

MAST® Autosampling Solution

A Versatile & Modality-Agnostic Aseptic Autosampling Solution for Reliable On-Line and Near Real-Time Sample Analysis

Current off-line sampling methods often present challenges related to sample source contamination, inadequate sample traceability and delivery, lengthy experimental turnaround times, and inconsistent results. Additionally, despite significant amounts of resource consumption (scheduled time, financial expenditures, staff utilization), the output and frequency of process-representative data points are oftentimes insufficient. To effectively overcome these challenges, automated aseptic sampling systems were designed to automatically collect on-line samples without manual intervention in near real-time. These samples are then efficiently transferred to analytical destinations for further processing or analysis. With this technology, you can accelerate your access to integral process and quality data points for your specific application.

As an essential Process Analytical Technology (PAT) tool, the MAST® Autosampling Solution enables you to perform near real-time, on-line measurements of critical process parameters (CPPs) and critical quality attributes (CQAs) at any process scale. This solution offers exceptional robustness, mitigates contamination, reliably transfers samples, provides intensified process results, and offers a modular design for flexibility to meet your sampling needs.





Benefits

Process Automation:

This sampling technique is fully automated and minimizes the need for off-line sampling, effectively reducing several operator touchpoints and promoting the collection of more consistent, process-representative data points.

Streamlined Analytics:

The automated and streamlined integration of the MAST® Autosampling Solution to sample preparation or analytical devices reduces the time and resources required for processing and analyzing collected samples.

Reduced Contamination Risk:

The MAST® Autosampling Solution ensures sample source sterility and consistent sample delivery to analytical destinations. The unique closed system design and high-pressure cleaning, sanitization, and drying process after sample collection provides robust sterility protection and minimizes contamination risks.

Intensified Results:

On-line, near real-time analytics improve process development turnaround times and reduce the number of experiments required to make key decisions. CPPs and CQAs are recorded more frequently, contributing to a more comprehensive understanding of the process.

Process Flexibility:

This PAT solution is modular in design, ensuring that your sampling methods evolve with your needs and without regulatory limitation. With the inherent ability to take concurrent samples from multiple vessels, the MAST® Autosampling Solution is configurable and able to expand to fit your specific processing needs.

Expert Support:

We offer a range of comprehensive product and technical services to ensure the successful implementation and utilization of this technology at any scale. Our team of experts is well-equipped to support you in achieving your sampling and PAT goals.

MAST® Autosampling Solution Components

The MAST® Autosampling Solution is available in several configurations suitable for various applications or usage methods. Its modular design allows integration with your current system and the ability to expand as your needs evolve.

Comprised of the following integral components, the MAST® Autosampling Solution is designed to fit your processing needs with ease:



Master Controller: Integrates the sample pilots with a series of valves and pumps that enable the system to collect from one source and correctly direct samples to a single analytical destination.

Analytical Navigator Controller:

Directs a sample to a primary analytical destination in conjunction with a Master Controller. The Analytical Navigator Controller can connect to up to four primary analytical devices, including the Gilson® GX-271 and the Nova BioProfile® FLEX2.



Sample Pilot (SP100, SP200): Primary component of the MAST® Autosampling Solution, specifically designed to ensure sample source sterility while reliably collecting samples for delivery to their intended destinations. The SP100 Sample Pilot is designed for connecting to stainless steel bioreactors, capable of drawing sample sizes of either 10 or 55 mL while the SP200 Sample Pilot is tailored for development scale and single-use bioreactors, allowing for sample sizes of 1 and 5 mL. These versatile configurations offer multiple connection capabilities (sterile weld, sampling dip tube, Kleenpak and Ingold) facilitating seamless integration of the MAST® Autosampling Solution into any facility.

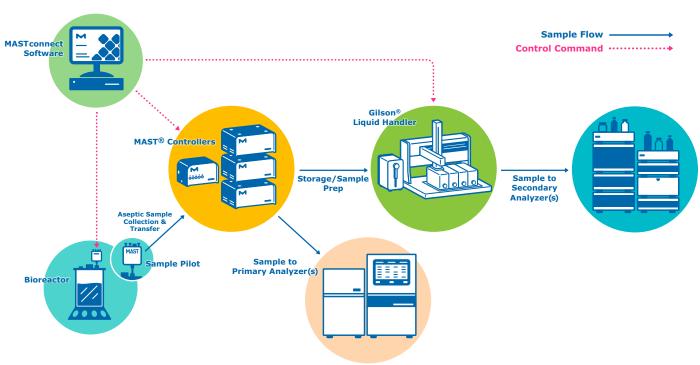


MASTconnect Software:

Allows the end user to control the operation of the MAST® Autosampling Solution. The modular interface provides effective integration of the software to meet any specific process application needs.

As a complete system, the MAST® Autosampling Solution can accommodate:

- Up to ten sample sources
- Up to four primary analytical destinations (including the Gilson® GX-271 and Nova BioProfile® FLEX2)
- Multiple secondary analytical destinations



Features

Sterility Assurance:

The Sample Pilot maintains sample source sterility through a combination of autoclaving, sterilization, sanitization, and filtration, coupled with robust system interlocks ensuring the integrity of the sample source in every collection cycle.

Consistent Delivery:

In contrast to other autosamplers, the MAST® Autosampling Solution pushes samples directly to their destinations. With the ability to push thick microbial samples up to 80 feet in distance, this solution ensures rapid and consistent sample transport to analytical destinations.

Frequent Sanitization:

Pre- and post-sample recovery sanitation, coupled with a holistic system cleaning, helps to mitigate the risk of contamination, reduce clogging occurrences, and minimize inconsistent process results.

Ease of Integration:

The MAST® Autosampling Solution interfaces with existing supervisory data management and control systems, including DeltaV $^{\text{TM}}$ and PI $^{\text{TM}}$. This compatibility, in addition to the availability of ancillary software solutions, helps to provide seamless integration and implementation.

Process Scalability:

The Sample Pilot units are designed to be used with any single-use or stainless-steel sample source of interest, whether it be at development or production scale. The SP100 connects through an Ingold fitting and the SP200 can be integrated into your process via dip tube, sterile tube welds, or Kleenpak integrations.

MASTconnect Software Suite

The MAST® Autosampling Solution is equipped with unique software capabilities and addresses a range of sampling needs through the MASTconnect software suite.

The MASTconnect software incorporates configurable modules that cater to varying system complexities required by the end user. This allows users to leverage aspects of the software relevant to their specific process application. The MASTconnect software modules include:

Master Controller Software:

Empowers scientists, engineers, and system operators to:

- Configure the MAST® Autosampling Solution to meet specific laboratory or manufacturing requirements.
- Operate, set up, and shut down the MAST[®] Autosampling Solution during a process run.
- Schedule sample collections and deliveries to multiple analytical devices.
- Create and load frequently used sampling protocols.
- Collect and review historical operational and sample data.

Sample Navigator Software:

Provides scientists and engineers operating the MAST® Autosampling Solution to configure up to ten fully independent sample locations when sampling from multiple sources. Additionally, unique sample sequence logic can be assigned for individual Sample Pilot units.

Analytical Navigator Software:

Enables MAST® Autosampling Solution operators to communicate with multiple analytical instruments by directing samples to one of four primary destinations and providing the ability to link multiple analytical devices in series, effectively eliminating the need for manual analytics.

Gilson Integration Software:

The MAST® Autosampling Solution offers multiple communication-based software solutions to interface effectively with a range of devices and control systems. One such solution is the MASTconnect Gilson Integration Software.

The **MASTconnect Gilson Integration Software** allows the end user to seamlessly integrate their MAST® Autosampling Solution with the Gilson® Liquid Handler:

- Configures to accommodate a wide array of vial sizes to meet end-users' diverse needs.
- Sends samples to the Gilson® Liquid Handler to be placed in up to four different/similar rack configurations.
- Delivers samples to the Gilson® Liquid Handler for chilled retain operations as well as further sample processing, such as Protein A purification, dilutions, aliquots, digestions, and solid-phase extractions.

Integrations

Successfully implementing PAT in your bioprocess requires prompt and efficient analysis of automatically collected samples. The versatile and method agnostic MAST® Autosampling Solution is designed to operate with various analytical technologies and devices.

Previously established analytical and liquid handling integrations include:

- Gilson® Liquid Handler
- Nova BioProfile® FLEX2
- Roche Cedex Bio HT
- Roche HiRes
- Waters[™] ACQUITY Systems via Empower[™]
- ThermoFisher LC Integration via Chromeleon™
- Agilent LC Integration via ChemStation
- MAST® Cell Removal System (CRS)

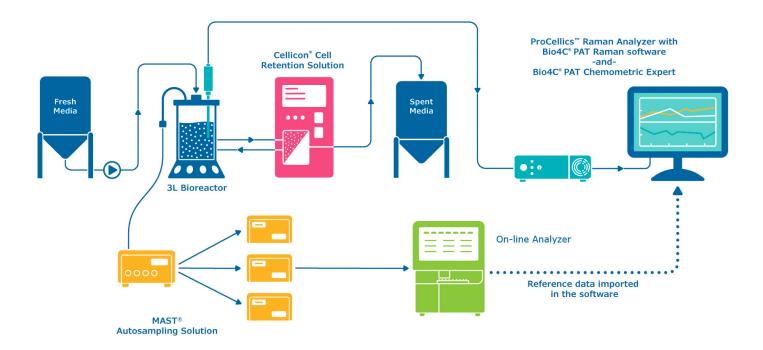
Please contact a representative for more insights into the MAST® Autosampling Solution's current integration capabilities by visiting our PAT web page:

PAT: Build Quality into Biopharmaceutical Processes with Real-Time Monitoring and Control (SigmaAldrich.com)

Part of the BioContinuum™ Platform – Accelerating Automation of Bioprocesses

As an essential PAT tool and part of the BioContinuum™ Platform, the MAST® Autosampling Solution supports industrial advancement towards a digitally enabled BioPharma 4.0. On-line measurements in near real-time provide faster access to critical process parameters (CPPs) and critical quality attributes (CQAs) through streamlined analytical integrations. This feature enables the prompt detection of system variabilities, facilitating quick corrective action.

In addition to being utilized as a standalone platform, the MAST® Autosampling Solution has integrative potential with other PAT offerings such as the ProCellics™ Raman Analyzer and various HPLC systems. The concurrent use of these components enhances the end user's ability to measure critical process parameters, reducing variations and enabling that quality control measures are embedded earlier in the process.



Services and Support

To facilitate seamless integration of the MAST® Autosampling Solution into your process, we offer comprehensive services delivered by our team of global experts. Our team provides services that help you save time, lower costs, and comply with relevant regulations.

Applications Assessment Services

Our presales services program allows you to experience the benefits of the MAST® Autosampling Solution prior to purchase.

M Lab™ Collaboration Center Visit with MAST® Autosampling Solution Demo

- Experience the MAST[®] Autosampling Solution in action through an on-site M Lab[™] Collaboration Center demonstration featuring a wide range of equipment.
- Supplement your experience with a comprehensive presentation on the solution's potential applications.
- Explore possible configurations of the solution through virtual consultations.

On-Site Evaluation of the MAST® Autosampling Solution

- Evaluate the integration of a base unit of the MAST® Autosampling Solution into your facility's process using your own samples to collect process-specific data points.
- Schedule the collection and delivery of a sample to a single destination. Destinations include the Gilson[®] Liquid Handler (provided) and the BioProfile[®] FLEX2 connection ready set-up (BioProfile[®] FLEX2 not provided).
- Run the MAST® Autosampling Solution for 1.5 months, which includes installation and basic system training.

Qualification Services

Our qualification services ensure the seamless integration of the MAST® Autosampling Solution into your process, adhering to your predetermined requirements, and verifying its proper installation and operation.

Pre-Installation Project Management Meetings

- Following receipt of the purchase order for the MAST® Autosampling Solution, a project manager will schedule regular pre-installation meetings.
- Meetings will include checklist reviews to ensure that the site is prepared for installation.
- During the meetings, questions and concerns will be openly discussed, possible changes to the timeline will be communicated.
- Any changes to the scope of the installation may result in amendments to the project scope and cost.

Installation Qualification and Operational Qualification (IQ/OQ) – Optional Service

- Completion of as-built system documentation
- Visual inspection
- Instrumentation verification
- · Performance verification
- Safety verification
- · Functional tests
- Full qualification report
- Installation of the MAST® Autosampling Solution
- Connection to primary and secondary analyzers specified in the Purchase Order
- Software settings and user management
- Guidance on verifying instrument operation, including troubleshooting, cleaning, and maintenance

Training Services

Comprehensive training ensures users have the expertise to properly implement the MAST® Autosampling Solution as part of their process.

Basic training exercises (as well as the assembly, installation, and testing) of the MAST® Autosampling Solution are included in our installation service packages. These training services cover:

- An overview of the components and functions of the MAST® Autosampling Solution.
- Safety information and recommendations.
- Utilization of the software interface to perform tasks such as data acquisition, management, and exportation.

Service Reliance Plans

To help you ensure optimum equipment uptime while mitigating risks, we have developed a wide range of services and support that allow you to select a coverage level that best fits your needs. Our System Service Reliance Plans, a complete range of services for your systems, offer priority access to support while ensuring your equipment is properly maintained.

For additional details, please refer to the System Service Reliance Plans Data Sheet (MK DS7881EN).

Available at SigmaAldrich.com/services-plans

				Risk Level
		Protection Level		
Services	Details	Total Reliance Plan	Advanced Reliance Plan	Essential Reliance Plan
System Eligibility		<10 years	<15 years	All ages
Preventive Maintenance (PM) visit	1 PM visit (labor & travel included) ^(a)	~	v	V
Preventive Maintenance (PM) spare parts kit	Yearly preventive maintance spare parts kit	×	×	×
Traceable and auditable documentation	Full service report	~	v	v
Spare parts storage assessment	Spare part advisory service (first year only)	v	V	V
Asset tagging solution	QR code sticker and cards			
Remote troubleshooting	Priority remote support on system and software ^(b) – phone and email	24 h ^(e)	24 h ^(e)	V
	Priority remote support on system and software ^(b) – remote connection ^(c)			×
On-site troubleshooting	On-site support – response time	Within 48 h ^(f)	Within 5 days ^(f)	No engagement on response time
	Troubleshooting/repair visit (labor and travel included)	Unlimited	1 per year (no carry over)	Billable services
Spare parts	Spare parts for repair ^(d)	Included	15% discount ^(g)	10% discount(g)
Software update	Minor software update execution(h)	✓	V	✓



= Remote connection



= Asset Tagging

- (a) Maintenance kit to be purchased separately prior to service.
- (b) Support provided via phone and email and limited to 10 cases per year and 30 h of investigation. Software update not included in System Service Reliance Plans.
- (c) Only for suitable systems and if the connection is tested upfront with customer.
- (d) Best effort is aimed at supplying spare parts and/or find equivalent over the system's lifetime, but no guarantee of availability over time.
- (e) 24 h from the customer's requests, to our service team returning the call. May vary depending on customer's location.
- (f) Five business days for Advanced, or 48 business hours for Total, from the time when it is agreed that a troubleshooting visit is necessary.
- (g) Discount on list price.
- (h) For Software developed by Merck only. Included if performed during the yearly PM visit. Post update qualification not included.

System Specifications

MAST® Autosampling Solution			
General Specifications			
Maximum Number of Sample Sources	10		
Maximum Number of Analytical Device Connections	4		
SP100 Sample Pilot Volume Options	10 mL, 55 mL		
SP200 Sample Pilot Volume Options	1 mL, 5 mL		
Operating Temperature Range	Ambient		
Delivery Options	Sample Volume Optimized Through Five Delivery Type Options: Full Line, Low Pressure Flow (LPF), Low Pressure Pulse (LPP), Low Pressure Flow & Pulse, CRS, Tick Tock		
Sample Wetted Materials	PEEK, FEP, PFA, PTFE, 316 Stainless Steel, EPDM, Polypropylene, Platinum-Cured Silicone, TPE, Polycarbonate, Copolyester		
SP100 Connection Types	Ingold Fitting		
SP200 Connection Types	Sterile Tube Weld, Sterile Connector (Kleenpak, CPC, etc.), Dip Tube		
Delivery Distance	Up to 80 ft (Application Dependent)		
Controller Specifications			
Dimensions (Width \times Height \times Depth)	15 inch (38.1 cm) \times 7 inch (17.8 cm) \times 13 inch (33 cm) (includes needed clearance)		
Weight	9.6 kg (21.2 lbs) to 12.1 kg (26.6 lbs)		
Enclosure Rating	IP20		
Compressed Air Supply	70-100 PSI, ISO 8573.1 Class 2		
Optional Purge Gas (e.g. Nitrogen)	30–100 PSI, Minimum N2.0		
Electrical Requirements	100 to 250 VAC, 0.75 to 1.5 A, 50 to 60 Hz		
Sample Navigator Assembly Specifications			
Dimensions (Width \times Height \times Depth)	8.3 inch (21.1 cm) × 4.3 inch (10.1 cm) × 4.3 inch (10.1 cm)		
Weight	1.5 kg (3.3 lbs)		
Sample Input Quantity	5		
Sample Pilot 100 Specifications			
Dimensions (Width \times Height \times Depth)	4.25 inch (10.8 cm) × 3 inch (7.6 cm) × 3.5 inch (8.9 cm)		
Weight	0.9 kg (1.9 lbs)		
Sample Pilot 200 Specifications			
Dimensions (Width \times Height \times Depth)	2.17 inch (5.5 cm) × 3.2 inch (8.1 cm) × 1.8 inch (4.6 cm)		
Weight	0.25 kg (0.57 lbs)		
Cleaning and Sanitization System Specifications			
Dimensions (Width \times Height \times Depth)	21.5 inch (54.6 cm) × 8.22 inch (20.9 cm) × 15.1 inch (38.4 cm)		
Weight (Empty)	4.5 kg (10 lbs)		
Sanitant Fluid	70% Isopropyl Alcohol		
Cleaner Fluid	0.1–1N NaOH		

Related Products

ProCellics™ Raman Analyzer

Specifically designed for the bioprocessing industry, ProCellics™ Raman Analyzer enables you to perform in-line and real-time measurement of CPPs and CQAs, from process development to manufacturing. Our Raman PAT Platform helps improve processes, save

time and provide flexibility to operators, reduce the risk of contamination and batch failures, and the ability to implement a nutrient control loop strategy, a first step towards process automation.



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For additional information, please visit www.SigmaAldrich.com/PAT To place an order or receive technical assistance, please visit www.SigmaAldrich.com/offices

