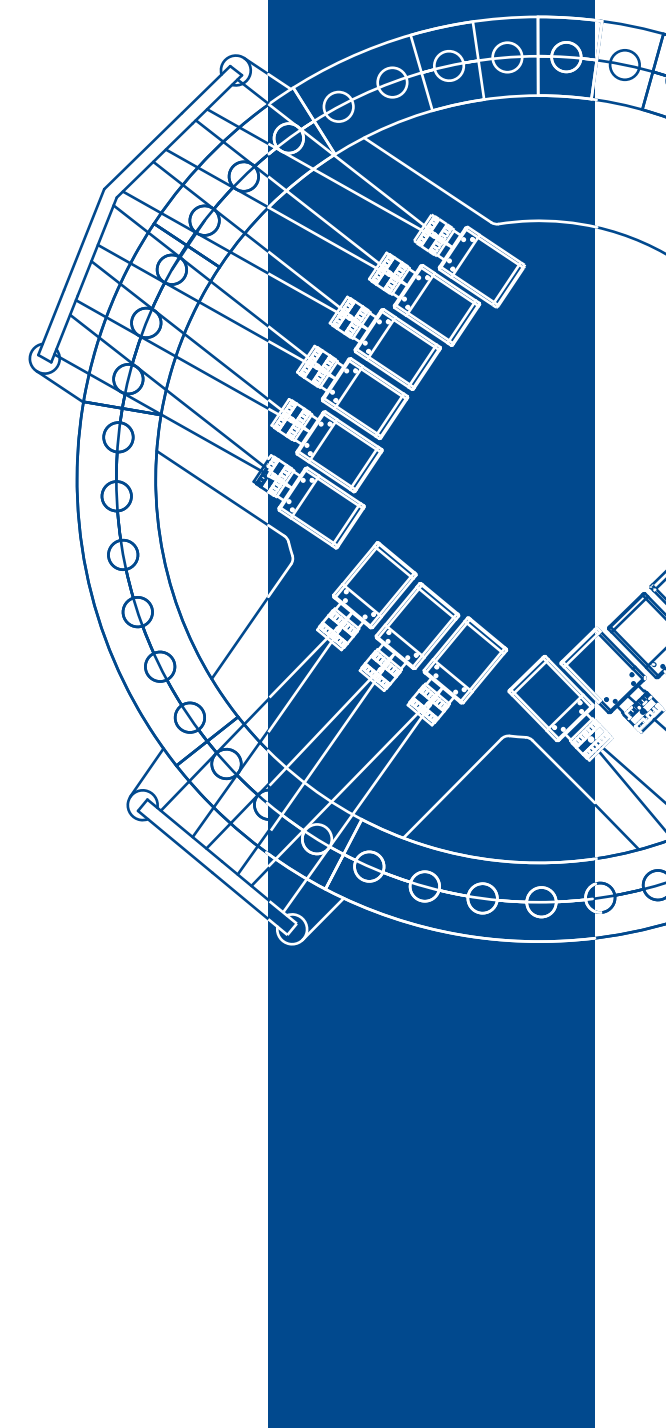


VISUAL INSPECTOR						LEAK TEST				MONOBLOC	
MODEL	ARGO PRIME		ARGO		ANGKOR	ICON		EVO			
PITCH	60	85	60	85	110	60	SVP - Small Volume	LVP - Large Volume	60	110	
FEATURES											
MAX SPEED [pcs/hour]	up to 4000	up to 3000	up to 24000	up to 18000	up to 12000	up to 18000	up to 18000	up to 12000	up to 18000	up to 12000	
MAX SPEED [pcs/min]	up to 66.6	up to 50	up to 400	up to 300	up to 200	up to 300	up to 300	up to 200	up to 300	up to 200	
MOTION	Intermittent		Continuous			Continuous		Continuous		Continuous	
NUMBER OF GRIPPERS	up to 14	up to 14	up to 48	up to 39	up to 28	up to 39	-	-	up to 39	up to 28	
NUMBER OF CHAMBERS	-	-	-	-	-	-	from 20 to 30	from 20 to 30	from 20 to 30	from 20 to 30	
CONTAINERS											
TYPE	Ampoules		Ampoules		Vials	Pre-filled syringes	Ampoules		Vials		
	Vials		Vials		Bottles		Vials		Bottles		
SIZE [mm]	Cartridges		Cartridges				Cartridges		Cartridges		
	A=10.75±36 B=47±67	A=10.75±67 B=47±132.5	A=10.75±36 B=47±67	A=10.75±67 B=47±132.5	A=46±98 B=76±223	6,85±17 in diameter	A=10.75±36 B=47±67	A=46±98 B=76±223	A=10.75±36 B=47±67	A=46±98 B=76±223	
VOLUME [ml]	1÷30	1÷250	1÷30	1÷250	50÷1000	1÷10	1÷30	50÷1000	1÷30	50÷1000	
MATERIAL	Glass		Glass			Glass	Glass		Glass		
	Plastic		Plastic			Plastic	Plastic		Plastic		
CONTENT	Liquid (solution, suspension, emulsion, oil based product)		Liquid (solution, suspension, emulsion, oil based product)			Liquid (solution, suspension)	Liquid (solution, suspension, emulsion, oil based product)		Liquid (solution, suspension, emulsion, oil based product)		
	Powder		Powder				Powder		Powder		
	Lyophilized		Lyophilized				Lyophilized		Lyophilized		
FUNCTIONS											
INFEED	Tray		Tray		Inline	De-nester unit	Tray	Inline	Tray	Inline	
	or inline (vials only)		or inline (vials only)			or inline	Inline (vials only)		Inline (vial only)		
CONFORMING OUTFEED	Tray		Tray		Inline	Re-nester unit	Tray	Inline	Tray	Inline	
	or inline (vials only)		or inline (vials only)			or inline	Inline (vials only)		Inline (vials only)		
REJECTS OUTFEED	Tray		Tray		Tray	Basket	Tray	Tray	Tray	Tray	
	or conveyor (vial only)		or conveyor (vials only)		or conveyor	or coveyor	Conveyor (vials only)	Conveyor	Conveyor(vials only)	Conveyor	
REJECT SYSTEM	Pneumatic		Pneumatic	Pneumatic	Pneumatic	Suction	Pneumatic	Pneumatic	Pneumatic	Pneumatic	
			or suction	or suction	or suction		or suction	or suction	or suction	or suction	
INSPECTION AND CONTROL											
NUMBER OF CAMERAS	1+1	1+1	2+2 ÷ 4+4	2+2 ÷ 3+3	1+1 ÷ 2+2	1+1 ÷ 3+3	-	-	1+1 ÷ 3+3	1+1 ÷ 3+3	
INSPECTION CHARACTERISTICS	Double independent station fitted each with two different illumination systems for proper detection of reflective and opaque particles		Double independent station fitted each with two different illumination systems for proper detection of reflective and opaque particles				Non-destructive integrity check with vacuum decay		Double independent station fitted each with two different illumination systems for proper detection of reflective and opaque particles + Non-destructive integrity check with vacuum decay		
STANDARD INSPECTIONS	Double particle and level		Double particle and level				Vacuum leak detection		Double particle and level		
OPTIONAL INSPECTIONS	Cosmetic (sidewall surface)		Cosmetic (sidewall surface)			Plunger	Cap/tip integrity Flip-off integrity and color		Cosmetic (vial surface)		
	Cap/tip integrity and quality		Cap/tip integrity and quality			Still particles on the plunger			Cap/tip integrity		
	Bottom (particles and surface)		Bottom (particles and surface)						Bottom (particles and surface)		
	Flip-off integrity and color		Flip-off integrity and color			Needle cover inspection			Flip-off integrity and color		
	Floating particles		Floating particles			Flange inspection			Floating particles		
	Powder/lyophilized inspection		Powder/lyophilized inspection			Glass defects			Powder/lyophilized inspection		
	Powder/lyophilized bottom inspection		Powder/lyophilized bottom inspection			Liquid between ribs			Powder/lyophilized bottom inspection		
					Hanger presence and integrity				Hanger presence and integrity		
OTHER OPTIONS											
LABELLING application & verification	•	•	•	•	•	-	•	•	•	•	
CODE application & verification	•	•	•	•	•	-	•	•	•	•	
RINSING	•	•	•	•	•	-	•	•	•	•	
BLOWING	•	•	•	•	•	-	•	•	•	•	
OTHER FEATURES											
DIMENSIONS L x D	1800x2000	2000x2000	Tbd	Tbd	Tbd	Tbd	Tbd	Tbd	Tbd	Tbd	
HEIGHT H	2500		2500			2500	2500		2500		
CONSTRUCTION	Stainless steel		Stainless steel			Stainless steel	Stainless steel		Stainless steel		
PLC	Siemens										
FUNCTIONS	Customized user access with password, Setting of control parameters and tolerances, Compatible with 21 CFR part 11 19" touch screen, Industrial PC (Windows OS)										
QUALITY AND VALIDATION	User requirements specifications review, Validation plan, Risk analysis, Functional design specification, Software design specification, Hardware design specification IQ/OQ protocol, FAT protocol, SAT protocol, Support to customer SOPs upgrade, Validation report										
SAFETY AND ALARMS	Alarms for safety guard opening, minimum load, failed rejection. Coloured warning lights and buzzers										
POWER SUPPLY	400 V 50Hz, UPS backup for PC										



VRI VISUAL ROTATING INSPECTORS



VRI VISUAL ROTATING INSPECTORS

VRI are inline and standalone machines designed to inspect a wide range of glass or plastic medical containers for liquids (such as solutions, suspensions, emulsions and oil-based products), powder or lyophilized drugs.

Visual Rotating Inspectors are made of four product families and ten different models to cover all inspection needs:

- the Argo and Angkor models combine particle checking, filling level checking with cosmetic and functional faults detection;
- the Icon models perform vacuum leak testing to verify the integrity of containers;
- the monobloc Evo models integrate all the above functions with labelling, rinsing and drying options.

The vast set includes machines able to inspect volumes from 1 ml to 1000 ml, ranging from the inspection of Small Volume Parenterals (vials, ampoules, cartridges, syringes) to Large Volume Parenterals (such as medical bottles or Blow Fill Seal).

Intermittent motion and high-speed continuous motion rotary systems allow productions up to 24.000 containers/hour.

Several light sources and different lighting techniques (direct light and back light) enable the identification of all the defects. The high resolution of the cameras and the optics used enable tiny defects to be identified, while sophisticated analysis algorithms minimise false rejections even in conditions of maximum sensitivity. Reject verification system based on "fail-safe" principle ensures that containers recognized as defective will not reach the channel of good products.

The machines can be run by a single operator through the built-in touch-screen display, where all the controls and configuring functions are available.

FEATURES AND BENEFITS

VERSATILE MACHINES

- Wide range of inspected formats (from 1 to 1000 ml).
- Inspection of small and large volumes plastic/glass containers or pre-filled syringes.
- Liquids, powder and lyophilized products inspection.
- Gripping pressure/strength is adjusted to the appropriate value according to the bottle size, weight and kind of cap using a pneumatic regulation.
 - In case of different neck/cap, pads can be easily and quickly replaced simply pushing the release button.
- Motor rotation speed is automatically set depending on product size and in control type.

PERFORMED CONTROLS

- Particle inspection inside the product.
- Leak test with vacuum trend analysis.
- Inspection of foreign bodies over the product level.
- Filling level checking.
- Container cosmetic and functional faults detection.
 - Flip-off seal cap: color and integrity.
 - Cap and tip integrity.
 - Aluminium vial seal: crimp quality, dents or snicks.
 - Container body, neck, upper and lower part: cracks, scratches, air bubbles, stains.
 - Containers bottom and bottom edge: breaks and chippings.
 - Hanger presence and integrity verification.
- Labelling application and verification.

SMART AND EFFICIENT

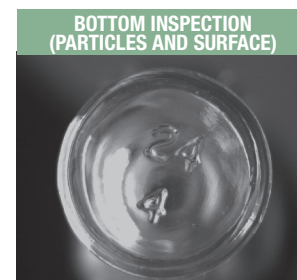
- High throughput (up to 24.000 containers/hour)
- High accuracy: detection of reflective and opaque particles inside the products up to 20 µm of dimension.
- High reliability: double independent particle inspection to provide redundancy
- Accurate cosmetic inspection with detection of defects up to 1mm x 1mm.
- Non-destructive integrity leak check with vacuum decay with an accuracy up to 20 µm.
- Automatic rejection system with various outlet channels depending on the nature of the defect.
- Latest vision technologies used to minimize number and complexity of inspection stations.
- Multiple cameras high resolution based inspection system with high speed vision capturing and processing system to increase accuracy and efficiency of the machine.
- Wizard menu for new formats or modification of current format.
- Leak test, visual inspection and labelling application/inspection in the same base.
- Quick change of container gripper pads without using tools.
- Fully automatic height adjustment of carousel by servo-assisted screw jacks to accommodate different bottle sizes.
- Easy exchangeable infeed screw starwheels and guides for rapid changeover of different product sizes.
- Carousel grip the containers from above keeping it clear for best illumination and inspection of all parts.
- Carousel supported from top for a comfortable access to mechanical and electrical equipment as well as to the vision system (cameras and illuminators) allowing an easy cleaning and a simpler maintenance.
- Advanced statistical analyses with detailed reject typology to help detecting the reject causes in the upstream production process.
- CFR 21 Audit Trail Reports can be printed on a laser printer built into the machine.

ADVANCED HMI

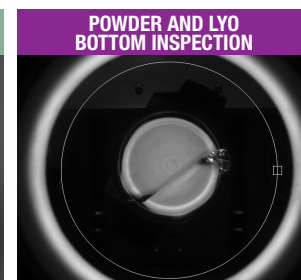
- Single touch-screen display to control all machine functions:
 - check of all cameras,
 - machine status,
 - programming of formats,
 - diagnostics.
- Industrial 19" PC Windows OS based.
- Easy and user-friendly graphic user interface.

QUALITY AND VALIDATION

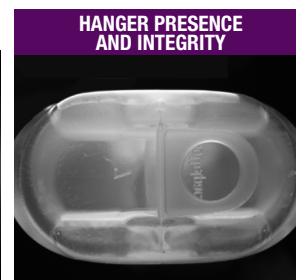
- Manages up to 5 user login levels.
- FDA 21 CFR part 11 and GMP Annex 11 compliant.
- Developed following GAMP 5 approach.
- Availability of all documentation involved in the GAMP approach.



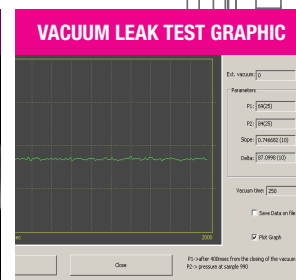
BOTTOM INSPECTION (PARTICLES AND SURFACE)



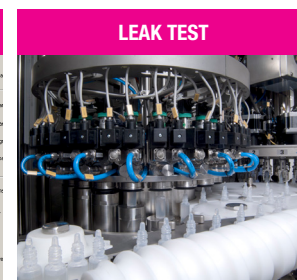
POWDER AND LYO BOTTOM INSPECTION



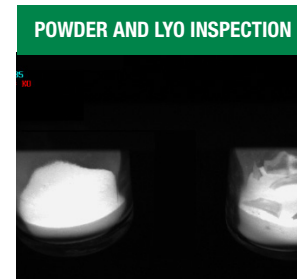
HANGER PRESENCE AND INTEGRITY



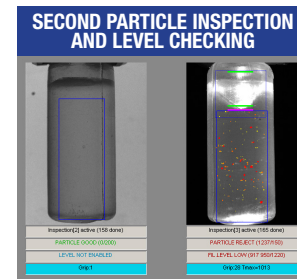
VACUUM LEAK TEST GRAPHIC



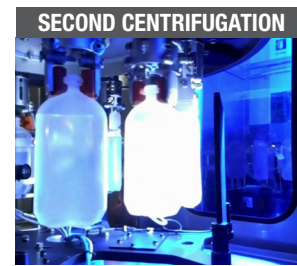
LEAK TEST



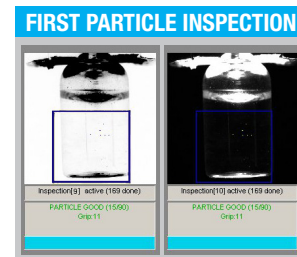
POWDER AND LYO INSPECTION



SECOND PARTICLE INSPECTION AND LEVEL CHECKING



SECOND CENTRIFUGATION



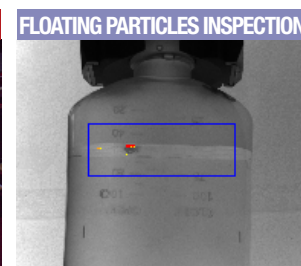
FIRST PARTICLE INSPECTION



FIRST CENTRIFUGATION



COSMETIC CONTROL



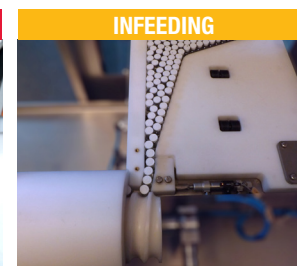
FLOATING PARTICLES INSPECTION



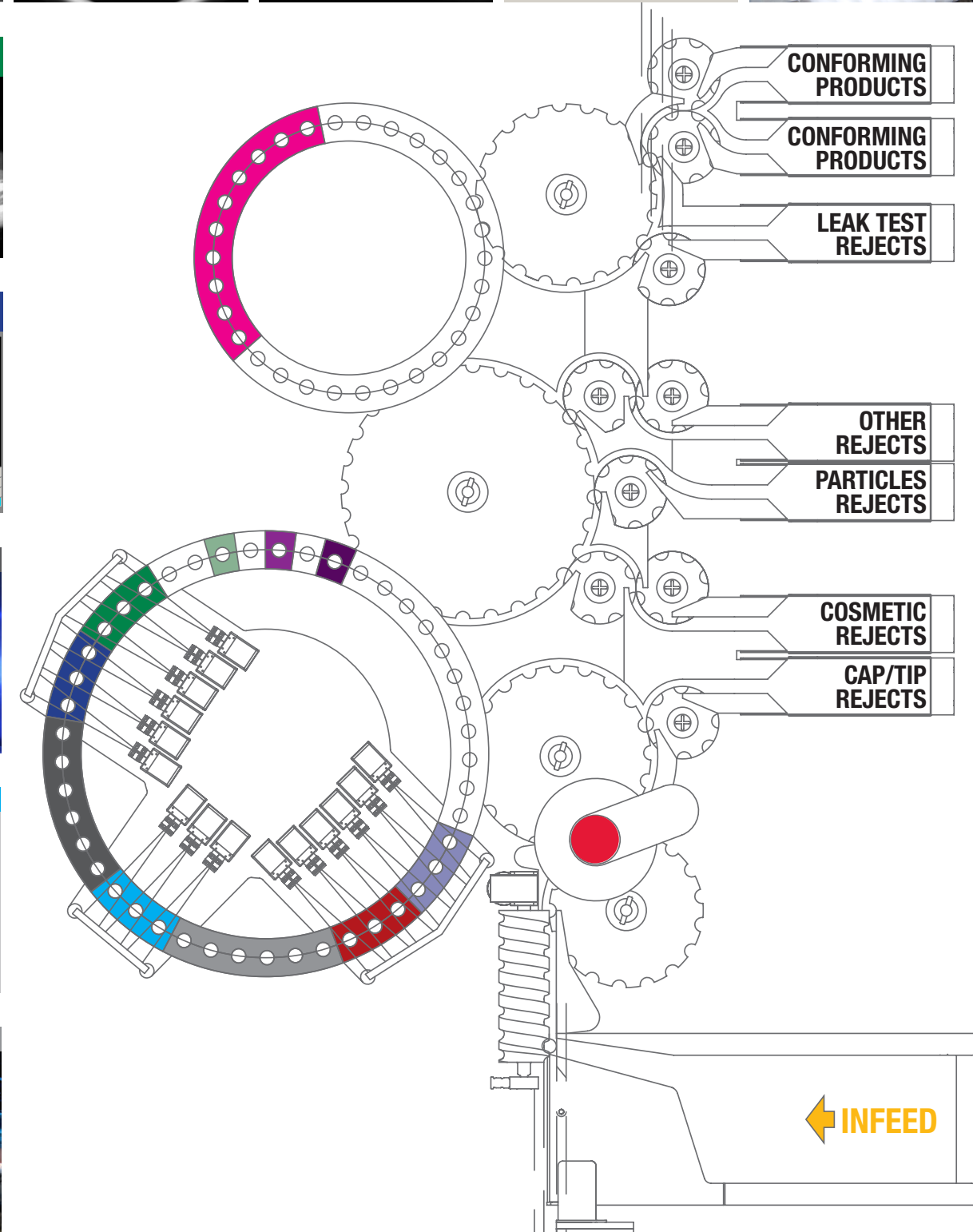
CAP INTEGRITY



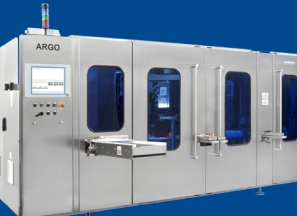
FLIP OFF COLOR



INFEEING



ARGO PRIME
for slow speed visual inspection of ampoules, vials and cartridges



ARGO
for high-speed visual inspection of ampoules, vials, cartridges, bottles



ICON
for leak test detection of ampoules, vials, cartridges, bottles



EVO
for visual inspection integrated with the leak test detection of ampoules, vials, cartridges, bottles



ANGKOR
for visual inspection of pre-filled syringes