

TAKE CONTROL OF YOUR UF/DF PROCESS

KrosFlo® FS-15 RPM™ System



Experience a seamless UF/DF process with automated process control from the initial stages to final concentration. No longer are you dependent solely on mass inputs and off-line, fixed-pathlength UV-Vis spectrophotometers. Say goodbye to manual interventions and streamline your process.

With the power of the fully automated KrosFlo® FS-15 TFF System and the real-time insights from the CTech™ FlowVPX® System, you can take control of your process.

- **Strengthen your process control** with high accuracy and reproducible results
- **Increase process efficiency** by reducing cycling time and increasing yield throughput
- **Reduce process risk** by ensuring accurate concentration throughout the TFF process

Take Control

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 **REPLIGEN**

KrosFlo® FS-15 System

AUTOMATION WITH THE POWER OF SCALE

Walk-Away Automation – 13 automated process control modes and manual operation to meet your PD needs.

Robust Processing – Allows for processing of volumes from 140 ml to 15 L, supporting a membrane surface area from 0.1–0.3 m² and utilizing a Quattroflow® diaphragm pump to deliver flow rates up to 3.0 liters per minute (LPM).

Safe and Secure – The diaphragm pump design offers gentle transference and excellent flow control capabilities, ideal for shear-sensitive biological products.

Scalable System – Confidently transition your FS-15 RPM System from lab to pilot-scale production, maintaining process consistency throughout your filtration endeavors.



REAL-TIME CONCENTRATION INSIGHTS

In-line integration of the FlowVPX instrument to UF/DF operations provides real-time protein concentration monitoring while allowing for feedback control.



Rapid Data Acquisition – Generates 12 “QC-grade” concentration measurements in 1 minute (5 pathlengths in 5 seconds) with continuous data acquisition during the UF/DF process.

Broad Dynamic Range – Allows for concentration measurements from 0.1 mg/ml to 300 mg/ml to be tested without dilution.

Better Accuracy – Variable Pathlength Technology (VPT) allows the system to adjust to the right pathlength range for accurate measurements regardless of the molecule.

KrosFlo® RPM™ Software

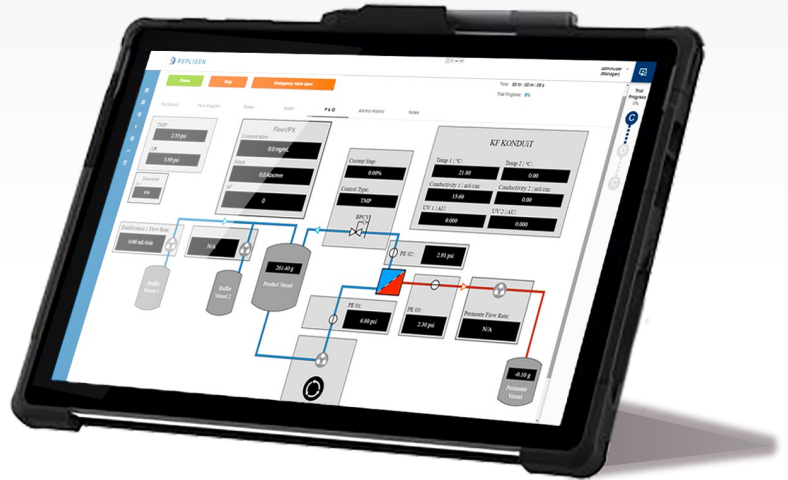
INTEGRATED DATA ANALYSIS

Real-Time **P**rocess **M**anagement Software (KrosFlo® RPM™ Software)

Integrated software combines the power of the FS-15 automation with the real-time insight from the FlowVPX System to give you the data you need and the control you've desired.

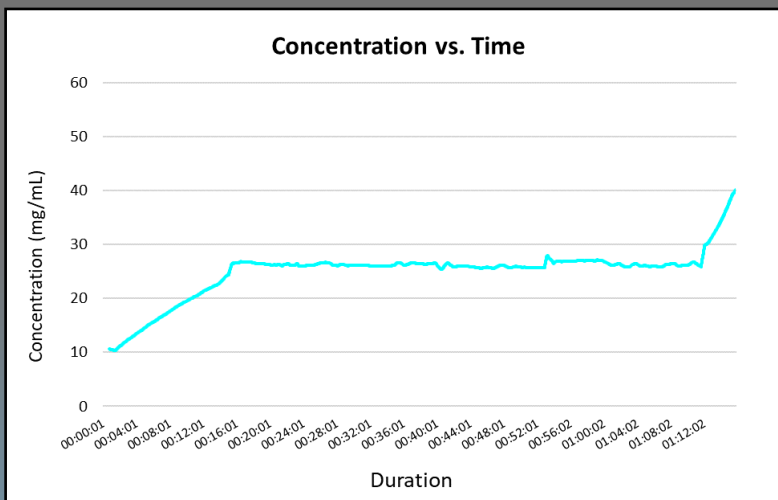
NEW dual-wavelength measurements enhance the system's capabilities to identify, quantify, and assess purity of nucleic acids and proteins.

- TFF automation control based on in-line concentration
- Provides real-time overview at every step of the filtration process
- Automatically graphs data and trends of critical inputs and outputs



BETTER INSIGHTS TO DRIVE BETTER OUTCOMES

Harnessing real-time concentration data eliminates the need for cumbersome upfront calculations or excessive adjustments to account for variations.



This empowers you with **critical process insights**, enabling a deeper understanding of your operations, slashing cycle times, and mitigating batch-related uncertainties.

Focus on the end goal by eliminating a common source of error seen with concentration factor (intermediate characteristic).

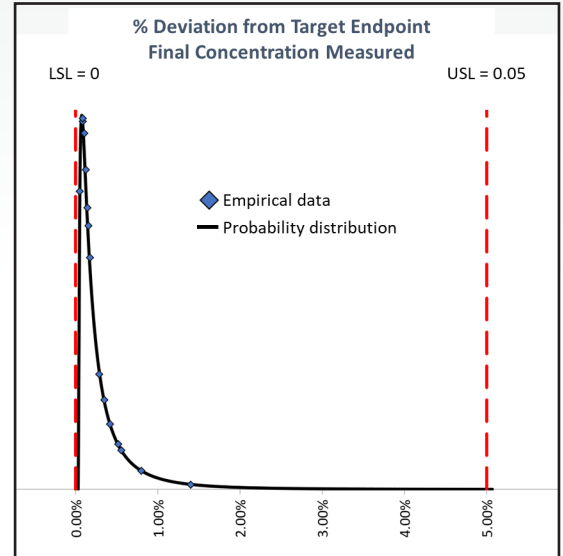
KrosFlo® FS-15 RPM™ System

Better Control Regardless of Process Variables

With in-line concentration data as the primary control factor for the UF/DF run, the process was able to reach target final concentration regardless of starting volume, crossflow rate, TMP, or retentate hold-up volume.*

A: Starting Concentration	B: Ending Concentration	C: Crossflow Rate	D: TMP	E: Retentate Hold Up	F: Starting Volume	Final Conc Deviation from Setpoint
5.0	50	6	8	5.0	2.0	0.08%
10.0	200	6	18	10.0	2.0	0.15%
7.5	125	9	13	7.5	2.5	0.18%
10.0	200	6	18	5.0	2.0	0.52%
5.0	200	12	18	5.0	3.0	0.35%
5.0	200	6	8	5.0	3.0	0.05%
10.0	50	12	18	5.0	3.0	0.29%
7.5	125	9	13	7.5	2.5	1.40%
5.0	50	6	18	10.0	3.0	0.42%
10.0	50	6	8	10.0	3.0	0.55%
5.0	200	12	8	10.0	2.0	0.13%
10.0	200	12	8	10.0	3.0	0.11%
5.0	50	12	18	10.0	2.0	0.80%
7.5	125	9	13	7.5	2.5	0.14%
10.0	50	12	8	5.0	2.0	0.08%

Target Spec Limits: -0 / +5%

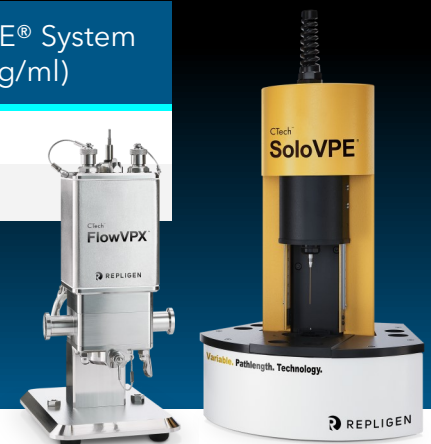


*Proof-of-concept data generated using KrosFlo® KR2i RPM™ System

ONE PLATFORM FOR MAXIMUM ALIGNMENT

Variable pathlength technology (VPT) drives alignment across various steps and functions. To complement the FlowVPX System's in-line analysis, the CTech™ SoloVPE® System offers the same accuracy in at-line or off-line measurements, providing reliable quality control at additional stages in the process.

Bioprocess Step	CTech™ FlowVPX® System In-Line (mg/ml)	CTech™ SoloVPE® System At-Line (mg/ml)
UF1/Diafiltration	47.7	47.6
Ultrafiltration 2	226	229



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