Tablet Compression - Performa™

Courtoy™

***Performance** by design*

GEA Process Engineering | **GEA Pharma Systems**

Where Inspiration meets Technology

GEA Pharma Systems supplies advanced technologies for the preparation and processing of Active Pharmaceutical Ingredients (API) for the production of oral and parenteral dosage forms.

GEA Pharma Systems strives for Price/Performance Leadership providing its customers with highly cost effective, integrated systems for the pharmaceutical industry. GEA Pharma Systems is dedicated to innovation and thereby providing durable quality through its well-established brands: Aeromatic-Fielder™ and Collette™ - batch and continuous granulation, drying, pelletizing and coating; Buck® -contained materials handling; Courtoy™ - tablet compression; Lyophil™ - pharmaceutical freeze drying and automated vial handling systems; and Diessel™ - fermentation and liquid formulation.

GEA Pharma Systems' activities include partnering with customers to develop new products and enhance clinical effectiveness; the supply of R&D-scale and stand-alone production equipment; and the installation of complete integrated production lines aiming at maximum operational reliability.

Financial Strength with GEA Group

As an internationally operating technology group the company focuses on process technology and components for demanding production processes in various end markets. GEA Group is a market and technology leader in the majority of its business lines, with over 20,000 employees worldwide, serving customers in 50 countries and a EUR 4.4 billion revenue in 2010.

The company is listed in the MDAX index (G1A, WKN 660200). In addition GEA Group has a sponsored level I ADR program in the USA.

Performa™ Range

The PERFORMA™ series is the latest addition to GEA Pharma Systems – Courtoy™'s innovative range of rotary tablet presses for the pharmaceutical and nutraceutical industries. The PERFORMA™ design, derived from the well-known MODUL™ machines, has as its centrepiece a large-pitch die table with a large number of punch positions. The PERFORMA™ concept, which incorporates several other new mechanical and control features, offers significant benefits:

- Increased output
- Increased yield
- Flexible tooling change-over
- Superior process control and tablet quality

Performa™ P

- For small to medium scale tablet production
- Featuring Exchangeable Die Disc and exchangeable turret
- Bi-layer capability available as an option
- Extended dwell time at pre-compression and main compression
- Tablet hardness control independent of weight control

Performa™ S

- For medium to high volume tablet production
- Featuring exchangeable turret and swivelling tablet chute
- Extended dwell time at pre-compression
- Tablet hardness control independent of weight control

PERFORMA™ P

With exchangeable turret and Exchangeable Die Disc (EDD)

On the PERFORMA™ P, the entire turret, including punches and dies, can be easily removed from the machine and replaced with a duplicate turret in less than 30 minutes.

Benefits of the exchangeable turret:

- Easy tooling change-over.
- Fast and easy cleaning of compression area and turret.
- Easy access to compression area and turret for inspection and maintenance.

Alternatively, the turret removal arm can be used to lift and swing out the upper punch guide part only. The middle part of the turret, holding the dies, is then easy to remove manually and can quickly be replaced by a duplicate Die Disc. The entire procedure to exchange the EDD takes less than 30 minutes.

Additional benefits of the Exchangeable Die Disc:

- Fast and easy format change over: duplicate EDD allows off-line fitting and locking of the dies in the Die Disc.
- More economical alternative to the exchangeable turret: only the Die Disc needs to be duplicated, instead of the entire turret.

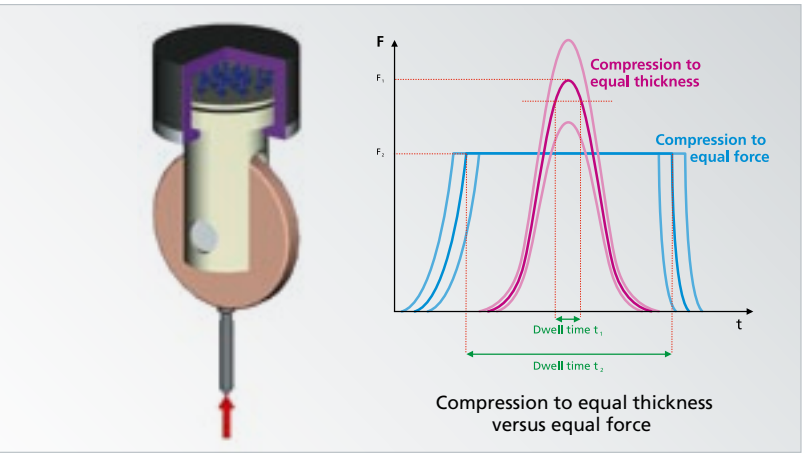
PERFORMA™ S

With exchangeable turret and swivelling tablet chute

The PERFORMA™ S offers an output unmatched by any other single-sided tablet press available on the market today. It can produce up to 405.000 tablets per hour.

Benefit: extremely high output

Whereas on rotary tablet presses speed is typically limited by weight variations, capping and hardness variations occurring as production speed is increased, the PERFORMA™ S overcomes these limiting factors through the implementation of several unique Courtoy™ technologies:



Compression to equal thickness versus equal force

fig 1 fig 2

- The oversized double-paddle feeder with independent drives for each paddle ensures optimal filling at high linear speeds, increasing the residence time of the die under the feeder.
- Dwell time is 2 to 3 times longer in comparison with other presses, thanks to the air compensator (fig 1), which enables compression to equal force instead of compression to equal thickness (fig 2). This unique method results in better de-aeration of the powder bed and improves particle rearrangement, which reduces the risk of capping and hardness variations at high speeds.

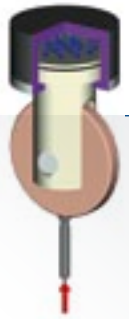
Benefit: enhanced flexibility and accessibility

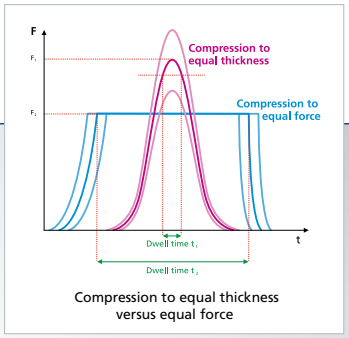
Exchangeable turret for:

- Easy tooling change-over.
- Fast and easy cleaning of compression area and turret.
- Easy access to compression area and turret for inspection and maintenance.

In addition to the exchangeable turret, the PERFORMA™ S features a swivelling tablet chute enabling fast turret removal and ejection set-up.

Superior Process Control





Compression to equal thickness versus equal force

Unique air compensator technology

The Courtoy™ air compensator technology offers:

AT PRE-COMPRESSION

- Easy adjustment of dwell time
- More uniform granule distribution within the die
- Better de-aeration of the powder volume
- Harder tablets and/or increased machine speed
- Reduced risk of capping and lamination

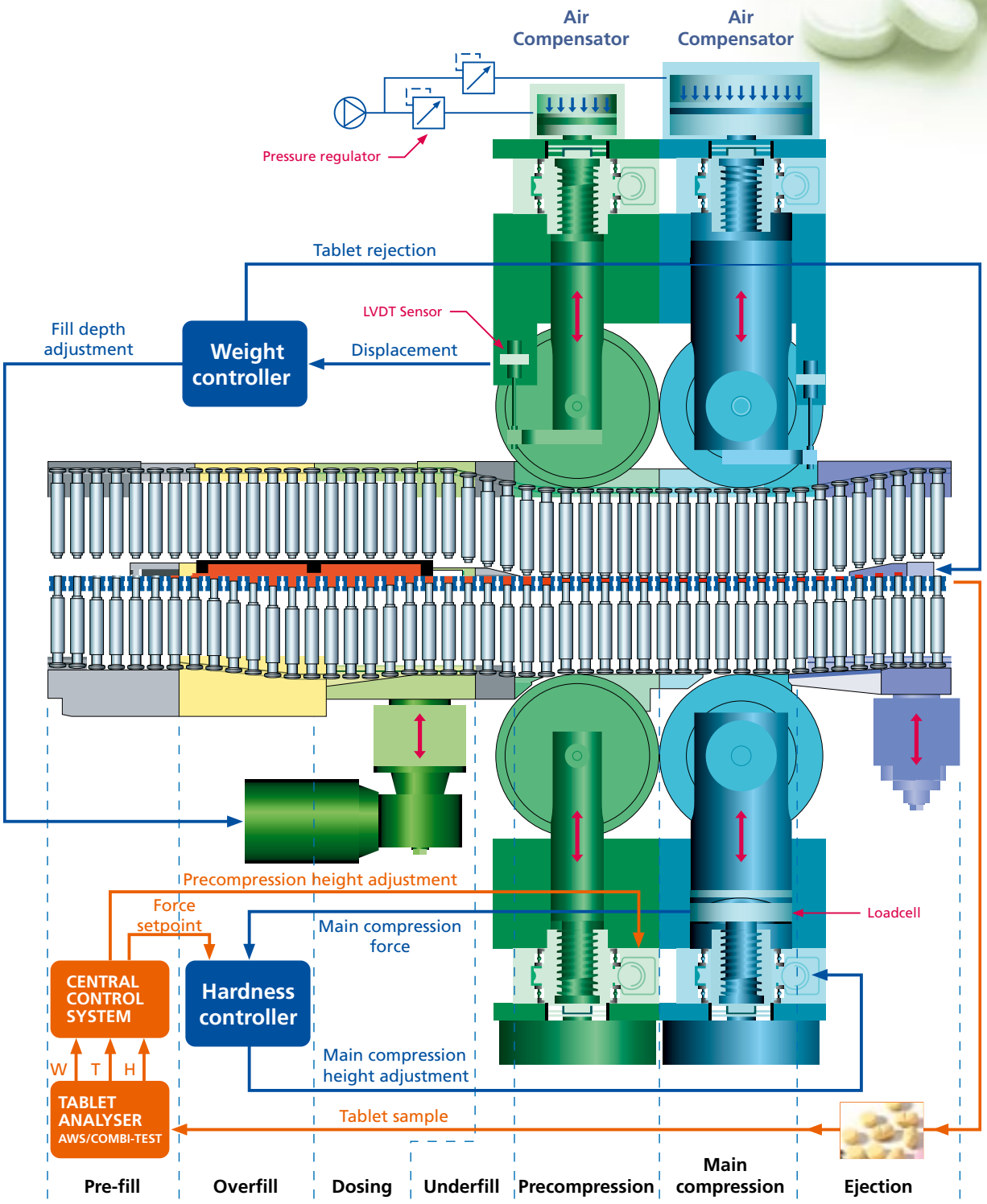
AT MAIN COMPRESSION

- Superior punch protection system
- Easy adjustment of dwell time (optional)
- Equal Porosity Tabletting (EPT) instead of conventional equal thickness compression (optional)
- Automatic dwell time correction at variable turret speeds (optional)

6 compression modes

	Mode 1 Classic Courtoy™ Method	Mode 2 Courtoy™ Dual Control Force Method	Mode 3 Courtoy™ Dual Control Displacement Method	Mode 4 Courtoy™ Dual Control Dwell Time Method	Mode 5 Classic Method	Mode 6 Hybrid Method
OPERATIONAL PRINCIPLE						
Pre-compression	Moving roller: equal individual force	Moving roller: equal individual force	Moving roller: equal individual force	Moving roller: equal individual force	Fixed roller: equal individual thickness	Moving roller: equal individual force
Main compression	Fixed roller: equal individual thickness	Fixed roller: constant mean force	Moving roller: equal individual force	Moving roller: equal individual force	Fixed roller: equal individual thickness	Fixed roller: equal individual thickness
CONTROL						
Weight control	On pre-compression by displacement measurement	On pre-compression by displacement measurement	On pre-compression by displacement measurement	On pre-compression by displacement measurement	On main compression by force measurement	On main compression by force measurement
Hardness control	–	On main compression by force measure-ment: automatic correction of main compression height to keep mean force constant	–	–	–	–
Porosity control	–	–	On main compression by displacement measurement: with increasing machine speed, the displacement on main compression stays the same	On main compression by displacement measurement: with increasing machine speed, the dwell time on main compression stays the same	–	–
ADVANTAGES						
Extended dwell time at pre-compression: better de-aeration and granule distribution in the die prior to main compression	■	■	■	■	–	■
Accurate weight control for small tablets and when low compression forces are required	■	■	■	■	–	–
Simultaneous and parallel – but independent – hardness control loop	–	■	–	–	–	–
All individual tablets are compressed to equal density and porosity	–	–	■	■	–	–
Extended dwell time at main compression	–	–	■	■	–	–
Automatic compensation for punch expansion during machine warming-up & powder compactibility changes	–	■	■	■	–	–
Higher weight control sensitivity with higher forces	–	–	–	–	■	■
AVAILABLE ON PERFORMA™ P	■	■	■	■	■	■
AVAILABLE ON PERFORMA™ S	■	■			■	■

Compression cycle

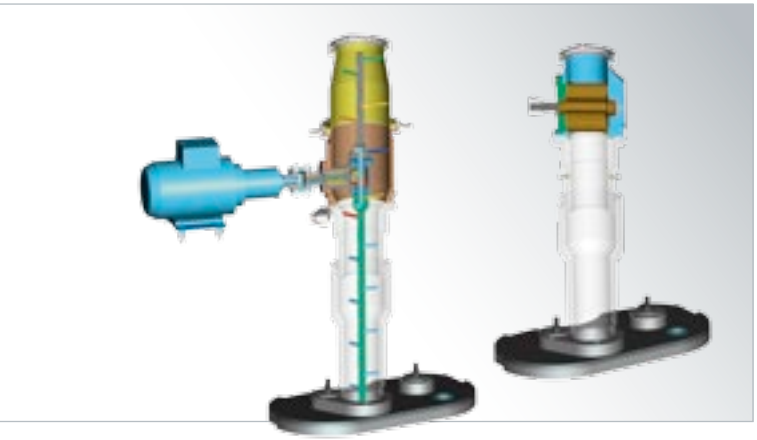


Weight control loop = standard control feature
Hardness control loop = optional control feature (Dual Control and Dual Reject)
Tablet analyzer = optional peripheral IPC device

Courtoy™ specific features and benefits

Controlled powder in-feed

Benefit: more uniform tablet weight / higher speed



"Agitator" system for poor-flowing powders and "constant level" system for constant powder pressure in the feeder.

The rotary valve of the "constant level" system.

Benefit: higher yield

Feeder base plate with slide-in wear plate.

Benefit: higher weight stability / higher speed

Double paddle feeder with 2 independent drive motors.

Features

Stand-out turret features

Benefit: longer lifetime, lower maintenance cost, easier and faster cleaning

- Forged steel, offering superior strength compared to cast iron (standard)
- Hard chromium coated die table surface (standard)
- Exchangeable top-punch sleeves with key ways (optional)
- Key ways for lower punches (optional)
- Removable plates for punch scraper seals (optional)

Multi-Control 4

General features:

- Fully automatic system for production and machine control
- Touch-screen based HMI
- Integration of peripheral equipment
- Unlimited number of recipes
- Manual or automatic re-correction of weight control loop
- Modem for remote diagnosis & maintenance
- PC with Windows XP & Win CC
- OPC standard for integration into higher-level management system
- CD-ROM back-up option
- Operator and maintenance manuals as well as mechanical assembly drawings and electrical schematics are fully integrated in the HMI.

Advantages:

- Fully graphical colour HMI is extremely user-friendly
- Statistical batch reporting (distribution and trending graphs)
- 21 CFR Part 11 compliant, ivncluding audit trail
- Configurable point verification
- Multi-level user access and password management
- Full data protection

Control cabinet:

- All standard components
- Contains PC and PLC of the MC4 control system, frequency drives etc.
- UPS power supply as standard
- Good accessibility
- Standard cooling unit
- Cable entry with connectors from top or bottom
- Stainless steel housing available as an option
- RAID 5 PC available as an option

PERFORMA™ technology matrix

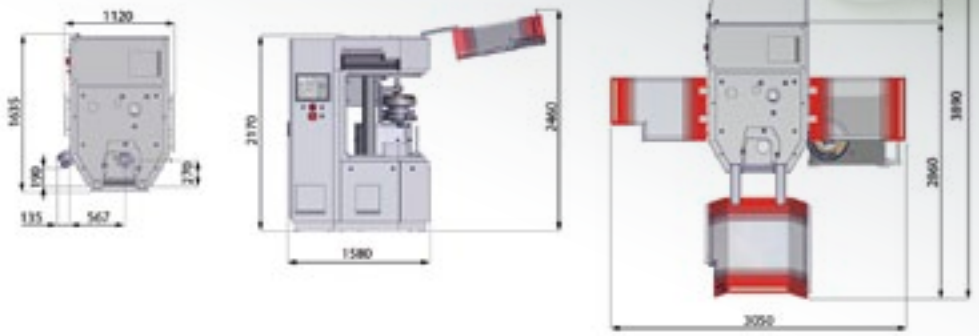
	PERFORMA™ P	PERFORMA™ S
EXCHANGEABLE TURRET / EDD		
Exchangeable turret	■	■
EDD (Exchangeable Die Disc)	■	–
COMPRESSION DWELL TIME		
Large compression rollers for long dwell time	■	■
Extended & freely adjustable dwell time at pre-compression	■	■
Extended & freely adjustable dwell time at main compression	■	–
PRODUCTION CONTROL		
Weight control by measurement of displacement at pre-compression	■	■
Weight control by measurement of compression force at main compression	■	■
Independent tablet weight and hardness control (Dual Control system)	■	■
Rejection of tablets outside weight tolerance limits	■	■
Rejection of tablets outside hardness tolerance limits (Dual Reject system)	■	■
PAT enabling tablet weight control system	■	■
Single reject of tablets	■	■
Tablet sampling gate	■	■
POWDER IN-FEED SYSTEM		
Double-paddle forced feeder with reduced volume	■	■
Independent speed adjustment of forced feeder paddles	■	■
Automatic regulation of constant powder pressure inside the feeder	■	■
Anti-bridging agitator system	■	■
Closed feeder with "slide in" wear plate seal	■	■
DUST EXTRACTION SYSTEM		
Manual underpressure regulation	■	■
Underpressure monitoring and alarm	■	■
Automatic underpressure regulation	■	■
PUNCH PROTECTION SYSTEM		
Acts independently from control system = safer than electromechanical system	■	■
Air cushion based system = safer & cleaner than hydraulic system	■	■
Punch tightness detection system for upper and lower punches	■	■
ADDITIONAL FEATURES		
Swivelling tablet chute	–	■
Bi-layer capability	■	–
Forged steel turret & die table	■	■
Hard chromium coated die table surface	■	■
Exchangeable top punch guidings and upper & lower keyways	■	■
Removable segmented plates for dies & punch scraper seals	■	■
Independent lubrication circuits for upper & lower punches	■	■
Thermally decoupled drive	■	■
Bad punch detection	■	■
Tablet jamming detection on tablet chute	■	■

■ Included ■ Option – Not available

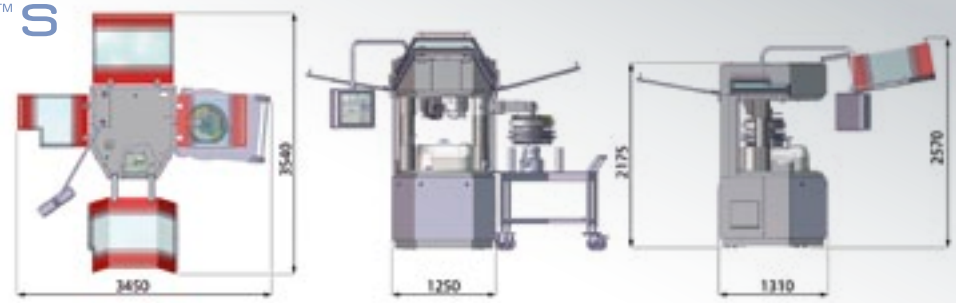
Specifications

Technical data and layout

Performa™ P



Performa™ S



	PERFORMA™ P				PERFORMA™ S			
Maximum pre-compression force	10 kN (under extended dwell time)				10 kN (under extended dwell time)			
Maximum main compression force	80 kN (60 kN in case of Equal Force Compression)				100 kN			
PUNCH TYPE (EUR OR TSM)								
	D	B			D	B		
Top punch penetration [mm]	1 to 4	1 to 4			1 to 4	1 to 4		
Punch body diameter [mm]	25,4	19			25,4	19		
Maximum fill depth [mm]	20	19			20	19		
DIE TYPE / PUNCH POSITIONS								
Number of punch positions	24	30	36	39*	31	38	46	50*
Die type	D	B	BB	BBS	D	B	BB	BBS
Max. tablet diameter / length [mm]	25	16 (L=19)	13 (L=14,3)	11	25	16 (L=19)	13 (L=14,3)	11
Output capacity [tab/h]	157.000	220.000	264.000	286.000	186.000	307.800	372.600	405.000
Die outside diameter [mm]	38,1	30,16	24	22	38,1	30,16	24	22
Die height [mm]	23,81	22,22	22,22	22,22	23,81	22,22	22,22	22,22
MACHINE SPECIFICATIONS								
Electrical requirements	3phase+PE — 380V / 400V / 415V / 460V 50Hz / 60Hz – 11,9 kVA				3phase + PE — 380V / 400V / 415V / 460V 50Hz / 60Hz — 14 kVA			
Compressed air requirements	7-8 bar / 500l/min				6-8 bar / 100l/m			
Dust extraction requirements	150 m³/h at 15 mbar				150 m³/h at 15 mbar			
Machine dimensions and weight	W 1030 mm x D 1555 mm x H 2170 m — 2500 kg				W 1260 mm x D 1300 mm x H 2200 m — 4100 kg			

* Only possible if no upper punch sleeves are selected, i.e. only possible in case no key ways are required on the upper and lower punches (no shaped tablets and no round tablets with double break-line).

www.geapharmasystems.com

Central know-how on a global scale

Based on a strong commitment to research and development, pharmaceutical technology centres in Belgium, Denmark, Switzerland, the UK, Singapore, and USA provide global technical support and know-how to the pharmaceutical industry. These centres of excellence give customers access to a range of test facilities and expert teams with technical and process know-how. Our teams work closely with our customers to optimise processes and evaluate their products, enabling them to achieve their process and production goals.

Contracting profitable experience

A world leader in supplying pharmaceutical equipment, GEA Pharma Systems offers manufacturers all over the world the opportunity to enter into a profitable partnership for development and contract. GPS combine advanced in-house technology with a thorough understanding of the pharmaceutical industry to help customers maximize their development results.

GEA Pharma Systems

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