

Tablet Compression - *modul*[™]



Courtoy Technologies

ECM-based rotary tablet presses

– Tablet Quality – Operator Safety – Productivity – Operational Flexibility

The concept: modul™

modul™ P

- For small-scale tablet production and formulation development
- Available with: C-ECM, HC-ECM, G-ECM, WOL-ECM and bi-layer ECM



modul™ S

- For medium-volume tablet production
- Available with: C-ECM, HC-ECM, G-ECM and WOL-ECM



modul™ D

- For large-volume and bi-layer tablet production
- Available with: C-ECM, HC-ECM and WOL-ECM



ECM Exchangeable Compression Module (patented)

GEA Pharma Systems -
Courtoy's revolutionary and
unique design, leading
to productivity, flexibility
and safety. All in one!

1 The ECM is a completely closed box

- Contains all product contact parts.
- Contains all format parts.
- Is isolated from the remainder of the machine.

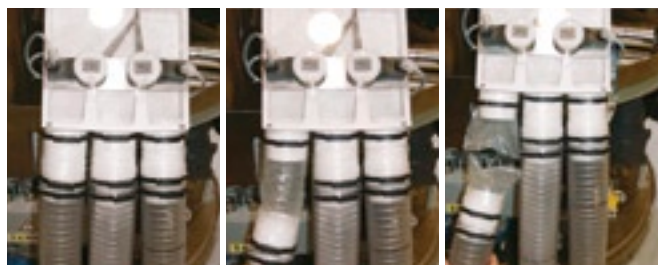
2 The 4 interfaces between the ECM and its environment

- Powder inlet
- Air inlet
- Tablet outlet
- Dust extraction

Contained disconnection using lay-flat tubing with
heat-seal and cut principle:



Lay-flat tubing and contained disconnection at tablet outlet:

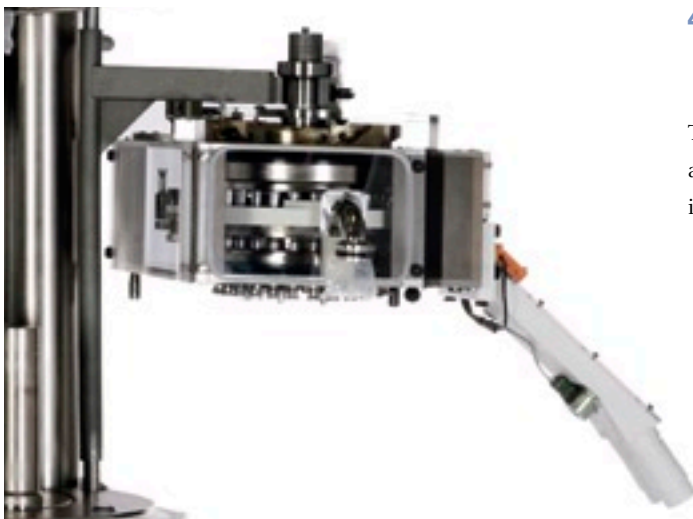


The concept: **modul**TM



3 The ECM is extremely easy and fast to remove from and re-insert in the machine

- ECM removal/insertion procedure is semi-automatic.
- All components are exchanged together as one single and closed unit.



4 The inside of the tablet press remains absolutely clean and contamination free

There is no need to clean the inside of the tablet press after removal of the ECM. Moreover, accessibility for inspection and maintenance is maximized.

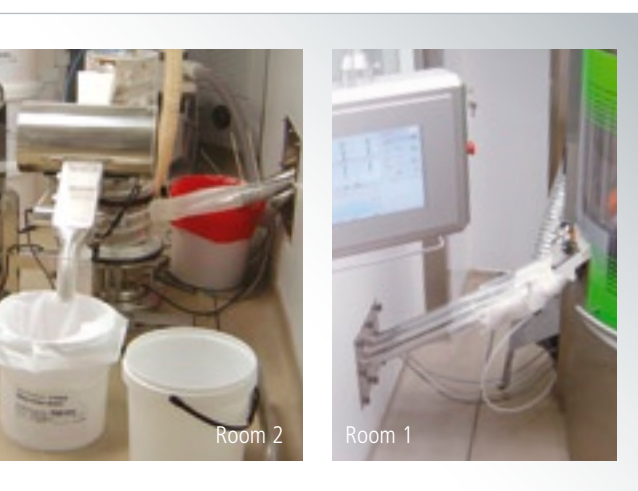
5 Cleaning and format change-over are performed **OFF-LINE**

- The dirty ECM is positioned on a trolley and transferred to a washing bay, where the ECM is opened, cleaned and prepared for a new batch.
- OFF-LINE: The time required for cleaning and format change-over of the ECM is NO downtime to the tablet press. While one ECM is being cleaned, the MODULTM is back in production with another ECM.



Productivity

The MODUL™ ECM-concept does not only present a considerable reduction in the change-over time of the press itself. It also drastically reduces the downtime of the entire tablet production line. Various solutions are available.



Through-the-wall installation.

- Duplicate ECM
- Two-room installation
- Room 1, containing the MODUL™ with closed powder in-feed system
- Room 2, containing standard peripheral equipment with open interconnections

At product change-over

- Room 1 does not need any cleaning, as no product is released from the equipment.
- Only the second - **small** - room requires cleaning.

Completely contained installation.

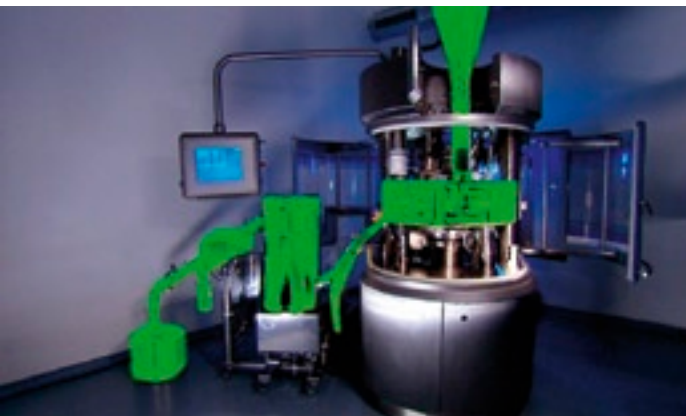
- All peripheral equipment is built and interconnected in “dust-tight” design.
- Room cleaning completely eliminated.
- Clean room can even be eliminated.
- Duplicate ECM and peripheral equipment.
- All components are transferred in isolated state to a washing bay for OFF-LINE cleaning.
- Product change-over of the complete production line in record time.



Your benefits

Dust control and operator safety

The ECM contains the product in a small isolated section of the tablet press.



Completely contained tablet production line: simultaneously offers full containment and extremely fast product change-over.



Easy upgrade to high-containment installation.

WOL-ECM:

High-containment ECM with wash-off-line capability

- Containment down to $1\mu\text{g}/\text{m}^3$
- Allows for automatic off-line washing after connection to a water preparation skid



Flexibility

The same basic MODUL™ tablet press can be equipped with a variety of ECMs to respond to all possible requirements and to be perfectly suited to handle any kind of product.

C-ECM: Contained ECM

- Containment down to $10\mu\text{g}/\text{m}^3$

HC-ECM: High-containment ECM

- Containment down to $1\mu\text{g}/\text{m}^3$
- Permanent monitoring of containment level

G-ECM: Galenic ECM

- Available on MODUL™ P and MODUL™ S
- For batches down to 1 kg
- Formulation development & clinical trial production
- Number of punches can be freely chosen
- Combination of different punch types is possible

WOL-ECM: High-containment ECM with wash-off-line capability

- Containment down to $1\mu\text{g}/\text{m}^3$
- Allows for automatic off-line washing after connection to a water preparation skid

Bi-Layer ECM: Special ECM for bi-layer tablet compression

- Available on the MODUL™ P only
- Allows for small-scale continuous tablet production, which makes it the perfect tool for R&D and formulation development



Your benefits

Peripherals

Standard peripherals:

Tablet deduster



Combined tablet-deduster and metal-checker



Automatic tablet tester for on-line quality control



Dust-tight peripherals:

Tablet deduster



Combined tablet-deduster and metal-checker



Automatic tablet tester for on-line quality control



Washable peripherals:

Tablet deduster



Combined tablet-deduster and metal-checker

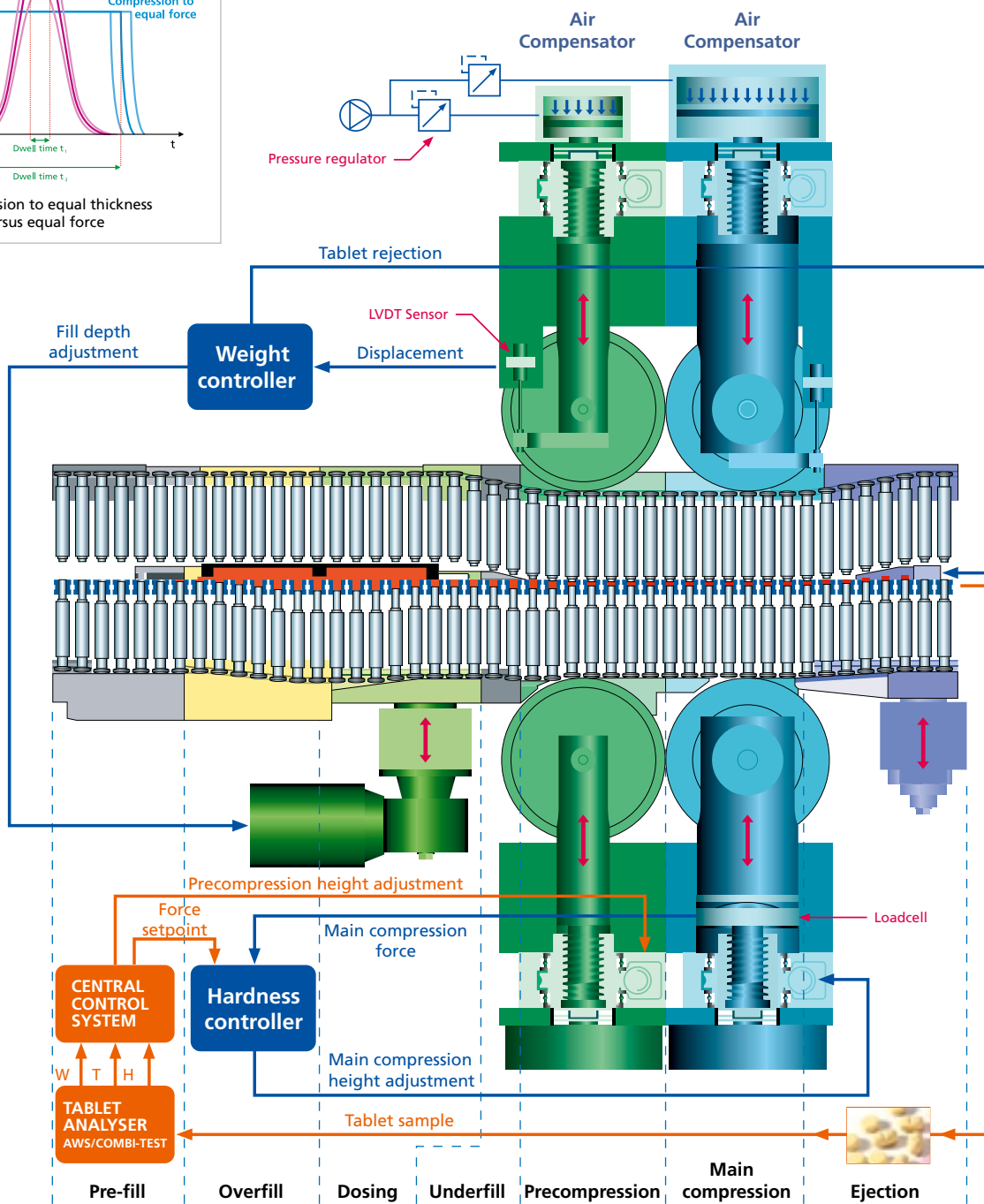
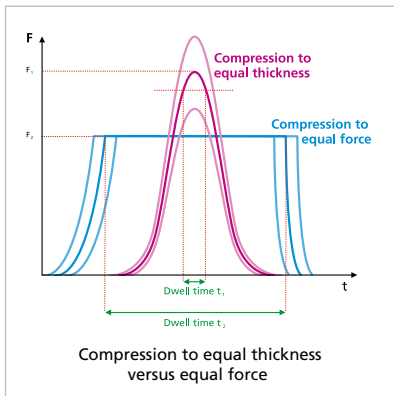


Combined tablet-deduster and metal-checker



PAT (Process Analytical Technology)

The **mgdul**™ compression cycle & enhanced process control



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

Multi-control 4

PLC/PC-based



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.

Advantages

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

MODUL™ specific

- ECM-exchange procedure is semi-automatic, guiding the operator step by step
- Each operator action is explained with text and visualized with photos
- Each operator action is to be confirmed.
- All sensor off-sets and scalings are entered in specific HMI screen buttons
- Many test and on-line help functions
- Optional Dual Control system for independent monitoring and control of tablet weight and tablet hardness
- Optional Equal Porosity Tableting (on MODUL™ P only) for reduced variability in tablet dissolution time and bio-availability

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



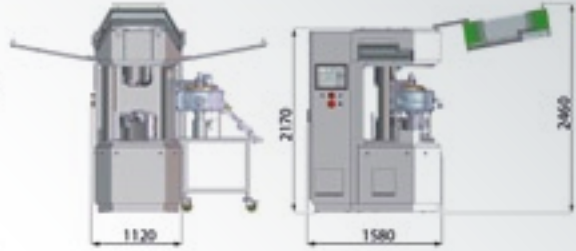
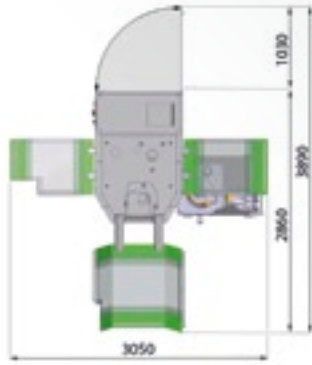
	MODUL™ P
EXCHANGEABLE COMPRESSION MODULES	
Contained ECM (C-ECM)	●
High-containment ECM (HC-ECM)	●
Wash-off-line ECM (WOL-ECM)	●
Bi-layer ECM (B-ECM)	●
Bi-layer kit	≠
Galenic ECM (G-ECM)	●
PERIPHERAL DEVICES	
Standard design	●
Dust-tight	●
Wash-off-line	●
Through-the-wall technology with open devices	●
ECM REMOVAL/INSTALLATION	
ECM removal time (minutes)	10
ECM installation time (minutes)	10
Total numbers of parts to be removed/installed on the press	2
COMPRESSION DWELL TIME	
Large compression rollers for long dwell time	●
Extended & freely adjustable dwell time at pre-compression (PC)	●
Extended & freely adjustable dwell time at main compression (MC)	●
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	●
COMPRESSION OPERATION PRINCIPLE	
Compression to equal thickness	●
Compression to equal porosity	●
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	●
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	
Forged steel turret & die table	●
Hard chromium coated die table surface	●
Exchangeable top punch sleeves 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	●

	MODUL™ S	MODUL™ D	Increased machine speed & productivity	Increased tablet quality	Increased yield	Increased reliability & maintainability
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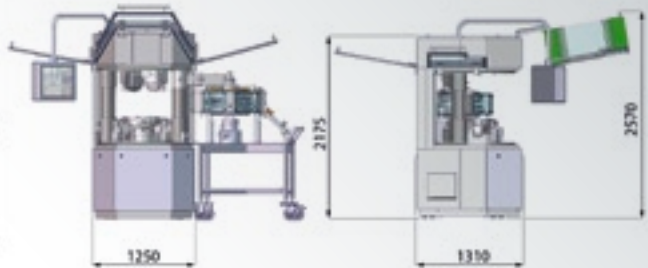
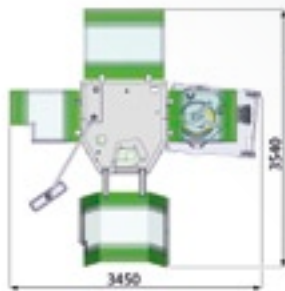
● Included ● Option ≠ Not available



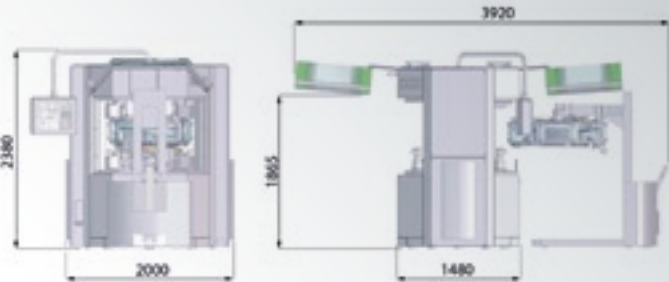
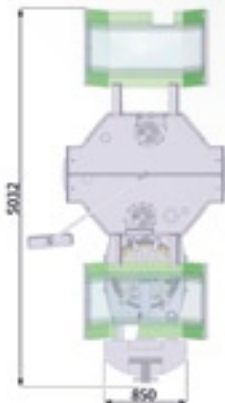
modul™ P



modul™ S



modul™ D



Tooling (EU or TSM)		D35 (Not applicable on MODUL™ P)	D	B	BB	BBS
Max. tablet diameter ¹	mm	35	25,4	16 (L=19)	13 (L=14,3)	8
Punch body diameter	mm	35	25,4	19	19	16
Die outside diameter	mm	52	38,1	30,16	24	22
Die height	mm	30	23,81	22,22	22,22	22,22

Number of stations		-	21	26	31	35
Maximum fill depth	mm	-	20	19	19	19
Top punch penetration	mm	-	1 to 4	1 to 4	1 to 4	1 to 4
Max. pre-compression force ²	kN	-	10	10	10	10
Max. compression force ³	kN	-	80	80	80	80
Max. production capacity ⁴	tab/hr	-	126.000	187.000	223.000	252.000
Electrical requirements		3 phase + PE - 380 V / 400 V / 415 V / 460 V - 50 Hz / 60 Hz - 7 kVA				
Compressed air requirements		6-8 bar / 100 l/min				
Dust extraction requirements		150 m ³ /h at 15 mbar				
Machine dimensions & weight		W = 1030 mm x D = 1555 mm x H = 2170 mm - 2500 kg				

Number of stations		23	31	38	46	52
Maximum fill depth	mm	20 (25) ⁵	20	19	19	19
Top punch penetration	mm	1 to 4	1 to 4	1 to 4	1 to 4	1 to 4
Max. pre-compression force ²	kN	10	10	10	10	10
Max. compression force ³	kN	100	100	100	100	100
Max. production capacity ⁴	tab/hr	118.000	186.000	274.000	331.000	374.000
Electrical requirements		3 phase + PE - 380 V / 400 V / 415 V / 460 V - 50 Hz / 60 Hz - 14 kVA				
Compressed air requirements		6-8 bar / 100 l/min				
Dust extraction requirements		150 m ³ /h at 15 mbar				
Machine dimensions & weight		W = 1260 mm x D = 1300 mm x H = 2200 mm - 4100 kg				

Number of stations		39	53	67	81	89
Maximum fill depth	mm	20 (25)	20	19	19	19
Top punch penetration	mm	1 to 4	1 to 4	1 to 4	1 to 4	1 to 4
Max. pre-compression force ²	kN	10	10	10	10	10
Max. compression force ³	kN	100	100	100	100	100
Max. production capacity ⁴	tab/hr	350.000	540.000	722.000	875.000	1.069.000
Electrical requirements		3 phase + PE - 380 V / 400 V / 415 V / 460 V - 50 Hz / 60 Hz - 25 kVA				
Compressed air requirements		6-8 bar / 100 l/min				
Dust extraction requirements		150 m ³ /h at 15 mbar				
Machine dimensions & weight		W = 2000 mm x D = 1500 mm x H = 2250 mm - 6000 kg				

¹ In case of special tablet shapes, it is recommended to contact GEA Pharma Systems - Courtoy.
² 10 kN under extended dwell time by air compensator. 100 kN is possible upon special request.

³ If the actual compression force required is above 70% of the maximum, please contact GEA Pharma Systems - Courtoy.

⁴ Real output depends on tablet and powder characteristics.
⁵ On special demand.



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.

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