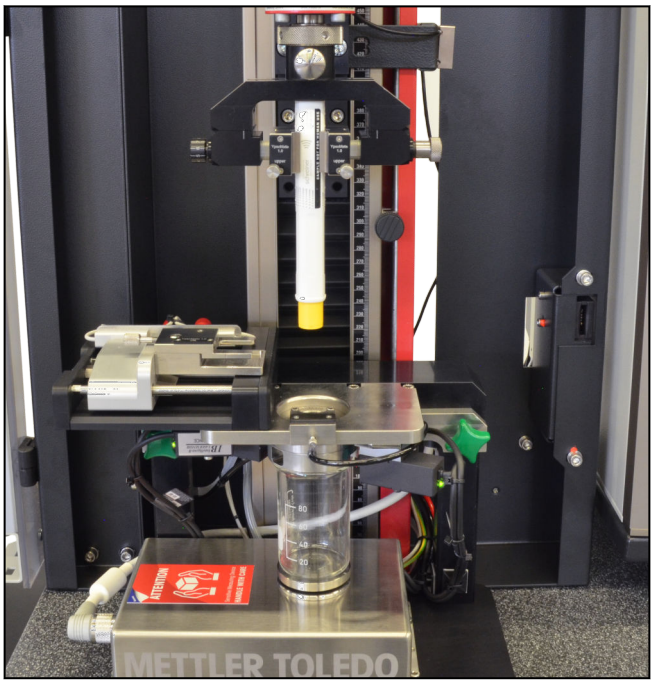
Zwick / Roell

Product Information

Autoinjector Testing System - zwickiLine 2.5 kN

CTA: 237840 237877



Applications

Autoinjectors and pens used for the subcutaneous administration of medications, represent a fast-growing market segment of medical products.

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

Currently there are two different types of autoinjectors on the market:

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

The zwickiLine autoinjector testing machine is designed for injector types with actuation via needle shield.

Standards

The following standards are pertinent:

- ISO 11608: Needle-based injection systems for medical use – Requirements and test methods – Part 5: Automated functions [1)]

Performance range of the autoinjector testing system

The following tests and measurements can be performed with the autoinjector testing system:

- Measurement of the pull-off force of the safety cap
- Measurement of the release force via the needle shield
- Measurement of the injection depth
- Measurement of the injection time
- Measurement of the weight of the fluid and calculation of the volume of medication, incl. the last drop
- Checking of the activated needle shield after the injection has been performed

System overview

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

- zwickiLine 2.5 kN materials testing machine with injector test fixture and XForce load cell
- testControl II machine electronics and measurement and control unit
- Software package for testing autoinjectors and injector-specific test programs

zwickiLine testing machine—target-oriented and focused

The zwickiLine testing machine is an easy to operate testing system ideal for testing autoinjectors in the field

1) Fulfillment of the test conditions in section 5.1.1 of the DIN EN ISO 11608-5 standard are the responsibility of the customer. ZwickRoell provides support in the fulfillment of this requirement (test conditions 5.1.1)

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of R&D, and for customers with reduced requirements in terms of throughput, but with high quality demands in the medical and pharmaceutical industry. The focus of its performance range was based on the established, semi-automatic autoinjector testing machine, the AllroundLine 5 kN. It includes the basic tests of functions for autoinjectors (see performance range).

The machine offers the proven operating concept with comparable results on a small footprint. and an overall cost-optimized solution.

testControl II machine electronics and measurement and control unit

The separate control unit contains all the electrical, electronic, and pneumatic components for the testing system. The testControl II testing machine control is also an integral component of the testing system.

The innovative EtherCAT® interface is integrated as standard. The time synchronized real-time bus system allows for seamless integration of different measurement value recorders.

testControl II has various electronic safety functions for the testing machine drive. With testControl II, high positioning and return speeds are ensured.

The added high speed return guarantees short cycle times. High data transmission rates guarantee fast measurements at highest levels of reproducibility through the synchronous measured-value acquisition rate of 500 Hz (regardless of number of measurement channels). Time-synchronous acquisition of measured values from all sensors connected to plug-in slots takes place at the fast system-frequency, as does data transmission to testXpert III. This ensures a high repeatability of the test results irrespective of the selected sensors and the test sequence.

Software package for testing autoinjectors and injector-specific test programs – traceable and reliable test results

The testXpert III testing software and the testControl II measurement and control electronics are perfectly matched to each other and are therefore able to provide efficient and reliable operation of the testing machine. 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.

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.

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Special features and functions

- Testing of injectors with actuation via needle shield
- Testing of all functions with a single specimen
- Small footprint of the testing system
- Fast cycle times
- The test program includes all necessary functions for injector-specific test performance
- Reduced test times for component tests and the complete sequence
- Complete sequence and components testing
- Quick implementation of design/device changes in the test sequence
- testXpert III traceability ensures data integrity according to FDA 21 CFR Part 11.
- The last drop of the injection is therapeutically relevant and is weighed during the test sequence and included in the result calculation.
- Reliable test results by avoiding anti-static influences on weighing results
- Adjustable torque wrench guarantees reproducibility
- Removal of the injection-related spray mist allows for reliable detection of the injection depth/time, thereby guaranteeing reliable test results.
- DQ - IQ - OQ — design, installation, and operational qualification
- Removal of the last drop of the injection allows for clear recognition of the needle tip, thereby guaranteeing reliable test results
- The electrically interlocked safety door protects the user from possible injury risks
- Guaranteed reliable test results achieved through systematic verification of all sensors:
  - Daily Check for load cell
  - Daily Check for laser system (injector-specific)
  - Daily Check for scale
  - Daily Check for injection time

Testing of prefilled syringes

Tests on prefilled syringes (PFS) can be performed using the autoinjector testing machine zwickiLine 2.5 kN by simply expanding the test fixture with inserts, without having to make modifications or adaptations to the testing machine. The inserts allow you to perform tests on the breakaway force, glide force and injection volume, also without the need for modifications to the actual machine.

- Test insert for prefilled syringes 1 ml
- Test insert for prefilled syringes 2.25 ml
- Test insert for prefilled syringes 1 ml with needle safety devices (NSD)
- Test insert for prefilled syringes 2.25 ml with needle safety devices (NSD)

Additional comprehensive features for the testing of autoinjectors are available in a semi-automatic autoinjector testing machine AllroundLine 5 kN

- Actuation via needle shield and actuation button
- Measurement of the pull-off force of the safety cap and disposal of the cap into a container
- Highly accurate, reproducible gripping force
- Universal cap gripper allows for the removal of different injector cap shapes
- Acoustic click recognition of the start and end of the injection
- Time synchronized HD video recording
- Mistake-proofing through design (combination Poka Yoke with scanner) to prevent incorrect insertion of specimens.
- Color recognition of injector components
- Separate electronics console as well as easy-to-clean design of the machine components in the test area fulfill the basic requirements for hygienic design (GMP)
- Daily Check devices for daily systematic verification of: Load cell, scale, microphone, laser sensors and color sensor
- Compliance with ISO 13849
- Measurement of ambient humidity/temperature
- Convenient expansion options for fully automated feeding of specimens using robotic systems (handling systems)

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Technical data
Autoinjector testing machine

Test load F_{max}	2.5	kN
Load frame		
Ambient temperature	+10 ... +35	°C
Drive system		
Motor	DC servo motor	
Control, set value preselection	Digital	
Crosshead speed v_{min} ... v_{max}	0.0005 ... 1000[1)]	mm/min
Drive travel resolution	0.0277	µm
Positioning repeatability (without reversal of direction)	±2	µm

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

Power specifications		
Power supply	100 ... 240	V, 1Ph/N/PE
Tolerance range	±10	%

Description	**Value**	
Machine electronics		
Power consumption (full load), approx.	1	kW
Measured value acquisition rate	500	Hz

Autoinjector testing fixture

Sensor technology		
Injection depth measurement	3.5 ... 11.5	mm
Cap removal, v_{max}	500	mm/min
Activation force of the autoinjector	1 ... 100	N
Test speed at activation v_{max}	1000	mm/min
Injection time	1 ... 30	s
Vacuum generator		
Suction capacity	34	Nl/min
Scale		
Peak load	220	g
Readability	0.001	g

All data at ambient temperature.

Subject to change in the course of further development.

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Required:

- Autoinjector testing machine zwickiLine (basic version, hardware), CE version
- Test fixture for autoinjectors
- Screw grips (manual), 100 N
- XForce load cell, 500N HP
- Interchangeable parts for Ypsomate 1.0, Ypsomate 2.25 and/or Molly 1.0
- Determination of the injection amount via precision scale
- Ethernet port for the precision scale
- testXpert III basic program
- Autoinjector testing software - standard system
- Standard test program for Ypsomate 1.0, Ypsomate 2.25 and/or Molly - incl. mechanical function testing, injection depth measurement, determination of fluid amount, determination of injection time
- PC hardware

Additional information:

- testXpert III IT documentation
- testXpert III White Paper 21 CFR Part 11
- Product Information Autoinjector Testing Machine – AllroundLine 5 kN

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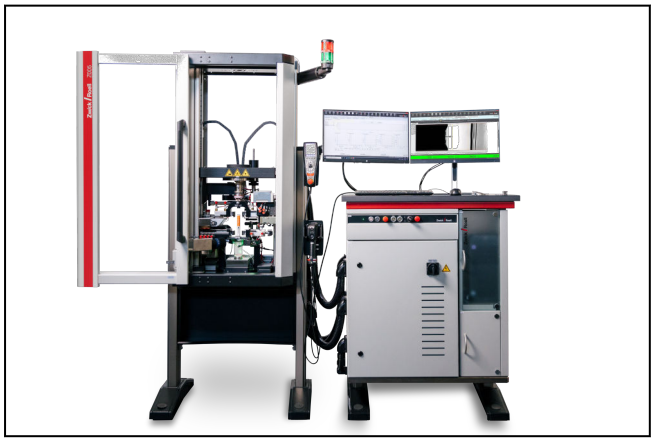

Autoinjector Testing Machine – AllroundLine 5 kN