



PRODUCT
INTEGRITY

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

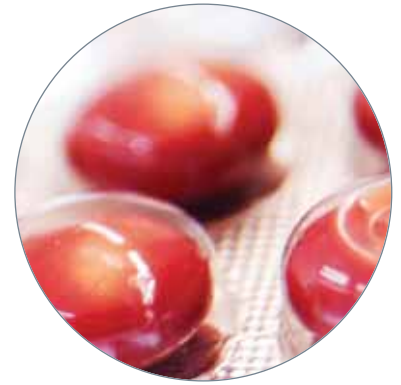
BlisterScan instantly pinpoints the location of a faulty pocket seal. Further graphical analysis is provided for each individual blister pocket.

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:

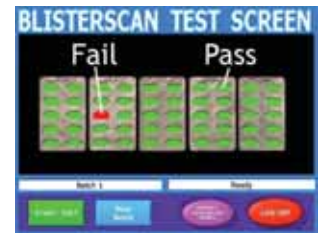
1. Custom tooling is inserted into the tooling holder and is automatically scanned as soon as the drawer is closed. BlisterScan automatically selects the correct test method and displays pre-determined information (e.g. Nest Number, Product Name, Test Method, Date and Time).
2. Operator fills in the 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