

**Frederick National Laboratory
for Cancer Research**

sponsored by the National Cancer Institute

Vaccine, Immunity and Cancer Directorate
Standard Operating Procedure

SOP Title: Operation, Use and Maintenance of the Water Purification Systems

Document ID: 26016

Version

1.0

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Supersedes

New

Effective Date:

26Jul21

Written by:

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1. PURPOSE

- 1.1. The purpose of this procedure is to describe the proper use and maintenance of the water purification systems.

2. SCOPE

- 2.1. This procedure applies to all water purification systems.

3. REFERENCES

- 3.1. Sartorius Arium Pro® Operating Manual
- 3.2. 15000: Waste Disposal at the Advanced Technology Research Facility
- 3.3. Arium® Dispense Gun & Multifunction Stand Variations Operating Manual
- 3.4. 10007: Non-Routine Equipment Maintenance
- 3.5. 10009: General Record Review
- 3.6. Milli-Q Integral 3 Water System User Manual

4. RESPONSIBILITIES

- 4.1. The Research Associate, hereafter referred to as Analyst, is responsible for reviewing and following this procedure, and documenting performance of equipment maintenance.
- 4.2. The Scientific Manager or designee is responsible for training personnel in this procedure and reviewing associated documentation.
- 4.3. The Quality Assurance Specialist is responsible for quality oversight and approval of this procedure.
- 4.4. Trained personnel perform equipment maintenance record review per "10009: General Record Review."

5. DEFINITIONS

- 5.1. As Needed Maintenance – maintenance that is performed outside of routine maintenance but is not performed in response to equipment malfunction.
- 5.2. Routine Maintenance – maintenance that is performed at planned intervals to identify and prevent problems before they result in equipment failure.

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- 5.3. Non-routine Maintenance – maintenance that is performed in response to equipment malfunction or failure.
- 5.4. LCD – Liquid Crystal Display
- 5.5. PPB – Parts Per Billion
- 5.6. REES – Rees Scientific is a provider of automated temperature monitoring systems
- 5.7. TOC – Total Oxidizable Carbon
- 5.8. Type I Water – Ultrapure/Reagent Grade/critical applications (Resistivity >18 MΩ-cm and TOC ≤ 50 ppb)
- 5.9. Type II Water – Pure/Analytical Grade, used for standard applications (Resistivity >1 MΩ-cm and TOC ≤ 50 ppb)

6. REAGENTS, MATERIALS AND EQUIPMENT

- 6.1. Chlorine Cleaning Tablets, ROProtect- CR (Fisher Scientific, Cat # 58-743-16024 or equivalent).
- 6.2. Plumbers Tape (Fisher Scientific, Cat # NC9033595 or equivalent).
- 6.3. Forceps
- 6.4. Milli-Q Integral 3 water System
- 6.5. Progard Pak (Progard TNP2 Pretreatment Pack Sigma Aldrich Cat # PR0G0TNP2 or equivalent)
- 6.6. Vent Filter (MilliQ vent filter Vent Filter for PE Tank (Type 2 Water) Sigma Aldrich Cat # TANKMPK01 or TANKMPK22 or equivalent)
- 6.7. Quantum Cartridge (Quantum TEX Polishing Cartridge Sigma Aldrich Cat # QTUM0TEX1 or equivalent)
- 6.8. POD Pak (BioPak CDUFB1001 PF13717 Biopak® Polisher Ultrafilter Sigma Aldrich Cat # CDUFB1001 or equivalent)
- 6.9. DI-PAK StartPak (VOC-Pak Sigma Aldrich Cat # CPDI000S1 or equivalent)
- 6.10. ROClean A (ROCAR A Sigma Aldrich Cat # ZWACID012 or equivalent)

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6.11. Sartorius Arium® Pro Ultrapure Lab Water System

6.12. Sartorius Arium® Advance Pure Water System

7. HEALTH AND SAFETY CONSIDERATIONS

7.1. Proper safety precautions should be taken while working in a laboratory setting. This includes, but is not limited to, proper protective equipment such as lab coats, safety glasses, closed-toe shoes, and non-latex gloves.

7.2. Refer to the respective Safety Data Sheet (SDS) when working with any chemicals.

7.3. Refer to 15000: Waste Disposal at the Advanced Technology Research Facility” regarding waste disposal processes at the Advanced Technology Research Facility (ATRF).

8. OPERATION

8.1. Milli-Q Integral 3 Water System

8.4.4. Dispense Type I Water Quality

8.1.2.2. To Optimize Water Quality

8.1.1.1.1. Press the Recirculation Keypad button on the Q-POD (the system will recirculate water for 3 minutes).



8.1.1.1.2. Wait for the displayed Resistivity (may take several seconds).

8.1.1.1.3. Wait for the displayed TOC to change (may take up to 9 minutes but can be shorter).

8.1.1.2 Dispensing Water using the Q-POD Plunger:

8.1.1.2.1 While the system is in Ready Mode, press down on the Q-POD Unit plunger as follows:

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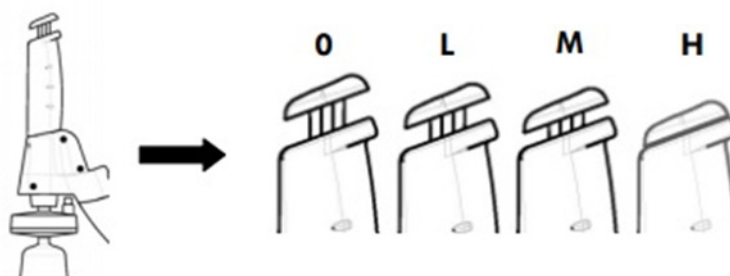
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Position	Water flow
0	No water delivered
L	Low Flow (push slightly)
M	Medium Flow (push 1/2 way down)
H	High Flow (push down and hold, release when done)
H	Continuous high flow (push down and release; push down again to stop).

8.1.1.3 Volumetric Dispensing from the Q-Pod Unit:

8.1.1.3.1 Make sure the Milli-Q System is in Ready Mode.



8.1.1.3.2 Place the Milli-Q System into a recirculation mode. To do this, press the Recirculation keypad button on the Q-Pod (see picture referred in step 8.1.1.1.1).

8.1.1.3.3 Press the (-) / (+) buttons to change the desired amount of water to dispense.

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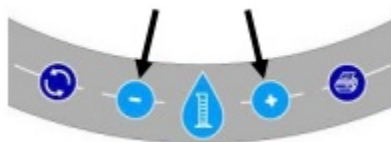
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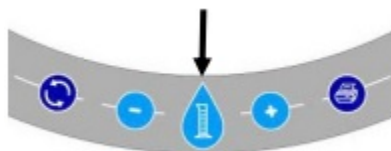
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8.1.1.3.4

Press the volumetric dispensing button. The Q-POD Unit will start dispensing water a few seconds later.



8.1.1.3.5

When the volumetric dispensing is finished, the Q-POD Display will look like the picture below For 3 minutes.



8.1.1.3.6

After 3 minutes, the Q-POD Display will look like the picture below.



8.1.2 Dispensing Type II Water Quality

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8.1.2.1 The Milli-Q Integral 3 water system has a reservoir tank that that provides type II water.

8.1.2.2 A hose connected to the nozzle is available to dispense type II water directly from the reservoir tank.

8.1.2.3 Turn the lever on the nozzle forward to open the valve and to dispense type II water and turn the nozzle back to close the valve.

Note: Do not empty the reservoir tank because the reservoir level sensor may malfunction. Additionally, air can enter the tubing and temporarily affect the sensors.

8.1.3 Extended Periods of Disuse

8.1.3.1 Follow the steps below to place the instrument in Lab Closed Mode:

Note: Lab Closed Mode will allow for periodic flushing of the system (1000 to 1030 mL everyday) to ensure optimal water quality when system is used.

Note: Do not turn off the power to the system if system is not used for more than a few days.

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Step	Action	Diagram
1	<ul style="list-style-type: none"> Go to the Manager Menu. See the Software Chapter Map for more information on how to enter the Manager Menu. Scroll down to <Lab closed>. 	
2	Press  .	
3	Press  .	

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Step	Action
4	<ul style="list-style-type: none"> Place a piece of tubing between a valve on the bottom of the Reservoir and a sink or drain. Open the valve. <p>NOTE:</p> <p>Do not place the tubing directly into a drain. This helps to minimise bacterial contamination.</p>

Follow the steps below to exit LAB CLOSED Mode.

Step	Action	Diagram
1	The Milli-Q System is in Lab Closed Mode.	
2	<ul style="list-style-type: none"> Go to STANDBY Mode. The Milli-Q System exits LAB CLOSED Mode. 	
3	Go to READY Mode.	

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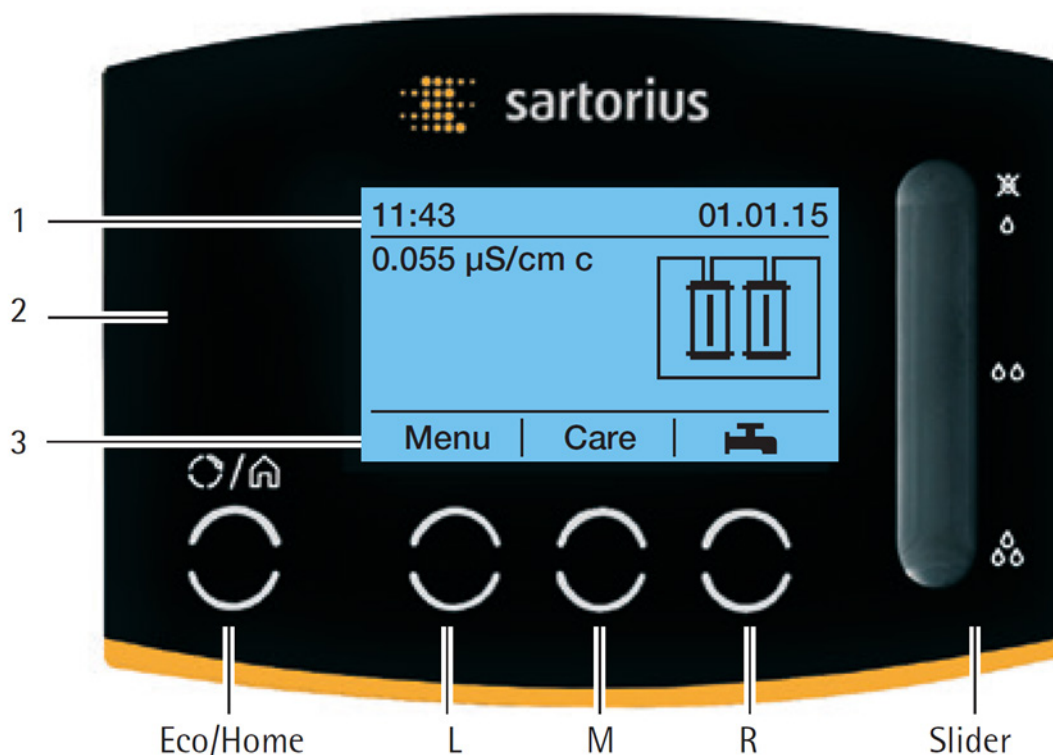
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8.2 Sartorius Arium Pro Water Purification System



8.2.1 Manual Dispensing Type I Water Quality

Note: Before each critical application, dispense and discard 100 mL of water.

- 8.2.1.1 Press the Eco/Home button to view the display. Place your finger in the slider and move it downwards to increase the volume flow or move the slider upwards to decrease the volume flow.
- 8.2.1.2 To stop the dispense routine, tap the top of the slider or press the R Key.
- 8.2.1.3 To set the flow to maximum volume, tap the bottom of the slider.
- 8.2.1.4 To set the flow to average volume, tap the slider in the middle.

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8.2.2 Time-controlled Dispensing Type I Water Quality

8.2.2.1 Press the Eco/Home button to view the display. Press the “R” Key and select “Set dispensing time.”

8.2.2.2 Set the desired dispensing time.

8.2.2.3 Switch to “Time-controlled” and click start.

8.2.2.4 To cancel time-controlled dispensing press stop.

8.2.3 Volume-Controlled Dispensing Type I Water Quality

8.2.3.1 Press the Eco/Home button to view the display. Press the “R” Key and select “Set Volume.”

8.2.3.2 Set the desired dispensing volume.

8.2.3.3 Switch to “Volume-Controlled” and press start.

8.2.3.4 To cancel, press stop.

8.2.4 Dispensing Type II Water Quality

8.2.4.1 To remove the dispense gun from the holder, turn the dispenser slightly clockwise until the stop and then remove the dispenser upward.

8.2.4.2 Press the dispensing button to begin dispensing water (the flow will stop as soon as you release the button).

8.2.4.3 Press the dispensing button and locking button simultaneously for a continuous flow of water, re-press the dispensing button to stop the continuous flow.

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8.2.5 Adjusting the height on the height adjustable stand slide

- 8.2.5.1 Turn and remove the lock button on the height adjustable stand slide.
- 8.2.5.2 Adjust the dispense gun holder on the height adjustable stand to the desired position and fix the holder to the stand, by re-securing the lock button by turning it.

Note: May leave the lock button in the pulled-out position to make frequent slide position changes easier.

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9. SYSTEM SUITABILITY

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Milli-Q® Water quality The water delivered from a Q-POD Unit has the following characteristics.

Parameter	Specification	Units
Resistivity	18.2	MΩ.cm @25°C
TOC	< 5	ppb
Particulates > 0.22 µm**	< 1	Particulates/mL
Bacteria**	< 1	cfu/mL
Pyrogens*	< 0.001	Eu/mL
RNases*	< 0.01	ng/mL
DNases*	< 4	pg/µL
Flow Rate**	0.05 – 2	L/min

(*) With BioPak Final Filter

(**) With Millipak or BioPak Final Filter

NOTE:

These specifications are valid for Elix water feed within specification and for routine operation. Some specifications may not be achieved at start-up.

9.2 Sartorius Arium Pro Water Purification System

Product water	18.2 MΩ*cm at 25 °C
Bacteria	< 1 CFU mL
TOC at 50 ppb feed water	< 5 ppb ¹ @ 25 °C
Flow rate	Up to 2.0 L/min at a minimum inlet feed water pressure of 2 bar (without final filter) Up to 1.6 L/min at a minimum inlet feed water pressure of 2 bar (with final filter)
Ambient conditions	Operation 5 °C – 30 °C; 80% relative humidity, non-condensing Storage 5 °C – 45 °C; 80% relative humidity, non-condensing

Note: Values can vary depending on the quality of the feed water and the content of impurities as well as the type of cartridge used.

10. MAINTENANCE

10.1. Annual Calibration

10.1.1 Milli-Q Integral 3 Water System

10.1.1.1 Contact the contracted vendor to perform the appropriate preventative, scheduled maintenance and calibration of the Milli-Q Integral 3 Water System annually.

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10.1.2.2. Print the service report and file.

10.1.2 Sartorius Arium Pro Water Purification System

10.1.2.1 Contact Facilities, Maintenance and Engineering (FME) to perform cartridge replacement on an annual basis according to the Sartorius Arium Pro Water Purification System operating manual.

10.1.2.2. Print the service report and file.

10.2 Monthly Maintenance

10.2.1 Sartorius Arium Pro Water Purification System

10.2.1.1 The sterile final filter should be changed on a monthly basis or sooner if the water flow rate is reduced and/or bacteria breakthrough is detected. To change the filter:

10.2.1.1.1 Release the old final filter from the quick connector on the display/dispenser unit by simultaneously pulling out the filter and pressing the retaining ring.

10.2.1.1.2 Press the new final filter into the quick connector of the display/dispenser unit.

10.2.1.1.3 Attach the bell assembly to the final filter.

10.2.1.1.4 Allow 6 liters of water to run through the final filter using either manual (8.1) or volume-controlled water dispensing to rinse and vent the final filter.

10.2.1.1.5 Vent the final filter using the attached vent valve.

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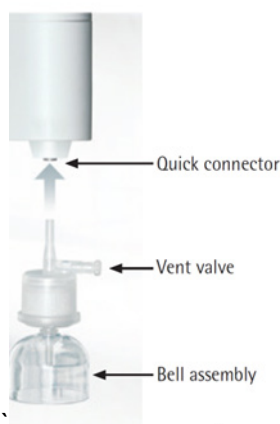
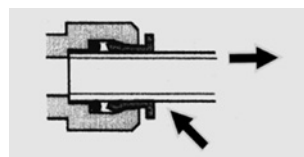
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- 10.2.1.1.6 After dispensing ultrapure water, attach the protective cap to the bell assembly.
- 10.2.1.1.7 After replacing the sterile final filter, the sterile final filter timer must be reset manually.
- 10.2.1.1.8 To rest the sterile final filter timer:
 - 10.2.1.1.8.1 Go to the care menu.
 - 10.2.1.1.8.2 Select sterile final filter timer.
 - 10.2.1.1.8.3 Confirm you want to reset the sterile final filter timer.
 - 10.2.1.1.8.4 The timer is now reset and the system will switch to the operating mode.
 - 10.2.1.1.8.5 Document the maintenance that was performed on the 26016 Water Purifications Systems Maintenance form.

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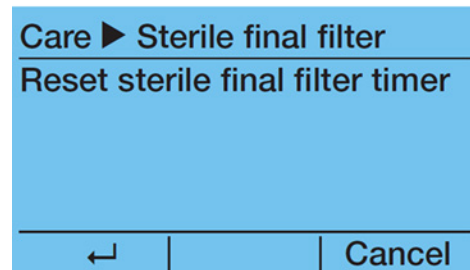
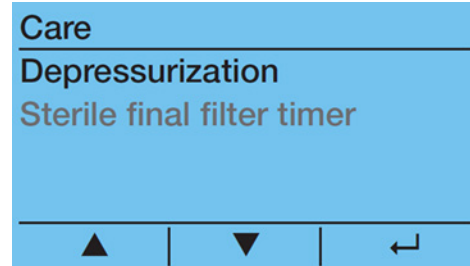
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10.3 As Needed Maintenance

- 10.3.1 Contact Facilities Maintenance and Engineering (FME to perform all as needed Maintenance according to the Sartorius Arium Pro Water Purification System Operating manual.
- 10.3.2 The Sartorius Arium Pro Water Purification System has two electrical fuses. Contact FME to replace defective fuses in accordance with the Sartorius Arium Pro Water Purification System operating manual.
- 10.3.3 The Sartorius Arium Pro Water Purification System Depressurization is recommended prior to transporting the system. Contact FME to perform this operation according to the Sartorius Arium Pro Water Purification System operating manual.

10.4 Non-Routine Maintenance

- 10.4.1 In the case that either unit is not operating correctly, transition processes being performed to another unit (when applicable). Post a sign stating the equipment is out of service and initiate non-routine maintenance documentation per "10007: non-Routine Equipment Maintenance.
- 10.4.2 Document the nature of the failure or malfunctions, how and when it was discovered and the personnel involved on "10007-01: Equipment Non-Routine Maintenance Form."

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10.4.3 Initiate a service request and complete the non-routine maintenance process following 10007.

10.4.4. Print service report and file.

11. REVISION HISTORY

Version	Change	Reason
1.0	Transferred and combined Water System SOP's into one SOP.	To combine Milli-Q and Sartorius Water System SOP's into SOP.

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Attachment 1: 26016-01_ Maintenance of the Water Purification Systems Form 1.1

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**Vaccine, Immunity and Cancer Directorate
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Equipment ID:

As Needed Maintenance

Date	Initials	Activity Performed	Cleaning Reagent Used/ Lot Number	Review By/Date:
			<input type="checkbox"/> N/A	
			<input type="checkbox"/> N/A	
			<input type="checkbox"/> N/A	
			<input type="checkbox"/> N/A	
			<input type="checkbox"/> N/A	

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