



**SA-41 AUTOINJECTOR & SYRINGE
TEST SYSTEM**



® OUR SOLUTION

The SA-41 automated autoinjector and syringe test system from AutomationsPartner ensures precision product quality control and is easy to operate. The SA-41 fulfills regulation requirements which state that prefilled syringes and autoinjectors must be tested by the manufacturer prior to batch release. The test system for autoinjectors is designed for GMP production environments. AutomationsPartner also offers the same functionality in automated in-line process control (IPC) systems, integrated into autoinjector assembly machines. Testing of prefilled syringes can be combined in the same platform or offered as a stand-alone solution.

BENEFITS

- Easy to use and designed for use in cleanroom production
- Standard automation components ensure a flexible solution
- Easy to adapt to specific customer requirements
- PLC platform ensures software stability

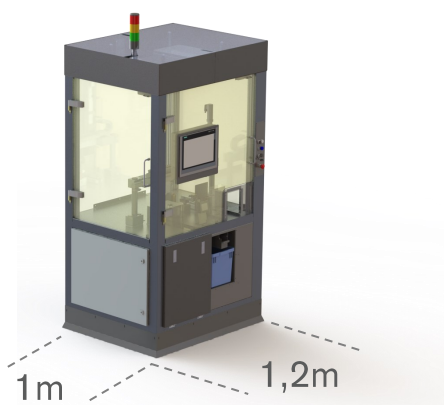
PLATFORM

- One stand-alone unit
- CE machinery directive compliant
- Designed for cleanroom (ISO class 8)

ATOMATION & SOFTWARE

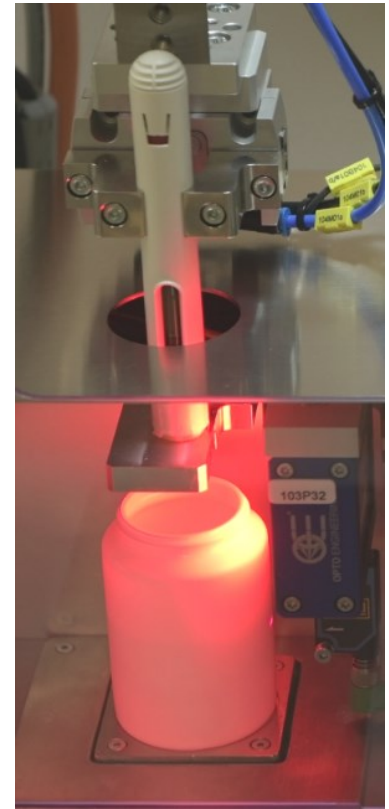
- Siemens PLC and HMI
- CFR 21 part 11 with audit trail
- Siemens servo motors
- Omron FHV7 vision system
- Mettler Toledo scales and load cells
- Digital test reports (digitally signed by the operator)

FOOT PRINT



FUNCTION

Autoinjectors are loaded into the machine, which collects one product at a time for testing. The protective cap is removed, and the force is measured and verified against pre-set values. The vision system triggers a timer when the injection starts and measures the time to complete the injection. The activation force of the device is measured and verified. The length of the needle is also measured by the vision system. The dispensed fluid is measured by a precision scale, and the volume is calculated automatically from the pre-set liquid density value.

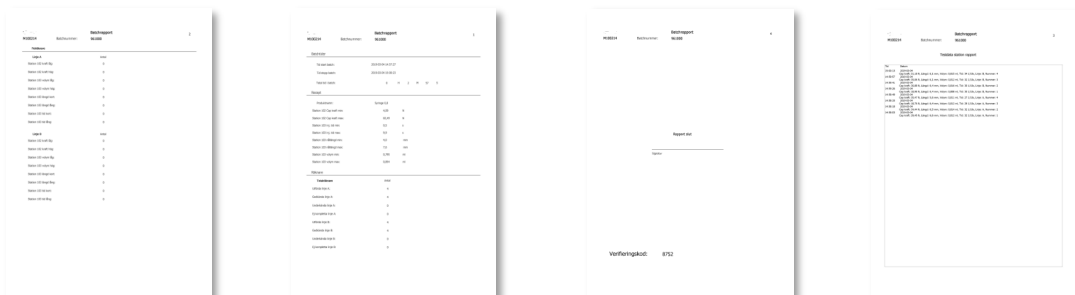


STANDARD TESTS INJECTORS

- Activation force — Needle cover activation or push-button
- Injection time — Liquid dispensing time measurement
- Dose accuracy — Precision weighing of dispensed liquid
- Injection depth — Measurement of needle extension after liquid dispensing
- Cap-removal force — Measurement of force required to remove the protective cap

STANDARD TESTS SYRINGES

- Needle shield removal force — Measurement of force required to remove the needle shield
- Break-loose force — Measurement of force required to initiate the plunger movement
- Glide force — Measurement of force to sustain plunger movement
- Dose accuracy — Precision weighing of dispensed liquid



Digital batch reports



OPTIONAL TESTS & FUNCTIONS

- Graphs of test values with high-speed sampling accuracy
- Secure, encrypted communication to other systems (OPC-UA)
- Verification of correct product by barcode or QR code
- Customer-defined number of devices to be loaded
- Convenient product infeed from trays



AUTOMATIONSPARTNER

AutomationsPartner designs and delivers production lines and production support systems for the medtech and pharma industries.

World-leading medtech companies enlist AutomationsPartner to engineer innovative, robust standardized and custom-made solutions. Since the early 1990's, AutomationsPartner has successfully supplied more than 400 automated production lines to the life science industry.

AutomationsPartner was founded 25 years ago in Helsingborg, Sweden and employs just over 50 people. It is built on strong and innovative Swedish engineering traditions.

AutomationsPartner utilizes fully implemented procedures for qualification and validation (DQ, FAT, SAT IQ and OQ) and a PDM-based system for project management, which ensures high quality equipment and on-time delivery.

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