Bioreactor Datasheet

Introduction

The system has been engineered to provide automated process control, flexible process sequence development, data acquisition, historical trending and batch reporting.

The process is controlled by the programmable control logic processor (PLC). Process data is acquired from the PLC via Enterprise software and stored in the SQL database on the HMI/PC. Real time and historical data trending and batch reporting functionality enable the operator with a viewing window into the acquired data.

System Specifications

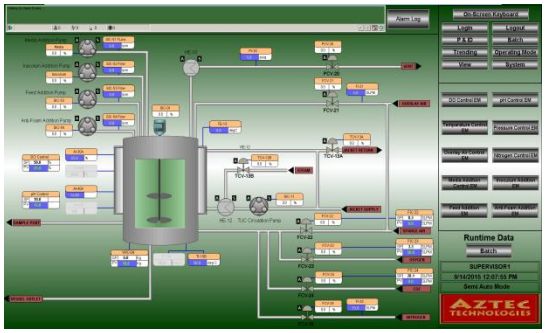
Process Instrumentation		
	Standard	**Additional Configurable options**
Pumps	3 Pumps are standard.	2 Pumps are available as options.
Control Valves	5 control valves are standard.	3 control valves are available as option.
pH Probes	2	
DO Probes	2	
Temperature Probes	2	
E-Stop	Integrated Safety Circuit for pumps, heaters and control valves	

Control Unit	
Integrated Control Panel	Built to GAMP5 standards/ 21 CFR Part 11 Compliant
Operator Interface	Factory-Talk View Site Edition Version 7.00.00
Data Historian	Factory-Talk View Site Edition data logging
Batch Development	Rockwell Batch Recipe Management Software
Reporting	Microsoft Reporting Software
Programming	Rockwell PLC based on RS-Logix 5000
SCADA Screen Resolution	Touch Screen (1920x1080)

Process Instrumentation Specifications	
	Ranges/ EGU are all configurable
Pressure	0-Max psig or bar
Dissolved Oxygen	0- Max %
Temperature	0- Max °C or °F
Air Flow Rate	0- Max lpm or slpm
pH	0-14
Weight	0- Max kg or g or mg
Inlet air pressure	High Pressure/ Low Pressure
Heat Exchanger	ON /OFF
Heater	ON /OFF

Operator Interface

The Process Overview screen is the root screen and displays on operator Login. It displays the status of the skid process including valve and pump status, flow rates, line pressures etc. This screen also provides operators the ability to gain control of field devices by switching their mode to Manual and manipulating their values. The root screen design also includes buttons which enable operators to navigate to standard screens such as Alarm, Trend screen display, Loop tuning etc. The buttons also provide Batch Management functions such as the starting of Recipes and transitioning them to HOLD, RESUME, ABORT states etc.



Control Strategies

Flexible closed loop control of critical process parameters support improved yields:

- Agitator Control
- Temperature Control
- Pressure Control
- DO Control
- pH Control
- Nitrogen Flow line Control
- Overlay Air Control
- Weight Control

Comprehensive, Real-Time Data Capture, Reporting and Trending

- The real-time data historian captures all process parameters and times, and offers accessible look-up.
- Export of data to other master data repository systems is supported with built-in functionality.
- Real time alarming protects process integrity and helps avoid lost batches.

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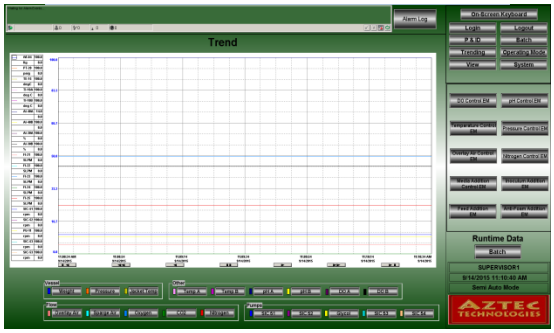
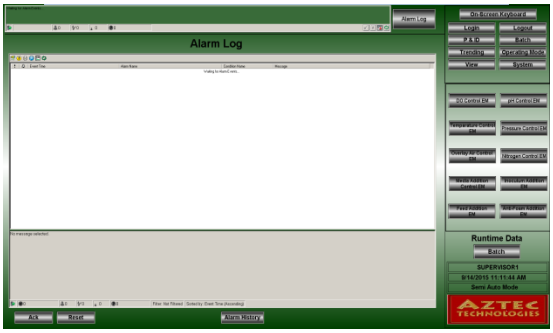
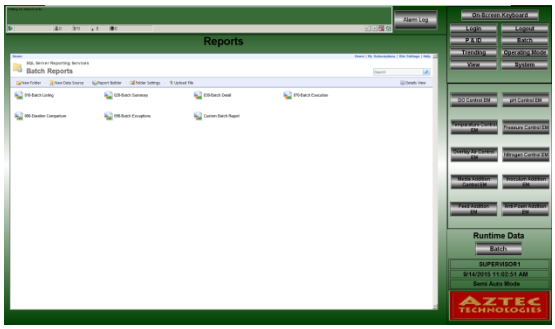




- All alarms are logged to database.
- All operator events are logged to database.



21 CFR Part11 Compliant Software

The following are configured to technically satisfy the requirements of the FDA 21 CFR Part 11 regulation in FactoryTalk View SE.

- Limit physical access to computer hardware.
- Use NTFS or other secure file system.
- Operating system security and domains.
- Configure FactoryTalk View SE user accounts to use Microsoft Windows security.
- Remove FactoryTalk View SE runtime security codes for all user accounts.
- Use a password-protected screen saver.
- Configure FactoryTalk View SE clients to automatically log out.
- Prohibit access to FactoryTalk® View Studio and other software programs.
- Use Windows account password aging and management.
- Set up the DeskLock feature.
- Do not allow operator access to Help.
- Secure FactoryTalk View SE Client stations.
- Log all FactoryTalk View SE activity and alarms to a central ODBC/SQL database.
- Set up re-verification of operator identity, or supervisor signoff.
- Use version control software.

Validation

- A Rockwell SoftLogix PLC emulator is used for all pre-FAT skid validation.
- Testing on an identical copy of the system image.
- IO verification and PIDE loop tuning performed on skid.
- Validation of the skid pre-configured recipes and parameters.
- Validation of all functionality of the Aztec Bioreactor Equipment Phases, Equipment Modules, Control Modules and HMI functionality (navigation, alarms, batch).
- Validation of data acquisition using Microsoft SQL Server.
- Validation will be performed using Validation SOPs as guideline documents for generating and execution of the test protocols.

Documentation

List of documents developed for chromatography skid along with P& ID and Electrical Schematic are:

- System Functional Specification (SFS)
- Validation Master Plan (VMP)
- Module Design Specification (MDS)
- Software Design Specification (SDS)
- Recipe Design Specification (RDS)
- Software User Manual (SUM)
- Traceability Matrix (TRM)
- Validation Plan Report (VPR)
- Module Test Protocol (MTP)
- Commissioning Test Protocol (CTP)
- Recipe Test Protocol (RTP)

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