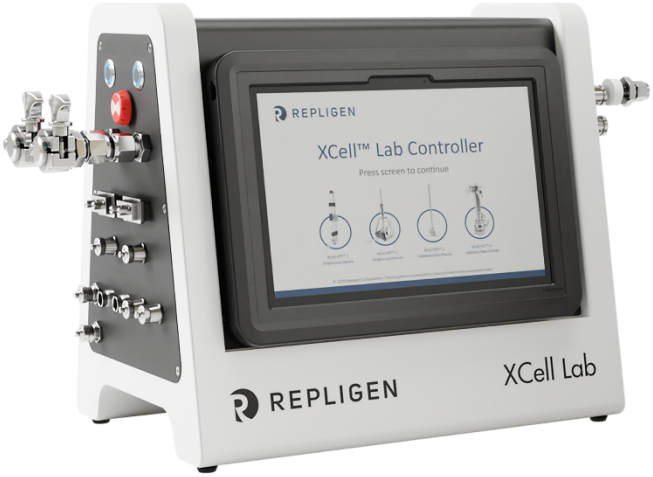
XCell®
Lab Controller

User Guide

PLC Software Version	1.17
HMI Software Version	1.16
Surface Pro	SP7+
Windows Version	10 Pro 20H2
Devices supported	XCell® ATF 1, 2 and 4



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Abbreviations

A-B	Allen-Bradley
AC	Alternating current
Amp	Ampere
ATF	Alternating Tangential Flow
ATF-A	XCell ATF Device A
ATF-B	XCell ATF Device B
AUX	Auxiliary
A2B	XCell ATF Device to Bioreactor connection
A2C	XCell ATF Device to Controller connection
CFM	Cubic feet per meter
CSPR	Cell specific perfusion rate
dB	Decibels
DC	Direct current
DO	Dissolved Oxygen
DPv1	PROFIBUS Decentralized Peripherals version 1
FAS	Field Applications Scientist
FC	Flow control

FS	Flow sensor
FSE	Field Service Engineer
HFM	Hollow Fiber Module
HMI	Human Machine Interface
Hz	Hertz
ID	Inner diameter
I/O	Input/output
kg	Kilograms
L	Liter
lbs.	Pounds
LPM	Liters per minute
mA	Milliamp
mL	Milliliter
mV	Millivolt
NPT	National pipe thread
OD	Outer diameter
OSI	Open systems interconnection
PCV	Pressure control valve
PID	Proportional, integral and derivative
PLC	Programmable logic controller
POI	Product of interest
PRV	Pressure Regulating Valve
PV	Process value
P2	PCV outlet pressure (Commanded pressure)
P3	Permeate pressure
PPE	Personal protective equipment
psi	Pounds per square inch
psig	Pounds per square inch gauge
QC	Quick Connect
SAPA	Supply Air Protection Assembly
SCADA	Supervisory Control and Data Acquisition
SP	Setpoint
SUB	Single-use Bioreactor
TC	Tri-clamp
TCD	Total cell density
TCP/IP	Transmission control protocol / Internet protocol
UF	Ultrafiltration
VCD	Viable cell density
VDC	Volt direct current
VT	Volumetric throughput
VVD	Vessel volume exchange per day

1. Introduction

The XCell® ATF Technology provides a complete solution for the retention of cells, removal of media and, ultimately, the intensification of upstream cell culture processes. It is the most widely used and proven cell retention solution in the world, having been specified in dozens of commercial processes. Thousands of XCell ATF Systems are currently utilized in process development and clinical manufacturing processes. As the gold standard for upstream process intensification, XCell ATF often delivers at least 10 times higher cell concentrations or product throughput than typical batch and fed-batch processes.

The XCell ATF System includes several components: a controller (with air and vacuum accessories), software, sensors and XCell ATF Device.

This User Guide serves as a reference document for your XCell Lab Controller and software; updates are made on a regular basis. For the latest version of this document, please visit the Repligen website. Installation by a trained Repligen Field Service Engineer (FSE) is highly recommended.

2. Product Information

Thank you for choosing the XCell Lab Controller for your laboratory and cell culture intensification needs. This next generation system provides proven upstream intensification performance on an industrial automation platform. The XCell Lab Controller combines performance intensification and ease of use into a single solution. Key components include an easy-to-use software, flow sensors, and air and vacuum accessories (Figure 1). The XCell Lab Controller is designed to meet the challenges of the next wave of high-density intensification processes, which are expected to exceed 250 x 10^6 cells/mL.

Figure 1. XCell Lab Controller and Accessories

1. XCell Lab Controller
2. XCell Lab Software and HMI
3. Flow sensor
4. Supply air protection assembly
5. Vacuum manifold
6. Vacuum pump

Existing XCell ATF users may jump to Section 5 for an abbreviated setup description.

3. About This Document

This manual uses several user attention phrases. Each phrase should draw the following level of attention:

Table 1. Explanation of User Attention Phrases

Phrase	Description
Note:	Points out useful information.
IMPORTANT	Indicates information necessary for proper instrument operation.
PRECAUTION	Cautions users of potential physical injury or instrument damage if the information is not heeded.
WARNING!	Warns users of potential serious physical injury if warnings are not heeded.

Table 2. Safety Precautions

Description of Precautions
Use of safety glasses is recommended during installation, set up, operation and while any service or testing is being performed on the system.
You must use the Supply Air Protection Assembly (SAPA) on your air source to ensure air is brought to a safe pressure, and suitably filtered to ensure pump functionality.
Vessels or bioreactors should not be pressurized unless otherwise specified by the manufacturer. Glass and single-use bags can explode if pressurized. When using any vessel or bioreactor, be sure to maintain an unrestricted vent or exhaust from the vessel. This will ensure that no significant pressure or vacuum occurs in the bioreactor. In the case of a diaphragm failure, for example, air will penetrate the XCell ATF Device, through the filter and into the vessel. A free exhaust from the vessel will minimize the build-up of pressure in the vessel.
You must replace the air filter on Stainless Steel XCell ATF Devices (ATF2 and ATF4) prior to operation.
When not in use, you should ensure all the tubing is capped or blocked using the provided caps and valves. It is recommended to keep unused tubing in the original sealed bag.

Table 3. Safety Warnings

Description of Warnings
Power: Do not open powered-on XCell Lab Controller enclosure. Remove power from equipment before attempting any maintenance. Calibration, preventive maintenance and repair to be performed only by trained, qualified personnel.
Use only Repligen provided power supply. Use only high voltage cord specific for your region provided by Repligen. Do not use a damaged power supply or damaged power cord.
Tubing: Tubing breakage between the XCell ATF filtration device and bioreactor may result in fluid being sprayed from pump. Use appropriate measures to protect operator and equipment.
Do not perform cleaning (wipe down) of the XCell Lab Controller when the enclosure cover is open. Confirm all connectors (connection bulkheads) are firmly seated in their respective sockets.
Weight: XCell Lab Controller weighs 44 lbs. (15.5 kg). When the enclosure must be moved, use necessary precautions prior to and during the movement. Make sure no electrical, pneumatic or signal connections are made when system is moved.
Wear standard laboratory PPE, including lab coat, protective eye wear and gloves.
Air and vacuum: XCell Lab Controller requires pneumatic connections of positive air pressure and vacuum using Repligen provided hoses with safety quick connectors. Positive air pressure tubing is colored red while vacuum tubing is colored blue. The connection points are identified as Pressure and Vacuum. The pneumatic lines should be kept free from dust and particles. Please ensure the following: • The air filters on the controller in the A2C line are always present, and changed out during the annual PM. • The A2C lines have ball valves that should be turned to closed position when they are not connected to an XCell ATF Device. • When the equipment is not being used, the A2C lines should be capped. • The SAPA unit should always be connected to the controller.
Supply Air Protection Assembly (SAPA): While almost all labs do filter incoming air, Repligen cannot warranty the controller without the use of a SAPA on the incoming line, which filters the air entering the XCell Lab controller. The Supply Air Protection Assembly must be mounted to a solid support, either a wall or table.

4. Quick-start Guide

If you are an experienced XCell ATF user and already familiar with the set-up guide and Health and Safety guidelines, then this section will help you get set-up quickly. If you need further guidance, please review the full User Guide, including the Appendices, or reach out to a local FAS.

4.1 Connections

Connect all components as described below:

1. Orient the controller on the bench as you see appropriate for your bioreactor setup. A maximum of two controllers can be stacked vertically.
2. Place the tablet in a convenient location, either on the controller or attached to a shelf.
3. Connect the XCell ATF Device(s) to the bioreactor using the A2B tubing kit supplied by Repligen.
4. Use the correctly sized/labelled A2C tubing for the XCell ATF Device you plan to use.
5. Connect the air utility line to the SAPA, through the manifold and then to up to four controllers. Use the supplied adaptors if needed.
6. Connect your lab vacuum supply or Repligen supplied vacuum pump to the vacuum manifold. Use the supplied adaptors if needed.
7. Prepare the XCell ATF Device(s) according to the appropriate device set-up guide.
8. Make sure the flow sensor is correctly oriented and stably positioned on the A2B tubing in a location where air bubbles are not likely to collect within the tubing.
9. Connect the permeate pressure sensor (P3), if used.
10. To supply power to the controller, connect the 24 V adaptor to the wall power source.

11. Turn on the controller and tablet. By default, no logon credentials are required for the tablet. The XCell Lab Software opens with the **Supervisor** account and displays the **Overview** screen.

Note: *Prior to changing or replacing the XCell ATF Device, disconnect the air utility line and vacuum supply line from the XCell Lab Controller and close the manual valve on the A2C tubing. Change or replace the XCell ATF Device, then open the manual valve on the A2C tubing and reconnect the air utility line and vacuum supply line.*

4.2 Software Set-up

Please note the following:

- The newly designed software interface allows you to make real-time changes to the setpoints.
- During operation, certain buttons are pre-programmed to be greyed out and remain non-functional to prevent unnecessary and undesired changes (for example, change of XCell ATF Device size is not allowed while the device is running).
- Certain options and buttons will not be visible if you are logged in as a **User** (limited access). With auto login enabled, the default user level **Supervisor** allows complete access.
- Default settings typically are suitable for most processes; no further adjustments should be required.

To get started:

1. On the main menu (top), click the **Settings** button, which displays the **Settings** sub-menu.
2. The first (and default) button, **ATF configuration**, allows selection of ATF size and filter type.
3. Click the second button, **Bioreactor configuration**, to change the default settings of one ATF attached to a bioreactor.
4. Other buttons allow you to change date and time formats, pump settings, flow rates etc.

4.3 XCell ATF Device Start-up

1. Click the **ATF** button on the main menu to open the **ATF Main** Screen.
2. Click the **ATF Flow** box or the ATF graphic, both of which open a pop-up window.
3. Click **Start**. The priming sequence begins, and the run starts.

Note: *The user can change the setpoints at any time before starting a run and during a run.*

4.4 Optimization

It is important to optimize process conditions. The guidelines in this document provide a useful resource as you plan your process development, but please reach out to your local FAS for consultation during optimization, scale-up and scale down experimental design or data review.

5. XCell ATF Technology Overview and Process Intensification

The XCell ATF Technology provides a complete solution for the retention of cells, removal of media and ultimately the intensification of upstream cell culture processes. XCell ATF Devices are often used in continuous upstream processes, also called perfusion, but are equally beneficial in fed-batch and hybrid processes. Examples of application of a cell retention device for fed- batch include:

- N-1 processes using short periods of perfusion to boost cell growth or regular media exchange
- High Productivity Harvest (HPH) application for fed-batch gene therapy, vaccine, mAb and recombinant processes to boost productivity while also eliminating both centrifugation and depth filtration unit operations.
- Perfusion for continuous processing
- Vaccine and viral process intensification

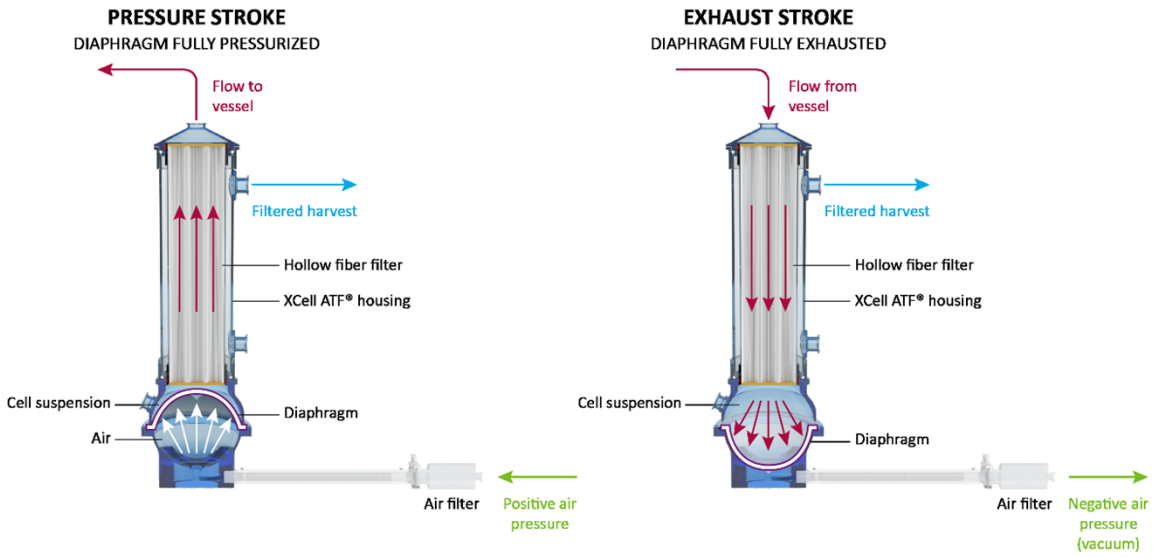
Repligen has an experienced global team of scientists ready to support the development, optimization, scale-up and troubleshooting of XCell ATF intensified cell culture processes. For support or troubleshooting, please contact your local FAS.

A preventative maintenance (PM) contract ensures continued operation of the system at optimal performance levels. The pneumatic parts that are connected to the controller and SAPA should always remain free of dust and particles. Refer to Table 2 for additional safety precautions.

5.1 Alternating Tangential Flow (ATF) Filtration

The diaphragm pump of the XCell ATF System generates alternating tangential flow (ATF) through hollow fiber filters. ATF is a low shear, rapid, pulsating, and bi-directional flow of cell suspension between a bioreactor and a diaphragm pump (Figure 2). Cell culture moves in a continuous back and forth motion through the lumen of the hollow fiber filters. Two strokes of the diaphragm pump, the Pressure stroke (P-stroke) and the Exhaust stroke (E-stroke), complete each back-and-forth cycle. Delivery of positive air pressure to the base of the diaphragm by the pressure control valve in the controller initiates the P-stroke. Positive air pressure pushes the diaphragm up from the *air-side* hemisphere of the device, driving liquid from the diaphragm pump through the lumen of the hollow fiber filters and back to the bioreactor. Replacement of the positive pressure under the diaphragm pump with a vacuum initiates the E-stroke. The vacuum pulls the diaphragm down from the *liquid-side* hemisphere of the device, pulling liquid from the bioreactor through the hollow fiber lumens and towards the diaphragm pump.

Figure 2. ATF Pressure and Exhaust Strokes



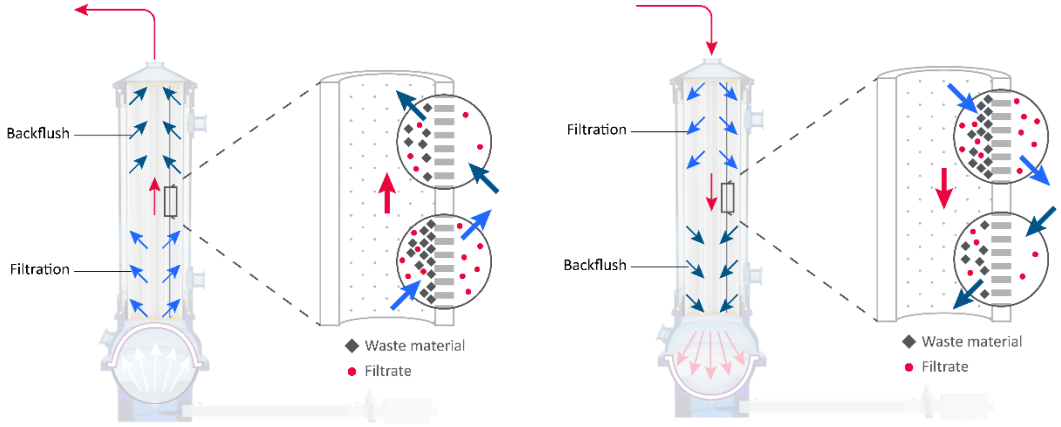
5.2 ATF Backflush

In most tangential flow filtration processes, liquid typically only moves across the filter from the retentate side to the filtrate side. During ATF, liquid moves both from the retentate side to the filtrate side as well as from the filtrate side to the retentate side. Liquid transfer from the filtrate side to the retentate side is referred to as *backflush* and the action plays an essential role in the differentiated ATF performance (Figure 3). Alternating flow generates negative pressure across the hollow fiber filter during each pump stroke. The section of the hollow fiber experiencing the negative pressure (and the consequential backflush) depends on the direction of the pump stroke. Backflush effectively reduces or eliminates filter fouling by displacing material from the lumen wall.

Incorrect ATF operation with insufficient pump displacement and/or low ATF flow rates create reduced levels of backflush, which can compromise results. Smart mechanisms, built into the algorithm and alarms (both default and user defined), automatically compensate and help minimize fouling. The Troubleshooting Section, provides additional approaches and solutions to fouling and other frequently observed challenges.

5.3 ATF Flow Rates and Displacement Volumes

Figure 3. Backflush Example



Backflush In Pressure Stroke (Left); Backflush In Exhaust Stroke (Right)

The flow rate of cell culture liquid from A2B does not remain constant over the course of a pump stroke. As the diaphragm begins to move from a stationary position, the flow rate starts relatively low. As the diaphragm travels further, the flow begins to increase and reaches a maximum value approximately at the midpoint. Toward the end of the diaphragm trajectory, the flow rate once again begins to slow. The change in the flow rate over the course of the pump stroke may therefore be considered sinusoidal. The controller records the *instantaneous flow rate* approximately every ~100 ms during each stroke (ml/min) and then averages all stroke measurements over the cycle to generate the *ATF flow rate*. The ATF flow rate contains data averaged over 10 cycles, which largely eliminates outliers and noise.

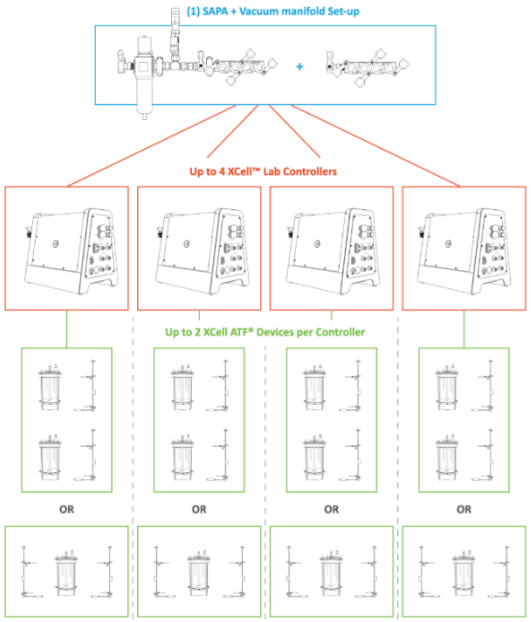
The ATF flow rate is controlled by entering a value for the *ATF Flow Rate Set Point*. Due to the sinusoidal nature of the flow rate over the course of an ATF cycle, the measured instantaneous flow rate may be either higher or lower than the reported ATF flow rate over the course of each stroke. Generally, you do not need to consider the Instantaneous Flow Rate, except during troubleshooting. A well-controlled XCell ATF Device will have the following flow rate properties:

- achieves maximum flow quickly
- switches smoothly between strokes
- minimal to no delay between strokes (referred to as the *Dwell Time*)
- maximum liquid displacement during strokes (referred to as *Displacement Volume*)

The recommended ATF Flow Rate Set Points and the typical Displacement Volumes are programmed into the ATF System as default values. The calculated average displacement volume from the flow sensor is updated every 30 minutes to further improve the response accuracy.

6. XCell Lab System Configurations

Figure 4. Configuration - Bioreactor, Controller, and Utilities



The XCell ATF Lab System is designed to support multiple controllers simultaneously. Each controller, in turn, supports multiple devices and bioreactors (Figure 4). The multiplicity from your utilities to your bioreactors provides significant facility and configuration flexibility. Both positive air pressure and the vacuum source lines connect to intermediate manifolds with one input and four outputs. Volumetric air flow and vacuum requirements will vary with the number of controllers as well as the number and the model of filtration devices used.

A dedicated tablet running the XCell Lab Software operates each controller.

- Each controller supports up to 2 XCell ATF Devices, depending on the model purchased.
- The XCell Lab Controller will run XCell ATF 1, 2, and 4 Devices, with adjustment of A2C tubing, A2B tubing, and flow sensor.
- Two XCell ATF Devices from a single controller may be connected to two bioreactors. Alternatively, two XCell ATF Devices from a single controller may be connected to a single bioreactor for an increased rate of media exchange.

6.1 XCell Lab Controller Features

XCell Lab Controller is available in two models (Table 4). Controller model number XC-LAB-D-P utilizes a permeate pressure sensor to gain insight into real-time filter performance and fouling characteristics. This data helps determine when a filter should be replaced and improves scale-up prediction.

Table 4. XCell Lab Controller Key Features

Features	XC-LAB-D	XC-LAB-D-P
Single ATF Operation	✓	✓
Dual ATF Operation	✓	✓
In/Out of Phase or Independent Dual Operation	✓	✓
Transmembrane Pressure (P3)	×	✓
Single Use XCell ATF 1	✓	✓
Single Use XCell ATF 2	✓	✓
Autoclavable XCell ATF 2	✓	✓
Autoclavable XCell ATF 4	✓	✓

If monitoring filter fouling and permeate pressure is important to your process, then you should consider purchasing the D-P model as this feature is not available on the D model. The controller is powered by a 110-220 V AC source that is converted to 24 V DC. International AC connectors for the United States, United Kingdom, European Union, and China are included with your shipment. Locations that utilize an adaptor outside this set of four will require a customer provided adaptor.

7. XCell Lab Controller Components and Hardware

The XCell LS Controller is powered by a 110-220 V AC source that is converted to 24 V DC. International AC connectors for the United States, United Kingdom, European Union, and China are included with your shipment. Other locations will require a customer-provided adaptor.

7.1 XCell Lab Controller Key Components (Enclosed)

7.1.1 Programmable Logic Controller

The PLC is an Allen-Bradley CompactLogix™ L19ER controller. It mounts to the DIN rail within the enclosure. The PLC has an embedded power supply module with an input voltage rating of 24VDC and an output voltage rating of 5VDC. The power supply provides power to the controller and I/O communication modules including Modbus communication cards.

7.1.2 Pressure Control Valve Assembly

The Pressure Control Valve (PCV) assembly is responsible for controlling the diaphragm pressure for each XCell ATF Device. The PCV is an assembly of two dedicated control valves mounted to the bottom of the enclosure, each driving one of the XCell ATF Devices: A or B. The valves have an integrated pressure sensor for ATF diaphragm pressure measurement and control. The assembly receives the pressure and vacuum supply lines and distributes them to each of the individual valves using a common manifold.

Each PCV output is connected to an XCell ATF Device using the A2C tubing kit. The A2C tubing contains a manual isolation valve to shut off the pneumatic connection at the XCell ATF Device.

The PCV requires clean, dry (≤-40° C dew point) air at 15 psig + 5% psig (25.00 to 26.25 psig), filtered with a 0.1-micron fine grade coalescing filter. All controller pneumatic outputs contain a 0.4-micron filter to protect the PCV from ingress of debris during the vacuum stroke. The PCV assembly runs on 24VDC.

7.1.3 Pressure Transmitter (XC-LAB-D-P model only)

A pressure transmitter that accepts the permeate pressure P3 sensor connections from the field and communicates the values over Modbus RTU to the PLC. The transmitter accepts two (2) signals to process permeate pressure on each ATF. It is mounted on the DIN rail inside of the enclosure. The transmitter runs on 24VDC.

7.2 Field Instrumentation

7.2.1 Flowmeters

Flowmeters are deployed on the A2B tubing to capture the flowrate of the fluid exchange between the ATF filter and the bioreactor. The retentate (A2B) flow signal is communicated to the PLC where it is totalized and inputs into the algorithm for adjusting the pressure curve. The XCell ATF 10 Device has the option to run one or two flowmeters. The flowmeters are connected back to the XCell ATF Controller using sensor cables. Options include FS-4, FS-6, FS-10L & FS-10R.

7.2.2 Permeate Pressure Sensors

Optional pressure sensors are deployed in the permeate tubing to measure the pressure. The sensors are connected to the pressure transmitter which communicates the values to the PLC. The beginning of the ATF process will yield a slight negative pressure, and over time will become more and more negative as the filter begins to foul.

8. Connecting the XCell Lab Controller

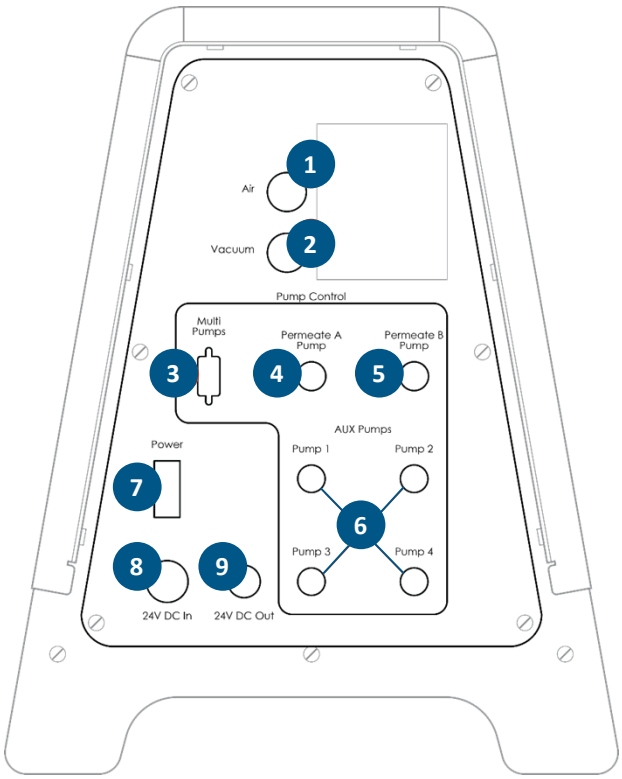
The controller has two faces with utility ports and controls. Face A of the controller governs utility inputs, including the vacuum, air and electric power to the enclosure (Figure 5). Face A also includes the power switch for the controller. Note that some ports on Face A may not be used in the current model.

Note: *The utility tubing set provided connects to the air and vacuum ports (Figure 5). The air tubing connects the controller to the SAPA, not directly to your lab utility source.*

Face B of the controller (Figure 6) governs output operations, including connection to the XCell ATF Device and relevant sensors.

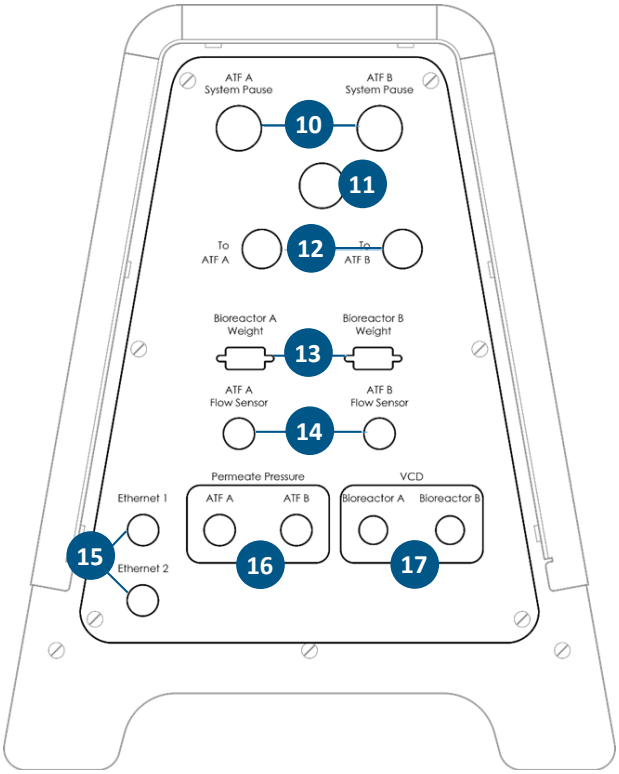
Note: *One ethernet port is required for a headless XCell Lab Controller unit to be integrated with the end-user DCS system.*

Figure 5. Face A of Controller



1. Air
2. Vacuum
3. Multi-pumps
4. Permeate A pump
5. Permeate B pump
6. AUX Pumps
7. Power switch
8. 24V DC in
9. 24V DC out

Figure 6. Face B of Controller



10. ATF A/B System pause
11. Alarm
12. To ATF A/B
13. Bioreactor A/B Weight
14. ATF A/B Flow Sensor
15. Ethernet
16. ATF A/B Permeate pressure
17. VCD – Bioreactor A/B

Table 5. Controller Face A and B Item Descriptions

	Item	Description
1	Air	Positive air pressure from SAPA
2	Vacuum	Vacuum line from facility line or vacuum pump manifold
3	Multi-pumps	*NOT CURRENTLY USED*
4	Permeate A pump	*NOT CURRENTLY USED*
5	Permeate B pump	*NOT CURRENTLY USED*
6	AUX Pumps	*NOT CURRENTLY USED*
7	Power switch	Power on/off
8	24V DC in	DC power from power supply
9	24V DC out	*NOT CURRENTLY USED*
10	ATF A / B System pause	Pause buttons for ATF A and ATF B LED light to indicate status
11	Alarm	Visual alarm (audio optional)
12	To ATF A / B	A2C connections for air pressure and vacuum to ATF filtration devices
13	Bioreactor A / B Weight	*NOT CURRENTLY USED*
14	ATF A / B Flow Sensor	A2B retentate line flow sensor connections from filtration devices

	Item	Description
15	Ethernet	1 and 2: Communication between controller and HMI (M12 via ethernet to RJ45 USB adapter on HMI); Two M12 8-pin bulkhead ports are provided to enable connection to an ethernet network using a M12 to RJ45 cable. The enclosure ports connect directly to the PLC ports, which contains a dedicated switch. These ports provide the infrastructure for the integration of the XCell Lab Controller into an existing distributed control system (DCS) system using Ethernet I/P protocols.
16	ATF A / B Permeate pressure	Permeate line P3 pressure sensor inlet connections
17	VCD – Bioreactor A / B	*NOT CURRENTLY USED*

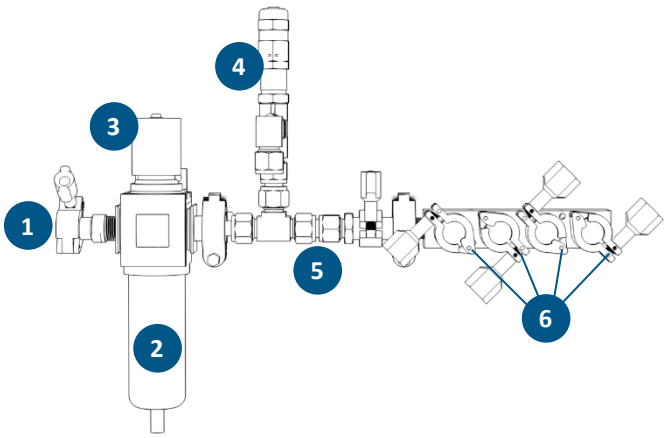
Two manual pause buttons (item 10) allow each device to be independently paused. The alarm (11) alerts the user when attention is required. The A2C lines (12) provide positive and negative air pressure to the XCell ATF Device. Pressure (16) and flow (14) sensor ports carry data from the device-mounted sensor to the controller. An ethernet port (15) transfers data to a tablet for viewing, processing, and analysis. Like Face A, some ports of Face B are not used in the current model.

The software interface is accessed through a Surface Pro tablet, provided in a protective case. The tablet may be mounted directly on the controller or to a shelf, using a bracket and moveable support arm. Each controller requires a dedicated tablet that uses a wired ethernet connection to the controller port.

8.1 Pneumatics Connectivity

8.1.1 Utility Supply to Controller — SAPA and Utility Tubing

Figure 7. SAPA Components



1. Manifold inlet
2. Filter unit
3. Pressure regulator
4. Pressure relief valve
5. Positive pressure supply manifold
6. Manifold outlets

Table 6. SAPA Item Descriptions

Item		Description
1	Manifold inlet	Pressurized air from air supply
2	Filter unit	Filters air routing from air supply to manifold Filter porosity: 0.3
3	Pressure regulator	Factory set air pressure supply regulator designed to downregulate the supply air to a lower pressure required to operate XCell ATF 1, XCell ATF 2 and XCell ATF 4 (do not adjust)
4	Pressure relief valve	Factory set air supply pressure relief valve set to relieve if inlet pressure exceeds the specification noted above (do not adjust)
5	Positive pressure supply manifold	Pressurized air to XCell Lab Controller(s)
6	Manifold outlets	Distributes air pressure to up to four XCell Lab Controllers

The SAPA normalizes air pressure from the lab utility line down to the required 15.6 psi. The minimum utility air pressure requirement is 30 psi. A pressure relief valve provides safety in case of the unlikely failure of the regulator (Figure 7). The regulator and relief valve are pre-set at the factory; no modification is required by the end user. Installation should be performed or supervised by an authorized Repligen service engineer.

Note: *The SAPA must be installed with the air filter oriented downwards and plumbed.*

8.1.2 ATF to Controller Connection

The A2C tubing set connects the XCell ATF Device to the controller via a pneumatic line. Each XCell ATF Device requires a specific A2B and A2C tubing set size. The controller ships with a collection of A2C tubing sets suitable for all devices (ATF1, ATF2 and ATF4). The A2C tubing may appear to be similar – but they are not – and each is designed to function with a specific XCell ATF device size. Labeling on the tube sets indicates use with an ATF1, ATF2 or ATF4 device.

8.2 ATF to Bioreactor Connection

Fluid management for XCell ATF Systems includes retentate (ATF-to-Bioreactor or A2B) tube set kits and accessories that connect the housing with the bioreactor, ensuring proper exchange of cell culture material.

8.2.1 ATF Process Flow and Pressure Measurements

A flow sensor on the A2B line, engineered specifically for XCell ATF applications, requires a specific tubing OD and tubing type. Tube sets with a permeate pressure sensor also are available. Both the flow sensor and the pressure sensor connect directly to the controller. The device specific setup-guides describe tube set specifications in detail. A brief summary is provided in the table below.

Table 7. A2B Tubing ID/OD

Device	Tubing ID /OD	Repligen Supplied Tube Set?
XCell ATF 1	⅛" / ¼"	Yes, part of device
XCell ATF 2	¼" / ⅜"	Yes, available separately
XCell ATF 4	⅜" / ⅝"	Yes, available separately

Please reach out to your local Repligen representative for more information.

9. XCell ATF Device Preparation and Set-up

Set up guides, included with each XCell ATF Device, describe how to assemble, wet, autoclave (if stainless steel), test, and connect the XCell ATF Device to the controller. For stainless steel devices, the autoclavable filter preparation guide comes in the box with each filter.

Please refer to the separate XCell Lab Controller Set-up Guide provided with the equipment. Access the most up to date version online.

9.1 IT, Wi-Fi and Network Connectivity

The XCell Lab is designed as a stand-alone control system. Both a wired ethernet and Wi-Fi are available for data transfer on the HMI tablet. Repligen does not support integration of the tablet into a network in any way. Please see Appendix B for further details.

9.1.1 Windows Environment

The Surface Pro comes with Windows® 10 Pro installed. The user bears full responsibility for modifications to the software system. These software changes include, but are not limited to, Windows software updates, anti-virus applications, and Microsoft® Office products. While we do not expect any impact to the functionality of the Repligen supplied programs through typical use and/or Windows maintenance, we cannot guarantee the correct functioning of the system.

XCell software is easy and intuitive to use. It is an AVEVA™ Wonderware View application, with several useful software modules included in this release including Historian, Query, and Trend.

9.1.2 Ethernet Remote Monitoring

Process data is recorded locally. XCell Lab also allows for remote monitoring by connecting to a DCS using DeltaV™.

9.1.3 DeltaV Integration Via DeltaV Landing Module

The DeltaV Landing Module is designed to facilitate the integration of an XCell Lab Controller to a DeltaV System. Please refer to the XCell Lab Controller Integration Guide and DeltaV Landing Module for further details. Integration into DeltaV is supported by the XCell Lab Controller architecture with physical connections to Ethernet/IP (M12, D-Code, female). Ethernet I/P communication protocols are supported.

DeltaV code is provided in the form of FHX (.fhx) files that can be imported into DeltaV. These files provide a synchronous relationship that enables control and status information to pass between the DeltaV System and the XCell Lab Controller PLC code.

10. XCell Lab Controller HMI

10.1 Human Machine Interface (HMI)

The XCell Lab HMI, offered as XC-LAB-HMI-KIT, is a Supervisory Control and Data Acquisition (SCADA) system that allows ATF configuration, process control, and monitoring of ATF operations. The interface enables users to monitor the status of equipment and issue command setpoints, enables quick user input and easy navigation between screens, and enables managing alarms, trending process data, and tracking events. The XCell LSC HMI allows a single user interface to control one XCell LS Controller, one user directory to manage log in and security, and Ethernet/IP based communication between XC-LAB-HMI-KIT and the XCell Lab Controller.

The user interface is designed to be intuitive and simple to use. Offered as an HMI tablet XC-LAB-HMI-KIT, hardware includes a Microsoft Surface Pro HMI tablet encased in an IP65 rated packaging, a US power cable, pedestal mount arm, Ethernet cable (RJ45 to M12), and three USB extension cables. The HMI tablet runs on Microsoft Windows 10 Professional operating system. Process visualization, control, and data management is accomplished via pre-installed AVEVA Wonderware SCADA software. AVEVA Wonderware Historian Database and the AVEVA Wonderware Trend and Query applications provide a point-and-click interface to access, analyze, and graph data (both current and historical). These applications can be accessed by all XCell Software users and do

not require any programming or database knowledge. Using the query tool, users can select tags and data reporting frequency and export the data as a .csv file for analysis.

The SCADA software notifies the user of any alarms that are triggered during runtime. Flow, pressure, configuration, communication, and applicable performance criteria are alarmed within the controller. These are visible in an alarm log where they can be acknowledged if necessary. The alarms are also stored in the historian database within the event logger tool with information about when they occurred and when the alarm was acknowledged and by whom.

The XC-LAB-HMI-KIT has level-based security that utilizes Windows user administration group assignments. During integration the end-user's system must have users appropriately assigned to the applicable user group for the security to be effective.

10.2 Touchscreen and Touchpad

Figure 8. Touchscreen Splash Display Example

The user interface is designed to be intuitive and simple to use. The XCell Lab Controller is controlled and operated using a touchscreen tablet. The touchscreen enables quick user input and easy navigation between different screens. A touchpad is also provided for use with the Query and Trend Tools, for executing more complicated and advanced selections.

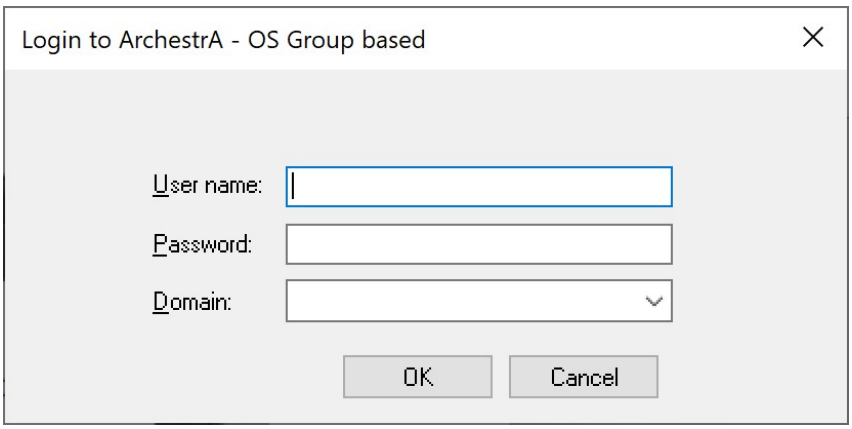
10.3 Initial Startup

The tablet will boot directly into the XCell Lab Software program and display the splash screen (Figure 8) when switched on. Login to Windows is not required. To add a Windows login, please see Appendix E.

As the program loads, it will display **Loading…** and then either ask for a login or go straight to the **Overview** screen if login is disabled.

10.4 Login Screen and Default Password

Figure 9. Login Screen Example

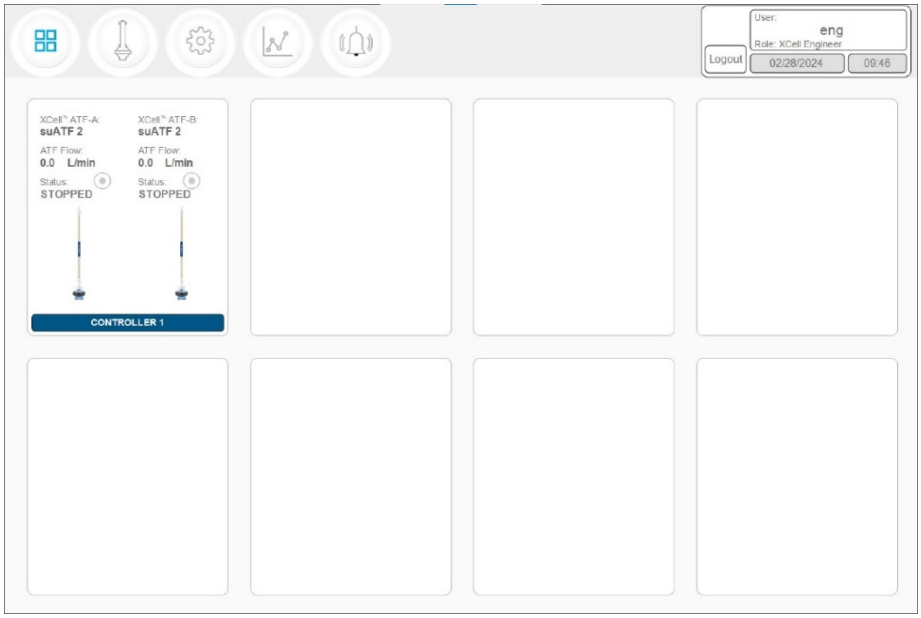


When you load the software for the first time, the login screen will not display. Security is turned off as a default setting. Once security is enabled, the following login screen (Figure 9) appears, requiring a username and password. Default usernames and passwords are in listed in Table 8.

Table 8. Preset Usernames and Passwords

Username	Password
Opr	1234
Eng	1234
Super	1234

Figure 10. Overview/SCADA Screen Example

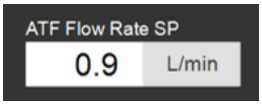


The **Overview** screen displays the connectivity of several controllers and devices (Figure 10). Currently, the XCell Lab Software manages one controller (up to two devices) per tablet.

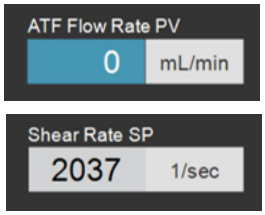
From this menu, you may choose to explore options by pressing a menu item in the top left. Access the **Main ATF** Screen by pressing the **ATF** Button.

10.5 User Interface Formats and Conventions

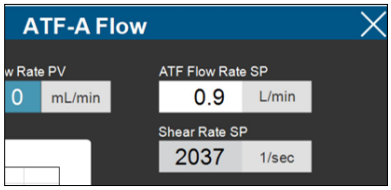
The software is designed with careful consideration of colors, formats, and conventions to quickly build familiarization. These are briefly described below.



Boxes that allow user input have white backgrounds (such as ATF flow rate setpoint).



Boxes that do not allow user input either have a colored background (such as some Process Values) or a grey background (such as fixed dimensions of a filter, shear rate or values for informational purposes only).



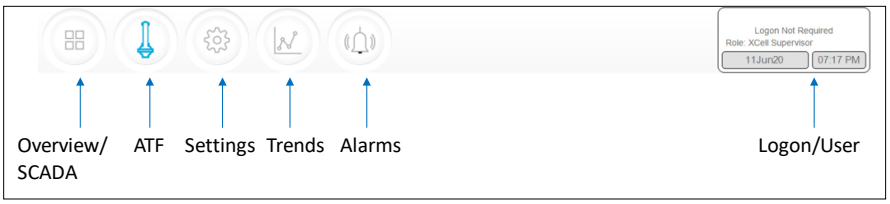
Close pop-ups by selecting X in the top right corner of the screen.

Device start, pause and stop features are highlighted green, yellow, and red, respectively, when active.

Note: *Some options may be greyed out or missing from your software version. This could be either due to the version of hardware purchased (S, D, or D-P), or because the device configuration chosen does not support that feature (e.g., dual mode with different sized XCell ATF Devices).*

10.6 Screen Navigation

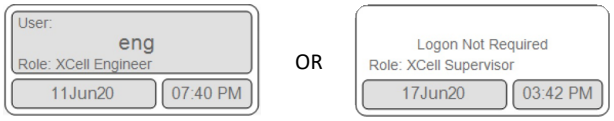
Figure 11. Menu Bar Example



The menu bar displays six options at the top of the screen (Figure 11). The blue highlighted button indicates the screen currently active. To change to another screen, just press one of the other buttons.

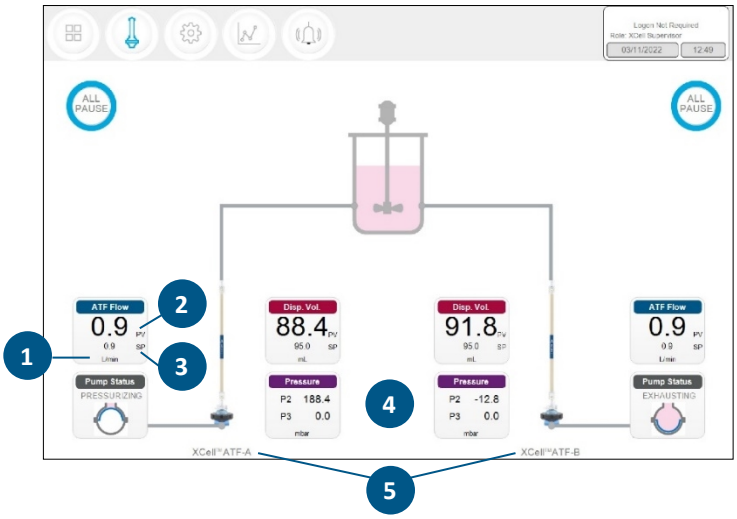
1. **Overview/SCADA Button**
   Navigates to the SCADA area that can show up to 8 connected controllers. Only one controller is currently supported by the XCell Lab Software.
2. **ATF Button**
   Navigates to the Main Screen, also called the ATF Screen.
3. **Settings Button**
   Displays settings for both controller and XCell ATF Devices. This screen enables access and modification of ATF size and type, bioreactor settings, engineering units, run time, and service information.
4. **Trends Button**
   Displays data trends and plots.
5. **Alarms Button**
   Displays historical alarms and settings for alarm set-up.
6. **Logon/User Button**
   If security is enabled, the logon sub-menu displays username and role. If security is disabled, then **Logon Not Required** message is displayed (Figure 12). The logon display also acts as a menu, accessing the option to switch users or log out. User roles, access level and permission rights are described in more detail in Appendix B. Date and time, the formats of which can be changed in **Settings**, are included in this display.

Figure 12. User Information



When security is enabled (left) vs disabled (right)

Figure 13. ATF Main Screen Example: Two XCell ATF Devices Attached to Same Vessel



1. Units
2. Process value (bold)
3. Set point (SP)
4. P2, P3
5. XCell ATF Device labels

The **ATF main** screen (Figure 13) displays sensors and information appropriate for connected hardware. **Figure 13** shows two XCell ATF Devices on a single vessel. The permeate pressure (P3) is also displayed on the screen (controller model XC-LAB-D-P).

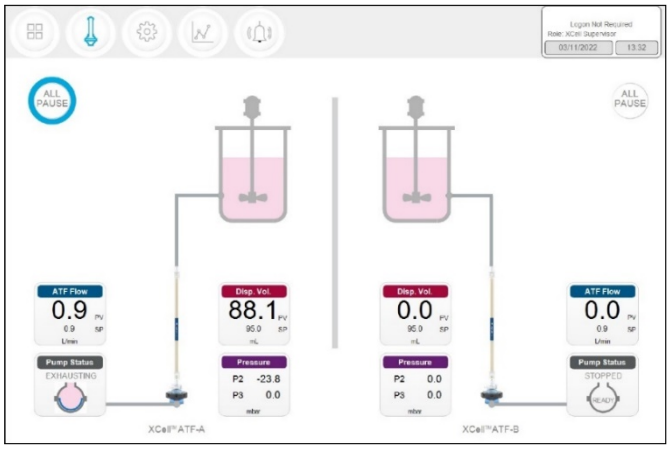
Note: *Throughout the software and this guide, each XCell ATF Device is described as* ***XCellATF-A*** *and* ***XCellATF-B****. XCell ATF Device sizes are specified in* ***Settings****.*

Note: *The* ***ATF DUAL*** *box is only displayed when it is possible to run in dual mode (i.e. two same sized XCell ATF Devices on one bioreactor) and includes the synchronization mode of the pumps. In independent mode, grey dotted lines appear from the* ***ATF Flow*** *box to the* ***Pump Status*** *box (Figure 13). In synchronized mode, grey dotted lines appear from the* ***ATF DUAL*** *box to the* ***Pump Status*** *box (Figure 14).*

Figure 14 shows two XCell ATF Devices connected to one bioreactor as a dual system with the two pumps working out-of-phase**.** The ATF DUAL box displays **Out of Phase** pump status. Please refer to Table 10 for pump status details.

Note: *To change the* ***ATF Flow Set*** *point, you must open the* ***ATF DUAL*** *box – you cannot change the setpoints in the respective* ***ATF-A Flow*** *and* ***ATF-B Flow*** *boxes since the devices are now linked out of phase.*

Figure 14. Example: Two XCell ATF Devices Attached to Two Bioreactors



Note: *When an XCell ATF Device is not running, the* ***ATF Flow*** *displays a zero value and the corresponding* ***All Pause*** *button is greyed out (Figure 15).*

Figure 15. Example: Dual or Single Controller Using Single XCell ATF Device

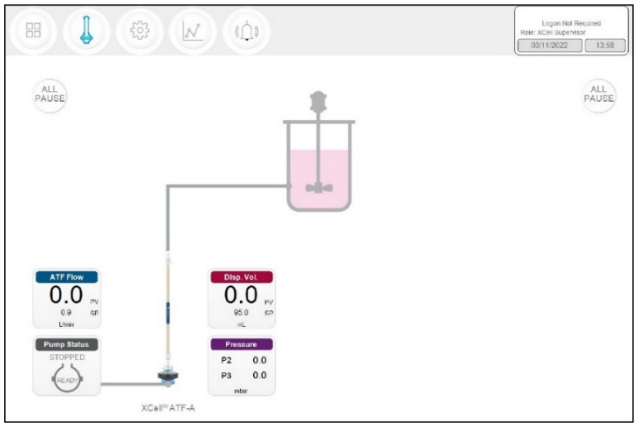
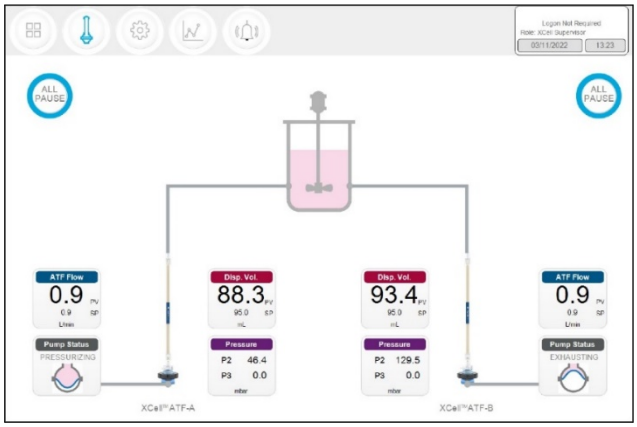
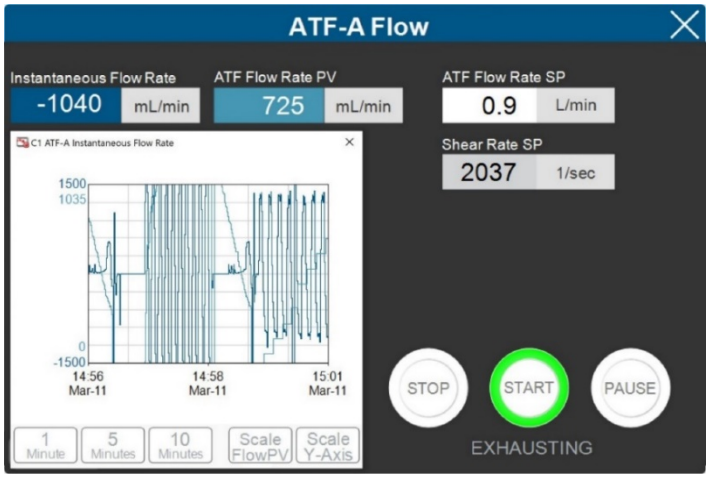


Figure 16. Example: Two Synchronized, Out of Phase, XCell ATF Devices Attached to the Same Bioreactor



A **D** (dual) or **D-P** model controller configured for a single XCell ATF Device will display one XCell ATF Device and one bioreactor (Figure 16).

Figure 17. ATF Flow Pop-up Example



A dedicated pop-up that contains more detailed information exists for each process variable (colored boxes). For example, the **ATF Flow** pop-up displays the ATF Flow Rate (PV and SP), the Instantaneous Flow Rate, Shear rate SP and a chart (Figure 17). When two devices are connected to the controller, an additional option is available for setting the dual ATF pump synch mode (Figure 19).

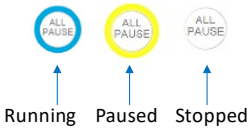
10.6.1 Changing ATF Flow Setpoints

ATF Flow Set Points (SP) can be changed at any time, including while the XCell ATF Device is running. When making a large change to the flow rate during a run, use small incremental steps to achieve your new desired SP. Pressing the white box of the ATF Flow Rate SP (Figure 17) opens a dialog box, prompting for the new setpoint. If the entered value lies within the allowable range, the new value is immediately implemented. The theoretical Shear Rate SP is also calculated and displayed below the ATF Flow Rate SP.
If you are unsure of what setpoint is right for your process, contact a local FAS to discuss the impact of changing the ATF Flow rate for your process.

Table 9. Starting, Pausing and Stopping an XCell ATF Device Instructions

Actions	Steps and Explanations
Start an XCell ATF Device	Press the corresponding **ATF Flow** Box which opens the **ATF-A (or -B) Flow pop-up** window, and then press **Start**
Pause an XCell ATF Device	1. Press **Pause** on the **ATF Flow pop-up OR** 2. Press corresponding **All Pause** button on ATF Main screen. Each **All Pause** button pauses one ATF in independent mode, and both ATF devices in dual mode. 3. Press the appropriate Device PAUSE button on the controller. The buttons on the hardware match the functionality of those on the software. A **Pause** is typically used mid-run, for instance to change out an XCell ATF Device, or to adjust something momentarily before continuing as before. If you plan to stop then restart the XCell ATF Device within the same process, the **Pause** button should be used instead of **STOP**. Upon pressing **Start** again, the controller will resume using the settings and valve positions at the time the process was paused. Once device is paused, **All Pause** button becomes colorless and cannot be pressed. Upon restart, the controller starts without utilizing previous settings.
Stop an XCell ATF Device	Press **Stop** on the **ATF Flow pop-up.** A **Stop** is recommended to be used only at the end of a run.

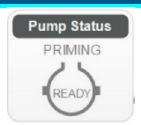
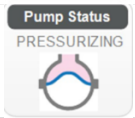
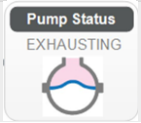
Figure 18. XCell ATF Device Status - Running, Paused, Or Stopped



10.6.2 Pump Status Box

An animated graphic in the **Pump Status** box shows real-time diaphragm movement. The message displayed describes the action performed by the controller on the diaphragm (Table 10).

Table 10. Pump Status Messages Examples

Image	Messages Displayed	Explanation
	Priming	The first series of cycles performed to prime the ATF pump and remove most or all of the air in the XCell ATF Device and tubing.
	Zeroing FT	The controller stops the ATF pump and waits until there is no flow in the A2B line and then zeros the flow sensor.
N/A	Waiting	Shown rarely in dual mode during the initialization stage, for example, if the system is waiting for liquid flow to stop in the second ATF before zeroing the sensors.
	Detecting MinPress	The controller runs an automated algorithm to determine the minimum driving pressure required to move the diaphragm.
	Stopped	A Stop button has been pressed on the HMI.
	Paused	A blue Pause button has been pressed, either on the HMI or on the side of the controller.
	Pressurizing	The controller is performing the P-stroke, i.e., pressurizing the diaphragm and moving it up displacing liquid into the vessel.
	Exhausting	The controller is performing the E-stroke, i.e., exhausting the diaphragm and moving it down displacing liquid into the ATF pump.

10.6.3 Dual Mode

XCell ATF **D** and **D-P** controller models can run two XCell ATF Devices at the same time. If the devices are same size and connected to a single bioreactor, they may be run in one of three synchronized modes (Table 11). To switch from the single to dual mode, open the settings > ATF configuration sub-menu (Figure 23) and select an XCell ATF Device for the B channel then bioreactor configuration and select a configuration (Figure 24) the ATF Flow Pop-Up and select the desired mode (Figure 17).

Note: *Modes can be switched even while the devices are running; it takes one to two full cycles before the new mode goes into full effect.*

Figure 19. ATF DUAL Pop-up Example

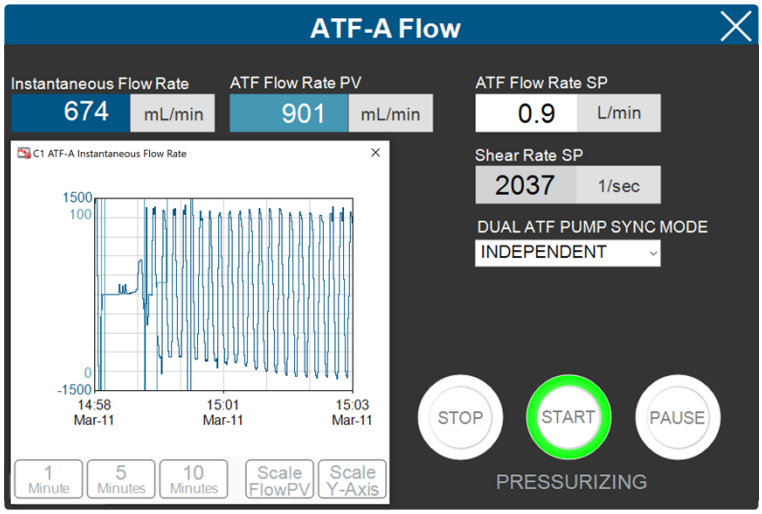


Table 11. ATF Modes - Independent and Dual

Mode	ATF Pump Sync Mode	Explanation
ATF DUAL	Independent	The phase of each XCell ATF Device runs without dependency on the other.
	In-Phase	The pressure and exhaust strokes of both XCell ATF Devices occur at the same time.
	Out-of-Phase	The pressure and exhaust strokes of both XCell ATF Devices occur in an alternating fashion. This is useful to keep a bioreactor volume constant when running two XCell ATF Devices on one bioreactor and is used most frequently.

Note: *When two ATF devices run independently, the setpoints can be adjusted in their respective ATF-A Flow or ATF-B Flow pop-ups. When the two ATF devices are run In-Phase or Out-of-Phase, ATF Flow setpoints for both the ATF A and ATF B pop-ups are linked and must be the same. Edit the setpoint for both devices at the same time in either the ATF-A Flow or ATF-B Flow pop-ups.*

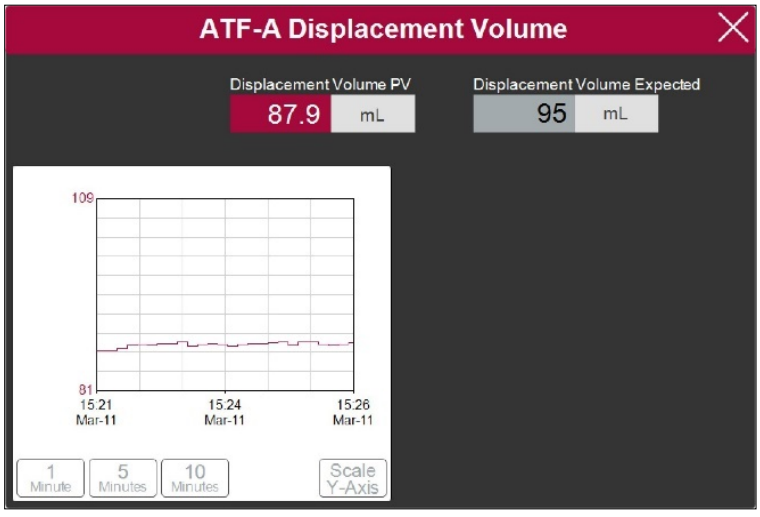
Table 12. Starting, Pausing, and Stopping XCell ATF Device(s) in Dual Mode

	Actions	Description
In-phase and out-of-phase	Start	Open either the ATF-A or ATF-B flow pop-up , select mode for dual control and then press **Start.**
	Pause	1. Software: Open either ATF-A or ATF-B Flow pop-up and press **Pause** 2. Software: Press the **All Pause** buttons on ATF Main screen 3. Hardware: Press either **Pause** button on controller Face B (Figure 6)
	Stop	Software: Press the **All Pause** buttons on ATF Main screen
	Start	1. Software: Open either ATF-A or ATF-B Flow pop-up and press **Pause** 2. Hardware: Press either **Pause** button on controller face B
Independent	Start	Open the relevant ATF flow pop-up and then press **Start.**
	Pause	4. Software: Open either ATF-A or ATF-B Flow pop-up and press **Pause** 5. Software: Press the **All Pause** buttons on ATF Main screen to pause the respective ATF unit (A or B) to pause. For example, if the all pause was pressed for ATF B while running in independent mode, then ATF B is paused and ATF A continues to run. Hardware: Press either **Pause** button on controller Face B (Figure 6)
	Stop	Press **Stop** on the **ATF Flow pop-up.** Upon restart, the controller starts without utilizing previous settings. A **Stop** is recommended to be used only at the end of a run.

Note: *It is not possible to restart in dual mode unless both ATF devices are paused and restarted together.*

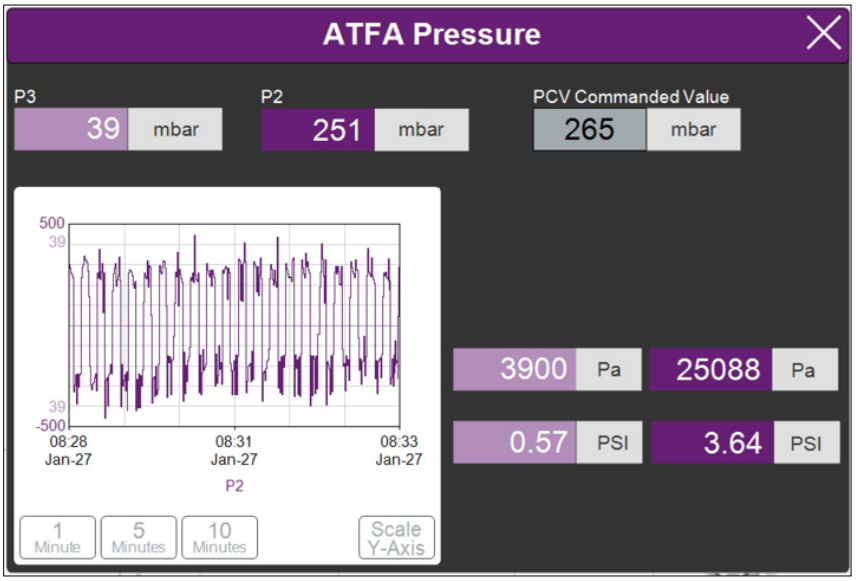
Note: *After pressing STOP, the setpoint value remains the same, which is the only user editable parameter. The most significant difference between STOP and PAUSE is that PAUSE keeps the XCell ATF Device in a hold position where it can resume when START is pressed a second time. Pressing STOP stops the running session; when start is subsequently pressed it goes through the start initiation process (Priming).*

Figure 20. ATF Displacement Volume Pop-up Example



The ATF displacement pop-up (Figure 20) displays the measured and expected displacement volume per cycle. A 5 - 10% variation between the two is typical. No changes are allowed on this screen; however, it is possible to set-up an alarm for this value.

Figure 21. ATF Pressure Pop-up Screen Example



The ATF Pressure pop-up (Figure 21) displays the measured pressures in the permeate line (P3), the A2C line (P2) and the PCV Set point for P2 (PCV commanded value). You may change the units of the values displayed on the **ATF Pressure pop-up** and the **ATF Main** Screen (in the **Settings** menu), but the values logged into the **Historian** are always 'mbar', which is shown at the top of the pop-up.

P3 pressure is typically either zero or negative. As permeate flow increases, the pressure (P3) drops. If the filter starts to foul, P3 is also expected to drop. P3 is a process-dependent value; no lower limit for alarm set-up has been established.

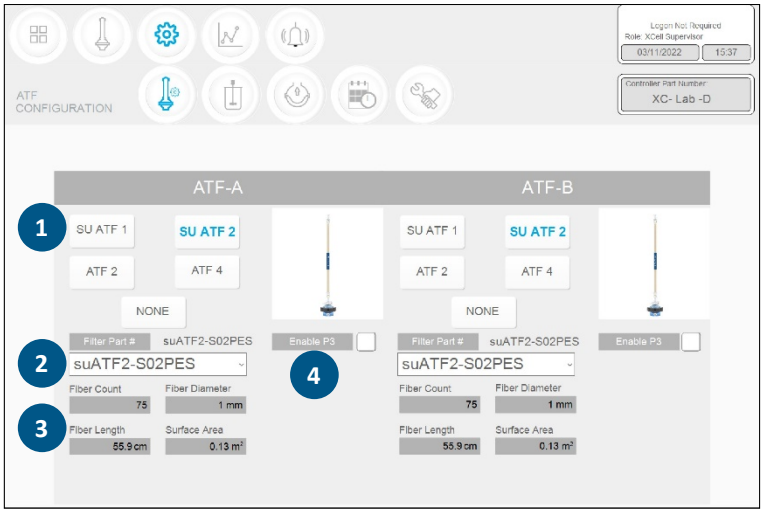
You may choose to alarm P3 via the Alarm Settings if it is critical for your process. Alarms for P2 are automated and cannot be changed by the user. Alarms are described in more detail later. Please contact your local FAS to discuss appropriate values and alarms settings.

Figure 22. Settings Sub-menu Example

1. Settings
2. XCell ATF Device Configuration
3. Bioreactor Configuration
4. Default Configuration
5. General Configuration
6. Service/Performance

The settings sub-menu (Figure 22) displays the options available to customize the device, bioreactor, controller, and software settings.

Figure 23. XCell ATF Device Configuration Example



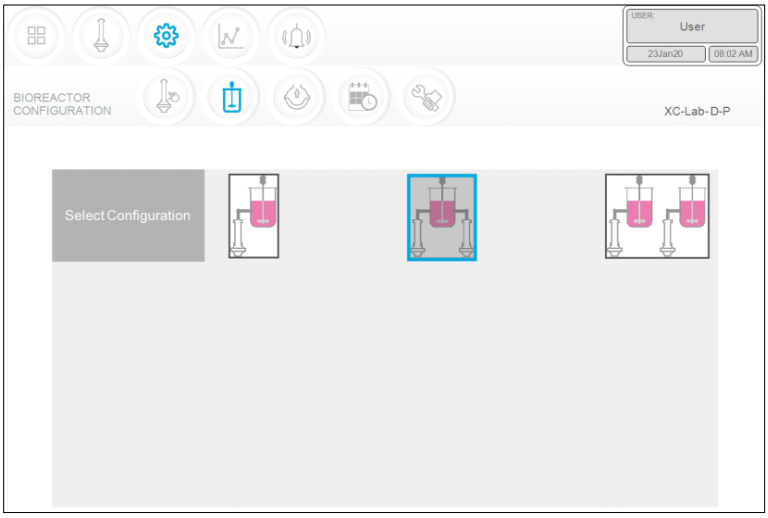
1. XCell ATF Device size, format
2. Filter P/N (dropdown)
3. Default filter settings
4. Enable/disable P3 sensor

The XCell ATF Device configuration sub-menu (Figure 23) allows selection of the XCell ATF Device(s) with a single click. Selection of a device opens default values and displays an image of the chosen device. To run only one device with the **D** or **D-P** controller models, select **NONE** for the other; device and the graphic will be removed from the device image appears blank. The **ATF Main** screen will be updated as well.

Once an XCell ATF Device selection is made, a filter part number can be selected from the drop-down list. This enables the system to display the correct physical characteristics of the chosen filter (shown below in grey), which is crucial for scale-up calculations.

Note: *Uncheck the P3 box when not in use to avoid alarms due to lack of communication with the P3 sensor.*

Figure 24. Bioreactor Configuration Example



For the **S** controller configuration, you will only be able to choose the first option with one device (Figure 24). With a **D** or **D-P** model controller, enabled controller, all three options are available; select the one that matches your lab setup (Figure 24).

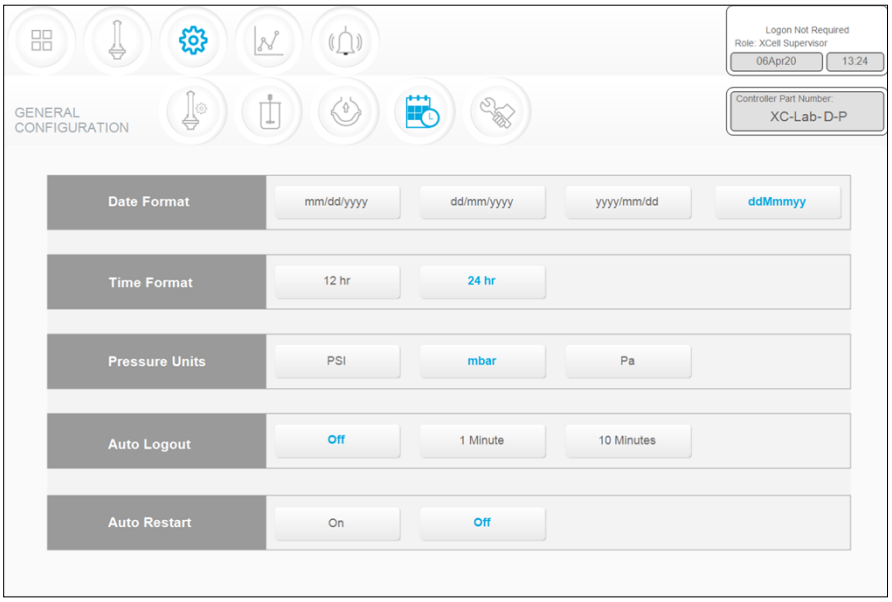
Figure 25. ATF Pump Settings Example

The Default Configuration menu (Figure 25) displays the ATF pump settings, which includes: expected pump displacement, minimum flow, maximum flow, and default flow.

These settings can be changed by clicking the relevant box and entering in a new value. **Default flow** represents the most frequently edited parameter and is typically set to the flow rate used in most of your processes. A Supervisor or Engineer may choose to restrict user input to a specific range of allowable flow setpoints by providing minimum and maximum flow values. For example, any flow rate between 70 ml/min to 200 ml/min can be used when running an ATF1 device. However, depending on your scale-up and process knowledge, the Supervisor or Engineer may choose to limit all users to a range of 140 – 180 mL/min, for instance, by specifying those as min and max flow values.

The user would not likely need to change the pump displacement value. The displacement value is integrated in the control algorithm; therefore, we recommend consultation with your local FAS, prior to editing. Modifications to the pump displacement value can cause some variations in performance.

Figure 26. General Configuration Example



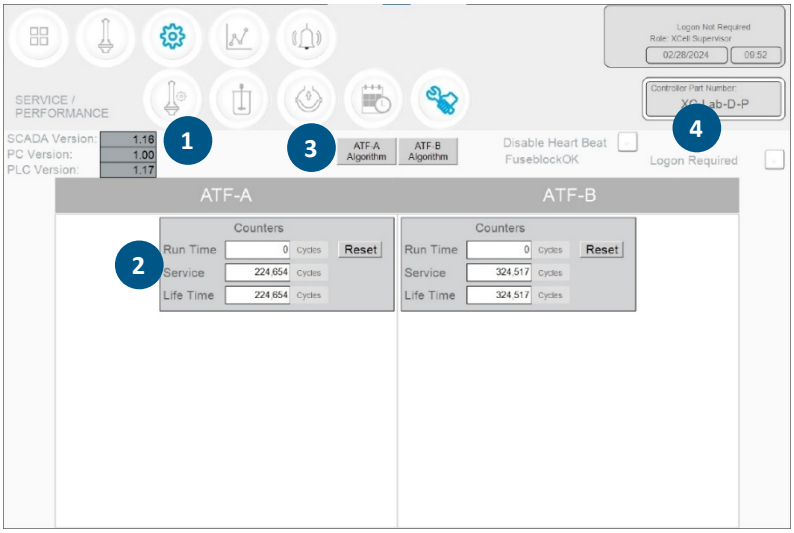
The General configuration menu (Figure 26) allows customization of date and time formats, pressure units, auto logout and auto restart settings.

Note: *The displayed units can be changed by the user, but the permanent logged data cannot.*

Auto logout is turned off by default. It is the preferred default setting for a lab environment. If you have multiple users in the facility and are concerned about accidental changes, turn on this security feature by choosing 1 Minute or 10 Minutes. Enabling auto logout requires the use of a password to log back in after the specified time period.

The auto restart is a useful feature to manage an accidental power outage. The controller displays an alarm when the power is lost unexpectedly. If **Auto Restart** is enabled, when power is restored, the controller restarts and continues to run with the settings used previously. This feature is useful only if the bioreactor also restarts, and the duration of the power outage is small. To have the equipment restarted manually after a power loss, turn **Auto Restart** OFF.

Figure 27. Service/Performance Example



1. SCADA and PLC version
2. Counters
3. XCell ATF Device algorithm
4. Logon Required – on/off

The Service/performance screen (Figure 27) displays the software versions, XCell ATF Device algorithms, counters (Table 13) and security status. It is useful for both users and Repligen engineers.

Table 13. ATF Service Parameters

Counter name	Description	Can Be Reset?
Run time	Number of cycles a diaphragm or device has completed since the last reset. Can be reset for every run.	Yes, by Operator
Service	Number of cycles completed since the last preventative maintenance or service or calibration.	Yes, only by Repligen FSE
Lifetime	Number of cycles performed by the controller during its lifetime	No

10.6.4 Logon Required - Security On/Off

If the **Logon Required** box (Figure 27) is left unchecked, no password is required, and each user has equal and full access (equivalent to a **Supervisor** level) to the XCell Lab Software. If the Logon Required box is checked off, users need to log on, enter credentials to access the XCell Lab Software; however, no Windows login is needed. In some R&D environments, leaving the logon box unchecked may simplify daily task execution, yet in other situations it may be critical to have security enabled. For additional security, timed auto-logout can be enabled in the **General Configuration** settings.

Figure 28. ATF-A Algorithm Pop-up Example

Clicking the **Algorithm** button displays a pop-up (Figures 28, 29), which shows various flow/pressure signals while the controller is running. This screen displays various signals and messages. It is not advisable to judge the algorithm performance without significant training and experience since the data can be misinterpreted. This screen is used by Repligen FAS during troubleshooting. Please consult a Repligen FAS if you suspect your XCell ATF Devices are not working satisfactorily.

Note (for control engineers): *A suitable comparison would be to consider the algorithm to be a series or matrix of PID algorithms combined in some interrelated relationship throughout the pump cycle, with the calculations or conclusions from these interactions displayed here. Tuning the algorithm is non-trivial.*

You can display one or both algorithm pop-ups at the same time, and easily switch between them. You may touch the screen or use the touchpad to move the pop-ups around. You do not need to exit the pop-ups (by clicking X) each time. If you navigate to the Main menu, the algorithm pop-ups will close automatically.

Note: *If the user has a question or issue, take a photo or video of one or both pop-ups to facilitate resolution.*

Figure 29. ATF-A and ATF-B Algorithm Pop-up Example

10.7 Trend Screen Options

Two trend or graphing utilities are available. XCell Lab Trend is located within the main program while the second, Trend (or Wonderware Trend), is part of the separate standalone Windows application. XCell Lab Trend screen likely will meet the vast majority of run time analysis and diagnostic requirements. XCell Lab Trend has been designed for simplicity and quick touchscreen-based user interaction. The Trend tool provides a deeper dive into current and historical data. It is not as straightforward as the XCell Lab Trend; however, a touchpad is provided for use.

Figure 30. XCell Lab Trend Screen Example

The XCell Lab Trend screen displays flows, pressures and displacement volumes for each XCell ATF Device (Figure 30). By clicking on the various buttons, you can select and simultaneously display multiple parameters. The buttons are colored if selected and greyed if not. Graph line colors are predetermined and cannot be modified.

Data can be displayed and analyzed by going back in time for a selected time interval. To explore a variety of time intervals, click **SHOW OPTIONS**. All available time intervals are displayed at the bottom of the screen and can be selected by clicking the appropriate button, which then appears blue when active. As an example, Figure 30 displays data in a window of the last 60 minutes. Viewing data options always describe the interval between the current time and a selected interval. Selection of a time interval between two points in the past is not supported.

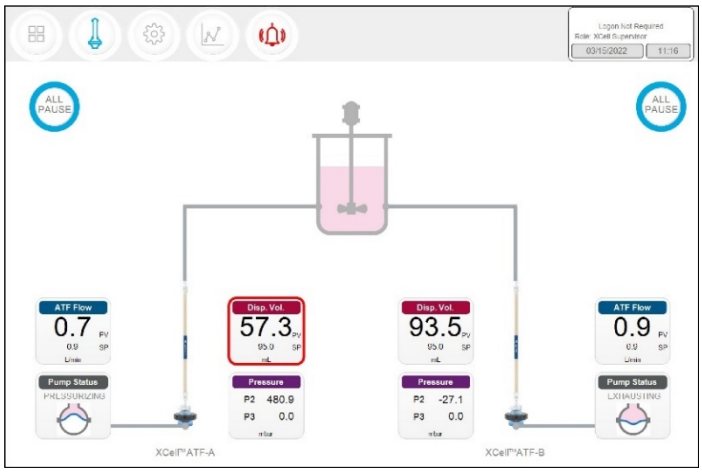
10.8 Alarm Categories/Types

The controller has alarms available at both the user level and system level. A complete list of Alarms is provided in Appendix D.

User-defined alarms
User-defined alarms allow you to change the limits that trigger the alarm as well as the actions taken when an alarm is triggered. These alarms generally cover process values and can be set-up in the Alarm Configuration screen.

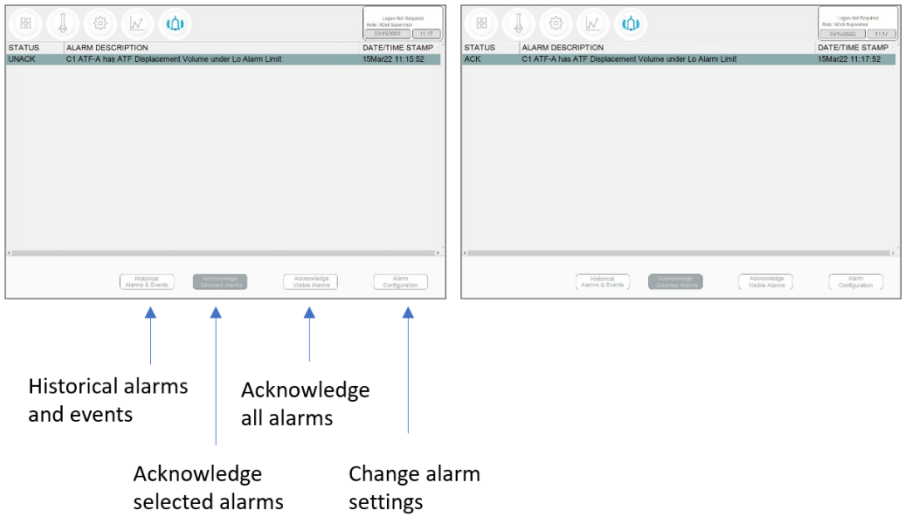
System alarms
System alarms cannot be modified. These are hard-coded and may not be modified by the user. System alarms serve the underlying core functions of the controller, (i.e., the presence of a sensors or loss of utilities, etc.).

Figure 31. Alarm Condition Example



If an alarm has occurred, even if briefly and then returned to normal, the **Alarm menu** button will flash red (Figure 31). The alarm may be reviewed by the user at their convenience when this icon is displayed. If an alarm is active, a red box will surround the displayed variable. As an example, an alarm for Displacement Volume on ATF-A is shown above.

Figure 32. Alarm Status

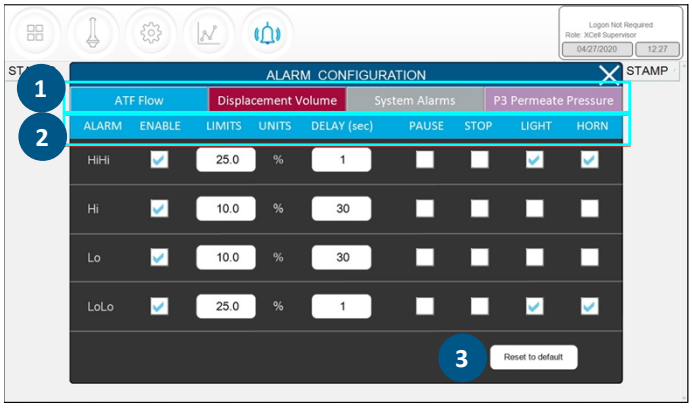


Pressing the **Alarm** menu opens the **Alarm screen** (Figure 32). Alarms are displayed until acknowledged by the user. Table 14 explains the alarm status messages you may encounter. A full list of alarms is provided in Appendix C.

Table 14. Alarm Status

Alarm Status	Explanation
UNACKN	An unacknowledged alarm
UNACK_RTN	An unacknowledged alarm, which has returned to a non-alarm state
ACK	An alarm acknowledged by the user
ACTIVE	A current alarm state

Figure 33. Alarm Configuration Example



1. Tabs
2. Commands
3. Reset to default values

The alarm configuration pop-up (Figure 33) has four tabs. The commands row matches the color of the active tab, indicating the active Alarm tab. As an example, Figure 33 displays ATF Flow tab as active.

10.8.1 ATF Flow Alarm Configuration

Four different alarm options are available for **ATF Flow** (Figure 33): **HiHi, Hi, Lo, LoLo**. You can select the alarm type, parameter limit, and delay time. Simply uncheck the relevant box to turn off an alarm. Flow alarms apply to all the ATF sizes and formats the controller can operate and are not limited to the specific XCell ATF Devices configured at the time the alarm is set.

Flow alarms are compared to the flow setpoint. Alarms are triggered when the flow setpoint is exceeded or reduced by the specified limits. For example (Figure 33), if the **ATF Flow** has a Setpoint of 0.7 LPM, then the **Hi** 10% and **HiHi** 25% alarms would be triggered when the ATF Flow PV is > = 0.77 LPM and > = 0.875 LPM, respectively.

The **Hi** and **Lo** triggers are set at 10% in this example. If the ATF Flow equals or surpasses the 10% limit (0.63 LPM or below for Lo, 0.77 LPM or above for Hi) in either direction, the relevant alarm would get triggered.

Occasionally, alarms may be caused by trivial events such as noise or a mistake (human or otherwise), which do not justify triggering actions that may include stopping the operation. The **Delay** timer feature manages this situation. A 30 second **delay** timer requires that the alarm be present for full 30 seconds after the first detection, for the alarm to display on the **Alarms screen** and to trigger action.

The last four columns show actions the controller can take if an Alarm is triggered. Each box and check box have a preset default value, which you may return to at any time by clicking the **Reset to Default** button.

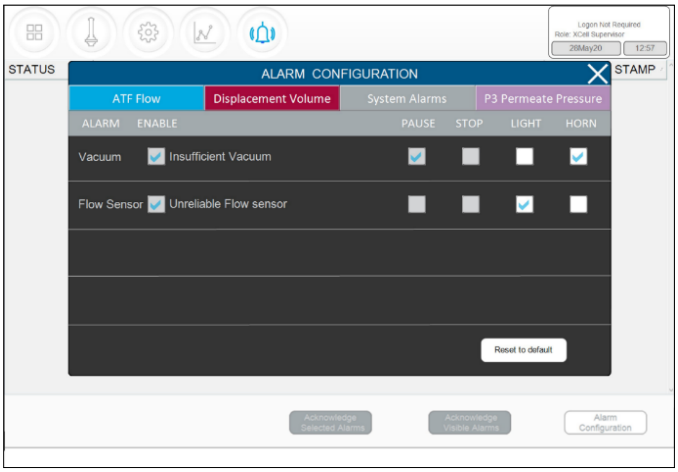
Note: *Pausing or stopping the controller requires manual interaction to restart the operation. Application of pause or stop as an action should therefore be carefully planned especially in case the alarms get triggered at an unattended moment.*

10.8.2 Displacement Volume Alarm Configuration

Like **ATF Flow**, the **Displacement volume** alarm configuration (Figure 34) has a layout, and functionality similar to **ATF Flow**. Like **ATF Flow**, the values on the selections apply to all ATF sizes and formats the controller can operate.

Figure 34. Displacement Volume Alarm Example

Figure 35. System Alarms Example



Two System Alarms are available in the Systems Alarms tab (Figure 35): vacuum and flow sensor. Neither the system alarm itself nor the triggered action may be disabled by the user (check boxes are greyed out). System alarms are therefore shown for informational purposes only. For instance, the vacuum alarm pauses the ATF when detected. You can, however, choose whether a light and/or horn alarm should be triggered in each case.

Figure 36. P3 Permeate Pressure Alarm Example

The layout of the **P3 alarm** configuration screen is very similar to other alarm screens. However, there are some notable differences. The permeate pressure (**P3)** alarms (Figure 36) are unique to each XCell ATF Device and sizes. P3 alarms for ATF-A and ATF-B may also be set independently of one another.

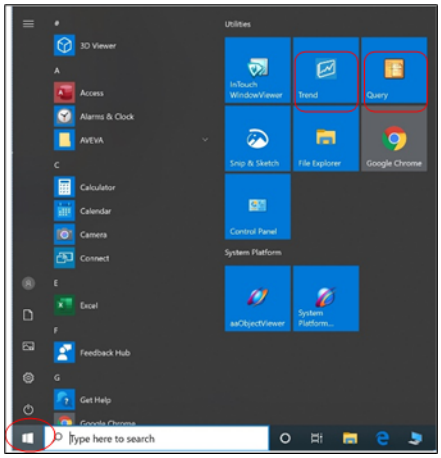
Note: *Because permeate pressure will decrease with membrane fouling,* ***Hi*** *or* ***HiHi*** *do not apply; only* ***Lo*** *and* ***LoLo*** *options exist within the P3 pressure alarm tab. In addition, permeate pressure is compared to the limit shown on this screen (not to a setpoint). Due to the variety of processes in which the XCell ATF Systems are employed in the industry today, operating values for permeate pressure (****P3)*** *span a wide range. P3 pressure value is process dependent and there is no established limit. Please ensure P3 alarms are set up correctly for each run if P3 sensor is used. Our recommendation is to set the* ***Lo*** *at a point where, for one specific process, it would trigger a* ***Light*** *and or a* ***Horn*** *warning at the first indication of filter fouling. Indications of fouling can be documented during development runs by sampling between the retentate and the permeate streams. The P3 alarm indicates the point where swapping should be considered. The* ***LoLo*** *alarm may then be set to a point at which filter replacement is deemed urgent and critical.*

11. Historian, Trend, and Query Applications

The tablet includes three Wonderware tools for additional functionality. These applications help you get up and running quickly with a point-and-click interface to access, analyze, and graph data (both current and historical). These tools can be accessed by all XCell Lab Software users and do not require any programming or database knowledge. A touchpad is provided for ease of use.

To access these applications, start with the Windows button or swipe right on the tablet to open the Start menu with tiles on the right (Figure 37). You can select **Trend** or **Query** or select **InTouch Window Viewer to** return to the XCell Lab Software. Swiping right again closes the start menu and displays all open applications.

Figure 37. Accessing Trend and Query Example

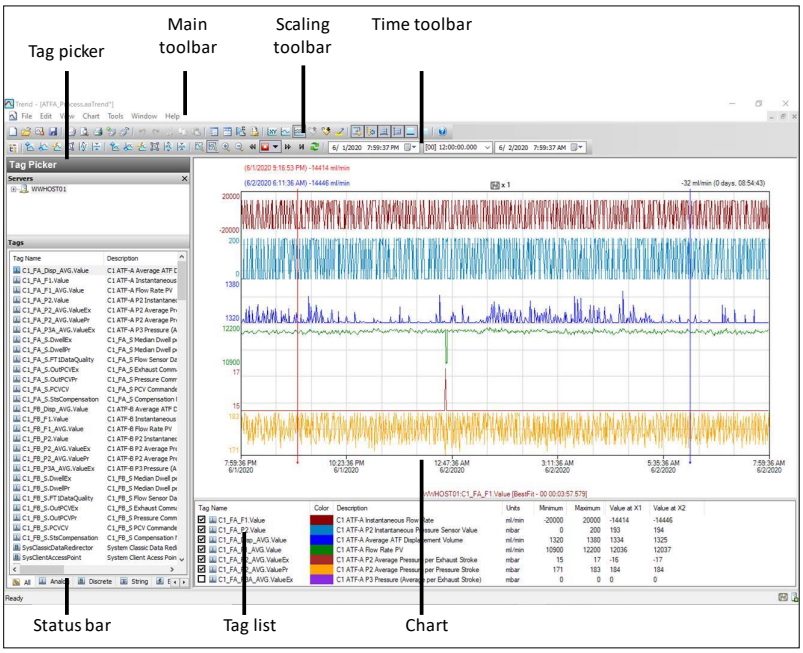


11.1.1 Historian Client Software

Wonderware Historian, a relational database that acquires and stores process data at full resolution, always runs in the background, providing real-time and historical data. Historian combines the power and flexibility of a Microsoft SQL Server with the high-speed acquisition and efficient data compression characteristics of a real-time system.

The Historian enables queries that can retrieve relevant data more efficiently from the database. Historian is stored locally; no remote access is allowed.

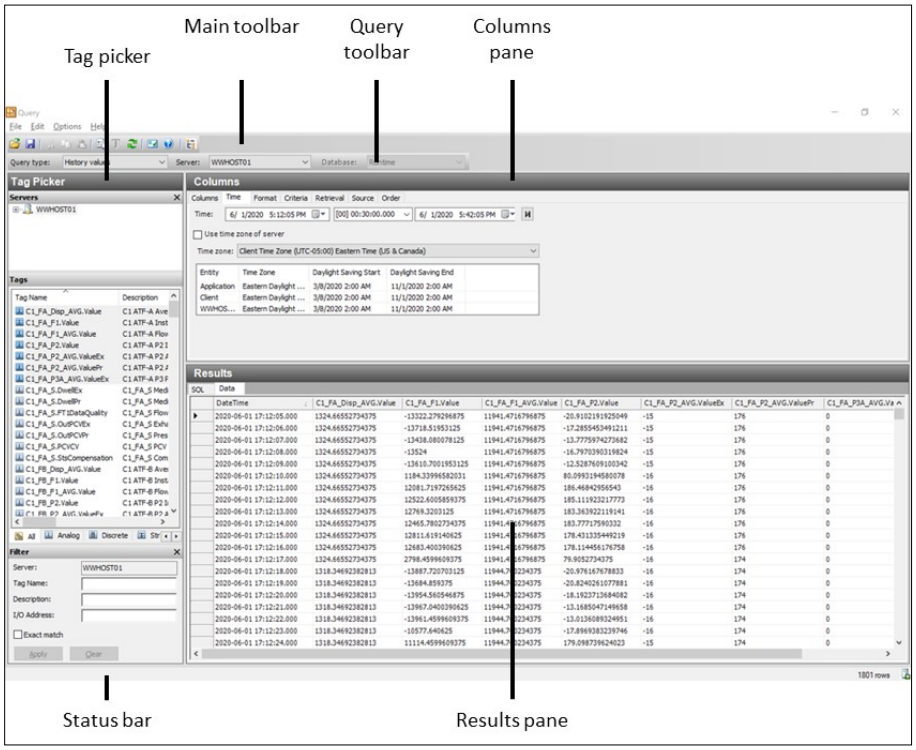
Figure 38. Trend Screen Example



The Trend application lets you query tags (data points or logged variables) from the Wonderware Historian database and plot them. When you start the Trend application for the first time, you are immediately prompted to connect to a Historian server. If you are opening an existing Trend file that includes at least one server configuration and the login was successful, you are not prompted to log in. It comes with 4 preconfigured trend files for your convenience. To simplify the setup, Repligen has pre-configured several options and configurations for you. For example, the tags are pre-loaded, and the screen layout has been optimized for viewing.

Trend supports two different chart types: a regular trend curve and an XY scatter plot. Multiple plot configuration and display options are available (Figure 38), and it is easy to save preferred layouts for future use.
For more information on using **tag picker** and **time picker** tools, please see Section 11.1.2.

Figure 39. Query Example

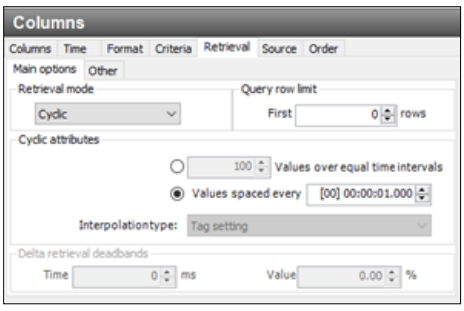


11.1.2 Exporting Data to Excel

To export data:

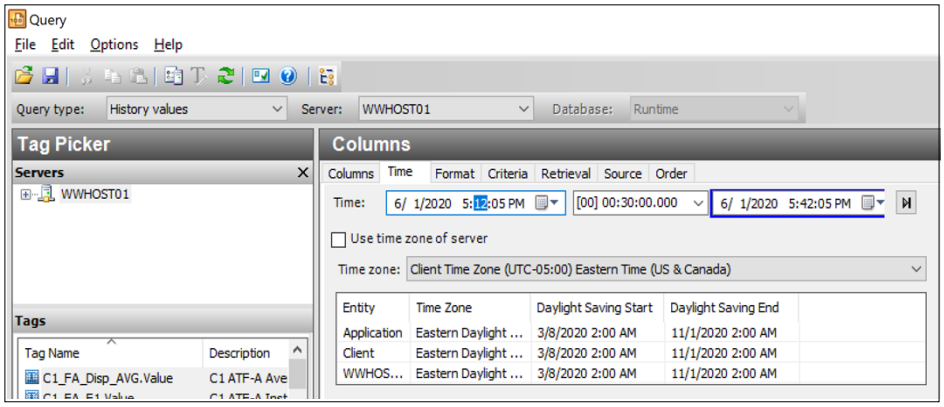
1. Select **History Values** from the **Query type:** drop-down menu (top left, Figure 39).
2. In the **Columns Pane** (Figure 40), go to the **Format** tab, select the **Wide query format**.
3. In the **Columns Pane**, go to the **Retrieval** tab, select **Cyclic** from the retrieval mode drop-down. For **Cyclic attributes,** select **Values spaced every** select **1 second** (as shown below).

Figure 40. Columns Pane — Subset of The Query Window



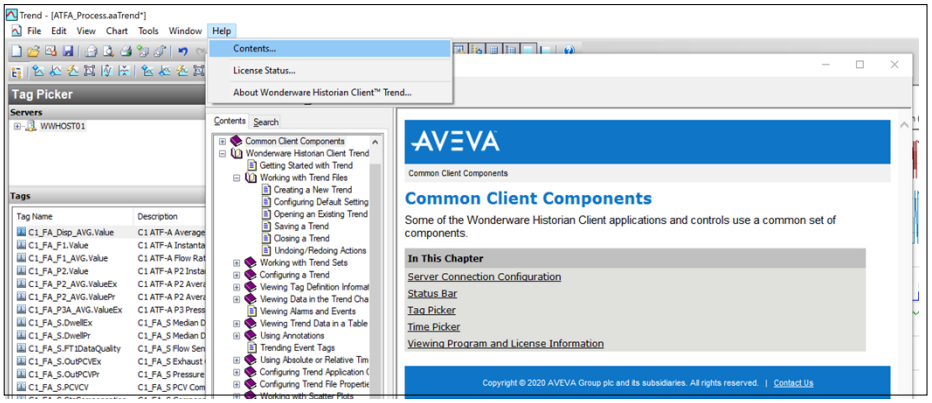
1. Go to **Tag Picker** section, select the tags (i.e., the data points) to populate the **Results Pane.**
2. Go to the **Columns Pane**, select the **Time** tab, and choose the start time and duration using a drop-down menu or by manually entering it (Figure 41).

Figure 41. Query Set-up



- Loading each new tag takes time. To speed up the process, set-up a quick query by selecting a short time interval (say 5 minutes), followed by selection of multiple tags, and then increasing the time interval to the desired duration.
- Press the **Save** button, select a filename and specify the storage location for your data.
- Copy data from the Surface Pro hard drive to a USB drive in .csv format which can be imported into Microsoft Excel® for further processing.

Figure 42. Help Feature



The Help/Contents section (Figure 42) offers a good resource to learn more about Trend, Query and Historian applications.

For information on using the **tag picker** and the **time picker** tools, please see **Common Client Components**. To show or hide toolbars or components, use the corresponding commands in the **View** menu.

12. Selection of ATF Flow Rate

Generally, higher ATF flow rates increase backflush efficiency and extend filter life. However, the optimum ATF rate depends on the cell line and the harvest and filtration rate requirements.

Type of cell line used: Fragile cell lines or cultures inoculated at low cell concentration may require gentle start-up using low ATF rates. As cells begin to grow and adapt, flow rates can be increased (i.e., to characterize the cells shear sensitivity). When a less shear-sensitive cell line is used, higher initial ATF rates may be used. Repligen FAS can assist with selecting the appropriate application, optimizing scale-down models, supporting process scale-up across all classes of biomolecules.

Harvest or filtration rate: Generally, higher filtration rates require higher ATF flow rates. The maximum filtration rate depends on the size of the filter relative to the process conditions, while the minimum filtration rate depends on the requirements of the cell culture. If the filtration rate is too high compared to the ATF Flow Rate, the filter will likely foul faster.

Table 15. Flow Rate Ranges for XCell ATF Devices

XCell ATF Device Size	Minimum Retentate Flow	Maximum Retentate Flow
XCell ATF 1 Device	70 mL/min	144 mL/min
XCell ATF 2 Device	0.4 L/min	0.9 L/min
XCell ATF 4 Device	2.5 L/min	8.0 L/min

Note: *The above flow rates are attainable in certain bioreactor configurations with specific cell culture fluid viscosities. For additional details and support, contact your local Field Application Scientist (FAS).*

Note: *ATF2 is unique since it is capable of a maximum flow rate of 1.5 LPM, yet for scale-up considerations, ATF2 rate should not exceed 0.9 LPM. Please refer to the Repligen Engineering Scale-up Guide (available from your local FAS) for additional details.*

Table 16. Recommended ATF Rate to Filtration Rate Ratios

Application	ATF Rate Ratio	Filtration Rate Ratio
Perfusion (> 30d) or CFB	100 – 200	1
High Productivity Harvest	50 – 150	1
N-1 Perfusion, or Cell Expansion	50 – 100	1
Short Duration Diafiltration	10 – 50	1
Rapid Media Exchange, Clarification or Cell Concentration	10 – 50	1

Note: *Many factors influence the optimum ATF Rate as well as the ratio. The default settings work for most applications, but please feel free to contact your local FAS to discuss your unique process needs.*

Note: *The values in Table 16 are suggestions. Higher ratios are ideal because it maximizes filter backflush, but lower ratios may be possible for short duration processes. It is important to work closely with your local FAS to ensure your ATF process is optimized appropriately.*

13. Troubleshooting

If your issue is not listed or resolved in the following scenarios, please contact your FAS as the first point of contact. Refer to Appendix D for a comprehensive list of alarms and their triggers, which can be helpful in troubleshooting.

13.1 Controller Will Not Turn On

Make sure the power cord to the controller is connected properly and fully inserted into a power outlet.

13.2 The HMI is not Communicating with the Controller

Check if the ethernet cable is properly connected to the USB/ethernet adapter, and the USB/ethernet adapter connected properly to the HMI.

The IP address may be incorrect (Appendix C).

13.3 Initialization Errors

13.3.1 Priming Failed

Priming failed errors are most likely caused by utilities not being present. Check that the pressure and vacuum sources are physically hooked up and turned on. Check that any manual ball valves are in the open position.

If priming still fails, manually check the PCV at various setpoints to see if P2 (pressure readback signal) matches the commanded value.

1. Log in as engineering level user.
    - Default username eng, password 1234
2. Go to Settings (gear icon), Diagnostics (wrench icon)
3. Click ATF-A PCV or ATF-B PCV button.
4. Set value at 0%
5. Check PCV in manual
    - Verify P2 is within ± 22 mbar.
6. Set value at 100%

Note *the P2 value. This may be limited by the pressure supply. If it is less than 950 mbar (13.8 psi), check the pressure supply.*

7. Set value at -95%

Note: *the P2 value. This may be limited by the vacuum supply. If it is greater than -850 mbar (-12.3 psi), check the vacuum supply.*

8. Set value at 50%
    - Verify P2 (readback signal) is within ± 35 mbar of 500 mbar.
9. Set value at -50%
    - Verify P2 (readback signal) is within ± 35 mbar of -500 mbar.
10. Uncheck manual operation when done.

If priming still fails, reset the initial priming setpoint values by going to the setup screen, selecting a different ATF device size and then re-selecting the desired ATF device size.

13.3.2 Minimum Force Detection Failed or No Retentate Flow

Minimum Force Detection Errors are caused by no flow detected after the priming cycle. Check the following items:

- Verify that source pressure and vacuum are adequate (Section 13.4)
- Check that manual ball valve on the A2C line is open. This is the pneumatic line to the XCell ATF device.

- Check that all clamps on A2B lines are open. This is the fluidic line from the filter to the bioreactor.
- Check that A2B lines are primed and not kinked.
- Check that the flow sensor is connected to the correct A2B channel.
- Verify flow sensor is oriented properly per the etched diagram on sensor housing.
- If the flow sensor reads the maximum value, there may be a flow sensor or flow sensor cable issue. Contact Repligen.

If there is no flow, the ATF diaphragm may be stuck in the up or down position. Manually control the PCV using the following procedure:

1. Log in as engineering level user.
    - Default username eng, password 1234
2. Go to Settings (gear icon), Diagnostics (wrench icon)
3. Tap ATF-A PCV or ATF-B PCV button for the ATF device.
4. Check the PCV in Manual checkbox and enter positive and negative pressure values for 30 seconds each:
    - If the diaphragm is at the bottom or in an unknown position, enter 70%
    - If the diaphragm is at the top, enter -70%
    - If no movement or flow is observed, increase the pressure or vacuum setpoint by 10% increments.
5. Observe whether the P2 values match the commanded pressure, if not, there is a source pressure or vacuum issue.
6. When testing is complete, uncheck the PCV in Manual checkbox.

13.4 ATF Flow Rate is Higher/Lower Than Expected

The controller is accurate to at least within ±10% of the setpoint. If the flow is consistently outside of this range, a correction must be made:

- Insufficient utilities. Repligen provides vacuum pumps suitable for achieving specified flow. See section 13.3.1 for troubleshooting pressure and vacuum utilities.
- Incorrect flow measurement. Check that each of these is working properly:
    - Flow sensor on the wrong A2B line for channel A and B
    - Flow sensor not oriented properly per etched diagram on sensor housing.
    - Flow sensor not positioned properly, there must be at least 2 flow sensor lengths of tubing on each side of the flow sensor.
    - Flow sensor not closed properly.
    - Presence of large air bubbles in the line (see below)
    - Incorrect A2B tubing – must use Repligen supplied tube set.
- A2C line leaks. The A2C line may not be connected correctly to the air filter at each end, or it may be leaking. Check connections and tighten parts. Check the utility lines and connections for leaks. Follow this procedure to check for leaks:
    - If the system is running, spray IPA on the fittings along the A2C line and feel for leaks on the pressure stroke.
    - If the system is not running, soapy water may be used to diagnose leaks. Soapy water is not recommended when the system is running as it may be pulled into the system on the exhaust stroke.
        1. Verify the system is not running and apply soapy water around the A2C fittings.
        2. Log in as engineering level user.
            - Default username eng, password 1234
        3. Go to Settings (gear icon), Diagnostics (wrench icon)
        4. Click ATF-A PCV or ATF-B PCV button.
        5. Set value at 100%
        6. Check PCV in manual
        7. Check for leaks.
        8. Remove the soapy water before continuing.
        9. Uncheck PCV in manual
- Device leakage. An air leak on the air side of the device can happen at points where steel-to-steel or steel-to-plastic connections are not properly threaded together.
- Kinks or blockages in the A2B line
- The dip tube is higher than the liquid level, or the incorrect dip tube is being used, leading to insufficient liquid being drawn into the XCell ATF Device.

- Excessive pressure in bioreactor. The bioreactor does not have a sufficiently large exhaust gas line or filter, or the filter is wet and blocked. Bioreactors built for standard fed-batch operation have filters and exhaust lines that are too small for the combined needs of higher oxygen demand and ATF flow. In addition, evaporation increases during ATF. We recommend oversizing the exhaust line and, in some cases, having two lines with one in place as a backup. If water regularly causes blockages, heating the filter can help.

If the value reported by the controller is near the far end of the 10% range, without moving closer to the desired setpoint, then the system is operating within specification. Stopping and starting the XCell ATF Device or changing the setpoint to a different value for a few minutes (and then returning to the original value) might help bring the flow within the middle of the 10% range.

13.5 Too Many Air Bubbles Inside the A2B Tubing

To remove large air bubbles mid-run, the XCell ATF Device can be lowered slightly, and the ATF Flow increased for several minutes, before returning values to their baseline levels. To avoid large air bubbles, place the dip tube or entry point for the A2B line as far away from the sparger as possible.

Small bubbles, even if numerous, should not impact sensor or controller performance.

13.6 Permeate Flow Too Low or Negligible

Upon first starting the permeate pump, time should be allowed for priming to complete (i.e., to draw liquid through the dead volume in the filter module and out to the permeate side). If the cell concentration is low, you may increase the permeate pump 10x to accelerate the priming process. If mid run, check the P3 pressure profile and inspect the filter for clogging.

13.7 A2B Flow Sensors Not Communicating

Confirm cables are connected properly.

13.8 Displacement Volume Alarm

This can happen when the system starts up and there is a mismatch between the filter size configured and the expected value of displacement volume. To resolve this issue, navigate to the Settings page, where default values are displayed, and modify one of the expected displacement volumes. Example: Set the displacement volume value for ATF4 to 410 instead of 411. Alternately, pressing the reset to default button also solves the issue.

13.9 Displacement Volume Too Low

The displacement volume varies slightly (up to 10%) from the expected value before the controller takes action. If the value is lower and outside the range but the ATF Flow is working correctly, then there is an error, and you should contact Repligen.

13.10 Flow Control Loses Accuracy

This could be because PCV command value (PCVcmd) is not closely tracking P2, meaning the valve is not responding correctly to the control output. Dust may be trapped inside the valve, causing it to stick or react in a jolting fashion. A service is required on the equipment.

13.11 Flow Control Erratic for the First Few Minutes of Operation

Startup includes this expected behavior. When the controller first starts, it performs an initialization routine that has periods of no flow and periods of irregular flow, to determine optimum settings for your configuration.

14. Maintenance and Service

The XCell Lab System design is robust and intended for use with other process and lab equipment. The frame, cabinet, and sensors can be cleaned by wiping down surfaces with mild cleaning agents and/or warm water, a damp cloth or lab wipes. The display should be cleaned with computer screen cleaner and computer screen wipes.

All repairs of the system must be performed by a qualified Repligen service engineer. Opening of the system and attempted repair by the user or third party shall void the product warranty.

An annual preventative maintenance is strongly advised to ensure equipment stays in prime condition and that performance is not affected. Failure to do so could lead to detrimental cell culture results.

14.1 Ongoing Service and Support

Repligen provides a range of service and support options to ensure your system is reliable and performs optimally.

- Preventative Maintenance (PM)
- Comprehensive Service Contracts
- Technical Support
- User Training
- Applications Support

A PM or service visit by our engineer would include verification and adjustment of the following key components as necessary:

PCV valves: These are finely tuned pneumatic valves that must be kept clean and calibrated for proper operation.

P2 sensor: This is linked to the PCV valves and any drift or noise will cause performance problems and must be rectified.

Controller filter: This should not be removed or replaced when vacuum is running, even in a clean room. An annual change is recommended for typical use.

For more information on spare parts, service and support, please visit our website www.repligen.com or email customerserviceUS@repligen.com.

15. Appendix A XCell Lab Controller Parts

Table 17. XCell Lab System Parts List

Category	Description	Part Number
Hardware and Accessories	XCell Lab Controller, dual ATF	XC-LAB-D
	XCell Lab Controller, dual ATF with permeate pressure	XC-LAB-D-P
	HMI tablet, software and accessories kit	XC-LAB-HMI-KIT
	XCell Lab PLC executable chip, Dual System upgrade	XCS-LAB-D-PLC_CHIP_V1.17
	Head plate fitting (HP) for XCell ATF 1, M10 fitting	HP-ATF1-6-M10
	HP for XCell ATF 1, PG13.5 fitting	HP-APP-M19
	Dip-tube for XCell ATF 1, barbed, 3mm OD, 200mm length	B-DIP-3-200
	Dip-tube for XCell ATF 2, TC, 1/4" ID, 250mm length	TC-DIP-LAB-.25/.5-250
	Dip-tube for XCell ATF 4, 250mm L, Tri-clamp Top	TC:DIP-10/250
	Dip-tube for XCell ATF 4, 450mm L, Tri-clamp Top	TC:DIP-10/450
	HP for XCell ATF 2, M10 fitting	HP-M10-.25
	HP for XCell ATF 2, PG13.5 fitting	HP-PG13.5-.25
	Flow Sensor for XCell ATF 1	FS-1
	Flow Sensor for XCell ATF 2	FS-2
	Flow Sensor for XCell ATF 4	FS-4
	Clamp on stand for XCell ATF 1 and 2	ATF12-STAND-CO
	Flow Sensor Cable	XC-FS-CABLE
	Pressure Sensor Cable	XC-PS-CABLE-V2
	SAPA Unit (complete) for XCell Lab	XC-LAB-SAPA
	Vacuum Sys, 1 ATF6, 2x4 or 4x2, 115V	VP-AT-642-115V
	Vacuum Sys, 1 ATF6, 2x4 or 4x2, 220V	VP-AT-642-220V
XCell ATF Devices	suATF1, 0.2um, PES	suATF1-S02PES
	suATF1, 0.2um, PES, with P3	suATF1-S02PES-P-V2
	suATF2, original, with ReadyMates	suATF2-S02PES
	suATF2 with AseptiQuiks	suATF2-S02PES-AQ
	suATF2 with AseptiQuiks, with P3	suATF2-S02PES-AQ-P-V2
	Assy, Filter Housing, XCell ATF 2	ATF2-PH
	Assy, Filter Housing, XCell ATF 4	ATF4-PH

Category	Description	Part Number
Autoclavable Consumables Tubing Sets	Diaphragm for XCell ATF 2	D2:S1
	Diaphragm for XCell ATF 4	D4:S1
	Filter, 0.2um Polyethersulfone, XCell ATF 2	F2:RF02PES
	Filter, 0.2um Polysulfone, XCell ATF 2	F2:RF02PS
	Filter, 30kDa Polysulfone, XCell ATF 2	F2:RF030PS
	Filter, 0.5um Polyethersulfone, XCell ATF 2	F2:RF05PES
	Filter, 50kDa Polysulfone, XCell ATF 2	F2:RF50PS
	Filter, 0.2um Polyethersulfone, XCell ATF4	F4:RF02PES
	Filter, 0.2um Polysulfone, XCell ATF 4	F4:RF02PS
	Filter, 30KDa Polysulfone, XCell ATF 4	F4:RF030PS
	Filter, 0.5um Polyethersulfone, XCell ATF 4	F4:RF05PES
	Filter, 50kDa Polysulfone, XCell ATF 4	F4:RF50PS
	O-Ring, 224, Sil, GMP, 2PK, XCell ATF 4 HFM	O:224-S-GMP
	Air Filter, XCell ATF 2, A2C line	F-AIR2
	Air Filter, ATF4/6, A2C line	F-AIR1
	Pressure sensor kit, for steel XCell ATF 2	SSATF2-PSK-V2
	Pressure sensor kit, for steel XCell ATF 4	SSATF4-PSK-V2
	Autoclavable A2B tubing kit for XCell ATF 4, TCs	ATF4-A2B-TC
	Autoclavable A2B tubing kit for XCell ATF 4, TC + AseptiQuik®	ATF4-A2B-TCAQ
	Half SIP A2B valving kit for XCell ATF 4, GMP	ATF4-CHV2-GMP
	Full SIP A2B valving kit for XCell ATF 4, GMP	ATF4-CFV2-GMP
	Full SIP A2B Gemu valving kit for XCell ATF 4, GMP	ATF4-CFV2-G-GMP
	Permeate and drain tubing kit, for steel XCell ATF 2	SSATF2-TSK
	Permeate and drain tubing kit, for steel XCell ATF 4	SSATF4-TSK
	Autoclavable A2B tubing kit for steel XCell ATF 2, TCs	ATF2-A2B-TC
	Single use A2B tubing kit for SU XCell ATF2, AseptiQuik	ATF2-A2B-AQ
	Autoclavable A2B tubing kit for SU XCell ATF 2, TC + AseptiQuik	ATF2-A2B-TCAQ
	Autoclavable A2B tubing kit for SU XCell ATF 2, TC + ReadyMate™	ATF2-A2B-RMTC
	Legacy C24 A2B tube for autoclavable XCell ATF 2 and 4	TU:S-3/4X14
	Yearly PM for 1x XCell Lab	SV-PM-XCLAB-1
	Yearly PM for 2x XCell Lab	SV-PM-XCLAB-2
	Yearly PM for 3x XCell Lab	SV-PM-XCLAB-3
	Yearly PM for 4x XCell Lab	SV-PM-XCLAB-4
	Yearly PM for 5x XCell Lab	SV-PM-XCLAB-5
	Installation and Training for 1x XCell Lab	SV-IT-XCLAB-1
	Installation and Training for 2x XCell Lab	SV-IT-XCLAB-2

Category	Description	Part Number
Installation and service	Installation and Training for 3x XCell Lab	SV-IT-XCLAB-3
	Installation and Training for 4x XCell Lab	SV-IT-XCLAB-4
	Installation and Training for 5x XCell Lab	SV-IT-XCLAB-5
	Factory Warranty+1yr Ext Warranty Qty 1	SV-WA-XCLAB-1+1YR-1
	Factory Warranty+1yr Ext Warranty Qty 2	SV-WA-XCLAB-1+1YR-2
	Factory Warranty+1yr Ext Warranty Qty 3	SV-WA-XCLAB-1+1YR-3
	Factory Warranty+1yr Ext Warranty Qty 4	SV-WA-XCLAB-1+1YR-4
	Factory Warranty+1yr Ext Warranty Qty 5	SV-WA-XCLAB-1+1YR-5
Spares	A2C Filter for XCell Lab	XC-FLTR
	Replacement internal SAPA filter	XC-LAB-SAPA-FLTR
	A2C tube set kit (1x XCell ATF 1,2,4)	XC-LAB-A2C-TK
	XCell Lab utility tube set	XC-LAB-UTILITY-TK
	Power supply kit for XCell Lab Controller	XC-LAB-PWR
	RJ45 to USB Converter	XC-LAB-HMI-USB-RJ45
	RJ45 to M12 Ethernet cable	CA-ETH-RJ45-M12
	Kit, spare parts for XCell ATF 2	KIT:A2-SVC1
	Kit, spare parts for XCell ATF 4	KIT:A4-SVC1
	Assy, Air Inlet, XCell ATF 2	ATF2:AIR-ASSY
	Assy, Pump Hemisphere, air side, XCell ATF 2	ATF2:PH-AA-AIR
	Assy, Pump Hemisphere, liquid side, XCell ATF 2	ATF2:PHLA-SMP
	Air Inlet Assembly, Male Adapter	A2:AIR:M
	Assy, Air Inlet, XCell ATF 4	ATF4:AIR-ASSY
	Assy, Pump Hemisphere, air side, XCell ATF 4	ATF4:PH-AA-AIR
	Assy, Pump Hemisphere, liquid side, XCell ATF 4	ATF4:PHLA-SMP
	CA, Aux pump 1 to I/O PCBA	SV-SPR-3000176
	CA, Aux pump 2 to I/O PCBA	SV-SPR-3000177
	CA, Aux pump 3 to I/O PCBA	SV-SPR-3000178
	CA, Aux pump 4 to I/O PCBA	SV-SPR-3000179
	CA, Pump A to I/O PCBA	SV-SPR-3000190
	CA, Pump B to I/O PCBA	SV-SPR-3000191
	CA, BR A - VCD Sensor Bioreactor A - Input 1	SV-SPR-3000192
	CA, BR B - VCD Sensor Bioreactor B - Input 2	SV-SPR-3000193
	CA, Multipump to I/O PCBA RS232H	SV-SPR-3000194
	CA, BR Weight B to I/O PCBA RS232F	SV-SPR-3000195

Category	Description	Part Number
	CA, BR Weight A to I/O PCBA RS232D	SV-SPR-3000196
	CA, Modbus to I/O PCBA	SV-SPR-3000197
	CA, Filter A P3 SCIPRES to P# bulkhead	SV-SPR-3000198
	CA, Filter A P3 SCIPRES to P# bulkhead	SV-SPR-3000199
	CA, 24v Power In	SV-SPR-3000200
	CA, On/Off switch	SV-SPR-3000201
	CA, I/O Board Power	SV-SPR-3000202
	CA, scilog DIN1 Filter A & B	SV-SPR-3000203
	CA, 24v Power out to ENET switch	SV-SPR-3000204
	Gold Standard Flow Sensor Retentate (ATF1)	SV-SPR-3000205
	Gold Standard Flow Sensor Retentate (ATF2)	SV-SPR-3000208
Spares	Gold Standard Flow Sensor Retentate (ATF4)	SV-SPR-3000209
	P Adapter: 1/4"CPC to TC	SV-SPR-3000338
	P Adapter: 1/2" OD to TC	SV-SPR-3000339
	RJ45 to USB Converter	SV-SPR-3000370
	P Reducer: 6MM x 1/4" SS	SV-SPR-3000371
	P Reducers: 1/4" 3/4" SS	SV-SPR-3000387
	Coupler, bulkhead, M12, 5 Pin, F/M	SV-SPR-3000388
	Air Filter, 1.6 Sq.ft Filtration Area	SV-SPR-3000995
	Microprocessor Board, IO, C110M	SV-SPR-CS-10748
	CA, 24VDC to Compactlogix L19 V terminal	SV-SPR-CS-11055
	CA, 24VDC to Compactlogix L19 FP terminal	SV-SPR-CS-11056
	CA, PLC to Sonalert (Buzzer)	SV-SPR-CS-11058
	CA, PLC 1 to Modbus Terminals	SV-SPR-CS-11104
	CA, PLC 2 to Modbus Terminals	SV-SPR-CS-11105
	CA, Enfield PRV01 to IO Bd Port PRV1	SV-SPR-CS-11106
	CA, Enfield PRV01 to IO Bd Port PRV2	SV-SPR-CS-11107
	CA, BRA Stop A - ATF A system Stop	SV-SPR-CS-11108
	CA, BRA Stop B - ATF B system Stop	SV-SPR-CS-11109
	CA, ATF A Flow Sensor (to Terminal Blocks)	SV-SPR-CS-11110
	CA, ATF B Flow Sensor (to Terminal Blocks)	SV-SPR-CS-11111
	PCV Assembly	SV-SPR-CS-11112
	SAPA Filter	SV-SPR-EKF22DD
	PRESS XMTR, 1.5"TC; 30"Hg-30psig, 4-20MA	SV-SPR-RM-10635
	Pressure Monitor, Din Mnt, 24VDC, Modbus	SV-SPR-RM-11598
	Cap, M12 Female, 6”’ SS Lanyard	SV-SPR-RM-11618
	Fuses, 5 x 20mm, 250mA, 250V	SV-SPR-RM-11907

Category	Description	Part Number
	Fitting, Bulhead, Quick connect, Male 1/2"	SV-SPR-RM-11921
Spares	Fuses, Fast Acting, 125V, 5 x 20mm, 1A	SV-SPR-RM-12016
	Stem protector, SS, Quick connect CAP	SV-SPR-RM-12019
	Fitting TC to 1/2 Swagelok	SV-SPR-RM-12020
	Controller, Compact Logix 5370 L1	SV-SPR-RM-12470
	Fuses, Fast Acting, 125V, 4A	SV-SPR-RM-12474
	Modbus RTU Comm Module	SV-SPR-RM-12498
	Fuses, Fast Acting, 250V, 3A, 5 x 20mm	SV-SPR-RM-12500
	Adaptor, Elbow, M12xRJ45, Female	SV-SPR-RM-12551
	Cable, 0.3m RJ45xRJ45 Male	SV-SPR-RM-12552

16. Appendix B XCell Lab Controller Specifications

Table 18. XCell Lab Controller Specifications

	XCell® ATF 1	XCell® ATF 2	XCell® ATF 4
Process Parameters			
XCell Controller model	XCell® Lab	XCell® Lab	XCell® Lab
Bioreactor working volume | Suspension culture	0.5 - 2 L	2 - 10 L	8 - 50 L
XCell ATF pump rate			
Recommended minimum	0.07 L/min	0.4 L/min	2.5 L/min
Recommended maximum for scale-up	0.144 L/min	0.9 L/min	8 L/min
Filtration rate (Perfusion | CFB) Recommended	2.1 L/day, 0.09 L/hr, 0.001 L/min	12.5 L/day, 0.52 L/hr, 0.009 L/min	74 L/day, 3.08 L/hr, 0.051 L/min
Ratio (XCell® ATF rate ÷ Filtration rate)	99	104	156
Recommended nominal flux	4.0 LMH	4.0 LMH	4.0 LMH
Filtration rate (Media exchange | Clarification)			
Maximum	0.44 L/hour, 0.01 L/min	2.6 L/hour, 0.043 L/min	16 L/hour, 0.26 L/min
Ratio (Maximum XCell® ATF rate ÷ Filtration rate)	20	21	31
Recommended flux	20.2 LMH	20 LMH	20.1 LMH
Pump displacement volume			
Minimum, maximum	0.016 L, 0.019 L	0.085 L, 0.115 L	0.38 L, 0.48 L
XCell Lab Controller pressure sensor (P2)			
Accuracy, range, number of sensors	± 0.2 psi (0.013 bar), -14 to 14 psig (-0.96 to 0.96 bar), 2 (1 per XCell® ATF Device)		
XCell ATF Device permeate pressure sensor (P3)			
Accuracy, range, number of sensors	± 0.3 psi (0.2 bar), -5 to 60 psig (-0.3 to 4.1 bar), 1 per XCell® ATF Device		
Physical Dimensions and Weights			
XCell ATF pump assembly			
Height, width	24 in (61 cm), 5 in (13 cm)	30 in (76 cm), 5 in (13 cm)	21 in (53 cm), 8 in (20 cm)
Nominal footprint	0.04 m^2	0.04 m^2	0.13 m^2
Weight (with stand and liquid hold-up)	2 kg	2 kg	9.1 kg
Filter housing height	57.9 cm	61 cm	36 cm
Process Connections and Operations			
Bioreactor port and nominal ID	diptube 3.175 mm	diptube 6.35 mm	diptube 10 mm, ING1 15.5 mm
XCell ATF connection			
SS XCell ATF - Tri-clamp	N/A (SU only)	3/8 in TC	3/4 in TC
SU XCell ATF - SU connector	AseptiQuik® S 1/8 in	GE Readymate™ Mini TC	N/A (SS only)
Weldable	Yes	Yes	Special tubing
XCell ATF to bioreactor connection (A2B)			
Maximum A2B tubing length	14 in (35.6 cm)	14 in (35.6 cm)	14 in (35.6 cm)
A2B ID	1/8 in (0.32 cm)	1/4 in (0.64 cm)	3/8 in (0.95 cm)
A2B OD	1/4 in (0.64 cm)	3/8 (0.95 cm)	5/8 in (16 cm)
Filtrate connection			
SS XCell® ATF (hose barb or tri-clamp size)	N/A (SU only)	3/8 in TC	3/8 in TC
SU XCell® ATF (hose barb)	1.8 in OD (3.2 mm)	1/8 in OD (3.2 mm)	N/A (SS only)
Sterilization			
SS XCell ATF - Autoclave maximum temperature	N/A (SU only)	253° F (123° C)	253° F (123° C)
SU XCell ATF - Gamma irradiation max exposure	50 kGy	50 kGy	N/A (SS only)

	XCell ATF 1	XCell ATF 2	XCell ATF 4
Utility Connections (2 XCell ATF Devices Per Controller)			
Compressed air			
Source air pressure, pressure regulation (factory set) Pressure relief (factory set), pressure maximum flow Required average flow, required peak flow	30 - 90 psig (2.1 - 6.2 barg), 15.3 psig (1.1 barg) 15.6 psig (1.1 barg), 15 psig (1 barg) 0.5 L/min, 0.9 L/min	3.3 L/min, 5.2 L/min	20 L/min, 32 L/min
Vacuum			
Pressure at peak flow	-12 psig (-0.86 barg)		
Required average flow, required peak flow	0.5 L/min, 0.9 L/min	3.3 L/min, 5.2 L/min	20 L/min, 32 L/min
Utility line connections			
Compressed air	Red, 10 ft, 3/4 in Tri-clamp, ID = 1/3 in, OD = 1/2 in tubing, QC connector		
Vacuum	Blue, 10 ft, 3/4 in Tri-clamp , ID = 1/3 in, OD = 1/2 in tubing, QC connector		
Electrical			
Power input	24 VDC (from 110 - 240 VAC, 60/50 Hz)		
XCell Lab Controller - peak current | average current	1.3 Amps | 0.8 Amps		
Tablet computer - average current	2.6 Amps		
System environment			
Operating temperature, humidity (non-condensing)	4° - 40° C (39° - 104° F), 15% - 95%, 10% - 50%		
Materials of Construction (MOC)			
MOC of product contact components			
SS XCell ATF	N/A SU only	Stainless Steel EPDM Silicone	Stainless Steel Glass EPDM Silicone PTFE
SU XCell ATF	Polycarbonate Silicone TPE	Polycarbonate Silicone TPE	N/A SS only
MOC of non-product contact components			
Enclosure	Powder coated 304 Stainless steel		
Device clamps on stand	ABS		
Flow sensors	Steel and Aluminum		
Flow sensor clamps on stand	Stainless steel		
HMI	Magnesium and Glass		
Utility air supply tubing kit	Polyurethane, Stainless steel		
Tri-clamps	Stainless steel		
Device stand	Stainless steel		
XCell ATF to Controller (A2C) tubing kit	Polyurethane, Stainless steel		

	XCell ATF 1	XCell ATF 2		XCell ATF 4	
Filter Specifications					
Company	Repligen Filter	Repligen Filter	Cytiva Filter	Repligen Filter	Cytiva Filter
Module length	61 cm, 24 in	61 cm, 24 in	66 cm, 26 in	35.8 cm, 14.1 in	35.8 cm, 14.1 in
Module diameter	0.95 cm, 0.375 in	1.9 cm, 0.74 in	5.8 cm, 2.3 in	1.9 cm, 0.74 in	5.8 cm, 2.3 in
End connections	1/2” Sanitary	3/4” Sanitary	1/2” Sanitary	See Filter Housing	
Filtrate connections	Female Luer	3/8” Barb			
Surface area	0.0218 m^2	0.13 m^2	0.09 m^2	0.77 m^2	0.46 m^2
Effective fiber length	58 cm, 23 in	56 cm, 22 in	56 cm, 22 in	29.5 cm, 11.6 in	29.5 cm, 11.6 in
Fiber count	12	75	50	830	520
Sterilization	Autoclave 1 cycle per ATF® Autoclave Guide ; Irradiate 1 cycle up to 45 kGy				

Membrane Specifications							
Company	Pore size	Material	Fiber ID	Fiber OD	Water Flux	Integrity Tested	Claims
Repligen	0.2 µm 0.5 µm 50 kD	Polyethersulfone (PES)	1.0 mm	1.5 mm	> 979 LMH/barg > 979 LMH/barg > 39 LMH/barg	Yes; 100%	USP VI ISO 10993 EMA/410/01
Cytiva	0.2 µm 30 kD	Polysulfone (PS)	1.0 mm	1.3 mm	≥ 1871 LMH/barg ≥ 87 LMH/barg		

Filter Options				
Part Number	Device	Manufacturer	Pore Size	Filter Housing Materials of Construction
F1:RF02PES	XCell ATF 1	Repligen	0.2 µm	Housing: Polysulfone; Membrane: Polyethersulfone; Potting: Polyurethane
F2:RF02PES	XCell ATF 2		0.2 µm	Housing: Polysulfone; Membrane: Polyethersulfone; Potting: Polyurethane
F2:RF05PES			0.5 µm	Housing: Polysulfone; Membrane: Polyethersulfone; Potting: Polyurethane
F2:RF50PS			50 kD	Housing: Polysulfone; Membrane: Polysulfone; Potting: Polyurethane
F2:RF02PS		Cytiva	0.2 µm	Housing: Polysulfone; Membrane: Polysulfone; Potting: Epoxy; Netting: Polypropylene
F2:RF30PS			30 kD	Housing: Polysulfone; Membrane: Polysulfone; Potting: Epoxy; Netting: Polypropylene
F4:RF02PES-V2	XCell ATF 4	Repligen	0.2 µm	Housing: Polysulfone; Membrane: Polyethersulfone; Potting: Polyurethane; Netting: Polypropylene
F4:RF05PES-V2			0.5 µm	Housing: Polysulfone; Membrane: Polyethersulfone; Potting: Polyurethane; Netting: Polypropylene
F4:RF50PS-V2			50 kD	Housing: Polysulfone; Membrane: Polysulfone; Potting: Polyurethane; Netting: Polypropylene
F4:RF02PS		Cytiva	0.2 µm	Housing: Polysulfone; Membrane: Polysulfone; Potting: Epoxy; Netting: Polypropylene
F4:RF30PS			30 kD	Housing: Polysulfone; Membrane: Polysulfone; Potting: Epoxy; Netting: Polypropylene

	XCell® ATF 1	XCell® ATF 2	XCell® ATF 4
Hardware and Software Specifications			
XCell Lab Controller Height, width([1]), width([2]), Depth, weight Type, compliance	H: 15.3 in (38.9 cm), W([1]): 16.2 in (41.1 cm), W([2]): 22.5 in (57 cm), D: 12 in (30.5 cm), WT: 44 lbs (20 kg) Allen-Bradley L19 Programmable Logic Controller, UL/CE/RoHS/REACH/WEEE		
Supply Air Protection Assembly (SAPA) Height([3]), width, depth, weight (approximately)	H([3]): 14 in (35.6 cm), W: 20 in (50.8 cm), D: 7.5 in (19.1 cm), WT: 11 lbs (5 kg)		
Vacuum pump Height, width, depth, weight	H: 15.51 in (39.4 cm), W: 7.13 in (18 cm), D: 14 in (35.6 cm), WT: 21 lbs (9.52 kg)		
HMI and software specifications	Surface Pro 7, Windows 10 Pro 2004 kb, Wonderware Version 2020 R2		

17. Appendix C IT, IP Addresses and External Communication

Either Ethernet port on the controller can be used to connect to the supplied tablet/HMI which runs Repligen XCell Lab Software. It should not be transferred to another Surface Pro or any other computer device.

The two ethernet ports are switched internally and hence equivalent. Future software updates will use the second port for advanced functionality. The Surface Pro tablet comes with Wi-Fi capability built in but is not used by the XCell Lab Software.
Connection to a corporate network, a remote DCS, supervisory monitoring and control system or domain management of tablet or mapped drives, is not recommended or supported.

Note: At shipping, the controller and Surface Pro are issued with the IP addresses: 192.168.1.101 and 192.168.1.167, respectively. The HMI is configured to look for these addresses on the process control network.

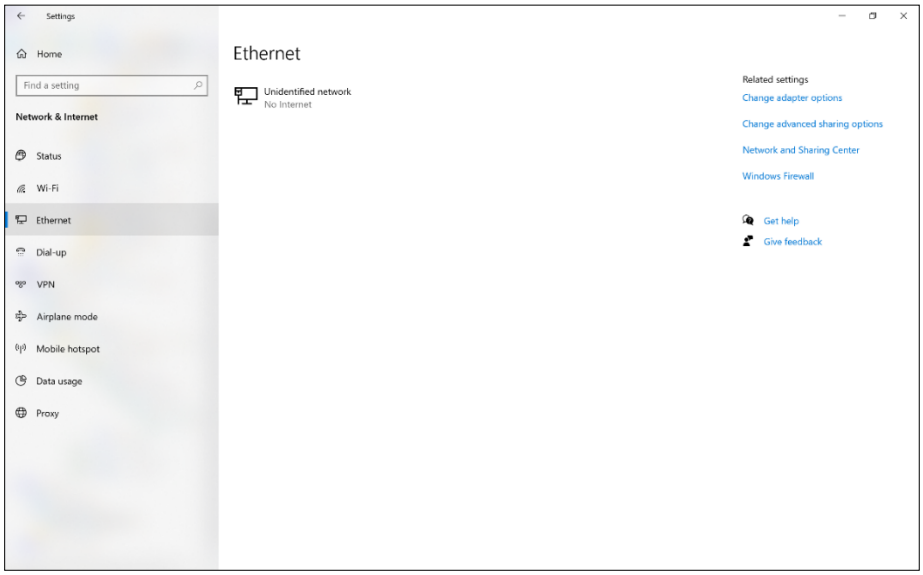
Precaution: *Please ensure that the ethernet cables are connected properly. If not, the XCell Lab Controller will trigger an alarm.*

17.1 Changing IP address on the HMI

If you find an error in communication between the tablet and the controller, you may need to edit the IP address of the tablet. Please see instructions below, which should only be carried out by a qualified IT or automation engineer or an authorized Repligen engineer.

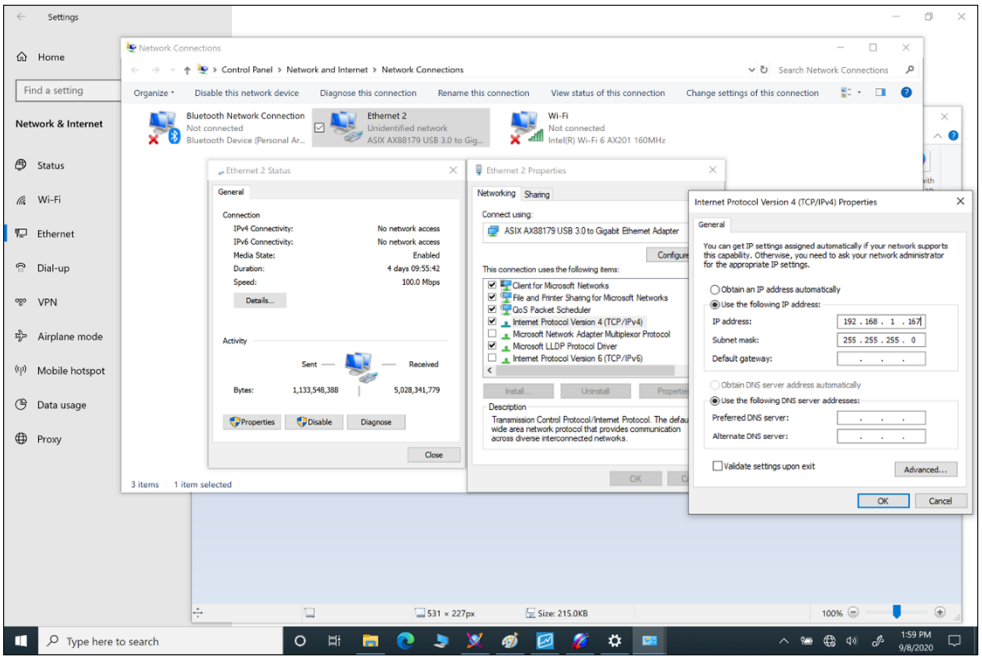
1. Open Control Panel (press Windows Start, then press the Gear Icon).
2. Click on Network and Internet.
3. Click on Ethernet.
4. On the right pane, click on Change adapter options.

Figure 43. Control Panel Network and Sharing Center



5. Click on the Ethernet 2 network icon (ASIX adapter). This can also be accomplished with a Right-click on the network adapter and selecting Properties.
6. Deselect Internet Protocol Version 6 (TCP/IPv6) if it is checked.
7. Select (Highlight) the Internet Protocol Version 4 (TCP/IPv4) option.
8. Click the Properties button.

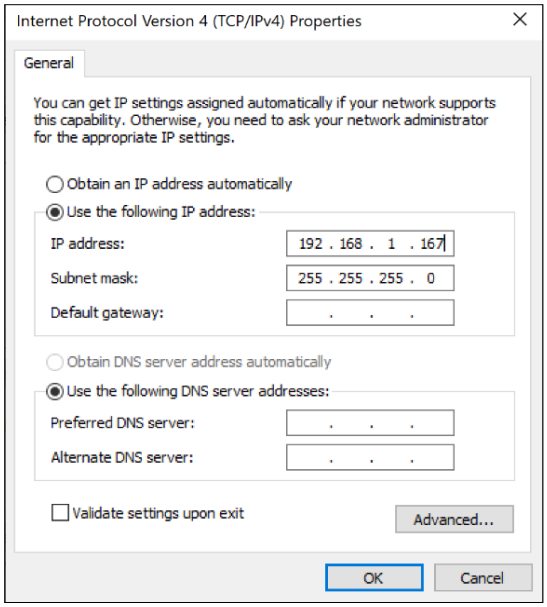
Figure 44. Control Panel Network Adapter Properties



9. Select the Use the following IP address option.
10. Set the IP address (192.168.1.167).
11. Press the Tab key.
12. Set the Subnet mask. Confirm the subnet mask is 255.255.255.0.
13. Leave the Default gateway alone.

14. Leave the Obtain DNS Server section below alone.
15. Click the OK button.

Figure 45. Windows 10 Network Adapter TCP/IPv4 Properties



16. Click the Close button again. Navigate back to the XCell Lab Software and test the new configuration to see if it works correctly.

18. Appendix D List of System-Defined Alarms

Table 19. Alarm List

Alarm/Interlock	Event Trigger	System Response	User Response
Configuration Parameter Outside Allowable Range	Hardware configuration is not compatible with the system (i.e., the following is invalid: filter size, fiber ID, filter length, number of fibers, both single and dual FT enabled, pressure sensor config, save command is given while filter is running)	System will not change to ATF Device size that is not allowed	Only use ATF Device sizes supported by the controller type
Setpoint Limited by Allowable Range	Flow rate entered is outside of the system range	XCell LS Controller restricts flow rate to the minimum or maximum flow, whichever is closer	See published ranges for ATF Device and verify input
Configuration Locked while ATF running	Requesting configuration change while ATF is running	System will not change configuration and will continue running	Stop controller before changing configuration
Invalid Dual Mode Command (DCS only)	Filter A and Filter B configuration do not match	Dual Mode will not turn on	Run in single-mode or change system configuration to matching device sizes
Fuse block has detected an open or blown fuse (DCS only)	Open or empty fuse in controller	Notification only, System will continue to run	Contact Repligen
System All Pause button pressed on Controller (DCS only)	Pause pushbutton pressed on side of controller	System pauses. Pause pushbutton blinks blue	Restart via HMI to resume run
SCADA communication to PLC has failed (DCS only)	Communication loss between ATF Controller and HMI	Historical data will not be stored	Check that the ethernet is connected and the ethernet LED is illuminated on the USB to Ethernet adapter. See Appendix B.
Insufficient Pressure Supply	Pressure supply is insufficient	System maintains running at current setpoint with no feedback changes to the pressure curve	Check pressure utility meets requirement for pressure and flow in Appendix A. See Section 13.3.1 for troubleshooting
Insufficient Vacuum Supply	Vacuum supply insufficient	System pauses for ATF-6 and ATF-10. ATF-4 will continue to run. In rare instances, this can indicate contamination of the pressure control valve (PCV)	Check vacuum utility requirement for pressure and flow in Appendix A. See Section 13.3.1 for troubleshooting
Retentate A2B Flow Sensor is not communicating	One of the A2B flow sensors is not communicating, usually due to a disconnected cable	If the system is not running, it will not be able to start the process. If the system is running when this alarm occurs, the system maintains run at current setpoint with no feedback changes to the pressure curve.	Check flow sensor cables. If running FS-10L only, verify “ATF10 2nd FS” is not selected in the ATF Configuration Screen.

Alarm/Interlock	Event Trigger	System Response	User Response
Retentate A2B Flow Sensor is not updating	All flow sensors are properly communicating, but one or more of the A2B flow sensors have not updated in 60 seconds or more (i.e., not attached to the A2B line), or if there is a mismatch of ±15% between the two A2B flow sensors in dual A2B mode	If the system is not running, it will not be able to start the process. If the system is running when this alarm occurs, the system maintains run at current setpoint with no feedback changes to the pressure curve	Check flow sensor fit and location on retentate line. See Section 13.3.2 for troubleshooting
Pressure sensor P2 not connected or faulty	Diaphragm pressure sensor (P2) analog input is out of range (0 – 10 V) or is disconnected from the PLC	Notification only	Contact Repligen
Permeate Pressure Sensor P3 not connected or faulty	Permeate pressure sensor (P3) is not communicating to the PLC, when it is configured to be present	Notification only	Check permeate pressure cable. If permeate pressure sensor is not in use, disable in configuration.
PCV not meeting command setpoint	The filter is running, but the diaphragm pressure sensor (P2) reads 35 mbar or more below the commanded pressure or exhaust value for more than 3 consecutive cycles	This alarm can be an indication of supply deficiencies. If the deficiency occurs on the vacuum command, the pressure command will be locked and not allowed to increase. If the alarm occurs due to a lack of pressure, the vacuum command will be locked and not allowed to increase.	Check pressure and vacuum utility meets requirement for pressure and flow in Appendix A. See Section 13.3.1 for troubleshooting
Initialization Step: Priming Failed	Insufficient pressure or vacuum supply detected	System will stop	See Section 13.3.1 for troubleshooting
Initialization Step: Minimum Force Detection Failed	Flow not detected	System will continue to run, using default driving force values.	See Section 13.3.2 for troubleshooting
Inconsistent displacement volume over 5 cycles	Flow data inconsistent for five sequential counts, as determined by totalized flow outside 10% error	System maintains running at current setpoint with no feedback changes to the pressure curve	See Section 13.4 for troubleshooting
Displacement volume 10% below minimum	10 sequential cycles of low displacement	Notification only. System continues to run	See Section 13.4 for troubleshooting

19. Appendix E: Editing and Adding Access and Passwords

19.1 Windows Accounts and Passwords

The industrial PC comes with two preset Windows accounts. One is a Windows Administrator account, which can create and edit users and passwords for both Windows and XCell Software. The other is a normal Windows user account which can run the XCell Software .

These two predefined Windows account logons are *User* and *0Admin* ([zero]Admin). By default, *User* will be logged in automatically, which then loads the XCell Software (called the “AVEVA Wonderware View” software application within Windows System) with a default username of ‘Supervisor’. A Supervisor has access to all areas of the XCell Software.

By using a single Windows User account for all users, all files and folder structures will be the same for all users. The Windows User account is a top-level group that contains all the XCell Software users. XCell Large-scale users of any kind are, by default, Windows Users.

Note: *It is only necessary to manually log into Windows to account usernames/passwords or change Windows administrator settings. All other settings are available to the default, automatically-logged-in, Windows User account.*

You need to login as 0Admin (Operating System Admin) if you need to modify existing XCell Software usernames or passwords (Table 20) or add new ones. It is recommended that a qualified IT or Repligen engineer carries out these tasks.

Note: *The 0Admin account cannot perform any action within the XCell Software. Use the User account for actions within the XCell Software.*

Table 20. Windows Usernames, Passwords, And Uses

User Type	Username	Password	Used For
Windows	0Admin	Admin123	Windows admin tasks and changing XCell Software usernames and passwords
Windows	User (logged in automatically)	User123	XCell Software

Note: *It is not recommended to create new Windows Users. Those accounts would not be able to access the XCell Software and the file structures would also be different.*

19.2 XCell Software and User Groups

To limit user access and enhance security in the XCell Software, you can set up users in the Windows environment and assign them to user groups.

Table 21. Large-Scale User Groups and Permissions

Windows Admin User Group Name	XCell Software Username	XCell Software Password	Change Network	Alarm and System Configuration	Start/Stop Flow SP Ack Alarms
XCell_Engineers	Eng	123	✓	✓	✓
XCell_Supervisors	Super	123		✓	✓
XCell_Users	Opr	123			✓

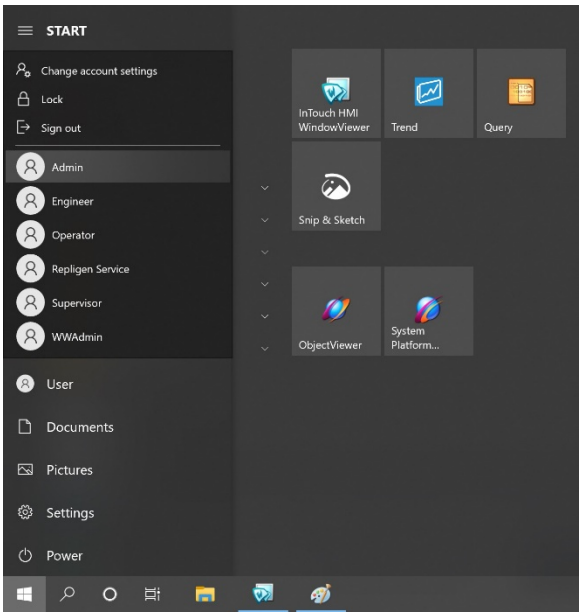
19.2.1 Setting up User Groups

To limit user access and enhance security in the XCell Lab software, XCell users can be set up in the Windows environment and be assigned to the Roles (user groups) listed in Table 21 above.

Please see below for instructions on how to create a user account (also applies to deleting and managing accounts). You may prefer to use the supplied touchpad for these set of actions.

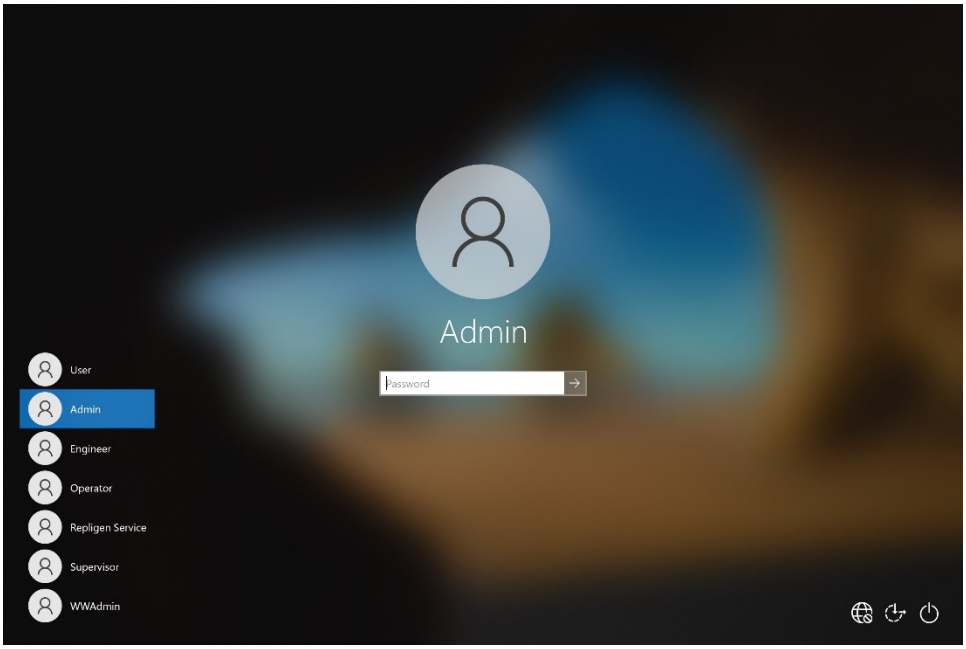
1. Press Start and prepare to log in as the Windows Administrator. If the start button (the windows icon) is not visible, you should press the Windows/Start button on the tablet, or swipe right.

Figure 46. Start Menu



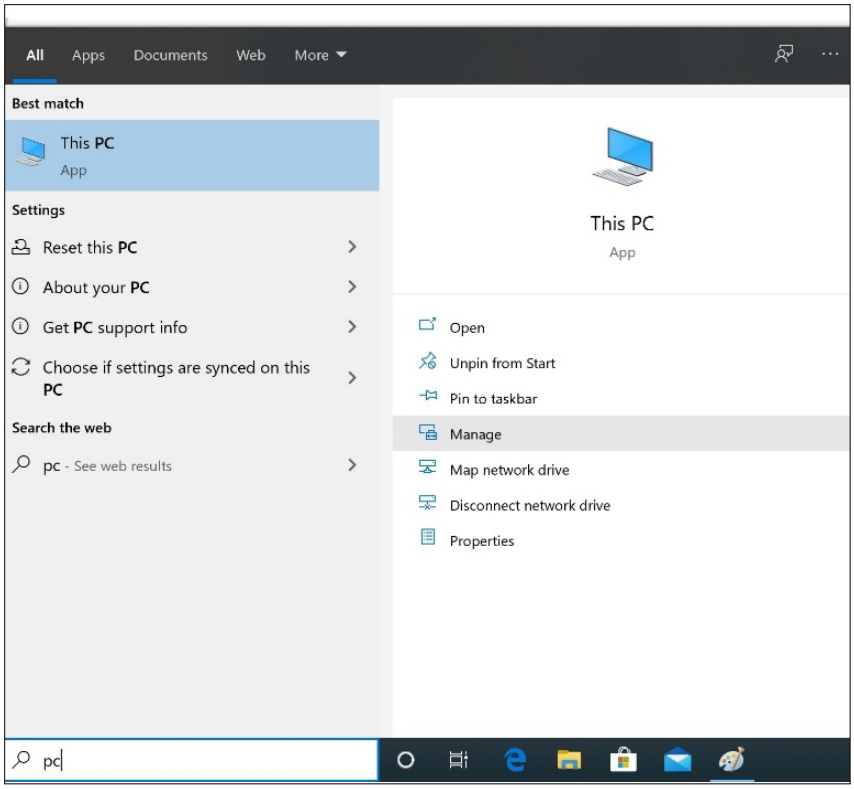
2. Click the circular user icon and Select the Admin user (see image above).

Figure 47. Admin Screen



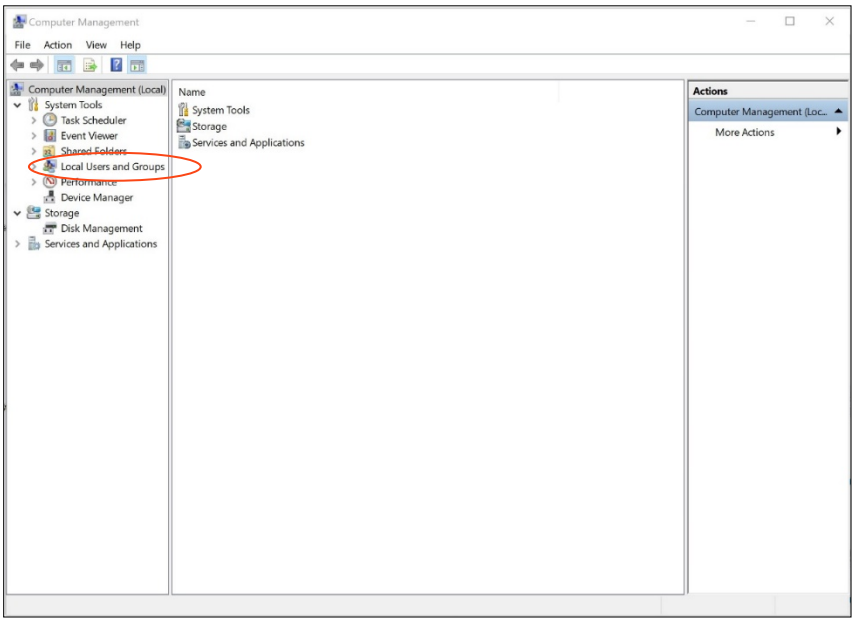
3. Enter Password Admin123.
4. The Windows Admin is logged in.
5. Next press the Windows Start button and type PC (see below).

Figure 48. Windows Start Button



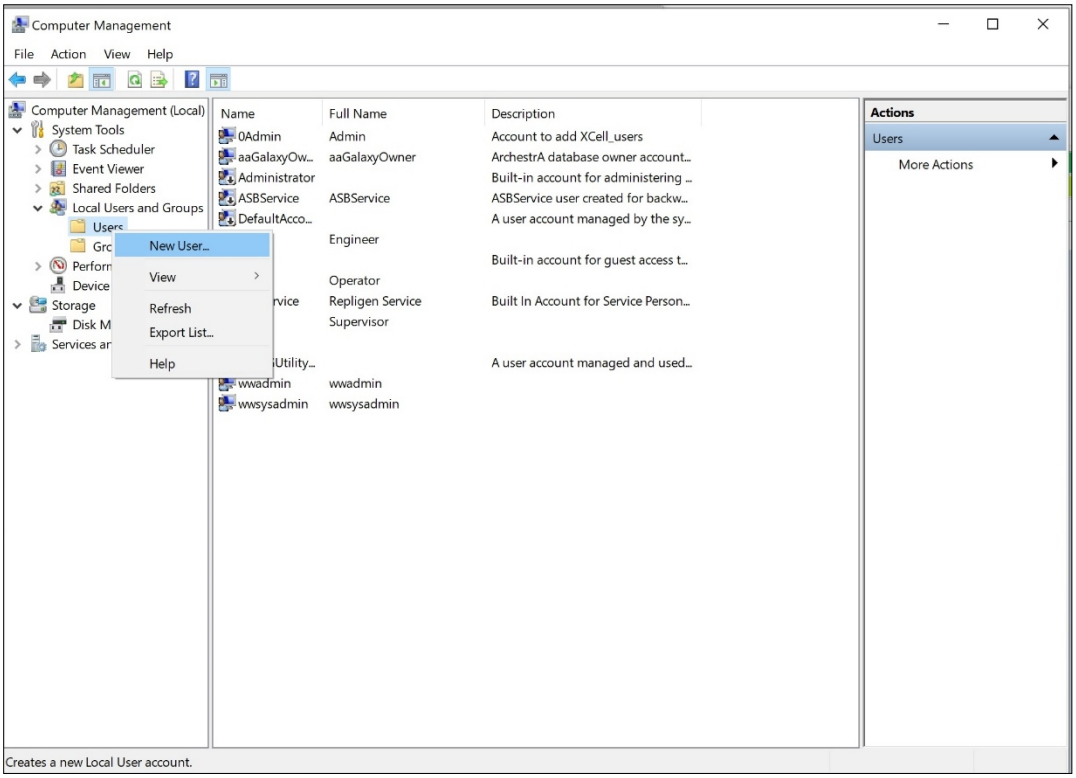
6. Select Manage. The Manager opens.
7. Navigate to Local Users and Groups.

Figure 49. Local Users and Groups



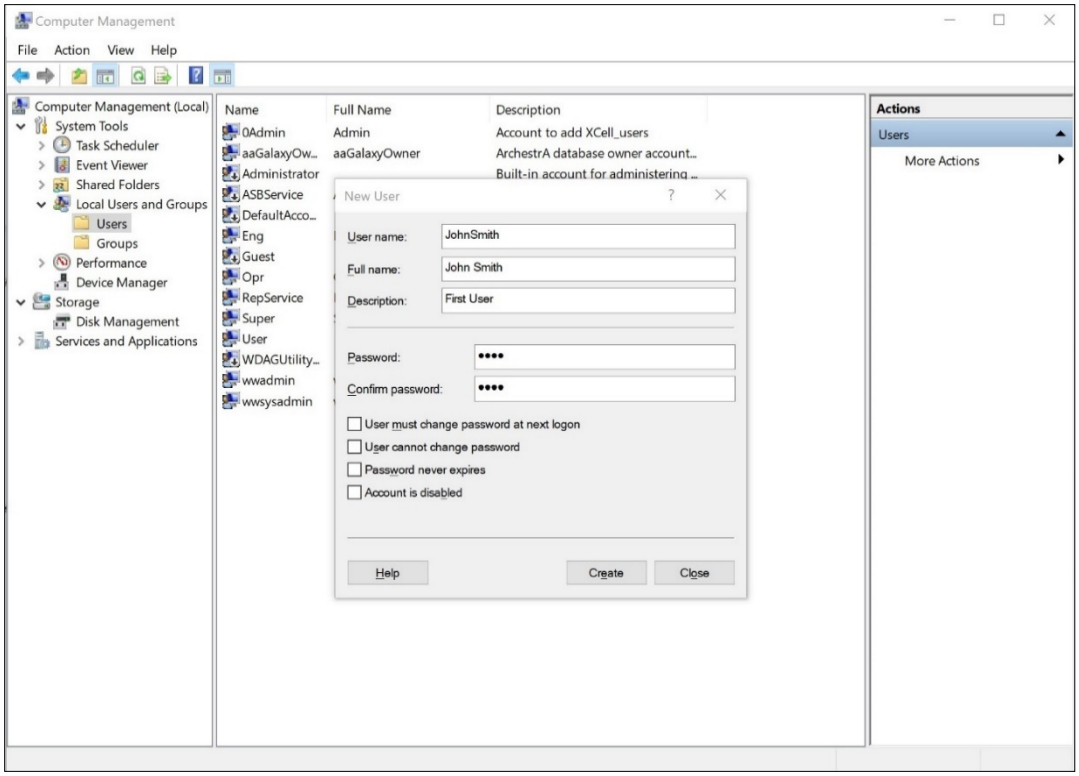
8. Right click on Users and select New User.

Figure 50. New User



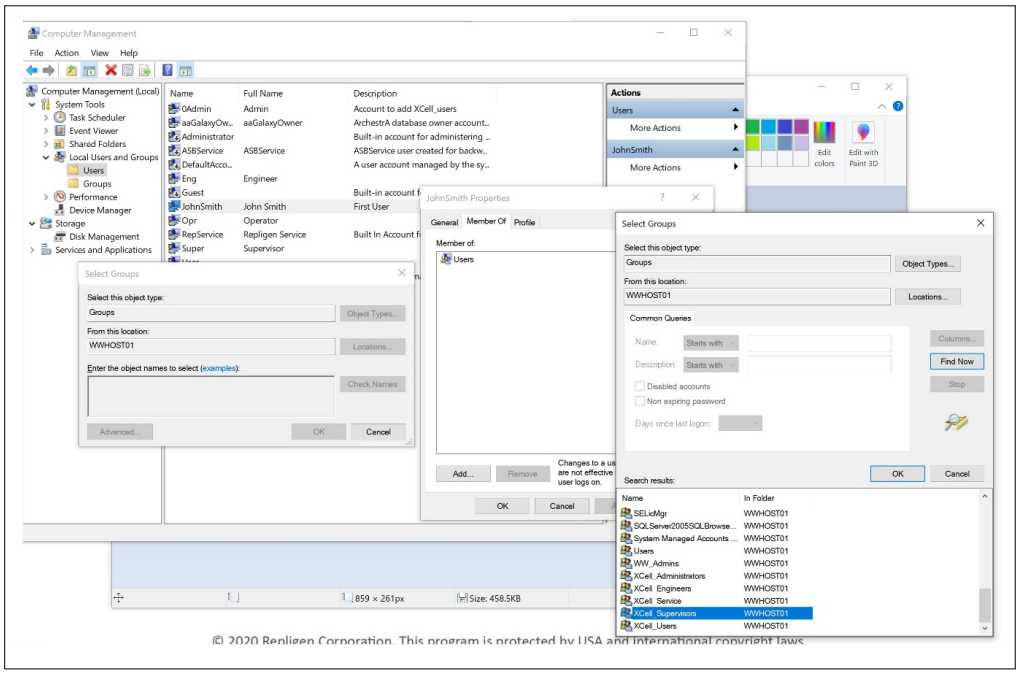
9. Enter user information. (Description and Full names are optional).

Figure 51. User Information



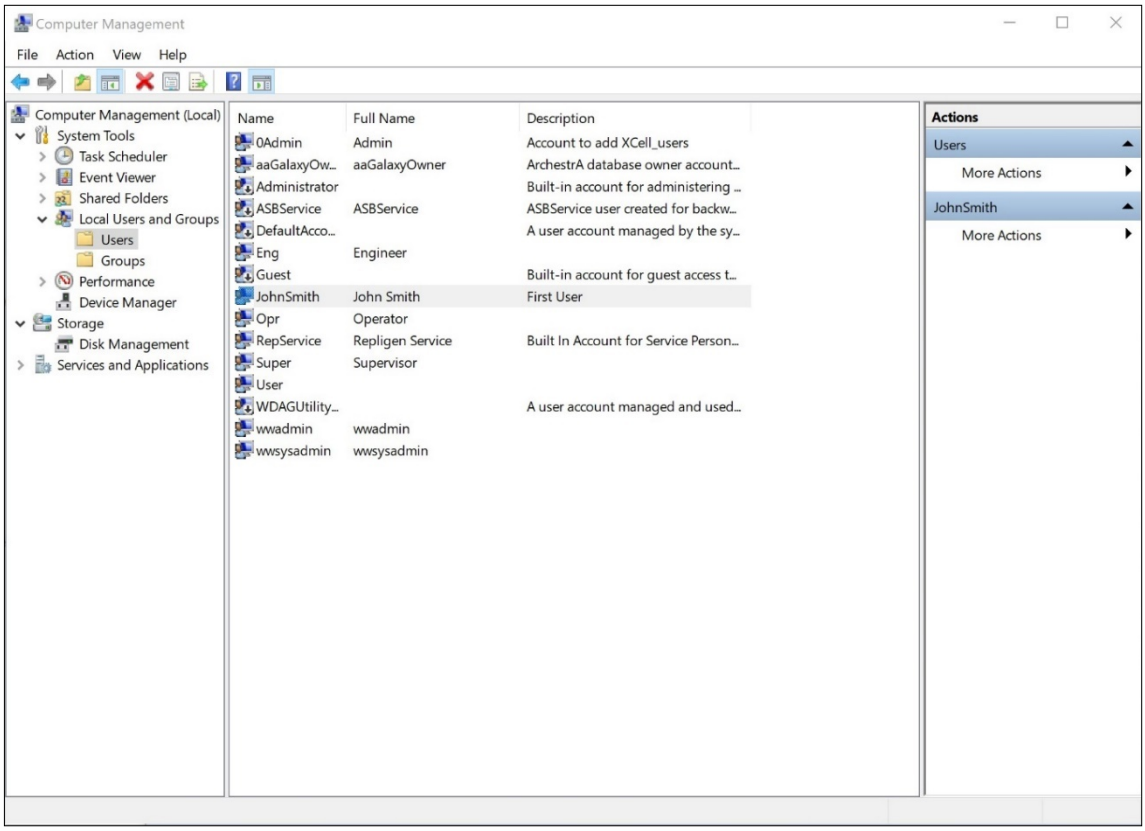
10. Important: Be sure to deselect User must change password at next logon.
11. Press the Create button. The user is added.

Figure 52. Select Group



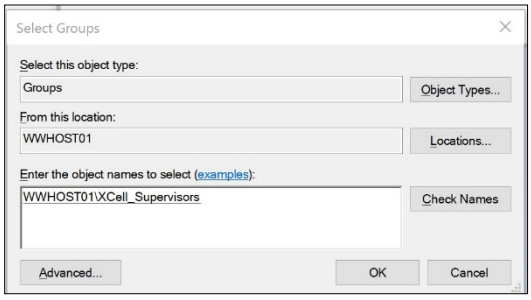
12. Assign to a group. Double click (or right click and select properties).
13. Navigate to the Member Of tab and press the Add button. Another window appears.

Figure 53. Member of Tab



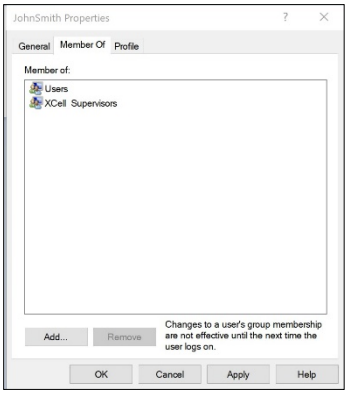
14. Press the Advanced Button. Another window appears. Press the Find Now button.
15. Scroll to the bottom and select one of the XCell groups. XCell Supervisors is selected.
16. Press the OK button. The window closes.

Figure 54. XCell Supervisors



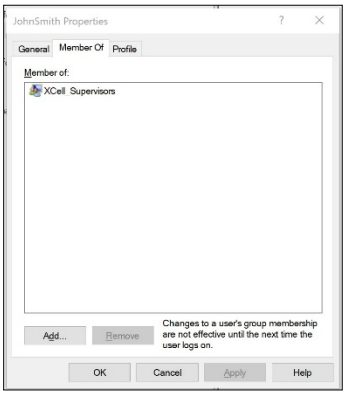
17. Press the OK button. The user is assigned.

Figure 55. Assigned Users



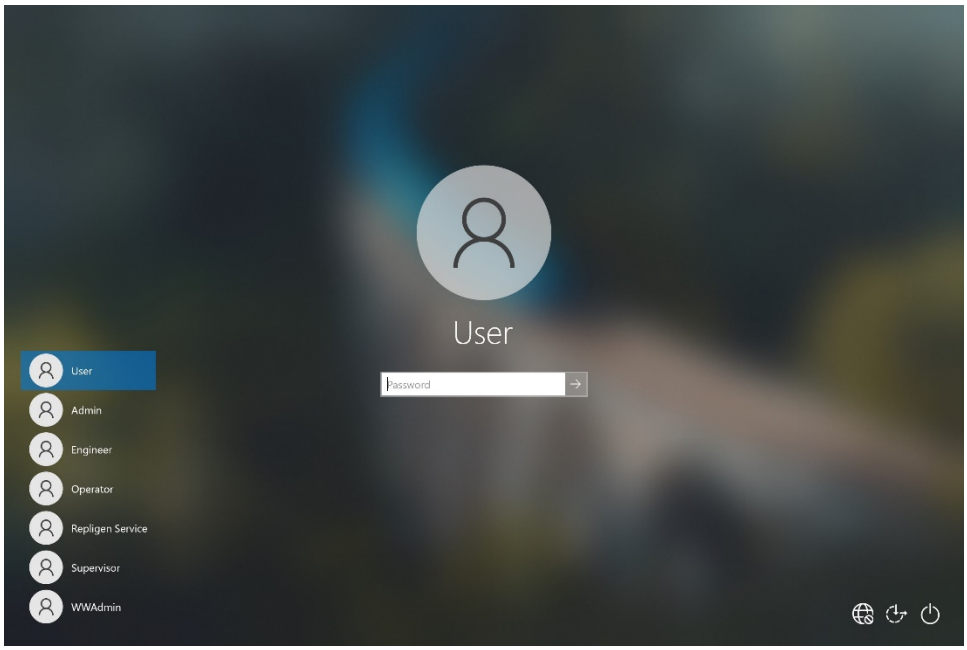
18. Select the Users group, and press the Remove button, then Press the OK button.

Figure 56. Remove Users



19. The user is only assigned to the appropriate group.
20. Add as many users as required while Admin is logged in.
21. When complete, sign out of the admin account (and best to restart the laptop).
22. Press Start, click the circular user icon and select sign out.

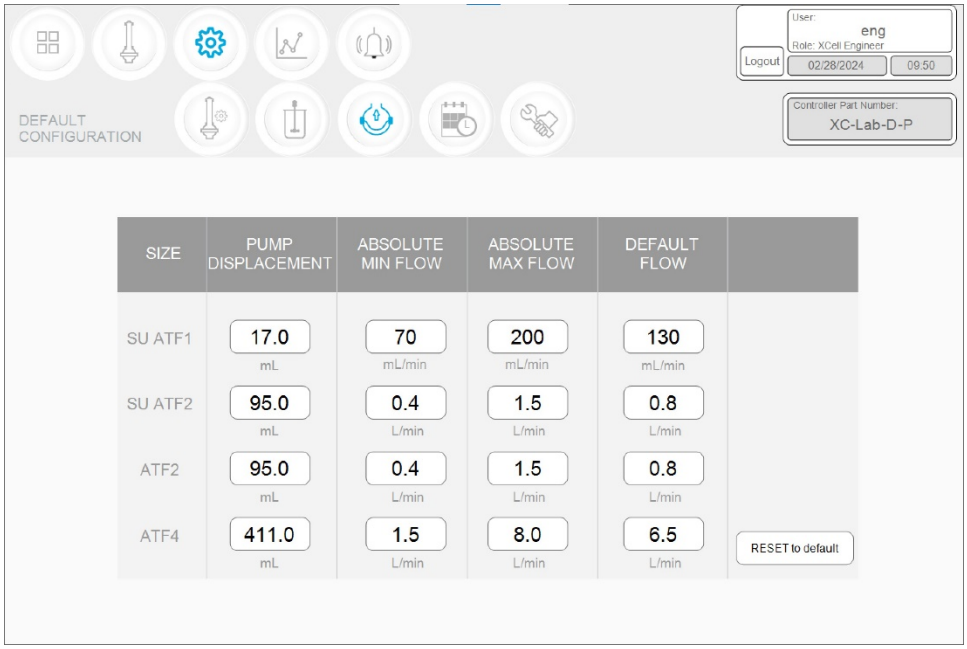
Figure 57. User Sign-out



23. Enter password User123 to return to the XCell windows user account.
24. If not already running (you can check by swiping right to show all active programs), restart the Wonderware View (XCell Lab software) application.

20. Appendix F Default Values on HMI

Figure 58. Default Values for ATF Pump Configuration



Note: *Default values for ABSOLUTE MIN FLOW and ABSOLUTE MAX FLOW are outside of our recommended flow rate ranges (Table 15).*

Figure 59. Default Values for ATF Flow Alarms

Figure 60. Default Values for Displacement Volume Alarms

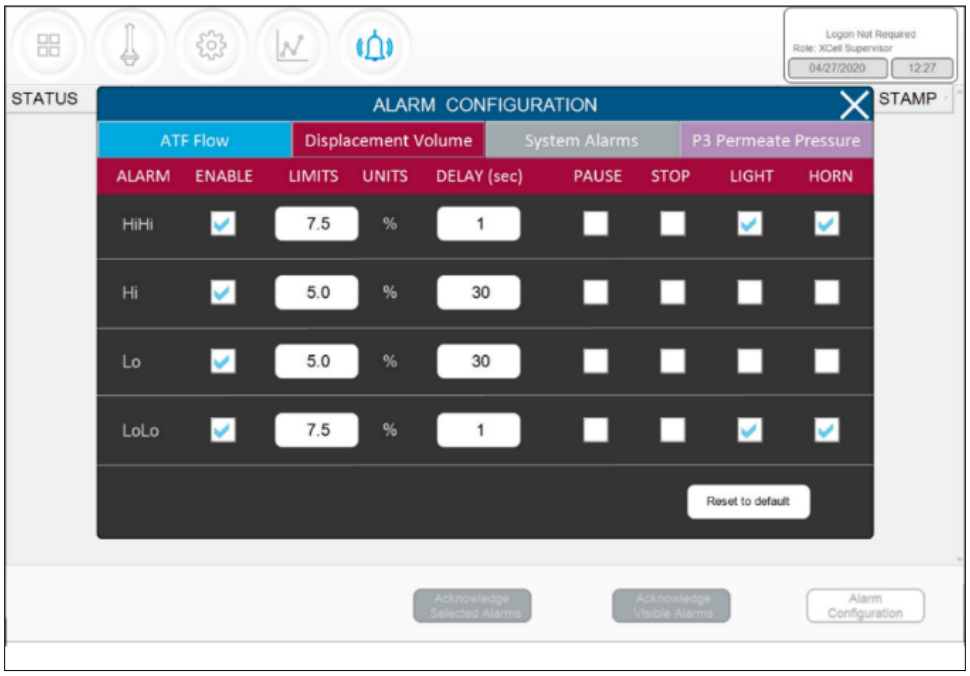


Figure 61. Default Values for System Alarms

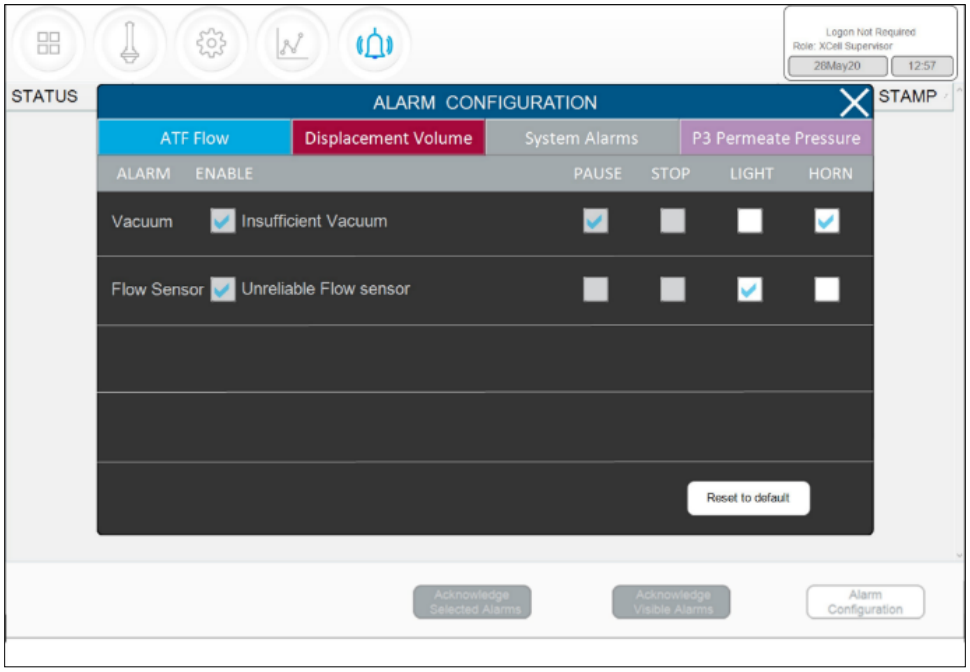


Figure 62. Default Values for P3 Permeate Pressure Alarms

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