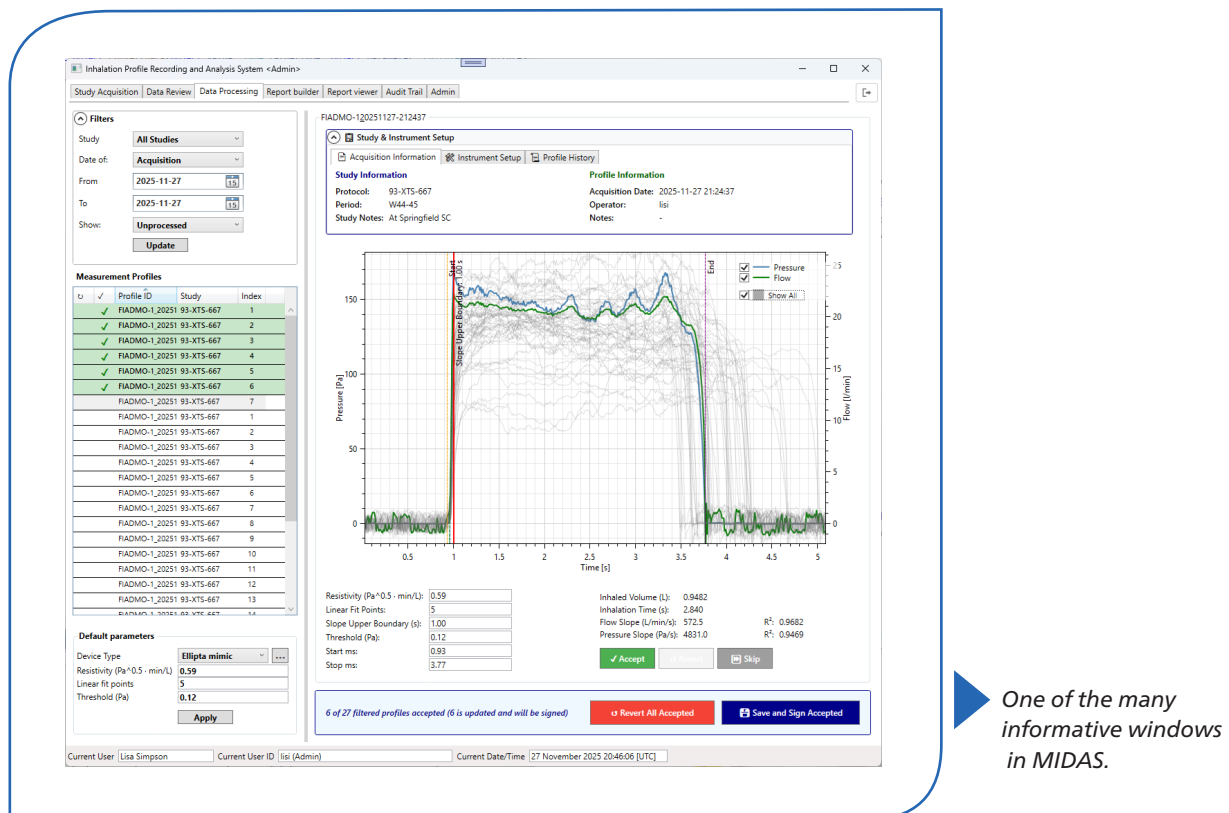


# Manage Inhalation Profiles in Clinical Studies with MIDAS

The powerful and versatile MIDAS is a cGCP compliant software for patient training purposes that can be used to:

- Streamline recording of thousands of profiles together with the Stig PL instrument
- Review, compare and perform mathematical operations on the profiles
- Create comprehensive reports, securely archived alongside the original data
- In addition, MIDAS can also record in-situ profiles from breath simulators in your lab.



## The MIDAS

The MIDAS (**Manage Inhalation Data Automatically and Securely**) application by AB FIA provides a powerful means of recording the inhalation profiles of study subjects in clinical trials and making them available for review and reporting.

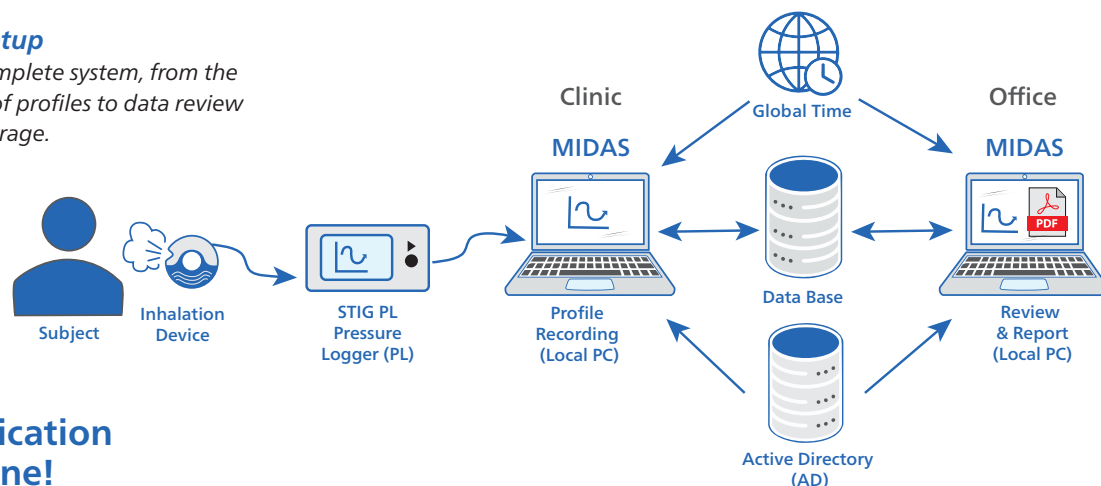
The application has been designed to operate in a dedicated IT framework, available from FIA.

The scope of the overall system is to record, manage, report and archive data and signed reports in compliance with the highest cGCP standards whilst meeting the ERES requirements of 21 CFR Part 11.



## MIDAS system setup

Typical setup of a complete system, from the point of acquisition of profiles to data review and secured data storage.



## MIDAS Application is for Everyone!

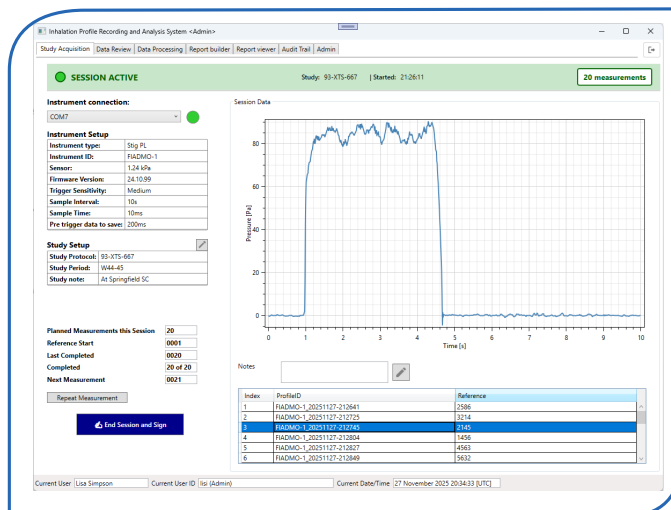
Application functionality is defined by user privileges. A user only sees what is relevant and appropriate for their role. Different functions are available in sections organised under tabs, following a workflow from left to right.

Starting from the left, the **Acquisition** tab enables the recording of profiles at the clinical centre by a study assistant when the computer is connected to STIG PL (art. no. C016666).

MIDAS gives immediate feedback of proper computer connection, and the recorded profile is visualised in a graph. Additional profiles may be recorded as part of a session and listed below the graph until the session is completed and electronically signed by the assistant. The profiles are then made available in the **Data Review** section (not shown), where the user can review them individually.

Subsequently, the profiles are available to users having access to the **Data Processing** section shown below. In this section, device resistivity (nominal or empirical) is added, from which the volumetric flow can be calculated and presented. Additional important data is presented, such as start and stop points, inhaled volume and initial flow slope. The selected profile is presented as a graph with zooming functionality, displaying pressure and/or volumetric flow at the device exit.

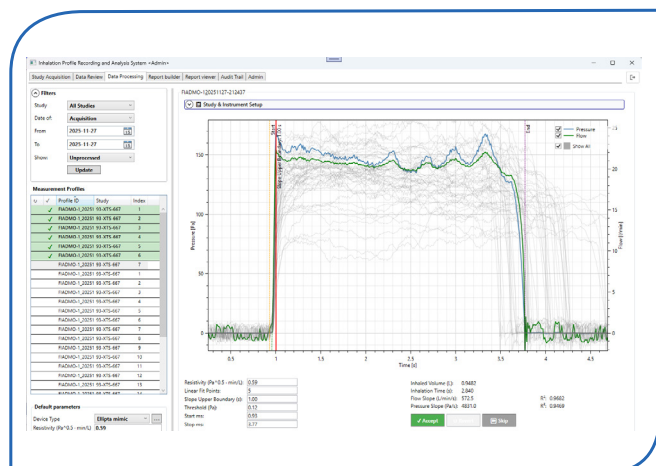
After the profiles have been processed and signed, a revision of the processed data is saved and protected from further editing.



The **Acquisition** tab, where the study assistant schedules a session and can quickly confirm that profiles have been recorded correctly.



MIDAS is optimally used with STIG PL, which is available from FIA. STIG PL can be connected with a tube to any device that has some kind of pressure port. FIA can assist with modifying devices and introducing a pressure port.



In the **Data Processing** window, profiles are shown graphically, together with pivotal data.

In the **Report Builder** section, the user can define the report content by filtering and view processed measurements of interest together with associated statistics for the selected set.

Pressing the **Generate and Sign Report** button stores the report, which contains data of one or several measurements depending on what has been chosen.

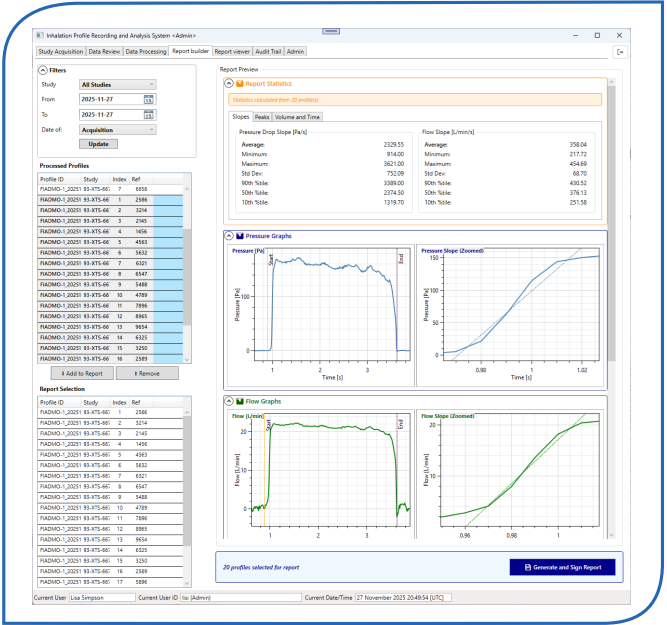
The user can search for created reports in the **Report Viewer** (not shown) section and review included profiles and statistics. The user can also export the report in different file formats. An example in pdf is shown below.

Once a library of profiles has been recorded and made accessible, researchers can easily import them into **breath simulators** commonly used in labs, such as the F-SIG 6300 by AB FIA. MIDAS will also be useful when replaying and validating these profiles on the simulator, creating an overlay of in vivo/in vitro profiles.

# System Architecture and Audit Trail – See Data in Real Time!

The complete (system) setup with the STIG PL instrument, the MIDAS application and the database is designed to meet the highest regulatory requirements while making the data accessible in a unique way as shown in the flowchart on p.2. The user authentication of the application integrates with corporate identity systems such as Microsoft® Active Directory. The application supports both local and centralized deployment with a Microsoft SQL Server® database or regulatory accepted cloud solutions. In the latter cases, researchers working remotely can access data as soon as it has been recorded at the clinical centre, which enables them to guide the study assistant and the trial subjects while the training is ongoing: a valuable and unprecedented opportunity in these contexts!

Pivotal data processing steps are electronically signed according to CFR 21 Part 11 regulations. These actions, together with other processing steps and stated purpose, are recorded in the audit trail.



Report Builder section.

## Inhalation Profile Analysis Report

Generated: 2025-11-28 08:44:02 UTC

Profile 2: FIADMO-1\_20251127-212725

Study: 93-XTS-667 | Index: 2

### Profile Information

|                   |                          |
|-------------------|--------------------------|
| Profile ID:       | FIADMO-1_20251127-212725 |
| Study Protocol:   | 93-XTS-667               |
| Reference:        | 3214                     |
| Acquisition Date: | 2025-11-27 21:27:25      |
| Operator:         | lisi                     |
| Instrument Type:  |                          |
| Instrument ID:    | FIADMO-1                 |

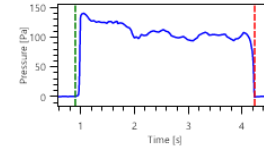
### Processed Data Results

|                      |                                         |
|----------------------|-----------------------------------------|
| Pressure Drop Slope: | 3470.00 Pa/s (R <sup>2</sup> =0.9348)   |
| Flow Slope:          | 380.61 L/min/s (R <sup>2</sup> =0.9126) |
| Pressure Drop Peak:  | 140.60 Pa                               |
| Flow Peak:           | 20.17 L/min                             |
| Inhaled Volume:      | 0.961 L                                 |
| Inhalation Time:     | 3.320 s                                 |
| Inhalation Region:   | 0.910 - 4.230 s                         |

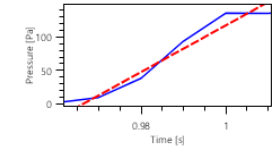
### Profile Graphs

#### Pressure Graphs

Pressure [Pa]

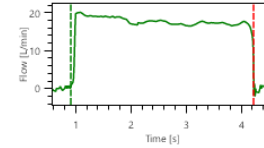


Pressure Slope (Zoomed)

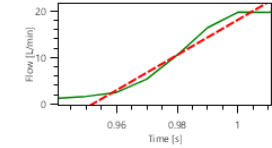


#### Flow Graphs

Flow [L/min]



Flow Slope (Zoomed)



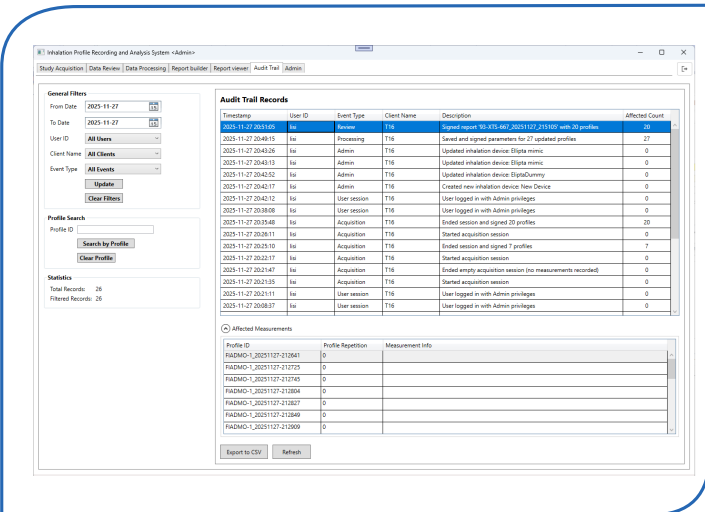
### Notes

Profile Note:

At Springfield SC

3 / 21

A section of a report in pdf format.



The Audit Trail.

## Larger Clinical Sessions

For larger clinical sessions with events recurring over a longer timespan, the secure database stores all data and is fully accessible to all members of the research team with a valid MIDAS license on their office computers.

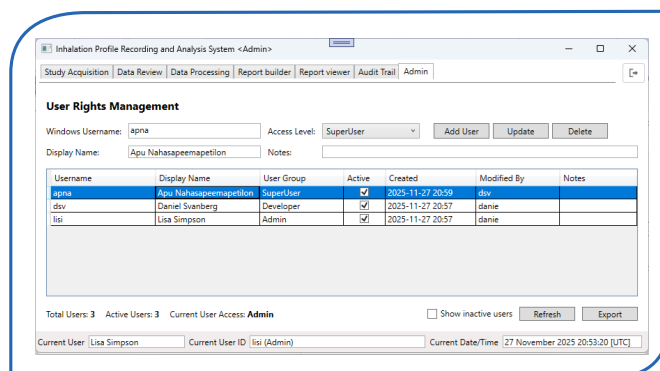
Our team of developers and IT engineers can assist both the clinical centre and the research unit in setting up the system to comply with corporate IT policies, based on dialogue with the relevant IT departments.

## Regulatory Compliance

AB FIA has a long experience of providing fully compliant cGMP/cGCP software and systems for the pharmaceutical industry. The setup including MIDAS, database and STIG PL can be configured to maintain data integrity according to predicate GMP rules by means of the security measures on STIG PL, the host computer and the database. STIG PL can be configured to make connection to a host computer mandatory for its operation, thus achieving full traceability between the event, time and data file.

## Other STIG Portable Products

Do you recognise STIG from other situations in an inhaler test laboratory? You have probably seen STIG as rise time and flow measurements instrument, or as a multifunctional pressure and flow logger. You find all available variants of this handy and portable format on our online store.



The Admin panel.



STIG PL comes in a case and can be conveniently carried between clinical units.

## Order Information

You find all our products on the online store at <https://shop.fia.se/>.

For training devices Enquire with FIA.

| Product                                                   | Article Numbers |
|-----------------------------------------------------------|-----------------|
| MIDAS (Manage Inhalation Data Automatically and Securely) | F1272 MIDAS     |
| STIG Pressure Logger Clinical Companion                   | C016666         |

For more information on the company refer to [www.fia.se](http://www.fia.se)

*Disclaimer - The MIDAS application and STIG PL device are not medical devices nor ISO 13485 certified. They do not claim to comply with the In Vitro Diagnostic Regulation (IVDR) and should not be used to diagnose actual patient conditions. Yet they comply with the rules and regulations of cGMP/cGCP when properly configured in dialogue with the customer.*



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