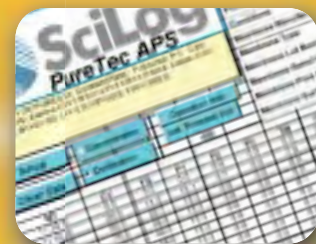


PureTec™

Laboratory TFF System

- Automates / Documents Tangential Flow Filtration (TFF)
- Ideal for TFF Method Development and TFF Scale-up Studies
- Real Time Data Collection during Concentration & Diafiltration
- Controls / Monitors Feed, Retentate and Permeate Line Pressures
- Controls / Monitors Trans-membrane Pressure (TMP)

i n t e l l i g e n t b i o p r o c e s s i n g s y s t e m s

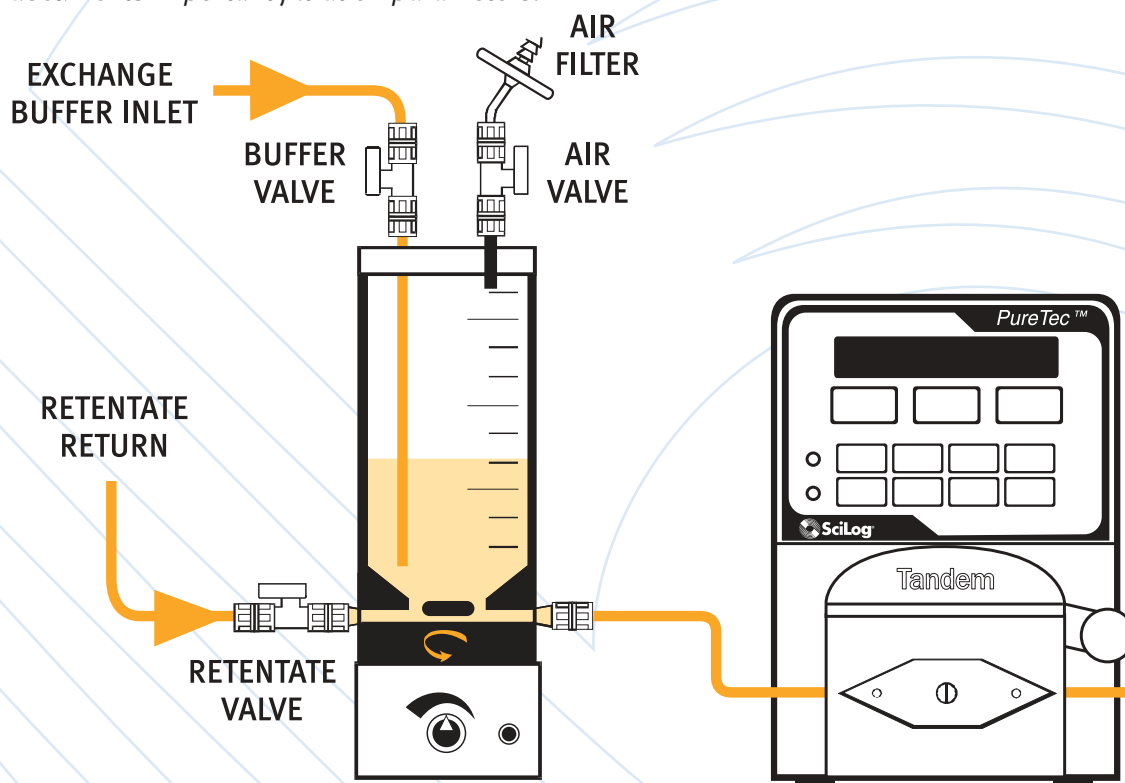


 **SciLog®**
Intelligent Bioprocessing Systems

PureTec™

Laboratory TFF System

Patented SciLog® technology includes an on-board software and hardware system that automates, optimizes and documents protein concentration and protein diafiltration. The PureTec™ System is an exclusive software-driven fluid delivery system that automatically adjusts cross flow rate and backpressure and documents important filtration parameters.



* US Patents:
5,947,689; 6,350,382; 6,607,669;
other patents pending

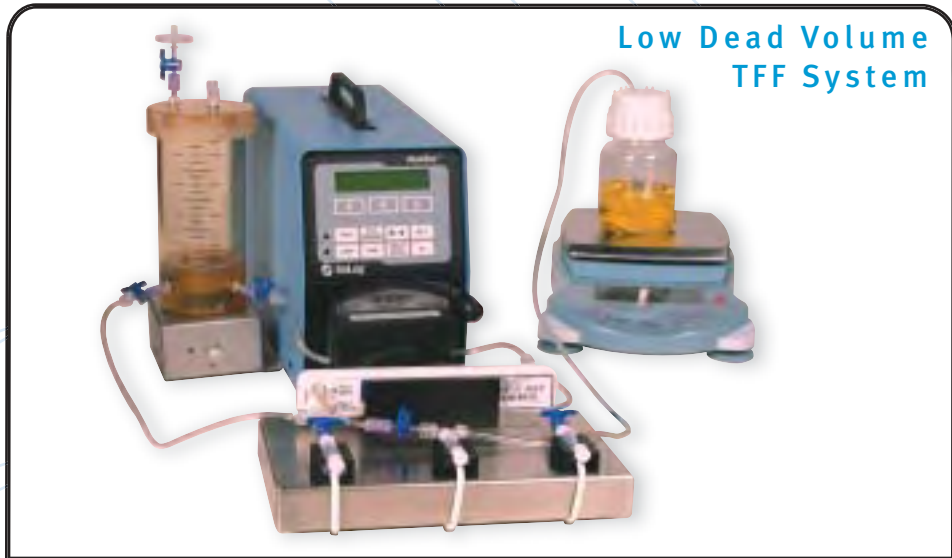
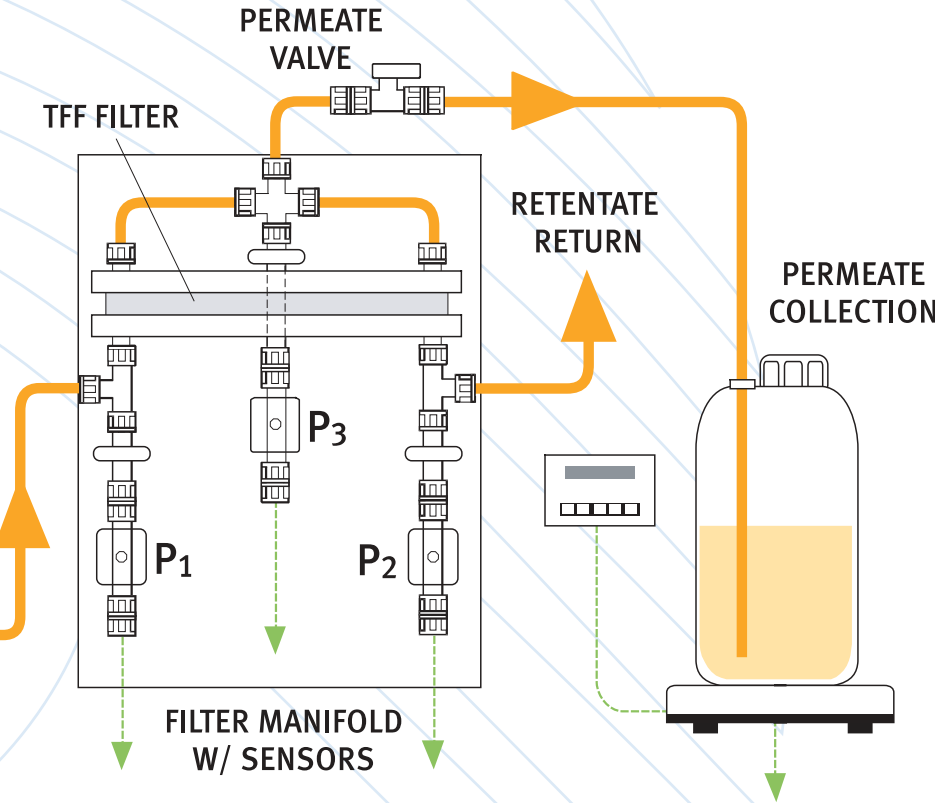
* Components not to scale.

Protein Concentration by TFF

In TFF concentration procedures, a dilute protein solution (~1.0 gram/liter) is pumped i.e. re-circulated, through a TFF device whose selected porosity allows only solvent (water) and dissolved salt to pass through the filter pores and is collected as permeate. The removal of water leaves an increasingly concentrated protein solution behind as retentate. For protein solutions, the gradual removal of water causes a gradual increase in solution viscosity during the TFF concentration step. Permeate flux, transmembrane pressure (TMP) and cross flow rate are significantly affected by solution viscosity changes. In order to maintain an optimal permeate flux, both cross flow rate and measured TMP require frequent, manual adjustment during the TFF concentration procedure. **In Constant Pressure Mode, the PureTec™ does this adjustment automatically – no more manual adjustments are required when you use the PureTec™ System!**

Protein Washing (Diafiltration) by TFF

In diafiltration procedures, a concentrated protein solution is “washed”, i.e. de-salted, using an exchange buffer to remove undesirable electrolyte (dissolved salt). The concentrated protein solution is pumped, i.e. re-circulated, through a TFF device whose selected porosity allows only the undesirable electrolyte to pass through the filter pores, which is collected as permeate. The permeate volume (undesirable electrolyte) that has been removed from the concentrated protein solution (retentate) is replaced with an (desirable) exchange buffer. In constant volume diafiltration or “washing” procedure, the collected electrolyte is automatically replaced by an equal volume of exchange buffer. Approximately ten (10x) volume exchanges are typically required for substantial removal of undesirable electrolyte from the concentrated protein solution. **User-selectable alarms provide automated, worry-free TFF performance with the PureTec™ System.**



1. Automated TFF Data Collection and Trend Graphing:

The PureTec™ is ideally suited for TFF method development, i.e. optimizing existing TFF procedures, and for TFF scale-up studies. The PureTec™ displays up to fifteen (15) TFF parameters. You can scroll through three PureTec™ display options, thereby obtaining an overview of the filtration progress and TFF system status. The SciLog® application software, SciDoc, is used to summarize filtration data and create graphical representations on your PC.

The SciLog® / SciDoc custom spreadsheet has three (3) data fields: 1. Summary of all PureTec™ related parameters including time / date stamp; 2. Information related to process solution and filter membrane, which is filled in by the operator; and 3. PC display of up to 15 filtration parameters that are updated at user-selected time intervals:

- MT Military Time, HH: MM:SS
- FQ Collected Filtrate Weight
- P1 Feed Line Pressure, psi
- P2 Retentate Line Pressure, psi
- P3 Permeate Line Pressure, psi
- TM Calculated Trans-membrane Pressure
- FF Nominal Feed Rate, ml/min
- FP Permeate Flow Rate, ml/min
- FX Permeate Flux Rate, lmh
- FR Calculated Cross Flow Rate ml/min
- CF Concentration Factor
- ST PureTec™ Status: RUN, STOP, EXIT
- AL PureTec™ Alarm: HP, LP, FQ, etc.
- DP Differential Pressure, P1 - P2

Figure 1

The screenshot shows the **SciLog PureTec APS** software interface. At the top, there is a header section with fields for Run ID, Date, Time, Product Name, Product Description, Conditions, and Membrane Information. Below this is a large data table with multiple columns and rows, displaying real-time or recorded filtration parameters. The table includes columns for time, flow rates, pressures, and other system metrics.

Specifications

Dimension:	Width: 5.75 in (14.6cm); Height: 8.5 in (212.6); Depth: 11in (27.9).
Weight:	14 lbs (6.4kg).
Enclosure:	16 Ga, aluminum baked epoxy blue.
PureTec™ Models:	
PureTec CP-8	Tandem 1081 peristaltic pump head with variable speed max. 8 RPM motor, Flow Range (depending on tubing size): 0.03 to 24.3 ml/min.
PureTec CP-120	Tandem 1081 peristaltic pump head with variable speed max. 160 RPM motor, Flow Range (depending on tubing size): 0.5 to 554 ml/min.
PureTec CP-200	Tandem 1081 & Tandem 1082 peristaltic pump heads mounted piggyback with variable speed max. 600 RPM motor, Flow Range (depending on tubing size): 2 to 2,258 ml/min. Tandem 1081 uses Masterflex peristaltic pump tubing (thin-walled) sizes: #13, 14, 16, 25, 17 & 18. Tandem 1082 uses Masterflex peristaltic pump tubing (thick-walled) sizes: #15, 24 & 35.
Pressure Range: Tandem Head Pump	Maximum pressure output at tandem peristaltic pump head is 45 psi. Has single point recalibration feature.
Pressure Displayed:	Pressure displayed with a resolution of 0.1 psi; choice of bar, psi, kpa.
Pressure Sensors:	Accommodates up to three (3) disposable pressure sensors. The calibrated pressure range is 0-60 psi. Any point within this range can be re-calibrated using an external pressure reference source.
Power:	115/220-240 VAC, 60/50Hz, 75 Watts; double fused: T1AL 250V (CE: IR35A 250VAC)
Encoder:	100 lines per motor revolution for 600 RPM motor. 120 lines per motor revolution for 8 and 160 RPM motors.
PureTec™ Balance Options:	<ul style="list-style-type: none"> • Balance with capacity of 2,000 grams x 0.01 g resolution included with PureTec™ CP-8. • Balance with capacity of 8,100 grams x 0.1 g resolution included with all other PureTec™ models.
PureTec™ Software:	<p>Main menu with five operational modes including:</p> <ul style="list-style-type: none"> • Rate Mode: Constant Rate Filtration with five user-definable alarms. • Pressure Mode: Constant Pressure Filtration with five user-definable alarms. • Choice of Inlet Pressure or TransMembrane Pressure for Control and Alarm.
Documentation Software for PC:	<ul style="list-style-type: none"> • SciDoc interface software with custom macros for Excel® for data compilation. Sent to you ready to use. • Complete process analysis with graphing of data. • Real-time verification and documentation of process parameters.
Use Range:	4° to 40° C, 100% Humidity.
Motor:	Choice of three (3) motors: 8, 160 and 600 RPM at 24 VDC, 3.8 Amperes, Variable Pump Speed, optically encoded servo-controlled motors.
I/O Ports:	<p>1) First serial port labeled "Balance", Male DB9 connector for hook-up of electronic scale. 2) Second Serial Port labeled "Printer", Female DB9; also used to interface to PC for data storage in an Excel® file in your PC. 3) External I/O port, Female DB37 connector; Used for remote On/Off control of PureTec™ via footswitch. 4) Pressure Sensor Box: Phone plugs for three(3) pressure sensors.</p>
Data Entry:	Membrane keyboard with auditory feedback.

The PureTec™ is used together with Pall® lab scale TFF devices

PALL® TFF DEVICE	FILTER AREA	CROSS FLOW RATE	TUBING	PUMP HEAD / MOTOR	PURETEC™ MODEL
"Minimate"	0.05	30 - 50	#16	Tandem1081 / 160RPM	PureTec™ CP-120
"LV-Centramate"	0.1 - 0.2	70 - 140	#16, #25	Tandem1081 / 160RPM	PureTec™ CP-120
"Centramate"	1.0 - 3.0	700 - 2100	#24, #35	Tandem1082 / 600RPM	PureTec™ CP-200

The PureTec™ is also compatible with equivalent TFF devices made by Millipore and Sartorius. For nano-filters used in virus filtration, the PureTec™ CP-8 is recommended, which comes with an 8 RPM motor and a 1081 peristaltic pump head and generates pump rate from 0.03 to 24.3 ml/min.

PureTec™ Applications

2. Tangential Flow Filtration (TFF) – Optimized

The PureTec™ APS is designed to automate and document your lab-scale TFF procedures, i.e. concentration and desalting (diafiltration) of protein solutions. The PureTec™ is ideally suited for TFF method development and TFF scale-up studies, as well as for routine TFF work.

The PureTec™ comes with a peristaltic pump head that provides feed rates from 0.03 ml/min to 2258 ml/min. Using three (3) disposable pressure sensors, the PureTec™ simultaneously monitors the feed (P1), retentate (P2) and permeate (P3) line pressure, then calculates and displays the corresponding trans-membrane pressure (TMP). The PureTec™ is hooked up to an electronic scale for quantitatively measuring the amount of collected permeate and for determining the permeate flow rate. The feed, retentate and permeate flow rates are continuously monitored.

An optional temperature probe can be hooked up to the PureTec™ to monitor solution temperature and provide the means to document a temperature-normalized permeability factor (NWP). The optional SciDoc reporting software summarizes all

PureTec™ settings, documents important TFF parameters and provides real-time graphs.

The PureTec™ has two operational modes: TFF by Constant Pump Rate or TFF by Constant Pump Pressure.

a) Constant Pump Rate Mode

In the Constant Pump Rate Mode, you can implement your selected pump rate and use some or all of five, monitored alarm conditions. The pump rate can be increased or decreased “on-the-fly” without stopping the pump action. In the Constant Rate Mode, increasing the feed rate in a stepwise fashion and simultaneously monitoring the permeate collection rate allows you to readily determine the optimal feed rate with the highest permeate yield.

b) Constant Pressure Mode

In the Constant Pressure Mode, the PureTec™ controls the pump output based on a constant filter pressure (45 psi max.). You have a number of options, including TFF by constant trans-membrane pressure (TMP) or TFF by constant inlet pressure (P1). The pressure setting can be increased or decreased “on-the-fly” without stopping the pump action. In the Constant Pressure

Mode, increasing the trans-membrane pressure (TMP) in a step-wise fashion and simultaneously monitoring the permeate collection rate allows you to determine the optimal TMP with the highest permeate yield.

c) User-Selectable Alarms

The PureTec™ provides for both the Constant Rate and the Constant Pressure mode, with five user-selectable alarms: a *High Pressure Alarm* (60psi max) to monitor filter plug-up conditions, a *Low Pressure Alarm* to monitor sudden system pressure drops (i.e. rupture of pump tubing), a *Cumulative Volume Alarm* to monitor the feed volume, a *Permeate Weight Alarm* to quantitatively measure the collected permeate weight/volume, and a *Run Time Alarm*, which will stop the pump action once a user-defined time limit has elapsed. In addition, the Constant Pressure mode has a *Low Flow Alarm* that will stop all pump action when the permeate flow rate falls below a user-defined, lower limit. All alarms, when triggered, provide an auditory signal and printout.

3. Concentration / Diafiltration Vessel:

The PureTec™ system comes with a graduated diafiltration vessel (500 ml) that can be removed from the SS magnetic stirrer base. An optional 50 ml diafiltration vessel is also available. The diafiltration vessels are made of FDA approved polysulfone and can be repeatedly autoclaved. Materials of construction are compatible with disinfectant, i.e. isopropyl alcohol or dilute sodium hydroxide solutions. Seals (Silicone) and sealing surfaces do not contact your process solution. All fluid connections consist of 316 SS Female Luer with 0.15” ID SS tubing lining all fluid channels. SS Luer connectors and SS tubing are permanently epoxied into the vessel body. Benefits: No exposed connector threads in which contaminating organism could flourish. All SS Luer connectors are double-threaded. This also prevents crosscutting and destruction of plastic Luer components during fluid line hook-up. The diafiltration vessel is designed to maintain an aseptic fluid environment.

Figure 2

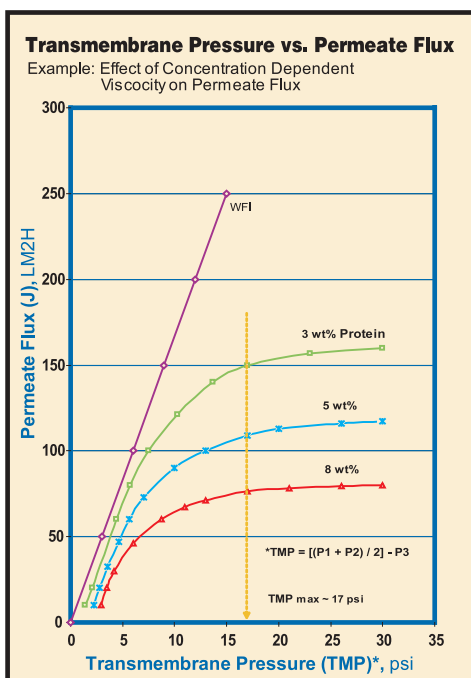
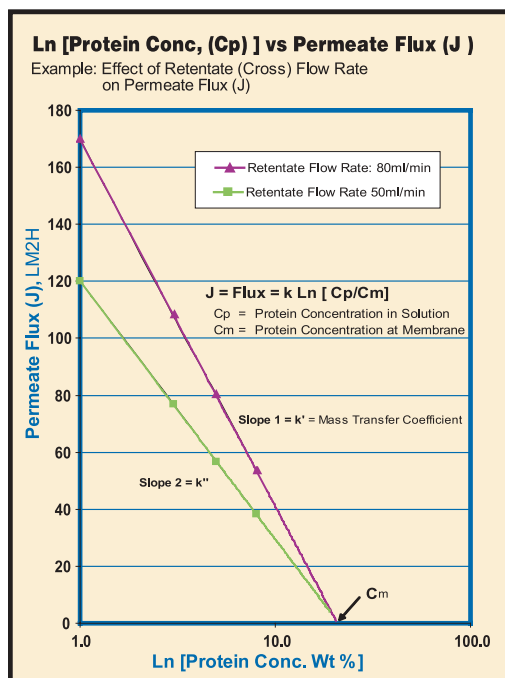


Figure 3



Summary of SciLog® Products

- High precision.
- Real-time data collection and graphing.
- User-friendly.
 - Safe, walk-away system operation.



- Each one optimizes a particular type of application.
- Built-in alarms and multiple I/O ports for interfacing with other devices, e.g. pressure sensors, balances, valves, printers, PCs, etc.

Performance validations available for all SciLog® models.

SciLog® Intelligent Lab Systems

FilterTec™ Dead End Filtration (DEF) System

- Filterability Studies and Vmax Determination
- SciDoc, Real-Time Data Collection of 15 Filtration Parameters and Graphing
- Increased DEF Filter Utilization up to 35%
- 3 Pressure Sensor Hook-ups for Filter Trains
- Safe, Walk-away System Operation

LabTec™ Smart Dispenser System

- Rapid, High Precision Dispensing/Filling, ml to liters
- Dispense by Weight or by Volume
- In-Line Filter Sterilization – Senses Filter Plug-up
- Sample Weighing and Auto-Diluting – Weight Ratio Capability
- Performance Validation Sent with Each LabTec™

ChemTec™ Bioreactor Metering System

- Automated Feed Regulation with Cell Growth Monitor
- Programmed Linear or Exponential Feed by Weight or Volume
- Real-Time Data Collection and Graphing
- Programmable Control of Two 6-Port Rotary Valves
- Other Apps include: Automated pH, Diafiltration and Perfusion

ACCU™ High Precision Digital Metering Pump

- High Precision Pump with Optically encoded Motor
- Proportional Pump Control: 4-20 mA or 0-5 VDC
- PC Interface Via Serial Port (RS-232); Footswitch Control
- Tachometer Output
- Available in Peristaltic, Piston and Magnetic Gear Models

PureTec™ CrossFlow Filtration System

- Ideal for Lab Scale CrossFlow, TFF, Protein Concentration, Diafiltration and Protein Washing
- Controls and Monitors TMP (transmembrane pressure)
- Filtration with Constant TMP/Constant Feed Rate
- SciDoc, Real-Time Data Collection of 11 Filtration Parameters and Graphing

SciDoc™ Real-Time Data Collection and Graphing Software

- Up to 15 Fluid Handling Parameters
- Data Collected and Compiled
- Real-Time Data Sent to Excel® File and Graphs
- Custom Spreadsheet with Macros
- User Defined Time Intervals for Data Collection
- Data Used to Characterize and Optimize your Application



SciLog® Intelligent Pilot Plant and Production Systems

Fill Master Smart Large Volume Dispenser

- Washdown, Mobile, Smart
- Rapid, High Precision Dispensing/Filling, liters
- Dispense by Weight or by Volume
- In-Line Filter Sterilization – Senses Filter Plug-up
- Automated Aseptic Fill into Multiple, Single Use Storage Bags

SciDoc™ Real-Time Data Collection and Graphing Software

- Up to 15 Fluid Handling Parameters
- Data Collected and Compiled
- Real-Time Data Sent to Excel® File and Graphs
- Custom Spreadsheet with Macros
- User Defined Time Intervals for Data Collection
- Data Used to Characterize and Optimize your Application

SciPure™ Automated TFF System

- Constant Flow Rate and Constant TransMembrane Pressure(TMP), Regardless of Viscosity Changes!
- Eliminates Operator Adjustment of Retentate Line Pressure During TFF
- Control, Monitoring and Documentation of TMP, Inlet Pressure, Retentate Line Pressure, Permeate Line Pressure, Permeate Quantity, Permeate Collection Rate, etc.
- SciDoc: Real-Time Data Collection and Graphing

SciPro™ Intelligent BioProcessing System

- Excellent Process Development Tool
- Programmable On-board Software for Purification and Chromatography
- Washdown, Mobile, Smart, High Precision
- 12 I/O ports to Interface with Scales, Sensors, PCs, Printers, etc.
- Pump Head Options: Peristaltic, Rotary Lobe, Magnetic Gear