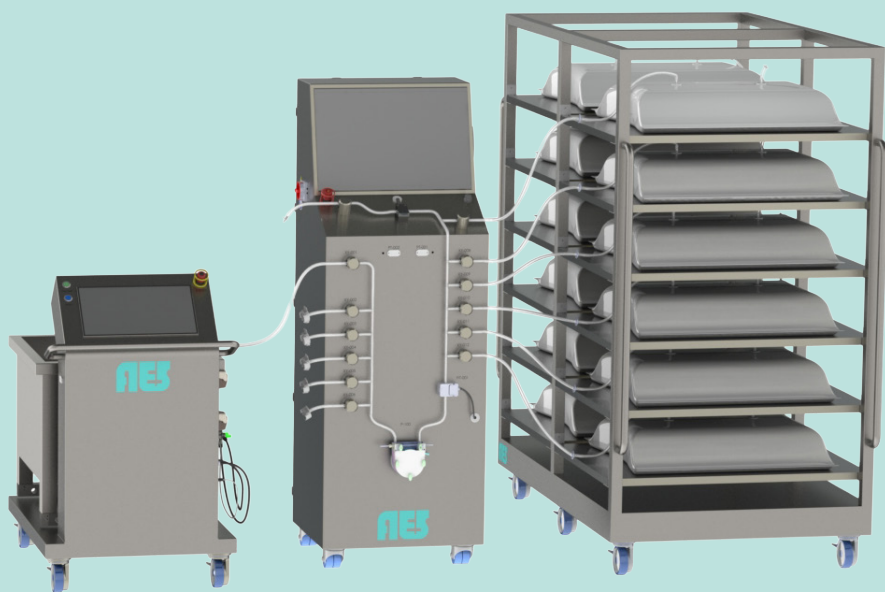




OPTIPREP SYSTEM

MEDIA & BUFFER PREP

PRODUCT SUMMARY

The AES OptiPrep System is an industry-leading solution designed for precision and reliability in media and buffer preparation. With its advanced control over liquid handling, the system ensures that your media and buffer preparation processes are efficient, consistent, and error-free.

APPLICATIONS:

Enhance your upstream bioprocessing operations with the AES OptiPrep System, a versatile and scalable solution designed to support a wide range of media and buffer preparation needs. The system is ideal for:

- Media Preparation
- Buffer Preparation
- Biopharmaceutical Manufacturing
- Clinical Research
- Quality Control

BENEFITS OF THE AES OPTIPREP 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.

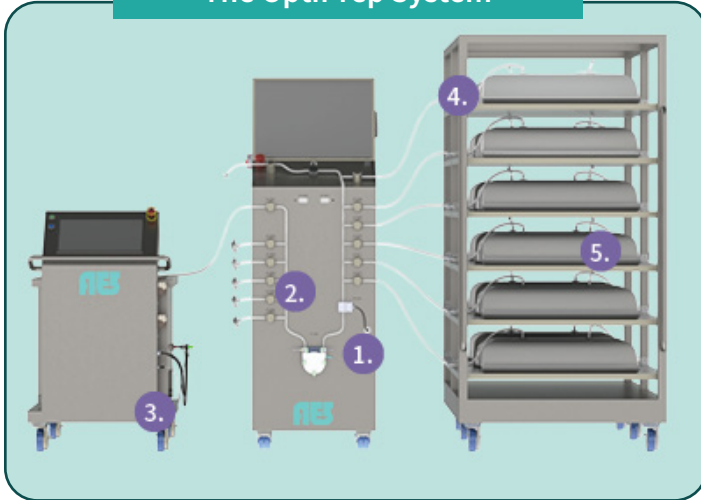
DESIGNED FOR A REGULATED ENVIRONMENT:

This OptiPrep 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 OptiPrep System is a comprehensive solution designed to deliver precision, flexibility, and optimal performance for media and buffer preparation. It includes essential components such as the Liquid Handling Unit, Single-Use Mixer, and Prep Rack, all supported by high-quality consumables. This system ensures seamless operation, reliability, and user-friendliness, making it an indispensable tool for biopharmaceutical manufacturing, clinical research, and quality control processes.

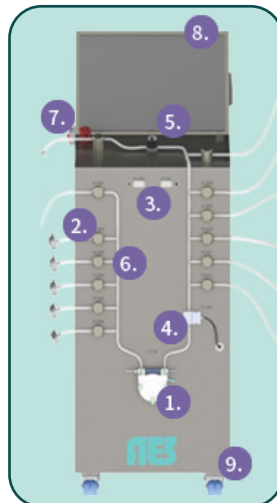
The OptiPrep System



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 (LHU) is engineered for unparalleled precision and control in bioprocessing applications. Featuring advanced pump technology, a flow and liquid sensor, and thirteen (13) automatic pinch valves, the LHU ensures precise and reliable liquid flow management. These components work together to deliver accurate volume control and consistent dispensing, achieving 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.

PREP RACK:

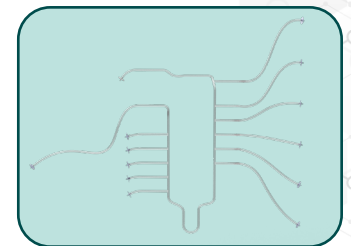
The Prep Rack is engineered to securely support and organize containers during media and buffer preparation. Designed for seamless integration with bags and adaptable to bottles, the Prep Rack ensures stability and accessibility, meeting the diverse needs of bioprocessing applications.

CONSUMABLES:

The OptiPrep's consumables are meticulously chosen to ensure seamless integration and maintain strict sterility throughout the media and buffer preparation process. With versatile container options, precision-engineered tubing, and SUM Bags, each component adheres to rigorous bioprocessing standards, providing the flexibility needed for a wide range of preparation applications.

OptiPrep Tubing Set:

The OptiPrep Tubing Set connects the SUM, LHU, and prep containers on the Prep 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 OptiPrep 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 OptiPrep 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.

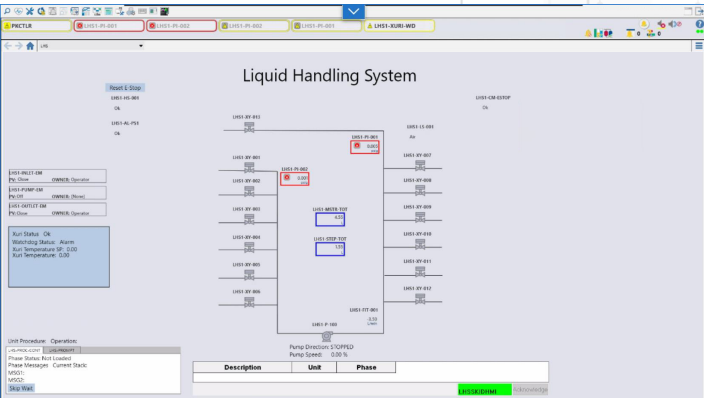
Key Capabilities:

- **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 OptiPrep 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 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.

OPTIPREP 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		
Prep Containers	AES OptiPrep Bags or Bottles	
Prep Filling Volume Range	100 mL - 500 mL	500 mL - 50 L
Target Prep 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	
PREP 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