XCell[®] LS Controller

User Guide

For XCell ATF 4, 6, and 10 Systems





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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

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

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
Ib Pound

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

PLC Programmable logic controller 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 Set point

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



VTVolumetric throughput

VVD Vessel volume exchange per day



WARNING! This product can expose you to chemicals including Cadmium which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.



1. Introduction

XCell® ATF Technology provides a complete solution for the retention of cells, removal of media, and the intensification of upstream cell culture processes. XCell ATF Technology includes several components and accessories including the controller hardware, software, sensors, and XCell ATF Device(s), and accessories. This system provides proven upstream intensification performance on an industrial automation platform and is designed to meet the challenges of high cell density intensification processes in the range of $10 - 250 \times 10^6$ cells/mL. Scale of operation ranges from 50L for pilot-scale installations to more than 2000 L for commercial installations.

This user guide serves as a reference document for XCell LS Controller and Software. For the latest version of this document, please visit the Repligen website. Installation by a trained Repligen Field Service Engineer (FSE) is highly recommended.

The XCell LS Controller unit is a stainless-steel enclosure that houses the components required for controlling the ATF operation. A programmable logic controller (PLC) holds the logic and receives/sends the necessary instrument and controls signals to a pressure control valve (PCV) that drives the ATF device diaphragm. Key components include easy-to-use software, flow sensors, and air and vacuum accessories to drive the operation of XCell ATF 4, XCell ATF 6, and XCell ATF 10 Devices in pilot, clinical and commercial GMP environments.

2. Product information

Product Family XCell LS Controller

PLC Software Version 1.15 HMI Software Version 1.15

Windows® Version 10 Pro 2004 kb

XCell ATF Devices supported XCell ATF 4, 6, 10 Devices

Table 1. Dimensions and weight

Component	Dimensions (H, W, D)	Weight
XCell LS Controller	16" x 20" x 8.8"	49 lb

3. About this document

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

Table 2. 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.



4. Safety and warnings

Table 3. 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 (XCell ATF 4, XCell ATF 6, and XCell ATF 10) 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 4. Safety warnings

Description of warnings



Power: Do not open the enclosure when powered on. Remove power from equipment before attempting any maintenance. Calibration, preventive maintenance, and repair is 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 Device and bioreactor may result in fluid being sprayed from pump. Use appropriate measures to protect operator and equipment.



Do not clean (wipe down) the XCell LS Controller when the enclosure cover is open. Confirm all connectors (connection bulkheads) are firmly seated in their respective sockets.



Weight: XCell LS Controller weighs 49 lbs. (22.2 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: The XCell LS Controller require 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 a translucent grey color. 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 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 LS Controller. The Supply Air Protection Assembly must be mounted to a solid support, either a wall or table.



5. Quick-start guide

If you are an experienced XCell ATF Technology user and already familiar with the Health and Safety guidelines, then this section will help you get set up quickly. If you need further guidance, please review this entire user guide, including the appendices, or reach out to a local Field Application Scientist (FAS).

Figure 1. XCell LS Controller and accessories

- 1. XCell LS Controller
- 2. XCell Software and HMI
- 3. Flow sensor
- 4. Supply air protection assembly
- 5. Vacuum pump





5.1 Connections

Connect all components as described below:

- 1. Place the HMI in a convenient location, either on the controller or attached to a shelf.
- 2. Connect the air utility line to the SAPA.
- 3. Connect vacuum supply or Repligen-supplied vacuum pump.
- 4. Prepare and connect the XCell ATF Device according to the user guide received with the
- 5. Ensure the flow sensor is correctly oriented and stabilized on the A2B tubing in a location where air bubbles are not likely to collect within the tubing.
- 6. Connect the permeate pressure sensor (P3), if used.
- 7. To supply power to the controller, connect the 24 V adaptor to the wall power source.
- 8. Turn on the controller and HMI. By default, no logon credentials are required for the HMI. The XCell Software opens with the *Supervisor* account.

5.2 Software set-up

Please note the following:

- The software interface allows real-time changes to the set points.
- During operation, certain buttons are grayed out to ensure proper operation. For example, the XCell ATF Device size selection option is disabled 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.

To get started:

- 1. On the top of the main menu, click the Settings button, which displays the settings sub-
- 2. Click the ATF configuration button to set the XCell ATF Device size and filter type.
- 3. Click the second button, Bioreactor configuration, to change the default settings of one XCell ATF Device attached to a bioreactor.



4. Use the other buttons in the settings sub-menu to change date and time formats, pump settings, flow rates, etc.

5.3 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 parameter details box to open the ATF Flow parameter details screen.
- 3. Click Start. The priming sequence begins, and the run starts.

Note: Set points can be changed at any time, both before and during a run.

5.4 Optimization

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

6. XCell ATF Technology overview and process intensification

XCell ATF Technology uses alternating tangential flow (ATF) to intensify upstream processes by retaining cells in suspension cultures, such as mammalian cell culture and viral vectors. An innovative diaphragm pump creates alternating tangential flow, leading to high viable cell densities and increased throughput with lower cost of goods. Typical applications include intensification of the following processes:

- N-1 fed-batch
- Long-term continuous processing
- Vaccine and virus production
- Gene therapy and media exchange

Repligen has an experienced, global team of scientists ready to support the development, optimization, scale-up, and troubleshooting intensified cell culture processes. For support or troubleshooting, please contact your local Field Application Scientist (FAS). For systems installation, testing, troubleshooting and validation support, Repligen Field Service Engineers are available for support.

6.1 Alternating Tangential Flow (ATF) filtration

The diaphragm pump of the XCell ATF Large-Scale System Device generates alternating tangential flow (ATF) through hollow fiber filters. ATF is a continuous, low shear, pulsating, and bi-directional flow of cell suspension between a bioreactor and a diaphragm pump (Figure 2). Cells move back and forth 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.



PRESSURE STROKE **EXHAUST STROKE** DIAPHRAGM FULLY PRESSURIZED DIAPHRAGM FULLY EXHAUSTED Flow to Flow from Filtered harvest Filtered harves Hollow fiber filter Hollow fiber filter XCell ATF® housing XCell ATF® housing Cell suspension Cell suspension Air filter Positive air Air filter Negative air pressure pressure

Figure 2. XCell ATF pressure and exhaust strokes

6.2 XCell 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 rate creates reduced levels of backflush, which can compromise results. XCell ATF controls, algorithm, and alarms are programmed to minimize filter fouling based on user-define parameters. The Troubleshooting Section, provides additional approaches and solutions to minimize fouling and achieve optimal filter performance.

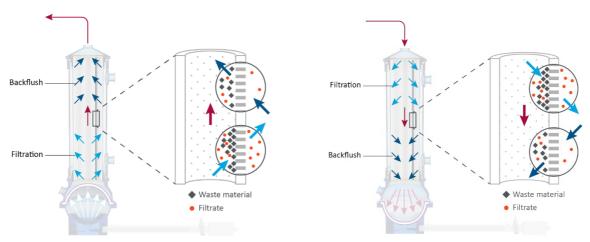


Figure 3. Backflush example

Backflush in pressure stroke (left); backflush in exhaust stroke (right)



(vacuum)

6.3 XCell ATF Device flow rates and displacement volumes

The flow rate of cell culture liquid from the XCell ATF Device to the bioreactor 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 again begins to slow, approximating a sinusoidal curve.

The controller records the instantaneous flow rate approximately every ~100 ms during each stroke (mL/min) and then averages stroke measurements over the cycle to generate the ATF flow rate. Due to the nature of the directional 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. The instantaneous flow rate is useful when troubleshooting ATF operation.

Under normal operating conditions, the displayed XCell ATF flow rate, which is an average of flow data over 10 pressure/exhaust cycles, is appropriate for managing ATF operation. The user can control the XCell ATF flow rate by entering a value for the XCell ATF flow rate set point. The recommended XCell ATF flow rate set points and the typical displacement volumes are programmed into the controller as default values. The calculated average displacement volume from the flow sensor is updated every 30 minutes to further improve the response accuracy. A properly operating system will achieve maximum flow quickly and switch smoothly between pressure and vacuum strokes. No delay is expected between pressure and vacuum strokes and a maximum diaphragm displacement is expected during strokes.

7. XCell LS Controller offerings

Available in GMP format, the XCell LS Controller will run XCell ATF 4, 6, or 10 Devices, with adjustments to the ATF to controller (A2C) tubing, ATF to bioreactor (A2B) tubing, and flow sensor. The controller is available in configurations that can operate either one (single) or two (dual) XCell ATF Devices from a single controller.

Table 5. XCell LS Controller system offerings

XCell LS Controller Family	Typical Scale of operation	Typical installation	Compatible XCell ATF Device
XCell Large-scale (ATF 4 and 6)	50 - 1000 L	Large-scale Development Facility, Pilot Laboratory; GMP	XCell ATF 4 Device XCell ATF 6 Device
XCell Large-scale Plus (ATF 6 and 10)	500 - 3000+ L	Clinical and/or Commercial GMP Manufacturing	XCell ATF 6 Device XCell ATF 10 Device

In a dual configuration, two XCell ATF Devices can be connected to a single XCell LS Controller and may be connected to one or two bioreactors. When operating two bioreactors from the same controller it is a possible to operate at different scales, depending on the model and configuration.

Single Channel XC Large-scale Controller (46)

- One XCell ATF 4 Device operation, or
- One XCell ATF 6 Device operation

Single Channel XC Large-scale Plus Controller (610)

- One XCell ATF 6 Device operation, or
- One XCell ATF 10 Device operation

Dual Channel XC Large-scale Controllers (46)

- Two XCell ATF 4 Devices simultaneously
- Two XCell ATF 6 Devices simultaneously



• XCell ATF 4 Device and an XCell ATF 6 Device simultaneously Dual Channel XC Large-scale Plus Controllers (610)

- Two XCell ATF 6 Devices simultaneously
- Two XCell ATF 10 Devices simultaneously
- XCell ATF 6 Device and an XCell ATF 10 Device simultaneously

Table 6. XCell LS Controller finished offerings

Category	Description	Part number	Recommended Spare
XCell LS Controller	XCell XC Large-scale LS46 Controller, Single, GMP	XC-LSC-46-S-P-GMP	
	XCell XC Large-scale LS46 Controller, Dual, GMP	XC-LSC-46-D-P-GMP	
	XCell XC Large-scale Plus LS 610 Controller, Single, GMP	XC-LSC-610-S-P-GMP	
	XCell XC Large-scale Plus LS 610 Controller, Dual, GMP	XC-LSC-610-D-P-GMP	
Hardware	XCell Safety Air Protection Assembly GMP	XC-LSC-SAPA-V2	Υ
and Accessories	XCell Industrial PC HMI Kit	XC-LSC-HMI	
710003301103	XCell Flow Sensor for ATF 10L	FS-10L	Υ
	XCell Flow Sensor for ATF 10R	FS-10R	Υ
	XCell Flow Sensor for ATF 6, Legacy	FS-6C	Υ
	XCell Flow Sensor for ATF 6	FS-6	Υ
	XCell Flow Sensor for ATF 4	FS-4	Υ
	XCell Flow Sensor Cable Kit 4.5M	XC-FS-CABLE-S450	Υ
	XCell Flow Sensor Cable Kit 4.5M, Dual	XC-FS-CABLE-D450	Υ
	XCell Pressure Cable Kit 4M	XC-PS-CABLE-400	Υ
	XC LSC ATF46-to-Controller Tubing	XC-LSC-A2C46	Υ
	XC LSC ATF10-to-Controller Tubing	XC-LSC-A2C10	Υ
	XC LSC Air Vacuum Utility Connection Kit	XC-LSC-AIRVAC	Υ
	XC LSC Universal Cart	XC-LSC-CART	
	XC LSC Vacuum Pump, XCell ATF4 and XCell ATF6	XC-LSC-VP46	
	XC LSC Vacuum Pump, XCell ATF 6 and XCell ATF 10	XC-LSC-VP610	
Service and Support	XCell LS System Installation (Required for installation, includes basic user training)	SV-IT-LSC-S SV-IT-LSC-D	
	XCell LS System Site Acceptance Testing (SAT)	SV-SAT-LSC-S SV-SAT-LSC-D	
	XCell LS System Extended Warranty (13-24 months)	SV-WA-LSC-46S SV-WA-LSC-610S SV-WA-LSC-46S SV-WA-LSC-610S	

NOTE: As part of system installation (IT), a Repligen Engineer assembles LS system on site, ensures that the system is fully operational and provides basic user training. Site Acceptance Testing (SAT) includes full functional testing and documentation for supporting users in qualify systems for GMP use. Additional Service support options such as Preventative Maintenance (PM) and Service Agreement (SA)are available. Please contact Repligen Service at serviceschedulingeu@repligen.com or serviceschedulingus@repligen.com for further information on commissioning and supporting XC LS Controller systems.



7.1 XCell LS Controller features

XCell LS Controllers are available in several models.

Table 7. XCell LS Controller key features

XCell LS Controllers	XC-LSC-46-S-P-GMP	XC-LSC-46-D-P-GMP
Single XCell ATF operation	✓	✓
Dual XCell ATF operation	×	✓
In/Out of phase or independent dual operation	N/A	✓
Transmembrane pressure (P3)	✓	✓
Single-use XCell ATF 6 Device	✓	✓
Autoclavable XCell ATF 4 Device	✓	✓
Autoclavable XCell ATF 6 Device	✓	✓
GMP ready	✓	✓

Table 8. XCell LS Controller-key features

XCell LS Controllers	XC-LSC-610-S-P-GMP	XC-LSC-610-D-P-GMP
Single XCell ATF operation	✓	✓
Dual XCell ATF operation	×	✓
In/Out of phase or independent dual operation	N/A	✓
Transmembrane pressure (P3)	✓	✓
Single-use XCell ATF 6 Device	✓	✓
Single-use XCell ATF 6 Device	✓	✓
Autoclavable XCell ATF 4 Device	✓	✓
Autoclavable XCell ATF 6 Device	✓	✓
GMP ready	✓	✓

8. XCell LS 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.

8.1 XCell LS Controller key components (Enclosed)

Programmable Logic Controller & I/O cards

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, relay output cards, analog output card and universal analog card.



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 (\leq -40° C dew point) air at 25 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.

Pressure Transmitter

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 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.

8.2 Field instrumentation

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.

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.

9. Connecting the XCell LS Controller

XCell LS Controller has two faces with utility ports and controls.

Face A enables utility connections, including the vacuum, air, and electric power to the enclosure (Figure 4). Face A also includes the power switch for the controller. The XCell LS Controller Software can be accessed through a Repligen-provided Industrial PC HMI that uses a wired ethernet connection at ports ETH 1 or ETH 2 on Face B of the XCell LS Controller. If the connection with ethernet cable is loose, the system might indicate Ethernet Cable connection error.

Face B of the controller (Figure 5) enables connections for output operations, including connections to the XCell ATF Device(s) and instrumentation.

Note: Ethernet ports are not used for a head-less XCell LS Controller unit that can be directly integrated to the end-user DCS system.



AIT A System Pause System Pause Paus

Figure 4. XCell LS Controller, Face A



PUMP CONTROL
ATF A ATF B BR B Φ 0 0 0 Φ Φ 0 0 0 PERMEATE PRESSURE ATF B FLOW SENSOR 0 13 ATF A FLOW SENSOR

Figure 5. XCell LS Controller, Face B

Table 9. XCell LS Controller ports

Item		Description
1	Air	Connection for positive air pressure from SAPA; push-to-connect bulkhead fittings feed the PCV supply manifold inside the enclosure
2	Vacuum	Connection for vacuum line from facility source or vacuum pump; push-to-connect bulkhead fittings feed the PCV supply manifold inside the enclosure.
3	Power switch	Power on/off
4	24V DC in	DC power from power supply; accepts 24VDC from external power supply and lands it on the terminal blocks inside the enclosure
5	ATF A/B System pause	Pause buttons for ATF A and ATF B LED light indicates status
6	Alarm	Visual and/or audible alarm
7	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 LS Controller into an existing distributed control system (DCS) system using Ethernet I/P and Modbus TCP protocols.
8	Profibus Ports	NOT CURRENTLY USED



Item		Description
9	Permeate A/B pump	NOT CURRENTLY USED
10	Media Addition and Cell Bleed Pumps	NOT CURRENTLY USED
11	To ATF A/B	A2C connections for air pressure and vacuum to XCell ATF Devices
12	Bioreactor A/B Weight	NOT CURRENTLY USED
13	ATF A/B Flow Sensor	Connection of Sonotec flowmeter cables for A2B retentate line flow sensor; two M12 5-pin bulkhead fittings, one for each XCell ATF Device; carry data to controller
14	ATF A/B Permeate pressure	Permeate line P3 pressure sensor inlet connections; two 14-pin bulkhead fittings, one for each ATF.
15	VCD – Bioreactor A/B	NOT CURRENTLY USED

9.1 XCell Pneumatics connectivity

9.1.1 Utility supply to controller—SAPA and utility tubing

The Supply Air Protection Assembly (SAPA) regulates air pressure from the facility utility line to the required 25 psi. The minimum utility air pressure requirement is 50 psi. A pressure relief valve provides safety in case of failure of the regulator (<u>Figure 7</u>). 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.

The utility tubing set (XC-LSC-AIRVAC) connects to the air and vacuum ports (Figure 6). The air tubing connects the controller to the SAPA, not directly to the site utility source.

Figure 6. SAPA connection to controller

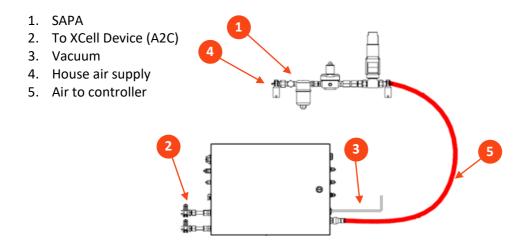




Figure 7. SAPA

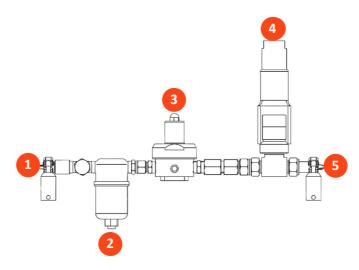


Table 10. SAPA components

Item Code: XC-LSC-SAPA-V2		Description
1	Assembly inlet	Pressurized air from air supply
2	Filter unit	Filters air routing from air supply Filter porosity: 0.1 μm
3	Pressure regulator	Factory-set air pressure supply regulator designed to downregulate the supply air to a lower pressure required to operate XCell ATF 4, XCell ATF 6, and XCell ATF 10 Devices (do not adjust).
4	Pressure relief valve	Factory set air supply pressure relief valve set to relieve if inlet pressure exceeds the specification (do not adjust).
5	Assembly outlets	Pressurized air to XCell LS Controller

Note: The SAPA must be installed with the air filter (item 2, <u>Figure 7</u>) oriented downwards and plumbed.

9.1.2 ATF-to-controller connection (A2C)

The A2C tubing set connects the XCell ATF Device to the controller via a pneumatic line (Figure 8). The controller ships with a collection of A2C tubing sets specific for each device type (XCell ATF 4 Device, XCell ATF 6 Device, or XCell ATF 10 Device). Although the A2C tubing sets may appear similar, they are not interchangeable; each is designed to function only with a specific XCell ATF Device type.

Labeling on the tube sets indicates the appropriate device. Be sure you are using the correct tube set for your device.



Figure 8. Connection of two devices to the controller

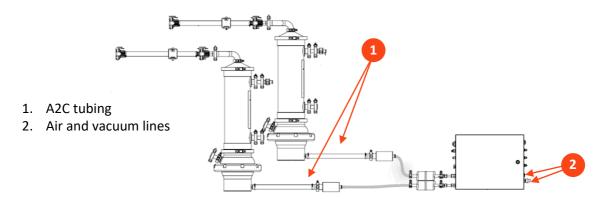


Table 11. Part numbers for tubing and vacuum accessories

Description	Part number
XC LSC ATF46-to-Controller Tubing (Figure 8, #1)	XC-LSC-A2C46
XC LSC ATF10-to-Controller Tubing (Figure 8, #1)	XC-LSC-A2C10
XC LSC Air Vacuum Utility Connection Kit (Figure 8, #2)	XC-LSC-AIRVAC
XC LSC Vacuum Pump, XCell 4 and XCell 6*	XC-LSC-VP46
XC LSC Vacuum Pump, XCell 6 and XCell 10*	XC-LSC-VP610

^{*}Not required if using house vacuum

9.2 Connecting XCell ATF Device to the bioreactor

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. Intended for use in pilot scale, clinical, and commercial bioprocessing environments, tube set kits work with XCell LS Controllers and legacy C410 controllers. A2B tube set kits are available in multiple configurations for each XCell ATF Stainless Steel Housing or XCell ATF Single-use Device, including options for both hard and soft connections. Choice of tube set depends on the type of bioreactor in use and the desired connectors. In addition to the tube set kits, several accessories may be required.

Permeate tubing (available as part of XCell ATF tube set kits for XCell ATF Single-use Devices or provided by end-user of XCell ATF Stainless Steel Devices) connects the XCell ATF Device to the harvest collection vessel and should be sterilized by autoclave or attached with a tubing welder or disposable sterile coupling.

Please refer to the XCell ATF 4, 6, and 10 Stainless Steel Housings User Guide or XCell ATF 6 and 10 Single-use Device User Guide for details on ATF process connections to bioreactor and to the harvest collection vessel.

9.2.1 ATF process flow and pressure measurement

Retentate flow data, critical to ATF operation, is measured using a clamp-on flow sensor on the A2B line. The sensor is engineered specifically for XCell ATF applications and is customized to tubing OD and tubing type. Tube sets with a permeate pressure sensor also are available. Both sensors connect directly to the controller. The device-specific setup guides describe tube set specifications in detail.



Table 12. Flow sensor and pressure sensor part numbers

Description	Part number
XCell Flow Sensor for ATF 10 L	FS-10L
XCell Flow Sensor for ATF 10 R	FS-10R
XCell Flow Sensor for ATF 6, Legacy	FS-6C
XCell Flow Sensor for ATF 6	FS-6
XCell Flow Sensor for ATF 4	FS-4
XCell Flow Sensor Cable Kit 4.5M	XC-FS-CABLE-S450
XCell Flow Sensor Cable Kit 4.5M, Dual	XC-FS-CABLE-D450
XCell Pressure Cable Kit 4M	XC-PS-CABLE-400
XCell Pressure Sensor Kits	Integrated with XCell ATF 6 and 10 Single-use Devices or available for purchase with XCell ATF 4, 6, and 10 Stainless Steel Housings. Please refer to the XCell ATF 4, 6, and 10 Stainless Steel Housings User Guide or XCell ATF 6 and 10 Single-use Device User Guide for details.

Note: Legacy FS-6C flow sensors integrate with the SUATF6-TUBESET kit only. All other SUATF6 tube sets require the standard FS-6 flow sensor.

Please contact your local Repligen representative for more information.

10. 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.

10.1 IT, Wi-Fi, and network connectivity

XCell LS Controllers are designed as stand-alone control systems. Both a wired ethernet and Wi-Fi are available for data transfer on the HMI. Repligen does not support integration of the HMI into a network (<u>Appendix B</u>).

10.1.1 Windows environment

The Repligen-provided HMI 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 Repligen does not expect any impact to the functionality of the Repligen supplied programs through typical use and/or Windows maintenance, it does not guarantee the correct functioning of the system.

XCell LS 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.

10.1.2 MODBUS/ethernet remote monitoring

Process data is recorded locally. The system does not support third-party interfaces or remote monitoring except for the DeltaV[™] Landing Module.



10.1.3 DeltaV integration via DeltaV Landing Module

The DeltaV Landing Module is designed to facilitate the integration of an XCell LS Controller to a DeltaV System. Please refer to the XCell LS Controller Integration Guide for DeltaV Landing Module for further details. Integration into DeltaV is supported by the XCell LS Controller architecture with physical connections to Ethernet/IP (M12, D-Code, female). Both MODBUS TCP and 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 LS Controller PLC code.

11. XCell LS Controller HMI

11.1 Human Machine Interface (HMI)

The XCell LS Controller HMI, offered as XC-LSC-HMI, 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 set points, enables quick user input and easy navigation between screens, and enables managing alarms, trending process data, and tracking events. The XCell LS Controller 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-LSC-HMI and the XC LS Controller.

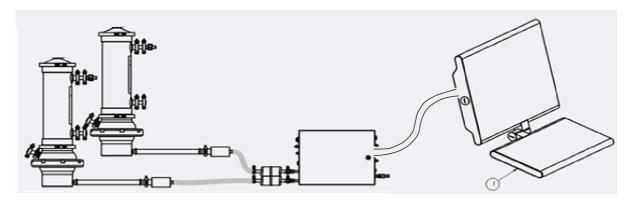


Figure 9. Connection to HMI

The user interface is designed to be intuitive and simple to use. Offered as an Industrial PC, XC-LSC-HMI hardware includes a Systec WAVE 221 PC incased in an IP65 rated packaging, a US power cable, pedestal mount arm, Ethernet cable (RJ45 to M12), and three USB extension cables. The Systec PC 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-LSC-HMI 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.

11.2 Initial startup

The HMI will boot directly into the XCell Software and display the splash screen (<u>Figure 10</u>). Logging into Windows is not required. To add a Windows login, please see <u>Appendix B</u>.

11.3 Login screen and default password

The login screen will not display the first time the software is used. Security is turned off as a default setting. Once security is enabled, the login screen appears, requiring a username, password, and domain. Default usernames and passwords are listed in <u>Table 13</u>.

Login to ArchestrA - OS Group based

User name:

Password:

Domain:

0K

Cancel

Figure 10. Login screen example

Table 13. Default usernames and passwords

Username	Password
Opr	1234
Eng	1234
Super	1234

11.4 User interface general formats and conventions

The software is designed using colors, formats, and conventions to convey information to the user. Fields which allow user input to have white backgrounds (such as ATF flow rate set point).

Figure 11. Example of a formattable field



Fields that cannot be changed by a user either have a colored background (such as some process values) or a gray background (such as fixed dimensions of a filter, shear rate, or values for informational purposes only).

Note: Some options described in this document may be grayed 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 is not supported).

Figure 12. Examples of un-editable fields



Device stop, start, and pause buttons are highlighted in red, green, and yellow, respectively, when activated.

Figure 13. Examples of active STOP/START/PAUSE buttons



Figure 14. Main menu layout



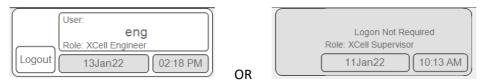
The main menu displays six options at the top of the screen (Figure 14) The active option is indicated with blue. Use the buttons to navigate to the desired screen.

Table 14. Main menu button descriptions

Button name	Description
ATF	Navigates to the ATF main screen. See <u>ATF Main screen</u> .
Settings	Displays settings for both controller and XCell ATF Devices. This screen enables access and modification of XCell ATF Device sizeand type, bioreactor settings, engineering units, run time, and service information. See Settings sub-menu.
Trends	Displays data trends and plots. See <u>Trend screen options</u> .
Alarms	Displays historical alarms and settings for alarm set-up. See <u>Alarms screen</u> .
Login/User	If security is enabled, the logon sub-menu displays username, role, and logout button. If security is disabled then the Logon Not Required message is displayed (Figure 15). 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 the settings screen, are included in this display.



Figure 15. Login/User panel examples



Security enabled (left) vs disabled (right)

The ATF main screen (Figure 16) displays sensors and information for the connected and configured hardware. The example shows a setup using two XCell ATF Devices on a single vessel operating in independent mode. The permeate pressure (P3) is also displayed on the screen.

Note: Throughout the software and this guide, the XCell ATF Devices are referred to as XCell ATF-A and XCell ATF-B. XCell ATF Device sizes are specified in the settings screen.

Figure 16. ATF main screen with XCell ATF Device flow rate and setpoint

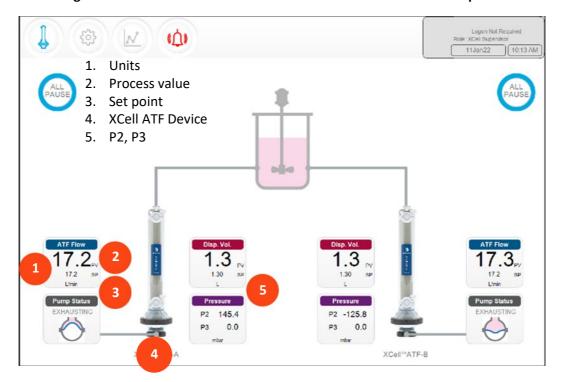


Figure 17. Two synchronized, out of phase, XCell ATF Devices attached to the same bioreactor

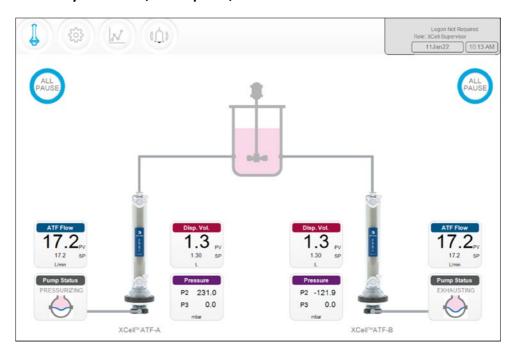
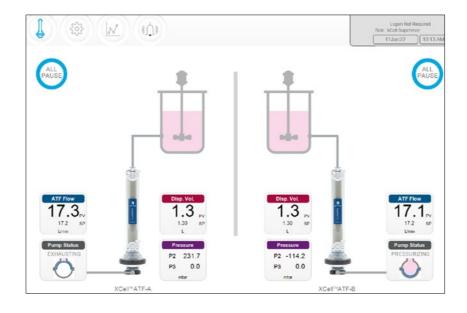


Figure 18. Two XCell ATF Devices attached to two bioreactors



Login Not Required Role XCell Supervisor

11 Jan 22

ALL
PAUSE

ATF Flow
17 3Pv
172 3P
130 3P

Figure 19. Dual controller and single XCell ATF Device

A single (S) model controller operates one bioreactor and one XCell ATF Device, which will be shown in the display. A dual (D) model controller configured for a single XCell ATF Device, will display the same (Figure 19).

Note: When an XCell ATF Device is not running, the ATF Flow box displays a zero value and the corresponding All Pause button is grayed out.

11.4.1 Pump status indicator

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

Table 15. Pump status messages examples

Image	Message	Explanation
Pump Status PRIMING	Priming	The first series of cycles performed to prime the XCell ATF pump and remove most or all of the air in XCell ATF Device and tubing.
Pump Status ZEROING FT	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 XCell ATF Device before zeroing the sensors.
Pump Status Detecting MinPress	Detecting MinPress	The controller runs an automated algorithm to determine the minimum driving pressure required to move the diaphragm.
Pump Status STOPPED	Stopped	The pump has been stopped.
Pump Status PAUSED	Paused	The pump has paused.
Pump Status PRESSURIZING	Pressurizing	The controller is performing the P-stroke, i.e., pressurizing the diaphragm and moving it up, displacing liquid into the vessel.
Pump Status EXHAUSTING	Exhausting	The controller is performing the E-stroke, i.e. exhausting the diaphragm and moving it down, displacing liquid into the XCell ATF pump.



Figure 20. ATF Flow parameter details screen



There is a parameter details screen for each process variable (represented by clickable, colored boxes on the ATF main screen). Click these boxes to see more details and make changes to each parameter.

ATF Flow Set Points (SP) can be changed at any time, including while the XCell ATF Device is running.

- 1. Click the ATF button to open the ATF Main Screen.
- 2. Click the ATF Flow Rate box to open the Flow dialog box (Figure 20).
- 3. Set your desired ATF Flow Rate SP.
- 4. If the entered value lies in the allowable range, the new value is immediately implemented. The theoretical Shear Rate SP is displayed below the ATF Flow Rate SP.

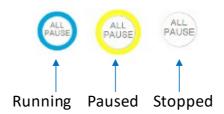
Note: Flow rate should be changed in increments of \leq 10%, allowing time for equilibration before changing again.

Start, pause, and stop commands control the run.

- Start Resumes using the settings and valve positions at the time the process was paused.
- Pause 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.
- Stop A stop is recommended to be used only at the end of a run. If you plan to stop and
 restart the XCell ATF Device within the same process, then pause should be used instead of
 stop.

The device status is indicated via the color surrounding the ALL PAUSE button on the Main Screen (Figure 21).

Figure 21. XCell ATF Device status





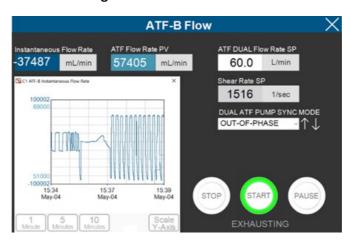
11.4.1.1 Starting, pausing, and stopping a single XCell ATF Device

- 1. Click the ATF button to open the ATF Main Screen.
- 2. Click the appropriate ATF Flow Rate box to open the Flow dialog box.
- 3. Use the Stop, Start, or Pause button to complete the action.

11.4.1.2 Starting, pausing, and stopping both XCell ATF Devices in dual mode

This section applies only to D-P controller models operating in dual mode. If the XCell ATF Devices are in independent mode; these options will not be available.

Figure 22. ATF Flow rate box



- 1. Click the ATF button to open the ATF Main Screen.
- 2. Click an ATF Flow Rate box.
- 3. Use the Stop, Start, or Pause button to complete your action.

Note: When in one of the dual modes, Stop, Start and Pause buttons apply to both XCell ATF Devices. In order to restart in dual mode, both XCell ATF Devices must be first paused.

11.4.1.3 Pausing both XCell ATF Devices from the ATF Main Screen

In D-P controller models, there is also the option to pause from the ATF Main Screen.

- 1. Click the ATF button to open the ATF Main Screen.
- 2. Click the appropriate All PAUSE button.
 - In dual mode, the All Pause button pauses both XCell ATF Devices.
 - In independent mode, the All Pause button pauses the XCell ATF Device on the same side of the screen as the button.

11.4.1.4 Pausing XCell ATF Devices from the hardware

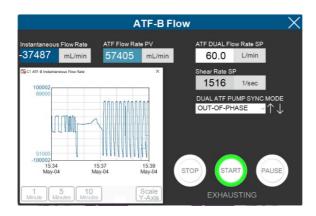
Press the appropriate Device System Pause button on face A of the Controller (Figure 4).



11.5 Running ATF in Dual mode, using ATF flow parameter details screen

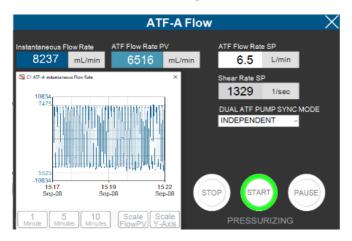
This section applies only to D-P controller models operating in dual mode with two devices of the same size.

Figure 23. ATF Flow parameter details screen (Dual Mode)



11.5.1 Changing modes

Figure 24. ATF flow rate box





These options are only available in dual mode.

- 1. Click the ATF button to open the ATF Main Screen.
- 2. Click an ATF Flow Rate box.
- 3. Select from one of the available modes (Table 16).

Note: Modes can be switched while the devices are running. However, it takes one to two full cycles before the new mode goes into full effect. Modes can be selected from either of the ATF Flow Rate Detail screens.

Table 16. XCell ATF modes

Controller type	ATF DUAL status	Explanation
Single	N/A	An XCell ATF Device runs separately on a bioreactor.
Dual	Independent	Each XCell ATF Device is run separetely on the same bioreactor. Set points and command states (Stop, Start, Pause) are adjusted in their respective ATF-A or ATF-B Flow screens.
	In-Phase	The pressure and exhaust strokes of two XCell ATF Devices are matched. Set points and command states (Stop, Start, Pause) are



	adjusted in either ATF-A or ATF-B Flow screens and apply to both devices.
Out-of-Phase	The pressure and exhaust strokes of both XCell ATF Devices are on opposite strokes. Set points and command states (Stop, Start, Pause) are adjusted in either ATF-A or ATF-B Flow screens and apply to both devices. This is useful to keep a bioreactor volume constant when running two XCell ATF Devices on one bioreactor.

The ATF displacement parameter details screen displays the measured and expected displacement volumes per cycle. A 5 - 10% variation between the values is typical. No changes are allowed on this screen. To set alarms for this value, see ATF Flow alarm configuration.

ATF-A Displacement Volume

Displacement Volume PV

17.5 nl

17.0 ml

20

20

30

31

30

34

3an-27

3an-27

3an-27

3an-27

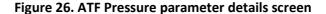
3an-27

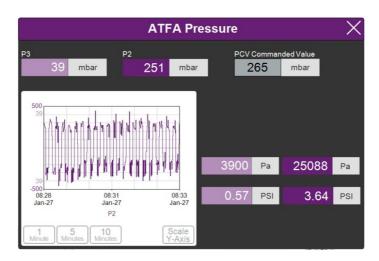
3an-27

3an-27

3an-27

Figure 25. ATF displacement volume parameter details screen





The ATF Pressure parameter details screen (Figure 26) displays the measured pressures in the permeate line (P3), the A2C line (P2) and the PCV Set point for P2 (PCV commanded value). The units of the values displayed on the ATF Pressure screen and the ATF Main Screen (in the Settings menu) can be changed, but the values logged into AVEVA Wonderware Historian are always in mbar.

P3 pressure is typically either zero or negative. As permeate flow increases, the pressure (P3) drops. If the filter starts to foul, P3 will decrease. P3 is a process-dependent value. No preset lower limit for alarm has been established, but alarms may be set if needed.

Alarms for P2 are automated and cannot be changed by the user (11.7). Please contact your local FAS to discuss appropriate values and alarms settings.



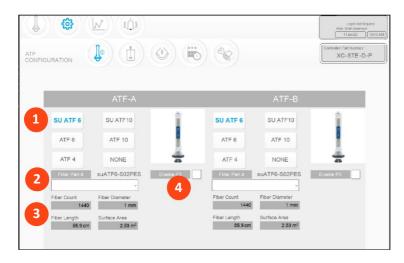
Figure 27. Settings sub-menu



- 1. Settings
- 2. XCell ATF Device configuration
- 3. Bioreactor configuration
- 4. Default configuration
- 5. General configuration
- 6. Service/performance

The settings sub-menu (<u>Figure 27</u>) displays options available to customize the XCell ATF Device, bioreactor, XCell LS Controller, and software settings.

Figure 28. XCell ATF Device configuration screen



- 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 screen allows the input of the number, size, format, and filter for the XCell ATF Device(s) and the option to enable or disable the sensor in the P3 line.

11.5.2 Setting XCell ATF Device configuration

- 1. Click the settings button.
- 2. Click the XCell ATF Device configuration button. The XCell ATF Device configuration screen opens (Figure 28).
- 3. Click the button that corresponds to the size and format for your devices.

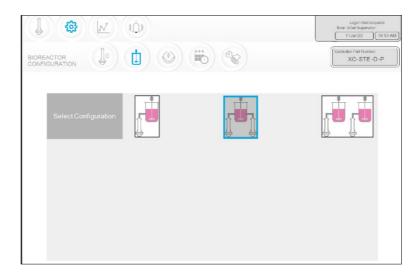
 If you are using the D-P Controller models, but want to use only a single device, click the NEVER button for the other device. The image of the device will disappear from the interface.
- 4. Choose your filter part number from the drop-down list.
- 5. If you are not using the P3 sensor in your set up, disable it to prevent spurious alarms.

This enables the system to display the correct settings for the physical characteristics of the chosen filter (Figure 29, in gray), 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 29. Bioreactor configuration screen



The Bioreactor configuration screen allows configuration of the controller system.

11.5.3 Setting Bioreactor configuration

- 1. Click the settings button.
- 2. Click the Bioreactor configuration button. The Bioreactor configuration screen opens (Figure 29).
- 3. Click the image that corresponds to the equipment setup. An S model Controller only shows the option for the single bioreactor configuration. The dual bioreactor configurations are only available with D-P model controllers.

€ ((()) Ū XC-STE-D-P ATF4 411 1.5 8.0 6.0 1.30 8.0 20.0 17.0 ATF6 6.80 80.0 60.0 ATF10 20.0 RESET to default

Figure 30. ATF pump settings screen

The ATF pump settings screen (Figure 30) displays allowable pump displacement, minimum flow, maximum flow, and default flow. You may choose to restrict users to a specific range of allowable flow set points by providing minimum and maximum flow values.



11.5.4 Setting pump configuration

- 1. Click the settings button.
- 2. Click the pump settings button. The ATF pump configuration screen opens (Figure 31).
- 3. Change the settings by entering your desired value in the appropriate box.

 Default flow is the most frequently edited parameter and is typically set to the most common flow rate used. The displacement value is integrated in the control algorithm and so can cause some variations in performance. We recommend consultation with your local FAS prior to editing this value.

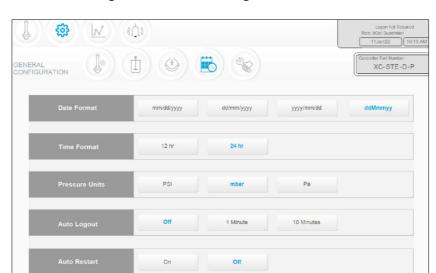


Figure 31. General configuration screen

The General configuration screen (Figure 31) allows customization of date and time formats, pressure units, auto logout, and auto restart settings.

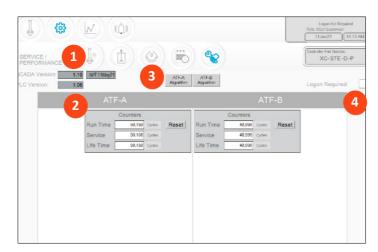
Note: The displayed units can be changed by the user, but the permanent logged data cannot.

11.5.5 Setting general configuration

- 1. Click the settings button.
- 2. Click the general configuration button. The general configuration screen opens (Figure 31).
- 3. Click the appropriate buttons to choose the formats and units used by your lab.
- 4. Set your Auto Logout option.

 Most labs set this to Off for the convenience of users. If you have multiple users in the facility and are concerned about accidental changes, we advise you choose the 1 Minute or 10 Minute option.
- 5. Set your Auto Restart option. The auto restart is a useful feature to manage a brief power outage. The controller will display a message 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 your bioreactor also automatically restarts, and the duration of the power outage is small. If you prefer to have the equipment restarted manually after a power loss, turn auto restart to OFF.

Figure 32. Service/performance screen



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

The Service/performance screen (Figure 32) displays the software versions, XCell ATF Device algorithms, counters, and security status. It is useful for both users and Repligen engineers.

Table 17. ATF service parameters

Counter name	Description	Can be reset?
Run time	Number of cycles a diaphragm or XCell ATF 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 XCell LS Controller during its lifetime	No

11.6 Logon required - security on/off

If logon is not required, all users have full access (equivalent to supervisor level) to the XCell Software. If logon is required, users must enter credentials to access the XCell Software; however, no Windows login is needed.

In some lab environments, not requiring logon may simplify daily task execution. In other situations, where security is more critical, it may be advisable to require logon. For additional security, timed auto-logout can be set up in Setting general configuration.

Figure 33. ATF-A Algorithm screen

The algorithm screen shows multiple flow and pressure signals and messages. This screen is used by Repligen FAS during troubleshooting. Judging algorithm performance requires significant training and experience since the data can be misinterpreted. 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.

Algorithm pop-ups can be displayed simultaneously or alternately using the touchscreen or touchpad. Navigating to the main menu automatically closes the pop-ups.

Note: If you have a question or issue, take photographs or videos of the data displayed on this screen for both XCell ATF Devices to send to your Repligen FAS to facilitate resolution.

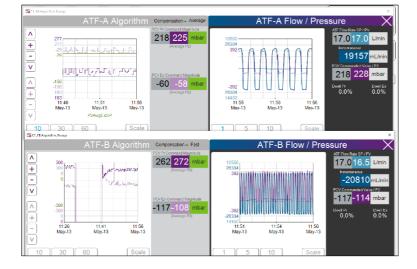


Figure 34. Algorithm screen showing both ATF-A and ATF-B algorithm data

Trend (AVEVA Wonderware Trend) is located in the Windows application menu. The XCell Software Trend screen (Figure 35) meets the majority of run time analysis and diagnostic requirements. It has been designed for simplicity and quick touchscreen-based user interaction. AVEVA Wonderware Trend_tool provides a deeper, more complex dive into current and historical data.



90

SCALE SCALE Clear All

Figure 35. XCell Trend screen

The XCell Trend screen displays flows, pressures, and displacement volumes for each XCell ATF Device (Figure 35). Screen buttons select which parameters are displayed. Graph line colors are preset and cannot be modified.

..10

60

Data can be displayed and analyzed by time. To explore a variety of time intervals, click SHOW OPTIONS.

Note: Preset time intervals (counted from the present time) are available; there are no custom time interval options.

11.7 Alarm categories/types

The XCell LS Controller has alarms available at both the user level and system level (Appendix C).

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 <u>Alarm Configuration</u> screen.

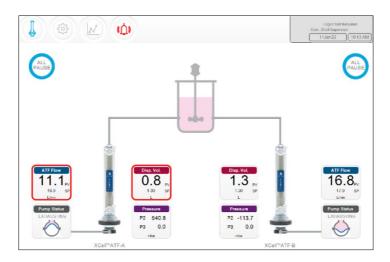
System alarms

System alarms cannot be modified. System alarms serve the underlying, core functions of the XCell LS Controller, (e.g., the presence of a sensor or loss of utilities etc.).

Figure 36. Alarm condition indicated

If an alarm has occurred, even briefly, the Alarm menu button will flash red (<u>Figure 36</u>). The alarm may be reviewed by the user at any time. If an alarm is active, a red box will surround the affected value (<u>Figure 37</u>).

Figure 37. Example of an active alarm



Clicking the alarm button opens the alarm status screen (<u>Figure 38</u>, <u>Table 18</u>). Alarms are displayed until acknowledged by the user.

Figure 38. Alarm status screen



Table 18. Alarm statuses

Alarm status	Explanation
UNACK	An unacknowledged, active 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 39. Alarm Configuration screen



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

The alarm configuration pop-up (Figure 39) has four tabs. The commands row matches the color of the active tab, indicating the active alarm tab. Here, the ATF Flow tab is active.

11.7.1 ATF Flow alarm configuration

Four alarm options are available for ATF Flow: HiHi, Hi, Lo, LoLo, permitting alarms for notification-level events and other alarms for failure-level events.

- 1. Click the Alarm button on the Main Screen. The Alarm Configuration screen opens.
- 2. Click the ATF Flow tab.
- 3. Use the Enable check box to turn on the alarm for each desired alarm level.
- 4. Set the options for each alarm level.
 - a. Set the LIMITS for each alarm.
 - b. Limits are compared to the flow set point. Alarms are triggered when the flow set point falls outside the set point by the specified limit. For example, if the ATF Flow has a Setpoint of 0.7 LPM, and the Hi alarm limit is set to 10%, the Hi alarm would be triggered when the ATF Flow PV is > = 0.77.
 - c. Set the Delay for each alarm. The delay function prevents spurious alarms, triggered by minor, brief changes caused by things such as noise or human error. It requires the alarm conditions be present for a set amount of time, such as 30 seconds, before triggering the alarm.
 - d. Set the actions you want for the alarm. You can configure the alarm by stopping or pausing the process. You can also cause a buzzer to sound or a light to light up on the XCell LS Controller.

Note: If the alarm system pauses or stops the controller, the operation will require a manual restart.

Carefully plan any application of these options to avoid the operation being paused or stopped when unattended

Note: Flow alarms apply to all ATF sizes and formats and are not limited to the specific XCell ATF Devices configured at the time the alarm is set.

11.7.2 Displacement volume alarm configuration

Four alarm options are available for displacement volume (<u>Figure 39</u>): HiHi, Hi, Lo, LoLo, permitting alarms for notification-level events and other alarms for failure-level events.

- 1. Click the Alarm button on the Main Screen. The Alarm Configuration screen opens (Figure 39).
- 2. Click the Displacement Volume tab.
- 3. Use the Enable check box to turn on the alarm for each desired alarm level.
- 4. Set the options for each alarm level
 - a. Set the LIMITS for each alarm.



Limits are compared to the displacement flow set point. Alarms are triggered when the displacement flow set point is exceeds or falls below the set point by the specified limit. For example, if the displacement flow has a setpoint of 0.7 LPM, and the Hi alarm limit is set to 10%, the Hi alarm would be triggered when the displacement flow PV is >= 0.77.

- b. Set the Delay for each alarm. The delay function prevents spurious alarms, triggered by minor, brief changes caused by things such as noise or human error. It requires the alarm conditions be present for a set amount of time, such as 30 seconds, before triggering the alarm.
- c. Set the actions you want for the alarm. You can configure the alarm by stopping or pausing the process. You can also cause a buzzer to sound or a light to light up on the XCell LS Controller.

Note: If the alarm system pauses or stops, it will require a manual restart. Carefully plan any application of these options to avoid the operation being paused or stopped when unattended

Note: Displacement volume alarms apply to all ATF sizes and formats and are not limited to the specific XCell ATF Devices configured at the time the alarm is set.



Figure 40. Displacement volume alarm tab





The system alarms are mostly non-configurable, so the system will always be paused when there is insufficient vacuum. The system can be set up trigger a light or a horn if either of these alarms are activated.



11.7.3 Permeate (P3) pressure alarm configuration

Use the P3 alarm to indicate the point where changing the filter is indicated (LoLo) or will soon be indicated (Lo). Membrane fouling will decrease permeate pressure. This decrease in pressure can be detected using the P3 sensor. If the P3 sensor is used in your system, make sure to set the correct values for permeate pressure for your run to avoid spurious alarms. Due to the wide variation across processes in which the XCell ATF Large-Scale System is employed in the industry, operating values for permeate pressure (P3) span a range with no preset limit. You can determine the P3 pressure indicative of fouling by sampling between the retentate and the permeate streams during development runs and comparing your results to the P3 pressure. Ensure P3 alarms are set up correctly for each run if P3 sensor is used.

The permeate pressure (P3) alarms are unique to each XCell ATF Device and size. P3 alarms for ATF-A and ATF B may also be set independently of one another.

- 1. Click the Alarm button on the Main Screen. The Alarm Configuration screen opens (Figure 39).
- 2. Click the P3 Permeate Pressure tab.
- 3. Use the Enable check box to turn on the alarm for each desired alarm level.
- 4. Set the options for each alarm level.
 - a. Set the LIMITS for each alarm.

 Permeate pressure is compared to the limit shown on this screen (not to a set point). Alarms are triggered when the P3 Permeate Pressure falls below the limit.
 - b. Set the Delay for each alarm. The delay function prevents spurious alarms, triggered by minor, brief changes caused by things such as noise or human error. It requires the alarm conditions be present for a set amount of time, such as 30 seconds, before triggering the alarm.
 - c. Set the actions (i.e., stopping or pausing the process) for the alarm. Set up a buzzer or light to indicate the alarm.

Note: If the alarm pauses or stops the system, the operation will require a manual restart. Carefully plan any application of these options to avoid the operation being paused or stopped when unattended.

Note: It is recommended to set the Lo alarm to trigger a Light and/or Horn warning at the limit level that indicates the start of filter fouling for your process. The LoLo alarm should be set to a point at which filter replacement is deemed urgent and critical.



Figure 42. P3 permeate pressure alarm tab



12. The Historian database and the Trend and Query applications

The HMI includes the AVEVA Wonderware Historian Database and the AVEVA Wonderware Trend and Query applications for additional functionality. These 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.

Trend and Query applications are accessed from the Windows start menu (Figure 43).

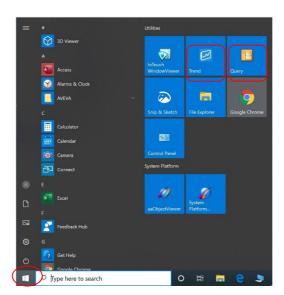


Figure 43. Accessing Trend and Query tools

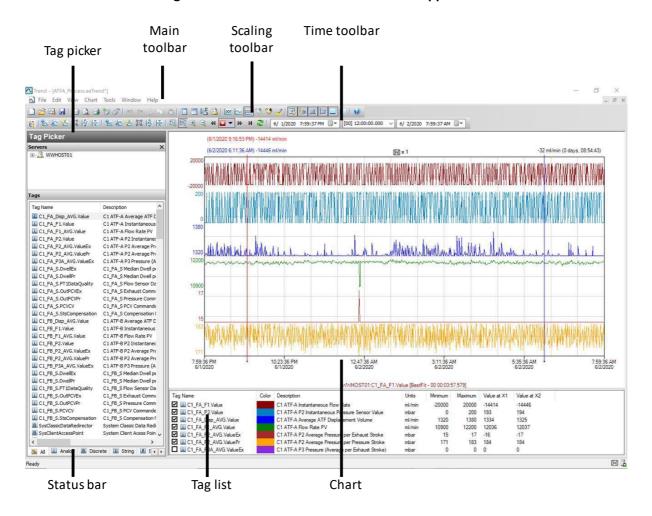
12.1 AVEVA Wonderware Historian database

AVEVA 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.



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

Figure 44. The AVEVA Wonderware Trend application



The Trend application allows the end user to query tags (data points or logged variables) from the AVEVA Wonderware Historian database and plot them. When first starting, the Trend application requests connection to a Historian server. Existing Trend files that include at least one server configuration and successful login do not request log in. Four preconfigured trend files are available.

Several options, such as tags and screen layout, are preconfigured and optimized.

Trend supports two different chart types: a regular trend curve and an XY scatter plot. Multiple plot configuration and display options are available, and layouts can be saved for future use.

Main toolbar Query Columns
pane

Tag picker

Toolbar pane

Figure 45. The AVEVA Wonderware Query Tool

12.2 Exporting query data to Excel

To export data:

- 1. In the Query type: drop-down menu (top left, Figure 45), Select History Values.
- 2. In the Columns Pane, click the Format tab and select the Wide query format.
- 3. In the Columns Pane, go to the Retrieval tab, select Cyclic from the retrieval mode drop-down.
- 4. For cyclic attributes, enter one second into the Values spaced every field (Figure 46).

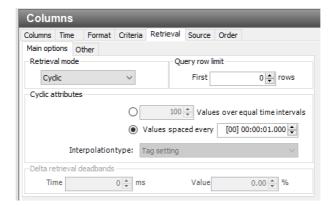
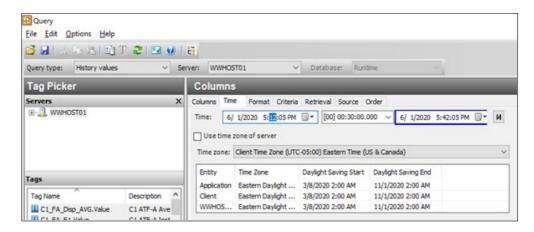


Figure 46. Columns pane of the Query window

- 5. In the Tag Picker pane (Figure 45), select the tags (i.e., data points) to populate the Results Pane.
- 6. In the Columns pane, click the Time tab, and choose the start time and duration using the drop-down menu or by manually entering it.



Figure 47. 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 (5 minutes), followed by selection of multiple tags, and then increase 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 hard drive to a USB drive in .csv format. You can then open this file in Microsoft Excel for further processing.

13. 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.

Note: Many factors influence the optimum ATF rate and filtration rate ratio. The default settings work for most applications. Contact your local FAS to discuss your unique process needs.

Table 19. Recommended Flow Rate Ranges for XCell ATF Devices

XCell ATF Device Size	Minimum Retentate Flow (LPM)	Maximum Retentate Flow (LPM)
XCell ATF 4 Device	5	8
XCell ATF 6 Device	10	17.2
XCell ATF 10 Device	20	80

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).



14. 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 C for a comprehensive list of alarms and their triggers, which can be helpful in troubleshooting.

14.1 Controller will not turn on

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

14.2 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 B).

14.3 Initialization Errors

14.3.1 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.



14.3.2 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 14.3.1)
- 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

14.4 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 14.3.1 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.

14.5 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.

14.6 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.

14.7 A2B flow sensors not communicating

Confirm cables are connected properly.

14.8 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.



14.9 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.

14.10 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.

14.11 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.

15. Maintenance and service

The XCell ATF Large-Scale 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.

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.

15.1 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 includes 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.
- If the connection between PCV and A2C tubing is loose, the system might indicate connection error. A2C tubing must be connected to PCV appropriately at all times while being used.
- If any contaminants are introduced in the A2C line, it might cause damage to PCV.



16. Appendix A: XCell LS Controller specifications

Table 20. XCell LS Controller specifications

	XCell ATF 4	XCell ATF 6	XCell ATF 10
Product Overview			
Models	Single, Dual, GMP	Single, Dual, GMP	Single, Dual, GMP
Typical Installation	Large-scale Development Facility, Pilot Laboratory; GMP	Large-scale Development Facility, Pilot Laboratory; GMP	Clinical and/or Commercial GMP Manufacturing
Item Number/Part Number	XC LS Controllers Only XC-LSC-46-S-P-GMP XC-LSC-46-D-P-GMP	XC LS Controllers XC-LSC-46-S-P-GMP XC-LSC-46-D-P-GMP XC LS Plus Controllers XC-LSC-610-S-P-GMP XC-LSC-610-D-P-GMP	XC LS Plus Controllers Only XC-LSC-610-S-P-GMP XC-LSC-610-D-P-GMP
Automation Platform	All	en-Bradley L19 Programmable Log	ic Controller
Channels	Single or Dual ATF	Single or Dual ATF	Single or Dual ATF
User Interface (Optional)	Systec WAVE 221 Indust	rial PC; IP65with pre-installed AVE Version 2017	VA Wonderware SCADA software,
Integration Protocols (Headless Configuration)	· ·	n to common commercial automat I/P, Modbus TCP. Delta-V Landing	
Regulatory Claims	UL/CE/F	RoHS/REACH/WEEE/21 CFR Part 11	. Compliant/ IP65
Required Accessories (Finished Offerings)	XCell Safety Air Protection Assembly GMP XCell Flow Sensor for ATF 4 XCell Flow Sensor Cable XCell Pressure Cable Kit XC LSC ATF-to- Controller Tubing XC LSC Air Vacuum Utility Connection Kit	XCell Safety Air Protection Assembly GMP XCell Flow Sensor for ATF 6 XCell Flow Sensor Cable XCell Pressure Cable Kit XC LSC ATF-to-Controller Tubing XC LSC Air Vacuum Utility Connection Kit	 XCell Safety Air Protection Assembly GMP XCell Flow Sensor for ATF10L or ATF 10R XCell Flow Sensor Cable XCell Pressure Cable Kit XC LSC Plus ATF-to-Controller Tubing XC LSC Air Vacuum Utility Connection Kit
Optional Accessories (Finished Offerings)	• XC LSC Vacuum Pump • XC LSC Universal Cart	XC LSC Vacuum PumpXC LSC Plus Vacuum PumpXC LSC Universal Cart	XC LSC Vacuum PumpXC LSC Plus Vacuum PumpXC LSC Universal Cart
Process parameters			
Bioreactor working volume Suspension culture	10 - 50L	50 - 200L	200 - 1000L
XCell ATF Modes of Operation	Single Mod	e, Dual Modes (In-Phase, Out-of-Pl	hase & Independent)
XCell ATF pump rate Recommended minimum Recommended maximum	5 L/min 8 L/min	10 L/min 17.2 L/min	20 L/min 80 L/min
Applicable XCell ATF Device Format/Hollow Fiber Pore Sizes	Stainless Steel ATF: 0.2 μm, 05 μm, 50 kDa	Stainless Steel ATF: 0.2 μm, 05 μm, 50 kDa Single-use ATF: 0.2 μm	Stainless Steel ATF: 0.2 μm, 05 μm, 50 kDa Single-use ATF: 0.2 μm
Filtration rate (Perfusion) Recommended nominal flux	≤ 5.7 LMH 105 L/day 4.4 L/hr 0.073 L/min	≤ 5.7 LMH 341 L/day 14.2 L/hr 0.24 L/min	≤ 5.7 LMH 1500 L/day 62.5 L/hr 1.04 L/min
Filtration rate (Media exchange Clarification) Recommended flux	≤ 20 LMH 15.5 L/hour 0.26 L/min	≤ 20 LMH 50.2 L/hour 0.84 L/min	≤ 20 LMH 221 L/hour 3.7 L/min
Filter effective surface area (Repligen)	0.77 m2	2.5 m2	11 m2
Pump displacement volume Minimum, maximum	0.36 L, 0.44 L	1.14 L, 1.34 L	5.4 L, 6.6 L
XCell LS Controller pressure sensor (P2) Accuracy Range Number of sensors		±0.2psig -14 to 14 psig 1 per XCell ATF Device	



XCell ATF Device permeate pressure sensor (P3) Accuracy Range Number of sensors	±0.3psig -10 to 60 psig 1 per XCell ATF Device		
Utility Requirements and Connect	tions (2 XCell ATF Device	s per controller)	
Compressed air Source air pressure requirement Pressure down regulation (factory set by Repligen) Pressure relief (factory set by Repligen)	50 - 110 psig 25 psig 30 psig	50 - 110 psig 25 psig 30 psig	50 - 110 psig 25 psig 30 psig
Source Air Flow Requirement	18 L/min	44 L/min	176 L/min
Vacuum Pressure at peak flow Required average flow, required peak flow	-12 psig (-0.86 barg) 100 L/min	150 L/min	830 L/min
Utility line connections			
Compressed air vacuum	Pressure: 10 ft, $3/4$ in Tri-clamp, ID = $3/4$ in, OD = $11/32$ in tubing, QC connector Vacuum: 10 ft, $3/4$ in Tri-clamp, ID = $3/4$ in, OD = $11/32$ in tubing, QC connector		
Electrical Power input XCell LS Controller - peak current	External Power Supply, Adapted to 24 VDC (from 110 - 240 VAC, 60/50 Hz) 1.3 Amps 0.8 Amps		
System environment Operating temperature Humidity (non-condensing)	4° - 40° C (39° - 104° F) 15% - 95% (10% - 50%)		
Materials of construction (MOC)			
Enclosure Flow sensors Utility air supply tubing kit XCell ATF to Controller (A2C) Tubing kit	304 Stainless steel Steel and Aluminum, Stainless steel, Magnesium, and Glass Polyvinylchloride, Stainless steel ATF4/6: Polyurethane, Stainless steel ATF10: Polyvinylchloride, Stainless steel		
Dimensions and Weight			
Controller Unit	H: 16 in (40.6 cm), W: 20 in (50.8 cm), D: 8.8 in (22.	4 cm), WT: 49 lb (22.3 kg)
Supply Air Protection Assembly (SAPA) Height, width, depth, weight (approximately)	H: 15.3 in, W: 19.8 in, D: 7.18 in, WT: 19 lb		
Vacuum pumps- Height, width, depth, weight XC-LSC-VP46	H: 12.68 in, W: 7.6 in, D: 25.47 in, WT: 70.55 lb		

17. Appendix B: IT, IP addresses, and external communication

Ethernet port on the controller can be used to connect to the supplied HMI/HMI which runs XCell Software. It should not be connected to any other computer device.

H: 12.76 in, W: 12.56 in, D: 26.42 in, WT: 165.34 lb

The two ethernet ports are switched internally and, hence, are equivalent. Future software updates will use the second port for advanced functionality. The HMI comes with Wi-Fi capability built in, but this feature is not used by the XCell Software.

Connection to a corporate network, a remote DCS, supervisory monitoring, and control system or domain management of HMI or mapped drives is not recommended or supported.

Note: At shipping, the controller and laptop 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.

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



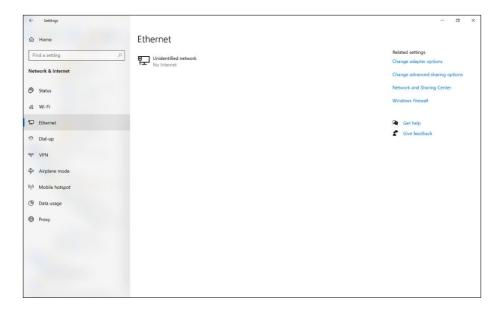
XC-LSC-VP-610

17.1 Changing IP address on the HMI

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

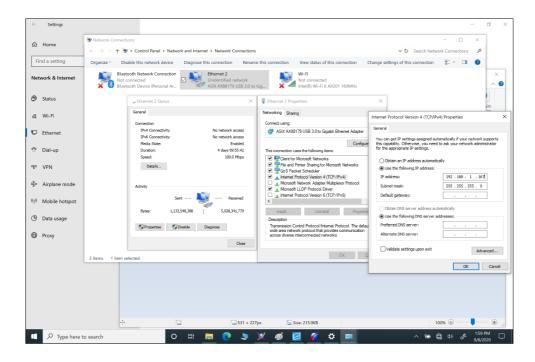
1. Go to Control Panel > Network and Internet > Ethernet and click Change adapter options.





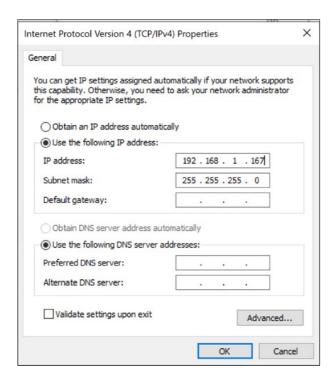
- 2. Click the Ethernet 2 network icon (ASIX adapter).
- 3. Deselect Internet Protocol Version 6 (TCP/IPv6) if it is checked.
- 4. Select the Internet Protocol Version 4 (TCP/IPv4) option.

Figure 49. Control Panel network adapter properties



- 5. Click the Properties button.
 - a. Select the Use the following IP address option.
 - b. Set the IP address to 192.168.1.167.
 - c. Confirm the Subnet mask is 255.255.255.0.
 - d. Leave the Default gateway field and DNS section blank.
 - e. Click OK. Then Close.

Figure 50. Windows 10 network adapter TCP/IPv4 properties



Open the XCell Software and test the new configuration.

18. Appendix C: List of system-defined alarms

Table 21. System-defined alarms

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



Alarm/Interlock	Event Trigger	System Response	User Response
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 14.3.1 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 14.3.1 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.
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 14.3.2 for troubleshooting



Alarm/Interlock	Event Trigger	System Response	User Response
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 14.3.1 for troubleshooting
Initialization Step: Priming Failed	Insufficient pressure or vacuum supply detected	System will stop	See Section 14.3.1 for troubleshooting
Initialization Step: Minimum Force Detection Failed	Flow not detected	System will continue to run, using default driving force values.	See Section 14.3.2 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 14.4 for troubleshooting
Displacement volume 10% below minimum	10 sequential cycles of low displacement	Notification only. System continues to run	See Section 14.4 for troubleshooting



19. Appendix D: 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 *OAdmin* ([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 OAdmin (Operating System Admin) if you need to modify existing XCell Software usernames or passwords (<u>Table 24</u>) or add new ones. It is recommended that a qualified IT or Repligen engineer carries out these tasks.

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

Table 22. Windows usernames, passwords, and users

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 23. 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

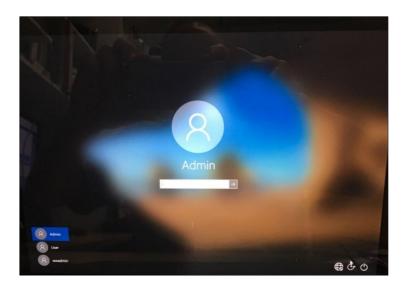
To limit user access and enhance security in the XCell Lab software, XCell users can be set up in the Windows environment and be assigned to the Roles (user groups) listed in <u>Table 25</u> above.

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.

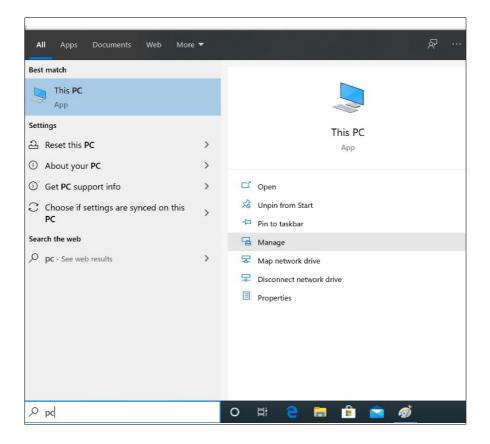


2. Click the circular user icon and Select the Admin user (see image above).

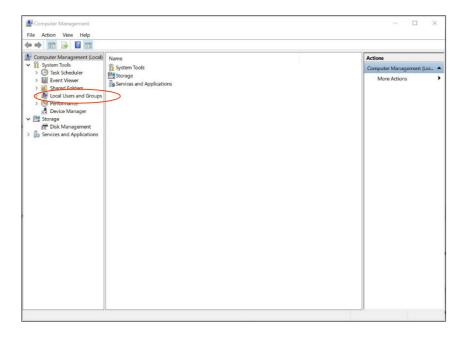


- 3. Enter Password Admin123.
- 4. The Windows Admin is logged in.
- 5. Next press the Windows Start button and type PC (see below).

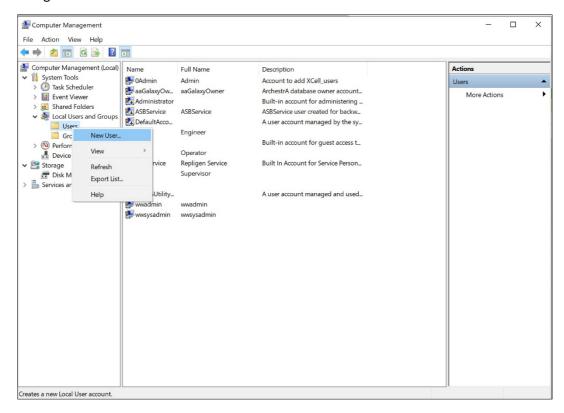




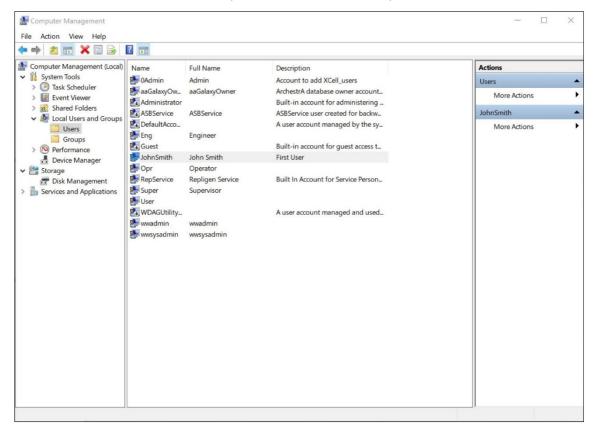
- 6. Select Manage. The Manager opens.
- 7. Navigate to Local Users and Groups.



8. Right click on Users and select New User.

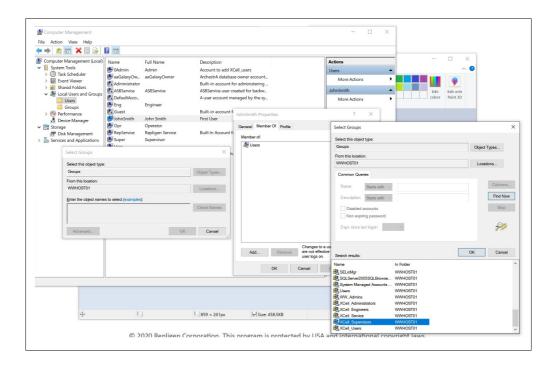


9. Enter user information. (Description and Full names are optional).

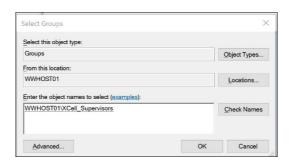


- 10. Important: Be sure to deselect User must change password at next logon.
- 11. Press the Create button. The user is added.





- 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.
- 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.



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

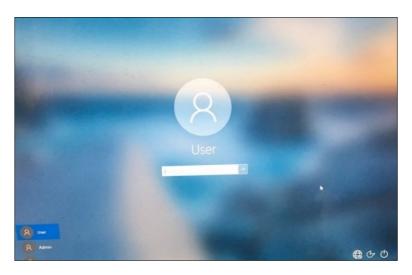


18. Select the Users group, and press the Remove button, then Press the OK button.





- 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.



- 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 E: Default values

Figure 51. Default values for ATF Pump Configuration



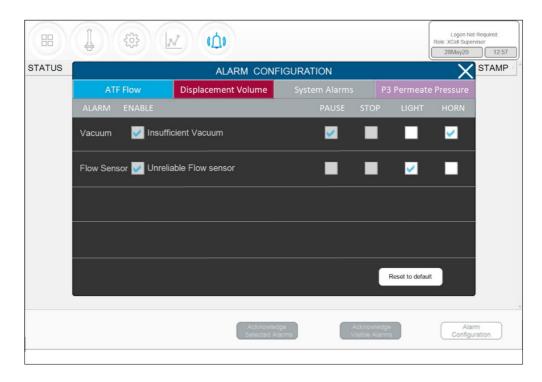
Figure 52. Default values for ATF Flow Alarms



Figure 53. Default values for Displacement Volume alarms



Figure 54. Default values for System Alarms



88 (()) STAMP STATUS ALARM CONFIGURATION Displacement Volume ATF-A Lo -345 V V -483 V V ATF-A LoLo 30 -345 V V ATF-B Lo V V ATF-B LoLo -483 Reset to default Alarm Configuration

Figure 55. Default values for P3 Permeate Pressure Alarms

21. Appendix F: LSC Cart user guide

Component Layout

All components are to be located as shown with mounting brackets and hardware. The optional ACP40 vacuum pump should be located toward back edge, centered, with the vacuum canister facing inward toward the SAPA assembly.

Figure 56. Component layout: front view

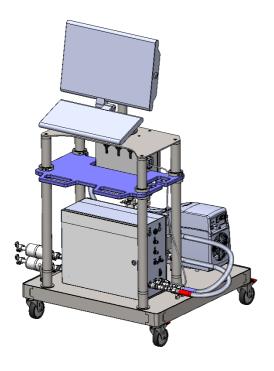
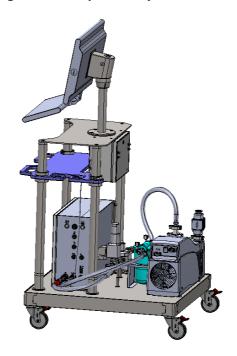


Figure 57. Component layout: side view



Caster Operation

To lock the caster, use your foot to press on the outer lever labeled <u>ON</u>. To unlock, use your foot to press the inner lever labeled <u>OFF</u>.

Figure 58. Locking the caster

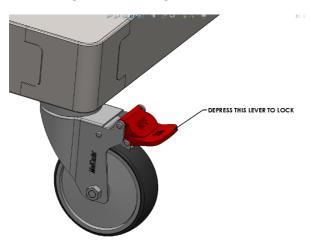
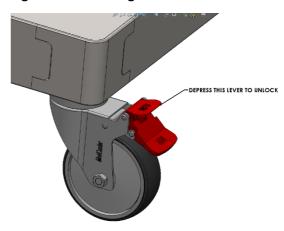


Figure 59. Unlocking the caster



Power strip breaker reset

Unlatch and open the junction box using flat bladed screwdriver. Depress the breaker reset. Close and latch once complete.

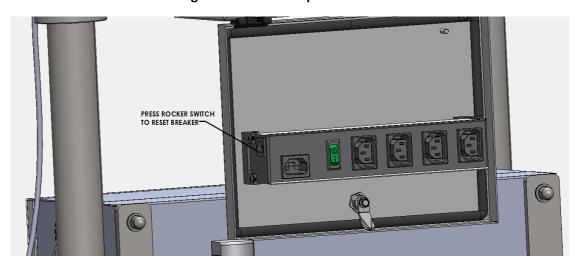


Figure 60. Power strip breaker reset

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