

	Water Quality Testing			Version: Rev 2
	SPS SOP for Sterile Processing Service			Status: Final
	Owner: SPS		Approver: Steve Askew	
Document Number: VHA-V11-610-SPS-SOP-SPS-00001	Print Date: 02/11/2021	Rescission Date: 02/10/2022	Approval Date: 02/11/2021	Page: 1 of 12
RME Category per Risk Assessment: Semi-Critical			Frequency to Review SOP: 1 Year	



1.0 Policy

It is the policy of this Medical Center to provide proper cleaning, disinfection, and sterilization of all Reusable Medical Equipment (RME), ensuring compliance standards for infection prevention and control and patient safety. The colorimetric dipsticks and Ultrameter II will be used to test the quality of utility water and critical water used in the Sterile Processing Service area. The Standard Operating Procedure (SOP) for the Northern Indiana VA Healthcare System will be in accordance with the manufacturer's instructions of the products listed below and the Associate Advancement of Medical Instrumentation Technical Information Report 34: 2017 (R). This SOP is appropriate for using the following equipment:

Vendor:	Product Name:	Reference/Serial Number:
Myron L. Company	Ultrameter II (Model #6PFC ^E)	Marion - Serial #6268360
		Fort Wayne - Serial # 6270974
Myron L. Company	pH/ORP Sensor Storage Solution	SS2OZ
Hach	Total Hardness Test Strips	27452-50

2.0 Procedure

Procedure

NOTE: Critical and utility water that is used in the Sterile Processing Service (SPS) will be tested and recorded daily and weekly by SPS technicians, according to AAMI recommendations and specifications. If any parameter is out of range, the technician will immediately notify the SPS Supervisor/Chief, who will contact Facility Management Service (FMS) to investigate.

SPECIAL NOTES for the Ultrameter II: The vendor will be responsible for calibrating the device monthly and recording the process/results in the computer on the website where water quality results are recorded.

A. SPS Responsibility – Using the Ultrameter II

• Turning the Ultrameter on/off

1. To activate the unit, push any of the following keys on the meter: COND, RES, TDS, ORP and pH. After 15 seconds of inactivity the meter will automatically shut off.

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Procedure

2. The device takes 1 9-Volt battery and a notification will present on the screen when it needs changed.

NOTE: The Ultrameter II is waterproof and can be fully immersed under water and is considered to be accurate $\pm 1\%$.

• Operation of the Keys

1. COND key is utilized for conductivity. Rinse the cell on the left 3x with the testing solution and then fill the cell with solution/water to test. Press the COND button for the result.

2. pH key is utilized for pH monitoring. Remove the protective cap from the right well and rinse 3x with the testing solution. Press the pH button for the result. NOTE: After use, the pH well **must** be refilled with Myron K Storage Solution and the cap placed securely.

B. SPS Responsibility – Water Quality Testing (Daily)

• Collecting a sample

- Run the water for at least **60** seconds before collecting a sample of either utility (tap) water or critical water.
 - Utility (tap) water must be a mixture of cold and hot water from the sink on the **far-left end** (where cleaning occurs and tap water mixes with detergent).
 - Critical water is collected from the RO spicket.
- Collect at least 100-300cc of the sample water into a glass beaker (sample cannot be collected with anything made of polypropylene).

• Color (Critical and Utility Tap Water)

- Inspect that the utility (tap) water and critical water (RO) are colorless, clear, and contain no residues.
- Record results in computer. See *ENTERING WATER QUALITY RESULTS* below.

• Conductivity (Critical Water and Utility Tap Water)

- Rinse the **left** cell on the Ultrameter II (the one that does not have a cap) 3 times with the sample solution. Ensure the pH protective cap is secure to avoid contamination.
- After 3 rinses, fill the cell completely with sample. Press **COND**. A **pass** conductivity result for critical water is less than 10 $\mu\text{S}/\text{cm}$. A **pass** conductivity result for utility water is less than 500 $\mu\text{S}/\text{cm}$.
- Record results in computer. See section *ENTERING WATER QUALITY RESULTS* below.
- After use, rinse the meter with clean water and dry with a lint-free towel dampened with alcohol.

• Temperature Monitoring (Reprocessing Sink, Ultrasonic, Cart Washer, Washer/Disinfector and Automatic Endoscope Reprocessor [AER])

- At the reprocessing sinks, use the Acu-SinQ to monitor and record that the temperature of the water is between 90-130°F when mixing with Prolystica 2X Concentrate Enzymatic or Neutral Detergent.
- In the ultrasonic, use the infrared thermometer to monitor and record the temperature of the detergent solution in the ultrasonic is between 90-130°F when using the Prolystica 2X Concentrate Neutral Detergent.
- For the automatic washer, use the temperature reading from the mechanical readout of the 'All-Clean' test. Use the temperature reading from Wash 1 **and** wash one, stage 2. See attachment C for soap temperature parameters. See highlighted mechanical printout example in attachment C.
- For the cart washer, use the temperature reading from the mechanical readout of the daily "Tempa-Check" test. Use the temperature reading from the 'heated wash' section. See attachment C for soap temperature parameters. See highlighted mechanical printout example in attachment C.

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Procedure

5. For the AER, use the temperature reading from the first load of the day on the mechanical readout under 'detergent' and 'basin temperature.' See attachment C for soap temperature parameters. See highlighted mechanical printout example in attachment C.

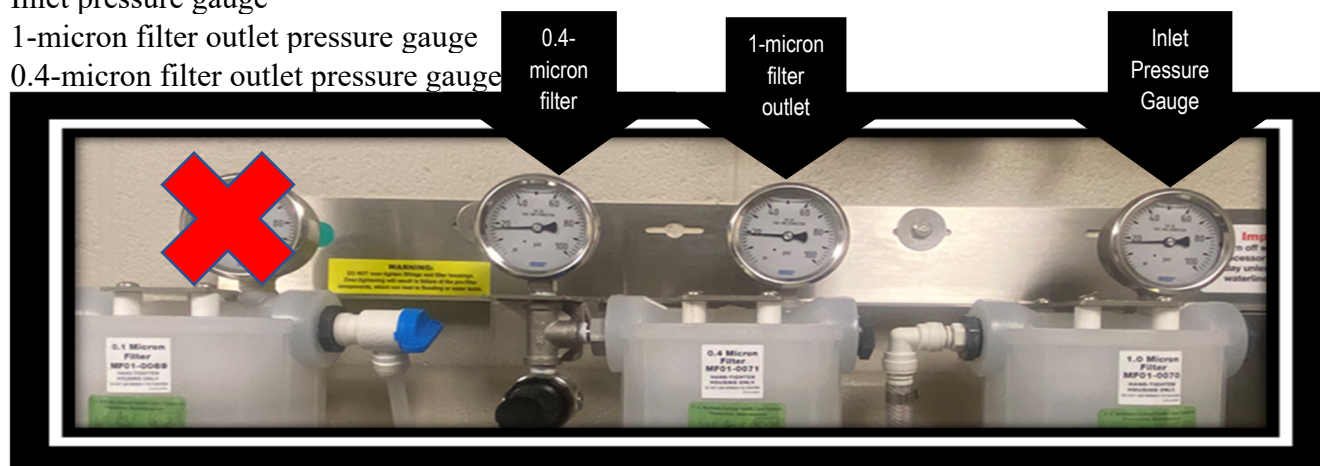
6. See section *ENTERING WATER QUALITY RESULTS* below.

• Filter Pressures (AER)

1. Pressures across the membranes of the filters used in the AER must be recorded daily. If water pressure drops below 40 PSI or the difference between the gauges is greater than 5 PSI, notify Biomed as this means the corresponding filter needs to be replaced.

2. The pressures gauges to be recorded daily are as follows:

- Inlet pressure gauge
- 1-micron filter outlet pressure gauge
- 0.4-micron filter outlet pressure gauge



3. See section *ENTERING WATER QUALITY RESULTS* below.

C. SPS Responsibility – Water Quality Testing (Weekly)

• pH (Utility Tap and Critical Water-Weekly, First day of the week)

1. Remove protective cap of the pH cell on the Ultrameter II by rotating while grasping and pulling up.
2. Rinse the pH cell 3 times with the sample solution. Shake out each sample to remove any residual liquid.
3. After 3 rinses, fill the cell completely with the sample and press pH.
4. Record results in computer. See section *ENTERING WATER QUALITY RESULTS* below.

A pH **pass** result is the following parameters:

- Utility (Tap) water = 6 - 9
- Critical water = 5 - 7

5. After use, rinse the meter and cell cup with clean water and dry with a lint-free towel dampened with alcohol. After drying, fill the pH cell (on the right) with the *Myron pH/ORP sensor storage solution*. Replace the black cap. The pH cell must **ALWAYS** be stored with the storage solution when not in use.

• Hardness (Utility Tap and Critical Water-Weekly, First day of the week)

1. Dip a Sofchek Total Hardness Test Strip into the water for **1** second. Remove. Shake off excess water gently.
2. Hold the strip level, with pad side up, for **15** seconds. Compare the color of the test pad to the color chart on the bottle.

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Procedure

3. A total hardness **pass** result is for the following parameters:

- Utility (Tap) water = < 150 ppm (as CaCO₃)
- Critical water = < 1 ppm (as CaCO₃)

4. Record results in computer. See section *ENTERING WATER QUALITY RESULTS* below.

NOTE: When opening a new bottle of the Sofchek Total Hardness Test Strips, a Certificate of Analysis (COA) must be printed. A COA request must be emailed to etscoareq@hach.com. In the **subject line** enter *COA REQUEST*. For the request verbiage type *Needing COA for Catalog # 2745250* and lot number on the bottom of the bottle. The company will email the certificate which needs to be printed and placed in labeled binder that is stored in the decontamination area.

D. SPS Responsibility – Entering Water Quality Results on the Website

NOTE: All SPS technicians are responsible for entering the results of the daily and weekly critical water and utility water testing into the computer. All results will be reviewed **daily** and reported by the Chief of SPS to the RME Committee **monthly**. If any parameter is out of range, SPS will contact Facility Management Service (FMS) to investigate.

1. To document water results, go to the following website:

- Go to www.weasreports.com and enter user ID and password (must use Google Chrome).

2. Once on the WEAS reporting website:

- Under *Select Facility*, choose the correct facility (Marion or FTW).
- Under *Select System*, choose SPS.

3. Under *REPORTS*, click on *CREATE REPORT* drop down menu, and choose *OPERATOR*.

4. Enter results of the testing completed in the corresponding name location on the report. A **failed** result will turn **red** when entered into the computer. A **pass** result will turn **green**. In the event of a **failed** result (**red**), notify SPS supervisor immediately.

5. Final Results:

- Save as a *DRAFT*. Supervisor will review and submit as *FINAL*.

E. Facility Management Service Responsibility – Utility and Critical Water Testing

NOTE: FMS is responsible for monitoring water quality for the reprocessing of medical devices wherever reprocessing occurs throughout the facility according to guidelines in AAMI TIR 34:2014 and ANSI/AAMI ST 79:2017. FMS will report the results of the monitoring/testing to the Reusable Medical Equipment (RME) Committee through the Chief of SPS. In addition, FMS will ensure the parameters recommended by the AAMI TIR 34:2017 are met.

1. Facility Management Service (FMS) will ensure the following parameters are met:

<u>Specification</u>	<u>Utility Water</u> (Flushing/Washing/Rinsing)	<u>Critical Water</u>
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Procedure				
			(HLD Rinse/Final Rinse/Steam)	
		< 150 mg/L	< 1 mg/L	
	Total Organic Carbon		< 1 mg/mL	
	Conductivity	< 500 µS/cm	< 10 µS/cm	
	pH	6 – 9	5 – 7	
	Chlorides	< 250 mg/L	< 1 mg/L	
	Bacteria		< 10 cfu/mL	
	Endotoxins		< 10 EU/mL	
2. FMS will work with an outside, contracted vendor to ensure the above parameters are met and maintained with required monthly and yearly water quality testing per attachment A. SPS will monitor and test water quality daily and weekly per Attachment B & C. If any parameter is out of range, SPS Supervisor/Chief will contact Facility Management Service (FMS) to investigate. Attachment A, B and C indicates what will be tested, the type of test conducted, the sample site where the test will be taken, and the frequency of the testing.				
3. To maintain steam purity and minimize the presence of potential contaminants in the steam, FMS should: • Treat the feedwater with boiler additives and/or feedwater conditioners so that its condition and/or chemistry do not damage the boiler or steam lines. • Monitor boiler additives and feedwater conditioners. • Use only additives and conditioners approved for use in the food and drug industries (21 CFR 173.310 and 21 CFR 200.11) • Install in-line filters that are as close to the sterilizer as possible and include a drip leg or trap for condensate material. • Develop procedures to monitor steam purity and provide corrective action.				
4. Facilities should NOT: • User boiler additives and feedwater conditioners on a batch basis. • Add boiler additives or feedwater conditioners to the steam in the steam distribution system. • Use amines for conditioning steam lines (as opposed to the use of amines in feedwater treatment)				
5. FMS must provide for the preventive maintenance, repair, and monitoring of boilers and steam distribution lines that provide steam for sterile processing and for the documentation of corrective actions. The monitoring and testing program for boilers should generally include determination of • Incoming water hardness, pH, Iron content, and alkalinity (daily) • Boiler water alkalinity and pH • Condensate return alkalinity, conductivity, sulfites, and pH.				

3.0 Appendices

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Myron L Company
Ultrameter II (7-20-21)



Hach Total



PUCHP temp VA

Hardness Test Strip North IN 011421.pdf

4.0 References

1. AAMI TIR 34:2017, Water for the Reprocessing of Medical Devices.
2. AAMI ST79:2017, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Healthcare Facilities
3. Water Testing Alert from the National Programs Office for Sterile Processing. May 30, 2019.
4. <https://www.hach.com/total-hardness-test-strips-0-425-mg-l/product-details?id=7640211604>

5.0 Revision History

Date:	Rev Number:	Revision Description:
07/23/20	Initial	Developed a new Standard Operating Procedure for Water Quality Testing in Sterile Processing Service.
09/24/20	Rev 1	Removed Resistivity and added Conductivity. Added Temperature testing section.
02/11/2021	Rev 2	Added Attachment A, B and C. Added certified letter from Steris on soap/temperature parameters. Added Cart Washer and AER under temperature/filter testing. Added instructions for FTW/Marion water documentation website. Added QA water document to chart action/interventions for out-of-range parameters.

Attachment A
Facilities Management Services/Vendor Responsibilities for
Utility and Critical Water Quality Monitoring and Testing Guidelines

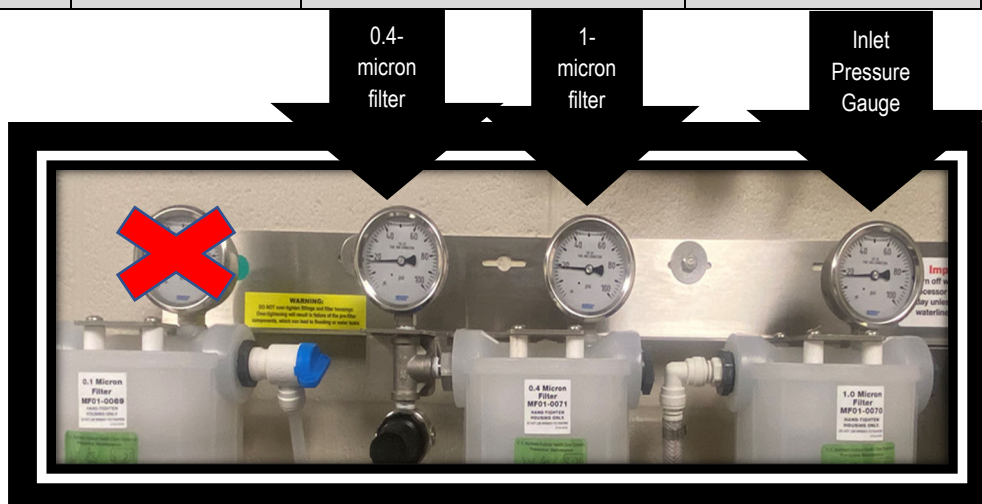
<u>Specification</u>	<u>Type of Testing</u>	<u>Sample Site</u>	<u>Range</u>		<u>Frequency of Testing</u>
			<u>Utility</u>	<u>Critical</u>	
Bacteria	Heterotrophic Plate Count	RO spicket in reprocessing area.	NA	<10 cfu/mL	Monthly
Endotoxins	LAL Test	RO spicket in reprocessing area. Storage tanks (if used), immediately downstream of water treatment process	NA	< 10 EU/mL	On installation, modification, or repair of the critical water treatment system or when persistent increased microbial levels are detected by heterotrophic plate count, ATP, or TOC.
Total Organic Carbon (TOC)	TOC Test	RO spicket in reprocessing area	NA	< 1 mg/mL	Monthly
Ionic Contaminants	Specific tests for	Main water feedlines into the facility and RO tank.			Quarterly until a years' worth of readings within range; Then Annually
	Chloride				
	Iron		<250 mg/L	< 1mg/L	
	Copper		NA	<0.2mg/L	
	Manganese		NA	<0.1mg/L	
pH	Ultrameter II/Vendor Testing Site	Reprocessing Area (sinks) and RO tank	6-9	5-7	Monthly
Water Hardness (Determination of ppm CaCO ₃)	Hach Test Strips	Reprocessing Area (sinks) and RO spicket	<150ppm	<1ppm	Quarterly until a years' worth of readings within range; Then Annually
Conductivity Meter	Ultrameter II/Vendor Testing Site	Reprocessing area and RO spicket. Storage tanks (if used), immediately downstream of water treatment process.	< 500 µS/cm	<10 µS/cm	Monthly
Color and Turbidity	Visual Inspection	Reprocessing area and RO Spicket. Storage tanks (if used), immediately downstream of water treatment process>	Pass/Fail	Pass/Fail	Monthly

NOTE: Per facility, the designated vendor will be responsible to perform monthly calibration on the Myron L meter. The completion of this task will be documented in the notes/comments section in the monthly vendor water testing results.

Attachment B

Sterile Processing Service Responsibilities for Water Quality and Testing Guidelines

<u>Specification</u>	<u>Type of Testing</u>	<u>Sample Site</u>	<u>Range</u>		<u>Frequency of Testing</u>
			<u>Utility</u>	<u>Critical</u>	
pH	Ultrameter II	Reprocessing area sinks and RO spicket	6-9	5-7	Weekly
Water Hardness (Determination of ppm CaCO ₃)	Hach Test Strips	Reprocessing area sinks and RO spicket	<150ppm	<1ppm	Weekly
NOTE: When opening a new bottle of the Sofchek Total Hardness Test Strips, a Certificate of Analysis (COA) must be printed. A COA request must be emailed to ctscoareq@hach.com . In the subject line enter <i>COA REQUEST</i> . For the request verbiage type <i>Needing COA for Catalog # 2745250</i> and lot number on the bottom of the bottle. The company will email the certificate which needs to be printed and placed in labeled binder.					
Conductivity	Ultrameter II	Reprocessing area sinks and RO spicket.	< 500 µS/cm	< 10 µS/cm	Daily
Color and Turbidity	Visual Inspection	Reprocessing area sinks and RO spicket.	Pass/Fail	Pass/Fail	Daily
Temperature	Acu-sinQ	Sinks - Detergent temperature	See attachment C for all soap temperature parameters • Cart Washer • Instrument Washer • Ultrasonic • AER • AquSinQ		Daily
	Infrared Thermometer	Ultrasonic - Detergent Temperature			
	Mechanical Printout	Equipment that monitors the water temperature for detergent: • Cart Washer • Instrument Washer • AER			
Filters AER Filter x3/medivator	Pressure across membrane	PSI needs recorded from the following pressure gauges: • Inlet pressure gauge • 1-micron filter outlet pressure gauge • 0.4-micron filter outlet pressure gauge	If water pressure drops below 40 PSI or the difference between the gauges is greater than 5 PSI the corresponding filter needs to be replaced		Daily



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Attachment C
Temperature Parameters for Soap

<u>Equipment</u>	<u>Soap</u>	<u>Temperature Range</u>	<u>Temperature Source</u>
Instrument Washer (Results from 'All Clean' Test)	Prolystica Ultra Concentrate HP Enzymatic Cleaner	100°F – 140°F	Mechanical Printout under 'wash 1 temperature'
	Prolystica Ultra Concentrate HP Neutral Detergent	100°F – 158°F	Mechanical Printout under 'wash 1, stage 2 temperature'
Cart Washer (Results 'Cart Wash Check' Test)	Prolystica Ultra Concentrate HP Neutral Detergent	100°F – 158°F	Mechanical Printout under 'Heated Wash'
Ultrasonic (SonoCheck)	Prolystica Neutral Detergent 2x	90°F – 130°F	Infrared Laser Thermometer
Aqu-SinQ (First water of the day)	Prolystica Enzymatic Cleaner 2x	90°F – 130°F	Aqu-SinQ Thermometer
	Prolystica Neutral Detergent 2x	90°F – 130°F	
Automatic Endoscope Reprocessor (AER) (first load of day)	Intercept	68°F – 95°F or 20°C -35°C	Mechanical Printout - basin temperature under 'detergent'

Instrument Washer Receipt

Wash 1
 Start time:
 9:40 AM
 Phase time:
 01:00
 Chemical pump:
 P1
 Chemical type:
 Ultra-concentrates
 Injection rate:
 1/10 oz/gal
 Water type:
 Cold & Hot water
 Heated:
 Yes
Temperature:
 122.0°F
 Number of stages:
 2
 Stage 2 time:
 02:00
Stage 2 temperature:
 150.0°F
 Chemical pump 2:
 P2
 Chemical type 2:
 Ultra-concentrates
 Injection rate 2:
 1/10 oz/gal

Cart Washer Receipt

Heated Wash
 Start time:
 3:13 PM
 Phase time:
 03:00
Temperature:
 135.0 °F
 Water type:
 Hot water
 Chemical pump:
 Detergent pump 2
 Chemical type:
 PUC Neutral
 Injection rate:
 1/10 oz/gal

AER Receipt

CYCLE : PASS
 2:48:39 PM 1 Endoscope disinfection
 2:48:39 PM 1 Leak test
 2:48:16 PM 2 Flush rinse
 2:54:49 PM 3 Wash
 3:00:17 PM 3
 Detergent contact time = 00:03:09
 3:00:17 PM 3
Basin temperature [°C] = 33.90
 3:00:17 PM 4 Flush rinse
 3:02:05 PM 5 Post rinse
 3:08:25 PM 5
 Rinse contact time = 00:02:06
 3:08:25 PM 5
 Basin temperature [°C] = 34.70
 3:08:25 PM 6 Wash
 3:08:26 PM 7 Flush rinse
 3:08:27 PM 8 Post rinse
 3:08:28 PM 9 Disinfection
 3:17:55 PM 9
 Disinfectant contact time = 00:05:15
 3:17:55 PM 9
 Basin temperature [°C] = 35.50
 3:17:55 PM 10 Flush rinse
 3:19:36 PM 11 Post rinse
 3:19:37 PM 12 Post rinse
 3:19:38 PM 13 Final rinse
 3:24:30 PM 13
 Rinse contact time = 00:02:28
 3:24:30 PM 13
 Basin temperature [°C] = 35.70

Daily Quality Assurance Monitoring on Daily/Weekly Water Testing for SPS

Daily/Weekly Water Testing Parameters for SPS

<u>Specification</u>	<u>Type of Testing</u>	<u>Sample Site</u>	<u>Range</u>		<u>Frequency of Testing</u>
			<u>Utility</u>	<u>Critical</u>	
pH	Ultrameter II	Reprocessing area sinks and RO spicket	6-9	5-7	Weekly
Water Hardness (Determination of ppm CaCO ₃)	Hach Test Strips	Reprocessing area sinks and RO spicket	<150ppm	<1ppm	Weekly
Conductivity	Ultrameter II	Reprocessing area sinks and RO spicket.	< 500 µS/cm	< 10 µS/cm	Daily
Color and Turbidity	Visual Inspection	Reprocessing area sinks and RO spicket.	Pass/Fail	Pass/Fail	Daily
Temperature	Acu-sinQ	Sinks - Detergent temperature	See soap testing parameters on back		Daily
	Infrared Thermometer	Ultrasonic - Detergent Temperature			
	Mechanical Printout	Equipment that monitors water temperature for detergent: AER, instrument washer and cart washer			
Filters AER Filter (x3)/medivator	Pressure across membrane	- Inlet pressure gauge 1-micron filter outlet pressure gauge 0.4-micron filter outlet pressure gauge See picture on attachment B of Water Testing SOP; VHA-V11-610-SPS-SOP-SPS-00001	If water pressure drops below 40 PSI or the difference between the gauges is greater than 5 PSI the corresponding filter needs to be replaced		Daily

Water/Soap Temperature Parameters

<u>Equipment</u>	<u>Soap</u>	<u>Temperature Range</u>	<u>Temperature Source</u>
Instrument Washer	Prolystica Ultra Concentrate HP Enzymatic Cleaner	100° F – 140°F	Mechanical Printout under wash 1 temperature
	Prolystica Ultra Concentrate HP Neutral Detergent	100° F – 158°F	Mechanical Printout under wash 1, stage 2 temperature
Cart Washer	Prolystica Ultra Concentrate HP Neutral Detergent	100° F – 158°F	Mechanical Printout under
Ultrasonic	Prolystica Neutral Detergent 2x	90° F – 130°F	Infrared Laser Thermometer
Aqu-SinQ	Prolystica Enzymatic Cleaner 2x	90° F – 130°F	Aqu-SinQ Thermometer
	Prolystica Neutral Detergent 2x	90° F – 130°F	
Automatic Endoscope Reprocessor (AER)	Intercept	68°F – 95°F or 20 C -35°C	Mechanical Printout under - Detergent - Basin temperature

Daily Quality Assurance Monitoring on Daily/Weekly Water Testing for SPS

Daily/Weekly Water Testing Parameters for SPS

Date and Time	Testing Parameter that is out of Range	Testing Result	Comments/Actions/ Maximo Number

All critical water testing results/out of range results for reprocessing activities must be reported to the VISN SPS Management Board, through the Facility RME Committee.

