

The background is a complex digital composition. It features a hand in a blue sleeve holding a pen, positioned as if writing on a surface. The entire scene is overlaid with a dense pattern of binary code (0s and 1s) and glowing blue circuitry lines. The overall color palette is dominated by purples, blues, and oranges, creating a futuristic and technical atmosphere.

# Lyophilization Control Systems



# Maestro Series Control System

The Maestro control system uses a higher grade Allen Bradley PLC and interface which comes with additional tags, slots and memory. It can be equipped with many more control options (see list below) and is available with custom programming. A complete Control System Qualification Package is also available with the Maestro, as well as a security package which is capable of complying with 21CFR11 including electronic signatures, audit trails, encrypted data storage and more.

## Features:

- Allen Bradley SLC 5/03 programmable logic controller
- Eight product probes
- Pirani vacuum transducer
- Sixteen step primary drying
- Twelve thermal treatment routines
- Secondary temperature and pressure control
- All required PLC hardware and interfacing
- Includes computer workstation with Windows and Microsoft Office installed, color printer and Maestro lyophilization software
  - Computer hardware to be Pentium IV processor, 256 MB Ram, 40 Gig hard drive, 3.5" diskette drive, CD/RW, 15" flat panel monitor

## Available options:

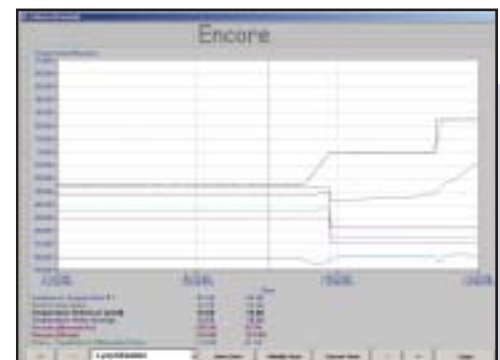
- Barometric endpoint and pressure rise advance/hold software. (Requires external condenser and isolation valve.)
- Smart-E Eutectic Monitoring Device.
- Additional product temperature probes and interfacing (in groups of four).
- Additional Pirani/Convectron vacuum transducer and interfacing.
- Capacitance manometer vacuum transducer in place of standard Pirani vacuum transducer. Note: Maestro can accept up to two capacitance manometers and two Pirani gauges. (One in chamber and one at pump.)
- Capacitance manometer in addition to Pirani gauge.
- Batch reports collect data from freeze drying cycle such as shelf, condenser and product probe temperature, vacuum, time, date, cycle name. The data is configured into a condensed report for printout.
- PID loop for vacuum level control includes modulating valve, analog output card and PID loop for control.
- Stoppering pressure setting - Allows partial breaking vacuum for stoppering at a set pressure.
- Remote View option allow full dial-up operation from any remote Pc location. Includes internal modem installed on computer workstation and



VirTis Encore



Recipe screen



Encore historical data screen

## Available options (Continued):

software for customer to use with home computer. (Modem for home computer not included.)

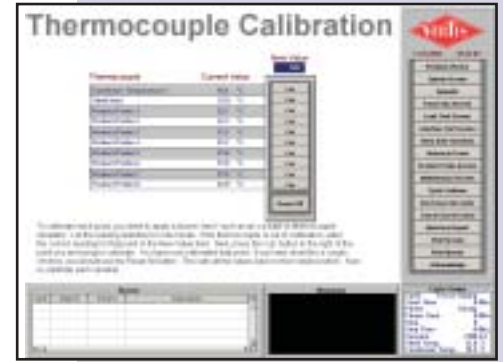
- Uninterrupted power supply for PLC system. System is to assure that power interruption is not to occur. All data points can be collected and documented during a black out.
- Moisture sensor for measurement of dew point in product chamber and determining the endpoint of primary drying. (Includes moisture probe and measurement software.)
- MKS flow meter with 500 sccm flow capability. Mass flow meter reading will be trended on the historical display.
- Pirani gauge capacitance manometer differential feed back endpoint determination. Compares the Pirani reading to CM reading to determine if product is dry enough to proceed to the next step.

## Security

- Security Option 1 - 3 levels
  - Guest - Can view the Main Menu only
  - Operator - Can view most screens and change some

setpoints.

- Supervisor - Can perform all functions - has access to all background tasks.
- Security Option 2 - 5 levels
  - Guest - Can view the Main Menu only.
  - Monitor - Can view most screens but not change any setpoints.
  - Operator - Can view most screens, change some setpoints.
  - Maintenance - Can view certain areas and has access to calibration.
  - Supervisor - Can perform all functions and has access to all background tasks.
- Security Option 3
  - Includes options to password protect and time and date stamp all critical entries to assist the user to comply with **21CFR 11**. Compliance with FDA requirements is always the user's responsibility. Depending on the customer's internal procedures and the extent of special programming required, custom programming, available at an hourly rate, may be necessary.



Thermocouple Calibration Screen



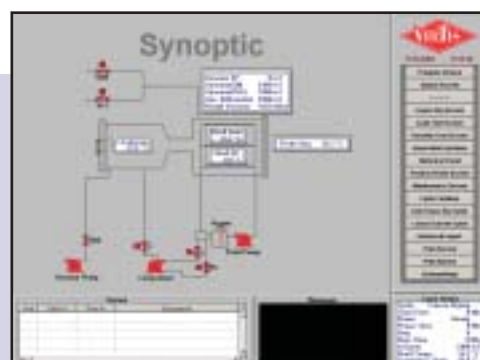
Semi-Auto Screen



Leak Test screen



Function Test screen



Synoptic screen



Historical Data Export screen

## *Control System Qualification Package*

-Generated by VirTis, customized for each customer, to provide industry standard required documentation of the functional and structural testing of the control system and workstation. This document and testing procedure provides test results to verify that the system is installed and operating properly. Control system (including its functionality) is validatable. Please consult factory for complete list of documentation and testing procedures.

## *SIP and CIP*

- Steam sterilization control system (Includes: software, interfacing and equipment components to fully automate the steam sterilization process.) available on Steam equipment.
- Clean In Place control system (Included: software, interfacing and equipment components to fully automate the Clean In Place process.) Available on Clean In Place equipment.
- Additional capacitance manometer (steam).
- Batch reports collect data from freeze drying cycle such as shelf, condenser and product probe temperature, vacuum, time, date, cycle name.

The date is configured into a condensed report for print-out.

## *Control system qualification package (Steam)*

-Our regular control system qualification package (CSQP) plus the additional information needed to show automated C.I.P. and S.I.P. control qualification.

## *Controllers & Recorders*

- Eutectic Point Monitor (Includes X-Y Recorder)
- Six point (5 temperature/ 1 vacuum)
- 12 point (11 temperature/ 1 vacuum)

Custom Programming  
for special applications  
and customer needs

is available  
at an hourly rate.

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