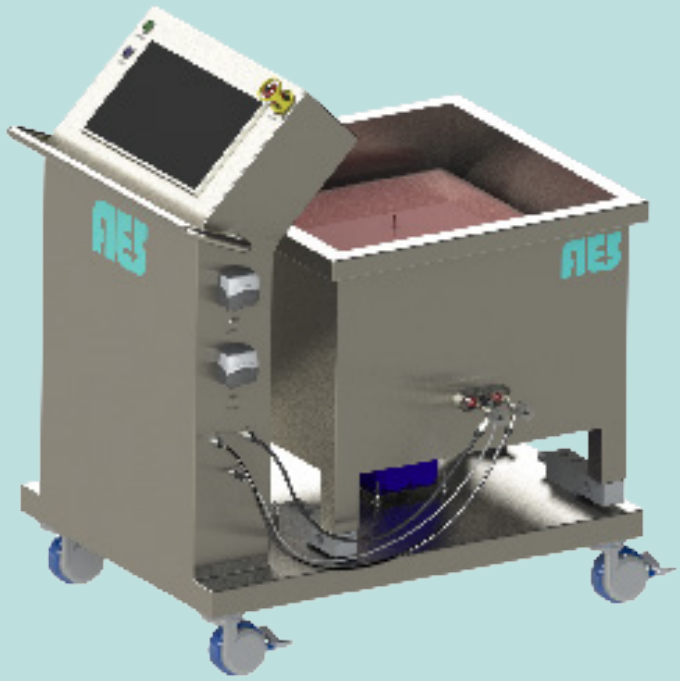
AUTOMATED ENGINEERING SERVICES, INC.

TECHNICAL BROCHURE



BIOMIX SINGLE-USE MIXER

Precision Mixing

PRODUCT SUMMARY

The AES BioMix Single-Use Mixer (SUM) enhances biopharmaceutical manufacturing by delivering precise mixing control through a bottom-mounted magnetic drive agitator, scalability with multiple volume options from 50L to 3000L, and efficiency by eliminating cleaning requirements with single-use bags. Designed for seamless integration, real-time monitoring, and regulatory compliance, the BioMix maximizes workflow performance.

APPLICATIONS:

The AES BioMix SUM is a versatile tool for bioprocessing, delivering flexibility and precision in R&D and commercial production. It ensures consistent, reproducible outcomes across critical applications, including:

- Buffer & Media Preparation
- Product Formulation
- Fill/Finish Operations

BENEFITS OF THE AES BIOMIX SYSTEM:

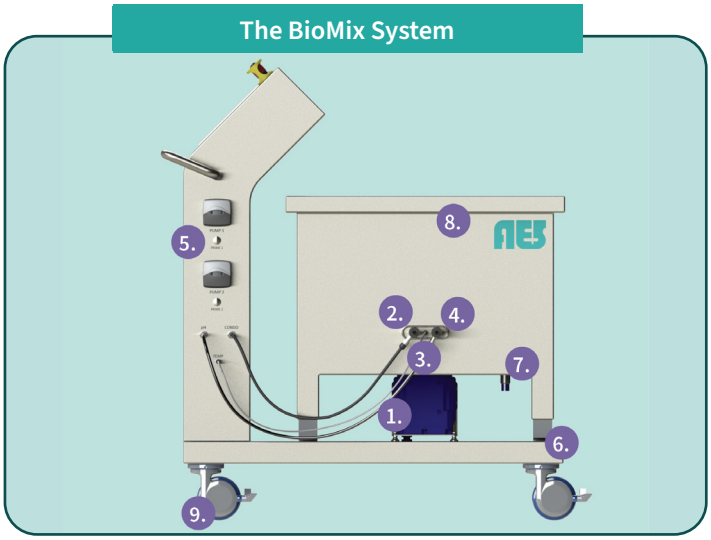
- **Optimized Mixing:** A bottom-mounted magnetic drive agitator ensures thorough and uniform mixing while minimizing shear stress.
- **Sterility & Contamination Control:** The sealed magnetic drive prevents direct motor-fluid contact, reducing contamination risks and ensuring sterility.
- **Scalability:** Available in a range of sizes, making the SUM adaptable for both small-scale R&D applications and large-scale commercial production.
- **Process Monitoring:** Real-time analytics for pH, temperature, conductivity, and pressure provide full visibility into critical process parameters, ensuring high reproducibility and regulatory compliance.
- **Low Maintenance & Cleanability:** The absence of mechanical seals and shafts reduces wear and tear, simplifying maintenance while improving cleanability and process reliability.

DESIGNED FOR A REGULATED ENVIRONMENT:

We designed the AES BioMix SUM to meet the rigorous demands and standards required in a regulated environment. The BioMix is GMP compliant and can be incorporated to meet 21 CFR Part 11 compliance regulations.

SYSTEM OVERVIEW

The AES BioMix SUM is a highly advanced system designed to streamline bioprocessing workflows with precision control and automation. The following explores the core features of the BioMix, including its innovative mixing technology, liquid control mechanisms, real-time process analytics, weight measurement capabilities, and easy-to-use single-use consumables. These elements work together to provide a seamless, efficient, and highly scalable solution for biopharmaceutical manufacturing.



1. Bottom-mounted Magnetic Drive Agitator; 2. Single-use Conductivity Sensor; 3. RTD Sensor; 4. Single-use pH Sensor; 5. (2) Peristaltic Pumps; 6. (4) Integrated Load Cells; 7. Drain Valve; 8. Mixing Basin; 9. (4) Casters with Brakes

MIXING SYSTEM:

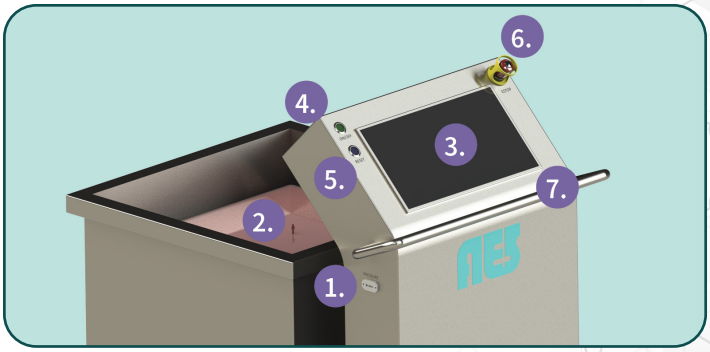
The AES BioMix SUM is built for durability and ease of use in bioprocessing environments. Its stainless-steel frame provides structural support and integrates sensors for real-time process monitoring. A built-in hand rail and cleanroom-grade swivel casters with brakes make it easy for operators to maneuver the unit while maintaining stability during operation. To ensure proper bag positioning before processing, the system supports manual air inflation, allowing operators to pre-inflate the bag for optimal shape and secure placement within the mixing basin.

Magnetic Drive Agitator:

The bottom-mounted magnetic drive agitator delivers efficient, uniform mixing with minimal shear stress, ensuring gentle handling of biologics. With a scalable speed range, it allows users to fine-tune mixing intensity for different batch sizes and process needs.

Mixing Basin:

The dedicated mixing basin securely holds the single-use AES BioMix bag, ensuring stability and optimal fluid dynamics for uniform mixing. A drain valve is located at the lowest possible point of the basin to minimize hold-up volume and maximize product recovery.



1. Single-use Pressure Sensor; 2. BioMix Bag; 3. Touchscreen HMI; 4. On/Off Button; 5. Reset Button; 6. E-Stop Button; 7. Hand Rail

BioMix Bags:

The mixing basin integrates seamlessly with AES BioMix bags, designed for sterility and regulatory compliance. These gamma-irradiated, multi-layer bags optimize purity and reduce downtime.

LIQUID CONTROL:

Precision liquid control is a hallmark of the BioMix SUM, with integrated peristaltic pumps it ensures controlled fluid movement. These components facilitate consistent, reliable transfers while minimizing contamination risks.

PROCESS ANALYTICS:

Equipped with a suite of real-time process monitoring sensors, the AES BioMix SUM provides comprehensive analytics for pH, temperature, conductivity, and pressure. These single-use sensors are seamlessly integrated into the system, allowing operators to maintain tight quality control and make informed adjustments throughout the process. Operators can optimize bioprocessing efficiency and ensure product consistency by capturing critical data in real-time.

DATA AND COMMUNICATION:

The AES BioMix SUM enables seamless data management and process communication, enhancing operational visibility, automation, and compliance. With real-time monitoring, remote access, automated data logging, and alarm notifications, operators can efficiently manage operations while maintaining regulatory adherence.

Human Machine Interface (HMI):

The BioMix features a user-friendly touchscreen HMI that provides real-time monitoring and control over key system parameters. Operators can easily adjust mixing speeds, liquid flow, and process analytics with an intuitive interface. The HMI supports Rockwell Automation or a preferred DCS, ensuring compatibility with existing bioprocessing workflows while streamlining operations.

Remote Monitoring & Data Logging:

To enhance operational efficiency, the AES BioMix offers remote monitoring capabilities, allowing operators to oversee processes from off-site locations. Automated data logging ensures comprehensive record-keeping for regulatory compliance, providing detailed tracking of critical process parameters. This feature supports data-driven decision-making and enhances traceability for GMP and FDA compliance.

TECHNICAL SPECIFICATIONS

SINGLE-USE MIXER SPECIFICATIONS						
Volume	50 L	100 L	200 L	1000 L	2000 L	3000 L
Geometry	Drain Valve is Located at Lowest Possible Point to Minimize Hold-up Volume					
On/Off Button	Yes					
Reset Button	Yes					
E-Stop	Yes					
Mobility	Mounted on (4) Cleanroom-grade Casters with Brakes					
Bag Inflation	Yes					
Mixing Basin						
Agitator Type	Bottom-mounted Magnetic Drive Mixer					
Agitator Speed	50 L - 200 L SUM				1600 rpm	
	1000 L - 3000 L SUM				240 rpm	
Agitator Turndown Ratio	1:20 - 1:40					
Liquid Control						
Onboard Pumps	(2) Pumps with Integrated Stepper Motors					
Pump Head Type	Peristaltic, Flip-Top Pump Heads					
Pump Range	.003 - 2050 mL/min					
Process Analytics						
Pressure Sensor	(1) Single-use Pressure Sensor Insert for Port Plate					
Pressure Range	0 - 6 psi					
Temperature Sensor	(1) RTD Sensor					
Temperature Range	-50°C to +260°C					
Temperature Accuracy	± 2% of reading					
pH Sensor	(1) Single-use pH Sensor					
pH Range	3 - 10 pH					
pH Accuracy	± 0.15					
Conductivity Sensor	(1) Single-use Conductivity Sensor					
Conductivity Range	100 uS/cm - 300 mS/cm					
Max Conductivity	up to 500 uS/cm					
Weight Measurement						
Load Cells	(4) Integrated, Analog Load Cells					
Load Cell Capacity	50L & 100L SUM				100 kg	
	200L SUM				200 kg	
	1000L SUM				1000 kg	
	2000 L SUM				2000 kg	
	3000 L SUM				3000 kg	
Load Cell Process Tolerance	0.5%					
Weight Indicating Transmitter	Supports Real-time Monitoring & Process Automation					
Control & Automation						
Touchscreen HMI	Yes					
Control System Integration	Rockwell Automation or Your Preferred DCS					

BIOMIX BAG SPECIFICATIONS

PRODUCT SPECIFICATIONS	
Bag Volume	50 L - 3000 L
Operating Temperature	-45ºC ~ 45ºC
Sterilization Method	Gamma Irradiation (25-40 kGy)
Packaging Form	Double Layer PE Bag vacuum packaging
Bag Composition	
Structure	LDPE, EVOH, ULDPE (liquid contact layer)
Thickness	0.325 mm
Compliance	ISO 10993-4: Hemolysis ISO 10993-5: Cytotoxicity ISO 10993-6: Implantation Test ISO 10993-10: Irritation & Sensitation Tests ISO 10993-11: Acute Systemic Toxicity Test USP <85>: Bacterial Endotoxions - LAL Test USP <88>: Biological Reactivity Testing, in vivo, Class VI USP <661>: Plastic Containers European Pharmacopoeia Test Ch. 3.1.5 ADCF
Packaging Form	Double Layer PE Bag vacuum packaging