



SEIDENADER
KÖRBER SOLUTIONS

ES-SERIES

Automatic inspection for
vials and ampules



PURITY AND STERILITY OF PARENTERALS – VITAL TO PATIENTS' HEALTH

In the pharmaceutical industry, quality standards are becoming more and more stringent, and production processes are getting faster and more complex. As a result, automated inspection systems are playing a key role in parenteral manufacturing processes. Efficiency and detailed documented information about the inspection process are key attributes that foster improved performance.

Besides sustaining their own quality standards, drug manufacturers have to make sure that their products follow the standards set by the respective government pharmacopeia or the USP. General requirements are that each final container of all parenteral preparations shall be inspected to the extent possible for the presence of observable foreign and particulate matter. In addition, products have to be inspected for other critical defects, such as cracked or defective containers or seals.



CAMERA INSPECTION

Liquid

Camera inspection detects moving particles such as glass, fibers, metal and coating fragments, as well as heavy particles on the bottom. Containers such as vials are mostly also checked for closure defects, cracks and scratches. Ampules can additionally be inspected for seal quality and ampule tip geometry.

Lyo

The process of freeze drying puts enormous stress on the glass container, especially the heel, often causing cracks. For lyo inspection a separate camera station is integrated into the inspection carousel to detect especially these cracks at the heel. Lyo inspection typically detects: missing product, over-/underfill, particles, cracked glass, scratches and dirt.

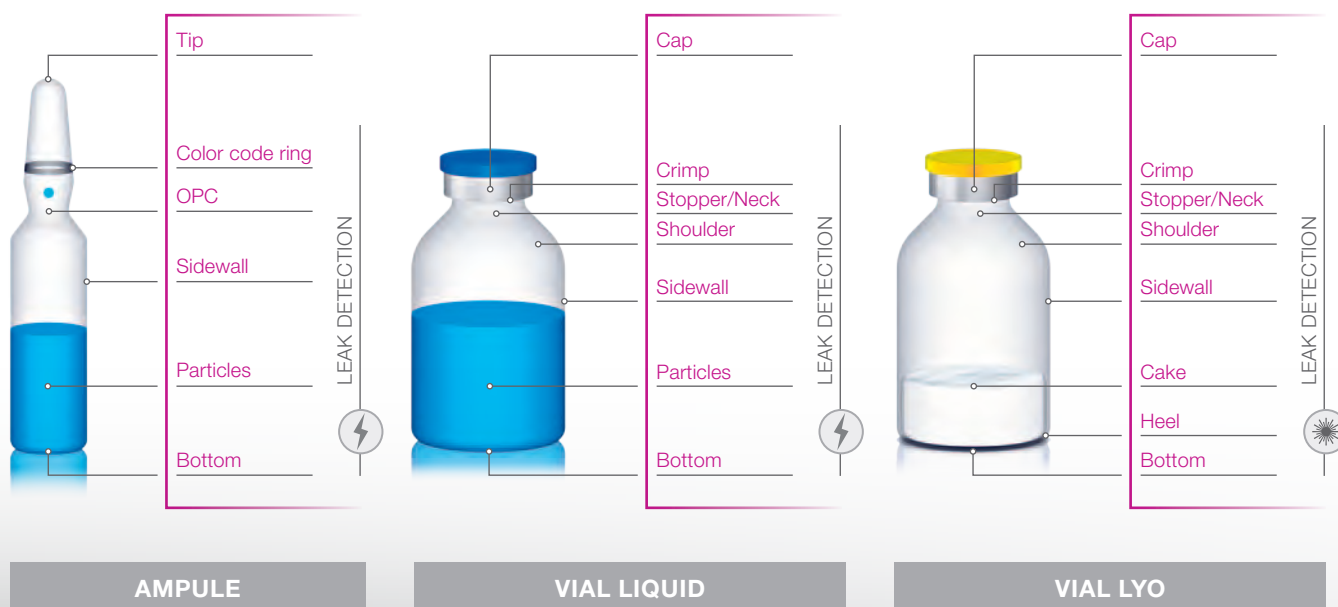
LEAK DETECTION

Liquid

Leakages such as micro-cracks or pinholes in the container may not be detected by cameras. To complement vision inspection for critical zones of containers filled with liquid product, high voltage inspection, such as the HVLD SLIM module, can be integrated into Seidenader ES machines.

Lyo

Variations of absolute pressure or water partial pressure in the headspace of vials filled with lyophilized product are used to verify the tightness of the containers. The compact HSA station can be integrated into a vacant position of the inspection carousel for 100 % testing, inline and at high speeds.



HIGH-QUALITY INSPECTION FOR SPECIAL REQUIREMENTS

The modular design of major machine functions for infeed, inspection and outfeed enables us to build customized machines from standardized modules. The Seidenader ES series are high-tech inspection machines for a wide range of parenterals and can be configured for liquid and lyophilized products. The ES platform is equipped as standard with vision systems for the inspection of vials and ampules up to Ø 52 mm. To complement camera inspection, additional technologies such

as high voltage or head space gas analysis can be included, to reliably verify container integrity and product sterility.

The ES machines meet the challenges of the pharmaceutical industry (speed, efficiency) as well as the regulatory requirements (FDA, GMP, GAMP etc.): As comprehensive as necessary, as simple as possible – highest value at the best price.

YOUR BENEFITS

- Inspection of up to 36,000 containers per hour
- Handling of ampules and vials up to Ø 52 mm, and up to 100 ml
- Enhanced inspection performance and reduced false reject rate thanks to up to 20 images per inspection
- Quick changeover thanks to fewer format parts
- Individual rotation profiles thanks to servo drives on each position in the inspection carousel



DESIGN FEATURES



1 STATIC PARTIAL IMAGING (SPI)

- No moving optical elements
- Less vibration, less abrasion
- Fewer spare parts, less maintenance

PROGRAMMABLE LOGIC CONTROLLER (PLC)

- Modular design
- Smart trigger technology
- Reduced qualification time



1 "HYSEPTIC" STANDARD

- Sealed and covered optical elements
- Column concept for good access and easy cleaning
- Trimmed edges, hidden cables
- Strict separation of product handling and machine engineering areas
- GMP-compliant

2 ENHANCED SOFTWARE DESIGN

- Advanced recipe manager
- Easy adjustment of inspection speed
- Reduced qualification effort thanks to B&R technology
- GAMP 5 compliant



3 INFEED

- Manual loading from trays with Seidenader A-MAG, with tight splitting at infeed starwheel to slow down its rotation speed at same throughput
- Inline interface with upstream machine to transport stable containers directly to the infeed timing screw
- Inline connection, with turntable for manual loading

4 PRODUCT HANDLING

- Vacuum transport for smooth product handling
- Reduced number of side guides to avoid friction
- Vacuum pump for reduced air consumption



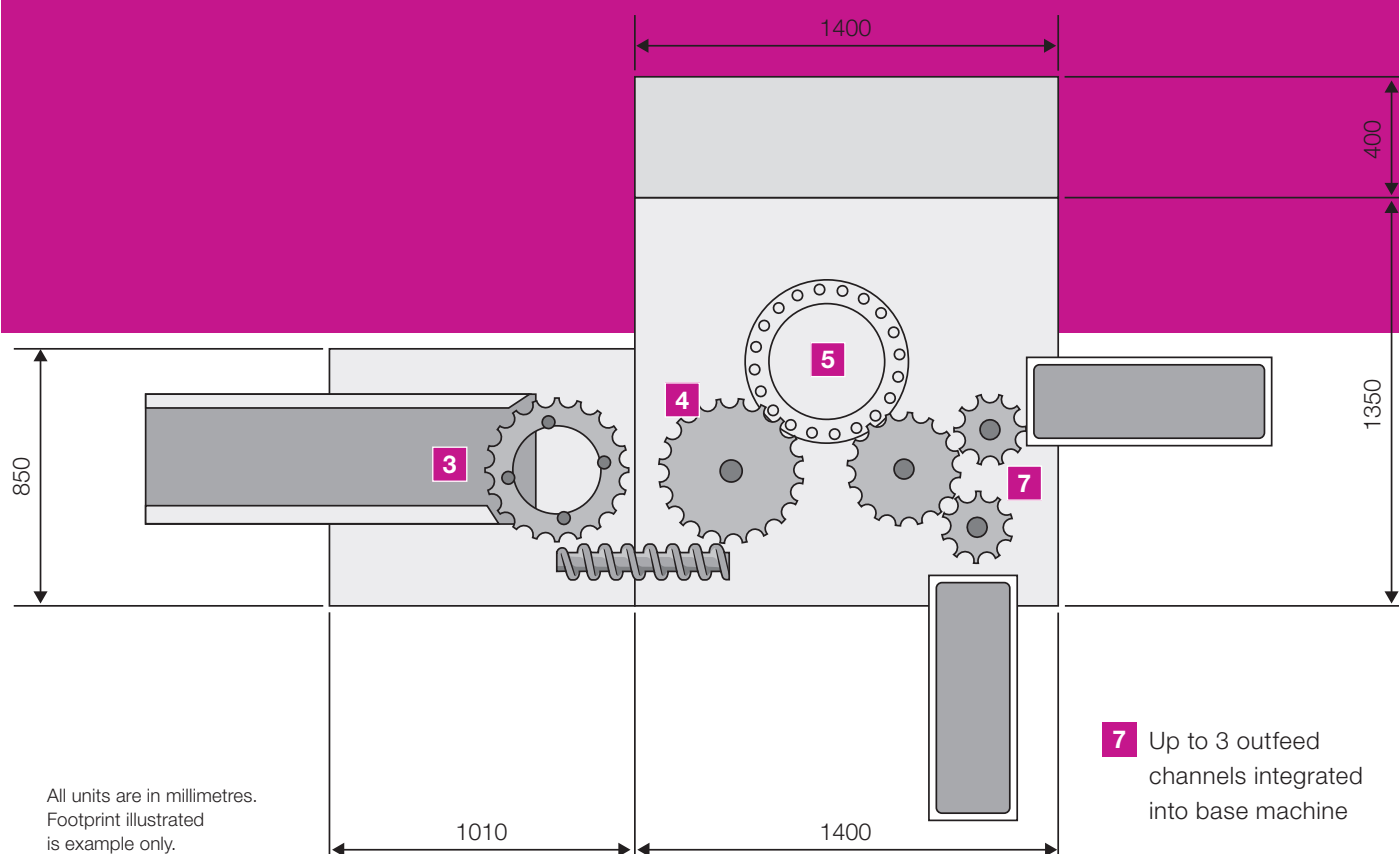
5 CAMERA INSPECTION

- Inspection carousel with either 20 or 40 inspection positions
- Servo drives for each position in the inspection carousel allow individual rotation profiles:
 - Different kind of liquids require different rotation speeds to generate the dedicated motion
 - Different kind of particles require different rotation speeds to be whirled up
 - Rotation speed and brake point are stored in the individual product configuration (recipe)

6 LEAK DETECTION

- Integrated high voltage leak detection (HVLDS SLIM) for liquid-filled containers, with one operator interface for camera and high voltage inspection – 360° inspection of the container guaranteed
- Head space analyzer (HSA), for 100 % testing of containers, inline and at high speeds, to verify container integrity of lyo-filled vials

TECHNICAL DETAILS



	Seidenader ES-30	Seidenader ES-40	Seidenader ES-60
max. throughput of containers/h (with HVLD module)	18,000 (18,000)	24,000 (24,000)	36,000 (24,000)
max. number of camera stations (in carousel)	5 (3)	5 (3)	5 (3)
servo-driven positions in carousel	20	40	40
range of container diameter up to	up to Ø 52 mm	up to Ø 52 mm	up to Ø 52 mm
range of containers	ampules and vials	ampules and vials	ampules and vials
range of products	solutions and lyos	solutions and lyos	solutions and lyos
dimensions of base machine approx.	1,400 x 1,750 mm	1,400 x 1,750 mm	1,400 x 1,750 mm

SEIDENADER SERVICES TAILORED TO YOUR NEEDS



Seidenader Customer Support

Our Customer Support Team is available during business hours to help you with urgent questions you may have about your Seidenader machine or any other technical issues. 24/7 support is also available as an additional option.



Seidenader After Sales Services

Maintenance, spare part orders or retrofit requests – your direct contact is a designated customer support team to coordinate all your inquiries regarding our comprehensive range of after sales services.



Seidenader Academy

Reduce your installation time to a minimum by taking advantage of customized training sessions for integrators and users of our products – from the basics to the tips & tricks to run your machine in the most efficient way.



Seidenader Qualification Support

Profit from our validation support package and minimize validation and start-up time. Our specialists develop test plans and qualification protocols and provide support during execution.

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