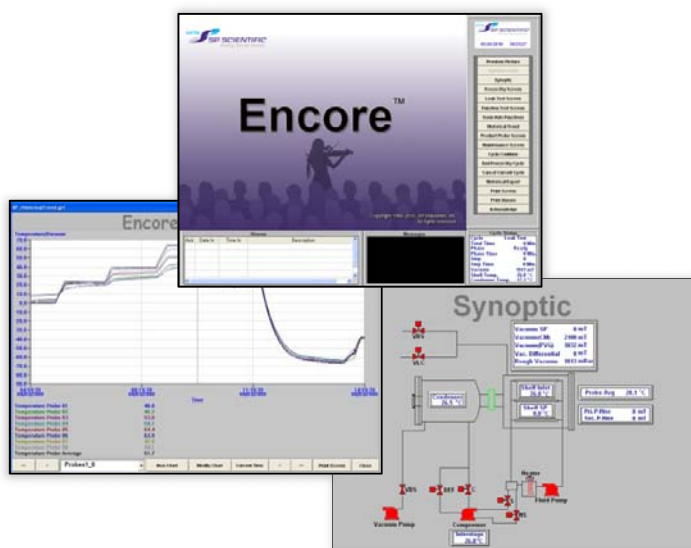


VirTis Encore™ Lyophilizer Control System



Overview

The Encore™ Control System is designed to meet the lyophilization requirements of pharmaceutical and biotechnology companies. The system utilizes the GE Fanuc Proficy® HMI/SCADA – iFIX solution for Windows® and an Allen-Bradley MicroLogix 1500 Programmable Logic Controller (PLC). The software system meets Current Good Manufacturing Practice (cGMP) standards and regulatory guidelines for computer systems used for pharmaceutical processing equipment.

The GE Fanuc operator interface is designed for ease of use as a Human-Machine Interface (HMI), while the iFIX SCADA engine is ideally suited for process-driven applications that require reliable performance and known response times. Installed on a Microsoft Windows-based PC, the software provides visualization, data acquisition and supervisory capabilities directly to the PLC.

Key Features

- CE (2006/42/EC), (2004/108/EC), (2006/95/EC)
- GE Fanuc Proficy iFIX HMI software.
- Graphical synoptic display with real-time system status.
- Full system alarming.
- Historical data trending.
- Comprehensive programming of up to 100 custom recipes.
- Semi-automatic and fully automatic modes of operation.

System Capabilities

- Up to sixteen (16) product temperature-monitoring probes.
- Time, temperature and vacuum level control for each step of the Primary and Secondary Drying phases.
- Up to twelve (12) Thermal Treatment (annealing) steps.
- Integrated performance and vacuum integrity testing routines.
- Door preseat routine.
- Cascade refrigeration handling with interstage control.
- Capacitance manometer vacuum gauge in addition to standard Pirani vacuum gauge.
- Single point eutectic display.
- Moisture sensor to aid in endpoint determination.
- Backfill to setpoint for highly controlled product storage.
- Up to three (3) levels of security to keep your workstation safe.
- Pirani / capacitance manometer differential endpoint determination to aid in product dryness detection.
- Isolation valve control allowing automated pressure rise testing during Primary Drying.
- Extensive alarming to protect personnel, product and equipment.
- Remote View option allowing remote monitoring and control of your lyophilizer.
- Thorough historical data trending with export function.
- Local area network (LAN)-ready.

Workstation Specifications (Minimum)

- Microsoft® Windows® 7 Professional, Service Pack 1.
- Intel® Core™ i3-3220 3.3 GHz Processor.
- 4 GB RAM.
- 1 TB Hard Disk Drive.
- CD/DVD Drive.
- USB Printer.
- 17-Inch Flat Screen Monitor.

Available Software Validation

- Comprehensive Installation and Operational Qualification (IQ/OQ) documentation package.
- Control System Testing (CST) to verify system operations and functions, as well as confirm hardware and software component operations under normal operating conditions.

VirTis Encore™

Lyophilizer Control System

VirTis 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.