

4400HX Sanitization Sequence

The following Tech Note provides documentation of the 4400MHX Sanitization Sequence and its compliance to ANSI/AAMI RD52:2004 and the Centers for Medicare and Medicaid Services (CMS) 42 CFR Part 494 Conditions for Coverage for End-Stage Renal Disease Facilities Interpretive Guidance (2009) identification Tag V218. This Tech Note will outline the Regulation and provide the 4400MHX systems compliance with that guidance through explanations while referencing screenshots and excerpts from the system operating manual.

Regulation:

ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42

CFR 494.40 (a)

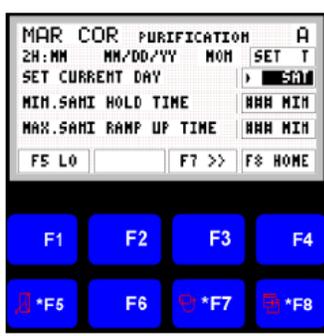
6.3.4 Bacterial control devices

6.3.4.3 Hot water disinfection systems: *monitoring*

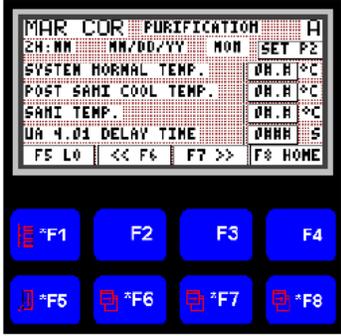
Hot water disinfection systems should be monitored for temperature and time of exposure to hot water as specified by the manufacturer.

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The control system monitors the temperature and time based on the settings in the panel view that is password protected. Settings can be manually recorded on the log sheet in the manual.

Screen Title: SET T	Screen Description: SET TIME SCREEN
Security Access: ADMIN	From Home Screen: F2
	<p>SET CURRENT DAY* : Use Up/Down Arrow keys (need to press and hold for 1.5 seconds to change) on the keypad to select the current day of the week and press the Ent key () to confirm. (Also see HOME screen to set current day)</p> <p>MIN. SANI HOLD TIME*: Sets the desired duration of the SANI Hold phase (20–120, default 60 minutes). </p> <p>MAX SANI RAMP UP TIME*: Sets the maximum allowable time for ramping up the SANI target temperature (60–480, default 480 minutes).</p> <p>* Place the cursor in the field first to input a value.</p>

Sanitization (Sani) Hold Time starts to count down once the Sani Temp is reached.

Screen Title: SET P2	Screen Description: SET PARAMETER SCREEN 2
Security Access: ADMIN	From Home Screen: F2 + F7 + F7
	<p>SYSTEM NORMAL TEMP*: Sets the Normal Temperature for system use (20P^{9P} – 49°C, default 35°C; 68° – 120°F, default 95°F).</p> <p>POST SANI COOL TEMP*: Sets the desired Temperature for completing the SANI Cool Down Phase (35° – 49°C, default 45°C; 95° – 120°F, default 113°F).</p> <p>SANI TEMP*: Sets the desired Temperature for hot water sanitization (65° – 85°C, default 80°C; 149° - 185°F, default 176°F). ←</p> <p>UA 4.01 DELAY TIME*: Sets the time delay for the ultraviolet sterilizer intensity alarm (0–1200 seconds, default 1200 seconds). UV Option Only, Refer to screen SEC FS to enable or disable the UV alarm.</p> <p>* Place the cursor in the field first to input a value.</p>

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Operations & Monitoring

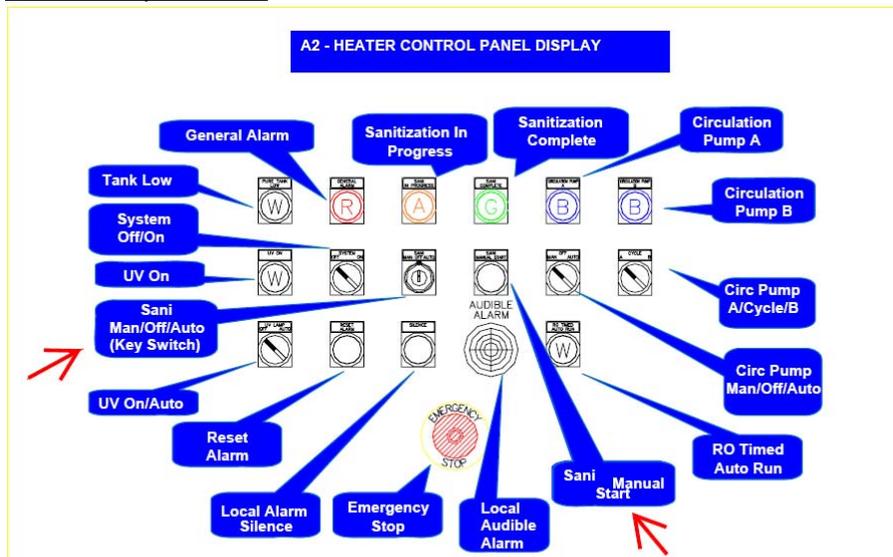
Regulation cont.:

Also, hot water disinfection should be performed at least as often as recommended by the manufacturer.

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The hot water sanitization can be either started manually or by schedule as required. Mar Cor Purification recommends a weekly hot water disinfection, however if system bacteria counts are not under control it maybe necessary to extend the sani hold time or increase disinfection frequency.

Manual Operation:



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Control Panel Display

Scheduled Operation:

Screen Title: SCH S1 & SCH S2	Screen Description: SANI SCHEDULE SCREEN 1 & 2
Security Access: SUPERVISOR/ADMIN	From Home Screen: F3 & F3 + F7
 	<p>F1, F2, F3 and F4 (on SCH S1): Changes the SANI target as RO Only, RO & Loop, or Loop Only on the corresponding day Sunday through Wednesday.</p> <p>F1, F2 and F3 (on SCH S2): Changes the SANI target as RO Only, RO & Loop, or Loop Only on the corresponding day Thursday through Saturday.</p> <p>MANUAL SANI SET (on SCH S2): Sets SANI target in MANUAL mode (Loop SANI, RO SANI or Combo SANI).</p> <p>* Place the cursor in the field first to input SANI start time.</p>

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Screen Title: SCH RE1 & SCH RE2	Screen Description: RO AUTO RUN SCHEDULE - EVERY DAY SCREEN 1 & 2
Security Access: SUPERVISOR / ADMIN	From Home Screen: F4 & F4 + F7
 	<p>EVERYDAY(1)...EVERYDAY(6):</p> <p>Every row contains four fields; the Hour and Minute fields of the scheduled START time, and the Hour and Minute fields of the scheduled STOP time.</p> <p>To schedule different START and STOP times of RO operation for each day of the week, use the Screen Selector switch to select the RO Operation Schedule Screen of the RO EVERYDAY, RO SUNDAY, RO MONDAY, RO TUESDAY, RO WEDNESDAY, RO THURSDAY, RO FRIDAY or RO SATURDAY. On each of the RO Operation Schedule Screens, there are a total of six rows for setting the START and STOP time to run the RO remotely on that particular day.</p> <p>* Place the cursor in the field first to input SANI start time.</p> <p>i NOTE: The product water is diverted to drain whenever the tank is full. This operation is performed to prevent bacterial growth in the system during prolonged periods of non-dialysis storage.</p>

Regulation cont.:

The temperature of the water should be recorded at a point farthest from the water heater—that is, where the lowest water temperature is likely to occur...and measured each time a disinfection cycle is performed.

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During a Loop heat sanitization, the temperature is measured on the loop return going back to the storage tank and is located after the last point-of-use. During a RO heat sanitization the temperature is measured on the RO product outlet.

Regulation cont.:

A record that verifies successful completion of the heat disinfection should be maintained. Successful completion is defined as meeting temperature and time requirements specified by the equipment manufacturer.

Additional Guidance:

Records of use of hot water disinfection systems must include logs or recorded evidence to verify that the specified water temperature was maintained for the specified period of time in order to accomplish the intended disinfection.

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Once a hot water sanitization (Loop or RO) is initiated manually or by schedule, the following message is recorded in the history with a time and date stamp. Message displayed depends on what part of the system is being sanitized.

31	LOOP SANI STARTED	Message: Loop sanitization operation is initiated.
32	RO SANI STARTED	Message: RO sanitization operation is initiated.

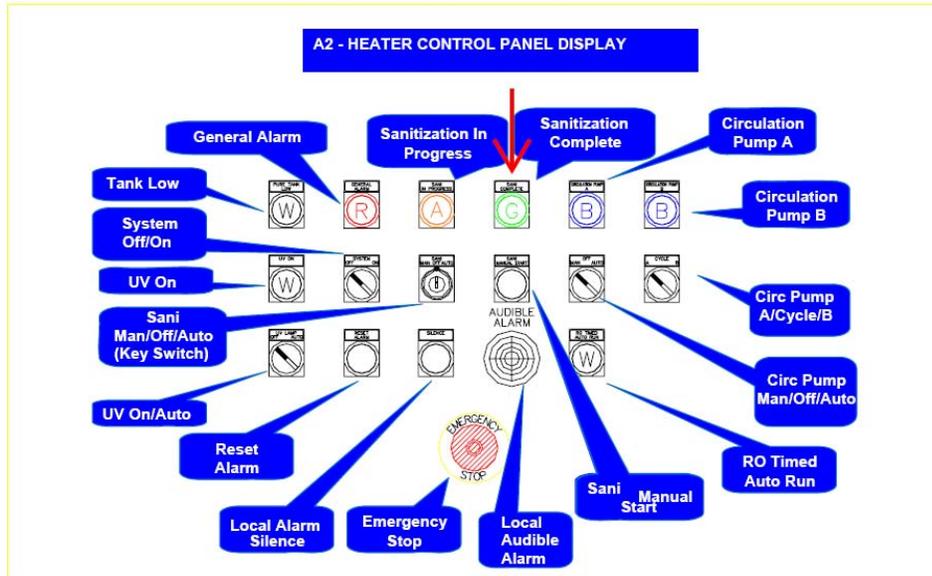
Once the temperature Sani Temp is reached and the Min Sani Hold Time is complete, the following message is recorded in the history with a time and date stamp. Message displayed depends on what part of the system is being sanitized.

24	SANI LOOP HOLD TIME COMPLETED (PER SETTING)	Message: Distribution loop sanitization Temperature Hold phase is completed.
25	SANI RO HOLD TIME COMPLETED (PER SETTING)	Message: RO sanitization Temperature Hold phase is completed.

Once the sanitization is completed the following message is recorded in the history with a time and date stamp.

18	SANI END	Message: Sanitization operation is stopped.
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The green “Sani Complete” light will turn on after a successful sanitization and the operator will acknowledge it by pressing the reset push button.



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Up to 100 messages can be viewed. The history cannot be erased.

Screen Title: SCH AH	Screen Description: SECURITY ALARM HISTORY
Security Access: ALL	From Home Screen: F5 + F7
	<p>SEC.AH, Alarm History Screen: Displays all the current or previously occurred alarm(s) in chronological order with the date and time stamp. Use the Up/Down Arrow keys to scroll between the Alarms on the list.</p>

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Operations & Monitoring

The 4400MHX system manual provides the following Time and Temperature parameters for the heat sanitization process:

1.1.8 How Is The Hot Water Sanitization Performed?

The 4400MHX Tank Feed Hot Water Sanitization system heats a fixed volume of RO water in order to sanitize a closed loop water distribution system and/or 4400M - PLC RO system and its associated piping. The RO device and the water distribution loop are heat sanitized separately.

The main modes of each hot water sanitization operation are as follows:

- Tank Adjust - The system automatically drains or fills the storage tank to a programmable heat sanitization level set-point with RO product water.
- Heat Ramp - The system heats the re-circulating product water and ramps up its temperature to a programmable set-point within a range of 149°-185°F (65°- 85°C).
- Heat Hold - The system maintains the water temperature for a programmable time period from a range of 20-120 minutes.
- Force Cool - Once the heat hold time elapses, the system cools down to a programmable set point within a temperature range of 68°-120°F (20°- 49°C).
- TOX RO Flush (during RO Sanitization Only) - After completion of RO heat sanitization, the RO flush starts and operates for 15 minutes. This will assure the endotoxin is flushed out from the system and the RO product water quality meets or exceeds the AAMI RD62:2006 and CSA.

Conclusion:

The 4400MHX RO system is compliant with ANSI/AAMI RD52:2004 and CMS Interpretative Guidelines Tag V218.

1. It measures the temperature at the end of the loop.
2. The time and temperature required by the manufacturer is a parameter that is set by the operator.
3. If the time and temperature as defined by the operator is achieved, a log is recorded in the system via a "Sani End" and is recorded in the logs with a time and date stamp.

4400MHX Hot Water Sanitization Flow Chart

4400MHX Hot Water Sanitization Sequence
Flow Chart

