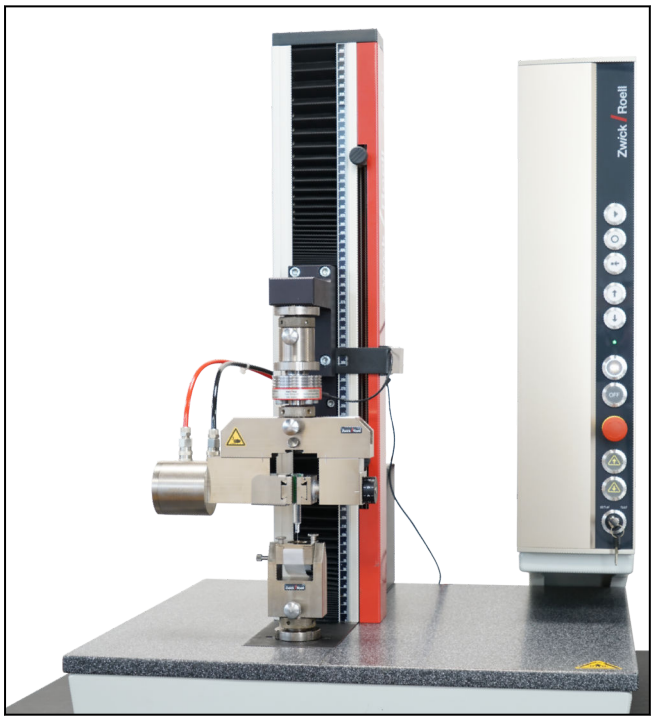
Zwick / Roell

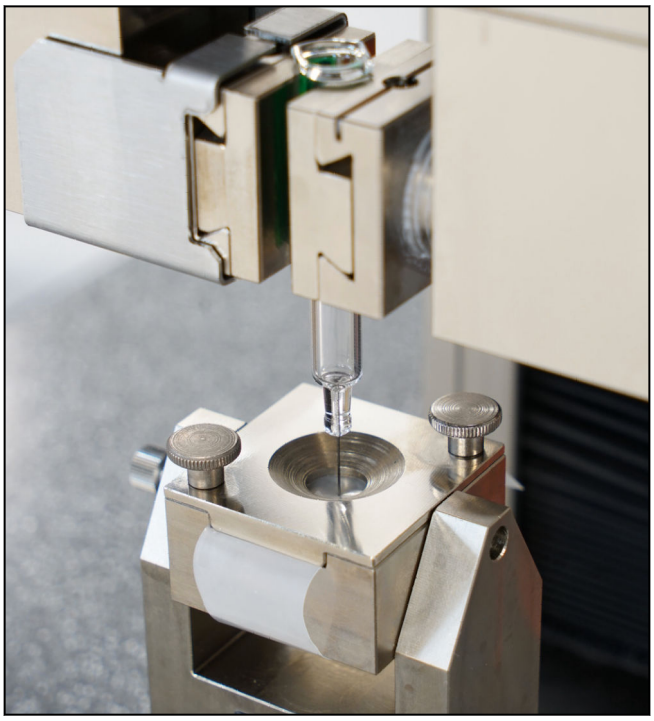
Product Information

ISO 11040-4/-6 Annex F - Needle penetration force

CTA: 167328 167985



Test arrangement with pneumatic grips and holding fixture for special film



Detail view with inserted syringe

Applications

Testing is performed on glass or plastic syringe barrels for injectables and sterilized subassembled syringes ready for filling.

Annex F describes the needle penetration test with special film that has properties similar to human skin.

To perform the test, the syringe is inserted into the upper pneumatic specimen grip, which is closed with the foot control. The protective cap is pulled off the syringe. Downward movement of the crosshead causes the needle to penetrate the film.

The expected force range is 2.5 N.

The test results contain the following information:

- Film specification
- Test speed
- Force curve
- Number of syringes tested
- Deviations

Advantages and features

- Variable test angle to test axis that can be locked at 30°, 45°, 60° and 90°
- Versatile pneumatic grips that can also be used for Annex G1, G3 and G6
- Secure gripping of sensitive specimens through adjustable gripping pressure
- Optional pneumatic control unit to open and close the specimen grips
- high stiffness and precise crosshead guidance with zwickiLine
- maximum safety for user, test results, specimen material and testing system.
- online correction of machine compliance guarantees very high travel-measurement and positioning accuracy
- traceable, reliable test results in accordance with FDA 21 CFR Part 11, guaranteeing complete, tamper-proof documentation of all actions and changes performed in the testXpert IIItesting software

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Technical data

Pneumatic specimen grips type 8097

Item No.	1106823	
Type	8097	
Operating principle/identification	Opposing jaw with stepped and stepless adjustment	
Test load F_{max}	0.5	kN
Operating pressure The operating pressure depends on the upstream components.	1 ... 10	bar
Gripping force at 3 bar	0.330	kN
Gripping force at 10 bar	1.313	kN
Opening width with jaws, 5 mm thickness[1)]	20	mm
Gripping travel of pneumatically operated side	10.5	mm
Gripping of the specimen	The specimen must be gripped with at least 2/3 of the jaw height.	
Dimensions		
Height	95	mm
Installation height	120	mm
Width	242	mm
Depth	60	mm
Depthwith connection unit	86	mm
Connection, hole	Ø 20	mm
Weight per specimen grip, approx.	1.5	kg
Ambient temperature	+10 ... +35	°C
Scope of delivery	1	piece(s)

1) The opening width is the result of using jaws with 5 mm jaw thickness.

Accessories required

Jaws (1 x required)

Item No.	Specimen thickness [mm]	Ambient temperature [°C]	Scope of delivery [pieces]
3003408	Ø 12 to 35	-15 to +40	1 pair = 2
3003407	Ø 5 to 12	-15 to +40	1 pair = 2

Spacers (1x required)

Description	ArticleNumber
Spacers, height 20 mm, for increasing the free space between jaw and grip body. Scope of delivery 2 pieces. 2 pieces required per grip.[1)]	**316559**

1) For convenient operation

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Pneumatic control unit (1x required)

The pneumatic control units can be used with testXpert III V1.7 (from 14.12.2022) and testControl II V8.62.

Description	ArticleNumber
Pneumatic control unit **or**	**1108557**
Pneumatic control unit with clamping pressure preselection via testXpert III testing software	**1108559**

Pneumatic hoses (1x required)

Description	ArticleNumber
Set of pneumatic hoses for connecting a pair of pneumatic grips	**1112640**

Type **Item No.**	**Needle puncture test fixture** **022358**	
Test load F_{max}	50	N
Specimen dimensions		
Specimen width	20	mm
Specimen thickness	Up to 1	mm
Specimen gripping and puncture opening	Ø 10	mm
Test angle, lockable with a pin	30°, 45°, 60° and 90°	
Connection, stud	Ø 20	mm
Ambient temperature	+10 ... +35	°C