



QuantaSep® Trusty 1000 LX

Dual Range Lab/Pilot Hybrid Development and Scale-Up Chromatography System

QuantaSep® Trusty1000 LX is a unique dual flow range, hybrid Development and Pilot Scale Chromatograph System. This is Sepragen's most popular system in its large line of Chromatography Systems ranging from Lab Scale System with flowrate from 0-100 mL/min to Production Scale System capable of running up to 40Lpm or 2400LPH and several system sizes in between. The QuantaSep® Trusty1000 LX is a "two systems in one" chromatography system that enables the user to operate with process development scale columns 5mL to 500mL and switch to pilot/small scale process scale cGMP columns from 500mL to 10L in the same system.



This system has two different flowpaths in the system, one which contains two 0-100mL/min pumps and 1/16" tubing and valves that enable operation in the 0-100mL/min range with gradient capability. The second flowpath also built into the system consists of two pumps and 1/4" sanitary tubing and valves that enable a flowrate of 0-1000mL/min also with gradient capability. Twelve buffer selection valves, ten fraction valves and 3 column valves are available with each flowpath.

The QuantaSep 1000 LX system has UV, pH and conductivity sensors for monitoring the separation and air, pressure and leak to ensure optional trouble free operation. The system is powered by the powerful, user friendly WIN 10 based QuantaSep software which is CFR 21 Pt. 11 compliant. It enables easy manual operation by clicking on the P&ID diagram and automated operation via simple excel style recipe builder where flowrates, buffer and fraction selection and step change parameters of time, volume, bed volume, UV, UV slope, air etc are easily set. Live chromatograms that display trends of all process variables and real time comparison of multiple runs, zoom and scroll capabilities along with peak analysis offer means for easy data collection and decision making. Generation of cGMP run reports ranging from calibration to user access reports, process data and event and alarm logs are available for comprehensive reporting capability.

- 4 pump based operation with dynamic flow range
 - 1-100ml/min & 10-1000ml/min
- Automates buffer time, volume, column switching, fraction collection, based on UV, pH and conductivity etc
- Small footprint can fit on bench-top, laminar flow hood or cold room
- WIN10 based graphical, intuitive software "dashboard" for easy operation and training (21CFR Pt 11)
- Automated GMP reports
 - Complete batch reports
 - Event logs
 - Chromatograms and calibration history
- On Screen Pump & Sensor Calibration
- Precision hardware
 - 100:1 turndown ratio for accurate gradients in both flowpaths
 - Low system volume in each flowpath
 - Integrated pH, UV, condition flow cell
- Safety features
 - Active air trap minimizes "bubble trap dilution"
 - Leak and pressure alarms
 - Built in safety interlocks
 - Software method checks
 - Software security prevents unauthorized operation and tampering of data



The QuantaSep® Trusty1000 LX

QuantaSep® Trusty1000 LX Hardware

The QuantaSep® Trusty1000 LX hardware is composed of control and a fluid handling modules combined into a single ergonomically-designed counter top cabinet. The bench top unit can be cart-mounted for easy mobility. The computer that houses the control software which is included with the system, can be integrated with or

separated from the system to provide the option of remote operation. The system is compatible with 1M NaOH and alcohol for CIP operations and is operable at 4°C for cold room processing.

The fluid handling module contains: Two flowpaths with 4 pump assemblies each consisting of two rotary piston pumps, static mixer, and silicone reinforced tubing. These are connected with sanitary clamp connections to 6 diaphragm type inlet valves, 3 column selection (forward, reverse & bypass valves) and 10 fraction valves. There are independent connections for each of the two flowpaths and temperature and pressure sensors, air sensor, air purge valve are integrated into each flowpath. Post column the flow goes through a common set of UV, pH and conductivity sensors before being diverted into their respective fraction manifolds for each flowpath. The components are mounted inside an enclosed stainless steel cabinet with a trough to which a leak detector is attached for leak detection.

Dual Flowpath

Each flowpath of this system is designed for easy cleaning and reduced holdup volume. Only one flowpath can be run at a time. Choosing which flowpath to run is done through QuantaSep software.

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 status LED's, an emergency stop switch, cables, computer interface, fuse blocks, etc. are included as well.



The QuantaSep® Trusty1000 LX Hardware:

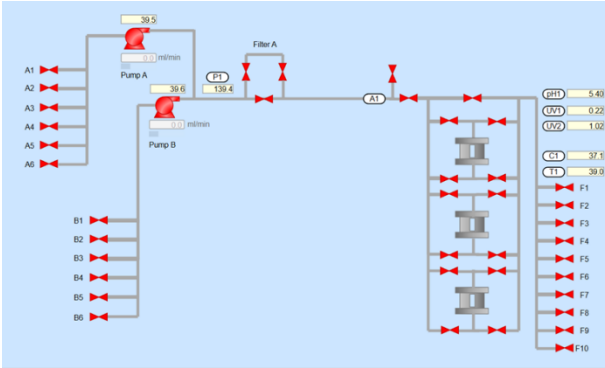
- (A) **24 selectable buffer ports per pump for total of 8** - Manifold of six diaphragm valves on each pump to provide flexibility ie 12 per flowpath
- (B) **Four precision positive displacement pumps** – Two pumps for 0-100ml/min range are used to allow one to purify small amounts and two pumps for 0-1000ml/min in the large flowpath are to enable large amounts of sample
- (C) **Pre-Column sensors** – Inline mixer, air sensor and pressure sensor in each flowpath
- (D) **Auto air eject** - An "active air trap" consisting of an air sensor and three-way air ejection valve continuously detects and for each flowpath removes unwanted air before the column thus preventing loss of raw material and valuable production time.
- (E) **Column forward/Reverse & Bypass capability manifolds for each flowpath** - 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.
- (F) **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.
- (G) **10 user selectable fraction ports** are available for each flowpath
- (H) **Lock Sensor** - Leaks in of the flowpath are instantly detected and alarmed



The QuantaSep® Trusty1000 LX

The QuantaSep® Trusty1000 LX 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.

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!

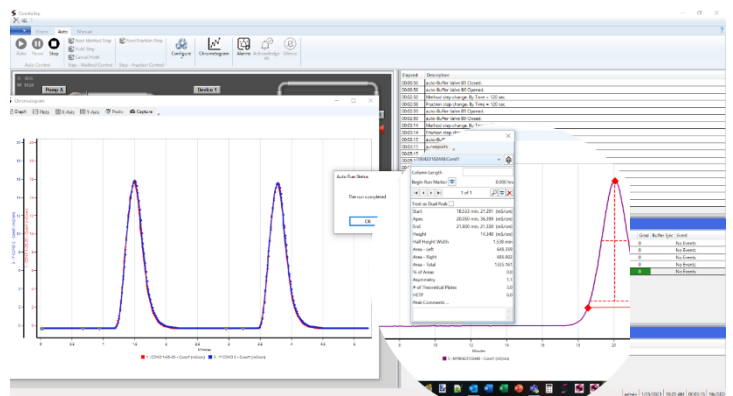
| # | Type | Label | A | B | A+B Flow mL/min | Col | Dir | FracV | CH Meth | CH Thrsh | CH Time | Slope | Gradient | Buffer | Event |
|---|------|----------------|---|----|-----------------|-----|-----|------------|------------|----------|---------|-------|----------|--------|------------------|
| 1 | - | HIC Rinse (a) | 0 | 49 | 1 | Fwd | 1 | Col Volume | 2,000 | 0 s | Pos | 0 | | | No Events |
| 2 | - | HIC Equil (a) | 0 | 49 | 1 | Fwd | 1 | Col Volume | 5,000 | 0 s | Pos | 0 | | | Pause Hold/Start |
| 3 | 1 | HIC Load | 1 | 25 | 1 | Fwd | 1 | Volume | 500,000 | 0 s | Pos | 0 | | | Zero the UV |
| 4 | - | HIC Wash 1 (2) | 3 | 25 | 1 | Fwd | 1 | Col Volume | 2,000 | 0 s | Pos | 0 | | | No Events |
| 5 | - | HIC Wash 2 (2) | 3 | 49 | 1 | Fwd | 1 | Col Volume | 4,000 | 0 s | Pos | 0 | | | No Events |
| 6 | - | HIC Elution | 0 | 1 | 49 | 1 | Fwd | 1 | Volume | 300,000 | 0 s | Pos | 0 | | No Events |
| 7 | - | Stop (X TE) | 0 | 4 | 49 | 1 | Fwd | 1 | Col Volume | 2,000 | 0 s | Pos | 0 | | No Events |

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 QuantaSep® Trusty1000 LX

QuantaSep® Trusty1000 LX Features

The Right Combination of Simplicity and Power



The QuantaSep® Trusty LX 1000 intuitive on-screen operations make the system easy to use from the moment you plug it in. The simplicity of QuantaSep® Trusty 1000 LX system's interactive graphical user interface gives the system its efficiency and power by making it easy to learn and use. You don't need to refer to printed flow diagrams and manuals.

QuantaSep® Trusty 1000 LX Has What It Takes

The QuantaSep® Trusty 1000 LX System can automate many of the routine manual tasks related to process development and advance key to meet mission critical deadlines. It allows process development departments to not (only optimize process parameters but also) 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!

To learn more call:

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QuantaSep® Trusty1000 LX Specs

- 2 x 12 user selectable buffers
- 2 x 3 user selectable columns forward/reverse/bypass mode
- 2 x 10 user selectable fractions with fraction collect capability
- Sanitary design
- Low flow range: 0-100 ml/min +/- 3%
- High flow range: 10-1000ml/min +/-3%
- Low flow hold volume: 18ml
- High flow hold volume: 120ml
- Small component footprint: 26" X 26" X 31"
- 5%-95% gradient capability
- Pressure rating: 50psi
- Low flow tubing: 1/16" I.D.
- High flow tubing 1/4" I.D.

Wetted Materials of Construction

Silicone, polyethylene and polypropylene tubing; polypropylene valves and fittings; P T F E diaphragms; glass/quartz/316L stainless steel sensor components

Components Specifications

280nm UV 0-2 Au
254nm UV 0-2 Au (optional)
Conductivity Sensor 0-200ms, +/-5%
pH Sensor 1-14 pH, +/-0.2
Air Bubble >0.20"
Pressure Sensor 0-100 psi +/-1psi
Leak Sensor 5ml leak volume

Warranty, Installation & Support

All QuantaSep Systems are backed by Sepragen's one year limited warranty. Installation and training, along with IQ/OQ are preformed by Sepragen Service Group. Preventive maintenance and Total maintenance service is provided at added cost. Validation support packages are also available.