

Merlin Software & Workstation

Lyophilizer Data Acquisition and Trending Software



Overview

The SP VirTis Merlin Controls Data Acquisition and Trending Software was developed to meet the lyophilization requirements of today's pharmaceutical and biotechnology applications.

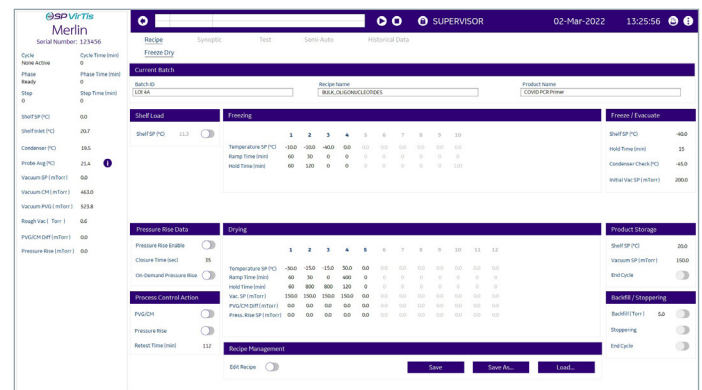
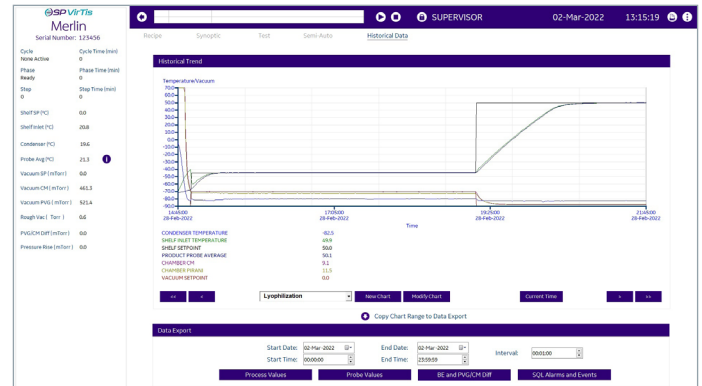
Installed on a PC with a Windows® based platform, the Software interfaces with the Siemens™ Touchscreen controller on the freeze dryer. The Merlin Software leverages the GE Proficy® HMI iFIX solution to deliver superior functionality.

Key Features

- GE Proficy iFix HMI software pre-installed on a PC
- Graphical synoptic display with real-time system status
- Continuous historical data trending
- Quick data export capability, customizable for date/ time range
- Recipe manager
- Semi-automatic and fully automatic modes of operation
- Automatic Leak Test and Function Test
- Proficy Historian for secured historical data archiving
- Secure ID/Password login with three permissioned user groups (guest, operator, supervisor)

Capabilities

Historical data trending	Available
Integrated performance and vacuum leak testing	Available
Batch reporting	Not Available
UPS power back up	Not Available
Backfill to setpoint	Available
Stoppering via HMI	Available
Recipe management with unlimited recipes	Available
Multi-level Login/PW security capability	Available
21 CFR Part 11 compliance with SQL database	Not Available
Ethernet/wireless communications	Available



PC Workstation Specifications (Minimum)

- Microsoft® Windows® 10 Professional, 64 bit
- Intel® Core™ i-3 6100 3.7 GHz Processor
- 8 GB RAM
- 500 GB Hard Disk
- 1 Network Interface Card (NIC)

Available Software Validation

The SP VirTis Merlin Software package has full validation ability 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 on-site control system IQ/OQ validation support and a comprehensive factory-initiated software validation.



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

