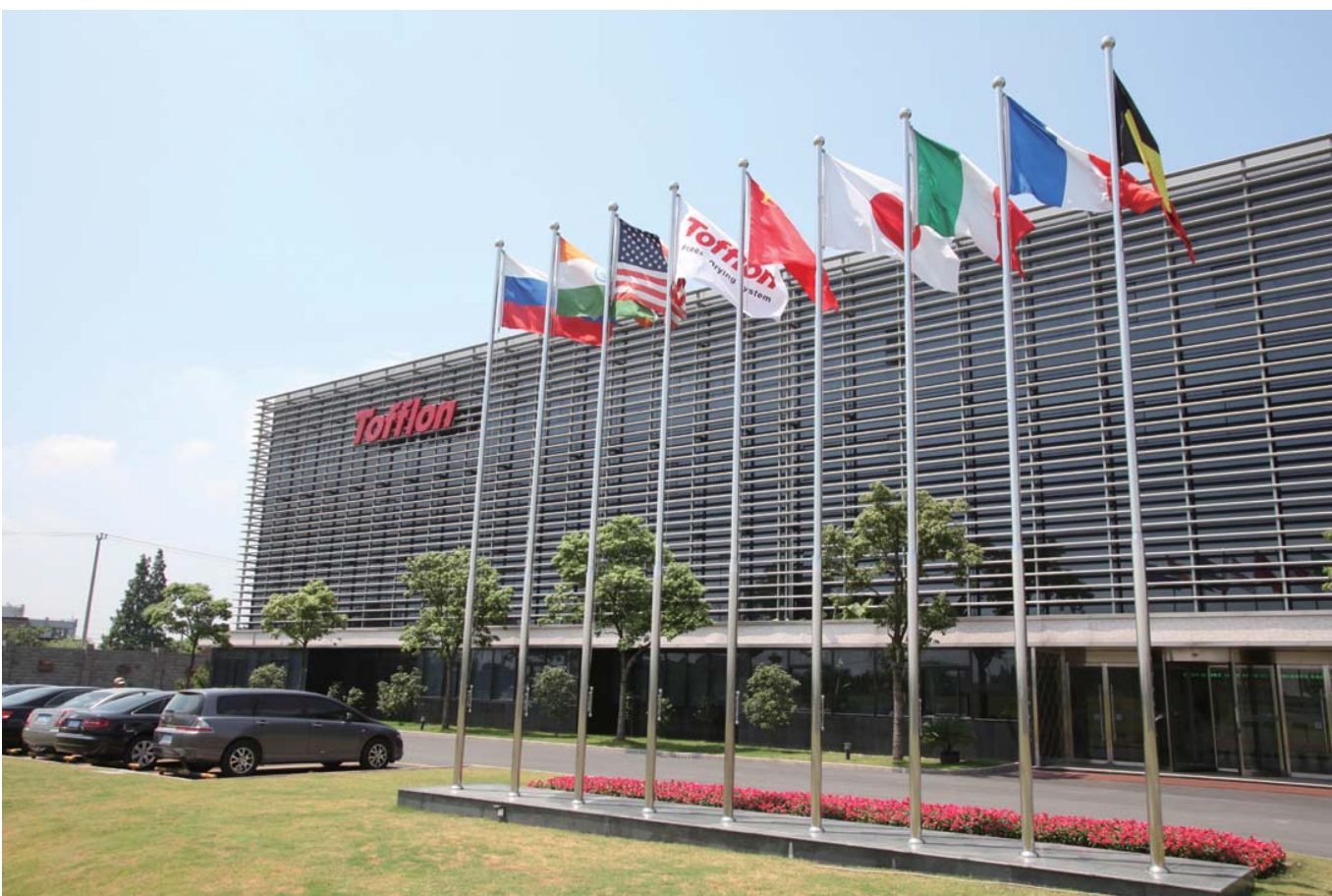


Tofflon



Aseptic Vial Filling Line

Expertise in Pharmaceutical Industry



Tofflon

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Tofflon Aseptic Vial Filling Line

We believe that “Automation, Isolation, Continuous Processing and Systems Integration” are becoming main stream for aseptic processing of sterile injectables. Thanks to the above concept and European technical source, Tofflon develops aseptic vial filling line, incorporated with the latest design, system thinking and best practice with isolator integration to meet the increasing cGMP expectations and the latest trends in pharmaceutical and biotech industry.

Today advanced aseptic processing is growing significantly to keep operator out of the aseptic processing as far as possible. Many new technologies are developed to meet advanced aseptic processing requirements. From design concept to technology choice, Tofflon adopts the industrial latest design in filling machine, washing machine, sterilization tunnel and capping machine to minimize microbiological contamination during production for sterility assurance.

During the critical aseptic process of sterile injectables, we focus on systems thinking and practice. We study materials transfer challenges and requirements. We study filling line integration with auto solution preparation systems, freeze dryer auto loading systems, stopper and cap aseptic transfer systems and barrier systems. Through mechanical integration with upstream and downstream equipments as well as complete process automation integration, we work for uninterrupted and consistent process establishment to continuously improve drug quality and production efficiency.

Today more and more oncology products come into market. Isolator Technology is becoming well-recognized technology for the processes requiring Grade A. But meanwhile Isolator Technology brings challenges for oncological production line, for example complex materials transfer and GMP quality requirements as well as safe handling of operators. In the recent years, as the isolated filling pioneer in the emerging markets, Tofflon designs and practices many advanced oncology injectables production lines in the markets which bring reputable names – KUFill and Mini KUFill.



Our Key Features and Advantages

- Advanced Aseptic Processing Design Concept to minimize human-generated contamination in the critical process.
- Systems thinking and integration with upstream and downstream equipments so that the aseptic processing line is highly integrated, safely interlocked and reliably recorded.
- Focus on RABS or Isolator integration by design.
- Good practice in High-Speed Filling Line for Large-Scale and High-Efficiency Injectables Manufacturing.
- Advanced KUFill System for Flexible Injectables Manufacturing.
- Usage of Robotic handling for advanced aseptic processing.
- Less operator need for production, low operating cost.
- Servo Motor Control to provide a high level of automation that leads to operational accuracy as well as process reproducibility.
- Self-diagnosis and self-maintenance.
Improving In-Process Control and reduce products loss.
- Automatically generate production batch reports in compliance with GAMP5 and 21CFR PART 11.
- Critical parameters available with control, indication, record, print and backup.
- Less change parts, fast parts change and change part with tool less.



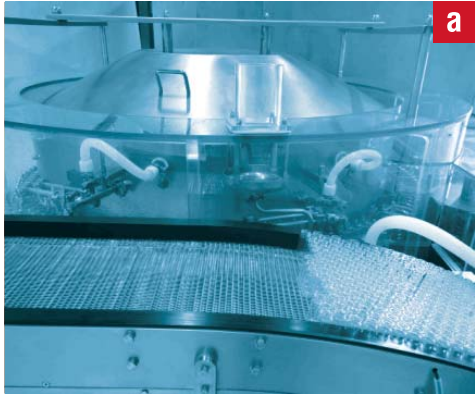
FWV Rotary Washing Machines Series

The washing machine is suitable to wash vials with automatically continuous or intermittent motion. The machine ensures the removal of at least 3 log of particulate contamination (particles such as glass, fibers, etc.). The washing cycle can include recycled water spraying, WFI spraying and compressed air blowing.

Key Features

- Intermittent or continuous motion machines are available.
- Full servo motor control.
- Ergonomic machine operation and format recipe management system.
- Flexible processing steps and capacity setting. Simple format conversion.
- Sanitary piping design: ASME BPE or ISO SMS Standard; TIG automatic orbital welding; boroscope inspection; passivation and electropolish.
- Pressure and temperature of the various media are monitored to ensure good and constant performances.





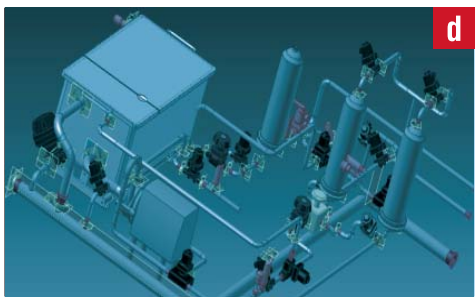
a



c



b



d



e

Options

- a. Auto lifting device for the safety hood
- b. Ultrasonic station
- c. Discharge device for the end process
- d. Automatic draining and compressed air drying
- e. Siliconization function



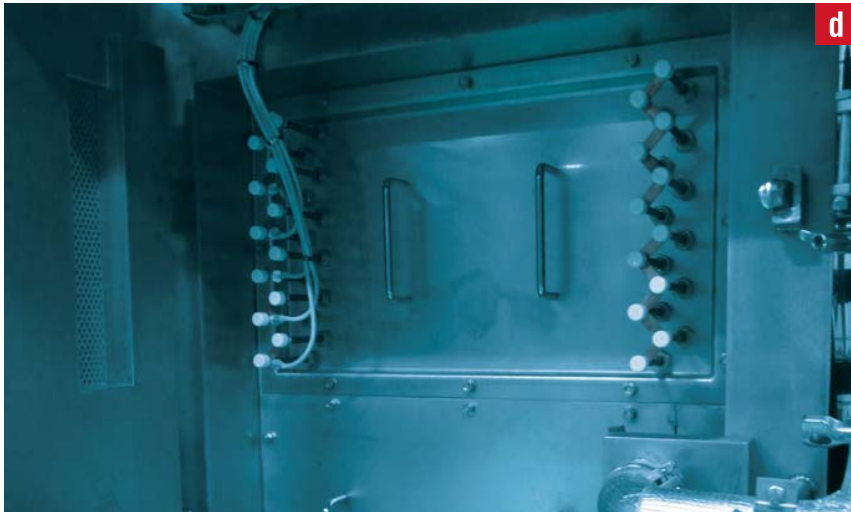
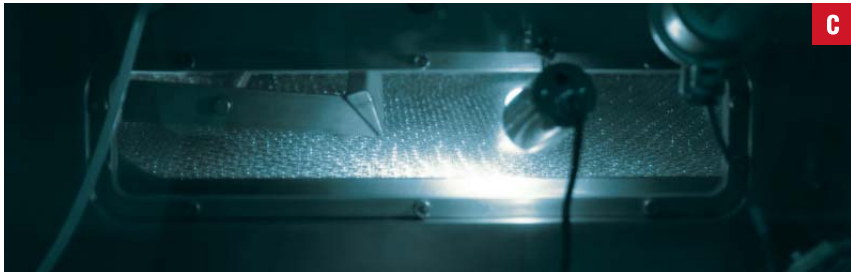
FTV Sterilization & Depyrogenation Tunnel Series

The tunnel is designed to sterilize and depyrogenise vials by a laminar flow of hot air with continuous process. Grade A is assured in all tunnel areas above the openings of the vials. Vials are transported through the preheating zone, heating zone and cooling zone by a conveyor belt made of stainless steel wire mesh.

Key Features

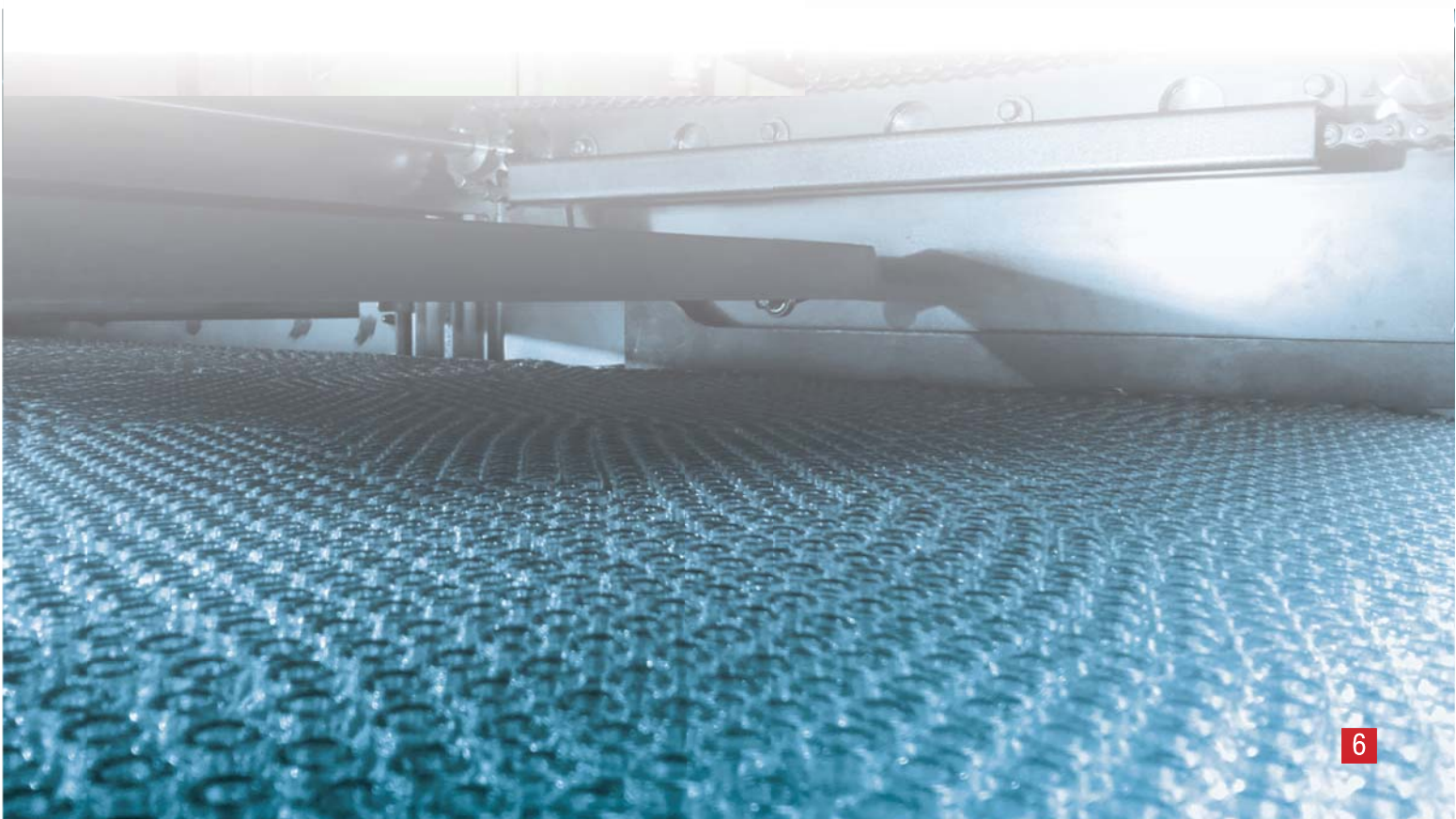
- Scientific calculation, modular design and Independent air duct design.
- Negative pressure sealing for the HEPA in the heating zone.
- Double cooling zone to prevent thermal shock.
- Flexible pressure zone concept for safe processes.
- Validation ports for filter integrity test, particle counting and air velocity.
- Power failure protection: backup power supply switch / compressed air cooling in the heating zone.
- Different working modes.
- Critical parameters of the process are continuously monitored and printed.





Options

- a. Automatic gate between different zones
- b. Automatic tight gate for cooling zone
- c. Discharge device for the end process
- d. Sterilize the cooling zone by heat



FFV Filling & Stoppering Machines Series

The filling and stoppering machine is suitable to fill sterile liquids into vials and insert stopper into vials stably. Half or full stopper insertion is available based on production requirement.

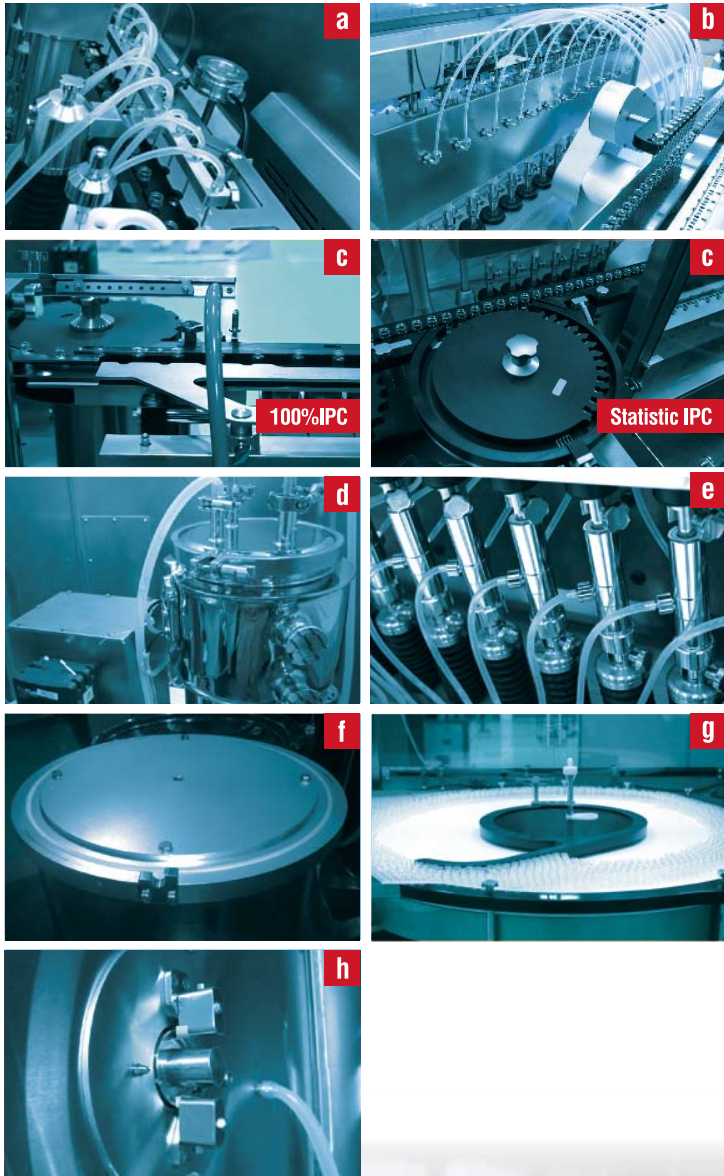
Key Features

- Through-wall Installation to physically separate processing area and maintenance area.
- Easy-to-clean surfaces in processing areas.
- Intermittent or continuous motion machines are available.
- Robot Technology.
- Advanced in-line process control.
- Suitable for RABS, cRABS or Isolator integration.



Options

- a. Flushing with an inert gas before, during and after filling
- b. On-line CIP/SIP of filling system
- c. IPC (100% or statistic In-Process Control)
- d. Buffer tank with cooling jacket and solution circulation
- e. Combo filling systems
- f. Bowl of stoppers automatically locked
- g. Environmental monitoring system
- h. RTU technology and disposable technology



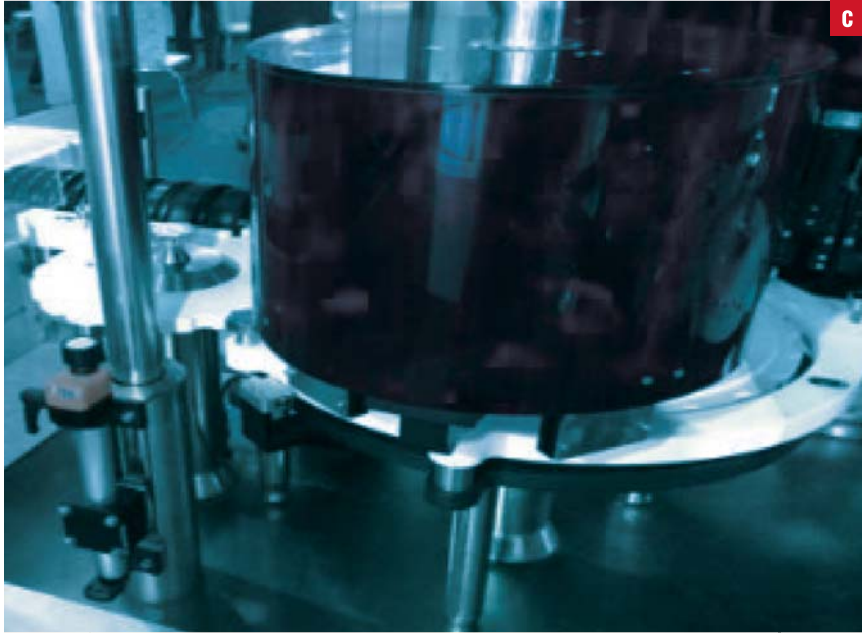
FCR Capping Machines Series

The capping machine is suitable to seal vials with Alu-caps with or without plastic cover (FLIPP OFF).

Key Features

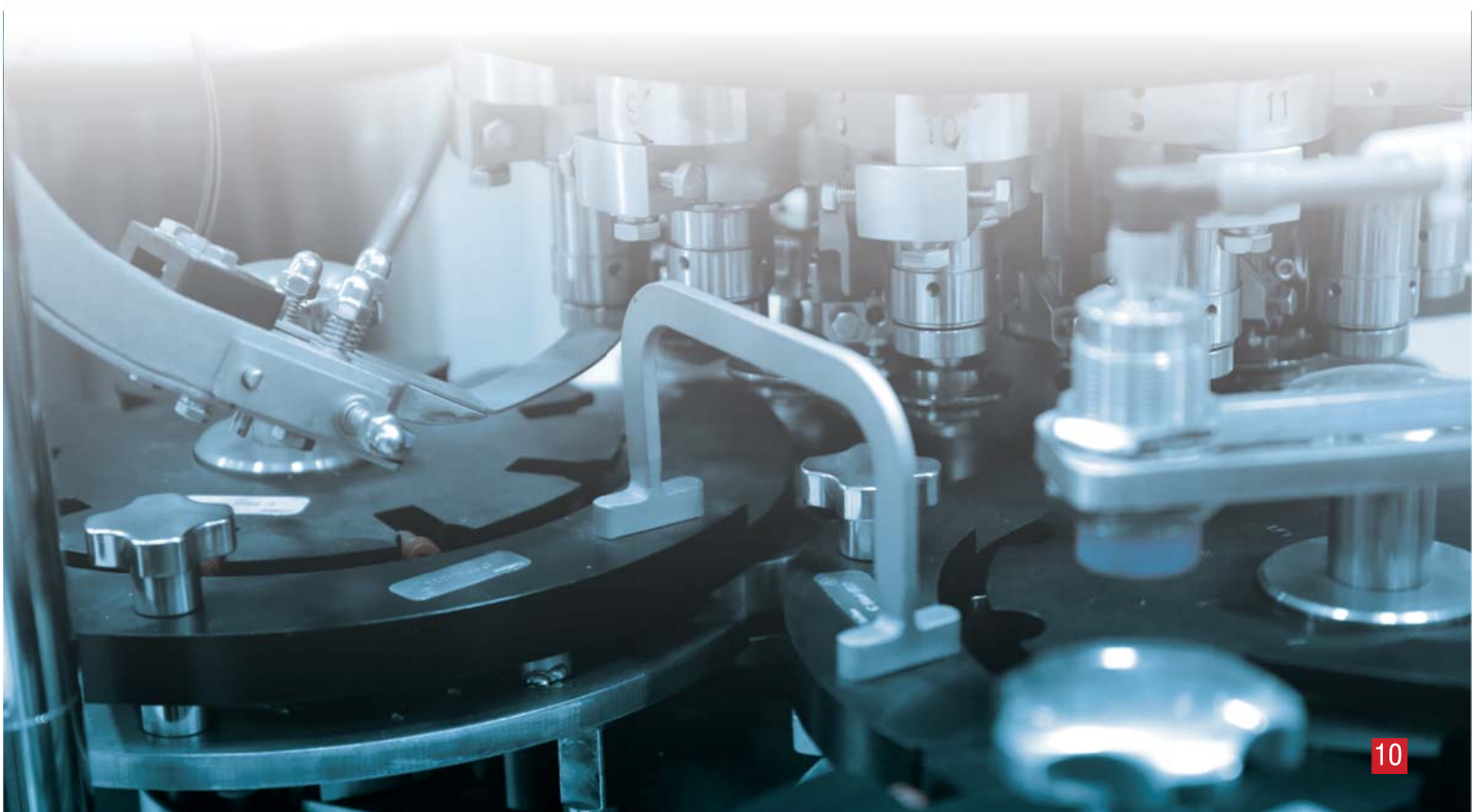
- Stoppers identification
- Automatic rejection in case of cap-absent
- Easy-to-clean surfaces in processing areas
- Intermittent or continuous motion machines are available.
- Suitable for RABS, cRABS or Isolator integration.





Options

- a. Rejection (no stopper) before capping
- b. Vacuum sucking for particles
- c. Vision checking



Technical Data

FWV Rotary Washing Machines Series

MODEL	FWV 02-10	FWV 02-20	FWV 02-30	FWV 02-40	FWV 02-50
Vial (ml)	2-100	2-50	2-30	2-20	2-20
Mechanical Output (vph)	6000	12000	18000	24000	30000
WFI Supply (m ³ /h)	0.4	0.6	0.7	0.8	0.9
Compress air Supply (L/min)	600	950	1100	1300	1500
Power Supply (kw)	7	12	12	12	12
Dimension LxWxH (mm)	2200x1400x1200	2400x2400x1500	2400x2400x1500	2600x2600x1500	2600x2600x1500
Weight (kg)	1500	2800	2800	3500	3500

FTV Sterilization & Depyrogenation Tunnel Series

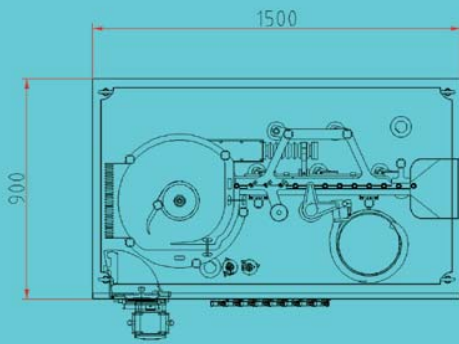
MODEL	FTV 01-10	FTV 01-20	FTV 01-30	FTV 01-40	FTV 01-50
Belt width (mm)	600	850	850	850	1000
Vial (ml)	2-100				
Mechanical Output (vph, base on 10ml vial)	6000	12000	18000	24000	30000
Cooling water (m ³ /h)	3	3	5	6	7
Power Supply (kw)	54	80	116	140	180
Dimension LxWxH (mm)	2800x2100x2500	2800x2100x2500	4400x2400x2500	5800x2400x2500	2800x2100x2500
Weight (kg)	3000	3500	4500	5500	7000

FCR Capping Machines Series

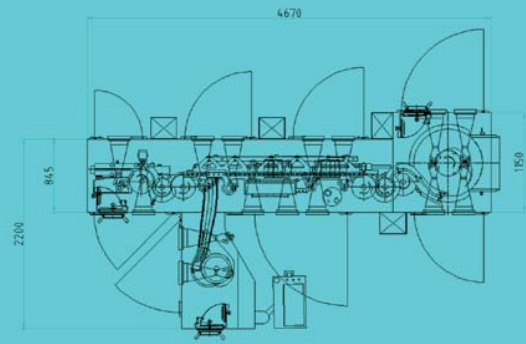
MODEL	FCVC 05/02	FCVC 10/06	FCVC 20/09	FCVC 30/09	FCVC 40/12	FCVB 50/18
Vial (ml)	2-100					
Motion	Intermittent	Continuous	Continuous	Continuous	Continuous	Continuous
Mechanical Output (vph)	3000	6000	12000	18000	24000	30000
Power Supply (kw)	6	7.5	7.5	7.5	7.5	7.5
Dimension LxWxH (mm)	1500x1000x1400	2500x900x1400	2700x1200x1400	2700x1900x1400	2700x1900x1400	3200x2600x1700
Weight (kg)	600	1000	1000	1000	1500	2000

FFV Filling & Stoppering Machines Series

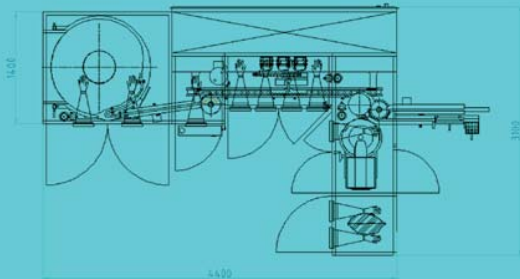
MODEL	FFVLS 05/01	FFVLP 10/01	FFVLS 20/01	FFVLS 30/01	FFVLS40/01	FFVLS 50/01
Vial (ml)	2-100					
Motion	Intermittent	Intermittent	Continuous	Continuous	Continuous	Continuous
Filling range (ml)	0.5-100					
Mechanical Output (vph)	3000	6000	12000	18000	24000	30000
Power Supply (kw)	8	9	12	12	12	12
Dimension LxWxH (mm)	1500x900x1400	4700x2200x1400	4400x3100x1400	5200x1500x1400	5200x1600x1400	5800x1600x1400
Weight (kg)	600	2800	2600	2800	2800	2800



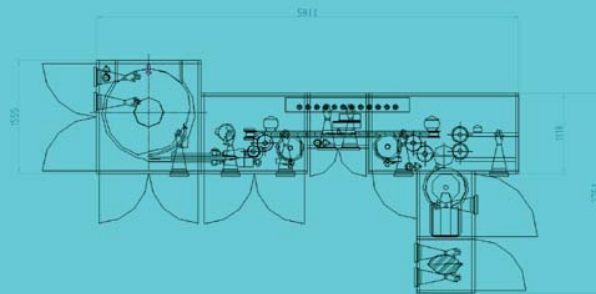
FFVLS 05/01



FFVLP 10/01



FFVLS 20/01



FFVLS 40/01