



SciPure[®] GMP

Automated TFF Systems



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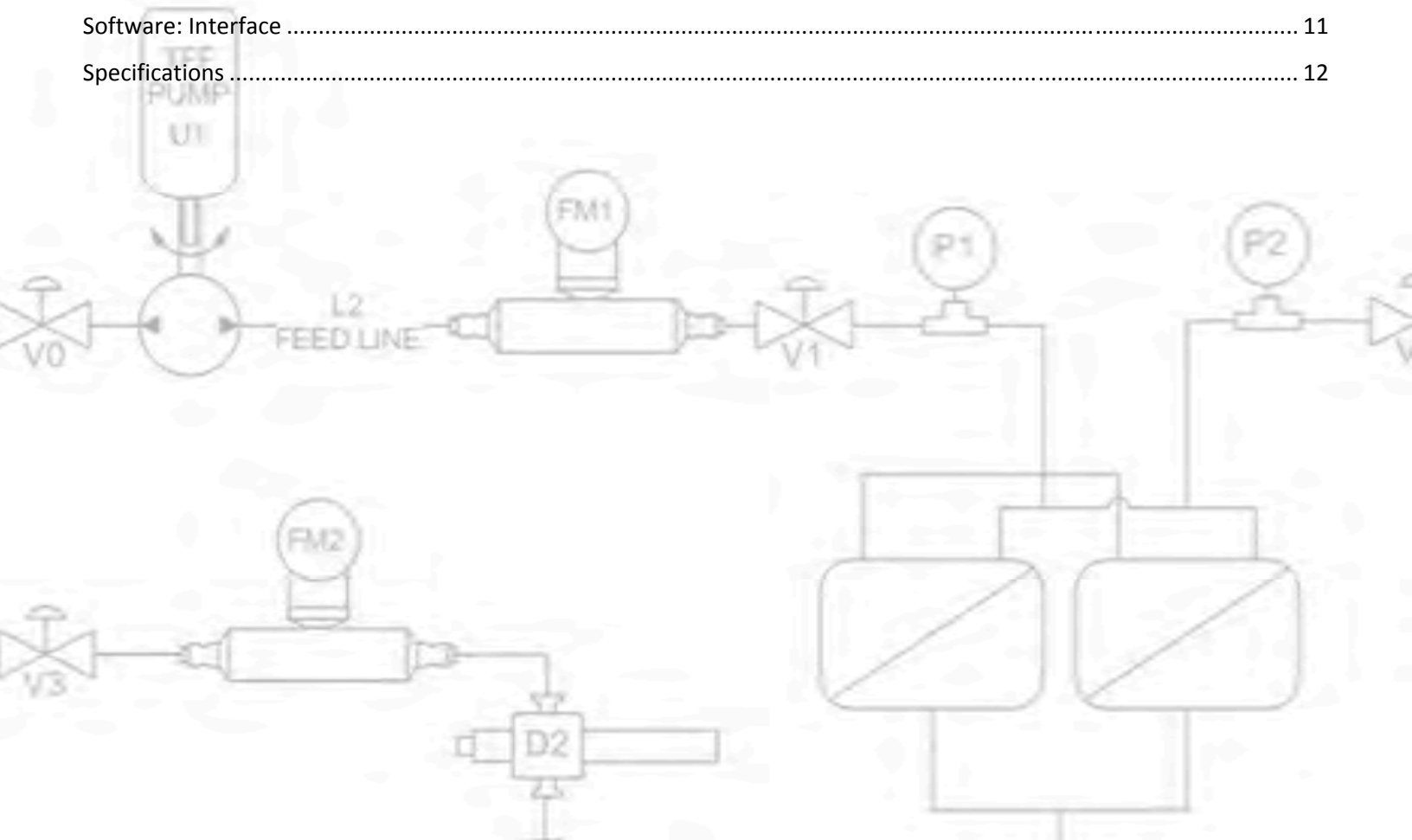
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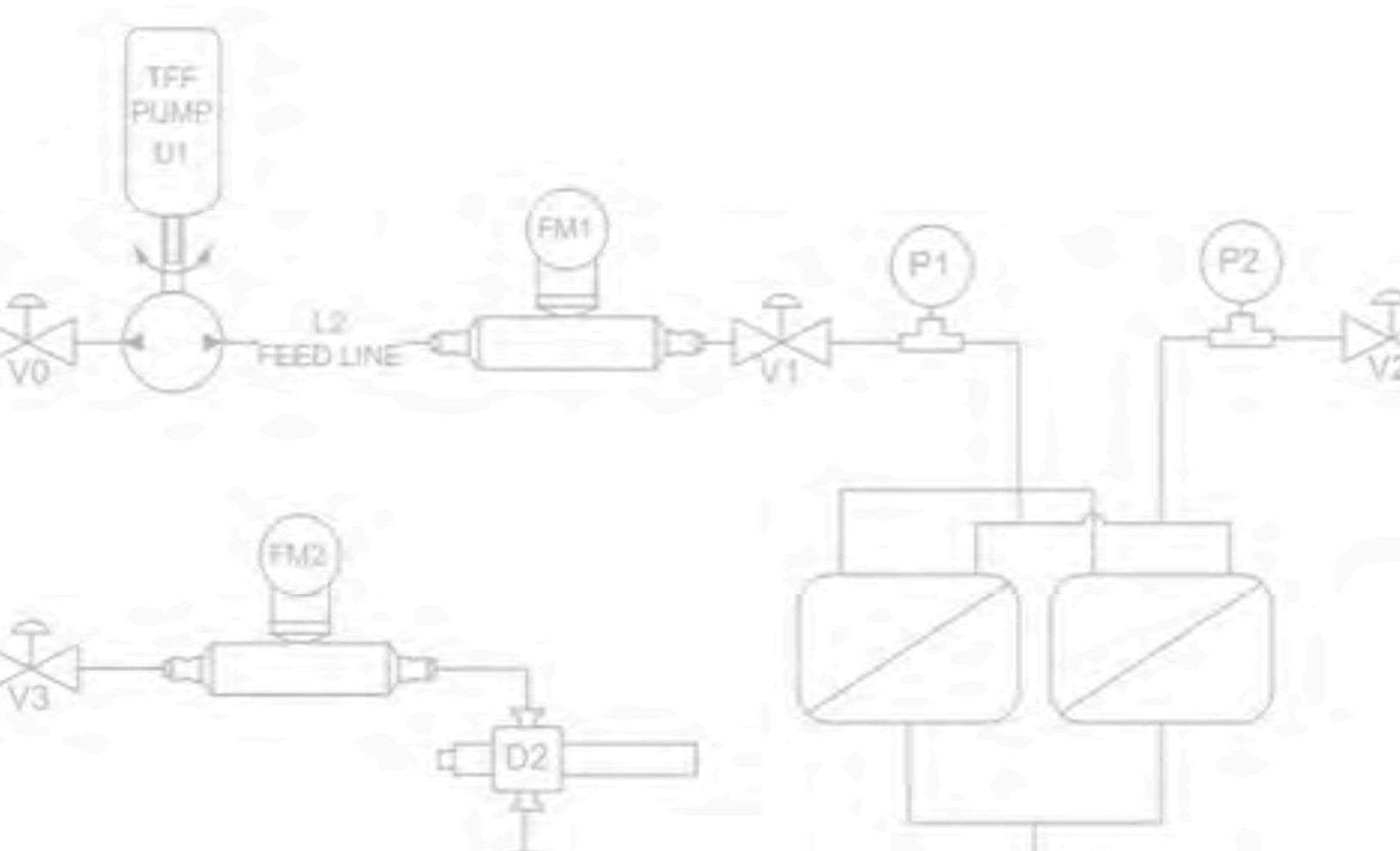
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Features & Benefits

- *Patented, software driven* fluid handling platform provides exceptional TFF performance.
- *Reliable, walk-away* system performance, safe TFF operation with user-defined alarms.
- Improved TFF *efficiency and increased yield* with automated pressure and flow rate control.
- *Complete control* of trans-membrane pressure (TMP) provides adaptive TFF at high protein concentration.
- *Maintain optimal TFF conditions* with user-programmable flow rate and pressure scans.
- Comprehensive, automated documentation – *Programmed for 21 CFR Part 11 compliance*.
- On-the-fly changes of pressure and/or flow rates permit *easy TFF method development*.
- *Increase productivity* with automated quantitative permeate collection and documentation.
- *Constant weight diafiltration*: automated exchange buffer addition.
- *Operational limit alarms*: constant monitoring of alarm conditions and parameters.



Process Control

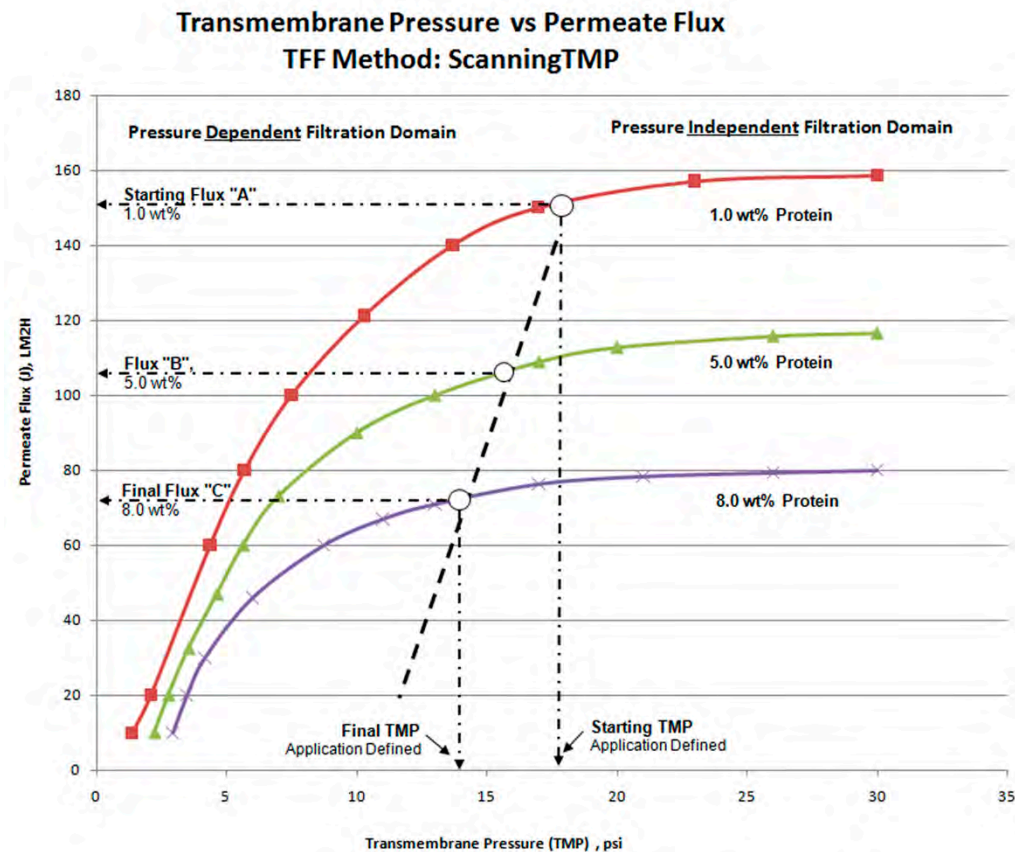
Optimal, flux-based TFF process control with the SciPure 300 GMP

- SciPure 300 GMP dual-loop control approach provides a number of TFF control options:
 1. TMP Set Point Control
 2. TMP-Scan Control
 3. Flux-Based Control
- SciPure 300 GMP automatically controls & adjusts pressure and/or flow rates in order to achieve optimal TFF control.

Dynamic Protein Concentration

The SciPure modulates the retentate line pressure by utilizing an electro-pneumatic control valve. The retentate control valve responds to any viscosity-induced pressure increase by proportionally opening the valve piston, thereby restoring the original, user-defined TMP. Once the control valve is completely open, the SciPure 300 GMP modulates the pump output in order to maintain a user-defined TMP or pressure scan.

- Protein concentration is a dynamic process, instead of using constant TMP or constant flow rate
- Use TMP-Scan Control or Flux-Based Control:
 1. Shorter Processing time - limit recirculation time to protect shear sensitive products
 2. Optimize Permeate Yield
 3. Automate TFF Process, "Self-Supervisory" TFF Operation
 4. Avoid filter plug-up - optimize use of available filter area



Hardware: Overview

- Simple, easy to clean design, compatible with SIP and CIP methods
- Wash down, Stainless Steel Construction
- Flexible, can be reconfigured if your needs should change in the future
 - pH, Conductivity, etc. sensors easily added as an upgrade in the future
- Compact design results in low hold-up volumes, ranging from 600mL to approximately 2.3L



Filter Holders

Flexible design supports many brands of TFF filters & holders

- GE
- Millipore
- Pall
- Meissner
- Dominick Hunter
- Sartorius



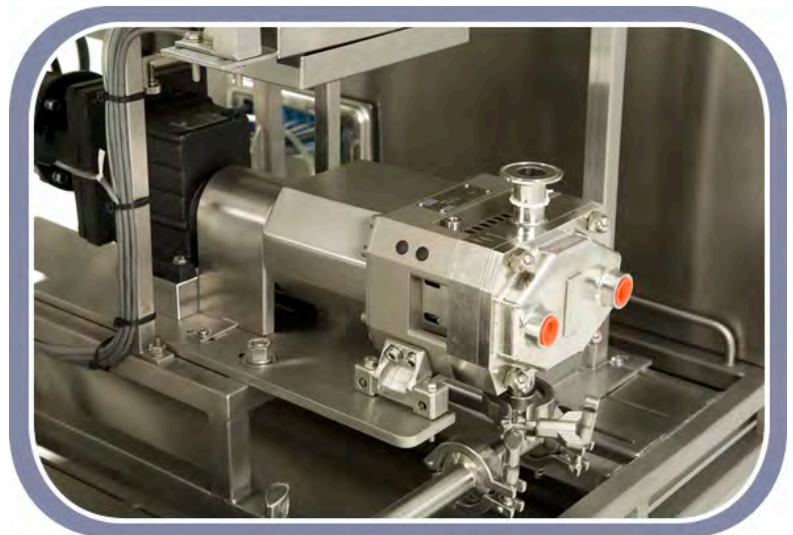
Pump Heads

Flexible design supports many brands of pump heads

- Flow rates up to 120 L/min[†]
- Handles up to 20 m² of filter surface area[†]
- Self-draining design
- High efficiency for low cps fluids

* Pictured: Viking SteriLobe Rotary Lobe Pump Head

[†] Dependent upon pump head, motor and filter configuration



Flow Meters

MicroMotion Coriolis Flow Meter

- *Straight through design for easy cleaning*
- *Adjust to changing temperatures and viscosities automatically*
- *Provides reliable, dependable digital or analog output (4 – 20 mA)*
- *Local output display available*
- *Located on Feed Line*
- *Choice of permeate flow meter or balance for Automated Flux Calculations*

** Flow meter pictured (right) includes **optional** local LCD display*



Control Valve

Burkert Control Valve

- *Pneumatically operated*
- *Automatically adjust retentate and/or permeate line pressure to control Trans-Membrane Pressure*
- *Optional control valve on permeate*
- *Supply air pressure: 65 – 85 psi*



Flow Path

Accessibility & Reliability

- Easy and open access to the fluid path, valves and flow meters
- Clean In Place / Steam In Place
- 316 SS tubing with custom elbows and tees
 - Inside surfaces electro-polished
 - TC connections

* Flow Path pictured (right) utilizes standard ½ TC connections and tubing. Higher flow applications may require a different pump head, filter size and tubing combination. Your SciLog sales representative can assist you in pricing and determination of proper configuration. Call SciLog at: 1-800-955-1993



Sensors & Transmitters

UV Sensor

- Safely automate operation with use of Hi UV Alarm/Limit
- UV value can be used as process endpoint

Conductivity & Temperature Sensor

- Temperature Range: 0 - 100°C
- Temperature Accuracy: $\pm 0.18\%$ at 100°C
- Conductivity Range: 0 – 200mS
- Conductivity Accuracy: $\pm 2\%$ full range
- Provides needed data for NWP calculations

All Sensors & Transmitters Feature:

- Sanitary Design
- Digital & Analog Reliability (4 – 20 mA)
- Safely automate operation with use of Hi/Lo Alarms or sensor/parameter value Endpoints

Pressure Transmitters

- Range: 0 – 150 psi
- Accuracy: $\pm 0.25\%$
- 3 Pressure Transmitters for easy TMP calculation:
 - TFF Feed Line
 - Retentate Line
 - Permeate Line

pH Sensors Also Available.



Human Machine Interface: Overview

B&R Touch Panel HMI

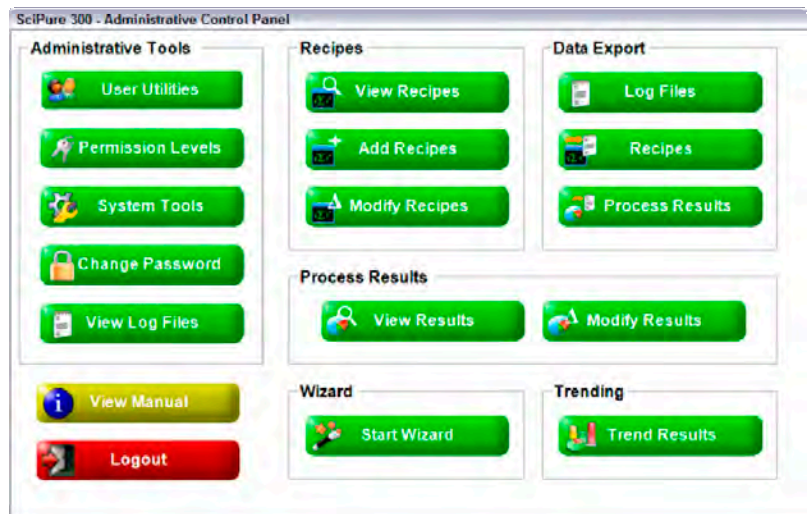
- 17" SXGA Touch Screen Display
- 1280 x 1024 resolution
- 600 MHz Intel Celeron Processor (or better)
- 512 MB RAM (or more)
- 40 GB Hard Drive
 - Approx. 7 GB used by OS & Software
- Network Connectivity (Ethernet)
 - Back up data to a corporate network
- Wash Down Construction
- Microsoft Windows XP Operating System
- Microsoft .NET



Software: Overview

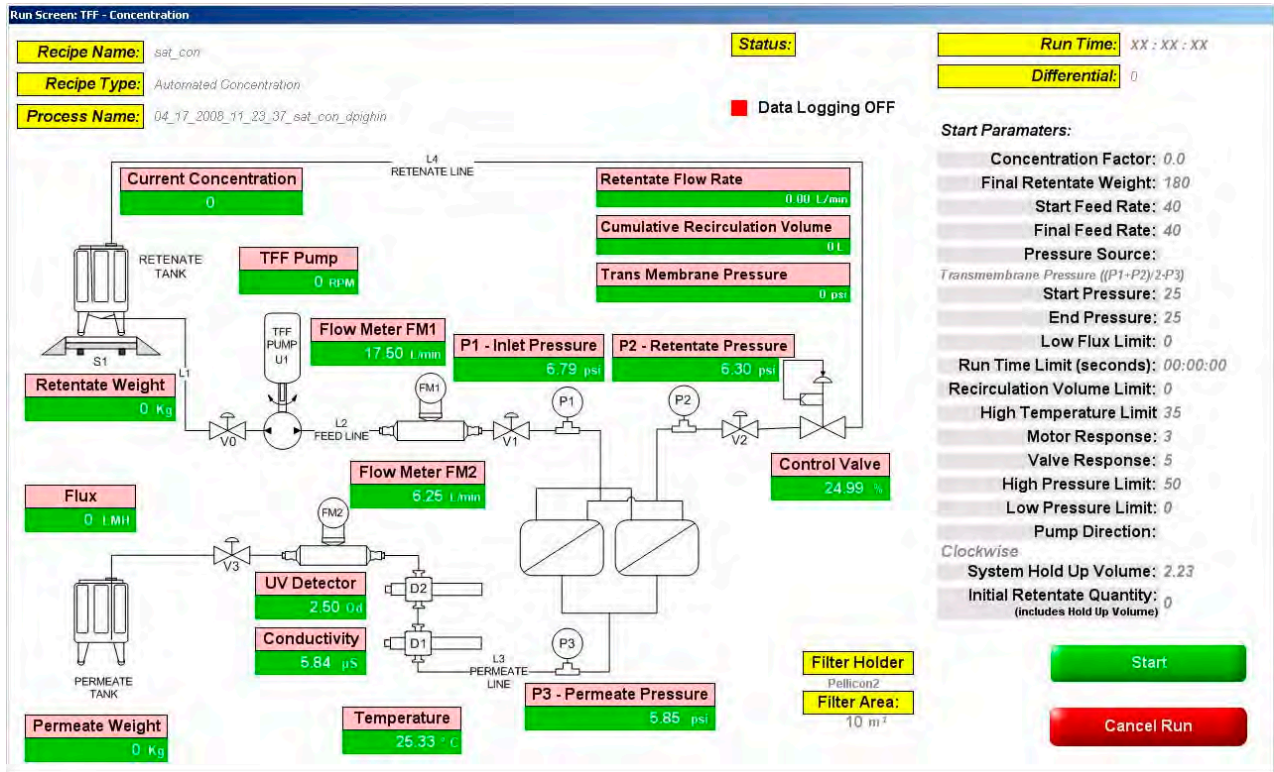
SciPure 300 GMP Master Control Software v. 1.1

- Intuitive, User-Friendly Interface
- Multiple User Accounts
 - Administrator Assigned Permission Levels
- Logging of All Program Variables:
 - Account Logins & Attempted Logins
 - Changes to User Accounts & Permissions
 - Recipe Creation & Modification
 - In Process Variables
 - Process Results & Modifications
- Local & Network Log File Export
- User Definable Limits & Alarms
- Five User Operation Modes:
 - Manual & Automated Diafiltration
 - Manual & Automated Concentration
 - Normalized Water Permeability
- User Definable Data Trending & Graphing
- Batch Reporting
- OPC Data Acquisition Available

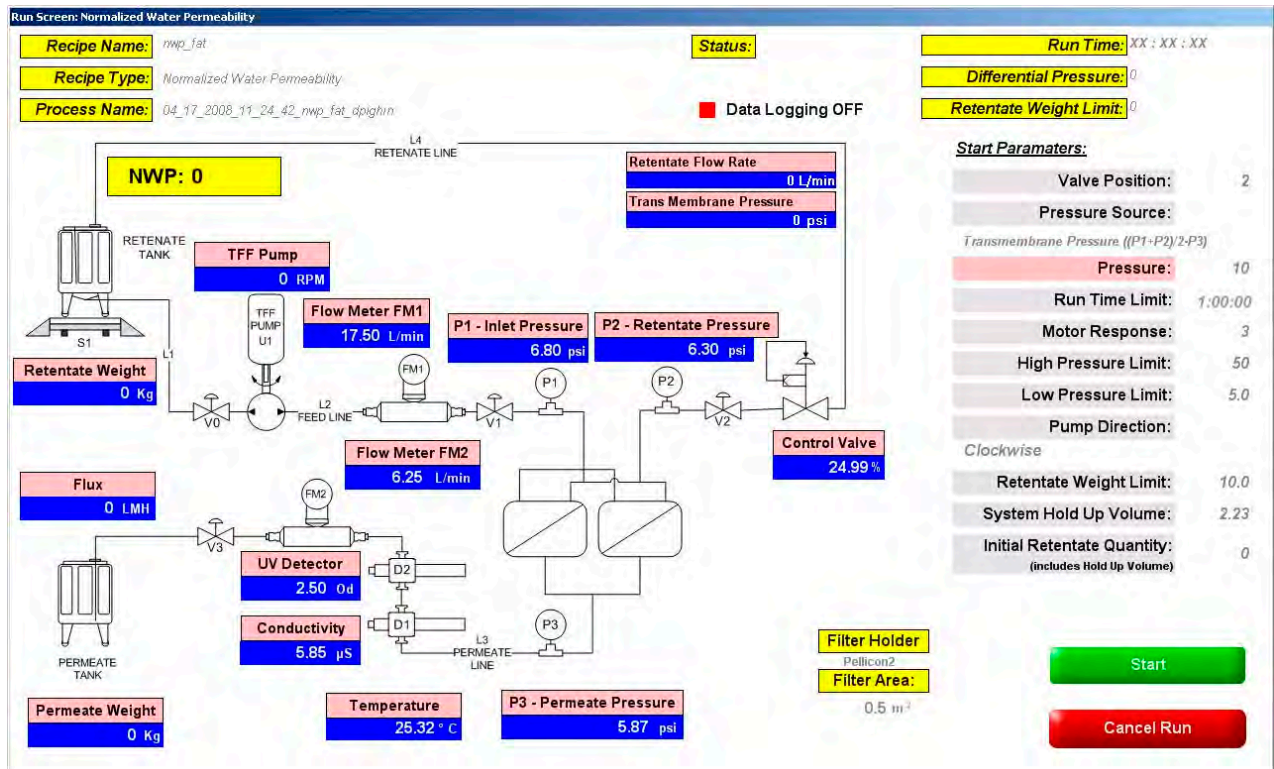


Pictured Above: SciPure 300 Administrative Control Panel Screen

Software: Interface



Pictured Above: Automated Concentration Mode Run Screen



Pictured Above: Normalized Water Permeability Mode Run Screen

Details: SciPure TFF Purification Systems

Capabilities

Flow Rate	0-60 L/Minute*
Filtration Area	20 m ² of Filter (max.)*
Document Tracking	<ul style="list-style-type: none">• In Process Variables (27x) every 10 seconds while process is running• Post Process Viewing with Trending and Export (via USB or Ethernet)• Recipe Creation, View, Modification, and Export• Log File Export, Archiving, and Restoring• Document Archiving and Restoring• Batch Reporting
Sanitization / Sterilization	Clean In Place, Steam In Place
Operational Modes	<ul style="list-style-type: none">• Automated Concentration• Automated Diafiltration• Manual Concentration• Manual Diafiltration• Normalized Water Permeability
Maintenance	<ul style="list-style-type: none">• Communication Diagnostics• Dynamic Control Loop System Tests
Alarm Notification	NEMA 4 IP65 Rated LED Stainless Stack Light

Control System

HMI & Software	<ul style="list-style-type: none">• 17" Industrial Touch Screen Panel IP65 Rated PC• Windows XP Professional Operating System, Service Pack 2• SciLog SciPure 300 GMP Master Control System v. 1.1 (or higher)
Motor	Servo Controller with 2.55 HP Motor IP54
I/O	<ul style="list-style-type: none">• Industrial Remote I/O• ModBus RTU & TCP/IP Skid Communication

Control Cabinet

Ratings	<ul style="list-style-type: none">• NEMA 4 IP65 Rating• 304 Stainless Steel
Power Requirements	<ul style="list-style-type: none">• 1x 230VAC, 3 Phase, 30 Amps• 1x 115VAC, 10 Amps - (Diafiltration Pump System)
Pneumatics Requirements	1x 85PSI of Compressed Gas

* Depends on motor, pump head, and filter configuration

Specifications: SciPure TFF Purification Systems

TFF Production Platform	SciPure 200 GMP	SciPure 300 GMP	SciPure 400 GMP
System Size/Parameters			
	A	B	
Recirculation Pump Rate, max	15 LPM	23 LPM	60 LPM
Recirculation Pump Rate, min	0.75 LPM	1.2 LPM	3 LPM
Pump Pressure, max	60psi		60psi
Feed Connections	1/2"TC	3/4"TC	1.0"TC
Retentate Connection	1/2"TC	3/4"TC	1.0"TC
Permeate Connection	1/2"TC	3/4"TC	3/4"TC
System Hold -up Volume:	0.7 to 2.0L ¹		2.0 to 6.0L ¹
System Footprint:	30"(W) x 36"(L)		36" (W) x 60" (L)
	A = W-M Peristaltic B = Viking, Rot. Lobe		
Utility Requirements:	85 psi Air		
Power Requirements:	3 -Phase 230VAC, 60 Hz, 30A		
Materials of Construction:	Wetted Surfaces: 316L Stainless Steel, EDPM		
TFF Platform	304 Stainless Steel		

1. Depends on configuration

Cassette Membrane Options

GE Healthcare: Kvick Lab/Flow	Kvick Lab	Kvick Flow	Kvick Flow
# Cassette Holders	1	1	2
Min/Max Cassettes	1/5	1/10	2/20
Min/Max Area (m ²)	0.11/0.55	0.46/46	0.92/9.2
Millipore: Pellicon	Pellicon 2	Pellicon 2	
# Cassette Holders	1	1 or 2	
Min/Max Cassettes	1/5	1/4 Maxi	N/A
Min/Max Area (m ²)	0.5/2.5	2.5/10	
Pall:	Centramate/Maximate	Centrasette 5	Centrastak 100AT
# Cassette Holders	1	1 or 2	2
Min/Max Cassettes	1/5	1/10	2/40
Min/Max Area (m ²)	0.1/0.5 0.2/1.0	0.5/10	1/20
Sartorius:	Sartocon Slice	Sartoflow 2	Sartoflow 20
# Cassette Holders	1	1	2
Min/Max Cassettes	1/5	1/10	1/20
Min/Max Area (m ²)	0.1/0.5	0.7/7	0.7/14

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