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# Product Information

## Autoinjector Testing System – AllroundLine 5 kN

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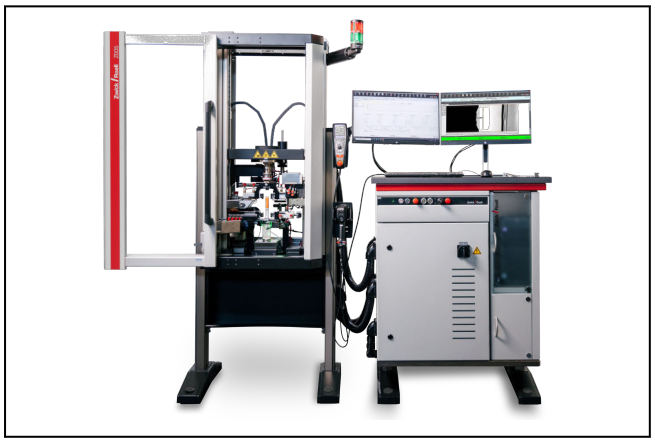

Autoinjector testing system

Autoinjector testing system

### Applications

The use of autoinjectors to administer medications has been growing at a steady pace for years. Numerous factors have contributed to this trend, including an increasing use of targeted therapies, the expanding field of biopharmaceuticals, and the growing prevalence for self-administration of drugs. Other advantages include the user-friendly functionality of autoinjectors, the assurance of precise dosages when compared to syringes, and the reduction of human error and misuse that often occur with traditional injection delivery methods.

To ensure that these devices function reliably and safely, they must be thoroughly tested by autoinjector manufacturers as well as pharmaceutical companies and the companies who fill them (CDMOs). For this purpose, reproducibility and traceability of test results, as well as reduced operator influences are of critical importance.

There are two different types of autoinjectors available on the market:

- Autoinjectors with actuation via needle shield
- Autoinjectors with actuation button

The AllroundLine 5 kN autoinjector testing machine is designed for testing both injector types.

### Applicable standards

The system can be used to meet the following standards:

- ISO 11608: Cannulae based injection systems for medical use – Requirements and test methods – Part 5: Automated functions
- DIN EN 13849-1: Safety of machinery – Safety-related parts of control systems

### System overview

The testing system for autoinjectors consists of these three main components:

- AllroundLine 5 kN materials testing machine with Xforce load cell and dedicated autoinjector test fixture
- Control console with testControl II machine electronics
- Software package for testing autoinjectors, including testXpert III testing software

### Performance range of the autoinjector testing system

- Pneumatic grips and cap grippers with automatic cap ejection into a container
- Testing of injectors with activation via needle shield and actuation force
- Measurement of the removal force of the injector safety cap
- Measurement of the actuation force via the needle shield or actuation button
- Measurement of the injection depth (optionally via HD camera)
- Measurement of the injection time (optionally via HD camera)
- Complete measurement of the weight of the fluid and calculation of the drug volume
- Checking of the activated needle shield
- Video recording of the injection process (time synchronous)
- Removal of injector caps in the upward direction allows for tests according to the latest requirements (optionally through use of rotating device)
- Acoustic click detection for the start and end of the injection
- Coding of interchangeable parts and correlation with test program (Poka Yoke)

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- Vision sensor (color, position and edge detection on autoinjector)
- Daily Checks for all sensors for systematic sensor check
- Testing of prefilled syringes with/without needle shield
- Measurement of ambient humidity and temperature
- OK/Not OK signal light
- Plausibility check of the injection time (scale) option

**Software package for auto injector testing guarantees traceability and data integrity according to FDA CFR Part 11 as well as reliable test results**

The testXpert III testing software and the testControl II measurement and control electronics are designed to work together seamlessly, supporting efficient, reliable, and safe testing machine processes. The workflow is consistent with the work processes in the corresponding work environment, and guides the operator throughout the entire process, from test preparation to performance to results analysis.

The comprehensive software package contains, as standard, important programs that make daily work routines in the testing laboratory significantly easier:

- testXpert III testing software for autoinjectors
- Parameterizable test programs for performing autoinjector tests
- Results Editor
- Layout Editor
- Report Editor
- Export Editor
- Organization Editor
- Virtual testing machine VTM
- Traceability for electronic records to FDA 21 CFR Part 11

Integrated user management allows you to define different user roles or directly adopt user roles that have been defined in the Windows accounts via LDAP.

**Special features and functions**

The multifunctional autoinjector testing machine provides a high level of flexibility by allowing for the performance of all components tests on autoinjectors:

- One specimen for all function tests—all values are created in one cycle
- Cost reduction due to reduced number of specimens
- Prevention of human error due to sequential process with a single specimen
- Reproducible and reliable test results in accordance with FDA 21 CFR Part 11

Removal of injector caps in the upward and downward direction allows for injector tests according to the latest requirements with reproducible results.

- Any autoinjector currently on the market can be tested sequentially in the removal directions described in the instruction leaflet, thereby securing the investment for the future.
- No modifications must be made to the test fixture to determine the cap removal force test result in both directions.

The Poka Yoke principle guarantees a maximum level of mistake-proofing for injector-specific interchangeable parts, which in turn leads to absolutely reliable test results and reduces costs for erroneously obligatory repeat tests.

A unique feature for reliable test results of autoinjectors are the Daily Checks, which can be very easily integrated into your routine procedure. Within a short time, the systematic functioning of all sensors can be determined and confirmed.

Equally unique is the testing of autoinjectors with retractable needles—the injection depth and injection times can be measured with high precision using innovative, camera-based methods. This function allows for the deployment of new patient-safe and market-defining injector functions.

The test program includes all possible functions for injector-specific test performance:

- Flexible test design from single tests to complete sequential processing
- Reduced test times for component tests and the complete test sequence
- testXpert III traceability ensures data integrity in accordance with the ZwickRoell white paper FDA 21CFR Part 11 and EU GMP Guideline Annex 11.

The cap gripper enables the removal of injector caps, regardless of design and material properties.

The AllroundLine 5 kN autoinjector testing machine provides convenient expansion options for fully automated feeding of specimens using robotic systems from ZwickRoell.

Removal of the injection-related spray mist allows for reliable detection of the injection depth/time, thereby guaranteeing reliable test results.

All data at ambient temperature.

Subject to change in the course of further development.

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An optionally available camera-based measurement method delivers reliable test results since the measurement sensors for injection duration and injection depth cannot get dirty.

Simultaneous registration of the injection process and measurement of the injection-specific values using a camera system save you investment costs.

Unique to ZwickRoell are highly accurate injection volume results due to the avoidance of static influences on the precision scale.

Removal of the last drop of the injection allows for a complete injection quantity result to be obtained and furthermore enables clear recognition of the needle tip, thereby guaranteeing reliable test results.

The separate electronics console as well as the cleaning-optimized design of the machine components in the test area fulfill the basic requirements for hygienic design (GMP). This simplifies cleaning processes as well as the release of the system.

The special alloy beaker avoids static charges that falsify the result of the injection volume through precision scales in glass beakers.

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**Components description - AllroundLine Z005 TN materials testing machine**

- High operating comfort
- High test speed consistent through to the nominal force
- Ergonomically adjustable working height through support legs
- Low noise generation
- Powerful, maintenance-free drive

The testing system can be used in a temperature range of +10 ... +35 °C.

| **Type** | **Z005 TN** | |
|---|---|---|
| Test load $F_{max}$ | 5 | kN |
| **Test area** | | |
| Height | | |
| Lower test area | 1030 | mm |
| Upper test area (additional crosshead required) | 1015 | mm |
| Width | 440 | mm |
| **Load frame** | | |
| Dimensions | | |
| Height | 1314 | mm |
| Width | 680 | mm |
| Relative humidity (non-condensing) | 20 ... 90 | % |
| Weight | | |
| Average noise level at $v_{max}$ measured at 1 m distance from the front of the machine | 67 | dB(A) |
| **Drive** | | |
| Motor | AC servo motor with concentrated windings, Hiperface® motor feedback system | |
| Crosshead speed $v_{min}$ ... $v_{max}$ | 0.0005 ... 3000[1)] | mm/min |
| Crosshead return speed, max. | 3000[1)] | mm/min |
| Deviation from the set drive speed, max. | 0.05 | % of $v_{actual}$ |
| Drive travel resolution | 0.959431 | nm |
| Controller | Adaptive | |
| Cycle time | 1000 | Hz |

1) Values apply to machines with the safety doors closed in automatic mode and to machines without safety devices. For machines with the safety door open, the speed is reduced to 600 mm/min.

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| Description | Value | |
|---|---|---|
| **AllroundLine 5 kN** | | |
| Drive | Maintenance-free AC servo motor with Hiperface® motor feedback system with motor holding break | |
| Control, set value preselection | Digital (real-time Ethernet, EtherCAT®) | |
| Crosshead speed $v_{min}$ ... $v_{max}$ | 0.0005 ... 3000 | mm/min |
| Controller/cycle time | Adaptive/1000 Hz | |
| Positioning repeatability (without reversing directions) | +/- 2 | µm |
| **Load cell (500N HP):** | Accuracy class 1 from 1 ... 5 N<br>Accuracy class 0.5 from 5 ... 500 N | |
| *Alternative* load cell (200N HP) | Accuracy class 1 from 0.4 ... 2 N<br>Accuracy class 0.5 from 2 ... 200 N | |
| **testControl II** | | |
| Slots | 4 pieces: I/O module, 5 module bus + 1 PCIe | |
| Standstill monitoring | Crosshead speed is monitored for standstill | |
| Rotation monitoring | To DIN EN 13849-1; crosshead speed is monitored for max. 600 mm/min | |
| Remote control | With 3.2” graphic display, rocker switch with dial | |
| Recording rate | 2000 | HZ |
| **Sensor technology** | | |
| Injection depth measurement | 3.5 ... 11.5 | mm |
| Cap removal | | |
| Speed (adjustable) | 50 … 500 | mm/min |
| Force of the needle shield lock | Fmax up to 80 N | |
| Activation force of the autoinjector | Adjustable 1 N ... 200 N | |
| Test speed during activation: | 50 ... 1000 | mm/min |
| Injection time (configurable) | 1 ... 30 | s |
| Precision weighing | 0.01 mg ... 220 g | |
| *Alternative* | 0.1 mg … 220 g | |
| Camera system | Resolution 1.3 megapixel; frame rate 60 fps | |
| Resolution | 1.3 megapixel | |
| Frame rate | 60 fps | |
| Visual color detection system | Adjustable for different colors | |
| Vacuum generator | 34 | Nl/min. |
| Hand-held barcode scanner | 2D and barcode | |
| Humidity and temperature measurement | | |
| Digital sensor for temperature and humidity<br>-10 … 50 °C (+/- 0.3 °C at 25 °C) | 10 … 90% r.H (+/- 1.8% r.H) | |
| **testXpert III software** | | |
| Software package for testing autoinjectors | • Results Editor<br>• Layout Editor<br>• Report Editor<br>• Export Editor<br>• Organization Editor<br>• Virtual testing machine VTM | |

All data at ambient temperature.

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| Description | Value |
|---|---|
| | • Traceability for electronic records to FDA 21 CFR Part 11 |
| Injector-specific Standard Test Program | • Measurement of the pull-off force of the safety cap and disposal of the cap into designated container<br>• Measurement of the activation force of the actuation button<br>• Measurement of the activation force of the needle shield<br>• Measurement of the injection depth - measurement of the injection time<br>• Measurement of the weight of the fluid and calculation of the volume of medication<br>• Verification of the activated needle shield after the injection has been performed<br>• Visual documentation of the injection process |