PRODUCT INTEGRITY

SEPHA PAKSCAN

Non-destructive leak testing for pouches, sachets and other flexible packs (non-porous materials) which contain dry powder or a solid component with a head space inside the packs.

FEATURES

- **Non-destructive test reduces waste costs**
  Tested samples can be replaced in the packaging line as they are not damaged during the test process. This test is clean and dry, unlike the Methylene Blue Dye method, therefore PakScan generates less waste and reduces associated waste disposal costs.

- **Test multiple packs simultaneously**
  PakScan inspects up to 4 large sachets simultaneously, each pack measuring up to 250mm x 80mm x 20mm. This speeds up testing and offers a more representative view of the entire production web. The machine can be customised for smaller or larger format areas or to accommodate users' specific sample size requirements.

- **Identifies leaks from 10µm**
  PakScan identifies leaks in individual packs as small as 10µm, depending on the pack size and format. The system can also be pre-programmed at the same rejection levels as the Blue Dye Test (usually 30-50µm), if required.

- **Fully validatable system**
  PakScan test results are generated automatically based on the pre-programmed test method used for each pack. As operator subjectivity is removed, the system can be validated. Complete GMP or GAMP validation documents are available.

- **Clear result indicator screen**
  Intact pouches show a green 'Pass' result and leaking pouches show a red 'Fail' results.

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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 air temperature 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

OPERATION	Semi-automatic	
CONSTRUCTION	All product contact areas constructed from Stainless Steel (Grade 316)	
PACK TYPE	Sachets, pouches, bags, MAPs - in flexible and non-porous materials	
PACK DIMENSIONS	250 x 80 x 20mm (10 x 3 x 0.8”) per pack	
POWER SUPPLIES	Electrical: Air:	110/230V 1kva Single Phase 6 Bar
OPERATING SPEED	Up to 4 cycles per minute	
SOFTWARE	System can be run in compliance with 21 CFR Part 11	
MACHINE DIMENSIONS	650 (W) x 750 (L) x 1660 (H) mm (25 x 30 x 65”)	
MACHINE WEIGHT	150kg (330lbs) / Shipping Weight: 180kg (400lbs)	
TOOLING CHANGEOVER	Approx. 3 minutes A different product nest is required for each product to be tested	

A touch screen user interface monitors the PakScan progress through a virtual instrument panel