

Inspection Machine Seidenader **SI** for Pre-filled Syringes

The Seidenader SI is a modular inspection machine for a wide range of pre-filled syringes. The machine is equipped with camera stations to detect particles in the product as well as cosmetic and functional defects of the containers. The syringes are inspected in hanging position. Optionally, an inspection in upright position is possible.

Inspection criteria:

Product: particles, fibres, glass, fill level
Container: cracks, scratches, inclusions, dirt
Flange: cracks, geometry
Plunger: position, orientation, liquid
 between ribs, damage
Tip/needle: presence, orientation, geometry

Mode of operation:

The syringes are supplied to the machine in hanging position and are picked by a system of starwheels for inspection of the flange area. To avoid downstream breakage, defects can be separated immediately after this inspection. A starwheel transfers the syringes to

an inspection carousel equipped with self centering grippers, allowing rotation at high speed, and a central oscillating mirror for more images to be taken per product.

Prior to the particle inspection, the syringes are rotated to whirl up any particles. As soon as the syringes appear in front of the camera, the rotation is stopped. The liquid continues to rotate and a sequence of images is taken. The images are compared to each other in the image processor. Objects which have shifted their location between the images are detected as particles. This inspection is repeated in a second camera station. Depending on the products, a third inspection station for particles using a different light technique can be provided. After particle inspection the syringes are checked for sidewall cracks, fill level, plunger and needle defects.

After the inspections have been completed, defective products are separated from good product. Physical separation of defects and sampling channels are available.

Good products are transferred to the next process.





Inspection Machine Seidenader SI

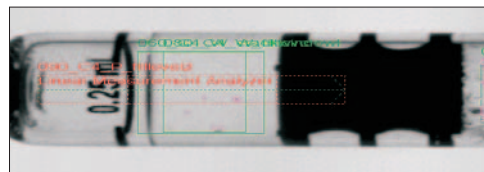
Options:

- Additional third camera station for particle inspection as well as further camera stations for detection of cosmetic and functional defects
- Turning device for transportation and inspection of the syringes in a "needle up" position
- Additional reject channels for defective flanges or to separate defects by category
- Printout of the configuration parameters for documentation of program changes
- Extended documentation and validation support at customer's site available through trained specialists
- Modem to assist maintenance, trouble shooting and training
- Connection to SCADA system

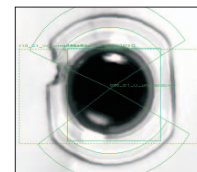
Since we are constantly working on the improvement of our high-quality machines, the texts, illustrations and figures on these pages are exemplary and not binding.

Advantages:

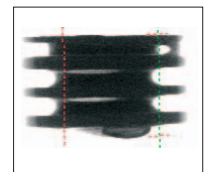
- Avoiding transport screws allows precise material handling as well as economical "plug in" change parts
- Continuous transport avoids unnecessary movement of the liquid, which might create air bubbles or foam
- In compliance with 21 CFR part 11 for vision processing, PLC and operator interface
- Central oscillating mirror for more images or syringes with less mass in movement
- The machine is equipped with a reject verification system ("fail safe principle") to guarantee that containers which were recognized as defects will not pass as good products
- Particle detection through image subtraction method. This technique requires less product agitation for reliable particle detection than other systems while maintaining reliable detection performance. Ideal for delicate biopharmaceuticals and viscous products
- The Seidenader Vision Inspection Module SVIM® is used as a standard vision processor, equipped with SVObserver® configuration software for quick and easy set up of the vision system parameters without any programming skills
- LED strobe lights for high resolution images at high transport speeds
- Consecutive and sequential defect logic to stop the machine after configurable defect occurrence
- Permanent monitoring of camera positioning and lighting, rotation speed and rotation time by PLC
- Printout of all batch data, defects per category and good product counts
- Relational database to compare complete batch status report inspection results



Inspection of sidewall and fill level



Flange inspection



Liquid between plunger ribs

Technical data Seidenader SI:

Application:	Pre-filled syringes
Range of sizes:	0.5 ml - 10 ml; max. diameter 15 mm
Throughput:	depending on size and product SI-20 up to 200 syringes/min SI-30 up to 300 syringes/min SI-40 up to 400 syringes/min
Design:	Complies with current GAMP 4 recommendations and 21 CFR part 11 regulations. The electrical standard is EN 60204-1
Voltage/frequency:	400 V, 3 Ph + N + PE, 50 Hz, ca. 3 kW standard; all other voltages possible through transformer
Compressed air:	Pressure min. 6 bar, consumption ca. 140 Nm ³ /h, connection 1/2"
Dimensions:	Base machine: ca. 1600 x 1785 x 2000 mm (LxWxH) Infeed height: 1200 mm ± 50 mm Outfeed height: 850 mm ± 50 mm Electrical cabinet: 1800 x 620 x 2100 mm (LxWxH)
Net weight:	Base machine: ca. 1200 kg, electrical cabinet ca. 800 kg

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