Quantasep® 5000

Process Automated Chromatography System for Clinical Production

- Reduce Time to Market
- Improve Product Quality Reliability
- Reduce Batch Failures by Fail Safe System
- Unattended Clinical Production 24/7 Now!
- Scale-Up 500X Easily
- Automatically Generates GMP Reports
- High Uptime Through On-Site Service
- Improve Process Economics by 50%
The QuantaSep® 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® 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 alcohol for CIP operations and is operable at 4ºC for cold room processing.

**The QuantaSep® 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.

**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.

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**Figure 1**
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 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.

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.
## QuantaSep® 5000 Features

### 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 precolumn pH, and conductivity sensors
  - Optional second 254 nm UV capability
  - Pressure, temperature, air, leak
- Safety features
  - "Active air trap" minimizes "bubble trap dilution"
  - Optional precolumn filter with differential pressure sensors
  - Leak and pressure alarms
  - Built in safety interlocks
  - Software method checks
  - Software security prevents unauthorized operation and tampering

## QuantaSep® 5000 Specs

### General
- 2 pumps - 4 plex positive displacement
- 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 ±0.05Au
- 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
- Valve Diaphragms
- Tubing
- Gaskets
- pH Electrodes
- Pump Body
- UV Flow Cell Window
- Pressure/Temp Sensors
- Chemical Compatibility
- 1M Sodium Hydroxide, 19% Alcohol
- Operating Temp: 4°C - 25°C

### Chemical Compatability
- 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 90 psi

### Physical
- Mobile Unit on Castors with brakes 22" deep by 27" wide by 46.5" tall

To learn more!
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