



Needle Penetration Tester



STANDARDS

ISO 7864 (Annex D)

Needle Penetration Tester - QualiMed™ NPT

Needle Penetration Tester - QualiMed™ NPT is a precision laboratory instrument designed to quantitatively measure needle penetration force and drag force during insertion into defined substrates.

This Needle Penetration Tester evaluates both the initial peak force required to pierce a material and the continuous frictional resistance experienced during needle travel, providing objective data for needle sharpness, coating performance, and overall insertion smoothness.

Engineered for medical device R&D, quality control, and regulatory compliance testing, QualiMed™ NPT delivers repeatable, high-accuracy force-displacement measurements aligned with international needle performance standards.

Image



APPLICATIONS

Needle Penetration Tester - QualiMed™ NPT Applications

- Hypodermic Needle Performance Testing (ISO 7864 Annex D)
 - Measures peak penetration force and average drag force to verify compliance with sterile single-use needle requirements.
- Medical Device Quality Control (ISO 7864, GB 15811)
 - Ensures consistent needle performance across production batches and suppliers.

- Needle Design & Coating Development
 - Supports R&D optimization of bevel geometry, lubricants, and surface coatings to improve insertion comfort.
- Comparative Needle Evaluation
 - Enables direct comparison of penetration and drag behavior between different needle types, gauges, or manufacturers.
- Substrate Material Testing
 - Assesses penetration behavior on rubber stoppers, elastomers, and skin-simulating materials used in medical packaging and device validation.

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Mounting Substrate

Mounting Needle

Standard:

ISO 7864 (Annex D)

Specifies the test method for measuring needle penetration force and drag force to evaluate sharpness and insertion performance of sterile hypodermic needles.

FEATURES

Needle Penetration Tester - QualiMed™ NPT Key Features

- Dual-Parameter Measurement
 - Simultaneously measures needle penetration force and drag force in a single test cycle.
- PLC-Controlled System with HMI Touchscreen
 - 7-inch color HMI enables intuitive parameter setup, real-time monitoring, and test control.
- High-Precision Motion & Force Control
 - Precision ball lead screw and calibrated load cell ensure stable motion and accurate force measurement.
- Programmable Test Parameters
 - Adjustable penetration depth and test speed support various needle types and substrate materials.
- Multiple Fixture Compatibility
 - Supports different needle geometries and substrate holders for flexible testing configurations.
- Integrated Safety Functions
 - Includes overload protection, position limiters, and automatic return after test completion.
- Built-In Micro Printer & Data Export
 - Allows immediate result printing with optional PC software for data traceability and reporting.
- Standards-Compliant Design
 - Fully compliant with ISO 7864 Annex D and GB 15811 testing requirements.

THEORY & METHOD

Theory and Method

The Needle Penetration Tester operates by driving a mounted needle vertically into a defined substrate at a controlled speed using a precision ball screw system and calibrated load cell.

During testing:

1. Penetration Phase – The needle penetrates the substrate at a constant speed, and the maximum peak force required to pierce the material is recorded.
2. Drag Phase – As the needle continues moving through the substrate, the system measures the average frictional resistance (drag force) over a defined insertion depth, typically up to 80% of penetration.
3. Data Analysis – A force-versus-time curve is generated, from which penetration force and drag force values are calculated and displayed.

This method provides an objective, repeatable evaluation of needle insertion performance directly correlated with user comfort, safety, and regulatory acceptance.

TECHNICAL SPECIFICATIONS

Needle Penetration Tester – QualiMed™ NPT Technical Specifications

Parameter	Specification
Model	QualiMed™ NPT
Test Type	Needle penetration force & drag force
Force Range	50 N (customizable)
Test Speed	1-500 mm/min
Displacement Accuracy	0.01 mm
Force Accuracy	±0.5% of full scale
Maximum Stroke	200 mm (without jig)
Display	7-inch color HMI touch screen
Control System	PLC

Parameter	Specification
Voltage	AC 110-220 V, 50/60 Hz
Standard Jigs	6% Luer conical fitting (1 pc), substrate holder (Ø10 mm test area, 1 set)
Data Output	On-screen display, built-in printer, optional PC software



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