Stevanato Group

ENGINEERING SYSTEMS

How to inspect glass containers before filling

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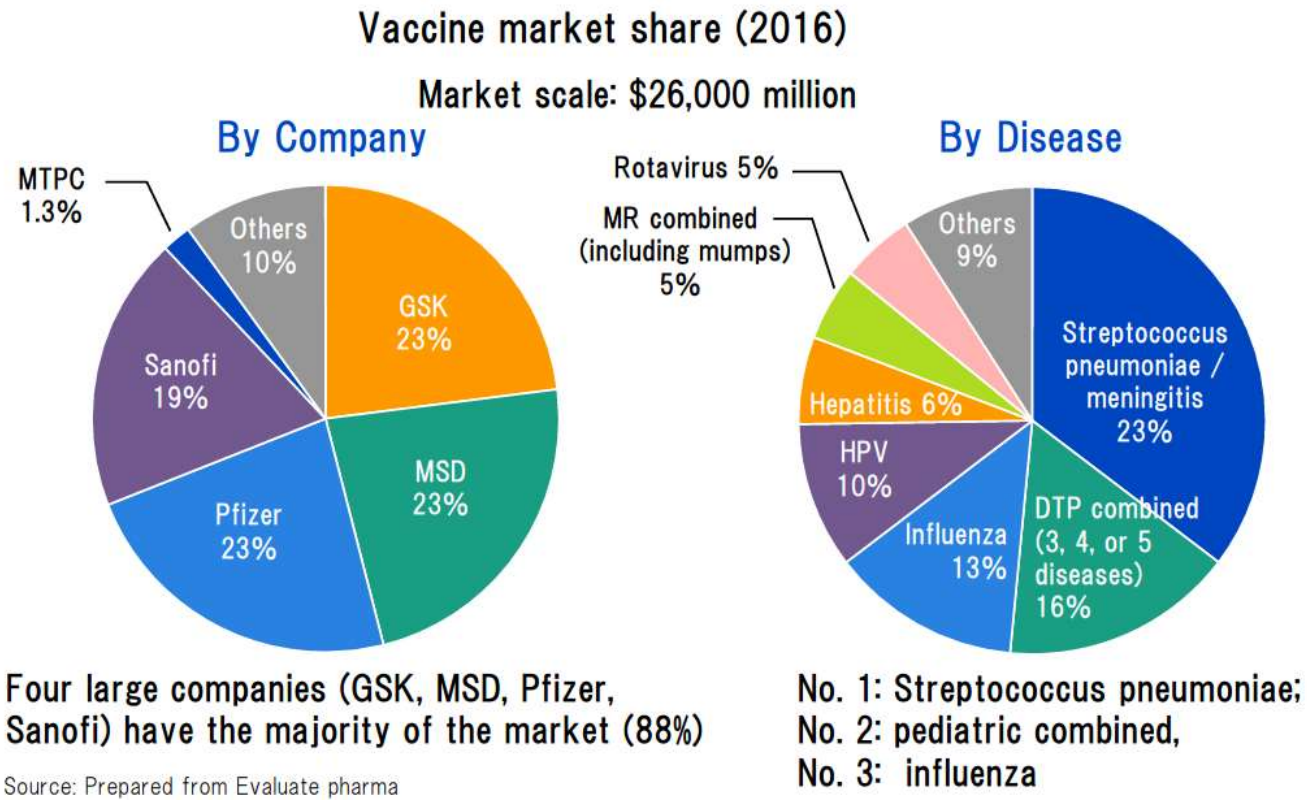
Global vaccine market

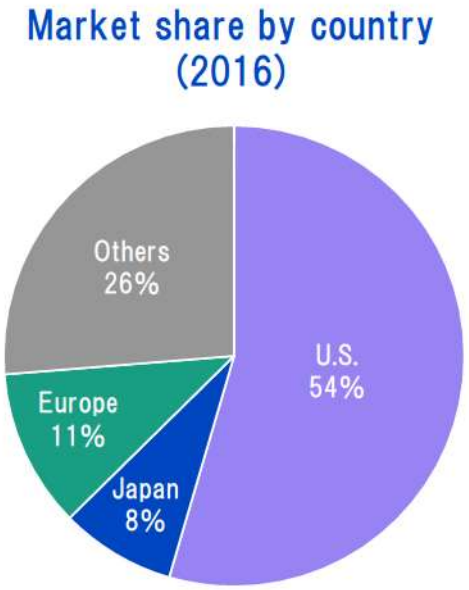


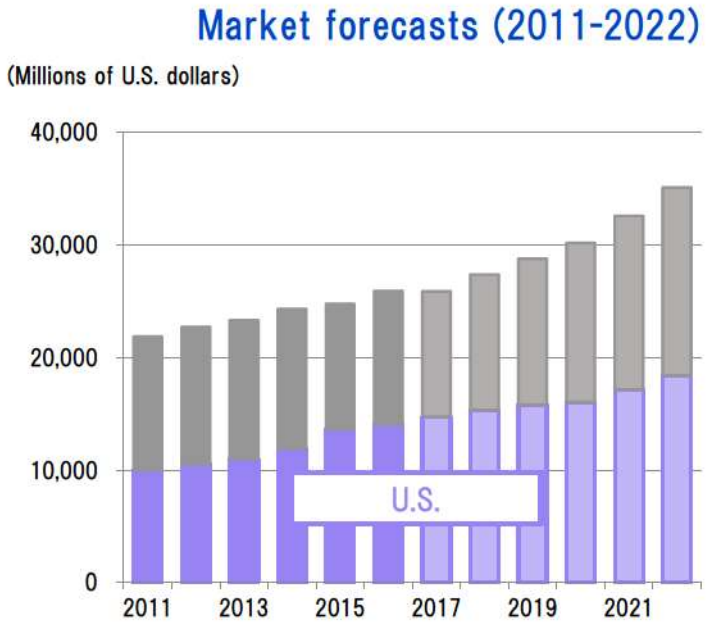
Four large companies (GSK, MSD, Pfizer, Sanofi) have the majority of the market (88%)

Source: Prepared from Evaluate pharma

No. 1: Streptococcus pneumoniae;
No. 2: pediatric combined,
No. 3: influenza

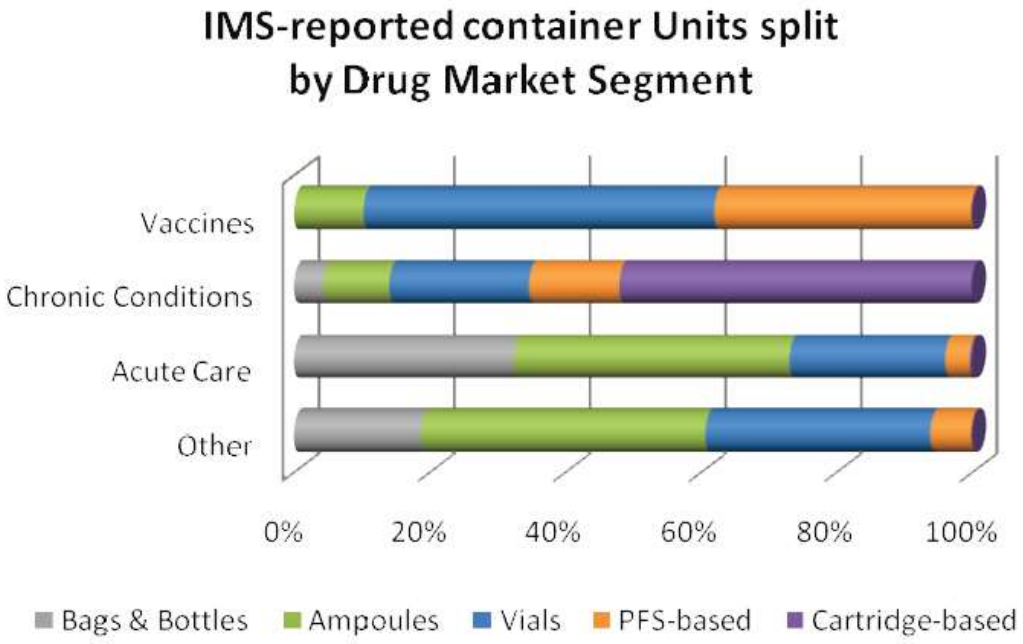
Vaccine market by region





Source: Prepared from Evaluate pharma

Injectables units by segment



Glass containers for pharmaceutical use

Market Trends

2013-2018

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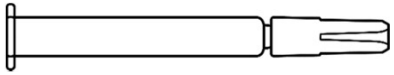
- Anti-Diabetics
- High Value Drugs in Valuable Markets
- Rare Diseases
- **Vaccines in Emerging Markets**



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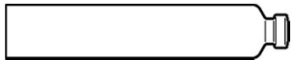
- Anti-coagulants
- **Vaccines**
- Anti-infectives
- Anti-inflammatory agents
- Haematological agents
- MS treatments
- Human growth hormones
- Obstetric agents
- Cancer therapies
- Pain relievers



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- Anti-Diabetics
- Self-Injections
- MS treatments
- Human growth hormones
- Haematologica

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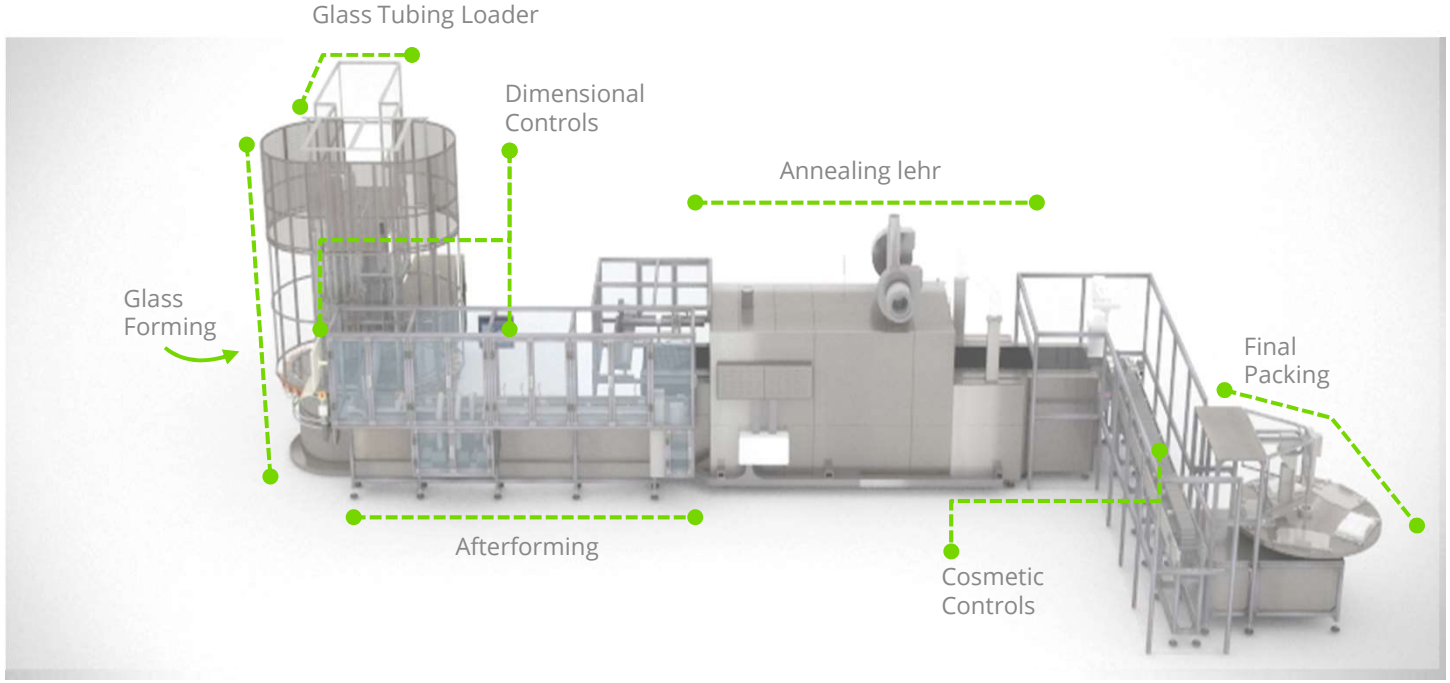
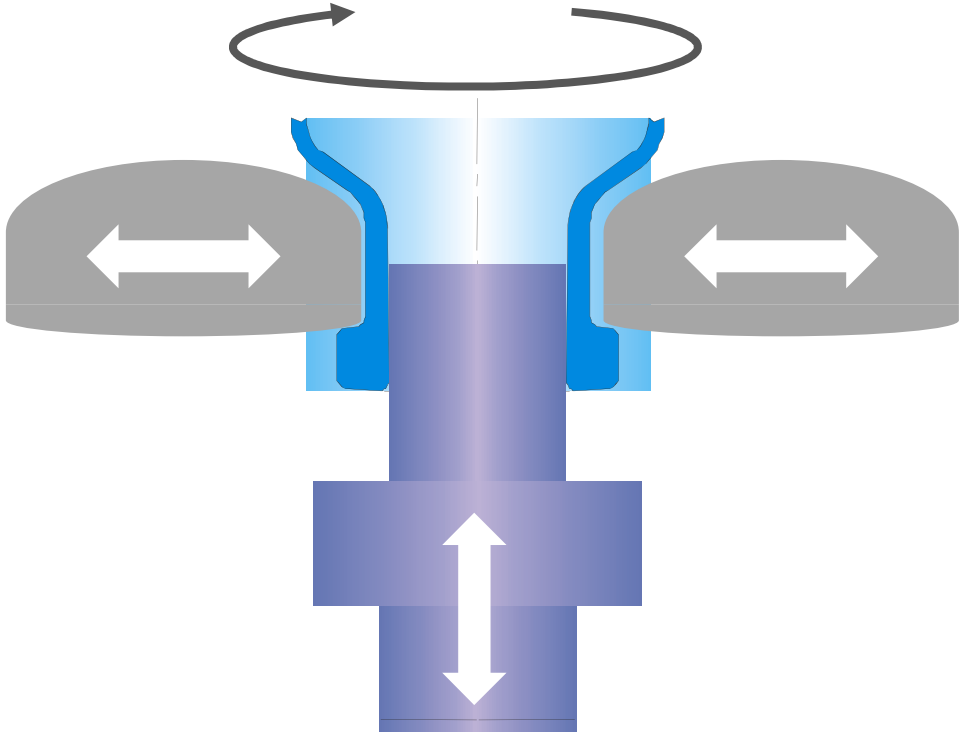
- 1° Healthcare

Glass converting line: typical configuration



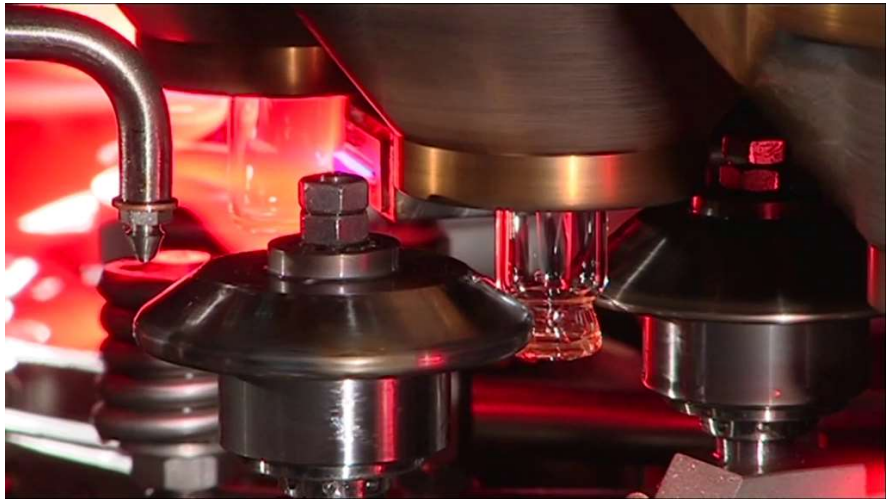
Suitable for Ampoules, Vials, Cartridges and Syringes

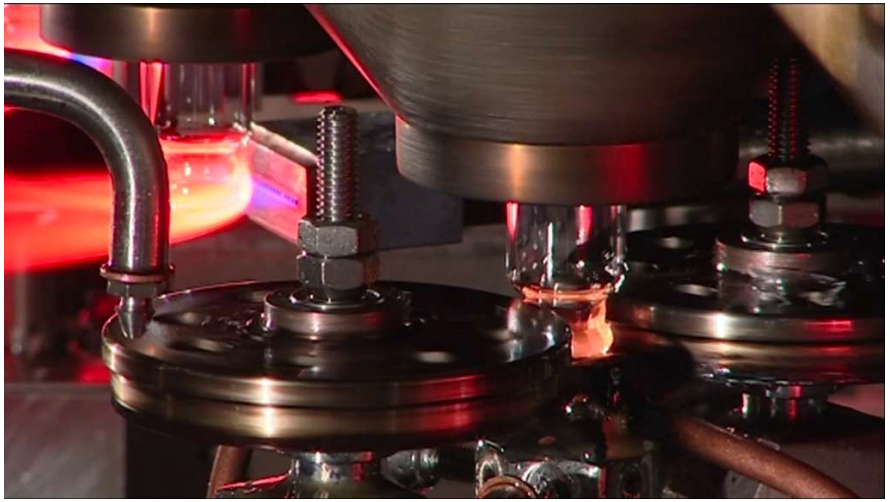
Neck/cone forming



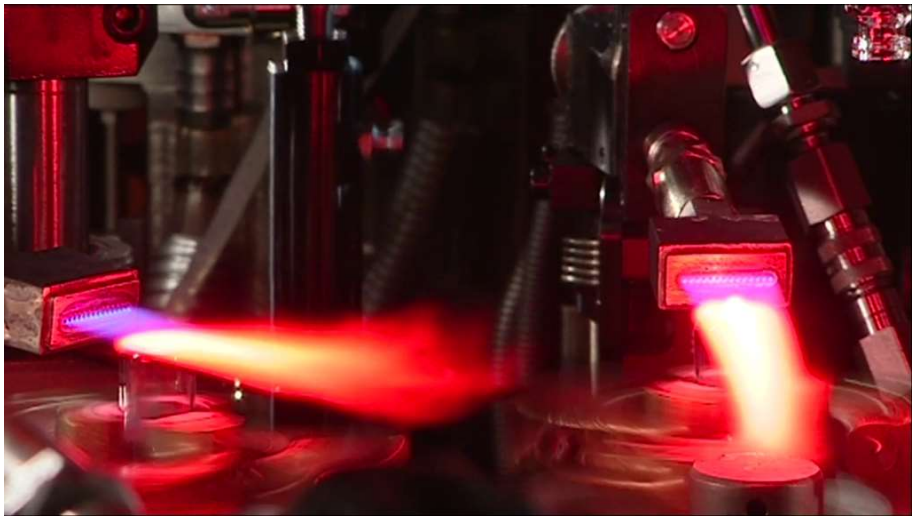
Forming tools to give the right shape to the neck / cone

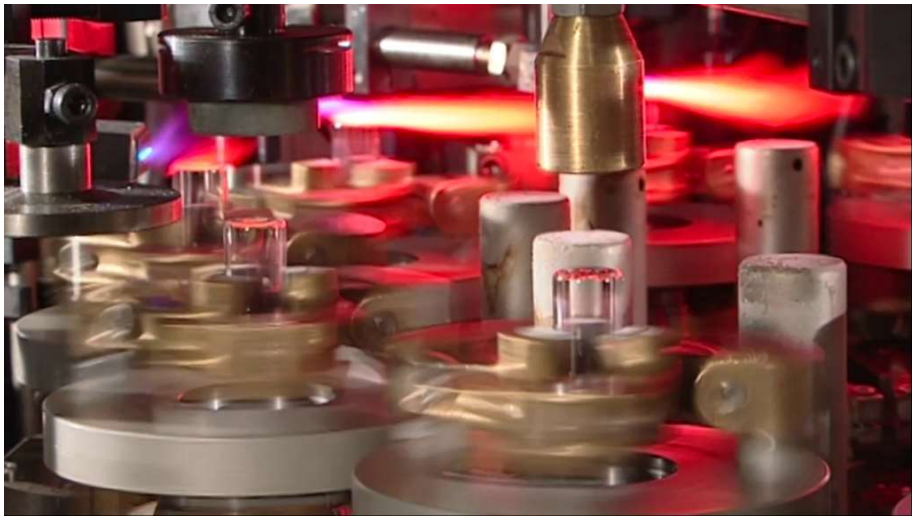
Glass converting process: mouth forming





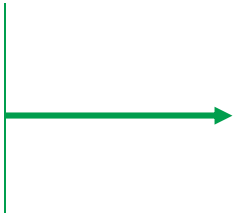
Glass converting process: bottom forming





Inspection technology

Inspection Technology

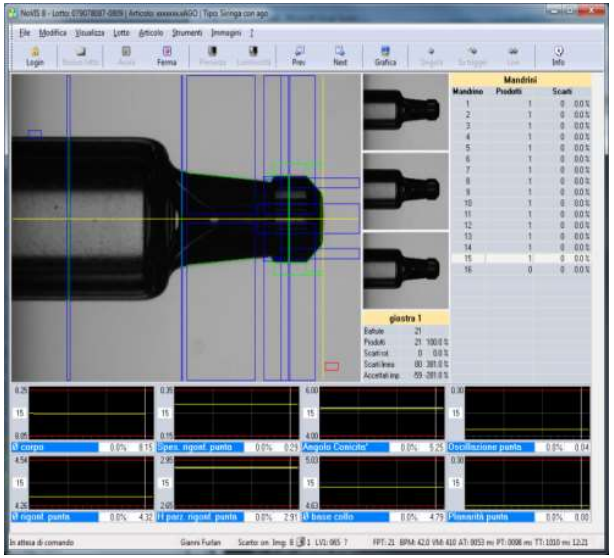


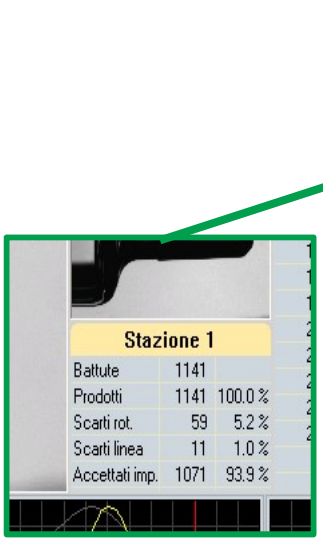
Dimensional Inspection

Cosmetic Inspection

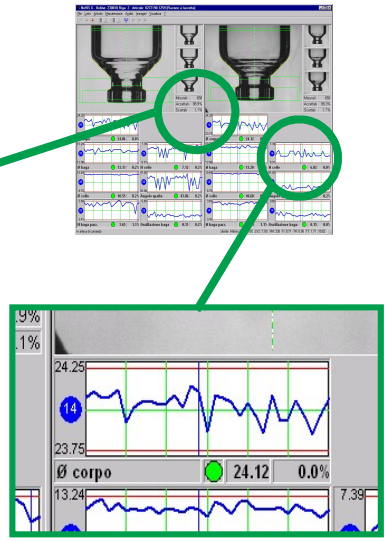
Dimensional inspection: introduction

- 100% inspection of all dimensions
- Automatic rejection of defective pcs
- Customizable quality level
- Automatic calibration system
- Performance per chuck
- Measurements and statistics in real time



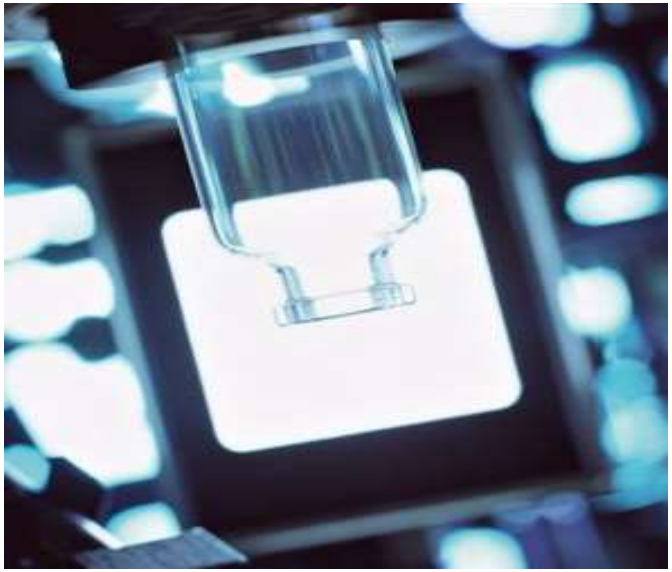


General production data

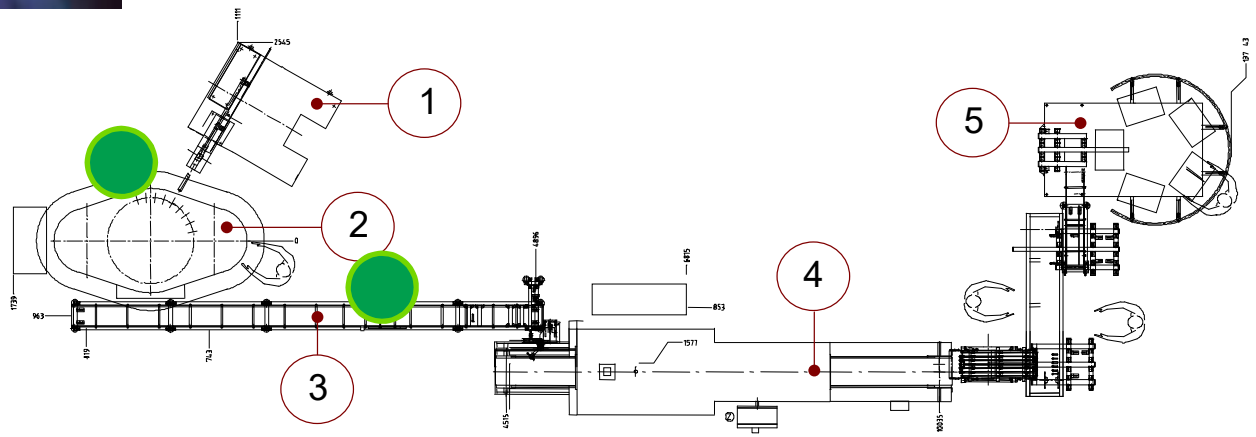


Details for each single parameter

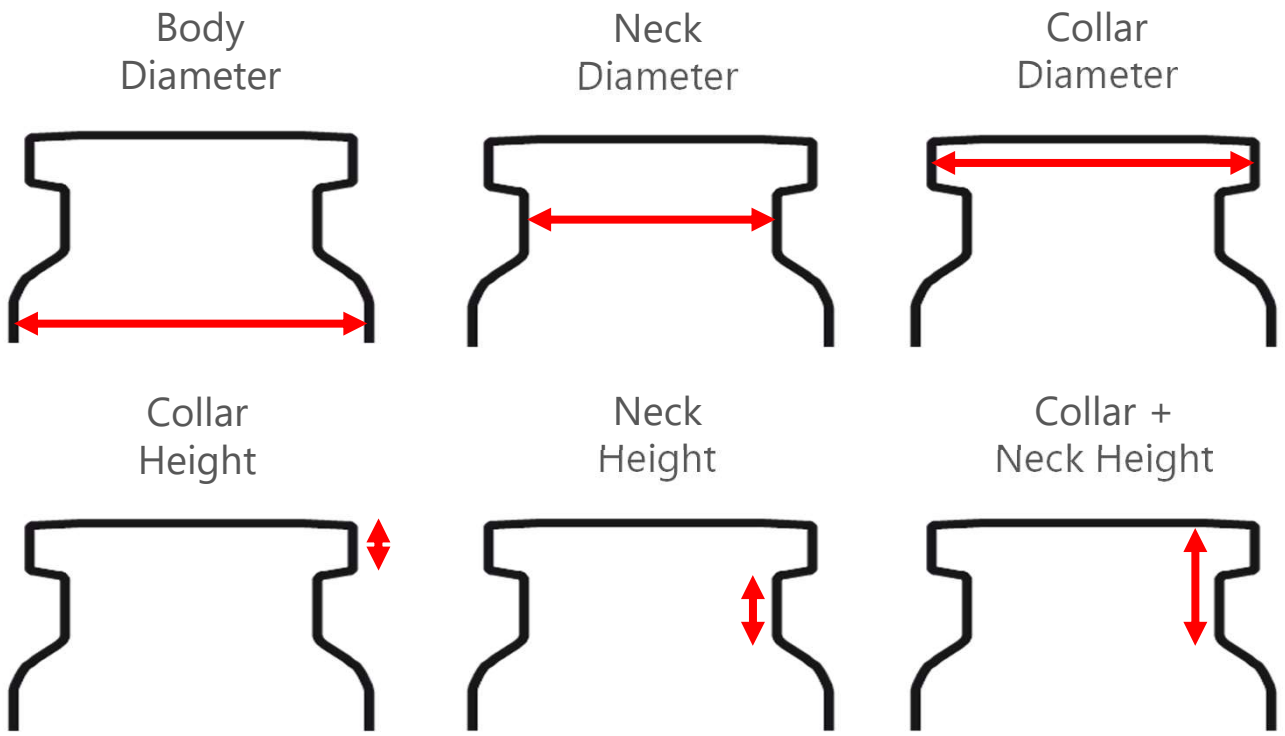
Dimensional inspection: vials



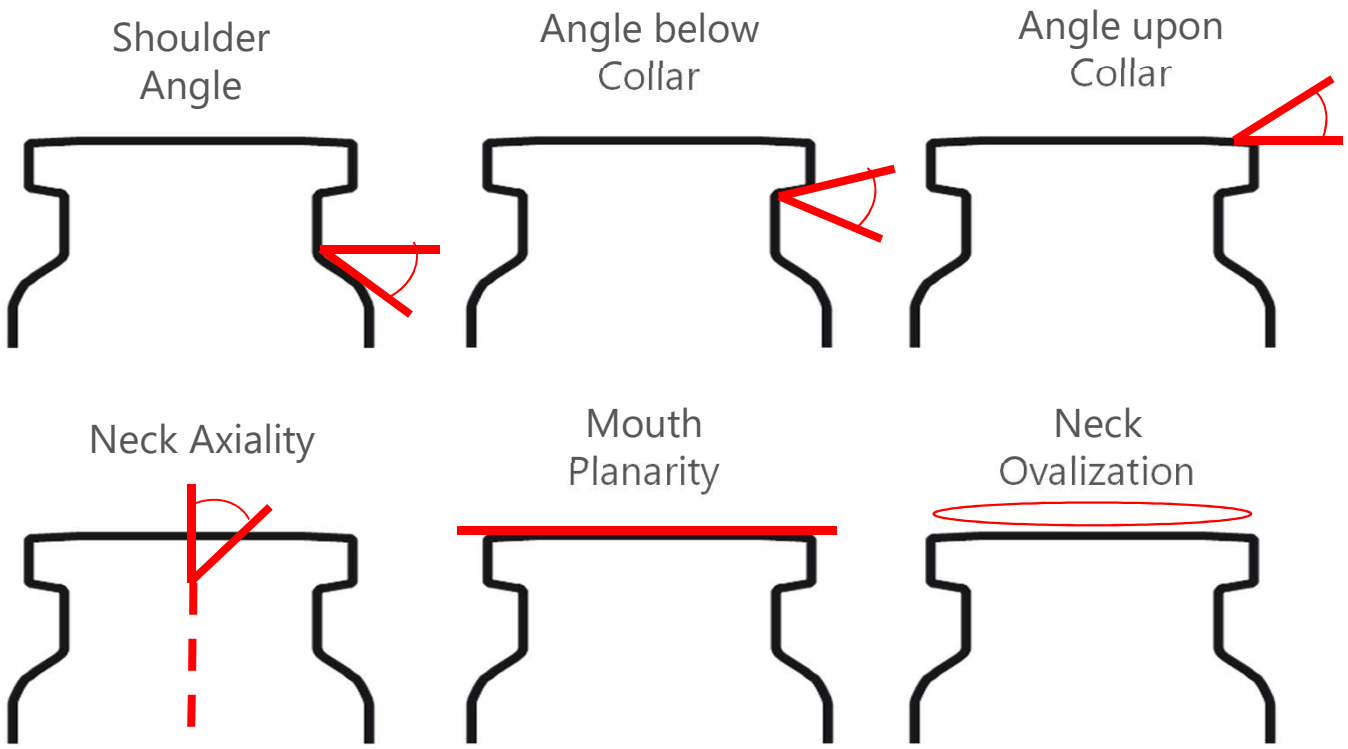
- 1-2 cameras for the **neck profile area** (installed on the forming machine)
- 1-2 cameras for the **internal diameter of the bottom area** (installed on the afterforming line)



Inspection Controls on the Neck Profile (1 of 2)

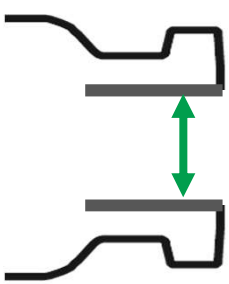


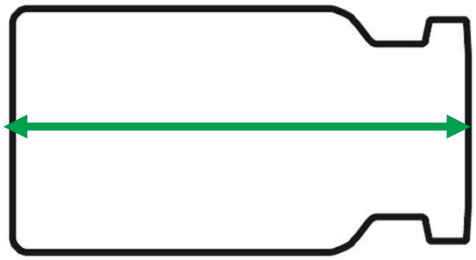
Inspection Controls on the Neck Profile (2 of 2)

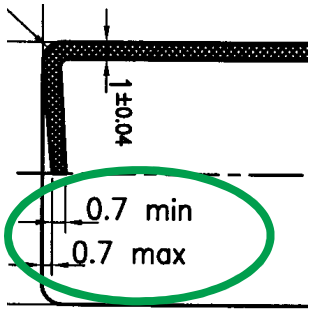


Internal controls

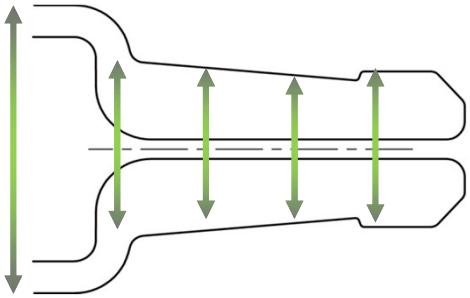
A dedicated **camera** measures the **internal diameter of the neck**, while an **electro-mechanical gauge** measures the total **length** and the **bottom concavity**

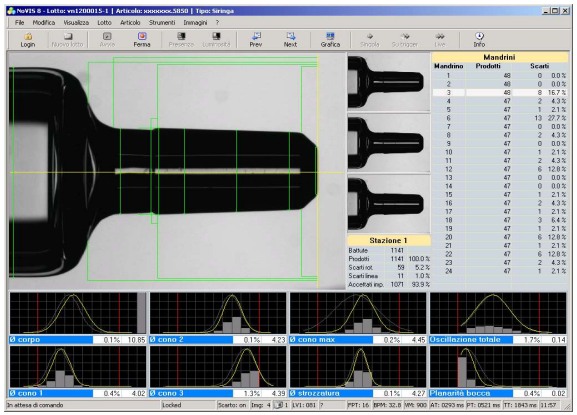




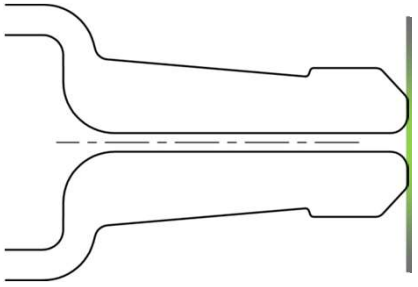


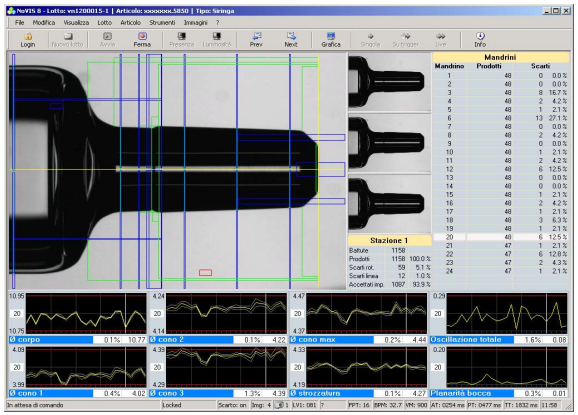
Syringes: cone inspection (1 of 3)





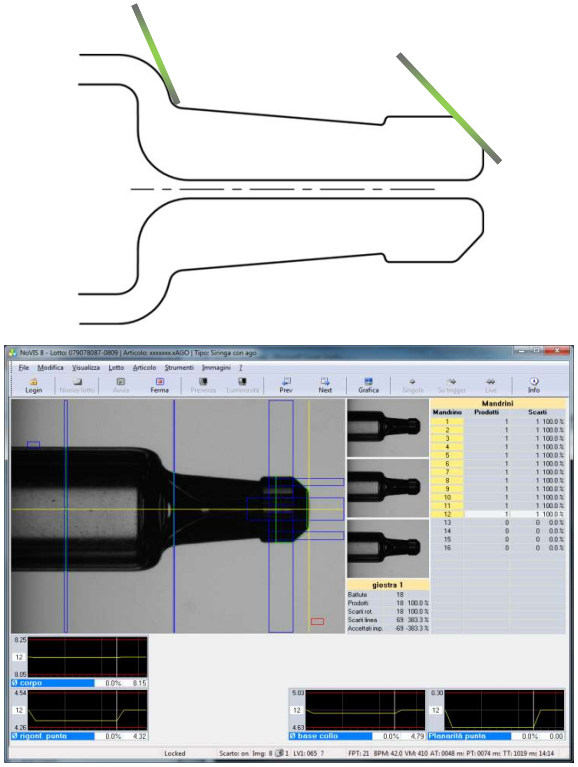
Cone/Body Diameters



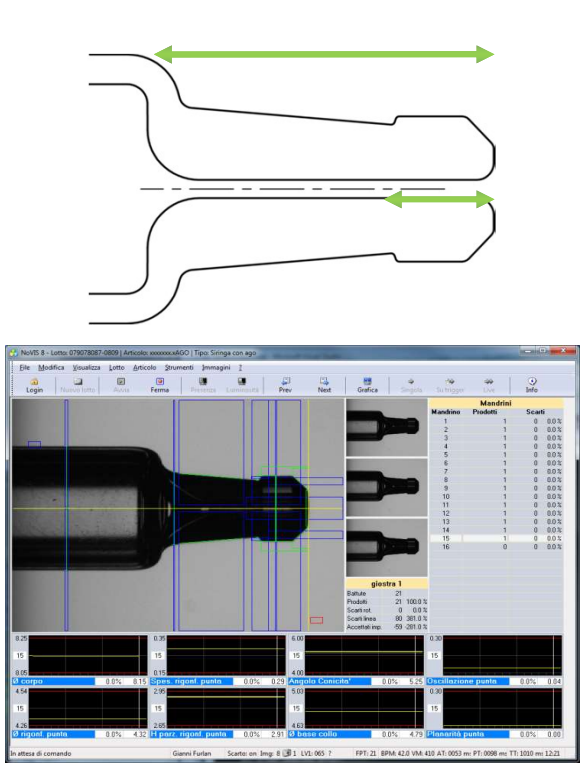


Cone Planarity/Perpendicolarity

Syringes: cone inspection (2 of 3)

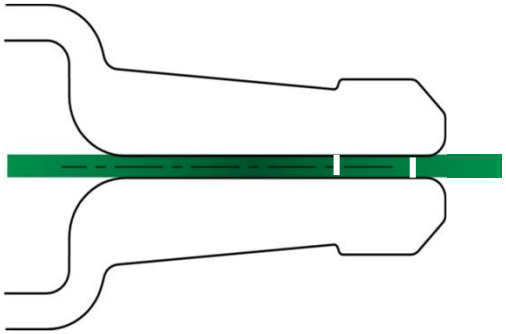


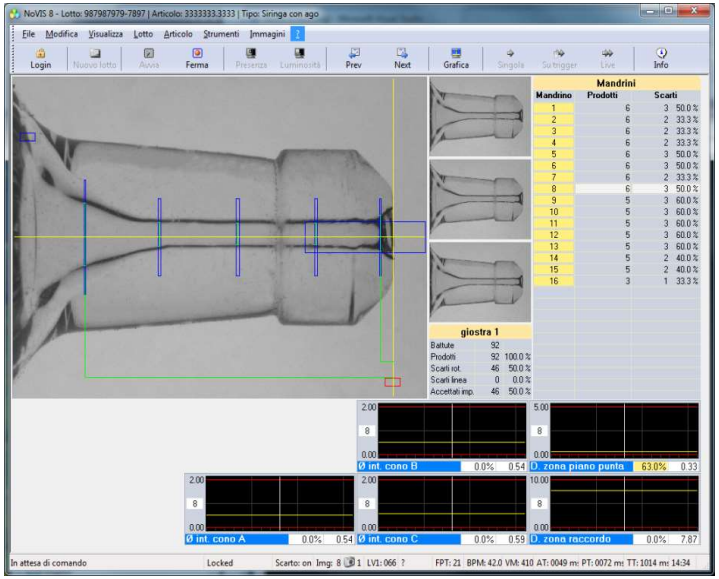
Cone/Shoulder Angles



Cone Heights

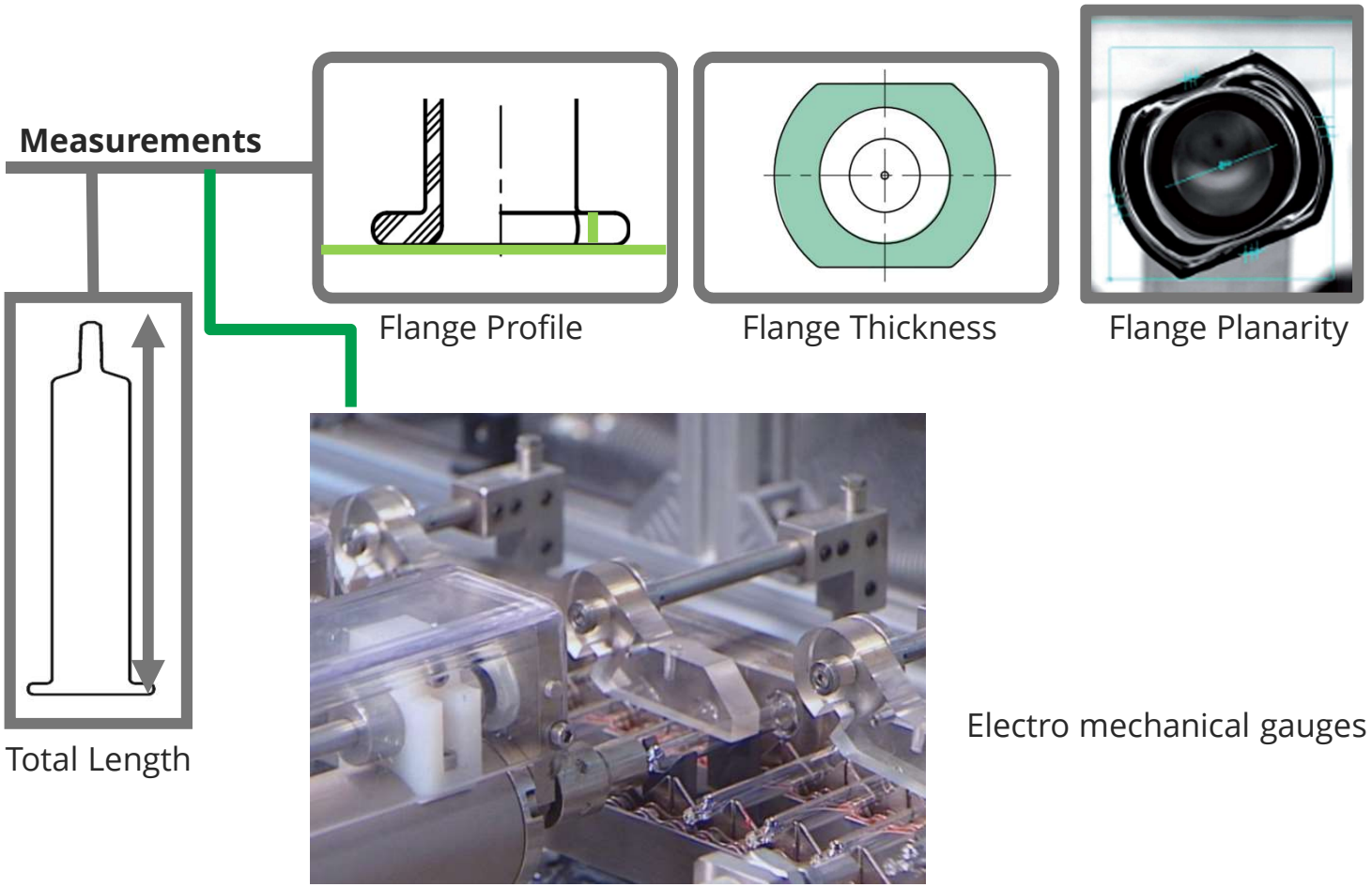
Syringes: cone inspection (3 of 3)





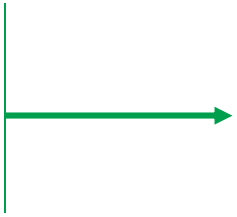
Measurements – Cone Inner Diameter

Flange and dimensional inspection



Inspection technology

Inspection Technology



Dimensional Inspection

Cosmetic Inspection

Inspection Technology

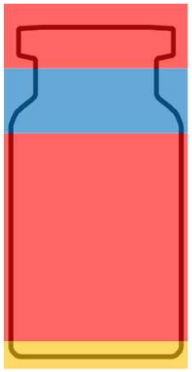
Dimensional Inspection

Cosmetic Inspection

Cosmetic inspection: in-line and off-line solutions

1-8 cameras for the inspection of:

- Body and collar area
- Neck area
- Bottom area
- Shoulder area



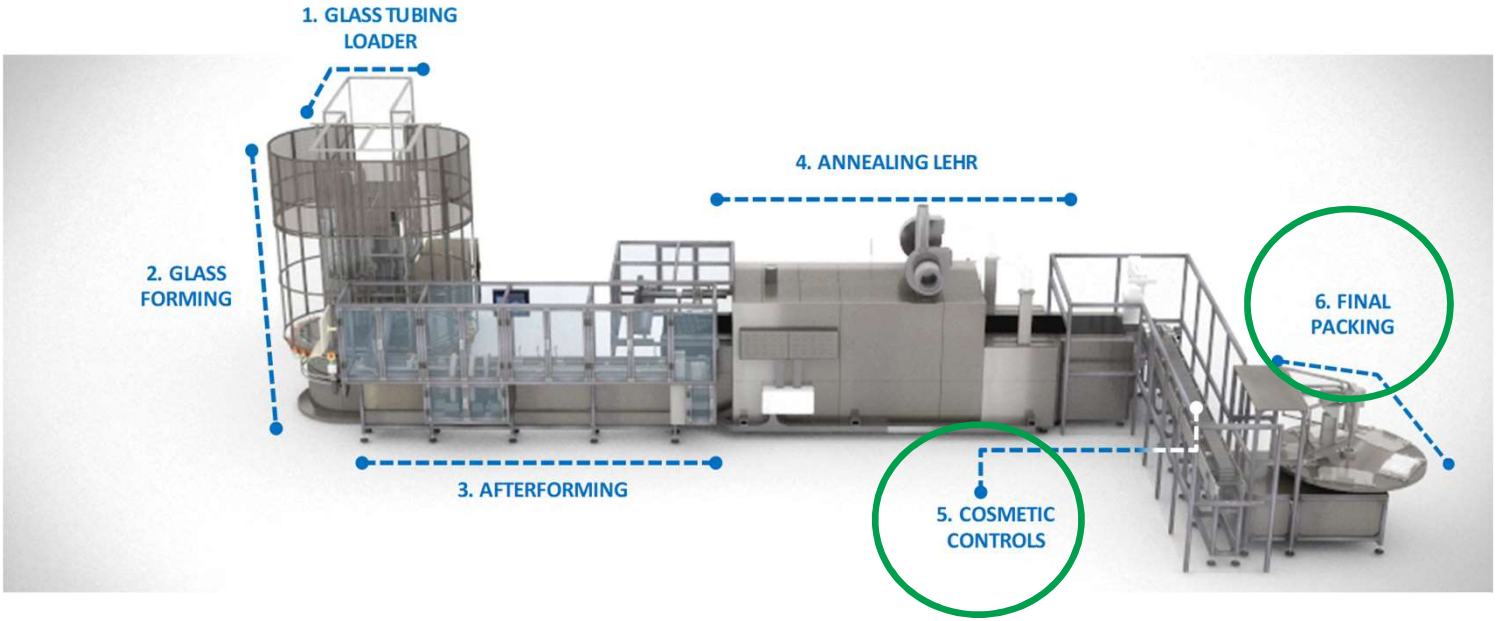
Areas of cosmetic inspection

There are two possible alternatives: in-line or off-the-line inspection systems

In-line inspection System

Off-line inspection machine

In-line cosmetic inspection



The cameras for the cosmetic inspection are installed on a line between the oven and the packing machine.
The **packing machine** and the **cosmetic inspection system** are **usually** installed inside a **clean room**.

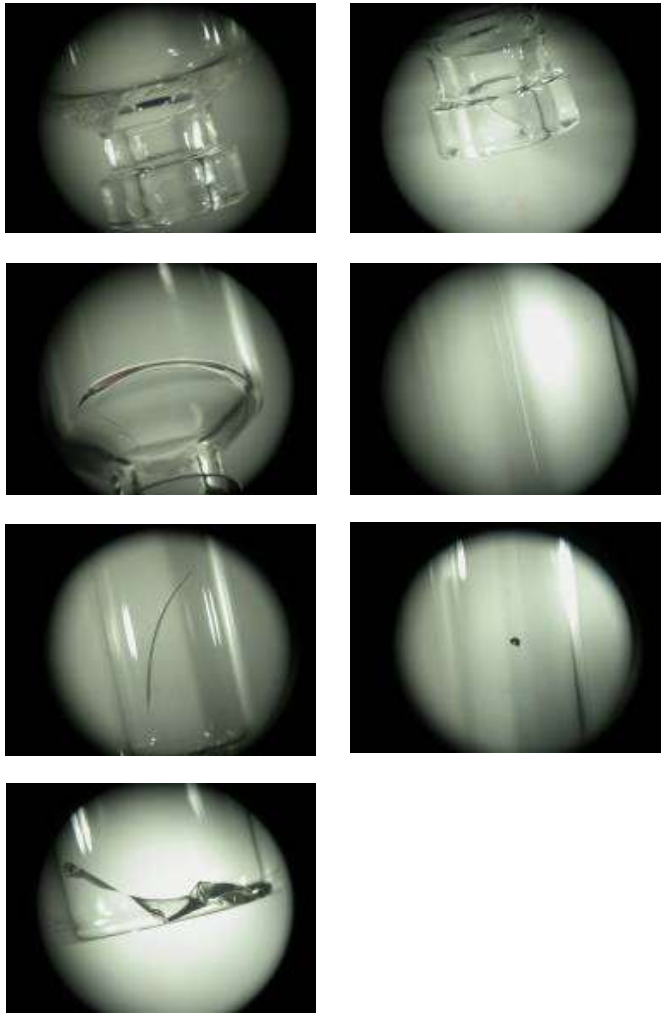
Examples of defects detectable by the system

In-line cosmetic inspection

The in-line system permits to **detect black spots with sizes starting from 0.3x0.3mm**

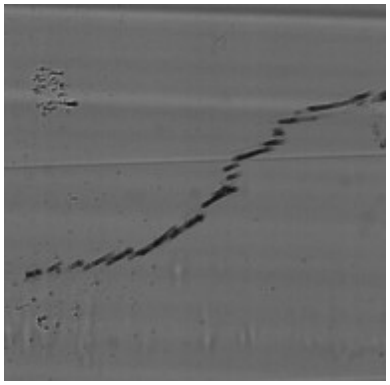
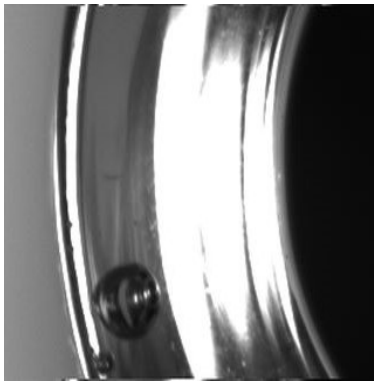
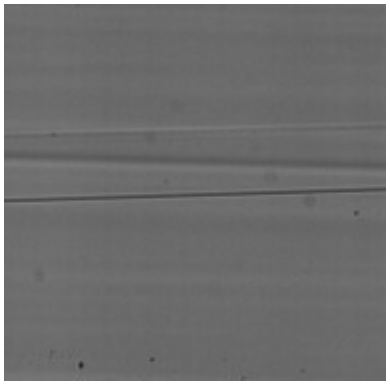
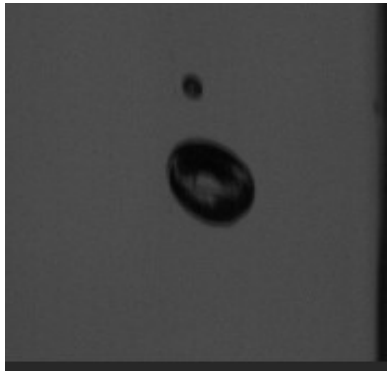
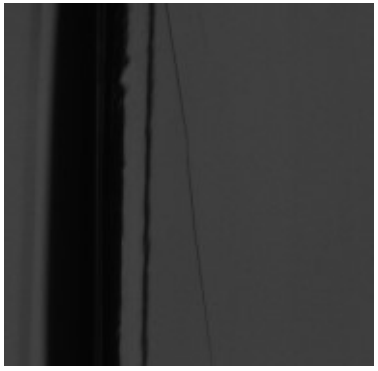
Surfaces that have been formed or with irregular thickness introduce a **level of noise** that is seen by the system as the presence of defects. This phenomenon is known as **false rejection** and it is the reason why the camera cannot be set with the minimum detectable limits for all the areas.

Improvements of the **lighting conditions** and increase of **camera resolution** contrast the false rejection allowing the progressive reduction of the rejection limits.

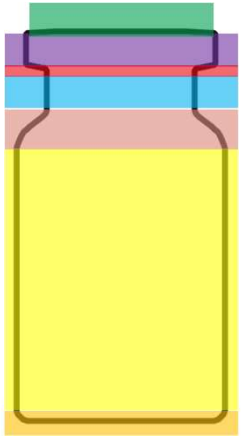


High resolution

Use of high resolution cameras in order to detect critical defects shapes

Cosmetic inspection

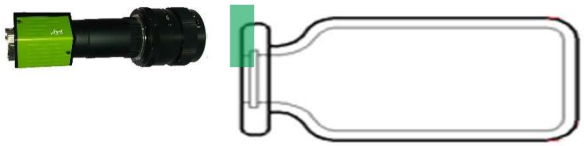


Areas of cosmetic inspection

1-8 cameras for the inspection of:

- Sealing surface area
- Collar area
- Lower Collar area
- Neck area
- Shoulder area
- Body area
- Bottom area

Sealing surface

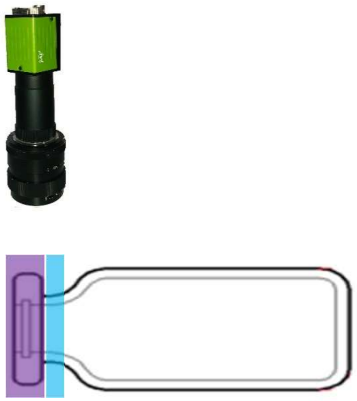


PARAMETER	FEATURES
Camera	Matrix
Position	In axis with vial
Resolution	0.020 mm
Minimum defect	0.200 mm

This camera is able to find defects on the **surface of the collar**:

- black dots
- scratches
- bubbles

Collar - neck

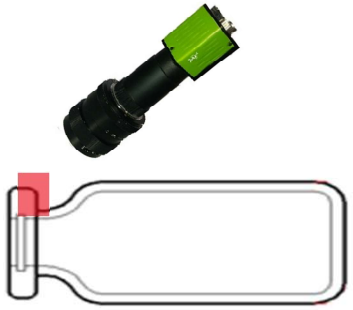


PARAMETER	FEATURES
Camera	Linear
Position	Perpendicular to the vial
Resolution	0.030 mm
Minimum defect	0.200 mm

This camera is able to find defects on the **collar and neck**:

- black dots
- folds
- scratches
- bubbles

Lower collar area

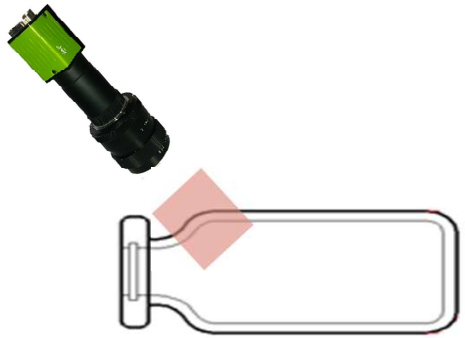


PARAMETER	FEATURES
Camera	Matrix
Position	Tilted about 12°
Resolution	0.030 mm
Minimum defect	0.100 mm

This camera is able to find defects on the **surface of the collar**:

- black dots
- bubbles

Shoulder

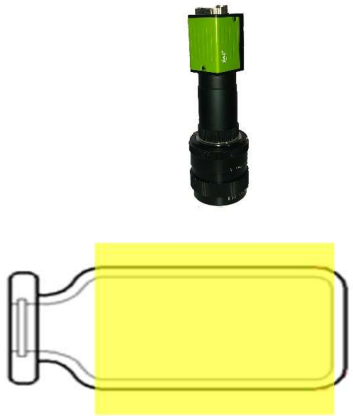


PARAMETER	FEATURES
Camera	Linear
Position	Tilted about 34°
Resolution	0.030 mm
Minimum defect	0.300 mm

This camera is able to find defects on the surface of the **shoulder**:

- black dots
- folds
- scratches
- bubbles

Body



PARAMETER	FEATURES
Camera	Linear
Position	Perpendicular to the vial
Resolution	0.030 mm
Minimum defect	0.300 mm

This camera is able to find defects on the surface of the **body**:

- black dots
- scratches
- folds
- airlines
- bubbles

Bottom rotation

PARAMETER	FEATURES
Camera	Matrix
Position	Tilted about 12°
Resolution	0.030 mm
Minimum defect	0.300 mm

This camera is able to find defect on the surface of the **bottom** and in the area close to the **body and bottom radius**:

- black dots
- scratches
- bubbles

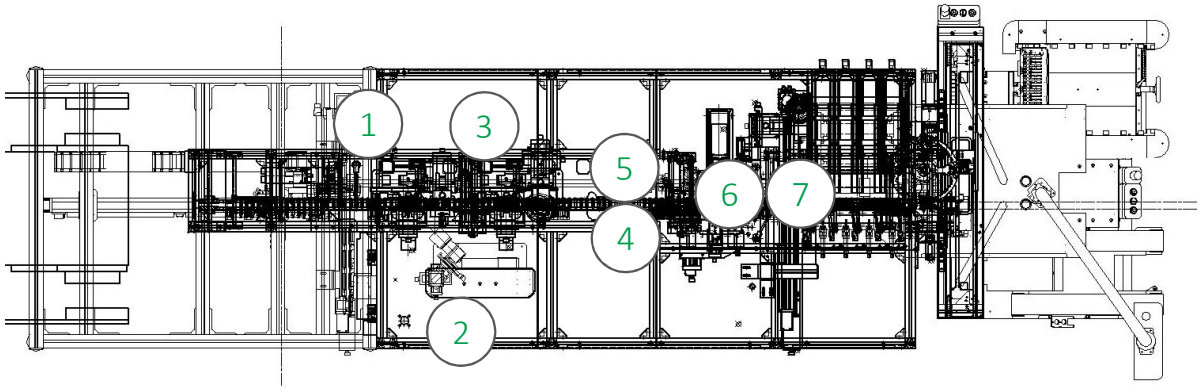
Bottom static

PARAMETER	FEATURES
Camera	Matrix
Position	In axis with vial
Resolution	0.030 mm
Minimum defect	0.300 mm

This camera is able to find defects on the surface of the **bottom**:

- black dots
- scratches
- bubbles

Syringes cosmetic inspection



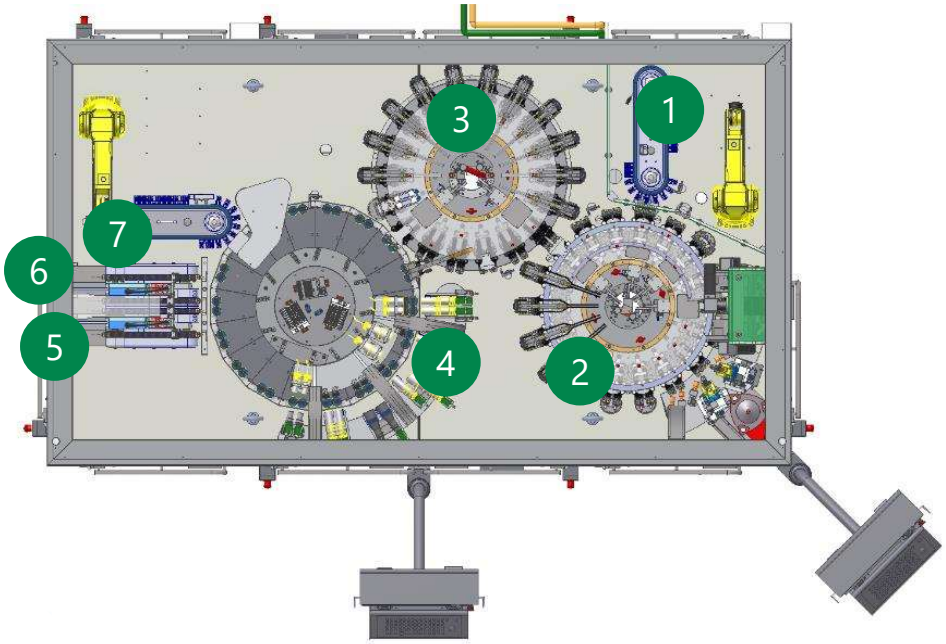
Pos.	Description	Pos.	Description
1	Cone cosmetic inspection	5	Internal Cone Inpsection
2	Shoulder cosmetic inspection	6	Flange shape Inpsection
3	Body cosmetic inspection	7	Flange surface Inpsection
4	Flange cosmetic Inpsection Radius body/flange inspection		

Syringes cosmetic inspection

The system detects any type of cosmetic defects, such as:

- Cracks
- Scratches
- Inclusions
- Air lines
- Dirty points
- Knots
- Chips
- Etc.

NAM HS – Needle assembling machine: configuaration



1. Inlet clip belt\dual belt
2. Needle assembling and pre-curing device
3. Curing area
4. Inspection area
5. Reject station
6. Selected reject station
7. Outlet clip belt\dual belt

NAM HS – Needle assembling machine: inspection list

Total lenght

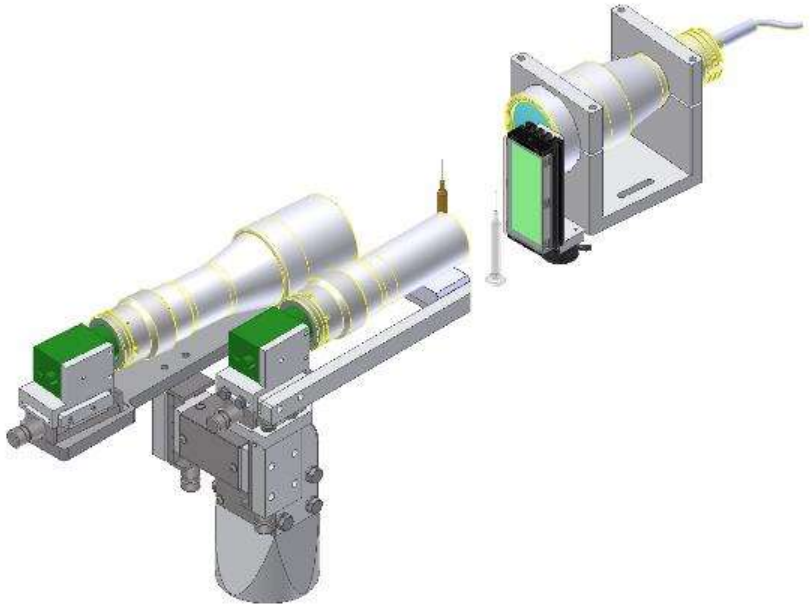
1. Chipping needle test
2. Straightness
3. Precision glue dispensing
4. Cupola glue geometry
5. Cosmetic body test
6. Deep glue test
7. Glue dispenser monitoring by inspection

All rotation test

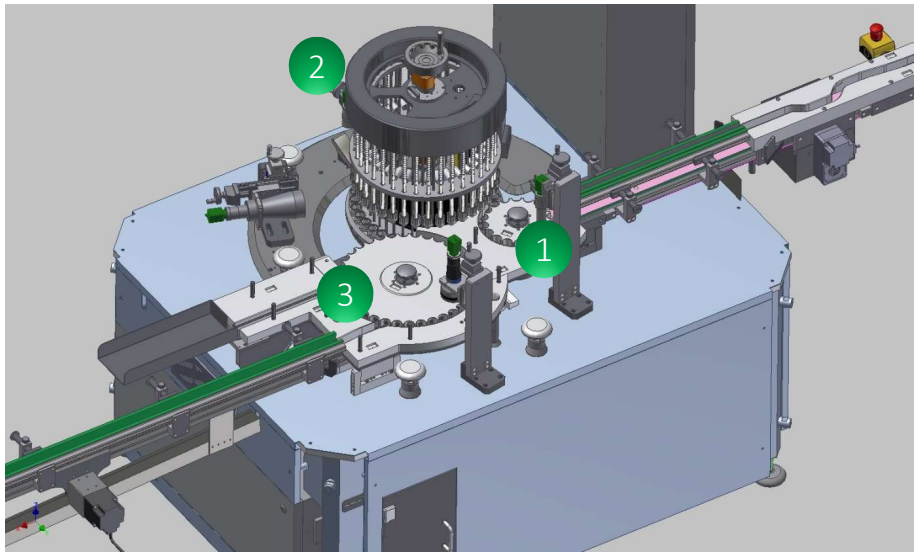
- Different rotation speed on demand
- 80% of the syringes free for analysis
- No metal contact on gripper
- Two reject station; one for generic reject and one for request reject
- Flow test

NAM HS - Needle assembling machine straightness and precision glue dispensing

Example



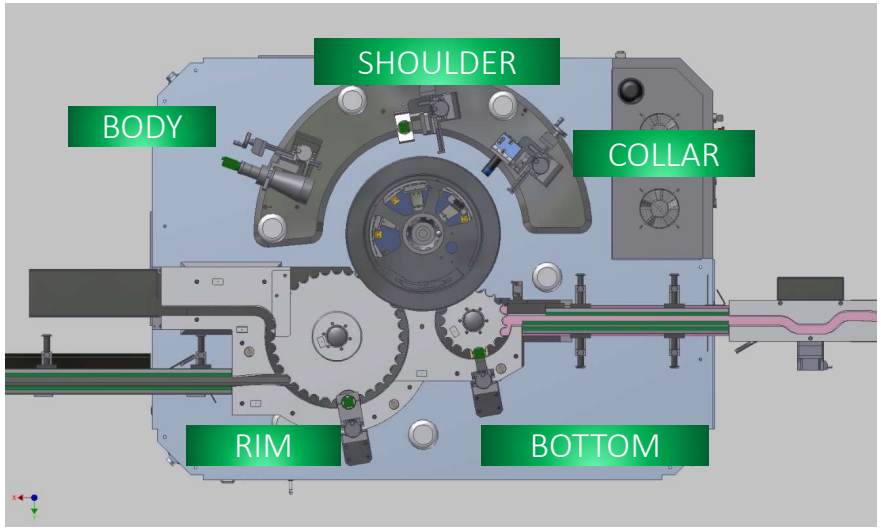
Off-line cosmetic inspection



Three inspection areas:

1. Star wheel 1
2. Main turret
3. Start wheel 2

Off-line cosmetic inspection



Station 1:

- BOTTOM inspection

Station 2:

- COLLAR inspection
- SHOULDER inspection
- BODY inspection

Station 3:

- RIM inspection

NOTE: In addition it is possible to equip the machine with the Printing inspection camera

Converting technology: tailor made solutions

A successful case history

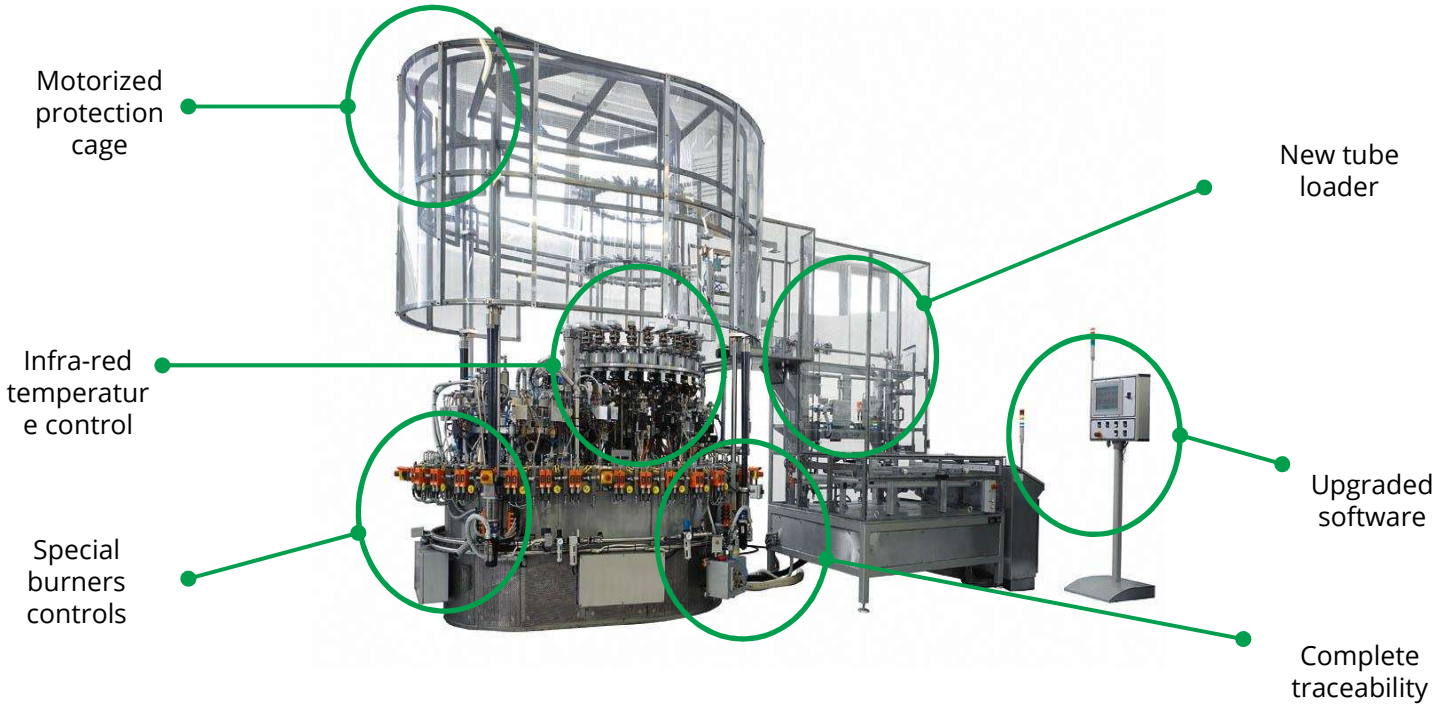
In 2005 a Japanese pharmaceutical company decided to produce internally prefilled syringes

The scope of the project was the construction of a machine to be put in line with a Gröninger washing/siliconization line, so compatible with the pharmaceutical Environment

Converting technology: tailor made solutions

- The task consisted in the introduction in the machine of many GMP concepts and customer's specific requirements in connection with the Japanese mentality.
- A specific requirement was moreover the strong elevation of the automation rate, since the company had no experience on glass working.

Converting technology: tailor made solutions



Converting technology: tailor made solutions

Thanks to the equipment supplied by *Spami*, in 2007 the company received the prestigious award of "*Best Facility of the Year*" (ISPE, Interphex) being the "pharmaceutical manufacturing facilities in the world that demonstrate global leadership by introducing cutting edge, innovative technology".

Converting technology: tailor made solutions

Spami has prepared a tailor made solution, which represents nowadays the most advanced production line for vials worldwide.

Several innovations introduced in this development, have been applied to other machines, contributing in this way to the general improvement of our technology.

Besides the many improvements on the forming and annealing process, the major innovations consist of:

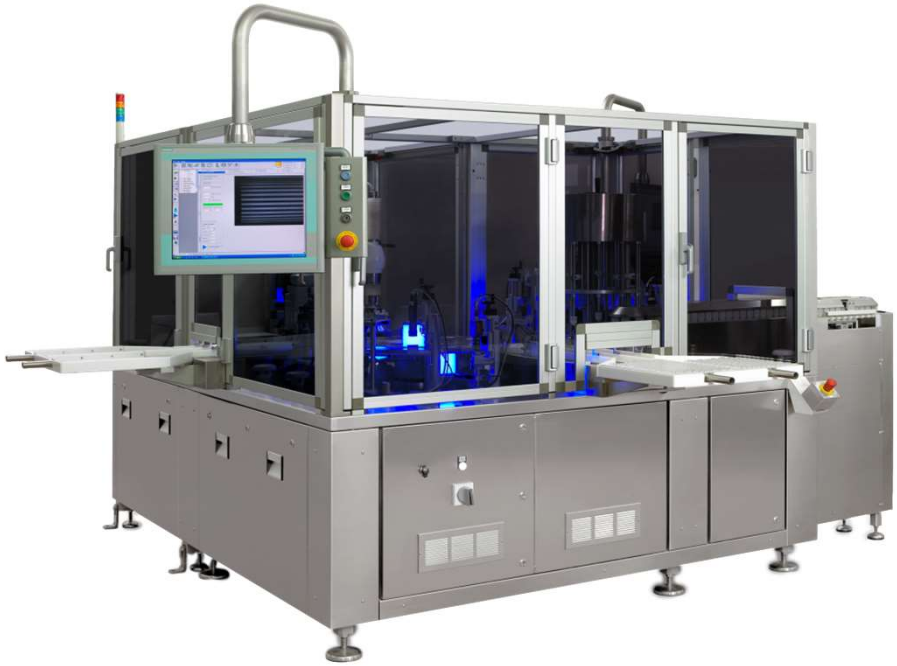
- **a glass tubing double washing machine**
- **an advanced cosmetic inspection system**

Converting technology: tailor made solutions

Advanced cosmetic inspection

Originally the final customer's specification foresaw a very accurate manual cosmetic inspection with specifically trained operators: 30" of control on each single vial.

SPAMI has developed a specific machine able to achieve the same accuracy of inspection, without the generation of high false rejection.



Thank You

For further infortmation please visit
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