Automated Engineering Services, Inc.

TECHNICAL BROCHURE

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:

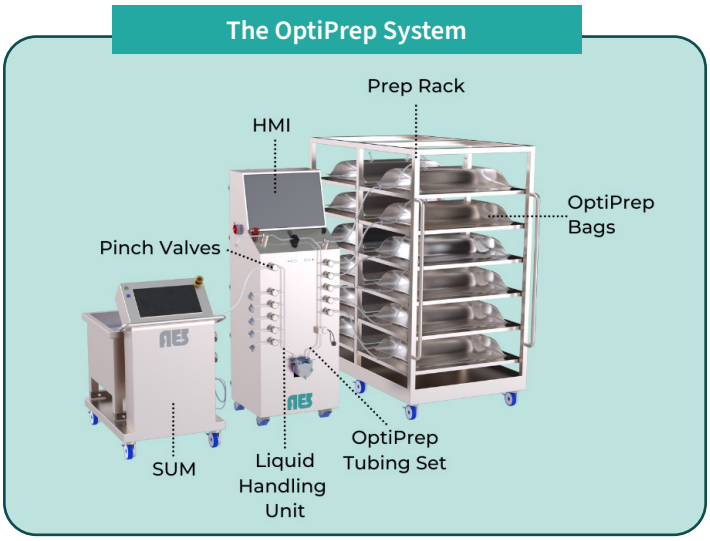
- The system provides high-accuracy filling, with flow rate precision of ±6 mL/min at low flow rates and ±20 mL/min at higher flow rates
- Use of pinch valves eliminate the need for additional pumps, streamlining the system and reducing equipment and costs.
- It is versatile and compatible with various storage containers, including bottles and bags.
- The user-friendly system features an integrated label printer for easy container identification and management, ensuring a smooth and intuitive operation.

DESIGNED FOR A REGULATED ENVIRONMENT:

This OptiPrep System can meet the rigorous demands and standards required in a regulated environment. It is designed with GMP and 21 CFR Part 11 compliance in mind, ensuring that your bioprocessing operations can meet the highest regulatory standards.

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.



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.

SINGLE-USE MIXER (SUM):

The OptiPrep System's Single-Use Mixer (SUM) is engineered for contamination-free, reliable mixing, ensuring consistency in media and buffer preparation across bioprocessing applications. Utilizing magnetic levitation, the SUM delivers uniform agitation, preserving product integrity throughout the process. Its adaptable volume capabilities accommodate both small and large-scale production needs. Constructed from high-grade stainless steel, the SUM is durable, easy to maintain, and designed for mobility within clean rooms. Real-time monitoring of temperature, conductivity, and weight provides precise control over the preparation process, promoting batch uniformity and quality.

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:

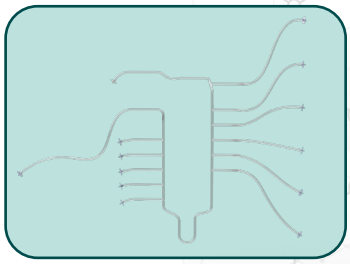
The OptiPrep System's consumables are meticulously chosen to ensure seamless integration and maintain strict sterility throughout the media and buffer preparation process. With versatile container options, precision-engineered tubing, and SUM Bags, each component adheres to rigorous bioprocessing standards,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

SUM Bags:

Specifically designed for the Single-Use Mixer, SUM Bags provide sterile, flexible containment suitable for various mixing volumes, ensuring product integrity during media and buffer preparation in sensitive 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.



OptiPrep Container Selection:

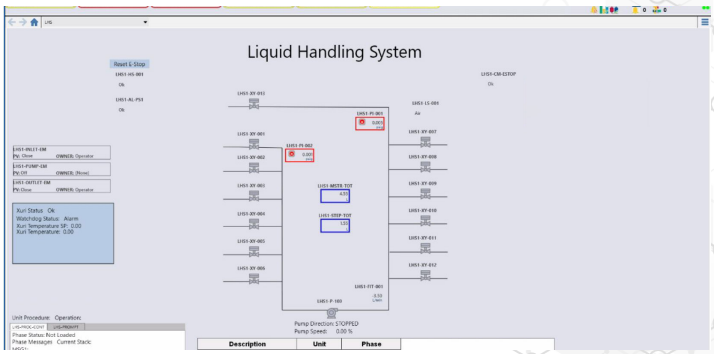
The OptiPrep System offers versatile container options, including OptiPrep Bags and Bottles, to cater to diverse liquid volumes. Specifications such as compatibility with storage conditions as low as -80°C can be provided upon request to meet specific bioprocessing requirements.

DATA AND COMMUNICATION:

The OptiPrep System delivers precise media and buffer preparation with advanced data management features. It includes remote monitoring, data logging, alarm notifications, and integrated label printing to enhance batch tracking and process reliability. With strong connectivity and real-time data transfer capabilities, the system ensures seamless integration and efficient workflow.

Human Machine Interface (HMI):

The OptiPrep System's user-friendly touchscreen HMI provides customizable access to operational data, enabling real-time monitoring and historical data analysis. This interface optimizes data management and labeling processes, supporting error reduction and streamlined workflows for efficient media and buffer preparation.



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) clean room casters	
Power Requirements	115 VAC, 50/60 Hz, 2300 Watts	
Certification	UL508A	
Liquid Control		
Prep Containers	AES OptiPrep 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: ±6mL/min	0 - 1,000mL/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	
E-Stop	Yes	
Label Printer	Yes	
HMI		
Touchscreen	Yes	
Display Size	19 in | 48.26 cm	
Certifications	UL & CE	

Single-Use Mixer Specifications									
Volume	50 L	100 L	200 L	500 L	1,000 L	1,500 L	2,000 L	2,500 L	3,000 L
Equipment Width (mm)	400	500	635	835	1,040	1,275	2,085	2,160	2,100
Equipment Length (mm)	400	500	635	835	1,040	1,275	1,120	1,220	1,200
Equipment Height (mm)	370	450	635	835	960	1,005	1,000	1,020	1,300
Geometry	The bottom outlet is designed with the lowest angle to facilitate drainage								
Enclosure Material	SS304								

Mobility	(4) Clean Room Casters & Push Handles
E-Stop	Yes
Power Requirements	120 - 230 VAC, 50/60 Hz, 1200 Watts
Agitation	
Agitation Direction Control	Magnetic Levitation
Motor Speed (Maximum Speed)	600 RPM
Liquid Control	
Onboard Pumps	(2) Pumps with Bi-Directional Stepper Motors
Pump Head Type	Peristaltic, Flip-Top Pump Heads
Pump Speed Range	0.2 - 200 RPM
Tubing Compatibility	L/S -13, -14, -16, -25, -17, -18
Process Analytics	
Temperature	(1) RTD Sensor
Temperature Range	20 to 60°C ± 0.15°C
pH	(1) pH Probe
pH Range	3 -10
Conductivity	(1) Conductivity Probe
Conductivity Range	0 - 100 mS/cm
Weight Measurement	(4) Integrated Load Cells
HMI	
Touchscreen	Yes
Certifications	UL & CE
Prep Rack Specifications	
Number of Stacks	Up to 6 per Rack
Enclosure Material	SS304
Mobility	(4) Clean Room Casters & Push Handles

*Optional Instumentation if configured

OPTIPREP 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 feet	
Sterilization Method	Gamma Irradiation	

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

SUM BAG SPECIFICATIONS

Product Specification	
Bag Volume	100 - 2,000L; customized options available
Operating Temperature	-45°C ~ 45°C
Sterilization Method	Gamma Irradiation (25-40 kGy)
Packaging Form	Double Layer PE Bag vacuum packaging
Membrane Material Information	
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