



QuantaSep® Fusion FT Elite 2000

2 Column Continuous Flow Thru Systems with In-Line Buffer Blending

The QuantaSep Fusion FT Elite 2000 is a fully integrated Process Chromatography with Flow Thru skid integrated with Buffer making/blending capabilities running at a flow rate range of 30 ml/min to 2L/min. The product contact flow path is single use and can be easily removed, and a new flow path assembled in less than 1 hour. The system has capabilities of (1) Running straight through process chromatography functions on two Columns with pre-column feed adjustment (pH and Conductivity) and a post 2nd column nano filtration step. The systems are capable of switching inlet/outlet and column direction, air election, monitoring pressure, conductivity and pH sensing (pre and post column), UV, eluate switching for each column. Also, it can process steps based on process parameters such as time, volume, bed volume and process values for loading, equilibration, wash, elution, and regeneration. The system provides alarms in the event of overpressure, air, or leaks. The system automatically generates reports of batch history, sensor data and all alarms and events for cGMP reporting. (2) Producing Buffers from concentrated stock acid and base buffer components, salt and water. Different combinations of buffers are made from recipe builder that combines different proportions of these four fluids and (3) Being used in multi-product campaigns by exchanging product contact flow path. The Buffer making functions include enabling use of different recipes of buffers made from a combination of each of the four fluid components.



The Skid is composed of the fluid handling module and the electronic module integrated into a single unit. The fluid handling module contains all the fluid handling components such as Pumps, valves, sensors and interconnecting pipes. The Control and Electronic module contain the PLC, I/O modules, power supplies, transmitters etc. The floor standing unit is mounted on Plastic casters for easy mobility. The Casters can be locked if needed. The QuantaSep Fusion FT Elite 2000 is compatible with 1M NaOH and 20% alcohol for CIP operations and is operable at 4°C for cold room processing. The System is rated for 3 Bar pressure.

The Industrial computer on which the SCADA based control software resides and controls the Skid via a PLC can be operated from a distance to provide for remote control. The software operates in a MS Windows environment and is 21CFR11 compliant.

✓ Continuous Production 24/7 Now!

✓ Increase Plant throughput

✓ Eliminate Buffer Prep

✓ Reduce Space & FTE's

✓ Improve Process Economics

✓ Increase Resin Utilization

✓ No Cleaning Validation

✓ Multi-product production with little downtime



The Key Advantage

The Dual-column continuous Flow Through:

The Dual-Column Chromatography Module operates in a traditional batch mode with the exception of flowing the 'load' through two columns rather than one.

It adjusts in-line pH of the MAB (after viral inactivation) and feeds the adjusted antibody product from a capture system through a series of two columns, an anion exchange column and then adjusts the salinity of the flow through in-line prior to the flow through going on to the next Column.

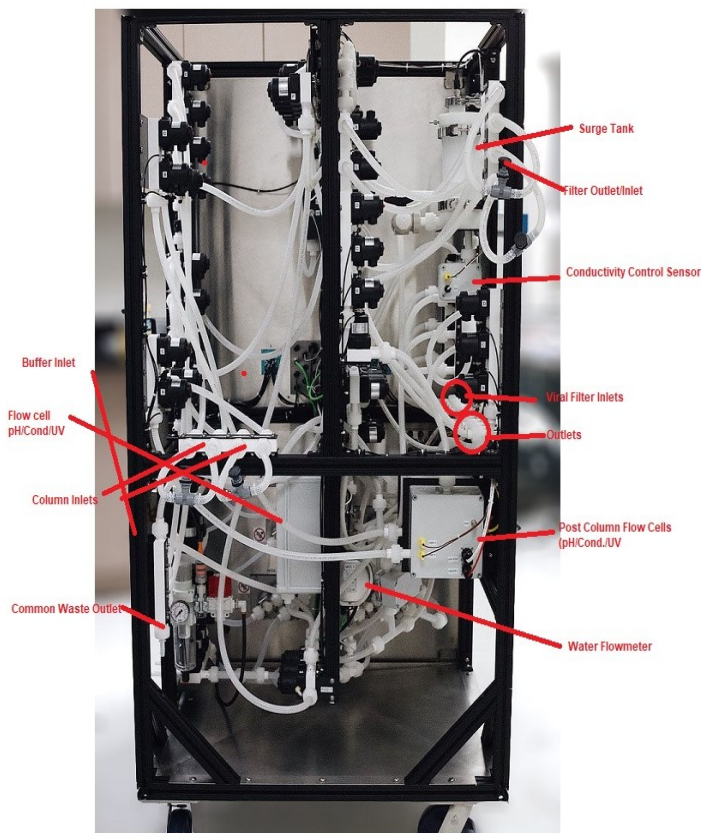
Thereafter the flow through goes through a nano filter to remove salt. Impurities such as leached Protein A, aggregates, host cell proteins and then salts are removed via these steps successively.

The flow-through is the purified antibody which is collected. Once the loading cycle is complete and the flow-through product collected, each column is independently washed, eluted, regenerated and equilibrated with buffers from the Buffer maker.

Column effluent from these steps involved with removal of impurities is sent to waste.

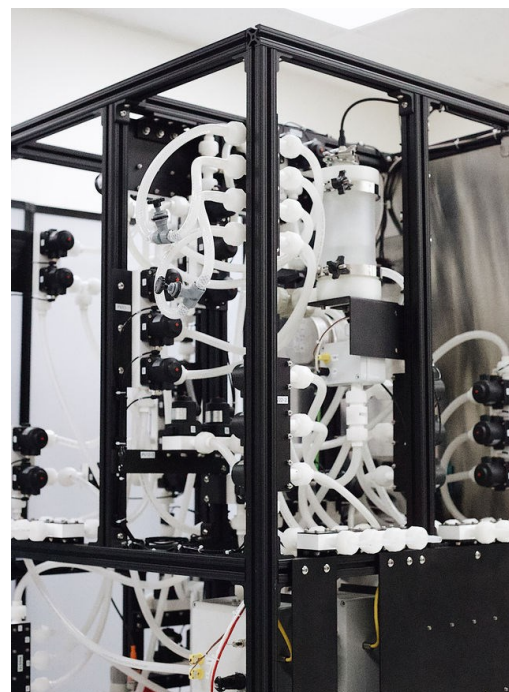
After equilibration, the next load cycle is started.

- It should be noted that the feed conductivity has to be adjusted by the addition of salt in-line prior to the 2nd Column.



In Line Buffer Maker

- The Buffer Making portion of the skid features five inlets for acid and base concentrated buffer components, salt and water.
- Each of the requisite component tanks has a positive displacement metering pumps followed by a flowmeter following which the lines are merged at an in-line manifold consisting of pneumatic valves followed by a static mixer that mixes the fluid components in line to provide a homogenous blend.
- Different buffer compositions are created by running the pumps at different flow rates and blending the resulting flow.
- The resultant fluid is then directed through pH and conductivity sensors, followed by an air sensor.
- The resultant buffer enters a final manifold, from which air can be ejected via a common waste line, or buffer can be directly collected or distributed to the rest of the system.



The QuantaSep® Fusion FT Elite Software

The Right Combination of Simplicity and Power

The simplicity of the QuantaSep® Fusion Elite 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.

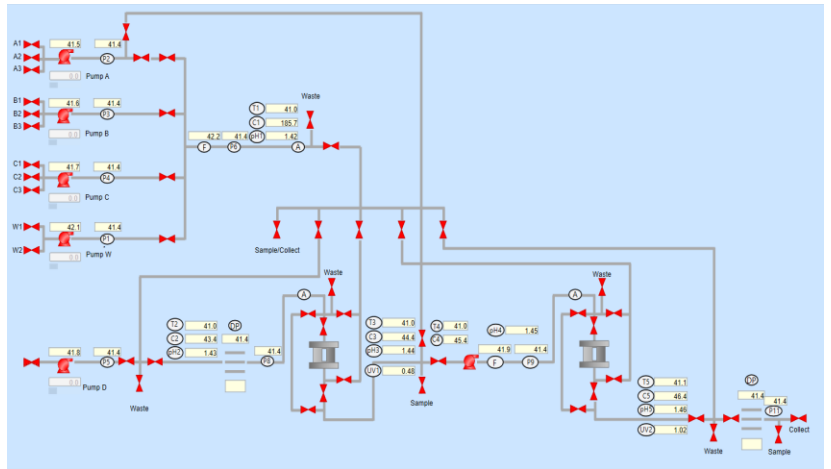


Figure 2

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!

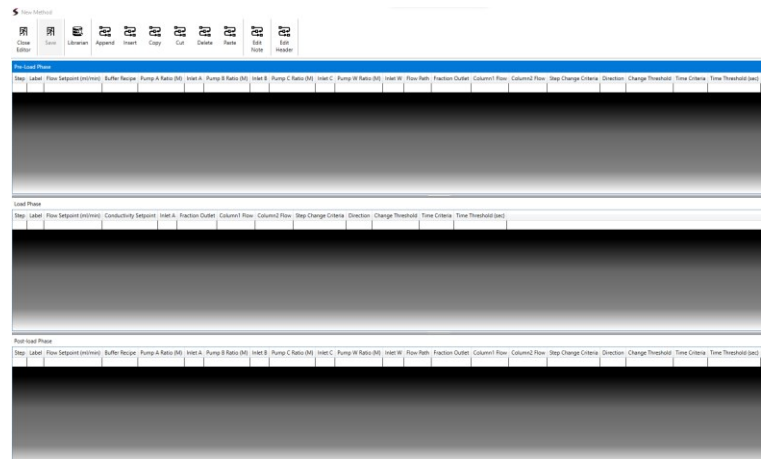


Figure 3

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.

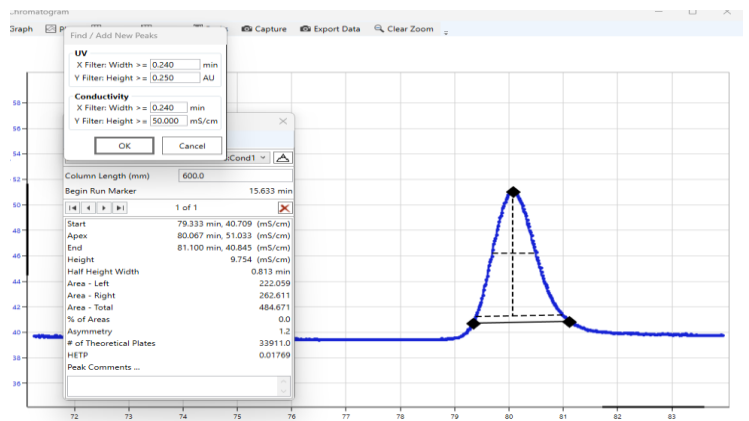


Figure 4

QuantaSep® Fusion FT Elite 2000 Has What It Takes

General

- Automates buffer making, 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.
- Automation and Control
 - PLC, Digital & Analog I/O & PC driven SCADA software
- Automated GMP reports
 - Complete batch reports
 - Method, Event and alarm logs
 - Chromatograms logged to disk
 - Calibration history
 - All trends stored once every second
 - Data Archival and Security
- Sensors
 - 2 **UV** detectors, one at egress of each column 280nm (Standard), 260nm (Optional)
Path length: 1.05 cm standard (0.1, 0.2, 0.5 cm optional)
Range: 0-2.0 AU/FS
Accuracy: $\pm 5\%$ of Reading
 - 5, **Conductivity** - 1x for buffer, 1x for feed line and 1x after each column; 1 after conductivity adjust
Range: 0.1 – 200mS $\pm 5\%$ Full Scale
 - 4 **pH** - Buffer, Feed and after each column
Range: 1 – 14 ± 0.1 pH
 - **Pressure** – 13 (5x Buffer Line, 8X Feed line)
 - **Temperature** – 4 – 30° C
 - **Air** – 3 (one for Buffer and two for feed line)
 - **Leak**
 - Bubble Trap – Optional (with Automatic Level detection and control)

Physical

Mobile Unit on Castors with brakes
48" deep by 36" wide by 60" tall

Warranty, Installation & Support

All QuantaSep® Fusion FT Elite 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



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General

Pump W -	2 L/m Positive displacement Rotary Pump
Pump A -	30 – 300 ml/m Positive displacement Rotary Pump
Pump B -	30 – 300 ml/m Positive displacement Rotary Pump
Pump C -	30 – 300 ml/m Positive displacement Rotary Pump
Pump D -	2 L/m Positive displacement Rotary Pump
Pump E -	2 L/m Positive displacement Rotary Pump

Pneumatic Mixing Valves
Sanitary diaphragm valves
Mixing Turn-down - 30:1 (low end 30ml/min)

Flow Meter - 2/5 (+0.1% - 1% Accuracy)

In-Line Mixer- 1 Static
Pressure- 0 – 50 psi

2 Column Manifold

Forward and Reverse and column Bypass

System Volume <1L (Excluding Bubble Trap and surge tank)
System Pressure 50 psi
Tube Size - 3/8" I.D.
Connection - Sanitary Mini Tri-Clamps

Surface Finish

SS wetted 0.8 μ m

Materials of Construction (Wetted Parts)

HDPE, P.P., PTFE, PVDF, Platinum cured or reinforced Silicone (USP Grade VI, ADI Free), Glass, 316 L SS, Ceramic, Quartz, Platinum and EPDM

Chemical Compatibility

1M Sodium Hydroxide, 19% Alcohol
Operating Temp 4°C - 30°C

Utilities Requirement

Power Requirement 20A @ 110 VAC
@ 50-60 Hz
Air Requirement Instrument quality
Regulated air at 50psi

To learn more call:

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