



## Custom Automated Chromatography Skids for Clinical Production

The QuantaSep® Skids are mobile, compact, and capable of providing an operating flow range of 10Lpm to 80Lpm. The integrated system has up to three pumps, 8-12 buffer selection valves, an inline mixer, pre and post column sensors, and up to 10 fraction collection valves. Its capabilities include but are not limited to buffer switching, gradient formation, pressure and air sensing and auto air ejection, Optional Flow detection, UV detection, Conductivity and pH sensing pre- and post- column, and forward and reverse flow through the column and column by- pass. An Optional disposable flow-path can be configured by using pinch valves and disposable sensors and tubing. The skid is run by a powerful easy-to-use software package. The software enables buffer and fraction switching based on process conditions, and activates alarms in the event of overpressure or air leaks. All events are automatically logged, archived and generated as cGMP reports for record-keeping purposes.

The QuantaSep® Skid is composed of a control module and a fluid handling module combined into a single ergonomically-designed system which is housed on a mobile platform. The computer that houses the control software can be integrated with or separated from the system to provide the options of local and remote operation. The Systems can be custom configured with air purged enclosures and intrinsically safe components for use in any Hazex or explosion proof environment and can be Class 1 Div 1 or Div 2 rated environment. The system is compatible with 1M NaOH and can be made compatible with alcohol or other organic solvents. It can also be suitable for CIP operations and is operable at 4°C for cold room processing.



- Scale-Up from 10 L/min to 80 L/min. Capable of Step or Linear Gradients
- Full Complement of Pumps; buffers, fraction, column up flow/ down flow valves, flow meters, and all sensors
- Optional disposable flow path
- Optional Purged Enclosure for Hazex package
- Manual and Automated runs with easy to use 21CFR pt. 11 compliant software
- Buffer and fraction changes based on time, volume and sensor based parameters.
- Generate Automated cGMP Reports.
- Full Validation Package, FAT/SAT & IOQ. Onsite Commissioning and Service



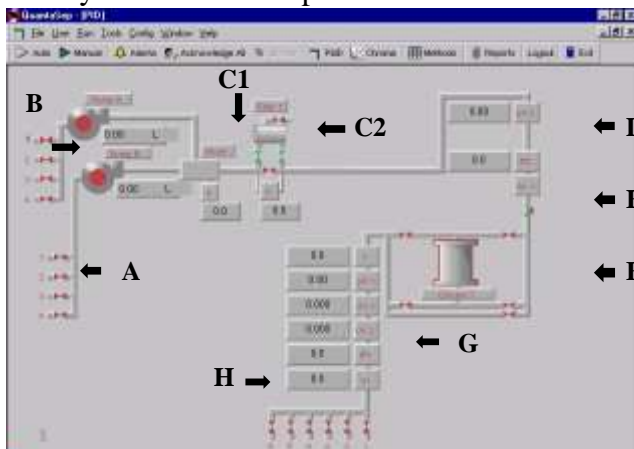
## QuantaSep® Skid Hardware

### Fluid Handling Module

The fluid handling module contains: up to 3 pump assemblies consisting of three diaphragm pumps, static mixer, and 316l S.S./silicone tubing. These are connected with sanitary clamp connections to diaphragm valves, optional flow-meters, UV, pH, leak, conductivity, temperature and pressure sensors, air sensor, air purge valve, sanitary inlets, outlets, and column connections. The components are mounted inside an enclosed stainless steel cabinet with a trough to which a leak detector is attached.



**Optional Disposable Flow- Path** The flow-path of this system can be designed for easy removal. This eliminates the need for cleaning validation and eliminates cross-contamination due to switching columns or products. Pinch valves and peristaltic pumps are used to enable easy changing of the pre-fabricated tubing assembly along with the integrated disposable sensor block, which can be easily removed and replaced as well.



**Controls Module** The controls module contains all power supplies, transformers, valve activation pneumatics, brain-boards, sensor controls and circuit boards, alarm controls, sensor electronics including A/D and D/A converters, and fuse assembly. The external chart recorder interface, status LED's, an emergency stop switch, cables, computer interface, fuse blocks, etc. are included as well. **For Hazex operation this is housed in a NEMA 4X purged enclosure.**

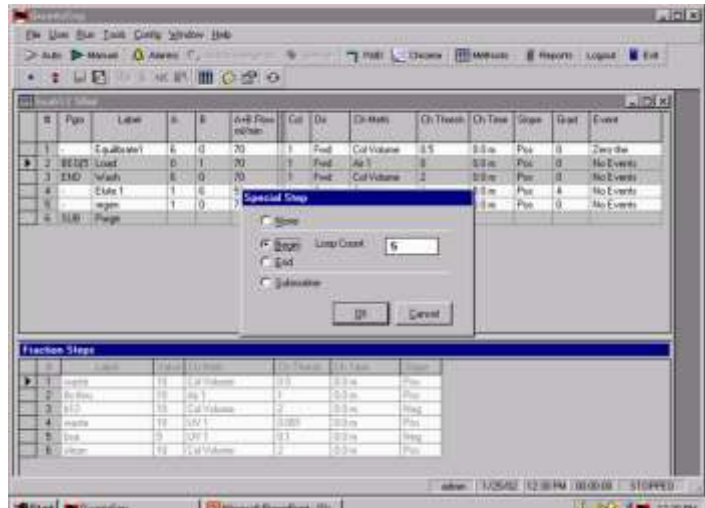
### The QuantaSep® Hardware

- A) **Up to 12 selectable buffer ports** – Manifold of four pneumatically actuated diaphragm valves on each
- B) **Up to three precision positive displacement pumps** – one for sample and two for buffer delivery with flow rates from 10 LPM to 80 LPM
- C) **1. Inline ΔP sensors** – The discharge of both pumps is manifolded together to a static mixer for effective gradient formation  
**2. Inline pre-filtering capability** – A manifold of sanitary valves with ΔP sensors enables the attachment of a prefilter for debris or particular removal pre-column
- D) **Optional Pre Column pH and conductivity sensors** – Can monitor pre-column pH and conductivity of buffers or load material. This helps prevent loading or wrong buffers and hence loss of product
- E) **Auto air eject** – An “active air trap” consisting of an air sensor and three-way air ejection valve continuously detects and removes unwanted air before the column thus preventing loss of raw material and valuable production time
- F) **Column forward/reverse capability** – The flow is directed to the column through a valve manifold, which can route flow to the column in a forward, reverse or bypass mode for flexibility in your product
- G) **Post column sensors** – Consist of a single flow cell capable of UV dual-wavelength (280 and 254 nm) detection and pH and conductivity detection. Minimize hold up volume of sensor lag time
- H) **Up to 10 user selectable fraction ports** – Fractions can be collected via a manifold comprising of 6 pneumatically actuated valves

# The QuantaSep® Software

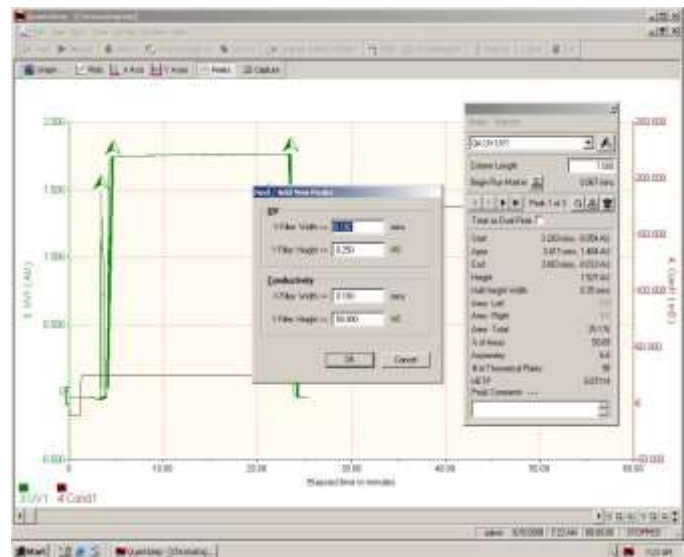
## The Right Combination of Simplicity and Power

The simplicity of the QuantaSep® interactive graphical user interface gives the system its efficiency and power by making it easy to use and learn. The main screen (Figure 1) displays a flow diagram of the system with all the main components and their real time status quickly and easily. By simply clicking the mouse, you can open or close a valve, stop or start a pump, set new flow rates, collect fractions and perform other system operations all from your workstation.



## Intuitive Protocol Design

Programming is simple. Open the method editor by clicking on the icon of the tool bar. Then key in steps in the table, stepping through different buffers and changing buffer or fraction steps based on UV, conductivity, pH or air. Simply click on the gradient box and choose your gradient profile. Click on the event box and zero the UV baseline before you start eluting your product!



## Security

The multi-levels of password protection restrict access to the system. For instance, an operator may have provision to run a method but not change the parameters; only the supervisor may be given that responsibility. In another instance, only the QA or metrology group may have access to setting calibration parameters. The security administrator in the software can enable all this and more.

## CGMP Documentation and Data Analysis

All events manual or automatic (including deviations) are recorded to the batch log. Reports consisting of the method, buffers used, all alarms and events, chromatogram data, and analysis can be printed or archived as part of the batch log. The Instant Data Analysis helps do a quick check of an ongoing process against baseline data hence preventing possible losses.

The screenshot shows the 'Events' log window in the QuantaSep software. The window has a title bar with a star icon and the text '★ Events'. The log contains the following entries:

Elapsed	Description
00:00:12	manual-Fraction Valve 9 - F 9 Opened.
00:00:19	manual-Column 3 Nev. Opened.
00:00:22	manual-Buffer Valve A2 - valve A2 Opered.
00:00:40	manual-Pump A Stated. 770 ml/min
00:00:42	Pump A Speed changed to 770 ml/min
00:02:13	manual-Buffer Valve B3 - valve B3 Opered.
00:02:23	manual-Pump B Stated. 434 ml/min

## QuantaSep® Skid Features



### General

- Automated buffer delivery, column switching, fraction collection, based on UV, pH and conductivity
- Compact mobile system can fit in a small production
- Graphical, intuitive software “dashboard” for easy operation and training
- Automated GMP reports
  - Complete batch reports
  - Event and alarm logs
  - Chromatograms and calibration history
  - Data Archival and Security
- Precision Hardware
  - Diaphragm/ Pinch valves
  - 8 optional up to 12 inlets
  - 6 optional up to 10 fractions
  - High pressure diaphragm/ peristaltic pumps
  - Large dynamic flow range
  - 30:1 turndown ratio for accurate gradients with diaphragm pumps
  - Low hold up volume and minimal dead legs
- Sensors
  - UV, pH and conductivity sensors
  - Optional Flow meter
  - Optional pre-column pH and conductivity sensors
  - Optional second 254/ 218 nm UV capability
  - Pressure, temperature, air, leak
- Safety features
  - Optional Purged Enclosure and intrinsically safe devices
  - “Active air trap” minimizes “bubble trap dilution”
  - Optional pre-column filter with differential pressure sensors
  - Leak and pressure alarms
  - Built-in safety interlocks
  - Software security prevents unauthorized operation and tampering

## QuantaSep® Skid Specs

### Flow rates

- 10 L/min – 80 L/min

### General

- 3 pumps – Diaphragm/ Peristaltic Pumps  
10-80 L/min  $\pm$  5%
- Gradients  
10-90% of ratio  $\pm$  7%
- Valves  
Diaphragm/ Pinch
- System Volume  
2-3 Liters
- Air Bubble Eject Size  
>0.25 tubing diameter
- UV Sensor (280)  
Range 0-2 Au;  
Path length 1.0 cm;  
Accuracy  $\pm$  1.0 psi
- Conductivity Sensor  
Range 0-200 ms;  
Accuracy  $\pm$  5% F.S.
- pH Sensor  
Range 1-14;  
Accuracy  $\pm$  0.2
- Pressure Sensor  
Range 0-100 psi;  
Accuracy  $\pm$  1 psi
- Inlet Buffer Selection  
8 up to 12
- Fraction Selection  
6 up to 10
- Column  
1 up to 3
- Pre-filter  
1

**Flow Path Materials:** 316L S.S., PVDF/  
Polypropylene and Glass

### Optional Disposable Flow Path Materials:

- Cond. Flow Cell  
Polypro/ Glass
- Fitting, Mixer  
Polypropylene
- Tubing  
Silicone
- Gaskets  
Silicone
- pH Electrodes  
Glass
- Pump Tubing  
Marprene (for disposable flow-path)
- UV Flow Cell Window  
Quartz
- Pressure/ Temp Sensors  
316L S.S.

All wetter materials are FDA grade/USP Grade VI compliant

### Chemical Compatibility

- 1M Sodium Hydroxide, Alcohol, Organic solvents
- Operating Temperature  
4°C - 40°C

### Utilities Requirement

- Power Requirement  
110/220V; 12 Amps

### Physical Dimensions

- 44” wide x 34” deep x 60” tall



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