

mPath™

OPERATIONAL INSIGHTS SOFTWARE (OIS)

mPath™ operational insights software is a centralized data analytics solution, facilitating root-cause identification of filter integrity false fails, errors and aborts, and reducing test-related wasted time. It aids in monitoring compliance to 21 CFR Part 11 and data integrity requirements, and it offers instant troubleshooting guidance to bring false fails to pass, improving process efficiency in individual cases.

Designed to facilitate process visualization and asset management, mPath OIS interfaces with the Palltronic® Flowstar IV and V filter integrity test instruments, centralizing audit trails, test records and test results analytics. It helps better visualize all integrity test instruments on site, detailing their calibration and maintenance status, and the number of tests performed per device. Thanks to real-time data transfer and acquisition, mPath OIS sends alerts to enable prompt action to improve process efficiency and reduce downtime.

Features and benefits

Features	Benefits
Real-time data analytics provides an overview on pass/fail/error/abort	Improves process efficiency
Troubleshooting guide to help bring false fails to pass	
Real-time alerts on test failures to enable quicker response times	Facilitates quality risk management
Analyzes audit trails for non-compliance and alerts for suspicious behavior	Facilitates monitoring regulatory compliance
Intuitive navigation	Readability, comfort, more accurate operation
21 CFR Part 11 compliant	Meets regulatory requirements
Electronic records and user access rights	Limits uncontrolled access
Test repeat comparison feature	Supports high quality levels or batch release
Configurable audit trail dashboard	Facilitates the detection of unauthorized record editing
Lightweight directory access protocol (LDAP)	Controlled easy access with less chance of forgetting user ID and password
Configurable reports out and automated backups	Reduces operator interaction, setup times, manual input errors



Fig 1. mPath operational insights software interface.

Modules

The software has six modules:

- Dashboard
- Reports
- Test analytics
- System analytics
- Settings
- Application configuration

1. Dashboard

Provides a centralized interface to view overall asset management and system events.

- Palltronic Flowstar filter integrity test instrument status: Offers a real-time overview of your entire fleet of instruments. At a glance, you can view the status of your systems and any alarms that need your attention.

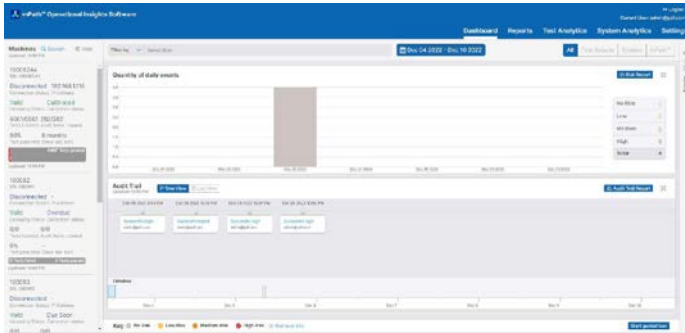


Fig 2. List of instruments and overview of their connectivity and calibration status.

- Summary of quantity of events with different configurable risk levels: Allows users to categorize events according to four distinct risk groups, with the ability to narrow the viewing selection to an event related to machine name / serial number, user, test type, filter serial number, product batch number, test program name / ID, test filter, product code, test outcome, and/or wetting liquid.

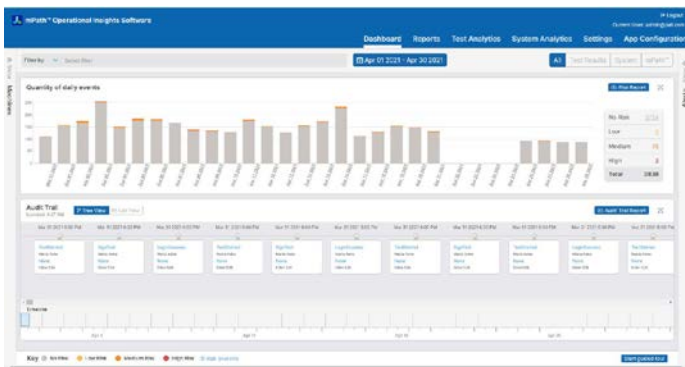


Fig 3. Overview of daily events categorized under risk levels.

- Summary of daily audit trails: Allows users to monitor audit trails by searching for audit trails of a selected machine name / serial number, user, test type, filter serial number, product batch number, test program name / ID, test filter, product code, test outcome, and wetting liquid.
- Test comparison: Allows users to select and compare two test repeats in the **Comparison mode** by clicking on one of the past tests linked to the test event. This comparison will indicate key differences between the event histories by highlighting the line items with changes.

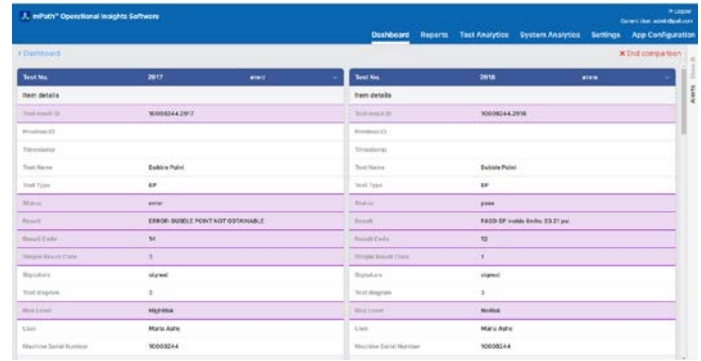


Fig 4. Test comparison can be easily performed within the Dashboard module by highlighting key differences in the event history.

- Troubleshooting guide to support bringing false fails to pass: Can be customized according to user's standard operating procedure (SOP).

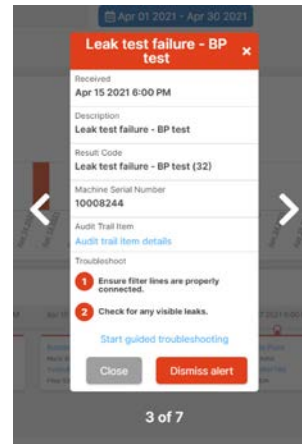


Fig 5. Example of a bubble point test troubleshooting guide with recommended actions to bring test to pass.

- Guided tour for navigating the application: Supports the user by highlighting multiple steps to help them understand the link between the settings and the results shown across screens.

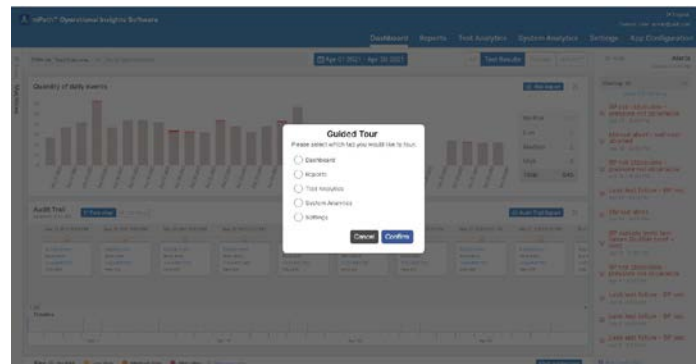


Fig 6. Guided tour for the separate modules helps first-time users to navigate the software.

- Configurable reports, including audit trail reports and troubleshooting report, which can be exported.

2. Reports

All reports created from a dataset in the application are stored in the report list under the **Reports** tab. A button on the tab also allows the user to define and use report templates to report data based on the search criteria.

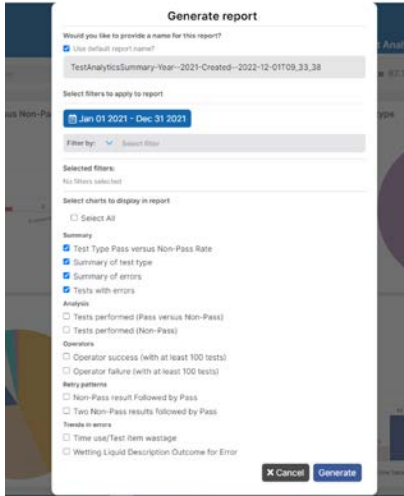


Fig 7. Customized reports can be generated from selected criteria.

3. Test analytics

Allows the user to analyze the individual Palltronic Flowstar instrument test data held in the mPath OIS database. The data can be filtered using the following keys, either singularly or in combination:

Date range, machine name, risk level, user, type, machine serial number, filter serial number, product batch number, test program name / ID, test type, test filter, keyword, comments, product name, test outcome and wetting liquid.

- **Summary:** A number of predefined summary graphs, generated from the outcome of the data filtering, assist the user in investigating issues.
- **Analysis:** Data on test outcomes, based on the outcome of the data filtering, assist the user in looking for trends and outliers in test passes and failures.
- **Operators:** A number of graphs, based on the outcome of the data filtering, show operator performance.
- **Retry patterns:** Data on the number of times a test is retried before a pass result is achieved, are based on the outcome of the data filtering.
- **Trends in errors:** Graphs, based on the outcome of the data filtering, show the trends in different types of errors recorded by the Palltronic Flowstar instrument.

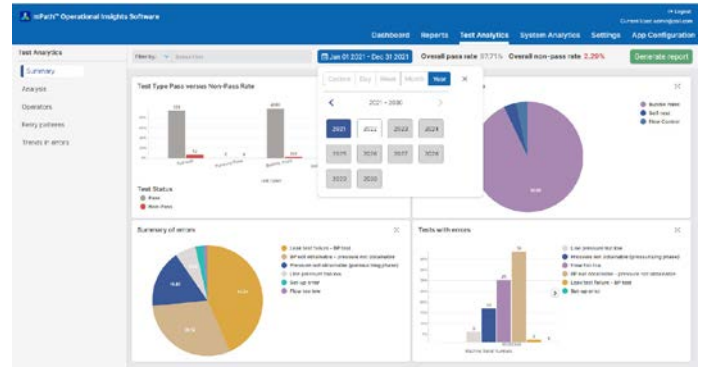


Fig 8. Test analytics allow the user to analyze the individual Palltronic Flowstar instrument test data.

4. System analytics

Allows the user to investigate trends in Palltronic Flowstar system events.

- **Summary:** Provides graphs giving an overview of the Palltronic Flowstar system events, based on the outcome of the data filtering.
- **Analysis:** Facilitates the investigation of issues by allowing the user to look at trends and outliers in the Palltronic Flowstar system events, based on the outcome of the data filtering.

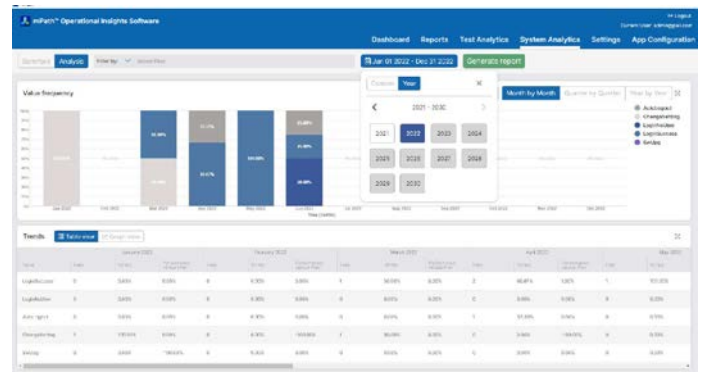


Fig 9. System analytics allow users to look for trends within filter integrity test results.

5. Settings

- Basic software parameters can be adjusted to fit local requirements (language, time zones, date formats and configuration). The email address of the local service center can also be added here, allowing maintenance snapshots and service requests to be sent directly. If an LDAP server is not enabled, an administrator can add, remove or change users' roles. Each user role can also be customized to fit the organization's requirements.
- User access: the lead owner / supervisor can define the permissions required for different users to access different screen options, depending on their role. The lead owner / supervisor can change access permissions when necessary.
The roles assigned to users are:
 - service
 - supervisor
 - admin (read-only access)
 - operator
 - quality assurance (QA)
- Automatic report styles are also defined here. They can then be used to generate reports in the appropriate software.

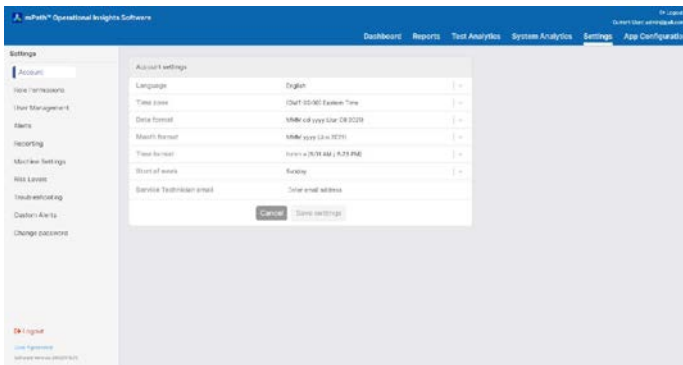


Fig 10. Settings offer language options, access management and report options.

Specifications

Compatible operating systems	Microsoft Windows 10
Compatible browsers	Microsoft Edge Google Chrome™
Supported file output/report formats	CSV, PDF, XML
Compatible Palltronic Flowstar instruments	Palltronic Flowstar IV (firmware 2.2F or later) Palltronic Flowstar V (firmware 1.4 or later)
Minimum hardware requirements	Hardware requirements will depend upon the number of Palltronic Flowstar instruments connected as follows: < 10: 8+ logical processors < 20: 12+ logical processors > 20: 16+ logical processors For all scenarios, RAM should be 8+ GB; 16 GB is recommended

6. Application configuration

Available only in the primary application, this feature allows an administrator to set up the software: to configure an SMTP server, set up the email addresses alerts can be sent to, register licenses and configure an LDAP server. It also allows the administrator to enable the backup of the data held by the mPath OIS system. Finally, it allows the administrator to set up the web server to allow other users to connect to the application.

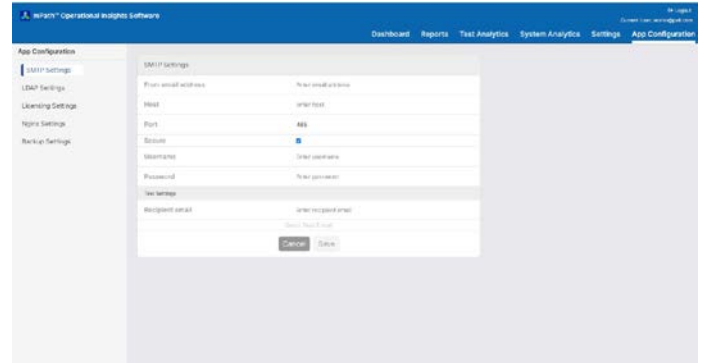


Fig 11. Application configuration includes settings for network connectivity and license activation.

Test analysis capability	Forward flow test (FF) Bubble point test (BP) Combined forward flow / bubble point test (FF/BP) Water intrusion test (WIT) Leak test (LT) Pressure decay test (PD) Self-test Flow check test Network test
Maximum number of connecten Palltronic Flowstar instruments	40
Data capacity	Data capacity is dependent on hard drive of host computer
Language options	Simplified Chinese, Dutch, English, French, German, Italian, Japanese, Portuguese, Russian, Spanish, US English

Networking capabilities

The mPath OIS software must be installed on the same network that contains the Palltronic Flowstar instruments that are to be connected. The application supports up to 40 instrument connections at one time. In order to connect to a particular instrument, a license must be obtained for its specific serial number. Once the license is obtained and imported into the application, the administrator enters the IP address of the Palltronic Flowstar instrument into mPath OIS and the application will automatically start importing historical records from the machine.

Palltronic Flowstar IV and V filter integrity test instruments need to be connected to an edge PC, local server to web server where the mPath OIS is installed, for data acquisition. Any PCs in the same network can then access mPath OIS through a web browser.

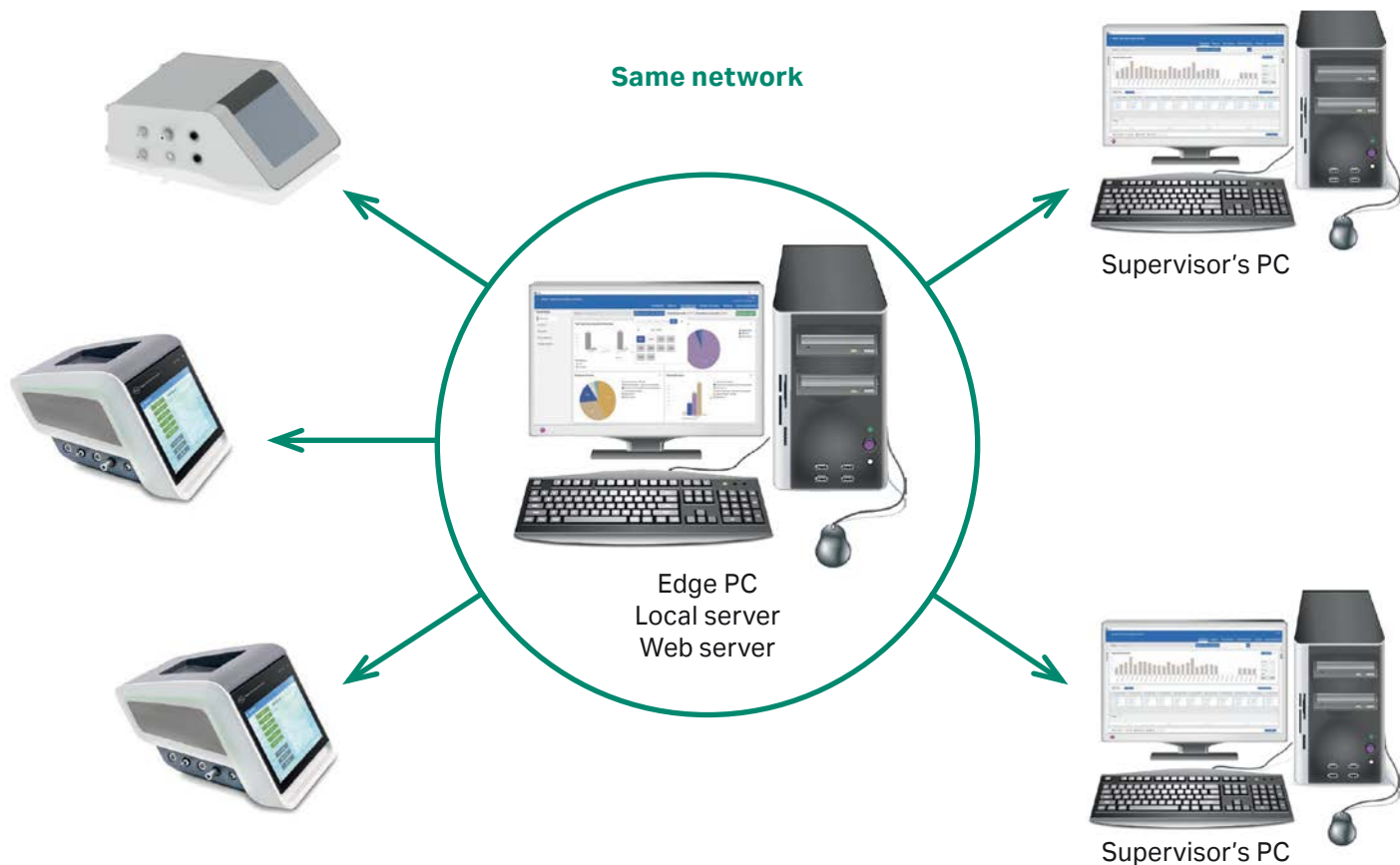


Fig 12. Software network setup.

Regulatory compliance

mPath OIS is compatible with the relevant sections of the Food and drug administration (FDA) 21 Code of Federal Regulations (CFR) Part 11 and is developed according to good automated manufacturing practices (GAMP) 5 guidelines. It exhibits a system audit trail and electronic records. Access is controlled via role-based access permissions, and individual users' access is password protected.

Ordering information

Product	Product code
mPath operational insights software installation package	FFS-OIS
License key to activate software, expires after 1 year	FFS-OISKEY1
License key to activate software, expires after 3 years	FFS-OISKEY3
License key to renew subscription, expires after 1 year	FFS-OISKEY1N
License key to renew subscription, expires after 3 years	FFS-OISKEY3N

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