

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 offer the most advanced line of 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.

It covers the full spectrum of tableting technology from single-layer to five-layer, as well as Tab-in-Tab. MEDELPHARM compaction simulators are the perfect complement to the KORSCH product line.

www.korsch.com

Flexibility of Use

The STYL'One Nano is a compact tabletop R&D tablet press that can be installed on an existing bench, on an optional mobile cart 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, such as external lubrication and an instrumented die, the STYL'One Nano is a flexible tableting research tool. Depending on future needs the machine can be retrofitted easily.

Material Understanding

API / Excipient characterization

- Work with minimal material quantities
- Assess criticality of material attributes
- Compare different material suppliers

Analytical development

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

Product Development

Tablet formulation development

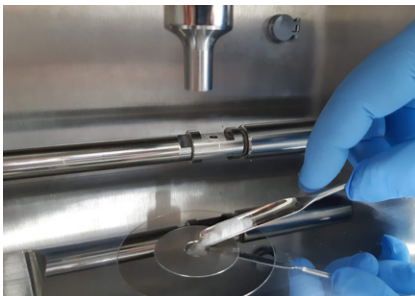
- Test and optimize formulations
- Evaluate the effect of Process Parameters (PP)
- Select the most suitable manufacturing process

Production of small batches

- Feasibility assessment and prototyping
- Early stability batches

Different Filling Solutions

■ Manual Die Filling



■ Gravity Feeder



■ Forced Feeder



Flexible Tooling

The machine permits the use of standard EU/TSM 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

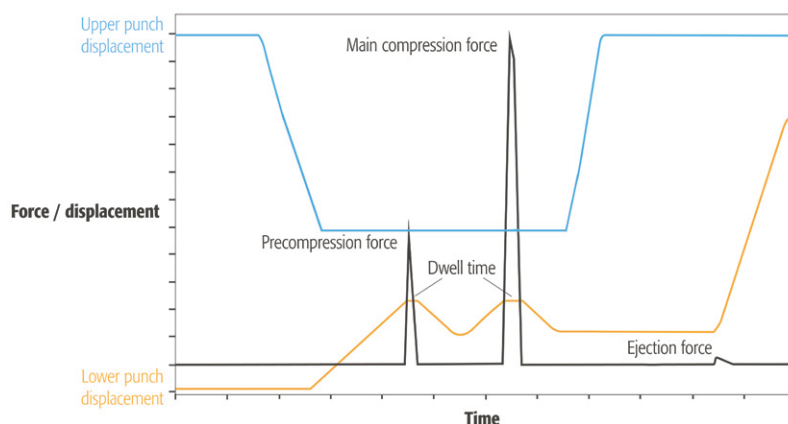


Advanced Instrumentation

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



Optional Instrumentation

- Radial die wall pressure

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 simulate 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 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 simulate compression dynamics and to study the effect of process parameters such as the precompression level. Force control combined with external lubrication is the mode of choice for API characterization.

Fast Lower Punch Dynamics

Compression displacement performed by the lower punch is similar to the punch travel on rotary tablet presses, where most of the pressure is applied by the lower punches. Punch velocity is twice as high as with any single-punch press.

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 understand 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 tooling and product changeover
- Easy to handle – easy to clean
- Ideal for minimal material quantities
- Different feeding modes
- Different compression profiles (USP<1062>)
- Full instrumentation (force & displacement)
- Fast Design of Experiment (DoE) execution
- Drives decision making during early product development
- Containment execution

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, computes and analyzes the generated data by plotting a wide range of USP<1062> graphs including manu-

facturability, tableability, compressibility and compactibility. Customized plots for any data parameters are easily developed to explore porosity, ejection stress or elastic recovery.

Control System

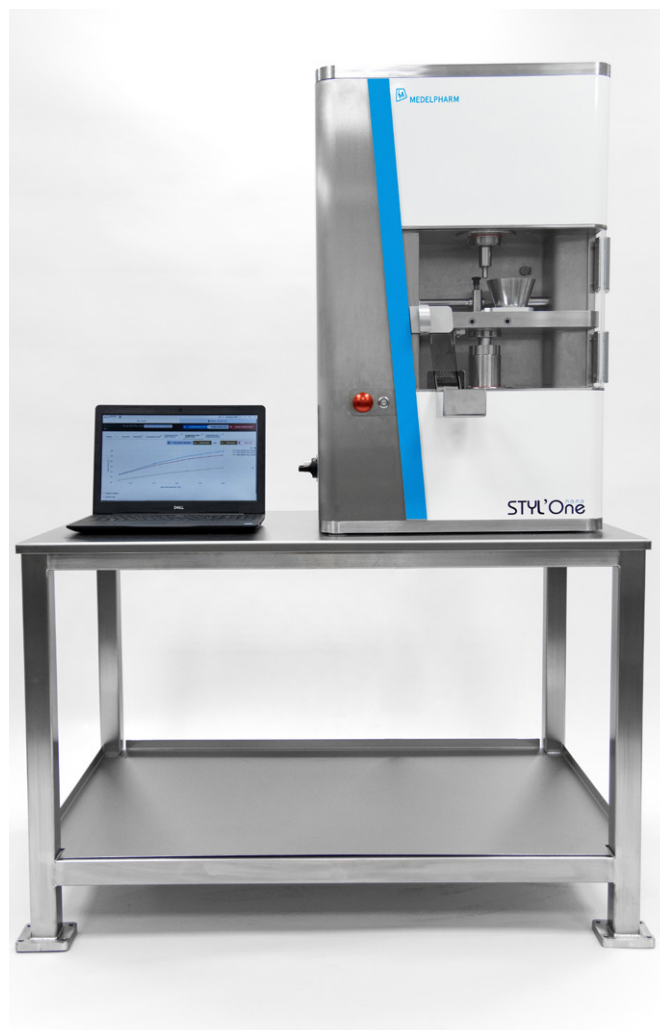
Like the flagship STYL'One Evo, STYL'One Nano is entirely controlled by software. Each process parameter is precisely entered through a Human Machine Interface (HMI):

- Filling and dosing height
- Force, pressure, solid fraction or punch distance for precompression and main compression
- Feeder parameters
- Number of tablets
- Ejection height

Data Acquisition and Analysis

The HMI 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 a powerful search engine.

- Get fast feedback on your experiment to drive your development
- 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.

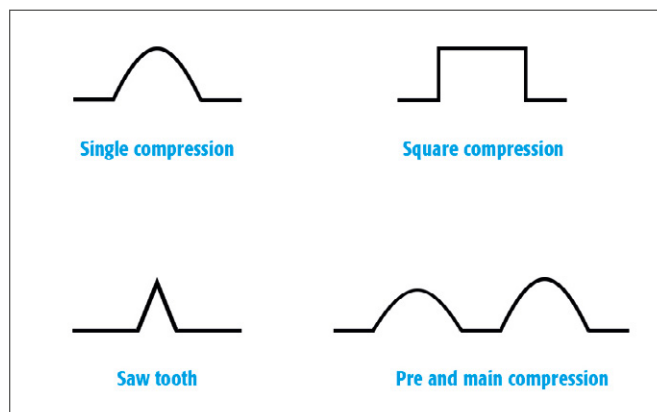
Profiles

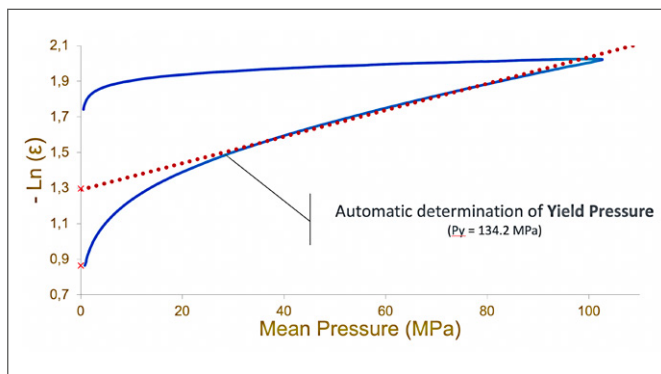
Specific R&D Profiles:

- 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:

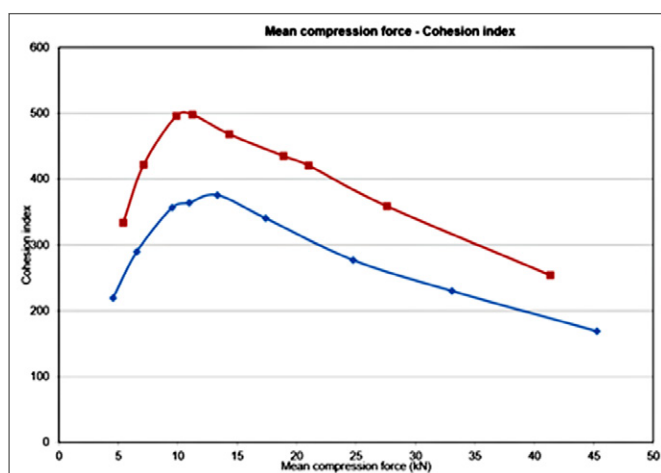
- Single or pre-/main compression to mimic the dynamics of small rotary tablet presses





Single Tablet Capability

This part of the software permits analysis of tests conducted on a single tablet. It allows the full waveform data to be exported to an Excel or CSV file. A report showing Heckel plots and the calculated energies (compression energy, flow energy, elastic energy, plastic energy) can also be generated.



Multi-Criteria-Analysis

The multi-criteria functionality permits the analysis on several tests containing several tablets. The values can then be exported into a single Excel or CSV file. Multi-criteria plots show the evolution of one criteria depending on one another. The following plots are possible:

- $Y=F(X)$ with any parameter
- Porosity
- Force - Hardness, Force - Solid Fraction
- Elastic recovery, ejection stress, etc.



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.

Containment Solution

The STYL'One Nano is designed to work under negative pressure and as such, the standard execution does offer a clean working environment. For applications requiring a higher level of operator safety, the system is available in a WipCon®

execution. Suitable for OEB 4/5, it offers a full Wash-in-Place capability, a containment isolator, and glove port access to the working area. The tablets are being produced and can be checked before exiting the isolator.

STYL'One Nano WipCon®

The STYL'One Nano WipCon® offers full high containment and a Wash-in-Place execution:

- Automatic negative pressure control and monitoring
- Continuous liner or RTP port to bring material in and out
- Safe cleaning with integrated vacuum wand and spray guns

The STYL'One Nano can safely run while the operator performs other tasks inside the isolator like measuring tablet weight and hardness or preparing the next experiments.

The STYL'One Nano WipCon® can also be safely operated with the isolator opened when working with non-hazardous material.



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 are providing advanced training to convey best practices for experimental design, data acquisition, data analysis and interpretation of the results.

- General machine operation
- Instrumentation
- External lubrication
- Material sparing methodology
- Streamlined material characterization
- Single-layer tablet formulation & optimization
- Compression analysis
- Radial die wall pressure
- Elastic recovery, energies and Heckel analysis
- USP<1062>: compactibility, ejection stress, compressibility and tableability
- Strain rate sensitivity (SRS)

Join the Community

Enhance your tableting skills by joining mySTYL'One resource center and user community. Benefit from additional mySTYL'One services to make the most of your compaction simulator.

SCIENCE LAB – MEDELPHARM LYON



INNOVATION CENTER – KORSCH BERLIN



INNOVATION CENTER – KORSCH BOSTON



INNOVATION CENTER – KORSCH HYDERABAD



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.

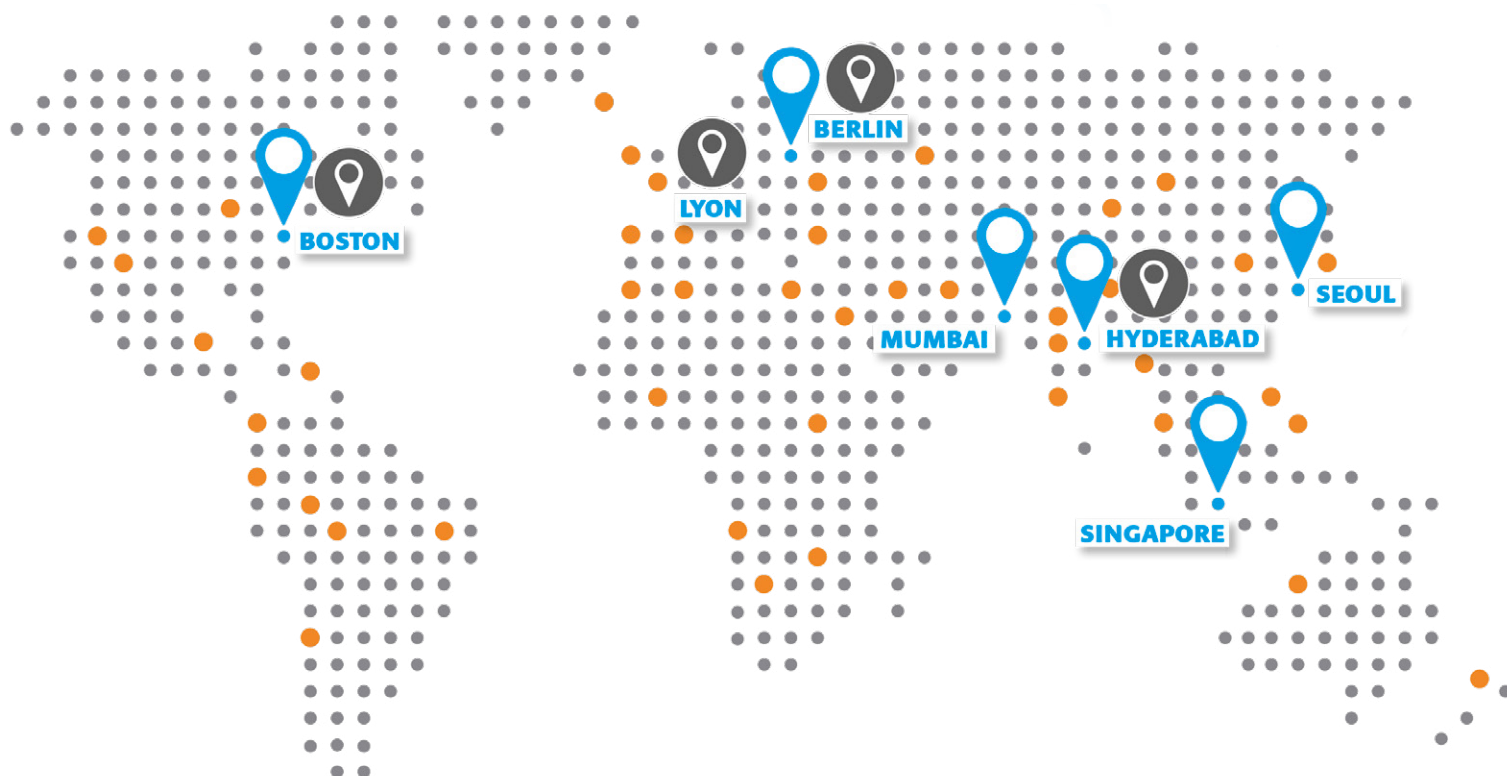
STYL'One Nano Machine Specifications

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 (contact us for special formats)
Max. Die Filling Height	mm	21 (B), 23 (D) (contact us for special formats)
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 ²	8,000
Dwell Time	millisecond	2 – 3,000
Tablet Format		Single layer, mini, core rod
Power Supply Voltage		Europe: 230 V 1-Phase 50/60 Hz USA: 220 V 3-Phase 60 Hz
Peak Power	W	3,600
Electric Protection	A	16
Fault Current Protection	mA	30
Compressed Air	Bars 10 L / min (nominal)	6
Weight	kg	255

Technical modifications reserved.

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

KORSCH Global Service Network



OUR SERVICE HELPLINE IN YOUR REGION:

Europe, Near East, Africa

Phone: +49 30 43576-300
service@korsch.de

America

Phone: +1-800-KORSCH-1
service@korschamerica.com



INNOVATION CENTERS

Eastern Asia and South-East Asia

Phone: +49 30 43576-300
service@korsch.de

Southern Asia

Phone: +91 98 19004298
service@korschindia.com

www.mattheis-berlin.de

www.korsch.com



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