



Customer Information Bulletin

PRODUCT: BioProfile® FLEX2

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Proper Long Term Shutdown Procedures for the BioProfile FLEX2 Analyzer

Dear BioProfile FLEX2 Customer,

Nova Biomedical recognizes that it is common practice for many BioProfile FLEX2 customer sites to undergo a laboratory or facility-wide shut down near the end of the calendar year. If your facility plans to power off the BioProfile FLEX2 analyzer or leave it with expired or empty Reagent Cartridges for a period greater than 72 hours, the system **MUST** be purged of all residual fluid in the internal tubing or flow paths.

Failure to purge the system for long periods of shutdown will result in reagent crystallization and blockages in the internal tubing, which may require service to resolve. **Improperly shutting down an instrument will not be covered under any service agreement or warranty. If a service visit is required due to improper shutdown, it will be billed at the current time and material rate.**

To prevent flow path blockages and potential damage to your BioProfile FLEX2 analyzer, please follow the recommended procedures for a long-term shutdown. There are two approved methods to properly perform a long-term shutdown on the FLEX2 analyzer: utilizing the Long-Term Shutdown Cartridges or utilizing the Long-Term Shutdown Flush Fixtures.

NOTE: All information discussed in this CIB can be referenced in Section 4.1.9 of the FLEX2 Instructions for Use Manual (LPN 57960).

Long-Term Shutdown Cartridges:

FLEX2 analyzers operating with software version 4.0 or newer can utilize the Long-Term Shutdown Cartridges to properly shut down the system for extended periods of inactivity. These cartridges are designed for one-time use and must be discarded following the completion of the long-term shutdown process.

Long-Term Shutdown Using the Shutdown Cartridges Requires the Following Items, Depending on Module Configuration of the Analyzer:

- PN 60608 pH/Gas Module Shutdown Cartridge
- PN 60610 Chemistry Module Shutdown Cartridge
- PN 60611 CDV Module Shutdown Cartridge
- PN 60612 ESM Shutdown Cartridge (if applicable)
- PN 60613 pH/Gas Auto QC Shutdown Cartridge

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To Perform a Long-Term Shutdown with Shutdown Cartridges:

1. Open the main door and remove all Reagent Cartridges, bottle packs, and QC cartridges from the BioProfile FLEX2. All MicroSensor cards, reference sensors, and pump tubing must remain installed.
2. Install all shutdown cartridges into the respective pack bays (the pH/Gas QC Shutdown Cartridge and ESM Shutdown Cartridge are optional). Ensure the fitments on the rear of each pack are fully engaged with the needle shrouds at the rear of the pack bays.

NOTE: For the Long-Term Shutdown sequence to initiate, shutdown cartridges for all available modules must be installed. Additionally, a Chemistry Auto QC Shutdown Cartridge is not required/offered for long-term shutdown.

3. Close the main door and the shutdown sequence will automatically begin. Shutdown solution will be pumped from the cartridges into all internal fluid lines and then purged with air. After approximately 8 minutes, the User Interface will turn black.
4. Once the User Interface screen is dark, wait one minute and power down the FLEX2 by toggling the power switch on the rear right side of the unit to the OFF position. Remove both the Chemistry and pH/Gas Pump Tubing Harness from the rollers and leave the Reference Sensors and MicroSensor Cards installed on the unit.

NOTE: Failure to properly switch off power to the FLEX2 following the Long-Term Shutdown procedure could result in analyzer damage.

Long-Term Shutdown with Flush Fixtures:

If the Long-Term Shutdown Cartridges are not available, the FLEX2 Flush Fixtures can be utilized to perform the Long-Term Shutdown sequence manually.

Purging the system requires the use of the following:

- FLEX 2 Flush Fixture 6 Port (x2) PN 58355
- FLEX 2 Flush Fixture 4 Port PN 59121
- FLEX 2 Flush Fixture 2 Port PN 57530
- 2 – 3 Beakers with at least 250 mL of DI or WFI H₂O
- 2 – 3 Empty Beakers (capable of holding 250 mL of water waste)

To perform a Long-Term Shutdown and Flowpath Purge:

1. Remove all reagent cartridges and packs from the BioProfile FLEX2 system; all sensor cards, reference sensors, and pump tubing must remain installed.

NOTE: If Onboard QC cartridges are installed, store the Onboard pH/Gas QC Cartridge at 2 – 8°C and the Onboard Chemistry QC Cartridge at or below -15°C during the shutdown period so they can be re-installed when the system is put back into use.

2. Install the two 6 port Flush Fixtures into the Chemistry and pH/Gas reagent pack bays. Make sure that the needle fitments at the rear of each fixture engage with the needle shrouds at the rear of the pack bays.

3. Install the 4 port Flush Fixture into the CDV reagent pack bay. Make sure the needle fitments at the rear of the fixture engage with the needle shrouds at the rear of the pack bay.
4. Install the 2 port Flush Fixture into the Chemistry Calibrator Cartridge pack bay. Make sure the needle fitments at the rear of the fixture engage with the needle shrouds at the rear of the pack bay.
5. Locate the length of tubing labeled “W” (Waste) on each fixture and place the end of each Waste tubing into an empty waste collection beaker. *Note, the 2 port Flush Fixture in the Chemistry Calibrator Cartridge pack bay does not have a tubing labeled “W”.*
6. Gather all the remaining lengths of tubing on each fixture and place them into a beaker containing at least 250 mL of H₂O. Make sure the ends of each piece of tubing are submerged and remain submerged throughout the shutdown procedure.
7. Select the Long-Term Shutdown button and then select Start to begin the Flowpath Purge sequence.
8. The analyzer will drain all residual reagents from its internal tubing and will flush each flowpath with water for several minutes.
9. When the sequence is complete, remove each length of flush fixture tubing from the water beaker and leave them exposed to air; leave the “W” tubing in the waste collection beaker.
10. Select the Start button again to purge the residual water from the internal flowpaths and flush each with air.
11. When the 2nd sequence is complete, remove the flush fixtures and power down the analyzer by using one of the Shutdown buttons from the User Interface.
12. When the User Interface screen becomes black, toggle the main analyzer switch on the back of the system to the OFF position to completely power down the analyzer.

NOTE: Failure to properly switch off power to the FLEX2 following the Long-Term Shutdown procedure could result in analyzer damage.

Start-Up Procedure After a Long-Term Shutdown:

Start-up after a long-term shutdown requires the following, depending on module configuration:

- PN 57510/57526 (x1) pH/Gas MicroSensor Card LV/HV
- PN 57512/57528 (x1) Chemistry MicroSensor Card LV/HV
- PN 57957/58102/54507 (x1) pH/Gas Calibrator Cartridge LV/MV/HV
- PN 58003/58101/53937 (x1) Chemistry Calibrator and Reagent Cartridges LV/MV/HV
- PN 55297 (x1) CDV Reagent Cartridges
- PN 55281 (x1) Chemistry Module Tubing Harness
- PN 55283 (x1) pH/Gas Module Tubing Harness
- PN 58644 (x1) Chemistry Module Deproteinization Card
- PN 58645 (x1) pH/Gas Module Deproteinization Card

To perform the Start-Up Procedure:

1. Ensure the FLEX2 is powered OFF, place both the pH/Gas and Chemistry Module Deproteinization Cards and new Reagent Cartridges, bottle packs, and QC Cartridges in the unit.
2. Install the pH/Gas and Chemistry Module Tubing Harnesses and ensure that the FLEX2 doors are closed.
3. Toggle the power button located in the rear right corner of the FLEX2 to the ON position. The User Interface screen will illuminate and ask for the operator to log in.
4. Once the operator has logged in, the user will have access to the FLEX2 User Interface screen.

The unit will go through several start-up sequences, including a pH/Gas and Chemistry module priming and CDV adjust intensity if applicable, and may take up to 8 minutes. The countdown timer will be displayed in the top right corner of the User Interface screen during the start-up sequence.

5. When the start-up sequence is complete and the countdown timer is no longer displayed in the top right corner of the screen, navigate to the second Home screen and select Maintenance. In the Maintenance menu, run a Module Deproteinization Sequence, which will take about 12 minutes to complete.
6. When the Module Depro Sequence has finished, remove the pH/Gas and Chemistry Module Deproteinization Cards from the unit and replace them with the pH/Gas and Chemistry MicroSensor Cards.

NOTE: The pH/Gas and Chemistry Deproteinization Cards are reusable.

7. The unit will hydrate both the pH/Gas and Chemistry MicroSensor Cards for the next 2 hours simultaneously. During this time, the pH/Gas and Chemistry modules will not be available for sample analysis.
8. Perform a CDV module calibration and/or an Osmometer module calibration using the external Cell Density and Osmo calibration standards if applicable.
9. When the pH/Gas and Chemistry MicroSensor Card hydration period is complete and all modules have been calibrated, test all applicable levels of Quality Control (QC) to verify analyzer performance for each test parameter. Once QC testing is complete, the analyzer will be ready for sample analysis.

If you have any questions/concerns, or require additional information regarding this bulletin, please contact Nova Biomedical Technical Support at (800) 545-6682 (USA) or at (800) 263-5999 (Canada). For customers outside the USA or Canada, please contact your authorized Nova Biomedical distributor.

Thank you for your continued support of Nova Biomedical products.