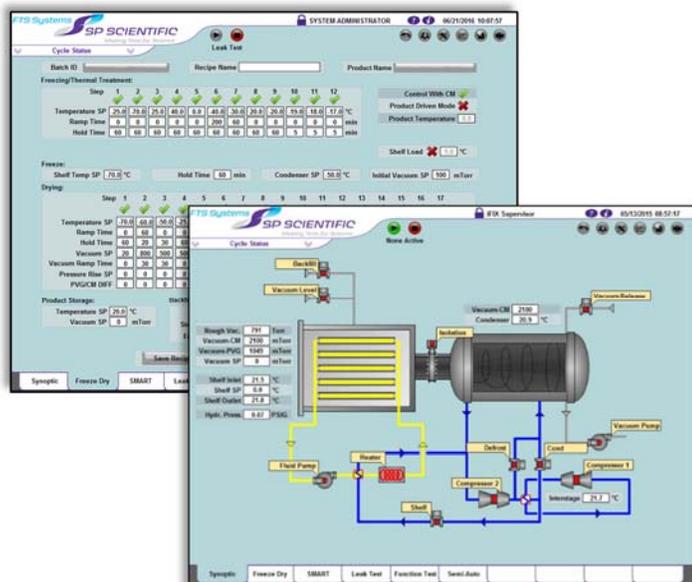


LyoS™ for Genesis, Ultra, VirTual Lyophilizer Control System



Overview

SP Scientific's LyoS™ 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™ 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™ 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 Fanuc Proficy iFix HMI software.
- Graphical synoptic display with real-time system status.
- Full system alarming.
- Historical data trending.
- 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™ control system software for Genesis, Ultra, and VirTual freeze dryers comes standard with features designed to help meet your process needs. These features include Batch Reports, 21 CFR Part 11 compliance capabilities (SEC3) 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® 7 Professional, Service Pack 1.
- Intel® Core™ i-3 4170 3.7 GHz Processor.
- 4 GB RAM.
- 1 TB Hard Disk.
- DVD-RW.
- SVGA video port.
- USB Printer.
- 19-inch Flat Screen 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.

Note: "Testing carried out by the manufacturer can form part of the IQ/OQ evidence if adequately controlled and documented. This can help reduce the amount of testing needed later, particularly in software OQ." - International Society for Pharmaceutical Engineering's (ISPE) GAMP Guide for Validation of Automated Systems.

LyoS™ for Genesis, Ultra, VirTual

LyoPhilizer Control System

Control Systems

Capabilities	Intellitronics™	Encore™	LyoS™
Up to 16 Primary and 1 Secondary Drying Steps**	No	Yes	Yes
Thermal Treatment (Annealing) Phase	Yes	Yes	Yes
4-8 Product Probes	Yes	Yes	Yes
9-16 Product Probes	No	Yes	Yes
17+ Product Probes	No	No	Yes
Integrated Performance and Vacuum Integrity Testing	Yes	Yes	Yes
Historical Data Trending	No	Yes	Yes
Batch Reporting††	No	Yes	Yes
Manual Pressure Rise (Barometric Endpoint) Testing	Yes	Yes	Yes
Automated Pressure Rise (Barometric Endpoint) Testing	No	Yes	Yes
Automated Pirani/CM Differential Feedback	No	Yes	Yes
Clean-In-Place (CIP) Cycle*	No	No	Yes
CIP Skid Integration*	No	No	Yes
Steam Sterilization Cycle*	No	No	Yes
Multi-Level Security Capability	No	Yes	Yes
Security Integration with Microsoft® Windows® 7	No	No	Yes
21 CFR Part 11 Compliance Capability with SQL Database	No	No	Yes
RS-232 Communications	Yes	Yes	No
Ethernet Communications	Yes	No	Yes

* Requires additional system components.

** VirTis Intellitronics Controllers allow up to 12 Drying Steps.

†† VirTis Intellitronics Controllers allow data to be saved to internal memory.