



QUANTASEP® 10000

Process Automated Chromatography System for Clinical Production

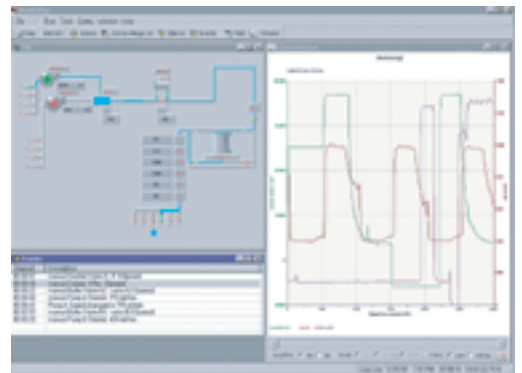
The QuantaSep® 10000 process chromatography system is mobile, compact, and capable of providing an operating flow range of 100-10000 ml/min. This sanitary system consisting of disposable tubing can process a 3000+ liter cell culture batch in one shift! It is ideal for GMP clinical manufacturing.

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. Precision pumping and mixing enables on-line dilution from buffer concentrates!

The QuantaSep® 10000 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 4°C for cold room processing.



QuantaSep® 10000 - Flow Range 100-10,000 ml/min



Intuitive, Easy to Use Software

8 Mission Control Ways a QuantaSep® Can Help Get Your Department In Control

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

QuantaSep® 10000 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 of data

QuantaSep® Has What It Takes

The QuantaSep® System can automate many of the routine manual tasks related to production and free up key operators time to handle additional mission-critical tasks. It allows the manufacturing departments to manage the deadlines to produce clinical material with consistent quality within existing headcount and budgetary constraints. The payback for these systems has ranged from 3-18 months!



SEPRAGEN
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QuantaSep® 10000 Specs

General

2 pumps - 4 plex positive displacement	
Gradients	100-10000 ml/min \pm 3% 5 - 99% of FS
Valves - 0.625" diaphragm wier type	
System Volume	1.2 L
System Pressure	50 psi
Air Bubble Eject Size	> 0.20"
UV Sensor (280 nm)	Range 0-2 Au; Path length 1.0 cm; Accuracy \pm 0.05Au
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 1.0 psi

Materials of Construction (Wetted Parts)

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

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 90psi

Physical

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

Warranty, Installation & Support

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

Call (510) 475-0650 to schedule a free confidential ROI/Efficiency assessment of your purification process.