

NO MORE **PROTEIN AGGREGATION** IN TFF



DON'T LET APUMP DAMAGE YOUR PRODUCT

Tangential Flow Filtration (TFF) is a crucial step in biopharmaceutical manufacturing that requires the highest possible protein yield. Conventional pump systems such as peristaltic or 4-piston diaphragm pumps cause protein degradation due to mechanically induced shear of valves and tube compression. Furthermore, such systems generate a pulsating flow, resulting in non-optimal filter performance and reduced flux.

Levitronix® pump systems are designed for demanding TFF applications where ultra low shear as well as a pulsation free and continuously controlled flow ensure the highest protein yield.

ADVANTAGES OF A LEVITRONIX® PUMP SYSTEM

Lowest Shear //

Highest Protein Yield

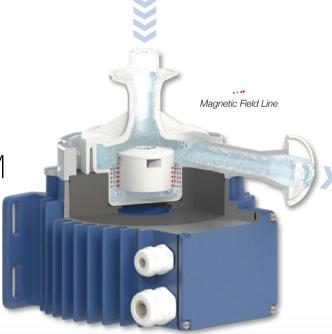
The magnetic levitation technology guarantees that no pump components come in contact with one another enabling a continuous and smooth flow.

Additionally, the pump design ensures that no protein is trapped or damaged by valve interaction or tube compression, eliminating virtually all shear.

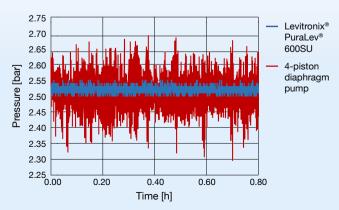
Pulsation Free Flow //

Constant Transmembrane Pressure (TMP) – Optimal Flux at Minimal Gel Layer Formation

Levitronix® pump systems deliver a pulsation free flow, independent of actual flow or pressure. With optional pressure or flow sensors, the Levitronix® control unit will keep the pressure / TMP or flux constant, independent of fluid or filter properties.



The very large gap between the rotor and pump housing guarantees that no protein is being damaged or trapped.



Pulsation of a Levitronix® pump system in comparison to a 4-piston diaphragm pump at 20 lpm and 2.5 bar.

Highest Turn Down Ratio //

High Concentrations Achievable With One Pump Size

Levitronix[®] pumps have the highest turn down ratio by being able to control and maintain the flow from a few ml/min up to the maximum flow rate.

Intrinsically Safe //

Keep Your Product and Staff Safe – No More Pressure Build-Up or Tube Ruptures

Set and limit the maximum pressure according to your tubing specifications and you will be assured that your media is safe no matter what occurs in your hydraulic flow path.

Lowest Particle Shedding //

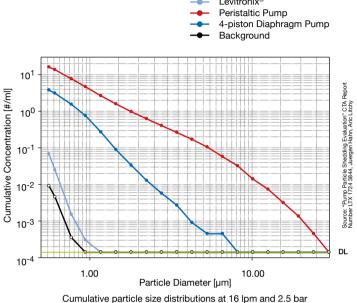
The Cleanest Pump System – Beyond Biopharma

TFF processes are generally at the end of the down stream process and any particle addition risks the purity of the final product. Due to the low shear factor plus no wear or mechanical contact between moving parts such as membranes or tubings, particle generation is eliminated. Levitronix® is the cleanest pump system and meets the purity demand of not only biopharma processes but also industries with much higher purity requirements such as semiconductor production.

Small Footprint, Low Noise Generation // Save Valuable Space

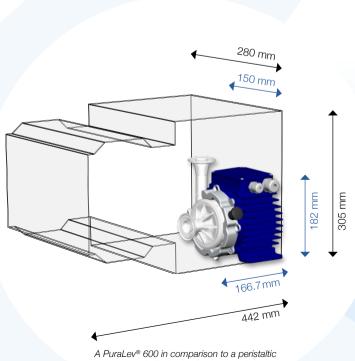
All Levitronix® pump systems have a much smaller footprint than competitive pumps of comparable hydraulic performance. The constant flow of these systems also eliminates any noise generation from your process.

LOWEST PARTICLE SHEDDING



Particle Diameter [µm]

Cumulative particle size distributions at 16 lpm and 2.5 bar



A PuraLev® 600 in comparison to a peristaltic pump of similar hydraulic characteristics.



Levitronix Console Easy Controllability of TMP and Flow

LCO-4000

Automated TFF processes require many different parts such as a pump in conjunction with multiple sensors, an external control unit and a user interface that connects all devices. The assembly of the loop from single components is typically complex, however complete packages are usually standardized and do not allow individual process adaption. This can lead to an unsatisfying process solution.

The Levitronix® LCO series deliver all-in-one control of the pump, sensors and complete process with a single

intuitive control unit. This plug and play solution allows configuration of all process relevant parameters with the 7" touch panel display.

Every control unit has an integrated PI controller. Just connect your sensor and run the system in closed loop feedback control at your desired process set point. The console has multiple flow and pressure sensors inlets, allowing easy and accurate control of flow, pressure or even TMP.

Highest Protein Yield //

Levitronix® in Comparison to 4-Piston Diaphragm Pump

Facts

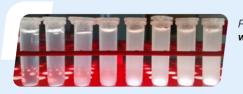
Shear stress in pumps causes protein aggregation, resulting in reduced yield.

Test conditions

Lysozyme solution was pumped into two identical closed loops by different pump technologies. Flow was set at 10 and 20 lpm with back pressures from 0 to 2.5 bar.

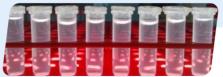
Results

- No protein aggregation was observed with the Levitronix® pump.
- Protein aggregation consistently increased when using the 4-piston diaphragm pump.
- Enzyme activity remained at 100% while using the Levitronix® pump compared to a total loss of enzyme activity when the 4-piston diaphragm pump was used for an extended time.
- Consistent results were achieved throughout all working conditions.
- Additional results on request.

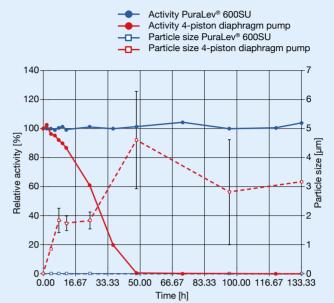


Protein Aggregation with Diaphragm Pump

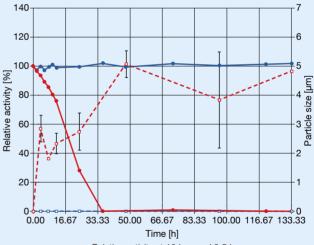




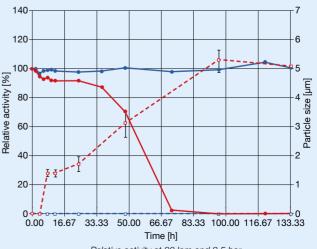
PROTEIN STUDY RESULTS High protein activity - small particle size



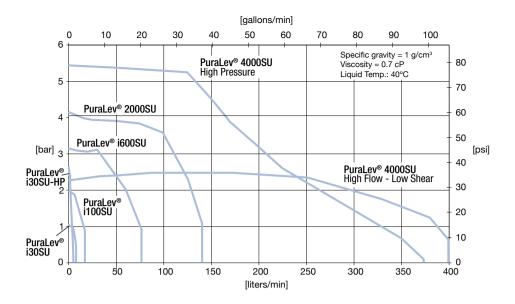
Relative activity at 10 lpm and 1.5 bar



Relative activity at 10 lpm and 2.5 bar



Relative activity at 20 lpm and 2.5 bar



Overview // SU Pump Systems

PuraLev® i30SU

1.0 bar (14.5 psi) 7.7 l/min (2.0 gpm)

PuraLev® i30SU-HP

2.6 bar (38 psi) 4.9 l/min (1.3 gpm)





PuraLev® i100SU 2.0 bar (29 psi) 17 l/min (4.5 gpm)

PuraLev® i600SU

3.1 bar (45 psi) 75 l/min (20 gpm) PuraLev® 2000SU

4.3 bar (62.4 psi) 140 l/min (37 gpm) PuraLev® 4000SU High Flow - Low Shear 2.5 bar (36 psi) 400 l/min (106 gpm)

PuraLev® 4000SU High Pressure 5.4 bar (78 psi) 374 l/min (99 gpm)















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