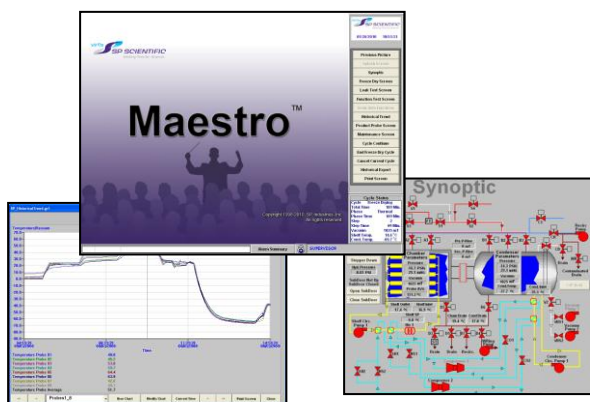# VirTis Maestro™

Lyophilizer Control System

Synoptic

The Maestro™ Control System is designed to meet the most demanding lyophilization requirements of pharmaceutical and biotechnology companies. The system utilizes the GE Fanuc Proficy® HMI/SCADA – iFIX solution for Windows and an Allen-Bradley 5/03 or 5/05 Small Programmable Logic Controller (SLC). The software system meets all Current Good Manufacturing Practice (cGMP) standards and regulatory guidelines for computer systems used for pharmaceutical processing equipment and is fully validateable.

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

- 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.
- FDA 21 CFR Part 11-compliant capable.

System Capabilities

- Customizable number of 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.
- Door preseal routine.
- Cascade refrigeration handling with interstage control.
- Capacitance manometer vacuum gauge(s) in addition to standard Pirani vacuum gauge(s).
- Single point eutectic display.
- Moisture Sensor.
- Auto-backfill and auto-stoppering for complete process automation.
- Fully automated clean-in-place and steam sterilization cycles.*
- Three (3), five (5) or a customized level of security to keep your workstation safe.
- CIP Skid integration.
- Pirani / capacitance manometer differential endpoint determination to aid in product dryness detection.
- Isolation valve control allowing automated pressure rise tests.
- Extensive alarming to protect personnel, product and equipment.
- Remote View option allowing remote monitoring and operation.
- Batch reporting.
- RS-232 or Ethernet connection between PLC and HMI.

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 XP, Service Pack 3.
- Intel Core 2 Duo Processor.
- 2 GB RAM.
- 500 GB Hard Disk Drive.
- CD/DVD Re-Writable & Floppy Disk Drives.
- USB Printer.
- 19-Inch Flat Screen Monitor.

Available Software Validation

- Comprehensive Installation and Operational Qualification (IQ/OQ) documentation package.
- System Integration Testing (SIT) for control system-level validation testing of the application software processes and related hardware.

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At a Glance: VirTis Control Systems

Capabilities:	Wizard 2.0	Wizard Workstation	Encore™	Maestro™
Up to 16 Primary and 1 Secondary Drying Steps	Yes	Yes	Yes	Yes
Thermal Treatment (Annealing) Phase	Yes	Yes	Yes	Yes
4-8 Product Probes	Yes	Yes	Yes	Yes
9-16 Product Probes	No	No	Yes	Yes
17+ Product Probes	No	No	No	Yes
Integrated Performance and Vacuum Integrity Testing	No	No	Yes	Yes
Historical Data Trending	No	Yes	Yes	Yes
Eutectic Point Monitoring with Data Trending	No	No	Yes	Yes
Batch Reporting	No	No	No	Yes
Manual Pressure Rise (Barometric Endpoint) Testing	No	No	Yes	Yes
Automated Pressure Rise (Barometric Endpoint) Testing	No	No	Yes	Yes
Automated Pirani/CM Differential Feedback	No	No	Yes	Yes
Clean-In-Place (CIP) Cycle*	No	No	No	Yes
CIP Skid Integration*	No	No	No	Yes
Steam Sterilization Cycle*	No	No	No	Yes
Multi-Level Security Capability	No	No	Yes	Yes
Security Integration with Microsoft Windows XP	No	No	No	Yes
21 CFR Part 11 Compliance Capability with SQL Database	No	No	No	Yes
RS-232 Communications	Yes	Yes	Yes	Yes
Ethernet Communications	No	No	No	Yes
Cycle Customization	No	No	No	Yes

Requires additional system components.