

XCell™ ATF System

With C410:V3 Controller

USER GUIDE

XCell™ ATF4

XCell™ ATF6

XCell™ ATF10



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1. Description of XCell™ ATF System and Process

The XCell™ ATF System provides an efficient means for fractionation of various mixtures. It may include separation of large particles such as microcarriers (~ 200 microns in size) from a suspending medium. It may include separation of mammalian cells (~ 10 microns in size) from culture medium; or it may include separation of some molecules from other molecules or from a suspending solvent. The focus in this manual will be on the use of the XCell™ ATF System and process for separation of these constituents by filtration, based primarily on size.

The XCell™ ATF System is an alternating tangential flow filtration system consisting of the following primary components (see also [Figure 1](#)):

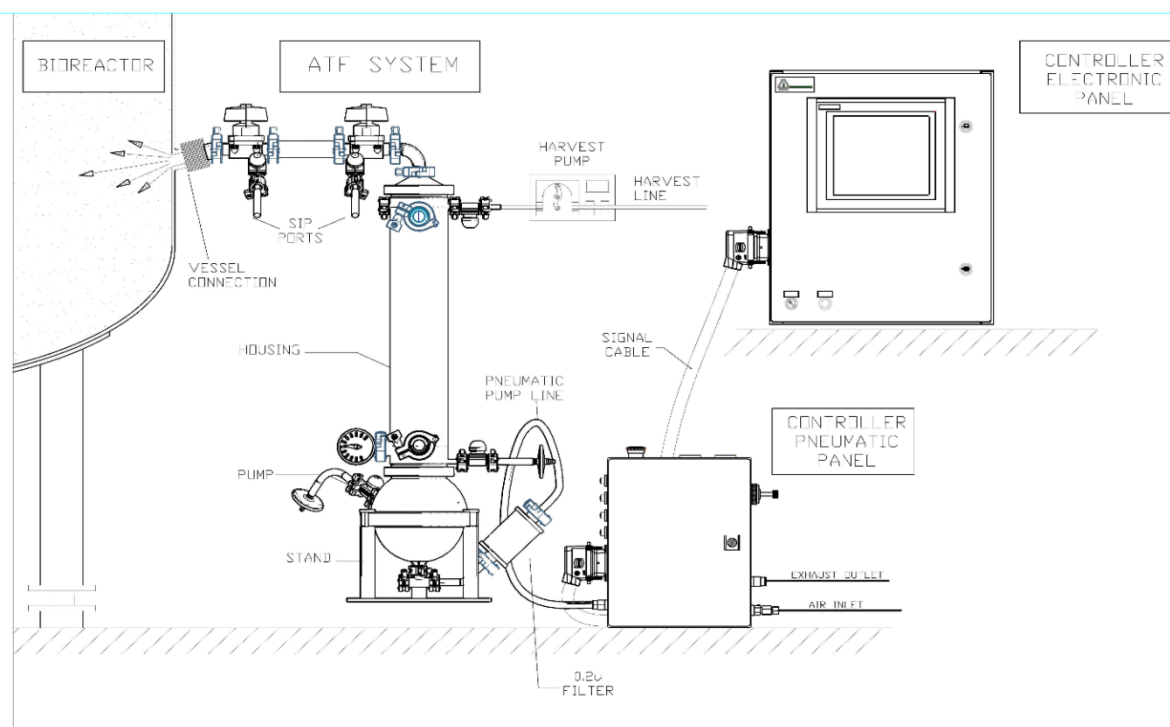
- **Controller:** a dedicated controller used to control and monitor XCell™ ATF System activity. It also provides the means for connecting to and controlling utility services.
- **Filtration Assembly:** a stainless steel assembly of two major elements, a filter housing and a diaphragm pump:
 - **Filter Housing:** steel housing containing the filtration element, either a hollow fiber module (HFM) or screen module (SM).
 - **Diaphragm Pump:** steel spherical housing in which a diaphragm membrane is moved up and down by pressurized air or vacuum, creating alternating flow.

The Filtration Assembly includes the following components for each process application:

- **Connection Assembly:** tubing assembly connecting the Filtration Assembly to a bioreactor or process vessel
- **Bioreactor Adaptor:** adaptor between the Connection Assembly and bioreactor port. Typical ports/connectors/adaptors for stainless steel bioreactors include an Ingold-type port or, if a single use bioreactor (SUB), then, a disposable aseptic connector (DAC) or equivalent.

A typical configuration of the XCell™ ATF System is shown in Figure 1. The Filter Housing accepts either a HFM, with pore sizes from 30kD to ~0.5 micron, or a SM for fractionation of larger particles, >70 microns. The separating element, the HFM or SM, is positioned between a process vessel or a bioreactor at one end and the Diaphragm Pump at the other end. The vessel serves as a storage container for the content to be filtered. The Diaphragm Pump provides the means for generating alternating tangential flow (ATF), back and forth, between the vessel and pump, through the hollow fibers of the HFM or through the SM. The ATF process provides the means for generating rapid, low shear, tangential flow. A filtrate pump as shown in Figure 1 is used for controlled removal of a filtered stream. The unfiltered material remains in the system. The XCell™ ATF System provides the means for confining the process. The entire process is enclosed. Only a single connection is required between the XCell™ ATF System and the vessel. As shown in Figure 1, that connection can be either through a head plate of the vessel or through a side or bottom port. Placing the Filtration Assembly next to the vessel requires only a short tubing to complete the connection between the two. That connection can be hard piped or soft piped. Either one may be used to make a sterile connection between vessel and the Filtration Assembly, as will be discussed further on.

Figure 1. Filtration Assembly connection to C410:V3 Controller and a bioreactor side port

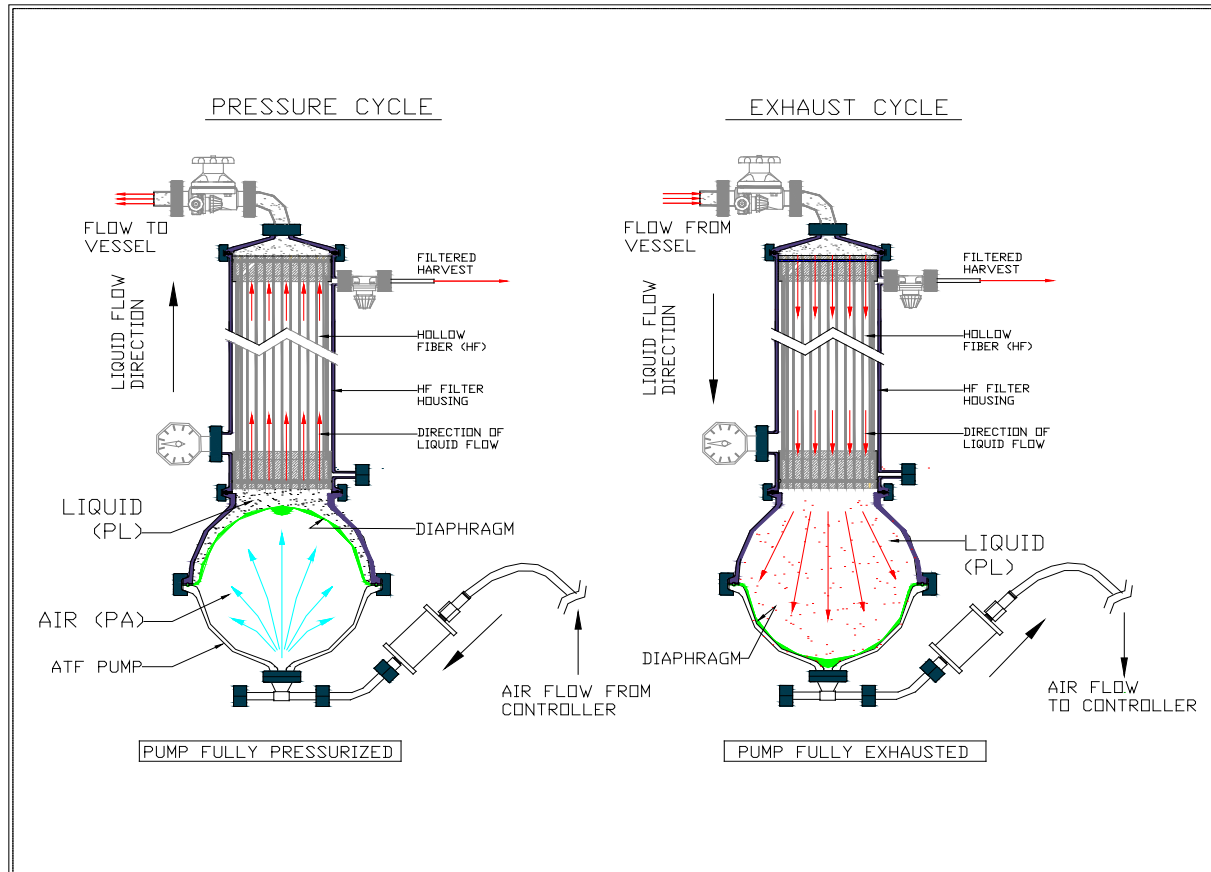


1.1 XCell™ ATF System Pump Cycle

The Diaphragm Pump is the heart of the ATF process. It produces an alternating flow through the HFM (lumen side) or SM. The XCell™ ATF System provides a pulsating, reversible, flow of liquid, back and forth, between the process vessel and the Diaphragm Pump. The following is a description of that process:

The Diaphragm Pump is partitioned into two chambers with a flexible diaphragm, Figure 2. One of the pump chambers, the **Pump Liquid (PL) chamber** is connected to the Filter Housing, which, in turn, is connected to the process vessel. Therefore, any flow between the Diaphragm Pump and process vessel will be through the filtration device. The second pump chamber, the **Pump Air (PA) chamber**, is connected to the pump flow control system. Typically, controlled addition of compressed air into the PA chamber increases the pressure in the chamber relative to the process vessel, forcing the flexible diaphragm partitioning the two chambers to move into the PL chamber and towards the vessel. Liquid in the PL chamber is forced through the filter to the process vessel. The flow through the HFM (lumen side) generates tangential flow in one direction. This pumping phase (or cycle) is called the Pressure Cycle. Inversely, with a pressurized process vessel relative to PA or PL, or with an external vacuum supply, liquid will flow in the reverse direction, from process vessel, through the HFM (lumen side), to the PL chamber, generating tangential flow in the other direction. This pumping phase (or cycle) is called the Exhaust Cycle. These alternating pump cycles are then repeated continuously. See also Figure 2.

Figure 2. XCell™ ATF System Pump Cycles

**Note on the Exhaust Cycle:****WARNING**

Glass bioreactors or single-use bioreactors (SUBs), unless otherwise specified by the manufacturer of the vessel, should not be pressurized. Such vessels can explode if pressurized.

Therefore, to increase the pressure in the vessel relative to the Diaphragm Pump, a vacuum service is required. The PA chamber can then be alternately pressurized and evacuated to produce ATF flow while maintaining the process vessel at atmospheric pressure.

On the other hand, when using a vessel that can be pressurized, vessel pressure can be used to drive the liquid from the vessel to the PL chamber. When vessel pressure is limited, it may be supplemented with vacuum. In either of the above schemes, one is driving the liquid from the vessel to the Diaphragm Pump by increasing the pressure in the vessel relative to the Diaphragm Pump.



When using a glass vessel or SUB, be sure to maintain an unrestricted vent from the vessel. In the case a diaphragm fails, the air flow into the Diaphragm Pump will proceed through the HFM or SM into the vessel. A free exhaust from the vessel will minimize the buildup of pressure in the vessel.

1.2 XCell™ ATF System Control Scope and Objectives:

The C40:V3 controller provides the process control functionality of the XCell™ ATF4, ATF6, and ATF10 Systems. The C410:V3 controller is designed to:

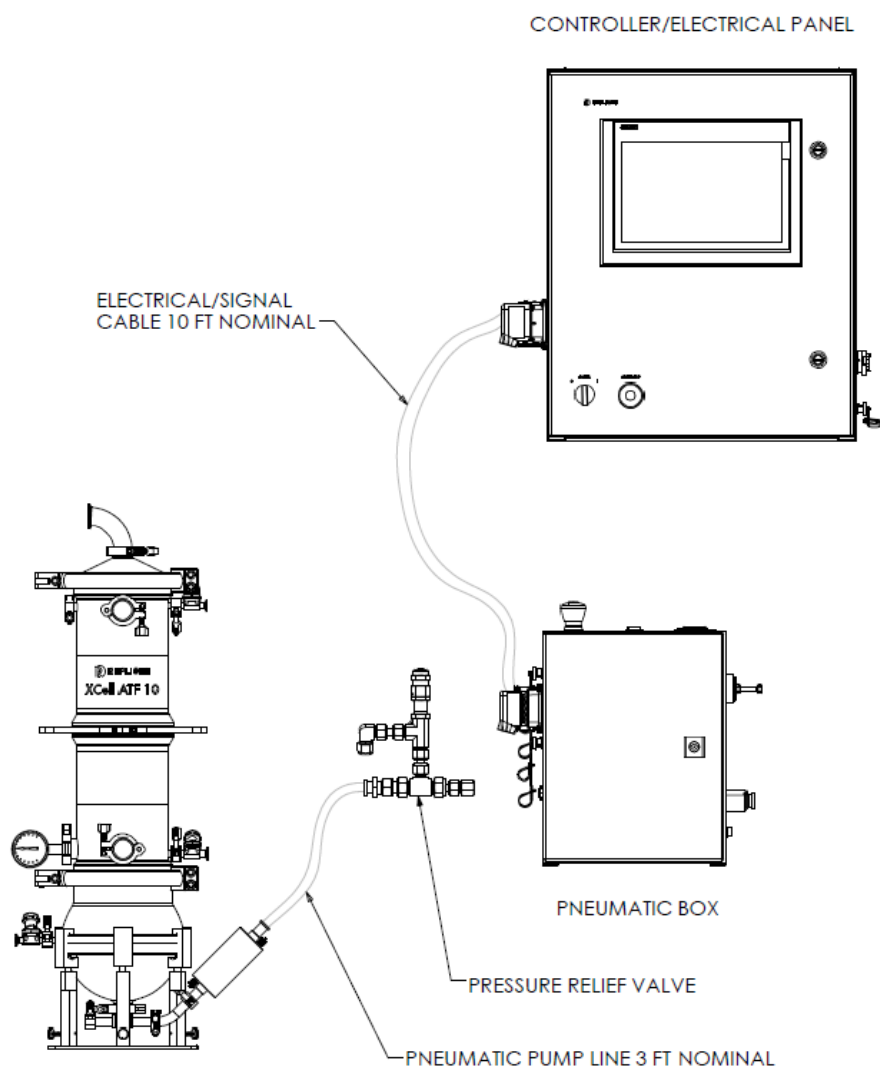
1. Control ATF flow rates in both pressure and exhaust phases
2. Provide a user interface capability for XCell™ ATF System control and monitoring
3. Set-up and select operation parameters
4. Display real-time process data
5. Alarm for error conditions
6. Provide “batch control” and user hierarchy
7. Have PLC software upgrades in the field by replacing memory modules
8. Have two major components, an Electronics Box (E-Box) and a Pneumatics Box (P-Box)
9. Allow the E-Box to operate an XCell™ ATF4, ATF6, or ATF10 System using specific software and modules.
10. Allow the P-Box hardware and process parameters to be specific to the size of the particular XCell™ ATF System being controlled.

1.3 XCell™ ATF Pump Housing and Controller Pairings

XCell™ ATF Pump Housing	XCell™ Controller	Description
XCell™ ATF4 Stainless Steel	C410:4V3	C410:V3 C410 controller for XCell™ ATF4 system with air tubing.
	C410:4V3-GMP	C410:V3 C410 controller for XCell™ ATF4 system with air tubing and standard GMP documentation and FAT.
	C410:4V4B-GMP	Profibus configured C410-V4B controller with power separation for XCell™ ATF4 system with air tubing, standard GMP documents and FAT.
XCell™ ATF6 Stainless Steel and Single-use	C410:6V3	C410:V3 C410 controller for XCell™ ATF6 system with air tubing.
	C410:6V3-GMP	C410:V3 C410 controller for XCell™ ATF6 system with air tubing, standard GMP documents and FAT.
	C410:6V4B-GMP	Profibus configured C410-V4B controller with power separation for XCell™ ATF4 system with air tubing, standard GMP documents and FAT.
XCell™ ATF10 Stainless Steel and Single-use	C410:10V3	C410:V3 C410 controller for XCell™ ATF6 system with air tubing.
	C410:10V3-GMP	C410:V3 C410 controller for XCell™ ATF10 system with air tubing, standard GMP documents and FAT.
	C410:10V4B-GMP	Profibus configured C410-V4B controller with power separation for XCell™ ATF10 system with air tubing and standard GMP documentation and FAT.

1.4 XCell™ System Interconnectivity Drawing

Figure 3. C410:V3 controller with XCell™ ATF10 stainless steel pump housing and pressure relief valve



2. Utility Requirements

UTILITY	REQUIREMENT	COMMENTS
PRIMARY COMPRESSED AIR	Maximum 90 psi / 6.1 bar	Oil free, dry, filtered gas, i.e., medical grade air.
SECONDARY PRESSURE	Typically: 35 psi / 2.4bar,	Working, regulated pressure
VACUUM SERVICE	~20" / 508 mm. Hg at maximum flow	use a service capable of sustaining ~20"Hg at full flow
EXHAUST		Untreated discharge or user specified
ELECTRICAL	100-240V AC, 50/60Hz	
ENVIRONMENT:	0-50°C ; 0 – 80 % RH	Temperature; Relative Humidity
STEAM (SIP)	~30lbs/hr.	Applicable to a steamable connection between Filtration Assembly and vessel.
CONDENSATE DRAIN		Condensate drain adequate with SIP requirements

3. Size and Weight

The size of a Filtration Assembly may vary slightly based on XCell™ ATF system configuration and accessories. The C410:V3 controller dimensions are fixed.

COMPONENT	DIMENSIONS			COMMENTS
	H	W	D	
C410:V3 Controller	inches			
PNEUMATIC BOX	17	15	8	Includes all plugs and connectors.
ELECTRIC BOX	24	20	9	Includes all plugs and connectors.
Filtration Assembly				Fully assembled system
XCell™ ATF 4 System	24	6	6x10	Indicated dimensions are estimates for the Filtration Assembly, as the connection to the bioreactor, the connections to the controller and to accessories can affect height and effective area.
XCell™ ATF 4MC System	44	10	8x12	
XCell™ ATF 6 System	44	10	8x12	
XCell™ ATF 10lgcy System	44	14	14x20	
XCell™ ATF 10 System	44	14	14x20	
XCell™ ATF 6 Single-use Device	38"	12"	10"	
XCell™ ATF 10 Single-use Device	38"	14"	18"	

C410:V3 Controller	Estimated WEIGHT (Kg)	COMMENTS
PNEUMATIC BOX	~13	Weight of the P-Box will vary depending on the particular ATF System it is configured to control.
ELECTRIC BOX	~23	
Filtration Assembly		
XCell™ ATF 4 System	~6	Weight does not include the weight of any liquid, filter or connection between the Filtration Assembly and the vessel
XCell™ ATF 4MC System	~14	
XCell™ ATF 6 System	~14	
XCell™ ATF 10lgcy System	~30	
XCell™ ATF 10 System	~40	
XCell™ ATF 6 Single-use Device	~ 6	Does not include the weight of liquid and A2B connectors
XCell™ ATF 10 Single-use Device	~ 5	Does not include the weight of liquid and A2B connectors

4. XCell™ ATF Pump Housing Assemblies

The Filtration Assembly of XCell™ ATF pump housing is shown in Figure 3. Certain parts may vary, depending on requirements and specifications. Optional components for the XCell™ ATF housing include bioreactor connection kits, pressure transducers, vacuum pump, and options for sanitary diaphragm valves. All are available upon request.

Figure 4a. Exploded View of XCell™ ATF 10 System Filtration Assembly (P/N ATF10:PH-GMP)

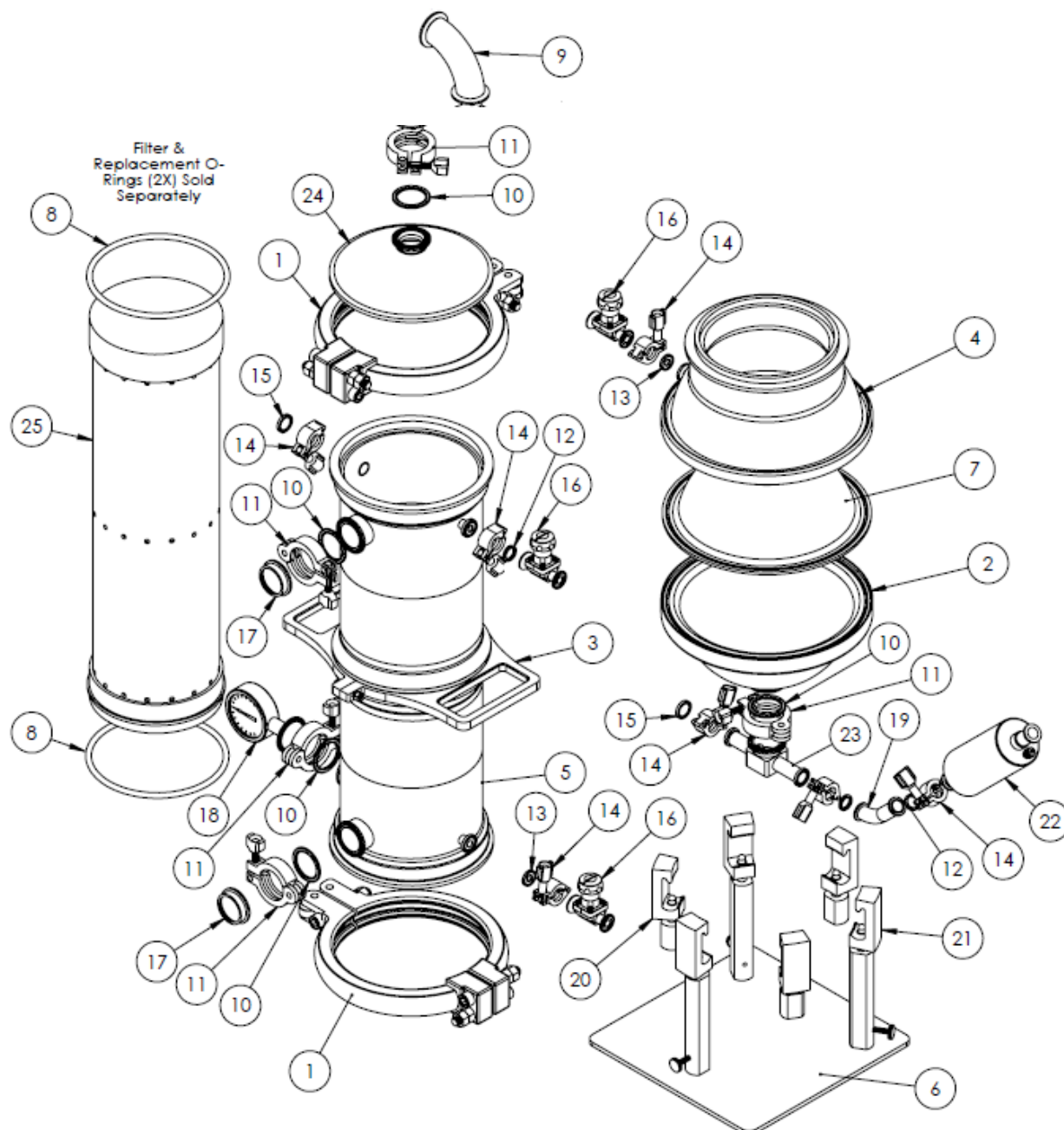


Table 4a. XCell™ ATF 10 Pump Housing Parts List

ITEM NO.	DESCRIPTION	Material	QTY.
1	ASME Clamp. Assembly. XCell™	316 SS	2
2	Pump Hemisphere Air Side.	SA479 316L SS	1
3	Lifting Handle. Assembly. XCell™	316 SS	1
4	Pump Hemisphere Liquid Side.	316 SS	1
5	Filter Housing Assembly. XCell™	316 SS	1
6	Stand. Assembly. XCell™ ATF10	316 SS	1
7	Diaphragm, Pump, XCell™	50A P.C. Silicone	1
8	0.295" C/S x 6.835" ID x 7.425"	Silicone	2
9	90 Degree Elbow. 1.5TC	316 SS	1
10	Sanitary Gasket. 1 1/2" TC	EPDM	5
11	Clamp. Sanitary. 1 1/2" TC	304 SS	5
12	Sanitary Gasket. 3/4" TC	EPDM	4
13	Sanitary Gasket. 1/2" TC	EPDM	3
14	Clamp. Sanitary 1/2-3/4" TC	304 SS	7
15	Sanitary Cap 3/4"	316 SS	2
16	Sanitary Diaphragm Valve. 1/2"	316 SS	3
17	Window. Sanitary 1.5"TC	AISI Type 316LSS	2
18	Pressure Gauge. 1.5" TC. 30 psi	SS	1
19	45 deg Elbow. 3/4" TC	SS	1
20	C Clamp w/ Lock-B. Assembly.	316 SS	3
21	C Clamp w/ Lock-A. Assembly.	316 SS	3
22	Air Inlet Filter. 0.2 micron. 1/2"	PVDF	1
23	Instrument Tee. 1.5" x 2X 3/4"	316 SS	1
24	Reducer. XCell™ ATF10	SA479 316L SS	1
25	Spectrum F10 2 Micron PES	NA	1
26	3/8" Hex Bit Socket, 3/8" Drive	Alloy Steel	1

Note: C-CLAMP (Hemisphere) Items #20,21 should be torqued to 20-25 ft-lbs with 1" wrench flats

See Appendix 7 for list of spares and accessories

Figure 4b. Exploded View of XCell™ ATF 10 Single-use Device with 0.2u PES Hollow Fiber Filter

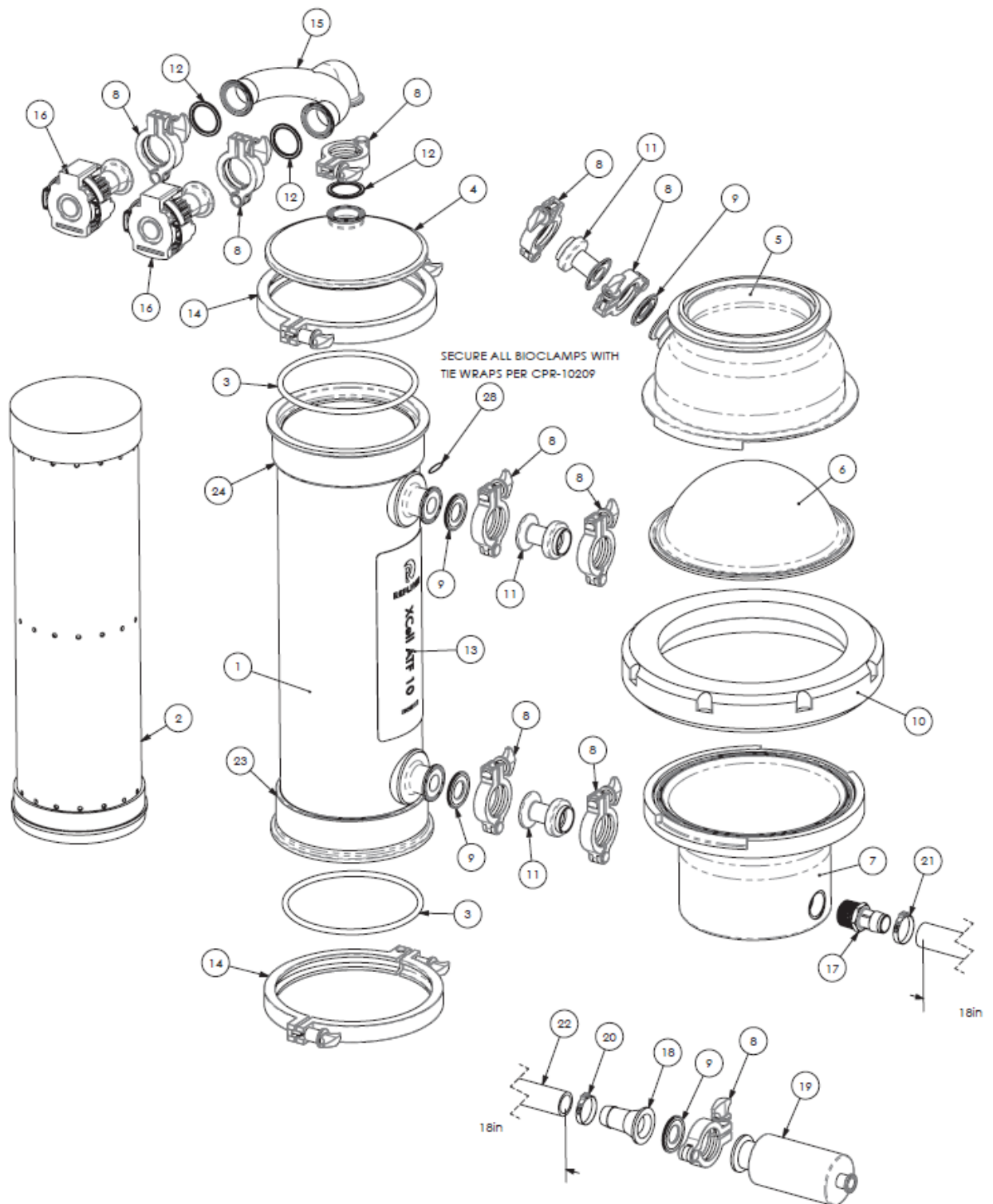


Table 4b. XCell™ ATF 10 Single-use Device Components

ITEM NO.	Repligen PN	DESCRIPTION	MATERIAL	QTY.
1	CS-10470	Housing Tube Assembly, suATF10	Polycarbonate (Lexan) HPS6	1
2	RM-10506	Spectrum F10 2 Micron PES Hollow Fiber Cartridge	NA	1
3	RM-10575	0.295" C/S x 6.835" ID x 7.425" OD O-Ring, 50A Hardness, Clear	Silicone	2
4	CS-10463	Reducer, Spectrum, suATF10	Polycarbonate (Lexan) HPS6	1
5	CS-10471	Liquid Side Pump Hemisphere Assembly, suATF10	Polycarbonate (Lexan) HPS6	1
6	CS-10165	Diaphragm, Pump, ATF10	50A P.C. Silicone: BlueStar LSR4350	1
7	CS-10460	Pump Hemisphere, Air Side, suATF10	Polycarbonate (Lexan) HPS6	1
8	RM-10774	1" TC BioClamp, Glass Filled Nylon	GF Nylon	10
9	RM-10466	1" Silicone Sanitary Gasket	Silicone	4
10	CS-10462	Pump Lock Ring, suATF10	Silicone	1
11	RM-10664	GE ReadyMate to 1" TC	Polycarbonate	3
12	RM-10708	1.5" Sanitary Gasket, Silicone	Silicone	3
13	RM-10919	XCell ATF 10 Branding Label	Vinyl Decal	1
14	RM-10945	8" TC BioClamp, Glass Filled Nylon	GF Nylon	2
15	RM-11065	U Adapter, 1.5" Sanitary Fittings	PVDF	1
16	RM-11059	Aseptiquik X Insert, 1.5" Sanitary	Polycarbonate	2
17	RM-11071	Adapter, 1" MNPT x 1" Hosebarb	PVDF	1
18	RM-11072	Sanitary Fitting Adapter, 1" TC x 1" Hosebarb	PP	1
19	RM-11069	Steridyne 0.2um Filter Capsule, 1" x 3/4" TC Flanges	PP	1
20	RM-11074	Oetiker Clamp, 1 3/8" to 1 1/2"	304 SS	1
21	RM-11215	Oetiker Clamp, 1 15/64" to 1 23/64"	304 SS	1
22	RM-11073	High Pressure EVA Tubing, 1" ID x 18'L	EVA	1.5FT
23	RM-10971	Bottom Lift Label, XCell suATF10	Vinyl	1
24	RM-10970	Top Lift Label, XCell suATF10	Vinyl	1
25	RM-10861	Henkel Loctite AA-3944 UV Adhesive, 25ml syringe	UV Adhesive	0.02
26	RM-10969	Bag, Poly Tube, LDPE, 6mil x 30" x 500'	LDPE	8FT
27	RM-10957	Gamma Radiation Sterilization Indicator Labels	UV Indicator	2
28	RM-10834	Box, Shipping, Single Use ATF10	Cardboard & Foam	1
29	RM-10963	Tie Wrap	Nylon	14
30	RM-11216	Bubble Wrap, 6" x 300'	LDPE	11FT

Figure 4c. Exploded View of XCell™ ATF 6 System Filtration Assembly (P/N ATF6:PH-GMP)

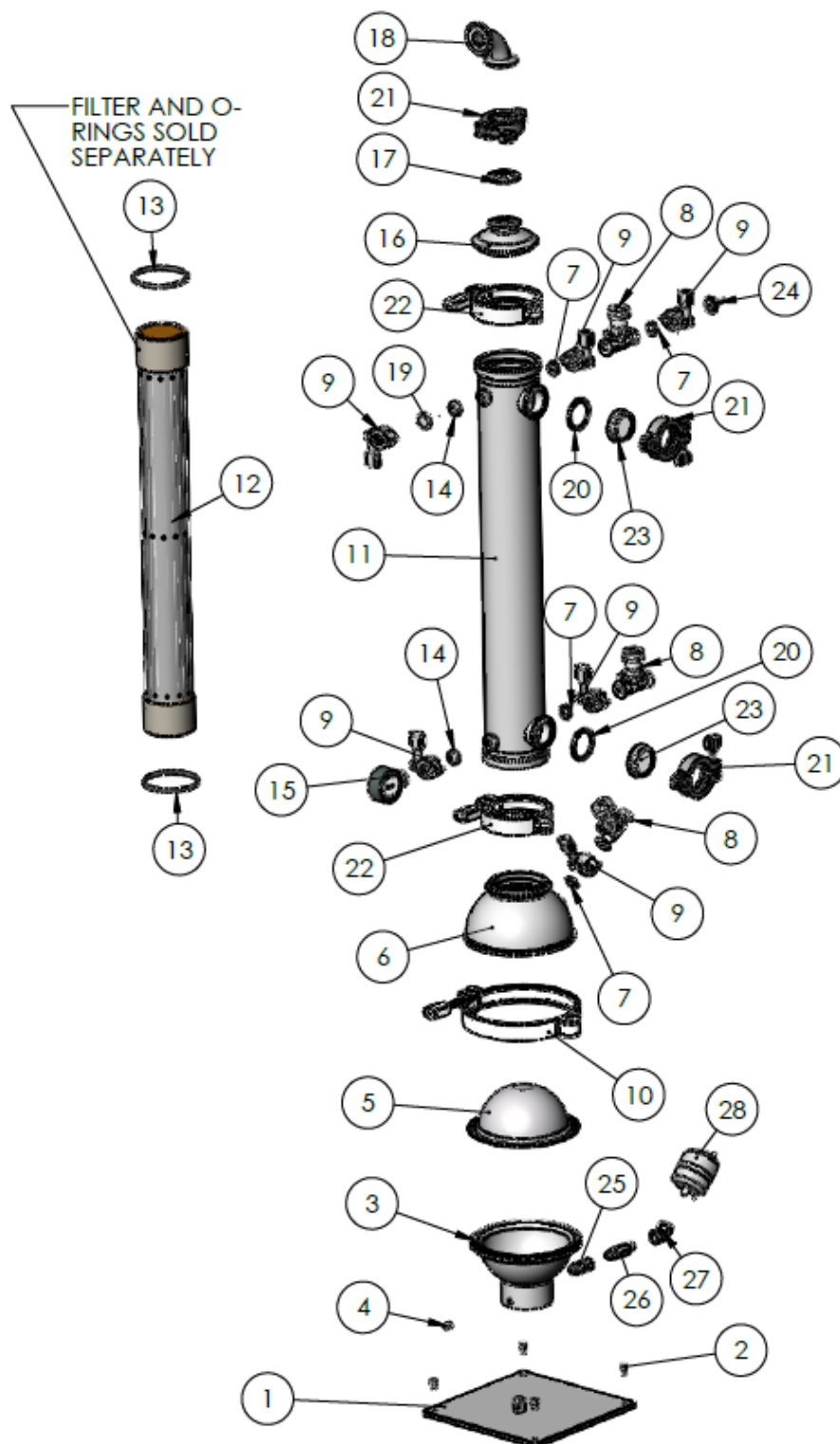


Table 4c. XCell™ ATF 6 Pump Housing Parts List

ITEM NO.	DESCRIPTION	MATERIAL	QTY.
1	Pump Hemisphere, Base Plate, Assembly, ATF6	AISI Type 316L stainless steel	1
2	Socket Head Cap Screw, 1/4-20 X 3/8 Lg	18-8 SS	4
3	Pump Hemisphere, Air Side, ATF6	SA479 316L SS	1
4	Socket Set Screw, Cup Point, 3/8-16 UNC x1/2 LG	18-8 SS	1
5	Diaphragm, Pump, ATF6	50A P.C. Silicone: BlueStar LSR4350	1
6	Pump Hemisphere, Liquid Side Assembly, ATF6	SA479 316L SS	1
7	Sanitary Gasket, 1/2" TC	EPDM	4
8	Sanitary Diaphragm Valve, 1/2" w/TC ends	316 SS	3
9	Clamp, Sanitary, 1/2"-3/4" TC	304 SS	6
10	Clamp, Sanitary 6.0" TC	AISI 304 SS	1
11	Filter Housing Assembly, ATF6	AISI Type 316L stainless steel	1
12	Spectrum F6 2 Micron PES Hollow Fiber Cartridge	PC/PS w/ Hollow Fibers	1
13	Silicone Size 337 70A O-Ring	Silicone	2
14	Sanitary Gasket, 3/4" TC	EPDM	2
15	Pressure Gauge, 3/4 TC 30PSI to -30" Hg	AISI Type 316L stainless steel	1
16	Reducer, ATF6	SA479 316L SS	1
17	Sanitary Gasket 1" TC	EPDM	1
18	Elbow 90 Deg -1.0 , TC Ends	316 SS	1
19	Sanitary Cap 3/4"	AISI Type 316L stainless steel	1
20	Sanitary Gasket, 1 1/2" TC	EPDM	2
21	Clamp, Sanitary, 1 1/2" TC	304 SS	3
22	Clamp, Sanitary, 3.0" TC, I Line Type	AISI 304 SS	2
23	Window, Sanitary 1.5"TC, With / Rem. Glass Insert	AISI Type 316L stainless steel	2
24	Sanitary Adapter, 3/4" Tri-Clamp x 1/4" Hose Barb Fitting	AISI Type 316L stainless steel	1
25	Straight Thread / Swivel Adapter, 3/8" Tube 9/16-18 M x 9/16-18 F	316 SS	1
26	Male Long Connector, 3/8" Tube OD, 9/16-18 M x 1/4" NPTM	316 SS	1
27	45 Deg Female Pipe Elbow, 1/4-18 NPT x 1/4-18 NPT	316 SS	1
28	Air Inlet Filter w/1/4" NPT male ends, & filter Vent Caps (2)	PVDF	1

Figure 4d. Exploded View of XCell™ ATF 6 Single-use Device with 0.2u PES Hollow Fiber Filter

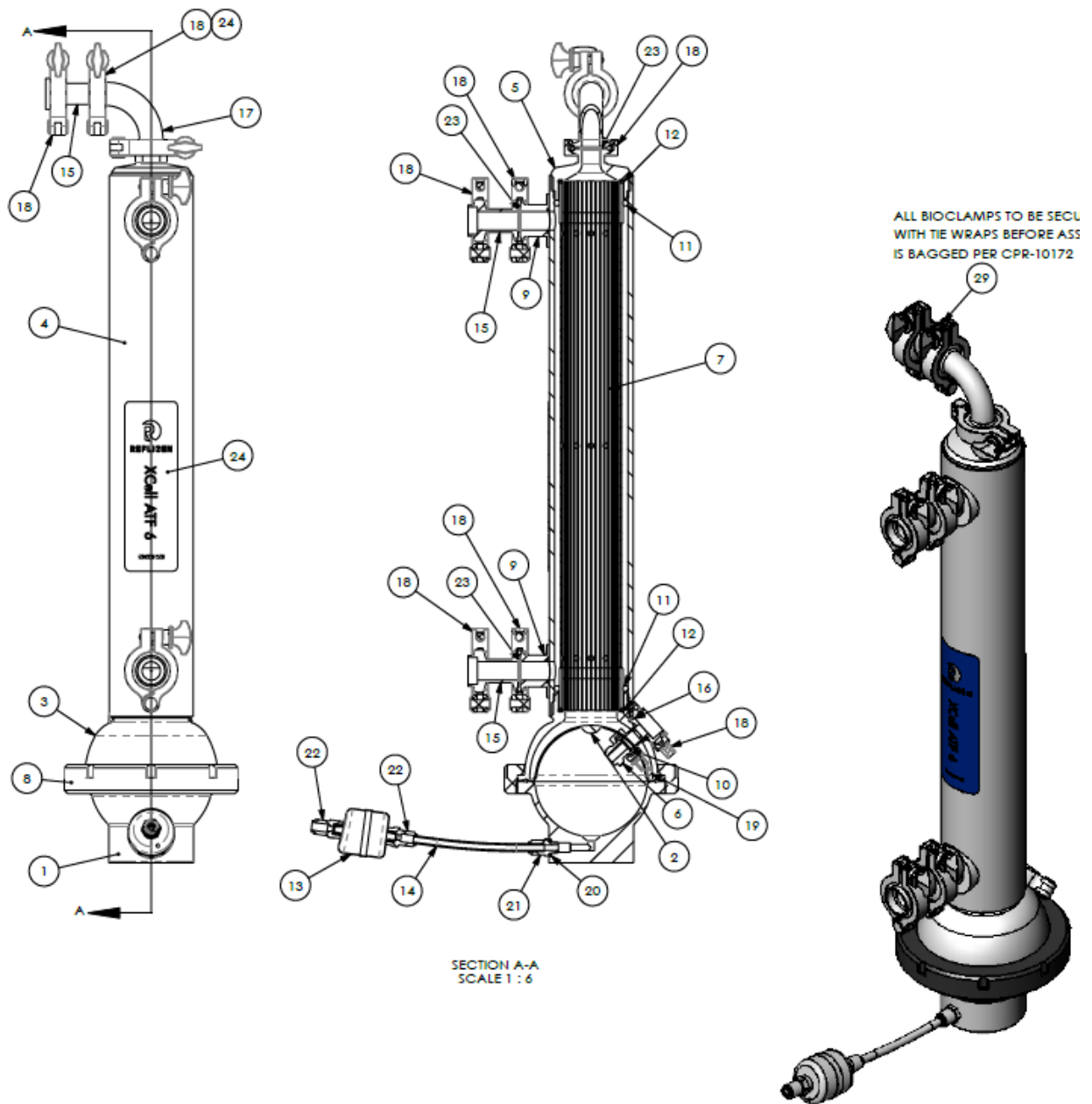


Table 4d. XCell™ ATF 6 Single-use Device Components

ITEM NO.	ITEM DESCRIPTION	QTY
1	Pump Hemisphere: Air Side: XCell suATF6	1
2	Diaphragm: Pump: ATF6	1
3	Pump Hemisphere: Liquid Side: XCell suATF6	1
4	Housing Tube: XCell suATF6	1
5	Reducer: XCell suATF6	1
6	3/4" TC: Pump Hemisphere: Liquid Side: XCell suATF6	1
7	Spectrum F6 2 Micron PES Hollow Fiber Cartridge	1
8	Pump Lock Ring: XCell suATF6	1
9	Permeate Port: Housing: XCell suATF6	2
10	Sanitary Gasket: Silicone: 3/4" TC	1
11	413 O-Ring: Class VI: 70A Silicone	2
12	233 O-Ring: Class VI: 70A Silicone	2
13	Air Inlet Filter w/1/4" NPT male ends (gamma stable)	1
14	Poly Tube: 1/4" ID x 3/8" OD: White	1
15	GE ReadyMate to 1" TC	3
16	GE ReadyMate to 3/4" TC	1
17	1" TC 90 Deg Elbow PVDF	1
18	1" TC BioClamp: Glass Filled Nylon	8
19	0.75" TC BioClamp: Glass Filled Nylon	1
20	O-Ring: Silicone: Size 207	1
21	3/8" Tube Push-to-Connect x 1/4 NPT Male	1
22	3/8" Tube Push-to-Connect x 1/4 NPT Female	2
23	1" Silicone Sanitary Gasket	4
24	XCell ATF 6 Branding Label	1
25	Henkel Loctite AA-3944 UV Adhesive: 25ml syringe	1
26	Roll: Poly Tube: LDPE: 6 Mil Heavy Duty: 20" x 500'	1
27	Gamma Radiation Sterilization Indicator Labels	1
28	Box: Shipping: Single Use ATF6	1
29	Tie Wrap	9

Figure 4e. Exploded View of XCell™ ATF 4 System Filtration Assembly (P/N XCell™ ATF4:PH-GMP)

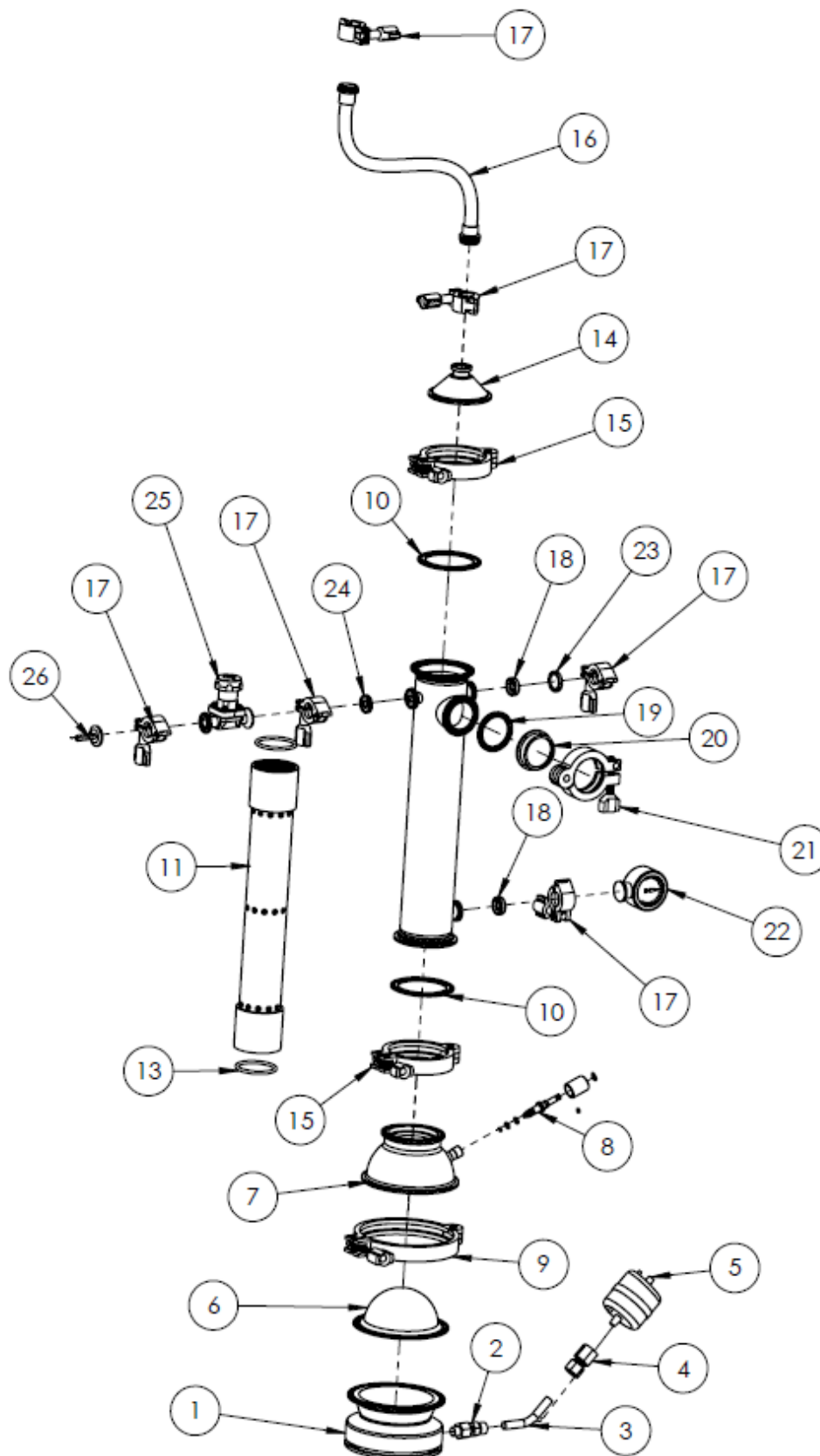


Table 4e. XCell™ ATF 4 Pump Housing Parts List

ITEM NO.	DESCRIPTION	MATERIAL	QTY.
1	Pump Hemisphere, Air Side, ATF4	SA479 316L SS	1
2	MS/SAE Male Straight Threaded Connector 7/16-20 x 3/8" Tube OD	AISI Type 316L stainless steel	1
3	TUBING, Air Inlet Line, 3/8" SS x Tube x 2.5 LG	AISI Type 316L stainless steel	1
4	Female NPT Connector, 1/4 NPT x 3/8" Tube OD	AISI Type 316L stainless steel	1
5	Air Inlet Filter w/1/4" NPT male ends, & filter Vent Caps (2)	PVDF	1
6	Diaphragm, Pump, ATF4	50A P.C. Silicone: BlueStar LSR4350	1
7	Pump Hemisphere Assembly, Liquid Side, ATF4	AISI Type 316L stainless steel	1
8	Sampler Port Stem Assembly, ATF2/4	See pg. 2	1
9	Clamp, Sanitary, 4" TC	AISI Type 316L stainless steel	1
10	Sanitary Gasket, 2 1/2" TC	EPDM	2
11	Hollow Fiber Module	PC/PS w/ Hollow Fibers	1
12	Filter Housing Assembly, ATF4	AISI Type 316L stainless steel	1
13	GMP O-Ring, ATF4	Silicone	2
14	Reducer, ATF4	SA479 316L SS	1
15	Clamp, Sanitary, 3" TC	AISI Type 316L stainless steel	2
16	Silicone Tubing W/ TC Ends, ATF2	Silicon	1
17	Clamp, Sanitary 1/2-3/4" TC	AISI 304 SS	5
18	Sanitary Gasket, 3/4" TC	EPDM	2
19	Sanitary Gasket, 1 1/2" TC	EPDM	1
20	Window, Sanitary 1.5"TC, With / Rem. Glass Insert	AISI Type 316L stainless steel	1
21	Clamp, Sanitary, 1 1/2" TC	AISI 304 SS	1
22	Pressure Gauge, 3/4 TC 30PSI to -30" Hg	AISI Type 316L stainless steel	1
23	Sanitary Cap 3/4"	AISI Type 316L stainless steel	1
24	Sanitary Gasket, 1/2" TC	EPDM	2
25	Sanitary Diaphragm Valve, 1/2" w/TC ends	AISI Type 316L stainless steel	1
26	Sanitary Adapter, 3/4" Tri-Clamp x 1/4" Hose Barb Fitting	AISI Type 316L stainless steel	1

See Appendix 7 for list of spares and accessories

5. C410:V3 Controller Layout

5.1 General Layout

The controller consists of two parts: the E-Box, Figure 5, and the P-Box, Figure 4. The two are interconnected with a cable that relays signal and power. A general layout of the two boxes with the XCell™ ATF System is shown in Fig. 1. The primary design objective is to produce a modular system that will maximize adaptability of the system to the various space requirements of the user's facilities. The Interconnect Cable, I-Cable, connecting the E-Box and the P-Box can be selected to the required lengths to

facilitate positioning and handling of the boxes within the facility. One can envision the P-Box in proximity to the Filtration Assembly, while the E-Box positioned distant to the Filtration Assembly, possibly mounted on a wall or a skid.

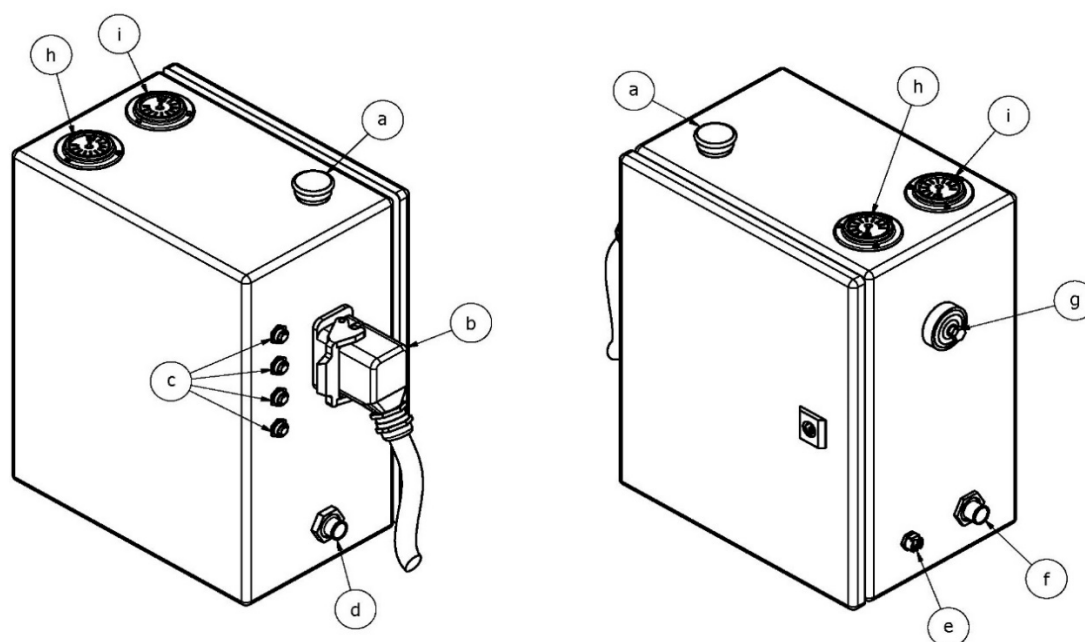
5.1.1 Filtration Assembly

This includes the Diaphragm Pump, Filter Housing, connection to the bioreactor, harvest line, pump air inlet assembly, stand, plus all the housing accessories as specified in the part list.

P-Box:

- a. System STOP Switch
 - b. Interconnect Cable Plug
 - c. Plugs for sensor inputs (4x4-20mA)
 - d. Connection for Diaphragm Pump
 - e. Connection for compressed air
 - f. Connection for vacuum supply
 - g. Pressure regulator (0 to 60psi, 0 to 4.1 bar)
 - h. Vacuum gauge (0 to -14psi, 0 to -0.95 bar)
 - i. Pressure gauge (0 to 60psi, 0 to 4.1 bar)
- (Not pictured in Figure 5) Pressure relief assembly – set to 40psi, 2.8 bar

Figure 5. Pneumatic Box (P-Box) Connections
P-BOX



E-Box

The E-Box contains the HMI and PLC components, including: the Siemens S7-1200 PLC. It is programmed using [Siemens Step 7 Basic v13](#). The Operator Interface Terminal (OIT or HMI) is a Siemens SIMATIC TP 1200 Comfort, programmed using [Siemens WinCC Advanced v13](#).

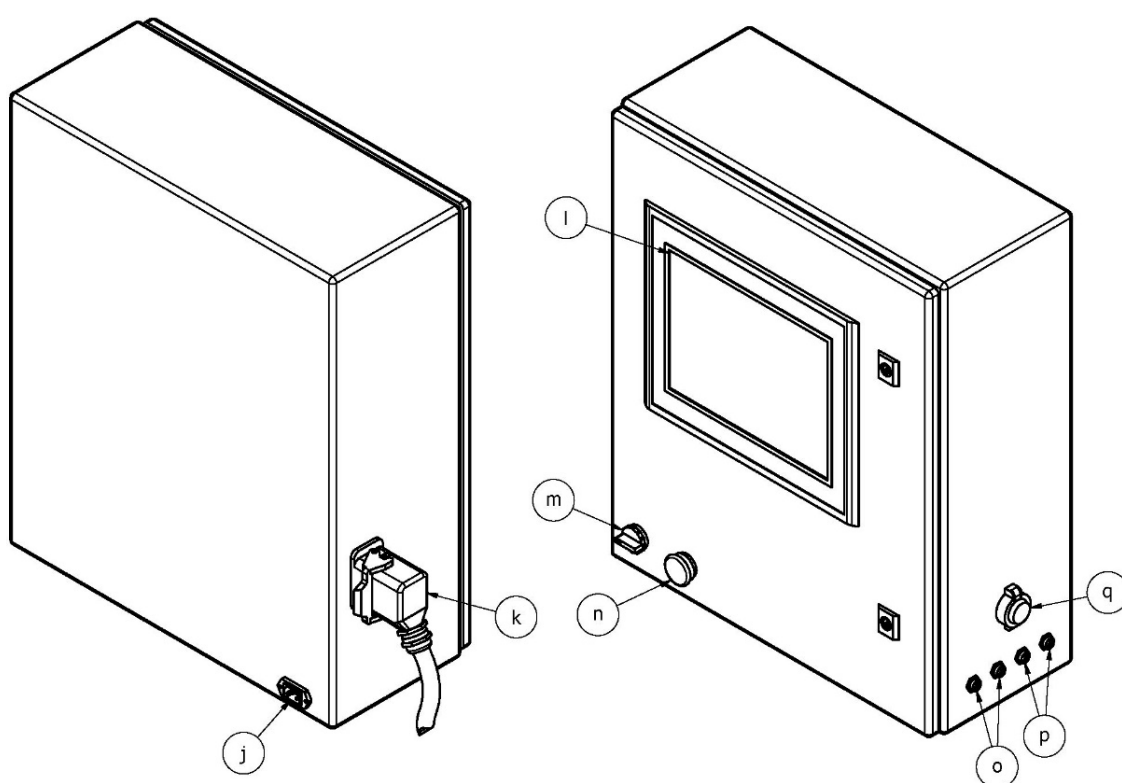
The E-box includes the following connections:

- j. 120/220vac power cable with plug

- k. Interconnect Cable Plug
- l. Operator Interface Terminal (OIT or HMI)
- m. Illuminated POWER ON/OFF Selected Switch
- n. Illuminated System STOP Push Button
- o. Alarm Relay Outputs (2)
- p. Harvest Pump Relay Outputs (2)
- q. Ethernet Plug

Figure 6. Electric Box (E-Box) Connections

E-BOX



5.2 Primary Pneumatic Services

Air inlet (e) - Located on the P-Box and provides an inlet to house compressed air source. Recommended minimum air pressure requirement is ~50psi / 3.4bar. Somewhat higher inlet pressures may be required, as needed, to generate higher flow rates or to drive pneumatic instruments.



Do not exceed 90 psi / 6.1 bar on the Air inlet

Exhaust/ vacuum line (f) - Located on the P-Box. This line is connected to a vacuum source. A vacuum source should always be connected to the exhaust line to ensure reliable operation of the XCell™ ATF.



In addition to vessel pressure, the hydrostatic pressure generated by the height difference between vessel liquid level and pump level may assist or hamper the exhaust flow

Pump line (d) - Located on the P-Box. The line connects the P-Box to the Diaphragm Pump. A hydrophobic 0.2micron filter in this line provides both a sterile barrier and also a potential barrier to the back flow of liquid from Diaphragm Pump to controller should a diaphragm rupture.



Be sure to use the hydrophobic filter in the pump line to prevent accidental flow of liquid from the Filtration Assembly to the P-Box.

Air Pressure regulator - Typical range of regulator is **0-60psi/ 4.1bar**. This is a second stage pressure regulator for regulating service air inlet pressure to a specified, user required, value.



Typically, the secondary air pressure is regulated to 35psi/2.4bar. That value is selected because that pressure is recommended to drive the proportional pressure control valve PRV1 and it is generally the upper limit of the pressure required to achieve set flow rates.

Air Pressure Gauge (i) - Located on the upper side of the P-Box. Typical range of gauge is 0-60psi. It shows second stage system pressure.

Vacuum Gauge (h) - Located on the upper side of the P-Box. Typical range of gauge is 0 to -30inHg / -0.95 bar. It shows primary vacuum pressure status.

5.3 Primary Electric Services

Electric plug (j) - Located on the E-Box. Electric power (standard 100-240V AC, 50/60Hz).

Power switch (m) - Located on E-Box.

Power indicator Light - same as the power switch. Lights green when power is ON

Stop Button(a, n) - Located on the P-Box and E-Box.

Either Stop Button, causes the system cease operation and default to Standby mode, when the Diaphragm Pump defaults to Exhaust.

5.4 Signal

A total of 4 Sensor input plugs (c) are provided on the P-Box. All inputs are analogue 4-20mA. Three plugs P3, P4 and P5 are for pressure inputs. One plug W1 is for a load cell input.

Ethernet (q) - communication port for data acquisition on E-Box.

Relays – Two relay outputs are for relaying alarm conditions (**o**). Two relays for driving a harvest pump (**p**).

Interconnect (Signal) Cable (I-Cable) - to relay signal and DC power between E-Box and P-Box.

5.5 C410:V3 Ethernet set-up and Connectivity

Ethernet Infrastructure

The communication link between the Windows environment and the XCell™ ATF Controller is based on Profinet®. Profinet® is an open Industrial Ethernet standard developed by the PROFIBUS Organization and is standard Ethernet (IEEE802.3). The Profinet® communication protocol sends and receives data using the open Ethernet TCP/IP standard at a bandwidth of 100 Mbit/s and functions identical to traditional industrial Ethernet in providing “real-time” channel for time-critical communications (i.e. process data)

Ethernet Configuration

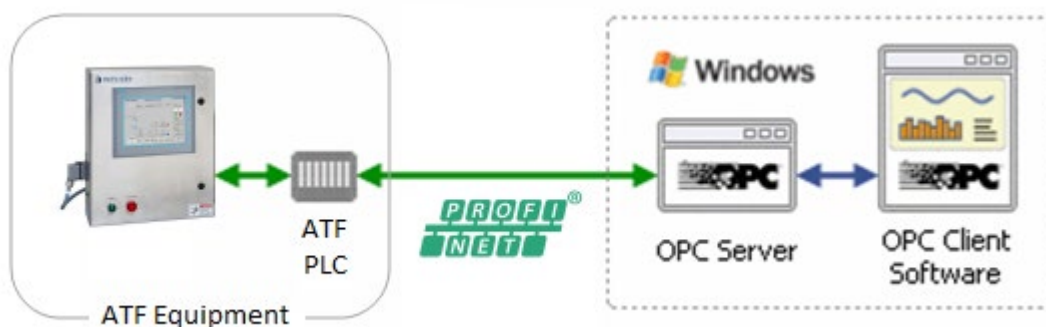
The communications interface between the controller HMI and PLC is based on Profinet (Industrial Ethernet). The controller is factory set to the following IP settings:

	IP Address	Subnet Mask	Default Gateway
HMI	192.168.1.167	255.255.255.0	None
PLC	192.168.1.168	255.255.255.0	None

This factory default setting has the HMI and PLC on the same subnet allowing proper communications to take place. If ‘#####’ appears in input fields and the software version is not displayed on the administration screen, the HMI and PLC may not be properly connected and the connection may need to be reset. See Appendix 4 for instructions on how to set IP Addresses and connections.

XCell™ ATF Operations- Remote Monitoring and Data Acquisition

The following diagram shows the network architecture for controlling the XCell™ ATF Equipment from an OPC Server and OPC Client Software over Profinet®:



The OPC Client Software is any OPC capable program that will connect through the OPC Server to the XCell™ ATF Equipment. The OPC Client Software will Control the XCell™ ATF Equipment remotely and/or read the status of the XCell™ ATF Equipment. Examples of OPC Client Software include Microsoft Excel, WinCC HMI by Siemens, and FTVIEW HMI by Rockwell Automation.

- The acronym "OPC" comes from "OLE (Object Linking and Embedding) for Process Control". Since OLE is based on the Windows COM (Component Object Model) standard, under the hood OPC is essentially COM. Over a network, OPC relies on DCOM (Distributed COM), which was not designed for real-time industrial applications and is often set aside in favor of OPC tunneling.
- OPC is implemented in Server/Client pairs. The OPC Server is a software application that bridges the communication of the PLC with the Windows environment and then with the OPC Client Software application. Some common OPC Server program suppliers include Delta Logic (OPC Server & Data Logger) and Siemens (WinCC Siemens).
- OPC also comprises several standards including OPC Data Access (OPC DA) and other standards for alarms & events, historical data, batch data and XML.

Proceed to Appendix "4" for details on OPC Integration for Remote Data Logging

6. C410:V3 Controller Process and Control

6.1 Interface and screens

A Siemens Operator Interface Terminal (OIT) provides the user with the following features:

1. Pump Status including cycle rate, flow rate, pressures, controller status and total batch cycles
2. Setup Parameters
3. Acknowledge and clear machine faults (i.e. warning and alarms)
4. Process Trending

When an input box is highlighted and pressed; a number pad or keyboard will appear on screen to enable data input.

For numerical entries as the value is being typed, a Min and Max range dialog box appears, showing the user the acceptable value range. Any value outside the min/max range, or any text strings or letters is not accepted.

The OIT will display the following Primary Screens:

Primary Screens - MAIN, SET UP, ALARMS, TRENDING, BATCH, ADMIN., LOGOFF.

Secondary Screens - Screens within the Primary Screens.

Screen	Description
LOG ON	Initial System Log On which appears when the C410:V3 controller first powers up
MAIN	Main Diaphragm Pump Control & Monitoring Displays Real Time Pump Status Access to all Primary Screens.
SET UP	Users Set Up of Process parameters, Calibration, and Diaphragm Pump Parameters
ALARMS	Display Diaphragm Pump Warnings and Faults
TRENDING	Graphical Real Time display of Flow Set Point, Exhaust Set Points, Flow Process Value, Vessel Weight.
BATCH INFO	Batch Set Up Screen
ADMINISTRATOR	Setting of users ID, security level and passwords, Close Application, PLC ON/OFF
LOG OFF	Users logoff

Description of Screens and Buttons

A.	LOGON
----	-------

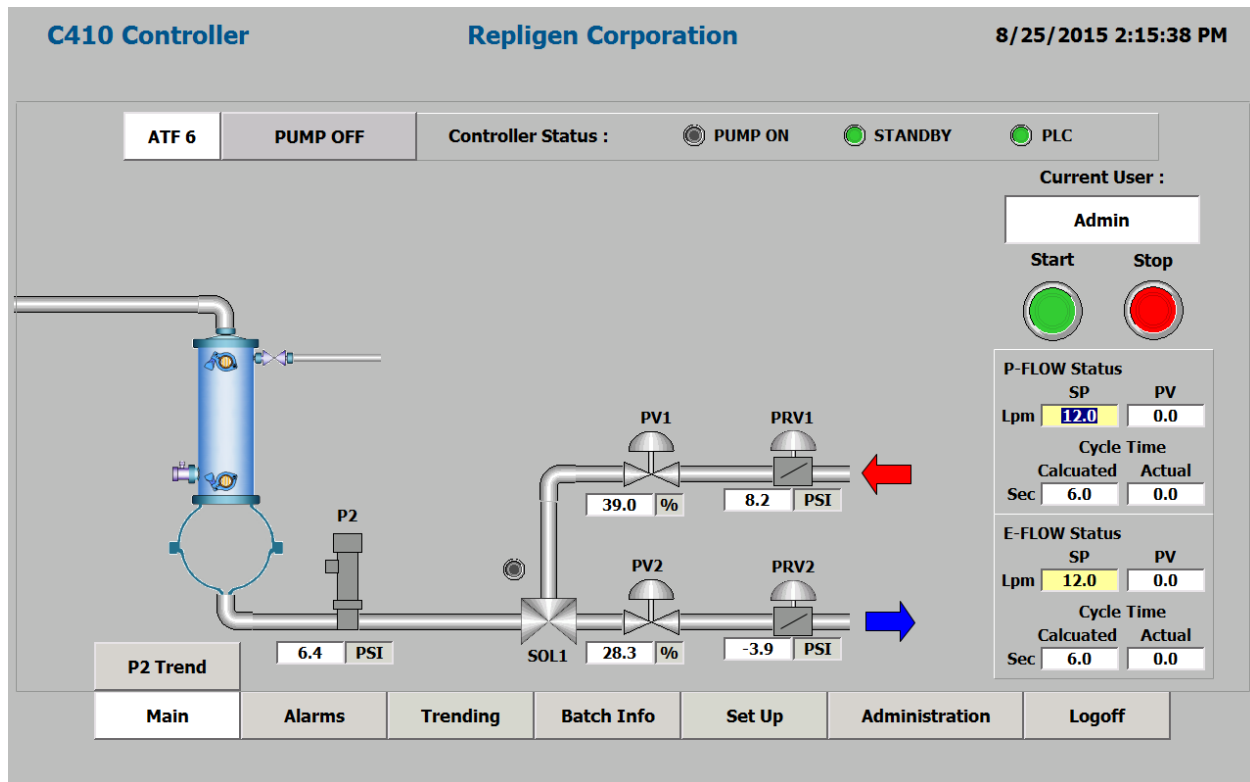


Logon screen appears when the C410:V3 controller is powered up. Click on LOGON to bring up User/Password Dialog Box and Keyboard. For first time use, enter ADMIN for USER and 1234 for PASSWORD.



B.

MAIN



The Main screen provides an overview of the process. It displays a pneumatic process schematic, an animated diaphragm movement /cycle, valve transition between pressure and exhaust cycles and flow direction. From the Main screen, an operator can:

1. Monitor and control XCell™ ATF System processes. In the Main screen and all subsequent screens, all data fields with a white background are for display only. The operator, based upon security levels, can change data fields with a beige background.
2. Start/Stop Diaphragm Pump
 - a. When starting the Diaphragm Pump, a dialog box will appear to enable the user to start with current settings, start with default settings or cancel and return to the main screen
 - b. When stopping the Diaphragm Pump, a dialog box will appear that enables the user to confirm the stop command, or to cancel and return to the main screen.
3. Access other screens based upon password security levels
4. Observe P2 trending. A P2 Trend button hides / reveals this screen.
5. Observe an animated Diaphragm Pump showing inflation and deflation cycles of the Diaphragm Pump.
6. Monitor Overtime condition- displayed in FLOW status sub screens, by change of actual cycle time field to red
7. Monitor Overflow condition- displayed in FLOW status sub screens, by change of actual cycle time field to orange

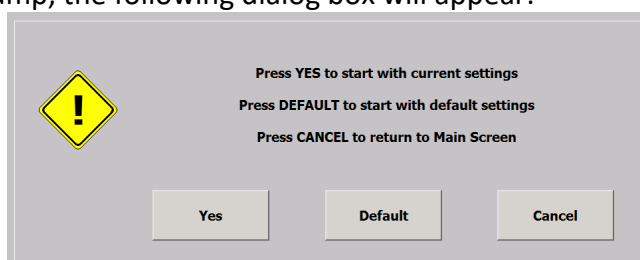
The main screen displays the parameters in the following tables:

Field	Description
Date/Time	Displays current Date and Time
User ID	Displays current User ID
Entries in Main Screen	Field entries by Administrator (or, if authorized, by Engineer) through the Main screen:
	P-Flow
	E-Flow
	PRV1
	PRV2
	PV1
	PV2
P-FLOW SP	Displays current P-Flow Set Point (SP) (LPM)
P-FLOW PV	When running, displays pump Flow rate Process Value (PV) of last pump cycle (LPM)
P-FLOW Calculated	Displays current P-Flow Calculated cycle time (Sec)
P-FLOW Actual	When running, displays Actual pump flow cycle Time of last pump cycle (Sec)
E- FLOW SP	Displays current E-Flow Set Point (SP) (LPM or Seconds)
E- FLOW PV	When running, displays pump exhaust Flow rate Process Value (PV) of last pump cycle (LPM)
E-FLOW Calculated	Displays current E-Flow Calculated cycle time (Sec)
E-FLOW Actual	When running, displays Actual pump exhaust cycle Time of last pump cycle (Sec)
PV1	Displays current position Set Point of Flow Proportional Valve (0-100%)
PV2	Displays current position Set Point of Exhaust Proportional Valve (0-100%)
PRV1	Displays current setting of automatic pressure regulator (0 to 35psi)
PRV2	Displays current setting of automatic exhaust regulator (-15 to 0 psi)
P2	Displays current pressure between controller and Diaphragm Pump (PSI)
Controller Status	Displays current controller status: PUMP OFF PUMP ON PUMP WARNING PUMP ALARM SYSTEM STOP PRESSED

Indicator	Description
PLC	Indicates Controller PLC is ON and in RUN mode
Pump ON	Indicates Diaphragm Pump is in RUN mode
Standby	Indicates Controller OFF/ON Status
SOL 1	Indicates Flow Direction Solenoid is OFF/ON

Button	Description
Start	Press to START Diaphragm Pump
Stop	Press to STOP Diaphragm Pump
P2 Trend	Press to Hide / Reveal the P2 Trending Screen
All Primary	All Primary Screen Buttons are displayed to navigate to those screens. Alarms, Trending, Batch Info, Set Up, Administration

When starting the pump, the following dialog box will appear:

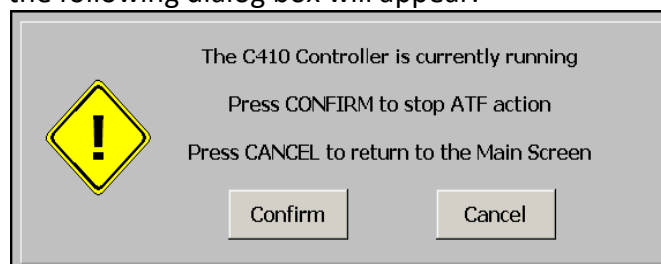


Yes setting is preferred when stopping the Diaphragm Pump and restarting with the same flow rate or process settings (i.e. same PRV and PV values as when the Diaphragm Pump last ran).

Default setting is preferred when starting the Diaphragm Pump with new flow rate settings or new process setup (e.g. different bioreactor configuration & parameters). This minimizes the number of cycles taken by the controller to reach the desired flow rate. At any selected flow rate, default simply resets the control parameters to factory preset values.

Cancel will return to the main screen without any action taken.

Stopping the pump, the following dialog box will appear:



C.	SET UP
----	--------

From the Set Up Screen, an Engineer/Administrator

can make entries in the following:

- Basic Set Up Screen
- Advance Set Up Screen
- Calibration Screen
- Help Guide
- Exit to Primary Screens
- Navigate to the following Secondary screens

C.1	BASIC SET UP
-----	--------------

C410 Controller **Repligen Corporation** 8/25/2015 2:17:39 PM

Basic Set Up

Controller Set Up

Pump Model Number	ATF 6	Slope Function Enabled	<input type="checkbox"/>
Control Mode	Flow	Bioreactor Pressure (PSI)	0.0
Alarm Delay (min)	1	Height Differential (cm)	+100

Pump Parameters	Pressure Cycle	Exhaust Cycle
Pressure Offset (PSI)	0.5	-0.5
Delay Time (%)	70	70
Over Time (%)	120	120
PV Step Size (%)	1	1

Alarm Set Points	Hi Hi Set Point	Lo Lo Set Point
P2 Pressure (PSI)	35.0	-15.0
Alarm Delay (10 ms)	75	75

Accept Changes Discard Changes

Basic Advanced Calibration 1 Help Guide

Main Alarms Trending Batch Info Set Up Administration Logoff

From the Basic Set-Up Screen, an Engineer/Administrator can:

1. Set initial Controller Set Up
2. Change Hi Hi and Lo Lo Alarm set points
3. Change Process Parameters
4. Access other screens based upon password security levels

The Basic Set-Up screen will display the parameters in the following tables:

Field	Description
Process Set Up	Groups the following fields:
Pump Model No	Press to select Pump Model No ATF4, 6, 8, 10, 10-R
Control Mode	Press to select Control Set Point units (FLOW or TIME)
Alarm Delay(min)	The amount of time in minutes the controller will stay in warning condition before switching to alarm condition. (If 0 is entered system will remain in warning condition.)
Slope Function Enable	Integrates P2 slope at Delay Time to extrapolate Cycle Switch Pressure. See warning below.
Bioreactor pressure	Expected bioreactor operating pressure
Δ height	The height difference between bioreactor liquid level and middle of Diaphragm Pump (in cm)
P2 limits	Sets P2 upper and lower allowable limits
HiHi Alarm Set Points	Sets a high limit on P2 pressure during the P-Flow Cycle If P2 is \geq HIHI, follow with ALARM and System Stop
LoLo Alarm Set Point	Sets a low limit on P2 pressure during the E-Flow Cycle If P2 is \leq LOL, follow with WARNING
Alarm Delay (msec)	Delays response to HIHI and LOLO Set Point. If the alarm parameter is set for 0 minutes it will remain in a "Warning" state. If the field is set 1 – 50 minutes, the system will go into an "Alarm" state should the condition for the alarm persists for the set elapsed time defined in this parameter. This will put system in a halt condition.
Pump Parameters	Groups Diaphragm Pump Parameters :
P-Pressure Offset (psi)	Pressure cycle: Pressure Offset or-Over pressure Set Point (P-OSP1) value (psi) above P2 to switch from Flow (or Pressure) cycle to Exhaust
E-Pressure Offset (psi)	Exhaust cycle: negative Over pressure Set Point (E-OSP2) value (psi) below P2 to switch from Exhaust cycle to Flow or Pressure cycle
P-Delay (%)	Sampling point of sP2 during the Pressure cycle (% of total cycle time, preset range 10 to 90%)
E-Delay (%)	Sampling point of sP2 during the Exhaust cycle (% of total cycle time, preset range 10 to 90%)
P-Overtime (%)	Sets the overtime limit to the Pressure cycle (% of calculated cycle time)
E-Overtime (%)	Sets the overtime limit to the Exhaust cycle (% of calculated cycle time)

P-PV Step Size (%)	Sets the (%) incremental change in PV1 when PRV1 exceeds its set limits
E-PV Step Size (%)	Sets the (%) incremental change in PV2 when PRV2 exceeds its set limits



Slope Function Enable: Don't enable this function unless you thoroughly understand its effects

Button	Description
Advance Set Up	Press to switch to Advanced Set Up Screen
Help Guide	Press to switch to Start up (Help) Guide Screen
Calibration	Instrument Calibration
Accept / Discard Change	Accept Change and Discard Change to accept or reject any parameter change on the screen.
All Primary	All Primary Screen Buttons are displayed to navigate to those screens

C.2 ADVANCED SET UP

C410 Controller **Repligen Corporation** 8/25/2015 2:19:40 PM

Advanced Set Up

User Set Point Ranges	Lpm	Seconds
Pressure Cycle Flow Max	20.0	14.4
Pressure Cycle Flow Min	0.0	0.0
Exhaust Cycle Flow Max	20.0	14.4
Exhaust Cycle Flow Min	0.0	0.0

Output (CV) Limits	Min	Max
PV1 (%)	5	95
PV2 (%)	5	95
PRV1 (PSI)	1.0	29.0
PRV2 (PSI)	-14.5	-1.0

Accept Changes Discard Changes

Basic **Advanced** Calibration 1 Help Guide

Main Alarms Trending Batch Info Set Up Administration Logoff

From the Advanced Set Up Engineer/Administrator can set the following Diaphragm Pump Parameters:

The Advanced Set-Up screen will display parameters in the following tables:

Field	Description
Max P-FLOW (LPM)	Maximum limit for PFLOW set point (LPM)
Max P-FLOW (sec.)	Maximum limit for PFLOW set point (Seconds)
Min P-FLOW (LPM)	Minimum limit for PFLOW set point (LPM)
Min P-FLOW (sec.)	Minimum limit for PFLOW set point (Seconds)
Max E-FLOW (LPM)	Maximum limit for EFLOW set point (LPM)
Max E-FLOW (sec.)	Maximum limit for EFLOW set point (Seconds)
Min E-FLOW (LPM)	Minimum limit for EFLOW set point (LPM)
Min E-FLOW (sec.)	Minimum limit for EFLOW set point (Seconds)
PV1 Max (%)	Maximum operating limit for PV1 (%)
PV1 Min (%)	Minimum operating limit for PV1 (%)
PV2 Max (%)	Maximum operating limit for PV2 (%)
PV2 Min (%)	Minimum operating limit for PV2 (%)
PRV1 Max (psi)	Maximum operating limit for PRV1 (psi)
PRV1 Min (psi)	Minimum operating limit for PRV1 (psi)
PRV2 Max (psi)	Maximum operating limit for PRV2 (psi)
PRV2 Min (psi)	Minimum operating limit for PRV2 (psi)

Button	Description
Basic Set Up	Press to switch to Basic Set Up Screen
Help Guide	Press to switch to Start Up Guide Screen
Calibration	Instrument Calibration
Accept / Discard Change	Accept Change and Discard Change to accept or reject any parameter change on the screen.
All Primary	All Primary Screen Buttons are displayed to navigate to those screens

C.3	START-UP GUIDE
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The Start Up Guide page shows a Quick reference guide for the operator. This information should be reviewed by all Users before operating the C410:V3 controller.

The Start Up Guide screen will display parameters in the following tables:

Button	Description
Basic Set Up	Press to switch to Basic Set Up Screen
Advanced Set Up	Press to switch to Advanced Set Up Screen
Calibration	Instrument Calibration
All Primary	All Primary Screen Buttons are displayed to navigate to those screens

C.4	TCP/IP
-----	--------

Ethernet Configuration, only accessible to the Administrator, the Ethernet Configuration allows the administrator to set up the communication interface of the HMI and PLC units.

Note: The HMI must be set through the set connection function in windows light to the PLC address for proper communication to occur.

See APPENDIX 4 for details on Setting IP Addresses and Setting Connection.

C.5
CALIBRATION

C410 Controller
Repligen Corporation
8/25/2015 2:20:53 PM

Calibration

Calibration	Select	Eng. Units	1st Point	Eng. Units	2nd Point	Act. Val.	
Analog Input P2	<input type="checkbox"/>	0.0	Capture	0.0	Capture	+6.4	Accept
Analog Input PRV1	<input type="checkbox"/>	0.0	Capture	0.0	Capture	+41.2	Accept
Analog Input PRV2	<input type="checkbox"/>	0.0	Capture	0.0	Capture	-16.0	Accept
Analog Input P3	<input type="checkbox"/>	0.0	Capture	0.0	Capture	+20.5	Accept
Analog Input P4	<input type="checkbox"/>	0.0	Capture	0.0	Capture	+20.5	Accept
Analog Input P5	<input type="checkbox"/>	0.0	Capture	0.0	Capture	+20.5	Accept
Analog Input W1	<input type="checkbox"/>	0.0	Capture	0.0	Capture	+20.5	Accept

Basic
Advanced

Calibration 1
Help Guide

Main
Alarms
Trending
Batch Info
Set Up
Administration
Logoff

Analog Input Configuration / Calibration: Only accessible to the Administrator and Engineer Login. The Analog Input Configuration / Calibration screen allows for the setup of analog inputs.

For each analog input the Administrator and Engineer will be able to configure the Engineering Units, the Minimum Engineering Value, the Maximum Engineering Value, and perform a two point calibration.

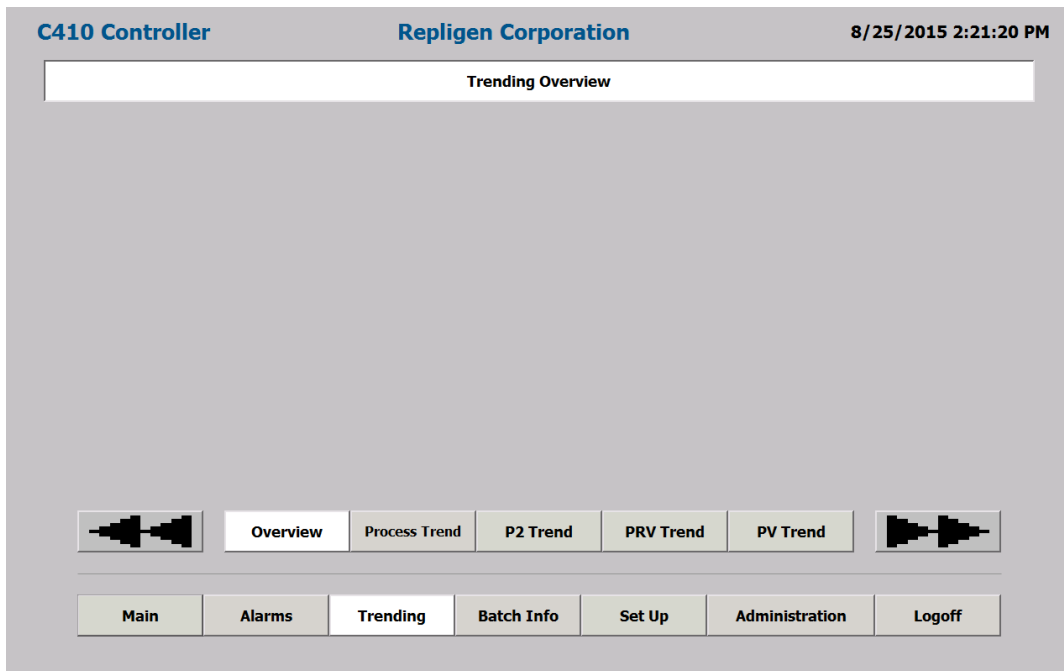
Note: this should only be performed by a qualified metrology personal or Repligen Field Service Engineer.

The Calibration screen will display parameters in the following tables:

Field	Description
Engineering Units	Enter the Engineering Units for the selected analog input
Minimum Engineering Value	Enter the Minimum Engineering Value for the selected analog input
Maximum Engineering Value	Enter the Maximum Engineering Value for the selected analog input
Calibration Point #1	Enter the first calibration point in Engineering Units in the range of Minimum Engineering Unit to Maximum Engineering Unit
Calibration Point #2	Enter the second calibration point in Engineering Units in the range of Minimum Engineering Unit to Maximum Engineering Unit

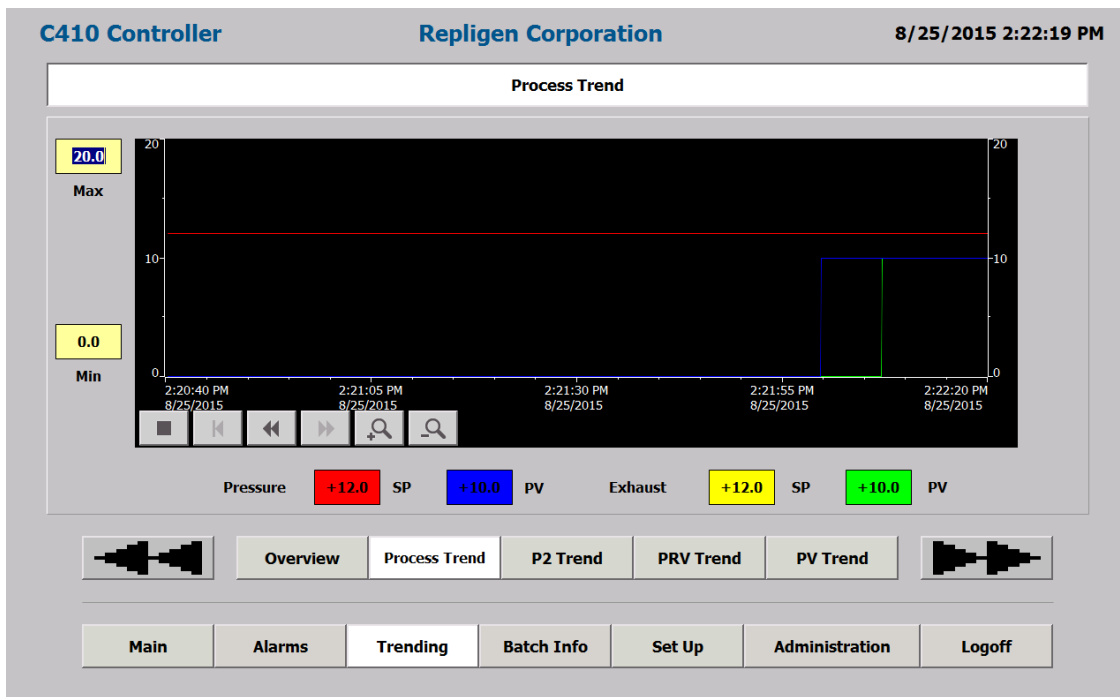
Button	Description
Accept Settings	This button will enable the new settings. Exiting the screen without Accepting the settings will discard them.
Analog Input Select	This button will select which of the Analog Inputs is selected
Capture First Calibration Point	This button will capture the raw input value for the first point for the selected analog input
Capture Second Calibration Point	This button will capture the raw input value for the second point for the selected analog input
Actual Value	This button will finalize the two point calibration performed for the corresponding line.
Basic Set Up	Press to switch to Basic Set Up Screen
Advanced Set Up	Press to switch to Advanced Set Up Screen
Help Guide	Press to switch to Start Up Guide Screen
Accept / Discard Change	Accept Change and Discard Change to accept or reject any parameter change on the screen.
All Primary	All Primary Screen Buttons are displayed to navigate to those screens

D. TRENDDING



The Trending screen displays an Overview screen from where the following trends are selected.

D.1 PROCESS TREND



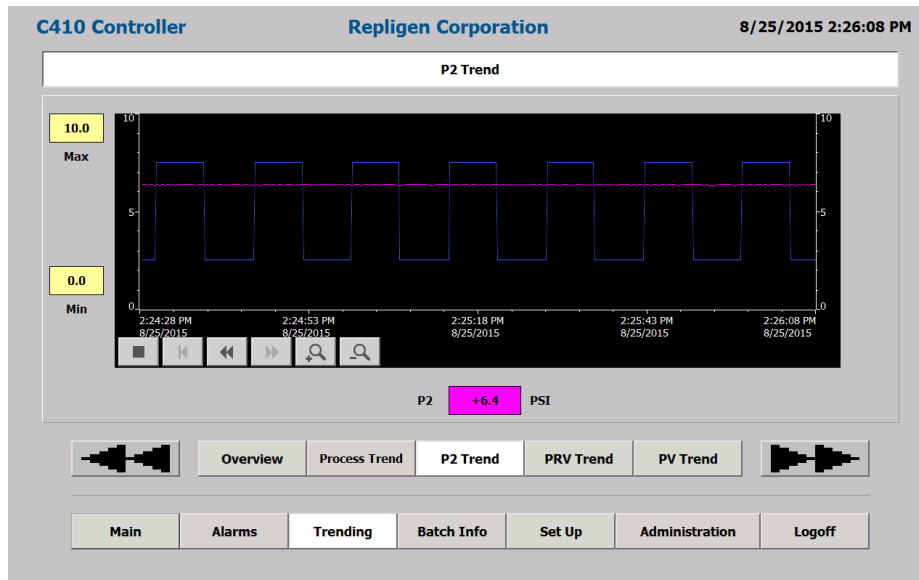
This screen monitors, in real time, the Flow and Exhaust Set Points and Process Values in LPM.

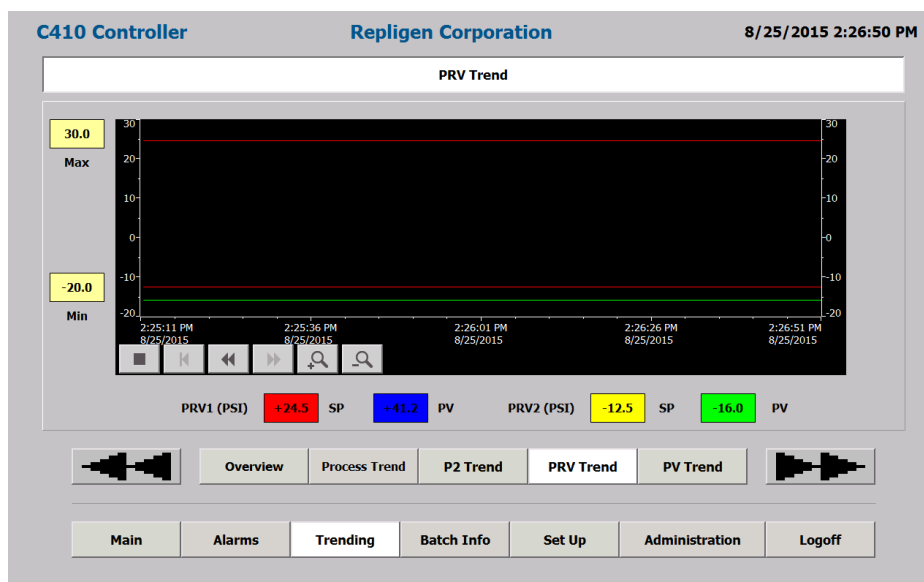
The Process Trend screen monitors, in real time, the Flow and Exhaust Set Points and Process Values in LPM. The screen has the following screen control options:

Field	Description
Max	Enter maximum value for the chart Y Axis
Min	Enter minimum value for the chart Y Axis

Button	Description
	Scrolls back to the beginning of the trend recording. The start values, with which the trend recording started, are displayed
	Zooms into the displayed time section
	Zooms out of the displayed time section
	Scrolls back one display width
	Scrolls forward one display width
	Starts or continues trend recording
	Stops trend recording
Primary Screens	All Primary Screen Buttons are displayed to navigate to those screens

D.2 PV, PRV, P2, P3, P4, P5, W1 TREND





These screens monitor, in real time, the specific analog signal. Trend buttons select trend to display. All screens have the following screen control options:

Field	Description
Max	Enter maximum value for the chart Y Axis
Min	Enter minimum value for the chart Y Axis

Button	Description
	Scrolls back to the beginning of the trend recording. The start values, with which the trend recording started, are displayed
	Zooms into the displayed time section
	Zooms out of the displayed time section
	Scrolls back one display width
	Scrolls forward one display width
	Starts or continues trend recording
	Stops trend recording
Primary Screens	All Primary Screen Buttons are displayed to navigate to those screens

WEIGHT TREND

Available in the TRENDED screen

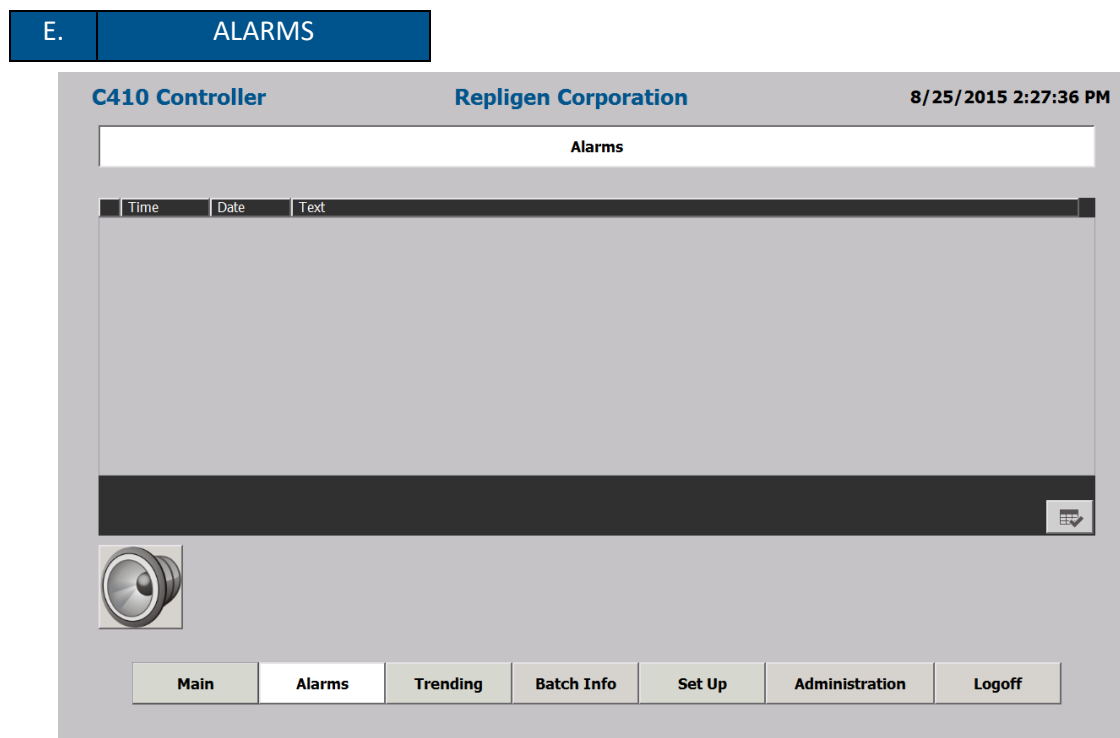
During the XCell™ ATF System cycle, the weight of the Filtration Assembly changes in response to the liquid flow to and from Diaphragm Pump. The weight profile is directly proportional to the position of the diaphragm within the Diaphragm Pump, (or to how much liquid is in the Diaphragm Pump). This provides useful real time information on the position of the diaphragm within the Diaphragm Pump.

That information may be used to:

- i. Monitor if the diaphragm cycles its full stroke.
- ii. Display the position of the diaphragm in the Diaphragm Pump.




While the PLC records the output from the load cell in milliseconds, the computer HMI is much slower and refresh rate is about once every 0.5-1.0 second; therefore, while one may not observe the details of the pump cycle on the HMI, (typically, between 4-10 seconds/half cycle), the PLC will continue to monitor the rapid weight change.



The Operator can view C410:V3 controller Warnings and Alarm conditions. All Warnings/Alarms are displayed with Time/Date stamping and full description of condition. Both Warnings/Alarms will activate the audible horn located inside C410:V3 controller cabinet. An Alarm condition will automatically stop the pump cycling action, while a Warning condition allows the pumping cycling action to continue. Warning and Alarm conditions are described in the following section.

The Alarm screen will display parameters in the following tables:

Field	Description
Time	Indicates time of Alarm
Date	Indicates Date of Alarm
Text	Describes Alarm

Button	Description
Horn Acknowledge	Press to turn off Horn
	Select Highlight Warning/Alarm message and press to remove
All Primary	All Primary Screen Buttons are displayed to navigate to those screens

Two (2) Pump Controller Status Relays are provided which energize per the following states:

XCell™ ATF System States	State #	RELAY #1	RELAY #2
POWER OFF / ALARM	A	OFF	OFF
POWER ON / STANDBY	B	OFF	ON
POWER ON / RUNNING	C	ON	ON
POWER ON / WARNING	D	ON	OFF

Two (2) Pump Interlock Relays are provided which energize per the following states:

HARVEST PUMP STATE	RELAY #3	RELAY #4
ACTIVE	ON	ON
NOT ACTIVE	OFF	OFF

An isolated Form C contact for each relay is provided for the end user to connect to any remote monitoring system. The Harvest pump is activated to Run mode, only and only if Relay #1 is ON, i.e. in Power On/ Running state #C or Power On / Warning state #D.

The following is a list of C410:V3 controller Warnings that can occur during normal operation:

- Flow Set Point cannot be reached. P-Flow Regulator (PV1) above maximum operating setting.
- Flow Set Point cannot be reached. P-Flow Regulator (PV1) below minimum operating setting.
- Exhaust Set Point cannot be reached. E-Flow Regulator (PV2) above maximum operating setting.

- Exhaust Set Point cannot be reached. E-Regulator (PV2) below minimum operating setting.

The following is a list of C410:V3 controller Alarms that can occur during normal operation:

- XCell™ ATF System Warning has not been acknowledged. XCell™ ATF System function halted.
- Main Power Loss (120/220) while Diaphragm Pump was running.

F.	ADMIN.
----	--------

Only accessible to the Administrator who can navigate to the following screens:

F.1	USERS
-----	-------

User	Password	Group	Logoff time
Admin	*****	Administrators	5
Eng1	*****	Engineers	5
Oper1	*****	Operators	5
PLC User	*****	Unauthorized	5

The screen allows creation/amending of User ID's and passwords.

There are three (3) levels of security:

1. Operator
2. Engineer
3. Administrator

The C410:V3 controller includes one (1) Administrator User ID and 1 predefined Engineer Level and 1 predefined Operator Level User ID's. Only the administrator will have security access to add/edit/delete all other User ID's by touching the appropriate fields.

Each User ID includes a field for Logoff Time (in minutes). When the time setting is reached, the current user will automatically be logged off. Access to other screens will prompt the user to log in again. To disable this feature, a time value of 0 can be entered into the Logoff Time Field.

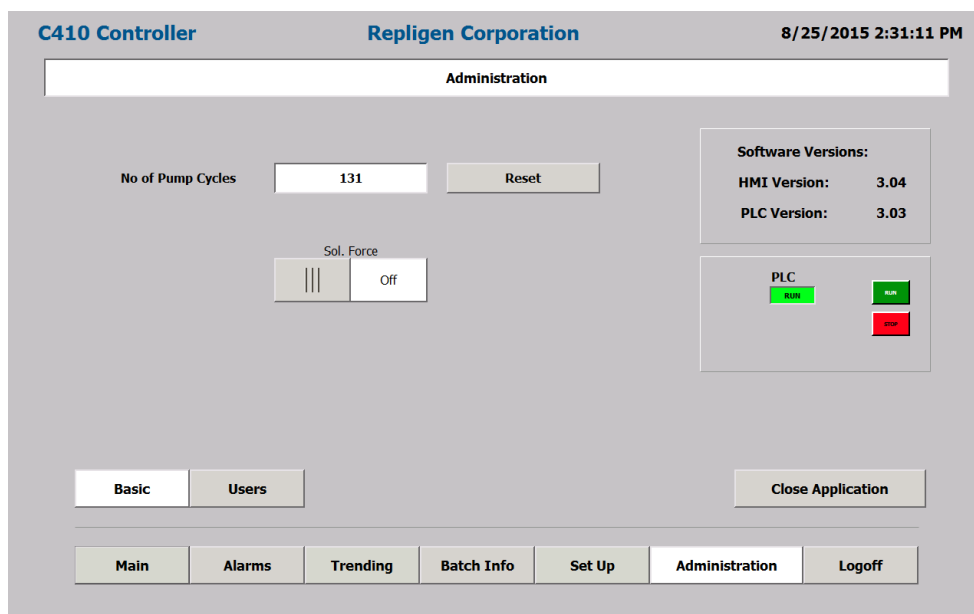
The Administration screen will display parameters in the following tables:

Field	Description
User	Enter User ID
Password	Enter Password
Group	Enter Group No. to define security level
Log Off Time	Set the amount of time in minutes before current user is automatically logged out. A value of zero will disable this feature.

Button	Description
All Primary	All Primary Screen Buttons are displayed to navigate to those screens
Basic	Navigates to ADMIN Basic Screens

Each level of security allows different levels of access to the C410:V3 controller control functionality please refer to Appendix 2 for details.

F.2	BASIC
-----	-------



Note: Software version numbers shown above may not match the most current software revision.

Available from the ADMIN screen. It allows the Administrator to reset Pump Cycle count. It also allows manual control of Flow Control Valve, SOL1; with that controlling flow direction of pneumatic system. The controller must be in the standby mode.

WARNING:

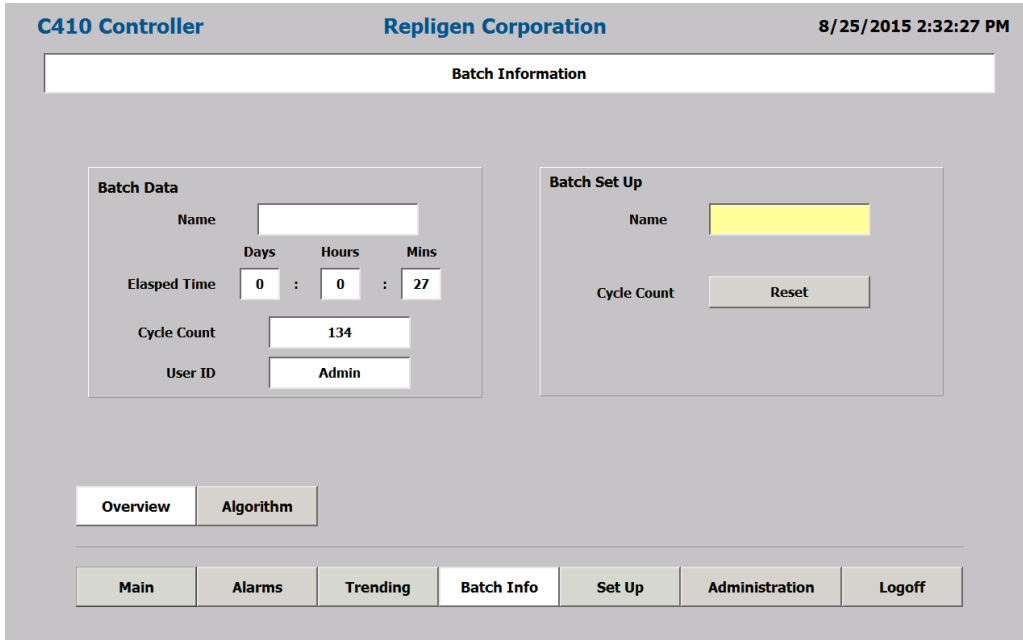


Do not turn the Sol. Force to the ON position when the XCell™ ATF is connected to the P-box (with air pressure utility). Doing so may over expand the diaphragm causing potential blowout.

G. BATCH INFO.

Display batch information as in the following screens

G.1 OVERVIEW



Overview of Batch information is shown

The Batch Info Overview screen will display parameters in the following tables:

Field	Description
Batch Data	Displays current Batch information
Elapsed Time	Displays Elapsed time of current batch run. Time is reset by changing Batch Name.
Cycle Count	Displays Diaphragm Pump Cycle count of current batch run
User ID	Displays Users ID: Engineer or Administrator
Batch Set Up	Set Batch Name and reset Cycle count
Name	Click on field to change batch name

Button	Description
Cycle Count - Reset	Resets Cycle count to zero in Batch Data field
Algorithm	Navigates to Batch Algorithm Screens
All Primary	All Primary Screen Buttons are displayed to navigate to those screens

G.2	ALGORITHM
-----	-----------

The screenshot shows the 'Algorithm Performance' screen in the C410 Controller interface. The header includes 'C410 Controller', 'Repligen Corporation', and the date/time '8/25/2015 2:33:51 PM'. The main content area is titled 'Algorithm Performance' and contains a table with the following data:

	Pressure Cycle	Exhaust Cycle
Primary Method	0	0
Override Timer	44	66
Overflow	30	0

Below the table is a 'Reset Counters' button labeled 'Reset'. At the bottom of the screen, there are navigation tabs: 'Overview' (selected), 'Algorithm', 'Main', 'Alarms', 'Trending', 'Batch Info', 'Set Up', 'Administration', and 'Logoff'.

XCell™ ATF System cycle change can occur by either of three algorithms. The screen tracks cycle change Algorithm performance. The three Algorithms are:

1. Set Point - normal process based on set up parameters.
2. Overtime - when P2 Set Point is not achieved in within 120% of calculated time.
3. Overflow - When P2 reaches P1 (+/- OSP) within the set delay time.

The Batch Info Algorithm screen will display parameters in the following tables:

Field	Description
Algorithm Performance	Tracks cycle change mechanism
Primary Method	Shows cycle count triggered by Set point method, tracks Pressure cycle and Exhaust cycle counts
Overtime	Shows cycle count triggered by Overtime, tracks Pressure cycle and Exhaust cycle counts
Overflow	Shows cycle count triggered by Overflow, tracks Pressure cycle and Exhaust cycle counts

Button	Description
Reset Count	Resets all counts, by Set Point, Overtime and Overflow to zero
Overview	Navigates to Batch Overview Screens
All Primary	All Primary Screen Buttons are displayed to navigate to those screens

H.	LOGOFF.
----	---------

On User logoff, the controller continues to operate normally. A user must log back on to make changes to setting.

6.2 Control Overview



To assure optimum results with the XCell™ ATF System, one should keep in mind the following two general rules:

1. The diaphragm motion must be a *continuous* one between the Pressure cycle and the Exhaust cycle and vice versa (i.e. no dwell time).
2. **Ideally**, the stroke travel of the diaphragm must be reversibly between fully Pressurized and fully Exhausted extremes.



There should be no dwell time for the diaphragm at any point of the cycle.

The continuous movement of the diaphragm assures continuous tangential flow through the filter. The maximum stroke of the diaphragm assures maximum mixing and minimizing “dead space” retention within the system.



The C410:V3 controller control of the XCell™ ATF System is based on the above two rules.

The XCell™ ATF System, having a constant pump volume, allows the controller to calculate the Diaphragm Pump cycle time based on a user’s flow rate selection, according to the following relationship:

$$\text{Pump displacement volume (L)} \div \left[\frac{\text{Cycle time (sec)}}{60} \right] = \text{Flow rate (LPM)}$$

The pump displacement volumes, with no pressure difference across the diaphragm, are:

XCell™ ATF4 System	0.44L
XCell™ ATF6 System	1.2L
XCell™ ATF10 Lgcy System	5.1L
XCell™ ATF10 System	6.0-6.7L

See also Appendix 1. Cycle time vs. Flow rate

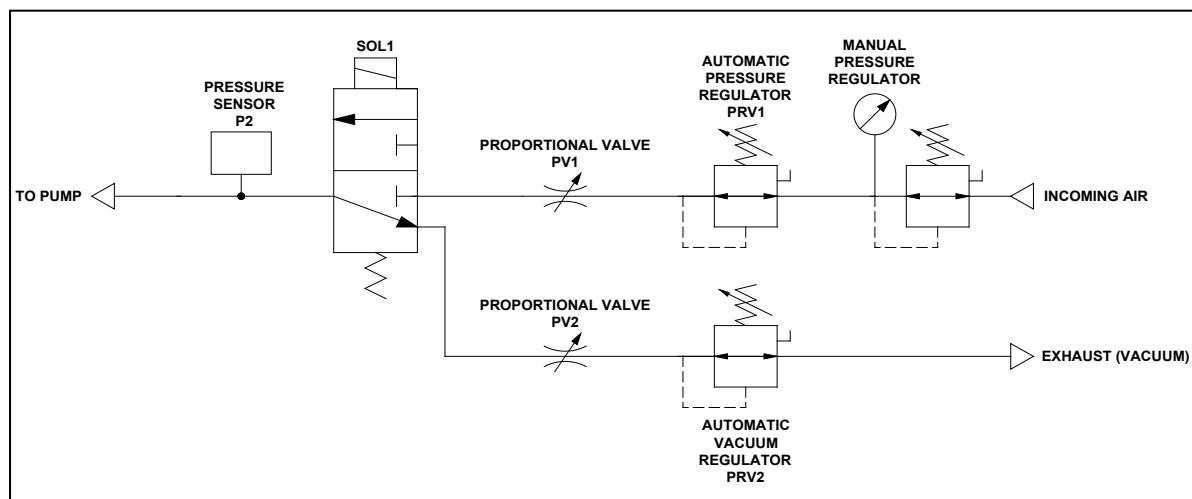
Therefore, selection of a **Flow Rate (L/min)** by a user, using an XCell™ ATF System with a known **Pump Displacement Volume (L)**, it is possible for the C410:V3 controller to calculate the **Pump’s Cycle Time, Calculated CT**.

At the end of each pump cycle, the Actual Cycle Time, **Actual CT**, is compared to the **Calculated CT**. The controller then uses the error between the two values to correct **Actual CT** to equal **Calculated CT**.

Similarly, the C410:V3 controller also allows the user to enter XCell™ ATF System cycle time (sec) directly to control flow rate; again, at the end of each pump cycle, the Actual CT is compared to the Calculated CT. The C410:V3 controller is designed to maintain the set flow rate automatically during the Pressure and Exhaust pump cycles. Based on an entered set point in either Liters per minute, LPM, or Time, in seconds, the C410:V3

controller will continually adjust the Pressure and Exhaust flow rates to match the entered set point flow rate.

Figure 7. Instrument Flow Control Schematic of C410:V3Controller



XCell™ ATF System Flow control is achieved by regulating the pneumatic air flow to and from the Diaphragm Pump; the pneumatic flow control is achieved with a two stage control, by regulating its pressure and with a flow restrictor. Two Proportional Pressure Regulators Valves, PRV1 and PRV2, are designed to make fine adjustments in pressure to the air stream flowing from the manual pressure regulator to a flow restrictor. Two automated flow restrictors, Proportional flow control Valves, PV1 and PV2, are designed to make coarse adjustments in flow. Final flow control is achieved by Step changes in PV orifice opening in combination with fine adjustments in the air flow stream pressure with the PRV.

Adjustments in flow are based on the error difference between Calculated CT and Actual CT. The proportional air pressure regulating valve, PRV1, and the exhaust pressure regulating valve, PRV2, will be adjusted by the PLC based on the Error. The error will cause pressures to be changed to affect the flow, positive or negative, respectively, to and from the pump to match flow set point for the next cycle.

If the new value for PRV1 and/or PRV2 exceed their set pressure limits, (e.g. PRV1 0 to 30 psi, PRV2 0 to -14.5 psi), then, the respective PV1 and PV2 will adjust incrementally, (e.g. by user defined increments (in the Basic Set Up Screen)), until the PRVs are back within operational range.

6.3 Start-up

Assembly of the XCell™ ATF System is described in the following sections. This section provides a startup guide for an XCell™ ATF System connected to a bioreactor and ready for use, with the following general conditions:

- An XCell™ ATF6 System is used in this example.
- An XCell™ ATF System flow of 12L/min is required.
- Bioreactor pressure is 0.0psi
- Δ height between pump midpoint and vessel liquid level is 0cm
- Regulated air pressure set to 35psi

- Vacuum source connected

6.3.1 Following LOGON and entry of BATCH Information, go to the SET UP screen.

6.3.2 Go to the BASIC SET UP screen, and enter the following field values.

Field	VALUE
Controller Set UP	
Pump Model No	Select ATF 6
Control Mode	Select FLOW
Slope Function Enable	Don't enable
Bioreactor pressure	0
Δ height (cm)	0
Alarm Delay(min)	1
Alarm Set Points	
HiHi Alarm Set Points	7 psi
LoLo Alarm Set Point	-7 psi
Alarm Delay (x10 msec)	50 for both
Pump Parameters	
P-Pressure Offset (psi)	0.5
E-Pressure Offset (psi)	-0.5
P-Delay (%)	70
E-Delay (%)	70
P-Overtime (%)	120
E-Overtime (%)	120
P-PV Step Size (%)	3
E-PV Step Size (%)	3

7.3.3 Press Accept Changes.

7.3.4 Go to the ADVANCED SET UP screen and enter the following field values

Field	VALUES				
User Set Point Range	XCell™ ATF4	XCell™ ATF6	XCell™ ATF8	XCell™ ATF10 Igcy	XCell™ ATF10
Max P-FLOW (LPM)	10	20	40	80	100
Min P-FLOW (LPM)	1	5	10	20	20
Max E-FLOW (LPM)	10	20	40	80	100
Min E-FLOW (LPM)	1	5	10	20	20
PV1 Max (%)	95				
PV1 Min (%)	5				
PV2 Max (%)	95				
PV2 Min (%)	5				
Output (CV) Limits		VALUE			
PRV1 Max (psi)	25				
PRV1 Min (psi)	1				

PRV2 Max (psi)	-1
PRV2 Min (psi)	-12

6.3.5 Press Accept Changes.

6.3.6 Go to the MAIN screen enter:

Field	VALUES
P-FLOW Status	
SP (Lpm)	12
E-FLOW Status	VALUES
SP (Lpm)	12

6.3.7 Note that PV and PRV fields are populated

6.3.8 Check all XCell™ ATF System connections.

6.3.9 Press START



Once the system begins to cycle, Note the following

- The deviation of Actual Flow from Set Flow. The deviation between the two should be small. Following few cycles, the Actual and Set Flows should be similar.
- Note if in P-Flow block, Actual Cycle Time field is flashing Orange or Red; the same for the E- Flow block, Actual Cycle Time field. If not flashing, the system is functioning properly. If flashing remains, stop the controller and recheck all entries and connections than restart. If problem persists check the following:
 - a. The ΔP between PRV1-P2 should be greater than **P-Pressure Offset** and ΔP between PRV2-P2 should be less than **E-Pressure Offset**. If not, manually lower PV in small increments.
 - b. Flow is too rapid- A flow that is too rapid during the Exhaust Cycle can be readily detected on the P2 trend by a rapid decline in pressure following a stable pressure profile. (The Pump exhausts too rapidly followed by a rapid pressure drop). Decrease PV2 or PRV2 to decrease flow as a corrective measure.
- Select the P2 trend in the MAIN screen and observe P2 profile, The P-Pressure Offset and the E-Pressure Offset should be apparent.



Any adjustments in P2 trend on the Main screen are performed from the P2 TREND screens

6.4 Examples

XCell™ ATF System process control settings will depend on the process requirements. Each user or process may have its own unique requirements. Hopefully, the example provides a guideline, to assist the users, in selecting and optimizing operating conditions.

When working with an XCell™ ATF System connected to an unpressurized vessel, refer to Figure 1 for an overview of positioning the Filtration Assembly, P-Box and E-Box relative to the bioreactor.

Example 1

Using an unpressurized bioreactor with an XCell™ ATF6 System:

When using a bioreactor that cannot be pressurized such as a glass vessel or a disposable vessel, i.e., SUB, the connection between the Filtration Assembly and the SUB will most likely not be an SIP type connection shown in Figure 1. Placement of the Filtration Assembly and controller relative to the bioreactor will, however, not change significantly.



Using a vessel that cannot be pressurized, both pressure and vacuum services are needed. See Utility Requirements, Section 2.



Repligen Corporation offers custom, disposable connections to most commercial SUBs. The connection procedure between the Filtration Assembly and vessel are provided separately.

Start

1. Connect the Filtration Assembly to bioreactor per separate instructions.
2. Place the P-Box in proximity of the Filtration Assembly.
3. Connect Signal cable between E-Box and P-Box.
4. Connect E-Box to an appropriate electrical power source
5. Connect the Air Line, Exhaust Line and Pump Line to their respective ports on the P-BOX. Do not connect the Pump Line from the C410:V3 controller to the Diaphragm Pump at this point.
6. Power ON the E-Box. Wait for system to boot up and display the XCell™ ATF System LOGON screen.
7. LOGON, the main screen will be displayed. Proceed to the SET UP screen.
8. Enter settings as in section 6.4.



Note XCell™ ATF System selection - Select ATF6 System. Note reactor pressure and Δ height- enter 0 and measured difference between Diaphragm Pump clamp and vessel liquid level in cm.

9. Power up compressed Air and Vacuum services, confirm pressure and vacuum services are on by observing the respective pressure gauges.
10. Connect pneumatic Pump Line to Diaphragm Pump air filter.
11. Activate the P2 trend on the MAIN screen. (Any setting adjustments in the P2 screen are made from the P2 TREND screen).
12. Press the START button on the MAIN screen.
13. XCell™ ATF System should begin cycling normally.
14. Observe for conditions described at the end of the last section.



Note the air purge from the system after start of XCell™ ATF System. Note also the small up and down change in vessel liquid level, indicating XCell™ ATF System cyclic flow.

Changing flow rate:

To change flow rates, simply go to the main screen select **P-Flow SP**. Enter the new flow rate on the pup-up menu. Press **Yes** to accept current PV and PRV values, or press **Default**

to accept default PV and PRV values. Default is recommended when entering new flow rates. Follow similar procedures to change **E-Flow SP**. It is recommended to **STOP** the controller prior to change of flow rate. Following the change, re-START the controller. It will start with the diaphragm in the fully exhausted position.

Filtrate or Harvest:

Start the **Filtrate (or Harvest) pump** only after XCell™ ATF System flow has stabilized. Stop the **Filtrate / Harvest pump** when stopping the XCell™ ATF System flow; accordingly, the C410:V3 controller provides relay outputs on the E-BOX for activating or deactivating a filtrate / harvest pump.

Contact Repligen Corporation for system specific instructions.

7. Hollow Fiber Module and Diaphragm Replacement

The following is a guideline for replacing a Hollow Fiber Module (HFM) or the diaphragm within the Diaphragm Pump. Since the procedures for replacing these parts are similar, a generalized description is provided. Where necessary, more specific references and descriptions will be provided.

Example 2

Replacing a HFM in Filtration Assembly connected to a pressure rated vessel:

Prerequisites: Steam is available and the HFM has to be replaced in mid run in a sterile manner. Refer to Figure 1.

7.1 Separating the Filtration Assembly from the bioreactor:

- 7.1.1 STOP the C410 :V3 controller.
- 7.1.2 Stop the filtrate / harvest pump.
- 7.1.3 Disconnect Diaphragm Pump pneumatic line from the pump air inlet filter.
- 7.1.4 Close or disconnect compressed air and vacuum services from the P-BOX.
- 7.1.5 Disconnect any sensors from the Filtration Assembly to P-BOX
- 7.1.6 If necessary, remove the P-BOX from the proximity of the Filtration Assembly.
- 7.1.7 Close and disconnect the filtrate line.
- 7.1.7 Disconnect the Filtration Assembly from the vessel as follows:
 - a1. Securely close both bivalves connecting the Filtration Assembly to the vessel.
 - a2. Drain liquid from the connection. Optionally, purge the connection with water, steam or some other medium.
 - a3. Disconnect the Filtration Assembly from vessel between the two bivalves.
 - a4. Remove the Filtration Assembly to an appropriate work area, i.e., a sink.

7.2 HFM removal:

- 7.2.1 Drain the system into a “sink”
- 7.2.2 Remove all sensors from the Filter Housing
- 7.2.3 Remove air inlet filter connected to the Diaphragm Pump and any other connections to the XCell™ ATF System

- 7.2.4 Open the clamp connecting the Filter Housing to the Diaphragm Pump and separate
- 7.2.5 Open the clamp connecting the Reducer to the Filter Housing and separate
- 7.2.6 The HFM may then be removed from the Filter Housing by firmly pressing it from one end
- 7.2.7 Remove the exposed “O” ring at the exposed end of the HFM
- 7.2.8 Press the HFM in the opposite direction to remove the HFM
- 7.2.9 Prepare Filter Housing for cleaning and reuse or for cleaning and setting aside

7.3 HFM insertion:



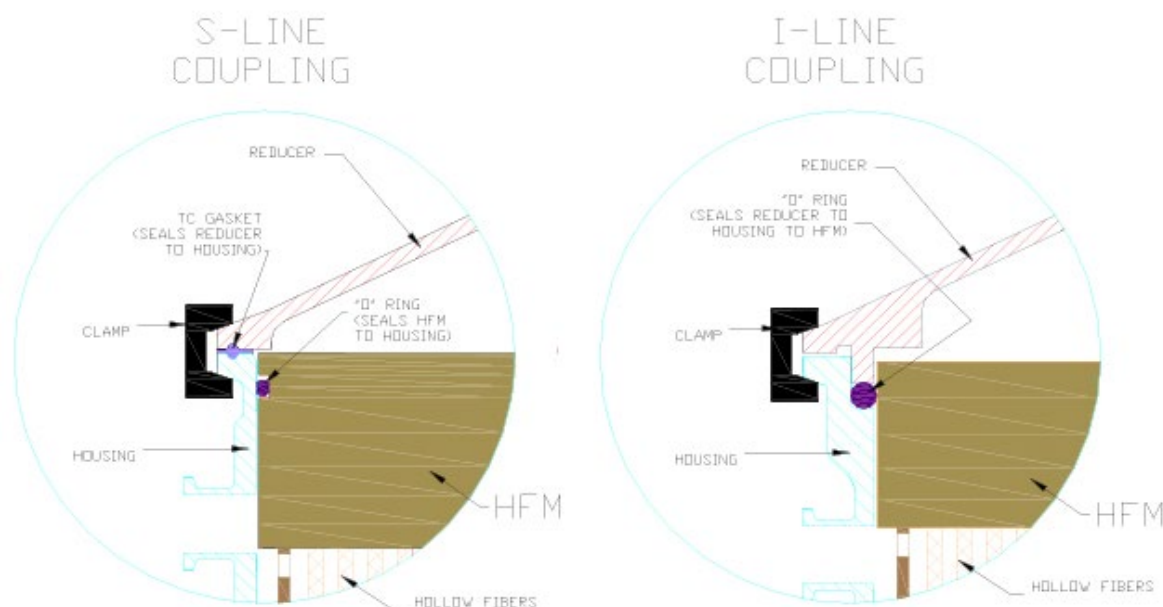
Prior to use, HFM may require wetting with water or buffer. In general, prior to use, please read the separate Hollow Fiber Module Preparation Instructions that are included with every hollow fiber. There are different preparation methods depending on the module type purchased.



Two types of HFMs are available for the XCell™ ATF System; accordingly, two types of Filter Housings are available:

- S-line Housing for use with HFM with “O” rings on the HFM ends for sealing against the housing inner ID.
- I-line Housing for use with HFM with no attached “O” rings. The “O” ring is placed in a recess at the housing ends, between HFM and Reducer (or Diaphragm Pump). Clamping the connection between Reducer (or Diaphragm Pump) and the Filter Housing squeezes the “O” ring effectively forcing the “O” ring against the filter wall, effectively sealing the three parts.

Figure 8. Types of Filter Housings



7.3.1 S-Line HFM insertion:

- 1 Lay the Filter Housing horizontally and insert HFM (without “O” rings) into the Filter Housing.



Step 2 is to avoid damage to the “O” ring during its insertion and sliding into the housing, to avoid crossing the Harvest port opening during insertion, as the Drain port is close to the housing end.

- 2 Expose HFM at the Filter Housing end distant to Drain port, in proximity to the Filtrate / Harvest port.
- 3 Place an “O” ring in the exposed HFM “O” ring groove.
- 4 Press the HFM with “O” ring firmly into the housing.



Assure the “O” ring is inserted smoothly and uniformly. Lubricate with WFI to facilitate this process.

- 5 Press until the HFM “O” ring groove is exposed at the other end, the Drain nozzle end.
- 6 Place 2nd “O” ring on the exposed end.
- 7 Press the HFM back into the Filter Housing until both “O” rings sealed against the housing ID.
- 8 Assemble the system.

7.3.2 I-Line HFM insertion:

- 1 Stand the Filter Housing vertically, with harvest port up.
- 2 Insert the HFM into the housing
- 3 Insert one “O” ring into the groove formed between HFM and Filter Housing end-ferrule wall.
- 4 Place the reducer onto the end, forcing the “O” ring into the groove.
- 5 Clamp the reducer to the housing, the compressed “O” ring is forced against the HFM. A seal is formed between the Housing, Reducer and HFM
- 6 On the other end of the Filter Housing, Place the second “O” ring into the formed groove between HFM and Housing end-ferrule.
- 7 Carefully place the Filter Housing onto the Diaphragm Pump, forcing the “O” ring deeper into the groove.
- 8 Clamp the Filter Housing to the Diaphragm Pump.
- 9 Assemble the XCell™ ATF System.

7.4 Screen Module replacement:

If the SM is being used, contact **Repligen** for replacement instructions.

7.5 Diaphragm replacement:

Replacement or placement of a diaphragm within the Diaphragm Pump is part of the Diaphragm Pump assembly process which differs slightly among the XCell™ ATF4 System, ATF6 System, and ATF10 System.

Diaphragm Replacement Procedure for the XCell™ ATF4 System and ATF6 System

- 1 Place cleaned Diaphragm Pump hemispheres, diaphragm and pump clamp on a table top

- 2 Place the PL pump hemisphere (hemisphere with a nozzle on the side) with the large opening in the upward position.
- 3 Place diaphragm, pointing down into the PL pump hemisphere. **Assure the diaphragm gasket “O” ring is positioned uniformly about the periphery of the pump “O” ring groove.**
- 4 Mate the PA-pump hemisphere, wide opening down, with the diaphragm in PL pump hemisphere. **Assure the diaphragm gasket “O” ring is positioned uniformly about the periphery of the PA “O” ring groove.**
- 5 The two hemispheres, with diaphragm in between, should be equally spaced.
- 6 Clamp the two hemispheres together.
- 7 Secure the Diaphragm Pump to the stand.

Diaphragm replacement Procedure for the XCell™ ATF10 System

- 1 The diaphragm within the Diaphragm Pump of the XCell™ ATF10 System contains a short right angle bend on the diaphragm periphery which mates with a counterpart groove in the PA pump hemisphere flange; therefore, for the XCell™ ATF10 System, these two parts are assembled first. The two Diaphragm Pump hemispheres are assembled with the diaphragm pointing into the PL pump hemisphere.
- 2 Clamp the two hemispheres with the C-clamps, use the three long clamps first, and place 120 degrees to each other about the Diaphragm Pump periphery.
- 3 Uniformly and sequentially tighten the clamps, so the diaphragm is compressed evenly about the periphery of the two pump spheres.
- 4 Add the second set of short C-clamps as described above.
- 5 Add on the air inlet assembly to the Air inlet nozzle on the PA part.
- 6 Carefully invert the assembled pump sphere, so it stands on the long C-clamps.
- 7 One may place the pump onto its stand and/or proceed to assemble the entire system.

7.6 Assembly

Fully assemble Diaphragm Pump, Filter Housing, reducer and accessories and prepare for Pressure test. See, Pressure testing and sterilization, (section 8).

7.7 Use

Following successful pressure testing and sterilization reconnect the Filtration Assembly to the bioreactor (section 9)

8. Sterilization



WARNING:

These procedures refer to steam sterilization procedures. Steam is supplied at high pressure and at high temperature, over 100°C and can exceed 125°C. All parts of the Filtration Assembly are rapidly heated. Use similar precautions after removal of a system from an autoclave. Such heated systems should only be handled by qualified personnel taking all proper safety precautions.

8.1 Preparation of Filtration Assembly for autoclaving

Repligen recommends sterilization of the Filtration Assembly by autoclaving. An appropriately sized autoclave is required. Contact **Repligen** for dimensional analysis of the autoclave. Sterilization of the Filtration Assembly by autoclaving is one of the simplest methods to sterilize the system.

Pre Autoclaving check list:

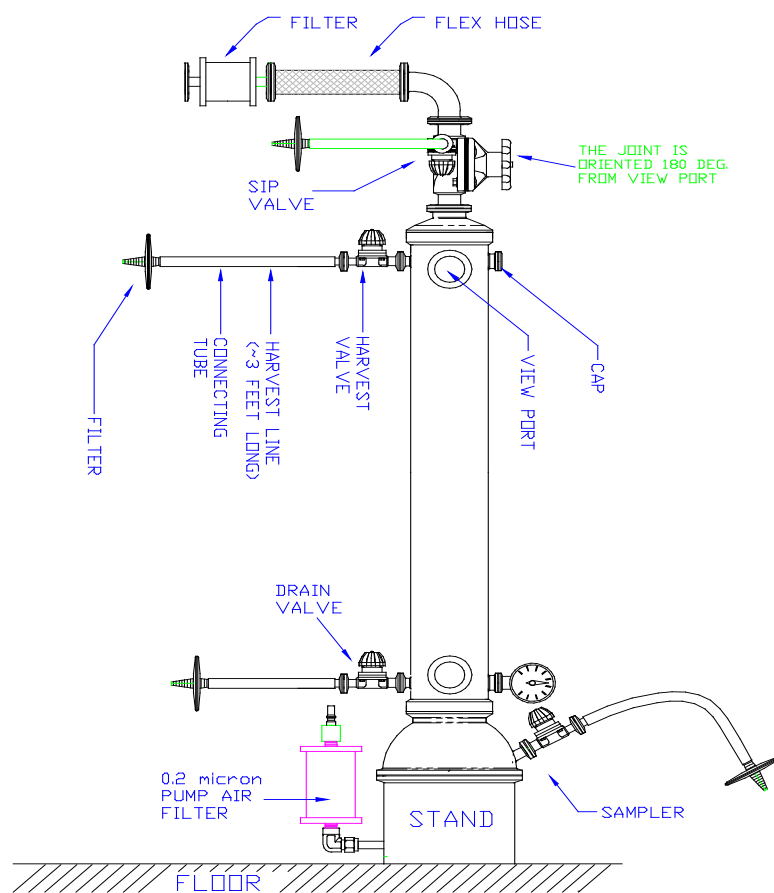
- 8.1.1 Thoroughly wet the HFM with appropriate wetting agent
- 8.1.2 Fully assemble Filtration Assembly as shown in Figure 9.
- 8.1.3 Perform a pressure test.
- 8.1.4 Vent all ports blocked with 0.2micron vent filters.



With both the filtrate and retentate sides vented, formation of pressure gradients across the hollow fibers membranes during sterilization is minimized. This assures free flow of steam into the unit and unobstructed pressure equilibration between all compartments within the unit; particularly, the filtrate and retentate sides are at the same pressure during the sterilization and cool down procedures.

Note: Use high capacity vent filters to allow unobstructed high flow of steam into and from the system.

Figure 9. Filtration Assembly prepared for Autoclaving



FILTER ATTACHMENTS:

USE ABOUT 3' TUBE LENGTH FOR HARVEST LINE AND ABOUT 6' FOR SAMPLER, SIP AND DRAIN VALVES.

8.1.5 Close all unprotected ports.

8.1.6 Depending on the size/configuration of the autoclave, the Filtration Assembly can be placed inside the autoclave either vertically or at an angle if necessary. Most autoclaves are not sufficiently tall for vertical placement.

8.1.7 Use caution during the procedure so not to damage attached parts or tubing. Avoid kinking or stressing attached tubing.

8.2 Autoclave Cycle

8.2.1 The XCell™ ATF systems have been designed to be sterilized using an autoclave. The XCell™ ATF System Filter Preparation and Autoclave Guide provides detailed guidance on the entire procedure including the recommended filter integrity test procedures and specifications. The features of the recommended cycle are intended to ensure that the system will be effectively sterilized and that there is minimal thermal stress imposed on the hollow fiber cartridge that could lead to integrity failures.

The recommended cycle will require custom programming to incorporate a 90 minute preheat and 2-3 moderated prevac pulses to control the rate of temperature change within the cartridge to a rate of 1 oC/min during the warm up. Repligen recommends that during the cycle development, several thermocouples should be positioned within the assembly to track the rate of

temperature change and confirm that all positions are at 121-123 °C for the duration of the sterilization section of the cycle.

8.2.2 While autoclave conditions may vary based on requirements, the following are typical autoclave conditions for the Filtration Assembly. Please refer to the XCell™ ATF System Filter Preparation and Autoclave Guide for more details. The entire cycle may take 4-5 hours.

- The assembly should be placed in the autoclave at a 45° angle and be allowed to warm up for a period not less than 60 minutes with steam in the jacket, but not in the chamber.
- The active cycle will begin with a 5 minute purge where steam flows through the autoclave directly to the drain with minimal increase in chamber pressure.
- Secondly, there are 2-3 vacuum pulses with “hold” periods in between. These are critical to evacuate all of the air within the assembly and ensure that there is a uniform temperature throughout the assembly prior to engaging the ramp up to reach the sterilization temperature.
- Follow with a 1 minute steam purge to about 6psi, and 108°C
- Ramp up slowly, 1°C/min, to sterilization temperature / pressure, of 121°C - 123°C / 16psi
- Sterilize for ~ 55-60 min.
- Ramp down slowly, with wet cycle exhaust protocol or 0.5-1°C/min to 100°C
- Allow the system to cool to 50 °C before handling

8.2.3 Open autoclave door, inspect the system, re-tighten all clamps (about ¼ turn).

8.2.4 Carefully remove the Filtration Assembly from the autoclave.

8.2.5 Preferably, remove the Filtration Assembly from autoclave into clean area.

8.2.6 Allow system to cool to room temperature in a clean area.

8.2.7 Pressurize system to about 5psi using sterile air source through one of the retentate vent filters. This step is optional.

8.2.9 After cool down to room temp or after pressurization of system, close all valves.
c1. The system may be stored until use.

8.3 Sterilization of Filtrate / Harvest line

The Filtrate / Harvest line with end filter will be sterile following autoclave. One must assure however that the Harvest line has been prepared with the appropriate tubing for use with the filtrate / harvest pump. One may also prepare the Filtrate / Harvest line, post autoclaving, using a tube welder. If a tube welder cannot be used, a disposable sterile coupling may be used.

9. Connection to Bioreactor

Two types of connections between Filtration Assembly and bioreactor are commonly available.

- 1 Hard connection that can be sterilized by SIP
- 2 Soft connection that use single use connectors such as the Kleenpak, AseptiQuik, Opta, Readymate DAC, Pure-Fit, or other connectors now available from various vendors.

9.1 Hard Connection

The user should verify the following procedure:

- 1 Typically used with stainless steel bioreactor systems where steam is readily available.
- 2 This connection consists of at least two isolation bivalves (Figure 1). One bivalve attached to the vessel and the second bivalve attached to the Filtration Assembly.
- 3 A flexible hose between the main branches of the two valves.
- 4 Steam inlet- The side valve on one of the bivalves may be used for steam inlet.
- 5 Condensate-The side valve on the other bivalve is used for drain condensate. This valve should be the low point valve to assure complete condensate drainage. Attach a steam trap to this valve and connect to a drain
- 6 Close both Steam inlet and Condensate valves.
- 7 Securely connect a regulated steam source to the steam inlet valve.
- 8 Open steam service.
- 9 Slowly open steam inlet valve.
- 10 Slowly open steam condensate valve.
- 11 Sterilize connection for about 20min. at 121⁰ C and ~16psi
- 12 Cool-down.
- 13 Close the Condensate valve.
- 14 Rapidly close the Steam inlet valve and immediately open the main valve into the Filtration Assembly to minimize a pressure drop in the connection.



Note that following SIP of the connection, the cool-down of the connection post SIP will generate a vacuum within the connection, which must be minimized.

10. Maintenance

10.1 Diaphragm

It is recommended that a new diaphragm be used with each new run. To avoid premature failure, it is important to ensure that the diaphragm is seated in the proper orientation.

Use with aqueous liquids only. For use with other fluids contact **Repligen**.

When used as instructed in this manual, the diaphragm is designed to last over 500,000 cycles.

10.2 Pump Air Inlet Filter

The replacement of the pump air inlet filter will be determined by how the system is configured. If the air filter is autoclaved with the Filtration Assembly, it is qualified for 135°C, for 30minutes, 3 times.

10.3 “O” Rings, gaskets and Quick Connects

The o-rings on the ventilation ports and quick connects (XCell™ ATF4 System and ATF6 System) should be replaced every two or three runs. Replacement kits are available from Repligen. HFM Filter “O” rings should be replaced with each new filter. For pump line, air supply, and vacuum source, all “O” rings and gaskets should be replaced periodically.

An approved lubricant may be used to facilitate coupling of parts containing an “O” ring seal.

10.4 Controller Maintenance

Bi-annual Maintenance

- 1 P2 verification or calibration
- 2 Complete system visual inspection for damage or risk to the operator or surrounding personnel
- 3 P-box vacuum system leak test
- 4 Verification that the pressure regulator is set to correct pressure
- 5 Inspection of air and vacuum connection to the P-box
- 6 Inspection of pneumatic fittings
- 7 Inspection of the pneumatic tube from the P-box to the XCell™ ATF pump housing
- 8 Inspection of enclosure for damage, locks and hinge performance, external electrical connection, cables and pneumatic tubing
- 9 PRV verification or calibration
- 10 PRV trend verification or calibration
- 11 PV verification or adjustment
- 12 Inspection that all components inside the enclosures are secured and intact
- 13 P2 verification or calibration
- 14 Inspection of touch screen alignment and performance
- 15 Flow test (low, middle and high flow rate)

Every Four Years

- 16 Replacement of complete pneumatic manifolds and pneumatic tubing
- 17 Annual maintenance routine

Appendix 1: XCell™ Cycle Time vs. Flow Rate

Cycle time vs. Flow rate

XCell™ System PUMP VOLUME (L)	ATF4 0.4	ATF6 1.3	ATF8 2.5	ATF10 Igcy 5.1	ATF10 6.0
Cycle time (sec)	FLOW RATE (L/MIN)				
4	6.0	18.8	37.5	76.5	90.0
6	4.0	12.5	25.0	51.0	60.0
8	3.0	9.4	18.8	38.3	45.0
10	2.4	7.5	15.0	30.6	36.0
12	2.0	6.3	12.5	25.5	30.0
14	1.7	5.4	10.7	21.9	25.7
16	1.5	4.7	9.4	19.1	22.5
18	1.3	4.2	8.3	17.0	20.0
20	1.2	3.8	7.5	15.3	18.0

Appendix 2: User Access

Access levels to the C410:V3 Controller

User Level	Option	Controller Function	Parameter	Permissions	
Operator	Main Screen	General Access	General	Access Upon Login	
		Start/stop	General	Allowed	
			LPM SP	Not Allowed	
		PFlow Staus	LMP PV	View Only	
			Sec Calculated	View Only	
			Sec Actual	View Only	
			LPM SP	Not Allowed	
			LMP PV	View Only	
		E Flow Status	Sec Calculated	View Only	
			Sec Actual	View Only	
			P2 Trend	Enable	View only (change range in trending)
				PV1	Input Value
			PRV1	Input Value	Not Allowed
		PV2	Input Value	Not Allowed	
		PRV2	Input Value	Not Allowed	
		P2	General	View Only	
		Alarms	View Only	General	Allowed
	Silence Alarm		General	Not Allowed	
	Clear Alarm		General	Not Allowed	
	Trending	Overview	General	View and allowed to adjust Min and Max	
		Process Trend	General	View and allowed to adjust Min and Max	
			P2 Trend	General	View and allowed to adjust Min and Max
		PRV Trend	General	View and allowed to adjust Min and Max	
		PV Trend	General	View and allowed to adjust Min and Max	
		P3 Trend	General	View and allowed to adjust Min and Max	
		P4 Trend	General	View and allowed to adjust Min and Max	
		P5 Trend	General	View and allowed to adjust Min and Max	

User Level	Option	Controller Function	Parameter	Permissions		
Engineer		WI Trend	General	View and allowed to adjust Min and Max		
			Name	View Only		
	Batch Info-Overview	Batch Data	Elapsed Time	View Only		
			Cycle Count	View Only		
			User ID	View Only		
			Name	View Only		
			Reset	View Only		
	Batch Info - Algorithm	General Access	General	Not Allowed		
			Primary Method	Not Allowed		
			Override Time	Not Allowed		
			Overflow	Not Allowed		
	Set Up	General Access	View	Not Allowed (no access to Set Up Screens)		
	Admin	Basic Users	General Access	Not Allowed		
			General Access	Not Allowed		
	Main Screen	General Access Start/stop	General	Access Upon Login		
			General	Allowed		
			LPM SP	Allowed		
		PFlow Staus	LMP PV	View Only		
			Sec Calculated	View Only		
			Sec Actual	View Only		
			LPM SP	Allowed		
			LMP PV	View Only		
		E Flow Status	Sec Calculated	View Only		
			Sec Actual	View Only		
			PV1	Input Value	Not Allowed	
			PRV1	Input Value	Not Allowed	
			PV2	Input Value	Not Allowed	
			P2	PRV2	Input Value	Not Allowed
				General	View Only	
	P2 Trend			Enable	View only (change range in trending)	
	General			Allowed		
	General			Allowed		
Alarms	View Only Silence Alarm Clear Alarm	General	Allowed			
		General	Allowed			
		General	Not Allowed			

User Level	Option	Controller Function	Parameter	Permissions
Engineer	Trending	Overview	General	View and allowed to adjust Min and Max
		Process Trend	General	View and allowed to adjust Min and Max
		P2 Trend	General	View and allowed to adjust Min and Max
		PRV Trend	General	View and allowed to adjust Min and Max
		PV Trend	General	View and allowed to adjust Min and Max
		P3 Trend	General	View and allowed to adjust Min and Max
		P4 Trend	General	View and allowed to adjust Min and Max
		P5 Trend	General	View and allowed to adjust Min and Max
		WI Trend	General	View and allowed to adjust Min and Max
	Batch Info-Overview	Batch Data	Name	View Only
			Elapsed Time	View Only
			Cycle Count	View Only
			User ID	View Only
		Batch Setup	Name	Allowed
			Reset	Allowed
	Batch Info - Algorithm	General Access	General	Allowed
			Primary Method	Reset Only
		Algorithm Performance	Override Time	Reset Only
			Overflow	Reset Only Allowed
	Set Up	General	General	
	Set Up-Basic	Controller Setup	Pump Model	Allowed to adjust
			Control Mode	Allowed to adjust
			Alarm Delay	Allowed to adjust

User Level	Option	Controller Function	Parameter	Permissions
		Pump Parameters	Slope Function Enabled	Allowed to adjust
			Bioreactor Pressure	Allowed to adjust
			Height Differential	Allowed to adjust
			Pressure Offset	Allowed to adjust pressure and exhaust cycle fields
			Delay Time	Allowed to adjust pressure and exhaust cycle fields
			Over Time	Allowed to adjust pressure and exhaust cycle fields
			PV Step Size	Allowed to adjust pressure and exhaust cycle fields
			P2 Pressure	Allowed to adjust HiHi and LoLo Fields
			Alarm Delay	Allowed to adjust HiHi and LoLo Fields
			Set Up-Advanced	User Set Point Ranges
	Pressure Cycle Flow Min	Allowed to Adjust LPM and Seconds field		
	Exhaust Cycle Flow Max	Allowed to Adjust LPM and Seconds field		
	Exhaust Cycle Flow Min	Allowed to Adjust LPM and Seconds field		
	Accept Changes	Allowed		
	Discard Changes	Allowed		
	Output (CV) Limits	PV1(%)		

User Level	Option	Controller Function	Parameter	Permissions
Engineer			PV2(%)	Allowed to adjust min and max
			PRV1(psi)	Allowed to adjust min and max
			PRV2(psi)	Allowed to adjust min and max
			Accept Changes	Allowed
			Discard Changes	Allowed
	TCP/IP	General Access	General	Allowed
			IP Address	Not Allowed
			Subnet Mask	Not Allowed
		Network Setup	Default Gateway	Not Allowed
			Remote TSAP	Not Allowed
	Calibration 1	General Access	General	Allowed
			Select	Allowed
			Eng Units	Not Allowed
		Analog Input P2	1 st Point	Not Allowed
			Eng Units	Not Allowed
			2 nd Point	Not Allowed
			Actual Value	Not Allowed
			Accept	Allowed (No changes occur)
		Analog Input PRV1	Select	Allowed
			Eng Units	Not Allowed
			2 nd Point	Not Allowed
			Eng Units	Not Allowed
			3 rd Point	Not Allowed
			Actual Value	Not Allowed
Accept			Allowed (No changes occur)	
Analog Input PRV2	Select	Allowed		
	Eng Units	Not Allowed		
	3 rd Point	Not Allowed		
	Eng Units	Not Allowed		
	4 th Point	Not Allowed		

User Level	Option	Controller Function	Parameter	Permissions
Engineer		Analog Input P3	Actual Value	Not Allowed
			Accept	Allowed (No changes occur)
			Select	Allowed
			Eng Units	Not Allowed
			4 th Point	Not Allowed
			Eng Units	Not Allowed
			5 th Point	Not Allowed
			Actual Value	Not Allowed
		Accept	Allowed (No changes occur)	
		Select	Allowed	
		Eng Units	Not Allowed	
		5 th Point	Not Allowed	
		Eng Units	Not Allowed	
		6 th Point	Not Allowed	
		Actual Value	Not Allowed	
		Accept	Allowed (No changes occur)	
	Select	Allowed		
	Eng Units	Not Allowed		
	6 th Point	Not Allowed		
	Eng Units	Not Allowed		
	7 th Point	Not Allowed		
	Actual Value	Not Allowed		
	Accept	Allowed (No changes occur)		
	Select	Allowed		
	Eng Units	Not Allowed		
	7 th Point	Not Allowed		
	Actual Value	Not Allowed		
	Accept	Allowed (No changes occur)		
	Select	Allowed		
	Eng Units	Not Allowed		
	7 th Point	Not Allowed		
	Eng Units	Not Allowed		
8 th Point	Not Allowed			
Actual Value	Not Allowed			
Accept	Allowed (No changes occur)			
Help	General Access	View only	Allowed	
Admin	Basic Users	General Access	Not Allowed	
Admin	Basic Users	General Access	Not Allowed	

User Level	Option	Controller Function	Parameter	Permissions	
Admin	Main Screen	General Access	General	Access Upon Login	
			Start/stop	General	Allowed
				LPM SP	Allowed
		PFlow Status	LMP PV	View Only	
			Sec Calculated	View Only	
			Sec Actual	View Only	
			LPM SP	Allowed	
			LMP PV	View Only	
		E Flow Status	Sec Calculated	View Only	
			Sec Actual	View Only	
			PV1	Input Value	Allowed
			PRV1	Input Value	Allowed
			PV2	Input Value	Allowed
			PRV2	Input Value	Allowed
			P2	General	View Only
	P2 Trend		Enable	View only (change range in trending)	
	Alarms	View Only	General	Allowed	
		Silence Alarm	General	Allowed	
		Clear Alarm	General	Allowed	
	Trending	Overview	General	View and allowed to adjust Min and Max	
		Process Trend	General	View and allowed to adjust Min and Max	
		P2 Trend	General	View and allowed to adjust Min and Max	
		PRV Trend	General	View and allowed to adjust Min and Max	
		PV Trend	General	View and allowed to adjust Min and Max	
		P3 Trend	General	View and allowed to adjust Min and Max	
		P4 Trend	General	View and allowed to adjust Min and Max	
		P5 Trend	General	View and allowed to adjust Min and Max	
WI Trend		General	View and allowed to adjust Min and Max		
Batch Data		Name	View Only		

User Level	Option	Controller Function	Parameter	Permissions
Admin	Batch Info- Overview	Batch Setup	Elapsed Time	View Only
			Cycle Count	View Only
			User ID	View Only
			Name	Allowed
			Reset	Allowed
	Batch Info - Algorithm	General Access	General	Allowed
			Algorithm Performance	Reset only
			Override Time	Reset only
			Overflow	Reset only
	Set Up	General Access	General Access	Allowed
	Set Up-Basic	Controller Setup	Pump Model	Allowed to adjust
			Control Mode	Allowed to adjust
			Alarm Delay	Allowed to adjust
			Slope Function Enabled	Allowed to adjust
			Bioreactor Pressure	Allowed to adjust
			Height Differential	Allowed to adjust
			Pressure Offset	Allowed to adjust pressure and exhaust cycle fields
			Delay Time	Allowed to adjust pressure and exhaust cycle fields
			Over Time	Allowed to adjust pressure and exhaust cycle fields
			PV Step Size	Allowed to adjust pressure and exhaust cycle fields
Set Up-Basic	Pump Parameters	P2 Pressure	Allowed to adjust HiHi and LoLo Fields	
		Alarm Delay	Allowed to adjust HiHi and LoLo Fields	
Set Up-Basic	Alarm Set Points	P2 Pressure	Allowed to adjust HiHi and LoLo Fields	
		Alarm Delay	Allowed to adjust HiHi and LoLo Fields	

User Level	Option	Controller Function	Parameter	Permissions
Admin	Set Up-Advanced	User Set Point Ranges	Pressure Cycle Flow Max	Allowed to Adjust LPM and Seconds field
			Pressure Cycle Flow Min	Allowed to Adjust LPM and Seconds field
			Exhaust Cycle Flow Max	Allowed to Adjust LPM and Seconds field
			Exhaust Cycle Flow Min	Allowed to Adjust LPM and Seconds field
			Accept Changes	Allowed
			Discard Changes	Allowed
	Set Up-Advanced	Output (CV) Limits	PV1(%)	Allowed to adjust min and max
			PV2(%)	Allowed to adjust min and max
			PRV1(psi)	Allowed to adjust min and max
			PRV2(psi)	Allowed to adjust min and max
			Accept Changes	Allowed
			Discard Changes	Allowed
	TCP/IP	General Access	General	Allowed
			IP Address	Allowed
Subnet Mask			Allowed	
Default Gateway			Allowed	
		Network Setup		

User Level	Option	Controller Function	Parameter	Permissions	
Admin	Calibration 1	General Access	Remote TSAP	Allowed	
			General	Allowed	
			Select	Allowed	
			Eng Units	Allowed	
		Analog Input P2	1 st Point	Allowed	
			Eng Units	Allowed	
			2 nd Point	Allowed	
			Actual Value	View Only	
			Accept	Allowed	
			Select	Allowed	
			Eng Units	Allowed	
			2 nd Point	Allowed	
			Eng Units	Allowed	
			Analog Input PRV1	2 nd Point	Allowed
		Eng Units		Allowed	
		3 rd Point		Allowed	
		Actual Value		View Only	
		Accept		Allowed	
		Select		Allowed	
		Eng Units		Allowed	
		3 rd Point		Allowed	
		Analog Input PRV2		Eng Units	Allowed
				4 th Point	Allowed
			Actual Value	View Only	
			Accept	Allowed	
			Select	Allowed	
			Eng Units	Allowed	
			4 th Point	Allowed	
			Eng Units	Allowed	
			5 th Point	Allowed	
	Analog Input P3		Actual Value	View Only	
		Accept	Allowed		
		Select	Allowed		
Calibration 1	Analog Input P4	Select	Allowed		
		Eng Units	Allowed		
		5 th Point	Allowed		

User Level	Option	Controller Function	Parameter	Permissions		
		Analog Input P5	Eng Units	Allowed		
			6 th Point	Allowed		
			Actual Value	View Only		
			Accept	Allowed		
			Select	Allowed		
			Eng Units	Allowed		
			6 th Point	Allowed		
			Eng Units	Allowed		
			7 th Point	Allowed		
			Actual Value	View Only		
			Accept	Allowed		
			Select	Allowed		
			Analog Input W1	Eng Units	Allowed	
				7 th Point	Allowed	
				Eng Units	Allowed	
				8 th Point	Allowed	
				Actual Value	View Only	
				Accept	Allowed	
				View only	Allowed	
				General Access	Allowed	
				No. of Pump Cycles	Reset	Allowed
				Sol. Force	Off/On	Allowed
				General Screen	Close Application	Allowed
					Admin-Basic	General Access
User	Allowed for all except Admin and PLC User					
Password	Allowed for all except for PLC User					
Group	Allowed for all but Unauthorized					
Logoff time	Allowed					

Appendix 3: Declaration of Conformity

EU Declaration of Conformity

The C410:V3 Controller for XCell™ ATF 4, ATF 6, and ATF 10 system operation has been assessed for CE regulations applicable under the Machinery Directive 2006/42/EC including the Essential Health and Safety Requirements of Annex 1, the Low Voltage Directive 2014/35/EU, and the Electromagnetic Compatibility Directive 2014/30/EU, and is designed to comply with the objective of the mentioned Directives.

XCell™ ATF4, ATF6, and ATF10 pump falls under the article 3.3 of the Pressure Equipment Directive 97/23/EC and indicate the pumps are compliant with the SEP (Sound Engineering Practice). For XCell™ ATF pumps shipped after July, 18, 2016, the XCell™ ATF4, ATF6, and ATF10 pump falls under the article 4.3 of the Pressure Equipment Directive 2014/68/EU and indicate the pumps are compliant with SEP.

As the pump and the controller are designed to be used as a system, the pump does not carry the CE mark. Per the Directives, it is considered to be part of the system covered by the Machinery Directive, which is extended to include the controller and pump housing. A sample Declaration of Conformity certificate is shown on the next page.

DECLARATION OF CONFORMITY

Name and Address of Manufacturer:

Repligen Corporation
41 Seyon Street
Building 1, Suite 100
Waltham MA 02453

Name and address of the company authorized to compile the Technical File:

Repligen Sweden A.B.
Box 965
Sankt Lars väg 47, 222 70
Lund, Sweden

Repligen Corporation declares under our sole responsibility that the product described as:

Equipment Name: EU Declaration of Conformity for the complete system: C140V3 Controller WITH ATF-4, ATF-6, ATF-8 or ATF-10 Filtration System
Generic Equipment Description: Controller for Alternating Tangential Flow Filtration System
Model/Type: C410v3
Serial number(s): Controller Enclosure: XXXX
Serial number(s): Pneumatic Enclosure: XXXX

Complies with the requirements of the following European Directives:

Machinery Directive 2006/42/EC;
Electromagnetic Compatibility Directive 2014/30/EU

Main standards considered:

EN ISO 12100:2010, EN 60204-1:2006 + A1:2009
EN 1672-2:2005 + A1:2009
EN 61000-6-2:2005, EN 61000-6-4:2007+A1:2011

Date: Month day, Year

Name of authorized company representative: Claire McGrath, Senior Director of Quality

Signature:

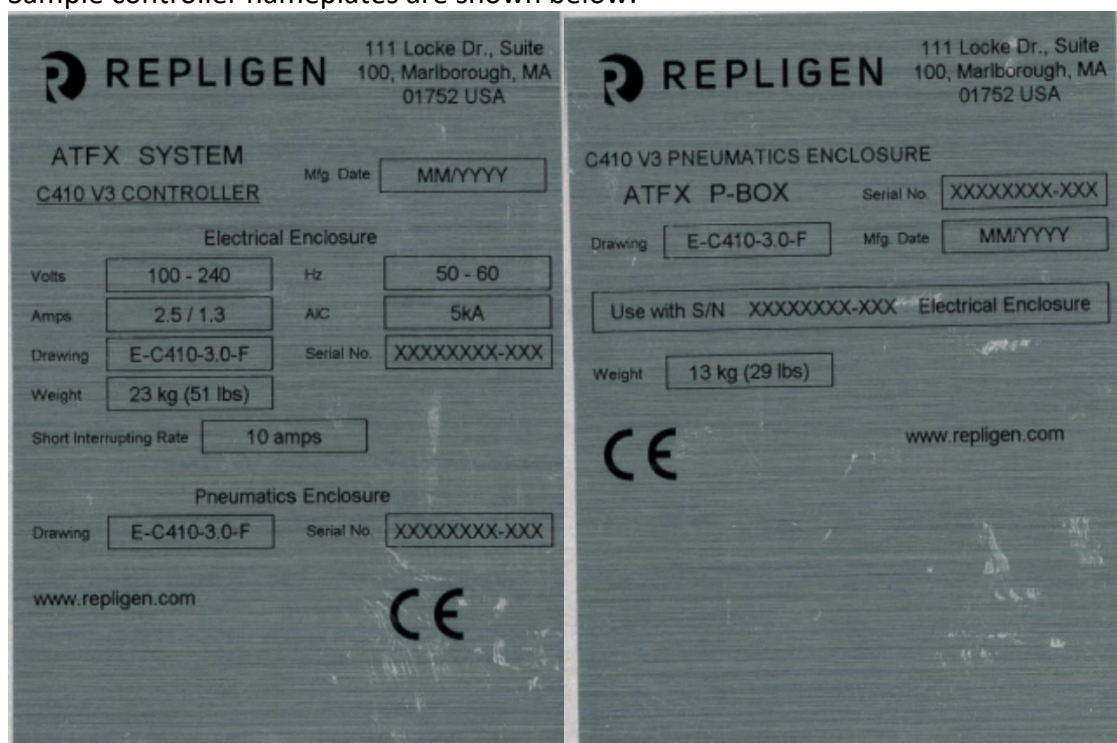
A copy of the Declaration of Conformity is included with the equipment.

Sample Nameplate

The XCell™ ATF System with C410 Controller, software v3 has been marked legibly and indelibly with the following information:

- Name and address of the manufacturer
- Serial number
- Designation of series or type
- CE mark
- Year of construction
- Rated voltage, full load amperage, and frequency
- Short-circuit Interrupting rating of the equipment
- The weight of the equipment
- Identification number of the electrical schematics

Sample controller nameplates are shown below:



General Information and handling Instructions

- Repligen XCell™ ATF system is rated for acceptable sound levels (60 dBA)
- Weight of C410 controller: E-Box 23 kg (50 lbs), P-Box 13 kg (28.6 lbs)
- Complete system visual inspection for damage or potential risk to the operator, surrounding personal, or equipment on a semi-annual basis
- Annual Safety Inspection
 - Conduct a vacuum system leak assessment
 - Replace the air filter between the XCell™ ATF System and the Controller
 - Inspect air and vacuum connections to the controller
 - Inspect that all components inside of the controller are secured and intact
 - Inspect enclosure for damage, locks and hinges for performance,
 - Inspect the XCell™ ATF system housing components, especially the internal and sealing surfaces for damage, rust, cracks, scoring
 - Perform a pressure hold test of the XCell™ ATF System

Handling Instructions



Transportation: The XCell™ ATF controller E-Box weighs 23 kg (50 lbs) and the P-Box weighs 13 kg (29 lbs). Care should be taken when lifting and transporting and use of a cart is recommended



Voltage: Hazardous voltage inside, disconnect power before opening

Appendix 4 Pressure Relief

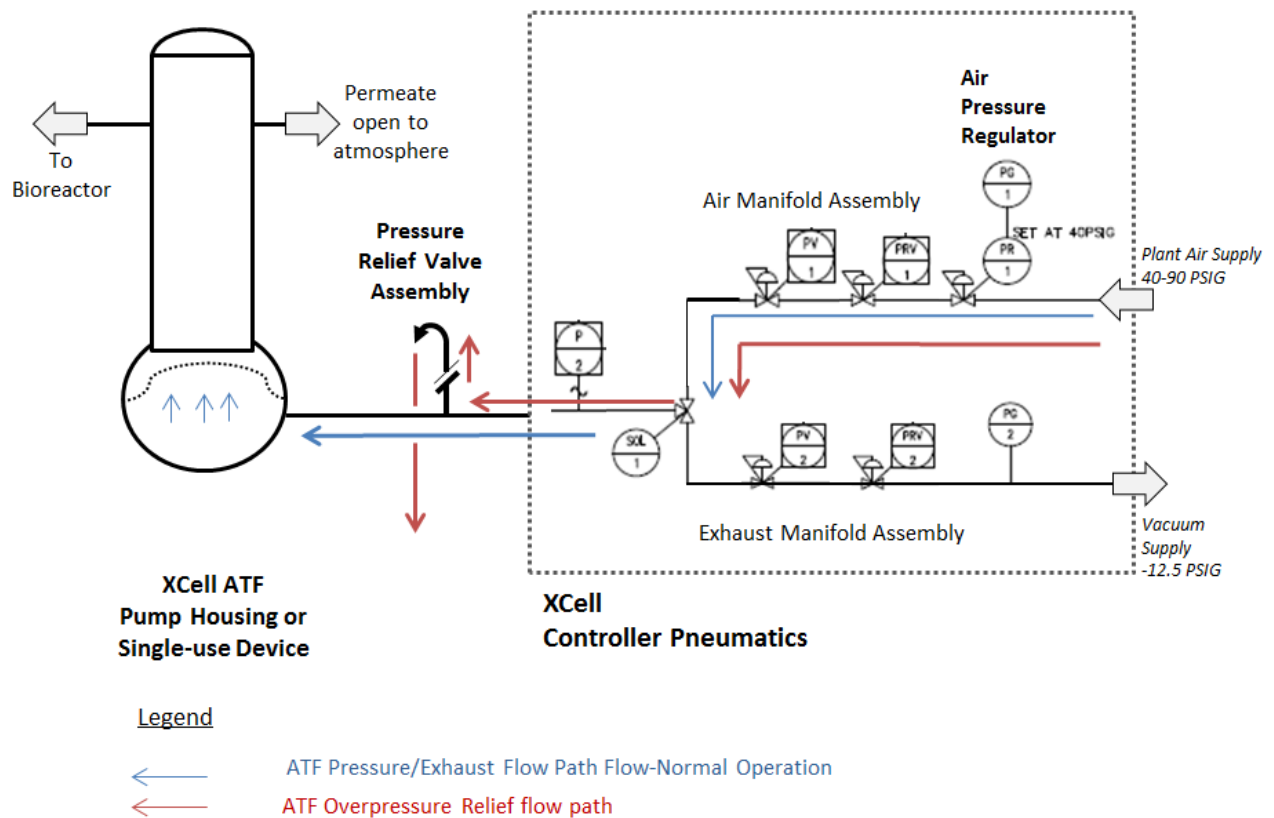
Pressure Rating of Pump Housings and Single-Use Devices

XCell ATF stainless steel pump housings are designed to maximum allowable working pressure of 45 PSIG at 140 °C. Stainless steel assemblies are pressure tested (hydrostatic pressure test at 70 PSI) and marked in accordance with the ASME Boiler and Pressure Vessel Code.

XCell ATF Single-use devices are designed and validated to withstand a pressure of 60 PSIG at 40 °C. All device units are subjected to a pressure hold of 30 PSIG as part of standard release testing.

Overpressure Relief

To protect the XCell housings and devices from reaching pressures > 40psig, a pressure relief assembly set at 40 PSIG is located on the outlet of pneumatic box supplying pressure and vacuum to the air-side hemisphere of the pump housing. The flow path of pressure relief is shown below.



Appendix 5: Profinet Communication

Set/Change IP Address of HMI

1. HMI IP Address setting:
 - a. Select settings from the start menu, select network and dial up connections, then select PN_X1.
 - b. From this interface, the IP Address, Subnet Mask and all other Ethernet Properties can be adjusted.
2. PLC IP Address setting:
 - c. Select settings from the start menu (or go back to the setting screen) and select Service & Commissioning.
 - d. Select IP config by pressing the right arrow to reveal the 5th tab.
 - e. From the Service & Commissioning screen, press the assign IP button.
 - f. On the following screen select network, scan and start. "Scan is running" appears at the bottom of the window.
 - g. After the scan is complete, the S7-1200 device should appear. Select the S7-1200 device and the device fields populate with the current configuration.
 - h. From this interface, the IP Address, Subnet Mask and all other Ethernet Properties can be adjusted.
 - i. Once the values have been entered, select device, download and IP to assign the address to the device. "IP suite settings could be assigned" appears at the bottom of the window.
 - j. Exit out of the assign IP
3. Set Connection between HMI and PLC:
 - k. From the Service & Commissioning screen, press the set connection button.
 - l. On the following screen press the Find Online button. After the scan is complete, the S7-1200 device should appear. Select it, and the IP Address box below contains the PLC's address. Note: It can also be entered manually.
 - m. Press OK to accept and close the window.
 - n. Press Save to set the connection. "Save is successful" appears at the bottom of the window.
 - o. Close the window to exit.
 - p. Close the Service & Commissioning window.
 - q. Close the Settings Window
4. Start the program again and ensure that '####' do not appear in the main screen fields.

Information for Remote data logging

Monitor Points List

Name	Data type	Offset	Address	Description
CYCLENO	DInt	0	%DB1.DBD0	Batch Cycle Count
TOTAL_CYCLENO	DInt	4	%DB1.DBD4	Total Cycle Count
PRV1	Real	10	%DB1.DBD10	Flow Regulator Value
PV1	Real	14	%DB1.DBD14	Flow Prop Valve Value
PV1MAX	Real	18	%DB1.DBD18	Flow Prop Valve Max Value
PV1MIN	Real	22	%DB1.DBD22	Flow Prop Valve Min Value
PV2	Real	26	%DB1.DBD26	Exhaust Prop Valve Value
PV2MAX	Real	30	%DB1.DBD30	Exhaust Prop Valve Max Value
PV2MIN	Real	34	%DB1.DBD34	Exhaust Prop Valve Min Value
PFLOW	Real	38	%DB1.DBD38	Pressure Flow LPM
PFLOWSP	Real	42	%DB1.DBD42	Pressure Flow Setpoint LPM
PFLOWMAXSP	Real	46	%DB1.DBD46	Max Pressure Flow Setpoint LPM
PFLOWMINSP	Real	50	%DB1.DBD50	Min Pressure Flow Setpoint LPM
EFLOW	Real	54	%DB1.DBD54	Exhaust Flow LPM
EFLOWSP	Real	58	%DB1.DBD58	Exhaust Flow Setpoint LPM
EFLOWMAXSP	Real	62	%DB1.DBD62	Max Exhaust Flow Setpoint LPM
EFLOWMINSP	Real	66	%DB1.DBD66	Min Exhaust Flow Setpoint LPM
PTIME	Real	70	%DB1.DBD70	Pressure Flow SEC
PTIMESP	Real	74	%DB1.DBD74	Pressure Flow Setpoint SEC
PTIMEMAXSP	Real	78	%DB1.DBD78	Max Pressure Flow Setpoint SEC
PTIMEMINSP	Real	82	%DB1.DBD82	Min Pressure Flow Setpoint SEC
ETIME	Real	86	%DB1.DBD86	Exhaust Flow SEC
ETIMESP	Real	90	%DB1.DBD90	Exhaust Flow Setpoint SEC
ETIMEMAXSP	Real	94	%DB1.DBD94	Max Exhaust Flow Setpoint SEC
ETIMEMINSP	Real	98	%DB1.DBD98	Min Exhaust Flow Setpoint SEC
TRENDTIME	Real	102	%DB1.DBD102	Trend Time Base
S2TMREAL	Real	106	%DB1.DBD106	STATE 2 Timer (Real)
PUMPVOL	Real	112	%DB1.DBD112	Pump Diaphragm Volume
PUMPSTATE	Int	116	%DB1.DBW116	Pump State
P_ERROR	Real	118	%DB1.DBD118	Set Point Deviation Error
PTIMEVAL	DInt	122	%DB1.DBD122	Fill Cycle Time
ETIMEVAL	DInt	126	%DB1.DBD126	Exhaust Cycle Time
STATUSREG	Word	130	%DB1.DB130	Pump Status Register
E_ERROR	Real	134	%DB1.DBD134	Set point deviation error
FDFOFST	Real	174	%DB1.DBD174	Flow Driving Force Offset for switching
EDFOFST	Real	178	%DB1.DBD178	Exhaust Driving Force Offset for switching
PRV1MAX	Real	218	%DB1.DBD218	Flow Regulator Value Max Value
PRV1MIN	Real	222	%DB1.DBD222	Flow Regulator Value Min Value

PRV2MAX	Real	226	%DB1.DBD226	Exhaust Regulator Value Max value
PRV2MIN	Real	230	%DB1.DBD230	Exhaust Regulator Value Min Value
PRV2	Real	498	%DB1.DBD498	Exhaust Regulator Value
FDRVFORCESP	Real	502	%DB1.DBD502	Flow Driving Pressure SP
EDRVFORCESP	Real	506	%DB1.DBD506	Exhaust Driving Pressure SP
FSOTSP	DInt	526	%DB1.DBD526	Flow Switch Override Timer SP
FDFDTSP	DInt	530	%DB1.DBD530	Flow DF Detect Timer SP
ESOTSP	DInt	534	%DB1.DBD534	Exhaust Switch Override Timer SP
EDFDTSP	DInt	538	%DB1.DBD538	Exhaust DF Detect Timer SP
PLC_Version	Real	552	%DB1.DBD552	PLC Software Version
P2_PV	Real	566	%DB1.DBD566	P2 - Process Value
PRV1_PV	Real	570	%DB1.DBD570	PRV1 - Process Value
PRV2_PV	Real	574	%DB1.DBD574	PRV2 - Process Value
P3_PV	Real	582	%DB1.DBD582	P3 - Process Value
P4_PV	Real	586	%DB1.DBD586	P4 - Process Value
P5_PV	Real	590	%DB1.DBD590	P5 - Process Value
W1_PV	Real	594	%DB1.DBD594	W1 - Process Value
Pres_Cyc_Override_Limit	Real	754	%DB1.DBD754	Pressure Cycle Override Limit (TEMP LOC MOVE)
Exh_Cyc_Override_Limit	Real	758	%DB1.DBD758	Exhaust Cycle Override Limit (TEMP LOC MOVE)
P2_Pressure_Slope_Total	Real	788	%DB1.DBD788	P2 Pressure Cycle Slope Total
P2_Exhaust_Slop_Total	Real	792	%DB1.DBD792	P2 Exhaust Cycle Slope Total
Bioreactor_Backpressure	Real	914	%DB1.DBD914	Bioreactor Backpressure
Model_Num_HMI	Int	918	%DB1.DBW918	Model Number SP
Height_Differential	Int	928	%DB1.DBW928	Height Differential SP
Press_Cycle_Delay_Time_SP	Int	930	%DB1.DBW930	Pressure Cycle Delay Time SP
Press_Cycle_Over_Time_SP	Int	932	%DB1.DBW932	Pressure Cycle Over Time SP
Vac_Cycle_Over_Time_SP	Int	936	%DB1.DBW936	Vaccume Cycle Over Time SP

Input/ Output List

Tagname	Description	PLC Tag Address	Engineering			Valve Fail Position	Real Time Trend
PP1	System Stop	%I0.0	N/A	N/A	N/A	N/A	N/A
PP2	System Stop	%I0.1	N/A	N/A	N/A	N/A	N/A
-	Spare	N/A	N/A	N/A	N/A	N/A	N/A
-	Spare	N/A	N/A	N/A	N/A	N/A	N/A
-	Spare	N/A	N/A	N/A	N/A	N/A	N/A
-	Spare	N/A	N/A	N/A	N/A	N/A	N/A
-	Spare	N/A	N/A	N/A	N/A	N/A	N/A
-	Spare	N/A	N/A	N/A	N/A	N/A	N/A
-	Spare	N/A	N/A	N/A	N/A	N/A	N/A
-	Spare	N/A	N/A	N/A	N/A	N/A	N/A
-	Spare	N/A	N/A	N/A	N/A	N/A	N/A
-	Spare	N/A	N/A	N/A	N/A	N/A	N/A
-	Spare	N/A	N/A	N/A	N/A	N/A	N/A
-	Spare	N/A	N/A	N/A	N/A	N/A	N/A
PL1	System Stop Indicator	%Q0.0	N/A	N/A	N/A	N/A	N/A
HN1	System Fault Warning Horn	%Q0.1	N/A	N/A	N/A	N/A	N/A
SOL1	Pump Inflate/Deflate Solenoid	%Q0.2	N/A	N/A	N/A	N/A	N/A
CR1	Pump Controller Status Relay #1	%Q0.3	N/A	N/A	N/A	N/A	N/A
CR2	Pump Controller Status Relay #2	%Q0.4	N/A	N/A	N/A	N/A	N/A
CR3	Pump Interlock Relay #3	%Q0.5	N/A	N/A	N/A	N/A	N/A
CR4	Pump Interlock Relay #4	%Q0.6	N/A	N/A	N/A	N/A	N/A
PL2	System Stop Indicator	%Q0.7	N/A	N/A	N/A	N/A	N/A
-	Spare	N/A	N/A	N/A	N/A	N/A	N/A
-	Spare	N/A	N/A	N/A	N/A	N/A	N/A
-	Spare	N/A	N/A	N/A	N/A	N/A	N/A
-	Spare	N/A	N/A	N/A	N/A	N/A	N/A
RAW_P2_PV_1	Pump Pressure	%IW96	Note 1 -14.7 - 30	1	PSI	N/A	Y
RAW_PRV1_PV_1	Inflation Pressure	%IW98	Note 1 0 - 40	1	PSI	N/A	Y

RAW_PRV2_PV_1	Deflation Pressure	%IW100	Note 1 -15 - 0	1	PSI	N/A	Y
RAW_AIW10_PV	Spare	N/A	N/A	N/A	N/A	N/A	N/A
RAW_P3_PV_1	Optional Pressure 3	%IW104	Note 1	N/A	PSI	N/A	Y
RAW_P4_PV_1	Optional Pressure 4	%IW106	Note 1	N/A	PSI	N/A	Y
RAW_P5_PV_1	Optional Pressure 5	%IW108	Note 1	N/A	PSI	N/A	Y
RAW_W1_PV_1	Optional Weight	%IW110	Note 1	N/A	LBS	N/A	Y
RAW_PRV1_CV	Inflation Pressure	%QW12	0-100	1	%	FC	Y
RAW_PRV2_CV	Deflation Pressure	%QW13	0-100	1	%	FO	Y
RAW_PV1_CV_1	Inflation Pressure Proportional	%QW13 2	0 - 40	1	PSI	N/A	Y
RAW_PV2_CV_1	Deflation Pressure Proportional	%QW13 4	-15 - 0	1	PSI	N/A	Y

Note 1: Depends on calibration

Alarm List

"DB1" .ALARM_REG(0)	XCell™ ATF Warning condition has not been reset within the alarm delay time, XCell™ ATF function halted.	%DB1 .DBX110.0	Pump is Running and Alarm Delay Timer Setpoint is Greater than Zero.	*See Note	1 min	Alarm, System Stop, Activate System Fault Warning Horn
"DB1" .ALARM_REG(1)	Main Power Loss (120/220) while Pump was running	%DB1 .DBX110.1	First Scan of PLC on Power Up.	On first scan Pump State is not 0	N/A	Alarm, System Stop, Activate System Fault Warning Horn
"DB1" .ALARM_REG(2)	P2 Pressure Above HI HI Limit	%DB1 .DBX110.2	Pump is Running	P2 pressure is greater than or equal to the P2 Hi HI Pressure alarm setpoint.	P2 Hi Hi Set Point Alarm Delay in 10ms increments	Alarm, System Stop, Activate System Fault Warning Horn
"DB1" .WARN_REG(0)	Flow Set Point cannot be reached. Air Supply Regulator (PRV1) above maximum pressure setting	%DB1 .DBX132.0	Pump is Running	PRV1>=PRV1 MAX	N/A	Warning, Activate System Fault Warning Horn
"DB1" .WARN_REG(1)	Flow Set Point cannot be reached. Air Supply Regulator (PRV1) below minimum pressure setting	%DB1 .DBX132.1	Pump is Running	PRV1<=PRV1 MIN	N/A	Warning, Activate System Fault Warning Horn
"DB1" .WARN_REG(2)	Exhaust Set Point cannot be reached. Vacuum Supply Regulator (PRV2) above maximum vacuum setting	%DB1 .DBX132.2	Pump is Running	PRV2>=PRV2 MAX	N/A	Warning, Activate System Fault Warning Horn
"DB1" .WARN_REG(3)	Exhaust Set Point cannot be reached. Vacuum Supply Regulator (PRV2) below minimum vacuum setting	%DB1 .DBX132.3	Pump is Running	PRV2<=PRV2 MIN	N/A	Warning, Activate System Fault Warning Horn
"DB1" .WARN_REG(4)	P2 Pressure below Lo Lo Limit	%DB1 .DBX132.0	Pump is Running	P2_PV <= Pressure Alarm Lo Lo Setpoint	P2 Lo Lo Set Point Alarm Delay in 10ms increments	Warning, Activate System Fault Warning Horn

Appendix 6: Spares List

XCell™ ATF Electronics Spares	
C410:EP-AD-CB-NC	Pushbutton, 22 mm Metal Latch with Twist-to-Release LED Illuminated Red, 24 VAC/DC, 40 mm Mushroom Operator 1 N.C. Contact Block
C410:E-AD-CB-NO-1252	Selector switch, 22 mm metal 2-position, maintained LED illuminated 24VAC/DC knob operator 1 n.o. contact block
C410:E-AX-MCB	Miniature Circuit-Breakers - 10 Amp - 2 Pole - Characteristic Curve B
C410:E-NI-ECF	BUSSMANN - BK/MDL-5-R - Electronic Cartridge Fuse
C2410V3:E-AX-CPU	CPU, SIMATIC S7-1200, 1214C, DC / DC / DC
C410V3:AX-TS	Siemens Simatic HMI TP1200 Comfort Panel
C410:E-Simatic-I	Module, Simatic s7-1200 analog input, SM1231
C410:E-Simatic-O	Module, Simatic S7-1200 Analog output SM1232
C410:E-GC-RP	24VDC relay 1 pole
C410:E-NI-LF	RFI line filter
C410:E-AX-24PS	24VDC power supply @ 10 AMPS – TRIO-PS/1AC/24DC/10
C410:E-PR-IA	Standard signal 3-way isolating amplifiers, not configurable. MINI MCR-SL-I-I
XCell™ ATF:CHIP-C410v4B-HMI	Chip, Disaster Recovery, HMI, C410v4B
XCell™ ATF:CHIP-C410v4B-PLC	Chip, Disaster Recovery, PLC, C410v4B
C2410:P-AX-RD1	SIEMENS S7-200 BATTERY CARTRIDGE
C410:E-PB-MOD	Profibus Module for S7-1200
C2410:E-AX-CPU	SIMATIC S7-200 CPU module
XCell™ ATF 6 Pneumatics Spares	
C410:P6-RF-PM	Pressure Manifold for C410:6
C410:P6-RF-EM	Exhaust Manifold for C410:6
C410v2:P48-RF-SOL1	ASSEMBLY, 3 way valve- SOL1 for C410 v1 & v2 XCell™ ATF4, XCell™ ATF6, XCell™ ATF8 Controller
C410:P-KN-PR-0-60	REGULATOR 0-60PSI
C410:P-1.5VG	1.5" Vacuum Gauge 0-30"Hg CENTER BACK 1/8" NPT,7216-1½-1/8 30/0 FLANGE MOUNT-Replaces C410:P-MF-PG-0-30FM
C410:P-1.5PG	1.5" PRESSURE GAGE 0-60PSI CENTER BACK 1/8" NPT, 7216-1½-1/8 0-60 FLANGE MOUNT-Replaces C410:P-MF-PG-0-60FM
XCell™ ATF46-PRV	Pressure Release Valve; XCell™ ATF4 or XCell™ ATF6
XCell™ ATF 10 Pneumatics Spares	
C410V2:P10-RF-PM	Pressure Manifold sub-assembly for C410v2 Controller for XCell™ ATF10 System
C410V2:P10-RF-EM	Exhaust Manifold sub-assembly for C410-v2 controller for XCell™ ATF10 system, with P2 and SOL1
C410V2:P10-RF-SOL1	ASSEMBLY, 3 way valve- SOL1 for C410v2 XCell™ ATF10 Controllers
C410:P-KN-PR-0-60	REGULATOR 0-60PSI
C410:P-1.5VG	1.5" Vacuum Gauge 0-30"Hg CENTER BACK 1/8" NPT,7216-1½-1/8 30/0 FLANGE MOUNT-Replaces C410:P-MF-PG-0-30FM
C410:P-1.5PG	1.5" PRESSURE GAGE 0-60PSI CENTER BACK 1/8" NPT, 7216-1½-1/8 0-60 FLANGE MOUNT-Replaces C410:P-MF-PG-0-60FM
C410-P-KN-PR-40-420-P10	PRV Assembly Replacement Part
C410V2:P10-RF-PV	PV1 valve with matching amplifier board for a C410V2:10 pneumatics
XCell™ ATF10-PRV	Pressure Release Valve; XCell™ ATF10

XCell™ ATF 6 Pump Housing Spares	
A6-H1	Filter Housing Assembly, XCell™ ATF6
A6:R1	Reducer, XCell™ ATF6
XCell™ ATF6:PHLA	Pump Hemisphere, Liquid Side Assembly, XCell™ ATF6
A6-BASE	Pump Hemisphere, Base Plate, Assembly, XCell™ ATF6
SG-05-E	Sanitary Gasket, 1/2" TC
SG-075-E	Sanitary Gasket, 3/4" TC
SG-1.5-E	Sanitary Gasket, 1 1/2" TC
O:337-S-GMP	Silicone Size 337 70A O-Ring
TC:PG:3/4	Pressure Gauge, 3/4 TC 30PSI to - 30" Hg
TC-EL1S	Elbow 90 Degree -1.0 , TC Ends
SG-1.0-E	Sanitary Gasket 1" TC
TC:W2-1.5	Window, Sanitary 1.5"TC, w/Rem. Glass Insert
TC-CAP-3/4	Sanitary Cap 3/4"
V1-S-0.5N	Sanitary Diaphragm Valve, 1/2" w/TC ends
SC-075	Clamp, Sanitary, 1/2"-3/4" TC
SC-1.5	Clamp, Sanitary, 1 1/2" TC
A6-BASE-SHCS	1/4-20x3/8 Socket Head Cap Screw (4)
SC-3L	Clamp, Sanitary, 3.0" TC
SC-6.0	Clamp, Sanitary 6.0" TC
TC-BRB1	Sanitary Adapter, 3/4" Tri-Clamp x 1/4" Hose Barb Fitting
XCell™ ATF6:AIR-ASSY	Air Inlet Assembly, XCell™ ATF6
P3-CPM1.5-TC3/4	Kit, PT, 1.5"CPM Fitting, 3/4"TC
XCell™ ATF6:PH-AA-AIR	Air Hemisphere, XCell™ ATF6 w/XCell™ ATF6:AIR-ASSY
XCell™ ATF 10 Pump Housing Spares	
A10-STAND	Stand, Assembly, XCell™ ATF10
A10RF-C3	ASME Clamp, Assembly, XCell™ ATF10
A10RF-H1	Filter Housing Assembly, XCell™ ATF10
A10RF:HA	Lifting Handle, Assembly, XCell™ ATF10
XCell™ ATF10:PHLA	Pump Hemisphere Liquid Side, Assembly, XCell™ ATF10
A10-R1	Reducer, XCell™ ATF10
A10RF-C3-RELIEF	ASME Clamp w/ Relief, Assembly, XCell™ ATF10
A10:C1-LOCK-A	C Clamp w/ Lock-A, Assembly, XCell™ ATF10
A10:C1-LOCK-B	C Clamp w/ Lock-B, Assembly, XCell™ ATF10
SG-05-E	Sanitary Gasket, 1/2" TC
SG-075-E	Sanitary Gasket, 3/4" TC
SG-1.5-E	Sanitary Gasket, 1 1/2" TC
TC-W2-1.5	Window, Sanitary 1.5"TC, With / Rem. Glass Insert 316L SS/Glass
TC-CAP-3/4	Sanitary Cap 3/4"
TC-EL-1.5S	90 Degree Ell, 1.5TC
TC-PG-1.5	Pressure Gauge, 1.5 TC, 30 psi
V1-S-0.5N	Sanitary Diaphragm Valve, 1/2" w/TC ends
SC-075	Clamp, Sanitary 1/2-3/4" TC
SC-1.5	Clamp, Sanitary, 1 1/2" TC
O-CTM-10H	O-Ring, 50 Duro, Clear, 0.295" C/S x 6.835" ID x 7.425" OD

O:349-S-GMP	O:349-S-GMP, "O:349-S-GMP; O-Ring for XCell™ ATF10 hollow fiber module, USP Class VI, package of 2"
XCell™ ATF10:NUT-HVY- 1/2"-13	XCell™ ATF10 ASME Monel Heavy Hex Nut 1/2"-13
XCell™ ATF10:NUT-FIN- 1/2"-13	XCell™ ATF10 ASME Monel Fine Hex Nut 1/2" -13
A:ST-TS	A:ST-TS, Thumb Screw for XCell™ ATF10 XCell™ ATF8 Base
XCell™ ATF10:AIR-ASSY	Air Inlet Assembly, XCell™ ATF10
XCell™ ATF10:PH-AA-AIR	Air Hemisphere, XCell™ ATF10 w/XCell™ ATF10:AIR-ASSY
P3-CPM1.5-TC3/4	Kit, PT, 1.5"CPM Fitting, 3/4"TC

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