

Modular Automated Sampling Technology™ Platform

Introduction

The bioprocessing industry demands a reliable system that transfers bioprocess samples directly from bioreactors to analytical devices while maintaining process sterility. Bend Research is developing the Modular Automated Sampling Technology™ (MAST) Platform to meet this need. The vision behind the MAST Platform is to help scientists collect the right data at the right time, making it possible to integrate process analytical technology (PAT) and to facilitate the evolution of the bioprocess industry toward advanced, real time testing, predictive control and overall bioprocess guidance.

As the MAST Platform advances toward commercialization, many components of the system are undergoing extensive testing by Pfizer, Eli Lilly and other pharmaceutical and biotechnology companies. Development continues to be funded by Pfizer, Eli Lilly and others.

This automated, aseptic bioreactor sampling system for development and commercial scale applications enables optimized sampling of media, cell, and product level information across scales, and will allow

- Hands off, contamination free sampling;
- automated sample scheduling;
- automated at-line analysis;
- increased sampling frequency;
- increased sampling reproducibility;
- increased data reliability; and
- reduction of labor.

The MAST Platform has multiple modules and can be easily adapted to each individual

customer's needs. The flexibility of the system ensures that customers purchase only what they need.

Introducing the Sample Pilot

The MAST Platform employs a highly innovative sampling system called the Sample Pilot. There



SP100

are currently two versions of Sample Pilot modules. The SP100 is specifically designed for Steam In Place (SIP) applications where the module can be affixed to a standard Ingold port on a fixed bioreactor. The SP200 Sample Pilot is specifically designed for autoclave applications such as development scale bioreactors and single use bioreactor interfaces, such as the bellows style Kleenpak Connector.



SP200

Most recently, six SP100 Sample Pilots and eight SP200 Sample Pilots have been successfully deployed, taking more than 2,400 samples in sterile systems. (See the MAST Sample Pilot Technical Brief for more detailed information.)

MAST User Interface and Software

Users create and manage the sampling schedule through the MAST Platform graphical user interface (GUI) powered by 21 CFP Part 11 compliant Ignition software. The MAST system has a suite of software products for sample scheduling, sample collection, and navigation,

interfacing with analytical equipment and database management.

The MAST analytical interface software has been developed for the Nova BioProfile FLEX and for the Gilson Liquid Handler systems. Software solutions are in varying stages of development and will interface with a variety of third party analyzers such as Roche Bio-HT, Waters UPLC, ViCell and Cedex.

The MAST data management system, also in development, will be a centralized repository for data from sampling activities, as well as data from all of the various analyzers.

MAST Hardware Modules

The MAST Platform is truly modular. Based on the user's requirements, the MAST system can be simple or complex, based on the demands of the application.

The *MAST Core* represents the base system capable of collecting samples from one reactor and sending those samples to one destination, such as the Nova BioProfile Flex or a Gilson Liquid Handler. Adding on the *Sample Navigator* modules to the base system allows samples to be obtained from up to eight bioreactors. Adding on the *Analytical Navigator* allows these samples to be sent to as many as four destinations.

When a custom solution is required, Bend Research has the engineering and integration experience to integrate to most analytical devices.

Proven Results

Currently there are 14 Sample Pilot modules collecting data in the development bioreactors, pilot scale single use bioreactors, and pilot scale fixed stainless steel bioreactors used to produce regulatory toxicology supplies. To date, the SP100 and SP200 units have collected more than 2,400 samples without contamination.

Click here to view a short video of the Modular Automated Sampling Technology™ (MAST) Platform <http://youtu.be/Fy93XuOKEyA>

The Future of Innovation

We believe that you deserve better technologies to meet your product quality goals. The MAST platform opens the door to gaining more fundamental understanding of the true cell environment. Coupling the right tools provides more intuitive guidance to ideally tune the environment to meet the needs of the cells themselves. At Bend Research we are constantly striving to remove the black box around the cell, providing the ultimate guidance to understand how system variables affect your overall product quality.

About Bend Research

For more than 35 years, Bend Research has worked with clients to solve their most difficult scientific and technical problems, advancing new medicines that improve human health. This success is based on a solid understanding of scientific and engineering fundamentals, enabling Bend Research to develop, progress, and commercialize pharmaceutical technologies. The firm's innovative drug delivery solutions grow from a solid base of scientific and engineering fundamental understanding.

Bend Research provides formulation and dosage form support, assists in process development and optimization, manufactures clinical trial quantities of drug candidates in its cGMP facilities, advancing promising drug candidates from conception through commercialization. It is a leader in novel formulations, including solubilization technologies such as spray dried dispersions and hot melt extrusion formulations, as well as controlled release, inhalation, and biotherapeutics.

Contact

Bend Research is looking for partners to collaborate in the development plan to advance the Modular Automated Sampling Technology™ Platform towards commercialization. Units are available for beta testing. Engineering support is available for assessment, implementation and full exploitation of the data management system. To discuss potential application of the MAST Platform to your bioreactor or other unit operation, please contact:

Clint Pepper, Ph.D.

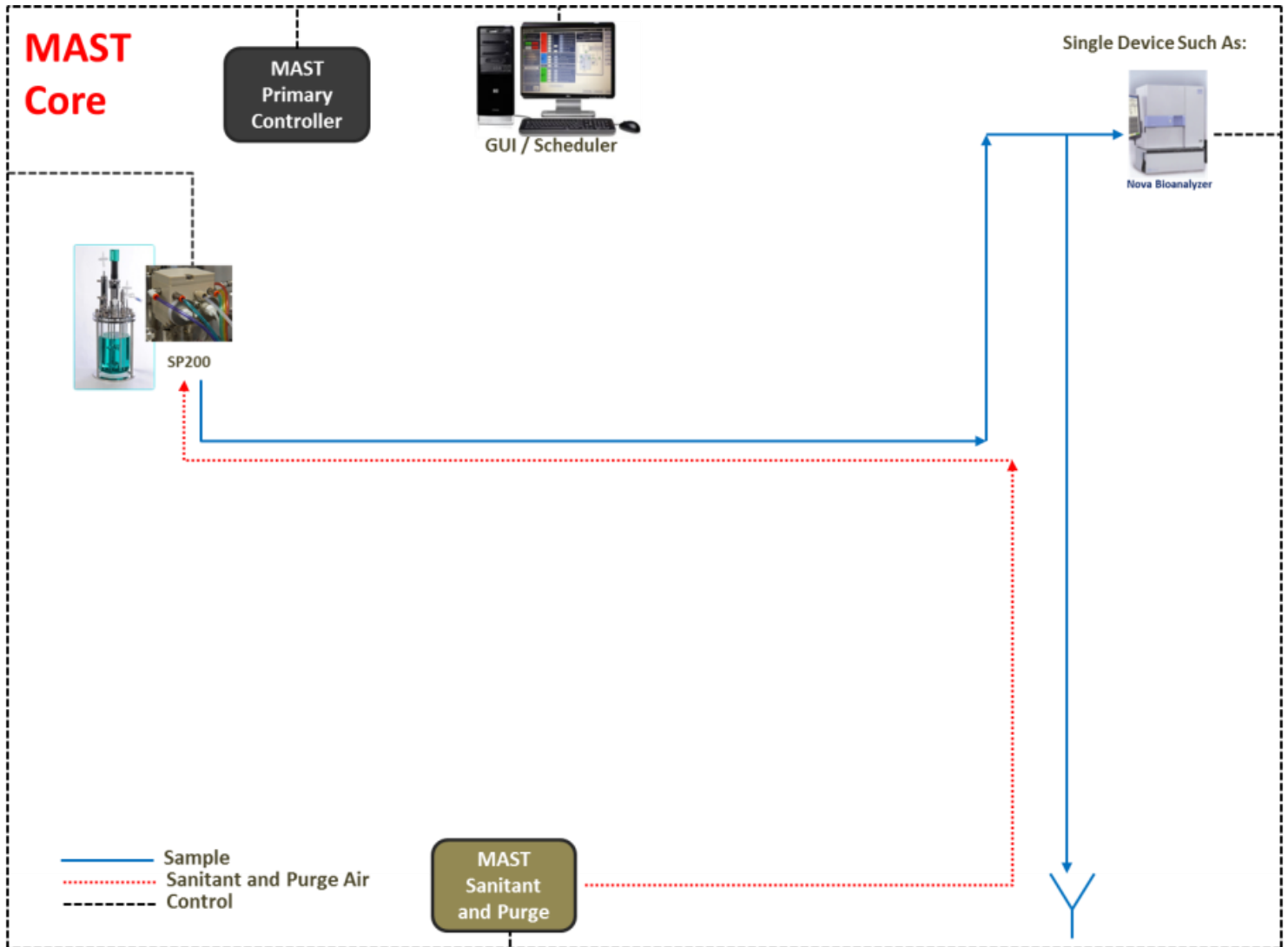
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MAST Core

An expandable system capable of collecting samples from one source and sending those samples to a single device such as a Nova BioProfile FLEX or a Gilson Liquid Handler

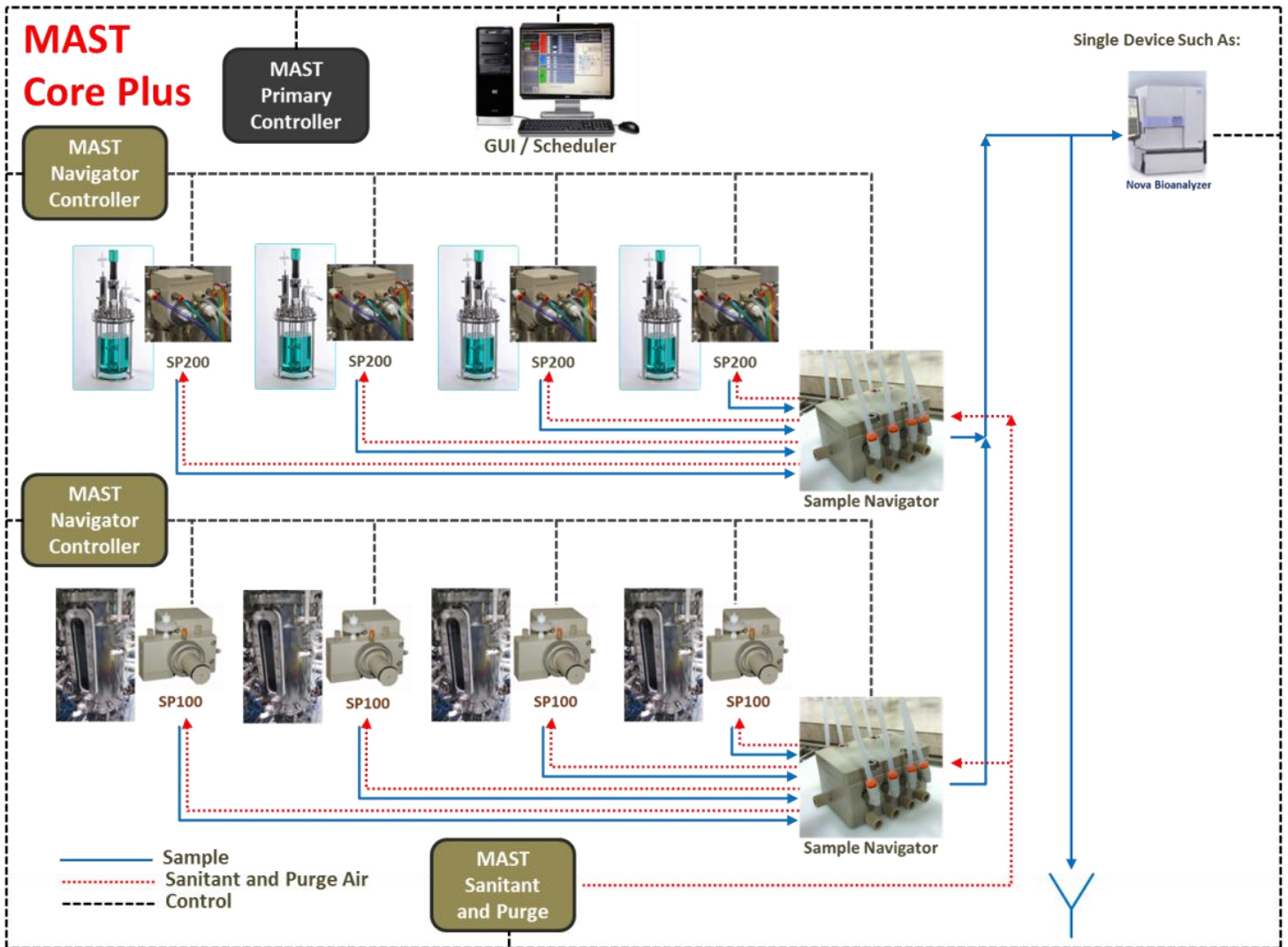


MAST Core Includes:

- Graphical user interface (GUI)
- Primary MAST programmable logic controller (PLC)
- Scheduling and database software
- Nova BioProfile Flex or Gilson Liquid Handler interface software
- Sanitant supply system
- An SP100 or SP200 depending on the application
- Desktop computer

MAST Core Plus

An expandable system capable of collecting samples from up to eight sources and sending those samples to a single device such as a Nova BioProfile FLEX or a Gilson Liquid Handler

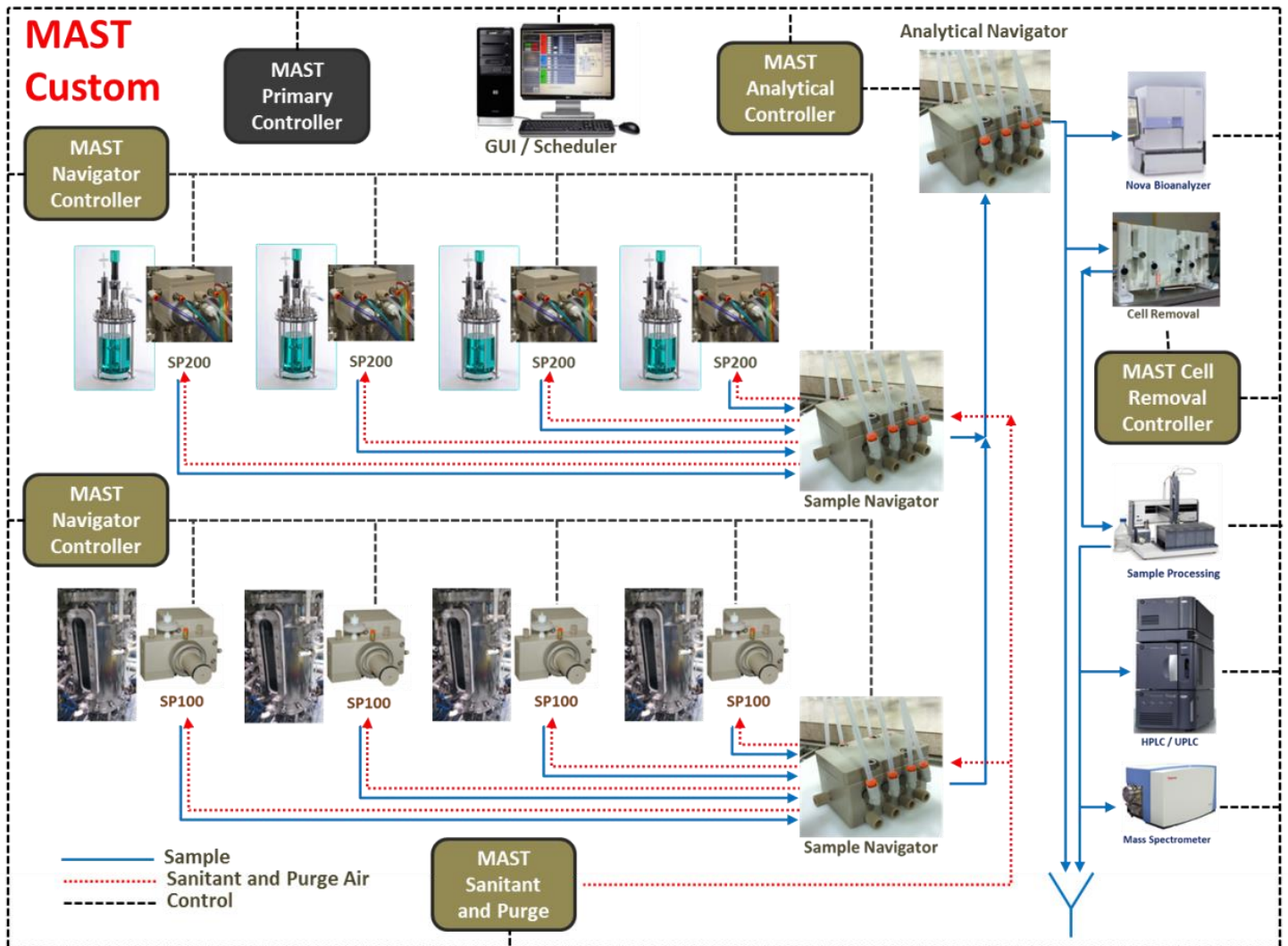


MAST Core Plus Includes

- All components available for MAST Core and
- 2X - Sample Navigator Controller and Sample Navigator Module
- Up to eight SP100 or SP200 depending on the application

MAST Custom

With the addition of the Analytical Navigator, samples from up to eight sources can be sent to as many as four analytical destinations. The addition of the Cell Removal System allows preparation of cell free samples for UPLC/LSMS testing. Bend Research integration and engineering specialists can facilitate the creation of software and hardware interfaces to most analytical devices.



MAST Custom Includes

- All components available for MAST Core Plus, and
 - Innovative hardware and software solutions to interface with most analytical equipment
- Analytical Navigator Controller and Analytical Navigator Module
- Cell Removal System Controller and Cell Removal System Module