



**SA-41 SA-61**

**AUTOINJECTOR TEST SYSTEM**



## ® OUR SOLUTION

The SA-41 and SA-61 automated autoinjector test systems from AutomationsPartner ensures precision product quality control and is easy to operate. The SA fulfills regulation requirements which state that combination products such as autoinjectors must be tested by the manufacturer prior to batch release. The test system is designed for GMP and ISO class 8 production environment. The system performs test in compliance with the ISO-standards. Four or six, pending on configuration, autoinjectors are loaded into the system for automated testing.

### BENEFITS

- Quick batch release close to the production
- Operator QA competence not needed
- Compact footprint
- Built on standard components

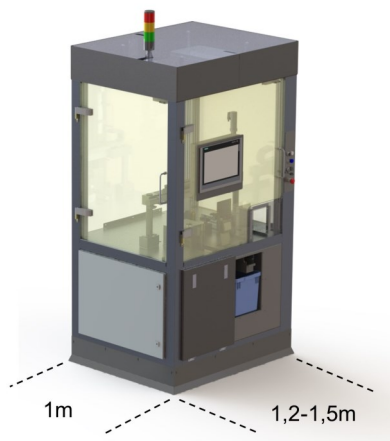
### COMPLIANCE

- ISO-11608
- CFR 21 Part 11 (audit trail)
- CE machinery directive
- ISO Class 8 cleanroom

### PLATFORM

- One stand-alone unit
- Siemens PLC and HMI
- Siemens servo motors
- Omron FHV7 vision system
- Mettler Toledo scales and load cells
- Digital test reports (digitally signed by the operator)
- Cabinet with frameless, laminated and toughened glass

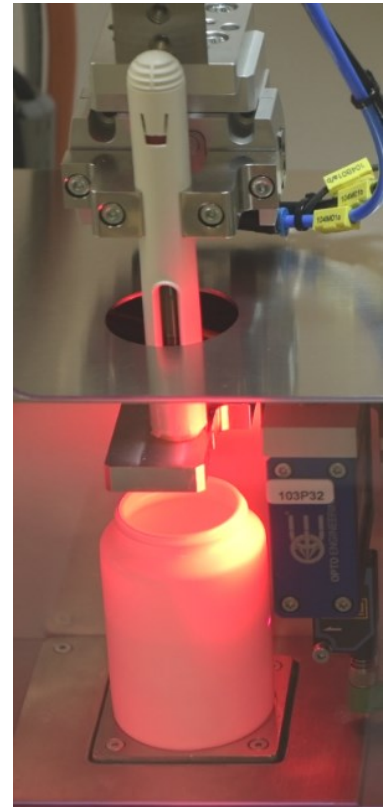
### FOOTPRINT





## FUNCTION

Autoinjectors are loaded into the machine, 4pcs (SA-41 or 6pcs (SA-61). One autoinjector will be tested at a time. The tests are performed automated and tested autoinjectors are collected in a waste container. If an autoinjector fails any of the tests the system will stop for that specific autoinjector. After verification of the operator the failed autoinjector will be placed in a specific container for failed products for further manual analysis. At the end of the batch a report will be generated with individual results for each autoinjector. Information such as approved or not approved will be presented as well as test limits and actual test values for each specific test.



## STANDARD TESTS

- **Cap-removal force** — Measurement of force required
- **Needle Cover pre-injection** — Measurement of force
- **Activation force** — Needle cover or push-button activation
- **Injection time** — Liquid dispensing time measurement
- **Dose accuracy** — Precision weighing of dispensed liquid
- **Injection depth** — Measurement of needle extension after liquid dispensing
- **Needle Cover override** — Applying force up to required limit and displacement measurement

## OPTIONAL TEST

- Separation force — Attributes test (performance vs specification)

[illegible]

Detailed digital or printed batch reports



## OPTIONAL 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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