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1.0 Purpose

This document is to instruct the reader in the basic use of CGMP Purification Systems running Unicorn Control Software.

2.0 Scope

This procedure applies to GE/Amersham systems running Unicorn and executing pre-written and manual programs. This procedure assumes the pumps, valves and outlets are filled with storage buffer and the system power is off.

3.0 Authority and Responsibility

- 3.1 The Manager, Late Process Sciences, and Biopharmaceutical Development Program (BDP) have the authority to define this procedure.
- 3.2 Individuals working with Unicorn software-controlled systems are responsible for following this procedure.
- 3.3 Biopharmaceutical Quality Assurance (BQA) is responsible for quality oversight of this procedure.

4.0 Equipment and Supplies

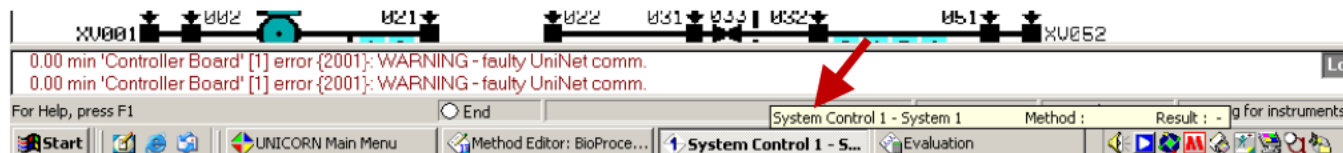
- 4.1 Buffers as defined by the BPR or other process the operator is planning on executing.
- 4.2 Waste Container
- 4.3 Collection containers as outlined by BPR (if applicable).
- 4.4 Safety equipment as required by the chemicals being used and the procedure being performed. If working in the Virus Production Facility [REDACTED] minimum safety equipment is outlined in **SOP 19410 - Gowning Requirements for Personnel and Visitors for the [REDACTED] Virus Production Facility**

- 4.5 Superloop (if applicable), of appropriate size, cleaned, released and ready for use, as per the BPR.
- 4.6 If a column is to be used, the column should have already been packed and attached to the System in the appropriate column position.

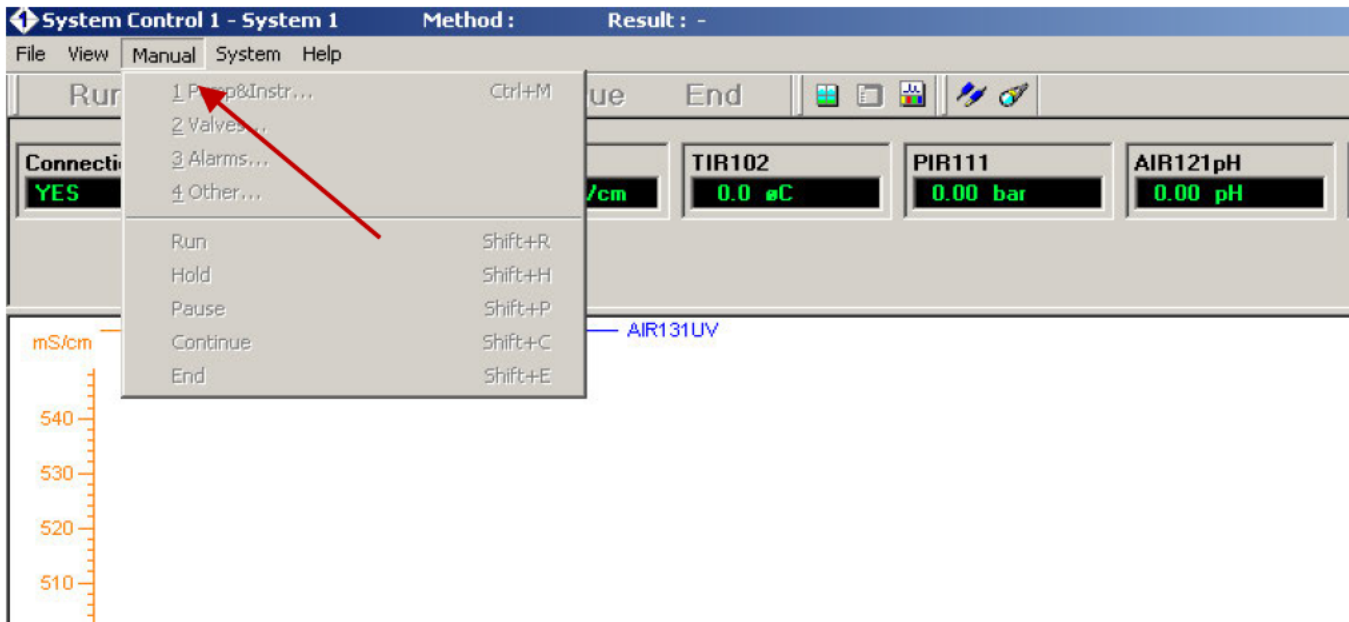
5.0 Procedure

5.1 Running a Program in Manual Mode

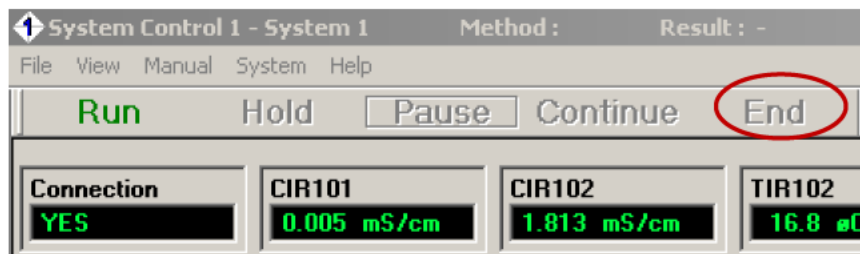
- 5.1.1 Turn on the System.
- 5.1.2 If applicable, open the Nitrogen supply to the system to the recommended pressure indicated by the User's Manual in references 8.5-8.9.
- 5.1.3 Turn on the Computer connected to the System.
- 5.1.4 Start the Unicorn control software.
- 5.1.5 Once the user has logged in with his/her username and password and the System and the computer are communicating with each other, click the system control bar on the bottom middle of the screen. (See image below).



- 5.1.6 Place the waste outlet, or other applicable outlets of the System into an appropriate size waste container. If collection containers are specified by a Master Production Record (MPR) then connect as instructed.
- 5.1.7 Attach the inlet(s) of the System to the applicable buffer(s).
- 5.1.8 Click "**Manual**" on the upper toolbar. (See image below). Click on "**Other**" from the "**Manual**" pull-down menu.



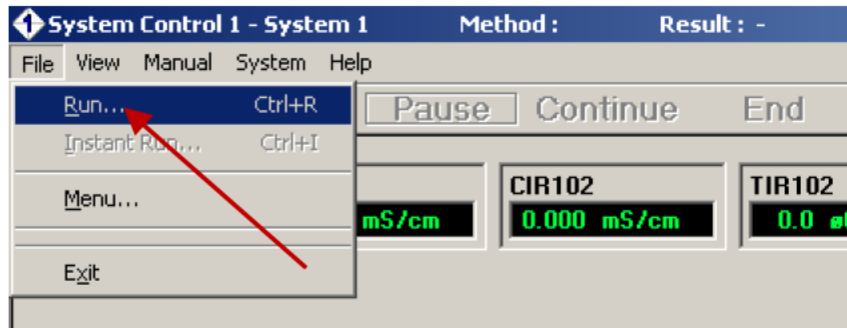
- 5.1.9 Commands are performed by first selecting the command from the menu, clicking the “Insert” box, followed by the “Execute” box. Multiple commands may be inserted prior to executing. To record activities the “Record On” function must be selected in the “Other” menu first. All data prior to execution of this command will not be recorded. If cleaning the System, in the Manual mode select the pathways that correspond to the System’s cleaning SOP in references 8.1-8.3. If following a BPR insert the recommended pathways instructed by the BPR.
- 5.1.10 Each system (e.g. Explorer vs. Pilot) is different in the commands that can be selected. Refer to the appropriate User’s Manual referenced in Section 8 of this SOP for definitions and uses of these commands.
- 5.1.11 When System activities have finished the current program must be ended by clicking the “END” button at the top of the window. See the image below for reference.



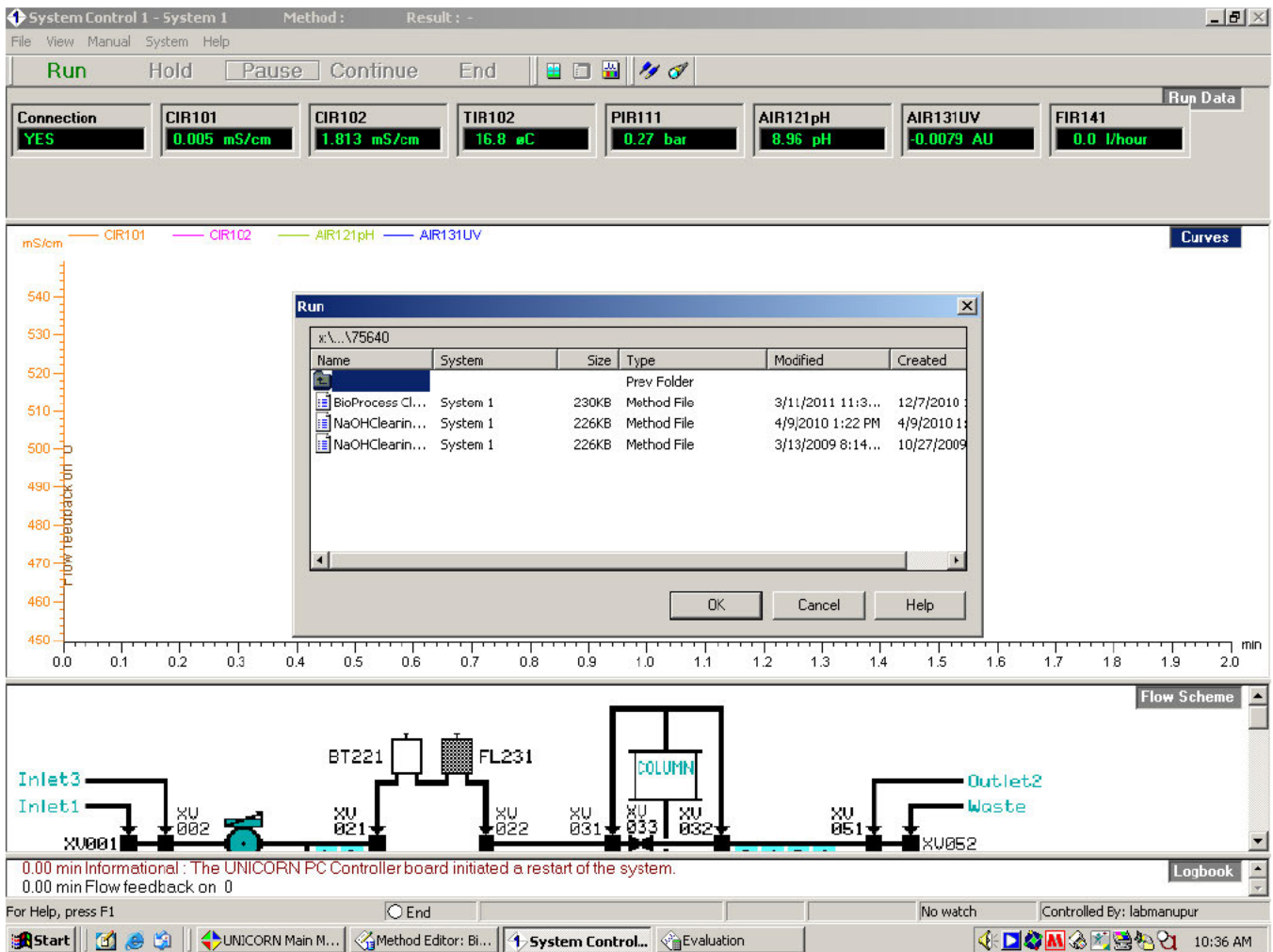
5.2 Selecting and Running a Pre-Written Program

- 5.2.1 Follow instructions in steps 5.1.1 through 5.1.7

5.2.2 From the “**System Control**” window, select “**File.**” From the dropdown menu, select “**Run.**” (See image below for reference).



5.2.3 From the popup window, select the pre-written program that is to be run and click the “**OK**” button. (See image below).





- 5.2.4 In the pre-written program, answer the questions (if any), direct the software to save the result file in the appropriate directory and select the **“Run”** button.
- 5.2.5 The pre-written program will now run.
- 5.2.6 When processing is complete, clean the System per its appropriate SOP in references 8.1-8.3.

6.0 Documentation

- 6.1 Document this procedure on the product specific MPR or another applicable form.

7.0 Definitions

- 7.1 **Sample** – Any solution loaded onto a column by either the sample inlet or the use of a superloop.
- 7.2 **System** – Either the ÄKTA purifier, Explorer, Pilot, Process, or BioProcess and the corresponding computer.

8.0 References and Related Documents

- 8.1 **SOP 14109** Standardization and Cleaning of the 6 mm Bioprocessor Chromatography System
- 8.2 **SOP 14133** Cleaning the AKTA Purifier Chromatography System for CGMP Processes
- 8.3 **SOP 14142** Standardization and Cleaning of the AKTA Pilot Chromatography System
- 8.4 **SOP 19410** Gowning Requirements for Personnel and Visitors for the ██████ Virus Production Facility
- 8.5 ÄKTA Purifier User’s Manual.
- 8.6 ÄKTA Explorer User’s Manual.
- 8.7 ÄKTA Pilot User’s Manual.
- 8.8 ÄKTA Process User’s Manual.
- 8.9 BioProcess System User’s Manual.
- 8.10 Unicorn User Reference Manual
- 8.11 Superloop 150 mL Instructions, Amersham Biosciences, Part 18-1028-73.
- 8.12 Superloop 10 mL, 50 mL Instructions, Amersham Biosciences, Part 56-3015-99.

9.0 Change Summary

