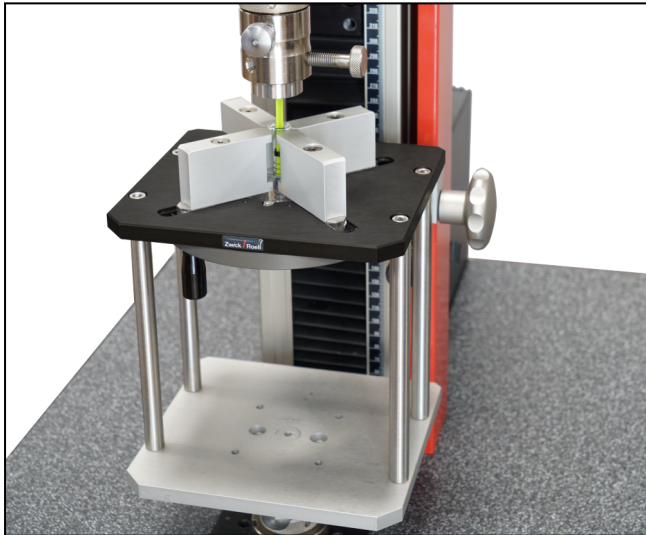


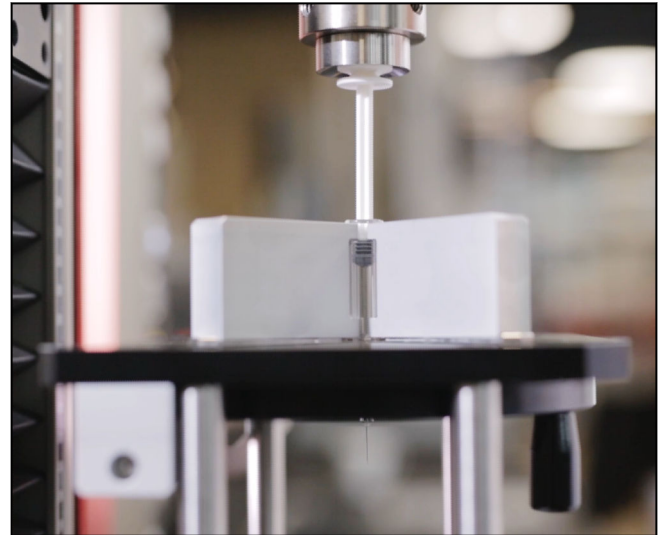
Product Information

ISO 11040-4/-6 Annex E / G2 - Syringe glide force / liquid leakage test

CTA: 133007 181947



Test arrangement with universal mount and compression die



Detail view with inserted syringe

Applications

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

In Annex E of the standard the glide force of the syringe without protective cap is tested.

Annex G2 describes the leakage test on a filled syringe with attached protective cap.

The plunger is pressed to the shoulder of the syringe at a defined force and speed.

The anticipated force ranges are:

- 40 N to Annex E
- 10 N to Annex G2

The test results contain the following information:

- Maximum glide force to Annex E
- Calculated average glide force to Annex E
- Applied pressure of force to Annex G2
- Test speed

- Number of syringes tested
- Deviations

Advantages and features

- The same test fixture can also be used for Annex C1
- For syringes with \varnothing 6 / 8.2 / 11 mm
- Adjustable syringe mounting for different syringe diameters and lengths
- Quick-lock system for secure holding
- High stiffness and precise crosshead guidance of the zwickiLine
- Maximum safety for the user, the test results, the specimen material, and the testing system
- Online correction of machine compliance guarantees very high accuracy of travel measurement and positioning
- Traceable and reliable test results in accordance with ZwickRoell whitepaper FDA 21 CFR Part 11: This guarantees complete, tamper-proof documentation of all actions and changes that are performed in the testXpert III testing software

Product Information

ISO 11040-4/-6 Annex E / G2 - Syringe glide force / liquid leakage test

Technical data

Item No.	082865	
Test load F_{max}	1	kN
Syringe diameter	5 ... 50	mm
Gripping ranges		
Gripping range 1 for syringe/carpule diameter	5 ... 26	mm
Gripping range 2 for syringe/carpule diameter	24 ... 50	mm
Syringe length	30 ... 150	mm
Height	220	mm
Width	220	mm
Depth	155	mm
Weight, approx.	3	kg
Ambient temperature	+10 ... +35	°C
Connection, upper	Adapter 16 ⁹⁶	
Connection, lower	Connector TK 40/75 mm Base crosshead (zwickiLine)	
Scope of delivery	Lower holding fixture, upper die, beaker for the collection of exiting fluids	