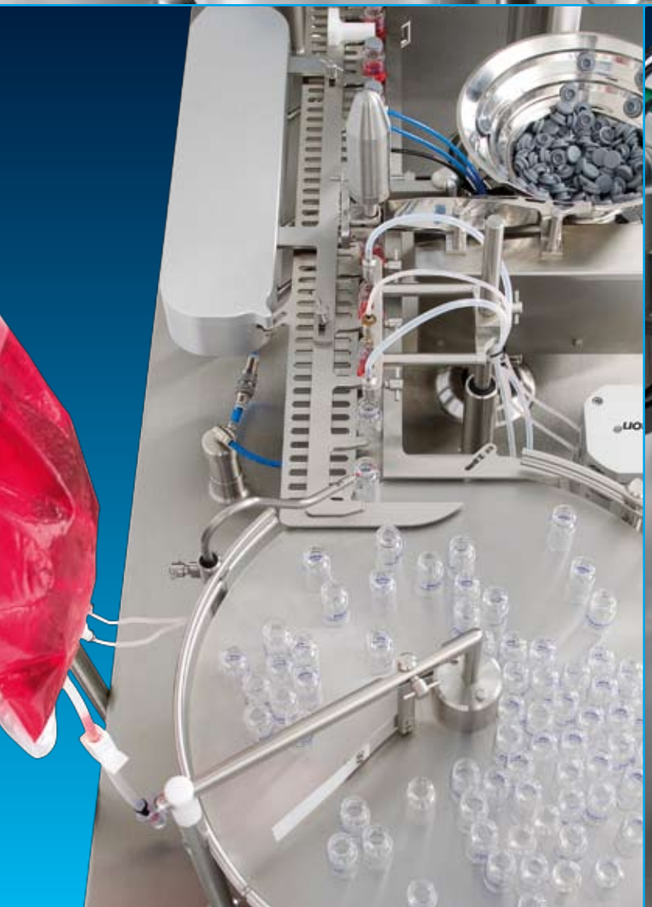
WATSON MARLOW Flexicon

FPC50

FILLING, STOPPERING AND CAPPING MACHINE

- Peristaltic aseptic filling from 0.1 to 100ml
- No cross contamination
- Disposable Aseptic Fluid Path simplifies validation (DAFPA)
- Universal format parts reduce costs
- Quick and easy change-over between batches

WORLD LEADERS IN ASEPTIC PERISTALTIC FILLING



FPC50 FILLING, STOPPERING AND CAPPING MACHINE

FPC50 is a highly flexible aseptic filling system with integrated full or partial stoppering and crimp capping of vials.

It provides a ready-to-use and easy to validate filling system for small batch production for vial sizes between 2ml and 100ml. Fill volumes range from 0.1ml to 100ml and a filling accuracy of ± 0.5% can be obtained.

The entire fluid path is designed for single use making cleaning validation extremely simple and permits fast change-over between the various liquids to be filled. Thus, the peristaltic filling system on the FPC50 eliminates time consuming and costly logistic procedures related to having product or volume dedicated pumps in stock.

The universal format parts supplied with the FPC50 can be used for a wide range of vials, stoppers and caps. Thereby, compared to other automatic filling systems, future investments in format parts are significantly reduced – or more likely not necessary, at all.

Change-over between various vials, stoppers and caps can be done within minutes by the operator, without any special tools or technical support from staff outside the cleanroom.

FPC50 is designed to be placed under a LAF or RABS unit and all materials and surfaces comply with GMP standards for aseptic filling. The FPC50 is also available in a special version, FPC50ISO, which is designed for integration into an isolator.

The FPC50 is the perfect solution for small batches at contract fillers and for a highly flexible production for clinical trials within R&D departments.

- **Fast and easy change-over between batches**
- **Disposable aseptic fluid path ensures simple cleaning validation**
- **High filling accuracy**
- **Universal format parts for stoppers and crimp caps**
- **Vial format parts are not needed**
- **No special tools needed for format changes**
- **Compact unit on castors with small footprint**
- **Special version for integration into an isolator is available (FPC50ISO)**
- **IQ/OQ documentation can be provided**
- **Standard machine with many reference customers**

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FPC50 TECHNICAL SPECIFICATIONS

A walking beam with central adjustment of guide rails transports vials from the rotary table to the different work stations. Thus, no format parts are required for the entire vial range between 2ml and 100ml.

Format parts for stoppers consist only of the chute, jaws and piston. Format parts for crimp caps consist only of the chute and crimping head.

The vibrator bowl for the stoppers can be applied for both 13mm and 20mm injection and lyophilisation stoppers. For the crimp caps the same vibrator bowl can normally be applied for both 13mm and 20mm caps.

FPC50 has integrated support of nozzles for gas purging before and after filling of liquid. A valve for gas purging is optional.

Vials can be loaded into the machine from a removable infeed tray from the front or from the left side of the machine. This allows installation of the FPC50 under a LAF unit or inside a RABS. Collection of vials takes place on a removable tray.

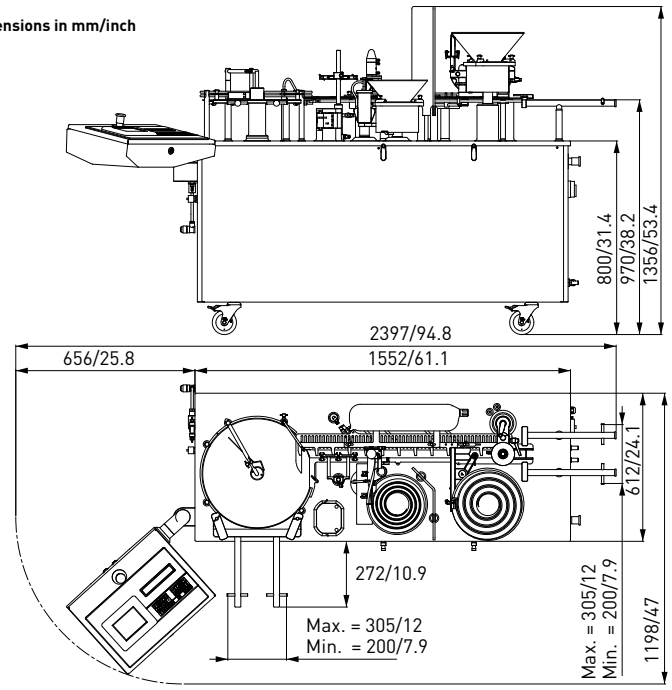
Operator interface is an easy-to-clean touch screen and keypad. The control panel is integrated into a control box, which is attached to the machine cabinet or supplied as a stand-alone unit to be placed at a distance from the machine.

The touch screen has self-explanatory menus for control of machine parameters. Sensors ensure no vial/no fill, no vial/no stopper and no vial/no cap. Moreover, the number of stoppers and caps in the chutes is monitored. Errors at the stoppering or capping stations, as well as at the outfeed, will stop the machine automatically.

It is possible to store up to 20 sets of parameters as complete programs. The programs and the various machine functions can be password protected.

Preparing the FPC50 for a new vial, stopper and cap is an easy task. The guide rails for the vial and the position of the format parts for the stopper and the cap are adjusted in a few minutes by turning four handles.

Dimensions in mm/inch



Applications:
– Filling and partial stoppering of lyophilisation stoppers
– Crimp capping
– Filling, full stoppering of injection stoppers and crimp capping

Stoppers:
Ø13 mm and 20 mm injection and lyophilisation stoppers (Samples to be sent to Watson-Marlow Flexicon prior to final quotation)

Caps:
Ø13 mm and 20 mm flip-off aluminium caps and/or plain aluminium caps. (Samples to be sent to Watson-Marlow Flexicon prior to final quotation)

Infeed and outfeed trays:
Width/open end min. 200mm/7.9"
– max. 305mm/12"

Production capacity
Up to 25 units per minute depending on fill volume and vial size

Filling volume:
0.1ml to 100ml

Accuracy:
± 0.5% can be obtained on liquids with a viscosity like water and a constant suction level

Mains:
110/230VAC – 50/60Hz

Power consumption:
Max. 1200W

Air supply / pneumatic connection:
Min. 5 bar clean and dry air

Air consumption:
Max. 100 litres per minute

Materials:
Stainless steel and anodised aluminium. Product and stopper contact parts in AISI316L

Interface:
2 x RS232 serial communication for balance and printer
1 x 24V output signal for nitrogen purge valve
2 x external error for interface with for example a particle counter
Communication with RABS (specified by Watson-Marlow Flexicon)

Ingress protection:
IP32 for machine base

IP54 for control panel

Weight:
400 kg

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