

# GENiSYS<sup>®</sup> R

Robotic Multi-Format  
Filling and Closing System



- Automated processing of ready-to-fill vials, syringes and cartridges
- Minimal change parts for quick change-over between batches
- Fully automatic in-process fill weight verification (IPC)
- Electronic Batch Reporting (EBR) & data collection

**AST**<sup>®</sup>

*Trusted partner for aseptic processing solutions*

# Sterile. Made Simple.



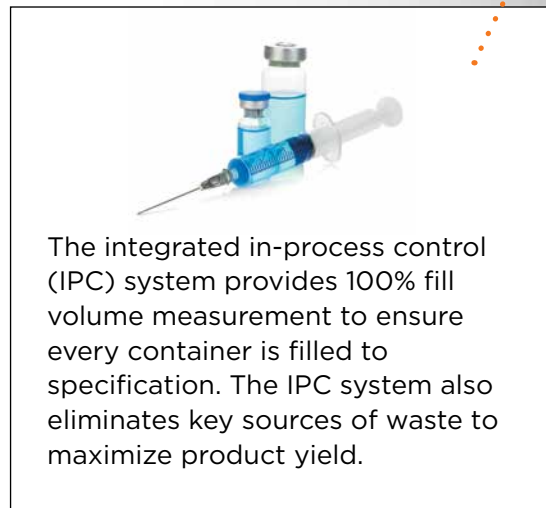
GENiSYS R's simple, aseptic design and materials of construction makes cleaning and bio-decontamination quick and easy.



System is provided with the latest isolator-barrier system and bio-decontamination technologies to ensure an optimal aseptic environment for sterile product processing.



ASTView provides intelligent and intuitive operation of the system. Animated walk-throughs of important setup, operation and end-of-batch functions are shown at the interface to support operator decision making and activities.



The integrated in-process control (IPC) system provides 100% fill volume measurement to ensure every container is filled to specification. The IPC system also eliminates key sources of waste to maximize product yield.



Critical batch and environmental information is recorded automatically to create a 21 CFR Part 11 compliant batch report. The histograms, data and event logs for the batch are generated in an easy to follow report.



Using robotic and servo technologies, system set-up automatically adjusts to recipe parameters without manual adjustments. With simple bolt-on change-parts the system can process multiple container options.



Built-in flexible robots can process pre-sterilized nested vials, syringes and cartridges with simple tooling and change-parts. No need for trollies or expensive add-on equipment to expand system capabilities.



GENiSYS R modular design allows easy configuration to meet unique customer requirements. Standard modules include semi-automatic bag opening, manual or automated tub opening, lyophilization and vial sealing.

# Specifications

**GENiSYS® R** is the latest robotic aseptic filling and closing system innovation engineered to meet the challenges of processing small batch sterile injectables, and is ideal for cell, gene and regenerative medicines. **GENiSYS R** adaptive architecture allows the same machine to process ready-to-use vials, syringes and cartridges with 100% in-process fill volume measurement to ensure no amount of valuable product or time is wasted. Leveraging the standard process module options, the **GENiSYS R** can be easily configured to include isolator-barrier systems, lyophilizer integration, and other capabilities to efficiently deliver a tailored system that meets your unique requirements quickly and efficiently.



GENiSYS R	
Approx. Standard System Dimensions (LxWxH): (SABO-MTO-FCM-VSM)	4225mm x 1400mm x 2405mm [166" x 55" x 95"]
Containers:	Pre-sterilized vials, syringes and cartridges
Vial Sizes:	2mL to 30mL (ISO 2R – 30R)
Syringe Sizes:	0.5mL to 20mL
Cartridge Sizes:	3mL, 5mL & 20mL
Production Rate:	Up to 20upm
Dispense Options:	Peristaltic & Rotary Piston
Filling Volume:	0.1mL to 250mL
Filling Accuracy:	Up to ±0.5%
Syringe / Cartridge Closing Method:	Vacuum & Vent-Tube
Barrier System:	Restricted Access Barrier System (RABS) or Isolator
Electrical Utilities:	230/480VAC - 50/60Hz.
Clean Air Utilities:	Clean dry air 7 bar, 0.5L/min free air
Materials of Construction:	Pharmaceutical grade stainless steel, plastics and elastomers
Human-Machine Interface (HMI)	ASTView on a 21" color touchscreen
Module Options:	Semi-Automatic Bag Opening (SABO) Manual Tub Opening (MTO) Lyophilization Prep / De-Nesting Module (LPM) Vial Sealing Module (VSM)
System Certifications:	NFPA-75 Compliant CE
Available Options:	In-process fill weight verification (IPC) and automated pump calibration Viable and non-viable environmental monitoring (EM) Electronic Batch Report (EBR) system Pre & post-fill container purging with inert gas

\* Figures are typical. Actual performance results and technical parameters may vary depending upon application requirements.

\*\* Subject to change without notice.

Please Contact:

