

# The MAST<sup>®</sup> Automated Aseptic Sampling System

## FAQs

### Hardware and software

#### What are the components of the MAST<sup>®</sup> System?

**Sample Pilots** are comprised of a patented valve and pumping system used to aseptically collect samples from sterile sources. These valves assure sterility of the sample source, and the pump ensures reliable sample volumes are delivered. The risk of clogging is significantly reduced due to our innovative sanitization, cleaning and sample movement technologies.

- The **SP100** is used in fixed applications where bioreactors are sterilized in place, and is available in 10 mL and 55 mL dispense models.
- The **SP200** is used in development scale and single-use bioreactor applications, and is available in 1 mL and 5 mL dispense models.

**MAST<sup>®</sup> System Controllers** automatically control sample aspiration and sample delivery for accurate, reliable results from any sample source to multiple analytical destinations.

- The **Master Controller** operates the MAST<sup>®</sup> System. It is required for every installation. This is the only controller needed to send samples from one source to one analytical destination.
- The **Sample Navigator Controller** connects to the Master Controller to increase the capability to sample from up to five sources. Add another Sample Navigator Controller and sample from up to 10 sources.
- The **Analytical Navigator Controller** delivers samples to up to four primary destinations. The Analytical Navigator's specially designed valve assemblies effectively route samples from their sources to their target destinations.

The **MASTconnect Software** was developed specifically for the MAST<sup>®</sup> System and is configured based on the MAST<sup>®</sup> System components, sample sources and destinations required for your sampling plan.

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## What software is provided with the MAST<sup>®</sup> System?

All systems are provided with the **MASTconnect Software System**. This user-friendly software allows users to schedule samples, monitor sampling progress, view sampling history and much more. For additional capability, there are several other software modules that can be added:

- If the Gilson<sup>®</sup> Liquid Handler is part of the system, this comes with its own Trilution™ software that controls the Gilson<sup>®</sup> functions. There is also a MAST<sup>®</sup> System / Gilson<sup>®</sup> interface software module.
- The MASTconnect Meta-Data Software allows external systems like OSI PI to collect sample specific data from our MAST<sup>®</sup> System database
- The MASTconnect Remote Control OPC UA Software allows external systems like Delta V to check the status of the MAST<sup>®</sup> System and direct the MAST<sup>®</sup> System to take samples.
- Other software modules are available for interfacing with analytical devices such as the Nova BioProfile<sup>®</sup> FLEX™ and FLEX2™, Roche Cedex BioHT and HiRes and HPLC devices from multiple manufacturers such as Thermo Fisher Scientific, Agilent and Waters.

## Sampling functionality

### How is the Sample Pilot connected to the bioreactor?

The Sample Pilots are normally connected via a dip tube that remains in-situ on the bioreactor. The dip tube is connected to the input port on the Sample Pilot. This provides a much higher level of sterility assurance than some other systems that actually project into the reactor to draw samples.

#### Dip tube considerations

The dip tube is often specific to the type of bioreactor and there are also considerations regarding clearance and space around the reactor. This means that normally we ask clients to send us their dip tubes and these are custom adapted for the installation.

### Is it possible to sample from bags, bottles etc.?

Yes and the options here vary greatly. Please contact the MAST<sup>®</sup> System team to talk through your specific application.

## What size of sample is drawn by the Sample Pilot?

There are two versions of the Sample Pilot currently available, which are designed to work with a variety of sizes of bioreactor.

#### SP100

This is the first Sample Pilot that was developed and is used specifically for fixed bioreactors that are sterilized in place. It comes in two models that draw and dispense in either 10 mL or 55 mL volume increments.

#### SP200

This version of the Sample Pilot is designed to work with smaller bioreactors and single use bioreactors. This also comes in two models that draw and dispense in either 1 mL or 5 mL volume increments.

## What level of cell density can the MAST<sup>®</sup> System handle?

As the MAST<sup>®</sup> System pushes the samples instead of pulling them we have successfully drawn and delivered extremely viscous fermentation samples and cell broths with over 150 Million cells/mL over 100 feet to the destination. We do not see a practical upper limit for viable cell density (VCD) for most applications.

## How long is the sample transit time?

Whilst this is a common question, it's quite difficult to answer simply in these FAQs because there are a lot of variables including the volume of sample collected, the distance the sample has to travel and the method we use to move the sample. For a typical cell culture application running a sample to a nearby Nova BioProfile<sup>®</sup> FLEX2™, the sample transit time is approximately 4 minutes. The important thing to realize is that timing will be very consistent, plus or minus a few seconds. Manual sample timings can have variations as long as a minute which has significant impact on some analytical results, such as dissolved gas concentration.

## How does the MAST<sup>®</sup> System deal with an analyzer that is inactive?

The MAST<sup>®</sup> System always makes sure the analyzer is ready to receive the sample before drawing it. The MAST<sup>®</sup> System constantly monitors the activity state of the analyzers and will place a sample request into a queue if that analyzer is busy with another task. In the meantime, the sophisticated management of the sample queue system will allow samples to be drawn for other analyzers that are available.

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## Is it possible to keep the cells retentate after cell removal?

No, in the current design, cells are regarded as waste, given the objective is to provide a cell-free permeate for various destinations such as HPLC or LC/MS etc. The contents on the retentate side of the filter cartridge is a mix of concentrated sample and post sample rinse fluid.

## How reproducible are the volumes delivered by the Sample Pilots?

The Sample Pilot uses a positive displacement pump inside the Sample Pilot body to push the sample. While very consistent, this pumping mechanism is not designed for high accuracy.

Normally the volume delivered from a Sample Pilot to a destination rarely needs to be highly accurate and volumes delivered are usually calculated to the nearest mL. In such cases where a higher degree of accuracy is needed, we recommend using the Gilson<sup>®</sup> Syringe Pump as an intermediary to deliver the sample to its final destination, which has a published accuracy of  $\pm 2\%$  of syringe size. As we use both the 10 mL and 500  $\mu$ L syringes, this can be as accurate as  $\pm 10 \mu$ L.

## MAST<sup>®</sup> System connections

### Is it possible to route a sample to an HPLC or LC/MS system without having to go through the Gilson<sup>®</sup> Liquid Handler?

All of the current integrations to HPLC or LCMS systems use the Gilson<sup>®</sup> Liquid Handler as our end users like the fact that the Gilson<sup>®</sup> can keep a retain of the sample and they can perform liquid handling activities such as Protein A chromatography. While the MAST<sup>®</sup> System modularity would allow such a configuration, sending samples directly to an HPLC or LCMS has not been tested.

### What is the function of the Gilson<sup>®</sup> Liquid Handler?

The Gilson<sup>®</sup> Liquid Handler collects retains, processes samples and can distribute those processed samples to analyzers. It collects samples of either whole broth direct from the bioreactor, or as cell free permeate from the cell removal system. Often times samples received by the Gilson<sup>®</sup> Liquid Handler are processed using pre-set methods, for example Protein A chromatography or amino acid digestion, before being sent to an analyzer.

Cell free permeate samples from the Gilson<sup>®</sup> would typically be routed to HPLC or LC/MS to determine, for example the degree of protein aggregation, the charge variance or the glycosylation pattern.

### Is it possible to interface the MAST<sup>®</sup> System to Tecan or Hamilton robots?

It is also possible to interface the MAST<sup>®</sup> System with other robotic liquid handling systems, such as Hamilton<sup>®</sup> or Tecan<sup>®</sup>. Connection to these systems usually requires some custom engineering and development, so please contact us to discuss the application.

### Can the MAST<sup>®</sup> System sample from downstream analytical systems?

Provided there is a representative sample reservoir, a Sample Pilot can be assigned to draw samples from any source in a similar manner to that used for a bioreactor. This may require some form of custom bag or bottle for the reservoir and an appropriate dip tube design, or modification of the MAST<sup>®</sup> System for this purpose.

### How does the MAST<sup>®</sup> System interface to bioprocess analyzers and/or LC/HPLC systems etc?

When delivering a sample to an analyzer, the MAST<sup>®</sup> System team considers the physical delivery of the sample as well as the integrated software solution. As one can imagine, each analyzer requires a unique hardware/software interface. The MAST<sup>®</sup> System team has developed unique integration solutions for the Gilson<sup>®</sup> Liquid Handler, the MAST<sup>®</sup> System Cell Removal System, the Nova BioProfile<sup>®</sup> FLEX™ and FLEX2™, the Roche BioHT and HiRes and HPLC devices from multiple manufacturers, such as Thermo Fisher, Agilent and Waters.

This results in multiple unique integration solutions. The MAST<sup>®</sup> System can communicate via OPC UA, or through server/client Ethernet protocols, serial and others.

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## MAST<sup>®</sup> System requirements

### What compressed gases are required and at what pressures?

Compressed air is used for **NON** sample contact actions and is used to actuate the valves and the Sample Pilot pump. It plugs into the back of the Master Controller and requires a gas pressure between 70-100 Psig, or 4.8 bar to 6.9 bar.

Normally a MAST<sup>®</sup> System installation team will route the compressed air from the Master Controller to the Sample Navigator Controllers and the Analytical Navigator controller.

The system also requires a Nitrogen supply, which is used as a purge gas. The N<sub>2</sub> supply is also connected to the Master Controller and needs a working pressure between 30-100 PSIG, or 2.1 bar to 6.9 bar. The actual usage pressure is typically 2.4 bar. This gas IS in sample contact and the primary reason for the use of N<sub>2</sub> here, is to help maintain dissolved gas concentration in samples that are sent to a BioProfile<sup>®</sup> FLEX2™ or other analyzer.

The MAST<sup>®</sup> System installation team will route the purge gas to the MAST<sup>®</sup> Sample Pilots and to the Sample Navigator Valve Modules. The use of N<sub>2</sub> as a purge gas also provides an oxygen free zone in the Sample Pilot for drawing in the next sample, thereby improving sterility assurance.

### What are the electrical requirements for the MAST<sup>®</sup> System?

The entire MAST<sup>®</sup> System, including the Gilson<sup>®</sup> Liquid Handler, can be operated using one 15A 50/60Hz 110V/220V circuit.

We strongly recommend that controllers, the Gilson<sup>®</sup> Liquid Handler and the computer be connected to Uninterruptable Power Supply (UPS).

### What are the IT requirements on site?

In the majority of installations, the end user provides the computer. The MAST<sup>®</sup> System requires a computer that complies with the MAST<sup>®</sup> System minimum computer requirement specification that is available on request. The MAST<sup>®</sup> System group can also provide the computer, as part of the quotation, if the end user would like us to do so.

Prior to installation, we also recommend that we have an in-depth communication with your IT stakeholders to ensure a satisfactory and efficient installation.

Early in the installation, it is very helpful to have an IT representative onsite, especially when it is required to interface the MAST<sup>®</sup> System to the end users internal network.

## Maintenance and support

### Does Lonza provide analysis methods with the system?

Analyzer methods are created by the end user in the specific analyzer that is receiving the sample from the MAST<sup>®</sup> System. In most cases, the MAST<sup>®</sup> System communicates with the analyzers to create a list of available methods at that analyzer. When scheduling a sample directed toward a specific analyzer, this list is used to create a drop down menu on the MAST<sup>®</sup> System scheduling screen. This allows the end user to select from the drop down menu which analyzer method is required when each sample is delivered to it's destination.

### What are the cleaning mechanisms for the MAST<sup>®</sup> System?

There are two cleaning procedures that the System undertakes:

#### Normal cleaning procedure

After each sample, the Sample Pilot and the sample lines are flushed with an alcohol based solution. This solution is passed throughout the lines and the Sample Pilot and held for a "kill" period to increase effectiveness, before being blown dry by a purge gas, typically nitrogen.

It is important to note that the design of the valve is very important to ensure thorough cleaning. Our patented valve design ensures there is no loss of linear velocity during the process making sure there is a full flush across the back of the valve, where you might expect a build up of cellular material.

The pump is also cycled during this process, to ensure that the pump is also fully cleaned.

After the flush and hold sequence, nitrogen gas is used to purge and dry the Sample Pilot and the lines. This provides an oxygen-free zone for the taking of the next sample.

#### Whole clean procedure

This is typically used after a bioreactor run to give the system a deep clean. A more aggressive cleaning solution is used instead of the normal alcohol based solution used in the post sample cleaning process.

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## What are the maintenance requirements for the System?

There is a MAST<sup>®</sup> System Technical Support, Hardware and Software Maintenance program. After a brief period of use, our customers often find that the MAST<sup>®</sup> System has much more capability than they originally assumed. The MAST<sup>®</sup> System subject matter experts are ready to listen to what the end users need and to help them get the results they are looking for.

Regarding hardware, the SP200 units are replaced and the SP100 units are rebuilt, on an annual basis. The MAST<sup>®</sup> System service also typically includes an annual onsite visit which includes a complete system inspection and preventative maintenance on the specific MAST<sup>®</sup> System components, the Gilson<sup>®</sup> Liquid Handler and the MAST<sup>®</sup> System Cell Removal System.

The MAST<sup>®</sup> System software maintenance includes updates to the existing software systems as improvements are implemented.

The customer should be performing routine maintenance as recommended in the user manual, such as replacing Sample Pilot filters after each autoclave cycle and cleaning the MAST<sup>®</sup> System Sample Pilots and sample lines with cleaning solution after each run.

## Is it possible to have a demonstration?

We do have a small number of the MAST<sup>®</sup> System demonstration units. Due to the modular nature of the system, a typical site installation can be quite complex. The demonstration systems are therefore designed for basic proof of concept with a minimal system. As all demonstration systems require on-site installation and training of the user, we normally charge a nominal cost for the demonstration.

## Contact us

To learn more about the MAST<sup>®</sup> System for your automated, aseptic sampling needs, please contact our MAST<sup>®</sup> Technical Specialist at:

[MASTsampling@lonza.com](mailto:MASTsampling@lonza.com)

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