



OPTIFILL SYSTEM

ASEPTIC FILLING

PRODUCT SUMMARY

The AES OptiFill System, a pinnacle of precision and reliability, is meticulously designed to meet the demanding needs of biopharmaceutical liquid handling. With its unparalleled accuracy in dispensing and controlling liquids, this advanced system instills confidence in the performance of your bioprocessing workflows, ensuring efficiency.

APPLICATIONS:

Unlock the potential of bioprocessing across a diverse range of applications with the OptiFill System. Tailored to meet the biopharmaceutical industry's ever-evolving needs, our filling system offers versatile solutions, ensuring it can adapt to your application needs.

- Biopharmaceutical Manufacturing
- Quality Control
- Clinical Research

BENEFITS OF THE AES OPTIFILL SYSTEM:

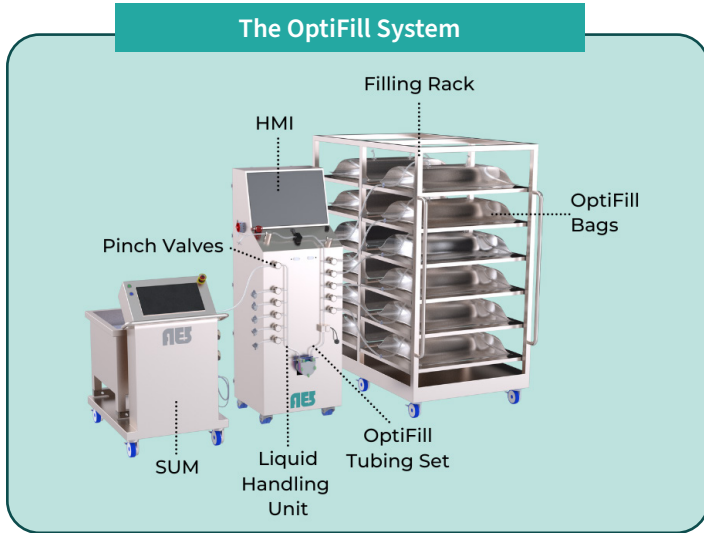
- The system provides high-accuracy filling, with flow rate precision of ± 6 mL/min at low flow rates and ± 20 mL/min at higher flow rates
- Use of pinch valves eliminate the need for additional pumps, streamlining the system and reducing equipment and costs.
- It is versatile and compatible with various 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 OptiFill 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 OptiFill System is a comprehensive solution that delivers precision, flexibility, and optimal performance across various bioprocessing applications. It comprises key components such as the Liquid Handling Unit, Single-Use Mixer, and Filling Rack with high-quality consumables. This system ensures seamless operation, reliability, and ease of use, making it an indispensable tool for biopharmaceutical manufacturing, clinical research, and quality control.



LIQUID HANDLING UNIT:

The Liquid Handling Unit (LHU) is engineered for unparalleled precision and control in bioprocessing applications. Featuring advanced pump technology, a flow 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:

The OptiFill System's Single-Use Mixer (SUM) is designed for contamination-free, consistent mixing, ensuring precise filling across bioprocessing applications. Using magnetic levitation, the SUM provides uniform agitation to maintain product integrity. With flexible volume options, it supports both small and large-scale requirements, making it versatile for various production needs. Built from high-grade stainless steel, the SUM is durable, easy to clean, and mobile for seamless use in clean rooms. Real-time monitoring of temperature, conductivity, and weight enables precise control over the filling process, enhancing batch consistency and quality.

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 System'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.

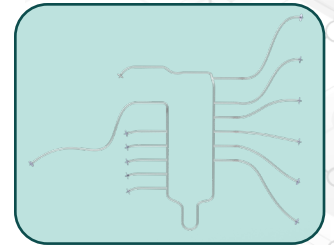
SUM Bags:

Designed specifically for the Single-Use Mixer, SUM Bags provide sterile, flexible containment for a range of mixing volumes, maintaining product integrity in sensitive 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:

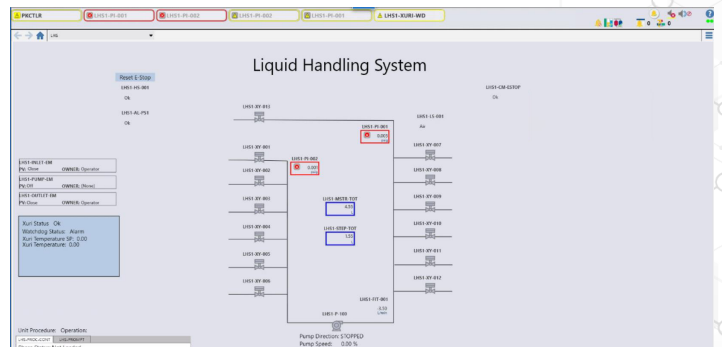
The OptiFill System offers flexible container options, including OptiFill Bags and Bottles, to accommodate diverse liquid volumes. Specifications, such as compatibility with storage conditions as low as -80°C , are available upon request to meet specific bioprocessing needs.

DATA AND COMMUNICATION:

The OptiFill System ensures precise aseptic filling operations 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 provides seamless integration and efficient workflow.

Human Machine Interface (HMI):

The OptiFill System's user-friendly touchscreen HMI offers customizable access to operational data, enabling real-time monitoring and historical data analysis. This interface optimizes data management and labeling processes, reducing errors and streamlining workflows for efficient aseptic filling operations.



The featured overview screen exhibits sample number 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) clean room casters
Power Requirements	115 VAC, 50/60 Hz, 2300 Watts
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: ±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
Filling Rack Specifications	
Number of Stacks	Up to 6 per Rack
Enclosure Material	SS304
Mobility	(4) Clean Room Casters & Push Handles

*Optional Instrumentation if configured

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 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. 3.15 ADCF
Packaging Form	Double Layer PE Bag vacuum packaging