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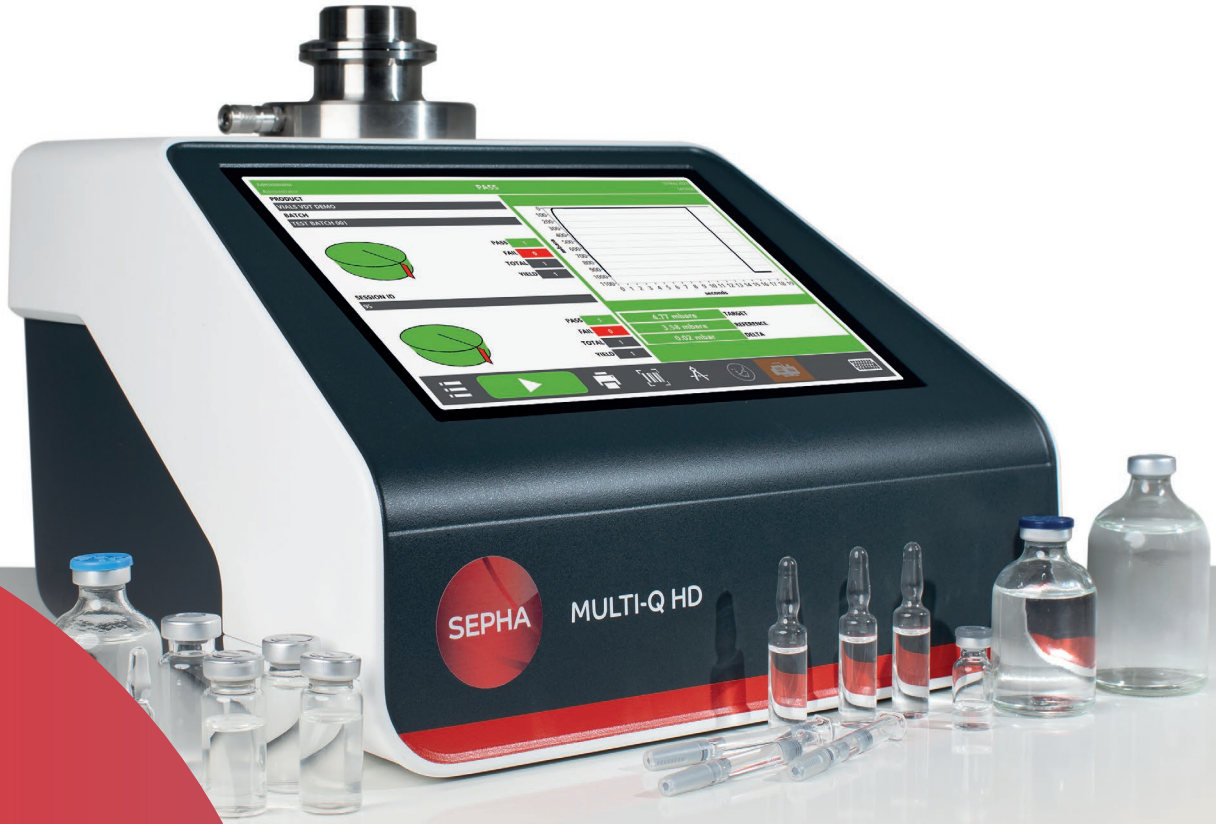


LEAK TESTING

# Multi-Q HD

The Sepha Multi-Q HD is a non-destructive, deterministic Container Closure Integrity Testing system for parenteral containers.

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# Multi-Q HD

## The Sepha Multi-Q HD is a non-destructive, deterministic and reliable Container Closure Integrity (CCI) test system developed to detect leaks down to 1µm* in parenteral containers.

**Manufacturers of parenteral containers including vials, ampoules, bottles, pre-filled syringes and blow fill seal strips, are required to demonstrate the integrity of their container and closure systems (CC). The CC systems need to protect sterile products from potential contamination to ensure product safety throughout its shelf life and guarantee patient safety.**

CCI is critical for parenteral applications as they often contain drugs that have a short shelf life and are highly sensitive to oxygen or moisture; even the smallest defect can affect sterility and efficacy of the drug. As the content is injected directly into the tissue or bloodstream, any compromised container can jeopardise patient safety. These applications often have a lower Maximum Allowable Leakage Limits (MALL) and require a higher level of sensitivity to demonstrate CCI. The Multi-Q HD has been developed to reach this sensitivity and offers a reliable solution down to 1µm*.

The Food and Drug Administration (FDA) and United States Pharmacopeia (USP) have implemented strict regulations for testing and verifying safety of these closure systems. The most common and more traditional methods used, are the dye ingress and microbial immersion methods. These destructive methods are subjective and time consuming, resulting in excessive waste.

The Sepha Multi-Q HD utilises vacuum decay according to ASTM F2338-09 standard test method, the FDA recognized consensus for non-destructive detection of leaks in packages by vacuum decay. The method is In line with new guidelines outlined in USP 1207 preferring deterministic and objective methods that provide reliable and repeatable results.

### Technical Specification

| | |
|---|---|
| Container Type | Ampoules, vials, pre-filled syringes, bottles, blow fill seal strips Medical Devices |
| Measurement Range | Down to 1µm* |
| Test Cycle Time | Starting from 10 seconds |
| Operation | Fixed tooling attachable to top of unit or via test port |
| Data Storage Capacity | Unlimited |
| ASTM Standard | ASTM F2338-09 |
| Machine Dimensions | 377mm (L) x 366mm (W) x 288mm (H) |
| User HMI | 10.1" PCAP touchscreen |
| Connectivity | Active directory, network printing, central network storage, custom data MES/OPC connectors available |
| Utilities | Electrical: 24V 5A \|Air Supply: Min. 200L/ min at 0.6MPa {ISO8573-1:2010 Class 2} or vacuum pump |
| Features | Flexible reports, 3x USB, 2x ethernet port, external calibrated leak port |

* Container type and content dependent

# Vacuum Decay: reliable testing down to 1µm

The vacuum decay test is a proven non-destructive, deterministic, sensitive, and reliable method to identify leaks in pharmaceutical containers. Newly developed advanced sensor technology enables the Multi-Q HD to detect defects down to 1 micron*. The ultra-sensitive technology has an improved signal-to-noise ratio that can pick up the slightest rise in pressure to detect even the smallest micron holes. The sensor is located at the point of measurement, which yields a faster response and more sensitive results.

To conduct a vacuum decay test, a container is placed in a tightly fitted chamber which is evacuated to a pre-determined level of vacuum. After reaching the pre-set vacuum, a sensor measures the vacuum level over a pre-determined time. If the integrity of the container under test has been compromised (it has a leak), there will be a rise in pressure measured inside the chamber.

This will result in a) a gross leak, if the vacuum doesn't reach the pre-set vacuum level; b) a medium leak, if the vacuum level drops below a pre-set vacuum level during the test or c) a decay or micron leak, if the vacuum level exceeds the decay limit during the test time.

## Key Features & Benefits

- Non-destructive, deterministic, quantitative test method
- Identifies defects down to 1µm*
- Ideal for testing vials, ampoules, bottles, pre-filled syringes and BFS strips containing water-based liquid
- Unlimited data storage
- Utilises ASTM F2338-09 standard test method to perform the test
- In line with USP 1207
- 21 CFR Part 11 compliant
- OPC Connectivity
- Active Directory


* Container type and content dependent

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