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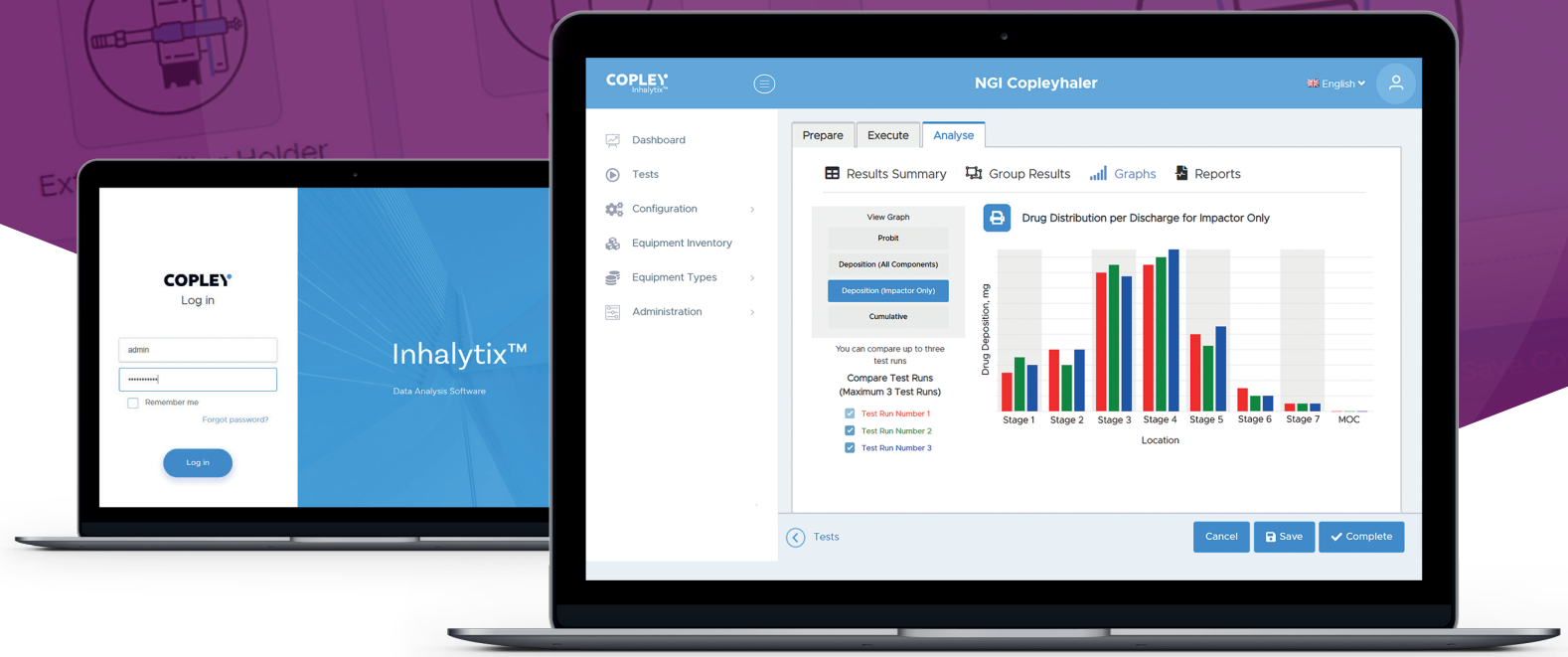


Inhalytix™

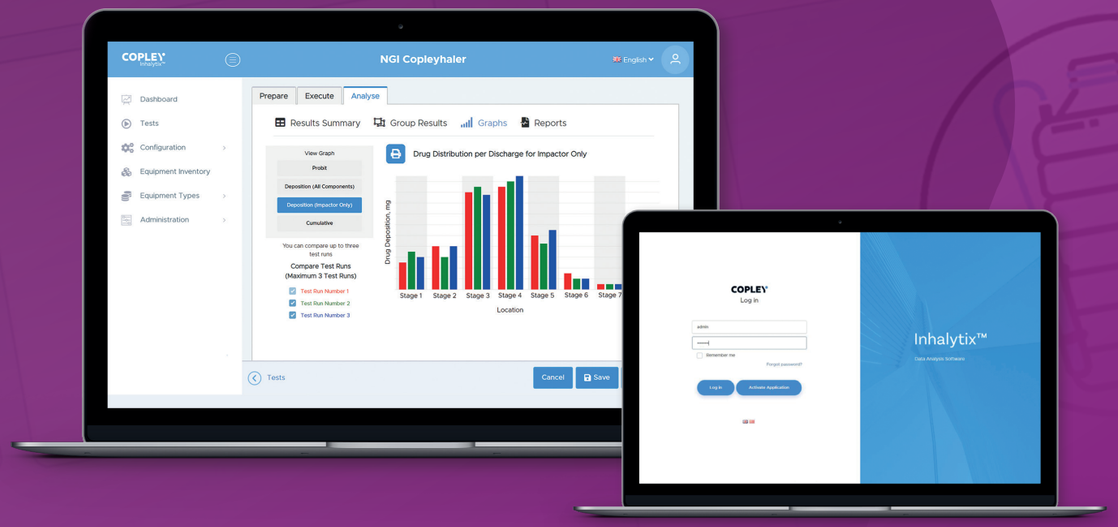
Flexible and fully validated inhaler testing data analysis software

2021 EDITION

Inhalytix™

USP Chapter <601> and Ph.Eur. Chapter 2.9.18 and draft USP Chapter <1604> specify various types of multi-stage cascade impactor that can be used for measuring the drug-specific aerodynamic particle size distribution (APSD) of orally inhaled and nasal drug products (OINDPs).

This process involves quantitative recovery and chemical analysis of the size-fractionated aerosol, typically by High Pressure Liquid Chromatography (HPLC). From the resulting assay a number of important metrics can be derived that are used to characterise the APSD, in accordance with pharmacopoeial specifications and various FDA and EMA guidance.

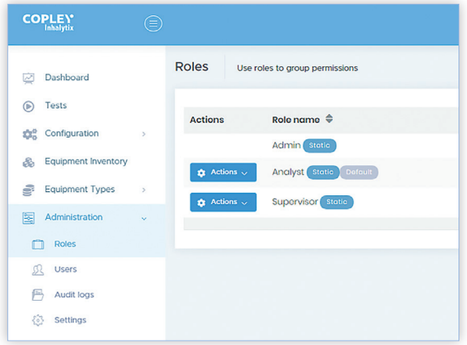


Inhalytix™ data analysis software is a flexible and fully validated solution for the entry, analysis and reporting of the APSD of drug output from all OINDPs. It also serves as a database for laboratory-based cascade impactor inventory and provides for the setting up and running of detailed test methods. User-configurable, the software will accept data from standard and customised cascade impactors, including the Andersen Cascade Impactor (ACI), Next Generation Impactor (NGI), Fast Screening Impactor (FSI), Fast Screening Andersen (FSA), Glass Twin Impinger (GTI) and Multi-Stage Liquid Impinger (MSLI).

Licensing

Inhalytix™ is available as a three user licence software package, based on named users that can be added or removed by the system administrator. The software is available via PC, server and cloud-based installations, with digital licence keys supplied by email. Additional packages of three users are available and can be added to the system at any time.

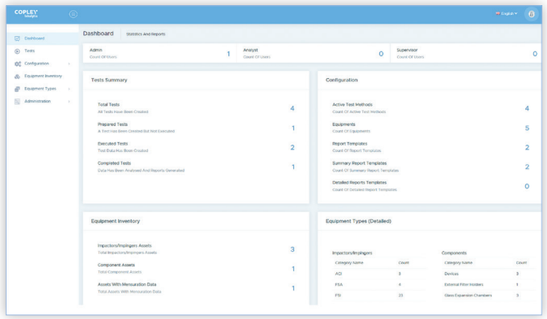
System Characteristics



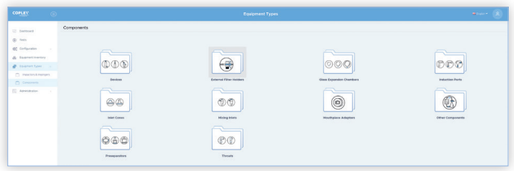
Quick and easy to install, **Inhalytix™** is 21 CFR part 11 compliant, enabling the creation of users, assignment of multiple roles (typically admin, supervisor and analyst) and access to audit logs, assisting in data monitoring and ensuring data integrity. The software will operate on Windows 7, 8 and 10 operating systems.

System Operation (Configure > Test > Report)

Dashboard: On entering the software the user is presented with a dashboard providing useful information about how the software is being used. This contains information such as the number of analysts and supervisors set up on the system, as well as the total number of tests prepared, executed and completed. It also summarises the number of tests, equipment and report configurations, as well as details of the equipment inventory, databased by type.



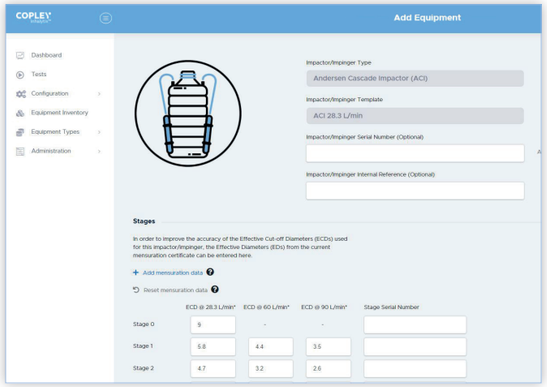
Equipment Types



The software is pre-populated with the most commonly used impactor types for immediate use. However, it is not uncommon for custom versions of cascade impactors to be used in some laboratories. In these circumstances, users can generate bespoke impactor types that can then be stored and recalled for use later. This function may, for example, allow a user to add or remove certain stages from an impactor or add special components to the software, such as modified induction ports.

Equipment Inventory

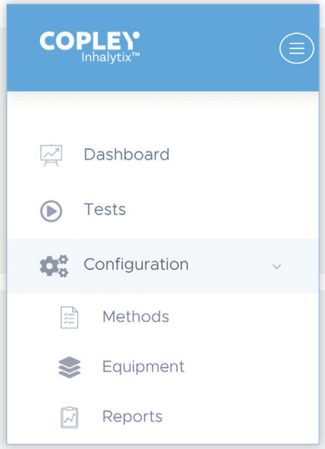
Keeping track of equipment inventory and associating it with the corresponding inhaler testing data can be a burden. For this reason, the **Inhalytix™** equipment asset library allows users to keep their equipment databased and include equipment-specific data in their testing reports. Not only does this allow users to keep track of equipment, it ensures full traceability by keeping comprehensive records of which specific pieces of equipment were used for each test. Furthermore, the software provides the user with the option to enter impactor-specific mensuration data, allowing the precise calculation of stage cut-off diameters, thereby enhancing the precision and accuracy of test results. The software will also notify users if an impactor is due for stage mensuration.



Configuration

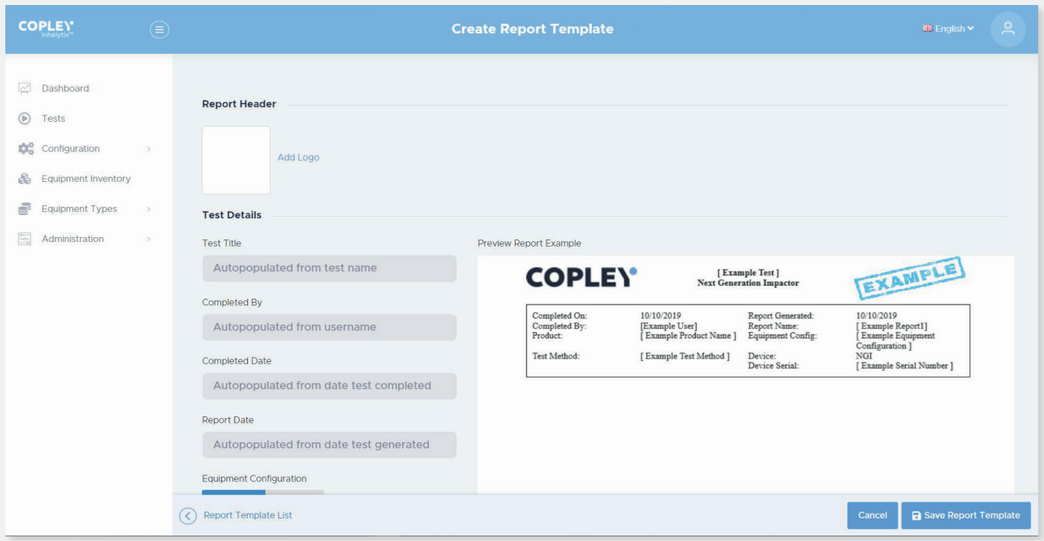
Testing of different drug products requires different methods to be in place, different equipment to be used and different metrics to be calculated. This configuration takes place in three easy steps:

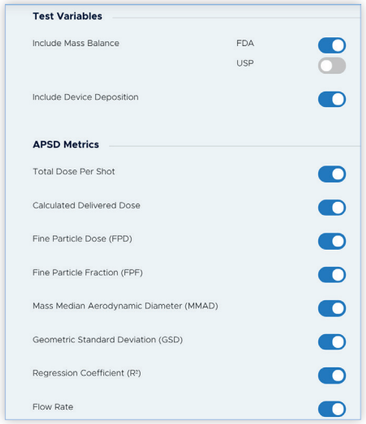
Reports • Equipment • Methods

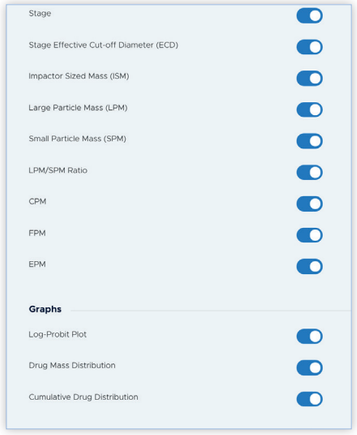


1. Reports

The Reports configuration screen allows users to create tailored report templates, which are then stored and can be paired with different test methods, allowing data to be reported as required.



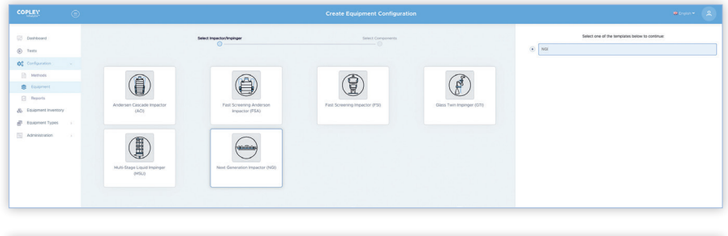


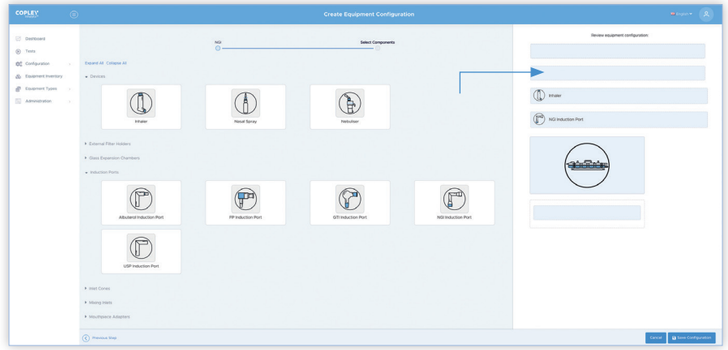


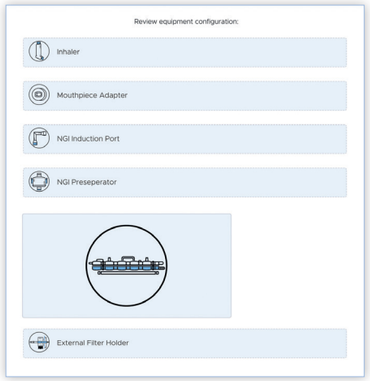
The software allows a high degree of customisation, including both a “Summary” or “Detailed” report template and toggles to turn on or off the reporting of a broad range of metrics. Company logos can be added to the report header if required.

2. Equipment

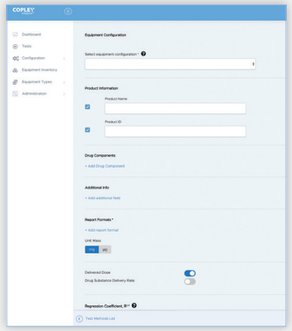
The equipment configuration screen allows users to generate specific combinations of impactor/impinger and components to match the equipment configuration described in the testing protocol. Users simply drag and drop the impactor and components of their choice into the equipment configurator. This, for example, could see the combination of an NGI, with external filter holder, NGI preseparator, NGI induction port, mouthpiece adapter and inhaler. The software automatically sorts the components into the correct order and ensures that only viable combinations can be created.

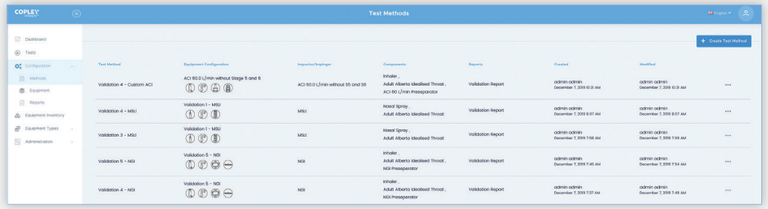






3. Methods



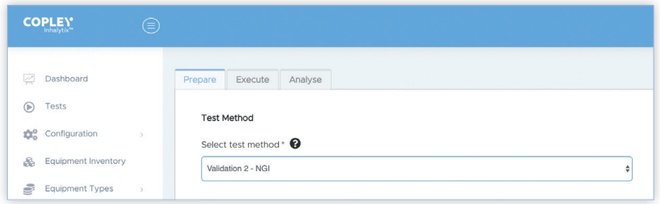


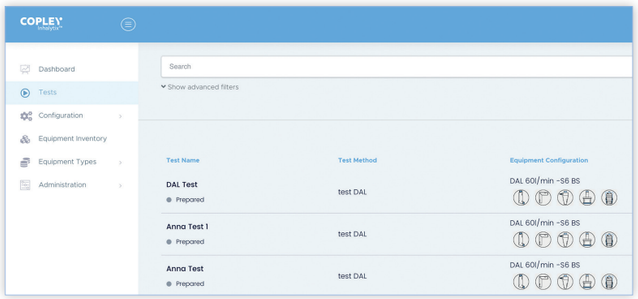
Creating a test method allows the user to combine detailed product information, such as drug components and device details, with equipment and report configurations. Users have the opportunity to define for example stage groupings and fine particle dose (FPD) specifications and to select whether delivered dose (when testing MDIs, DPIs, ADIs etc.) or drug substance delivery rate (when testing nebulisers) is recorded. Configuring the product specific method is the final step before a user can run a test and analyse their results.

Tests

Once the necessary report, equipment and test method configurations are in place, the user is ready to enter the data and complete the analysis. This function can be found under the 'Tests' tab. Tests are completed in three steps:

Prepare • Execute • Analyse

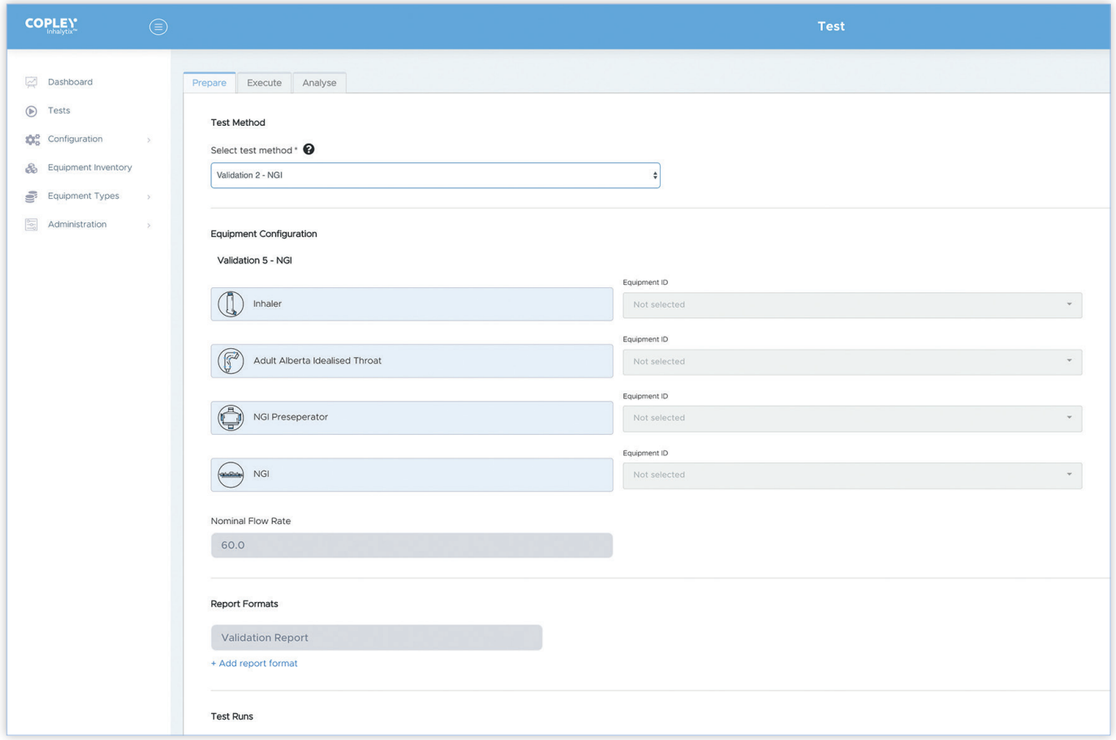




All tests are databased and their current status can be monitored to see if they are at the prepared stage, whether results have been entered or whether they are complete.

1. Prepare

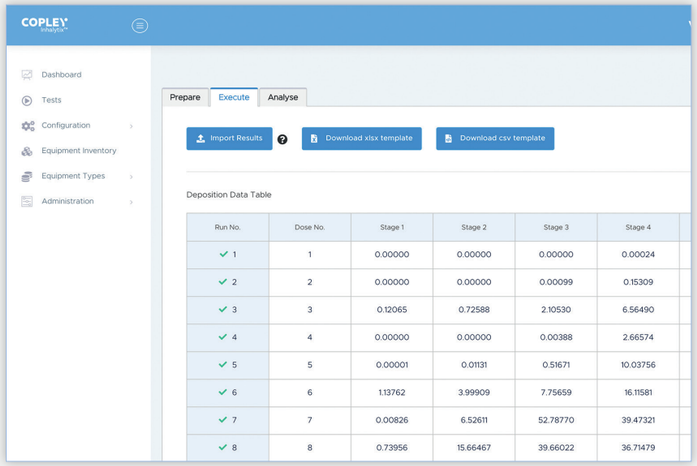
To prepare for a test, users are required to recall the test method relating to the product to be tested. During this step, users will have the opportunity to enter test specific information, including the number of runs to be performed.



2. Execute

The user then executes the test by entering the number of doses actuated and drug deposition values for each stage of the impactor, as well as any additional components included in the equipment configuration. This process is then repeated for all additional runs. Alternatively, data can be automatically imported from a CSV or XLSX file.

All values are easily displayed in a scrollable table and can be edited at any point prior to analysis, for example when importing data from HPLC software or exporting data for report writing.



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3. Analyse

Once all data has been entered or imported the software analyses the data and presents it to the user in the form of:

- **Results Summary** – provides all the key metrics for all test runs in a scrollable table for immediate review.
- **Groups Results** (where used) - displays the drug fractions for each stage or size grouping defined in the method.
- **Graphs** – allows viewing of log-probit plot, drug deposition (by impactor stage/component) and cumulative drug distribution for each run. Also allows the comparison of up to 3 runs from the same test or other tests, so long as the same equipment configuration and data analysis specifications have been set previously.
- **Reports** – allows viewing and printing of standard and customised reports.

Summary of Key Features

- Standardised approach to the analysis of impactor data
- Ph. Eur. 2.9.18 and draft USP <1604> compliant
- 21 CFR Part 11 compliant
- Fully validated with in-built auto-validation protocols
- Supports PC, server and cloud-based installations
- Equipment inventory and test-related database
- Impactor-specific mensuration data log
- Bespoke configurations, methods and reports
- Data import and export capability for use with HPLC software
- Quick 3-step results analysis: **Prepare** - **Execute** - **Analyse**
- Runs and/or Tests comparison capabilities

Inhalytix

Cat. No.	Description
8260C	Inhalytix Data Analysis Software (3 user licences) - Cloud
8260P	Inhalytix Data Analysis Software (1 user licence) - PC
8260S	Inhalytix Data Analysis Software (3 user licences) - Server
8261	Additional 3 User Licences for Inhalytix (Cloud & Server)
8263	Annual Support and Upgrade Package (per user)

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