



## Chromatography Skid 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
<b>Pumps</b>	Single pump is standard.	One Additional Pump is available as an option.
<b>Valves</b>	In Outlet Valve Equipment Module 4 valves are standard	In Outlet Valve Equipment Module 4 valves are optional.
	In Column Equipment Module 3 valves are standard	In Column Equipment Module 2 valves are optional
	In Preparation Equipment Module 1 valve is standard	In Preparation Equipment Module 4 valves are optional (BT) and 3 valves are optional(Filter)
<b>E-Stop</b>	Integrated Safety Circuit for pumps and valves	

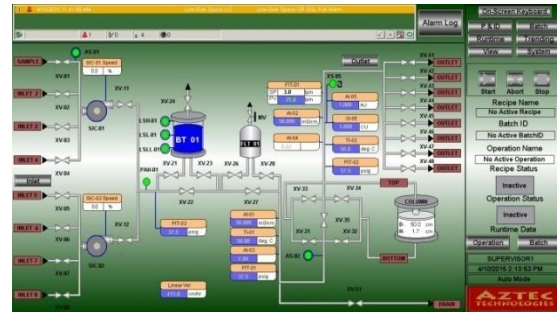
Control Unit	
<b>Integrated Control Panel</b>	Built to GAMP5 standards/ 21 CFR Part 11 Compliant
<b>Operator Interface</b>	Factory-Talk View Site Edition Version 7.00.00
<b>Data Historian</b>	Factory-Talk View Site Edition data logging
<b>Batch Development</b>	Rockwell Batch Recipe Management Software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

Process Instrumentation Specifications	
	Ranges/ EGU are all configurable
<b>Pressure</b>	0-Max psig or bar
<b>Conductivity</b>	0-Max mS/cm or $\mu$ S/cm
<b>Temperature</b>	0- Max $^{\circ}$ C or $^{\circ}$ F
<b>Flow Rate</b>	0- Max lpm or mlpm
<b>pH</b>	0-14
<b>UV Absorbance</b>	0-2 AU
<b>UV Intensity</b>	0-2 CU

<b>Inlet air switch</b>	Liquid/ Air
<b>Pre-column air switch</b>	Liquid/ Air
<b>Low-Low bubble trap switch</b>	Liquid/ Air
<b>Low bubble trap switch</b>	Liquid/ Air
<b>High bubble trap switch</b>	Liquid/ Air
<b>P-01 pressure switch</b>	Low pressure/ High Pressure
<b>Low air pressure</b>	High Pressure/ Low Pressure
<b>Post Column UV Lamp fail</b>	OFF/ ON

### Operator Interface

The Process Overview screen is the primary screen which gets displayed on operator Login. It is an active display that depicts the current status of the skid process including status of valves, pumps, flow rates, line pressures etc. This screen can be utilized by operators to gain control of field devices by switching to Manual mode and manipulate their values. This screen 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:

- Flow
- Linear Velocity
- Ratio
- Conductivity
- pH

### 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.

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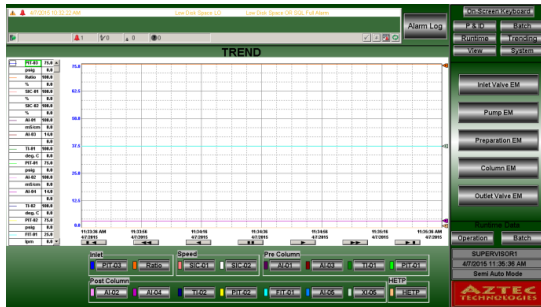
Aztec Consulting 101, C, Khanamet, Madhapur, Hyderabad - 500 081, Phone: +91-40- 40638200, Email: indiasales@aztec-consult.com

Aztec Technologies 132 Central Street, Suite 213, Foxboro, MA 02035, Phone: (508) 203 – 4220, Email: sales@aztec-consult.com

Visit us on: [www.aztec-consult.com](http://www.aztec-consult.com)

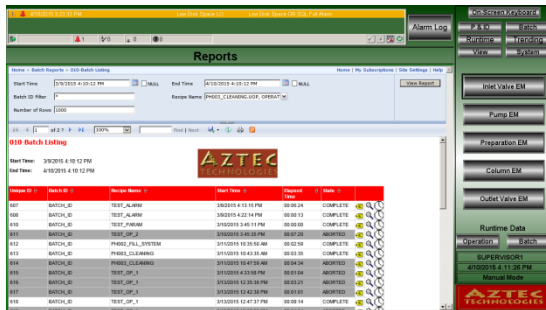
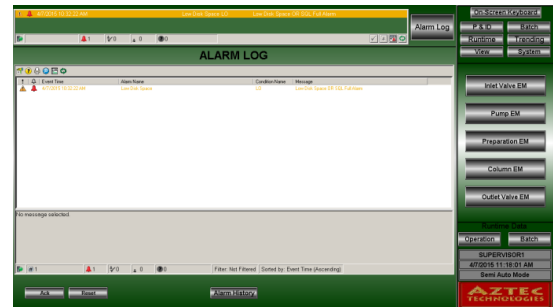


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- Real time alarming protects process integrity and helps avoid lost batches.
- All alarms are logged to database.
- All operator events are logged to database.

- Use version control software.



### 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.

### 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 Chrome Skid 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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