1. Purpose

This document provides instruction for the utilization of the Milliflex Plus Pump.

2. Scope

This document shall be followed by all personnel operating the Milliflex Plus Pump.

3. References

3.1 Operator’s Manual for the Milliflex Plus Pump
3.2 ATS Safety Manual and Material Safety Data Sheet (MSDS) Archive Binder
4. Equipment and Materials

4.1 Milliflex Plus Pump
4.2 Milliflex filtration funnels
4.3 Millipore media cassettes

5. Safety


6. Responsibility

6.1. It is the responsibility of the President to assure that this document remains current.

6.2. It is the responsibility of the President, or any trained technician designee, to provide documented training in the utilization of this device.

6.3. It is the responsibility of the President to assure the general maintenance of this device and to assure that the recalibration is performed in a timely manner.

6.4. It is the responsibility of the individual(s) operating this equipment to follow the procedures specified by this document.

7. Preliminary Considerations

Collect all equipment necessary to conduct the desired operation.

8. Operation

8.1 Preparation for Testing

Note:
It is recommended that the pump head be autoclaved before the first use and after each workday.
Whenever the pump head is removed, the Tare cycle must be run. It is recommended that the pump interior be sanitized before the first use and after each workday, and if the pump is unused for more than a day.

If the pump is to be placed in a laminar flow hood or clean area, the exterior surface must be cleaned with a soft cloth, moistened with alcohol.

Install the pump head, as described in the Installation section of the User’s Manual.

Run the Tare cycle, as described in 8.1.2.

To prepare for testing, switch on the pump, by pressing the ON/OFF button on the keypad. After the power-up display, the Main Program Screen for the previously selected program is displayed.

8.1.1 Main Menu

The Main Menu provides access to the following functions used in regular operations: **Tare, Sampling, Sanitizing, Configuration, Export Data**. To reach the Main Menu from any main Program Screen, press OK. The display shows **Tare**. (This is the entry point to the Main Menu). Use the up and down arrows to scroll to the required function.

8.1.2 Tare

The Tare procedure adjust the measurement system in the pump for the weight of the installed pump head. The Tare procedure should be performed whenever the pump head is changed, and whenever the display does not show “0”, with an empty funnel on the head. Millipore recommends that the Tare procedure be performed before starting each run of tests.

1. When the display shows Tare, press OK. The display shows:
   remove expendable
   press start
2. Remove anything on the pump head (e.g. cover or disposable) and press START. The displays shows:
   measuring…
   please wait…

After a few seconds, the display returns to the Main Program Screen for the previously-selected program.
8.1.3 Sampling Setup

The Sampling Menu provides access to the Auto Sampling, Dilution and Manual modes of operations, when the user wants to switch to a different sampling program (or add or delete a custom program).

Setup for Manual Sampling

1. In the Main Menu, use the up or down arrows to select Sampling, and press OK. The displays shows:
   Manual
2. Press OK. The display shows:
   Volume OFF

In Manual testing, the user can chose whether to have the pump indicate the volume in the funnel, as follows.

3. To turn off volume measurement press OK. The display shows:
   Manual

   This is the Manual Testing Screen (when Volume OFF is selected): testing can begin.

   To turn on volume measurements press the down arrow. The display shows:
   Volume ON
4. Press OK. The display shows:
   Milliflex 100
5. If using the Milliflex 100 funnel, proceed to Step 6.

   If using the Milliflex 250 funnel, press the down arrow, so that the display shows:
   Milliflex 250
6. Press OK. The display shows:
   Density (g/ml):
   1,00
7. Use the up and down arrows to select the density of the liquid to be tested.

   Press OK.

   The display shows:
   Manual
   Mil250/1,00 ___

   This is the Manual Testing Screen (when Volume ON is selected): testing can begin. See the sample Processing section below.
Setup for Auto Sampling

1. In the Main Menu, use the up or down arrows to select **Sampling**, and press OK. The display shows:
   Manual

2. Press the down arrow once. The display shows:
   Auto Sampling

3. Press OK. The display shows the name of the last Auto Sampling program selected. The factory-installed programs are:
   - **MFX10**: 10 ml of water, with Milliflex 100 disposable
   - **MFX100**: 100 ml of water, with Milliflex 100 disposable
   - **MFX2x100**: 2 100 ml of water, with Milliflex 100 disposable
   - **RINSE3x100***: 3 100 ml of liquid (for rinsing), with Milliflex 100 disposable
   - **MFX200**: 200 ml of water, with Milliflex 250 disposable

   * NOTE: The rinsing program RINSE3x100 is reported during Data Export, but is **not** assigned a number in the list of samples filtered.

   In addition up to five custom programs can be added by the user to meet particular requirements. See Adding, Editing or Deleting a Program in the User’s Guide.

4. Use the up and down arrows to move through the list of programs to the required program. Press OK. The display shows:
   select

5. (If this is a previously added program, and you want to edit it, press the down arrow.) To proceed with the selected program, press OK. The display shows the Main Program screen for the selected program. For example:
   - **MFX100**
     Mil 100/100ml _____

   Testing can begin. See the Sample Processing section, below.

NOTE: The Auto Sampling program can be changed during testing, without returning to the Sampling Menu, by pressing the up or down arrow at the Main Program Screen.

Dilution Sampling
See User’s Manual
8.1.4 Sanitizing
Millipore recommends that the pump interior be sanitized before its first use, after each workday and if unused for more than a day. The Sanitizing cycle enables the user to sanitize the interior surfaces of the pump, according to a fixed regimen. Acceptable sanitizing agents:
- Bleach 250 ppm
- Peracetic acid 0.125%
- Quaternary ammonium
In the sanitizing cycle, the pump automatically circulates a measured quantity of sanitizing agent through the interior of the fluid-handling mechanisms; pauses for ten minutes, while the interior surfaces are still wetted with the agent; circulates the rest of the agent through the pump; and then circulates multiple rinses. The user is prompted to add the appropriate liquid when required, at each stage. A drying cycle completes the process.
Millipore recommends the Milliflex HA (mixed cellulose esters membrane) funnel for sanitization using any recommended agent except for solutions containing alcohol, where the Milliflex HV (PVDF membrane) is required. If the agent and the membrane used are not compatible, remove the membrane from the funnel before sanitizing.
CAUTION: Install the exhaust tubing and waste receptacle at the same height as the pump, to prevent sanitizing agent being siphoned out of the pump during the ten minutes of contact time.
1. At the Main Program Screen, press OK, to enter the Main Menu. The display shows: Tare
2. Press the down arrow until the display shows:
   Sanitizing
3. Press OK. The display shows:
   Put expendable
   press start
4. Place an aseptic spacer and Milliflex 100 funnel, without its cover, on the pump head and press START. The display shows:
   Fill 100 ml of Agent
   press start
5. Fill the funnel with 100 ml of sanitizing agent and press START. 
   (If the pump detects too little agent, the display will show:
       Error not enough agent
   If this display is shown, press C and refill the funnel.)
   If enough agent is detected, the pump starts and the display shows:
       Sanitizing
   The pump pulls through 50 ml of agent, pauses for ten minutes, and then pulls through
   the remaining 50 ml. A bar graph at the bottom of the display shows the progress of the
   operation.
   After the pump has emptied the funnel, it runs a drying cycle and then the display shows:
       Fill 100 ml of water
       press start
6. Fill the funnel with 100 ml of sterile water and press START. The rinsing cycle is
   performed as before. Then the display prompts for the funnel to be filled again, for each
   rinse, for a total of four rinses. When the fourth rinse has been completed, the display
   shows:
       Rinsing
   The pump empties the funnel and runs a drying cycle. Then the display shows:
       Sanitizing finished
       press start
7. Fill the funnel with 100 ml of sterile water and press START. The rinsing cycle is
   performed as before. Then the display prompts for the funnel to be filled again, for each
   rinse, for a total of four rinses. When the fourth rinse has been completed, the display
   shows:
       Sanitizing finished
       press start
8. Press START. Remove the funnel and discard it. The display shows:
       Sanitizing
9. Press C to go back to the Main Program Screen.
Remove the head and autoclave it. Sanitize the protective mounting post cover with
alcohol and put it on the mounting post. The pump is now sanitized.
8.2 Sample Processing

The following procedures describe typical sampling processing, in Manual or Auto Sampling mode and in Dilution mode.

8.2.1 Sample Processing: Manual or Auto Sampling
1. Position a tray of Milliflex 100 funnels with the Millipore name facing the operator.
2. Remove a funnel from its packaging tray. A notch in the tray is uncovered: this will facilitate picking up the spacer.
3. Use sterile forceps to place the aseptic spacer on the pump head. Firmly press the funnel onto the pump head.
4. Remove the cover from the funnel, while maintaining the funnel in position with the other hand.
5. Pour a sample into the funnel, using the graduations to help achieve the required volume:
   a. In Manual mode, if Volume ON has been selected, the display will show the volume filled.
   b. In Auto Sampling mode, the buzzer will sound when the required volume has been reached.
When the required volume has been reached, stop pouring. Leave the cover tilted on top of the funnel, but not closed, during the next two steps.
6. a. In Manual mode, pres START to start the pump.
   b. In Auto Sampling mode, filtration starts automatically.
7. a. In Manual mode, operate the pump until the sample has been filtered, then press START to dry out the pump head. Wait for the pump to stop.
   b. In Auto Sampling mode, when the sample has been filtered, the pump switches automatically to drying. Wait for the pump to stop.
8. Remove the white/opalescent cover from the solid cassette or the paper cover from the liquid cassette.
9. Remove the funnel from the pump head and reinstall the funnel cover.
10. Inspect the underside of the membrane, to verify membrane integrity. When viewed from beneath the funnel, the membrane should have a convex shape.
11. Place the funnel base down over (and the filter membrane onto) the exposed medium cassette. The membrane should be fully in contact with the medium.
12. Assure and secure membrane contact with the medium, by pressing slowly and firmly on the cover with the thumb and forefinger of each hand.
13. Press down on the top of the funnel with the palm of one hand. Start with a form vertical pressure and gradually increase your hand pressure until the funnel breaks off. The funnel will shear off at the groove on the unit.

NOTE: If the working position is uncomfortable, e.g. in a vertical laminar flow hood with the shield in a low position, then the funnel may be broken in two steps, thus requiring less strength. Press slightly to one side of the funnel first, until a “snap” is heard, then press on the opposite side of the funnel until a second “snap” is heard.

14. After the funnel section has broken off, remove the cover from the funnel and place it on top of the filter cassette assembly.
15. Incubate upside down.

9. Maintenance

This section describes normal maintenance.

9.1 Autoclaving
Autoclave the pump head before first use and after each workday. Autoclave at 121°C for 30 minutes, or at 134 °C for 10 minutes.

9.2 Sanitizing
After each workday, or when the pump is unused for more than a day, sanitize the pump interior, using the automated procedure provided with quaternary ammonium.

9.3 Exterior Cleaning
If the pump is to be placed in a laminar flow hood or clean area, the exterior surface must be cleaned with a soft cloth, moistened with alcohol.

9.4 Calibration
Calibration should be performed at installation, and thereafter at least every twelve months by a qualified technician in accordance with reference 3.1, section 4.3.3.