



## BLISTERSCAN

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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
- Easily validated - 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
- Mobile work station available as an optional extra

### 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

<b>PACK TYPE</b>	Blister pack	
<b>TEST AREA</b>	320mm x 160mm (12.6 x 6.3")	
<b>OPERATION</b>	Semi-automatic	
<b>CONSTRUCTION</b>	Stainless Steel (Grade 304)	
<b>USER INTERFACES</b>	17" 1280 x 1024 SXGA TFT display with resistive touch screen	
<b>UTILITIES</b>	Electrical:	110/230V single phase
	Air:	6 Bar
<b>CONFIGURATION</b>	2 x USB ports	1 x Ethernet port
<b>TEST CYCLE</b>	1-6 minutes	
<b>TOOLING CHANGEOVER</b>	Approx. 30 seconds	
<b>AUDIT COMPLIANCE</b>	Can be run in compliance with 21CFR Part 11	
<b>MACHINE DIMENSIONS</b>	746(W) x 600(D) x 810(H) mm (29.4 x 23.6 x 31.9")	
<b>MACHINE WEIGHT</b>	90kg (198lbs) / Shipping Weight: 225kg (496lbs)	
<b>WARRANTY</b>	Supplied with a 12 month warranty. (Service Level Agreements are available for additional support).	