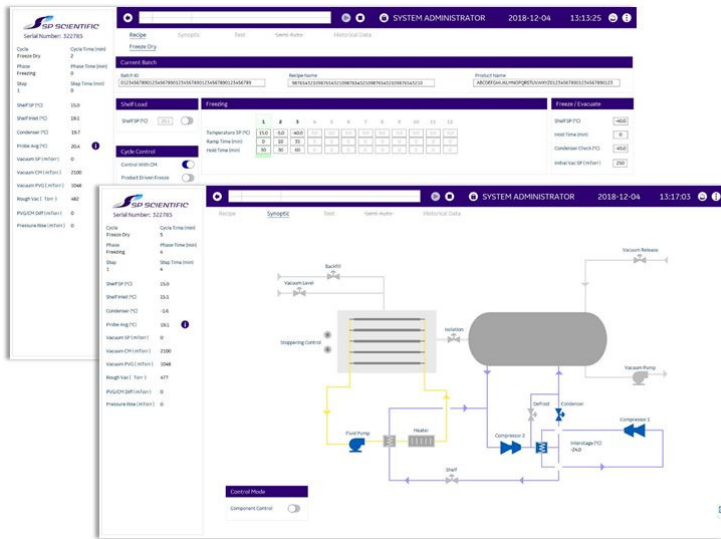


LyoS™ 2.0 for Genesis, Ultra, VirTual Lyophilizer Control System



Overview

SP Scientific'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 Scientific'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.
- Semiautomatic and fully automatic modes of operation.
- Assortment of configurable options.

Standard Features

The LyoS™ 2.0 control system software for Genesis, Ultra, and VirTual 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, 21CFR11 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).

Available Software Validation

The LyoS™ control system software is both fully configurable and fully validatable for regulated pharmaceutical and biotechnology applications. SP Scientific 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.

LyoS™ 2.0 for Genesis, Ultra, VirTual

LyoPhilizer Control System

LyoS 2.0 Control System

Capabilities	Package L	Package R	Package P
Up to 17 Drying Steps	Yes	Yes	Yes
Thermal Treatment (Annealing) Phase	Yes	Yes	Yes
8 Product Probes	Yes	Yes	Yes
9-16 Product Probes	Option	Option	Option
Integrated Performance and Vacuum Integrity Testing	Yes	Yes	Yes
Historical Data Trending	Yes	Yes	Yes
Batch Reporting	No	Yes	Yes
UPS Power Back Up	No	Yes	Yes
Manual Pressure Rise (Barometric Endpoint) Testing with purchase of Isolation Valve	Yes	Yes	Yes
Automated Pressure Rise (Barometric Endpoint) Testing (requires Iso valve)	Yes	Yes	Yes
Capacitance Manometer with Automated Pirani/CM Differential Feedback	Yes	Yes	Yes
Automated Backfill	Yes	Yes	Yes
Stoppering via HMI (stoppering units)	Yes	Yes	Yes
Auto Stoppering in recipe	Yes	Yes	Yes
Multi-Level Security Capability	Yes	Yes	Yes
Security Integration with Microsoft® Windows® 10	No	No	Yes
21 CFR Part 11 Compliance Capability with SQL Database	No	No	Yes
Ethernet Communications	Yes	Yes	Yes