7000 Medical & Pharmaceutical WVTR

SYSTECH illinois

Precision water vapour permeability analysis of medical & pharmaceutical packaging

Applications

- Pharmaceutical packaging
- Bottles
- Pill containers
- Closures
- Surgical dressings
- Syringe products
- Bags
- Needles

Conforms to 21CFR Part 11

Features & Benefits

- Analytical Systems Manufactured traceable to NIST.
- System validation with certified gas or film for speed and convenience.
- Absolute moisture measurement - No calibration required.
- Wide measurement range.
- Over 25 yrs experience of Proprietary Coulometric P_2O_5 sensor.
- Flow, temperature and humidity control for ultimate responsiveness and repeatability.
- Intuitive Windows based software.
- No liquid coolants, catalysts or special gas mixtures required.

Why measure permeability?

The measurement of permeation is often critical in medical and pharmaceutical applications:

- for protection
- to prevent contamination
- to extend the shelf life and potency of drugs
- to ensure powders do not clog

Permeability testing is used in the design and manufacture of blister packs, bottles, pill containers, surgical dressings, needles and syringe products.

Package integrity is necessary to maintain the quality of a drug product throughout its shelf life. Therefore the container and closure need to demonstrate their suitability to the product. The permeation of moisture through a package is a critical quality attribute for solid oral dosage forms, with moisture uptake being a common cause for product package failures.

The 7000 permeation analysers can assist in fulfilling your medical and pharmaceutical packaging requirements.

Conforms to: 21CFR PART11 ASTM F-1249* ISO 15106-3 ISO 15105-2 DIN 53122-2

Manufacture traceable to NIST

All Systech Illinois analysers are certified traceable to NIST. In addition, analytical performance is validated using NIST certified gases and NIST traceable films. A set of validation films and a spare P_2O_5 sensor comes as standard with all of the water vapour permeation analysers.

P_2O_5 Sensor Technology

The two most common sensor types for measuring moisture are IR (infra-red) and P_2O_5 (phosphorous pentoxide). The P_2O_5 sensor is more sensitive and stable than IR and does not require calibration. P_2O_5 is the primary method for absolute moisture measurement. Systech Illinois have over 25 years experience of using P_2O_5 sensor technology.

*The Systech Illinois 7000 analysers comply with ASTM standard F-1249 with the exception of the sensor technology. The standard relates to an infra-red sensor whilst the Systech Illinois analyser uses a coulometric sensor - a dedicated method of moisture analysis.

Wide measurement range

The 7000 series offer a wide measurement range providing research grade flexibility.

- Measurement range of 0.002-1000 g/m^2/day with masking.
- Quality Assurance orientated speed and agility.
- Up to five expansion modules available to increase testing throughput.

Precision control

These analysers offer precision temperature and humidity flow control providing ultimate responsiveness and repeatability.

- Test gas and carrier flow gas controlled by premium electronic mass flow controllers.
- Wide sample temperature range of 5 to 50°C.
- Accurate relative humidity range from 20% to 90%.

Laboratory Testing Services

Our test laboratory will perform your Permeation Testing and Headspace Analysis. Whether you are developing innovative materials and packages or validating that your supplier is meeting specification. We can exceed your expectations with:

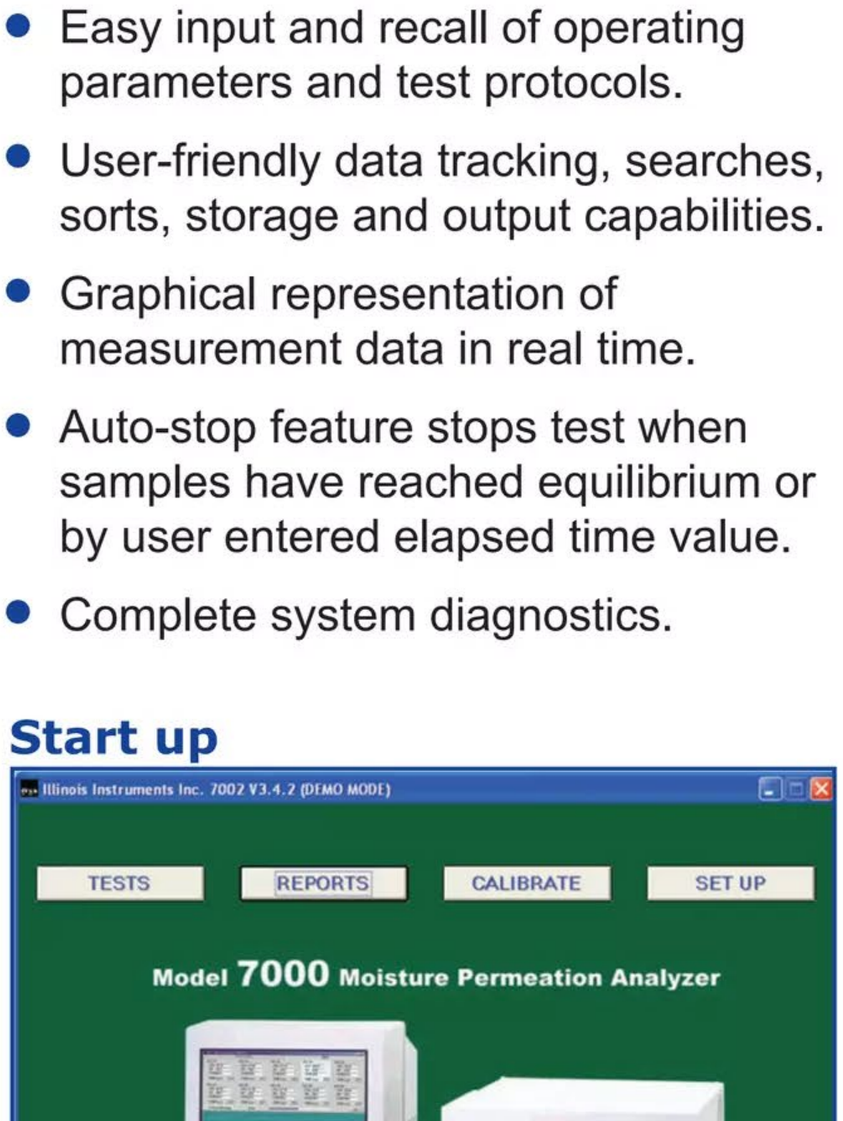
- Competitive Prices
- Fast Turnaround
- Independent non-biased results
- 25 Years Experience

21CFR Software

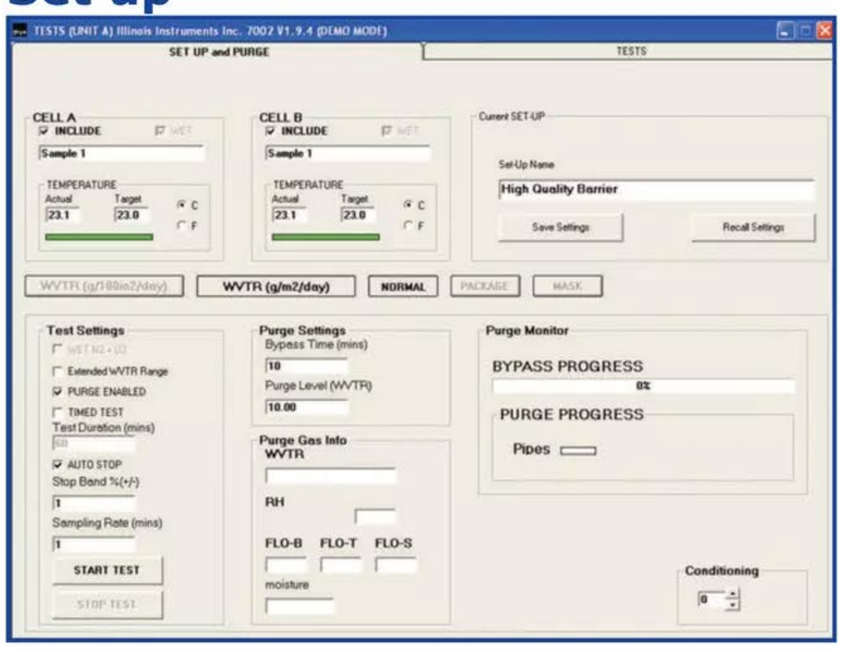
Used in conjunction with Microsoft® Windows.

- Password protected User Log-In.
- Test files are encrypted and cannot be altered.
- Audit files are created and encrypted recording date, time, user and action.
- Easy input and recall of operating parameters and test protocols.
- User-friendly data tracking, searches, sorts, storage and output capabilities.
- Graphical representation of measurement data in real time.
- Auto-stop feature stops test when samples have reached equilibrium or by user entered elapsed time value.
- Complete system diagnostics.

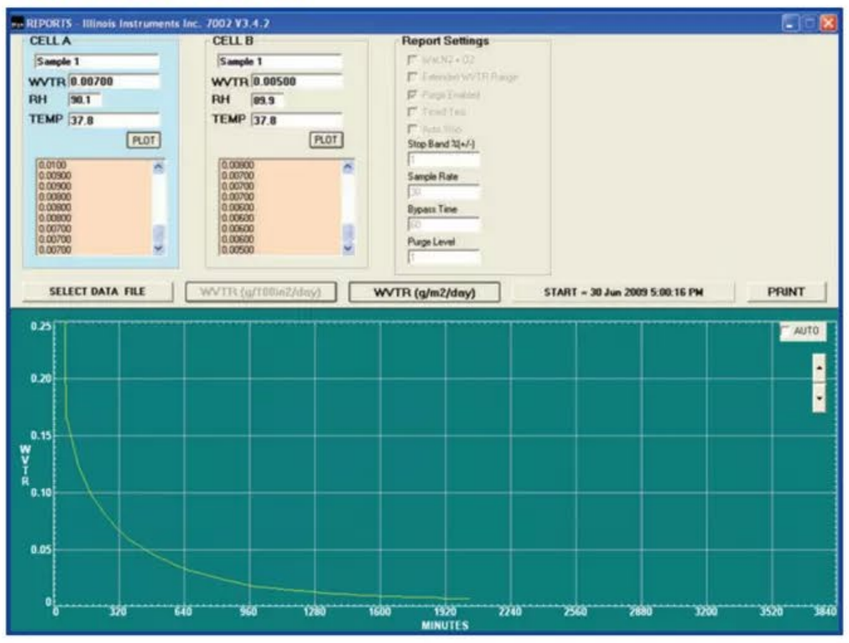
Start up



Set up



Actual data

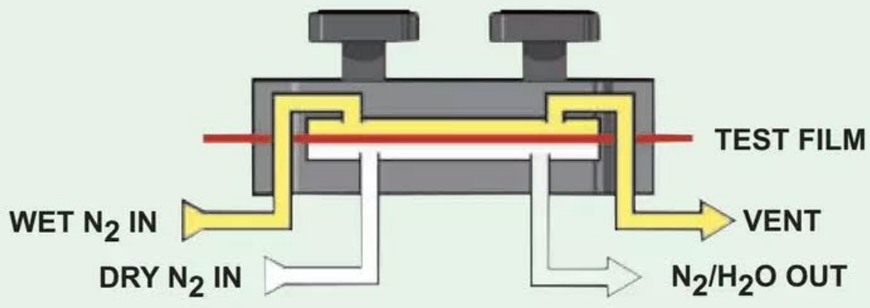


Principle of Operation

Utilising our proprietary sensor technology to detect water vapour transmission rates, samples are clamped or attached to a diffusion chamber. Wet nitrogen is then introduced into the upper half of the chamber while a moisture-free carrier gas flows through the lower half.

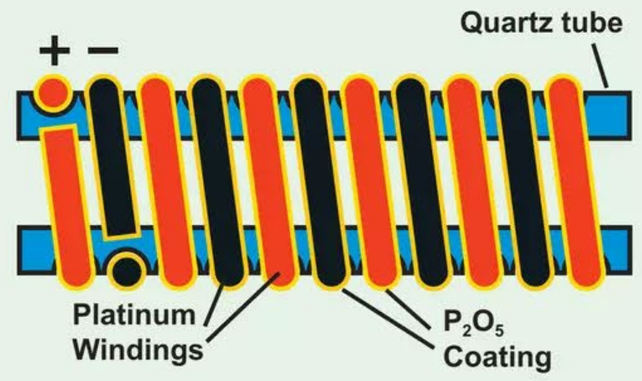
Molecules of water diffusing through the sample into the lower chamber are conveyed to the sensor by the carrier gas.

Sample Test Chamber



This allows a direct measurement of the water vapour without using complex extrapolations. Water vapour transmission rate of the test sample is displayed as either g/m²/day or g/100in²/day.

P_2O_5 Sensor



To achieve an absolute measure, the technology draws upon a fundamental principle of physics.

The phosphorous pentoxide (P_2O_5) moisture sensor consists of a dual platinum winding formed around a quartz tube.

The change in the resistance across the windings creates a change in the measured current. According to Faraday's Law this is directly proportional to the amount of moisture in the gas stream.

7000 Water Vapour Permeation Analysers

Systech Illinois' range meets the requirement for the testing of any application.

Systech Illinois' 7002 Water Vapour Transmission Analyser delivers the same high performance as the 7001 but with an extended measurement range for more demanding applications.

Technical Specifications

Measurement Range

7001	Unmasked	0.002 to 10 g/m²/day
	Masked	0.02 to 70 g/m²/day
7002	Unmasked	0.002 to 70 g/m²/day
	Masked	0.02 to 1000 g/m²/day
Test Temperature Range		5°C to 50°C (41°F to 122°F)
Test RH Range		20 to 90% RH
Sample Size		50cm², adaptors available for smaller samples

Operating Conditions	Standard laboratory environment
Power Requirements	100-240 VAC, 50/60Hz, 840 VA (max)
Supply Pressure	1.7 bar regulated
Gas Fittings	1/8 in. Swagelok (supplied)
Enclosure	Epoxy coated heavy gauge steel
Dimensions	533 x 533 x 305 (mm)
Weight	23.6kg

Options

Expansion Modules 7011	Available for simultaneous WVTR analysis of up to 12 samples
Environmental Chambers	For package testing

Systech Illinois have over 25 years experience of providing analysis solutions for a wide range of industries. From our manufacturing plants in the UK and U.S we produce gas analysers for industrial process industries, headspace analysers for monitoring gas flushing of food products and our range of permeation analysers.

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