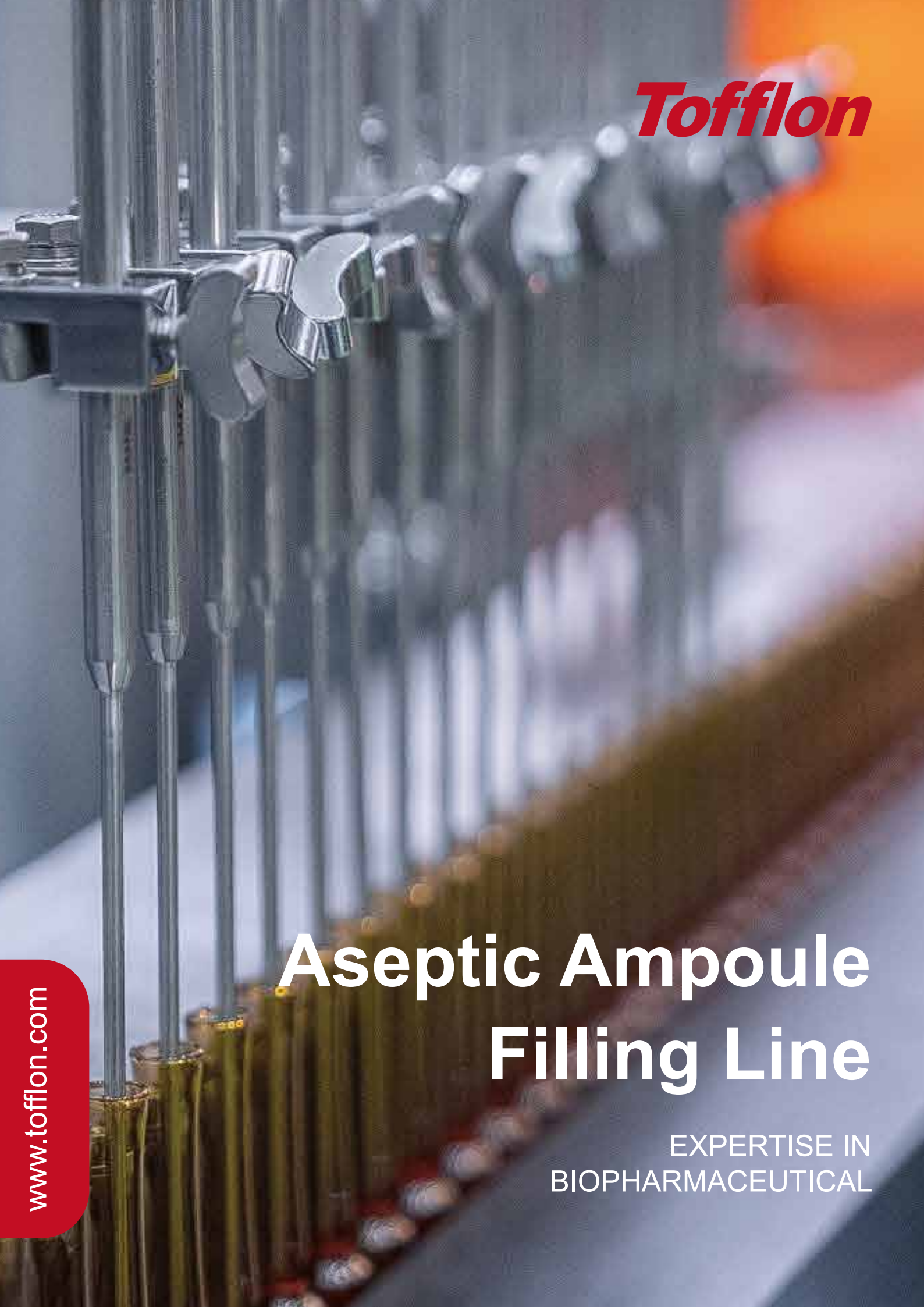

Tofflon

Aseptic Ampoule Filling Line

EXPERTISE IN
BIOPHARMACEUTICAL

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Aseptic Ampoule Filling Line

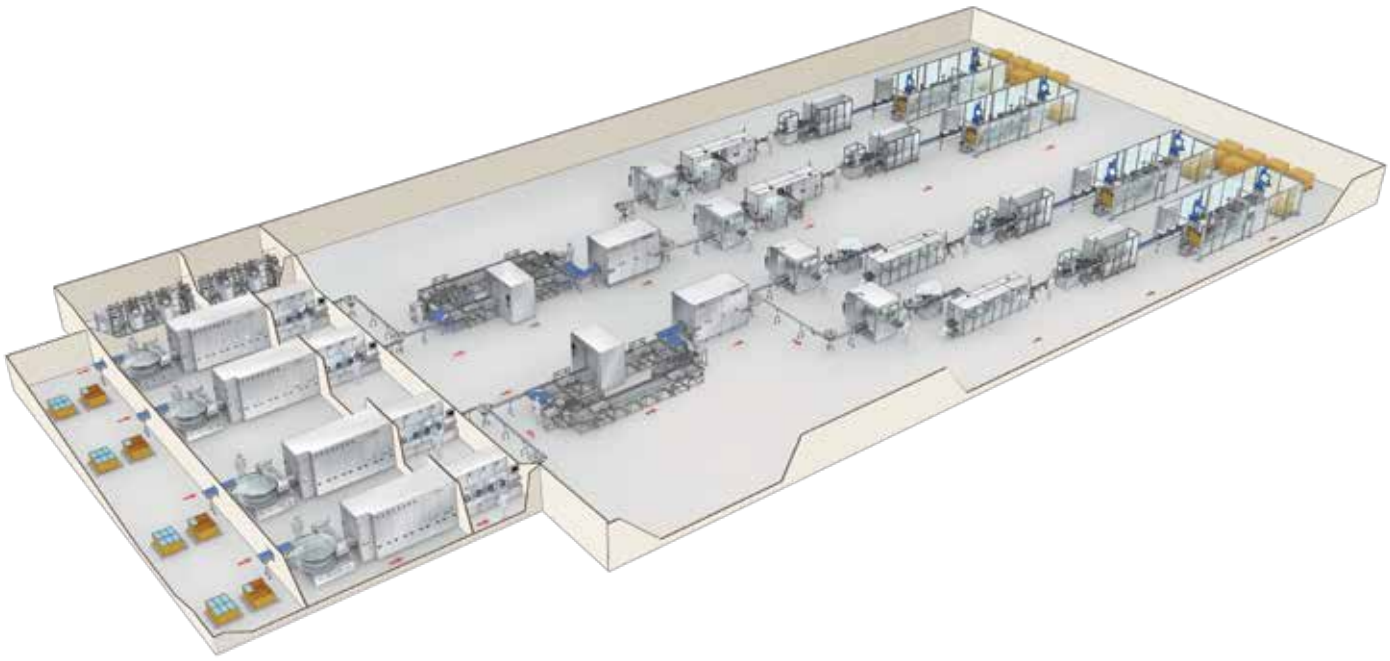
We believe that “Automation, Continuous Processing and Systems Integration” are becoming main stream for aseptic processing of sterile injectables. Thanks to the above concept and European technical source, Tofflon has developed aseptic ampoule filling line, integrated with the barrier system in order 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 advance aseptic process requirements. From conceptual design to technology selection, Tofflon adopts latest industrial design in washing machine, sterilization tunnel and filling & sealing machine, in order to minimize microbial contamination during the aseptic process.

During the critical aseptic process of sterile injectable, we focus on system automation and operator isolation. We study materials transfer requirements and challenges. We study filling line integration with auto solution preparation systems and barrier systems. Through mechanical integration and process automation of upstream and downstream machines, we have developed uninterrupted process to improve the drug quality and production efficiency. With 30 years of consistent experience “Expertise in Pharmaceutical Industry” , Tofflon has become global leading service provider of pharmaceutical equipment.

Key Features

- Advanced Aseptic Processing Design minimize the human-generated contamination in the critical process.
- Systems thinking and integration with upstream tunnel and downstream equipments so that the aseptic processing line is highly integrated, safely interlocked and reliably recorded.
- Focus on RABS integration by design.
- Good practice in High-Speed Filling Line for Large-Scale and High-Efficiency Injectables Manufacturing.
- Less operator need during the production, low operating cost.
- Servo Motor control system provides high level of automation which leads to operational accuracy as well as process reproducibility.
- Automatically generate production batch reports in compliance with GAMP5 and 21CFR PART 11.
- Critical parameter monitoring and control with record, print and backup option.
- Less number of change part and Tool-less design enables quick change over.



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Rotary Washing Machine

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The washing machine is suitable to wash ampoules with continuous automatic rotary motion. The machine ensures the removal of at least 3 log of particulate contamination (particles such as glass, fibers, etc.). The washing cycle includes recycled water spraying, WFI spraying and compressed air blowing.

Key Features

- Full servo design.
- Ergonomic design with easy operation and maintenance.
- Easy, tool-less and quick change over design.
- Sanitary piping design: ASME BPE or ISO SMS Standard; TIG automatic orbital welding; Borescope inspection.
- Passivation and electropolishing.
- Pressure and temperature of the various media are monitored to ensure good and constant performances.
- All material of manipulator is SS304, the gripper with torsion spring shall be open from one side to achieve better working life.
- The manipulator shall reverse without stretching out and draw back.
- All the pipeline are designed as per the 3D principle, slope of 1/100 mm given in drain piping.

Options

a. Manual inspection station

b. Automatic draining and drying of piping system

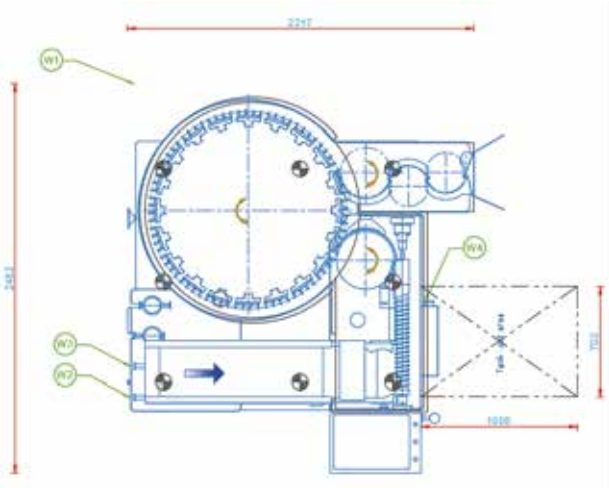
c. Vapor discharging fan with bellows and anti-backflow valve

d. ASME BPE Pipeline

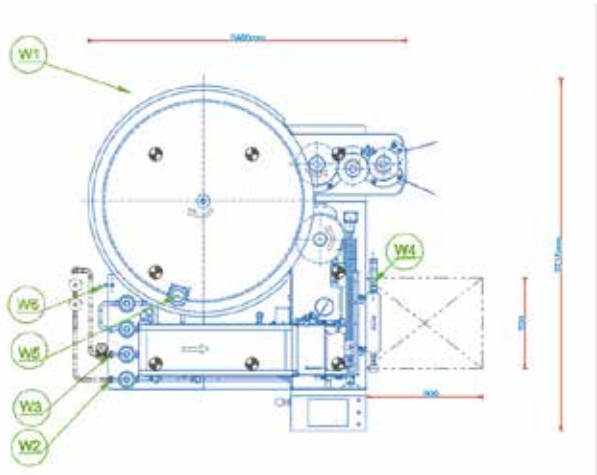
Techinical Data

Model	FW05080	FW05120	FW05160
Ampoule(ml)	1-20	1-20	1-10
Machine Capacity (APH based on 2ml)	300	450	600
WFI Supply(m^3/h)	0.6	0.8	1
Compress Air Supply(L/min)	1000	1400	1600
Power Supply(kw)	11	15	15
Dimension L*W*H(mm)	2217x2482x1580	2460x2715x1600	2460x2715x1600
Weight(kg)	2800	3500	3500

FW05080



FW05120/FW05160



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Sterilization & Depyrogenation Tunnel

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The tunnel is designed to sterilize and remove pyrogen attached to the glass containers by a laminar flow of hot air with a continuous process. Class A is assured in all tunnel areas above the openings of the containers.When the cleaned containers are sent to the Sterilizing Depyro-genation Tunnel automatically, they will be dried in the preheating zone.

After the containers are pre-heated, they will go to the heating zone, the temperature will increase to nearly 320°C or other using temperature validated by the customer (can be adjusted to max. 330°C) to achieve depyrogenation. At its coldest point, the standard sterilization and depyrogenation program is calculated with an equivalent time of 30 min. (3 log depyrogenation, ref. E Coli z = 46.4°C, D = 5 min., T° ref. = 250°C).

Then the containers will be sent to the cooling zone to be cooled, and then will be sent to the Filling & Sealing Machine.The machine has been designed and manufactured conforming to cGMP standards.

Key Features

- Scientific calculation, modular design and Independent air duct design.
- Negative pressure sealing for the HEPA in the heating zone.
- Simple and user-friendly filter exchange.
- Gentle temperature changeover from heating zone to cooling zone.
- Air speed and air pressure are balanced by laminar flow fan and exhaust air fan.
- Validation ports for filter integrity test, particle counting and air velocity.
- Critical parameters of the process are continuously monitored and printed.
- Power failure protection: backup power supply switch / compressed air cooling in the heating zone.
- Different working modes.
- Air-cooling type tunnel, no need chilled water.
- Self-cooling fan motor without extra cooling medium.

Options

a. Automatic doors for zone

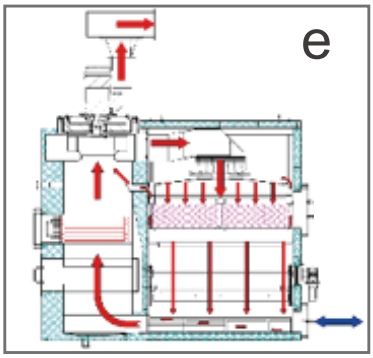
b. CIP function for belt

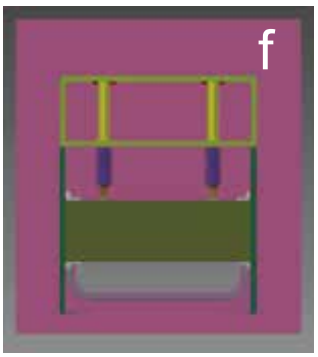
c. Multi channel recorder

d. Water-cooling type tunnel

e. Cooling zone sterilization(SIP function for water-cooling type tunnel)

f. Sealing door(Fit with SIP function or Isolator)





Techinical Data

Model	FT0430	FT0460	FT0360
Ampoule(ml)	1-20	1-20	1-20
Mechanical Output (VPH based on 2ml)	350	700	600
Belt width	600	600	600
Chilled water(option)	2-3	2-3	2-3
Power Supply(kw)	40	72	72
Dimension L*W*H(mm)	2705x1440x2487	4483x1640x2487	4209x1640x2255
Weight(kg)	2500	4000	4600

FT0430	FT0460	FT0360

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Filling & Sealing Machine

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The filling and sealing machine is suitable to fill sterile liquids into containers and seal containers stably. It is possible to install different dosing systems according to product characteristics. Class A is assured in all process areas above the openings of the containers. The machine has been designed and manufactured conforming to cGMP standards.

Key Features

- Suit for natural gas/LPG/hydrogen gas .etc
- Transfer ampoules smoothly by the arc infeed auger.
- Position ampoules accurately before filling by special design.
- Servo motor drive for main motor and filling motor enables precise operation.
- Nitrogen flushing station before and after liquid filling.
- Sampling function is available.
- Easy to connect with downstream machine.
- Easy-to-clean surfaces in processing areas.
- Easy, quick and tool less change over.
- Linear layout or ”L” layout is available.

Options

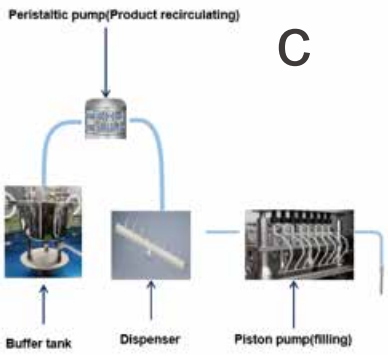
a. Nitrogen flushing station(before and after filling)

b.Jacket buffer tank for low temperature solution filling

c. Circulation system for suspension solution filling

d. Magnetic stirrers for suspension solution filling

e. Hydrogen and oxygen generator(Clean fuel)

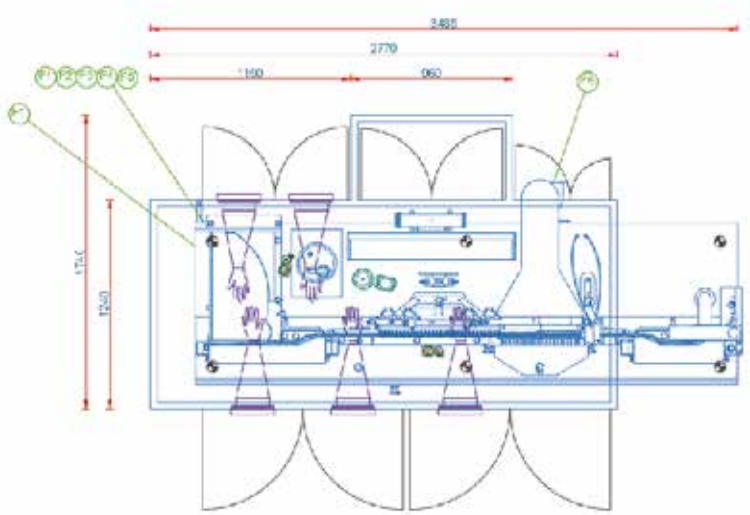


Techinical Data

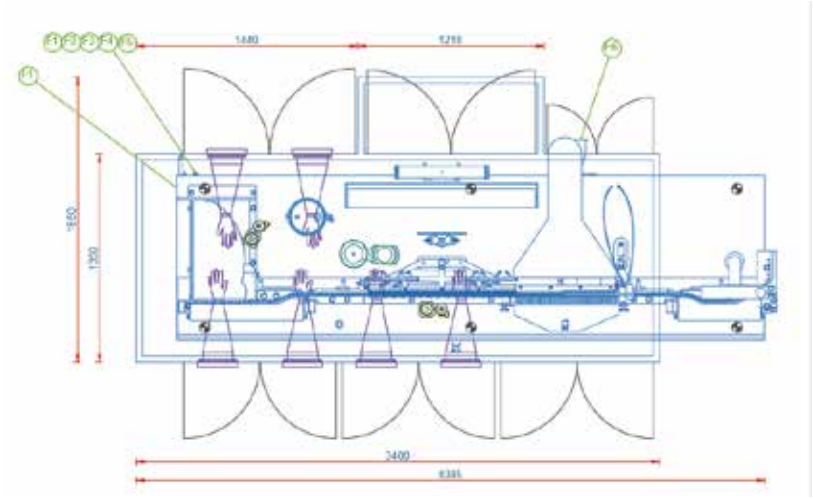
Model	FF0508	FF0510	FF0512
Ampoule(ml)	1-20	1-20	1-10
Machine Capacity (APH based on 2ml)	300	380	450
Filling Range	0.5-20	0.5-20	0.5-10
Power Supply(kw)	11	15	15
Dimension L*W*H(mm)	3485x1740x2730	3485x1740x2730	3485x1740x2730
Weight(kg)	2700	2700	2700

Model	FF051201	FF0516
Ampoule(ml)	1-20	1-10
Machine Capacity (APH based on 2ml)	450	600
Filling Range	0.5-20	0.5-20
Power Supply(kw)	11	12
Dimension L*W*H(mm)	4085x1850x2730	4085x1850x2730
Weight(kg)	3200	3200

FF0508/FF0510/FF0512



FF051201/FF0516



Tofflon

Qualification

ISO 9001:2015
ISO 45001:2018

21 CFR Part 11

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As we all know, resource efficiency is a high priority among companies with sustainability measures.

A paperless environment can be more efficient with resources. By “paperless,” we mean that all documentation, files, and records go into a digital format.

Global paper usage has grown by an astonishing 400% in the last 40 years.

The increase in paper consumption has had a direct impact on the environment, with approximately two million trees being cut down daily for paper production. This amounts to a staggering four billion trees annually.

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From paperless office to the concept of energy-efficient & eco-friendly design, Tofflon is committed to reducing environmental impact for a greener future.

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