

STYL'One Evo

Advanced 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

The Most Versatile Compaction Simulator

The STYL'One Evo is the most advanced compaction simulator and has the capability to produce virtually any tablet format. The machine features 50 kN pre/main compression force capability as a standard, up to 120 kN as an option.

The machine permits the use of standard EU/TSM B, D, and EU-441 tooling. Special tooling for larger formats, or multi-tip tools for mini-tablets can also be utilized. The STYL'One Evo is an easy to use, easy to clean R&D press.



- Work with minimal material quantities
- Work with USP<1062> compression profiles
- Work with compression kinetics similar to production

**Understand
and Formulate
your Product**



- Single-layer
- Multi-layer
- Tab-in-Tab

**Develop any
Type of Tablet**



- Simulate any high-speed production press
- Define optimal process parameters
- Produce small technical and clinical batches

**Scale-up to
Production**



- Simulate any roller compactor
- Determine suitable production parameters
- Fast feasibility assessment with minimal amount of powder

**Study Dry
Granulation**

The STYL'One Evo is very flexible and can be equipped with a wide range of accessories and software modules to accommodate virtually any product development requirement. The powerful software is very intuitive and the machine permits tablet format changes in just minutes.

Compression studies can be planned and executed in a simple and efficient manner, with the capability to create an experiment using standard profiles (saw tooth or square wave), or replicate a high-speed production press. The STYL'One Evo is offered in DryCon® and WipCon® containment executions.

Characterization of API and Formulations

The STYL'One Evo comes fully instrumented to provide precise understanding of powder tableting behavior and to evaluate the effect of Process Parameters (PP) on tablet Quality Attributes (QA). Additional accessories enable you to measure radial die wall pressure and take-off force. The heated die enables the evaluation of the temperature influence on your powder compression.

- With minimal quantities
- Comparison of different sources of material
- Formulation development and optimization

Flexible Configuration

The STYL'One Evo permits the production of single-layer and multi-layer up to five-layer tablets with three different products. A core feeding system permits automated positioning of cores onto the powder bed for Tab-in-Tab applications.

- Intuitive multi-layer and Tab-in-Tab software modules
- Quick conversion between the different tablet formats
- Retrofittable at any time

Simulation of any Rotary Tablet Press

The STYL'One Evo can reproduce the high compression speed of large production rotary presses. A micro dispensing unit allows tablet development using external lubrication. The machine can be connected to tablet testers for automatic data transfer and computation.

- Comprehensive library of rotary press compression profiles
- External lubrication feasibility assessment
- Good and bad tablet sorting chute
- GMP production module with automatic weight regulation

Simulation of any Roller Compactor

Lab-size roller compactors have identical roller diameters of those installed on production-scale machines, requiring a large amount of powder, whereas a unique tool like the STYL'One Evo can simulate roller compactors with a very limited amount of product.

- Roller compaction software module
- Dry granulation feasibility assessment
- Specific library of roller compactor profiles
- Quickly target a specific solid fraction

STYL'One Evo Advanced Compaction Simulator

Tableting has never been so easy to investigate, from pure API characterization and formulation development to scale-up at production speeds. The versatility of the STYL'One Evo covers all tablet formats from single to five-layer, including core placement for Tab-in-Tab.

The machine is equipped with a unique drive technology in a compact footprint which is ideal for the laboratory

environment. The simulator can operate in a displacement mode to replicate any rotary press, or in a compression force mode where the system will produce tablets at preset force targets.

The powerful and intuitive data acquisition and analysis software is integrated in the STYL'One Evo which supports full understanding of powder tableting behavior.



Benefits at a Glance

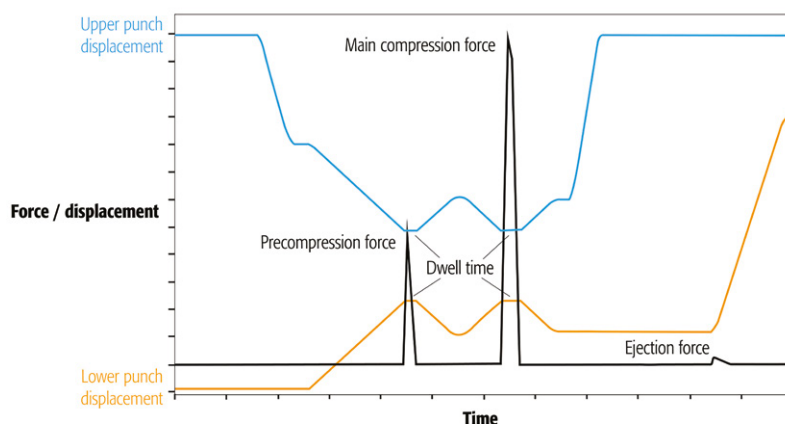
- Easy handling and cleaning
- Innovative drive technology
- Standard EU/TSM B&D tooling
- Full instrumentation (force & displacement)
- Ideal for minimal quantities
- Simulation of any rotary tablet press
- Multi-layer & Tab-in-Tab modules
- Roller compactor simulation module
- Powerful data acquisition and analysis software
- Fast Design of Experiment (DoE) execution
- DryCon® and WipCon® executions

Advanced Instrumentation

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

Standard Instrumentation

- Precompression force
- Main compression force
- Ejection force
- Upper punch displacement
- Lower punch displacement



Optional Instrumentation

- Radial die wall pressure
- Take-off force
- Dual scale

Innovative Drive Technology

At the heart of the STYL'One Evo is a powerful drive system and a low-inertia brushless motor controlled by the Analis software which supports high punch acceleration and velocity required to simulate production rotary press kinetics. The base of the STYL'One Evo is a unique system to drive both the upper

and lower punch independently with planetary roller screws, a maintenance-free technology without hydraulics used in the aeronautic industry. The die is stationary and the feeders move over the die to fill it. An innovative system allows feeding of one layer or multi-layer with up to three feeders.

Pre- and Main Compression

A powerful drive technology allows to replicate precompression and main compression of rotary tablet presses at high punch 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 and Independent Upper and Lower Punch Dynamics

Compression displacement is performed by the upper and lower punch to simulate vertical punch travel on a rotary tablet press. The upper punch penetration can be adjusted

to assess the criticality of this process parameter. Both asymmetric and symmetric compression can be easily achieved to evaluate the impact on tablet quality attributes.



Powerful Software Platform

The user-friendly Analis software is installed on a laptop or on a panel PC. Analis controls the STYL'One Evo, collects, computes and analyzes the generated data by plotting a wide range of USP<1062> graphs including manufac-

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

Control System

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

- Filling and dosing height
- Force or punch distance for precompression and main compression
- Upper punch penetration depth
- Ejection height
- Feeder parameters
- Number of tablets

Data Acquisition and Analysis

The HMI simplifies the design and execution of experiments. Tablet tester data can be uploaded automatically to support subsequent reports and graphs.

- 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

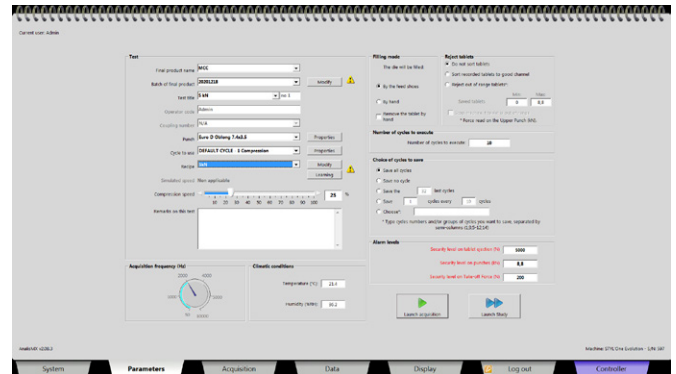
Efficient Analysis

The Analis software has been designed with different modules to accommodate a wide range of tablet formats while keeping ease of use and ergonomics at the heart of the development. Pre-defined compression cycles are readily accessible for almost all existing production tablet presses. In

addition, R&D compression profiles are available, and new profiles can be generated to evaluate filling time, compression time of precompression and main compression, relaxation time between pre- and main compression, time before ejection, and ejection speed.

User Friendly Interface

The interface looks like a laboratory notebook which simplifies and streamlines experimental design and data analysis. The setup of experiments is done by specifying the tooling type and the compression dynamics (cycles and process parameters). After high frequency data collection, the system moves seamlessly to data analysis and graph generation.



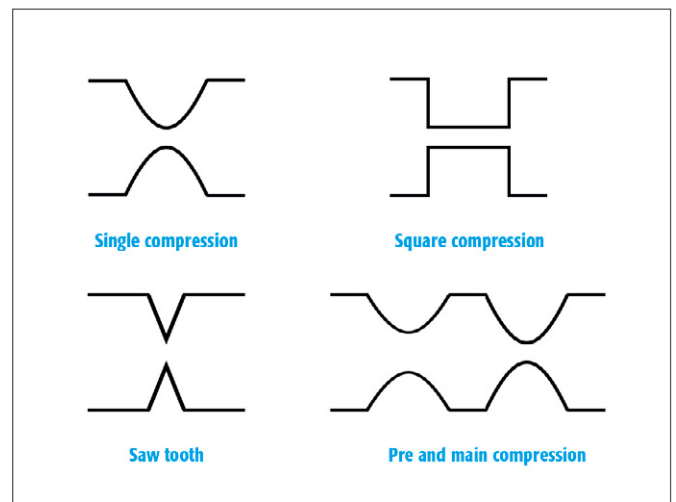
Profiles

Specific USP<1062> 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 visco-elasticity analysis (analyze particle rearrangement)

Pre-loaded rotary tablet press profiles:

- Full library of rotary press profiles to perform development / troubleshooting under production conditions



Connection to Tablet Tester

Analis 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 Evo.

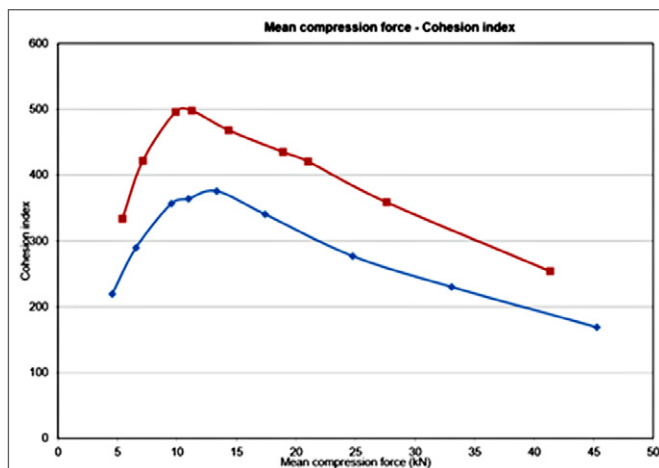
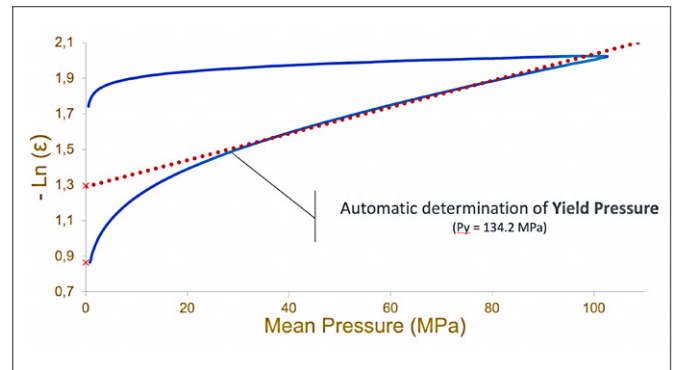


Analisis acquires all data in real time. USP<1062> plots for tablet characterization are integrated into STYL'One Evo software. Manufacturability profiles (tablet breaking force vs compression force) and tabletability profiles (tensile strength

vs pressure) are readily available. Compressibility and compactibility profiles can be used when powder true density is known. The user can also build customized plots and reports. As a result, Analisis expedites research projects.

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.

Scale-up and Production Support

The GMP production module for clinical and commercial batch production permits the quantity of tablets to be produced with automatic weight regulation and tablet rejection, with a corresponding audit trail. The micro dispensing unit allows production using external lubrication. The integration of a tablet tester permits In-Process Control (IPC) for direct weight or hardness regulation.

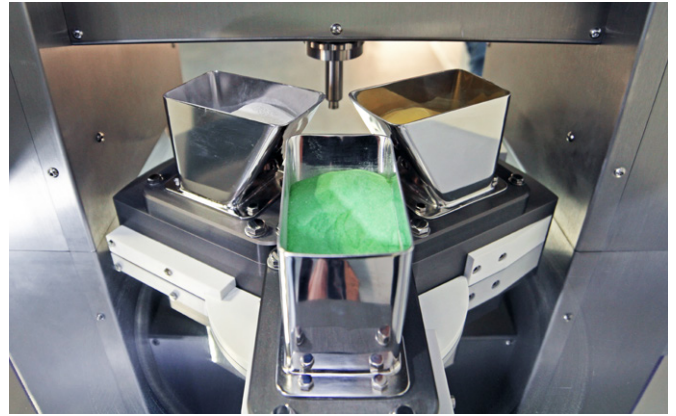


Unprecedented Flexibility

The STYL'One Evo is a flexible research tool that can accommodate virtually any tablet size, shape, and format, making it an ideal choice for OSD development applications.

Multi-Layer up to five Layers

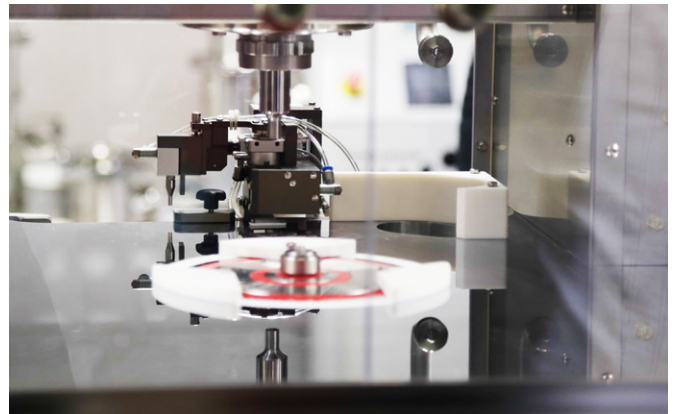
The STYL'One Evo can be fitted with up to three gravity or forced feeders to produce tablets up to five layers. The multi-layer software module permits the layer parameters to be defined based on the tablet format. Critical process parameters including tamping force and filling height of each individual layer as well as precompression, main compression and ejection forces can be easily assessed. Multi-layer tablets can be designed using high-speed rotary tablet press profiles.



Tab-in-Tab

In addition to the multi-layer package, the system can be configured with a Tab-in-Tab device for the easy and fast production of core coated tablets.

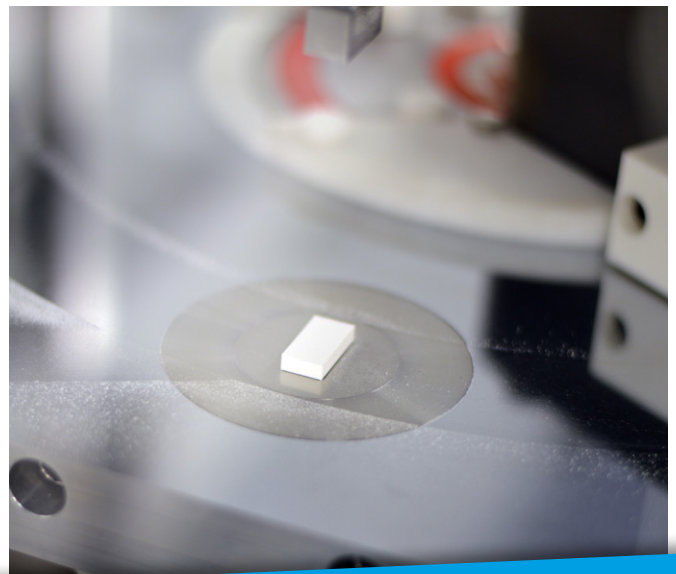
- Precise positioning of cores on three axes (X, Y, Z)
- Easy installation with magnetic fixing system
- Assessment of critical process parameters



Dry Granulation

By targeting solid fraction of "riblets" = "ribbon tablets", the system permits a feasibility assessment as to whether a dry granulation is a suitable process, and predefines the setup parameters of its roller compactor (gap, speed, pressure).

- Simulates sinusoidal kinetics of roller compactors
- Preset solid fraction
- Preset compaction pressure
- Preset gap



Containment Solutions

The STYL'One Evo 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 offered in a DryCon® and WipCon® containment executions. The DryCon® execution

includes improved seals, negative pressure regulation and an inlet HEPA filter. The WipCon® execution, suitable for OEB 4/5, 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 Evo DryCon®

The STYL'One Evo DryCon® adds extra safety by reducing operator exposure to airborne particles during operation:

- Automatic generation and control of air flow ensure permanent negative pressure in the compaction area of the simulator.
- Interlocked doors, glove ports, pass-through box, continuous liners and alarm management permit a safe operation of the equipment and collection of tablets.
- The execution is SMEPAC tested by design and can be certified by a third-party.
- Compaction area can also be flooded with nitrogen allowing experiment with oxygen-sensitive or explosive powders.

The STYL'One Evo DryCon® can also be safely operated with glove ports opened when working with non-hazardous material.



STYL'One Evo WipCon®

The STYL'One Evo 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
- Safe operation while the operator performs other tasks inside the isolator like measuring tablet weight and hardness or preparing the next experiments

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



Advanced Training

The STYL'One Evo is a sophisticated compression data acquisition tool, and to ensure that the full capability of the system can be leveraged, our team of experts is providing advanced training to convey best practices for experimental design, data acquisition, data analysis, and interpretation of the results.

- Understanding of your APIs & excipients
- Product characterization
- Formulation development and optimization
- Scale-up
- Troubleshooting

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 technology 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.

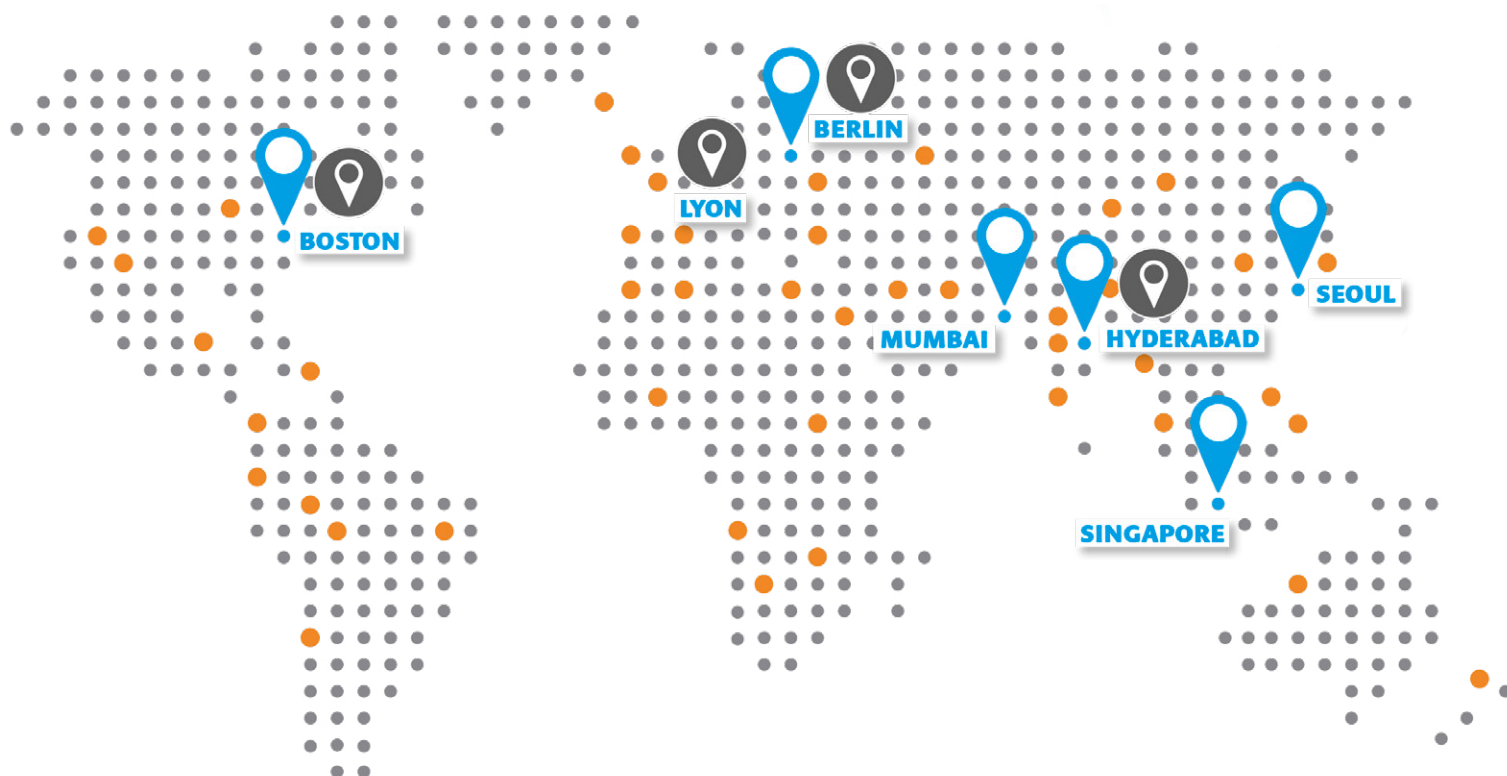
STYL'One Evo Machine Specifications

| Description | | |
|--------------------------------|-------------------|---|
| Punch Stations | | 1 |
| Tool Type | | EU / TSM B and D and non-standard |
| Die | | BBS, BB, B, D and non-standard |
| Max. Production Output | tabs/h | 1,750 |
| Max. Tablet Diameter | mm | 25 or 40 (contact us for special formats) |
| Max. Die Filling Height | mm | 21 (B), 23 (D), 34 (contact us for special formats) |
| Compression Mode | | Force or displacement driven |
| Upper Punch Penetration Depth | mm | 2 – 12 |
| Max. Precompression Force | kN | 50 (up to 120 optional) |
| Max. Main Compression Force | kN | 50 (up to 120 optional) |
| Load Application | | Upper and/or lower punch |
| Punch Velocity (per punch) | mm/s | 490 |
| Powder Bed Reduction | m/s | ~ 1 |
| Punch Acceleration (per punch) | m/s ² | 25,000 |
| Dwell Time | millisecond | 2 – 3,000 |
| Power Supply Voltage | | Europe: 400 V 3-Phase 50/60 Hz USA: 480 V 3-Phase 50/60 Hz |
| Power | kW | 7 kW nominal 2 kW during operation |
| Electric Protection | A | 32 (Type C) |
| Fault Current Protection | mA | Leakage current : 300 (Type Asi) |
| Compressed Air | Bars | 6 |
| | L/min (nominal) | 10 |
| Flow required for Aspiration | m ³ /h | 10 – 30 |
| Weight | kg | 1,075 |

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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