LEAK DETECTION

Verifies integrity of container and sterility of products
CONTAINER INTEGRITY – ONE OF THE MAJOR CONCERNS IN TERMS OF PATIENT SAFETY.

Invisible leakages such as pinholes or cracks of microscopic dimensions weaken the mechanical properties of the container. Besides the penetration of oxygen and its possible reaction with the product, the loss of sterility of parenteral products (e.g. injections, infusions) is the most serious threat to the health of patients. Our range of leak detection technologies complementing camera inspection at the point of final quality control provides reassurance that your products are safe.

HEAD SPACE ANALYZER (HSA O₂)

This spectroscopic method is used for leak testing of containers which have been filled with lyo product and sealed at negative pressure and in a protective atmosphere. If there is a leak, after lyophilization ambient air penetrates the vial – until the pressure is equalized. In addition, the O₂ molecules continue to diffuse even after pressure equalization, until the same O₂ concentration prevails inside and outside. To analyze the oxygen content, a laser beam is directed through the container above the lyo cake (Head Space). Oxygen molecules absorb a certain wavelength of light. The more O₂ there is available in the Head Space, the less intensity of the laser beam reaches the sensor.

HIGH VOLTAGE LEAK DETECTION (HVLD)

Seidenader applies high voltage for the detection of the smallest micro-cracks and pinholes in the sidewall, bottom and closure zone of pharmaceutical containers, provided that the liquid inside has a minimum conductivity as low as 1μS/cm. All containers – rotating, so that the inner surface is moistened with solution – are placed between electrodes to which an alternating high voltage is applied. They become part of an HV circuit and, together with the electrodes they represent an electrical resistance in this circuit. Leakages in the container lead to a reduction of the resistance and hence to an increase in the electrical flow. A container with a measured current higher than a defined maximum will be rejected.
The **HSA O₂** station consists of a laser and a sensor, plus the sensor electronics and a powerful processor. The station is integrated into a vacant position of the inspection carousel. This ensures precise container handling and optimal inspection results.

**DESIGN FEATURES**
- For glass containers filled with powder and lyophilized products
- Fully embedded in Seidenader inspection machine, PLC and HMI structure
- Can be combined with other inspection methods
- Precise and smooth handling system with top and bottom support of the container

**YOUR BENEFITS**
- Easily integratable into standard inspection machines
- No extra space required for a separate machine
- Lower investment costs
- High speed analysis up to 24,000 containers per hour
- Only one sensor needed. This guarantees lower validation effort and reproducibility
- No necessity for N₂ purging
- Retrofitting possible in existing inspection machines
- Also available: stand-alone HSA machine
- Handling of containers up to Ø 52 mm

The heart of the **HVLD PRO** high-speed inspection module is a pivot carousel which allows the product to be smoothly rotated, and presented precisely to the electrodes. Flexible swivel arms tilt the containers at different angles allowing even low fills to be inspected reliably. For complete HV inspection of the container, a bottom station is integrated.

**DESIGN FEATURES**
- For ampules, vials, cartridges filled with liquid product
- High sensitivity thanks to specific HV needle electrodes
- Mass electrodes moving with the containers provide best detection results
- Active drive system for reproducible rotation delivering consistent inspection results, with two swivel arms moved by one servo drive
- Precise and smooth handling system with top and bottom support of the container in the swivel arm

**YOUR BENEFITS**
- Inspection of up to 36,000 containers per hour
- Handling of containers up to Ø 52 mm
- Inspection of complete container of low fills thanks to tilt angles of 75° - 105°
- Stand-alone HVLD PRO machine, or HVLD PRO module integrated into Seidenader MS or VI inspection machines
- Bypass function for rejects from previous camera inspection, or for all products in case no HVLD is required (optionally)

---

**HVLD PRO**
- low fill, high speed
- All units are in millimetres.
- Footprint illustrated is example only.
The HVLD SLIM is a module with a vertical inspection carousel and thus a smaller footprint, where the containers are tilted into a 90° position and rotated in a controlled mode along the longitudinal axis, supported at the bottom and the closure. For complete HV inspection of the container, a bottom station is integrated on the machine platform.

**DESIGN FEATURES**

- For ampules, vials or cartridges filled with liquid product
- Reproducible 360° rotation thanks to active drive system for consistent inspection results, with all axes moved by one servo drive
- Vacuum transport system places the containers in the 90° position
- Precise and smooth handling system with top and bottom support of the container in the vertical HV inspection carousel

**YOUR BENEFITS**

- Inspection of up to 36,000 containers per hour
- Handling of containers up to Ø 52 mm
- Stand-alone HVLD SLIM machine, or HVLD SLIM module integrated into Seidenader ES, CS, MS und VI inspection machines
- Bypass function in case no HVLD is required

The HVLD PRO-S is an inspection carousel for syringes to be presented individually and needle-down to the electrodes. Servo driven grippers rotate the syringe with high-speed to wet its complete inner sidewall previous to HVLD. For complete HV inspection of the syringe, a HVNSI station is integrated into the machine platform to check for pierced needle shields.

**DESIGN FEATURES**

- For pre-filled glass and plastic syringes
- Reproducible 360° rotation thanks to servo-driven handling system of each position in the carousel
- Precise and smooth syringe handling with grippers of insulating material

**YOUR BENEFITS**

- Inspection of up to 36,000 syringes per hour
- Handling of syringes up to Ø 22.5 mm
- Stand-alone HVLD PRO-S machine, or HVLD PRO-S module integrated into Seidenader MS-S or VI-S inspection machines

**OVERALL BENEFITS OF SEIDENADER HVLD MODULES**

- Reduced false reject rates thanks to very small and precise electrode-to-container distances
- Autonomous operation thanks to ozone extraction system with catalyst
- Extensive measures for operator safety
- Frictionless rotation of containers for safe 360° inspection
SEIDENADER LIFE CYCLE SERVICE

Seidenader Service Desk
The Service Desk is staffed by qualified experts. They can provide 24/7 service 365 days a year. The Service Desk combines maximum competence with short response and solution times.

Seidenader Academy
Our customized training and support programs impart theoretical and practical knowledge to enhance the productivity of your employees.

Seidenader Field Service
Our technicians have the expertise and understanding that comes from time, training, dedication to their craft and the determination to provide superior service to every customer.

Seidenader Original Spare Parts
We stock an extensive inventory of original spare parts at our locations worldwide to ensure speedy delivery. Machine-specific spare parts packages are also offered to give you in-house stock for immediate installation.

Seidenader Retrofit/Upgrades
Retrofit: For more flexibility and functionality take advantage of the modularity and expandability of your machines and profit from consistently modern equipment. Upgrades: Improve your installed equipment and software with upgrades.

Seidenader Process Optimization/OEE
Consulting and technical support to increase equipment performance, availability and reliability.