

# STYL'One Nano

The Benchtop Compaction Simulator



# Research and Development in Focus

With over 125 years of combined experience with small-scale, fully instrumented machines, KORSCH and MEDELPHARM have entered into a strategic partnership agreement focused on offering the most advanced line of R&D tablet compression technology in the world.

The combined R&D product line meets and exceeds every requirement, from early-stage powder characterization and formulation development, to scale-up and production support.

The new R&D line covers the full spectrum of tableting technology from single-layer to five-layer, as well as core coating. MEDELPHARM compaction simulators are the perfect complement to the KORSCH product line.

[www.korsch.com](http://www.korsch.com)

# Flexibility of Use

The STYL'One Nano is a compact tabletop unit that can be installed on an existing bench, on its optional mobile base or even inside a downflow booth.

The machine is easy to clean due to a GMP working area featuring smooth surfaces and full accessibility.

It permits very small material quantities to be utilized and characterized very quickly with a minimum of setup.

With a range of options and accessories the STYL'One Nano is a flexible research tool. Depending on future needs the machine can be retrofitted easily.

## Fields of Application

### API / Excipient characterization

- Work with minimal material quantities
- Assess Material Attributes
- Compare different material suppliers

### Analytical development

- Easy and consistent sample production for analytical method development and validation

## Formulation development

### Formulation development

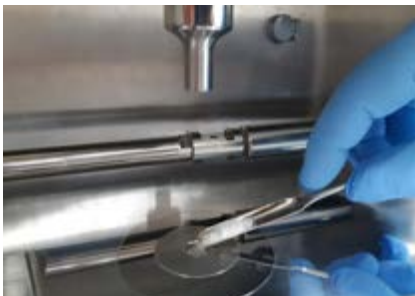
- Formulation feasibility and optimization
- Evaluate the effect of Process Parameters (PP)
- Assess Quality Attributes (QA)

### Production of small batches

- Prototyping
- Feasibility assessment
- Early stability batches

## Different Filling Solutions

- Manual Die Filling



- Gravity Feeder



- Force Feeder



## Flexible Tooling

The machine permits the use of standard TSM / EU B, BB, BBS and D tooling of any shapes, including multi-tip and oversized tooling. The STYL'One Nano permits a wide range of tablet formats, including mini-tablets of 2 mm to a maximum tablet diameter of 40 mm.

- Simple tool setup and exchange
- Minimal parts to assemble
- Change over in 5 minutes
- Up to 40 mm diameter oversized tooling

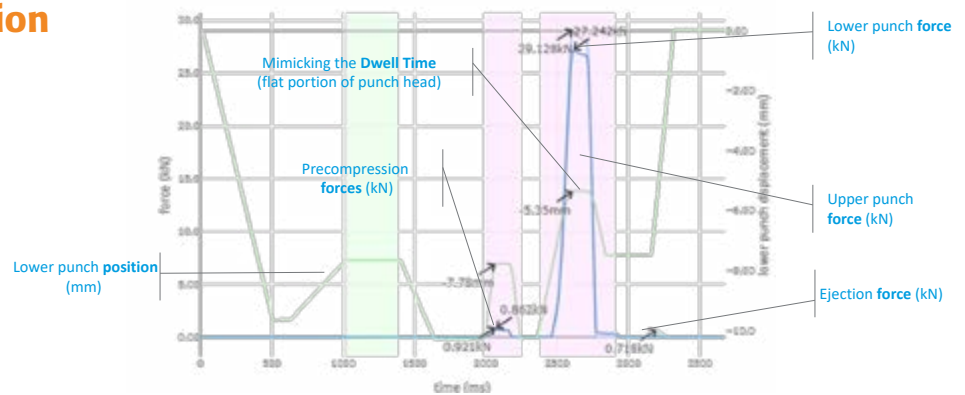


# Advanced Instrumentation

The STYL'One Nano is designed with the most advanced instrumentation to measure the upper and lower compression force and punch position. Mechanical deformation is automatically measured and compensated for by the software

## Standard Instrumentation

- Precompression Force
- Main Compression Force
- Ejection Force
- Upper Punch Displacement
- Lower Punch Displacement



## Innovative Drive Technology

At the heart of the STYL'one Nano is a powerful drive system and a low-inertia brushless motor controlled by the Alix software, which supports high punch acceleration and velocity required to mimic R&D rotary press kinetics. The base of the STYL'One Nano is a unique system to drive the lower punch with planetary roller screws, a maintenance free technology used in the aeronautic industry. Upper

punch movements are carried out by a pneumatic actuator with two positions (up or down) and a mechanical stop for the lower position. This technology is hydraulic-free and benefits from mechanical repeatability. The die is stationary and the programmable feeder moves over the die to fill it either with several oscillations or passages, or even with a forced feeding paddle system.

### Pre- and Main Compression

A powerful drive technology allows to replicate the precompression and main compression of research rotary presses at the same velocity.

### Force and Position Control

Position control is the preferred choice to mimic compression dynamics and to study the effect of precompression level. Force control is the mode of choice for API characterization or to quickly plot tablet breaking force vs compression force.

### Fast Lower Punch Dynamics

Compression displacement is performed by the lower punch which is similar to the punch travel on rotary tablet presses, where most of the pressure is applied from the lower punches. Punch velocity is twice as fast as any eccentric press..

### Independent Fill Height and Compression Thickness Adjustment

Unlike eccentric single-punch presses, adjusting the fill height is independent of the compression thickness.

# STYL'One Nano Benchtop Compaction Simulator

Tableting has never been so easy to investigate, from pure API characterization to formulation assessment.

The STYL'One Nano features not only all advantages of single-punch presses at formulation stage like an easy operation for small amounts of API but it also includes in a small footprint the unique and powerful drive technology, normally

reserved for an Elite of premium compaction simulators.

Scientists can use the flexibility to drive the punches at high velocity to replicate the pre- and main compression of an R&D rotary tablet press. The powerful Alix data acquisition and analysis software allows you to screen your formulation in less than 5 minutes.



## Benefits at a Glance

- Compact & Mobile
- Easy access to the compression zone
- Standard EU/TSM B&D Tooling
- Quick changeover
- Easy to handle – Easy to clean
- Ideal for minimal material quantities
- Different feeding modes
- Different compression profiles (USP <1062>)
- Full Instrumentation (Force & displacement)
- Driven by Alix, the most powerful data acquisition and analysis R&D software
- Drives decision making during early product development

# Powerful Software Platform

Alix, installed on a laptop, guides the user step by step on a user-friendly interface. The software controls the STYL'One Nano, collects the data generated and analyzes the data by

plotting a wide range of parameters including manufacturability, tableability, compressibility and compactibility. Customized plots for any data parameter are easily developed.

## Control System

Like the flagship STYL'One Evo, STYL'One Nano is entirely controlled by software. Each process parameter is precisely entered through a Human Machine Interface (HMI):

- Filling and dosing height
- Force, Pressure or Punch distance for precompression and main compression
- Feeder parameters
- Number of tablets

## Data Acquisition and Analysis

The HMI interface simplifies the design and execution of experiments. While running an experiment, tablet tester data can be uploaded and graphs generated. Build for instance your own database of APIs and excipients or optimize your formulation, with powerful search engine.

- Get fast feedback on your experiment to drive your development
- No need to export the data for subsequent analysis
- Access data from any computer to simplify data analysis



# Efficient Analysis

ALIX™ acquires all data in real time. Pre-defined USP <1062> plots for tablet characterization are natively integrated into STYL'One Nano software. Manufacturability profiles (tablet breaking force vs compression force) or tabletability profiles (tensile strength vs pressure) are readily available.

Compressibility and compactibility profiles are also available when powder true density is known.

The user can also create its own custom plots and generate reports. As a result, Alix expedites research projects.

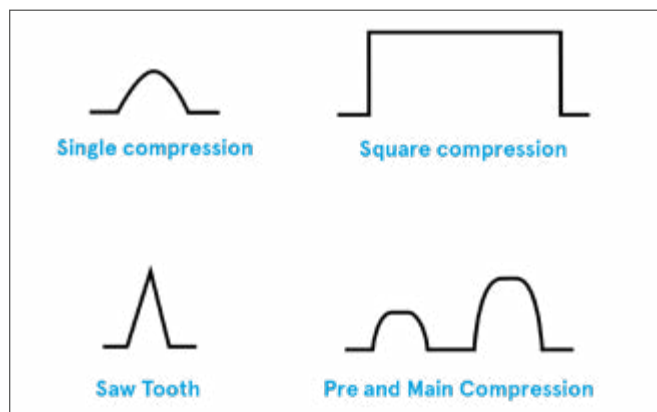
## Profiles

Specific R&D Profiles:

- Saw tooth = constant compression speed to characterize API & Excipient or evaluate formulation. Largely used to analyze and standardize strain rate sensitivity tests (speed sensitivity).
- Square compression = extended dwell time for viscoelasticity analysis (analyze particle rearrangement)

Small Rotary Press Profiles:

- Single or pre/main compression to mimic the dynamics of small rotary tablet presses



## Connection to Tablet Tester

ALIX™ can be connected to external tablet testing equipment (tablet weight, thickness, tablet breaking force, length, width) to automatically collect and process the corresponding data in correlation with the compression force data measured on the STYL'One Nano.



# Advanced Training

- The STYL'one Nano is a sophisticated compression data acquisition tool, and to ensure that the full capability of the system can be realized, our teams of experts can provide advanced training to convey best practices for experimental design, data acquisition, data analysis and interpretation of the results.
- Characterize APIs & Excipients
- Formulation Development and Optimization

## Join the Community

Enhance your tableting skills by joining MySTYL'One.com resource center and user community to share information and access a comprehensive library of STYL'One scientific content.



SCIENCE LABORATORY



MEDELPHARM LYON



INNOVATION CENTER



KORSCH BERLIN



INNOVATION CENTER



KORSCH BOSTON

## Formulation Development Services

KORSCH and MEDELPHARM scientists have been collaborating with customers on tableting projects for decades. Our mission and passion are problem solving and helping accelerate your product development. Our international network of tableting experts and laboratories is equipped with the latest techno-

logy to provide formulation services from early API characterization all the way to high-speed process optimization. All we need from you is a few grams of powder to generate data and suggestions to help with your decision making.



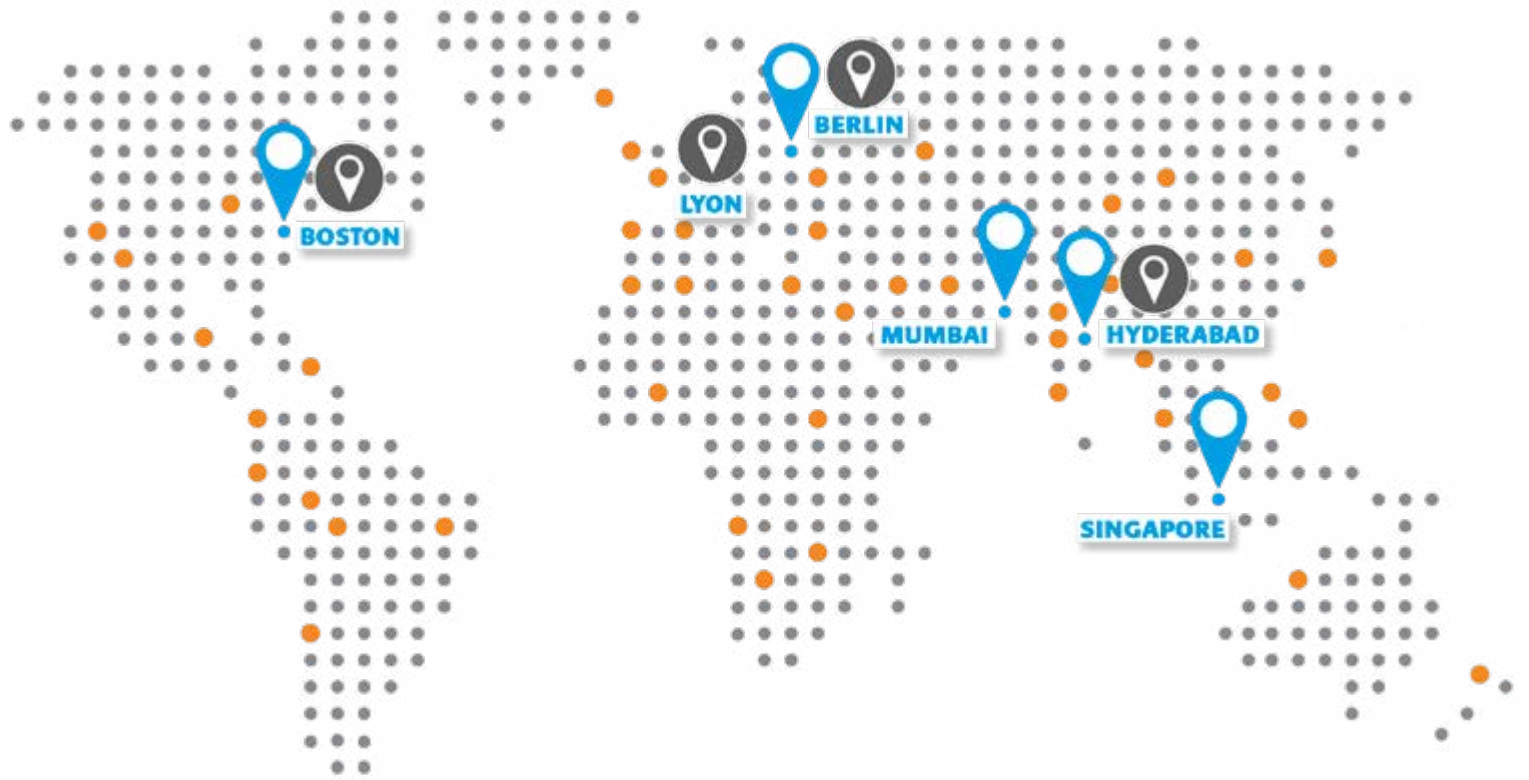
# STYL'One Nano Machine Specifications

| Description                   |                              |  |
|-------------------------------|------------------------------|--|
| Punch Stations                |                              | 1  |
| Punch Type                    |                              | EU/TSM B+D, EU-1-441 and non-standard                      |
| Die Type                      |                              | BBS, BB, B, D and non-standard                             |
| Max. Production Output        | tabs/h                       | 1,800  |
| Max. Tablet Diameter          | mm                           | 25 or 40 (non-standard)                                    |
| Max. Die Filling Height       | mm                           | 21 (B), 23 (D or non-standard)                             |
| Compression Mode              |                              | Force or displacement driven                               |
| Upper Punch Penetration Depth | mm                           | 3 fixed  |
| Max. Precompression Force     | kN                           | 50   |
| Max. Main Compression Force   | kN                           | 50   |
| Load Application              |                              | Lower punch  |
| Lower Punch Velocity          | mm/s                         | 90   |
| Lower Punch Acceleration      | mm/s <sup>2</sup>            | 8,000  |
| Dwell Time                    | millisecond                  | 2 – 3,000  |
| Tablet Format                 |                              | Single-layer only  |
| Power Supply Voltage          |                              | Europe: 230 V 1-Phase 50/60 Hz<br>USA: 220 V 3-Phase 60 Hz |
| Peak Power                    | W                            | 3,600  |
| Electric Protection           | A                            | 16   |
| Fault Current Protection      | mA                           | 30   |
| Compressed Air                | Bars<br>10 L / min (nominal) | 6  |
| Weight                        | kg                           | 255  |
| Load distribution             | kg/m <sup>2</sup>            | 910  |


Technical modifications reserved.


The technical specifications included in this document represent optimal parameters and are dependent on product quality and machine settings.

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