



LEAK TESTING

MediScan

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MediScan is a tool-less, non-destructive leak detection device for non-porous pouches, sachets and medical device packaging.

Smart Innovation

SEPHA



MediScan is a tool-less, non-destructive leak detection device for non-porous pouches, sachets and medical device packaging.

• • The system provides accurate and objective measurements and identifies leaks as small as 10µm* in non-porous flexible barrier packaging including:

- Pouches
- Sachets
- Medical device packaging

MediScan incorporates leak detection technology and software, developed by Sepha, that is utilized on a daily basis by top global pharmaceutical companies to ensure product packaging integrity.



• • Technical Specification

Pack Type Sachets, pouches, bags, MAPs and flexible packaging (non-porous)	Machine Construction 304 Stainless Steel Casework	Configuration 2 x USB ports, 1 x Ethernet port	Warranty Supplied with a 12-month warranty. (Service Level Agreements and/or extended warranties are available for additional support).
Test Area Up to 250mm (L) x 200mm (W) x 100mm (D)	User Interface 8.4" SVGA (800 x 600) colour TFT LCD display	Tooling Changeover No tooling required.	
Test Cycle From 20 seconds per test cycle	Utilities Electrical: 110/230V Single Phase AC 50/60 Hz Air Supply: Min. 200L / min at 0.6Mpa (ISO8573-1:2010 Class 2)	Machine Dimensions 400mm(L) x 700mm (W) x 500mm (H)	
Operation Semi-automatic		Weight Machine: 90kg Shipping Weight: 190kg	

Machine Operation
Sample packs are loaded into a standard or custom designed product nest and the test chamber lid is closed. There are then 4 key test phases:

- 1. Evacuation Phase:**
A pre-determined level of vacuum is applied to generate an expansive force which is monitored throughout the test cycle.
- 2. Stabilisation Phase:**
Following evacuation of the vacuum, a stabilisation phase allows the conditions to normalise.
- 3. Decay Test Phase:**
The decay test phase measures any reduction in head space pressure. If the expansive force decays by more than a set amount the pack will be classed as a failure.
- 4. Gross Hole Identification Phase:**
At the end of the decay phase, if the reactive force is less than the pre-determined level in the test method, a pack will be classed as a gross leak failure.

*Pack dependant

Key Features

- Non-destructive seal integrity and leak detection device
- Capable of storing multiple test methods for up to 30,000 product types
- Fast, efficient test speed
- No tooling required, making it highly flexible across several pack types and sizes
- User defined password protection ensuring multiple operator use
- Audit data available and fully 21 CFR part 11 compliant.
- Capable of detecting weak seals, channel leaks and holes down to 10µm*
- Fully validated system
- Network connectivity to a central server
- Table top device
- Production of objective and repeatable results
- Easy operator use via touch screen interface and easy load chamber
- Test results can be printed, exported via USB (x2) or integrated into local quality control system via Ethernet cable

* Pack dependent





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SEPHA Ltd.
Unit 25 Carrowreagh Business Park
Carrowreagh Road, Dundonald
Belfast, BT16 1QQ
United Kingdom

+44 2890 48 48 48
www.sepha.com
info@sepha.com