

МИКСЕРЫ MOBIUS POWER MIX



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Mobius® Power MIX Single-use Mixing Systems

High Performance Mixing Technology and Ergonomic Design Features



The Mobius® Power MIX single-use mixing systems combine high performance mixing technology with design features that make them easy-to-use. The impeller design and motor are based on our magnetically coupled NovAseptic® mixing technology, a proven mixing technology in stainless steel tanks. These systems efficiently mix the most challenging buffers, media and biopharmaceutical ingredients.

Features and Benefits

- Range of sizes available from 100 L to 3000 L
- Powerful magnetically coupled impeller designed to efficiently mix the most challenging buffer, media and biopharmaceutical ingredients
- Broad working volumes that range from 10% of the nominal volume to 10% above (size dependent) for processing flexibility
- Stainless steel units have doors that open to one half the mixer's diameter for easy bag loading
- The 1000, 2000, 2500 and 3000 L sizes have an easily accessible off-set drain for easy bag loading
- 100, 200 and 500 L models are available in plastic or jacketed stainless steel
- Optional integrated hoist for powder delivery available on the Mobius® Power MIX 2000 model
- Integrated load cells and temperature sensor
- In-process pH and conductivity measurement option
- Closed, sterile, and zero deadleg sampling directly from the mixing bag
- Backed by industry-leading technical support and services

Ergonomic Design Features

All the models of the Mobius® Power MIX systems are designed with operator ease and safety in mind. Handling single-use assemblies for volumes greater than 1000 L can be difficult to maneuver, so the Mobius® Power MIX 1000, 2000, 2500 and 3000 have additional features for end-user ease-of-use. One operator is able to safely load the bag. The doors open to one half the carrier's diameter, and the impeller and drain are positioned for easy bag loading. The bag can easily be secured to pins positioned around the top of the carrier to further help with bag loading.

Proven NovAseptic® Technology for Mixing of Challenging Buffer and Media Powders

The design of the Mobius® Power MIX mixing systems is based on proven NovAseptic® mixing technology, traditionally used with stainless steel. The off-set bottom-mounted impeller contained in the mixer bag is magnetically coupled to the motor assembly, which has been redesigned for single-use. The magnetic coupling does not use a bearing surface.

The design properties of the impeller, such as the surface area, diameter, wing angle and number and type of magnets, were matched to the NovAseptic® impeller to achieve similar mixing performance.

Ready To Connect Control Box

The Mobius® Power MIX can be monitored and controlled locally or remotely. Plug the ready to connect control box to the network and use Ethernet IP communication protocol to monitor speed, weight, temperature, pH and conductivity remotely. The ready to connect control box is a separate box on a four wheels chassis that can be easily moved around the Mobius® Power MIX carrier. Optimize your layout and get a better access to control your Mobius® mixing system by freely positioning the control box around it. The 21 CFR Part 11 compliant data recorder option displays data trends in real time and ensures process data integrity when recording.



Figure 2. Ready to connect control box



Figure 1. Mobius® Power MIX 2000 has double doors that open to one half the diameter of the carrier; the Mobius® Power MIX 100, 200, and 500 have a single door that opens to one half the diameter of the carrier.

In-Process Measurement Options

The Probe Ports enable easy insertion of your standard PG13.5 threaded probes for in-process pH and conductivity measurement. They may be attached to the Mobius® single-use mixer bag at the position of the needle-free sample port.

Safe, Sterile Sampling Directly from the Mixing Containers

The standard Mobius® Power MIX single-use bag contains two needle-free sampling valves. The unique design of the sample device eliminates dead legs ensuring a representative sample while avoiding loss of valuable product. The closed concept allows users to obtain a sample directly from the mixing bag without the risk of cross contamination. Once a sample is obtained, the sample bag is separated from the mixing bag using the NovaSeal™ crimping tool that crimps the collar on the sample tube, resulting in two closed, sterile ends.



Figure 3. Needle-free sample ports with sample bags

Mobius® Power MIX: Scalability in Mixing



Executive Summary

The Mobius® Power MIX single-use systems provide an effective mixing platform for biopharmaceutical manufacturing in a range of sizes including 100, 200, 500, 1000 and 2000 L. Each unit is constructed based on the proven technology of our magnetically coupled NovAseptic® mixers, to deliver the high power necessary to incorporate buffer and media powders efficiently, while also showing capability for liquid-liquid mixing. Characterization of each size is complete, providing a comprehensive understanding of liquid-liquid mixing, and mixing of both sinking powders (buffers) and floating powders (media). Details of these studies can be found in individual notes for each size.¹ This document gives a summary of results, showing the scalability between sizes in the three main categories of mixing; liquid-liquid, sinking powders and floating powders.

Dimensional Scalability

Each of the Mobius® Power MIX units is designed with scalable dimensions; keeping the aspect ratio close to 1:1 at nominal volume, allowing for maximum volume at least 110% over nominal, providing sampling and real time monitoring at minimum volumes between 15-25%, with impellers and motors chosen to provide scalable mixing performance. **Table 1** summarizes the dimensional characteristics of each system.

Table 1. Key Dimensions in Mobius® Power MIX

Mixer	Min Sampling Volume (liters)	Max Volume (liters)	Diameter (inches)	Diameter (mm)	H/D (at nominal volume)	Impeller Diameter (mm)	Impeller Wing Height (mm)	Impeller Power Number	Motor Size	Max RPM
100	25	110	20.59	523	0.89	120	38.75	23	1/3 HP	380
200	40	220	25.75	654	0.91	120	38.75	23	1/3 HP	380
500	100	550	35.59	904	0.86	145	47	9	1/3 HP	375
1000	200	1100	43.50	1105	0.94	183	50	4	1/2 HP	380
2000	300	2200	53.50	1359	1.01	183	50	4	1/2 HP	380

Liquid-Liquid Mixing

In order to understand the capabilities of each Mobius® Power MIX unit, a comprehensive study of liquid-liquid mixing is performed. Mixing time at four volumes (25%, 50%, 75% and 100% of nominal) and four speeds (25%, 50%, 75% and 100% of maximum) are measured using the tracer method to track the change in conductivity when a small amount of highly concentrated salt solution is added to DI water. From these results, a mixing characterization map can be depicted, showing the relationships between mixing time and impeller speed, at key volumes within each vessel. These characterization maps are shown in **Figure 1**.

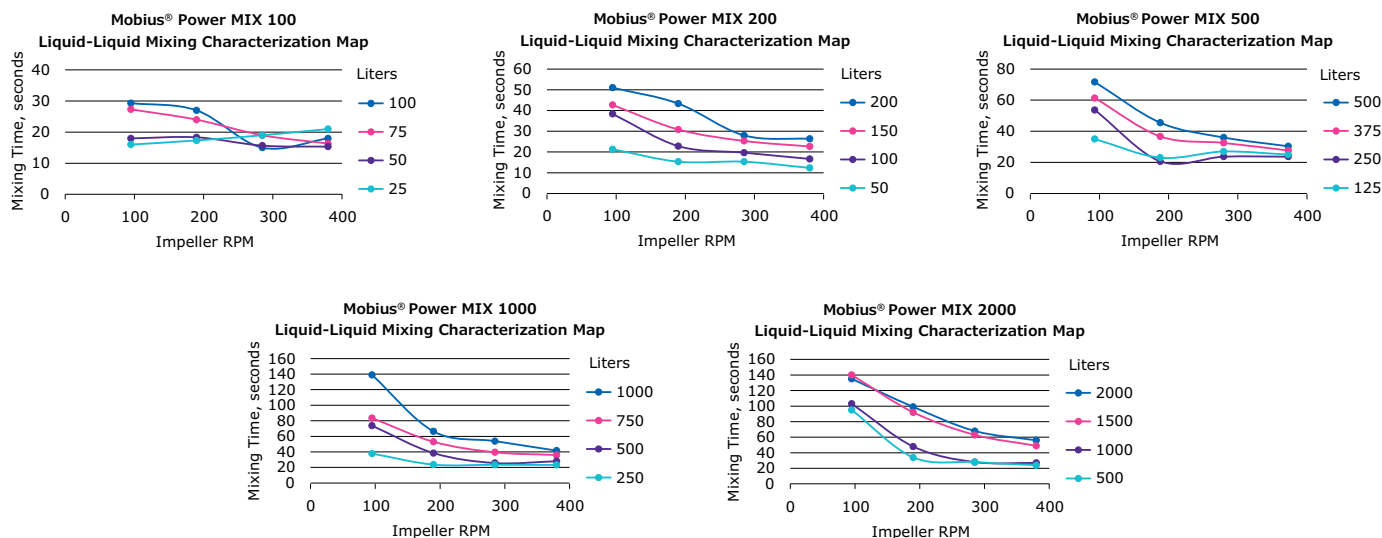


Figure 1. Liquid-Liquid Mixing Characterization Maps for Mobius® Power MIX.

Combining the characterization maps to show performance across the range of sizes is easily accomplished as shown in **Figure 2**.

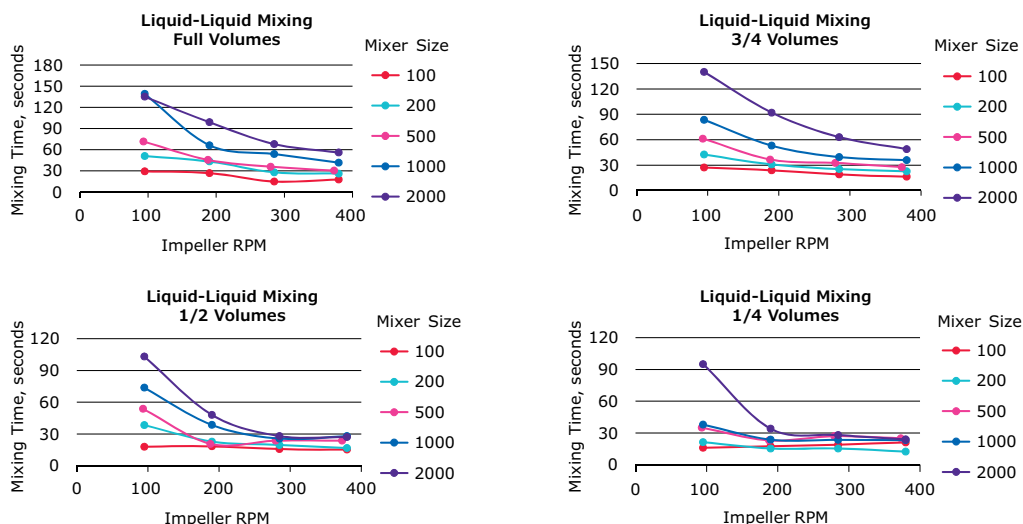


Figure 2. Liquid-Liquid Mixing Characterization grouped by relative volume in each vessel.

Floating Powder (Media) Mixing

To demonstrate scalability of floating powder mixing, two sets of media mixing trials are performed in the Mobius® Power MIX; mixing DMEM (Dulbecco's Modified Eagle's Medium) powder into solution and mixing a chemically defined CHO medium (Custom Merck CHO Medium). DMEM powder is one of the easier floating powders to mix, while the chemically defined media can be more difficult, including a pH adjustment step to bring particles into solution. Evaluation of media mixing in the Mobius® Power MIX systems is done according to manufacturers' recommended process conditions at 80% starting liquid volume, at maximum impeller speed. As with the sinking powder trials, mixing time is determined not solely by conductivity trace, but also through visual record and a measure of particles in solution with the FBRM® particle probe. Details of experimental setup and records of each trial are found in the Mobius® Power MIX Characterization Notes.¹

Results for DMEM mixing are summarized in **Figure 8**. Using power input alone to scale floating powder mixing results in two distinct relationships; one for the 100/200/500 mixers and one for the 1000/2000. A secondary factor is needed to describe the mixing potential for floating powders. In mixing floating powders, the vortex is key to wetting out and breaking up the powder on the surface of the liquid. A factor relating vortex volume to total liquid volume can be used to rescale power input. Evidence of vortex size is shown in **Figure 9**. Based on the new factor of power input times relative vortex size, there is once again a predictable, scalable relationship across all volumes of Mobius® Power MIX.

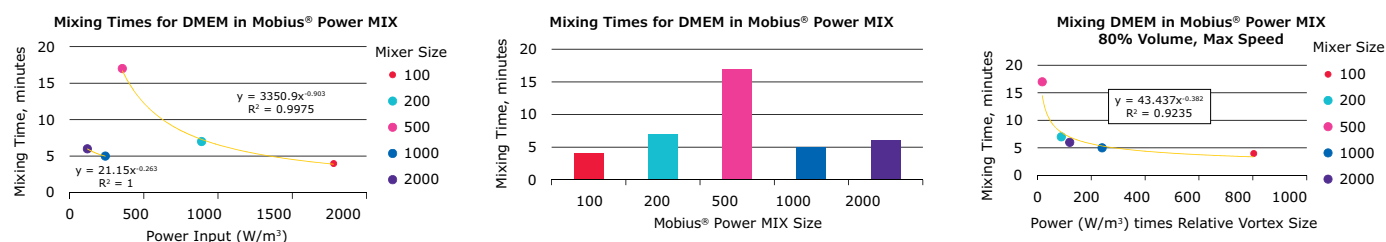


Figure 8. Scalability in mixing DMEM in Mobius® Power MIX from 100 L to 2000 L.



Figure 9. Vortex at 80% volume, maximum speed in Mobius® Power MIX from 100 L to 2000 L.

Results for mixing Custom Merck CHO medium are shown in **Figure 10**. As with the DMEM, scalability based on power input alone shows two distinct relationships for 100/200/500 and 1000/2000. However, by using the relative vortex factor, there is a scalability trend through all sizes.

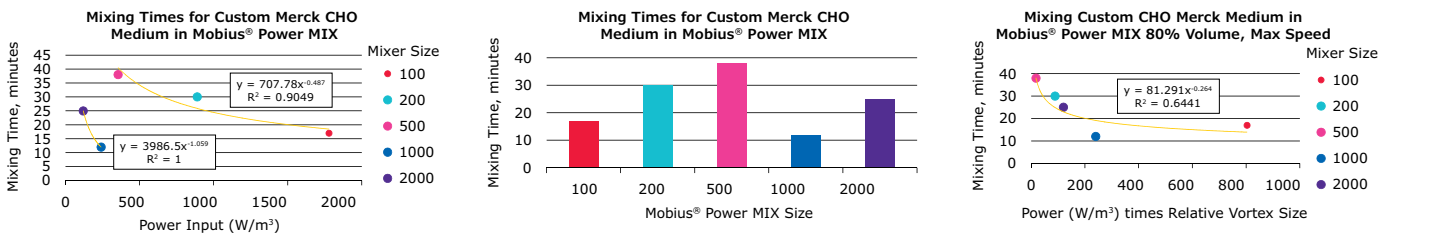


Figure 10. Scalability in mixing Custom Merck CHO Medium in Mobius® Power MIX from 100 L to 2000 L.


Conclusion

The Mobius® Power MIX systems are designed for effective mixing of buffers and media in scales from 100 L to 2000 L. Starting with systems designed for scalability in liquid-liquid mixing, effective performance in buffer and media mixing has been confirmed. Results of trials with a typical buffer solution demonstrate mixing times of less than 2 minutes for all sizes. In a more difficult sinking powder trial, with concentration 10 times typical buffer solutions, mixing times for all sizes are still below 15 minutes, with predictable relationship between mixing time and mixer size. Mixing efficiency for media is highly dependent on media type, but even the most challenging media are mixed in less than 40 minutes, in all sizes. A model can be developed to show a scalable relationship between mixer size and mixing time for a variety of media powders. The Mobius® Power MIX systems have proven effective in meeting the needs for buffer and media preparation in a single-use system at scales from 100 L to 2000 L.

For more information on the Mobius® Power MIX, refer to Mobius® Power MIX Data Sheets and Specification Sheets.

References

1. Mobius® Power MIX 100 Mixing Characterization for Buffer and Media Preparation
Mobius® Power MIX 200 Mixing Characterization for Buffer and Media Preparation
Mobius® Power MIX 500 Mixing Characterization for Buffer and Media Preparation
Mobius® Power MIX 1000 Mixing Characterization for Buffer and Media Preparation
Mobius® Power MIX 2000 Mixing Characterization for Buffer and Media Preparation



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