LEVITRONIX® PUMP SYSTEMS FOR BIOPROCESSING



THE MOST **GENTLE PUMP TECHNOLOGY IN BIOPROCESSING**

Levitronix[®] pump systems are designed for demanding fluid applications where ultra low shear, a pulsation free and continuously controlled flow eliminate any formation of particles resulting in a highly reliable solution. Based on the principle of magnetic levitation, the pump impeller is suspended, contact-free, inside a sealed casing and is driven by the magnetic field of the motor resulting in a continuous smooth flow. It combines all the advantages of a centrifugal pump but avoids problems related to the breakdown of mechanical bearings and seals found in competitive pump systems. Levitronix[®] pump systems offer distinctive advantages to the bioprocessing industry that will greatly improve your product yield.



Technical Benefits of the Levitronix® Pump System

Lowest Shear

Proven by Industry. The magnetic levitation principle and pump design guarantee that no components come in contact with one another enabling a continuous and smooth flow which virtually eliminates all shear.

Lowest Particle Shedding

Maintain your liquid purity. Because of the low shear factor plus no wear or mechanical contact between moving parts, particle generation is eliminated which maintains the purity of your liquid.

Completely Pulsation Free

Not just less pulsation, but completely pulsation free processing.

High Flow Capabilities

Levitronix[®] offers pump systems with flow rates up to 200 lpm (53 gpm), all with the smallest footprint and highest controllability.

Intrinsically Safe

No more 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.

Extremely Long Life Time

Because there are no bearings to wear out or seals to breakdown, equipment uptime increases which extends the life of your process equipment and also reduces maintenance costs.

Small Footprint, Low Noise Generation

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.

Highest Turn Down Ratio

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

Integrated Flow or Pressure Controller

Integrate a flow, pressure or temperature sensor into your pump system and create a feedback loop which will allow you to automatically maintain your desired process conditions.

Capable of Slurry [Solid/Liquid] Processing

Levitronix[®] has the unique capability to deliver solid liquid mixtures without particle agglomeration or pump wear out.

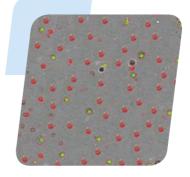


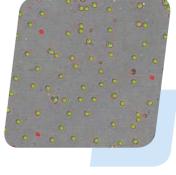
LEVITRONIX IN COMPARISON TO OTHER PUMP SYSTEMS





Cell viability with Levitronix®





Cell viability with peristaltic pump

Cell viability // comparison to peristaltic pump systems

Facts

Shear stress due to the pump has a negative effect on cell viability and causes cell death.

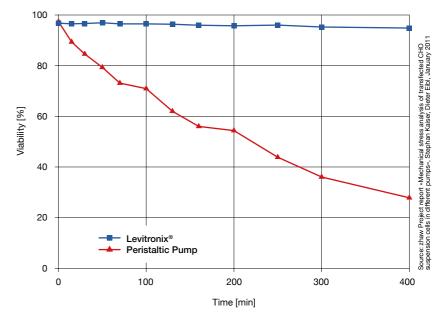
Test Conditions

The goal of this study was to compare the mechanical stress on CHO cells created by a Levitronix[®] pump system vs. a peristaltic pump system. From beakers, CHO cells were pumped into two identical closed loop configurations. Flow rate was set at 3.4 lpm with a limited low backpressure for a period of over 400 minutes. Cell viability was consistently measured and compared.

Results

The cell viability of the Levitronix[®] pump system was consistently above 95%. The peristaltic pump system reached 28%. Similar results have been achieved at four different pressure levels up to 0.5 bar.

CELL STUDY RESULTS Low shear forces - high cell viability



Time-dependent cell viability in suspension cells pumped at 3.4 lpm under a backpressure of 31 ± 2 mbar

Protein Aggregation with Levitronix®





Protein Aggregation with Diaphragm Pump

Protein Yield // comparison to 4-piston diaphragm pump

Facts

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

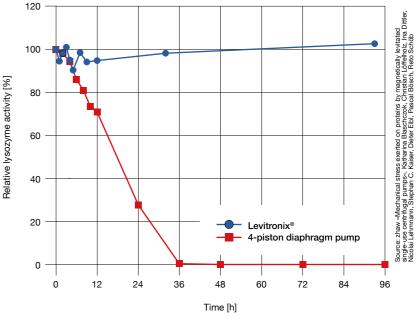
Test conditions

Lysozyme enzymes were pumped into two identical closed loops by different pump technologies. Flow was set at 10 lpm with different back pressures of 1, 2 and 3 bar over 48 hours.

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.
- Identical results were achieved at pressure levels between 0-3 bar.

PROTEIN STUDY RESULTS High protein activity - small particle size



Relative lysozyme activity at 10 lpm and 1 bar



Particle Generation // comparison to high purity diaphragm pump

Facts

- The Levitronix[®] pump system is the only pump system with no mechanical contact between moving parts.
- Mechanical contact causes abrasive wear and is the main reason for particle generation.

Test conditions

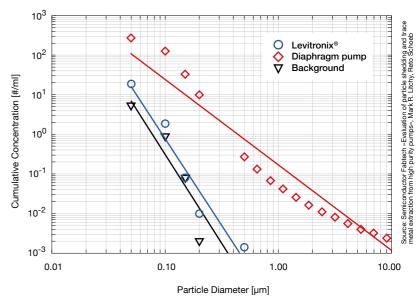
UPW was pumped into two identical closed loops by two different pump

technologies. Particle measuring devices were used to measure particles from 50 nm up to 10 μm size.

Results

The cumulative particle concentration was found to be up to 100 times higher with high purity positive displacement pump systems in comparison to the Levitronix[®] pump systems.

ULTRA LOW PARTICLE SHEDDING



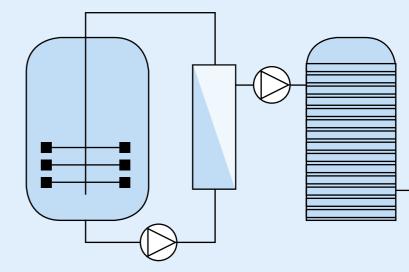
Particle generation at 19 lpm and 0.7 bar



HOW DO LEVITRONIX PUMPS BENEFIT YOUR **PROCESS**

Perfusion // increase your cell viability

High cell density and viability are the major goals in the perfusion process. Proven by both Academia and Industry, Levitronix[®] pump systems are a perfect fit for shear sensitive cells. Because the levitating impeller rotates contact-free inside the pump casing, there are no obstructions or any movements that can damage your cells, ensuring your process the highest cell viability. Also, avoid any risk of tube rupture by limiting the maximum pressure with the user-friendly touch panel. The pump systems are very easy to install and simple to use. The Levitronix[®] pump systems will run as long as your process requires. No tube adaption is necessary and there is no reduction in performance, making Levitronix® products ideal for continuous processing.



Clarification // small footprint for all sizes

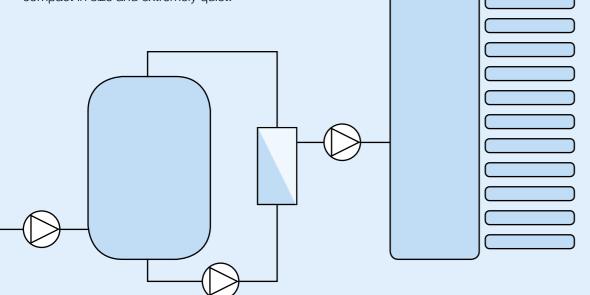
Cell harvesting and clarification are crucial steps for the outcome in downstream processing. Levitronix[®] pump systems generate a completely pulsation free flow, resulting in optimal filter performance. With its very high turn down ratio, a continuous flow is generated over a wide flow range, allowing the use of one pump size for different levels of depth filtration. With the integrated pressure controller and an external sensor, the filter can safely be operated at the optimal pressure. The additional pressure limiting feature assures that the pressure never exceeds the maximum pressure rating of the tubing specification. Levitronix[®] pumps deliver an optimal flow for your depth filtration process, very compact in size and extremely quiet.

TFF // increase your protein yield

Filtration processes such as UF/DF applications require a system design that ensures the highest product yield. The Levitronix[®] pump systems recirculate extremely sensitive liquids and virtually eliminate protein aggregation. A pulsation free flow additionally improves filter performance and avoids membrane damage.

Transfer // save time and money

Time is a critical parameter in today's bioprocessing applications. Levitronix[®] pump systems offer the fastest liquid transfer, the smallest footprint and the lowest amount of noise generation. Due to the efficient pump technology, a pulsation free flow is generated that allows a continuous discharge of liquid. With a user-friendly control unit, the maximum pressure can be adjusted to your hydraulic loop specification, enabling fast liquid transfer without any risk of product loss or rupture of tubing.



Filling // high accuracy

At the end of your process there is nothing more catastrophic than tube rupture. The integrated pressure limiting feature in a Levitronix[®] pump system ensures that the pump pressure will never exceed your specification and the product will be safely delivered. Because there is no physical contact between rotating and static parts of the pump head, the result is a virtual particle-free product with the lowest possible contamination level.





EASY, FAST AND SAFE EXCHANGE

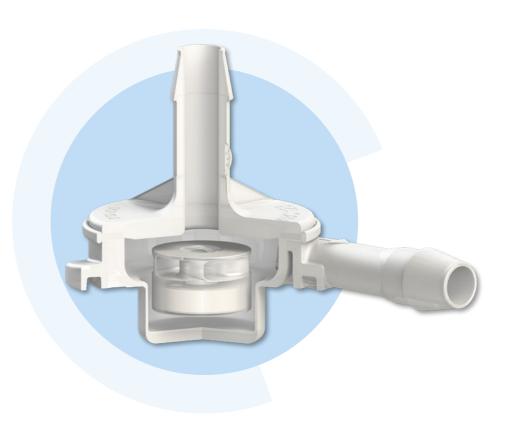


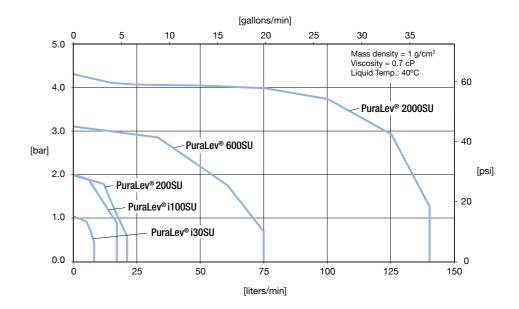
Single-Use Pump Systems

A Levitronix[®] disposable single-use pump head consists of only two pieces, the rotating impeller and the pump housing. During operation, the impeller levitates in the center of the pump housing, rotates, and at no time comes in contact with the static pump housing. The pump head is completely enclosed and there are no bearings to wear out or seals to breakdown.

In single-use bioprocessing, time is an essential factor, therefore, Levitronix® pump heads are very easy to use and both fast and safe to exchange. With no tools required, a pump exchange takes only a few seconds.

All wet surfaces are made of gamma stable polypropylene that meets the highest biocompatibility requirements such as FDA. USP-VI and BSE/TSE free.





Overview // SU Pump Systems





Multi-Use Pump Systems

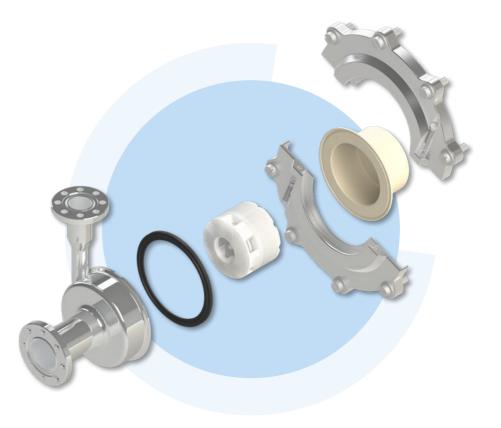
A Levitronix[®] multi-use pump head consists of the rotating impeller, a static seal and the pump housing.

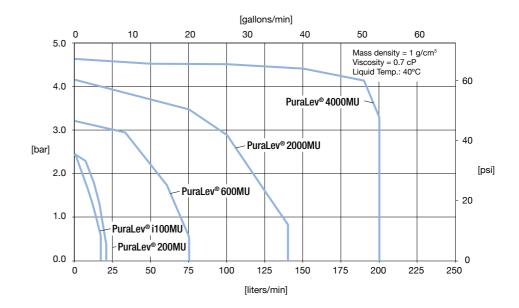
The absence of any mechanical contact between rotating and stationary parts leads to a virtually wear-free product. This unique feature ensures a very long lifetime with virtually no risk of leaking.

All liquid contacting materials meet the highest biocompatibility requirements such as FDA, USP-VI, and BSE/TSE free.

In order to ensure sterility after every cycle, the pump head can be either cleaned in place (CIP), steamed in place (SIP) or autoclaved. The pump head is composed of fluorocarbon resins or stainless steel 316L that are resistant to both heat and chemical compounds.

Levitronix® multi-use pump heads are available with or without a drain port.





Overview // MU Pump Systems

21 l/min (5.5 gpm)

17.4 l/min (4.6 gpm)



140 l/min (37 gpm)

75 l/min (20 gpm)

13

200 l/min (53 gpm)

Control Unit Intelligent pump control units for demanding applications

The Levitronix[®] control unit delivers intuitive and intelligent pump control. It allows configuration of 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. Accurate control of flow, pressure, temperature or any other process parameter has never been easier.

The control unit allows to run specific recipes, such as transmembrane pressure and transfer rate.

Facts

- Easy-to-use interface
- Precise flow monitoring or control
- Integrated signal converters for pressure and temperature monitoring
- Data collection capabilities
- Easy configuration and customizable with software





Flow Sensors

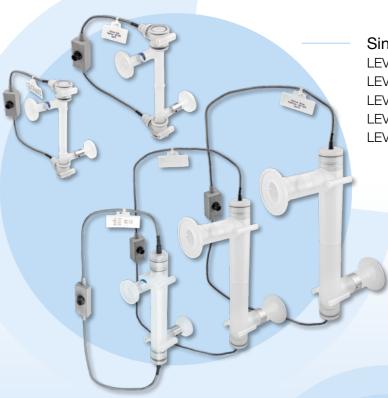
The LEVIFLOW[®] single-use and clamp-on flowmeters are designed for non-invasive flow measurements of high purity fluids using either flexible or rigid tubing.

Two piezoelectric transducers, mounted in the sensor housing, generate and receive an ultrasonic wave. The wave going in direction of the flow is accelerated and the wave going against the flow direction is slowed down. The difference between the transit time of both waves is proportional to the velocity and therefore the flow of the fluid.

All wet materials are fabricated from biocompatible (FDA, USP-VI and BSE/TSE free) gamma stable polypropylene (PP).

Facts

- Ultrasonic transit time measurement
- High precision flow measurement (single-use accuracy 1%, clamp-on sensor accuracy 3%)
- Wide flow range
- · No contamination thanks to non-invasive flow measurement
- No moving parts -> no particle generation



Single-Use Sensor LEVIFLOW® LFS-03SU LEVIFLOW® LFS-06SU LEVIFLOW® LFS-10SU LEVIFLOW® LFS-15SU LEVIFLOW® LFS-20SU

Clamp-on Sensor LEVIFLOW® LFSC-08D LEVIFLOW® LFSC-12D LEVIFLOW® LFSC-22D LEVIFLOW® LFSC-30D

Converter LEVIFLOW® LFC-1C-PC

