly turn on the inlet water valve switch. This will release pressure from the feed water hose. When the pressure is released, turn the switch off.

NOTE:

If the Millenium™ RO is to be stored for more than 24 hours (RO not being operated), the RO should be stored in an approved disinfectant or storage solution (Not 'RENALIN®' or other type oxidizing products). Refer to the disinfection or storage procedure in this manual.

5. Disconnect from the utilities and store the RO.



NOTES:



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Millenium RO System

CHAPTER FOUR: ROUTINE MAINTENANCE



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4.1 Routine Maintenance of Millenium™ RO System

GE Osmonics Millenium™ RO systems have 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 GE Osmonics reverse osmosis system is limited to maintaining performance logs, cleaning and disinfection, replacement of damaged or failed parts and periodic lubrication. The maintenance procedures have been categorized by their frequency of action and are as follows:

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.

WARNING:

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

4.1.1 Daily Maintenance

1. Test and record the hardness level of the feed water in the pretreatment log.
2. Observe and record salt level in the brine tank (for systems with water softener pretreatment).
3. Observe and record the Chlorine/Chloramine concentrations in the pretreatment log. Follow the instructions included with each test kit.

WARNING:

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

4. If you are using cartridge pre-filters with your Millenium™, 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. Remove the old filter, install the new filter and re-install the filter bowl.
5. Observe and record the percent rejection and TDS water quality readings in the operation log.

4.1.2 Weekly Maintenance

1. Observe, or measure, and record the waste and product flow rates on the operation log. Allow the water temperature to stabilize before attempting to record the results. This will help prevent errors due to fluctuating temperature.
2. Observe, or measure, and record the feed water temperature. Systems with blending valves have thermometers installed in the plumbing. A hand held thermometer may also be used. The water temperature has a significant effect in the product flow rate of the RO membrane and on the evaluation of the membranes' need to be cleaned.
3. Disinfect the system if needed. Refer to the disinfection procedure in this chapter.

4.1.3 Monthly Maintenance

1. Take a product water culture to test for bacteria colony forming units count (<200 cfu/ml). Refer to the product water culture procedure in this chapter.
2. Visually inspect the pre-filter core, if you are using cartridge pre-filtration.

CAUTION:

On occasion, the pressure differential between the two pre-filter gauges will not alter significantly, however, the pre-filter will be soiled. If the core of the pre-filter is dirty, particulates are breaking through the pre-filter and traveling downstream and causing damage to the pump and RO membranes. If this is the case, the pre-filter will require more frequent replacement on a routine basis.

3. Check the pump pressure settings. The pressure should be 190 PSI \pm 10 PSI, and should not exceed 200PSI.
4. Check the maximum product pressure setting. If it is above the original set point, reduce the pressure with the regulator inside the cabinet.
5. Perform trend analyses from the log sheets.

4.1.4 Quarterly Maintenance

1. Clean the RO Membranes. Refer to the RO membrane cleaning procedure in this chapter.
2. Disinfect the RO machine. The RO should be disinfected after cleaning. Refer to the membrane disinfection procedure in this chapter.
3. Verify the TDS and percent rejection readings with an independent monitoring device every 3 months.
4. Check the quick-disconnect fittings and hoses. They should seat securely and fluid should shut off when they are disconnected.



4.1.5 Semi-annual Maintenance

1. Check and clean the Millenium™ cooling fan and grill.
2. Check the Product Recirculation check valve for proper operation. Refer to the check valve test instructions in this chapter.

4.1.6 Annual Maintenance

1. An AAMI Water Quality Analysis of the product water should be conducted at least yearly. (Refer to the Water Quality Analysis Procedure in Chapter two.)
2. Check the monitoring for accuracy.
3. Check the gauges for correct functioning.
4. Check the ball valves for correct operation.
5. Check the tubing and fittings for leaks or wear.
6. Check the switches and lights for correct operation.
7. Check all pre RO devices for correct operation.
8. Lubricate the motor. Refer to the lubricating instructions in this chapter.

4.2 Specific Maintenance Procedures and Instructions**4.2.1 Motor Lubricant Procedure**

1. Remove the plastic plugs at both ends of the motor housing near the motor shaft.
2. Add three drops of SAE 20 wt. non-detergent motor oil into the opening.
3. Replace the plastic plugs.
4. Turn on the motor and run for 10 minutes.

4.2.2 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:

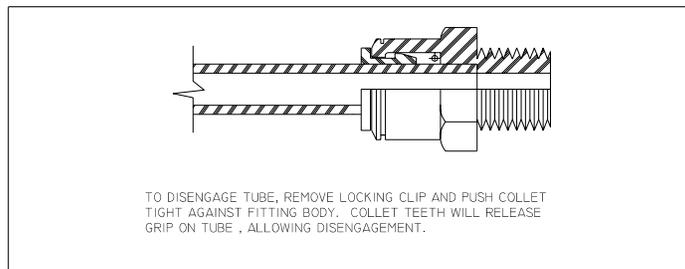
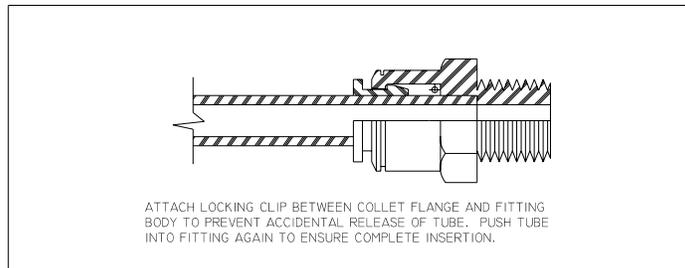
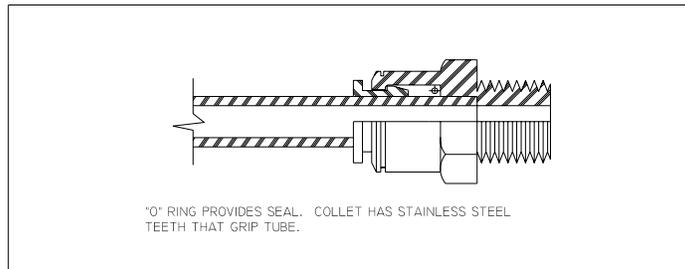
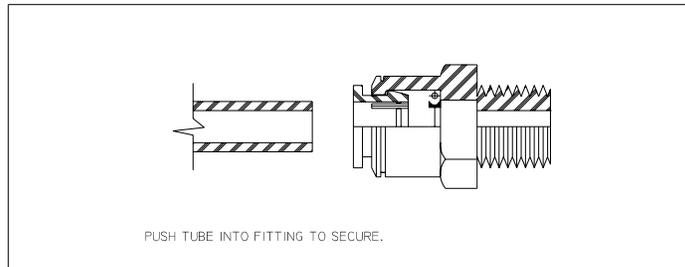
Use FDA/NSF approved silicone sealant on all threaded connections.

Threaded Connections:

1. Prior to performing this maintenance on any threaded fitting, release the pressure on 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 Teflon tape. (It is not necessary to remove the old Teflon tape, although it may be advisable to do so if it is in very bad shape).
4. Re-insert the threaded fitting into the opening and tighten hand tight. Be careful to avoid cross threading. Tighten further using a wrench only if necessary, and only about one-half turn.
5. Re-connect piping, pressurize, and inspect for leaks.
6. If the leak is still present, de-pressurize system again and tighten the fitting another quarter-turn. Check again for leaks. (Over tightening can crack the female fitting).
7. If the leak continues, it may be necessary to replace the male threaded fitting and/or the female threaded 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 this maintenance on any tube fitting, release any pressure on 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 dark gray collar in towards the body of fitting (light gray). This releases the ‘gripper’ which holds the tubing in place.
4. Hold the gray collar in while gently pulling the tube away from the fitting. It may be helpful to wiggle the tube side-to-side slightly while pulling.
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. (Inspect the collar to insure that all grippers are intact.)
6. Rinse the O-ring with warm running water to remove any dirt, debris, or crusty concentrate 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 dirt or debris. Be sure not to leave any cotton fibers from the swab or towel inside the fitting.
8. Lubricate the O-ring 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” to 1” of the 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 in the socket (completely ‘bottomed out’).
12. Pull back on the tubing to seat the grippers, and re-install the locking clip (if applicable) between the light gray body of the fitting and the dark gray collar (flat side towards the body).
13. Re-pressurize the system (if applicable) and inspect for leaks.
14. If the leak is not resolved, start over or simply replace the entire tube fitting or tube.

4.2.4 Product Recirculation Check Valve Test

With Valve In RO Unit

1. Measure TDS of Product water using a handheld meter. If RO display and TDS measurement do not match within a small amount, replace check valve. If values match, check valve is functioning correctly.
2. Measure and record the Product water flow (using a flow meter or graduated cylinder and stopwatch). After determining flow rate, slowly kink the waste line being careful to not close off the flow completely. Measure Product water flow again and compare against previous results. If there is a noticeable increase in flow, the check valve needs replaced.
3. If none of the above occurs, check valve is functioning correctly. For further verification, proceed with the following test.

With Valve Removed From RO Unit

1. Apply pressure in opposite direction of flow indicated on check valve. Check pressure reading (using a gauge) and for seepage. Remove pressure from valve and cycle it (push in direction of flow several times using care not to scratch or damage valve). Reapply pressure in opposite direction of flow and recheck pressure and for seepage. If pressure does not drop and no seepage is found, valve is functioning correctly.

4.3 Millenium™ 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. 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 pH or low pH).

Routine cleaning of the RO membranes in conjunction with regular disinfection 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, encourage bacterial growth and will eventually impair the RO membranes' ability to perform. Disinfection kills most of the bacteria that may be present in the system, but it does not remove the deposits on 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 temperature compensated flow rate drops by 10%. A loss in the membrane performance (percent rejection) or increase in TDS of the product water may also be an indication to clean the membranes. A good preventative maintenance practice is to clean the membranes on a quarterly basis, and more often if needed.

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.

4.3.1 Pre-Cleaning Preparation

There are two types of cleaners available, a low pH cleaner (Calcium/Iron removal) and a high pH cleaner (Silt/Organics removal). GE Osmonics provides these cleaners in liquid form. The low pH cleaner attacks mineral scale deposits such as calcium, magnesium and iron build-up, and should be used first. The high pH cleaner will remove accumulated silt and organic matter from the RO membrane.

CAUTION:

The different cleaners must not be mixed together. Introduce the low pH cleaner first, thoroughly rinse the system, and then use the high pH cleaner.

WARNING:

The solution is a mild irritant to eyes and skin. It is recommended that protective gloves and eye protection be worn when handling the cleaner. Neither respiratory protection nor special ventilation are required.

Materials Required:

Liqui-Clean 403™ – (Low pH liquid) - GE Osmonics Part No. 1228653 (1 Gal)

Liqui-Clean 211™ – (High pH liquid) - GE Osmonics Part No. 1228791 (1 Gal)

- high and low pH cleaner
- 2 Gallons pretreated water
- clean wide mouth container with volume of 2 ½ gallon or more
- pH test strips
- product rinse line (clear hose with male QD fitting on one end, open on the other)
- “DO NOT USE” warning labels (not provided by Osmonics)
- cleaning / disinfect log sheets
- most current log sheets for water quality comparison

4.3.1.1 Pre-Cleaning Procedure

Read and understand instructions on cleaner container before beginning procedure.

1. Connect the water inlet line to the water supply, and the waste and product lines to drain. Turn the RO unit and water supply on.
2. Establish a pre-cleaning % rejection, TDS and pH record on the cleaning disinfect log sheet.
3. Prepare the cleaning solution by adding the amount of cleaner as specified on the labeling to two gallons of pretreated or RO product water.

CAUTION:

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

4. Turn the RO pump power and inlet water valve switches off.

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. Connect the disinfect hose quick-disconnect fitting to the disinfect port on the RO. Place the open end in the cleaning solution.
6. Connect the product rinse line to the product port and place the open end in the cleaning solution.
7. Place the open end of waste line in the cleaning solution.

4.3.1.2 Cleaner Recirculation and Dwell Time

1. Turn the Operate/Flush valve to the Flush position. The Flush mode will allow the flow of cleaner only to the rejection side of the RO membrane to flush surface particulates away. Very little or no product water will be made in flush mode.
2. Push and hold the disinfect switch to operate the RO pump for three minutes.

CAUTION:

Some pump noise (chattering) is normal in the flush position. Excessive pump noise (chattering) can be damaging to the pump. The RO is in "flush" from the full open (flush) position to just before the fully closed (operate) position. Adjust it by partly closing the flush valve to reduce chattering of the pump.

CAUTION:

DO NOT ALLOW PUMP TO RUN DRY. Damage will occur if pump is run dry.

CAUTION:

Check that there is waste flow within 10 seconds. If not, release the button (switch) and verify that the disinfect-line is connected properly.

CAUTION:

Do not allow air or foam to be drawn into the RO system, as this will damage the pump.

NOTE:

The cleaners will foam; this is normal. If using a closed container, provide a vent to the atmosphere to relieve pressure.

3. Let the RO stand dormant with cleaning solution in it for thirty minutes.
4. Remove the waste hose from the cleaning solution and place it in the drain.
5. Using the disinfect switch, turn the RO on and flush approximately 1/2 gallon of the solution to the drain. This prevents fouling the cleaning solution with the first

output after the dwell time.

6. Place the waste hose back in the cleaning solution container.
7. Using the disinfect switch, turn the RO on and operate it for five minutes.
8. Remove the product and waste hoses from the cleaning solution tank and place them in the drain.

4.3.1.3 Post-Cleaning Rinse Procedure

1. Using the disinfect switch, turn the RO on and run cleaning solution to the drain until the container is empty. This aids in emptying the container of cleaning solution.

CAUTION:

DO NOT ALLOW THE PUMP TO RUN DRY. As an alternative, the solution may be poured in the drain.

2. Rinse and drain the cleaning solution tank and the hoses then let them air dry.
3. Disconnect the disinfect hose from the RO.
4. Ensure that the water supply to the RO unit is on. If it is partially closed, rotate the operate/flush valve to the full flush position.
5. Place the inlet water valve switch in the on position. Let water flow to the drain for one minute.
6. Rotate the operate/flush valve to the operate position.
7. Set the RO pump power switch in the ON position. Rinse for 20 minutes with the Operate/Flush valve in the Operate position until the % rejection and TDS monitors' displays normalize (e.g. 'usual' % rejection and 'usual' TDS reading). Refer to your operating log for 'usual' readings and compare to the pre-cleaning values.
 - A. During this rinse period, rotate the Operate/Flush valve to the Flush position briefly and then back to Operate three times to build-up and release pump pressure. This aids in flushing the cleaner from the system.
8. Test the product water for post-cleaning pH and compare it to the pre-cleaning pH level. The values should be the same or very close to the pre-cleaning pH. If it is not, continue rinsing in the Operate position until equalization of the value occurs.
9. When all of the parameters (% Rejection, TDS, pH) have normalized, operate the RO for an additional 20 minutes in rinse mode.
10. Repeat the cleaning procedure with the other pH cleaner. GE Osmonics recommends using a low pH cleaner first, followed by a high pH cleaner after rinsing thoroughly.



11. Turn the RO pump and inlet water valve switches OFF. Disconnect the product rinse line, and drain and store it.
12. Reconnect the product line to its original connection.
13. Remove the “**Do Not Use/Contains Cleaner**” warning label.
14. **The Millenium™ RO system is now ready for use.**

4.3.2 BIOSAN™ Pre-Cleaning Preparation

BIOSAN™ is a liquid cleaner/descaler agent intended for use in removing mineral scale and organic biofilm and is a short-term storage solution for RO water systems.

CAUTION:

BIOSAN™ is not intended for use in Hemodialysis Machines.

WARNING:

The solution is a mild irritant to eyes and skin. It is recommended that gloves (latex/vinyl) and eye protection be worn when handling BIOSAN™. Neither respiratory protection nor special ventilation are required.

Materials Required:

- BIOSAN™ cleaner
- product water
- clean wide mouth container with volume of 2 ½ gallon or more
- pH test strips
- product rinse line (clear hose with male QD fitting on one end, open on the other)
- “DO NOT USE” warning labels (not provided by Osmonics)
- cleaning / disinfect log sheets
- most current log sheets for water quality comparison

4.3.2.1 BIOSAN™ Cleaning Procedure

Read and understand all BIOSAN™ cleaning instructions before beginning procedure.

1. Connect the water inlet line to the water supply, and the waste and product lines to drain. Turn the RO unit and water supply on.
2. Establish the pre-cleaning % rejection, pH and TDS readings and record them on the Cleaning/Disinfect Log Sheet.
3. Prepare the BIOSAN™ solution in accordance with the manufacturers instructions.
4. Turn the RO pump power and inlet water valve switches off.

WARNING:

Label machine with appropriate warning signs such as "Do Not Use / Contains BIOSAN™" to prevent use of RO until properly rinsed.

CAUTION:

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



5. Connect the disinfect line quick-disconnect fitting to the disinfect port on the RO. Place the other (open) end of the line in the cleaning solution.
6. Connect the product rinse line to the product QD port and place the other end of the line in the cleaning solution.
7. Place the end of the waste line in the cleaning solution.

4.3.2.2 BIOSAN™ Recirculation and Dwell Time

1. Rotate the Operate/Flush valve to the Operate position. This will allow the BIOSAN™ to pass from the rejection side of the membrane through to the product side of the membrane for total system exposure to the cleaning solution once the RO is turned on in disinfect mode (step #2).
2. Push and hold the disinfect switch to operate the RO pump for three minutes.

CAUTION:

Check that there is waste flow within 10 seconds. If not, press the disinfect switch to turn RO pump off and verify that the disinfect line is connected properly.

CAUTION:

DO NOT ALLOW PUMP TO RUN DRY. Damage will occur if pump is run dry.

CAUTION:

Do not allow air or foam to be drawn up into the RO unit, as this will damage the pump.

NOTE:

Biosan™ will foam; this is normal. If using a closed container, provide a vent to the atmosphere to relieve pressure.

3. Turn the Operate/Flush valve to the Flush position and hold the disinfect switch for an additional 3 minutes. The Flush mode will allow the flow of cleaner only to the reject side of the RO membrane to flush particles away. Very little or no product water will be made.

CAUTION:

Some pump noise (chattering) is normal in the flush position. Excessive pump noise (chattering) can be damaging to the pump. The RO is in “flush” from the full open (flush) position to just before the fully closed (operate) position. Adjust by partly closing the flush valve to reduce the chattering of the pump.

4. Allow the BIOSAN™ to dwell in the RO for a minimum of one hour.



NOTE:

Thin-film RO membranes: The Millenium™ RO unit may be stored in BIOSAN™ for up to two weeks.

5. Remove the waste and product lines from the cleaning solution and place them in the drain.

4.3.2.3 BIOSAN™ Post-Cleaning Rinse Procedure

1. Using the disinfect switch, turn the RO on and run the cleaning solution to the drain until the container is empty.

CAUTION:

DO NOT ALLOW THE PUMP TO RUN DRY. As an alternative, the solution may be poured in the drain.

2. Disconnect the disinfect line from the RO.
3. Ensure that the water supply to the RO system is on. If it is partially closed, rotate the operate/flush valve to the full flush position.
4. Push the inlet water valve switch to the ON position. Let water flow to the drain for one minute.
5. Rotate the Operate/Flush valve to the operate position.
6. Set the RO pump power switch in the ON position. Rinse for 20 minutes with the Operate/Flush valve in the Operate position until the % rejection and TDS monitor displays normalize (e.g. 'usual' % rejection and 'usual' TDS reading). Refer to your operating log for 'usual' readings and compare to the pre-cleaning values.
 - A. During this rinse period, rotate the Operate/Flush valve to the Flush position briefly and then back to Operate three times to build-up and release pump pressure. This aids in flushing the cleaner solution from the system.
7. Test the product water for post cleaning pH and compare it to the pre-cleaning pH level. The values should be the same or very close. If it is not, continue rinsing in the Operate position until equalization of the value occurs.
8. When all of the parameters (% Rejection, TDS, pH) have normalized, operate the RO for an additional 20 minutes in rinse mode.
9. Turn the RO pump and inlet water valve switches OFF. Disconnect the product rinse line, and drain and store it.
10. Reconnect the product line to its original connections.
11. Remove the '**Do Not Use/Contains BIOSAN™**' warning label.
12. **The Millenium™ RO System is now ready for use.**

4.4 Millenium™ 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 over 200 CFU/ml (maximum AAMI standard) is detected. 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, longer dwell times, or alternative chemical agents may be employed.

CAUTION:

Glutaraldehyde and Actril™ are not recommended disinfectants for the Millenium™.

4.4.1 Formaldehyde Disinfection Preparation

CAUTION:

New replacement thin film membranes must be rinsed to drain with normal pressures for a minimum of six (6) hours before first exposure to formaldehyde, or irreversible damage may occur. No mandatory pre-rinse of the membranes is required for future disinfections.

WARNING:

Always wear rubber gloves, apron and facemask. Use proper ventilation during disinfection and rinse-out. A face respirator with an organic cartridge to remove formaldehyde fumes may be worn. **DO NOT BREATHE FUMES OR ALLOW FORMALDEHYDE TO COME IN CONTACT WITH SKIN OR EYES.** Refer to MSDS supplied by manufacturer of the formaldehyde or formalin product.

Materials Required:

- 800 ml. Formaldehyde, 37%
- 2 gallons pre treated or RO water
- clean wide mouth container with volume of 2 ½ gallon or more
- formaldehyde test kit
- product rinse line (clear hose with male QD fitting on one end, open on other)
- “DO NOT USE” warning labels or signs (not provided by Osmonics)
- cleaning / disinfect log sheets
- most current log sheets for water quality comparison
- proper protective body wear

WARNING:

Label the machine with appropriate warning signs such as "Do Not Use / Contains Formaldehyde" to prevent use of the RO until it is properly rinsed.

4.4.1.1 Formaldehyde Pre-Disinfection Procedure

1. Turn the Millenium™ RO off.
2. Disconnect the RO system from the dialysis machine.
3. Connect the RO product rinse line to the product port and place the open end in a drain.
4. Connect the waste line to the RO and run the other end to a drain.

NOTE:

Follow your facility's procedure for formaldehyde disposal. The drain line may have to be placed in a container. Verify that the operate/flush valve is in the OPERATE position.

5. Prepare a 4% solution of formaldehyde (800 ml of 37% formaldehyde to 2 gallons of pre-treated water. The 2 gallons of solution is adequate for the Millenium™ RO).

CAUTION:

Formaldehyde or Formalin is usually provided in a clinical setting in a 37% solution. Check the labeling on the packaging to make certain this is the case. If the solution is other than 37%, the dilution will require adjustment. The end solution should not exceed 4.2%. Consult the Medical Director or Director of Nursing to determine the correct solution strength. Osmonics will not be responsible for any damaged components due to incorrect solution strength.

6. Attach the quick-disconnect end of the disinfect line to the disinfect port of the RO. Place the open end of the disinfect line in the disinfectant.

4.4.1.2 Formaldehyde Disinfection and Dwell Time

1. Push and hold the disinfect switch to operate the RO pump. Allow the RO to operate until the disinfectant has been drawn into the machine.

CAUTION:

Check that there is waste flow within 10 seconds. If not, push the switch once and verify that the disinfect line is submerged in the solution and the QD is connected correctly. Do not allow air to be drawn into the RO system, as this will damage the pump.

2. Test for the presence of formaldehyde in the product line (the RO must be running).
3. Release the disinfect switch.



4. Momentarily turn the inlet water valve switch on (approximately 5 seconds), then turn it off again. This allows the water to rinse the disinfectant from the disinfect line and quick-disconnect connection.

WARNING:

Failure to perform this step creates a potentially dangerous situation (FORMALDEHYDE SPILLAGE) and prolongs the rinsing out of the disinfectant.

5. Disconnect the disinfect line from the quick-disconnect port.
6. Ensure that the FORMALDEHYDE warning label is clearly visible.
7. Remove the product rinse line and waste line from disinfect tank and RO.
8. Rinse the disinfect line and the disinfect tank with water to remove the formaldehyde, and store it appropriately.
9. Allow the disinfectant solution in the RO to remain in contact for a minimum of two hours, or, preferably, overnight.

NOTE:

The RO may be stored for up to one year at this time. If this is the case, a 0.5% solution may be used instead of 4%.

4.4.1.3 Formaldehyde Post-Disinfection Rinse Procedure

1. Connect the product rinse line, input water and waste lines to the RO.
2. Ensure that the product rinse and waste lines are in the drain.
3. Turn the operate/flush valve to the flush position.
4. Turn on the inlet water valve and allow the system to rinse for 2 minutes.
5. Turn on the RO power switch and run the RO for 10 minutes.

CAUTION:

Some pump noise (chattering) is normal in the flush position. Excessive pump noise (chattering) can be damaging to the pump. The RO is in “flush” from the full open (flush) position to just before the fully closed (operate) position. Adjust it by partly closing the flush valve to reduce the chattering of the pump.

6. Rotate the operate/flush valve to the operate position.
7. Turn RO pump power switch off for 1 minute. Turn the RO pump switch on for 2-3 minutes. This will aid in the rinsing out any trapped formaldehyde in the Millenium™ RO.
8. Continue to rinse for an additional 5 minutes.
9. Check the product line for residual disinfectant with an appropriate test kit. If the test is positive, continue to rinse until a negative test is obtained.
10. Disconnect the product rinse line and store it.



11. Remove the warning signs from the RO only after a negative test confirms the absence of formaldehyde.
12. **The Millenium™ RO System is now ready for use.**

NOTE:

Success of the disinfection procedure may be ascertained by taking a water culture after completion. See the Product Water Culture Procedure in this chapter.

4.4.2 Peracetic Acid/Peroxide-Based Compounds (Renalin®) Disinfection Procedure

Renalin®, **Minnicare™**, **Peracidin™** and others are trade names for compounds based on Peracetic Acid and Hydrogen Peroxide compounds, and are common in dialysis facilities. The products referred to in this procedure typically have 20% hydrogen peroxide and 4% peroxacetic acid before dilution. Other products are available with these same chemicals in different ratios; these are not acceptable for use in the Millenium™ RO. **Actril™ and other compounds with different combinations of these chemicals must not be used on polyamide (thin-film) membranes.** The name, “Renalin®” will be used in this manual to refer to acceptable products.

CAUTION:

New replacement thin film membranes must be rinsed to drain with normal pressures for a minimum of three (3) hours before first exposure to Renalin. No mandatory pre-rinse of the membranes is required for future disinfections.

WARNING:

Follow all Material Safety Data Sheet (MSDS) precautions and OSHA Standards.

CAUTION:

‘RENALIN®’ is corrosive to most metals other than stainless steel. The Millenium™ uses only compatible materials. ‘RENALIN®’ type products contain oxidizing agents and 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 performance and the warranty.

Materials Required:

- correct amount of disinfectant, per manufacturers’ instructions
- 2 gallons RO water
- clean wide mouth container with volume of 2 ½ gallon or more
- product rinse line (clear hose with male QD fitting on one end, open on the other)
- “DO NOT USE” warning labels or signs (not provided by Osmonics)
- cleaning / disinfect log sheets
- most current log sheets for water quality comparison

4.4.2.1 Renalin® Pre-Disinfection Preparation**CAUTION:**

When 'RENALIN®' is to be used as a disinfectant, several preparatory steps are required by GE Osmonics as well as the membrane manufacturer. Failure to comply with these instructions, which incorporate instructions from the membrane manufacturer, will jeopardize the system performance and warranty.

- a. The system must be free of all incompatible materials.
- b. Clean the membranes with an acid such as 0.1% HCl or 0.4% phosphoric acids. Calcium and Iron Cleaner may be used as an alternate. It is essential that all iron and other transition metals be removed from the membrane surface.

CAUTION:

The RO system must be disconnected from the tempered water source (if present). The solution temperature must be monitored closely. At temperatures above 25° the 'RENALIN®' solution becomes very aggressive towards the RO membranes and will damage them in a short period of time. The disinfection procedure will raise the temperature of the solution. The operator must be prepared to add ice to the solution or discontinue the procedure when the water temperature approaches 77°F /25°C.

1. Read and understand the 'RENALIN®' disinfection procedure. Pay particular attention to steps a and b in CAUTION statement above before initiating the procedure.
2. Ensure the cleaning/disinfectant container is clean. Add two gallons (7.6 liters) of RO permeate (product water) to the container.
3. Add 2.6 ounces (80 milliliters) of disinfectant concentrate to the container and mix to prepare a 1:100 (1%) dilution.

WARNING:

Label the machine with appropriate warning signs such as "Do Not Use/ Contains Disinfectant" to prevent use of the RO until properly rinsed.

4. Disconnect the dialysis machine from the RO product port and install the product rinse line. Place the open end in the disinfectant solution container and ensure the product valve is open.
5. Attach the quick-disconnect end of the disinfect line to the disinfect port of the RO. Put the open end of the disinfect line in the disinfectant.
6. Disconnect the waste line from the drain connection and place the open end in the disinfectant solution container.

4.4.2.2 Renalin® Disinfection and Dwell Time

1. Verify that the operate/flush valve is in the OPERATE position.
2. Use the disinfect switch to circulate the solution through the system for five minutes. After three minutes of circulation, test the product line for the presence of disinfectant. Continue circulating until a positive test is achieved.

CAUTION:

Do not allow the solution temperature to climb above 25°C during this step. Failure to control temperature will result in rapid deterioration of the membrane, resulting in poor rejection.

3. Place the product and waste lines into a drain. Protect the product line from contamination.
4. Using the disinfect switch, turn the RO on and run solution to the drain until the container empties. Alternately, the container may be carefully poured in the drain.
5. Turn off the RO; do not operate the RO dry.

CAUTION:

Do not allow air to be drawn up into the RO unit as this will damage the pump.

6. Momentarily turn the inlet water valve switch on (approximately 5 seconds.) This allows the water to rinse the disinfectant from the disinfect line and quick-disconnect connection.

WARNING:

Failure to perform this step creates a potentially dangerous situation (DISINFECTANT SPILLAGE) and prolongs the rinsing out of the disinfectant.

7. Remove the disinfect line from the disinfect port. Rinse, drain and store it.
8. Allow the RO to soak in the disinfecting solution for 36 minutes -12 hrs. Thirty-six minutes contact time is expected to result in 90% bacteria kill; 12 hours is expected to kill 99% of the bacteria. The minimum amount of soak to achieve disinfection is better for the membranes.

4.4.2.3 Renalin® Post-Disinfection Rinse Procedure

1. Ensure that the product rinse line is connected to the RO.
2. Ensure that the product rinse and waste lines are connected to the drain.
3. Rotate the operate/flush valve to the flush position.
4. Turn on the inlet water valve switch and allow the system to rinse for 2 minutes.
5. Turn the RO pump power switch on and run the RO for 10 minutes.

CAUTION:



The operate/flush valve may need to be rotated partially closed, (towards the operate position) if the pump makes excessive noise.

6. Rotate the operate/flush valve to the operate position.
7. Turn the RO pump power switch off for 1 minute. Turn the RO pump switch on for 2-3 minutes. This will aid in the rinsing out of any potentially trapped disinfectant in the Millenium™ RO.
8. Continue to rinse for an additional 5 minutes.
9. Check the product line for residual disinfectant with an appropriate test kit. If the test is positive, continue to rinse until a negative result is achieved.
10. Disconnect the product rinse line and store it.
11. **Remove the 'Do Not Use/Contains Disinfectant' warning label. The Millenium™ RO System is now ready for use.**

4.5 Product Water Culture

FREQUENCY: Once a month or more often, depending upon culture results, and unit protocol. We recommend before and after disinfection.

Materials Required:

- Bucket or similar container
- Sterile specimen container, such as Millipore (red) or 3M Commercial Standard Plate count sampler, or a container your lab may require

RATIONALE: This procedure will help ensure that the microbial count of the product (RO) water falls within the AAMI Hemodialysis Water Standard. The AAMI standard maximum allowable concentration for bacteria in product water is 200 colony-forming units. A bacterial count above the maximum level may be harmful to the hemodialysis patient.

OTHER: 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. 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 tryptic soy agar or equivalent agar, NOT blood or chocolate agar. If tested incorrectly, the results may be inaccurate. The sample should be assayed within 30 minutes of obtaining it, or refrigerated (5°C) immediately and assayed within a 24 hour period. Obtain the samples wearing long sleeves and a mask to prevent contamination of samples, use a "mid-stream" "clean catch" type procedure.

4.5.1 Product Water Culture Procedure

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

1. Connect the product rinse line to the product port. Place the other end in a drain.
2. Connect the waste line to the waste port. Place the other end in a drain.
3. Turn on the RO unit. Allow the RO unit to run for 10-15 minutes.
4. Remove the product rinse line from the drain.
5. Using aseptic technique, hold the product line over a container, and allow approximately 100 cc of product (RO) water to flow to the drain (or allow product water to flow for 30 seconds).
6. Maintaining aseptic technique, hold the product line over the sterile container with the product water flowing.
7. Fill the container with RO product water. (If using commercial samplers, follow the manufacturer's instructions.)
8. Aseptically cap the specimen container immediately.
9. 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
10. The samples should be assayed within 30 minutes of obtaining or refrigerated at 5° C immediately and assayed within a 24-hour period.

4.6 System Storage

This storage procedure has been established to store Millenium™ RO machines. It is not recommended that a unit be dormant longer than 24 hours without disinfectant. ROs that have been left unused for more than 24 hours risk the possibility of colonizing bacteria and exceeding acceptable limits. ROs to be stored should first be disinfected with one of the procedures in this chapter. The RO should be stored in a location where it cannot freeze or become overly hot.

CAUTION:

‘RENALIN®’ products (Renalin®, Minncare™, Peracidin™. etc.) are not acceptable disinfectants for storage of systems. Exposure of more than 12 hours to RENALIN® will result in irreversible damage to the membranes.

4.6.1 Formaldehyde Storage Procedure

WARNING:

Always wear rubber gloves, an apron and a facemask. If the room has ventilation, use it. If not, wear a face respirator with an organic cartridge to remove formaldehyde fumes. **DO NOT BREATHE FUMES OR ALLOW FORMALDEHYDE TO COME IN CONTACT WITH SKIN OR EYES** Refer to the MSDS supplied by the manufacturer of the formaldehyde/formalin product.

1. If formaldehyde is chosen to disinfect the RO, follow the instructions for formaldehyde disinfection.
2. Do not rinse out after the disinfectant has been circulated in the machine.
3. Disconnect the disinfect line, the feed water line, the waste line, power and the product line.
4. Coil the hoses and power cord, and cover the RO with a large plastic bag to protect the RO from dust.

NOTE:

All ROs can be safely stored in 0.5 to 4 % formaldehyde for up to one year.

WARNING:

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

4.6.2 BIOSAN™ Storage Procedure

WARNING:

It is recommended that gloves (latex/vinyl and eye protection be worn when handling BIOSAN™.

1. Disinfect and rinse the RO with an acceptable disinfectant.
2. Follow the BIOSAN™ procedure in this chapter.
3. Do not rinse the RO out after BIOSAN™ has been circulated in the RO.
4. Disconnect the disinfect line, waste line, feed water line, power and product line.
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™ RO may be stored for up to two weeks in BIOSAN™. After two weeks, if longer storage is needed, the Millenium™ RO may be rinsed and re-packed with BIOSAN™.

WARNING:

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



NOTES:



Millenium RO System

CHAPTER FIVE:
TROUBLESHOOTING



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5.1 RO Fails to Run

1. **Power off.**
 - a. Check position of inlet and pump switches.
 - b. Check power cord (plugged in).
 - c. Check outlet and circuit breaker/fuse panel for power with voltmeter.
 - d. Check fuses in RO.
2. **Improper line voltage.**
 - a. Verify that line and equipment voltages are compatible.
3. **Loose electrical connections.**
 - a. Check all wiring connections to verify solid connection.
 - b. Verify that plug is securely connected to outlet.
4. **Inlet water valve switch not activated.**
 - a. Check position of switch.
 - b. Check switch with voltmeter.
 - c. Replace switch.
5. **Power switch inoperative.**
 - a. Assure inlet water valve is open.
 - b. Check switch with voltmeter.
 - c. Replace switch.
6. **Pump motor inoperative.**
 - a. Verify that voltage supply is correct and motor is wired for correct voltage. Correct as necessary.
 - b. Motor thermal overload switch tripped (most motors have automatic internal reset). Motor will restart when it cools approximately 10-15 minutes. Correct reason for the overload.
 - c. Remove pump head and try restarting motor.
 - d. Replace motor.
7. **Pump inoperative.**
 - a. Inspect pump and motor coupling for wear.
 - b. Clean any debris or liquid from connection area.
 - c. Replace pump.
 - d. See 5.5.

5.2 RO Runs Intermittently

1. **Loose electrical connection.**
 - a. Verify that all wiring connections are secure.
 - b. Verify that plug is securely connected to outlet.



2. **Pump pressure too high.**
 - a. Adjust pressure at pump head.
 - b. Check waste flow-path for obstruction.
 - c. See 5.1.6
 - d. See 5.1.7
3. **Thermal overload trips**
 - a. Verify line voltage and motor amperage draw.
 - b. Disassemble pump/motor at clamp and inspect coupler for wear.
 - c. Pump pressure too high (see 5.2.2).

5.3 Motor Runs Hot

1. **Pump/motor binding.**
 - a. Remove pump head and try restarting motor.
 - b. Inspect pump and motor coupling for wear.
 - c. Clean any debris or liquid from connection area.
 - d. See 5.5
 - e. Replace pump.
2. **Fan obstructed or inoperative.**
 - a. Verify no debris is obstructing fan vent.
 - b. Verify fan operation.
3. **Excessive current draw.**
 - a. Verify that flow rates and pressures are within RO specifications.
 - b. Check motor/pump coupling for alignment.
 - c. Confirm amperage draw with meter.
 - d. Motor insulation shorted, replace motor.
4. **Voltage too low.**
 - a. Check voltage against serial label and motor label, correct condition.

5.4 Water Produced While RO is Off

1. **Faulty inlet water solenoid valve.**
 - a. Cycle valve off and on with inlet water valve switch to clear obstruction.
 - b. Remove valve and clear obstruction.
 - c. Replace valve.
2. **Fault inlet water valve switch.**
 - a. Verify switch is in OFF position.
 - b. Check switch with ohm meter, replace switch.

5.5 Low Pump Pressure

1. **No pressure develops above level of feed pressure.**
 - a. Verify motor operation and water line connections.
 - b. Verify flush valve is in the operate position.
 - c. Verify (lower than normal) flow from product, if high see membrane problem.
 - d. Verify (lower than normal) flow from waste, if high check flush valve operation.
 - e. Pump damaged or worn out, replace pump.
2. **Pressure develops but does not achieve normal operating pressure.**
 - A. Waste or product flow too high.**
 - a. Check water temperature and flow rate.
 - b. Check quality of product water.
 - B. Faulty inlet pressure regulator.**
 - a. Replace regulator.
 - C. Pump adjusted improperly**
 - a. Adjust pump at pump head and regulator.
 - D. Pump worn out or damaged.**
 - a. Replace pump.

5.6 Pressure Gauge Vibrates Erratically

1. **Air in gauge tubing.**
 - a. Loosen tube fitting at gauge to bleed air.
2. **Obstruction in pressure gauge orifice.**
 - a. Remove obstruction.
3. **Product return check valve operation (Product Gauge Only)**
 - a. Check and remove obstruction in return check valve.
 - b. Replace check valve.
4. **Faulty gauge.**
 - a. Replace gauge.
5. **Inlet regulator faulty.**
 - a. Replace regulator.

5.7 Excess Product Pressure (too high)

1. **Inlet pressure regulator improperly adjusted.**
 - a. Decrease pressure regulator to adjust maximum product setting.



2. **Product flow rate too high.**
 - a. Decrease pump operating pressure if above specifications.
 - b. Feed water temperature too high. Reduce temperature or discontinue use of RO to prevent damage to membranes.
 - c. Damage or failure of membrane has occurred, replace membranes.
 - d. Faulty product return check valve.

5.8 Product Flow Too Low

Low water temperatures, fouled membrane elements, or inadequate pump pressure can cause low product flow. A partial blockage of the 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 (defective check valve) in the product flow path may cause reduced flow.

1. **Pump pressure too low.**
 - a. See 5.5
2. **Low feed water temperature.**
 - a. Verify product production with Tech Note 121 Temperature Correction.
 - b. Install or adjust temperature blending valve.
3. **Membrane fouled or scaled.**
 - a. Review trend analysis logs for flow.
 - b. Clean membrane with both high and low pH cleaners.
 - c. If flow is not recoverable, replace membrane.
4. **Center tube of ROMA collapsed from operating at high temperatures.**
 - a. Correct temperature problem.
 - b. Replace membrane.
5. **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.
6. **Product recirculation check valve failed.**
 - a. Refer to Maintenance Procedures for Check Valve Test.

5.9 Product Flow Too High

1. **Rejection Satisfactory**
 - A. **Pump pressure too high.**
 - a. Adjust pressure regulator setting to specifications.
 - B. **Feedwater temperature too high.**
 - a. Adjust temperature blending valve.
 - b. Correct plumbing error that allows the cold water to be heated.
 - C. **Quick disconnect tubing connections not in correct port.**
 - a. Verify QD connections.
 - D. **Product recirculation check valve failed.**
 - a. Refer to Maintenance Procedures for Check Valve Test.
2. **Rejection Unsatisfactory**
 - A. **Waste flow too low.**
 - a. Check waste flow rate.
 - b. Check for blockage or kink in waste line.
 - c. Quick disconnect not connected completely.
 - B. **High pH and chlorines in feed water.**
 - a. Check feedwater for higher than 8.5 and the presence of chloramines.
 - b. Check pH reduction equipment if applicable.
 - c. Contact GE Osmonics.
 - C. **ROMA internal seals damaged, dirty, or dislodged.**
 - a. Disassemble ROMA, clean and inspect “O” rings and seals.
 - D. **Membrane hydrolyzed (exposed to oxidant).**
 - a. Verify condition of pretreatment equipment.
 - E. **Membrane damaged (or ruptured).**
 - a. Check for high product pressure.
 - b. Check for product line being back pressured.

5.10 Leaks

1. 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.
2. Refer to the Maintenance Procedures for Leak Repair.

5.11 Low Percent Rejection

The overall membrane performance can be affected by a number of factors. Poor rejection performance, as well as high TDS, can result from fouled membranes, low pump pressure, inadequate waste flow, or feed water problems. An apparent performance problem could be caused by a defective sensor or circuit board, and not be a membrane issue at all. The recommended first step for any ‘membrane performance’ question is to confirm the rejection percentage and product TDS with a hand-held RO/TDS meter. If the product water quality is poor, investigate the membrane. However, if the water quality tests ‘normal’, investigate the monitoring circuits.

1. **Waste flow too low.**
 - a. Disinfectant or cleaner not rinsed from RO.
 - b. Check waste flow control.
 - c. Check for obstruction or kink in waste line.
2. **Pump pressure too low.**
 - a. Adjust pressure regulator.
 - b. Adjust pump settings.
3. **Product flow too high.**
 - a. See 5.9
4. **Membrane scaled or fouled.**
 - a. Verify condition of 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.
 - b. Check all quick-disconnect connections.
 - c. Replace inlet water sensor probe.
 - d. Replace product water sensor probe (percent rejection).
 - e. Replace monitor circuit board.
6. **Membrane failure.**
 - a. Replace membrane.
7. **Change in feed water TDS.**
 - a. Verify feed and product water quality with independent meter.
 - b. Softener problem, rinsing out high levels of salt.

5.12 TDS Value High

The overall membrane performance can be affected by a number of factors. Poor rejection performance, as well as high TDS, can result from fouled membranes, low pump pressure, inadequate waste flow, or feed water problems. An apparent performance problem could be caused by a defective check valve, sensor or circuit board, and not be a membrane issue at all. The recommended first step for any 'membrane performance' question is to confirm the rejection percentage and product TDS with a hand-held RO/TDS meter. If the product water quality is poor, investigate the membrane. However, if the water quality tests 'normal', investigate the monitoring circuits.

1. **Waste flow too low.**
 - a. Measure and compare to original data. Correct as necessary.
2. **Waste pressure too low.**
 - a. Adjust pump settings.
3. **Product flow too high.**
 - a. See 5.9
4. **Membrane scaled or fouled.**
 - a. Verify condition of pretreatment equipment.
 - b. See membrane cleaning procedure in this manual.
5. **Erroneous meter readout.**
 - a. Verify water quality with independent meter.
 - b. See 5.12.8
 - c. TDS water probe wire disconnected or loose.
 - d. Replace TDS water sensor probe.
 - e. Replace thermistor.
 - f. Replace monitor circuit board.
6. **Membrane failure.**
 - a. Replace membrane.
7. **Change in feed water TDS.**
 - 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. **Product recirculation check valve failed.**
 - a. Refer to Maintenance Procedures for Check Valve Test.



5.13 RO Fails to Draw Disinfectant

1. **Pre-filter bowl leaking on vacuum.**
 - a. Tighten bowl
 - b. Inspect and clean pre-filter bowl seal / replace seal.
 - c. Replace filter bowl
2. **Disinfect line kinked or plugged.**
 - a. Clear disinfect line.
3. **Air leak on disinfect draw line.**
 - a. Check that quick disconnect fitting is connected securely.
 - b. Immerse tube in solution.
 - c. Check tube for cracks or holes.
 - d. Replace quick disconnect fitting.
4. **Solenoid failure in open position.**
 - a. See 5.4

5.14 RO Pump Leaks

1. **Tubing connection leaking.**
 - a. Tighten or reconnect tubing fitting.
2. **Mechanical seal failure (leaks out vent hole).**
 - a. Replace pump.

5.15 TDS Value Fluctuates

1. **Product recirculation check valve failed.**
 - a. Refer to Maintenance Procedures for Check Valve Test.



NOTES:



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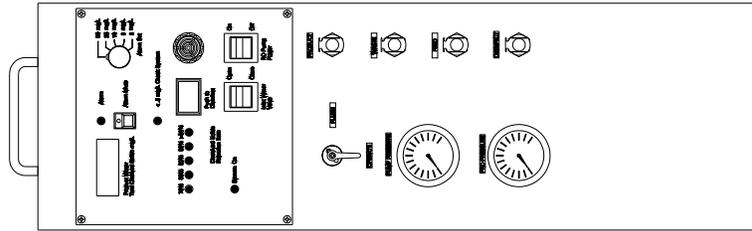


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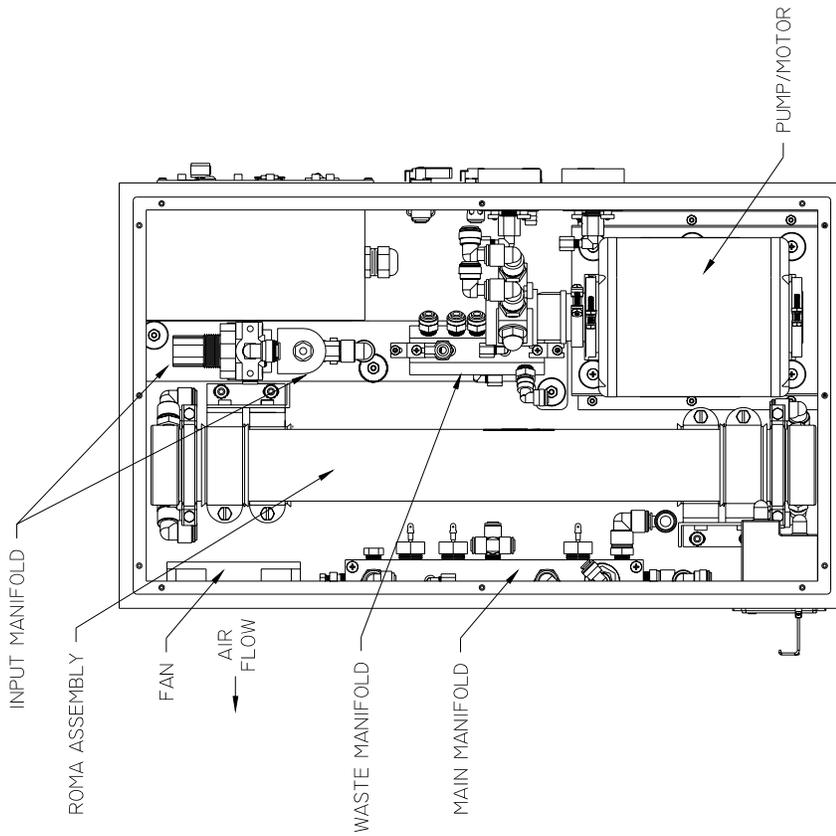
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DRAWINGS



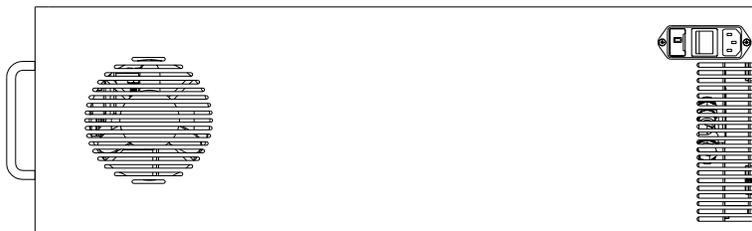
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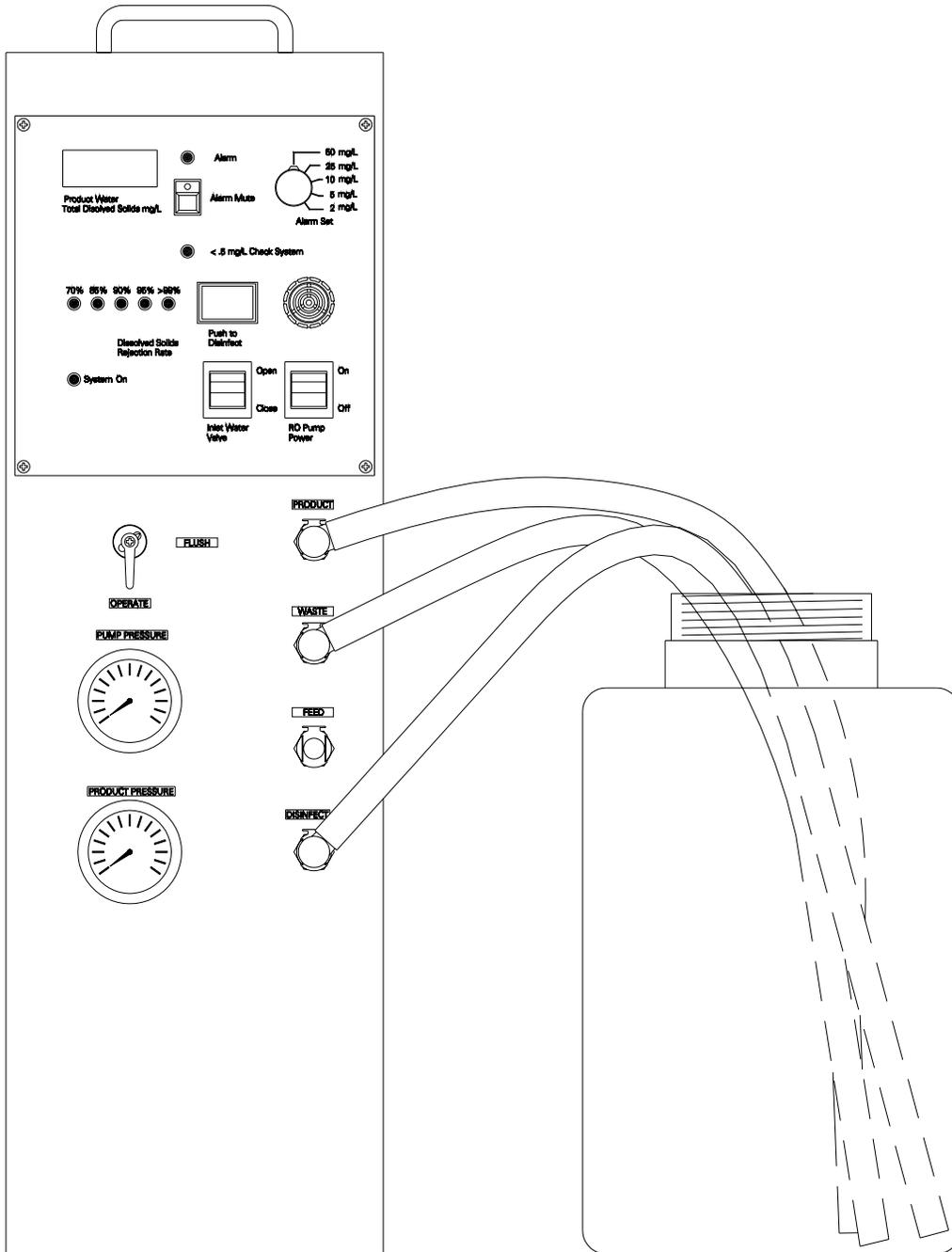


SIDE VIEW

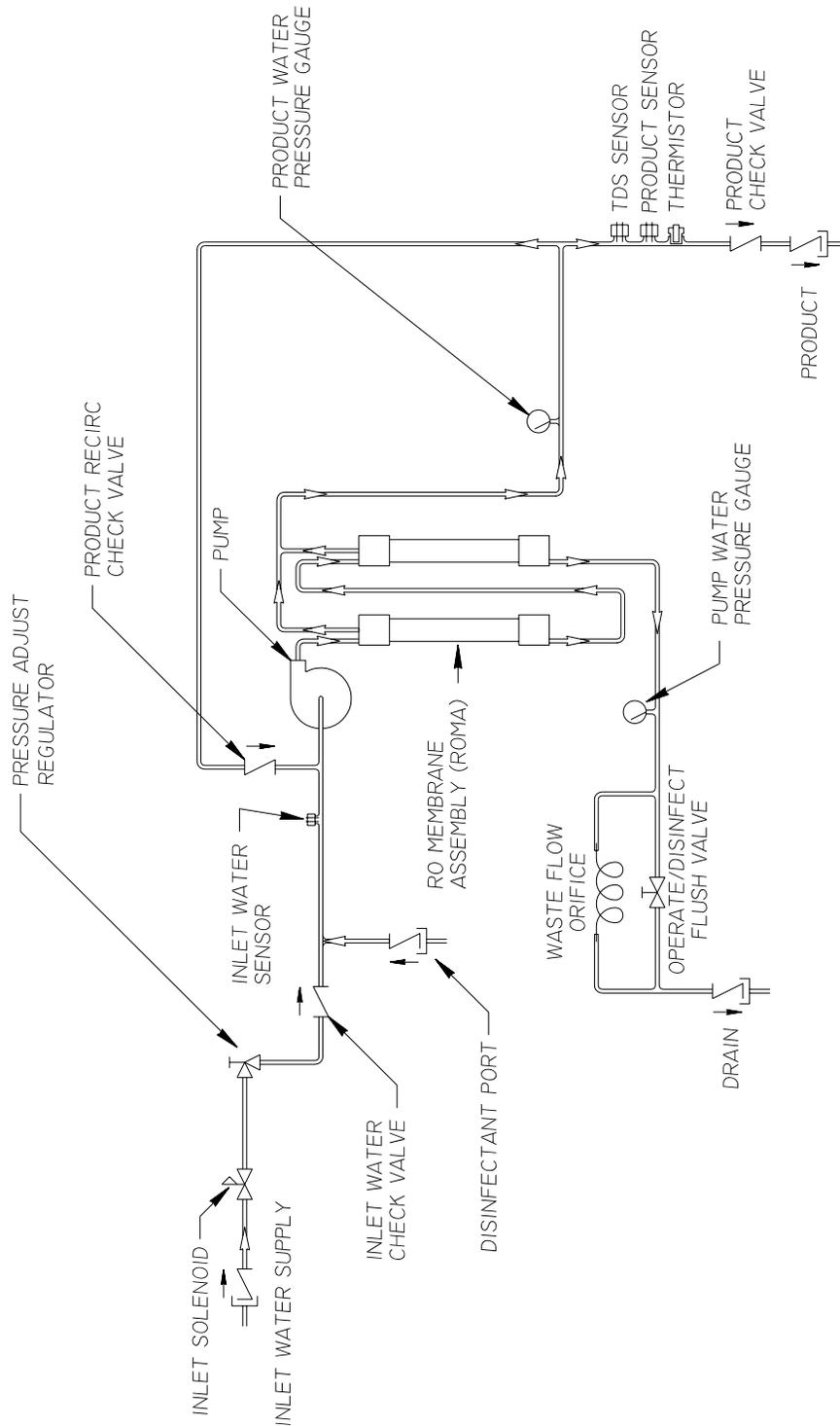


REAR VIEW

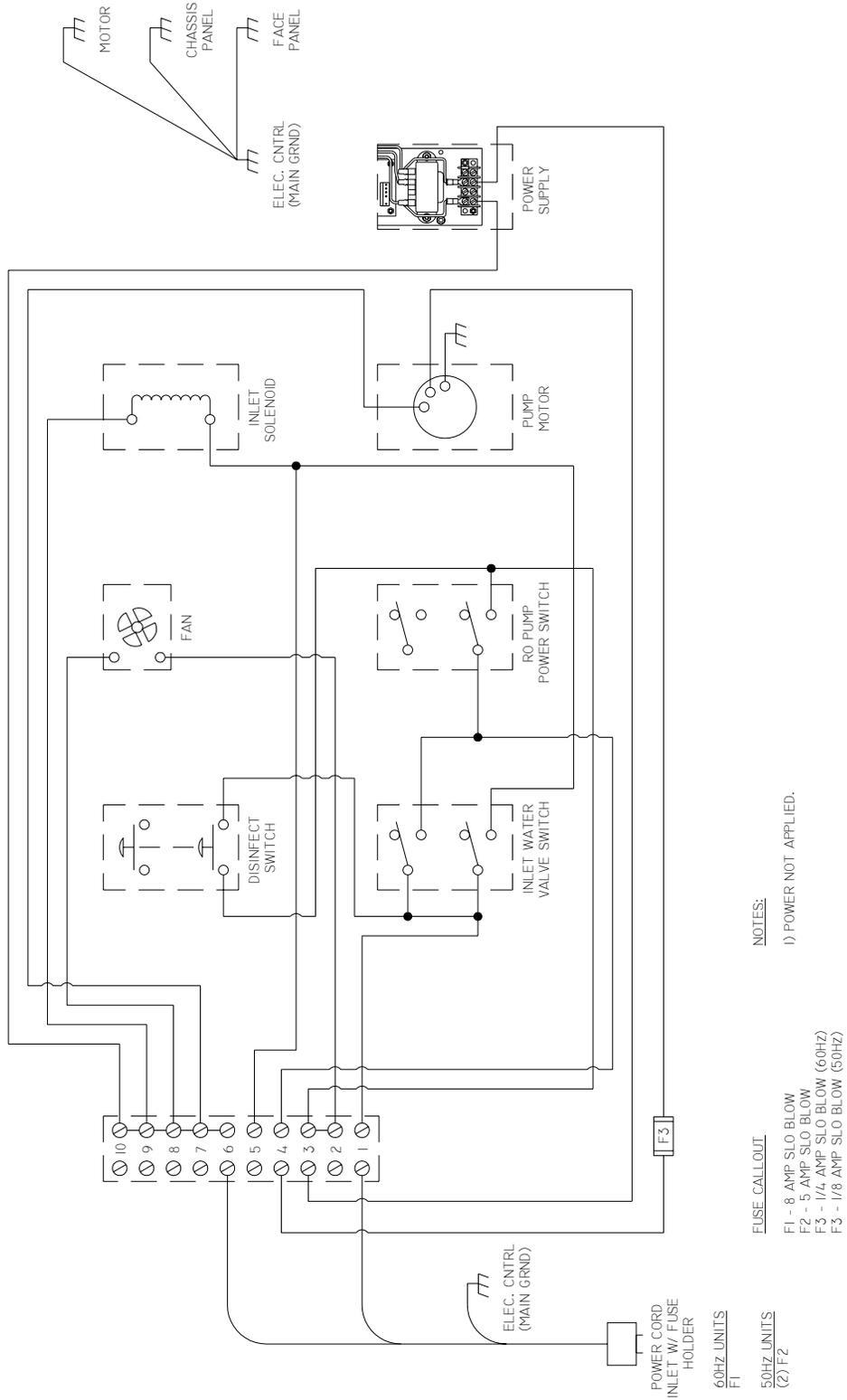
Millenium RO
(Component Layout)



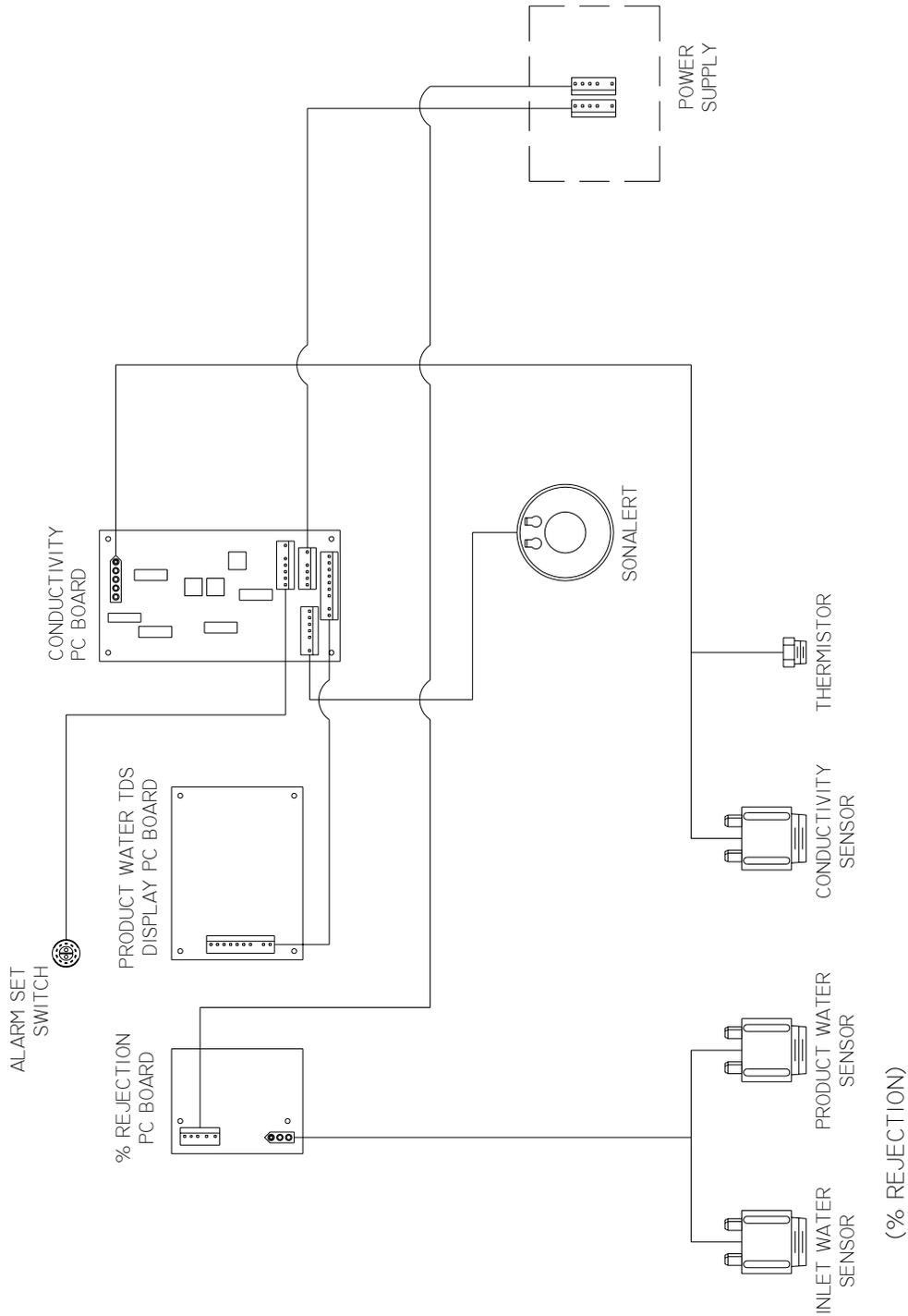
Millenium RO
(Disinfect View)



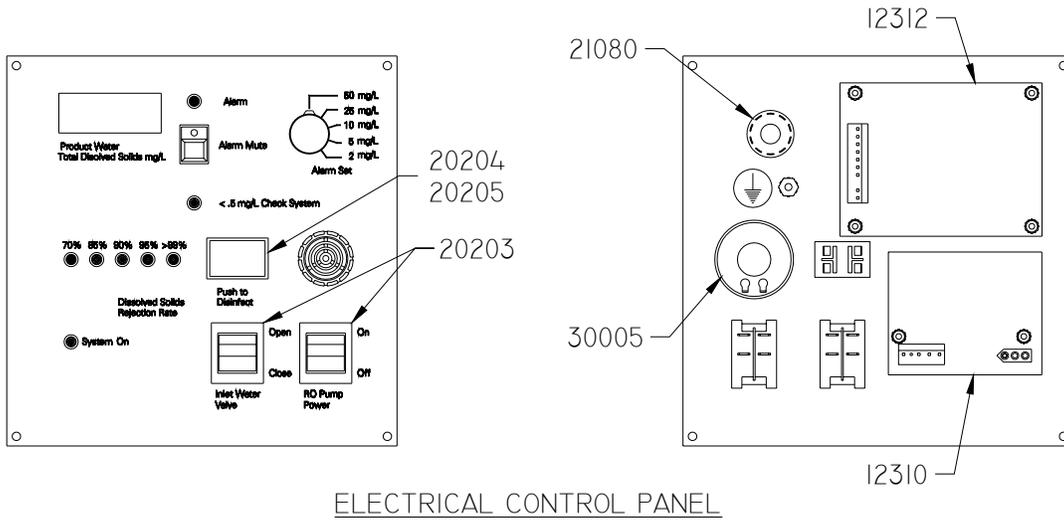
Millenium RO
(Flow Schematic)



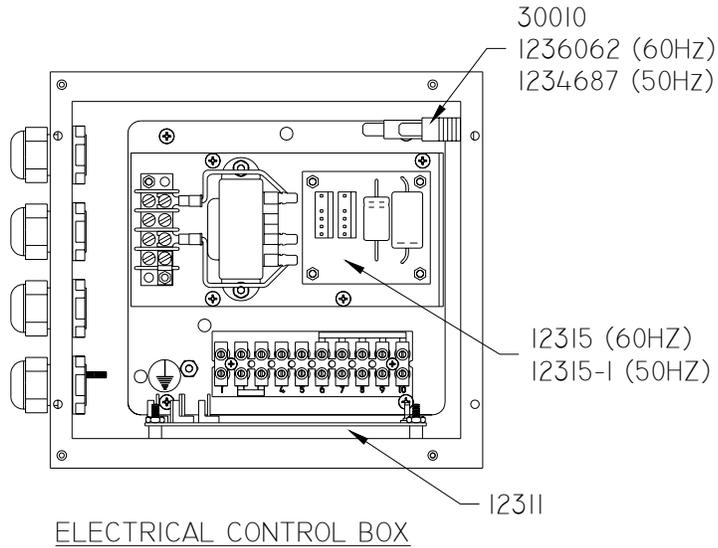
Millenium RO
(Electrical Schematic, High Voltage, 50/60Hz)



Millenium RO
(Electrical Schematic, Low Voltage, 50/60Hz)



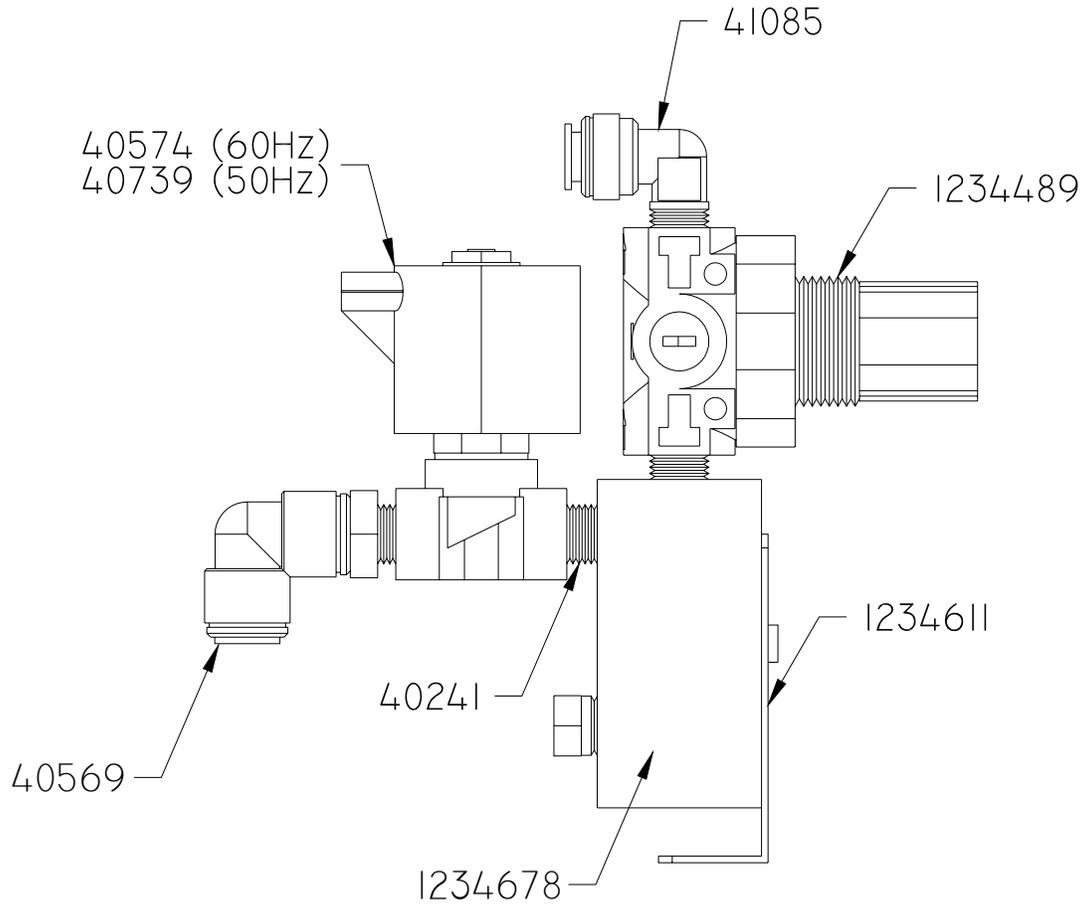
ELECTRICAL CONTROL PANEL



ELECTRICAL CONTROL BOX

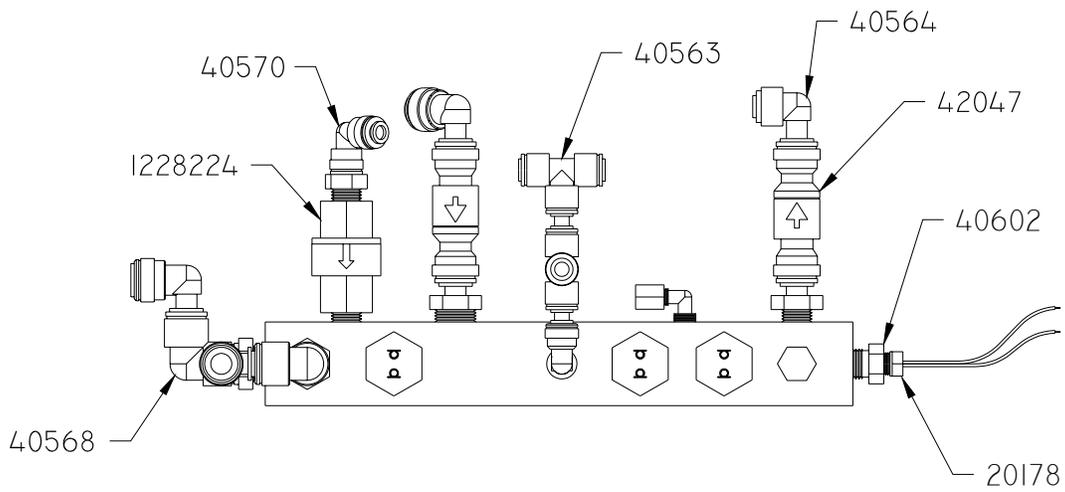
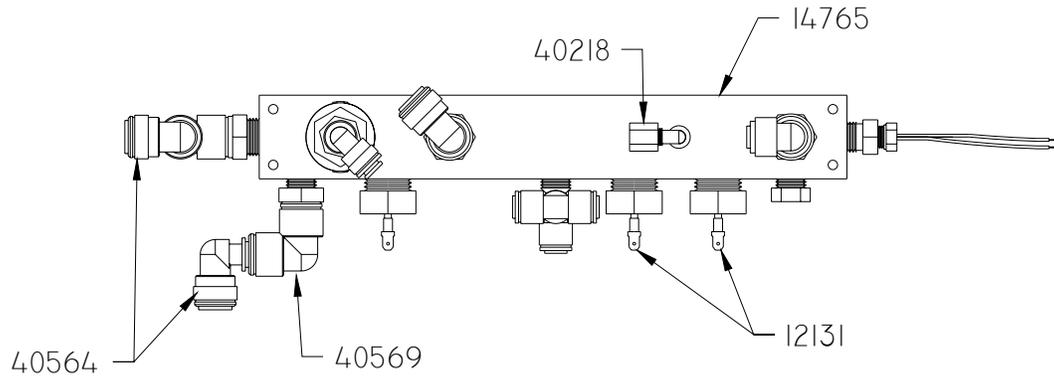
PART NO	DESCRIPTION
12310	PCB ASSY, % REJECTION
12311	PCB ASSY, CONDUCTIVITY
12312	PCB ASSY, DISPLAY
20203	SWITCH, POWER, DPST
21080	SWITCH, ROTARY, 2 POLE 5 POS
30005	SONALERT
30010	FUSE HOLDER
20204	SWITCH, DISINFECT
20205	SWITCH, LENS
12315	POWER SUPPLY, 60HZ
12315-1	POWER SUPPLY, 50HZ
1236062	FUSE, 1/4AMP SLO BLOW
1234687	FUSE, 1/8AMP SLO BLOW

Millenium RO
(Electrical Layout)



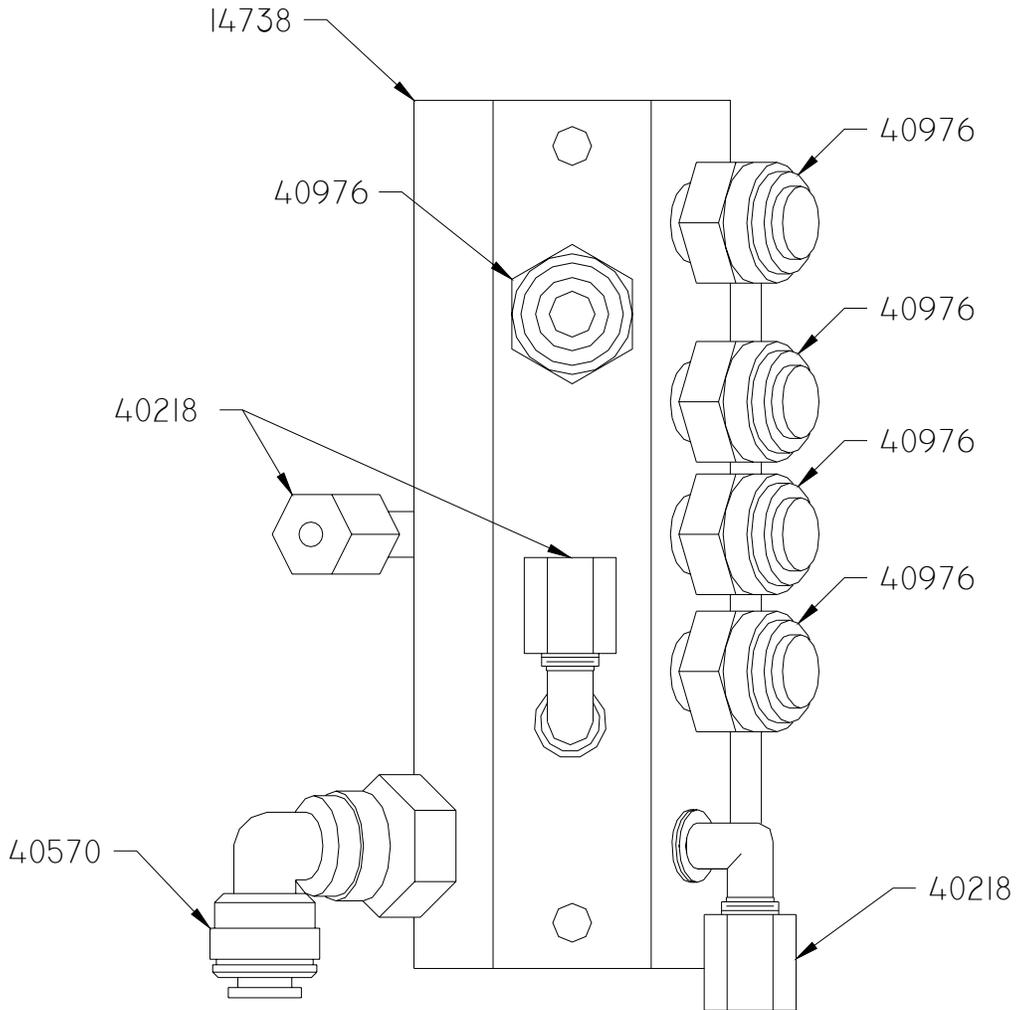
PART NO	DESCRIPTION
1234678	INPUT MANIFOLD
1234489	REGULATOR, 1/4FNPT
40241	NIPPLE, SS, 1/4XCLOSE
40569	ELBOW, SWIVEL, 3/8SF X 1/4NPT
40574	SOLENOID, 110V, 60HZ
40739	SOLENOID, 220V, 50HZ
41085	ELBOW, RIGID, 3/8SF X 1/4MNPT
1234611	MOUNTING BRACKET

Millenium RO
(Input Manifold 50/60Hz)



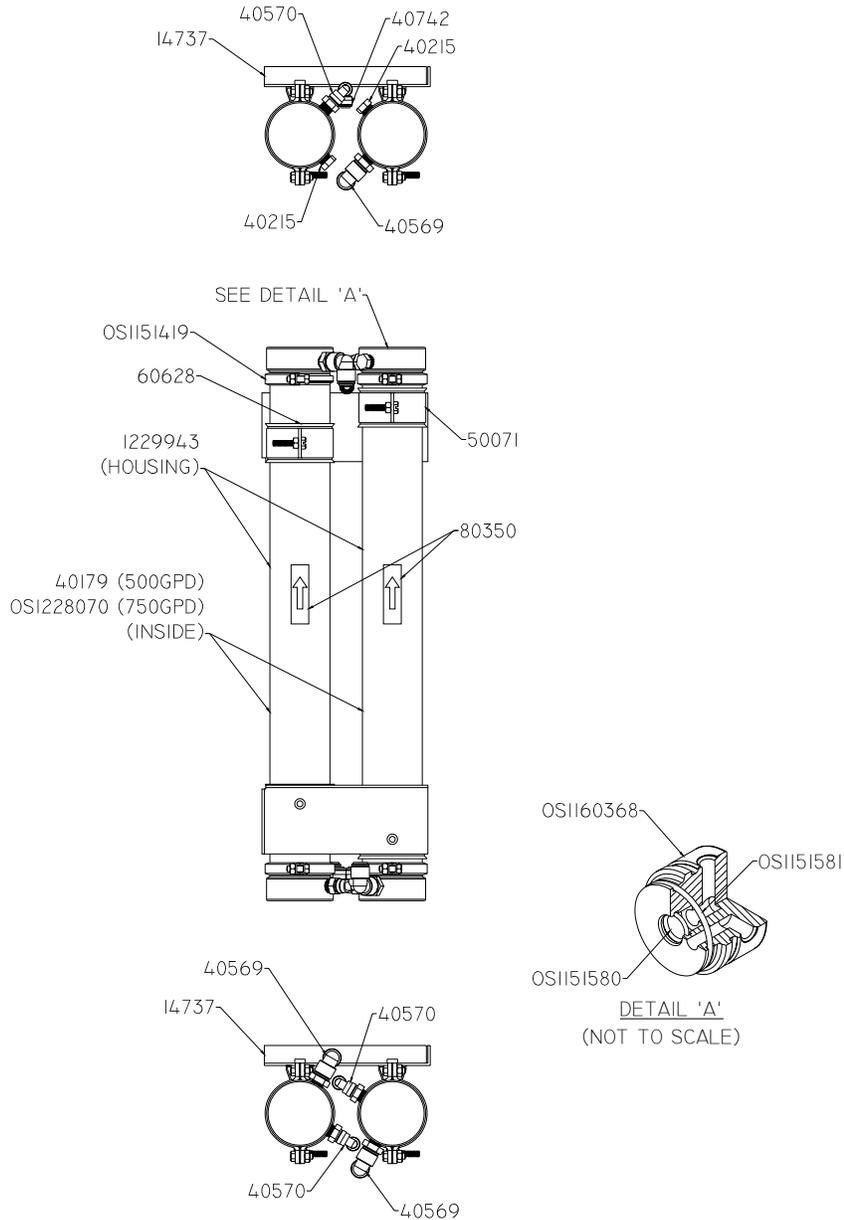
PART NO	DESCRIPTION
12131	SENSOR ASSEMBLY
20178	THERMISTOR
40218	ELBOW, 1/8 TUBE X 1/4NPT
40563	TEE, 1/4SF
40564	ELBOW, 3/8SF X 3/8STEM
41084	ELBOW, RIGID, 1/4SF X 1/4NPT
40568	ELBOW, SWIVEL, 3/8SF X 3/8NPT
40569	ELBOW, SWIVEL, 3/8SF X 1/4NPT
40570	ELBOW, SWIVEL, 1/4SF X 1/4NPT
40602	BUSHING, SS, REDUCER
1228224	VALVE, CHECK, 1/4"NPT, 8#
42047	VALVE, CHECK, 3/8SF
14765	MAIN MANIFOLD

Millenium RO
(Main Manifold)



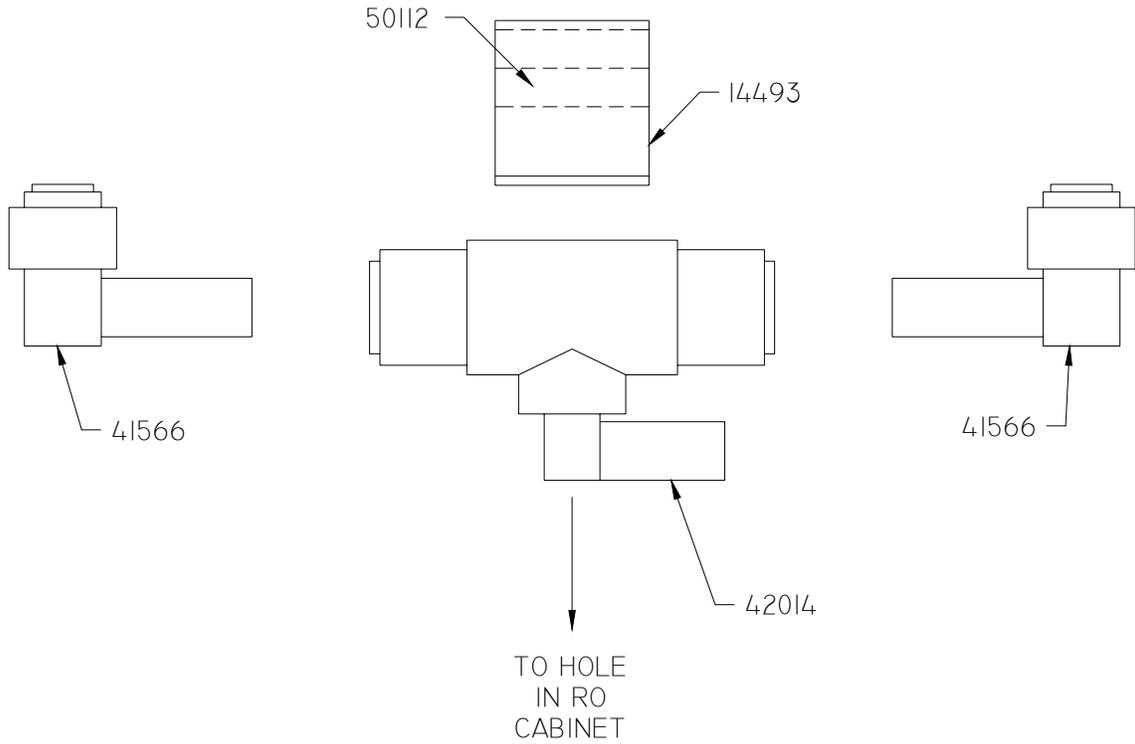
PART NO	DESCRIPTION
40218	ELBOW, 1/8 TUBE X 1/8NPT
40570	ELBOW, SWIVEL, 1/4SF X 1/4MNPT
40976	STRAIGHT, 1/4SF X 1/4MNPT
14738	WASTE MANIFOLD

Millenium RO
(Waste Manifold)



PART NO	DESCRIPTION
P00249	BRKT, ROMA, MILLENIUM
1229943	ROMA, 2.4 X 21, TF, MILNM
OS1228070	MEMBRANE, TF, 2.4 X 21, TAPE, 415GPD, DESAL
40570	ELBOW, SWIVL, 1/4SF X 1/4MNPT
40742	ELBOW, 1/4SF X 1/4STEM
40569	ELBOW, SWIVL, 3/8SF X 1/4MNPT
40215	PLUG, PE, 1/4"NPT
OS1151419	CLAMP, HALF, 2.5, SS
80350	LABEL, ARROW ONLY, 3/4 X 2.5
50071	CLAMP, 2-1/2"
60628	UNICUSHION, P2600
OS1160368	ENDCAP, SH, PVC, 2.4, SIDEPR
OS1151580	O-RING, EPDM 116, 70 DUR
OS1151581	O-RING, EPDM 227

Millenium RO
(ROMA Assembly)



PART NO	DESCRIPTION
14493	BRACKET, VALVE
41566	ELBOW, 3/8STEM X 1/4SF
42014	VALVE, BALL, 3/8SF, BLK
50112	FOAM TAPE

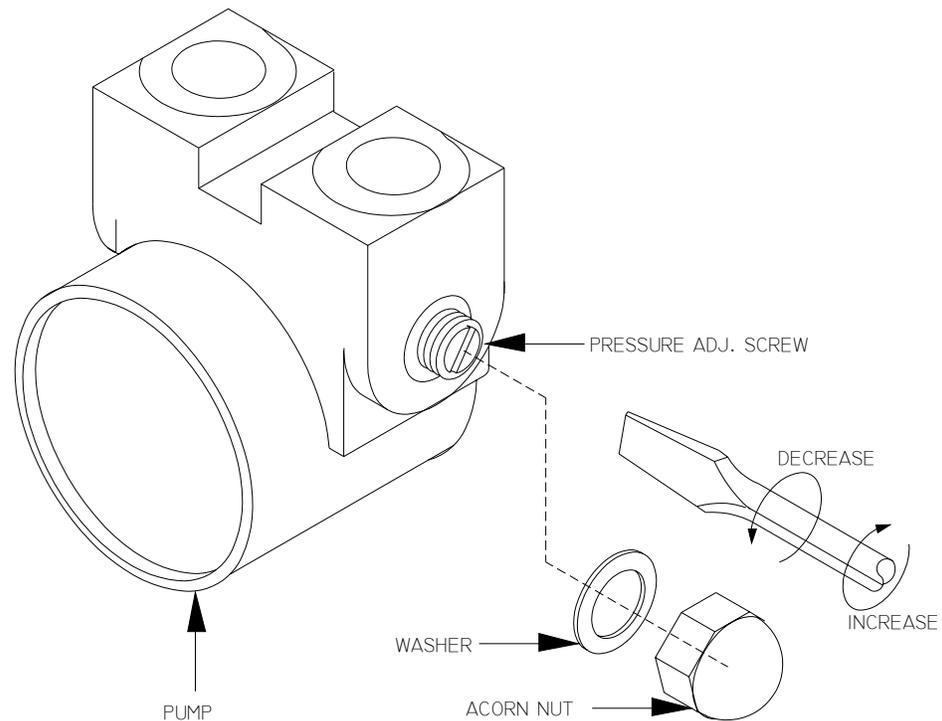
Millenium RO
(Flush Valve Assembly)

TOOLS REQUIRED:

1. FLAT BLADE SCREWDRIVER.
2. 3/4" WRENCH OR EQUIVALENT.
3. TOWEL.

PROCEDURE:

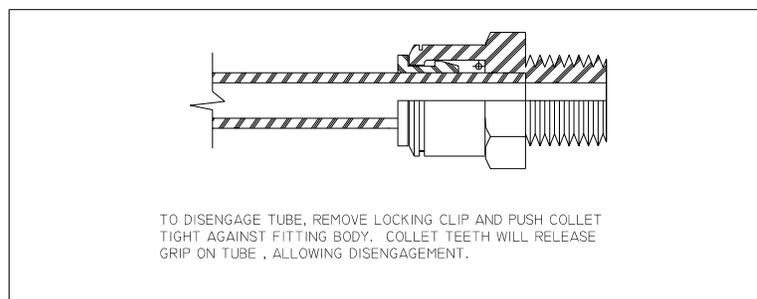
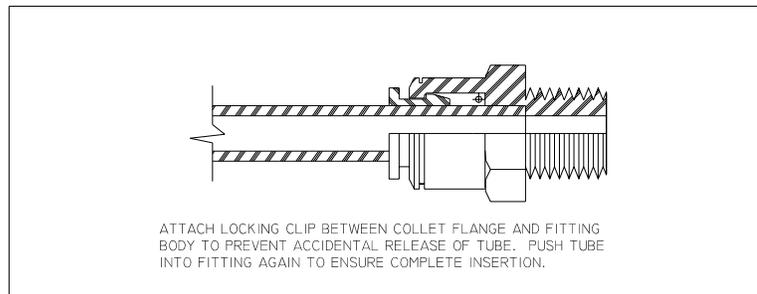
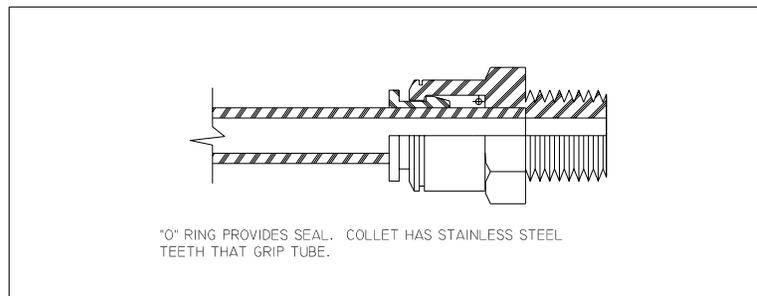
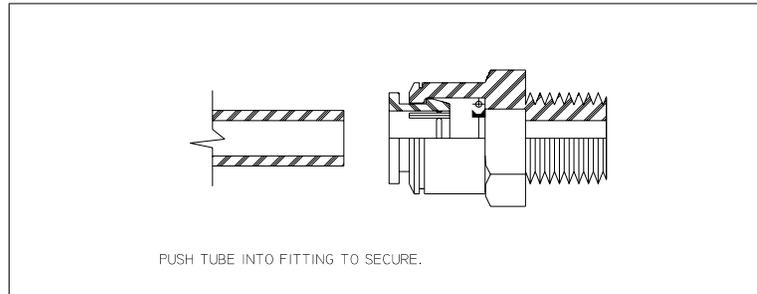
1. TURN OFF POWER AND WATER TO UNIT.
2. OPEN FRONT COVER AND EXPOSE PUMPHEAD.
3. REMOVE ACORN NUT. NOTE: DO NOT LOSE WASHER.
4. USE SCREWDRIVER AND TURN SCREW AS SHOWN. CLOCKWISE TO INCREASE PRESSURE, COUNTER CLOCKWISE TO DECREASE PRESSURE. EACH 90° ROTATION WILL CHANGE PRESSURE ABOUT 25 PSI.
5. REPLACE WASHER (IF IT CAME OFF) AND ACORN NUT.
6. TURN ON WATER AND POWER AND THEN CHECK PRESSURE READING. REPEAT AS NECESSARY.



Millenium RO
(Pump Pressure Adjustment Procedure)



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



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NOTES:



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Millenium RO System

CHAPTER SEVEN:
SPARE PARTS LIST



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Millenium RO System
SPARE PARTS LIST

NOTE: Part Numbers are subject to change and should be verified when ordering spare parts.

CATALOG NUMBER	DESCRIPTION
<u>PARTS</u>	
42047	Check Valve, Feed Line
42047	Check Valve, Product Line
1228224	Check Valve, Product Return
1236062	Fuse, 1/4 AMP, Slo Blow
1234687	Fuse, 1/8 AMP, Slo Blow
30010	Fuse Holder, Panel mount
1234685	Fuse, 8 AMP, Slo Blow
20290	Fuse, 5 AMP, Slo Blow
1234348	Fuse drawer, 1 Pole
1234347	Fuse drawer, 2 Pole
1234349	Power cord retainer
1234350	Inlet power module
30382	Power Cord (50Hz RO only, use w/ P/n 1236173)
1236173	Plug End (50Hz RO only, use w/ P/n 30382)
42048	Gauge, Product Pressure
42074	Gauge, Pump Pressure
40179	Membrane, Tape Wrapped, for 500 GPD RO (2 required)
OS1228070	Membrane, Tape Wrapped, for 750 GPD RO (2 required)
30014	Motor, 1/3 HP, 110/230 V, 50/60 Hz
35328	Fan and Motor, Cooling, 220VAC, 50Hz
35329	Fan and Motor, Cooling, 110VAC, 60Hz
35330	Power cord for Cooling Fan
12315	Power Supply PCB, 110/120 V, 60 Hz
12315-1	Power Supply PCB, 220/240 V, 50 Hz
12310	Printed Circuit Board, % Rejection
12311	Printed Circuit Board, Conductivity
12312	Printed Circuit Board, Display
20204	Disinfect Switch
20205	Lens for Disinfect Switch
40165	Pump, 100 GPH, SS, W/Regulator
50041	Pump-to-Motor Coupling
1234489	Regulator, Product Pressure Adjustment
12131	Sensor Probe, Total Dissolved Solids, Feed, Product



CATALOG NUMBER DESCRIPTION

PARTS (cont.)

20203	Switch, Inlet Water Valve
20203	Switch, RO Pump Power
40574	Valve, Feed Water Solenoid, 110 V, 60 Hz
40739	Valve, Feed Water Solenoid, 220 V, 50Hz
42014	Valve, Operate/Flush
42014	Valve, Product
50003	Clamp, Pump to Motor
30335	Selector Knob
41611	Selector Knob Shim
OS1151419	Half Clamp for ROMA housing
OS1151580	O-ring, Small
OS1151581	O-ring, Large
OS1160368	Endcap, Side port
41555	Hose Clamp, 5/8"
1231491	Terminal Butt Splice, no crimp

FITTINGS

40513	Disinfect Port, Quick-disconnect (Female)
40568	Elbow, speed-fit, 3/8 x 3/8 mnpt, swivel
40564	Elbow, speed-fit, 3/8 x 3/8 stem
41566	Elbow, speed-fit, 1/4 x 3/8 stem
40742	Elbow, speed-fit, 1/4 x 1/4 stem
40569	Elbow, speed-fit, 3/8 x 1/4 mnpt, swivel
40570	Elbow, speed-fit, 1/4 x 1/4 mnpt, swivel
40601	Feed or Inlet Port, Quick-disconnect, (Female)
40605	Garden Hose Thread, female
40604	Garden Hose Thread, male
42046	Product & Waste Port, Quick-disconnect, (Female)
40603	Quick-disconnect (Male) for hoses
42051	Quick-disconnect (Male) for hoses, elbow

CLEANERS

1228653	Cleaner, Liqui-Clean403™, 1gal., Low pH, liquid
1228791	Cleaner, Liqui-Clean211™, 1gal., High pH, liquid
14962	Membrane Cleaner, BIOSAN™ II, 1 gal., liquid

TESTS

50033	Hardness Test Kit
14604	Silt Density Index (SDI) Test Kit
11656	Total Chlorine Test Kit
70001	Water Test Kit, AAMI Standards

OPTIONAL



12128	Pre-filter Housing Assembly
40694	O-ring, Pre-filter (9 7/8")
40695	Filter, 1 Micron, 9 7/8"
40696	Filter, 5 Micron, 9 7/8"
40698	Filter, Carbon, 9 7/8"
14924	Kit, Mil, Prefilter Install (Mounts prefilter to RO or to wall. Includes all necessary parts.)



NOTES

Call (253) 395-2200 for additional information, (800) 633-3080 in the U.S., or visit www.osmonics.com



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