

TECHNOLOGICALLY ADVANCED, NON-DESTRUCTIVE
PACKAGE LEAK TESTING MACHINES THAT DELIVER
ACCURACY, EFFICIENCY AND PRODUCT INTEGRITY
ACROSS PHARMA, FOOD AND OTHER MARKETS.



2. PRODUCT INTEGRITY





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INNOVATIVE, NON-DESTRUCTIVE PACKAGE LEAK DETECTION EQUIPMENT THAT ENABLES OUR CUSTOMERS TO IMPROVE THE ACCURACY OF THEIR LEAK DETECTION PROCEDURES AND REDUCE COSTS.

“OUR GOAL IS TO DEVELOP SMARTER, MORE ACCURATE, NON-DESTRUCTIVE LEAK DETECTION EQUIPMENT THAT IS SIMPLE TO USE, SAVES OUR CUSTOMERS TIME AND MONEY, IMPROVES THEIR ENVIRONMENTAL FOOTPRINT AND GUARANTEES MORE ACCURATE, RELIABLE AND REPEATABLE RESULTS.”

Our technology based, non-destructive leak detection range is capable of detecting leaks in a wide range of pharmaceutical blister packs, sachets, pouches and medical device packaging. Our test process is clean and dry, allowing product that has been tested to be recovered and returned to the production line.

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.

21 CFR Part 11

All of our machines have data capture and export capabilities, and can form part of a 21 CFR Part 11 compliant system.

ACCURATE AND CLEAR READINGS

Academic studies and whitepapers have proven that Sepha technology is significantly more accurate and reliable at detecting leaks in blisterpacks than other destructive methods of leak detection. Our detection technology can test for leaks as small as 7 micron and will identify the precise pocket or area of the pack that is leaking. These results can then be stored and exported for quality control and audit records.

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



BLISTERSCAN

BLISTERSCAN

NON-DESTRUCTIVE LEAK DETECTION DEVICE FOR BLISTER PACKS. USES NON-CONTACT LASER SCANNING TECHNOLOGY TO DETECT LEAKS AND WEAK SEALS IN INDIVIDUAL POCKETS.

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

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).



SEPHA LEAK TEST SERVICE GIVES CUSTOMERS A 'SNAPSHOT' OF THE QUALITY OF THEIR CURRENT STABILITY BATCHES. THE TEST DATA RESULTS ARE RETURNED IN GRAPHICAL AND TABULAR FORM FOR ANALYSIS.



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	DVD	CD-ROM drive
OPTIONS	Ethernet	2 x USB
POWER SUPPLIES	Electrical:	110/230V AC Single Phase
	Air:	6 Bar
USER INTERFACES	VGA LCD MMI colour wide angle touch screen display	
HARDWARE	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.	



VISIONSCAN

VISIONSCAN

VISIONSCAN IS A TOOL-LESS, NON-DESTRUCTIVE LEAK DETECTION DEVICE FOR PHARMACEUTICAL BLISTER PACKS.

FEATURES

- Non-destructive seal and leak detection device designed for blister packs
- Incorporates high resolution imaging technology that will detect defects in individual blister pockets, channel leaks and weak seals down to 15 micron
- Tool-less. Ideal for production lines running multiple products
- Can test multiple packs per test cycle
- Rapid test time of less than 60 seconds per test
- Operating system can store up to 30,000 product types
- Simple operator use via a touch screen interface
- Can test packs that contain tablets / capsules in multiple material / design formats
- Objective, repeatable pack test for each product
- Capable of storing and exporting data for audit and quality control purposes
- Can form part of 21CFR part 11 compliant system
- Improved environmental impact
- Flexible, mobile table top device

Using the latest camera imaging technology, it offers modern pharmaceutical manufacturers a flexible, reliable, objective and cost saving alternative to destructive blister pack test methods such as blue dye. VisionScan is simple to operate and requires no tooling, making it ideal for high volume pharmaceutical manufacturers and packagers where high levels of quality control, cost reduction and multiple product changes are required.





MACHINE OPERATION

VisionScan utilizes high resolution camera and projection technologies, combined with vacuum pressure to determine if weak seals or leaks are present in blister packs. It is simple to operate and generates accurate, reliable, repeatable results with clear pass or fail information. Test methods are developed for various pack formats and are stored in the inbuilt PC as 'recipes' for the pack type.

1. LOAD PACKS AND SELECT PRODUCT (IMAGE 1)

Packs are loaded by the operator into the test chamber and the drawer closed. The operator then selects the product being tested from the product recipe library.

2. START TEST AND ACQUIRE REFERENCE IMAGES (IMAGE 2)

Once the drawer is closed the operator presses the 'Start Test' button. An LED light grid is projected onto the blister packs, the camera takes

a reference image and the operator then confirms that correct number of packs is present. This image is then referenced against the pre-stored 'recipe'.

3. VACUUM PHASE (IMAGE 3)

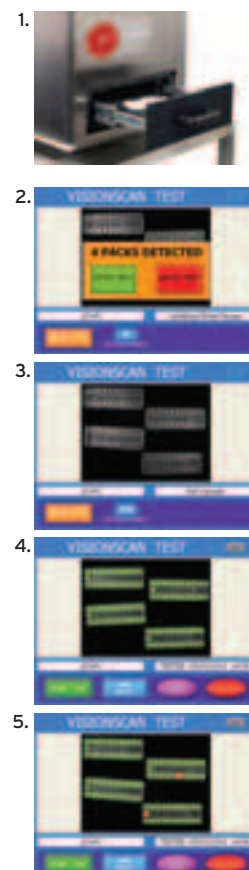
A vacuum is then applied in the test chamber. The camera captures an image of the packs under vacuum, and after a set dwell time the process is repeated, with the images referenced against the pre-stored recipe for the pack type. VisionScan software will then determine irregularities and defects in the packs and give a pass or fail result for each individual pocket in the blister packs.

4. PASS OR FAIL SCREEN - PASS (IMAGE 4), FAIL (IMAGE 5)

The results for each blister pack and individual pocket will then be available for the operator to see on the screen. A simple 'green' for pass or 'red' for fail result will be shown for each pocket. VisionScan is capable of detecting defects down to 15 micron.

TECHNICAL SPECIFICATION

OPERATION	Semi-automatic
CONSTRUCTION	304 Stainless Steel casework
TEST AREA	220mm x 160mm
CAMERA RESOLUTION	1600 x 1200
MEASUREMENT RANGE	Will detect defects down to 15 micron
MINIMUM BLISTER	5mm deep x 5mm wide
POCKET DIMENSIONS	(pack dependent)
OPERATING SPEED	Less than 60 seconds per cycle
MACHINE DIMENSIONS	450 (W) x 500 (L) x 725 (H) mm
SOFTWARE	Windows XP PC with 15" touch screen operator interface 2 x USB ports, 1 x Ethernet port
AUDIT COMPLIANCE	Can be 21 CFR part 11 compliant
MACHINE WEIGHT	80kg / Shipping Weight: 100kg





PAKSCAN

PAKSCAN

NON-DESTRUCTIVE MULTI-PRODUCT LEAK TESTING FOR POUCHES, SACHETS, SMALL MEDICAL DEVICES AND OTHER FLEXIBLE PACKS (NON-POROUS MATERIALS) WHICH CONTAIN DRY POWDER OR A SOLID COMPONENT.

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 275mm x 90mm x 50mm. 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, 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' result.



A TOUCH SCREEN USER INTERFACE MONITORS THE PAKSCAN PROGRESS THROUGH A VIRTUAL INSTRUMENT PANEL.



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	275 x 90 x 50mm (10.8 x 3.7 x 2") 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



MEDISCAN

MEDISCAN

MEDISCAN IS A TOOL-LESS, NON-DESTRUCTIVE LEAK DETECTION DEVICE FOR LARGER SINGLE NON-POROUS POUCHES, SACHETS AND MEDICAL DEVICE PACKAGING.

IT 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

- 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, channel leaks and holes down to 10 micron
- 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 10,000 product types
- User defined password protection ensuring multiple operator use
- Fully validatable 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



A NON-DESTRUCTIVE LEAK TEST MACHINE GIVING ACCURATE, OBJECTIVE MEASUREMENTS TO ENSURE OPTIMAL PRODUCT INTEGRITY.



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	304 Stainless Steel Casework
PACK TYPE	Sachets, pouches, bags, MAP's and flexible packaging (non-porous)
PACK DIMENSIONS	Up to: 250 (L) x 200 (W) x 100 (D) mm
OPERATING SPEED	Up to 2 cycles per minute
SOFTWARE	Easy to use operator touchscreen interface
MACHINE DIMENSIONS	700 (W) x 400 (L) x 500 (H) mm (27 x 15 x 20")
MACHINE WEIGHT	80kg / Shipping Weight: 100kg
TOOLING CHANGEOVER	No tooling required