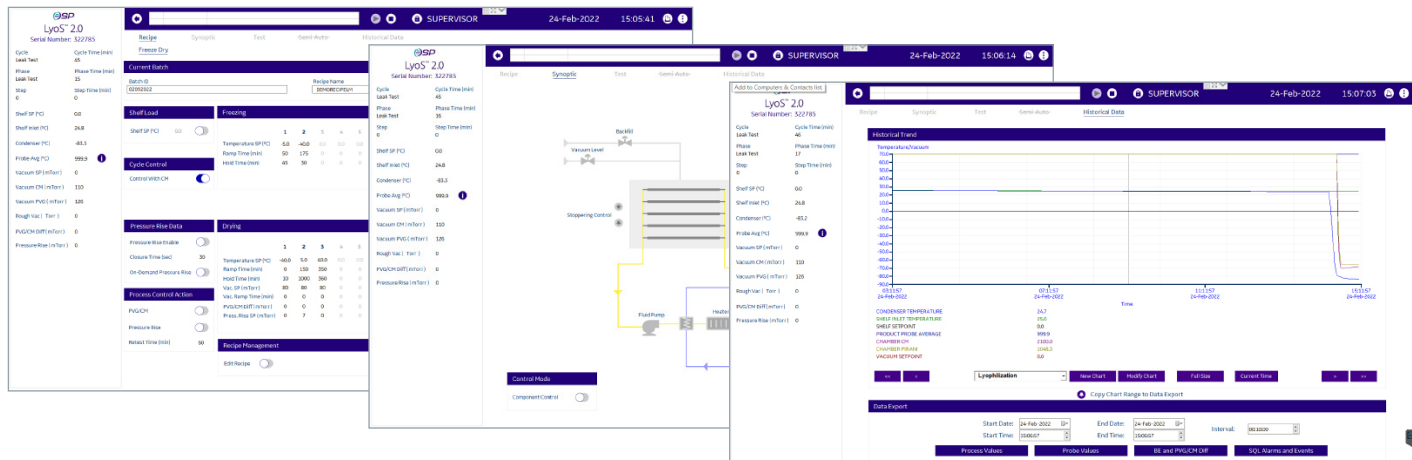


LyoS™ 2.0 for Genesis and Ultra Lyophilizer Control System



Overview

SP's LyoS™ 2.0 control system was developed to meet the lyophilization requirements of today's pharmaceutical and biotechnology applications.

Building on the proven experience of SP's engineering team, and contributions from renowned industry experts, the LyoS™ 2.0 control system packs the highest level of process control and flexibility into a software package that is as easy to use as it is multi-functional.

Installed on a Windows®-based platform, LyoS™ 2.0 leverages the GE Proficy® HMI/SCADA iFix solution to deliver superior functionality, as well as faster, more intelligent control of the freeze-drying process and related functions.

Key Features

- GE Proficy® iFix HMI software
- Graphical synoptic display with real-time system status
- Full system alarming
- Historical data trending, with quick export capability
- Power outage protection including product recovery routines
- Comprehensive programming of unlimited custom recipes
- Semi-automatic and fully automatic modes of operation
- Assortment of configurable options

Available Software Validation

The LyoS™ control system software is both fully configurable and fully validatable for regulated pharmaceutical and biotechnology applications. SP offers testing protocols intended to support the processes that will be performed by the purchaser and/or end user, as well as onsite control system IQ/OQ validation support and a comprehensive factory-initiated software validation.

Standard Features

The LyoS™ 2.0 control system software for SP VirTis Genesis and Ultra freeze dryers comes standard with features designed to help meet your process needs. These features include drying endpoint tools like Pirani/Capacitance Manometer comparison, automatic pressure rise testing, automatic backfill testing, and stoppering capability.

Optional Features

Available optional features include automatic Batch Reports, 21 CFR Part 11 compliance capabilities, and Uninterruptible Power Supply (UPS).

21 CFR Part 11 Compliance Capabilities

- E-Signatures attached to all recipe changes
- Secure Microsoft® SQL alarms and events database
- Proficy® Historian for secured historical data archiving
- Full security integration with the Microsoft® Windows operating system environment
- GE iFix secure recipe manager

Workstation Specifications (Minimum)

- Microsoft® Windows® 10 Professional, 64 bit
- Intel® Core™ i-3 6100 3.7 GHz Processor
- 8 GB RAM
- 1 TB Hard Disk
- DVD-RW
- SVGA Video Port
- USB Printer
- 22-inch Flat Screen LED Monitor
- Mouse and Keyboard
- 2 Network Interface Cards (NICs)



At a Glance: SP VirTis Control Systems for Pilot Freeze Dryers

Capabilities	Merlin Touchscreen	Merlin with PC Software Workstation	LyoS 2.0 Package L	LyoS 2.0 Package R	LyoS 2.0 Package P
Primary and Secondary Drying Steps	12	12	17	17	17
Thermal Treatment (Annealing) Phase	10	10	12	12	12
Product Probes, Standard Configuration	8	8	8	8	8
Additional Product Probes Available	No	No	Up to 16 Total	Up to 16 Total	Up to 16 Total
Capacitance Monometer in Addition to Pirani Gauge. Includes Automated Pirani/CM Differential Feedback	Option	Option	Yes	Yes	Yes
Integrated Performance and Vacuum Leak Testing	Yes	Yes	Yes	Yes	Yes
Historical Data Trending	No	Yes	Yes	Yes	Yes
Configurable Data Export (CSV File)	No - USB only	Yes	Yes	Yes	Yes
Batch Reporting	No	No	No	Yes	Yes
UPS	No	No	No	Yes	Yes
Manual Pressure Rise Testing (Units Configured with Isolation Valve)	Yes	Yes	Yes	Yes	Yes
Automated Pressure Rise Testing (Units Configured with Isolation Valve)	Yes	Yes	Yes	Yes	Yes
Multi-Level Security Capability	Limited	Yes	Yes	Yes	Yes
Security Integration with Microsoft Windows	No	Yes	Yes	Yes	Yes
21 CFR Part 11 Compliance Capability with SQL Database	No	No	No	No	Yes
Ethernet Communications	No	Yes	Yes	Yes	Yes
Security Customization	No	No	No	No	Yes

