

# SCILOG<sup>®</sup> NFF+ PF

## Automated NFF with PUPSIT capabilities.

Designed to be integrated into your downstream bioprocess, the SciLog<sup>®</sup> NFF+ PF supports compliance to EU GMP Annex 1 (2022) for final fill and bulk filling applications. The SciLog<sup>®</sup> NFF+ is a multipurpose Normal Flow Filtration (NFF) system with on-board Pre-Use Post-Sterilization Integrity Testing (PUPSIT), in a compact footprint for GMP operating environments.

Combining single-use sensing technology and automation, the system guides the operator through PUPSIT and the bioprocess to minimize user error. The fully automated sequence can be configured to monitor, adjust and record pressure and flow rate, to optimize processing times and maximize filter life and efficiency.

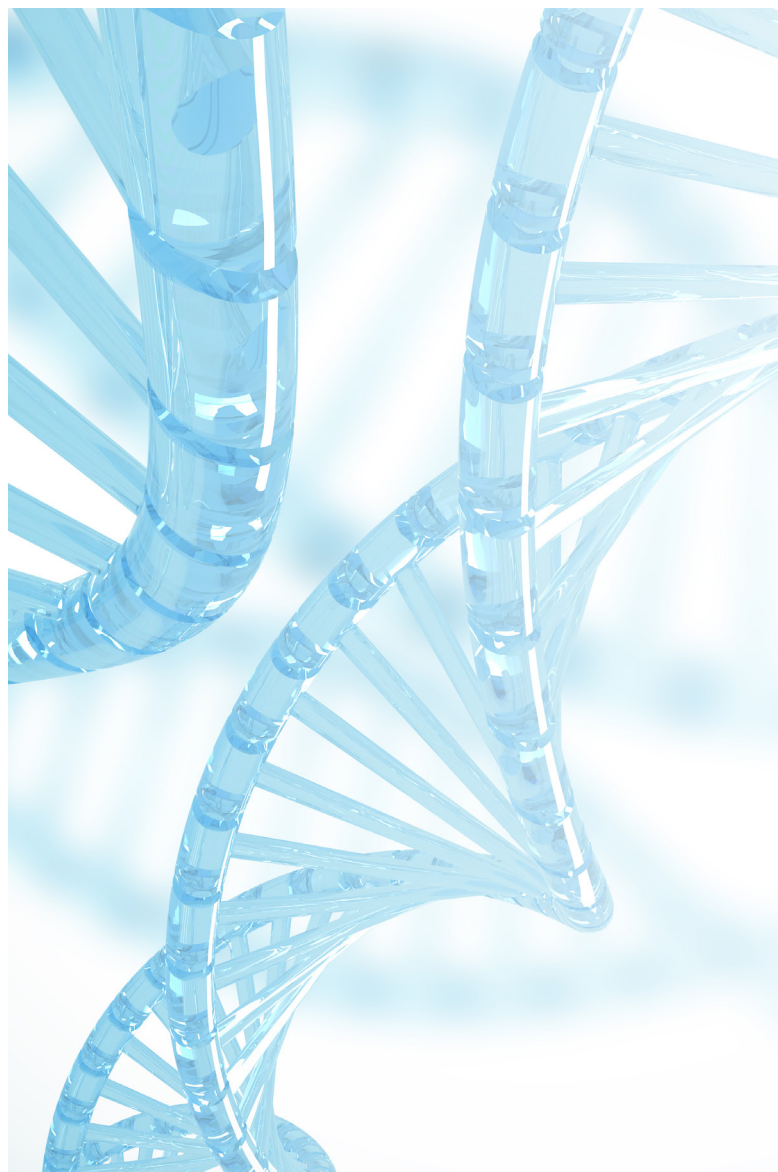
The integrated PUPSIT capability allows for the integrity of the filter to be validated before progressing to product filtration.



Fig.1 - SciLog<sup>®</sup> NFF+ PF

## Features

- Configurable recipe creation to control the process
- SIEMENS TIA Portal based control system
- On-board integrity testing capability
- GMP compliance, including FDA 21 CFR Part 11 and EudraLex Annex 11
- Adheres to the S88 standard for effective batch process control
- Touch-screen HMI with intuitive graphical interface
- Manual mode control through HMI
- User configurable alarms and interlocks
- Communicate real-time process parameters via OPC to a plant historian and integrate with local active directory, or operate as a stand-alone unit
- Up to two integrated scales for highly accurate filtration endpoints (optional)
- Redundant filtration variant available (SciLog<sup>®</sup> NFF+ PFR)



## Benefits

- Manifold leak test on installation
- PUPSIT to validate filter integrity directly before processing
- Post-use testing to validate filter integrity after the the process
- User-friendly workflow
- Designed to mitigate operator error

## Functionality

The SciLog® NFF+ PF is an advanced offering, designed to provide a simplified solution for PUPSIT integration during the final fill. Figure 1 summarizes the functionality of the SciLog® NFF+PF systems.

## Customization

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

## 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.

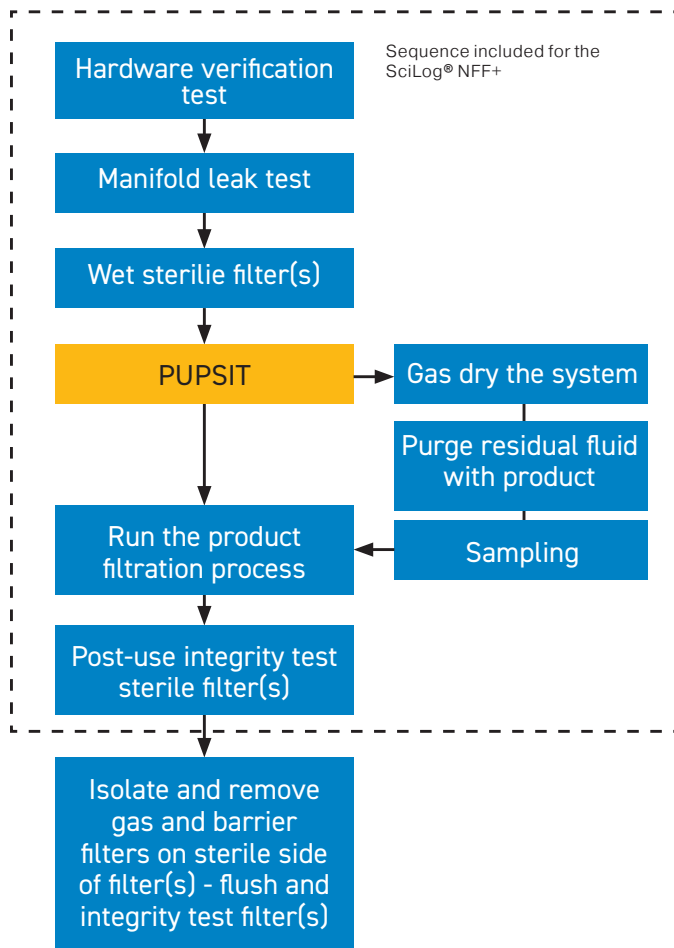


Fig 2 - SciLog® NFF+ PF automated sequence and capability

## 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+ PFR with redundant filtration offers an integrated solution, with designated flow path to simplify and support PUPSIT execution.



Figure 3 - SciLog® NFF+ PFR with redundant filtration

## Specifications

Feature	SciLog® NFF+ PF Sterilizing NFF skid with PUPSIT capability	SciLog® NFF+ PFR Sterilizing NFF skid with PUPSIT capability with redundant filtration
Enclosure and Rating	304L stainless steel framework (316L 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"	
Pressure Sensor Connections (DIN)	3	6
Number of Pressure Sensors	up to 2	up to 4
Pressure Sensor Type	Single-use, in-line sensors and fixed, membrane sensors options available	
I/O Ports	Ethernet port for plant communication. Connections for 2 x scales	
Operational Modes	Constant flow, constant pressure, R/P Stat, and manual mode	
Pump Options	Peristaltic or Diaphragm	
Flow Rates	0.2 - 6.5L/min	
Control System	SIEMENS S7 - 1500 with TIA Portal	
Software Compliance	FDA 21 CFR Part 11, EudraLex Annex 11	
Connections to DCS	OPC, Ethernet IP	
Dimensions (W x H x D)	1.2 x 1.9 x 0.7 m	1.5 x 1.9 x 0.7 m
<b>Other Features</b>		
Automated Manifold Leak Test	✓	✓
Filter Integrity Test (Pre-use and Post-use)	✓	✓
Flexible Filtration Methods	✓	✓
In-line Sampling	✓	✓
Filter Drying	✓	✓
Optimized Product Recovery	✓	✓
Active Directory Integration	✓	✓
Customizable Filter Selection	✓	✓
Redundant Filtration	x	✓

### Support Included with System

- 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
- WeighStation™ measurement options



#### DOWNLOAD WHITEPAPER

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



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Date of Issue: 12/24  
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