



KrosFlo® Systems

For use with:

- KrosFlo® KTF Tangential Flow Filtration (TFF) System
- KrosFlo® KPS Perfusion (KPS) System
- KrosFlo® TFDF® Tangential Flow Depth Filtration (TFDF) System



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Contents

1. Introduction	8
2. Safety Precautions	8
2.1 Signal Words.....	8
2.2 Safety Symbol Icons	9
3. Safety Guidelines.....	10
3.1 Intended User Guide Audience	10
3.2 Intended Use of the System	11
3.3 Warnings for Moving, Installing, and Storing the System	11
3.4 Warning for System Preparations	12
3.5 Warnings for System Operation	12
3.6 Warnings for System Maintenance	15
4. System Specifications	16
5. System Dimensions	18
6. RoHS and WEEE Compliance	18
7. System Overview.....	19
7.1 Main System.....	19
7.2 Cassette Holder Cart (optional)	20
7.3 Auxiliary Cart (optional)	20
8. Unpacking the System	21
9. Performing Mechanical Installation	22
9.1 Main System Assembly.....	22
9.2 Cassette Holder Assembly (optional)	24
9.2.1 Cassettes Installation.....	24
9.2.2 Hydraulic Pump Preparation	25
9.3 Single-Use Flow-path Assembly	27
9.3.1 Recirculation Pump Preparation and Connections.....	27
9.3.2 Feed Tank/Reservoir Connections.....	31
9.3.3 Installing Auxiliary Pump Tubing	33
10. Performing Electrical Installation.....	34
10.1 Sensor and Communication Cables.....	34
10.1.1 Pressure Sensors.....	34
10.1.2 Installing Ferrite Bead for Pressure Sensors.....	35
10.1.3 Installing Permeate Flow Sensors.....	36
10.1.4 Other Sensor and Communication Cables.....	36
10.1.5 Connecting the System Power Cables	37
11. Using the System HMI	37
11.1 Human Machine Interface (HMI) Overview	37
11.2 Getting Started.....	38
11.3 Loading and Running Recipes.....	39
11.4 Home Screen	40
11.5 Process Screen	41
11.6 Alarms Screen.....	43
11.7 Diagnostics Screen	44
12. Operating the System.....	45
12.1 Executing Reports.....	45
12.2 System Emergency Stop and Responses	46
12.2.1 Stopping the System Using the E-Stop Button	46
12.2.2 Restarting the System after an Emergency Stop	46
12.3 System Power Loss and Responses	47
12.3.1 System Power Loss	47
12.3.2 Restarting the System after a Power Loss	47
12.4 Shutting Down the System.....	47

- 13. Performing System Maintenance.....48
 - 13.1 Making the System Safe for Maintenance48
 - 13.2 Cleaning the System48
 - 13.3 Cleaning the Flow-path48
 - 13.4 Flow-path disassembly and storage49
 - 13.5 System Moving and Storage.....49
 - 13.6 KrosFlo® System Spare Parts50
- 14. Troubleshooting the System53
- 15. Index54

List of Tables

Table 1. Signal words, definitions, and colors	8
Table 2. Safety Symbol Icons	9
Table 3. KrosFlo® System Feature/Component Specifications	16
Table 4. KrosFlo® System Electrical Specifications	17
Table 5. KrosFlo® System Environmental Specifications	17
Table 6. KrosFlo® System Spare Parts.....	50
Table 7. Basic System Troubleshooting Steps	53

List of Figures

Figure 1. Sample Machine Designation Label.....	17
Figure 2. KrosFlo® System Dimensions.....	18
Figure 3. KrosFlo® System Overview	19
Figure 4. Optional Cassette Holder Cart.....	20
Figure 5. Optional Auxiliary Cart.....	20
Figure 6. Pump Stand Assembly	23
Figure 7. Cassette Installation	24
Figure 8. Hydraulic Pump Components	25
Figure 9. Typical Flow Path with Hollow Fiber and Cassette Filter Connections	27
Figure 10. Typical Feed Tank or Reservoir Connections	31
Figure 11. Recipe Selection Screen.....	39
Figure 12. Sample Home Screen.....	40
Figure 13. Sample Process Screen	41
Figure 14. Sample Alarms Screen	43
Figure 15. Sample Diagnostics Screen	44

Abbreviations

Amp	Ampere
C	Celsius
CF	Concentration factor
cm	Centimeter
DV	Diafiltration volume
ES	Electrical schematic
EU	Europe
F	Fahrenheit
FDS	Functional design specification
ft	Feet
GA	General arrangement drawing
HDS	Hardware design specification
HMI	Human machine interface
Kg	Kilograms
TFDF	Tangential depth filtration system
lbs.	Pounds
LCD	Liquid-crystal display
lpm	Liters per minute
M	Meter
mA	Milliampere, or milliamp
MBT	Module bag tubing
NWP	Normalized water permeability
P&ID	Piping and instrumentation diagram
PID	Proportional integral derivative (tuning)
PLC	Programmable logic controller
Psi	Pounds per square inch
rpm	Revolutions per minute
SAS	Standard alert symbol
SDS	System design specification
TFF	Tangential Flow Filtration
TMP	Transmembrane pressure
VAC	Volts AC power
VVD	Vessel volumes per day (perfusion exchange rate)

1. Introduction

KrosFlo® Systems from Repligen provide ready-to-use, flexible flow-path solutions for commercial-scale microfiltration and ultrafiltration process operations.

Each system includes magnetic drive centrifugal pump(s), clamp-on flow meters, pressure sensors, peristaltic pumps, custom flow path assemblies with or without filters, and connections for additional process monitoring. Other optional components of the system include valves, external input(s), and communication accessories.

The system includes a Human Machine Interface SCADA (Supervisory control and data acquisition application) to initiate actions.

Additionally, there is a PLC (Programmable Logic Controller) and or Remote I/O platform contained in a stainless steel skid that serves as the support structure. All units run on 200-240 VAC power. The System is intended for indoor use only.

2. Safety Precautions

2.1 Signal Words

The signal word and color distinguish the severity level of a hazard. Signal word definitions and colors are listed in [Table 1](#).

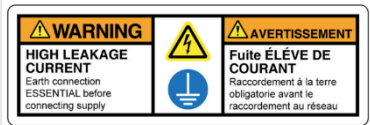
Table 1. Signal words, definitions, and colors

Icon	Description
	Safety Alert Symbol (SAS) - used when a hazard to personnel is present. The SAS is omitted when the hazard is related to property/equipment damage only.
	A DANGER notification indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.
	A WARNING notification indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
	A CAUTION notification indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.
	A CAUTION notification without the Safety Alert Symbol  indicates a potentially hazardous situation which, if not avoided, may result in property/equipment damage.

2.2 Safety Symbol Icons

The typical safety symbol icons - hazard, prohibition, and mandatory action - used on Repligen Systems are listed in [Table 2](#). The icons are pictograms that communicate hazards quickly and across language barriers.

Table 2. Safety Symbol Icons

Safety Symbol Icons Used in this Document		
		
Electrical Hazard	Heavy Object	Heat Hazard
		
Radiation Hazard	Crush Hazard	Pinch Hazard
		
Inhalation Hazard	Authorized and Qualified Personnel Only	Read the Manual
		
Noise Level Hazard	UV Hazard	

3. Safety Guidelines

3.1 Intended User Guide Audience

This User Guide for KrosFlo Systems is intended to be used by experienced users, working in pilot or production facilities. Users should have advanced understandings and working experiences of upstream and downstream processes.

Because this User Guide only focuses on the equipment set-up and its detailed operations, users should have the support from both Process Subject Matter Expert and Automation Expert to set-up the process parameters and operate the System.

This User Guide is intended to act as a reference only, in conjunction with other materials, such as application notes, automation documents, component manuals, or maintenance manuals. It should not be used as the sole source of knowledge. Users must not expect to operate the System by just reading this User Guide.

If users do not have the above experience or technical support, or they do not understand any instructions in this User Guide, contact Repligen for assistance or training before proceeding.

The instructions in this user guide are not a substitute for the observance of the System owner's company-specific regulations and requirements.

Note:

This User Guide presents and describes a sample KrosFlo System configuration. Sample HMI screens are included that represent this configuration. As a KrosFlo System may be customized to support a particular bioprocessing development process, your KrosFlo System hardware, automation software, and HMI screens may differ from this sample configuration. Safety information presented in this user guide applies to all KrosFlo Systems.

Please refer to the following system design documents included in the electronic Turn Over Package (eTOP) for details about your KrosFlo System software and hardware configuration, and capabilities:

- Hardware Design Specification (HDS)
- Core Standard Platform Software Operations Manual (SOM)
- KrosFlo® Systems Software Operations Manual (SOM)
- Recipe Editor Software Operations Manual (SOM)
- CFR 21 Part 11 Regulatory Compliance Guidance (REG)
- General Arrangement (GA) Drawing
- Piping and Instrumentation Diagram (P&ID)
- Electrical Specifications (ES)

3.2 Intended Use of the System



WARNING – Only Authorized and Qualified Personnel are allowed to use this equipment. Ensure installation, maintenance, and operation are completed by qualified and trained personnel.



WARNING – If you use the System in a manner not specified in this user guide, you may be exposed to hazards leading to personal injury or equipment damage. Do not operate the System at temperatures or pressures above those stated in this user guide.



WARNING – Always wear the personal protective equipment required by the System owner's safety program. This includes equipment to prevent exposure to process fluids.

The KrosFlo® System is designed to execute traditional batch processes for concentration, with several buffer exchange or wash steps.

The System will be fully configured for the disposable ProConnex® flow-paths, which include flexible tubing, Hollow Fiber module or Cassette, disposable levitating pump head, pressure transmitters, with associated connections or thermal plastic weldable tubing.

The System is assembled, wired, configured, and tested by Repligen prior to shipping and installation at the client site.

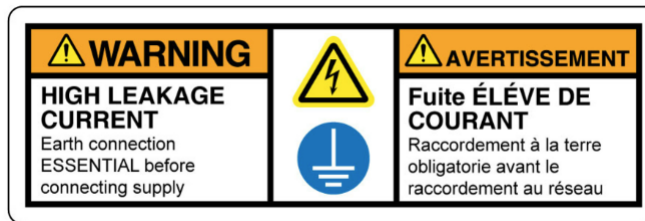
Consumables such as Hollow Fiber Filter, Cassettes, Sensors, or Flow-paths are integrated parts of the System, but they may require specific maintenance methods. Refer to the vendor-provided User Guides for more information on these consumables.

3.3 Warnings for Moving, Installing, and Storing the System



1. The KrosFlo System is intended to be unpacked and installed by trained service personnel only.
2. Do not attempt to lift the System. The System should only be moved by carefully rolling the System on its casters. The System shipping crate includes an integral ramp that allows the System to be rolled out of the crate.
3. Be sure to set the brake on each caster to prevent unintended motion.
4. The System is heavy and can cause crushing injury during a moving mishap. To prevent injury, wear toe protection, such as steel-toe work boots.
5. Using a forklift (or other equipment moving machinery) of insufficient capacity can result in unexpected dropping of the System, resulting in injury or death. To prevent injury or death due to unexpected dropping, use a forklift rated to lift the weight of the System.
6. Careless moving of the heavy System can result in workers being squeezed or crushed against other equipment or walls. To prevent squeezing and crushing injury, move the equipment slowly and ensure workers do not position themselves where injury could result.
7. Do not allow the wheels of the System to run-off of ramps. Use a sufficient number of movers to maintain control of the System, particularly when the System is on ramps.

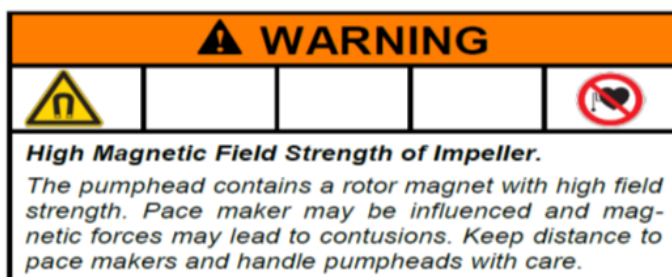
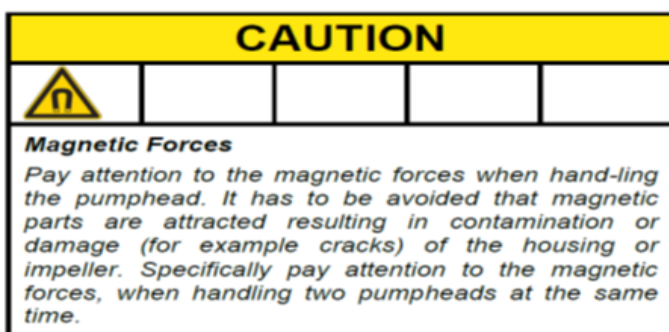
3.4 Warning for System Preparations



1. Perform a risk assessment for the area in which you plan to use the System, to ensure the classification of the area does not change.
2. To provide quick access for disconnecting power in case of emergency, do not block access to the System power switch, receptacles where the power cords are plugged in, or the main circuit disconnect.
3. To prevent the System from overheating, do not block the air intake or exhaust openings on the Controller Cabinet.
4. To avoid risk of electric shock, this equipment must only be connected to AC mains with protective earth using a twist lock connector. No modification of this equipment is allowed.
5. To avoid injuries from tripping, route and secure all piping and tubing sensibly and keep them out of the user's way.
6. Before starting up the System, inspect all mechanical and electrical components thoroughly for potential damages. These include punctured bags and tubing, damaged connections, and loosen electrical connections.
7. Only use the System in an indoor environment with an ambient atmosphere meeting the operating specifications.
8. Do not plug in or introduce electricity to the System during Mechanical Assembly.
9. Do not introduce power or plug the System in a power outlet during Electrical Connections procedure until instructed to do so.

3.5 Warnings for System Operation





1. If the KrosFlo System is used in a manner not specified by the manufacturer, the protection provided by the unit may be impaired.
2. Obtain work authorization and check the status of the System. Using the System without physical supervision (for example, if System is remotely controlled), when it is damaged or has malfunctioned, can led to personal injury.
3. If untrained or unauthorized personnel operate the System incorrectly, System damage can result. To prevent System damage due to improper operations, ensure personnel are trained appropriately for their levels of access and use secured access passwords to prevent unauthorized operation.
4. Running the System manually without adequate training can lead to equipment damage. To prevent equipment damage, ensure personnel do not run the System manually unless they are adequately trained and have the correct authorization level.
5. Pressing the emergency stop button does not disconnect power from the electrical control panel and pumps.
6. The System flow-path may remain filled and slightly pressurized during power lost or emergency-stop. Opening a line, connector, or component could release biologically or chemically hazardous materials, resulting in injury or death.
7. To prevent exposure to hazardous materials, follow the procedures and appropriate instructions for the correct assembly, setup, verification, and operation of the System. Follow the System owner's PPE requirements.
8. Moving the System or vibration during operation can loosen connections, resulting in a spill of a potentially hazardous process fluid leading to injury. To prevent spills, exposure, and injury, ensure all process connections are securely connected and all legs are leveled and locked, then replace the appropriate components as soon as possible, for example the flow-path.
9. Maintain a safe distance from the System during System startup or other activities that may involve splashing.

10. Never exceed the operating limits detailed in this user guide or on the System label. Operating the System outside of the stated limits may result in equipment damage and personal injury.
11. Using process or cleaning fluids that are incompatible with the flow-path materials can damage the System.
12. Do not connect components that are not rated for the System, this includes owner-supplied cassettes, flow-paths, hoses, tanks, and any other accessories.
13. Drain connections must be connected unrestrictedly to drain header and maintained at atmospheric pressure. Any valves in this path shall be locked open with suitable owner-safe procedures in place. Avoid pooling in drain lines.
14. Use a harmless fluid, for example water, during startup to enable detection of leaks without exposure to hazardous fluids.
15. Set alarm limits within the specifications noted in this User Guide or within the limits recommended in the software.
16. When alarms are triggered, address all of them one-by-one before continuing with System operation.
17. Due to a noise level of 80 decibels or greater, ear protection is required when the System pumps are operated at a speed of greater than (>) 6000 RPM.
18. For Systems equipped with an optional UV photometer, note the following safety guidelines:
 - **WARNING:** The photometer can emit light from $\approx 200 - 1100\text{nm}$. Hazardous UV and IR radiation are emitted from the unit. Never directly stare into the source/return ports on the photometer or the fiber optic cables, as this can cause eye damage. The viewer-related risk is dependent on how the users install and use the product.
 - Ensure that both ends of the fiber optic cables (photometer and flow cell connections) are properly secured (firmly hand tight) before powering on the photometer.
 - The photometer should always be powered off when handling the fiber optic cables. If you must handle the fibers when the unit is powered on, protective eyewear must be worn.
 - In the event of product failure, do not attempt to open the unit or replace the LED. There are no user-serviceable parts.

3.6 Warnings for System Maintenance



1. Obtain work permits such as lockout/tagout and other permits—per System owner's safety procedures before servicing or maintaining the System.
2. Improper opening of the electrical panel and incorrect lockout/tagout can lead to electric shock resulting in injury or death. To prevent injury or death from electric shock, follow your company's lockout/tagout and electrical panel entry procedures.
3. Due to a noise level of 80 decibels or greater, ear protection is required when the System pumps are operated at a speed of greater than (>) 6000 RPM.
4. If unqualified personnel open and work inside electrical power panels, injury can result from electric shock. To prevent injury by electric shock, ensure only qualified maintenance personnel open electrical power panels.
5. Only personnel authorized by Repligen should perform service, installation, and maintenance inside the System's electrical panels.
6. To ensure safe and correct operation, use accessories and replacement parts that are approved or supplied by Repligen.
7. Before inspecting or working on the System using ladders, check and follow local regulations for fall protection.
8. System must be turned off when replacing fuses to prevent electrical hazard. Any electrical work beyond the electrical connections procedure and fuse replacement should be performed by trained personnel only.
9. Opening the flow-paths without flushing them may result in injury from exposure to hazardous process fluids. To prevent this, purge, flush, and decontaminate the System before opening flow-paths. Always check the pressure readings on the System HMI to confirm depressurization has been achieved before performing maintenance activities.
10. Peristaltic pumps must be turned off when replacing either tubing or pump heads to prevent crushing/pinching hazard.
11. Repligen does not recommend use of Vaporized Hydrogen Peroxide (VHP) to clean the KrosFlo system.

4. System Specifications

Table 3. KrosFlo® System Feature/Component Specifications

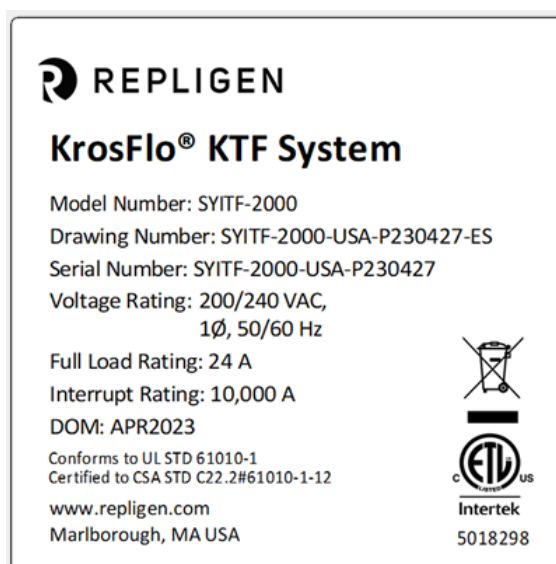
KrosFlo® System Feature/Component	Specification
Typical process volumes	30 L - 5000 L
Maximum filter area	2 each up to 17.2 m ² (Hollow fiber) 2 each up to 20 m ² (Cassettes)
Recirculation Pumps	Up to 2 Mag Lev (100 to 2000-series) Maximum configurable speed for the 2000SU recirculation pumps is: 6500 RPM
Flow rate	Each pump up to 85 LPM
Maximum pressure	Up to 2.0 Bar
Minimum hold up volume	200 mL to 6.0 L
Tubing	3/8 in ID to 1 in ID
Feed/Retentate flow meters	Clamp-on flow meter ultrasonic
Permeate flow meters	Clamp-on or flow through flow meter ultrasonic
Feed scale or Client signal (4 - 20 mA)	Up to 5000 Kg+
Cabinet width	30 inches (one or two recirculating pumps)
TMP control	Non-invasive/No-product contact
Pressure sensors	PS 0.25 in, 0.375, 0.5 in, 1.0 in, and 1.38 in
Auxiliary pumps	Tri-lobe SS Peristaltic pump
Programmable Logic Controller	Allen Bradley
Software	AVEVA® System Platform (formerly Wonderware) • AVEVA® InTouch • AVEVA® Historian • AVEVA® Historian Client • AVEVA® Application Server • Allen-Bradley® AVEVA® Operations Integration
DeltaV	DeltaV Connectivity Capable
GMP	21 CFR Part 11 Enabled

Table 4. KrosFlo® System Electrical Specifications

KrosFlo® System Model	Power Utility Required
SYIPS/TF/DF-200	200-240 VAC (±10%), 1Ph (Neutral and Ground), 50/60 Hz, 20A
SYIPS/TF/DF-600	200-240 VAC (±10%), 1Ph (Neutral and Ground), 50/60 Hz, 20A
SYIPS/TF/DF-700	200-240 VAC (±10%), 1Ph (Neutral and Ground), 50/60 Hz, 20A
SYIPS/TF/DF-1000	200-240 VAC (±10%), 1Ph (Neutral and Ground), 50/60 Hz, 30A
SYIPS/TF/DF-1600	200-240 VAC (±10%), 1Ph (Neutral and Ground), 50/60 Hz, 30A
SYIPS/TF/DF-2000	200-240 VAC (±10%), 1Ph (Neutral and Ground), 50/60 Hz, 30A

Note:

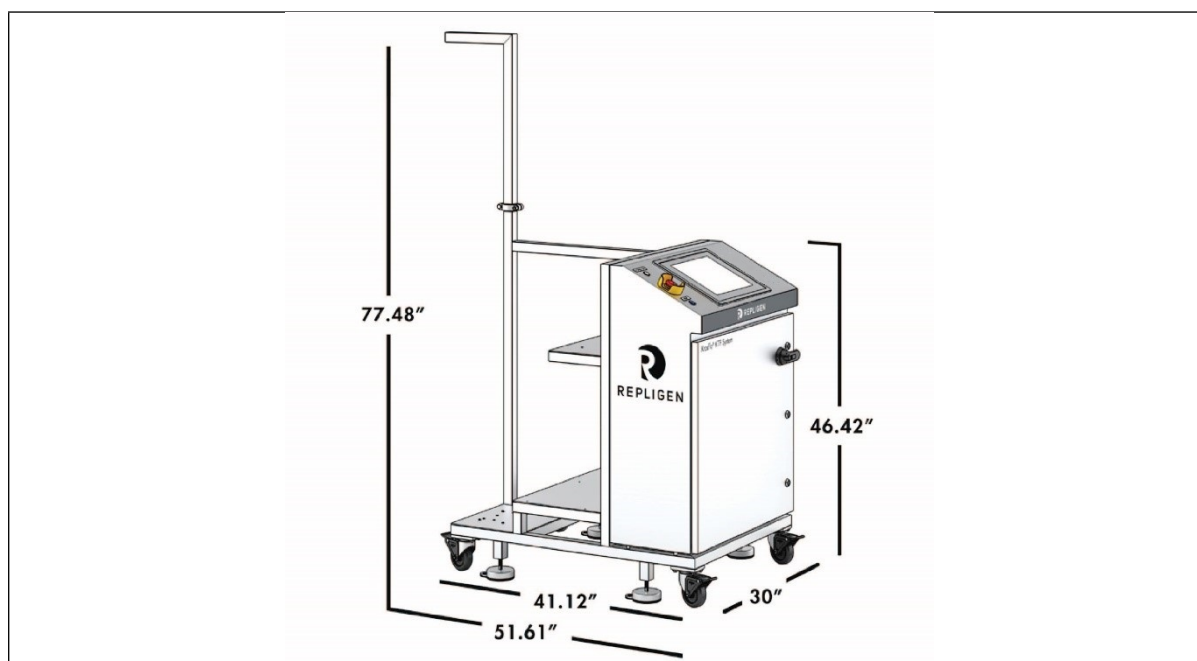
Below is a sample System machine designation label, located on the back side of the controller cabinet. Observe all listed electrical ratings and ensure those are met before using the System.

Figure 1. Sample Machine Designation Label**Table 5. KrosFlo® System Environmental Specifications**

KrosFlo® System	Specification
System Weight	300 lbs./135 Kg (approximately)
Operating Temperature	0 to 40° C/32 to 104° F
Operating Humidity	≤ 80%
Operating Altitude	Up to 2000 m
Pollution Degree	Pollution Degree 2
Chemical Resistance	Frame and Controller Cabinet: SS-304 Casters: SS-304 and Polyurethane Flow-path Components: Polypropylene, polycarbonate, Polysulfone, and C-Flex/Pharmapure materials
Intended Use Environment	For Indoor Use Only

5. System Dimensions

Figure 2. KrosFlo® System Dimensions



30-inch Controller Cabinet Models:

KTF-200, KTF-600, KTF-700, KTF-1000, KTF-1600, and KTF-2000

6. RoHS and WEEE Compliance



Repligen Corporation sources and uses only RoHS compliant materials in all applicable product lines and has met its obligations to the EU WEEE and Battery Directive by registering in those countries to which The Repligen Corporation is an importer.

Repligen Corporation has also elected to join WEEE and Battery Compliance Schemes in some countries to help manage customer returns at end-of-life.

The presence of the crossed-out wheeled bin label on this product implies that the product contains electrical or electronic materials that may be hazardous and present a risk to human health and the environment when waste electrical and electronic equipment (WEEE) is not handled correctly. Electrical and electronic equipment and batteries must be disposed of in an appropriate manner, separate from standard unsorted waste streams. As legislation and disposal facilities may vary throughout the European Union member states, please contact Repligen Corporation (customerserviceus@repligen.com) for further information regarding the proper disposal of products marked with the crossed-out wheeled bin label.

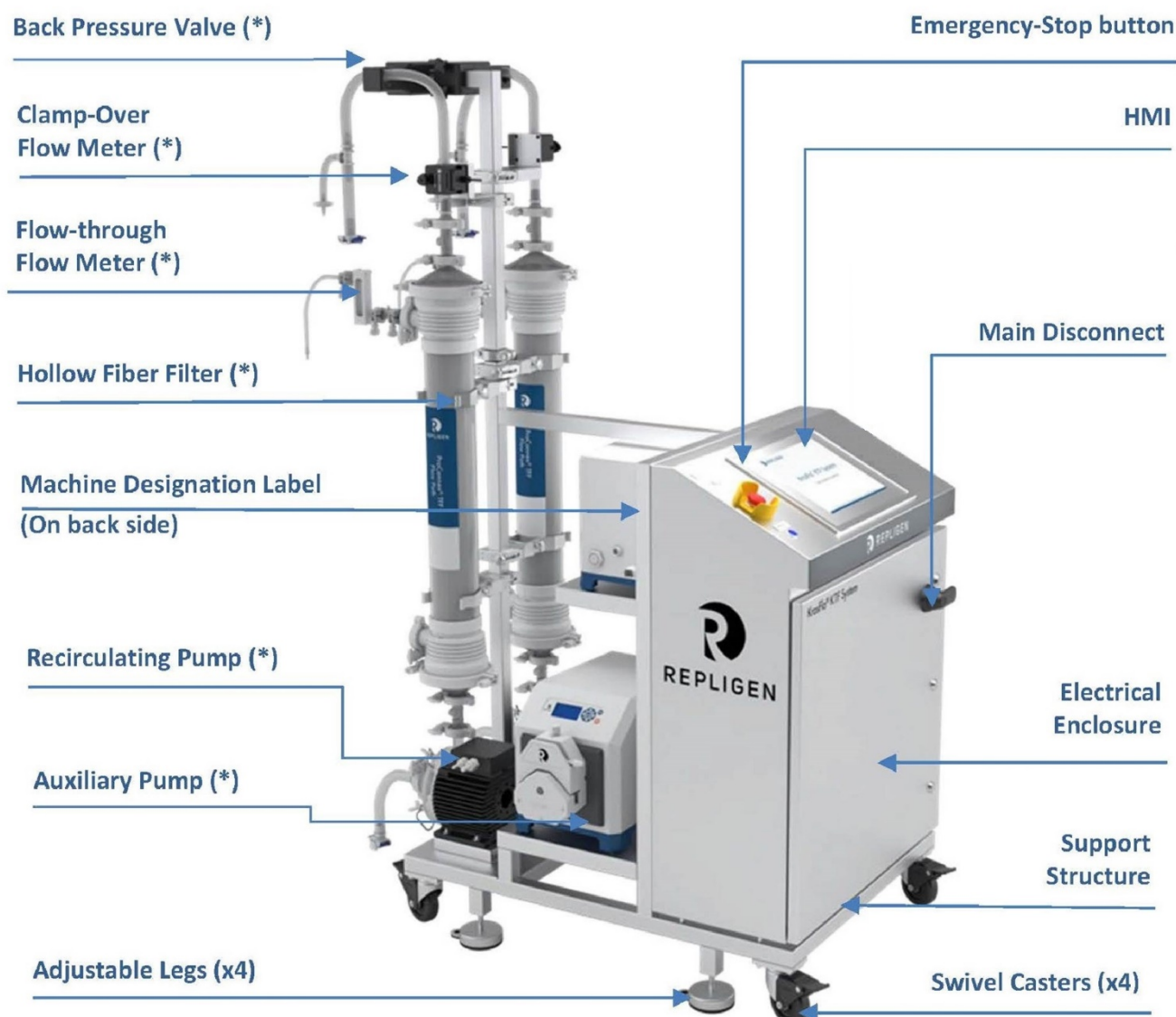
For disposal in countries outside of the European Union. This symbol is only valid for use within the European Union (EU). If you wish to discard this product, please contact your local authorities for the correct method of disposal.

7. System Overview

7.1 Main System

An overview of the typical System is presented below.

Figure 3. KrosFlo® System Overview



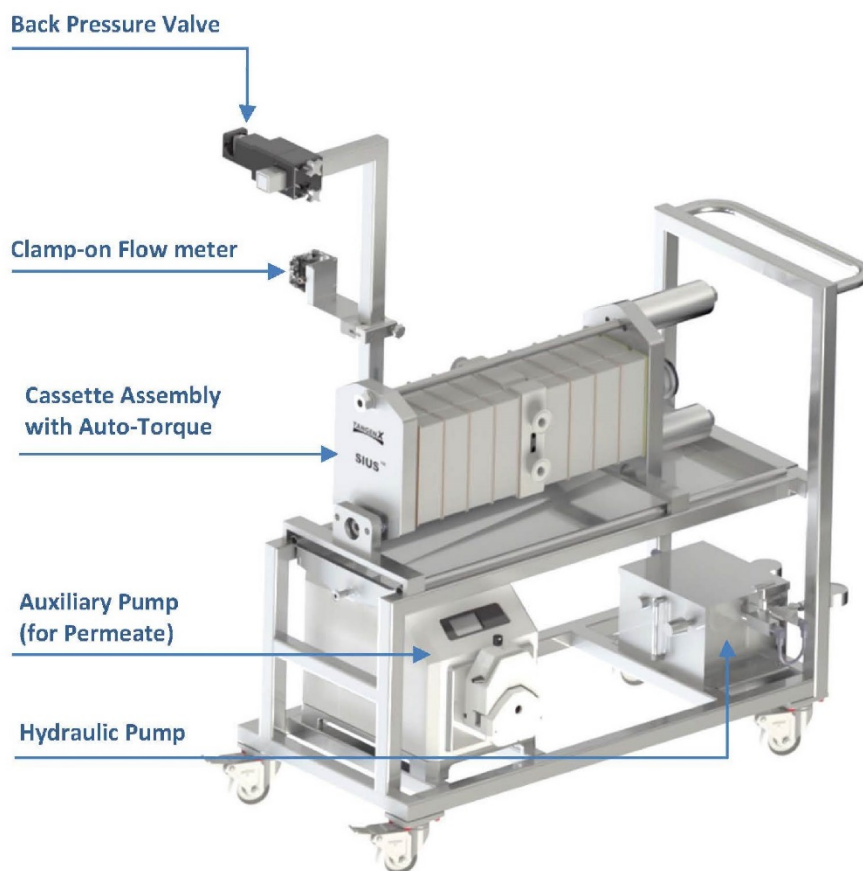
Note:

(*) The specifications and quantity of these components are subject to change depending on System configuration.

(**) The System may come with other kits and carts such as scales, cassette carts, tanks, etc. Refer to individual component User Guides for more information.

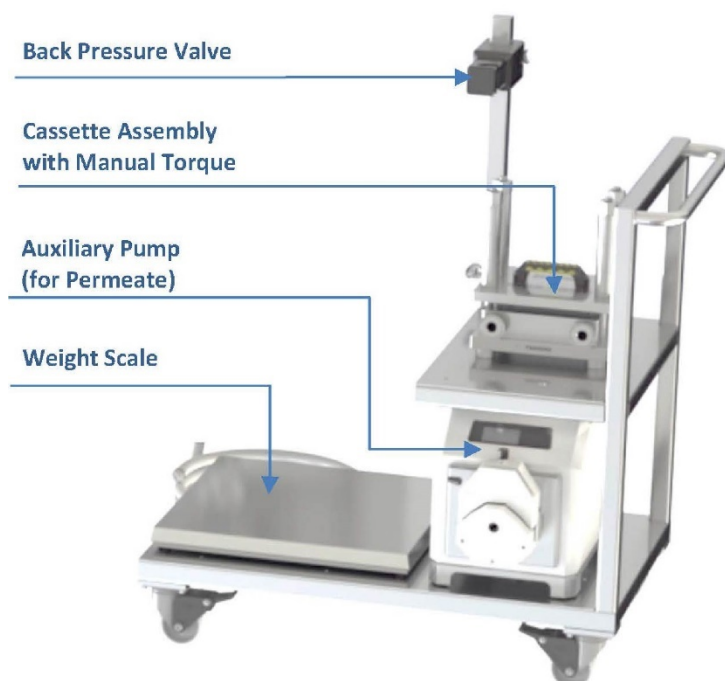
7.2 Cassette Holder Cart (optional)

Figure 4. Optional Cassette Holder Cart



7.3 Auxiliary Cart (optional)

Figure 5. Optional Auxiliary Cart



8. Unpacking the System



WARNING – Refer to section 3 for complete Safety Precautions.

The KrosFlo System is intended to be unpacked and installed by trained service personnel only. Do not attempt to lift the System. The System should only be moved by carefully rolling the System on its casters. The System shipping crate includes an integral ramp that allows the System to be rolled out of the crate. Be sure to set the brake on each caster to prevent unintended motion.

Follow the high-level steps below to unpack the KrosFlo System:

1. Check and confirm that all boxes have been received. The wooden crate contains the System.
2. Place the forklift blades under the crate in a centered position, and transport the System close to its intended operating location.
3. Unscrew and remove the front panel (the panel with the ramp built-in).
4. Safely set that panel down, close to the crate. This panel will act as a ramp.
5. Unscrew and remove three reinforcing bars from the crate.



6. Unlock the System two front wheels.
7. Using at least two people, carefully pull the System out the crate and move it off the ramp.
8. Unwrap the System.
9. Visually inspect for any possible shipping damages. If found, notify Repligen immediately.
10. Extend the leveling feet and adjust them until the System is properly leveled.
11. Check the rigidity and tightness of components to their supports, ensuring vibration during shipping did not loosen them.

Note:

- Loose components such as auxiliary pumps, back pressure valves, flow meters, and other miscellaneous components are packed separately in several carton boxes.
- Open all the boxes and check if all components are received.



9. Performing Mechanical Installation

The KrosFlo System has a small footprint and requires only a small clean area (approx. 3m x 3m/10 ft. x 20 ft.) for assembly. No tools are needed for System assembly, though some basic hand tools such as screw gun, pliers, and screwdrivers are needed to uncrate the System.

Some of the major components listed above are mounted on the cart. The other components can be removed from boxes and installed on the cart for use in the process.



WARNING – Refer to section 3 for Safety Precautions

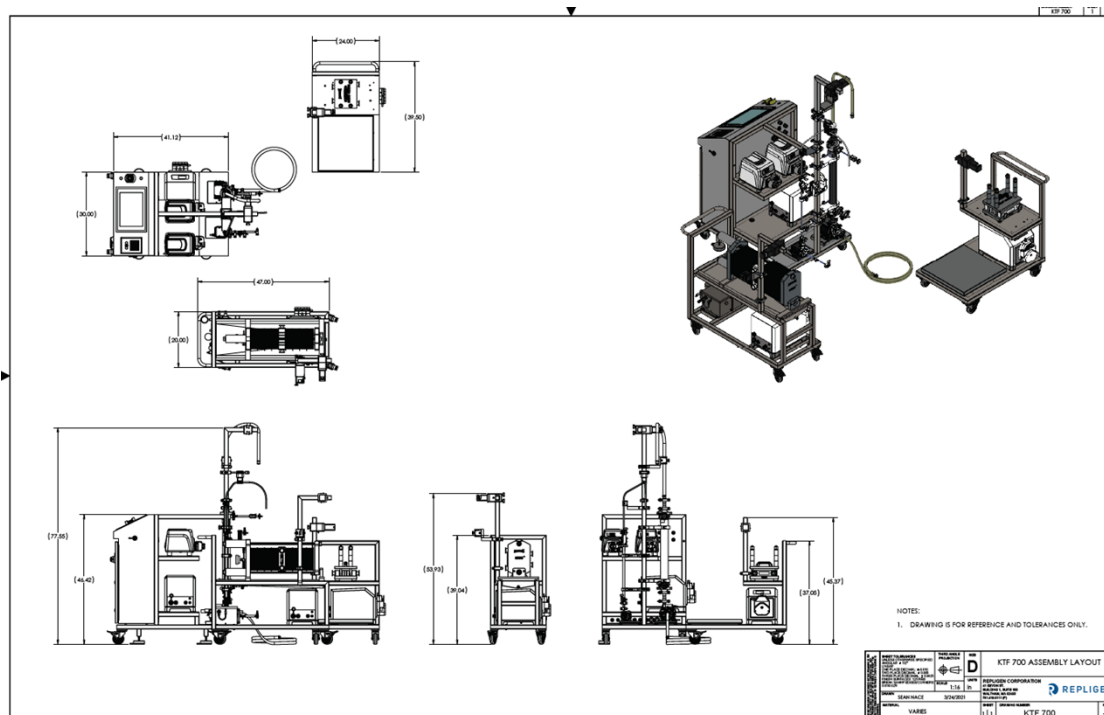


WARNING – Do not plug in or introduce electricity to the System during Mechanical Assembly.

9.1 Main System Assembly

Follow these high-level steps to assemble and install the main System:

1. Uncrate the System and remove all packaging material from the System components.
2. Refer to the System General Arrangement to verify relative locations of all components.



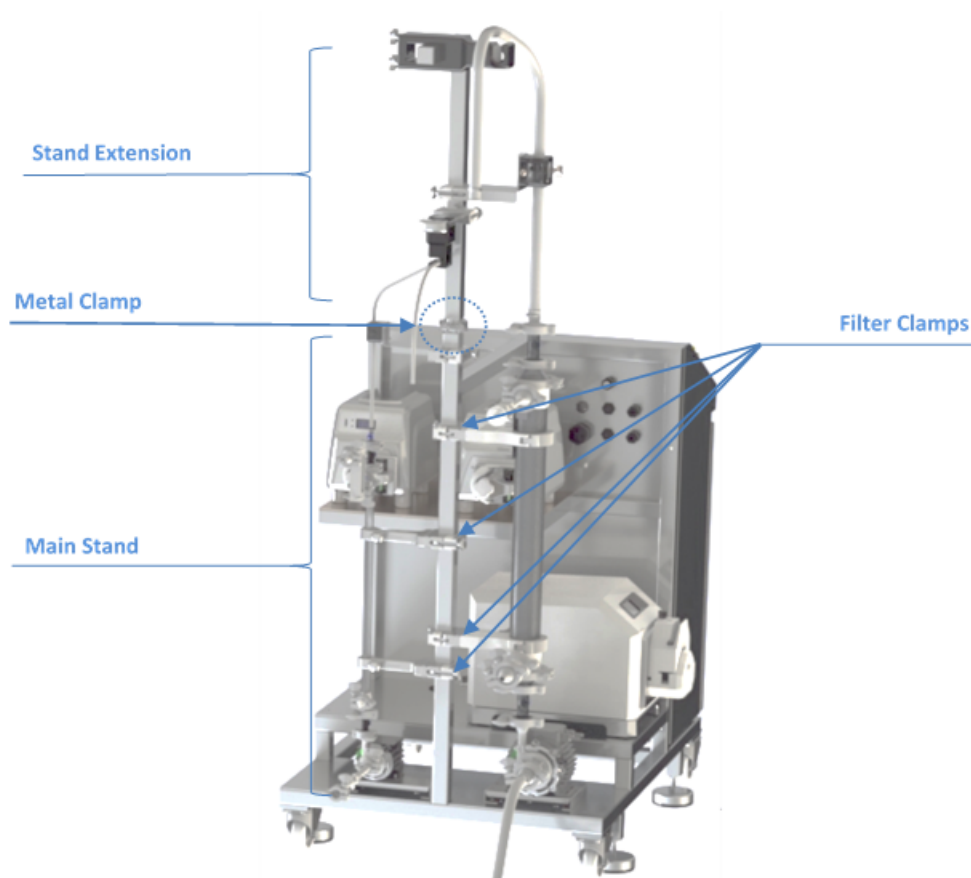
3. Remove the Stand Extension from the frame.
4. Place a black rubber gasket between the Stand Extension and Main Stand.

5. Attach the Stand Extension.
6. Secure the Extension with the provided metal clamp and hand tighten, or with a wrench.
7. Locate and attach the proper filter brackets to the frame.
8. Place the Buffer Pumps on the lower cart frame.

Note:

- The Recirculating Pump(s) come already mounted.

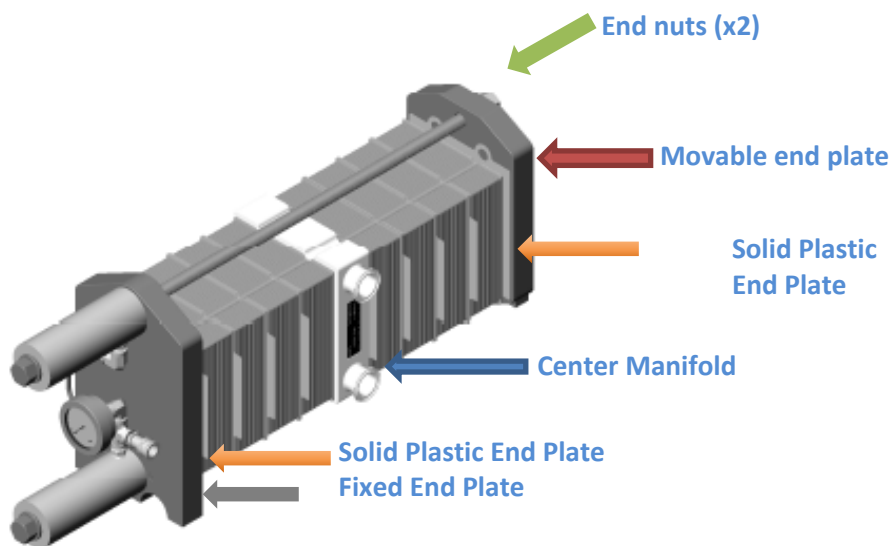
Figure 6. Pump Stand Assembly



9.2 Cassette Holder Assembly (optional)

9.2.1 Cassettes Installation

Figure 7. Cassette Installation



To install cassettes into the holder:

1. Place the single-use Center Manifold into the holder first. (Blue Arrow)

Note:

- The feed and retentate ports need to face the System's main recirculation pump.
- The ports are clearly labeled.

2. Properly and evenly extend out the 2 end nuts (Green Arrow) by loosening them to the proper length, a length that can accommodate all required cassettes on each side.

Note:

- If only one cassette is used, then it should be placed up on the fixed side or piston-end (left side), followed by the Center Manifold.

3. Add cassettes from the fixed end plate (Gray Arrow) towards the Center Manifold.
 - a. Start with Solid Plastic End Plate (Orange Arrow) against metal facing side.
 - b. Then add a cassette block.
 - c. Wet the gasket, then install it right next to the cassette block.
 - d. Repeat steps b) and c) above until the required number of cassettes is installed.

Note:

- A gasket must be wetted and installed between a cassette and the Center Manifold.
- Gaskets need to be aligned carefully and should not block channels on the cassettes.

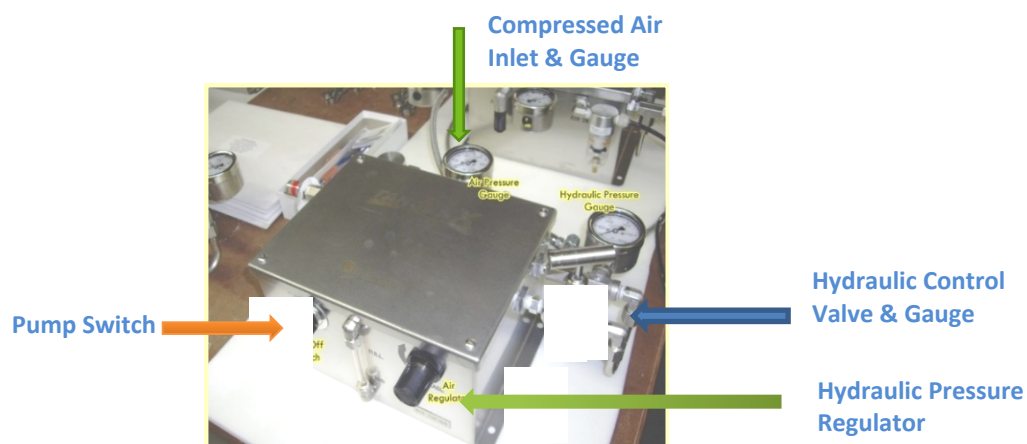
4. Repeat everything in step 3) on the movable end plate (Red Arrow), to get an equal number of membrane "blocks" on each side of the Center Manifold.

Note:

- Another Solid Plastic end plate should be installed between the movable end plate and a cassette block.
5. Slide movable end plate (Red Arrow) up against the cassettes, as close as possible.
 6. Tighten two end nuts (Green Arrow), leaving an approximate ¼" gap to the endplate.

9.2.2 Hydraulic Pump Preparation

Figure 8. Hydraulic Pump Components



To prepare the hydraulic pump (also referred to as an auto-torque):

1. Make sure Pump Switch (**Orange Arrow**) is in “off” position.
2. Make sure Hydraulic Valve (**Blue Arrow**) is in “close” position by turning it clockwise.
3. Make sure a hydraulic hose is firmly installed between the Hydraulic Pump and the Cassette Assembly.
4. Connect Compressed Air supply to the air inlet (**Red arrow**).

Torquing:

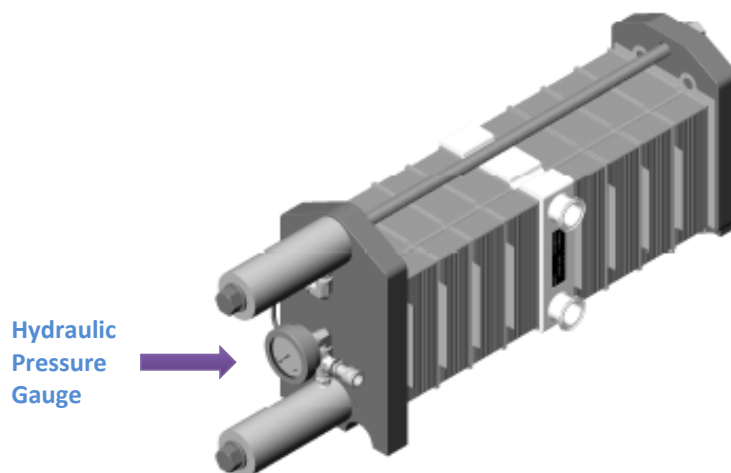


WARNING – Exert extreme caution to prevent crushing or pinching hazards during torquing.

5. Pull the regulator control knob (**Green Arrow**) and turn it counterclockwise to reset hydraulic pressure.
6. Introduce Compress Air into the air inlet (**Red arrow**). Observe the pressure on the gauge and make sure it is within 60-100 psig.
7. Turn the Pump Switch to “on” position (**Orange Arrow**).
8. Open the Hydraulic Valve (**Blue Arrow**) by turning it counterclockwise.
9. Pull the regulator control knob (**Green Arrow**) and turn it clockwise to increase hydraulic pressure.

Note:

Observe the pressure readings on Hydraulic Pressure Gauges, located either on the hydraulic pump (**Blue Arrow**) or on the cassette assembly (**Purple Arrow**). These two readings should match.



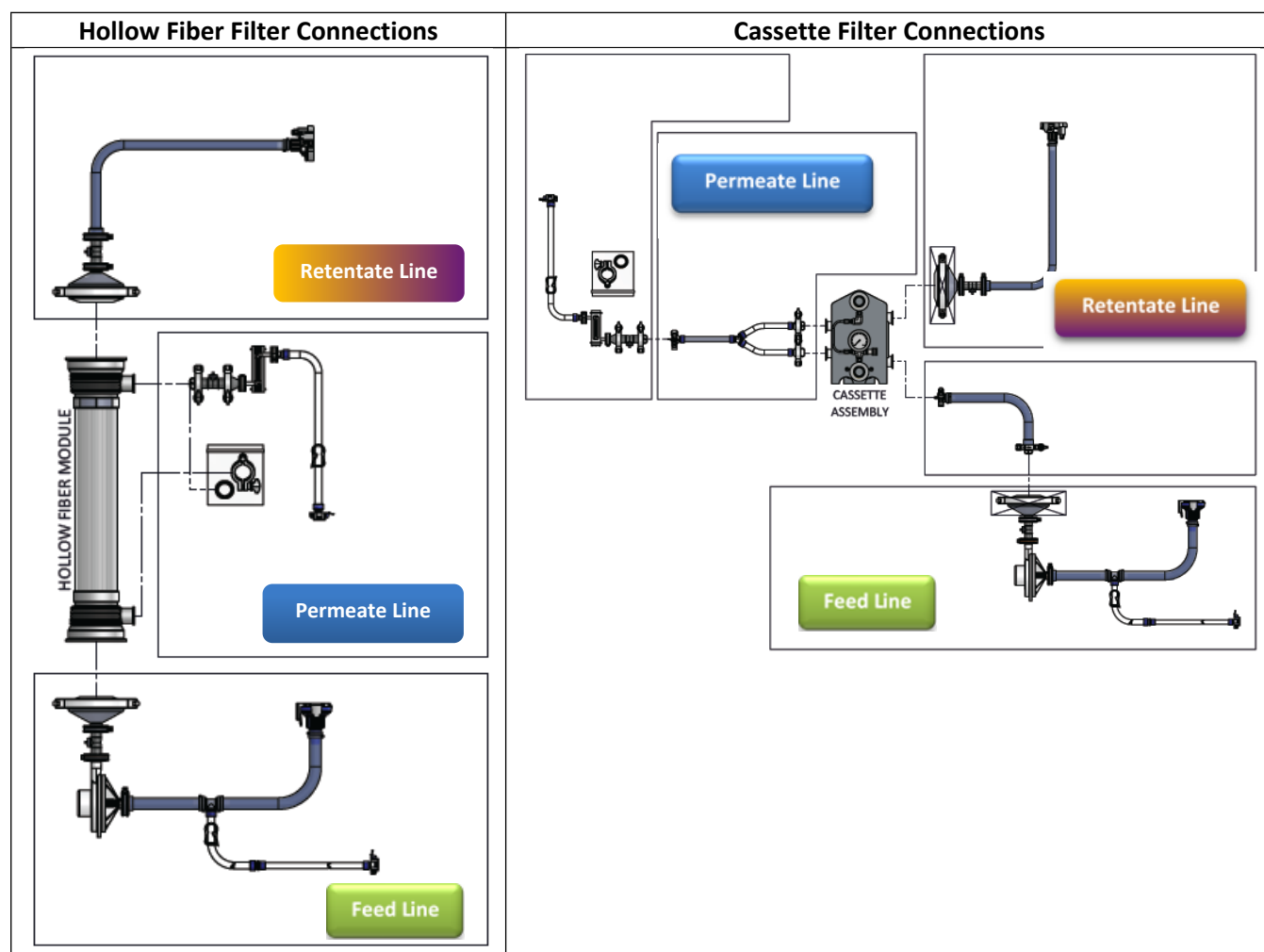
Below are some recommended pressures. Refer to Manufacturer's datasheets for more information.

Cassette Brand	Suggested Pressure
TangenX	1200 psig
Millipore	1800 psig
Pall	1200 psig
Sartorius	1300 psig

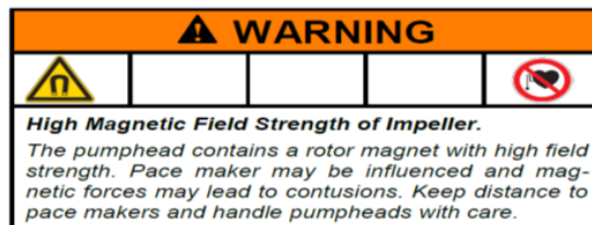
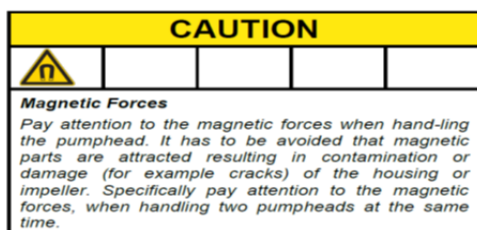
9.3 Single-Use Flow-path Assembly

Below is an overview of a typical flow-pathset with optional connections to either Hollow Fiber or Cassette Filters.

Figure 9. Typical Flow Path with Hollow Fiber and Cassette Filter Connections



9.3.1 Recirculation Pump Preparation and Connections



Follow these high-level steps to install and assemble the Single-Use Flow-path:

1. Remove backing material of disposable pump head, which contains a plastic cup and a large metal washer.
2. Line up pump head to the wing nut mounting holes and pump socket (**Blue Arrow**).
The locking pin will click into place once pump head is properly oriented with motor.

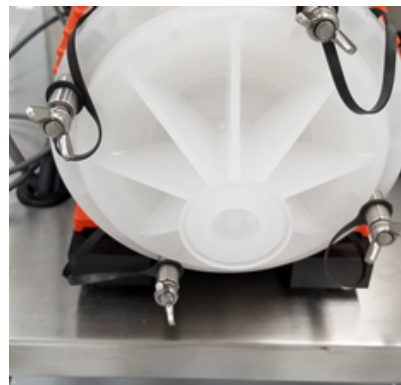
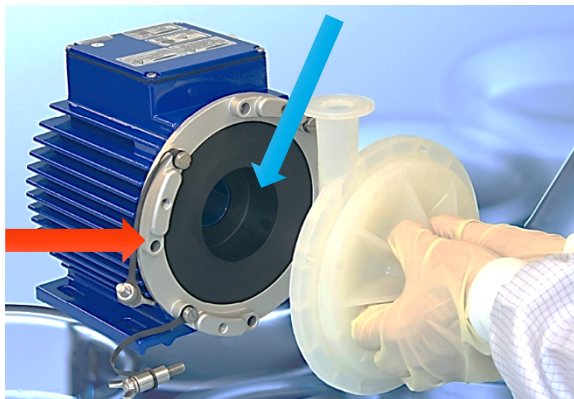
Note:

- A strong magnetic force will suddenly pull the pump head into the motor socket. Be careful not to pinch finger between pump head and motor.
- To avoid rubber straps being tangled, pull them out of the way during this step.

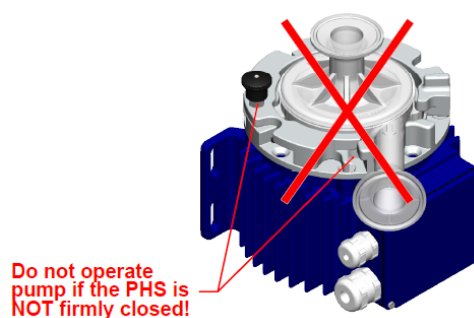
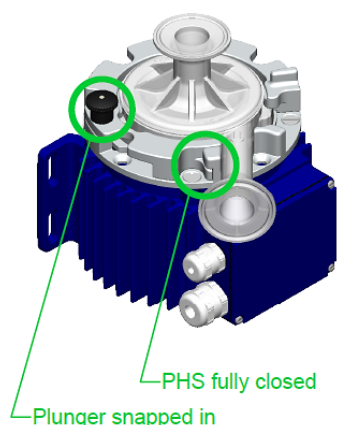
3. Use fixation screws to secure pump heads to the motor

Note:

Hand-tight is enough because the screws are only used to keep pump head in place. Overtightening these screws may cause damages.



4. Alternatively, if the pump has Head Socket, rotate the top ring CCW until the plunger is snapped in and Pump Head Socket (PHS) is firmly closed.



If Hollow Fiber Filter is Used (continue with these steps):

1. On Support stand, locate two black clamps and set them open.
2. Align the components below:
 - Outlet of Recirculation pump head.
 - Inlet of Hollow Fiber filter assembly.
 - Centers of two clamps.

Note:

- Make sure the clamps attach to the clear section of the housing, not on end fittings.
3. Close the clamps, one by one.

Note:

- Inspect the filter and pump before tightening clamps in place. There should be no strain placed upon any of the filter, pressure sensor, or pump connections.
 - Make sure pump is not tilting or being pulled off center since the integrity of the set up could be compromised.
 - Check and hand-tighten any Tri-Clamps on the assembly.
4. Open the “door” of the flow meter, place tubing inside the channel Run retentate through the flow meter (**Red Arrow**). Make sure tubing is clean and free of debris.

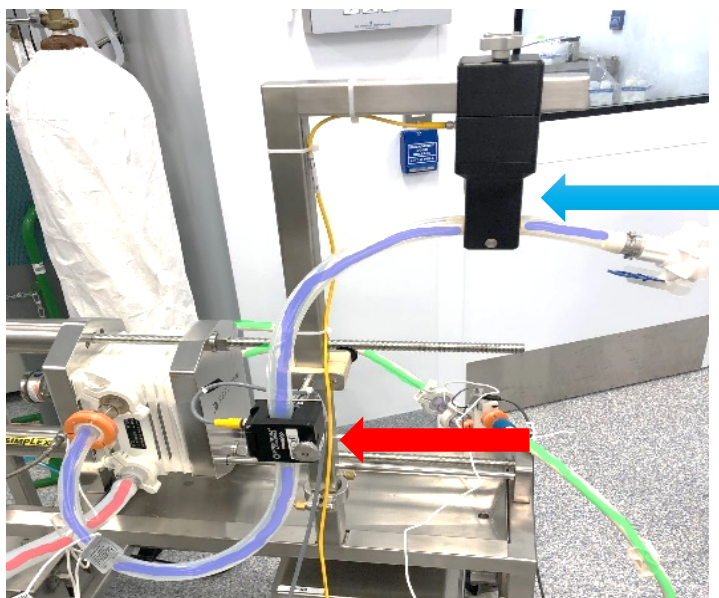
Note:

- Leave 10 to 15 cm (4 to 6 in.) of straight run tubing on each side of the flow meter.
 - Make sure the tubing flow direction arrow on meter should point in up direction.
5. Position retentate tubing through the open part of the back-pressure valve. Pushing the tubing into the valve and making sure it rests totally within the cavity of the valve (**Blue Arrow**)

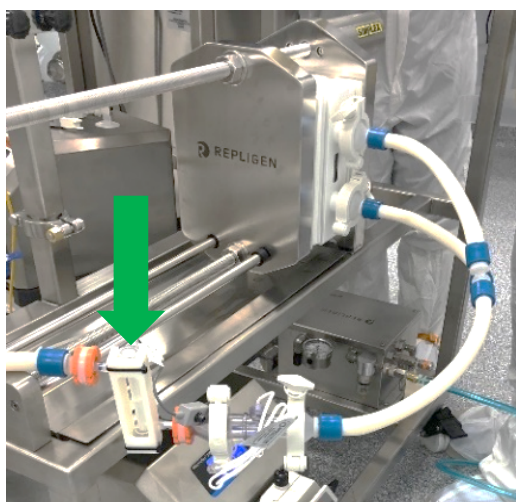


If Cassette Filter is Used (continue with these steps):

1. Make sure the Cassette Assembly has been properly prepared and torqued.
2. Open the “door” of the flow meter, place tubing inside the channel. Run retentate through the flow meter (Red Arrow). Make sure tubing is clean and free of debris.
3. Position retentate tubing through the open part of the valve. Pushing the tubing into the valve and making sure it rests totally within the cavity of the valve (Blue Arrow).



4. Make sure the flow through ultrasonic flow meter is in the vertical position with outlet at the top, so air bubbles will not be trapped in the meter (Green Arrow).
5. Secure the flow meter, by tying it to the base plate of the cassette holder (Orange Arrow).

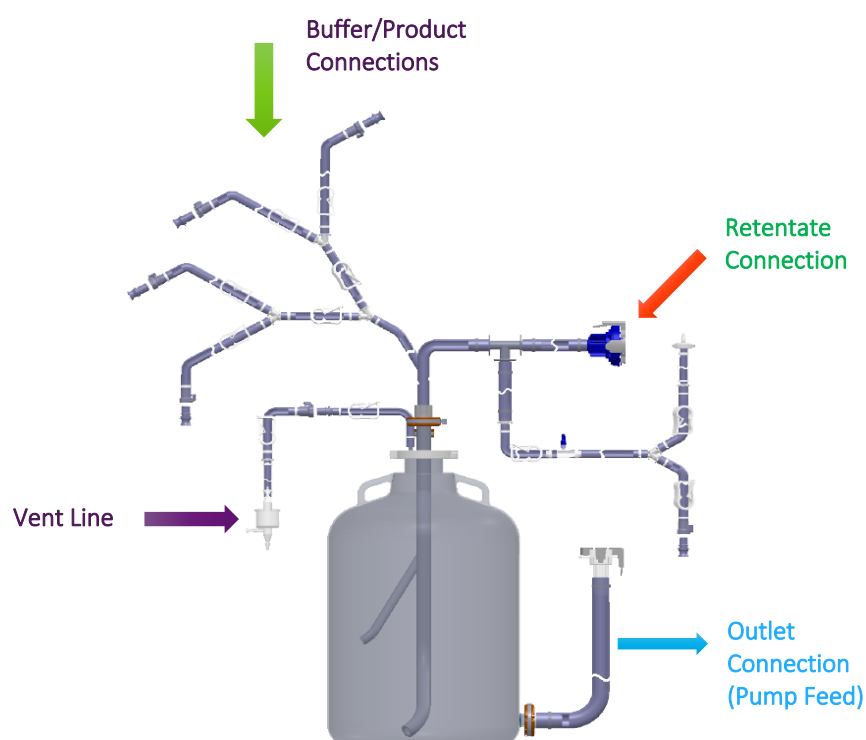


9.3.2 Feed Tank/Reservoir Connections

A typical Feed Tank or Reservoir is presented below:

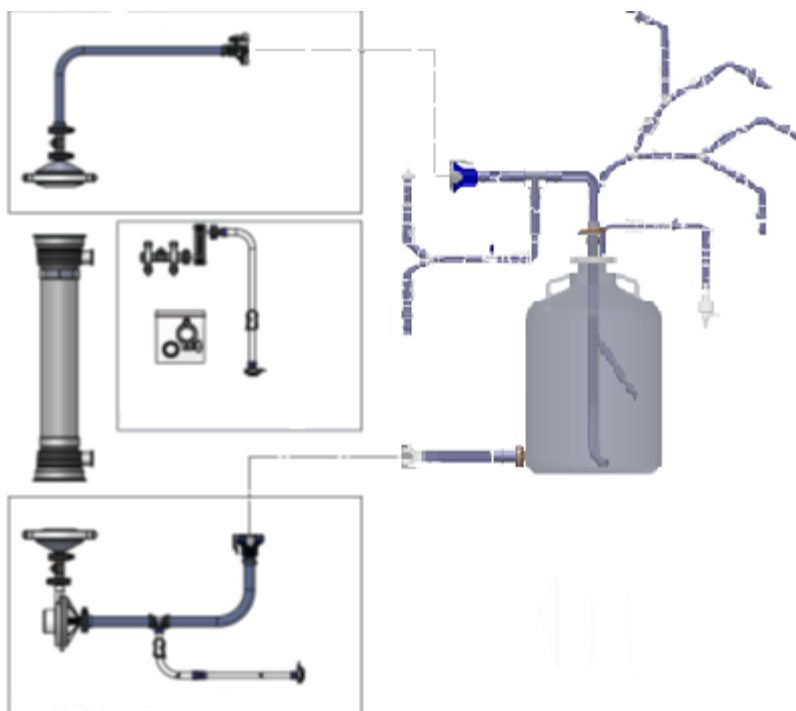
- The lowest tube is the pump feed line.
- The bent dip tube is the retentate/return which should be rotated to the wall of the reservoir to minimize foaming and to amplify mixing.
- Buffer/Product-in is through the top port of the cap.
- The vent line is connected to a filter. This filter must be sized properly to minimize any vacuum which could impact TMP control valve and permeate flux rate.

Figure 10. Typical Feed Tank or Reservoir Connections

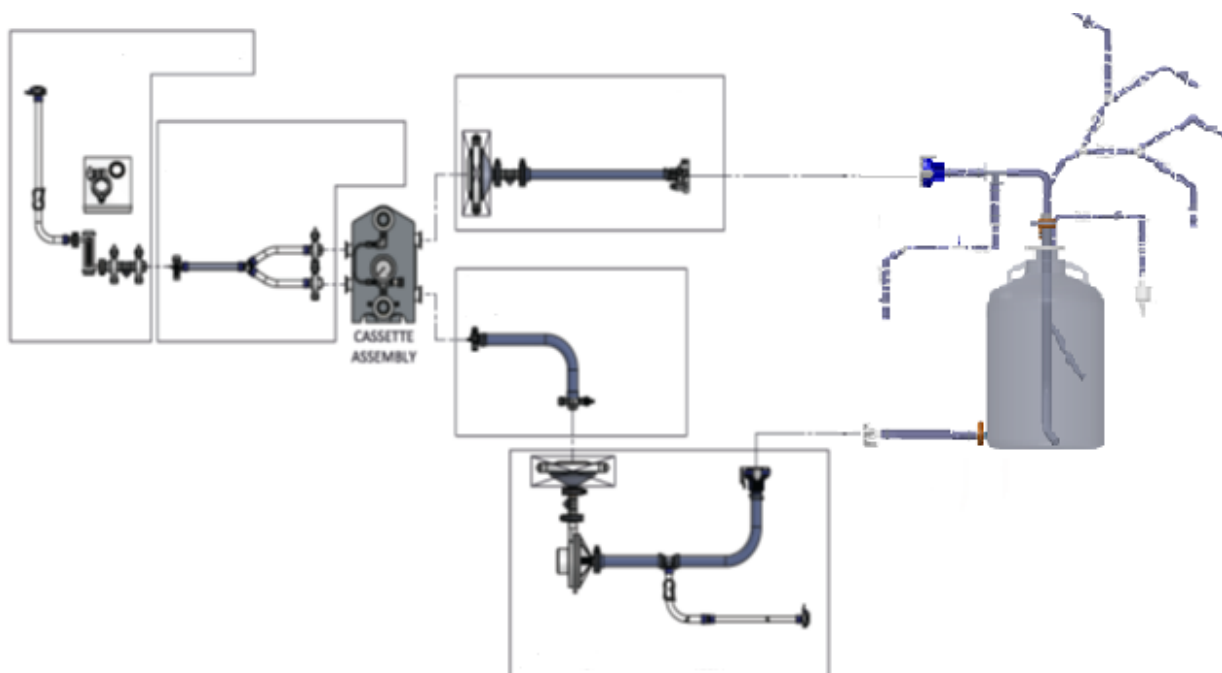


- Typical Feed Tank/Reservoir to KrosFlo System connection diagrams are presented as below:

If Hollow Fiber Filter is used:



If Cassette Filter is used:



9.3.3 Installing Auxiliary Pump Tubing

CAUTION

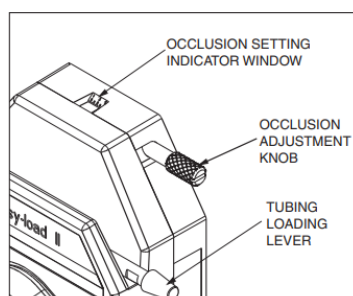
Make sure the tubing is appropriate for the process flow rates and the pump.

CAUTION

Make sure the pump rotation is in accordance with process flow direction.

Note:

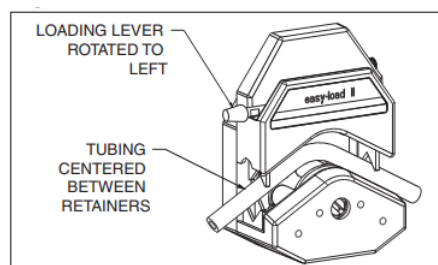
- The following tubing installation procedure is for MasterFlex I/P pumps with standard pump heads. For other model/maker pumps or pump heads, please refer to the manufacturer user documentation.
- Set occlusion adjustment knob to “1”.
 - Open pump head by turning the loading lever to the left.



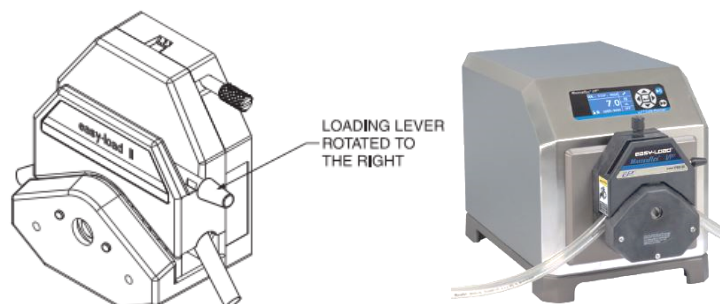
- Place tubing on the center of the rollers with the IP pump head and use the lever on top of pump head to close.

Note:

- Keep the tubing length on the pump inlet as short as possible (less than 2 meters / 6 feet). Make sure tubing is properly centered and not pinched by the retainers.



- Close pump head by turning the loading lever to the right.



- Adjust Occlusion setting to “3” in normal performance, “4” or “5” is for increased head pressure or if more suction is required.

Note:

- The occlusion knob tends to get stuck due to salts, please inspect and clean frequently.

10. Performing Electrical Installation

All electrical connections are made with the plugs and sockets located on the rear side of the controller cabinet.

CAUTION

When connecting cables, make sure the component tags and cable labels match.

10.1 Sensor and Communication Cables

10.1.1 Pressure Sensors

Polysulfone pressure sensors/transmitters are included as part of the sterile disposable ProConnex® flow-path that is shipped with your System.

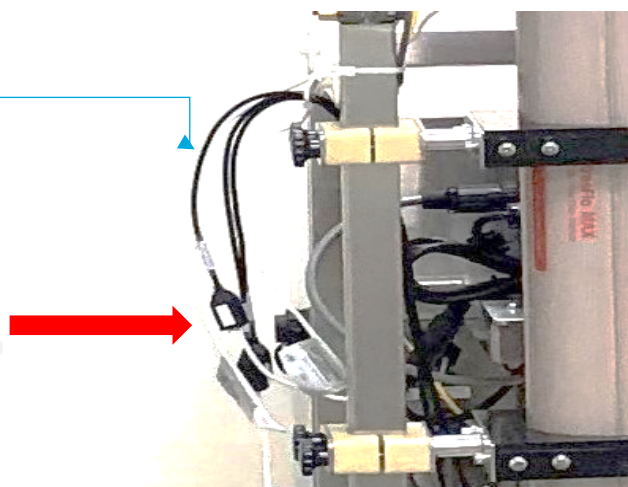
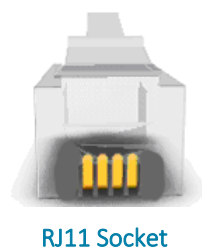


Typically, there are three pressure sensors one on the System, one on Feed line, one on Retentate line, and one on Permeate line.

Each pressure transmitter is terminated with a RJ-11 connector (similar to a phone jack (**Red Arrow**)).

1. Look for the labels on the octopus-cable and plug the designated connectors to the labelled sockets.
2. Make sure all three pressure sensors are all connected, per each flow-path. This includes one on filter feed line, one on retentate line, and one on permeate line.

Octopus cable



10.1.2 Installing Ferrite Bead for Pressure Sensors

A ferrite bead (P/N 3000541) is provided for each pressure sensor to protect it against possible electromagnetic interference (EMI). It is recommended to install the ferrite bead on each flow-path pressure sensor cable to provide EMI protection for the pressure sensor.

To install the supplied flow-path pressure sensor ferrite bead:

1. Locate the ferrite bead as close as possible to the flow-path pressure sensor while ensuring there is enough cable to wrap around the ferrite bead.
2. Open the ferrite bead.



3. Seat the flow-path pressure sensor cable in the bead.



4. Wrap the cable around the bead.



5. Snap the bead closed.



The installed Ferrite Bead and Pressure Sensor should look like this.



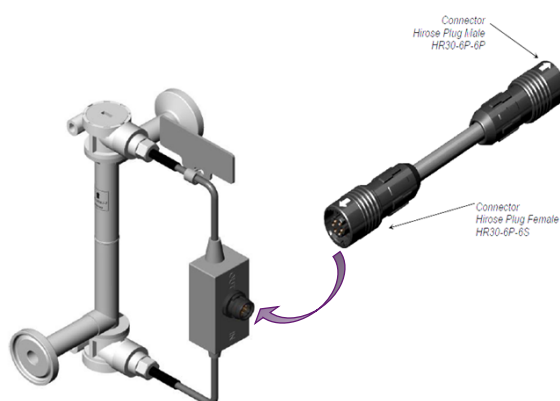
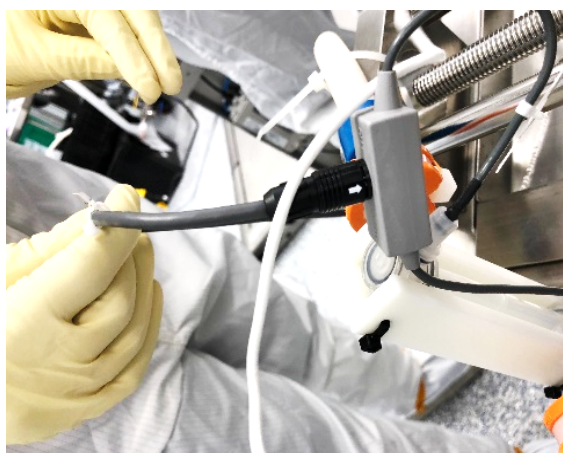
10.1.3 Installing Permeate Flow Sensors

A Flow-through Permeate Flow Sensor is included as part of the sterile disposable ProConnex® flow-path (Module Bag Tubing - MBT) that is shipped with your System.

1. Align white arrow on cable to white dot on the flow transmitter.
2. With the collar pulled back, slide the connector into position.
3. Push the collar forward to lock the connector into place. This is a push to connect connection.

Note:

- Use cable extensions if needed.
- Before disconnecting, the collar should be retracted first.

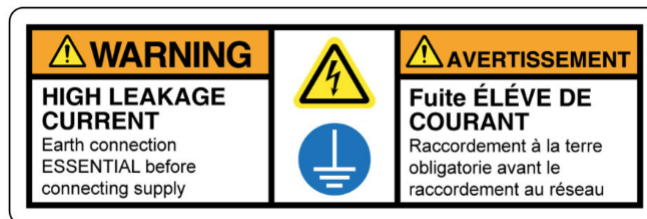


10.1.4 Other Sensor and Communication Cables

Connect the sensor plugs to the waiting sockets. Depending on the System configurations, these connections may include:

- Flow meters
- Pump Communication
- External inputs from permeate tanks or bioreactors.
- Integrated Scales
- Ethernet cables.
- Conductivity Sensors
- Turbidity Sensors

10.1.5 Connecting the System Power Cables



WARNING – To avoid risk of electric shock, this equipment must only be connected to AC mains with protective earth using a twist lock connector. No modification of this equipment is allowed.

WARNING – Do not plug in or introduce electricity to the System until instructed to do so.

Note:

- The KrosFlo System power cord is shipped without a power connector attached to the power cord cable.
- Attach a power connector that is appropriate for the local power supply to the KrosFlo System power cord cable (a SJOOW, 12-gauge, three-wire cable).

To complete the System electrical connections:

1. For pumps on the main skid, connect power connectors to the panel.
2. For pumps on the auxiliary skids, connect power connectors to the external power outlets.
3. Connect **Main Panel power cord** to a suitable electrical outlet using an IEC 60309-compatible twist lock connector. (See section 4 for detailed ratings).

11. Using the System HMI

11.1 Human Machine Interface (HMI) Overview

The KrosFlo System Operating System is an AVEVA® (Wonderware)-based program installed on a touchscreen HMI PC. The program consists of five primary screens – **Home**, **Process** (Operational), **Alarms**, **Settings**, and **Diagnostics**. Screen navigation is performed using the navigation bar buttons on the top left side of each primary screen. Simply touch the button to go to the desired screen.

To end a session, select the Logout button to log out of the HMI, then close the HMI program before turning off computer.

Following a configurable period (0 to 10 minutes) of HMI inactivity, the user will be logged out and must log back in before being able to resume system operations using the HMI.

Note:

Note that for the sample HMI screens that follow, a sample HMI screen may not match the HMI screen supplied with your installed system exactly, but the functions referenced will still be present, and the general screen layout (Left, Right, Top, Bottom) will be consistent.

11.2 Getting Started

The KrosFlo System is ready to run after all Mechanical and Electrical Installation steps have been completed.



To start up the System:

1. Make sure that the Emergency Stop button is pulled to OUT (inactive) position.
2. Rotate the Main Power Disconnect for 90 degrees clockwise.
3. The computer starts and the control software loads automatically.
4. Press the Reset button on Control Panel.
5. Once the computer is booted up, the system is set to automatically logon a special named account without any user interaction.
6. If a different user is required for logon, wait for the system to completely boot and logon, and then use the logout function of Secure Desktop to exit the user session to return to a Windows Login Screen.
7. Once the PC boots up, wait at least 2 to 5 minutes before opening the HMI application (InTouch WindowViewer). This is to allow the various AVEA (Wonderware) software components and services to all load up in the background. If InTouch is opened too soon, the application will not connect to the underlying AVEVA® software components and not function correctly.
8. Select the Process  icon to navigate to the Process screen.

Note:

- Press “Logout” first if the System is still shown as being logged-in by another user.
 - At startup, the KrosFlo System will display all alarms as being active; they should be acknowledged, and a reset should be performed to clear any latched faults before operating the KrosFlo System.
9. To log-in to the System, select Login, enter a pre-configured user account name and password, and then press OK.

Note:

- Contact IT Administrator of User's organization for pre-configured account details.
For a detailed matrix of actions and security levels, please refer to the Security and Logon subsections in the chapter on security in the *Core Standard Platform Software Operations Manual*.

10. From the Process screen, select the Ack Alarms button. All Alarms will be cleared.

Note:

- Pressing the Reset button on the control panel enclosure will only reset the Master Control Relay at startup, power outage, or Production Stop.
- All other alarm conditions are reset from the HMI.
- Be sure to exit the HMI, and shutdown Windows before shutting down the System.

11.3 Loading and Running Recipes

A recipe is set of instructions that are executed automatically by the PLC and HMI to run a Tangential Flow Filtration (TFF), Perfusion, or Tangential Flow Depth Filtration (TFDF) process on the KrosFlo System.

There are two basic types of recipes, Operations and Unit Procedures. An Operation executes a series of pre-configured phases. Each phase contains a set of transitions and/or a prompt that controls which phase is executed next. Unit Procedures execute a series of pre-configured, approved Operations. The operations in a Unit Procedure are specified as a single list that are executed in the configured order. There is no logic or branching in a Unit Procedure.

Recipes are created and modified using the standalone Recipe Editor program, and are stored in the KrosFlo System database. Refer to the *Recipe Editor Software Operations Manual (SOM)* for detailed instructions on using the Recipe Editor.

Figure 11. Recipe Selection Screen

The screenshot shows the 'Recipe Selection' window. At the top, there is a 'Recipe Type' dropdown set to 'All Recipes' and a 'Filter' input field. A 'Recipes Refreshed' button is in the top right. Below this is a table of recipes:

Description	Version	Status	Product	Name
CDC Lines 1 and 2	5	Approved		op-KTF-CDC-L1L2
Fill Vessel using Product Pump P401	2	Approved		op-KTF-P401Fill
Product 1 Batch	1	Approved		up-KTF-Product1-Batch
Product 1 Fed-Batch	1	Approved		up-KTF-Product1-FedBatch
Retest Procedure: Other Discrete Commands	2	Approved		OP-KTF-SFAT-OtherDiscreteCo
Test Procedure: Basic Functions & Security	2	Approved		OP-KTF-SFAT-S88OpBasicFunc
Test Procedure: Basic Functions & Security	1	Approved		UP-KTF-SFAT-S88OpBasicFunc
Test Procedure: Batch Report Parameter Summary for Parameters Updated by a User	1	Approved		op-KTF-SFAT-OBS15-Paramete
Test Procedure: Batch Report Parameter Summary for Parameters Updated by a User	1	Approved		up-KTF-SFAT-OBS15-Paramete
Test Procedure: Critical Alarms	2	Approved		OP-KTF-SFAT-CriticalAlarms
Test Procedure: Equipment Behavior During Pause	3	Approved		OP-KTF-SFAT-EquipmentPause

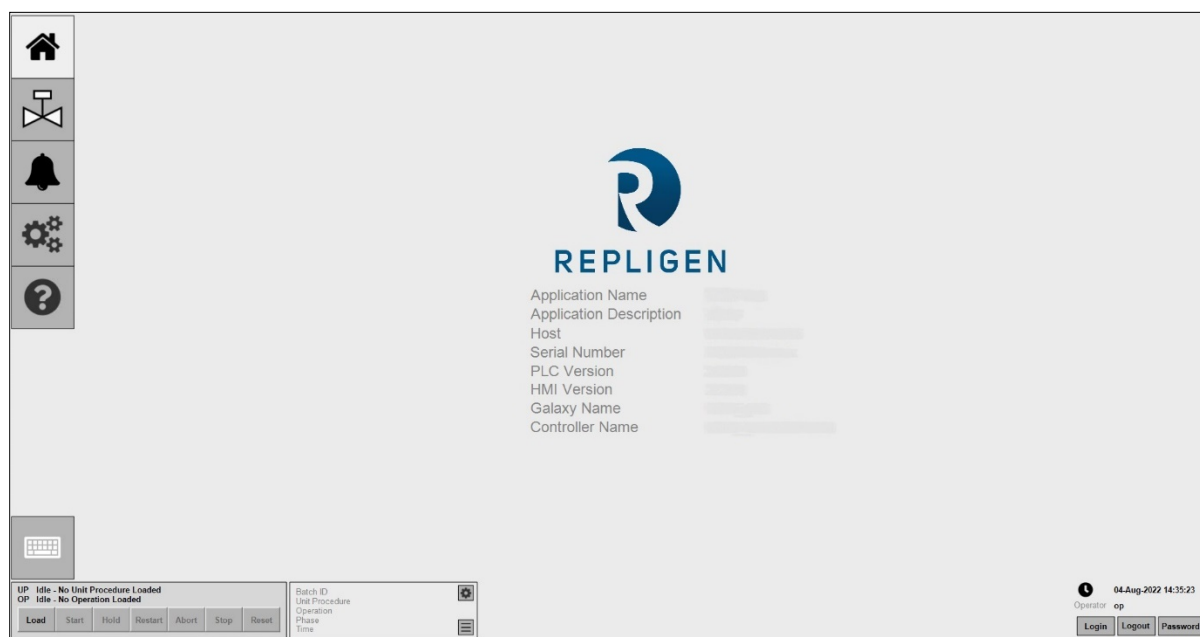
Below the table, the 'Selected Recipe' is 'op-KTF-CDC-L1L2', with 'Recipe Type' as 'Operation' and 'Recipe Version' as 'Latest'. A 'Batch ID' field contains 'KTF-Type-18JHEIE' and a 'Generate' button is next to it. At the bottom, there are buttons for 'Download Recipe', 'Reset', 'Retry', and 'Cancel'. A 'Download Progress' status indicator is also present.

To load and run a recipe:

1. Select **Load** from the Process screen.
The Recipe Selection screen appears.
2. Select the recipe to load from the displayed list.
3. Enter a Batch ID for the process. Alternatively, select **Generate** to automatically generate a Batch ID for the process.
4. Select **Download Recipe** to load the recipe for use.
5. Close the Recipe Selection screen, and select **Start** from the Process screen to run the loaded recipe.

11.4 Home Screen

Figure 12. Sample Home Screen



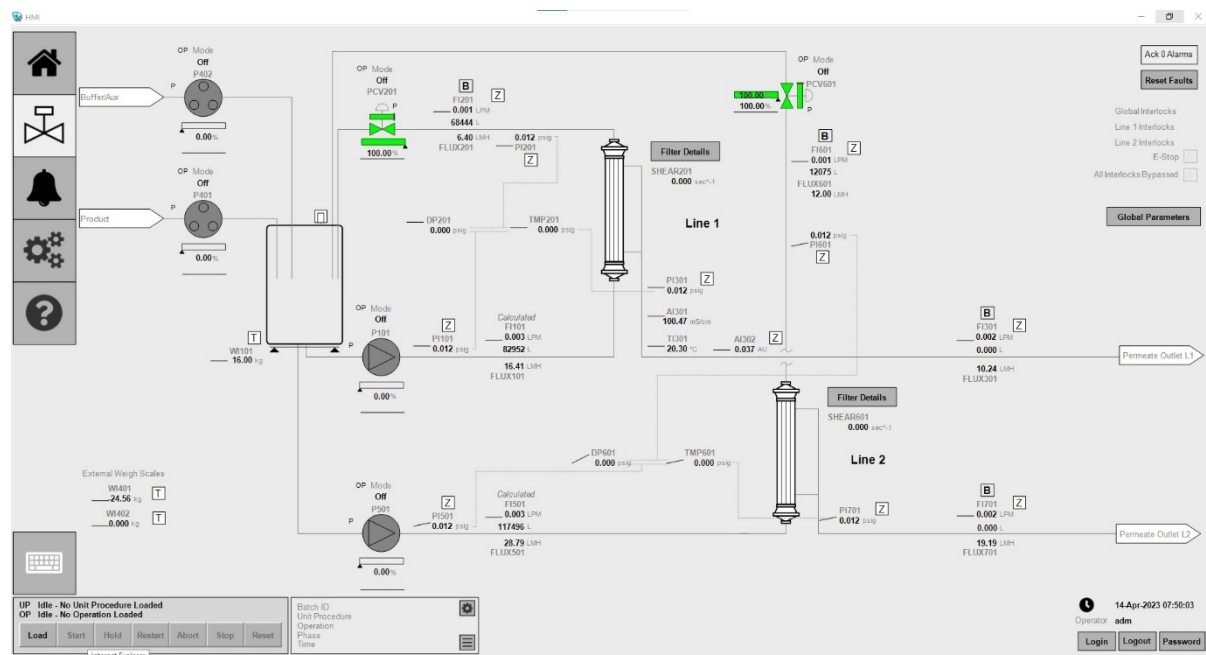
The Home screen identifies the KrosFlo system by Serial Number and Model, and lists the software revisions of important applications running on the system.

The Home screen provides the following system information:

- **Application Name:** Application name as assigned by the customer
- **Application Description:** General description of the application
- **Host:** Name of Windows PC hosting the application
- **Serial Number:** Unique serial number for this system
- **PLC Version:** Application version of PLC Code
- **HMI Version:** Application version of HMI Code
- **Galaxy Name:** Wonderware Galaxy Name
- **Controller Name:** PLC Controller Name

11.5 Process Screen

Figure 13. Sample Process Screen



The Process screen displays the System operational flow-path. The System operation and control features can be observed on the Process screen. System components are identified by their ID tags listed in a grey font. Process data (flow, pressure, volume) is displayed on screen in real time. Process data outputs are displayed in the **bolded** display fields.

Operator and Hand (that is, Manual) modes of operation for the Recirculating and Product pumps are selected here. The System can operate independently (outside of an automated process sequence), allowing the operator greater flexibility in performing trials to optimize filter performance prior to entering a run.

Setpoint data is entered by tapping a configurable component. Enter the new Setpoint data on the component faceplate.

Press **[Z]** to zero out the corresponding displayed values for flowmeters and pressure sensors.
Select **[T]** to tare the corresponding scale.

Select **Filter Display** to show a list of specifications for the currently installed filter, including:

- Part Number: Filter part number.
- Module Family: Filter module family.
- Chemistry: The filter chemistry value.
- MWCO: The molecular weight cutoff value.
- Fiber ID: Real value indicating the fiber inner diameter in mm.
- Effective Length: Real value indicating the filter effective length in cm.
- Fiber Count: Integer indicating the filter fiber count.
- Module Surface Area: Real value indicating the surface area per filter in cm².
- Quantity: Integer indicating the number of filters installed.

You may modify these filter values by selecting **Update Current Filter**.

Select **Ack [N] Alarms** to acknowledge all unacknowledged alarms where **N** indicates the current number of unacknowledged alarms.

Select **Reset Faults** to issue a reset command to all modules. This will reset Pump Faults, Valve Faults, Interlock First-Outs, Config Error First-Outs, and other resettable faults. A small red dot will be visible (blinking or solid) on a final element device when a reset is required, or the device is not ready.

The **Line 1/Line 2/Global Interlocks** status indicator indicates when an interlock is active.

The **E-Stop** status indicator indicates the status of the E-Stop safety system.

The **All Interlocks Bypassed** status indicator indicates whether or not the All Interlocks bypassed function has been activated. All Interlocks Bypassed is an engineering function that can only be activated from the PLC itself and has no method for setting from the HMI.

Select **Global Parameters** to show an interactive list of current Global Parameters.

Select **Report Records** to show an interactive list of current Report Records. This selection is only visible when an Operation is active.

Select **OP Parameters** to show an interactive list of current Operations Parameters. This selection is only visible when an Operation is active.

Select **UP Parameters** to show an interactive list of current Unit Procedure Parameters. This selection is only visible when a Unit Procedure is active.

Select **External Parameters** to show an interactive list of current External Batch Parameters. This selection is only visible when External Batch Mode is active.

Select **PAUSE** to pause a running process, and Select **RESUME** to resume a paused process.

Select **Load** to load a process recipe.

Select **Start** to run a loaded process recipe.

Select **Hold** to pause a running process.

Select **Restart** to run a held (paused) process.

Select **Abort** to terminate a running process.

Select **Stop** to stop a running process in an orderly shutdown.

Select **Reset** to clear Batch parameter settings.

Select **Login** to log into the HMI using a pre-configured user account name and password.

Select **Logout** to log out from the HMI.

Select **Password** to change the password for the logged in user.

11.6 Alarms Screen

Figure 14. Sample Alarms Screen

The screenshot displays the Alarms screen interface. At the top, there is a header bar with icons for Home, Alarm, History, and Help. Below this is a table of alarms with columns: Timestamp, State, Name, AlarmComment, Type, Limit, CurrentVal, AlarmDuration, Operator, UnAckDuration, and Priority. The table shows several alarms, including 'ACK_RTN', 'ACK_RTN', 'UNACK_RTN', and 'UNACK_ALM'. Below the table is a 'History' section with a table of events. The history table has columns: EventStamp, AlarmState, TagName, Description, Area, Type, Value, CheckValue, Priority, Category, Provider, Operator, DomainName, UserFullName, UnAckDuration, and User1. The history table shows several events, including '27-Jun-2022 10:00:00', '27-Jun-2022 10:00:00', '27-Jun-2022 10:00:00', and '27-Jun-2022 10:00:00'. At the bottom of the screen, there is a status bar with buttons for 'Test', 'Retrieve', 'Cancel', 'Write', 'Group-by', and 'Aggregate'. The status bar also displays 'UP Idle - No Unit Procedure Loaded' and 'OP Idle - No Operation Loaded'. The bottom right corner shows the date and time '27-Jun-2022 10:36:06' and the operator 'eng'.

The Alarms screen lists all alarms that are either active or unacknowledged, and includes the following information and selections:

- **Current Alarms:** The top grid displays all alarms that are either active or unacknowledged.
- **Ack Alarms Button:** Acknowledge all unacknowledged alarms. The button will show the current number of unacknowledged alarms.
- **History:** Provides a quick way to review alarm or event history over a defined period of time. Alarm history includes any event associated with the alarm cycle such as coming into alarm, going out of alarm, and acknowledgment. Events include any operation interaction where they may set a value from the HMI. Events may also encompass various other system level events.

To review historical alarm data:

1. Select Alarms or Events.
2. After selecting Alarms or Events select the time duration. The time reflects the amount of time from the current time backwards.
3. Click Retrieve

Click a column heading to sort the historical alarm data based on that filter (EventStamp, AlarmState, etc.).

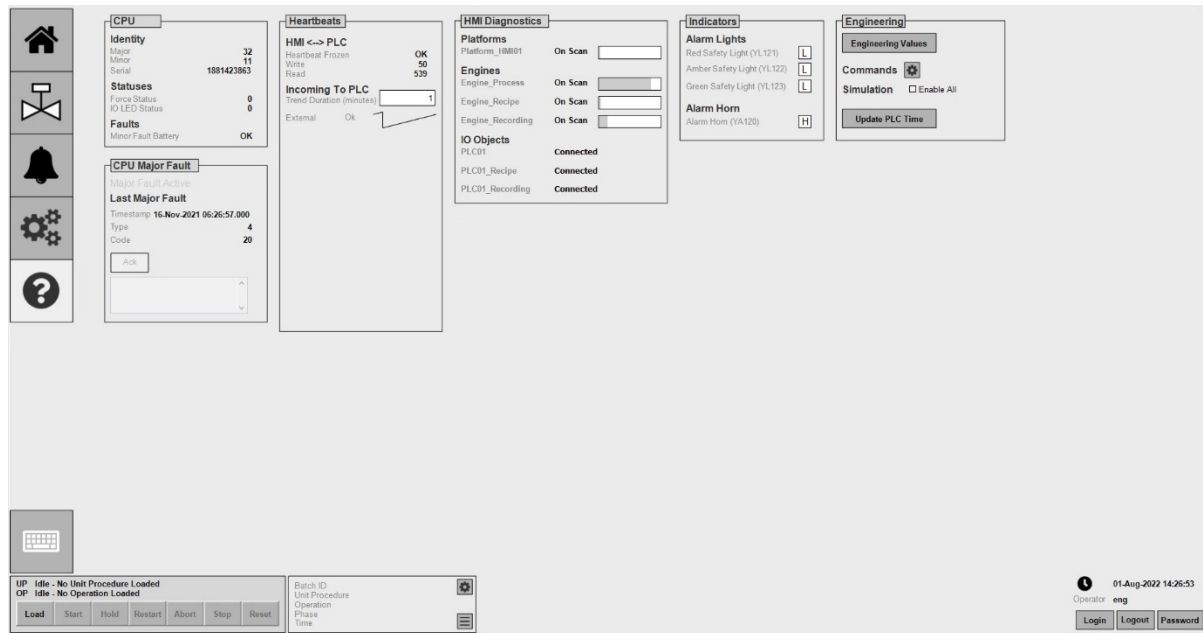
You may perform the following queries on retrieved historical alarm data:

- **Test:** Tests the connection for the alarm/event history data grid.
- **Retrieve:** Re-runs the query for the alarm/event history data grid.
- **Cancel:** Can cancel a log running query for the alarm/event history data grid.
- **Write:** This selection is built into the data grid but is non-functional. The alarm/event history views are read-only on the database / Wonderware Historian side. It is typically greyed out.

- **Group-by:** Investigate patterns in the data by grouping rows based on user-defined conditions. Use of this query is described in more detail the Core Standard Platform Software Operations Manual (SOM).
- **Aggregate:** Investigate patterns in the data by aggregating rows based on user-defined conditions. Use of this query is described in more detail the Core Standard Platform Software Operations Manual (SOM).

11.7 Diagnostics Screen

Figure 15. Sample Diagnostics Screen



The Diagnostics screen displays real-time results of system diagnostics including:

- **CPU:** Detailed information about PLC CPU diagnostics.
- **CPU Major Fault:** Details about the last or current CPU Major Fault. If the Major Fault Active text is not bright red, then there is no major fault active.
- **Heartbeats:** Information about the bidirectional heartbeats between the PLC and HMI. The length of the trend showing the heartbeat signal can be adjusted from this screen to view a longer-term period.
- **HMI Diagnostics:** Displays performance and status information about the software components for the HMI. All items should either be On Scan or Connected.

Clicking on the names of the components will display a detailed faceplate with diagnostics and engineering functions. All users can view the faceplate, only users with engineering-level security can execute functions.

- **Indicators:** The current status of miscellaneous indicators for the system that don't fit on the process screen. Note that the instruments and layout of this section of the Diagnostics Screen may not represent your installed system as some functions may not be available.
 - **Alarm Lights:** The current state of the alarm lights (stack lights) as well as the ability to test the outputs for each light. This is only available on systems with system alerts. Alarm Lights testing can only be performed by users with Supervisor level security.
 - **Alarm Horn:** Displays the current state of the alarm horn as well as the ability to test the outputs for each horn. This is only available on systems with system alerts. Alarm Horn testing can only be performed by users with Supervisor level security.

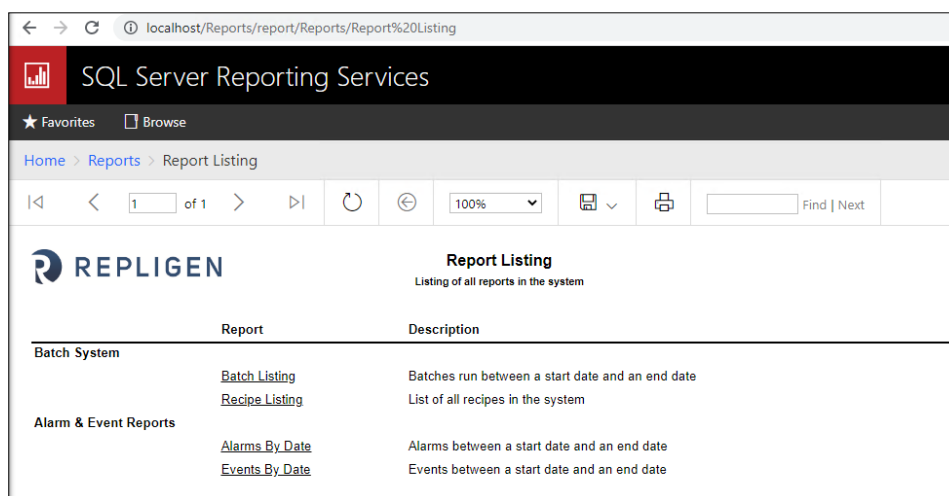
- **Engineering:** Engineering Functions are visible only to engineers and provide advanced diagnostics and maintenance functions. Functions can only be accessed by users with Engineering level security.

12. Operating the System

12.1 Executing Reports

The KrosFlo System continually logs collected data. Electronic batch reports are pre-configured on the System to allow users to generate records that can be saved as PDF files or printed.

1. To begin executing reports, start the Chrome Browser on the HMI. The default home page will be a listing of available reports.



2. To navigate to a report, click on underlined text.
3. If a report has multiple pages, click on the arrows () in the section of the toolbar to page through the report.
4. Click the () button to refresh the current report.
5. Click the () button to navigate back to the previous report.
6. Use the Zoom dropdown () to zoom in or out on the contents of the report.
7. Click () to access a standard print dialog to print the report.
8. Use the find field () to search through the text of the report.

All timestamps in the reporting system are shown in the local time zone with applicable daylight savings time settings. These are rendered from the raw UTC timestamps in the data with the time zone settings in the Windows operating system.

Refer to the *Core Standard Platform Software Operations Manual* for additional details about the reporting system.

12.2 System Emergency Stop and Responses

12.2.1 Stopping the System Using the E-Stop Button

In the event of an emergency, a user can stop the System quickly by pressing the emergency stop button on the control panel.



Pressing the emergency stop button will stop all the pumps, reset all back-pressure control valves to 0% closed, and send an alarm. The active process sequence is put into a hold state.

The AC power is still connected to the control panel. The dedicated power supply for the PC and HMI remains being powered up.



WARNING – To prevent spraying fluids, avoid breaking any mechanical, process, or electrical connections after an emergency stop.

12.2.2 Restarting the System after an Emergency Stop

Follow these steps to restart the System after an emergency stop:

1. Ensure the System is safe to start.
2. Rotate and pull out the Emergency-Stop button.
3. Press the blue Reset button on the control panel.
4. Once the computer is booted up, the system is set to automatically logon a special named account without any user interaction.
5. If a different user is required for logon, wait for the system to completely boot and logon, and then use the logout function of Secure Desktop to exit the user session to return to a Windows Login Screen.
6. Once the PC boots up, wait at least 2 to 5 minutes before opening the HMI application (InTouch WindowViewer). This is to allow the various AVEA (Wonderware) software components and services to all load up in the background. If InTouch is opened too soon, the application will not connect to the underlying AVEVA® software components and not function correctly.
7. Select the Process  icon to navigate to the Process screen.

Note:

- Press “Logout” first if the System is still shown as being logged-in by another user.
- At startup, the KrosFlo System will display all alarms as being active; they should be acknowledged, and a reset should be performed to clear any latched faults before operating the KrosFlo System.

12.3 System Power Loss and Responses

12.3.1 System Power Loss

If power is lost while the System is running, all power and control components are de-energized. The pump motors coast to stop, back-pressure control valves are reset to 0%, and an alarm is triggered. The active process sequence is put into a hold state.

The PC and HMI remain shut-down.



WARNING – To prevent spraying fluids, avoid breaking any mechanical, process, or electrical connections after a power lost.

12.3.2 Restarting the System after a Power Loss

When possible during a power failure, it is recommended that the System main power disconnect switch be turned off to facilitate the following power up sequence:

1. Ensure the System is safe to start.
2. Turn the main power disconnect switch to the “On” position.
3. Rotate and pull out the emergency stop button.
4. Press the blue Master Reset button.
5. At startup, the KrosFlo System will display all alarms as being active; they should be acknowledged, and a reset should be performed to clear any latched faults before operating the KrosFlo System

Note:

- If the power loss is brief, the System may be able to continue without any disruptions.
- When power is restored, the System will automatically power up to the point where the active sequence was put on hold, but users need to press the Master Reset button. However, it is always recommended to follow the restarting procedure above instead.

12.4 Shutting Down the System

To shut down the System:

1. To perform a system power down, click the Exit function () on the Secure Desktop.
2. After the HMI shuts down, execute a power down from the Windows Login screen.

Note:

- After Windows shutdown, power down the System by turning the main power disconnect counterclockwise to “Off” position.

13. Performing System Maintenance

The KrosFlo® System is of robust design and intended for use with process equipment. As such, lab or plant cleanliness and care are all that is needed to ensure quality operation when used in the System's intended manner.

Refer to section 3 for detailed Safety Guidelines. An Electrical Schematic and a list of all major components (Process and Control Panel items) is also provided with the System should any service be required.

13.1 Making the System Safe for Maintenance



WARNING – Refer to section 3 for Safety Precautions

Before performing adjustments and maintenance on the System, you must make the System safe by following these steps:

1. If possible, flush the System.
2. Shut down the System properly (see Appendix section).
3. Lockout the System in accordance with the System owner's lockout/tagout procedures.
4. Wear the PPE required by the System owner's safety program.
5. Verify again that all power sources, utilities, and chemicals have been removed from the System.

13.2 Cleaning the System

CAUTION

Repligen does not recommend use of Vaporized Hydrogen Peroxide (VHP) to clean the KrosFlo system.

The frame, cabinet, and pumps can be cleaned by manual wipe-down using mild cleaning agents and/or warm water and a damp cloth or lab wipes. The HMI/Touchscreen should be cleaned with computer screen cleaner and computer screen wipes.

Cleaning products are readily available from supply houses and the user must make sure the selected agent(s) are acceptable with their facility and compliant with System materials of construction.

13.3 Cleaning the Flow-path

Thoroughly clean and flush the flow-path with purified water and allow it to drain and dry – if possible.

Alternately, the flow-path may be stored full of a suitable storage buffer if it is to remain in place until the next use. Ensure that thermal expansion is thoroughly considered and calculated, or environmental temperature must be maintained at an appropriate temperature.

13.4 Flow-path disassembly and storage

To disassemble and store the flow-path:

1. In reverse order, follow the steps listed in Section 6 to disassemble the flow-path.
2. Cap all the feed, column, and outlet ports.
3. Put the flow-path into the storage box.

13.5 System Moving and Storage



WARNING – Refer to section 3 for Safety Precautions

To move and store the System:

1. Retract the leveling feet.
2. Unlock the wheels and have at least 2 people roll the System to the storage location.
3. Lock the wheels
4. Extend the leveling feet and use them to support and level the System.

13.6 KrosFlo® System Spare Parts

The table below lists the spare parts that may be ordered to prevent any downtime of the KrosFlo System should a minor failure occur. To order a spare part, contact your Repligen Field Service Engineer, and reference the Service Part Number listed below.

Table 6. KrosFlo® System Spare Parts

Part Description	Service Part Number
Master Control Relay	SV-SPR-RM-12161
Power Supply 24VDC	SV-SPR-RM-12377
Power Supply 48VDC	SV-SPR-RM-12179
Strain Gauge 4-20 Signal Converter	SV-SPR-3000971
FUSE, 2 AMP	SV-SPR-601-14149-000
Fuse, 5 AMP Class CC	SV-SPR-3000230
Fuse, 10 AMP	SV-SPR-RM-12067
Fuse, 15 AMP Class CC	SV-SPR-3000232
Fuse, 20 AMP Class CC	SV-SPR-3000233
Pump, PuraLev 2000SU.8	SV-SPR-HWP0516
2000 Pump Controller	SV-SPR-RM-12173
Adaptor Cable for Sensors, MCAS-600.2-05	SV-SPR-RM-12174
Adapter Cable for Power, MCAP-2000.2-05	SV-SPR-RM-12175
Adaptor Cable for Power, MCAP-600.2-05	SV-SPR-RM-12178
Cable, Octopus 18 Pin Pressure Female	SV-SPR-3000762
Cable, Remote Control, IP Pump	SV-SPR-RM-12347
Flowmeter, Clamp-On, i35	SV-SPR-3000907
Flowmeter, Clamp-On, i25	SV-SPR-3000908
Cable, Octopus 18 Pin Pressure Male	SV-SPR-3000761
Cable, Octopus Spectrum 18 pin	SV-SPR-603-12355-002
Fiber Optic Cable, 3ft	SV-SPR-3000954
Small Flow Meter Assembly	SV-SPR-3000432
Filter Clamp, T	SV-SPR-3001008
Filter Clamp, S	SV-SPR-3001006
Filter Clamp, N MINIKROS	SV-SPR-3001009
Filter Clamp, K KROSFLO	SV-SPR-3000375
Filter Clamp, X KROSFLO MAX	SV-SPR-3000374

Part Description	Service Part Number
Pump, Peristaltic Masterflex IP 650 RPM with Pump Head	SV-SPR-RM-12447
IP Pump head, Peristaltic	SV-SPR-3000260
1.375" Back Control Pressure Valve	SV-SPR-900-14742-000
Back Pressure Valve, KTF/KPS 600/700	SV-SPR-900-12652-000
BPCV cable to BPCV (Back Pressure Valve)	SV-SPR-3000765
Leviflow Converter	SV-SPR-613-14123-000
Leviflow Sensor CABLE (for single use flow sensors) External	SV-SPR-603-14091-000
Single Flow Meter Assembly	SV-SPR-3000438
Conductivity sensor	SV-SPR-3000264
Fuse, 10 AMP Class CC	SV-SPR-3000231
FUSE, 10 A, 250 VAC, 1/4" x 1 1/4"	SV-SPR-RM-12067
Flowmeter Cable for I25/I35 with ferrite cable, 12 wire, ICS-2.4-50	SV-SPR-3001406
LeviFlow Sensor Cable, LFI-C.2-10 (Internal cable)	SV-SPR-603-14125-000
Cable, USB, A R/A to B R/A, 3ft	SV-SPR-3001408
Assy., Enclosure, Back Pressure PCB	SV-SPR-3000847
Cable, power supply, black E 14AWG/3Cond	SV-SPR-3000237
Cable, SJOOW, 12 Gauge, 3 wires	SV-SPR-3001367
Flowmeter Cable for I25/I35 w/out ferrite Cable, 12 wire, ICS-2.4-50	SV-SPR-3001405
Power Supply, 12 VDC, 20 Watt	SV-SPR-RM-12376
Switch, DIN Rail Mount	SV-SPR-3000591
Fuse Holder, 2 Pole, 30a	SV-SPR-3000876
Terminal Power Feed, Offset Lug, Busbar Accessory	SV-SPR-3001100
Network Switch, Unmanaged 4 Port	SV-SPR-RM-12246
2-position E-Stop w/o illumination	SV-SPR-3000601
E-Stop Ring	SV-SPR-3000602
Connector, RJ-45, female passthrough	SV-SPR-RM-12348
Connector, USB, female, passthrough	SV-SPR-RM-12349
Disconnect Shaft, Piston Handle	SV-SPR-3000845
Disconnect, Pistol Handle (main Handle))	SV-SPR-3000874
Shroud, E-Stop, 30mm	SV-SPR-3000976
Strain Relief, 2-hole, 5.0mm, ½" NPT	SV-SPR-3001639
Warning Horn, 24 VDC	SV-SPR-3000610
Cable, Octopus 18 pin Pres, Female, long	SV-SPR-3001295
HMI, 15", SST, 4:3, 256GB, Windows 10	SV-SPR-3000843
Pump Extension Cord	SV-SPR-3001366
Flow Sensor, Clamp-on, LFSC-i19X	SV-SPR-3000967
UV Photometer, 4 20mA Output	SV-SPR-3002601

Part Description	Service Part Number
Fiber Optic Cable, 2 M	SV-SPR-3001685
Scale, Floor, SST, 500kg	SV-SPR-3000823
Scale, Ramp, Floor, SST	SV-SPR-3000824
Processor, Ethernet/IP, no Display	SV-SPR-3000842
Connector Cover, Dust For SCPU Series	SV-SPR-RM-12350
Clamp -K	SV-SPR-3001014
Clamp -X	SV-SPR-3001013
Flow Sensor, Sonotec 60 1/8"ID X 1/4"OD	SV-SPR-RM-12436
Flow Sensor, Sonotec 80 3/16"ID X 3/8"OD	SV-SPR-RM-12437
Flow Sensor, Sonotec 140 3/8"ID X 5/8"OD	SV-SPR-RM-12439
Mount, Pump 100	SV-SPR-3000556
Turbidity System, Panel Mount	SV-SPR-3001127
Master Control Relay Socket	SV-SPR-RM-12163
Flow Sensor, Clamp-on, LFSC-i10X	SV-SPR-3000965
Flow Sensor, Clamp-on, LFSC-i16X	SV-SPR-3000966
Flow Sensor, Clamp-on, LFSC-i19X	SV-SPR-3000967
Flowmeter, Clamp-On, i35	SV-SPR-3000907
PuraLev 600SU (LPM-600.9-10) Pump (Black)	SV-SPR-3001593
PuraLev 2000SU (LPM-2000.11-10) Pump (Black)	SV-SPR-3001594
Controller Ext, PuraLev LPC 2000.2-04	SV-SPR-3001595

14. Troubleshooting the System

If you encounter an issue with System operations, refer to the table below for basic troubleshooting suggestions. Contact Repligen Customer Service (customerserviceUS@repligen.com / 1-508-845-3030 (Option 1)) if issues persist.

Table 7. Basic System Troubleshooting Steps

Problem	Probable Causes	Corrective Actions
Pump		
Pump does not run	No power at motor	Check if there is any error light or message on pump controller, located inside the cabinet. Check if there is any fuse is blown. A qualified electrician to check motor power cables for damages or loose connections.
	Interlock is active	Find the active interlock and resolve the problem causing the interlock to be activated.
	Peristaltic (permeate/buffer/product) pumps are in the wrong mode.	Ensure permeate/buffer/product pumps are in the correct mode (remote).
Pump does not deliver required flow rate	Broken or worn-out components in pump head, and/or there is some noise.	Replace pump head unit. Consult the pump operating instructions in the pump user manual.
	Tubing is bent or occluded.	Check HMI for abnormal pressure values, then check tubing for any potential occlusion.
Increased running noise	Pump or tubing cavitation	Increase pump speed Slightly reorient or shake the tubing so that the air bubbles can flow through
System		
System does not power up	The facility's primary disconnect is in "off" position.	A qualified electrician should check the power cables from facility power source to the power outlet, then to the System's main disconnect.
	System power plug is not plugged in.	Plug power plug into the power outlet.
	System's main disconnect is in "off" position.	Turn the main disconnect clockwise to "on" position.
System does not run	Alarm or Interlock is active	Navigate to the Alarms screen, resolve the issues that caused the alarm(s) or Interlock, then acknowledge the alarms and press "Reset" button.
	Emergency Stop button is active	Resolve the issue, then rotate and pull the E-stop, then press "Reset" button.
	User does not have the right access level	Ask a user with appropriate access level to complete the task.
No signal or value from pressure sensor	Sensor cables are not connected	Connect the cables following their respective tag numbers.
	Sensor is damaged	Replace the sensor
Pressure values on HMI seem not right	Pressure sensor cables are plugged incorrectly.	Connect the cables following their respective tag numbers.
Fluid leaks	Components on flow-path are damaged or ruptured.	Stop the System, wait for the leaks to stop, drain the flow-path, and replace it.
On-screen keyboard has disappeared	User press "exit" on keyboard application.	Press the keyboard icon located in the bottom left corner of the navigation pane.
Selected filter modules are not propagating properly	User is not waiting 30 seconds after selecting a filter type before selecting a filter module on the Settings screen.	To avoid possible issues, it is important wait 30 seconds for the selected filter module type to propagate before selecting an individual filter module for use in a TFF process.

15. Index

Audience, user guide	10
Auto-torque for cassette holder	25
Auxiliary cart	20
Auxiliary pump tubing, installing	33
Cassette holder	20, 24
Caution	9, 11
Cleaning the system	48
Customer Support, contacting	3
Dimensions, System	18
Electrical connections, system	37
Electrical specifications	17
Emergency stop button	38, 46
Environmental specifications	17
Feed tank connections	31
Ferrite bead installation	35
Flow-path assembly	27
Flow-path, cleaning	48
Human Machine Interface (HMI)	37
Icons, safety	9
Intended use of System	11
Label, system	17
Loading lever, pump head	33
Machine designation label	17
Maintenance, performing system	48
Moving the system	11, 49
Pause/resume button	42
Power cables, system	37
Power loss	47
Pressure sensors, installing and connecting	34
Pump head, installing	28
Recipes, loading and running	39
Reports, generating and viewing	45
Restarting the system	46, 47
Rubber gasket, stand extension	22
Safety	8, 9, 10
Shutting down the system	47
Spare parts	50
Stand extension	22
System components	19
Tare button	41
Troubleshooting the system	53
Tubing, installing auxiliary pump	33
Warning	11
Zero button	41