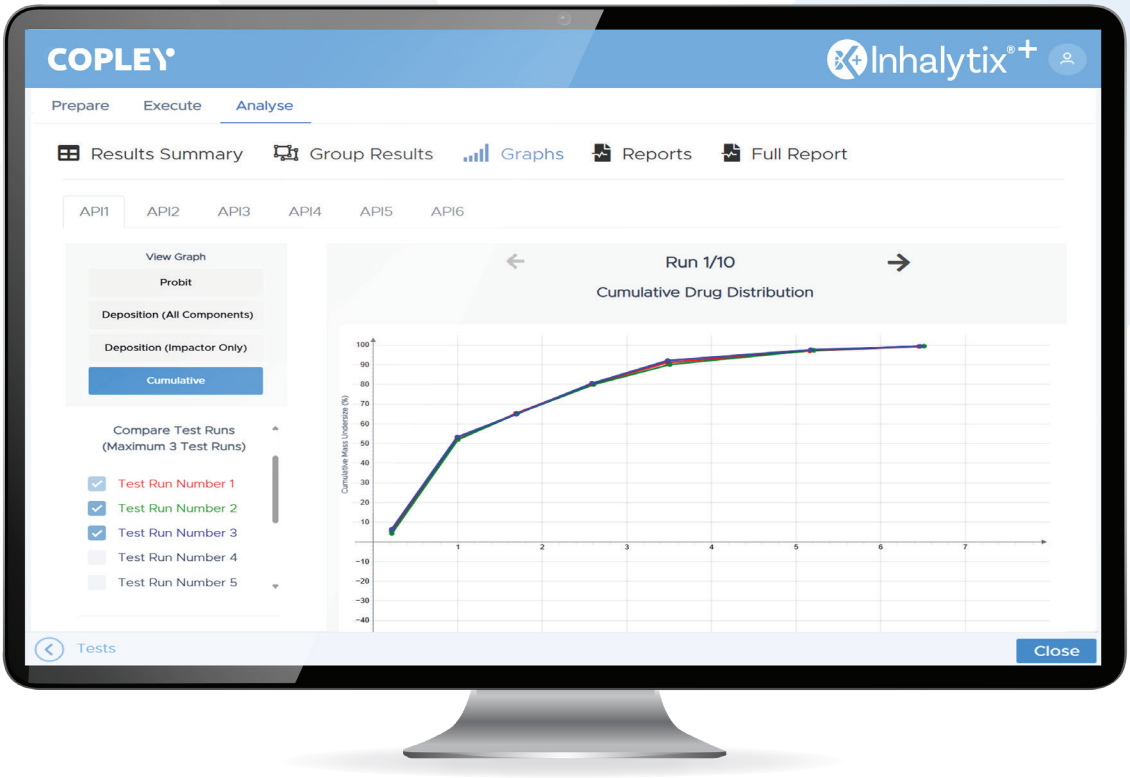
NEW

Inhalytix®+

The Complete Platform for APSD Data Management



Compliant Data. Confident Decisions.

One Connected Platform.

INNOVATIVE
COMPLIANT
TRUSTED

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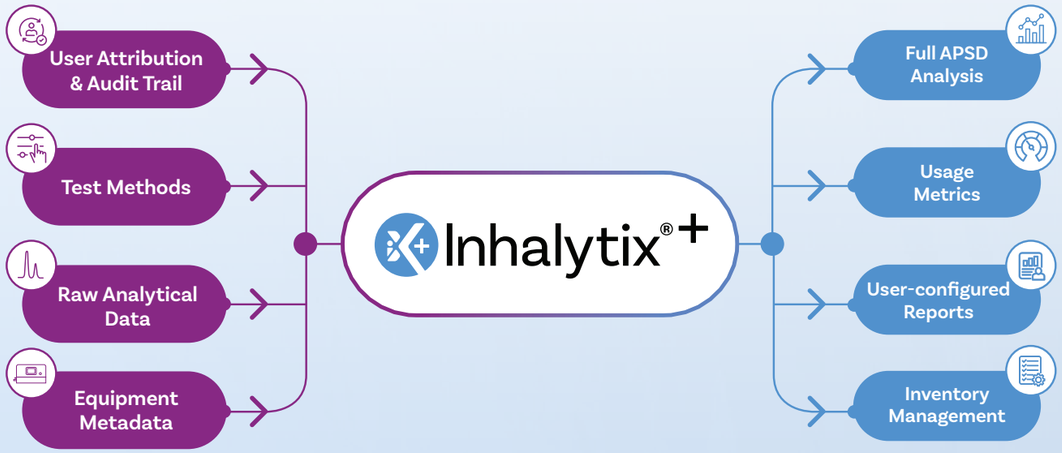
Generating accurate Aerodynamic Particle Size Distribution (APSD) data is a critical requirement in OINDP testing. However, this process is frequently challenged by fragmented workflows and manual data handling. Analysts often need to enter data across multiple systems, validate spreadsheets, and track down essential test parameters and metadata. These factors contribute to inefficiencies, compliance risks, and increased potential for errors.

Connected Insights with Inhalytix®+

Inhalytix+ overcomes these challenges by unifying the entire APSD data lifecycle in a single, structured platform. From method setup and equipment configuration through test execution, analysis, and reporting, every step is managed in one connected environment. This includes direct integration with compatible Copley ancillary and automation tools, enabling operational parameters and test data to flow straight into the system for a more connected, accurate view of inhaler testing results. This approach ensures consistent data capture, traceable results, and a workflow designed for audit readiness.



Intended for use in both R&D and QC settings, Inhalytix+ delivers comprehensive APSD data analysis, detailed usage metrics, and fully customisable reports all integrated within a unified inventory management system. This supports faster results, informed decision-making, and streamlined regulatory compliance.

Why Users Choose Inhalytix®+

✓ All-in-One Platform for APSD Analysis

Inhalytix+ integrates every stage of the APSD data management workflow into a single, connected system. Method preparation, equipment connectivity, data capture, and reporting are all managed within one environment to minimise manual steps and promote consistent operations.

✓ Instant Calculation of Key Metrics

The platform automatically calculates critical values such as MMAD, GSD and FPD from test data, enabling timely review and decision-making.

✓ Improved Data Integrity

By allowing automated data transfer from connected equipment, Inhalytix+ reduces the potential for manual errors. Built-in controls further ensure data reliability and support regulatory compliance.

✓ Clear Data Attribution

Every result is linked to its originating method, user and equipment setup, ensuring full traceability across the entire data lifecycle.

Compliance & Data Integrity

Inhalytix®+ is specifically designed to support the compliance needs of regulated laboratories. It fully aligns with Good Manufacturing Practice (GMP) and 21 CFR Part 11 for electronic records. Every feature supports data integrity throughout the entire testing process - from method setup to final reporting.

Built-in Compliance Features:

Role-based Access Controls

Secure, permission-based user management with defined 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.

Structured Report Sign-off

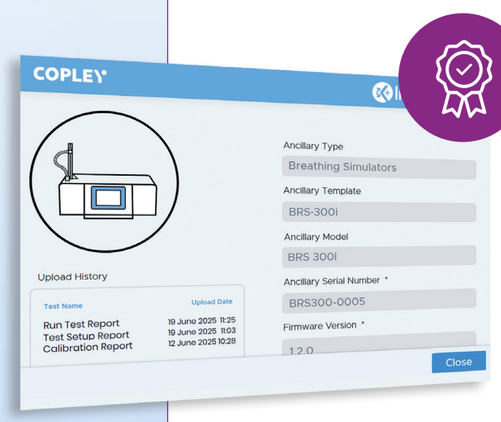
Enforces formal review and approval workflows in line with electronic record-keeping standards.

Audit Trails

Automatic, comprehensive logs of all user actions, data changes, and system events provide complete traceability.

Electronic Records & Data Integrity

All results are securely stored with linked metadata, method details, and equipment information to maintain full data integrity.



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 meets the global regulatory standards from the outset.

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

Structured Workflow for Consistency

Inhalytix®+ leads users through a structured, three-step workflow that standardises data capture and strengthens traceability at every stage of APSD data analysis.

1. Prepare

Define Method, Equipment, and Reports

- **Method Configuration**

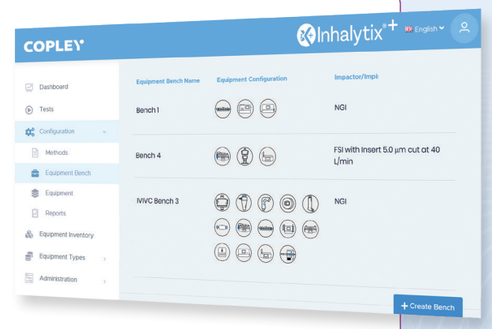
  Each test method is tailored to the specific product and its analytical requirements. Users can define APIs, stage groupings, Fine Particle Dose (FPD) thresholds, and reporting settings. Depending on the product type, either delivered dose or drug substance delivery rate can be selected. Inhalytix+ supports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

- **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. Inhalytix+ also connects with automation tools such as Vertus® III/Plus shake & fire systems, and the Impactor Genie IG 200i for automated drug recovery. These integrations capture key parameters directly, minimising manual data entry and ensuring 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 eliminates repetitive data entry, saves time, and ensures consistency across methods, teams, and sites.



- **Report Customisation**

  Report templates are fully customisable and can be saved for reuse 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 APSD metrics using validated algorithms, ensuring consistent, reliable outputs. Each result is fully traceable, linked to the specific method, equipment configuration and metadata used in the test.

Results are available in multiple formats to support different review and reporting needs:

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

Calculated Metrics

To support in-depth product evaluation, Inhalytix+ generates a comprehensive set of standard APSD 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)

Connectivity & Equipment Integration

Centralised Inventory with Metadata Integration

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 is automatically connected to the related test method and results, enhancing traceability and making audits more straightforward.

Online and Offline Equipment Integration

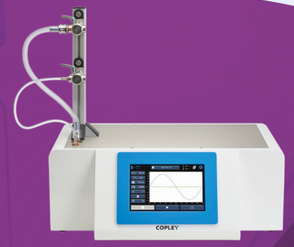
Inhalytix+ supports two flexible ways to integrate equipment data:

- **Online Devices**: Newer Copley ancillary and automation tools can connect directly to Inhalytix+, enabling automatic import of metadata and operational parameters like flow profiles, test duration and cycle counts during method setup or test execution.
- **Offline Devices**: For older or non-networked Copley equipment, users can manually record the specific equipment used in a particular test. This ensures consistent record-keeping and traceability across all equipment, regardless of connectivity.

Compatible Equipment Includes:

Flow Controllers and Flow Meters

Automated Shake & Fire Systems (e.g. Vertus®)



Breathing Simulators

Cascade Impactor Preparation Systems

Drug Recovery Tools

Built for Today, Ready for Tomorrow.

Inhalytix®+ is designed not only to support today's connected testing environments, but also to lead future developments in inhaler testing integration. Compatibility with connected equipment is a core design principle, and future tools will continue to be developed with seamless Inhalytix+ integration in mind. This ensures that labs adopting Inhalytix+ today are positioned for long-term success as testing environments modernise.

Technical Specifications

Installation & Deployment Options

Inhalytix®+ offers flexible installation choices to fit your lab's IT infrastructure and workflow:

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 between Inhalytix+ and connected equipment

Subscription & Support

All-Inclusive Subscription Model

Inhalytix®+ is provided as a subscription that includes:

- ✓ **Unlimited test run analyses**
- ✓ **Continuous compliance 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**

Frequently Asked Questions

How long does it take to install and set up Inhalytix+?
Typical installation takes less than a day, depending on your IT environment. Pre-configured method templates and the Equipment Bench feature help speed up method setup and analysis.

What support is available after installation?
All subscriptions include full technical support and access to software updates. Additional training packages are available upon request.

Can we migrate existing data from older systems or spreadsheets into Inhalytix+?
Yes. Historical data and spreadsheets can be imported into Inhalytix+ to help you maintain continuity and centralise all your legacy information.

How often is the software updated?
Software updates are released regularly and include feature improvements and regulatory alignment. Updates are included as part of an active subscription.

Frequently Asked Questions (continued)

Can Inhalytix+ be integrated into a larger LIMS or digital lab workflow?

While Inhalytix+ is designed to work as a standalone data analysis platform, exported reports can be used downstream in broader digital lab systems.

Do I need internet access to use Inhalytix+?

No. Inhalytix+ runs on local PCs or servers within your lab's secure environment. An internet connection is only required for initial licensing activation and for software update downloads.

How are user roles and permissions managed?

User access is role-based, with customisable permissions to control who can edit methods, run tests, approve results, or generate reports, supporting data integrity and compliance.

Is training required to use Inhalytix+?

Inhalytix+ is designed with an intuitive, user-friendly interface that makes it easy for analysts to get started with minimal onboarding. Most users are up and running quickly without the need for formal training. However, if additional support is required, our technical team is on hand to help, and tailored user training is available to suit your workflows and team needs.

See Inhalytix®+ in Action

Inhalytix+ delivers clarity, consistency, and confidence at every stage of APSD measurement. From data capture to regulatory-ready reporting, it unifies processes and supports efficient, decision-focused workflows.

If you would like to see how Inhalytix+ could work for you, we recommend booking a personalised demo with one of our Application Specialists. This is the most effective way to explore the platform's features, understand integration options, and discuss your specific requirements.

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

sales@copleyscientific.co.uk

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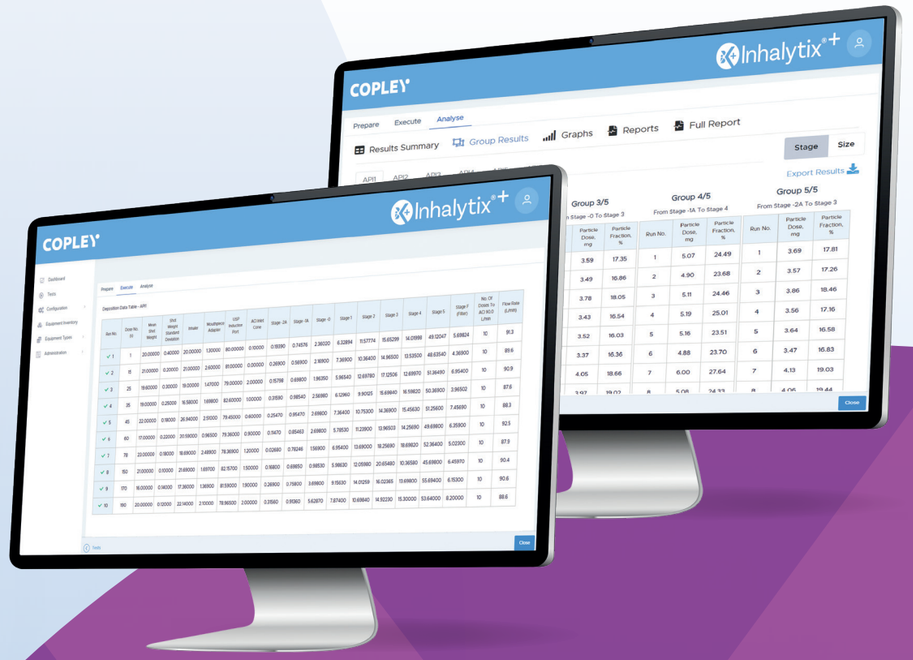
Ordering Information

Cat. No.	Description
8265P	Inhalytix+ Software Licence (3 users, valid for 3yrs) - PC
8265S	Inhalytix+ Software Licence (3 users, 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+

8021, 8022 or **8024** are required to connect ancillary and automation equipment to Inhalytix+. Direct connection is only supported for devices with compatible firmware. To check compatibility with existing equipment, please contact **sales@copleyscientific.co.uk.**



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Discover how Inhalytix+ can transform your APSD workflows. Scan the QR code opposite.

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