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BECAUSE SUPPORT MATTERS

Removing the Risk of Concentrated Salt Solutions to Precision Dispense Pumps

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Introduction

IVD instrument OEMs require high accuracy pumps for dispensing reagents, wash fluids and samples. The types and concentrations of fluids dispensed by these pumps vary widely and can be excessively damaging to the internal parts of pumps. For this reason, pump designers are continually challenged to create products that can survive increasingly aggressive environments.

Historically, there is a known and begrudgingly accepted short coming of all available pumping solutions utilized for Clinical Diagnostics fluid handling. Fluids with high salt concentrations such as 10% NaOH, or even as benign as 0.9% saline, destroy pumps in very short order. The wetted components, or those components in the fluid path, are made from engineered plastics, ceramics, borosilic glass, stainless steel, or gem stones, such as sapphires and rubies, that are chosen for their chemical inertness, resistance to corrosion, and avoidance of leaching into the fluids pumped. Despite efforts to avoid unwanted chemical reactions, pump components may still be at risk from the sediment that can be left behind when the liquids evaporate. For example, in pumping fluids having a high concentration of salts, such as sodium hydroxide or sodium chloride, a premature failure of the pump's seal is very common. This occurs as the fluid is pulled across the seal on the piston surface, where it evaporates, leaving behind crystallized salt deposits on the piston. As salt builds up and adheres to the surface of the piston, both mechanically and chemically, it will abrade the seal, causing leakage, and thus pump failure. It is generally agreed that this occurs in typical pumps within 500k-1million cycles, well short of the operational life of the instrument.

As will be explained later in this document, some methods utilized to protect pumps from this risk can introduce significant reliability concerns for the instrument. With traditional dispense pump technologies, instrument designers face a difficult decision between utilizing critical pumps that are expected to fail prematurely or protect the pumps by risking sample test reliability. Neither choice is desirable.

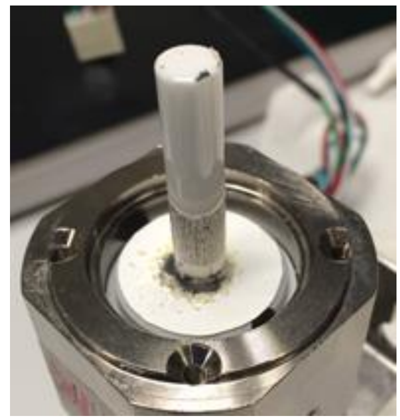
BioChem Fluidics has engineered the solution to this dilemma. The next extension of its Maestro family of piston pumps is not a typical piston pump. The new Maestro ULTRA provides the precision, accuracy, and long life required from high performance piston pumps, and it is immune from the risks associated with dispensing high concentration salt solutions.

State of Technology

Fluidics system design engineers utilize a few different system architectures in IVD instruments today, none of which are completely effective against high salt concentrations. For the purposes of this discussion, we will classify these architectures based on whether a standard or non-standard pump is utilized.

Standard Pumps

- **Syringe Pump:** A standard syringe pump is occasionally utilized, but it is expected that salt will shorten the life of the pump, requiring technician intervention to routinely replace the syringe plunger, stopper and barrel. This results in frequent instrument down time with the potential for catastrophic failures. The initial system cost is generally higher than a piston pump, and this routine maintenance results in high total cost of ownership with reduced instrument profitability.
- **Piston Pump:** Typical piston and seal materials used in piston pumps today are PEEK, ceramic zirconia TZP, 316 Stainless Steel, and UHMWPE. These materials are generally hydrophilic in nature, increasing wettability, allowing fluids to wet through the piston/seal interface in insignificant volumes, providing some lubrication, but generally not causing any issues. When dispensing high concentrated salt solutions, a standard piston pump, provides a slight increase in life compared to syringe pumps. Yet, premature failure is still inevitable. As you can see in the photo to the right, taken after approximately 1 million aspiration/dispense cycles, there is a significant salt build up in the bottom end of the ceramic piston. The surface is clean where the piston remains wetted. There is clear evidence of particulate on the piston from seal abrasion. Over time, this solidified coating destroys the seal, until there is catastrophic fluid leakage. Like a syringe pump, this too would require technician service, but is much more involved with a higher replacement cost, as the entire pump must be removed. While the service is less frequent, it is more likely to be unplanned following pump failure, which will prolong instrument down time and again increases cost of ownership over the life of the instrument, as seen here.



Item	Unit Cost	System Cost
Standard Pump (Replace)		
Pump	$ 350	$ 350
Flush System	$ -	$ -
Replacements (3x over life)	$ 350	$ 1,050
Service (3x over life)	$ 200	$ 600
Total Cost		$ 2,000

Non-Standard Pumps

- **Flushed Seal Pump:** The theory behind Flushed Pumps and practical result is fluid is passed around the piston behind the primary seal, thereby keeping the piston wet so the salt cannot dry out. It also continuously dilutes and transports the salt solution away from the piston towards waste. While effective at extending the life of the piston pump, there are issues which keep users from pursuing this architecture.
  - *Pump Size*: This design requires a second seal, therefore a longer piston, and longer pump head to accommodate the volume of the chamber.
  - *Complexity and Cost*: This larger pump is more expensive than a standard piston pump, and it also requires a separate controllable Flush circuit, with its own pump, tubing, and fittings, driving additional validation effort to release an instrument with a Flush system. All of these components add cost to the system and additional points of potential failure, resulting in additional routine maintenance over the life of the instrument.

Item	Unit Cost	System Cost
Flush Pump		
Pump	$ 450	$ 450
Flush System	$ -	$ 250
Replacements (0x over life)	$ -	$ -
Service (7x over life)	$ 50	$ 350
Total Cost		$ 1,050

- *Sample Contamination*: It is known that fluid passes by the seal of a piston pump under normal operation, it is logical to conclude that the fluid in the Flush stream mixes with the reagent or sample being dispensed by the pump. Tests, as outlined later in this document, have proven that worn seals in a Flush seal pump allow enough fluid transfer to change the chemistry of the fluid on either side of the primary seal. Because the system is configured as two intersecting streams, this contamination may not be detectable, as there would be no catastrophic failure.
- *Exothermic Reaction*: It is common practice to have several pumps moving different fluids, daisy chained on the same Flush circuit. In this scenario, you may see incompatible fluids mixing, reacting, and potentially causing precipitation that occludes the Flush circuit, and/or resulting in an exothermic reaction, causing peripheral damage to local components and instrument downtime.

BioChem decided to run a small experiment to study the effects of a failing Flush Seal Pump. The summary is found below:

Test Protocol

- Two Maestro FS-500-CAV-11200 Flushed Seal Piston Pumps were utilized, the first was a working pump, and the second was a pump with an artificially created leaking seal. These pumps were placed upright on a laboratory bench. Aspiration and dispense were conducted via a single 0.062"id tubing and standard stainless steel 0.060"id probe (with a total volume of approximately 300µl) placed in a 40ml saline solution reservoir. The priming port was not utilized. The pumps were run at 1Hz, which equates to 1 second per full stroke aspiration/full stroke dispense cycle. The flushed circuit was driven by a Longer T60-S50/WX10-18-A peristaltic pump running at a flow rate of approximately 10ml/min, drawing from and dispensing into a single 80ml reservoir of Distilled Water.

- A qualitative method employing blue dye in the saline solution was initially performed to visually observe fluid transfer as proof of concept. This was only performed using the pump that had a verified leak in its primary seal.

- Secondarily, the team attempted to quantify this fluid transfer. Fresh solutions of each test fluid were introduced and conductivity of the saline and distilled water solutions were measured using an Oakton CON150 conductivity meter and probe, regularly and reported over time in both configurations.

Test Results – 10% NaCl

- The blue dye was seen to transfer from the saline solution to the distilled water solution within a few hours, resulting in a light blue coloration. A significant change in coloration was seen after two days.

- Conductivity of the saline solution and distilled water remained fairly constant over the 8 days in the pump with no leak in the primary seal; while the conductivity of the saline solution and distilled water moved using the pump with a verified leak in its primary seal starting within the first 24 hours and generally reaching equilibrium within 72 hours, as predicted in the qualitative method described above. Note that the rate and magnitude of change in the conductivity will be affected by severity of the seal/piston degradation, as well as the pressure differentials in the specific application. It would also be expected that the rate of fluid transfer would be accelerated in the presence of surfactants. See Figure 1 below for an analysis of the resulting data.

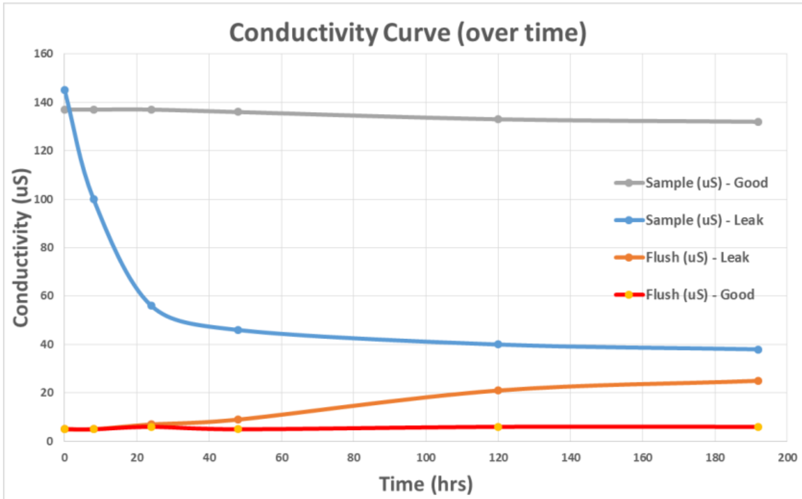


Figure 1 Concentration changes in sample over time

Test Conclusions

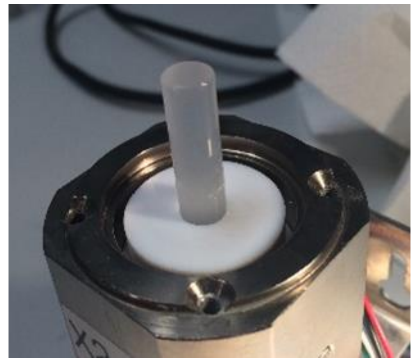
The data collected, both qualitative and quantitative, supports the hypotheses above that fluid will transfer across the primary seal of a Flushed Seal Pump, at rates dependent on the application's differential pressures, and the end user will not likely notice this phenomenon. Since Piston Pumps are not equipped with internal conductivity sensors and there is no change in the dispensed volume of fluid, there is no direct means of determining if this is occurring. All of these failures lead to either poor test results or increased downtime and maintenance, while costing more for the pump itself and the flushed circuit.

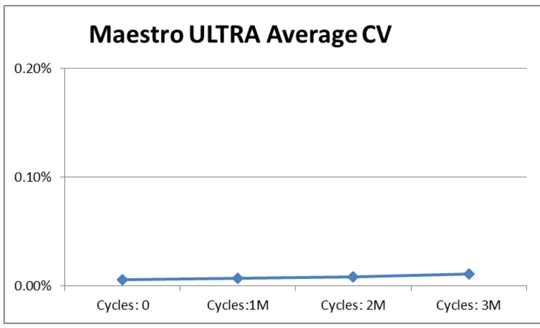
- **Double Seal Pump:** A more recent attempt at solving the problem is a simple combination of the design philosophies above. Some designers have utilized a Flushed Seal pump, but without the Flush system. This creates a solution with a redundant seal, maintaining the high precision and accuracy of the standard Piston Pump, to simply gain additional life. The theory behind this is that by isolating the environment behind the primary seal, you may maintain a humid environment, or at least retard the evaporation process enough to prevent the salt from drying and adhering to the piston surface. It is the author's experience that these effects are limited, and one may see a potential doubling in expected life up to 2 million cycles, but not much beyond.

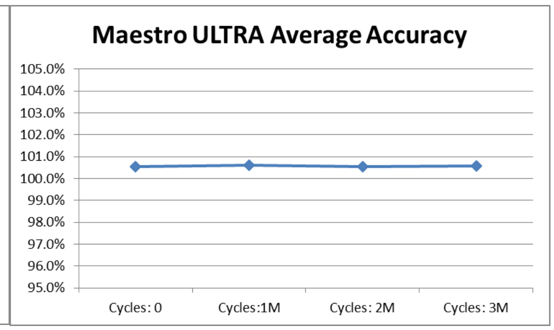
<u>The Solution – Maestro ULTRA</u>

BioChem Fluidics incorporated its materials and machining expertise to eliminate these significant risks in the current state of technology. Building upon its evolutionary Maestro Piston Pump product family, BioChem designed Patent Pending pistons which resist salt and other precipitate adherence, thus constructing a Piston Pump that prevents seal degradation caused by concentrated salt solutions.

The Maestro ULTRA provides an elegant and robust solution to this industry-wide problem by creating hydrophobic, low surface energy pistons. This combination decreases wettability and prevents materials from adhering to its surface, thereby resulting in “non-stick” pistons. As illustrated in the photo to the right, following 3 million full aspirate/dispense cycles of use, there is no evidence of seal abrasion and no presence of salt crystals. The hydrophobicity and low surface energy of the Patent Pending piston in the Maestro ULTRA eliminates seal degradation, allowing long service life of the piston pump in concentrated salt solutions. The Maestro ULTRA has the same expected high performance as standard Maestro products with Cv of less than 0.04%, and accuracy within 0.7% dispense volume, from 10% to 100% of total dispense volume, as seen below.







Maestro ULTRA removes the risk of sample contamination, costly repairs, and system complexity. It provides worry-free performance for the life of the instrument, speeding time to market. It is the most cost effective and reliable option for pumping high concentration salt solutions. The Maestro ULTRA is operationally identical to the standard Maestro pumps, enabling seamless transitions for OEMs that decide to “upgrade” to the ULTRA should they need to at a later date or project.

<u>Conclusion</u>

Salt damages pumps in IVD instruments. This is supported by historic knowledge and evidence presented herein. The wettability of traditional piston pumps allows fluid to seep behind the primary seal forming a thin layer, which quickly evaporates, leaving behind a thin layer of adhered salt. Over hundreds of thousands of cycles, this layer thickness increases and becomes substantial, thereby abrading the seal, and destroying the pump. Traditional methods of combatting this problem, like flushing behind the seal, are more costly and introduce unnecessary performance risks.

BioChem Fluidics, a New Jersey based veteran manufacturer of high-purity specialty valve and pump solutions, designed Patent Pending pistons which resist salt and other precipitate adherence. Thus, constructing a Piston Pump that is immune from the seal degradation caused by concentrated salt solutions. The results presented above demonstrate that the revolutionary new Maestro ULTRA is not just a typical piston pump, but something extremely unique, solving a critical unmet need, while increasing instrument safety and reliability.