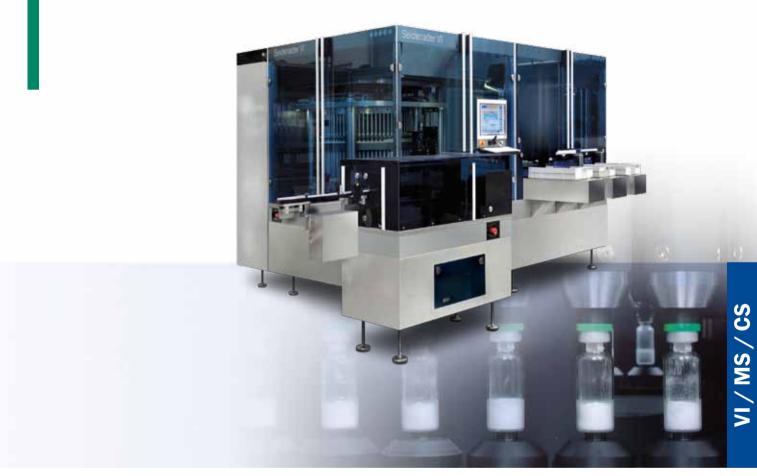
Seidenader

Pharma Technology Solutions



High-Performance Inspection for Ampules, Cartridges, Vials and Bottles



Modular system

Major machine functions are designed as modules that can be chosen regarding customer requirements.

• Infeed:

- inline / offline
- buffer system for stable / unstable products
- Inspection stations for:
- solutions
- suspensions
- emulsions
- oil based products
- lyophilized products
- Outfeed:
- separation in up to 8 outfeed channels
- compact outfeed system for 4 channels



Seidenader VI/MS/CS sophisticated inspection machines to meet highest demands of large production environments

The Seidenader VI, MS wide range of parenter based or lyophilized procan be combined with I The modular design of allows to build customiz The VI, MS and CS platti tion of ampules, cartrid additional technologies analysis or glass stress



VI - MS - CS

These machine series take advantage of the same technologies for infeed, product transport, and particle detection. Most of the modules can be used for either platform. Differences between the three machine

Up to 8 selectable outfeed channels The Seidenader VI, MS and CS series are high performance inspection machines for a wide range of parenteral products: solutions, suspensions, emulsions as well as oil based or lyophilized products. The basic inspection for cosmetic defects and particles can be combined with lyo inspection in one machine.

The modular design of major machine functions for infeed, inspection and outfeed allows to build customized machines from standardized modules.

The VI, MS and CS platforms are basically equipped with vision systems for the inspection of ampules, cartridges and vials up to 100 ml. To complement camera inspection, additional technologies, like high voltage, near infrared spectroscopy, head space gas analysis or glass stress verification can be included.

> series can be found in platform size, number of camera stations, size of the inspection carousel, reinspection process, and in throughput of containers per hour.

Advantages

4 5

- 24-image technology to maximize inspection performance.
- Continuous motion no moving cameras, no moving lights.
- Wide range of products in one machine: liquids, suspensions, lyos in different container types of various sizes.
- Closed loop operation for quick and easy validation runs for all inspection stations.
- LED illumination for minimal maintenance and heat generation.
- Minimal breakage and friction due to special guides and vacuum transport system.
- Reject verification system (fail safe principle) to make sure that containers recognized "defect" will not reach the channel for good products.
- Print-out of all configuration parameters to document program changes.

- Full audit trail for HMI. PLC and vision parameters.
- Wide range of products in one machine: liquids, suspensions, lyos in different container types of various sizes.
- Material and machine design comply with GMP recommendations, e.g. trimmed edges and column concept for good access and easy cleaning, no visible cables.

Seidenader VI/MS/CS high-performance inspection for ampules, cartridges, vials and bottles

Special features

- New infeed system with split timing screw and synchronized star wheel to feed the containers smoothly at the fastest possible rate, and separate them to inspect product by product at an optimal pitch.
- Special vacuum transport system and minimized number of side guidings with teflon inlays to avoid friction.
- tion method.
- suspension products.



Infeed with buffer system for stable products



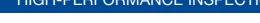
Infeed with back pressure system for instable products



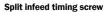
Integrated automatic re-inspection

Reduced friction by special

guide part design







www.seidenader.de

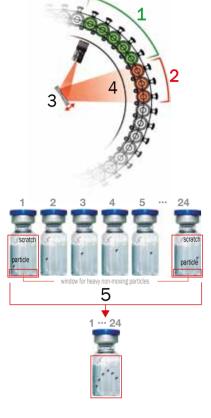
• Particle detection through image subtrac-

• Large inspection turret to optimize rotation and inspection time, even for viscous and

- Each position in the inspection carousel is equipped with a programmable servo drive for fast and synchronized rotation.
- Separation of good products, statistical samples and up to 8 reject groups.
- Regression testing for quick verification of vision system modification – electronic sample set.
- Integrated automatic re-inspection of defined defect parameters to minimize false reject rates.

Each inspection position is equipped with programmable servo drive





• Up to 24 images per particle station. • Up to 3 light techniques per particle

station.

• Up to 4 particle stations.

Particle inspection

Each product is inspected in up to four particle inspection stations using the image subtraction method:

- **1** Container and liquid are rotated at high speed by a servodrive in each position of the inspection carousel.
- **2** Rotation of container is stopped, the liquid continues to move, particles move with the liquid.
- **3** A central inspection mirror moves synchronized with the transport of the container.
- 4 The camera acquires a sequence of up to 24 images.

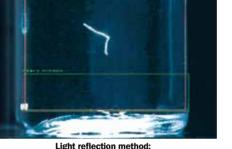
5 The images are sent to the image processor and are compared to each other in an overlay image, pixel by pixel.

Objects which change their location between the images are identified as particle defects. Using two or three particle inspection stations allow to vary the rotation speeds to detect lighter and heavier particles. The set points for rotation speed and brake point are stored together with the product inspection configuration (recipe) for each product. Programmable servo drives in every position of the inspection carousel allow reproducible rotation distances and rotation speeds. No belt drives - no abrasion.

Seidenader VI/MS/CS particle and cosmetic inspection up to 36.000 containers/hour

Cosmetic inspection

In addition to the standard particle inspection stations, Seidenader machines can be equipped with a variety of camera stations to detect cosmetic and functional defects.



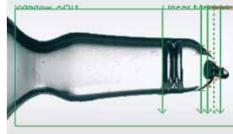
Depending on product range and container

type different illumination techniques and

combinations can be used. Matrix cameras

can represent particle defects as a real time

picture on the monitor.



and OPC noint

Concentrated light is sent through the container bottom. The camera looking from the side detects light reflections scattered by the particle against a dark background.



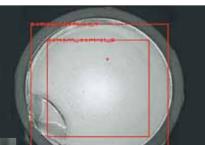
Inspection of cap, neck and stopper, optional inkiet and OCR function

Lyo inspection

inspection or as a combination lyo/liquid inspection. The inspection carousel provides enough space to add camera stations like neck, shoulder, sidewall, heel and bottom inspection to cover all typical defects in lyophilized products.



lyophilized products

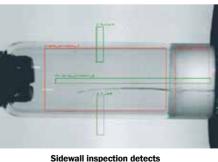


Bottom inspection of lyo cake

Heavy non-moving particles on the

container bottom can be detected reliably

by an additional window tool utilizing a special light technique



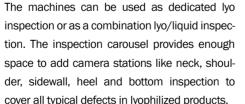
cracks and fill level





camera looking from the other side of the container detects shadows created by the particle,







Cake surface inspection in

Inspection of the ampule head, color ring

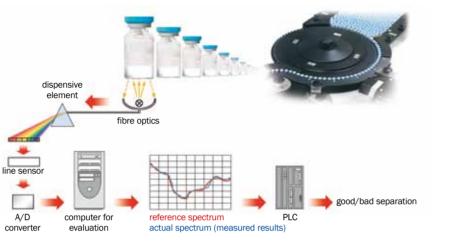




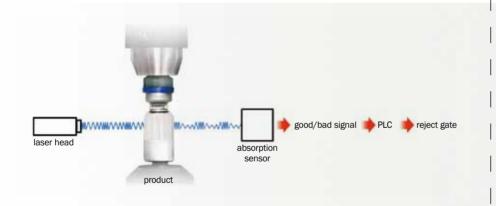
Options

- Camera stations for liquid and lyo inspections can be combined in one machine.
- Outfeed module with up to 8 channels for good product, rejects, or non-inspected units, or inline connection to downstream machine can be chosen.
- Gross defect rejection inspection process to increase machine availability.
- Automatic reinspection system PRF inline!
- Choice of short distance reinspection or long distance reinspection.
- Remote access of PLC and vision system through Net Op, Remote Control.
- Exact counting into trays.
- Integration of inspection stations with complementary technologies like:
- NIR technology for product identification and residual moisture test.
- head space analysis to verify container/ closure integrity.
- polarimetric analysis for the detection of stress in glass.
- high voltage leak detection module.
- Integration of product coding/code verification system to avoid cross contamination.
- Extended documentation and machine qualification through trained Seidenader specialists.
- Color inspection with color camera system or sensor.

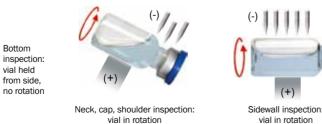




Near infrared spectroscopy to monitor concentration of active ingredients and of residual moisture, and to identify cross-contamination



Head space analyzer to detect oxygen content, water partial pressure and absolute pressure in pharmaceutical containers



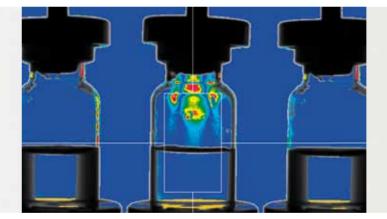


nhole and leak detection with high voltage for reliable integrity of pharmaceutical containers

Sometimes there is more required than cameras: additional inspection technologies

Complementary inspection technologies

To complement visual inspection, Seidenader R&D team continuously reviews technologies which may provide additional product information at the point of final quality control. A variety of technologies can now be included



Polarimetric analysis for secure sterility of your product and reduce breakage by verifying stress conditions in glass



as modules in the Seidenader automatic inspection machines of the VI, MS and CS series to verify product quality, container and closure integrity, and to prevent product cross contamination.

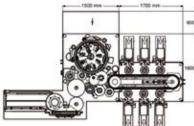


Integrated high voltage leak detection module

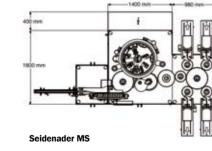
Seidenader VI/MS/CS highly precise mechanical handling for reproducible inspection results

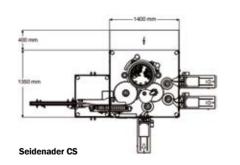
The Seidenader VI/MS/CS machine include a number of innovative design features which allow to operate at very high throughput speeds while the products are handled very smoothly:

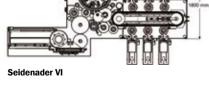
• Infeed, inspection machine and outfeed modules are electronically synchronized.



-	0.11		0.11
Technical data	Seidenader VI	Seidenader MS	Seidenader CS
throughput container/h max.:	36.000	24.000	18.000
number of camera stations (in carousel) max.:	(8) 13	(6) 9	(4) 7
additional inspection stations with complementary technologies:	HVLD, HSA, NIR, X-ray, GSI	HVLD, HSA, NIR, X-ray, GSI	HVLD-LX, HSA, NIR, X-ray, GSI
gross defect camera and rejection station:	yes	no	no
servo-driven positions in carousel:	72	60	40
central oscillating mirror:	yes	yes	no
autom. reinspection:	yes (long and short)	yes (only short)	no
liquid/lyo-combination:	yes	yes	yes
range of containers:	ampules, vials, cartridges, bottles (max. 100 H)	ampules, vials, cartridges, bottles (max. 100 H)	ampules, vials, cartridges, bottles (max. 100 H)
range of container diameter:	8.15 - 51.6 mm	8.15 - 51.6 mm	8.15 - 51.6 mm
dimensions base machine incl. internal cabinet:	1,500 x 2,400	1,400 x 2,000	1,400 x 1,750
net weight base machine approx.:	4,500 kg	2,400 kg	2,000 kg
dimensions external electrical cabinet:	3,600 x 600 mm	3,000 x 600 mm	3,000 x 600 mm
net weight external electrical cabinet approx.:	1,000 kg	1,000 kg	1,000 kg
internal/external electrical cabinet:	yes	yes	yes
voltage/frequency:	400 V, 3Ph+N+PE	400 V, 3Ph+N+PE	400 V, 3Ph+N+PE
current consumption approx .:	8 kW	8 kW	8 kW
vacuum transport technology with external electrical vacuum pump:	yes	yes	yes
air consumption approx. (by using vacuum pump):	10 Nm ³	10 Nm ³	10 Nm ³









Expertise on material handling and inspection of a vast variety of pharmaceutical containers filled with liquid and dry sterile products, combined with the experience and suggestions of our customers have helped us to create a full line of automatic high-performance inspection machines for parenteral products.

These machines fulfil the most stringent requirements of the pharmaceutical industry in their reliable detection of particles, cosmetic and functional defects in the rough environment of 24 hours production per day.

- Infeed systems for inline / offline operation
- One central oscillating mirror for more images/product with less mass in movement.
- No moving cameras or lights.
- Each position in the inspection carousel has a programmable rotation drive to eliminate friction belts and bulky rotation stations.

Seidenader

Pharma Technology Solutions



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The product range of Seidenader Maschinenbau GmbH includes:

- automatic inspection machines
- semi-automatic inspection equipment
- complementary inspection technologies
- track and trace solutions
- equipment for inspecting and sorting of tablets
- exterior washing machines
- industrial vision systems
- automation & IT solutions for pharmaceutical packaging lines

Since we are constantly working on the improvement of our high-quality machines, the texts, illustrations and figures on these pages are illustrative only and not binding.



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