SCILOG® NFF+ PM

The manual support unit for bioprocessing.

Designed to address filtration and PUPSIT (pre-use post-sterilization integrity testing), the SciLog® NFF+ range supports compliance to EU GMP Annex 1 (2022) for final fill and bulk filling applications.

The SciLog® NFF+ PM is a stand-alone unit for intuitive installation of the manifold and handling during the bioprocess. This enables efficient filtration and supports the execution of pre-use post-sterilization integrity testing (PUPSIT) and post-use integrity testing of the sterilizing filter.

The mobile solution requires the use of an external integrity tester, pressure monitoring, and pump.

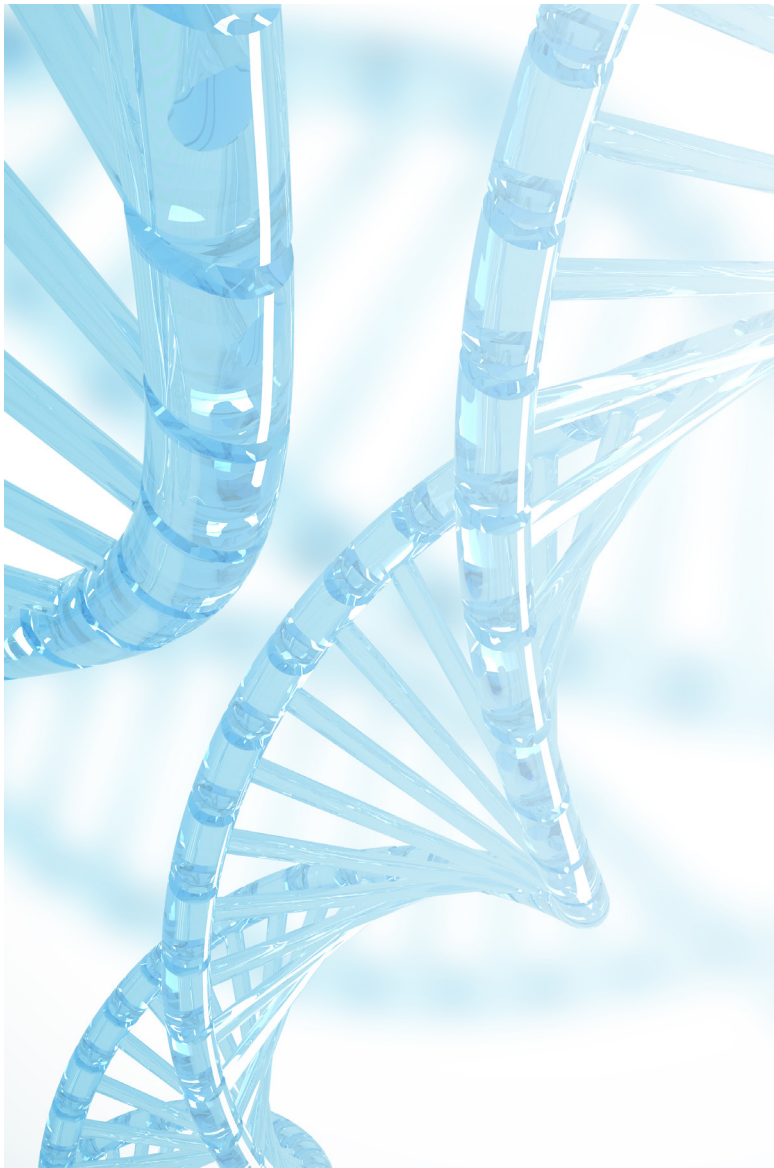
Fig.1 - SciLog® NFF+ PM

Features

- Manual valve control
- Configured to support the manifold in a vertical position, with tube and component supports
- Designed in a compact footprint
- To be used in-line with GMP manufacturing
- Castor mounted and fully mobile
- Redundant filtration variant available (SciLog® NFF+ PMR)

Benefits

- Complete process visibility with upright support - system design
- Improved handling with intuitive installation and operation
- Simple integration into current process
- Closed system designed for the cleanroom
- Upstream component supports positioned to minimize air traps



Specifications

Feature	SciLog® NFF+ PM Manual sterilizing NFF skid with PUPSIT capability	SciLog® NFF+ PMR Manual sterilizing NFF skid with PUPSIT capability for redundant filtration
Enclosure and Rating	316L stainless steel (304L body available on request), mobile platform. Clean room compliance.	
Application (examples)	Bulk filtration Final fill	
Number of Product Sterilizing Filters	1	2
Product Filter Size	1" to 30"	
Valve Control	Manual	
Pressure Sensor Type	Single-use, in-line sensors and fixed or membrane sensors options available.	
Number of Pressure Sensors	2	4
SciPres® Monitors Required	1	2
Pressure Sensor Connections	3	6
Pump Options	Pump not included (additional cost)	
Flow Rates	Pump dependent	
Dimensions (W x H x D) approx	1.2 x 1.9 x 0.7 m	1.5 x 1.9 x 0.7 m

PUPSIT Support and Consultancy

Parker Bioscience, we understand there may be challenges in the implementation of PUPSIT with retrofitting and validation, conditions of the clean room, integration and limited footprint. Parker can support with the integration of PUPSIT with automation and single-use technology.

Redundant Filtration

Redundant sterile filtration is employed to mitigate the risk of post-use filter integrity test failure in the primary filter. The incorporation of redundant filtration creates an additional complexity with the added flow paths and connections. The SciLog® NFF+ PMR with redundant filtration offers an integrated solution, with a designated flow path.

Single-use Manifolds

Parker offers a portfolio of components to develop a single-use solution suited to your process. This can be designed in tandem with your SciLog NFF+ system solution to ensure effective processing and liquid handling. Design factors include low hold-up volume, upstream/ downstream sampling, integrated waste bag etc.

If your process is validated with specific components, we aim to integrate these into the design, where possible. The manifold can be designed within the footprint of the system.

System Support and Documentation

- Factory Acceptance Testing (FAT) and Site Acceptance Testing (SAT) - where applicable
- User training, if required
- Installation, operation and maintenance instructions
- Material certificates
- Hardware Design Specification (HDS)

Additional Support Options

- Retrofitting and process validation support
- Servicing
- On-site training
- IQ / OQ / PQ document package(s)
- IQ / OQ execution

DOWNLOAD WHITEPAPER
Application of Pre-Use Post-Sterilization Integrity Testing (PUPSIT)

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Date of Issue: 03/25