



Mobius® MIX Single-Use Mixing Solution

Integrated Mixing and Filtration Technology Delivers Economic and Processing Flexibility

The Mobius® MIX single-use mixing solution delivers advanced technology for mixing pharmaceutical ingredients from intermediate to final drug products and for the preparation of process solutions, such as buffers and media.

This single-use integrated mixing solution offers economic and operational efficiency, saving valuable processing and validation time.

You can also configure the appropriate filter, connector, and tubing for your specific application and environment, including sterile interfaces, from fermentation to final fill. Our proven, scalable, ready-to-use systems and processing technologies reduce the risk of contamination, improve economic and processing flexibility and deliver reproducible results.



Benefits

- Decreased risk of contamination
- Reduced downtime for cleaning validation
- Minimizes operator exposure to powders
- Validation, quality and regulatory compliance support
- Single-use technology for increased production capacity in multiproduct facilities
- Easy setup and use
- Convenient and easy to transport
- Closed, sterile sampling system enables representative samples
- In-process pH and conductivity measurement option

Mixing

Mobius® MIX Single-use Mixers

The Mobius® MIX family of single-use mixers offers optimum mixing performance and process turnover. Each single-use mixing container includes a magnetically-driven levitating impeller for improved mixing consistency and efficiency. Unlike traditional stainless steel mixers, single-use mixers reduce downtime due to CIP, SIP, cleaning validation, and process engineering. Mobius® MIX single-use mixers also offer operational flexibility and can be up and running in less than five minutes. They are capable of mixing speeds up to 1000* RPMs meeting the broadest range of mixing production requirements.

* Mixer size dependent consistent mixing

The offset, bottom-mounted levitating magnetic impeller provides consistent mixing performance.

- No paddle
- No stir bar
- No shaft
- No bearings
- No mechanical contact

Quicker Process Turnaround

The Mobius® mixing system is ideally suited for multiproduct facilities with high production requirements. Set up of this single-use mixer is easy and can be completed in approximately 5 minutes. Once setup is complete, an operator simply turns the mixer on and begins mixing. The Mobius® mixer does not require a warm up time, which significantly improves process turnaround and productivity. Modular by design, the Mobius® MIX10 and MIX50, MIX100 and MIX200 and the Mobius® MIX500 and MIX1000 allow you to freely interchange the electronic drive unit, motor, and handheld control for production flexibility and cost-savings. When mixing is complete and you need to process another batch elsewhere on the floor, simply disconnect the electronic drive unit, motor, and controller and take them to another Mobius® system carrier and begin mixing. It's that simple.

Ready To Connect Control Box

The Mobius® 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® 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 1. Ready to connect control box

Safe, Sterile Sampling Directly from the Mobius® Mixing Containers

Every Mobius® MIX container includes optional 1, 2 or 3 needle-free sampling valves (depending on the size of the container). 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 container without the risk of cross contamination. Once a sample is obtained, the sample container is separated from the mixing container using the NovaSeal™ crimping tool that crimps the collar on the sample tube resulting in two closed, sterile ends.

In-process pH and Conductivity Measurement with Mixing

The probe ports enable easy insertion of your standard PG 13.5 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.



Figure 2. Mobius® MIX sample ports

Mobius® MIX Solution Benefits

- Proprietary magnetically-driven levitating impeller
- Fast, easy set up and use — instant-on electronics — no warm up needed
- Compact footprint and mobile carrier construction for enhanced flexibility
- Available in a range of sizes 10, 50, 100, 200, 500, and 1000 L
- Safe, sterile sampling directly from the mixing container without dead legs
- Integrated load cells and temperature sensor
- In-process pH and Conductivity Measurement with Mixing
- Monitor & control remotely with Ready To Connect control box
- Data collection with 21 CFR Part 11 compliant Chart Recorder



Figure 3. The Mobius® family of single-use mixers

PureFlex™ Films for Consistent Performance

Reliable, Robust PureFlex™ Films

The mixing containers are made of PureFlex™ or PureFlex™ Plus single-use process container films.

The PureFlex™ family of single-use process container films are high purity, medical grade and coextruded to provide strength, flexibility (with maximum resistance to flex-crack), excellent gas barrier performance and inert contact. The fluid contact layer of both types of PureFlex™ films is made of ultra low density polyethylene (ULDPE). The gas barrier for both films is made of polyethylene vinyl alcohol polymers (EVOH). The outer layer of PureFlex™ are made of ethylene vinyl acetate (EVA) and ULDPE while PureFlex™ Plus film is constructed with a tough, linear low density polyethylene (LLDPE) outer layer, designed specifically for the demanding applications often encountered in large volume operations (>500 L).

The contact layers of PureFlex™ films comply with the Food and Drug Administration (FDA) regulation 21 CFR Part 177, 1520. Every layer of the PureFlex™ films passes USP <87> and USP <88> tests under 100% extraction, i.e. worst-case conditions, providing product protection in the event of a cross leach of the internal film layers to the contact layer.

Certification Levels

You demand quality, cost containment and regulatory compliance at every stage of process development. The Mobius® mixing and sampling assemblies are available in either Gold or Bronze certification levels.

Certification	Shelf Life Claim	Sterility Claim	LAL and Particulate	Leak Testing	Class VI USP (88)
Gold	2 years	Sterile, Quarterly Validation	Lot Release	100% of lot on full assembly and container*	Post-gamma, component family
Bronze	None	Gamma-irradiated >25 kGy, not validated sterile	No testing performed	No testing performed	Pre-gamma resin only

* Complete assembly testing is performed unless prohibited by the design.

Services

Installation Qualification/Operational Qualification (IQ/OQ)

Our IQ/OQ service ensures your system is fully documented, operational, compliant with pharmaceutical regulatory requirements, and ready for your Performance Qualification.

IQ/OQ includes static and dynamic tests:

- Completion of as-built system documentation
- Visual inspection
- Mechanical tests
- Electrical tests
- Instrumentation verification (depending on system option)
- Functional tests

Preventive Maintenance (PM)

With our PM service, your equipment will be verified using established protocols to ensure documented compliance with quality requirements. Maintenance kit parts will be replaced (parts to be purchased separately). Maintenance recommendations and a full report of the services performed will also be provided to ensure that the validated state of the equipment is maintained.

Corrective Maintenance

In the unlikely case your system does experience a problem, our engineers will provide on-site technical support to get you back up and running as quickly as possible.

Spare Parts

Utilizing our service offerings also provides direct access to the spare parts needed to maintain and repair your system. Purchasing spare parts directly from us is the only way we can guarantee that you get the right parts every time, with the same level of performance as the original.

For Regulatory reference: This document was reviewed by Ushma Mehta

To place an order or receive technical assistance, visit

[EMDMillipore.com/contactPS](https://www.emdmillipore.com/contactPS)

For additional information, visit

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