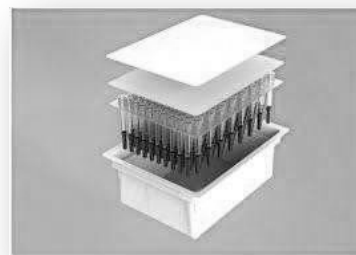


SEMI-AUTOMATIC SYRINGE FILLING AND CLOSING MACHINE FOR NESTED PFS

Model : FVEPFS-50



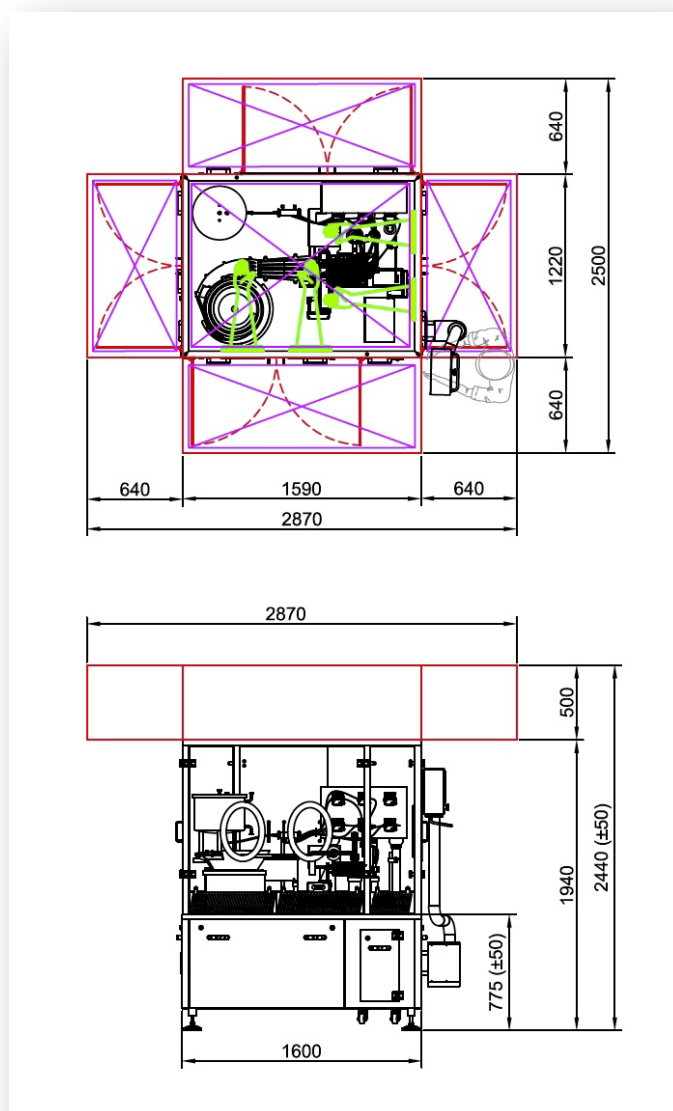
FVEPFS-50 is the best choice for the biotech and pharmaceutical industries looking for production of PFS (Pre-filled syringes) products.

FVEPFS-50 Semi-Automatic PFS filling and stoppering machine is our latest 5-head model used to precisely fill nested RTU (Ready-to-use) syringes and to apply stopper in the filled syringes to produce PFS products in the most easiest and compliant manner meeting all cGMP compliances.

FVEPFS-50 is equipped with any one set of change parts consisting of filling table, filling nozzles, nozzles header piston pump, stopper bowl and liner stopper track, stopper transfer flap, stopper insertion rod header and stopper guide tube header.

MACHINE TECHNICAL PARAMETERS

Machine Model	FVEPFS-50
Speed	60-80 PFS/min at 1 ml nest depending upon operator speed and fill volume
Filling range	0.1 to 10 ml with help of change parts
PFS Handling Range	1.0 ml to 10 ml with help of change parts
PFS Matrix	16 x 10 (1 ml) , 10 x 10 (2.25 ml)
Filling Tolerance	+/-2% (Peristaltic Pump based filling)
No. of Filling heads	5
Dimensions	2500 x 2870 x 2400 mm (with extended LAF units for operator added on 4 sides)
Electrical power supply	3-phase ,440 V, 50 Hz
Electrical Power consumption	16 kW
Compressed Air Supply	6-8 bar 10 KG/cm ²
Nitrogen Supply	2-3 bar 10 KG/cm ²
Noise Level	Less than 76 dB
Net weight	3358 kg

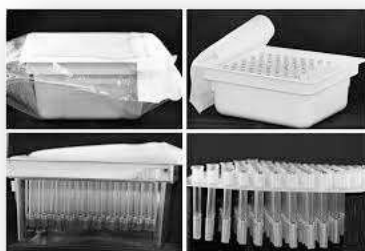


MACHINE CONSTRUCTION

- Machine is made of SS 304 frame structure, SS 304 top plate with SS 304
- All contact parts are of SS 316L and non-contact parts are of aluminium/ SS 304
- All electrical components and drives are placed beneath the machine
- Adjustment of dosing is with servo control for each individual filling head. filling volume can be adjusted through PLC-HMI

MACHINE OPERATION

- After the manual Tyvek removal and the Tyvek seal from the PFS tub. place the PFS nest on the PFS filling and stoppering table.
- PFS filling and stoppering table will move to the filling and stoppering station and filling and stoppering process are carried out
- After completion of filling and stoppering the PFS filling and stoppering table will return to the home position
- To unload the PFS nest manually from the filling table and will reinsert the PFS nest in the PFS tub manually.
- The filled and stoppered PFS tub are collected by operator for process



FILLING & STOPPERING PROCESS

- A buffer tank of capacity of 2 liters are provided with level sensor / load cell to maintain the product level
- Buffer tank outlet is connected with the multi hose adaptor or manifold
- Liquid product is transferred to the volumetric piston pumps (Qty - 5 nos.) through which the product is filled in to the PFS with the help of filling nozzles
- The volumetric piston pumps are servo based and the filling volume can be adjusted with the help of servo controls through HMI
- The filling nozzles are of concentric type which carry both pre and post nitrogen flushing inside the PFS to remove the oxygen
- In the filling and stoppering operation, the PFS filling and stoppering table will move in zig-zag manner in x-y plan and filling are carried out row by row with the help of 5 nos. of filling nozzles.
- After completion of filling operation of the first two rows of the PFS nest, stoppering operation are carried out.
- Pre-sterilized rubber stoppers are loaded into the rubber stopper bowl with the vibratory assembly.
- The rubber stoppers are then transferred to the linear track due to the vibration, after that the rubber stopper are picked up by the stopper transfer flap and the rubber stoppers are aligned with stopper guide tube
- The stopper pushing rod will push the rubbers stoppers inside the filled PFS in the stoppered position.

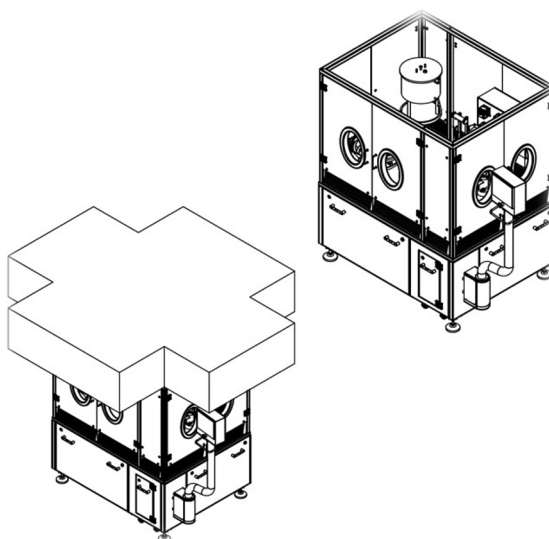
MACHINE CONTROLS, MONITORING DEVICES & ELECTRICALS

- Machine are controlled through PLC (OPCUA enabled) (make: Mitsubishi)
- Machine monitoring & configuration through HMI having 10" touch screen (make: Mitsubishi).
- Machine operation console with emergency switch, on/off switch and vibration frequency controller speed pot.
- All drives & components are fixed beneath the machine with exhaust fan and illumination.
- Audio visual light are provided for the alarms and machine status.
- UPS is provided for the HMI & PLC backup machine safety interlocks & alarms.
- No nest – no fill and no stopper.
- No stopper in track – machine stop with alarm, machine restart with operator intervention.
- Low stopper qty in bowl – machine hold with alarm, machine restart with operator intervention.
- If motors overload – machine stop or hold depending upon criticality
- Any servo drives fault – machine stop or hold with alarm, depending upon criticality.
- Stopper bowl vibrator trips - machine stop with alarm.
- Robot not healthy – machine stop with alarm.
- Air pressure low – machine stop with alarm.
- Nitrogen pressure low – machine stop with alarm.
- LAF stop – machine stop with alarm.

- Door open – machine hold with alarm.
- Stopper bowl vibrator trips – machine stop with alarm.
- Communication error – machine hold with alarm.
- Outfeed track full – machine hold with alarm, machine restart with operator intervention.
- Emergency stop – machine stop with alarm.

LAMINAR AIR FLOW SYSTEM OVER THE MACHINE

- ISO class 5 clean air flow station with HEPA filter
- SS 304 perforated laminator grills below the HEPA filter
- Analog Magnehelic gauge to measure the differential pressure



- ISO class 5 clean air flow station with HEPA filter
- SS 304 perforated laminator grills below the HEPA filter
- Analog Magnahelic gauge to measure the differential pressure
- PVC curtains over the extended LAF

SOFTWARE COMPLIANCE

- Licensed SCADA software for controlling, monitoring and analysing the machine.
- 21 CFR part 11 compliant system for electronic records and signatures with date and time stamp to fall under US FDA-regulations.
- Non-editable batch summary reports.
- Non-editable audit trail reports.
- Batch set parameters reports.
- Record search based on time, date and batch for the ease of report search
- User friendly interface between the men and machine
- Data backup and restoration facility to restore and replace the lost or damaged data.
- Disaster recovery system to restore access and functionality of the machine in the operational state after a disaster event.
- User management up to access level-4 with unique login id and masked password with alpha-numeric complexity, periodic password expiry facility and system lock with multiple.
- Wrong password inputs.

ENVIRONMENTAL CONDITION

To achieve best results, FVEPFS-50 machine is suitable to operate in the following environmental condition and background environment:

- Room air classification: Class B
- Temperature: $22.5 \pm 2.5^{\circ}\text{C}$
- Humidity level: Not more than 60 %

FVEPFS-50 is top choice if looking for economical semi-auto model of nested PFS filling and stoppering machine providing ease of operation and helps efficiently for achieving production targets while meeting all regulatory requirements.