

Measuring Flow Rates through DPIs in Clinical Studies

**Introducing the STIG PL, a GCP compliant device
that can be used to:**

- Train subjects how to inhale correctly through DPIs
- Record the flow/pressure drop profiles that subject generated through the DPIs



The STIG Pressure Logger (PL) from AB FIA provides a portable solution to record the inhalation profiles from study subjects in clinical trials in a convenient and secure way. The instrument lends itself particularly well to passive devices such as dry powder inhalers, from low to high resistance with a properly configured STIG PL.

A typical set up consists of the STIG PL instrument, an inhalation device and a Windows® computer.

The device is connected to a pressure port on STIG PL with a tube. When the patient inhales through the device STIG PL measures the pressure profile during a set time and saves the profile. The pressure can be mathematically converted to flow.





Training Device

A training device with an appropriate tube connected to the pressure port of STIG PL.



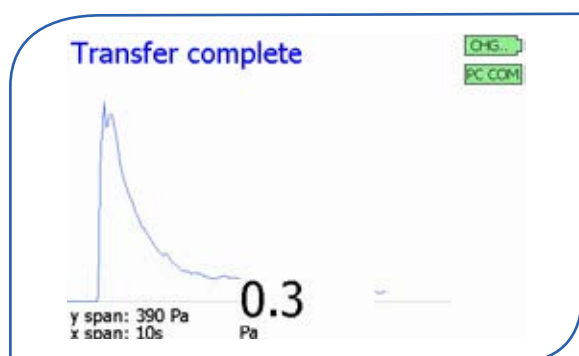
User Guidance

The user is guided by messages on the screen. Once a pressure pulse is sensed by the instrument the profile is recorded.

In the Clinical Context

For a clinical study STIG PL is well-suited due to its portability and simple operation. The study assistant assigns a number for the coming profile by typing on STIG PL's touch screen and puts the instrument in a waiting mode, ready for the next inhalation. The file name constitutes

of the reference number and a timestamp. The user is further guided by the screen showing the profile, albeit information is kept simple since the evaluation of the profiles are best made in a dedicated software on a computer.



Recorded Profile

The picture shows a recorded profile with auto-adjusted axis scales and the current pressure (in the resting state, close to zero).



Connecting a mouthpiece

The simplest way of achieving a device which mimics the target inhaler is by connecting a mouthpiece of interest to an adapter with a set flow resistance and a pressure tap.

Connected to your Inhaler

The resistance of the device when breathing through it, creates a pressure drop which is sensed and recorded by STIG PL. There are different ways to record the pressure drop of an inhaler which at a first glance might not seem that obvious. The most straightforward way is if there is a training device available which sufficiently simulates the device of interest ("target") and has an accessible pressure tap. A range of devices are available from, e.g., Vitalograph Inc., such as the one shown in the picture above. FIA can be of assistant choosing a suitable device.

Alternatively, a representative device can be manufactured to different levels of sophistication. The resistance at known flows through the target device is first recorded in a lab and a dummy device is manufactured which mimics the resistance. A simple narrow-bore tube of

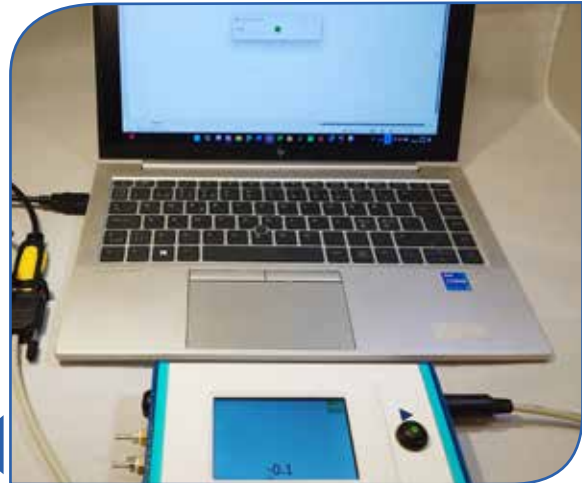
medical grade plastic with a set resistance can constitute the dummy device, possibly with a mouthpiece fitted which mimics the target inhaler, as seen in the picture below.

A more sophisticated solution is to 3D print a body with similar look and feel as of the target device. Depending on the construction of the target device, a pressure tap could be introduced into air passage channels of the device, as long as it does not compromise the function and patient interaction of the device.

Lastly, a conventional pharmaceutical device can be put into a customised air-tight box where the pressure difference of the incoming and outgoing air is measured.

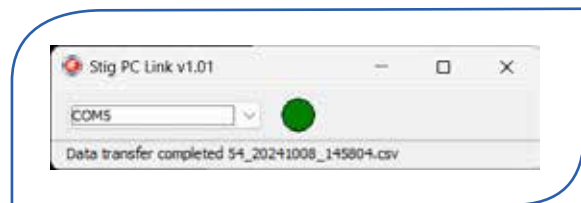
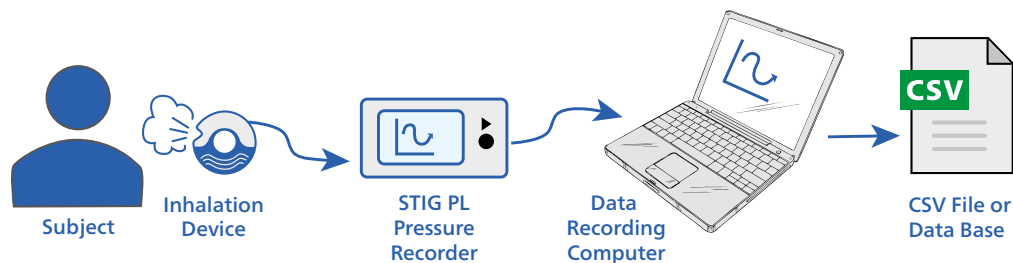
The Inhalation Profile and Data

The data from STIG PL is pressure (flow) against time and meta data such as date, study number/subject etc. The sampling frequency and duration are configurable upon ordering but typically 100 Hz and 10 s. The measurement data is stored as a CSV file which is transferred to a USB stick inserted into STIG PL. Alternatively directly through a speciality cable to a computer with the PCLink software available from FIA. The latter improves data integrity controls. Instead of a CSV file the data can be directly formatted for remote database storage. FIA can assist the customer to set up an appropriate database.



Connected to Computer

STIG PL when connected to a computer, the readiness of the system is signalled by green indicators on both screens.



Message on STIG PCLink

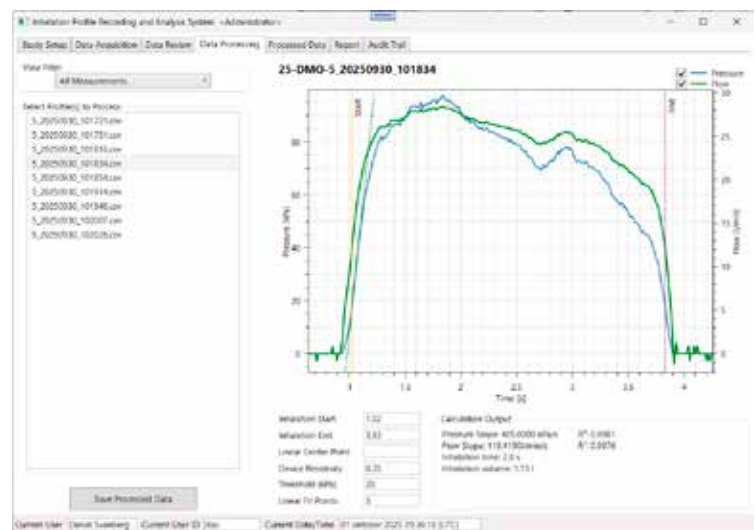
Message which appears on STIG PCLink on the computer after the file has successfully been transferred.

Analysing Inhalation Profile Data

FIA can offer evaluation tools for the profiles of various functionality, from validated Excel templates to dedicated inhalation profile software. Please enquire about these opportunities with FIA.

The raw data of the STIG PL file is a simple data set, which can be further analysed in suitable applications and reported as in this example available from FIA according to customer configuration.

In 2026 we will launch our dedicated inhalation profile software which will cover the full data life cycle from acquiring and analysing the profile (example shown), to comprehensive electronically signed reports.



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.



Regulatory Compliance

AB FIA has a long experience of providing fully compliant cGMP/cGCP software and systems for the pharmaceutical industry. In the context of STIG PL and PCLink software the setup can be configured to maintain data integrity according to predicate cGCP rules by the security measures on the STIG PL and host computer. For larger trials with recurring events a secure database can store the data from the host PC. STIG PL can be configured so connection to a host computer is mandatory in order to operate STIG PL, to achieve full traceability between the event, time and data record.

STIG PL

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 Number
STIG Pressure Logger Clinical Companion	C016666
STIG PCLink Windows Application	F1258 STIG

For a general company introduction refer to www.fia.se

Disclaimer - The STIG PL device is not a medical device, nor ISO 13485 certified, nor complies with In Vitro Diagnostic Regulation (IVDR) or to be used to diagnose actual patient conditions. It complies however with the rules and regulations of cGMP/cGCP with proper configuration in dialogue with the customer..



AB FIA

Medicon Village, Building 401
223 81 Lund, Sweden
+46 46 13 90 00
i@fia.se • www.fia.se

AB FIA Member of



www.mvic.se