

RMA

The ideal platform for reliable assembly of medical devices.

Proven, reliable and flexible.

Manual loading / unloading with fully automated assembly delivers the same precision as higher-output machines.

Its modular design ensures repeatable assembly across device types and manufacturers.

Easy to operate, maintain and clean, and simple to expand - giving you maximum flexibility to adapt quickly to market change.

MACHINE HIGHLIGHTS

- Modular, reliable, and robust production platform.
- For clinical trials and small batches.
- Fully automated assembly process according to the OEM assembly guides.
- Easily accessible and operator friendly design.
- Quick and easy format change.
- GMP and 21 CFR part 11 compliant.



The machine follows the Syntegon design philosophy on scalability, and therefor our customers enjoy a seamless and easy transition to machines with higher outputs, when increasing capacity towards a market launch.

Additional modules can be fitted within the assembly cell depending on customer specific requirements.

Standard equipment

- Complete basic machine with a travel- and force assembly module electrical cabinet and control panel (HMI) mounted on an adjustable swing-arm.
- Machine control system based on industrial PC.
- Quick format couplings for future device expansions.
- CE/UL compliance.

Optional equipment

- Shelf system for storage of format parts.
- Pen and AI combi compatibility.
- Reject functionality.
- Kistler maXYmos advanced monitoring software.
- Primary container inspection (i.e. Syringes flange, RNS and plunger).
- Laser engravement on drug device (i.e. 2D matrix code).
- Barcode scanner.



Technical data

Processing range.

Capacity	Pens	Auto-Injectors
Device composition	Standard 4-piece configuration, incl. primary container	Standard 3-piece configuration, incl. primary container
Capacity	Depending on specific assembly process and operator training Assembly process: approx. 20 seconds	Depending on specific assembly process and operator training Assembly process: approx. 20 seconds
Footprint (Length/Width/Height)	1.900 mm / 1.100 mm / 2.000 mm	
Loading and Unloading	Manual	
Control System	Industrial PC - Siemens® PLC - Zenon® Software	
Clean Room	ISO 7 (class 10 000)	
Validation / Compliance	According to GAMP 5 - CE and UL marking available	
Electrical connection	380 V / 50 - 60 Hz	
Compressed air connection	6 Bar - Compressed air quality ISO 8 573-1 Point 6.3 Class 1	

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