



QuantaSep® Trusty 5000

Process Automated Chromatography System for Clinical Production



- ✓ Reduce Time to Market
- ✓ Improve Product Quality and Reliability
- ✓ Reduce Batch Failures by Fail Safe System
- ✓ Unattended Clinical Production 24/7 Now!
- ✓ Scale Up 1000X Easily
- ✓ Automatically Generates GMP Reports
- ✓ High Uptime Through On-Site Service
- ✓ Improve Process Economics by 50%



The Inside Story

The QuantaSep® Trusty 5000 system is mobile, compact, and capable of providing an operating flow range of 50-5000 ml/min. The integrated system has two positive displacement pumps, 8 buffer selection valves, inline mixer, filters and 6 fractions collection valves. It has capabilities of buffer switching, gradient formation, feed pre-filtering, air ejection, conductivity and pH sensing pre and post column, forward and reverse flow in powerful easy-to-use software package. The software enables buffer and fraction switching based on process conditions and alarms in the event of overpressure, air or leaks. All events are logged and archived.

The QuantaSep® Trusty 5000 hardware is composed of a fluid handling and control modules integrated into a single ergonomically designed counter high cabinet. The mobile floor standing unit is mounted on plastic castors with brakes for easy mobility. The computer that houses the control software is separated from the system to provide the option of remote operation. The system is compatible with 1M NaOH and

The QuantaSep® Trusty Hardware

Fluid Handling Module

The fluid handling module contains: 2 pump assemblies consisting of four (4) positive displacement metering pump heads, static mixer, and silicone tubing. These are connected with sanitary clamp connections to diaphragm shielded pneumatic valves, 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 is attached a leak detector.

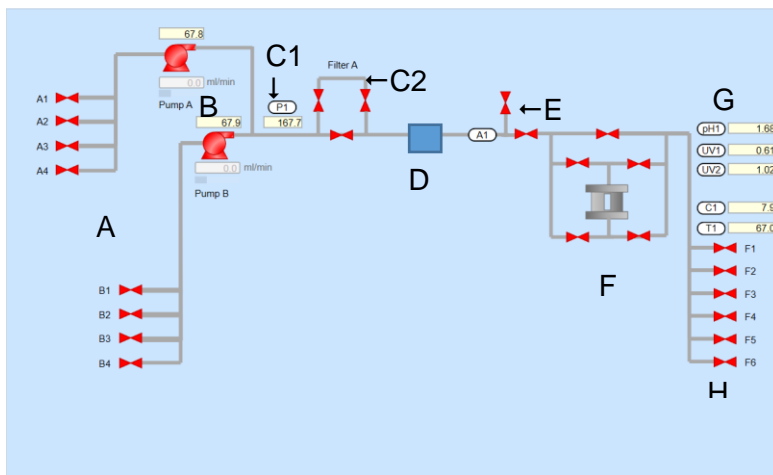


Figure 1

Controls Module

The controls module contains all power supplies, transformers, valve activation pneumatics, brainboards, 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.

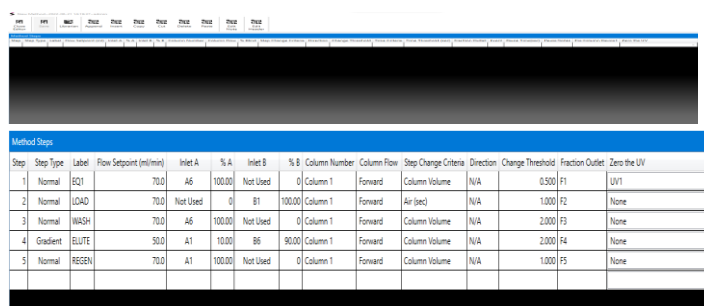
The QuantaSep® Trusty Hardware:

- (A) **8 selectable buffer ports** - Manifold of four pneumatically actuated diaphragm valves on each pump to provide flexibility.
- (B) **Two precision positive displacement pumps** - Each at 50-5000 ml/min are used to allow one to purify small and large amounts using the same unit.
- (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 pre-filter for debris or particular removal pre-column.
- (D) **Optional pH and conductivity sensors** - Can monitor pre-column pH and conductivity of buffers or load material. This helps prevent loading of 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) **6 user selectable fraction ports** - Fractions can be collected via a manifold comprising of 6 pneumatically actuated valves.

The QuantaSep® Trusty Software

The Right Combination of Simplicity and Power

The simplicity of the QuantaSep® Trusty 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 work station.



Step	Step Type	Label	Flow Setpoint (ml/min)	Inlet A	% A	Inlet B	% B	Column Number	Column Flow	Step Change Criteria	Direction	Change Threshold	Fraction Outlet	Zero the UV
1	Normal	EQ1	70.0	A6	100.00	Not Used	0	Column 1	Forward	Column Volume	N/A	0.500	F1	UV1
2	Normal	LOAD	70.0	Not Used	0	B1	100.00	Column 1	Forward	Air (sec)	N/A	1.000	F2	None
3	Normal	WASH	70.0	A6	100.00	Not Used	0	Column 1	Forward	Column Volume	N/A	2.000	F3	None
4	Gradient	ELUTE	50.0	A1	10.00	B6	90.00	Column 1	Forward	Column Volume	N/A	2.000	F4	None
5	Normal	REGEN	70.0	A1	100.00	Not Used	0	Column 1	Forward	Column Volume	N/A	1.000	F5	None

Figure 2

Intuitive Protocol Design

Programming is simple. Open the method editor by clicking on the icon on 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 load your product or program in a pause 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.

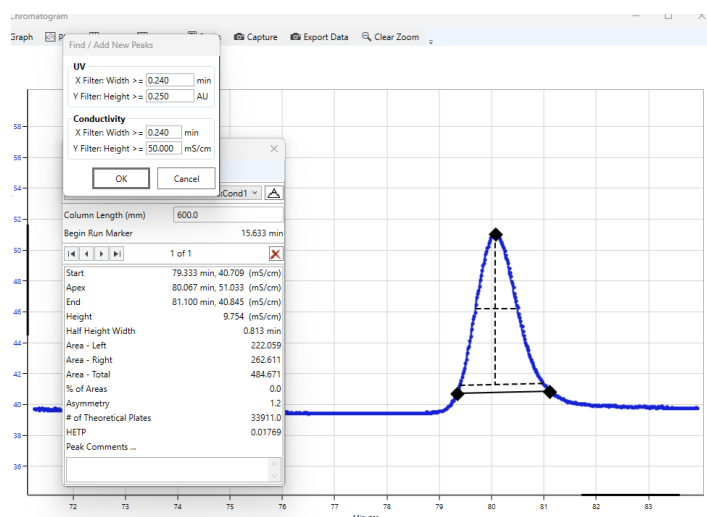


Figure 3

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.

Event Time	Description
00:00:01	Manual Mode running.
00:00:05	F9 open.
00:00:11	LCREV3 open.
00:00:11	LCREV3 open.
00:00:17	A2 open.
00:00:31	Pump A Flow Rate target is now 770.0 ml/min
00:00:34	Pump A running.
00:00:39	B3 open.
00:00:45	Pump B Flow Rate target is now 434.0 ml/min
00:00:47	Pump B running.

Figure 4

QuantaSep® Trusty 5000

General

- Automates buffer delivery, column switching, fraction collection, based on UV, pH and conductivity.
- Compact mobile system can fit in a small pilot plant or cold room.
- 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
- Sanitary Flow Path
 - Low system volume
 - Minimal dead legs
- Precision Hardware
 - Wier diaphragm valves
 - Positive displacement pumps
 - Large dynamic flow range
 - 100:1 turndown ratio for accurate gradients
- Sensors
 - UV, pH and conductivity sensors
 - Integrated flow cell
 - Optional pre-column pH and conductivity sensors
 - Optional second 254 nm UV capability
 - Pressure, temperature, air, leak
- Safety features
 - “Active air trap” minimizes “bubble trap dilution”
 - Optional pre-column filter with differential pressure sensors
 - Leak and pressure alarms
 - Built-in safety interlocks
 - Software method checks
 - Software security prevents unauthorized operation and tampering of data

QuantaSep® Trusty Has What It Takes

The QuantaSep® Trusty System can automate many of the routine manual tasks related to process development and free up key scientists’ time to handle additional mission-critical projects. It allows process development departments to manage deadlines to produce clinical/pre-clinical material, scale-up processes and troubleshoot or downscale production problems all within existing headcount and budgetary constraints. The payback for these systems has ranged from 3-18 months!



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QuantaSep® Trusty 5000 Specs

General

2 pumps – 4 plex positive displacement	50-5000 ml/min ±3%
Gradients	1-99% of FS
Valves – 0.5” diaphragm wier type	
System Volume	~650 ml
System Pressure	50 psi
Air Bubble Eject Size	>0.20”
UV Sensor (280 nm)	Range 0-2 Au; Path length 1.0 cm Accuracy ±0.05 Au
Conductivity Sensor	Range 0-200 ms; Accuracy ±5% F.S.
pH Sensor	Range 1-14; Accuracy ±0.2
Pressure Sensor	Range 0-100 psi; Accuracy ±1.0 psi

Materials of Construction (Wetted Parts)

Manifolds, Flow cell,	
Fitting Mixer	Polypropylene
Valve Diaphragms	PTFE
Tubing	Silicone
Gaskets	Silicone
pH Electrodes	Glass
Pump Body	Polypropylene & Ceramic
UV Flow Cell Window	Quartz
Pressure/Temp Sensors	316L Stainless Steel

Chemical Compatibility

1M Sodium Hydroxide, 19% Alcohol	
Operating Temp	4°C - 25°C

Utilities Requirement

Power Requirement	110/220V; 6Å
Air Requirement	Instrument quality Regulated air at 50psi

Physical

Mobile Unit on Castors with brakes
22” deep by 27” wide by 46.5 tall

Warranty, Installation & Support

All QuantaSep® Trusty systems are backed by Sepragen’s one year limited warranty. Installation and training, along with IQ/OQ are performed by the Sepragen Service Group. Preventive maintenance services are provided at additional cost. Validation support packages are also available.

To learn more call:
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