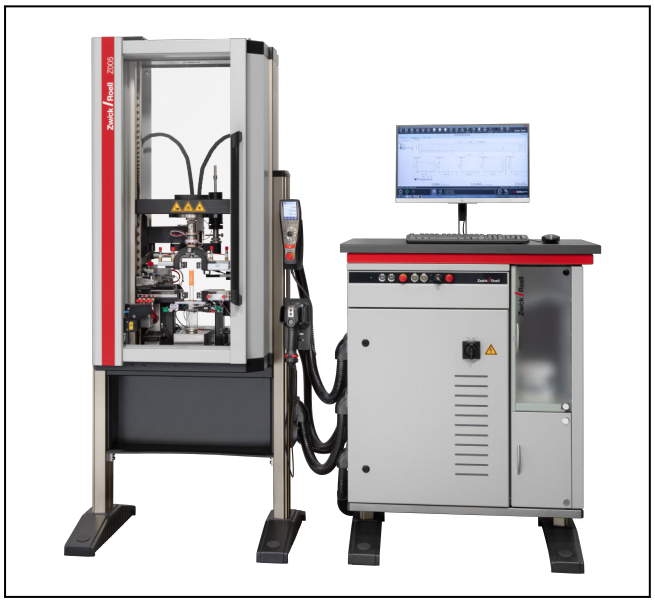
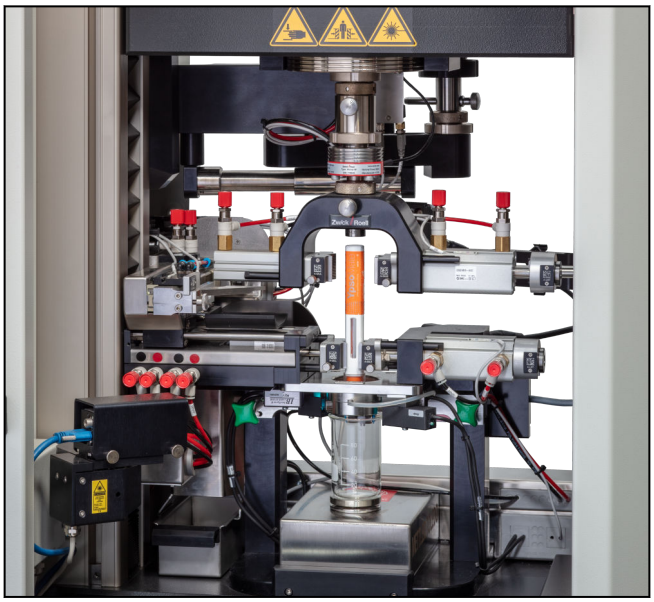
Zwick / Roell

Product Information

Autoinjector testing system - AllroundLine 5 kN

CTA: 215642 209448





Autoinjector testing system AllroundLine 5kN

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 AllroundLine autoinjector testing machine is designed for injector types with actuation via needle shield and actuation button.

Standard compliance

The following standards are met:

- ISO 11608: Needle-based injection systems for medical use - requirements and test methods; Part 5: Automated functions
- DIN EN 13849-1: Safety of machinery 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
- Control console with testControl II machine electronics
- testXpert III testing software

AllroundLine materials testing machine - individual and versatile

The AllroundLine materials testing machine is ideal for autoinjector test requirements. A proven operating concept combined with flexible, modular load-frame design guarantees an optimum solution for demanding testing applications. It is equally ideal for quality-control testing or as part of research projects.

Control console with testControl II machine electronics

The separate electronics console fulfills basic requirements for hygienic design (GMP) and includes all electrical components for power supply to the testing machine, as well as measurement and test components. In addition, the electronics console contains the testControl II machine electronics.

It has two module bus plug-in slots, one PCIe plug-in slot and a DCSC module for the load cell.

The innovative EtherCat® interface is incorporated as standard. The time synchronized real-time bus system

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allows for seamless integration of different measurement value recorders.

testControl II has various electronic safety functions for the materials 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 2000 Hz (regardless of number of measurement channels). The testControl II effective resolution is 24 bit. 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.

testXpert III testing software—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.

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 and disposal of the cap into a designated receptacle.
- Measurement of the activation force of the needle shield and the actuation button
- Measurement of the injection depth
- Measurement of the injection time
- Acoustic click recognition of the start and end of the injection
- Measurement of the weight of the liquid and calculation of the volume of medication, incl. the last drop
- Verification of the activated needle shield after the injection has been performed
- Visual documentation of the injection process (HD video) optionally time synchronized
- Coding of injector-specific interchangeable parts according to the Poka Yoke principle (error prevention through design)
- Daily Check devices for daily systematic checking of load cell, microphone, laser sensors, color sensor and scale

Traceability and reliable test results for electronic records in testXpert III

With the 21 CFR Part 11, the FDA specifies requirements on electronic records and signatures. The Zwick-Roell whitepaper accurately describes the scope of the option in testXpert III. It enables logging of actions and changes before, during and after the test, making test results traceable and protecting them from tampering.

The traceability option can be configured as needed, and the degree of traceability can be defined. The logging entries are stored (automatically and according to type) in the system audit trail or in the relevant test program/test series.

Special features and functions

- The multifunctional materials testing machine provides a high level of flexibility by allowing for the performance of all components tests on autoinjectors:
  - One specimen for all components tests; all values are created in one cycle
  - One results file for all components tests: Reproducibility
  - Cost reduction due to reduced number of specimens
  - Prevention of human error due to sequential process and one specimen
- One platform for many injector configurations
- Modular design of the testing system for higher flexibility in terms of expansion and service
- Faster cycle times (< 3 min)
- Semi-automatic testing of autoinjectors for avoid operator errors
- Convenient expansion options for fully automated feeding of specimens using robotic systems
- Guaranteed reliable test results achieved through Daily Checks for force, weight, injection depth, fluid and acoustics
- Encapsulated system (testing machine) through front and rear safety device; advantage: Operator protection, and reliable test results achieved by not influencing the sensors
- Separate electronics console fulfills basic requirements for hygienic design (GMP)

All data at ambient temperature.

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- Mistake-proofing through design (combination Poka Yoke with scanner) to prevent incorrect insertion of specimens. This leads to reliable test results and reduces costs.
- Validation is supported by ZwickRoell qualification documentation: Standardized document layout enables rapid project implementation.
- Operation via PC or remote control: Supports ergonomic and efficient operation of the testing system
- A universal cap remover (gripper) enables design independence of injector caps.
- Measurement of ambient humidity/temperature
- Optimization of drug weighing through ionization of ambient air
- Removal of the injection-related spray mist allows for reliable detection of the injection depth/time, thereby guaranteeing reliable test results
- DQ- IQ-OQ – qualification of design, installation and work processes
- Synchronous visual documentation of the injection process for accurate traceability of the test sequence with critical results
- Acoustic actuation detection helps the patient recognize the start and end of the injection
- Color recognition of the plunger rod or the actuation button for clear identification of the specimen and the dose amount
- The last drop of the injection is therapeutically relevant, and only ZwickRoell weighs it as part of the test sequence and includes it in the result calculation.
- Removal of the last drop of the injection allows for clear recognition of the needle tip, thereby guaranteeing reliable test results
- Reliable test results by avoiding anti-static influences on weighing results
- Good/bad/good signal light on the testing machine indicates the test result after each test

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Technical data

Description	Value	
Test load F_{max}	100	N
Weight, approx.	600	kg
Ambient temperature	+10 ... + 35	°C
Compressed air		
Minimum pressure	6.5	bar
Basic system, CE		
Power specifications		
Power supply connection	230	V, 1 Ph/N/PE
Permissible voltage fluctuation	± 10	V
Power consumption (full load), approx.	2	kVA
Power frequency	50/60	Hz

Description	Value	
AllroundLine 5 kN		
Drive system	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 reversal of direction)	+/- 2	µm
Load cell (500N HP):	Accuracy class 1 from 1 ... 5 N Accuracy class 0.5 from 5 ... 500 N	
Alternative load cell (200N HP)	Accuracy class 1 from 0.4 ... 2 N 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

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Description	Value
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	
-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 • Layout Editor • Report Editor • Export Editor • Organization Editor • Virtual testing machine VTM • 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 • Measurement of the activation force of the actuation button • Measurement of the activation force of 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 • Verification of the activated needle shield after the injection has been performed • Visual documentation of the injection process

Additional information can be found in the current testXpert III IT documentation and the testXpert III White Paper 21 CFR Part 11.

All data at ambient temperature.