

Saltus[®]

Single-Use Mixing System



Saltus® M200 Mixing System

Over the past decade, single-use systems (SUS) and implementation of automation have been two of the pharmaceutical industry's largest technology initiatives. Ironically, these two initiatives are not always in sync, and have moved counter to each other in application. Traditional multi-use mixing systems often incorporate PLC controls, while process control for single-use mixing systems is often far less sophisticated. Meissner's next generation mixing platform, Saltus®, realigns these two important initiatives and provides robust, reproducible, predictable mixing performance in a single-use format.

Saltus® mixing systems are based on a design philosophy that emphasizes usability and automation. From the easy to install, self-deploying, single-use mixing assembly to the fully automated, one-button start of the control system, Saltus® mixers provide unparalleled usability and ease of operation.

The M200 unifies smart integrated infrastructure to incorporate heightened levels of automation and process control, with simple pre-sterilized fluid contact surfaces to maximize the benefits provided by single-use mixing systems. This unification, coupled with outstanding mixing performance, allows the Saltus® M200 to deliver on the premise of next generation single-use mixing for your process.

- Highly effective, low shear mixing performance
- Quick, easy setup and rapid campaign changeover
- Fully automated with true one-button start functionality



A New Twist on Time Proven Technology

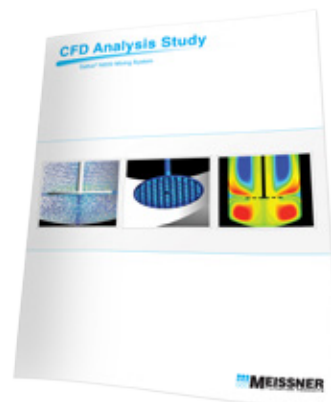


The Saltus® M200 integrates well established vibromixing and single-use biocontainer technologies into a novel process solution that offers pharmaceutical manufacturers a unique alternative to reusable and disposable impeller based mixers. Vibromixing is recognized for its ability to effectively disperse microsolids in liquids. It is also exceedingly effective in liquid-liquid mixing applications, offering performance similar to stirred-tank systems, but with a much more gentle mixing action.

The Saltus® mixing system's gentle, highly effective mixing capability is ideal for a wide variety of applications, including hydration of cell culture media, buffer preparation, product reconstitution from concentrated solutions or powders, homogenization of dispersions or solutions, and chemical inactivation to affect viral clearance, all under aseptic operating conditions.

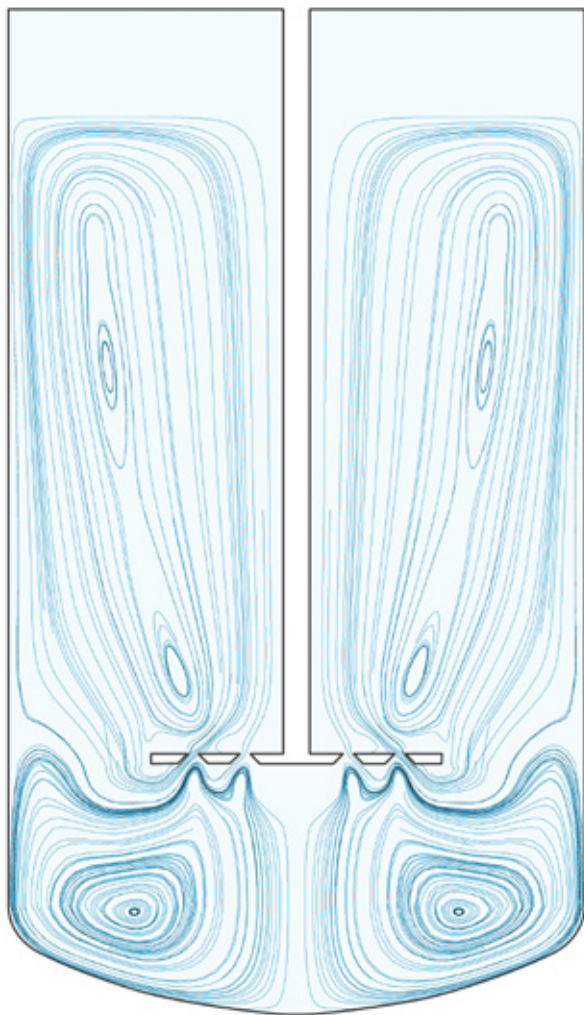
CFD Analysis Study

In order to reliably predict the operational performance of the Saltus® M200 mixing system, Meissner conducted a thorough Computational Fluid Dynamics (CFD) study. The study evaluated the performance of the system's single and dual disc agitator configurations over a range of fluid fill volumes at multiple agitation frequencies, spanning the range of typical operation. A CFD analysis summary and video clips illustrating the mixer's capabilities are available for download at www.meissner.com/saltus/cfd. The full CFD analysis report can be requested through Meissner for evaluation.

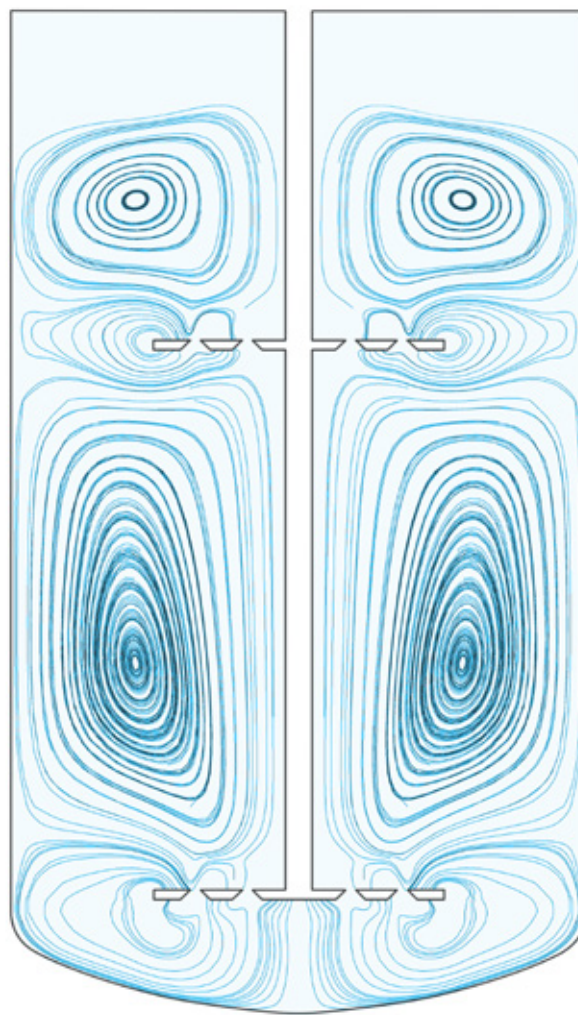


What is a Vibromixer?

Vibromixers utilize a fluid agitator comprised of perforated disks attached to a shaft that is moved vertically through a fluid at a high rate of speed over a small distance. These disks contain a multitude of conical shaped openings which generate jets of liquid that move on a trajectory opposite the direction of the agitator. The resulting venturi effect induces a rapid upward flow which then cascades down the outer portion of the mixing vessel. The degree of agitation is controlled by varying the disk's oscillation frequency.



Mixing path of a single oscillating disc



Mixing path of dual oscillating disc

Applications:

- Liquid-liquid mixing of low density process solutions and bulk drug product
- Hydration of powders for media and buffer preparation
- Suspending of liquids and adjuvants in formulation
- Chemical inactivation of viruses

Single-Use Advantage

Saltus® single-use mixing biocontainer assemblies do not require rotary seals, bearings or metallic components. Instead of relying on dynamic sealing or magnetic couplings to impart fluid motion, agitation in Saltus® single-use assemblies is accomplished via an agitator plate that is oscillated at a relatively small amplitude, but at relatively high frequency. Saltus® single-use assemblies are simply able to take advantage of the flexural properties of the TepoFlex® biocontainer to which the agitator is permanently welded. By replacing dynamic sealing with a permanent weld, Saltus® biocontainer assemblies eliminate a common source of system integrity failure. Further, the Saltus® single-use assemblies do not contain any plastic-on-plastic abrasion regions, which eliminates particulate generation concerns commonly associated with these areas.

Meissner offers four standard single-use mixing assembly configurations that have been designed to accommodate both powder-liquid and liquid-liquid mixing. Additionally, these assemblies can be easily customized to meet specific process requirements. Meissner's proprietary fabrication process allows for a true centerline drain to provide optimized fluid recovery, and up to three sample ports can be accommodated along the side of the single-use assembly. All single-use mixing assemblies are manufactured in an ISO 7 cleanroom environment and provided gamma irradiated at 25-40 kGy prior to delivery. Saltus® single-use mixing biocontainer assemblies are fully supported by an extensive qualification guide.



Box to Batch in Seconds

It is quick and easy to install the Saltus® single-use mixing biocontainer assembly into the support vessel. The wide 100° door allows the assembly to be placed into the tank and a quick TC connection attaches the agitator to the drive system. Two identical and therefore error proof gas support lines can be attached via quick connect fittings, which completes the installation. The single-use assembly can now be deployed with the press of a button from the HMI screen. After the fluid(s) and/or powder have been introduced into the single-use assembly, the operator can select the appropriate stored recipe with another press of a button and the fully controlled mixing process will be executed.



Control System

Integrated advanced functionality is controlled through a single large format HMI. All operations of the Saltus® M200, from single-use mixing assembly deployment to batch completion, are recipe driven which facilitates both ease of use and process repeatability, all via one-button process initiation. Operation of the system is protected via a three-tiered permissions level structure, and includes unique user accounts that ensure appropriate levels of interaction and track specific users' activities.

The control system features recipe storage, the ability to set user defined process tolerances, on screen production history, live data capture, advanced user settings, and much more. All process conditions are continuously monitored, even in the case of the system being operated in manual mode. If an alarm state is encountered, the Saltus® M200 will automatically revert to a safe state and broadcast the condition via the HMI, as well as illuminate signage at the top of the unit.

All required utilities and optional features are fully integrated into the unit, as well as the control system. The onboard inflation system includes all of the required infrastructure to automatically deploy the single-use mixing assembly and to precisely control the pressure during operation, so that the only process connection required at a client's facility is an electrical outlet. The control system also takes advantage of smart sensing options thus limiting the complexity of the consumable. This philosophy increases operational robustness, while at the same time, mitigating process risk.

The Saltus® M200 comes standard with remote connectivity, and is also available with advanced networking options. Both of these options allow for online - real time - technical support from our engineering staff.

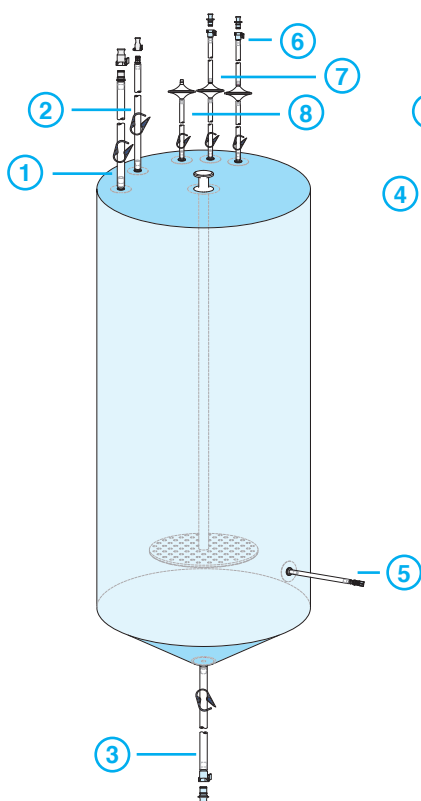


Data Acquisition

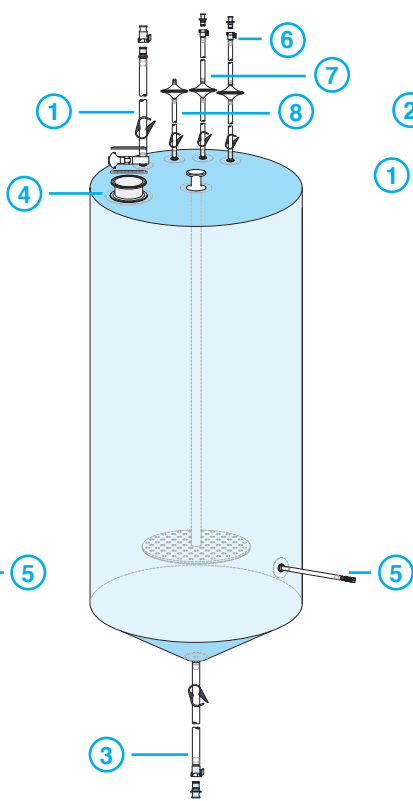
The Saltus® M200 continually logs process parameters during operation and two types of data files are generated when any process is completed. A batch record certificate in a non-corruptible data format captures general process information, including, but not limited to, the recipe used, the serial number of the single-use mixing assembly, the operator(s), and the date and time. It is compliant with the requirements for electronic batch records. An Excel file is also generated simultaneously, capturing all of the data from the same run, which can be useful for trending analysis. Both files are automatically stored to a flash memory device that is secured in a restricted access area on the M200.

Biocontainer Assemblies

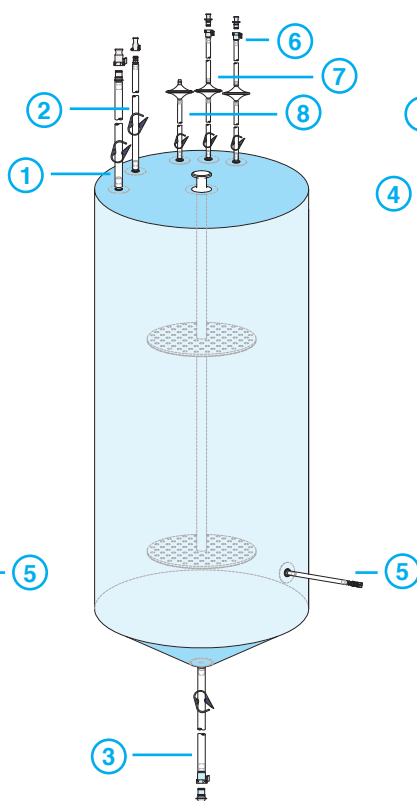
Liquid-liquid Mix



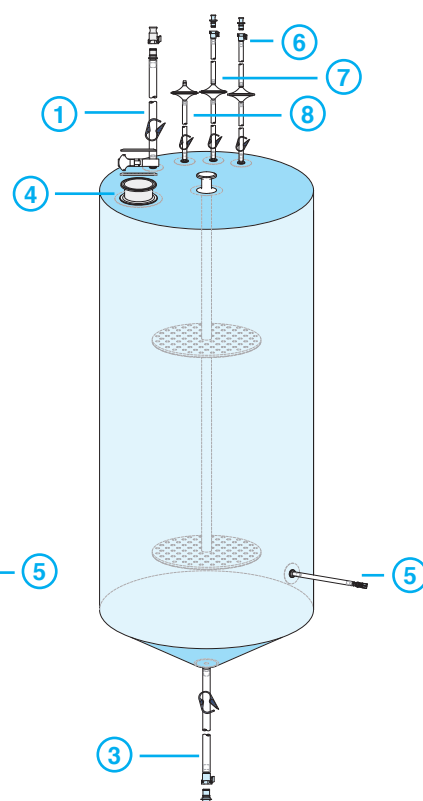
Powder-liquid Mix



Liquid-liquid Mix



Powder-liquid Mix

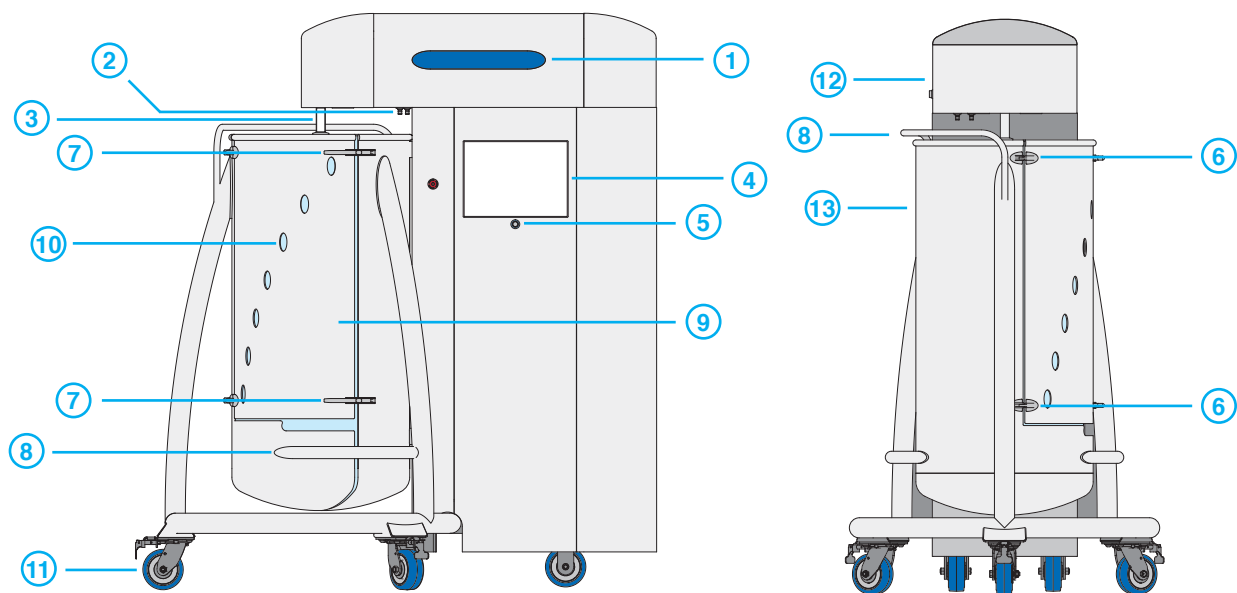


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| ① 1/2" ID x 3/4" OD Tubing with Male MPX | ⑤ Needleless Sampling Site |
| ② 3/8" ID x 5/8" OD Tubing with Male MPC | ⑥ Gas Inlet: 1/4" ID Tubing with Female MPC and Filter |
| ③ 1/2" ID x 3/4" OD Tubing with Female MPX | ⑦ Pressure Monitoring: 1/4" ID Tubing with Female MPC and Filter |
| ④ 3" TC Port | ⑧ Gas Outlet 1/4" ID Tubing with Filter |

Ordering Information

Part Number	Description
KMS7609B-D01-B2235-01	Liquid-Liquid Mixing with Single Disc Agitator
KMS7609B-D01-B2236-01	Powder-Liquid Mixing with Single Disc Agitator
KMS7609B-D02-B2235-01	Liquid-Liquid Mixing with Dual Disc Agitator
KMS7609B-D02-B2236-01	Powder-Liquid Mixing with Dual Disc Agitator

Saltus® M200



- ① Machine status indicator light
- ② Error-proof air ingress & pressure sensor ports
- ③ 1 1/2" sanitary flange agitator connection
- ④ 12" color touch screen HMI
- ⑤ Power button
- ⑥ Heavy duty 304 stainless steel hinges
- ⑦ Ergonomic 304 stainless steel door latches with tamper evidence provisions
- ⑧ Conveniently located tubing supports
- ⑨ 200 L 304 stainless steel tank (available with jacket)
- ⑩ Graduated sight holes
- ⑪ 304 stainless steel casters with non-marking, low rolling resistance urethane wheels
- ⑫ Locking rear access panel
- ⑬ External compressed gas ingress port

Ordering Information

Saltus® Model	Tank Type	Configuration	Nominal System Volume	Voltage	Control I / Data Acquisition / Network Package	Options
KMHS	S	B	09	E	C01	00
KMHS	S = Standard; 304 stainless steel J = Jacketed tank; 304 stainless steel	B = Base configuration; side and top retaining bars, no support tray	09 = 200 L	U = US version; 110V / 60 Hz E = European version; 220V / 50 Hz	C01 = Standard Control Package - with internal USB storage, USB and external Ethernet port (bottom) EC1 = C01 Option + Network system access for online system support provided through a router (dynamic IP address) AC1 = C01 Option + EC1 Option + Expanded hardware to support advanced capabilities including Load Cells, Temperature Control and future expansion	00 = Standard Product 1N = Includes external gas ingress port to accommodate compressed gas L1 = Includes integrated load calls LN = Includes 1N and L1 options

