



LEAK DETECTION

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LEAK TESTING

VisionScan 3D

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Smart Innovation





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The Sepha VisionScan 3D takes non-destructive leak testing to a new level. The next generation machine is built around a new and patented 3D measurement technique to test the integrity of pharmaceutical blister packs.

The 3D technology is used in combination with differential pressure and vacuum and enables the machine to detect leaks in individual blister pockets as low as 5µm*. The new technology can be applied to all foil types, including busy text patterns. Different pack configurations can be tested with one setting, allowing for easy calibration, quick set up times and a streamlined validation process across different foil types.

The VisionScan 3D requires no tooling, while the large test area of 297x210mm enables multiple blister packs to be tested simultaneously. It is ideal for operations where multiple product changes are required. The machine offers pharmaceutical manufacturers a flexible, reliable, deterministic and cost saving alternative to destructive blister leak test methods. The method does not affect the integrity of the blister pack, allowing packs that have passed the test to be returned onto the production line.

Machine Operation

Test methods are developed for each pack format and are stored as 'recipes' for that pack type.

1. Load packs and select product.

- Login
- Select Product



Technical Specification

Pack Type

Blister pack

Test Area

297mm x 210mm

Measurement Range

Will detect defects down to 5µm (pack & material dependent)

Test Cycle

Typically from 30 seconds for gross test and from 60 seconds for decay

Operation

Semi-automatic

Construction

Anodised Aluminium, Acrylic and Polyurethane Case

User Interface

18.5" FULL HD, 1080 x 1920 pixels with PCAP touch screen

Utilities Electrical:

240-100v AC single Phase, 220W Compressed Air: Min. 200L/min at 0.6Mpa [ISO8573-1:2010 CLASS 2]

Configuration

4 x USB ports, 1 x Ethernet port

Tooling Changeover

Tool-less

Audit Compliance

21CFR Part 11 compliant.

Machine Dimensions

691mm (L) x 489mm (W) x 701mm (H)

Weight Machine:

68kg Shipping Weight: 110kg

Warranty

Supplied with a 12-month warranty. (Extended warranties are available for additional support).

- Select or enter batch details,
- Load packs
- Close drawer
- Press start

2. Reference image and vacuum Phase image.

Pack detection: VisionScan 3D scans the test area and automatically identifies the pack locations.

Gross hole detection

The system first captures a reference topographic scan, applies a vacuum and captures a second topographic scan. At this point in the sequence, the system calculates the response of the applied vacuum in the form of volumetric change (mm3).

Micron hole detection

If additional sensitivity is required, the system will enter the decay phase of the test. During this phase, the system holds the vacuum for a predetermined dwell time before capturing a final topographic scan. All scans are then compared and analysed for pocket volumetric change using product specific parameters.

3. Pass or fail screen

The results screen shows a pass or fail result for each individual pocket. If the volumetric change meets the required pass criteria, the pocket is deemed good and highlighted 'Green'. If the pocket does not meet the pass criteria, the pocket is deemed a fail.

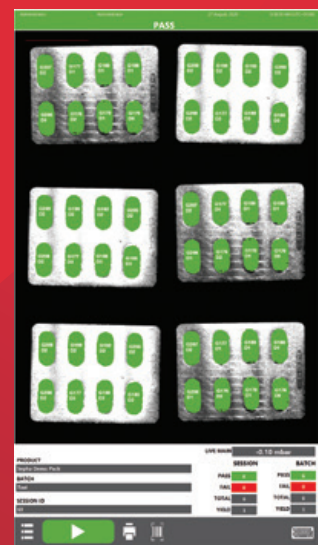
Failed pockets are indicated 'Red' for gross defects and 'Purple' for micron defects.

*Pack and material dependent

Key Features

- Non-destructive, deterministic blister leak test device designed to test all foil types
- Incorporates patented 3D technology that can detect leaks in individual blister pockets, channel leaks and weak seals down to a $5\mu\text{m}^*$ laser drilled pin hole
- Tool-less device making it ideal for production lines running multiple products
- Large test area (297x210mm) provides high throughput
- Can test multiple packs per test cycle
- Can test packs that contain tablets / capsules in multiple material / design formats
- Streamlined validation process for different foil types
- Rapid test time down to 60 seconds for micron holes and as low as 30 seconds for gross holes
- Simple operator use via a touch screen interface
- Operating system can store unlimited product types
- Network connectivity to a central server
- Can form part of 21CFR part 11 compliant system
- Capable of storing and exporting data for audit and quality control purposes
- Active Directory and flexible reporting built-in

*Pack and material dependent





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