



## TRAINING UPDATE

**Lab Location:** GEC  
**Department:** Core

**Date Distributed:** 1/2/2013  
**Due Date:** 1/31/2013

### DESCRIPTION OF PROCEDURE REVISION

<b>Name of procedure:</b>
<b>Millipore (AFS – Analyzer Feed System), Siemens Dimension® Xpand GEC.C28 v1</b>
<b>AFS-8(D) Daily Maintenance Log - System Readings (log) AG.F101.002</b>
<b>Description of change(s):</b>
Section 1,2,3: Specify Xpand analyzer Section 5: Edited component names 5.3.12 & 5.3.13: Revised step by step procedures based on new User Guide 5.3.14: Added LIS ordering steps  Update log to match SOP - bacteria check only required monthly

Document your compliance with this training update by taking the quiz in the MTS system.

Approved draft for training all sites (version 001)

Non-Technical SOP

<b>Title</b>	<b>Millipore (AFS – Analyzer Feed System), Siemens Dimension® Xpand</b>	
<b>Prepared by</b>	Ashkan Chini	Date: 4/29/2011
<b>Owner</b>	Robert SanLuis	Date: 10/26/2012

<b>Laboratory Approval</b>		
<b>Print Name and Title</b>	<b>Signature</b>	<b>Date</b>
<i>Refer to the electronic signature page for approval and approval dates.</i>		
Local Issue Date:		Local Effective Date:

<b>12 month (or new) management review and approval:            Signature acknowledges SOP version remains in effect with NO revisions.</b>		
<b>Print Name</b>	<b>Signature</b>	<b>Date</b>

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### **1. PURPOSE**

The purpose of this procedure is to outline the use and maintenance of the Millipore AFS Water Purification System. The Millipore AFS Water Purification System will be utilized as the Analyzer Feeder System for Dimension **Xpand** analyzers.

### **2. SCOPE**

This procedure applies to Laboratory staff who operate the Dimension **Xpand** analyzers.

### **3. RESPONSIBILITY**

Laboratory staff who operate the Dimension **Xpand** analyzer, prepare reagents, utilize water or culture the system are responsible for monitoring and/or maintenance of the Millipore system.

### **4. DEFINITIONS**

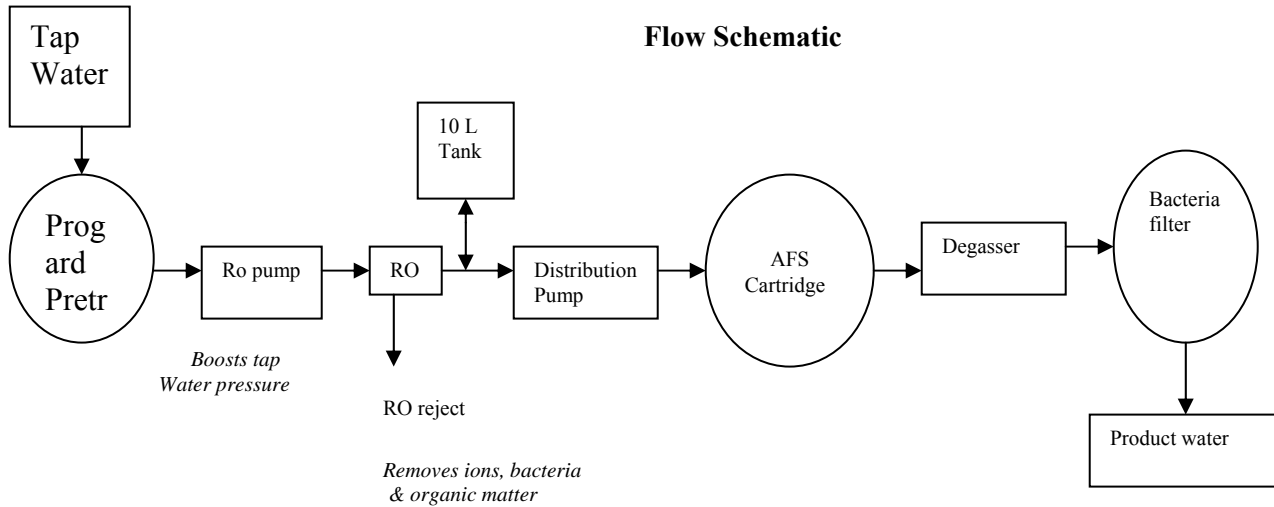
AFS – Analyzer Feed System; a water purification system that produces NCCLS Type I Product Water directly from potable tap water. The system combines Reverse Osmosis (RO) and Ion Exchange technology to accomplish this. The product water then feeds the analyzer directly, without any extra user interaction. The FAS system is designed to produce NCCLS Type I quality water.

### **5. PROCEDURE**

#### **5.1 Operating Principle**

Potable tap water enters the **Progard** Pretreatment Pack. The **Progard** is used to prevent mineral scaling, organic fouling and chlorine oxidation of the Reverse Osmosis (RO) cartridge. The **Progard** is an **expendable device**. The RO pump is used to boost the tap water pressure. This will create more permeate flow from the RO cartridge. The RO cartridge removes a large percentage of ions from the tap water. In addition, the RO

cartridge removes a large percentage of bacteria and organic material. The RO has a waste (reject) stream, which is directed to drain. All ions, bacteria and organic material removed by the RO are directed to the waste stream. The permeate flow from the RO is stored temporarily in the 10 Liter Tank.



## 5.2 General Information

Parameter	NCCLS/CAP specification for Type I Water
Maximum bacterial content	< 10 CFU/ml*
Minimum resisitivity	10 MΩ-cm**
Maximum silicate level	< 0.05 mg/L
Particulate matter	0.22 micron filter
Organic contaminants	Activated carbon*** or Reverse Osmosis or Distillation
pH	Not specified

\*CFU/ml = colony forming units per ml

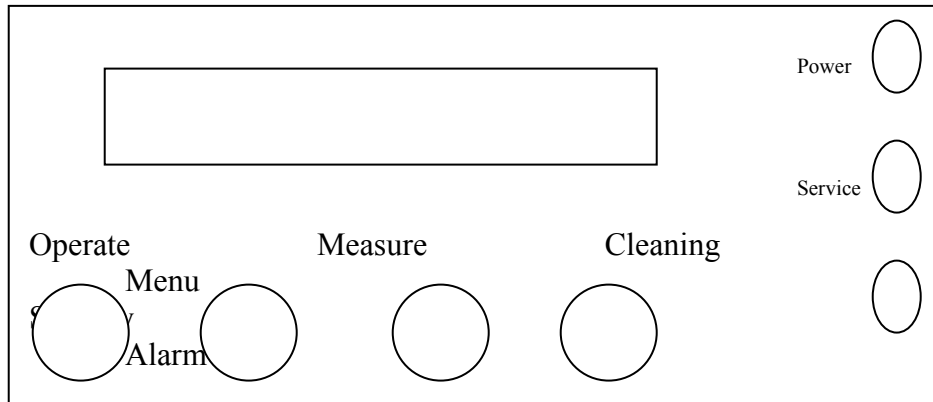
\*\* MΩ.cm=Megohm.cm compensated to 25° C

\*\*\* Not required by CAP

## 5.3 Operation

### 5.3.1 Operate/Standby Button

The keypad allows you to interface with the system. Changing the software modes, reviewing the system’s performance, and initiating maintenance procedures can be done via the keypad.



**Standby** – This mode is displayed when the system is not operating any of the internal components. Normally this mode is used when starting a maintenance procedure. The system performs an automatic flush of the RO cartridge every 6 hours (all operating modes). The flush mode rinses the RO to remove anything that has built up on the membrane surface. No water will be sent to the analyzer when the system is in this mode.

**Filling Tank** – This operating mode is displayed when the 10-liter tank is being filled with RO water. If the analyzer requires water, the distribution pump will send the water to the analyzer as needed.

**Tank Full** – This operating mode is displayed when the 10-liter tank is full of RO permeate water. If the analyzer requires water, the distribution pump will send water to the analyzer as needed.

**Production** – This operating mode is displayed when the water is being sent from the AFS to the analyzer. The AFS switches automatically to PRODUCTION mode if the system is in TANK FULL or in FILLING TANK mode.

The Resistivity of the product water is shown in the bottom left corner of the display. The displayed resistivity is temperature compensated to 25° C. The actual temperature of the product water is displayed in the bottom right corner of the display.

You can get product water from the AFS for a maximum of 18 continuous minutes. This is a software feature, which prevents the Distribution Pump from running dry. The Distribution Pump will stop after 18 minutes of continuous use. DISP. TIME OVER (Dispensing Time Over) will alternate with PRESS OPERATE in the display. You must change the system into STANDBY mode in order to reset the timer. (Hold down the OPERATE/STANDBY button for two seconds). After the timer is reset, the AFS should be changed to FILLING TANK or TANK FULL mode so that water can be sent to the analyzer if needed.

DISP TIME OVER will reset automatically as soon as the tank is full.

If you use a tank greater than 10 liters, contact your local Millipore office.

The Measure Button allows you to see various water quality related parameters.

### **5.3.2 Measurements when in Filling Tank or Tank Full Mode**

Various measurements are made when the Tank is being filled with permeate water from the RP membrane.

**Reminder:** The permeate water from the RO membrane is not the final product water.

#### **Press the Measure Button**

The top line of the display will show the pressure of the water that is going into the RO cartridge. This pressure results from the RO pump increasing the tap water pressure. The bottom line of the display shows the ionic percent rejection of the RO membrane. This is determined using the feed water conductivity and permeate conductivity values. The RO ionic % rejection represents the percentage of ions that are rejected by the RO membrane and then sent to the drain.

#### **Press the Measure Button Again**

The top line of the display shows the pressure of the water that is going into the RO cartridge. The electrical conductivity of the RO feed water is shown on the bottom of the display.

#### **Press the Measure Button Again**

The top line of the display shows the pressure of the water that is going into the RO cartridge. The electrical conductivity of the RO permeate water is shown on the bottom line of the display.

#### **Press the Measure Button Again**

The system returns to FILLING TANK or TANK FULL mode.

### **5.3.3 Measurements in Production Mode (Water is Being Sent to the Analyzer)**

The Resistivity Value (compensated to 25° C) and the Temperature of the Product Water are displayed at all times when in PRODUCTION mode.

(See Measurements when in FILLING TANK or TANK FULL mode).

### **5.3.4 Cleaning Button**

The Cleaning button is used to initiate either the Chlorine Sanitization cycle or the pH Cleaning cycle. Refer to the Maintenance section of the User Manual for a complete description of both cycles.

### **5.3.5 Menu Button**

The menu button can be used to access various Customer Menus. Hold down the MENU button for 2 seconds to access the Customer Menu. The Customer Menu can be accessed in any Operating Mode.

### **5.3.6 Pak Life**

The first screen shows the number of days remaining before the **Progard** Pretreatment Pack needs to be exchanged. Both a day-to-day timer and a measurement of water usage calculate the number of days remaining by the system. The number of days will count down (decrease).

When a new **Progard** Pretreatment Pack is installed, the display will show NO DATA for seven days. This message is necessary so the system can determine an accurate rate of water usage.

Press the MENU button. This scrolls the display over to the OPTIONS portion of the Customer Menu.

### **5.3.7 Language**

This gives you the option to change the language seen on the display. The Arrow Buttons can be used to scroll between various languages.

Press the OPERATE/STAND BY Keypad Button to scroll down to the next choice in the OPTIONS selection.

### **5.3.8 External Alarm**

An external alarm (buzzer, light, etc.) can be connected to the AFS system. When an Alarm or Service message is shown on the display, the system will send either a 100/120/230 volt signal to an external alarm connected to the system. The voltage of the signal depends upon the voltage supplied to the system.

Use the Arrow Buttons (MEASURE or CLEANING) to activate (ON) or deactivate (OFF) the External Alarm.

Press the OPERATE/STANDBY Keypad Button to scroll down to the next choice in the OPTIONS selection.

### **5.3.9 Pressure Units**

You can change the units that are displayed for the pressure measurements when the system is in operation. We will choose psi.

### **5.3.10 Resistivity or Conductivity Display**

This option changes the displayed units during PRODUCTION mode. These units include resistivity (MΩ.cm) or conductivity (uS/cm).

**Note: When you scroll to the following menu option, you will have 10 seconds before the software automatically starts the System Rinse. In order to prevent this from happening, press the MENU again before the end of 10 seconds.**

Press the MENU Keypad Button to scroll over to the next menu option.

### 5.3.11 System Rinse

The System Rinse starts automatically after a 10 second delay. If you want to start a 240-minute System Rinse, wait 10 seconds when this display is shown.

**If you accidentally start a System Rinse and want to cancel it, call Your Local Millipore Office for assistance.**

The purpose of the System Rinse is to rinse the preservatives in the RO membrane. The 10-liter Tank will not fill during the 240 minutes of the System Rinse.

**Note: Poor water quality could result if a new RO cartridge is not rinsed for the required time.**

Press the MENU Keypad Button to scroll over to the next menu selection.

Press the MENU Keypad Button to exit the Customer menu.

### 5.3.12 Replacement of Consumables

Table for quick reference for when the consumables should be exchanged:

<b>Consumables names</b>	<b>When to change the Consumables</b>
Progard Pretreatment Pack	Replace the Progard when the message “EXCHANGE PROGARD” is shown on the display. Also replace the PROGARD if the system has been turned off for more than 48 hours. System should be powered on and in STANDBY mode when the Progard is replaced.
Bacteria Filter	Replace the Simfilter or Millipak when the Progard is exchanged.
Millex Vent Filter	Replace the Millex when the Progard is exchanged.
<b>AFS Cartridge</b>	Replace the <b>AFS Cartridge</b> when the system displays “PRODUCT < S.P.” message. Replace it only after opening the manual Product Line Drain Valve and draining any water that may have stayed stagnant in the cartridge.

**See troubleshooting Section for more information if the system is producing Low Flow.**

Form revised 3/31/00



### a) Replacing Progard Pretreatment Pack

- The system should be turned on and in STANDBY mode when replacing the pack. Place the system into STANDBY mode by holding the OPERATE/STANDBY button down for 2 seconds. The STANDBY display flashes to indicate depressurization of the system.
- Wait until the STANDBY display stops flashing. Lift the pack adapter cover to the top position.
- Pullout the used Progard.
- Remove the protective caps from the new Progard. Wet the two O-rings on the new Progard with water.
- Slide the pack onto the metal guide pin (F). Lift up the pack slightly in order to push the bottom of the pack into the slot at the bottom of the system. Push the pack completely onto the pack adapter. The metal guide pin (D) should be visible now.
- Lock the pack in place with the metal locking clip on the end of the metal guide pin (F).
- Lower the adapter cover (E) over the newly installed Progard.
- **Note: Replace the Progard if the system has been turned off for more than 48 hours.**

### b) Replacing AFS Cartridge

- You will need AFS cartridge and at least 5 liters of water in the Tank (approximately half the Tank).
- Make sure the AFS system is in STANDBY mode. Wait for the STANDBY display to stop flashing if necessary.
- Open the product Line Drain Valve and release any pressure in the distribution tubing.
- Close the Product Line Drain Valve.
- Open the front blue door by pressing on the 2 latches on the right side and pulling the door open. Pullout the AFS Cartridge
- Remove the two protective caps from the new AFS Cartridge, and wet the two pack o-rings using a few drops of purified water.
- Insert the AFS Cartridge into the system. Push it in as far as it will go.
- Close the door. It is necessary to fully snap the latches shut to hold the AFS Cartridge inside. You should here both latches "click" shut.
- Press the OPERATE / STANDBY button to change the system into FILLING TANK or TANK FULL mode. The system may initially display PRODUCTION until the pressure rises.
- With the tubing from the Product Line Drain Valve secure in the drain, open the Product Line Drain Valve to change the system into PRODUCTION mode.
- Allow approximately 5 Liters of water (half of the Tank) to pass through the AFS Cartridge in order to rinse the ion exchange resin correctly.

### c) Simfilter (BIO-PAK)

The Simfilter should be changed at the same time as the Progard. The Simfilter can be used immediately after installation.

- Locate the Quick Disconnect Fitting, which is normally connected to the analyzer. Separate the fitting by pushing down on the metal piece and pulling the fitting apart. If a Quick Disconnect fitting is not used, remove the tubing connected to the fitting on the analyzer.
- Unscrew the metal nut and remove the tubing from the Quick Disconnect fitting. Screw the nut back on the fitting so it does not get misplaced.
- Connected directly onto the Simfilter is a fitting. Unscrew the nut and remove the tubing coming from the AFS. Discard the Simfilter, including the attached fitting. The new Simfilter comes with a fitting and tubing already attached.
- The new Simfilter can be installed at this time. Unscrew the nut from the fitting and place the nut on the tubing coming from the AFS.
- Push the tubing onto the fitting on the Simfilter. Screw the nut back onto the fitting to secure the tubing.
- Connect the tubing on the other side of the Simfilter to the fitting connected to the analyzer. If this fitting is the Quick Disconnect fitting coming with the system:  
Unscrew the nut on the Quick Disconnect fitting  
Slide the nut onto the tubing from the e Simfilter  
Push the tubing onto the fitting  
Tighten the nut onto the fitting so that the tubing is locked into place  
Reconnect the Quick Disconnect fitting to the analyzer

### 5.3.13 Maintenance

#### a) Cleaning of the Screen Filter

The screen filter must be cleaned each time the **Progard** is replaced. Cleaning the screen filter will allow a better flow rate to reach the system. It also aides in preventing any large foreign particles from causing damage to the system. The screen filter is in the ½ inch FNPT fitting connected to the feed water valve. This is the valve, which supplies water to the system.

- Put system into **STANDBY** mode. Hold the **OPERATE / STANDBY** button down for two seconds if you are in one of the operating modes
- Close the feed water valve.
- Disconnect the tubing from the fitting connected to the feed water.
- Unscrew the fitting from the 1/2 inch FNPT fitting connected to the feed water. Locate the screen filter.
- Clean the screen filter to remove any particles that were trapped by the filter. This can be done by running water through it in the opposite direction as normal.
- Reconnect the tubing to the feed water. More Teflon® tape may be needed on the 1/2 inch MNPT fitting to prevent leaks.
- Open the feed water valve.

## b) Chlorine Sanitization of the Reverse Osmosis Cartridge

Chlorine sanitization should be performed when the message “START AUOCLAEN” appears on the display. The yellow service light also flashes.

- Place the system in STANDBY mode by holding the OPERATE/STANDBY button down for 2 seconds. The STANDBY display flashes to indicate the depressurization of the system.
- Once the STANDBY display stops flashing, unscrew the sanitization port plug and put a chlorine tablet in.
- Replace the sanitization port plug. Hand tighten only.
- Start the cleaning cycle as follows:

Hold the **CLEANING** button down for two seconds. The chlorine cleaning cycle starts after a 10 second delay. The remaining time of the cleaning cycle is displayed.

**Note: During the cleaning cycle, water can be drawn from the 10 Liter tank to feed the analyzer. The cleaning cycle is 15 minutes. At the end of this cycle the system automatically changes to FILLING TANK or TANK FULL mode.**

## c) PH Cleaning of the Reverse Osmosis Cartridge

A pH cleaning should be performed as needed. If the % ionic rejection drops several points or if the flow rate coming from the AFS has decreased, a pH cleaning of the RO could renew the cartridge.

- **Use the ROClean-A (acid) when necessary**, when the feed water entering the AFS has a high level of hardness. A high level of hardness is defined as > 150 ppm Calcium/Magnesium and > 30 ppm Alkalinity.
- **Use the ROClean-B (base) when necessary** in order to remove organic buildup on the membrane. It is recommended to use the ROClean-B if the Fouling index of the feed water is greater than 5.
- Place the system in STANDBY mode by holding the OPERATE/STANDBY button down for 2 seconds. The STANDBY display flashes to indicate depressurization of the system.
- Once the STANDBY display stops flashing, unscrew the sanitization port lug and add the ROClean-B cleaning pouch.
- Screw the sanitization port plug back in place.
- Start the additional cleaning cycle:  
Hold the **CLEANING** button down for 2 seconds  
Press once on **CLEANING** to display the pH Cleaning mode  
The pH cleaning cycle will start after a 10 second delay. The remaining time of the cleaning cycle is displayed.
- **Note: During the pH cleaning cycle, water can be drawn from the 10-liter tank to feed the analyzer. The pH cleaning cycle is 90 minutes. At the end of this cycle**

**the system automatically changes to FILLING TANK mode or TANK FULL mode.**

### 5.3.14 Monitoring Bacterial Levels in Water

To meet NCCLS requirements for the specification of bacteria count, periodic testing is recommended. Bacteria cultures need to be performed **monthly**.

- a) To obtain water for culture:
  - 1) Sanitize the sampling port: working from the inside out, wash the port with a 10% bleach solution.
  - 2) Open the sampling port on the AFS product line and let it run for at least 1 minute.
  - 3) Collect 10 ml of water in a sterile container (urine culture collection cup).
  - 4) Record collection of water (date/tech code) on the AFS-8(D) Daily Maintenance Log
  
- b) To order culture:
  - 1) Via the LIS:
    - a. Function: **REI**
    - b. Press the “/” key (forward slash)
    - c. Now press the “↑” key, then
    - d. Press the “**HOME**” key to choose “**HOSP. NO**”.
    - e. Hospital number: type **MILL-7** (choose **MILLIPORE-GEC**)
    - f. TEST1: type **XH2O** and for
    - g. SREQ: type **WATER**.
    - h. Label the containers using the LIS accession labels.
  - 2) Microbiology staff will:
    - a. Inoculate a Standard Methods Agar (SMA) plate with 1 mL of water utilizing a 1 mL pipette.
    - b. Let plate sit in hood specimen side up until water absorbs into medium.
    - c. Send to Chantilly for incubation and reading.
  
- c) Group Lead will:
  - 1) Retrieve results from printer
  - 2) Record results as CFU/mL on the AFS-8(D) Daily Maintenance Log
  - 3) Acceptable values are  $\leq 10$  CFU/mL.
  - 4) Document corrective action if value is unacceptable.

### 5.3.15 AFS Daily Maintenance Log

Complete AFS-8(D) Daily Maintenance Log - System Readings form (see Addenda)

## 6. RELATED DOCUMENTS

None

## 7. REFERENCES

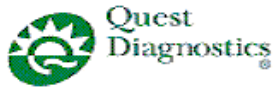
User manual, Millipore, 2003. [www.millipore.com](http://www.millipore.com), [www.millipore.com/techservice](http://www.millipore.com/techservice)  
1-800-645-5476

**8. REVISION HISTORY**

<b>Version</b>	<b>Date</b>	<b>Reason for Revision</b>	<b>Revised By</b>	<b>Approved By</b>
		Supersedes SOP C050.004		
000	10/26/12	Update owner Section 1,2,3: Specify Xpand analyzer Section 5: Edited component names 5.3.12 & 5.3.13: Revised step by step procedures based on new User Guide 5.3.14: Added LIS ordering steps	A. Chini	R. SanLuis

**9. ADDENDA**

AFS-8(D) Daily Maintenance Log - System Readings (see Attachment Tab of Infocard)



### AFS-8(D) Daily Maintenance Log - System Readings

Month/Year \_\_\_\_\_

S/N \_\_\_\_\_

**\*\* Make sure the Millipore is NOT in Standby when performing Daily Maintenance.\*\***

1. Turn on Millipore water and let drain into a container.
2. Press the Measure button.
3. Remember to record the vacuum pressure on the right side of the Millipore.

		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
1	Product Quality (> 10MΩ-cm)																															
2	% Rejection (>90%)																															
3	Feed Temp (5 - 35°C)																															
4	Feed (F) Conductivity (No Range)																															
5	Permeate (P) Conductivity (No Range)																															
6	Product Vacuum in Hg																															
7	Change Simfilter (BIO-PAK), Pro-Filters, AFS Cartridge																															
8	Change Millipore Pre-Pak Filter																															
	Tech																															
9	Collect water for Bacterial content	Preformed monthly Date: _____ Tech: _____																														
	Bacterial content (≤ 10 CFU/mL)	Result: _____																														
Weekly review:									Weekly review:									Weekly review:														
Weekly review:									Weekly review:									Monthly review:														