SCILOG® NFF+ PS

Semi - Automated NFF with PUPSIT capabilities.

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+ PS is a multipurpose Normal Flow Filtration (NFF) system designed to facilitate the execution of pre-use and post-use filter integrity testing, with semi-automated control.

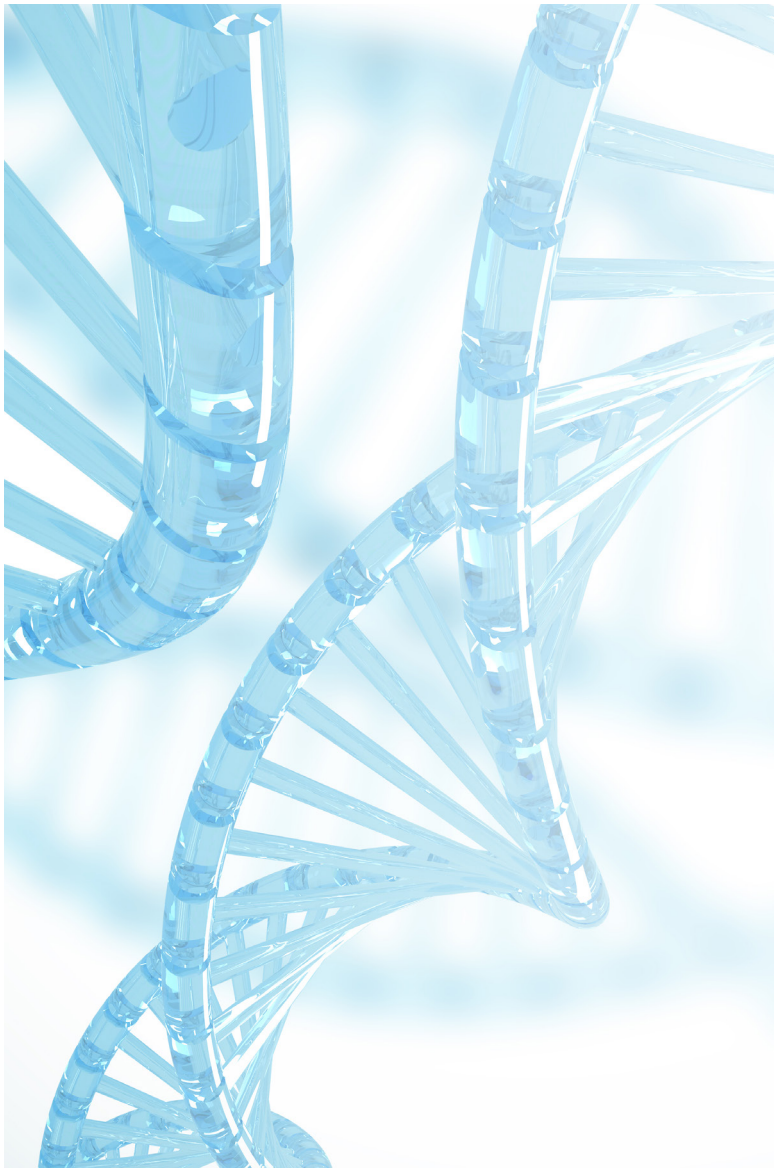
Combining single-use sensing technology and automation, the system is designed to overcome operator challenges with fluid-air management. Configured with defined flow paths, the operator can select a process step, enabling the pneumatically-controlled values to automatically configure the flow path.

The system supports the use of an external integrity tester and pump, incorporated within the compact footprint for GMP operating environments.

Fig.1 - SciLog® NFF+ PS

Features

- SIEMENS TIA Portal based control system
- Pre-defined options for valve control for final fill process steps, including PUPSIT and post-use integrity testing
- Execute PUPSIT as part of the sequence before continuing to product processing
- Visual indicator for valve positioning (open / closed)
- Touch-screen HMI with intuitive graphical interface
- User configurable alarms and interlocks
- Supports the use of an external integrity tester, pressure monitoring and pump
- Redundant filtration variant available (SciLog® NFF+ PSR)



Benefits

- Improved efficiency with intuitive manifold installation and programmed process operations.
- Error-proofing approach and complete process visibility.
- Process step selection supporting automated valve control for simplified process operation and minimizing human error.
- Supports use of an external integrity tester enabling the use of validated equipment.
- Sterilizing filter can be integrity tested and validated on the system, before proceeding to filtering; or integrity testing the sterilizing filter post-use directly on the system / in the assembly - optimizing process steps/ resource and minimizing risk of batch losses.
- Closed system designed for the cleanroom.

Functionality

The Scilog® NFF+ PS is designed to provide a simplified solution for PUPSIT integration during the final fill. Figure 2 is an example sequence with the process steps available with the Scilog® NFF+ PS system.

Single-use Manifold

The manifold can be designed within the footprint of the system, configured to ensure a low hold up volume. If your process is validated with specific components, we aim to integrate these into the design, where possible. The single-use manifolds can be provided gamma irradiated (Sterile to ISO 11137) .

PUPSIT Support

At 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.

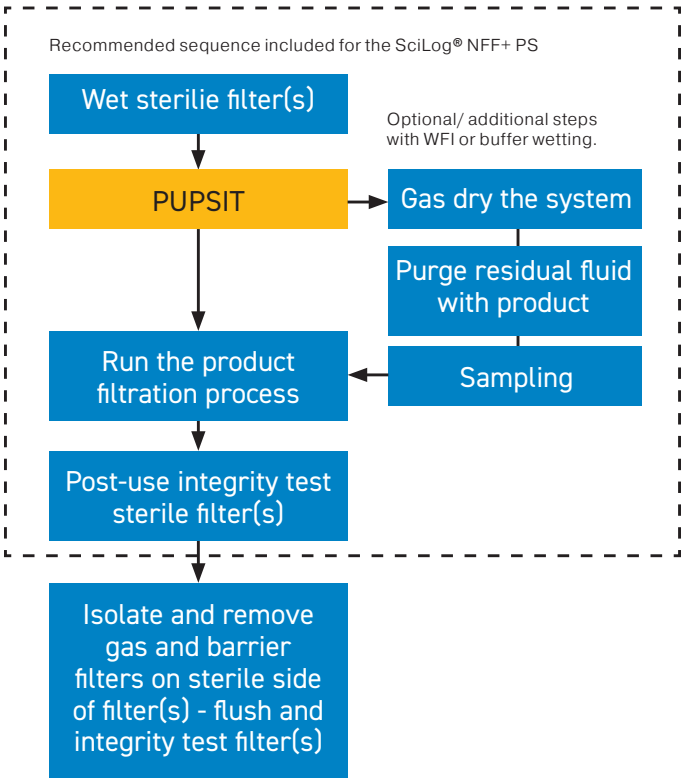


Fig 2 - SciLog® NFF+ PF automated sequence and capability

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+ PSR with redundant filtration offers an integrated solution, with controlled flow paths - simplifying PUPSIT execution.

Specifications

Feature	SciLog® NFF+ PS Semi-automated sterilizing NFF skid with PUPSIT capability	SciLog® NFF+ PSR Semi-automated 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. IPx5.	
Application	Bulk filtration Final fill	
Number of Product Sterilizing Filters	1	2
Product Filter Size	1" to 30"	
Valve Control	Pneumatic	
Pressure Sensor Connections (DIN) - Optional DinPress® or SciPress® monitor	3	6
Pump Options	Pump not included (additional cost)	
Flow Rates	Pump dependent	
Control System	SIEMENS S7 -1500 with TIA Portal	
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

Flow Path Control Options

The system can be configured with defined steps and flow paths, enabling the operator to select a function to control the pneumatically actuated valves. Automated valve controls ensure the correct flow paths are always created - simplifying the execution of the filtration process and handling by the operator. This supports fluid- air control, optimizing filter wetting, and minimizes fluid hold up and waste.

The selectable steps could include:

- Manifold installation / uninstallation
- Line priming
- Filter wetting
- Flush to waste
- Product filtration to filling line
- Filter integrity testing, including filter wetting, pressure hold and venting
- Upstream and / or downstream sampling
- Product recovery / blowdown

Inlets to the flow path would require your specified connections to connect to the process pump and integrity tester.

System Support and Documentation

- Factory Acceptance Testing (FAT) and Site Acceptance Testing (SAT)
- User training during FAT and SAT
- Declaration of conformity
- Installation, operation and maintenance instructions
- Pneumatics and Instrument Diagram (P&ID)
- Electrical schematic
- Critical spares list with manuals or datasheets
- Material certificates
- GAMP document package including:
  Functional Design Specification (FDS),
  Hardware Design Specification (HDS),
  Software Design Specification (SDS)

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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