Superior results with SmartFlow Technologies’ complete family of validated cGMP automation packages

Complete cGMP turnover package

Low hold up volume

Complete drainability

Modular design accommodates OPTISEP® 7000 and 11000 holders

Designed to operate multiple membrane formats such as cassettes, hollow fibers, and ceramics

PUROSEP™ Gemini
Tangential Flow Filtration System

Full Featured cGMP Production System

As one of the industry’s leading innovators of filtration technology, SmartFlow Technologies has designed and built the PUROSEP™ Gemini to provide a robust production platform offering unparalleled versatility and performance. The Gemini’s feed and bleed loop design with dual rotary lobe pumps provides the required recirculation velocity for larger membrane area applications without fear of pump cavitation due to the action of the feed pump. The Gemini can be configured to meet the largest production volumes and throughput requirements.

This unique design provides unparalleled quality and lifetime in a manufacturing suite by utilizing high-end components, such as sanitary pumps, 316L stainless steel fluid path components, and high-resolution instrumentation. Intuitive, easy to use automation packages allow for precise process control and accurate measurement of operating conditions and membrane performance to assist you in optimal process quality control. Equipped with the Validated Controller software, cGMP production is up and running from time of delivery to hundreds of batches, years later.

The PUROSEP Gemini is offered in several pre-engineered standard capacities with retentate loop sizes ranging from 1” to 6”. For lower process volumes and dilute starting materials, the 1” retentate loop paired with the 1” OPTISEP® 7000 filter holder is the perfect solution to low hold-up volume, high concentration factor applications. The larger 3”, 4”, and 6” systems can accommodate far larger starting volumes. SmartFlow Technologies’ multi-loop Gemini designs with OPTISEP 11000 filter modules process fermentation volumes in excess of 100,000L. In addition to SmartFlow Technologies’ cutting edge, patented OPTISEP® filter modules and holders, the Gemini can operate other filter module formats such as hollow fiber, ceramics, and cassettes. This flexibility makes the PUROSEP Gemini the ideal manufacturing system.
### Applications

- Clarification
- Ultrafiltration
- Microfiltration
- Concentration
- Diafiltration

### Automation Packages

<table>
<thead>
<tr>
<th>Automation Package</th>
<th>Benefits</th>
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<tbody>
<tr>
<td>Gemini (Manual)</td>
<td>Economic solution providing manual control for system functions and two displays with alarms for process monitoring and protection</td>
</tr>
<tr>
<td>Gemini Manager (Operation Level Automation)</td>
<td>Programmable HMI for automated control of recirculation flow and trans membrane pressure (TMP) control</td>
</tr>
<tr>
<td>Gemini Controller (Procedure Level Automation)</td>
<td>Robust recipe building capabilities for complete walk away functionality</td>
</tr>
<tr>
<td>“Plus” Option (Data Recorder)</td>
<td>Add the “Plus” option to any of the above configurations to include integrated 21 CFR Part 11 data recording</td>
</tr>
<tr>
<td>Gemini Integrator</td>
<td>Completely automated process control combining the functionality of the Controller package above with integrated 21 CFR Part 11 data recording, and full PC based historian package</td>
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SmartFlow Technologies makes configuring the optimal system for your process easy by providing standard automation packages comprised of all required components to ensure the best solution possible. These packages include manual control (Manual), automated flow and TMP control (Manager Package), and fully-automated control with recipe mode for complete walk away functionality (Controller Package). Integration with your existing SCADA or process network is also possible with these automation packages. In addition to the standard automation offerings, SmartFlow Technologies offers a host of additional hardware accessories to accommodate the most demanding process. These optional accessories include:

- Stainless Steel Jacketed Tanks
- pH / UV / Conductivity Sensors
- 21 CFR Part 11 Compliant Video Recorder
- Steam in Place
- OPTISEP 7000 / OPTISEP 11000 Filter Holder and Module

The PUROSEP Gemini has been SmartFlow Technologies’ most successful product launch, installing systems on a worldwide basis since our inception. The unique dual pump feed and bleed design has proven so reliable that every system installed to date is still operational with minimal annual maintenance and instrument calibration. Typically, filter elements are installed with single pump system designs that frequently fail due to problems of pump cavitation and leaking seals. The Gemini designs eliminate all these difficulties by controlling the required cross-flow velocity via the recirculation pump and feeding the recirculation loop with the feed pump while bleeding the recirculation loop via the bleed control valve. These reliable standard designs feature low hold-up volumes and unprecedented reliability regardless of the service life and location requirements of your application. In addition to providing the most robust and technically advanced system, the Gemini is also backed by SmartFlow Technologies’ professionally trained applications and technical support staff.

When partnering with SmartFlow Technologies, you gain the advantage of decades of innovation and quality enhancements in both systems and filter modules. For a complete, high quality, turn-key solution, you can trust SmartFlow Technologies to deliver.
Specifications

| Tank | Multiple Stainless Steel Jacketed Tanks available |
| Feed Pump | Positive Displacement Rotary Lobe Pump per specification  
Capacities from 4 LPM to 250 LPM |
| Recirculation Pump | Positive Displacement Rotary Lobe Pump per specification  
Capacities from 16 LPM to 3,600 LPM |
| Flow Meters | Magnetic recirculation rate flow meter  
Mass flow meter for the permeate fluid  
Local and remote display on data acquisition video recorder |
| Retentate Flow Path | 316L SS, 15 Ra electro-polished (EP) ID, 32 Ra max OD  
Sanitary, re-sealable silicone tubing for permeate fluid |
| Filter Holder | OPTISEP 7000 / OPTISEP 11000, hollow fiber, cassettes, ceramic,  
and spiral housings and filtration elements |
| Retentate Loop | Two pump Feed and Bleed |
| Electrical Requirements | Typically 3 phase 50 Hz or 60 Hz per specification |
| Dimensions | Length: 63in. (161cm)  
Width: 39in. (99cm)  
Height: 73in. (203cm) |
Validation and Support

In addition to its market leading Applications and Technical Support, SmartFlow Technologies also offers Validation Support. These programs provide experienced and dedicated application specialists, process engineers, and validation support engineers to assist you with process development and process optimization programs as well as integrating PUROSEP systems and OPTISEP filter modules into your process so that you can more easily and quickly realize the benefits provided by SmartFlow™-TFF.

System and Options

<table>
<thead>
<tr>
<th>Description</th>
<th>Catalogue Number</th>
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<tbody>
<tr>
<td>PUROSEP Gemini</td>
<td>0050-00-00</td>
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<tr>
<td>OPTISEP 7000 Holder 1” TC Inlet/Outlet</td>
<td>40-900-2100</td>
</tr>
<tr>
<td>OPTISEP 7000 Holder 2” TC Inlet/Outlet</td>
<td>40-900-2200</td>
</tr>
<tr>
<td>OPTISEP 11000 Holder 3” TC Inlet/Outlet</td>
<td>70-900-2300</td>
</tr>
<tr>
<td>OPTISEP 11000 Holder 4” TC Inlet/Outlet</td>
<td>70-900-2400</td>
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<tr>
<td>UV Absorbance Sensor</td>
<td>NSUB-05-01</td>
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<td>pH &amp; Conductivity Sensor</td>
<td>NSUB-05-30</td>
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<tr>
<td>Steam in Place Piping</td>
<td>0050-SIP</td>
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<tr>
<td>Filter Cart</td>
<td>0050-53-02</td>
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To Place an Order or Receive Additional Information, please contact our global headquarters:

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SmartFlow™ TFF: “Delivering the promise of TRUE TFF Functionality”

The SmartFlow™ performance advantage comes from the patented SmartFlow tangential flow filtration technology. The SmartFlow technology in the OPTISEP® filter modules is comprised of two primary developments: 1) unique flow channels and 2) diagonally opposed inlet and outlet ports provide uniform fluid dynamics. These advancements allow for consistent fluid distribution across the entire membrane surface. The benefits of SmartFlow technology include: improved cleaning, increased flux rate, true linear scalability, and increased yields resulting in more efficient downstream processes than in traditional TFF.