



## SciLog® FD System

- final bulk filtration & dispense
- fully automated processing
- fully enclosed sterile flow path

The SciLog® FD System is an automated single-use system for the bulk filtration and dispense of biopharmaceutical products into either bags or bottles.

Both the hardware and the consumables have been designed in tandem to minimize product losses and maximize yield.

As the flow path is completely enclosed, the two operations of filtration and dispensing can be performed in areas of lower classification, thereby eliminating the need for vertical laminar flow cabinets.

The SciLog® FD System is designed and built to ensure containment, protecting both the operators and the product.

### Features and Benefits

#### Automated system for filtration and dispense of bulk pharmaceutical ingredients

- Standardized and simple operation
- Recipe driven process control
- Significant operational cost savings
- High dispense accuracy coupled with low processing time
- Reverse flow and purge options maximize product recovery
- Fully enclosed system protecting the operator and product
- Optional manifold integrity test ensures leak free processing

#### Flexibility in functionality and filling format

- Compatible with bags or bottles
- Four standard dispense modes

#### Supports compliance and regulatory requirements

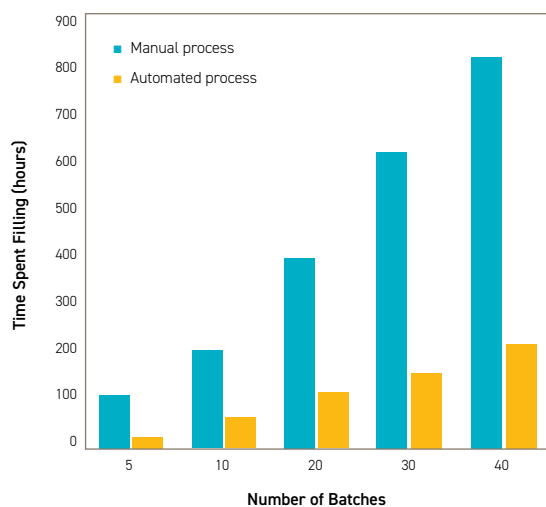
- Full validation package available
- Fully programmable alarms and interlocks protect the product and the process
- Calibrated SciPres pressure monitors ensure validated limits are not exceeded
- Option to specify ten samples during dispense process
- Optional in-line pre- and post-use filter integrity test
- Integrated label printer
- Full audit trail and batch record data securely retained

#### Custom designed manifolds

- Available gamma irradiated or with sterile claim
- Designed to minimize product hold-up
- Standardized manifold families reduce inventory requirements
- Validated bottle shipping solution available to reduce risk of damage in transit.



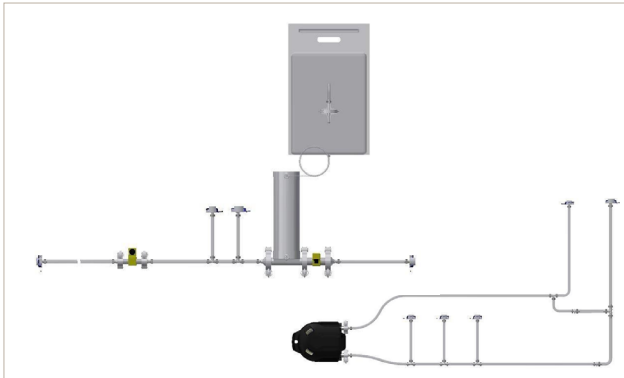
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Time Saving With Automation

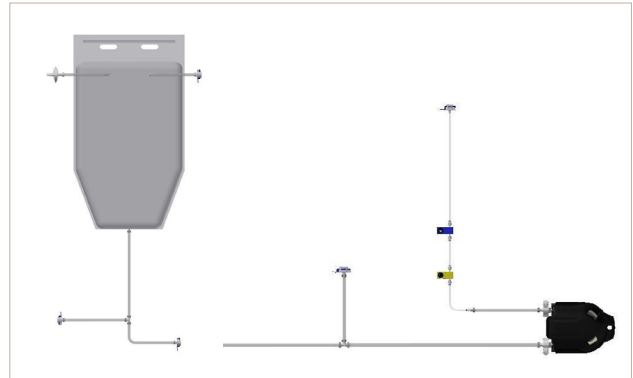
## Standard Assemblies

A family of standard assemblies are available for the SciLog® FD System to facilitate ease of use and minimize inventory. Delivered within eight weeks, assemblies can be supplied gamma irradiated or with a full sterility claim.



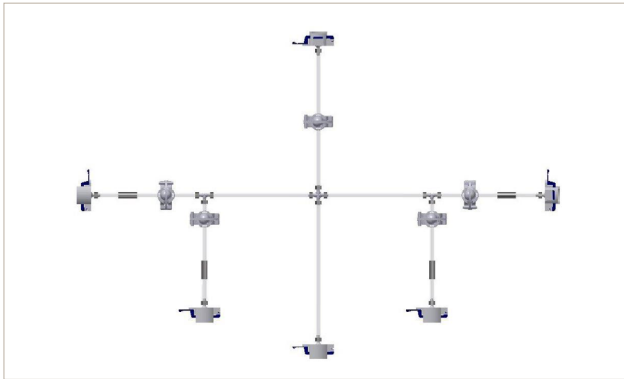
### Filtration Manifold

- Vendor neutral filters
- In-situ flushing conditioning and integrity testing



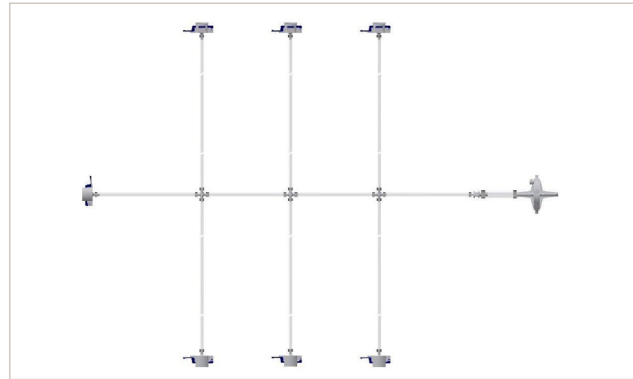
### Header Bag

- Ensures efficient filling process
- Optional (system can be fed directly from off skid bag or tank)



### Multiplier Manifold

- Allows large batch processing



### Dispensing Manifold

- Bags or bottles
- Minimal connections and hold-up volume

## Validated Shipping Solution

Drawing on extensive material science expertise within Parker, and in collaboration with users, key issues associated with foaming during filling, variable sealing of bottles at low temperature and transport damage risks have been addressed.

### Patented Sealing Technology



- Integrity validated down to -89°C
- Wide range of connections available
- Silicone or TPE tubing

### Integrated J-Tube



- Foaming minimized
- Filling time optimized

### Protective Transport Cap

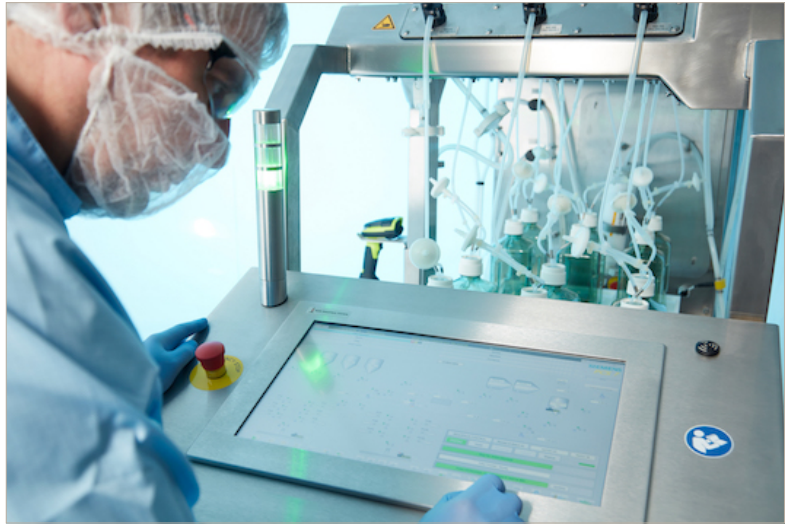


- Validated shipping
- Crimped tubing protected during shipping via transport cap
- Validated to ASTM D4169

## Software

The SciLog® FD software incorporates an intuitive HMI based on industry standard PLCs. It will communicate with common SCADA or BMS platforms via OPC.

- Simple recipe driven processing
- Four user access levels
- Three dispense modes:
  - Manual
  - Semi-automatic
  - Automatic
- Batch records creation and storage
- Audit trail
- User configurable alarms
- Diagnostic monitoring of critical components
- Enables compliance with 21 CFR Part 11 and EudraLex Vol 4, Annex 11
- Barcode reader for tracking of manifolds
- Software developed to GAMP 5



## Global Services and Support

### FAT

- Included

### IQ/OQ

- Standard documentation available
- Execution support available

### Training

- Standard user training included
- Custom packages available

### SAT

- Standard documentation available
- Execution support available

### Maintenance and support

- Standard package available depending on use
- Custom service and support packages available

## Specifications

System Detail	
Approx. Footprint	0.9 m (W) x 2.5 m (L) x 2.2 m (H) / 35" (W) x 98" (L) x 87" (H)
Label Printer	Cryogenic compatible labels
IP Rating	IP 54
Integration	OPC driven communication with third party systems
Material of Construction	316L stainless steel (frame and cabinet)
HMI / PLC	19" touch screen
Load Cells (Receiving)	2 (0 - 120 kg range)
Load Cell (Intermediate Bag)	2 (0 - 100 kg combined)
Pump	2 peristaltic (transfer and dispense)
Filling Range (Volume)	50 ml to 20 L
Receiving Containers	Bottles or bags
Filling Points	Maximum of 12 per cycle (batch limit 9999)
Pressure Rating Assemblies	1.2 barg / 17.4 psig (3.4 barg / 49.3 psig reinforced section for integrity testing)
Max / Min Flow Rate	0.04 L / min and 12.0 L / min (design flow rate 19 L)
Product Recovery	Pump and / or air blow down
Dispense Accuracy	1000 - 2000 g $\pm$ 10 g (Accuracy dependent on dispense rates)

Compliance	
21 CFR Part 11	Software enables compliance
EudraLex Vol 4, Annex 11	Software enables compliance
GAMP	Meets the requirements of GAMP 5
CE MARK	Yes
2006/42/EC	Machinery Directive
2014/68/EU	Pressure Equipment Directive
2014/30/EU	Electromagnetic Compatibility Directive
ATEX	No
Recipe Creation	Follows S88 protocol
Validated bottle shipping	ASTM D4169 - Cycle 13 level 11
Sterile Assemblies	Current ISO 11137

Utilities	
Power Requirements V / Hz / Ph	230 / 50-60 / 1
Compressed Air Quality	Minimum ISO 8573-1:2010 [-:4:-]
Air Supply Pressure / Volume	5.5 barg (79.8 psig) / <0.2 m <sup>3</sup> /hr
Operating Environment Temperature	5 - 30°C (41 - 86°F)
Noise Level	<80 dB (A) at 1 m
Approx. System Weight	700 kg

## Ordering Information

**386-FD-440PS-02**

Please contact your local Parker representative to discuss your application in detail