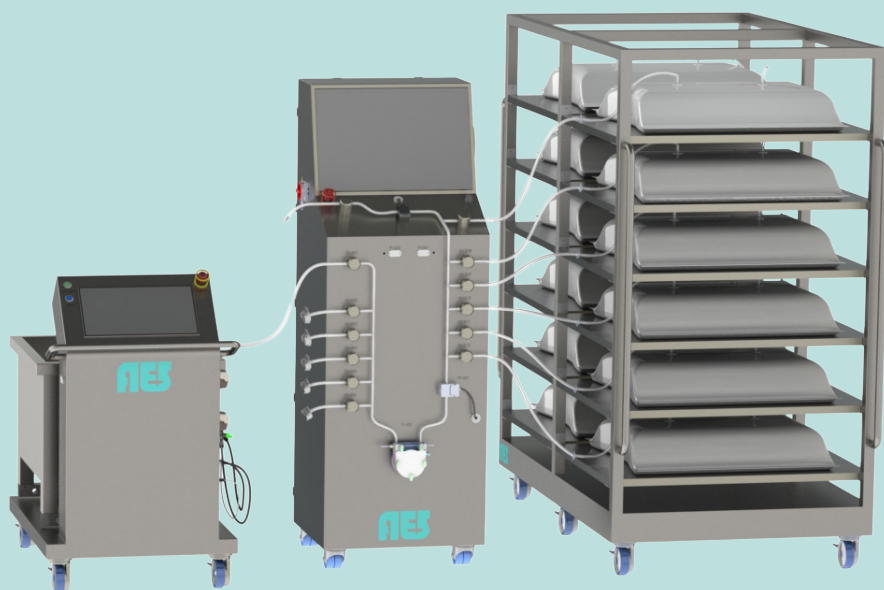




OPTIFILL SYSTEM

ASEPTIC FILLING

PRODUCT SUMMARY

The AES OptiFill System is engineered specifically for biopharmaceutical liquid handling, combining precision, compliance, and reliability in one modular platform. With high-accuracy dispensing and seamless automation integration, it ensures consistent results and confidence in every batch.

APPLICATIONS:

Ideal for a wide range of bioprocessing workflows, the OptiFill System supports:

- **Biopharmaceutical Manufacturing:** precise liquid transfers for GMP operations
- **Quality Control:** repeatable filling and sampling accuracy
- **Clinical & Process Development:** adaptable configuration for pilot-scale production

BENEFITS OF THE AES OPTIFILL SYSTEM:

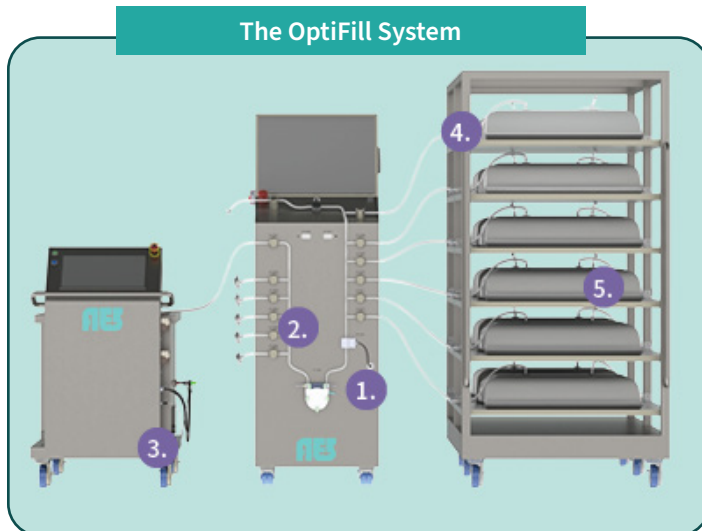
- **High-accuracy filling** with flow rate precision of ± 6 mL/min at low flow rates and ± 20 mL/min at higher flow rates
- **Automatic pinch valves** eliminate the need for additional pumps, minimizing system complexity and maintenance while reducing costs.
- **Flexible compatibility** supports both bottles and bags to fit your existing process
- **Integrated label printer** simplifies batch traceability and GMP documentation.

DESIGNED FOR A REGULATED ENVIRONMENT:

This OptiFill System can meet the rigorous demands and standards required in a regulated environment. Built to meet GMP and 21 CFR Part 11 standards, the OptiFill System simplifies validation and ensures complete data integrity across your bioprocess.

SYSTEM OVERVIEW

The AES OptiFill System is a fully integrated aseptic filling platform that combines precision, flexibility, and reliability across every stage of bioprocessing. Designed for seamless operation in regulated environments, the system unites automated liquid handling, single-use mixing, and secure filling into one cohesive workflow. Each subsystem is engineered for accuracy and ease of use, helping biopharmaceutical manufacturers maintain efficiency, compliance, and product integrity.

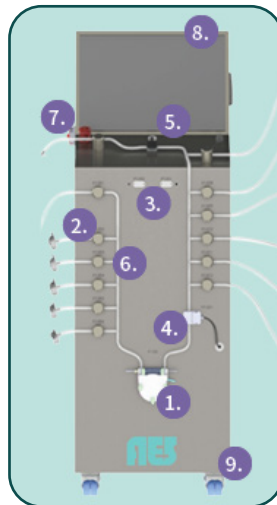


1. Liquid Handling Unit; 2. OptiFill Tubing Set; 3. Single-Use Mixer; 4. Filling Rack; 5. OptiFill Bags

LIQUID HANDLING UNIT:

The Liquid Handling Unit delivers precise flow control and reproducible filling accuracy for a wide range of bioprocessing applications. Built with advanced pump technology, a clamp-on flow meter, and thirteen automatic pinch valves, the LHU provides accurate, consistent fluid management with flow-rate precision within ± 6 mL/min at low flows and ± 20 mL/min at higher flows.

1. Bi-directional Pump; 2. (13) Pinch Valves; 3. (2) Pressure Sensors; 4. Flow Meter; 5. Liquid Sensor; 6. OptiFill Tubing Set; 7. E-Stop Button; 8. Touchscreen HMI; 9. Cleanroom-grade Casters with Brakes



BIOMIX SINGLE-USE MIXER:

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 System:

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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.

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.

FILLING RACK:

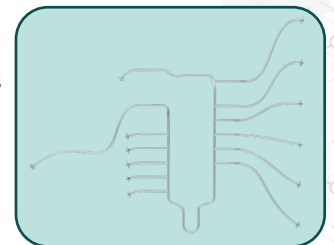
The Filling Rack is engineered to securely support and organize containers during the filling process. Designed for integration with bags and adaptable to bottles, the Filling Rack ensures stability and accessibility to meet the diverse requirements of bioprocessing applications.

CONSUMABLES:

The OptiFill's consumables are carefully selected to ensure seamless integration and strict sterility throughout the filling process. From versatile container options to precision-engineered tubing and SUM Bags, each component meets stringent bioprocessing standards, offering flexibility for various applications.

OptiFill Tubing Set:

The OptiFill Tubing Set connects the SUM, LHU, and fill containers on the Filling Rack, ensuring aseptic fluid transfer. With options available for both low-flow and high-flow applications, the tubing is designed to accommodate various flow rates and volumes to meet your specific needs.



OptiFill Container Selection:

The OptiFill System offers flexible container options, including OptiFill Bags and Bottles, to accommodate diverse liquid volumes. Specifications, such as compatibility with storage conditions as low as -80°C , are available upon request to meet specific bioprocessing needs.

BioMix Bags:

Designed specifically for the BioMix, these single-use bags provide sterile, flexible containment for a range of mixing volumes, maintaining product integrity in sensitive applications.

DATA AND COMMUNICATION:

The OptiFill System provides advanced digital connectivity to ensure accuracy, compliance, and real-time visibility across every batch. Integrated monitoring and data management tools give operators and quality teams full control of the aseptic filling process.

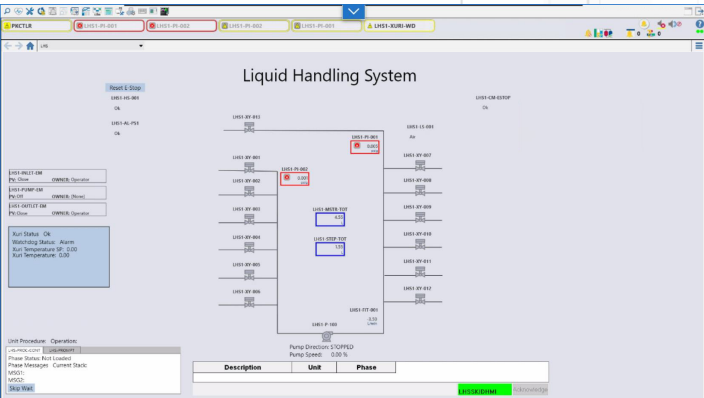
Key Capabilities:

- **Real-time monitoring:** Continuous display of critical process parameters and system status for proactive oversight
- **Comprehensive data logging:** Secure batch records that meet GMP and 21 CFR Part 11 standards, simplifying validation and audit readiness
- **Automated Alerts:** Built-in alarms notifications help prevent deviations and ensure timely corrective action
- **Remote Access:** Enables secure data review and system oversight from networked workstations

Human Machine Interface (HMI):

The OptiFill System's touchscreen HMI provides operators with a clear, intuitive interface for process control and data management. Its configurable design allows for user-level access, customizable settings, and real-time visibility of all operational parameters.

Through the HMI, users can monitor live filling activity, review historical data, and generate reports directly from the system. This integrated functionality helps reduce manual data handling, minimize errors, and support digital recordkeeping requirements under GMP and 21 CFR Part 11.



The featured overview screen exhibits sample numbers exclusively and is subject to variation based upon the client's operational process workflow.

OPTIFILL TECHNICAL SPECIFICATIONS

Liquid Handling Unit Specifications		
Enclosure Material	SS304	
Equipment Width	57.3 cm 22.6 in	
Equipment Length	65.1 cm 25.6 in	
Equipment Height	162.9 cm 64.1 in	
Mobility	Mounted (4) Cleanroom-grade Casters with Brakes	
On/Off Button	Yes	
E-Stop	Yes	
Power Requirements	115 VAC, 50/60 Hz, 2300 Watts	
Label Maker	Yes	
Certification	UL508A	
Liquid Control		
Fill Containers	AES OptiFill Bags or Bottles	
Filling Volume Range	100 mL - 500 mL	500 mL - 50 L
Target Filling Rate	±5%	
Type of Measurement	SW Totalizer from Flow Meter	
Tubing Size	L/S 13	L/S 18
Flow Meter	(1) Enclosure Mounted Clamp-on Flow Meter	
Flow Meter Range	6 - 3,000 mL/min	20 - 10,000 mL/min
Flow Rate Accuracy	0 - 300 mL/min: ±6 mL/min	0 - 1,000 mL/min: ±20 mL/min
	300 - 3,000 mL/min: ±2%	1,000 - 10,000 mL/min: ±2%
Onboard Pumps	(1) Pumps with Bi-Directional Stepper Motors	

Pump Head Type	Peristaltic, Flip-Top					
Pump Speed Range	0.2 - 410 RPM					
Pump Flow Rate Range	0.006 - 24 mL/min			0.400 - 1,640 mL/min		
Valves	(13) Valves					
Valve Actuation Type	Automatic Pinch Valves					
Pressure Sensors	(2) Sensors (-0.7 - 7.5 psig)					
Liquid Sensor	(1) Sensor					
Automation & Control Software						
Control System	Emerson DeltaV or Preferred Control System upon Request					
Automated System Control	PK controller or Preferred PLC upon Request					
HMI						
Touchscreen	Yes					
Display Size	48.26 cm 19 in					
Certifications	UL & CE					
BIOMIX SUM SPECIFICATIONS						
Volume	50 L	100 L	200 L	1,000 L	2,000 L	3,000 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 & Push Handle					
Bag Inflation	Yes					
Mixing Basin						
Agitator Type	Bottom-mounted Magnetic Drive Mixer					
Agitator Speed	50 L - 200 L SUM			1,600 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	50 L & 100 L SUM	100 kg
	200 L SUM	200 kg
	1,000 L SUM	1,000 kg
	2,000 L SUM	2,000 kg
	3,000 L SUM	3,000 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	
FILLING RACK SPECIFICATIONS		
Number of Stacks	Up to 6 per Rack	
Enclosure Material	SS304	
Mobility	(4) Cleanroom-grade Casters with Brakes & Push Handles	

OPTIFILL TUBING SET SPECIFICATIONS

Production Specifications		
Pressure Sensors	(2) Sensors	
Aseptic Connectors	(12) Polycarbonate Connectors	
Equal Tee Fittings	(11) Polypropylene Fittings	
Filter	(1) Polyvinylidene Fluoride Filter	
Tubing Material	Polycarbonate-Silicone	
Tubing Size**	L/S 13	L/S 18
Tubing Inner Diameter (ID)**	1/32 in	5/16 in
Tubing Outer Diameter (OD)**	5/32 in	7/16 in
Tubing Wall Thickness**	1.6 mm	1.6 mm
Tubing Bore**	0.8 mm	7.9 mm
Tubing Length	13.063 ft	
Sterilization Method	Gamma Irradiation	

**Changing Tubing will increase or decrease filling accuracy due to flow rates.

BIOMIX BAG SPECIFICATIONS

PRODUCT SPECIFICATIONS	
Bag Volume	50 L - 3000 L
Operating Temperature	-45 °C ~ 45 °C
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