Inhalytix®+

Inhaler Testing Data, Managed with Confidence

Specialist software for inhaler testing data management, analysis and reporting.

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Connected Data Management for Inhaler Testing

Generating accurate data is a critical requirement in inhaler testing, supporting the development and quality control of MDIs, DPIs, nebulisers, SMIs and nasal products. However, data management is often challenged by fragmented workflows, manual data handling and the need to maintain traceability from methods set-up through to reporting and review. Analysts often need to enter data across multiple systems, validate spreadsheets, and track down essential test parameters and metadata. These factors contribute to inefficiencies, compliance risks, and increased potential for errors.

Inhalytix®+ addresses these challenges by providing a controlled digital environment for inhaler testing data management, analysis and reporting of data generated during inhaler testing. Version 2.0 strengthens the links between software, equipment information and workflow records, while expanding key analysis and connected-workflow capabilities. This helps laboratories manage more of the testing process digitally, supporting clearer attribution, greater consistency and more traceable test records.

Bringing key workflow information together within one connected digital environment.

Compliance and Data Integrity

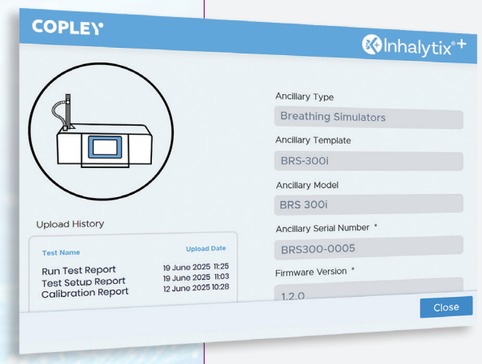
Inhalytix⁺ is designed to support the data management requirements of regulated pharmaceutical laboratories, aligning with GMP principles and electronic record requirements in accordance with 21 CFR Part 11. By linking results to the originating method, user, equipment configuration and associated metadata, Inhalytix⁺ supports clear attribution and a more complete digital test record.

Key features supporting compliance and traceability include:

- **Role-based user management**: secure, permission-based user management with defined and user-generated roles, strong password policies and accountability tracking
- **One-click auto validation**: system-wide validation verifies that all calculation algorithms work correctly, ensuring data reliability and regulatory compliance.
- **Comprehensive audit trails**: key user actions, method changes, data edits, report review steps and system events are recorded, helping laboratories understand how records were created, changed, reviewed and approved.
- **Electronic data records**: all results are securely stored with linked metadata, method details and equipment information to maintain full data integrity.
- **Structured report sign-off**: enforces formal review and approval workflows in line with electronic record-keeping standards.

Supporting a QbD approach to APSD assessment

Inhalytix⁺ supports Analytical Quality by Design (AQbD) principles by helping laboratories define, control and review key APSD method parameters and performance metrics. Controlled method set-up, standardised equipment configurations, validated calculations, result comparison and trending can support a more systematic understanding of test performance and variability.



Aligned with Global Pharmaceutical Regulatory Standards

Inhalytix⁺ supports compliance with major international pharmacopoeias and regulatory authorities including Ph. Eur., EMA, USP, FDA, JP, CFDA and ChP. This ensures data meet the global regulatory standards from the outset.

Inhalytix⁺ enables laboratories to maintain efficient digital workflows while adhering fully to regulatory requirements.

Connected Equipment Management

Inhalytix+ helps laboratories build a more complete and traceable workflow record by bringing equipment information into the process through centralised inventory records, method configuration and supported connectivity with compatible Copley equipment. Depending on the product, model, firmware and connection type, equipment information can be linked to methods, configurations and analytical records, helping laboratories maintain clearer visibility of the equipment used across the testing workflow.

Centralised Equipment Inventory

Inhalytix+ creates a digital inventory that consolidates all equipment records in one place. Each item can be linked to key details such as:

- **Model and serial number**
- **Firmware version**
- **Calibration and maintenance history**
- **Usage and operational data**

This metadata can be linked directly to test methods and analytical results, supporting traceability and improving the visibility of equipment usage across the laboratory.

How Equipment Information is Captured

Equipment records can be brought into Inhalytix+ in three main ways, depending on the product, model, firmware and connection type.

Connected instruments
Supported instruments can exchange selected information directly with Inhalytix+. This includes reports, operating information and, where available, approved methods and user permissions.

QR-coded equipment and components
Where supported, QR-coded equipment and components can be scanned using the **QR Code Connector** to capture key identifiers, helping reduce manual entry and confirm what was used during the test.

Equipment inventory records
Equipment can also be added manually to the Inhalytix+ *Equipment Inventory* and included in methods and equipment configurations, helping laboratories maintain a centralised record of the equipment used across the APSD workflow.

Inhalytix®+

Built to Evolve with Your Laboratory

Inhalytix+ provides a scalable digital hub that can evolve with your laboratory. It brings methods, equipment records, analytical data, reports and audit trails into a controlled workflow, while supporting greater connected capability through compatible Copley equipment as requirements develop. This allows laboratories to strengthen data management today and build a more connected inhaler testing workflow over time.

A Structured Workflow for Inhaler Testing Data

Inhalytix+ supports the management, analysis and reporting of data generated during OINDP testing. By bringing data import, review, calculation and reporting together in one place, the software helps laboratories move from raw results to clear, traceable outputs. This is structured around a defined three-step workflow, standardising data capture and reinforcing traceability at every stage of analysis.

1. Prepare

Define Method, Equipment, and Reports

• Method Configuration

Each test method is tailored to the specific OINDP product and its analytical requirements, supporting workflows for MDIs, DPIs, nebulisers, SMIs and nasal products. Users can define APIs, stage groupings, Fine Particle Dose (FPD) thresholds, and reporting settings. Depending on the product type, either delivered dose or drug substance delivery rate can be selected. Inhalytix+ supports up to six APIs per method, making it suitable for combination products and complex formulations.

Where supported, defined methods configured in Inhalytix+ can be made available on connected Copley equipment, helping analysts work from approved settings during testing.

• Equipment Setup

Using a visual drag-and-drop interface, users can build product-specific equipment setups from a built-in library that includes impactors, impingers, flow controllers, breathing simulators, and other ancillaries. The system guides users to select only valid equipment combinations. Connected Copley equipment can transfer selected parameters and operating information into Inhalytix+, helping reduce manual entry and support consistency across tests.

Equipment Bench

The *Equipment Bench* lets users create and save their own custom equipment setups, reflecting the specific configurations used in different labs or test environments. Multiple benches can be created and recalled instantly, allowing teams to select the appropriate setup based on where a test is being run. This reduces repetitive data entry and supports consistent set-up across methods, analysts and sites.

• Report Customisation

Report templates are fully customisable and can be saved for re-use across different methods. Users can select between detailed or summary formats and can control which metrics are included. Company branding can be added to the report header, making the reports suitable for both internal reviews and external submission.

2. Execute

Enter or Import Data

Once the method, equipment and reporting setup are defined, users can begin testing by entering the number of doses actuated and recording drug deposition values for each stage of the impactor. This includes any additional components configured in the test setup, such as induction ports or preseparators. This process is repeated for each run in the series.

Data can be imported from CSV or XLSX files or entered manually. All entries are displayed in a clear, scrollable table, allowing users to review and edit values before proceeding with analysis.

3. Analyse

Calculate and Review Result

Inhalytix⁺ calculates metrics using validated algorithms, ensuring consistent, reliable outputs. Each result is linked to the selected method, equipment configuration and relevant test information, supporting review and traceability.

Compare, trend and report APSD results with confidence

- **Scrollable summary tables**
- **Grouped results by stage or component**
- **Standard or fully customised reports**
- **Side-by-side comparisons of up to six tests**
- **Graphs including log-probit plots and deposition profiles**

These tools help laboratories compare APSD performance across runs, methods or products, supporting clearer review and method understanding.

Calculated Metrics

To support in-depth product evaluation, Inhalytix⁺ generates a comprehensive set of standard performance metrics, including:

- Total Dose per Shot
- Delivered Dose
- Fine Particle Dose (FPD)
- Fine Particle Fraction (FPF)
- Mass Median Aerodynamic Diameter (MMAD)
- Geometric Standard Deviation (GSD)
- Regression Coefficient (R^2)
- Large Particle Mass (LPM)
- Small Particle Mass (SPM)
- Impactor-Sized Mass (ISM)
- LPM/SPM Ratio
- Fine Particle Mass (FPM)
- Extra-Fine Particle Mass (EPM)
- Coarse Particle Mass (CPM)

Metrics such as MMAD, GSD, FPD and FPF can support product understanding, performance monitoring and QbD-led review of critical quality attributes.

Summary of Key Features

- Specialist software for inhaler testing data management, analysis and reporting
- Structured workflow for method configuration, execution and analysis
- Automated calculation of key APSD performance metrics
- Role-based user management with comprehensive audit trails
- Test method parameters and equipment metadata linked to each test run
- Centralised equipment inventory and traceability
- Supports compatible connected instruments, QR-coded components and non-connected equipment records where available
- Customisable report templates and graphical data outputs
- Designed to support electronic records in regulated laboratory environments

Technical Specifications

Installation options are available to support different laboratory IT environments:

Standalone installation:
Ideal for single users or smaller teams, the software is installed directly on a PC, with all data stored locally on that machine.

Network installation:
Suitable for larger teams, the software can be deployed on a central server within your local network. This setup allows authorised users to access Inhalytix⁺ from connected workstations, enabling centralised data storage, simplified backups, and access to the same validated software version.

Both installation options support compliance with data integrity standards and can be validated according to GMP or 21 CFR Part 11 requirements.

Minimum System Requirements

Operating System:
Windows 10 or Windows 11, Windows Server 2016, 2019, 2022 and 2025

Processor:
Dual Core CPU

Memory:
Minimum 8 GB RAM

Storage:
500 MB of available disk space required for install

Display:
1280 x 768 (suggested minimum), 1920 x 1080 (recommended)

Connectivity:
Ethernet required for communication with supported connected equipment

Subscription & Support

Inhalytix+ is provided as a subscription that includes:

- ✓ Unlimited test run analyses
- ✓ Ongoing software and feature updates
- ✓ Built-in audit trails
- ✓ Customisable methods and reporting
- ✓ Full technical support
- ✓ Optional user training packages

Licensing

- ✓ Three-year subscription
- ✓ Licences available for teams of three users or more

Inhalytix®+

Cat. No.	Description
8265P	Inhalytix+ Software Licence (3 team, valid for 3yrs) - PC
8265S	Inhalytix+ Software Licence (3 team, valid for 3yrs) - Server
8266	Additional User Licence for Inhalytix+ (valid for 3 yrs) (each)
8021	1 Port RS-232 to Ethernet Adapter for Inhalytix+
8022	2 Port RS-232 to Ethernet Adapter for Inhalytix+
8024	4 Port RS-232 to Ethernet Adapter for Inhalytix+

Ethernet Adapter for Inhalytix+

Compatible ancillary and automation equipment may connect to Inhalytix®+ via ethernet adapter **(Cat. Nos. 8021, 8022 or 8024)** or, where supported, through direct connection using compatible firmware. Available functionality depends on product, model, firmware and connection type. To confirm compatibility with existing equipment, please contact sales@copleyscientific.co.uk.

See **Inhalytix®+** in Action

Inhalytix+ delivers clarity, consistency, and confidence across inhaler testing data management, from data capture and analysis, through to review and reporting.

If you would like to see how Inhalytix+ could work for you, we recommend booking a personalised demo with one of our team. This is the most effective way to explore Inhalytix+ software features, understand equipment compatibility and discuss how the Inhalytix+ can support your inhaler testing workflow.

To arrange a demo or discuss your needs in more detail, please contact us:

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