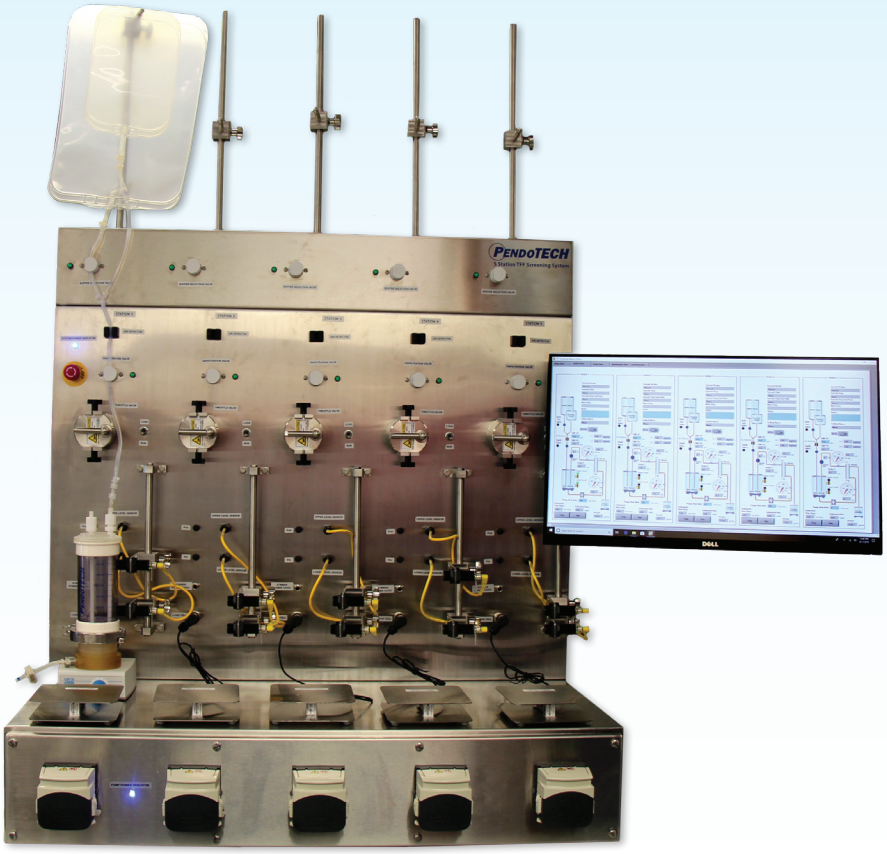
5 Station TFF Screening System

PENDOTECH

Adding Value To Your Process

Product Highlights

- 5 Stations of a Tangential Flow Filtration (TFF)/Crossflow Filtration Process with completely independent control
- Ideal for many applications in biopharmaceutical processing:
  - Ultra-Filtration / diafiltration (UF/DF) of proteins and viruses
  - Formulation process development
  - Clarification of cells
- Provides ability to conduct parallel experiments in a compact footprint
- Complete batch control with 6 built-in programmable recipes
- System interaction via a PC-based Graphical User Interface (GUI)
- Real time trending and all data is written to a file for the permanent record
- Features use of PendoTECH® Pressure Sensors® that can be cleaned and re-used extensively
- Optimized vessels to maximize concentration factors and facilitate easy product recovery
- Built in Proprietary PendoTECH Throttle Valve to control back pressure
- Three pump options available in the pump base station:
  - High pressure pumping with diaphragm pump options that can provide up to 60psi/4 bar of pressure
  - Peristaltic pump with a wide range of flow options
- Compact load cells used for filtrate volume measurement as well as estimating filtrate flow and flux
- Conductivity measurement with PendoTECH Conductivity Sensors
- DeltaP control option that facilitates processing high viscous concentrations
- One input per station for collection of additional process data



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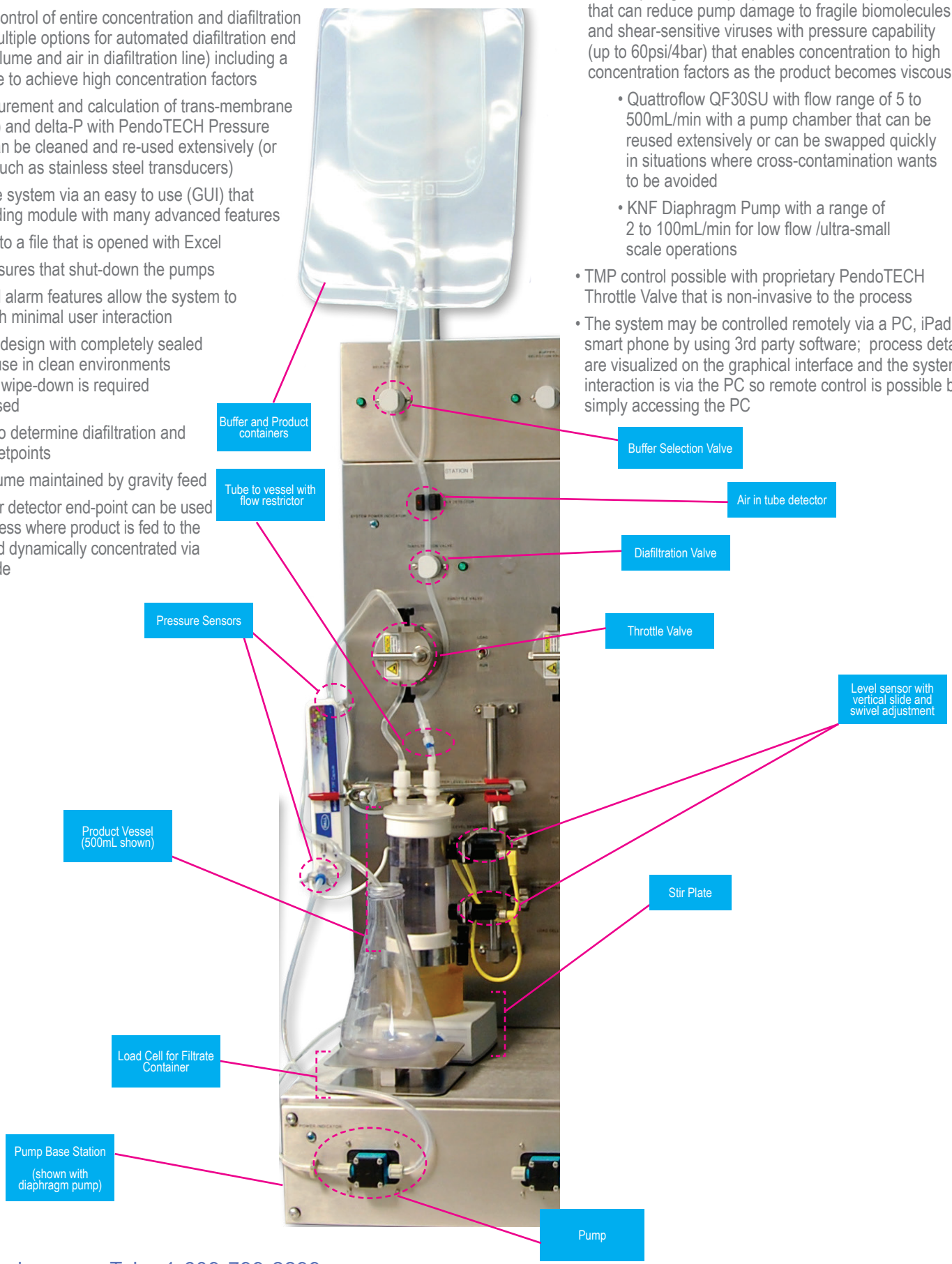
Product Overview

- Completely and efficiently automates 5 Stations of a TFF/Crossflow Filtration Process
- Recipe based control of entire concentration and diafiltration process with multiple options for automated diafiltration end point (filtrate volume and air in diafiltration line) including a fed-batch recipe to achieve high concentration factors
- Pressure measurement and calculation of trans-membrane pressure (TMP) and delta-P with PendoTECH Pressure Sensors that can be cleaned and re-used extensively (or other sensors such as stainless steel transducers)
- Interact with the system via an easy to use (GUI) that includes a trending module with many advanced features
- Data collection to a file that is opened with Excel
- Alarms for pressures that shut-down the pumps
- Automation and alarm features allow the system to be operated with minimal user interaction
- Stainless Steel design with completely sealed front panel for use in clean environments where frequent wipe-down is required and NaOH is used
- Level sensors to determine diafiltration and concentration setpoints
- Diafiltration volume maintained by gravity feed
- Non-invasive air detector end-point can be used "fed-batch" process where product is fed to the main vessel and dynamically concentrated via diafiltration mode

- Peristaltic pump with a wide range of flow rates
- Two Diaphragm Pump Options with low shear operation that can reduce pump damage to fragile biomolecules and shear-sensitive viruses with pressure capability (up to 60psi/4bar) that enables concentration to high concentration factors as the product becomes viscous:
  - Quattroflow QF30SU with flow range of 5 to 500mL/min with a pump chamber that can be reused extensively or can be swapped quickly in situations where cross-contamination wants to be avoided
  - KNF Diaphragm Pump with a range of 2 to 100mL/min for low flow /ultra-small scale operations
- TMP control possible with proprietary PendoTECH Throttle Valve that is non-invasive to the process
- The system may be controlled remotely via a PC, iPad or smart phone by using 3rd party software; process details are visualized on the graphical interface and the system interaction is via the PC so remote control is possible by simply accessing the PC



Graphical User Interface

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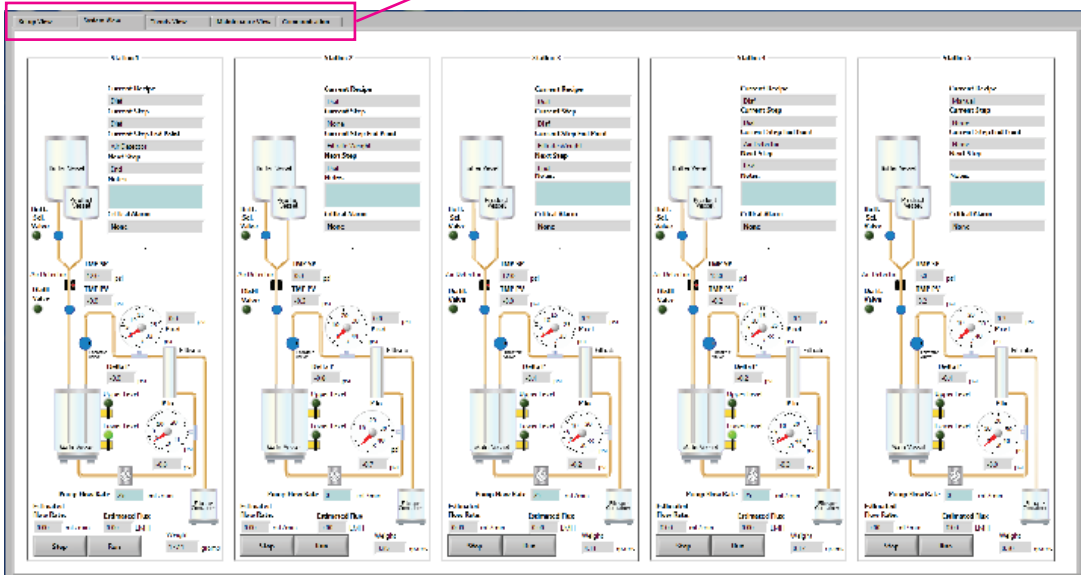
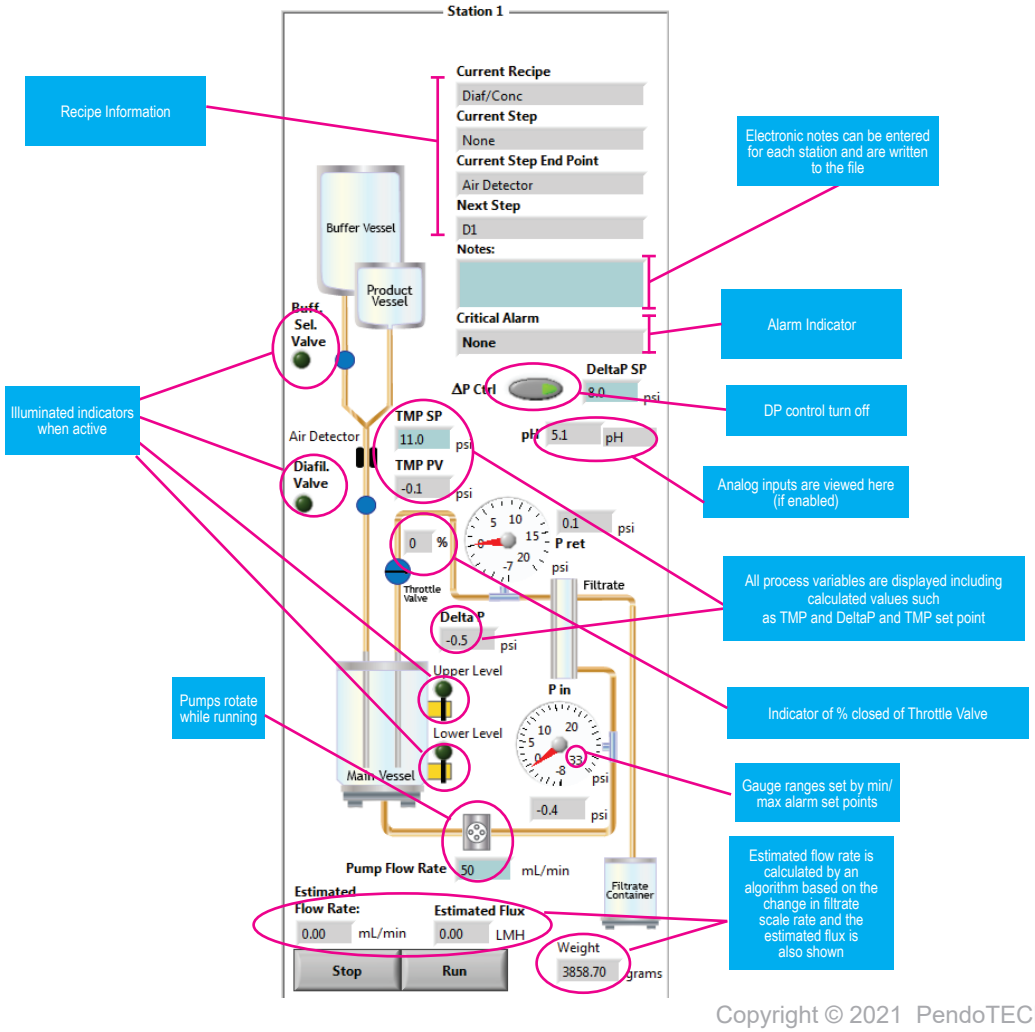
The GUI is designed for use with a mouse or touch-screen operation. The system comes with a 24inch HD touch-screen monitor for clear wide screen viewing. Clicking a numeric field is followed by appearance of a pop-up key pad for data entry. Values entered that are out of range are rejected with a message. There are five tabs for easy navigation:

1. Setup View - used to enter experiment information, program recipe, set alarms and to create a data file where all process data will be stored
2. System View - used to view current process values and change pump flow rates
3. Trends View - utility to trend process variables that is loaded with features to dynamically view the data of interest, quickly auto-scale or manually scale the axes, export a trend of interest either as data or a graphics file, and the ability to instantly open data of interest in Excel
4. Maintenance View - used to set up pumps based on pump parameters, calibrate the load cells via easy to use wizards, tare pressure sensors, configure analog inputs, enter DeltaP control parameters and more

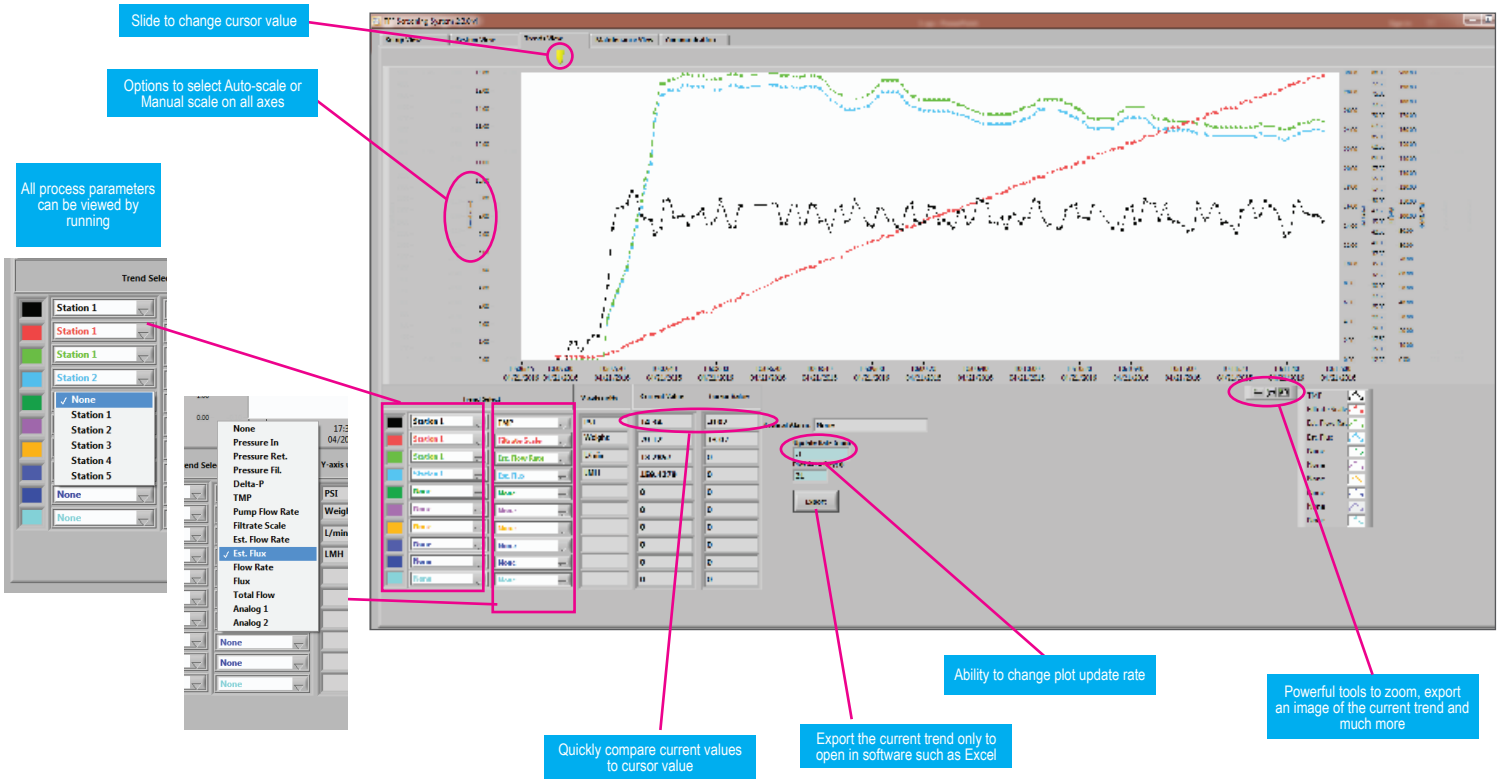




User Interface Details

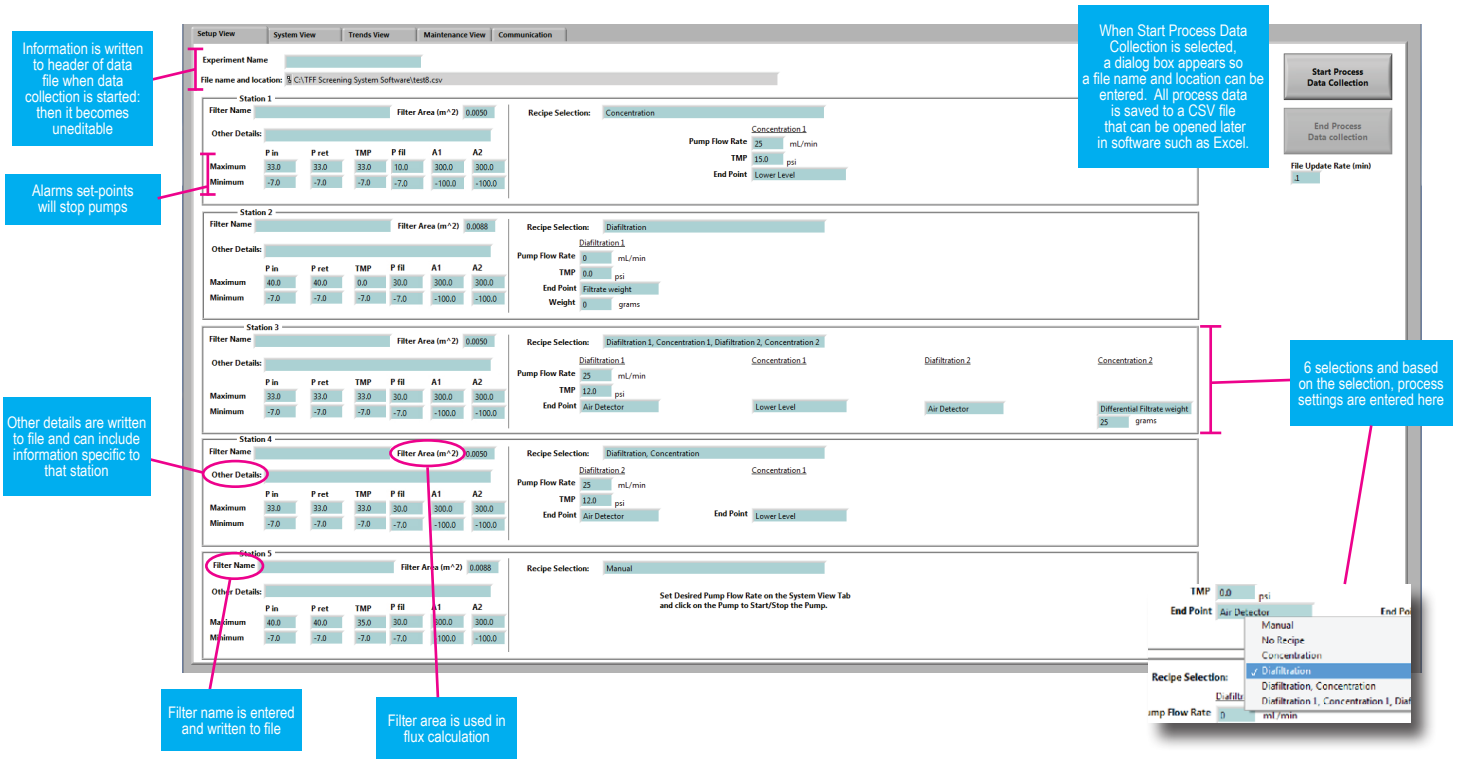
Trends

Utility to trend process variables with features to view the data of interest, auto or manual scale the axes, and export a trend as a data or graphics file



Setup

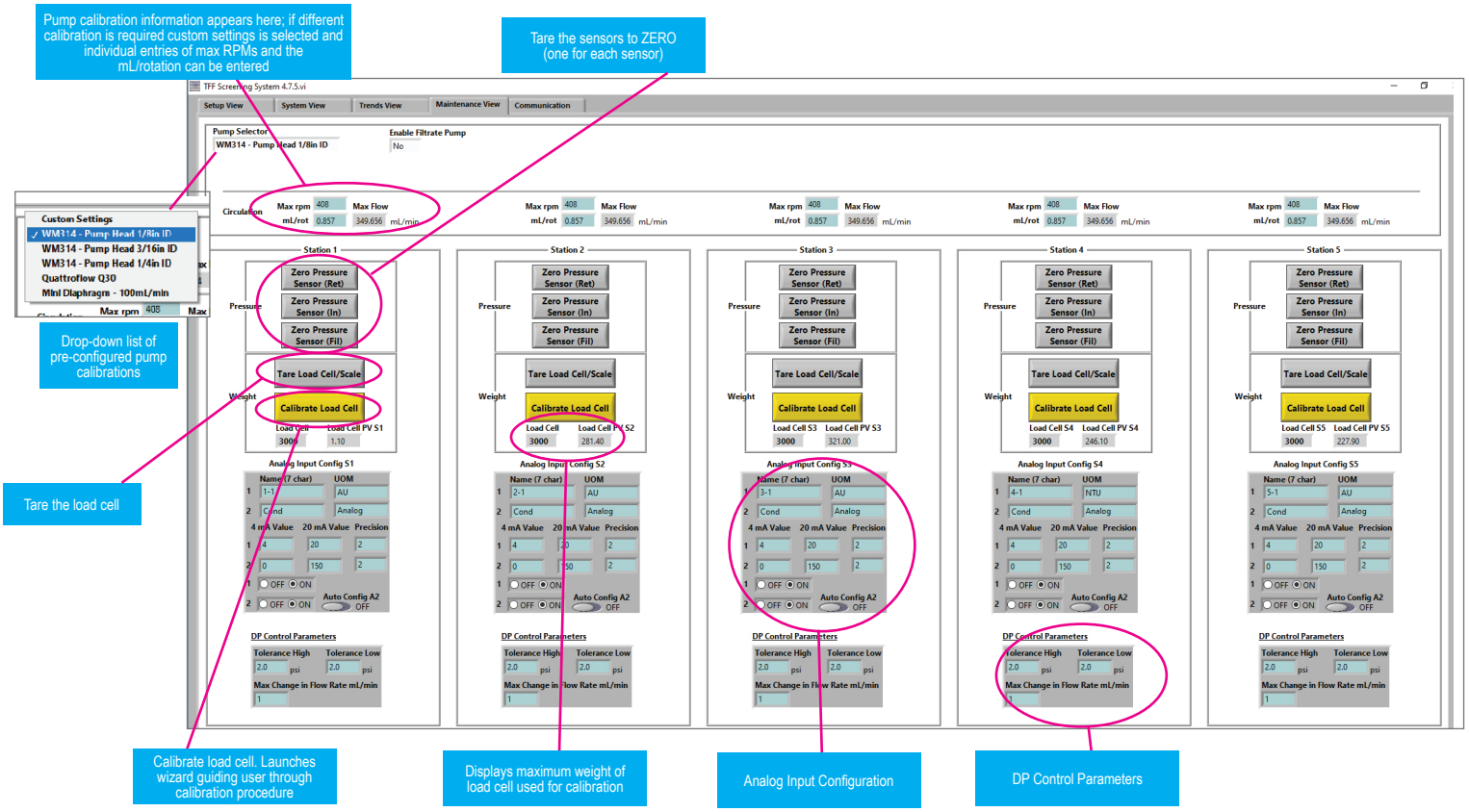
Setup View is used to enter experiment information, program recipe, set alarms and to create a data file where all process data will be stored



Maintenance View

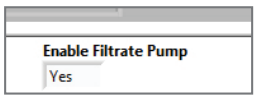
The Maintenance View is used for the following functions:

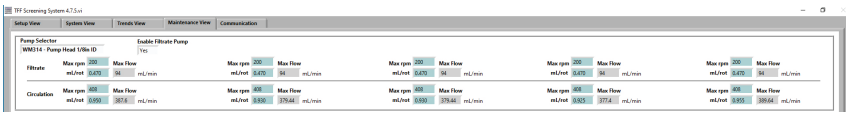
- Zero pressure sensors - this is done at atmospheric pressure
- Set-up pumps and enter pump calibration data
- Select range, tare and calibrate load cells
- Configure analog inputs for conductivity and other sensor options
- Enter DeltaP control parameters to control inlet pressure to filter pressure
- Ability to activate and configure the Filtrate Pumps



Filtrate Pump Option

When the Enable Filtrate Pump option is changed to yes as shown below the calibration fields appear. The filtrate pumps are connected to the left side panel and designed for control of the Watson-Marlow 120U/DV.

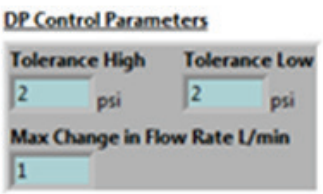




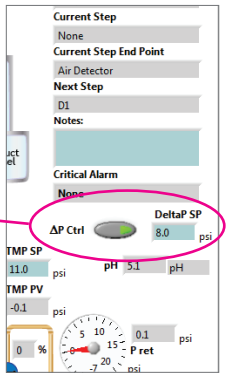
Watson-Marlow 120 Pump

DeltaP Control

For each station there is the ability to turn on DeltaP control mode. In this mode, the maximum DeltaP in controlled by lowering the flow rate on the pump. The control is fine-tuned by the settings entered on the Maintenance View.



Turned on and S.P. entered on System View



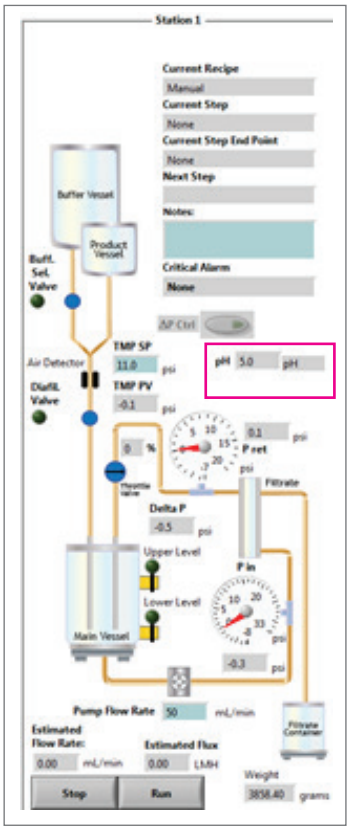
System view with DeltaP control turned on and field to enter the setpoint

The tolerances are entered and this set the "dead band" which the pump will not adjust. For instant if the set point is set to 20psi, and both tolerances are set to 2, then the pump will not adjust between 22 and 18psi.

The control acts every 3 seconds in the following manner as an example: if flow rate is 50mL/min and your DeltaP SP is 20, to +/-2 and the max change is 1mL/min. If the pressure is 22.5 then (1-20/22.5)*50mL/min=5.55mL/min. But since the maximum change is 1 mL/min, it will only change 1 mL/min.

Analog Inputs & Conductivity Inputs

There is one input available for each station for other sensors/transmitters with 4-20miliamp outputs. This enables data collection of additional process data, such as UV absorbance, pH, temperature, flow rate, or other. The 2nd input is preconfigured to measure conductivity using the PendoTECH Single Use Conductivity Sensor in the range of 0-100mS. They are configured on the Maintenance View as shown below. Analog inputs that are turned on appear at the location noted below on the System View with their name, value, and units of measure.



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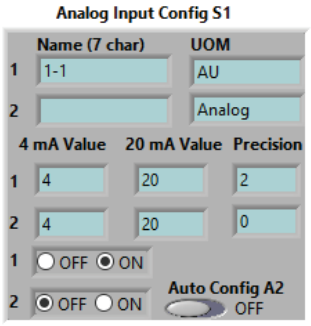
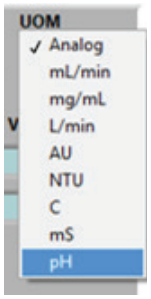
Analog Input Configuration Selections

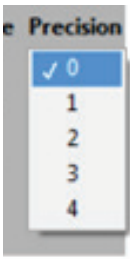
- Activate ON/OFF - when ON appears on System View
- Name (Up to 7 characters)
- Select Units of Measure from List
- Set Range of Input to match external sensor transmitter range
- Select Digits of Precision



Setting the Range



Select Units of Measure



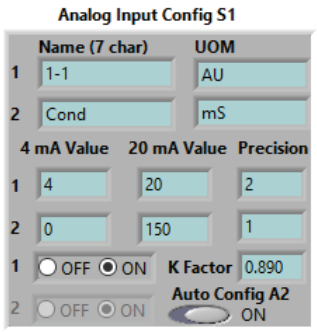
Select Digits of Precision

They also appear in the Trends Select and the Data File

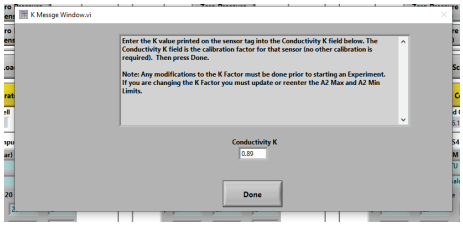
Est. Flux (LMH)	Pump Flow Rate (mL/min)	Filtrate W	pH (pH)	Alarm Code
0	50	3859.1	4.9	No Error
0	50	3858.9	4.9	No Error
0	50	3858.9	5	No Error
0	50	3858.9	5.1	No Error
0	50	3858.7	5	No Error

Example of the Analog Input in the Data File

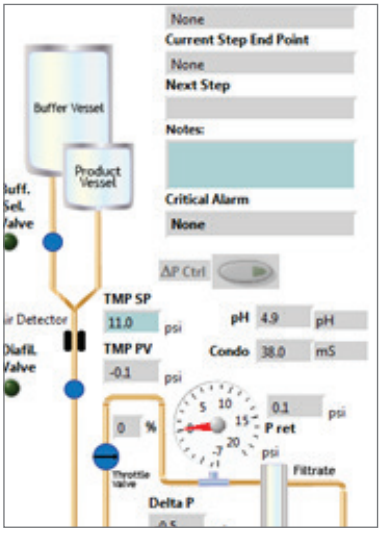
Configuration of Analog 2 can be configured to read the PendoTECH Single Use Conductivity Sensor when turned on. These sensors have pre-determined K factors that alleviates the need for calibration. This K factor is entered into the software. The sensor can read 0-100mS and the input is set to a range of 0-150mS with one digit of precision.



Analog 2 Configured as Conductivity; the K factor entry cell appears



When the K factor is selected, the dialog box to enter the sensor K appears



Both analog inputs shown

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Pump Calibration

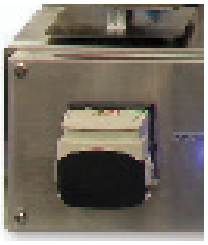
There are two factors used to calibrate any pump- one is its maximum motor speed in RPMs; the other is how much liquid is delivered each time the motor turns and this is quantified in mL/rotation. When these two values are multiplied, you get a maximum flow rate possible. In a peristaltic pump, the mL/rotation is based on the tubing inner diameter; and for a diaphragm pump, the mL/rotation is based on the pump chamber. For fine-tuning the mL/rotation can be modified. For more details on pump calibration, please view he PendoTECH Pump Calibration Tech Note.

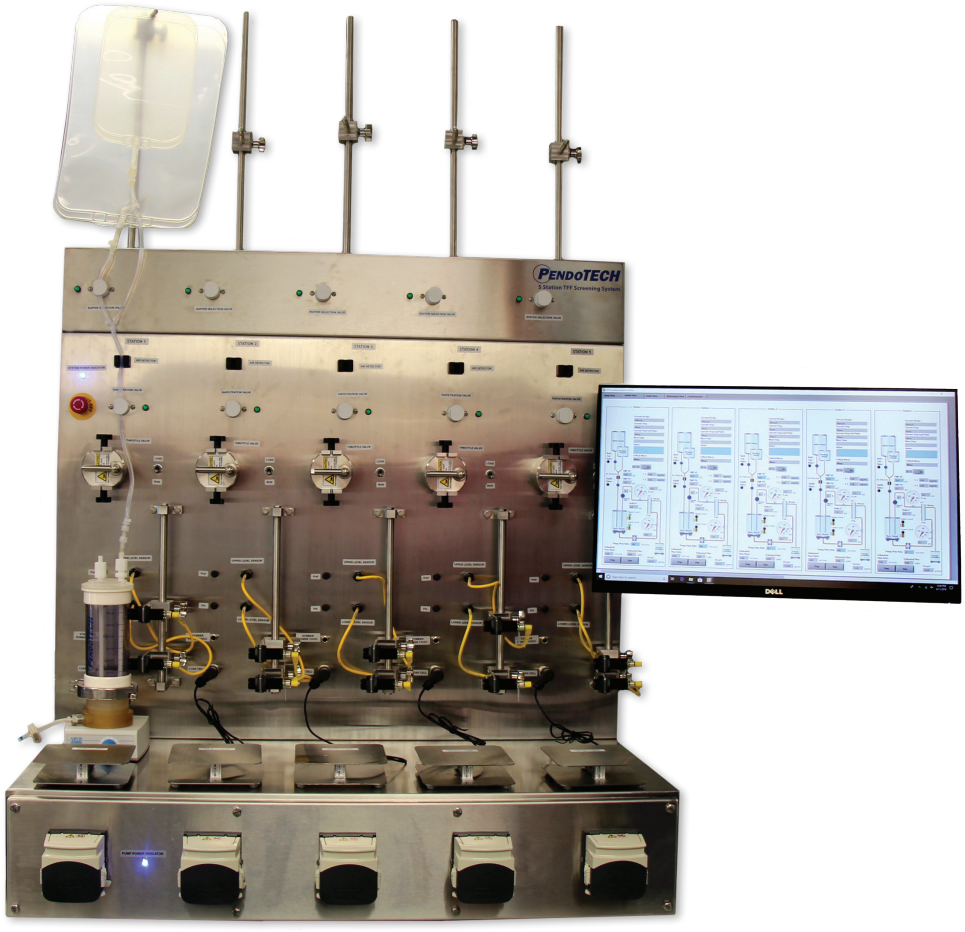
Max rpm	408	**Max Flow**	
mL/rot	0.857	349.656	mL/min

Peristaltic Pump Details

Tubing Size ID (in)	1/8	3/16	1/4
Tubing Size ID (mm)	3.2mm	4.8mm	6.4mm
Masterflex L/S ref - thick wall (2.4mm)	-	15	24
Masterflex L/S ref - thin wall (1.6mm)	16	25	17
Flow Range (mL/min)	6.8-350	15-780	24-1224
mL/rotation	0.857	1.91	3.00
MAX RPM	408		

The panel mount pump is the Watson-Marlow model 314. There are two different pump head options that are interchangeable that accommodate two different wall thicknesses. They are noted in the table to the left.





Quattroflow™ QF30SU Pump Details

The method of operation of Quattroflow pumps allows them to gently, safely and securely convey aqueous solutions and biological products that are sensitive to shear force. The design does not feature a mechanical shaft seal or wetted rotating parts, ensuring total product containment without abrasion. Additionally, the pumping principle enables risk-free dry-running, low pulsation, self priming, and minimal particle generation.

The QF30SU pump offers the following features:

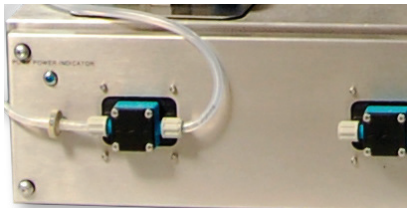
- Flow range of 5 to 500mL/min and pressure up to 4bar (58psi) which is generally not achievable with peristaltic technology
- The pressure capability enables concentration to high concentration factors as the product becomes viscous
- The pump design is for low shear operation that can reduce pump damage to fragile biomolecules and shear-sensitive viruses
- A pump chamber that can be reused extensively or can be swapped quickly without the use of tools in situations where cross-contamination wants to be avoided

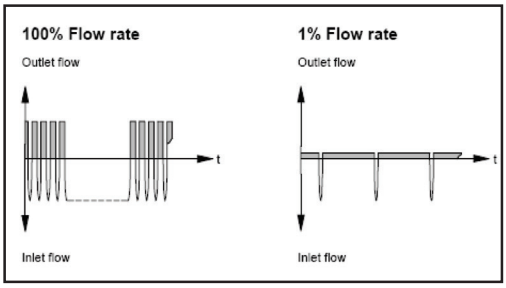
mL/rotation	0.5
MAX RPM	1000

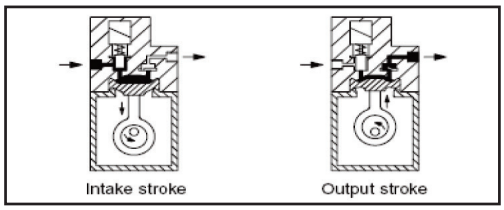
Pump chamber (system comes with 5 chambers & additional ones can be purchased)

KNF Diaphragm Pump Details

The KNF diaphragm pump has range of 2-100mL/min. Inlet/outlet fittings are compression fittings to secure size 16 tubing (1/8inch ID/ 1/4inch OD). There is a 35 micron inlet filters included in-line to protect pump check valves. The diaphragm pump technology has the ability to generate pressures up to 60psi/4bar which is generally not achievable with peristaltic technology.







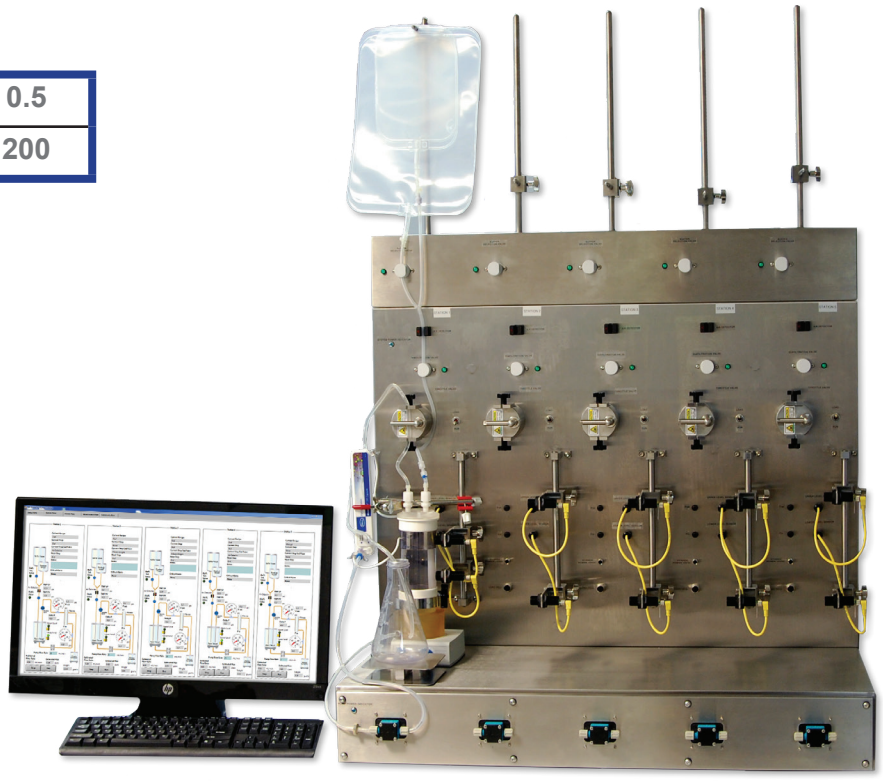
The "Heart" of the System - Precision Diaphragm Pump

The stepper motor driven diaphragm pump provides the required accuracy and precision along with low shear in a compact design. This pump also has low pulsation due to its unique operating method where the intake stroke is very rapid compared to a varied outlet stroke so that liquid is dispensed evenly. (See picture at left)

A flexible diaphragm is moved up and down by an eccentric connected to the motor shaft. During its downward movement, liquid is sucked through the inlet valve into the chamber; by its upward movement, liquid is pushed through the outlet valve. The pump's working chamber is hermetically separated from the motor to protect the liquid from contamination. The intake stroke is carried out at maximum speed, and the output stroke is varied so liquid can be dispensed evenly — resulting in a quasi-continuous, low-pulsation flow.

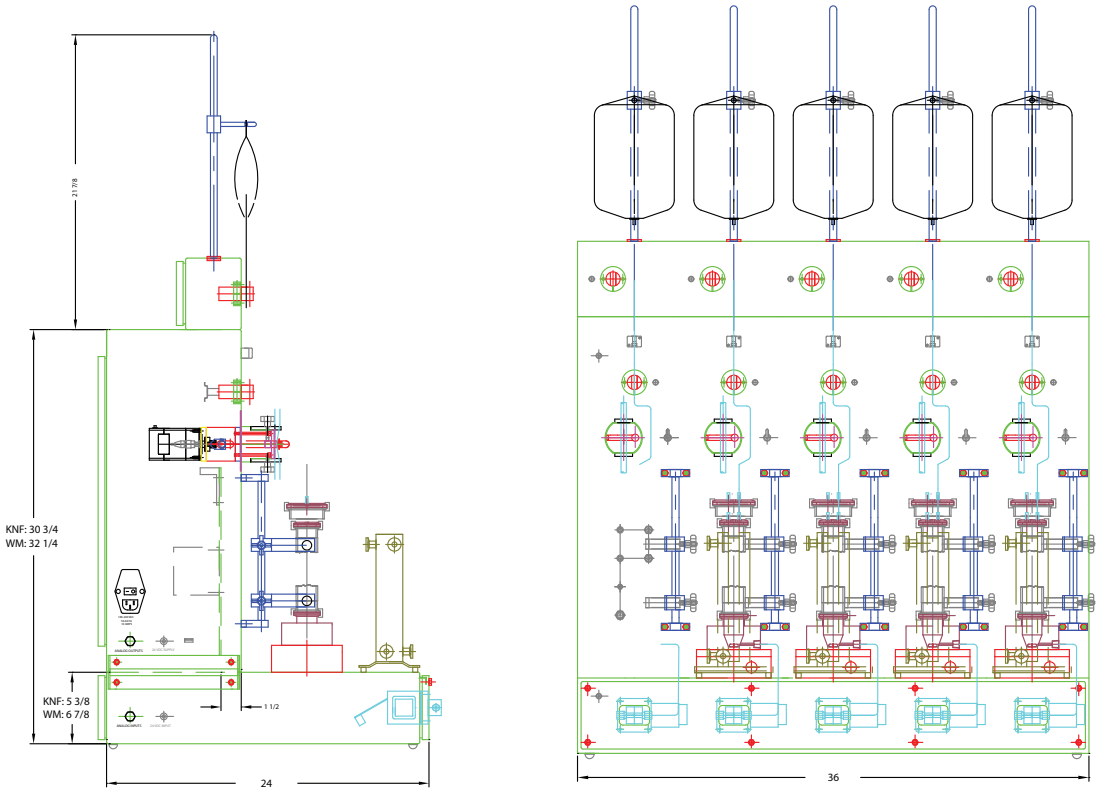
The pump continues to deliver the set flow rate across the range of back-pressures that may be encountered during a normal flow filtration process.

mL/rotation	0.5
MAX RPM	200



Hardware Input/Output Details

The efficient design enables high throughput in a very compact footprint. A very impressive and creative engineering effort was utilized to achieve this optimized design. The dimensions are shown in the drawing below.



There are 13 inputs/outputs per station for a total of a very impressive 65 in the system. They are shown in the pictures below which includes the ability to add a filtrate pump to the system via the left panel connection. NOTE: valves and air detector not shown.

Left side panel

Front panel inputs

Lab Scale Process Vessels

Two different size vessels with Low Hold-up Volume - the key to minimizing overall system holdup. Both have a conical bottom with mixing and a low point drain.

- Available in 2 different sizes of 600mL and 140mL
- Design with conical base with low-point drain minimizes liquid hold-up
- Luer outlet at base that facilitates easy integration to any process flow path
- Lid with 3 holes easily inserts into vessel - 2 holes for placement of dip tubes and one for venting
- Locater at bottom for stir bar included for process mixing
- Transparent with graduation marks for accurate process volume measurement
- Made of polysulfone which is compatible with many chemicals including sodium hydroxide
- 3 way stop-cock to facilitate easy recovery

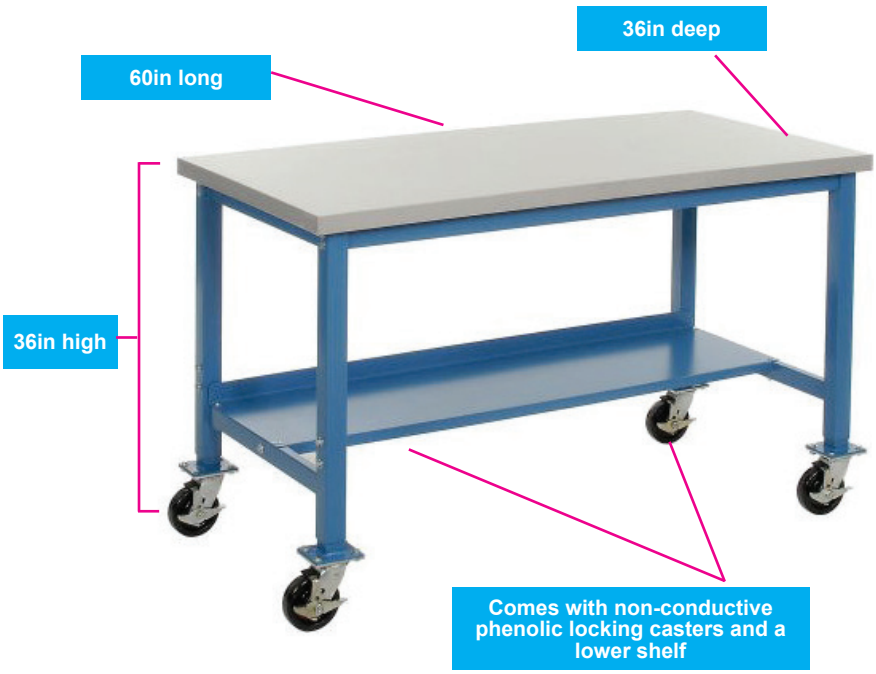
Contact Materials
Vessel: Polysulfone
Dip Tubes: Nylon

600mL with 40mL in conical section

140mL with 12mL in conical section

System Table Details

System comes with a table with a depth greater than a typical lab bench. This provides work space in front of pumps or for potential location of load cell in the case of a larger filter in use. Additionally, rear access for potential service or upgrades.



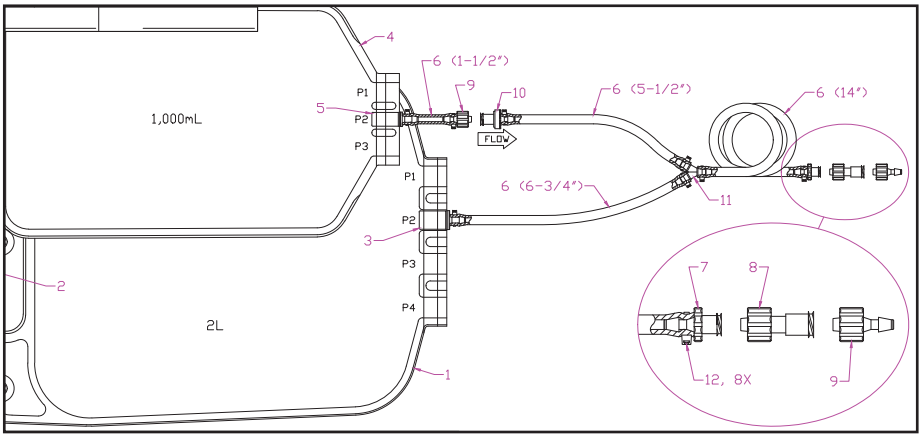
Filter Holder Clamps

The system is designed to work with different filter types such as hollow fiber and cassette from different manufacturers. The filter may rest on the work surface or the system comes with filter clamp holders that can be used to hold the filter and save work surface area. The clamp holder attaches to the level sensor alignment post and the filter clamp is held in place by the holder.

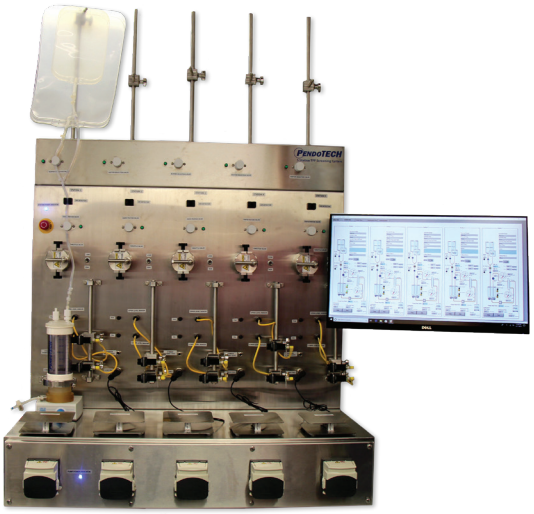
Hollow Fiber Filter Shown

Fluid Path

The non-sterile fluid path that comes with the system is designed to deliver the fluid into the vessel. The filter and fluid path around the filter and pump is user supplied. The fluid path can be re-used by refilling the one and two liter bags. Additional fluid paths can be assembled from the commonly used parts shown below. Additional kits, including any variations, can be ordered by 3rd parties that specialize in these items.



NO.	QTY.	UOM	DESCRIPTION
12	8	EA	Cable Tie, Sub Miniature, HTSN
11	1	EA	Connector, WYE, 1/8 ALL, PP
10	1	EA	Fitting, Check Valve, 0.087psi CP, FLL x 1/8 HB, 80505
9	2	EA	Fitting, Male Luer, 1/8 HB, PP
8	1	EA	Fitting, Orifice 2.5mm MLL/FLL, PP/SS, RPLR2551015S
7	1	EA	Fitting, Female LUER, 1/8 HB, PP
6	2.4	FT	Tubing, Advantapure Class VI Silicone, 1/8 x 1/4
5	1	EA	Port Tube, 3/8 Barrel X 1/8 HB, LDPE
4	1	EA	Chamber, Flextreme, 1L, FlexClr BPMBPM
3	1	EA	Port Tube, 1/2 Barrel X 1/8 HB, LDPE
2	1	EA	Ridged Support Rod, L8-3/4
1	1	EA	Chamber, Flextreme, 2L, FlexClr BPMBPM



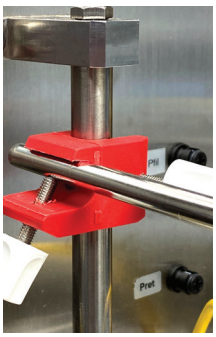
Ordering Information

SYSTEM	
PDKT-PCS-5S-TFF*	PendoTECH 5 Station TFF Process Control and Monitoring System with PC-based Graphical User Interface Software and PC
PDKT-PCS-5S-TFF-PBWM	PendoTECH 5 Station TFF pump base station, Watson Marlow peristaltic no pump heads
PDKT-PCS-5S-TFF-PBQ30	PendoTECH 5 Station TFF pump base station, Quattroflow Q30 (includes 5 chambers)
PDKT-PCS-5S-TFF-PBKNF	Pendotech 5 Station TFF Pump Base Station, KNF Diaphragm Pump (2-100ml/min)
PDKT-TNK125M	140mL - conical bottom vessel (polysulfone) with low point drain, includes lid, 2 dip tubes, 1 polysulfone 3 - way stopcock, and stirbar - (DOES NOT INCLUDE STIR PLATE)
PDKT-TNK500M	600mL - conical bottom vessel (polysulfone) with low point drain, includes lid, 2 dip tubes, 1 polysulfone 3 - way stopcock, and stir bar - (DOES NOT INCLUDE STIR PLATE)
PUMP-WM-314D-HEAD	Watson Marlow 314D Pump Head for thin wall 1.6mm wall tubing for Five Station Peristaltic Pump station
PUMP-WM-314D2-HEAD	Watson Marlow 314D2 Pump Head for thick wall 2.4mm wall tubing for Five Station Peristaltic Pump station
PREPS-N-000	Single Use Pressure Sensor, non-sterile, polysulfone, luer inlet/outlet
PREPS-N-012	Single Use Pressure Sensor, non-sterile, polysulfone 1/8inch hose barb
PREPS-N-025	Single Use Pressure Sensor, non-sterile, polysulfone 1/4inch hose barb
PREPS-N-5-5	Single Use Pressure Sensor, non-sterile, polysulfone, 3/4inch Sanitary Flange Inlet/Outlet
CONDS-N-012	Single Use Conductivity Sensor, non-sterile, polysulfone 1/8inch hose barb
CONDS-N-025	Single Use Conductivity Sensor, non-sterile, polysulfone 1/4inch hose barb
PUMP-WM-120-TW	Watson-Marlow 120U/DV 200RPM Pump Fitted with 114DV flip-top four roller pump head for thin wall tubing
PDKT-WM15-5STFF-V	Interface cable from 5STFF System to a Watson Marlow 101 and 120 pump with D15 connector, voltage control, 6 feet (2meters)
RPLR2551015S^	Male to Female Luer flow restrictor 2.5mm orifice for liquids 1500 LOHM (integral into fitting from part RESM0505000S)

^ Orifice in the luer flow restrictor limits the buffer flow to approximately 50mL/min

Includes*:

- System
- PC and monitor mounted on 3 position arm
- Mobile table for system
- Five stir plates
- Five 3000gramx0.1gram load cells
- Fifteen luer pressure sensors range -10 to 60psi
- Five 600mL vessels (Part #: PDKT-TNK500M)
- Five starter fluid path kits into vessel
- Five nylon clamp holders
- Five filter clamps



Clamp Holder