



PRODUCT
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*Technologically advanced non-destructive
leak testing machines that deliver accuracy,
efficiency and product integrity across
Pharma, food and other markets*

Our PRODUCT INTEGRITY range of machines offers state-of-the-art non-contact scanning technology at an affordable price.

With the ability to handle pharmaceutical or medical blisters, sachets, pouches and bags, our scanning machines offer a non-destructive alternative to other messy tests on the market.

The clean and dry process allows samples which pass the test to be replaced in the packaging line reducing waste.



PRODUCT INTEGRITY

“ Our philosophy is to develop equipment that is simple for non-skilled users; equipment that saves time and money; and equipment that solves problems, not creates them. ”

Why test blister packs for leaks?

Testing is vital to ensure drug stability through protection from moisture, air and bacteria. Leak testing also minimises reject blisters and reduces deblistering and excess waste disposal. Performing leak testing before stability studies will confirm that all results apply to blisters which are known to be properly sealed.

Fully validated results

With a reliable validation process as standard, operator subjective judgments and errors are avoided.

Accurate and clear readings

While other tests can only detect holes above 50 microns, our detection technology tests for leaks as small as 7 microns and identifies the precise pocket or pack that is leaking. Detailed results are then available for analysis.

To compare various leak testing methods visit www.sepha.com



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SEPHA BLISTERSCAN

Non-destructive leak testing for blister packs utilising state-of-the-art non-contact scanning technology at an affordable price. The perfect alternative to the messy Blue Dye test.

FEATURES

- Detects leaks as small as 7µm in individual blister pockets
- Non-destructive clean and dry process so packaging and its contents are not damaged. Fewer samples are destroyed - less waste generated
- Fully validatable - faults identified by machine not operator removing subjectivity. Comprehensive GMP or GAMP validation documents available
- Full web testing, with no limit on number of pockets
- Can be set to operate at same rejection level as Blue Dye Test (30-50µm)
- Fast, semi-automatic set-up with self-testing mechanism to verify the functionality of the sensor each time
- Automatic sampling and statistical testing
- Test data can be automatically collected, printed and stored or downloaded for post-test analysis. Results stored for 10 years min.
- Innovative product recognition feature means product-specific test data is stored automatically in pre-designated file locations
- Easy calibration using tool supplied. Select calibration options through the touch screen display

▼ BLISTERSCAN



TRACING THE SOURCE OF A LEAK

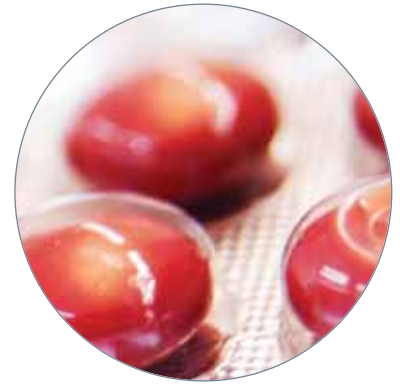
BlisterScan instantly pinpoints the location of a faulty pocket seal. Further graphical analysis is provided for each individual blister pocket.

This improves your blister packing process by enabling engineers to trace and identify the source of a leak, according to current PAT (Process Analytical Technology) thinking.

The BlisterScan screen shows a pass (green) or fail (red) result for each blister pocket and also indicates the absence of a blister pack (black).



BLISTERSCAN



MACHINE OPERATION

No specialist knowledge or training is required:

1. Custom tooling is inserted into the tooling holder and is automatically scanned as soon as the drawer is closed. BlisterScan automatically selects the correct test method and displays pre-determined information (e.g. Nest Number, Product Name, Test Method, Date and Time).
2. Operator fills in the relevant batch data via the touch screen and keyboard.
3. The drawer is opened and the blister pack is placed onto the plate.
4. The drawer is closed to seal the test chamber. The operator presses the START button on the touch screen.
5. A Pass or Fail result is indicated immediately on completion of the scans (approx. 2 minutes after the start).

LOW COST TOOLING

Test method development, and two low-cost custom-made plates, are required for each different blister format.

TEST METHOD

A beam of light scans the individual pockets before and after applying a vacuum. After a set dwell time the blister pockets are scanned again. A Pass or Fail result is given based on a comparison of the 'before' and 'after' readings against a predetermined leakage acceptance level. From the results, a correlation with the hole size can be made.



TECHNICAL SPECIFICATION

BLISTER WEB	Up to 320mm width (13")	Up to 150mm length (6")
TEST CYCLE TIME	1 - 6 mins	
MEASUREMENT RANGES	Down to hole size of less than 7 microns	
TOOLING CHANGEOVER	Approx. 30 seconds	
CONFIGURATION OPTIONS	DVD Ethernet	CD-ROM drive 2 x USB
POWER SUPPLIES	Electrical: Air:	110/230V AC Single Phase 6 Bar
USER INTERFACES HARDWARE	VGA LCD MMI colour wide angle touch screen display with virtual instruments. Integral QWERTY keyboard. Printer	
SOFTWARE	System can be run in compliance with 21 CFR Part 11	
CONSTRUCTION	Stainless Steel (Grade 316L)	
MACHINE DIMENSIONS	630 (W) x 770 (L) x 1600 (H) mm (25 x 30 x 63")	
MACHINE WEIGHT	125kg (275lbs) / Shipping Weight: 300kg (660lbs)	
WARRANTY	Supplied with a 12 month warranty. After this period we recommend the customer takes out a Service Agreement.	

SEPHA Leak Test Service gives customers a 'snap-shot' of the quality of their current stability batches. The test data results are returned in graphical and tabular form for analysis



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.

▼ PAKSCAN



Pack 1	Pack 2	Pack 3	Pack 4
PASS	GROSS FAIL	UPPER GROSS FAIL	UPPER GROSS FAIL
Gross Force 2261 g	Gross Force -2 g	Gross Force 5079 g	Gross Force 5633 g
Force Decay -2 g	Force Decay -12 g	Force Decay 214 g	Force Decay 118 g



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:	110/230V 1kva Single Phase
	Air:	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



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SEPHA FOODSCAN

A non-destructive, table mounted leak test machine for pouches, sachets, food trays and other forms of flexible packaging.

The FoodScan utilizes the leak detection technology that Sepha has developed over 30 years in the pharmaceutical field to offer the food market a technology driven alternative to blue dye testing, ensuring optimal package integrity.

FEATURES

- **Identifies leaks from 10 micron**

FoodScan is capable of identifying leaks in individual packs as small as 10 micron, depending on pack size. The system can be programmed to detect to the same levels as traditional Blue Dye tests (usually 30-50 micron), if required.

- **Cost saving, non-destructive test**

Packs are tested in a non-destructive environment, enabling them to be returned to the production line after test. In an environment where high value food is being tested, this represents a major cost saving over traditional destructive test methods.

- **Easy to use system and interface**

Minimal training is required to operate FoodScan. A simple user interface is used to enable the operator to pass or fail scanned packs.

- **Flexible pack size and product type**

Products in flexible packaging that contain either wet or dry products can be tested in a variety of sizes up to 100mm x 300mm x 300mm.

▼ FOODSCAN





FOODSCAN



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 areas constructed from 304 Stainless Steel
PACK TYPE	Sachets, pouches, bags, MAP's and flexible packaging
PACK DIMENSIONS	Up to: 300 (L) x 300 (W) x 100 (D) mm
OPERATING SPEED	2 cycles per minute
SOFTWARE	Easy to use operator interface
MACHINE DIMENSIONS	650 (W) x 500 (L) x 400 (H) mm (25 x 20 x 15")
MACHINE WEIGHT	80kg / Shipping Weight: 100kg
TOOLING CHANGEOVER	No tooling required

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



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SEPHA MEDISCAN

MediScan is a non-destructive, table mounted leak test machine for pouches, sachets and larger medical packs.

It utilizes the leak detection technology that Sepha has developed over 30 years in the pharmaceutical field to offer a technology driven alternative to blue dye testing, ensuring optimal package integrity for larger pack sizes.

FEATURES

- **Identifies leaks from 10 micron**

MediScan is capable of identifying leaks in individual packs as small as 10 micron, depending on pack size. The system can be programmed to detect to the same levels as traditional Blue Dye tests (usually 30-50 micron), if required.

- **Cost saving, non-destructive test**

Packs are tested in a non-destructive environment, enabling them to be returned to the production line after test. In an environment where high value product is being tested, this represents a major cost saving over traditional destructive test methods.

- **Easy to use system and interface**

Minimal training is required to operate MediScan. A simple user interface is used to enable the operator to pass or fail scanned packs.

- **Flexible pack size and product type**

Products in flexible packaging that contain either wet or dry products can be tested in a variety of sizes up to 100mm x 300mm x 300mm.

▼ MEDISCAN





MEDISCAN



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 areas constructed from 304 Stainless Steel
PACK TYPE	Sachets, pouches, bags, MAP's and flexible packaging
PACK DIMENSIONS	Up to: 300 (L) x 300 (W) x 100 (D) mm
OPERATING SPEED	2 cycles per minute
SOFTWARE	Easy to use operator interface
MACHINE DIMENSIONS	650 (W) x 500 (L) x 400 (H) mm (25 x 20 x 15")
MACHINE WEIGHT	80kg / Shipping Weight: 100kg
TOOLING CHANGEOVER	No tooling required

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