

SEPHA

MEDISCAN

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



SEPHA MEDISCAN

A non-destructive leak test machine giving accurate, objective measurements to ensure optimal product integrity.



MediScan incorporates the leak detection technology and software, developed by Sepha, that is utilized on a daily basis by top global pharma companies to ensure product integrity in their pharmaceutical production lines.

Features & Benefits

- Non-destructive seal integrity and leak detection device
- No tooling required, making it highly flexible across a number of pack types and sizes
- Capable of detecting weak seals and holes down to 10µm*
- Table top device
- Capable of handling wet** or dry non-porous packages up to 100mm x 200mm x 250mm
- Easy operator use via touch screen interface and easy load chamber
- Capable of storing multiple test methods for up to 30,000 product types
- User defined password protection ensuring multiple operator use
- Easily validated system
- Production of objective and repeatable results
- Test results can be printed, exported via USB (x2) or integrated into local quality control system via Ethernet cable
- Fast, efficient test speed
- Audit data available and fully 21CFR part 11 compliant
- Active Directory and OPC Connectivity available on request

* Pack dependent

** Product dependent



Machine Operation

Sample packs are loaded into a 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.

Technical Specification

PACK TYPE:	Sachets, pouches, bags, MAPs (non-flexible, non-porous materials)	
TEST AREA:	200(W) x 250 (L) x 100(D)mm (7.9 x 9.8 x 3.9")	
OPERATION:	Semi-automatic	
CONSTRUCTION:	Stainless Steel (Grade 304)	
USER INTERFACE:	8.4" SVGA (800 x 600) color TFT LCD display	
UTILITIES:	Electrical:	110/230V AC Single Phase
	Air:	6 Bar
CONFIGURATION:	2 x USB ports	1 x Ethernet port
TEST CYCLE:	From 20 seconds	
TOOLING CHANGEOVER:	N/A	
AUDIT COMPLIANCE:	Can be run in compliance with 21CFR Part 11	
MACHINE DIMENSIONS:	Width: 700m (27.56")	Depth: 550m (21.65") Height: 560mm (22.05")
MACHINE WEIGHT:	63kg (138lbs) / Shipping weight:113kg (249lbs)	
WARRANTY:	Supplied with a 12 month warranty. (Service Level Agreements and/or extended warranties are available for additional support).	



TASITEST

PACKAGING TEST
& INSPECTION

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