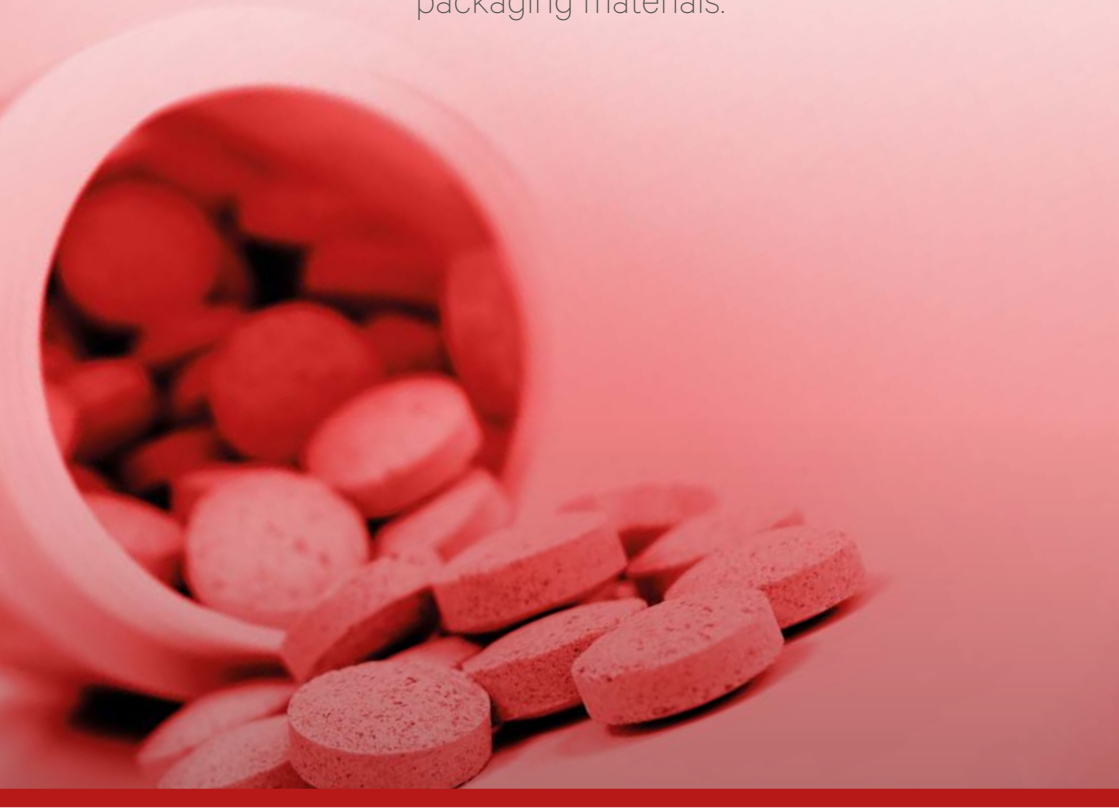
PRODUCT INTEGRITY

Blister packing machines and services that offer flexibility and high quality blister packs from a wide variety of packaging materials.



TASITEST

WWW.TASITEST.COM

Sepha is a well-established brand in the global pharmaceutical market, known for its continuous innovation and customer-focused solutions.

ABOUT US
SEPHA

Established in 1980, Sepha is an award winning specialist engineering business based in Belfast, Northern Ireland. Our focus is on the global pharmaceutical and medical packaging market, and our main areas of expertise involve supplying innovative packaging solutions, inspection and recovery products to clients who manufacture blister packs.

At our Belfast HQ we have a young, highly educated and skilled workforce, who design, develop and manufacture all our products in-house, and we export to over 35 countries globally.

Sepha is a well-established brand in the global pharmaceutical market, known for its continuous innovation and customer-focused solutions.

We have developed a strong global sales, customer service and support network in all major pharmaceutical manufacturing markets. As a result, we can include the world's top 10 pharmaceutical companies as clients.

Our products incorporate unique, innovative and patented technologies to help meet the requirements of our demanding client base. In particular, our products are chosen for their ability to improve quality assurance procedures and to reduce manufacturing costs, enabling clients to efficiently meet the stringent regulatory requirements of the industry.

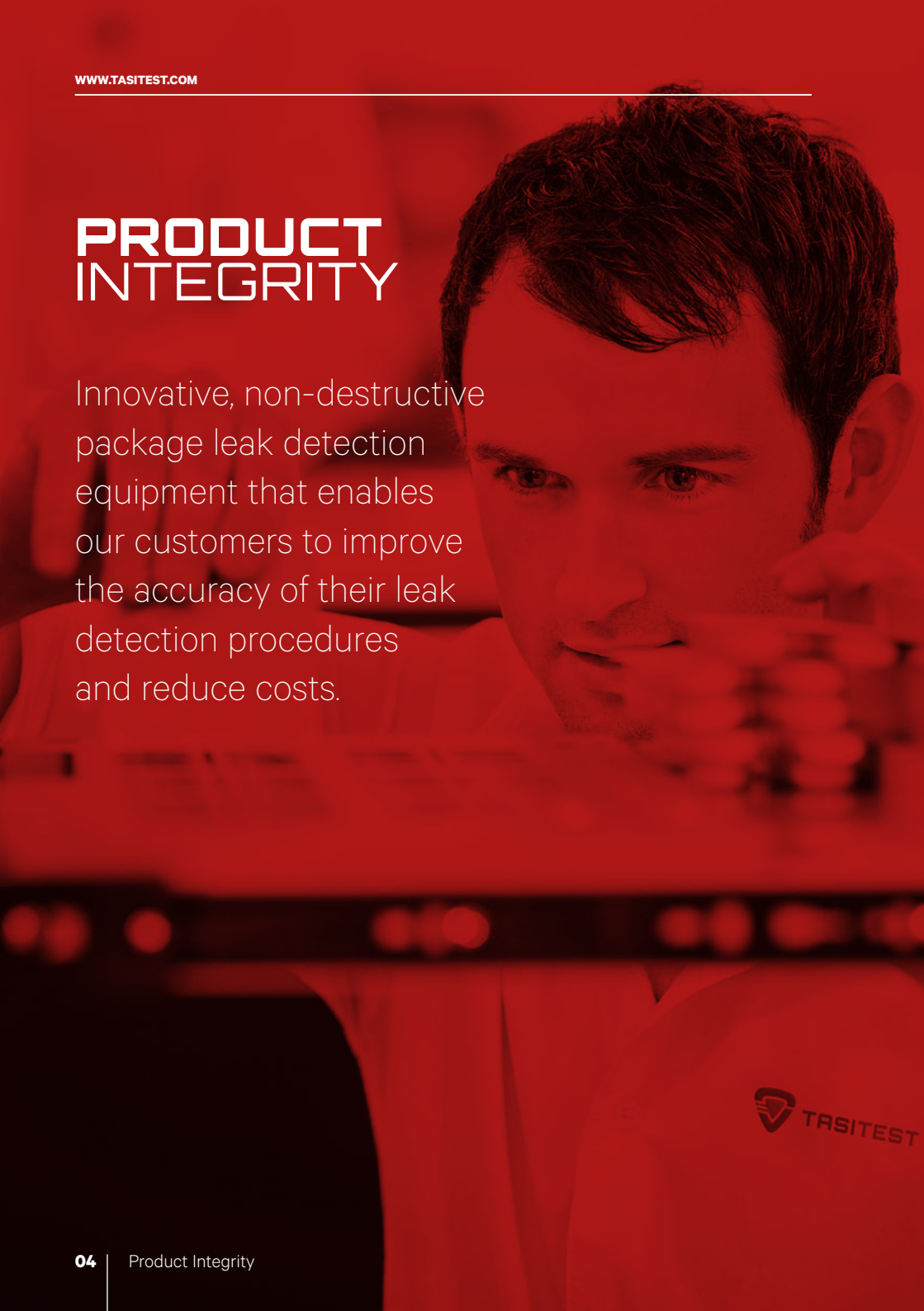
Our product range incorporates 3 main divisions:

- Packaging Solutions
- Product Integrity Testing
- Product Recovery

In 2013, Sepha joined the TASI Group of companies and in so doing, has become part of the single largest pharmaceutical test and inspection group worldwide.

PRODUCT INTEGRITY

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 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, induction-sealed bottles, 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 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.

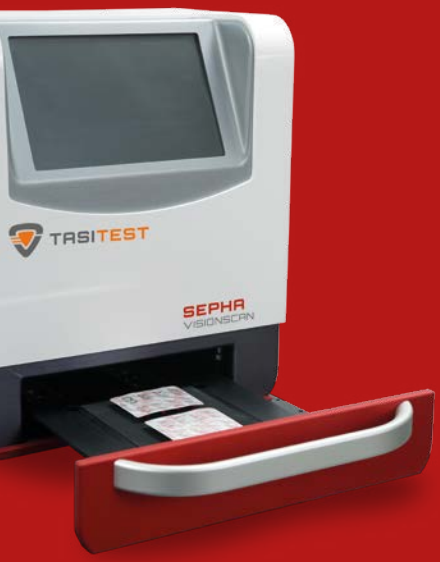
ACCURATE AND CLEAR READINGS

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 10 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.

For more information on non-destructive leak testing visit www.sepha.com.

SEPHA VISIONSCAN

VisionScan is a tool-less, non-destructive leak detection device for pharmaceutical blister packs.



VisionScan is simple to operate and requires no tooling, making it ideal for high volume pharmaceutical manufacturers and packagers reduction and multiple product changes are required.

It uses camera and projection technologies, combined with differential pressure to detect weak seals or leaks in blister packs. VisionScan generates accurate, reliable and repeatable product types results with clear pass or fail information.

1

2

3

4

5

Features & Benefits

- Non-destructive seal and leak detection device designed for blister packs
- Incorporates imaging technology that will detect defects in individual blister pockets, channel leaks and weak seals equivalent to a 7µm* laser drilled pin hole.
- Tool-less. Ideal for production lines running multiple products
- Can test multiple packs per test cycle
- Connectivity, has the ability to connect to an OPC server or database
- Active Directory and flexible reporting built-in
- Rapid test time down to 10 seconds for micron holes and as low as 6 seconds for gross holes
- Operating system can store unlimited 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
- Compact and lightweight, mobile table top device with improved environmental impact

* Pack and material dependent

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 (Image 1 & 2)

- Login
- Select Product
- Select or enter batch details
- Load packs
- Close drawer
- Press start.

2. Reference image and vacuum Phase (Image 3)

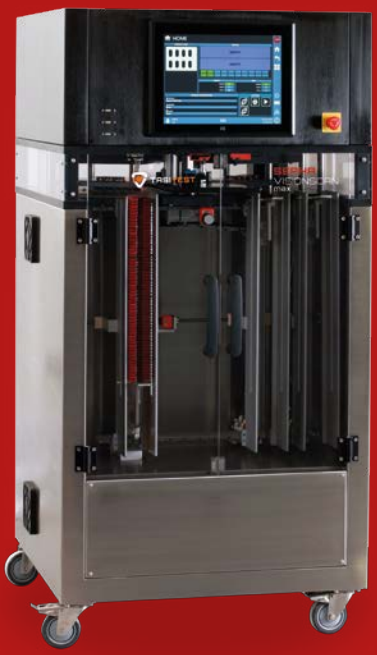
VisionScan then takes an image of the packs, pulls a vacuum, takes a second image and compares the two. If required, small holes can then be detected by waiting for a set dwell time, releasing some of the vacuum and capturing another image. All of the images are then compared and analysed for pocket movement using product specific parameters.

3. Pass or fail screen (Image 4 & 5)

The results screen shows a pass or fail result for each individual pocket. If movement is identified, a simple 'green' for pass will be displayed on the pocket, indicating that there are no defects present. If no movement is identified, the pocket is defective and a 'red' fail result will be shown on that defective pocket. VisionScan is capable of detecting defects down to 7µm.* a new level of problem-solving ability as well as an ever increasing range of custom projects and existing standard solutions.

SEPHA VISIONSCAN max

VisionScan Max offers pharmaceutical blister pack manufacturers the ability to automatically leak test full production batches with minimal operator input at speeds of up to 8 packs per minute*.



VisionScan Max is an objective, non-destructive alternative to the traditional blue dye leak test for blister packs with an automated feed magazine for minimal operator involvement. It enables pharmaceutical manufacturers and packagers to meet the stringent quality control requirements of the industry while reducing waste and costs. VisionScan Max generates accurate, reliable pass/fail results and its tool-less design improves efficiency where multiple product changeovers are required.

Features & Benefits

- Non-destructive, automated, tool-less seal and leak detection device for blister packs
- Incorporates imaging technology capable of detecting defects in individual blister pockets, channel leaks and weak seals down to 7µm*
- Stand-alone at line unit with magazine feed
- Automatic sorting of good and bad packs into segregated collection magazines
- High throughput of up to 8 packs per minute*
- Ability to perform 100% batch testing
- Easy to use touch screen interface. Access any menu with just '2 clicks'
- Tool-less set-up. Ideal solution for production lines running products in multiple materials/design formats.
- Operating system can store up to 30,000 product types
- Can be part of a 21 CFR Part 11 compliant system
- Active Directory included and OPC Connectivity is available on request

* Pack and material dependent

** Recipe dependent

Machine Operation

Test methods are developed for each pack format and are stored as 'recipes' for that pack type. The operator loads a magazine of blisters into the unit, the unit automatically runs the tests, and sorts packs into relevant pass or fail magazines. VisionScan Max can be part of a 21 CFR compliant system and also features a new user friendly HMI interface.

1. Load Packs and Select Product:
Set magazine to correct pack dimensions and load packs into magazine, and select relevant product test method from the product recipe library. Assign batch details.

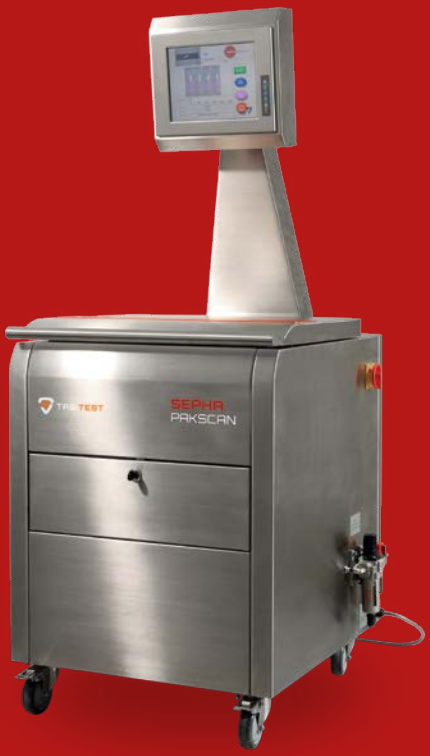
2. Start Test and Identify Packs:
Press Start. The system selects the first pack from the magazine, indexes the pack into the test cell and then loads the second pack. Packs one and two are presented to the test cells for analysis.

3. Reference Image and Vacuum Phase Image:
After the packs are indexed into the test cell a reference image is taken of the packs. A small amount of 'positive pressure' is applied to the packs** to make all pockets uniform. An appropriate vacuum is then applied in the test chamber and an image of the pockets is captured under vacuum. The difference between the reference image and the vacuum phase image is calculated and will define 'gross' failures. The vacuum is then reduced and further images are taken to detect 'decay' failures. The packs are then automatically PASSED or FAILED and segregated into relevant PASS/FAIL magazines.

4. Pass or Fail Results:
PASS or FAIL results are presented on screen. A summary of the last 10 tests, batch details and individual test results per cell are all shown on screen simultaneously. VisionScan Max is capable of detecting defects down to 7µm*.

SEPHA PAKSCAN

A touch screen user interface monitors the pakscan progress through a virtual instrument panel.



Using force decay technology, PakScan offers a clean and dry leak detection solution for modern manufacturers and packaging companies that pack dry product in pouches, sachets and other non-porous flexible packaging. The system can detect leaks as small as 10µm in up to four packs simultaneously and provides an objective pass/fail result. Data can be stored and exported for audit purposes.

Features & Benefits

- Non-destructive seal integrity and leak detection device that uses force decay technology to detect weak seals and holes down to 10µm
- Can test up to 4 packs simultaneously as standard (5 & 6 pack options also available)
- Capable of handling dry, non-porous packages up to 275mm x 90mm x 50mm
- Easy operator use via touch screen interface and easy load chamber
- Capable of storing multiple test methods for up to 30,000 product types
- User defined password protection ensuring multiple operator use
- Easily validated system
- Repeatable test with objective pass/fail results
- Test results can be printed, exported via USB (x2) or integrated into local quality control system via Ethernet cable
- Audit data available and fully 21CFR part 11 compliant
- Active Directory and OPC Connectivity available on request

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 conditions to normalise.

3. Decay Test Phase

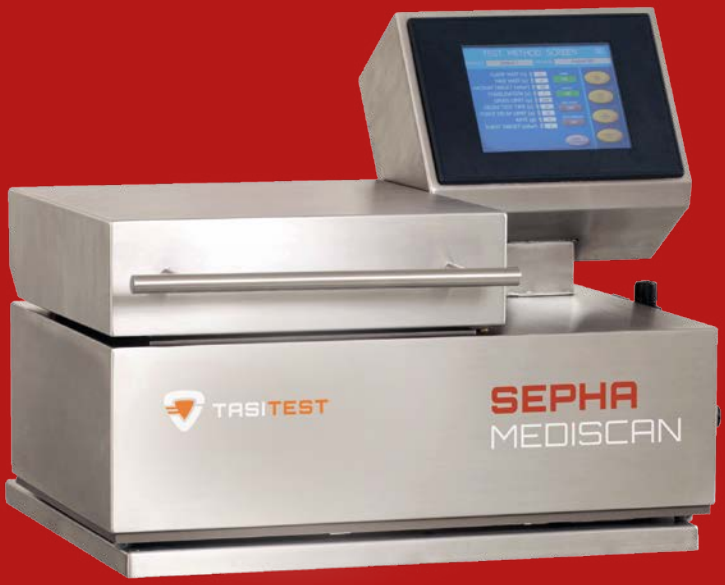
The decay test phase measures any reduction in head space pressure. If the expansive force decays by more than a set amount the pack will be classed as a failure.

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.

SEPHA MEDISCAN

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



MediScan 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 & Benefits

- 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 and holes down to 10µm*
- 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

* Pack dependent
** Product dependent

- Capable of storing multiple test methods for up to 30,000 product types
- User defined password protection ensuring multiple operator use
- Easily validated 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
- Active Directory and OPC Connectivity available on request

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 conditions to normalise.

3. Decay Test Phase

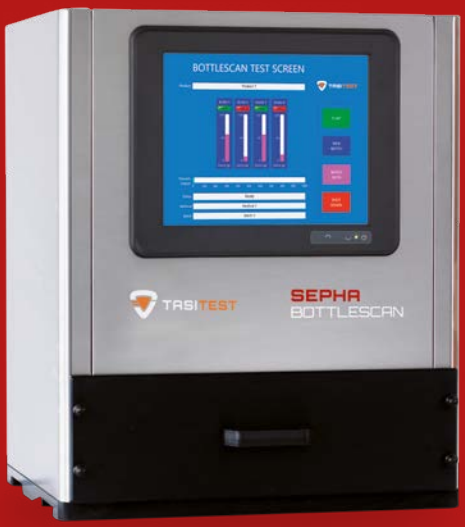
The decay test phase measures any reduction in head space pressure. If the expansive force decays by more than a set amount the pack will be classed as a failure.

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.

SEPHA BOTTLESCAN

BottleScan is a non-destructive integrity tester for induction-sealed pharmaceutical bottles that contain solids or powders.



BottleScan has a unique ability to test up to 4 bottles per test cycle, a tool-less design and incorporates force decay technology to offer a technologically superior QA/QC check as part of cGMP.

Features & Benefits

- Non-destructive inspection device that detects defects in bottles and induction seals down to 15µm*
- Tests up to 4 bottles per test cycle in a test time of 30-90 seconds
- Operating system can store up to 30,000 product types
- No tooling required so ideal for production lines with multiple products

* Dependent on bottle type

- Quick, repeatable test with objective pass/fail results
- Audit data available and can form part of 21 CFR Part 11 compliant system
- Can handle multiple bottle sizes
- Configurable methods allow user to decide machine sensitivity
- Simple operator use with minimal training required
- Active Directory and OPC Connectivity available on request

Machine Operation

Test methods are developed for each bottle size/shape and are stored as recipes for that specific bottle.

1. Load Bottles And Select Product:

From the Test Screen, navigate to the Batch Data Screen and select product from dropdown display. Batch details are entered in the Test Screen. Open drawer, remove cap from bottles to expose induction seal and place into the machine nests. Close drawer.

2. Test Process:

Press “Start Test”. The product nests automatically adjust to the size of the bottle and a vacuum is pulled. At the end of the test cycle the vacuum is vented. The force generated by the bottle is measured throughout this process.

3. Results

The machine issues a PASS/FAIL result for each bottle depending on the force it has generated under vacuum. Graphical information along with batch data is available for every test.

Rapid and objective integrity test for induction sealed bottles. Stores and exports data to optimise quality control systems.

TASITEST

PACKAGING TEST
& INSPECTION

Unit 25 Carrowreagh Business Park
Carrowreagh Road, Dundonald
Belfast, BT16 1QQ
United Kingdom

☎ +44 2890 48 48 48
www.tasitest.com
www.sepha.com

2440 W Corporate Preserve Drive,
Suite 600, Oak Creek,
WI 53154 USA

☎ +1 4146 713 332

Dongfang Rd 3601,
Harvest Industrial Park
No.7 Building, Room 403,
Pudong, Shanghai, 200125
China

☎ +86 2158 366 290

Liebigstrasse 5
D-85757 Karlsfeld
Germany

☎ +49 8131 593 910

Via Rondona, 33
44049 - Vigarano Pieve (FE)
Italy

☎ +39 0532 715 631