



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 measurement with optional pH probe port or Hamilton OneFerm Single-use pH Sensor

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.

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 Measurement with Mixing

Two options for in-process measurement of pH with mixing are available: the Probe Port, for use with re-usable probes, and the Hamilton OneFerm pH sensor, a classical electrochemical pH sensor designed for single-use applications. The Probe Port enables the easy insertion of your standard PG 13.5 threaded probe. The Hamilton OneFerm pH sensor is provided gamma-irradiated in the mixer bag for applications requiring sterility. Both the Probe Port and the Hamilton OneFerm pH sensor may be attached to the Mobius® single-use mixer bag at the position of the needle-free sample port.

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 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.

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 L, 50 L, 100 L, 200 L, 500 L and 1000 L
- Safe, sterile sampling directly from the mixing container without dead legs
- Integrated load cells and temperature sensor (standard with 1000 L mixer)*
- In-process pH measurement with optional pH probe port or Hamilton OneFerm Single-Use pH Sensor

* Available with 10 L, 50 L, 100 L, 200 L and 500 L as custom.



Figure 1. The Mobius® family of single-use mixers

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.

Specifications

Mobius® MIX – Hardware

HDPE Carriers (10 L and 50 L)

Materials of Construction	
Tank	HDPE
Stand	304L stainless steel
Casters	Polyurethane
Dimensions – H x W x D in. (cm)	38.4 (97.5) x 29.5 (75) x 25.6 (65)
Weight – lb (kg)	123 (56)
Storage	0–40 °C non-condensing environment
Operating temperature	4–40 °C non-condensing environment

LLDPE Carriers (100 L, 200 L, 500 L)

Materials of Construction	
Tanks	LLDPE
Stand	HDPE
Latch	18-8 stainless steel
Casters	Polyurethane
Dimensions	H x W x D in (cm)
100 L	48 (122) x 35 (89) x 31 (79)
200 L	49 (124) x 38 (97) x 32 (81)
500 L	66 (168) x 48 (122) x 39 (99)
Weight	lb (kg)
100 L	74 (33.6)
200 L	86 (39)
500 L	200 (90.7)
Storage	0–40 °C non-condensing environment
Operating temperature	
100 L, 200 L	4–40 °C non-condensing environment
500 L	4–30 °C non-condensing environment

Stainless Steel Carriers (100 L, 200 L, 500 L, 1000 L)

Materials of Construction	
Tank	304L stainless steel
Stand	304L stainless steel
Latch	18-8 stainless steel (1000 L only)
Casters	304L stainless steel
Dimensions (Stainless Steel Jacketed)	H x W x D in (mm)
100 L	49.8 (1264.9) x 32.7 (829.6) x 26.4 (669.8)
200 L	51.6 (1309.7) x 36.9 (937.7) x 31.3 (793.8)
500 L	65.4 (1661.1) x 45.8 (1161.7) x 41.3 (1048.3)
1000 L	69.7 (1770.5) x 57.75 (1446.8) x 49 (1244.6)
Dimensions (Stainless Steel Unjacketed)	H x W x D in (mm)
100 L	49.8 (1264.9) x 32.7 (829.6) x 26.4 (669.8)
200 L	51.6 (1309.7) x 36.9 (937.7) x 31.3 (793.8)
500 L	65.4 (1661.1) x 45.8 (1161.7) x 41.3 (1048.3)
1000 L	69.7 (1770.5) x 53.9 (1368.4) x 49 (1244.6)

Weight (Stainless Steel Jacketed)	lb (kg)
100 L	410 (186)
200 L	485 (220)
500 L	825 (374)
1000 L	1200 (544)
Weight (Stainless Steel Unjacketed)	lb (kg)
100 L	285 (129.3)
200 L	325 (147.4)
500 L	530 (240.4)
1000 L	900 (408.2)
Fluid volume in jacket (approx.)	gal (L)
100 L	1.6 (6)
200 L	2.1 (7.8)
500 L	4.4 (16.8)
1000 L	5.4 (20.5)
Heat transfer area in jacket (approx.)	sq. ft. (sq. m.)
100 L	10.4 (0.97)
200 L	13.2 (1.23)
500 L	28.5 (2.65)
1000 L	34.9 (3.23)
Maximum working pressure	150 psi
Stainless Steel Jacketed Mixers ASME U-1 code stamped	optional
Integrated load cells	optional; Mettler Toledo SWB505 MultiMount™ with Model #0745 load cells
Ingress protection rating	IP68
Hamilton OneFerm™ pH VP 70 Pt1000	optional
RTD Temperature Sensor	optional; Minco™ part no. AS5010PDY30TC20N3S
Storage	0–40 °C non-condensing environment
Operating temperature	4–60 °C non-condensing environment

Motor for 10 L and 50 L

Weight lb (kg)	3.1 (1.4)
Electrical (max)	50 W
Design speed	up to 1000 RPM
Maximum operating speed has to be validated for each process individually, depending on volume, viscosity, etc.	
Cable length in. (cm)	78.7 (270)
Ingress protection rating	IP67
Regulatory information	CE marked

Motor for 100 L and 200 L Mixers

Weight lb (kg)	10.8 (4.9)
Electrical (max)	300 W
Design speed	up to 500 RPM
Maximum operating speed has to be validated for each process individually, depending on volume, viscosity, etc.	
Cable length in. (cm)	118.1 (300)
Ingress protection rating	IP67
Regulatory information	CE marked

Motor for 500 L and 1000 L	
Weight lb (kg)	29 (13.1)
Electrical (max)	1200 W
Design speed	up to 250 RPM
Maximum operating speed has to be validated for each process individually, depending on volume, viscosity, etc.	
Cable length in. (cm)	118.1 (300)
Ingress protection rating	IP67
Regulatory information	CE marked

Control Box for 10 L and 50 L Mixers	
Materials of construction	304L stainless steel
Weight lb (kg)	24.3 (11)
Electrical	115/230 VAC 50/60 Hz single phase
Cable length in. (cm)	78.7 (270)
Ingress protection rating	IP65
Regulatory information	CE marked

Control box for 100 L and 200 L Mixers	
Materials of Construction	304L stainless steel
Weight lb (kg)	19.76 (13.5)
Electrical	115/230 VAC 50/60 Hz single phase
Cable length in. (cm)	98.4 (250)
Ingress protection rating	IP65
Regulatory information	CE marked

Control box for 500 L and 1000 L	
Materials of Construction	304L stainless steel
Weight lb (kg)	29.76 (13.5)
Electrical	208 VAC 3 phase or 230 VAC single phase
Cable length in. (cm)	98.4 (250)
Ingress protection rating	IP55
Regulatory information	CE marked

Hand Control for 10 L, 50 L, 100 L, 200 L, 500 L, 1000 L	
Weight oz (kg)	8.81 (0.25)

Mixing	
MIX Container Assembly (10 L, 50 L, 100 L, 200 L, 500 L, 1000 L)	
Materials of Construction	
Mix container	PureFlex™ Plus upon custom request
Adapters	SterilEnz™ LDPE
Luer plugs	Kynar® Polyvinylidene Fluoride
Connectivity	CPC® Polysulfone
Tubing	Silicone
Pinch clamp	PVDF
Impeller	Sintered neodymium magnet NdFeB encased in polypropylene
Bung port	Polyethylene
TC gasket	Silicone
TC clamp	Nylon
TC end cap	Polypropylene
Cup	HDPE
Probe Port	
Materials of Construction	
Port	HDPE
O-ring	Silicone
Plug	Polypropylene

Ordering Information

Mix Carriers

	MIX10	MIX50	MIX10/50	MIX100	MIX200	MIX500	MIX1000
LLDPE and HDPE Carrier with Electronics*							
115/230 VAC 50/60 HZ	SN5MIX10EL1	SN5MIX50EL1	SN5MIX1050EL1	—	—	—	—
120V, 50/60 HZ	—	—	—	MIX0100L100	MIX0200L100	—	—
208V, 50/60 HZ	—	—	—	—	—	MIX0500L100	—
230V, 50/60 HZ	—	—	—	MIX0100L101	MIX0200L101	MIX0500L101	—
Carrier Only							
HDPE	SN5MIX10ELO	SN5MIX50ELO	SN5MIX1050ELO	—	—	—	—
LDPE	—	—	—	MIX0100L102	MIX0200L102	MIX0500L102	—
Stainless Steel Jacketed	—	—	—	MIXJ100L102	MIXJ200L102	MIXJ500L102	MIXJ1000L102
Stainless Steel Jacketed, ASME Certified	—	—	—	MIXJ100L102A	MIXJ200L102A	MIXJ500L102A	MIXJ1000L102A
Stainless Steel Jacketed with Load cells	—	—	—	MIXJ100L102L	MIXJ200L102L	MIXJ500L102L	MIXJ1000L102L
Stainless Steel Jacketed, ASME Certified and Load cells	—	—	—	MIXJ100L102LA	MIXJ200L102LA	MIXJ500L102LA	MIXJ1000L102LA
Stainless Steel Unjacketed	—	—	—	MIXU100L102	MIXU200L102	MIXU500L102	MIXU1000L102
Stainless Steel Unjacketed with Load Cells	—	—	—	MIXU100L102L	MIXU200L102L	MIXU500L102L	MIXU1000L102L
Accessories							
Control box unit, 120V	—	—	—	MIX0200L103	MIX0200L103	—	—
Control box unit, 208V	—	—	—	—	—	MIX0500L103	MIX0500L103
Control box unit, 230V	—	—	—	MIX0200L104	MIX0200L104	MIX0500L104	MIX0500L104
Control box unit, 240V	SN5SPKCTRLBX	SN5SPKCTRLBX	SN5SPKCTRLBX	—	—	—	—
Motor	SN5SPKEL1MIXER	SN5SPKEL1MIXER	SN5SPKEL1MIXER	MIX0200L107	MIX0200L107	MIX0500L107	MIX0500L107
Hand control and cable	MIX0200L106	MIX0200L106	MIX0200L106	MIX0200L106	MIX0200L106	MIX0200L106	MIX0200L106
Electrical power cord (country specific)**	—	—	—	MIX0200L108	MIX0200L108	—	—
Stainless Steel Mixer Spare Parts							
Quick-connect coupling, male, 3/4" NPT	MIXSST0109442						
Quick-connect coupling, female, 3/4" NPT	MIXSST0109441						

*Includes carrier, control box unit, motor, hand-held control and cable.

**A power cord is ordered separately for countries Argentina, Australia, Columbia, New Zealand, Paraguay, Uruguay, Denmark, Israel, Chile, Ethiopia, Italy, Bangladesh, Burma, Pakistan, S. Africa, Sri Lanka, and Switzerland.

Volume	Mix Containers	Qty/ Pk	Certification		Top Ports						Needle-free Sample Ports	Bottom Ports		
			Bronze	Gold	2" ID	4" Powder Port	1/4" ID	1/2" ID	3/4" ID	1" ID		1/2" ID	3/4" ID	1" ID
10 L	MIX0010LB05	5	✓		✓			✓ (2)				✓		
	MIX0010LG05	5		✓				✓ (2)				✓		
	MIX0010LSG05	5		✓				✓ (2)			✓ (1)	✓		
	MIX0010LLIN	5	✓									✓		
50 L	MIX0050LB05	5	✓		✓			✓ (2)					✓	
	MIX0050LG05	5		✓				✓ (2)					✓	
	MIX0050LSPB05	5	✓			✓		✓ (2)			✓ (1)		✓	
	MIX0050LSG05	5		✓				✓ (2)			✓ (1)		✓	
	MIX0050LLIN	5	✓										✓	
100 L	MIX0100LB05	5	✓		✓		✓	✓	✓			✓		
	MIX0100LG05	5		✓			✓	✓	✓	✓		✓		
	MIX0100LSPB04	4	✓			✓	✓	✓		✓	✓ (2)	✓		
	MIX0100LSG04	4		✓			✓	✓	✓	✓	✓ (2)	✓		
	MIX0100LLIN	5	✓									✓		
200 L	MIX0200LB05	5	✓		✓		✓	✓	✓			✓		
	MIX0200LG05	5		✓			✓	✓	✓	✓		✓		
	MIX0200LSPB04	4	✓			✓	✓	✓		✓	✓ (2)	✓		
	MIX0200LSG04	4		✓			✓	✓	✓	✓	✓ (2)	✓		
	MIX0200LLIN	5	✓									✓		
500 L	MIX0500LB04	4	✓		✓			✓	✓	✓				✓
	MIX0500LG04	4		✓				✓	✓	✓				✓
	MIX0500LSPB04	4	✓			✓		✓	✓	✓	✓ (2)			✓
	MIX0500LSG04	4		✓				✓	✓	✓	✓ (2)			✓
	MIX0500LLIN	5	✓											✓
1000 L	MIX1000LSPB03	3	✓			✓			✓	✓ (2)	✓ (3)			✓
	MIX1000LSPG03	3		✓		✓			✓	✓ (2)	✓ (3)			✓

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