

MAGMA™

KEEPS YOUR FLOW MOVING

Single-Use Liquid-Liquid Mixer

LOW SHEAR LIQUID-LIQUID MIXING



CP biotools

www.cpbio.tools.com

Magma Single-Use Liquid-Liquid Mixer Key Features:

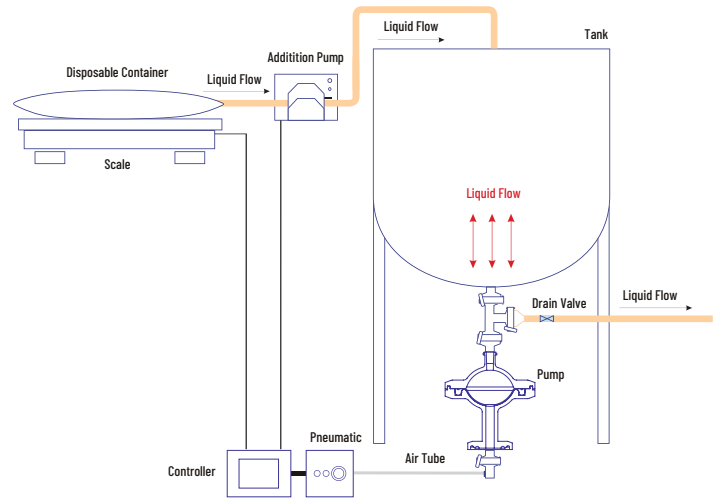
- Ideal for low shear mixing of readily miscible liquids without the use of an impeller.
- Perfect for applications requiring dilution or process storage steps where stagnation, separation and stratification must be avoided.
- Single-Use design with replaceable, single-use insert.
- 200L volume can be operated at a reduced working volume down to 50L.
- Mixing driven by a diaphragm pump mounted on the bottom of the insert, where gravity allows liquid to drain into the pump at a controlled rate to fill it, then air pressure is used to push the liquid at a controlled rate out of the pump to create a jet of liquid that disrupts the liquid up to the liquid surface.
- An economical, low energy system because the mixing process is facilitated by the diaphragm pump driven by compressed air and gravity.
- Can be completely drained of liquid after mixing via the tee end of assembly on the tube to/from the pump.
- Sensors can be added for analytics, such as temperature and pH measurement on the bag ports.

Magma Liquid-Liquid Mixer

The Magma Advanced Pumping System (APS) can be used for low shear mixing of readily miscible liquids without the use of an impeller by providing gentle agitation of the liquid in the process vessel. The mixing is driven by a diaphragm pump mounted on the bottom of the vessel, where gravity allows liquid to drain into the pump at a controlled rate to fill it, then air pressure is used to push the liquid at a controlled rate out of the pump to create a jet of liquid that disrupts the liquid up to the liquid surface. The 200 liter mixer under final development features use of the part #APSP-PH860-SU (Magma APS-860D Dome Pump Head), which has a volume of 860mL, with the silicone diaphragm part #APSP-DIA860D (Magma APS-860 Dome Diaphragm) secured between the two pump halves. For liquid-liquid mixing applications, it is an economical, low energy system because the mixing process is facilitated by the diaphragm pump driven by compressed air and gravity.

With the designed configuration, the product contact surfaces are part of a single-use insert that can be delivered gamma-irradiated and disposed of after use. With the single-use insert design in combination with a unique hardware design, the mixer can be completely drained of liquid after mixing. With the Magma APS weight control option, an automated mixing and dilution system can be configured. Additionally, sensors can be added for analytics, such as temperature and pH measurement.

An illustration is shown here:



Covered by U.S. Patent No. 7,972,058 for Apparatus and Method For Mixing with Diaphragm Pump

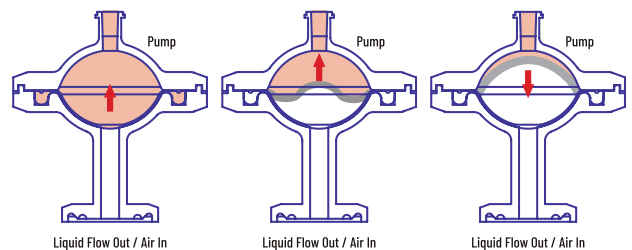
The Heart of the Mixing System: Pump and Diaphragm

Designed for Low Shear and Sterile Processing

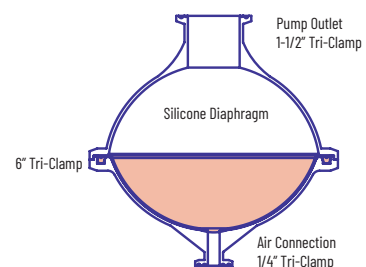
Low Shear - Through the air inlet/exhaust sanitary fitting on the pump, air from the control system enters to push liquid from the pump and through the fitting that is connected to the bottom of the single-use bag assembly. The only pressure generated is from process back-pressure. After the pump has discharged the liquid, liquid then flows into the pump by gravity at the desired flow rate.

Sanitary - The specially designed silicone diaphragm is sealed with an industry standard sanitary clamp into the pump. It is designed of materials that meet industry guidelines and compatible with gamma irradiation for sterilization.

Proven Performance - Silicone Diaphragm material is USP Class VI and all sizes tested to run > 1 million cycles (~60 days continuous use). The pump heads are proven for sterile operations with years of customer use.



Mixer Pump



Pump Volume = 860mL

Customized Magma Liquid-Liquid Mixer Process Skid

The single use assembly drops into the top of the tank that is attached to the frame which is mounted to the skid base.

- The pump head fits through a hole in the bottom of the plastic tank and into its holder underneath the plastic tank.
- There is a slit in the side of the plastic tank for the ports on the side of the bag to be accessible and enabling precise insertion of the assembly. This allows any tubing attached to the ports or probes to slide down during the insertion process.
- The casters on the bottom of the base make it portable to move around the facility.
- The two components of the control system which are the control box and the pneumatic box rest on convenient locations on this skid.
- Once the single use assembly is put into place and the pump is placed into its holder, the drain line is inserted into the pinch valve and the air from the control box is connected to the pump head.

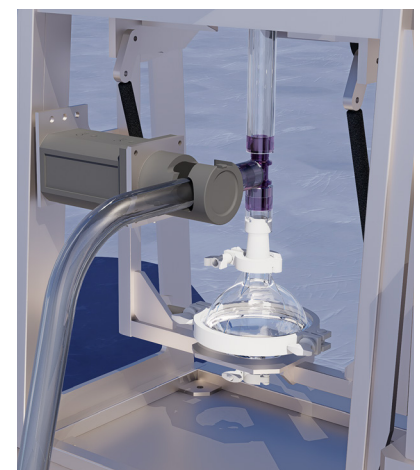
The pneumatic pinch valve has a manual switch which when activated, will open the valve which is normally closed. Once the tube is inserted the switch is put back to its original position and the pinch valve will close.



Process Skid with Single-Use Assembly Inserted

The drain line pinch valve:

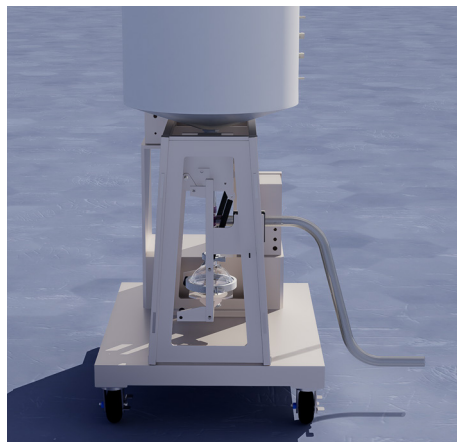
- The pneumatic pinch valve has a 2-way manual switch and its default position with no air supplied to valve is closed meaning the tube will be pinched and any flow restricted (referred to as Normally Closed)
- Moving the switch from its default position, will allow the process air to access the pinch valve and it is moved to an open position
- This will open the valve and once the tube is inserted, the switch is put back to its default position and the valve will be closed
- The valve is mounted so it moves with the bottom of the single-use assembly when the pump is moved to the drain position



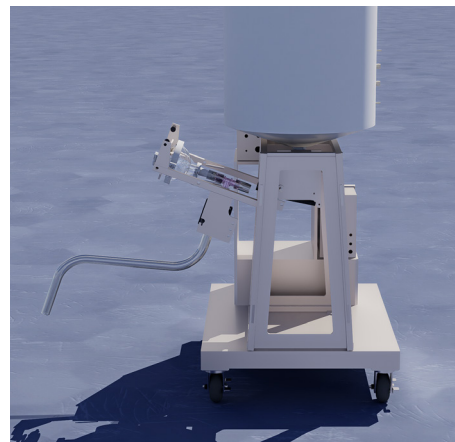
Close-up of the Drain Line Inserted into the Pinch Valve

The hinged mechanism to both precisely hold the pump and to enable precise draining:

- The pump is at its low point as installed during operation
- During the process step to empty the vessel the hinged mechanism is released and with lift-assist pistons, it is moved and latched into place as shown in the picture as the drain position
- When the pinch valve switch is moved from its default position, the process air accesses the pinch valve and then it is moved to an open position and liquid can flow from the mixer and pump head
- When the diaphragm pump is stopped, it remains slightly inflated with air to minimize the liquid retained in the pump and to allow optimal draining
- Once the mixer is empty, the pinch valve is moved back to the default position and the hinged mechanism is released and slowly descends to its installed position



Side View in Operational Position with the Hinged Mechanism Holding the Pump at the Low-Point

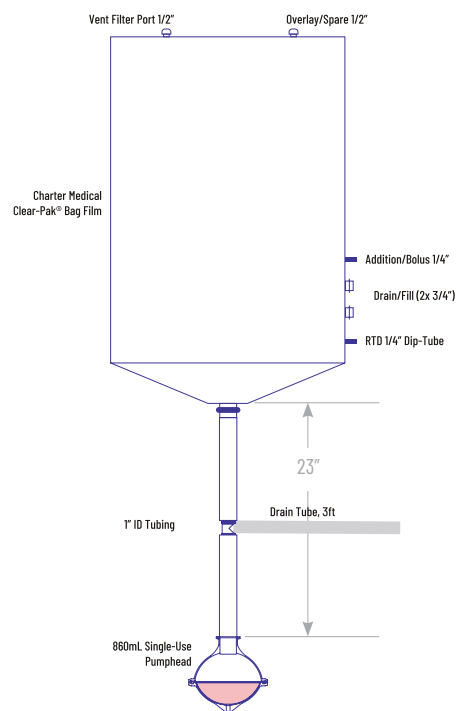


Side View in Draining Position with the Hinged Mechanism Holding the Pump in the Tilted Position

Single-Use Assembly

The rendition of the single-use product under final product development and the single-use assembly insert is shown. The single-use bag-style product contact component has a variety of addition ports and ports for sampling or probes, and can be provided gamma-irradiated with a sterile claim if needed. All materials used in the assembly are the same as used in many bioprocess single use process assemblies and meets USP Class VI requirements. The details of the default configuration is shown to the right and includes an RTD sleeve for non-product contact insertion of an RTD.

Sampling and Sensor ports are on the side and there are 2 ports on the top. The pump and draining portion of the assembly drops through the bottom of the tank and rests in the holder underneath the tank.



Rendering of Single-Use Bag-style Product

Investigation of Mixer Efficiency Visually and By Measure of Conductivity Convergence in an Aqueous System

Experiments were conducted to outline the mixing visualization and efficiency.

In order to measure the performance of the CP Biotools Magma Mixer, experiments were designed for both qualitative and quantitative testing.

The 200-liter vessel used for conducting the experiments, which is the same one that will hold the single-use bag-style insert, was outfitted with the Magma APS single-use 860mL pump head and a tubing assembly to simulate the proposed design. This assembly was attached to a hose barb mounted to the bottom opening of the vessel, as shown in Figure 1, which is a picture of the test setup.

Experimental Procedure Overview

For the testing, four different experiments were conducted to evaluate performance across a range of working volumes in addition to a control with the pump turned off (no mixing). The experiments are:

1. Control with no mixing
2. Full 200-liter working volume
3. 150-liter working volume to test the performance if the vessel is not full
4. 50-liter working volume to test the performance at this lowest suggested limit, because below 50-liter there is proposed smaller mixer to complement the 200-liter mixer in development

For the Magma pump operation, no vacuum was used to draw liquid into the pump- the liquid pressure head facilitates a gravity drain into the pump. The Magma Pump Control System uses regulated compressed air to drive the liquid out of the pump head. The flow in/out of the pump is controlled by the flow control valves on the control system.

The pump cycle time[^] for the three experiments was as follows:

- 1. 200 liter**
Liquid out = 4.3 sec
Liquid in = 6.1 sec for a total of 10.4 sec cycle for an average flow rate of 9.9 liter/min
- 2. 150 liter**
Liquid out = 4.3 sec
Liquid in = 7.3 sec for a total of 11.6 sec cycle for an average flow rate of 8.9 liter/min
- 3. 50 liter**
Liquid out = 4.3 sec
Liquid in = 9.2 sec for a total of 13.5 sec cycle for an average flow rate of 7.6 liter/min

High-concentration potassium chloride (KCl) was poured into the top of the vessel, and the conductivity was measured versus time to determine the time until the conductivity was uniform in the vessel.

[^] less pressure head results in a longer fill time, but this can be adjusted with the flow control valve, however for these experimental demonstration purposes, it was not adjusted for the different volumes



Figure 1.

For the Qualitative Testing

5 drops of red food dye were dripped into the top surface of the liquid with four drops around the edge and one in the center. The pump was turned on before the drops were added, and the mixing action was filmed to visualize the dispersion.

For the quantitative testing

Four conductivity probes were inserted into the vessel through bulkhead fittings that were inserted into the vessel wall through holes that were drilled into the vessel wall (Figure 1). There were three on the side wall and one placed in proximity to the pump inlet/outlet (Figure 2).

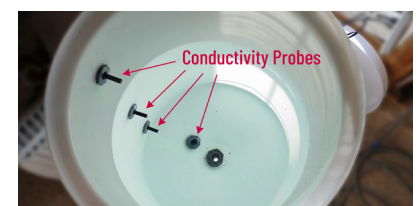


Figure 2.

Results of Qualitative Testing

Shown below are still-captures at the increments noted at time=0, after 1.5 minutes, and 3 minutes (except the 50-liter working volume only has 1.5 minutes) for each of the four experiments.

Control

Time = 0



Time = 1.5 minutes



Time = 3 minutes

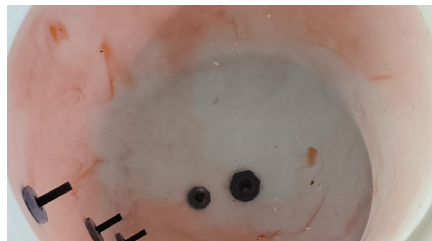


200L Full Working Volume

Time = 0



Time = 1.5 minutes



Time = 3 minutes



150L Working Volume

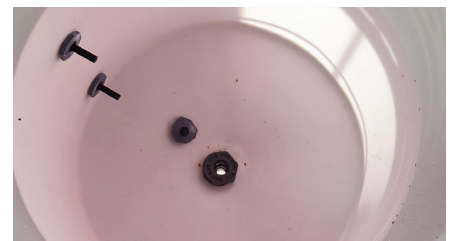
Time = 0



Time = 1.5 minutes



Time = 3 minutes

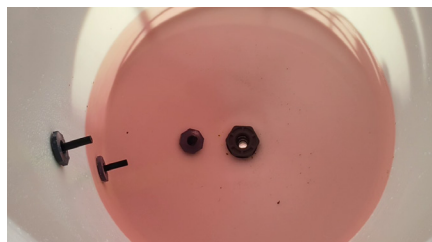


50L Working Volume

Time = 0



Time = 1.5 minutes



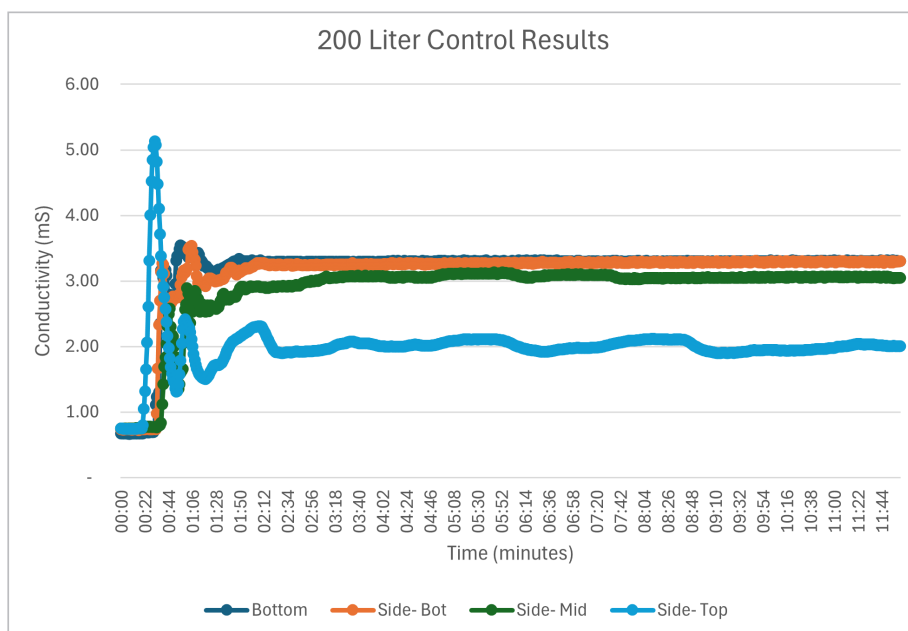
As seen in the pictures, the control indicated some swirling of the dye, but does not indicate any significant mixing. In the 200L and 150L experiments, the dye appears to be dispersed by the 3-minute time mark. The 50L experiment, the dye appears to be dispersed within the 1.5-minute mark.

Quantitative Testing Results

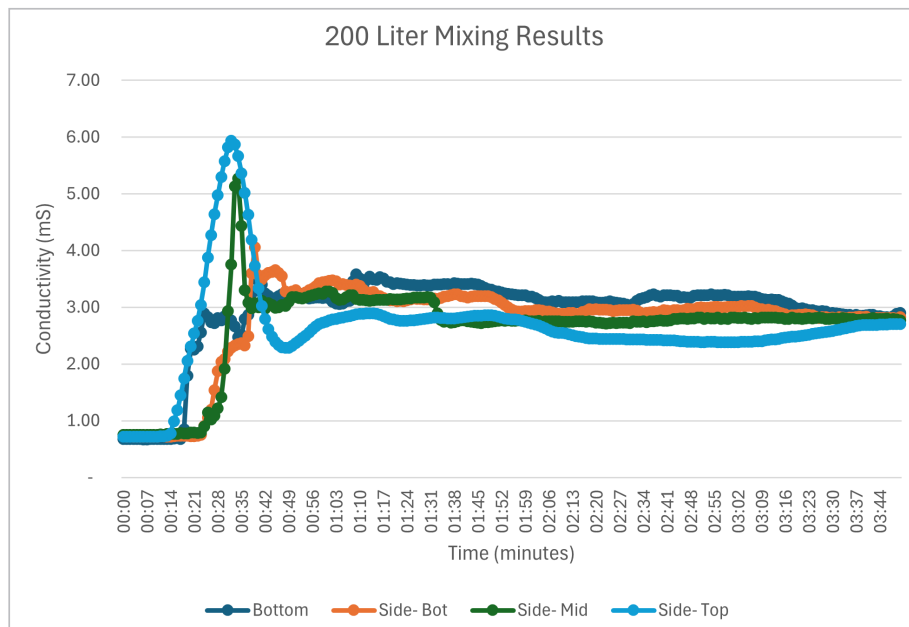
For each of the four experiments, the concentrated KCl was prepared as noted, then added to the vessel over the noted time. Descriptions for each experiment:

- 1. Control with no mixing experiment-** Solution prepared by adding 4 x 8oz bottles (total 32 oz) of 3M KCl into two 1-gallon jugs (2 bottles / 16oz per jug) and then loaded it into the top of the vessel with a 30-second pour time (both gallons were poured at the same time).
- 2. 200L experiment-** The pump was turned on. Solution prepared by adding 4 x 8oz bottles (total 32 oz) of 3M KCl into two 1-gallon jugs (2 bottles / 16oz per jug) and then loaded it into the top of the vessel with a 25-second pour time (both gallons were poured at the same time).
- 3. 150L experiment-** The pump was turned on. Solution prepared by adding 3 x 8oz bottles (total 24 oz) of 3M KCl into two 1-gallon jugs (2 bottles / 16oz in one jug; 1 bottle / 8oz in one jug) and then loaded it into the top of the vessel with a 25-second pour time (both gallons were poured at the same time).
- 4. 50L experiment-** The pump was turned on. Solution prepared by adding 1 x 8oz bottle (total 8 oz) of 3M KCl into a 1-gallon jug and then loaded it into the top of the vessel with a 25-second pour time for the one gallon.

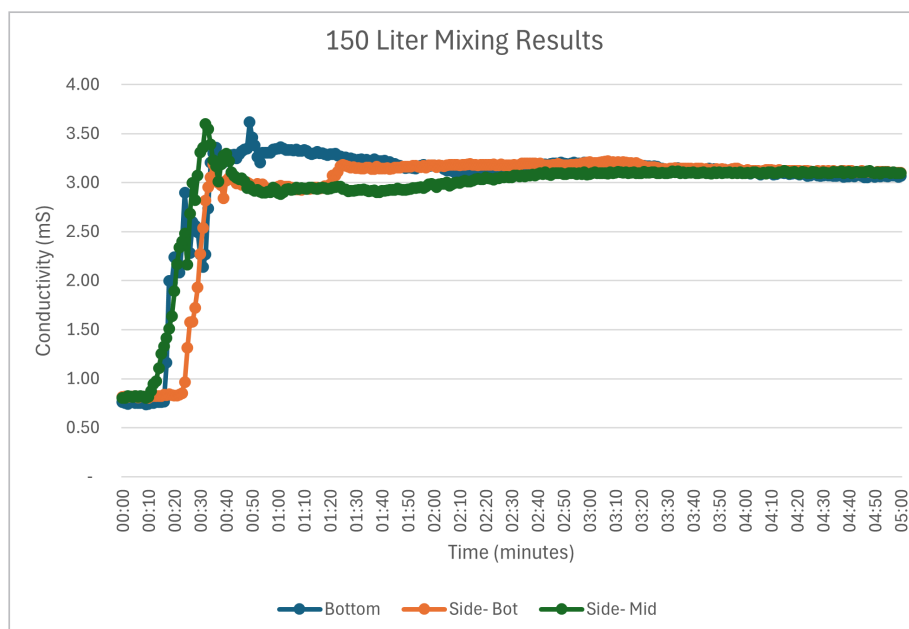
The results are shown in the following graphs of conductivity versus time, and the legend indicates the probe location.



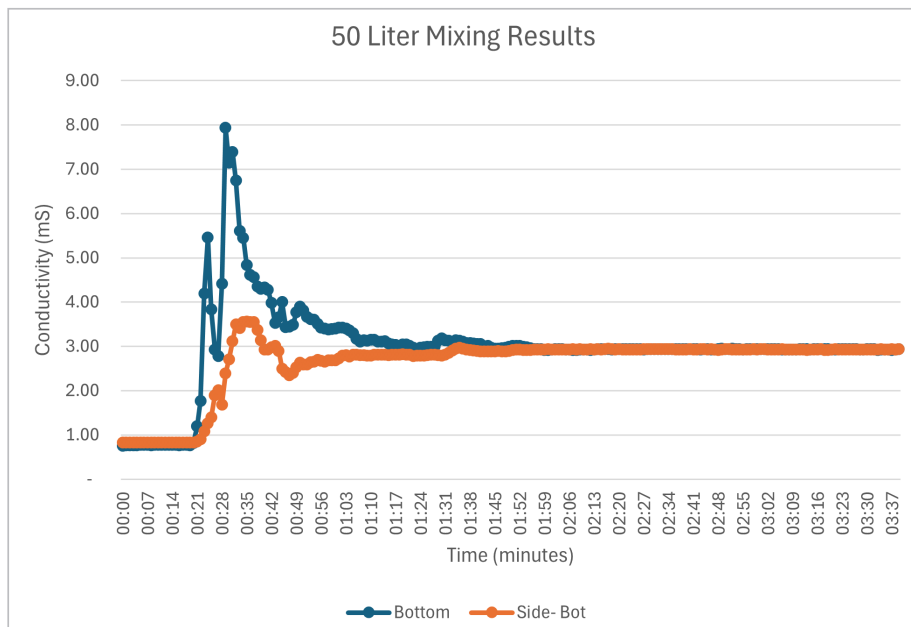
As observed in the graph, there is an initial spike of the top conductivity sensor as the solution was poured into the vessel. After the spike, the concentrated KCl moves to the bottom and the middle and top sensor are lower than the bottom and the side-bottom. After about 3 minutes the conductivity reaches an equilibrium type of condition and no significant changes occurs through the remaining time shown on the graph area. This demonstrates what would occur in a storage vessel with the solution with no mixing.



In the 200-liter mixing experiment, there is a spike as the solution is poured into the top of the vessel with the top and middle conductivity sensors. After that spike it appears the concentrated KCl solution drifts towards the bottom and away from the top sensor. There is then an increase in the bottom and the side-bottom sensor. After 3 minutes 45 seconds all the sensors converge to about 3 mS shown on the graph.



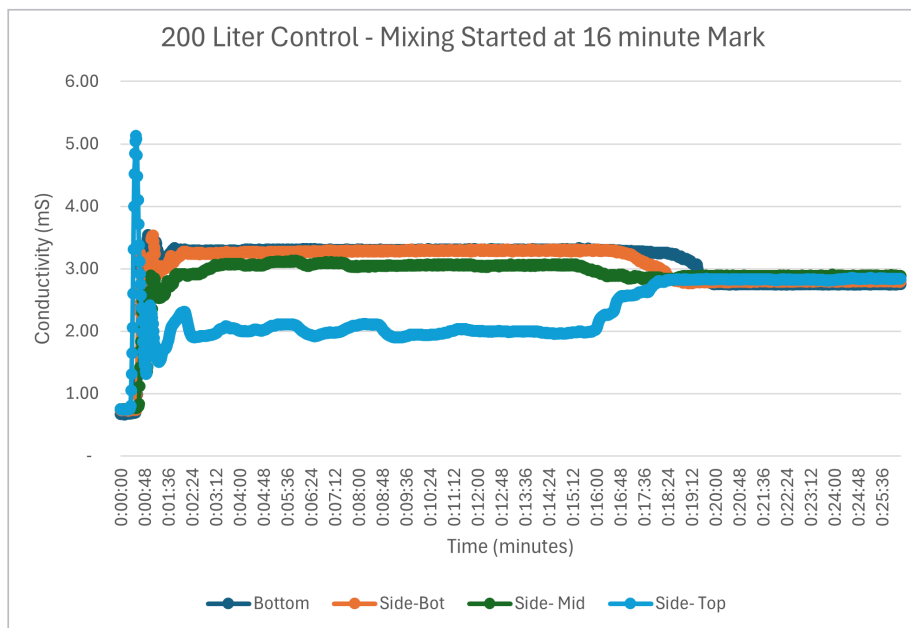
In the 150-liter mixing experiment, the top sensor is not wetted so it is omitted. There is a spike in the middle sensor as the solution is poured into the top of the vessel. After that spike it appears the concentrated KCl solution drifts towards the bottom and away from the middle sensor and the bottom one spikes followed by the side-bottom. There is then an increase in the bottom and the side-bottom sensor. After 3 minutes 30 seconds all the sensors converge to about 3 mS shown on the graph.



In the 50-liter mixing experiment, the top sensor and middle sensor are not wetted so they are omitted. There is a spike in the bottom sensor as the solution is poured into the top of the vessel and the concentrated KCl solution drifts towards the bottom. After 2 minutes, the sensors converge to about 3 mS shown on the graph.

Additional Insight

To further demonstrate a vessel with no mixing versus the gentle, low-shear mixing, the control experiment was continued for 16 minutes, then the pump was turned on. With the same time frame as the 200-liter experiment, in under 4 minutes, sensors converge to about 3 mS indicated effective mixing.



Pump

Material: Udel® Polysulfone
 Tri-Clamp: Nylon
 Details: See Page 2

Diaphragm

Material: Molded from platinum cured silicone that meets USP Class VI Medical Grade Specifications

Magma Control System

Control System Enclosure Dimensions (DxWxH):
 Base: 13.25in x 12.25in x 11.25in
 Top: 7.25in x 12.25in x 11.25in
 Control System Weight: 23.5 pounds

Enclosure Material: Stainless Steel
 Enclosure Material: Stainless Steel
 Power Requirements: 100-240 Volts, 50-60 Hertz, 2.5 amp
 Pumps Remote Signals : Dry Contact Relay
 Scale Inputs: RS232 communication protocol configurable in software
 External Pressure Inputs: PendoTECH Single Use Pressure Sensors
 Data Communication: Ethernet Connection with OPC UA and MODBUS protocols

Magma Pneumatic Box

Enclosure Dimensions (DxWxH):
 Base: 13.25in x 6.5in x 11.25in
 Top: 7.25in x 6.5in x 11.25in
 Pneumatic Box Weight: 17.0 pounds

Air Pressure Regulator

Input: 125 psi max (8.6 bar)
 Output: 2-25 psi (0.14 - 1.7 bar)

Magma Pump Connection

Female 1/8 for Quick-Disconnect Coupling, 1/8 Coupling Size, for 1/4" Tube OD
 [reducers for use with 5/32in tubing and 1/8in tubing]

Air Connection

Male 1/8 for Quick-Disconnect Coupling, Socket with Shut-Off, 1/8 Coupling Size, for 1/4" Tube OD

Exhaust Connection

Female 1/4 for Quick-Disconnect Coupling for Air, 1/4 Coupling Size, for 3/8" Tube OD

Skid Specifications

Mainly 316L Stainless Steel (DxWxH):
 40in x 30in x 66in [shown in the picture on the right]
 1/4inch push connect fitting for air to activate pinch valve

Ordering Information

Diaphragms (part of single-use assembly)

Part #	Description
APSP-DIA860D	Magma APS-860 Dome Diaphragm, Silicone

Plastic Pump Heads (part of single-use assembly)

Part #	Description
APSP-PH860-SU	Magma APS-860D Dome Pump Head, Polysulfone*

Magma Advanced Pumping System

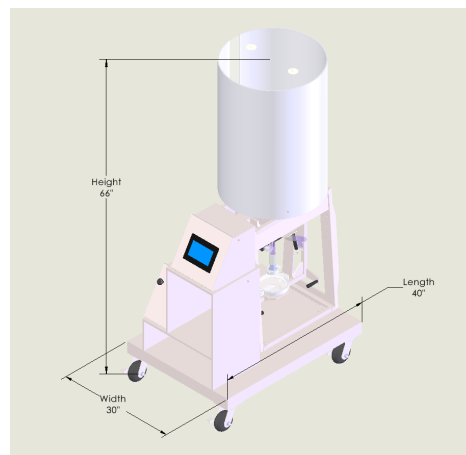
Part #	Description
MAPS-BA1-L	Magma Advanced Pumping System- Large (for Pump Size 860)

Single-Use Mixing Skid with Shelf for Magma APS

Part #	Description
MAPS-MIXER-200	Magma 200L Mixing Skid

Single-Use Assembly for Magma Mixer

Part #	Description
APSM-200L-D1	Single-Use Assembly for 200L Magma Mixer Default Configuration



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Warranty

For warranty information see our website at www.cpbio.tools.com/about