

	Standard Operating Procedure Millipore Water System		SOP Number F-503	Revision 512
			Effective Date 01/01/10	Page Page 1 of 4
Written by/ Date Written dot r 11/11/09 dra		Reviewed by/ Date S/X 08/17/10		Approved by/ Date *1 (K) 08/17/10
Title: QC Laboratory Supervisor		Title: QC Laboratory Director		Title: VP of Quality

1.00 Purpose

The purpose of this procedure is to provide instruction on the operation and maintenance of the Integral 5 Millipore Water System.

2.00 Scope

This procedure applies to the Millipore Milli-Q Integral Water Purification System for use in the QC Laboratory at Ion Labs, Inc.

3.00 Responsibility

- 3.1 It is the responsibility of QC Laboratory Personnel to perform daily, or as needed inspections of the system, to change the cartridges during scheduled replacement, and to perform periodic system flushes.
- 3.2 It is the responsibility of QC Laboratory Management to implement this procedure and to ensure that the procedure is being followed.
- 3.3 It is the responsibility of QC Laboratory Management to keep this SOP current with latest Ion Labs practices.

4.00 Definitions

- 4.11 QC = Quality Control

5.00 References

- 5.1 Millipore User Manual, Milli-Q Integral 3/5/10/15 systems
- 5.2 E-705, SOP, Water Use, Sampling, and Testing
- 5.3 E-705-F2, Form, Purified and Millipore Water Test Ticket - Microbial Limit (pH, Conductivity, TOC)
- 5.4 E-705-F3, Form, Conductivity Stage 2 Test Ticket

6.00 Procedure

CONFIDENTIAL: For ION Labs use only.
 0 12/17/10 *** JMT 09-10-10

6.3.6.2.4 Select "Menu" then "Sanitize/Clean" and then select "RO CL2 Cleaning", the process will last approximately 19 minutes.

6.3.6.3 RO pH Cleaning = approximately every 6 months in place of CL2 Cleaning

6.3.6.3.1 Open the Sanitization port and place a ROClean pouch into the port.

6.3.6.3.2 Put the cap back on and tighten it.

6.3.6.3.3 Go into "Standby" mode

6.3.6.3.4 Select "Menu" then select "Sanitize/Clean"

6.3.6.3.5 Select "RO pH cleaning", the cleaning will last 142 minutes.

6.3.6.3.6 Remove the ROClean pouch the next time the Sanitization port is opened

Note: Do not perform CL2 and pH cleanings at the same time. pH Cleaning is used as a supplement to the CL2 cleaning

6.4 Step-By-Step Maintenance Instructions

6.4.1 Refer to the Millipore User Manual, Milli-Q Integral 3/5/10/15 systems for step-by-step instructions on replacing cartridges and performing system maintenance checks and flushes.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	07/01/10	Original	-	-
1	07/29/10	Removed conductivity testing requirements, changed testing from each tank change to quarterly checks	-	-
2	04/04/13	Updated SOP format, name, and SOP number, changed SOP to reflect the Millipore water system	13-203	B. Johos
3	01/05/16	Biennial review: Updated SOP format. Added consumable part #s. Expanded information for routine maintenance and daily inspections.	16-0024	N. Zhang
4	04/08/19	Scheduled review: added items to checklist.	19-0239	J. Maignan
5	12/23/19	Revise SOP to reflect current practices and added sanitization steps per instrument manual	19-0964	I. Ganett
6	08/26/20	Included Reference to SOP for Millipore Water Testing and removed specifications of system that are not needed	20-0802	L. McWade

6.2.9 ROCare A Pouches = Part# ZW A(Cl)012

6.3 Routinemaintenance

6.3.1 The maintenance schedule is automated for the Millipore Integral 5 Water purification system. Alerts will appear on the display when a cartridge change, lamp change or cleaning process is nearing the maintenance date. The indicator light will turn yellow when an alert is active.

6.3.2 When the system is out of specification and/or maintenance is due the indicator light will turn red and water production will be suspended until the alert is addressed.

6.3.3 The system will need to be put into standby mode when a cartridge is changed or a cleaning procedure is being followed. The alert will need to be reset at the completion of the task before water production will resume.

6.3.4 Document all maintenance and service, including cartridge changes in the Millipore Water logbook.

6.3.5 Consumable Replacement Schedule:

Consumable	Replacement Intervals
Proguard Pak	Every 6 months or when the system check recommends a replacement
Quantum Cartridge	
POD Pak	
22 µm POD Filter	
Tank Vent Filter	
EDM Module	Checked or replaced when alarm dictates that current is not maintained at needed level
UV Lamps	Every 3 years or when the system check recommends a replacement

6.3.6 Sanitization of RO Cartridge

6.3.6.1 Perform RO Cartridge sanitization in 3 and 6 month intervals

6.3.6.2 RO CL2 Cleaning = approximately every 90 days

6.3.6.2.1 Open Sanitization Port and place a chlorine tablet in the port.

6.3.6.2.2 Put the cap back on and tighten it

6.3.6.2.3 Go into "Standby" Mode

6.1 Daily Inspections

- 6.1.11 Ready mode as indicated by a green light should be displayed on the Main Unit's LED screen when normal water production and delivery are required.
- 6.1.12 A yellow light will display as a caution to notify the user of impending service requirements such as a cartridge change or system flush.
- 6.1.13 After turning on water flow at the Q-POD gun and check the indicator display on the Q-POD during dispensing to ensure that no warnings are displayed and water metrics are within tolerance.
 - 6.1.13.1 The reservoir is represented by ten graphic bars, each bar representing 10% capacity of purified water in the tank.
 - 6.1.13.2 Resistivity should read > 18MQ.
 - 6.1.13.3 TOC oxidizable carbon level <10 ppb.
 - 6.1.13.4 Water temperature should be near ambient.
 - 6.1.13.5 The Proguard Pak is in use as indicated by the symbol.
 - 6.1.13.6 The QUANTUM Cartridge is in use as indicated by the symbol.
 - 6.1.13.7 No warnings or maintenance alerts are displayed.

6.1.14 Inspect the system for leaks.

6.2 Consumables

- 6.2.1 Proguard Pak - Part# PROG0T0S2US
- 6.2.2 Bactericidal UV Lamp- Part# ZLXUVLP01
- 6.2.3 Photooxidation UV Lamp- Part# ZMQUVLP01
- 6.2.4 QUANTUM Cartridge - Part# QTUM0TEX1
- 6.2.5 A10 TOC Monitor Lamp- Part# ZFA10UV01
- 6.2.6 POD22µM Filter- Part# MPCP04001
- 6.2.7 Tank Filter- Part# TANKMPK01
- 6.2.8 Sanitization Tablets (US)- Part# 5874316024