

Flexicon FPC60

Uniquely configurable fill/finish system



Flexicon...Filled with experience

Flexicon FPC60 — Uniquely configurable fill/finish system

Flexicon specializes in the development and manufacture of aseptic filling systems for biotechnology, diagnostic and pharmaceutical markets with an emphasis on precision, efficiency and flexibility. As an experienced leader in aseptic filling, Flexicon has developed every part of our products and services around the fundamental principle of reducing risk. At the heart of all the Flexicon filling systems is the low shear, gentle pumping action of our peristaltic fillers which ensure your valuable product is transferred undamaged with high accuracy and precision.

Built around our highly accurate peristaltic filler, the FPC60 is a uniquely configurable small batch aseptic fill/finish system with a wide variety of options designed to work together to provide the ultimate filling solution. The FPC60 system can be designed and built with a choice of optional solutions allowing adaptation of each stage of the fill/finish process including vial infeed, filling, stoppering, capping, auto-reject and product outfeed.

Flexicon has an excellent record in working to meet short and reliable delivery times. With more than 30 years of experience, Flexicon provides seamless FAT and IQ/OQ tests; all working towards avoiding costly project delays.

Unparalleled value

- Increased batch consistency between operators
- Zero waste of highly valuable product in batch start up
- Pneumatic free
- No format parts for the entire vial range
- Reduce contamination sources and save time with hand-free initial calibration
- Highly accurate filling of better than $\pm 1\%$ from 0.2ml up to 100ml
- Up to 2700 vials per hour (45 vials/min)
- No tools and minimal setup between batches

New advanced features

- Auto reject for minimal operator intervention*
- Independent validation of capping force*
- No vial — no fill sensor prevents miss filling and contamination of the filling environment*
- One-handed open/close pump design for easy change fluid-path in RABS and isolators*

*optional features

To meet the needs of aseptic fill finish applications, Flexicon provides full turnkey FPC60 solutions for LAF and oRABS systems. Integrated isolator solution for the FPC60 are also available through Flexicon in collaboration with our preferred partners.



Flexible modular design

FPC60 is highly flexible. When ordering a machine, options for each module can be selected to meet your specific demands and requirements.

asepticsu™
Filling

Flexicon peristaltic filling combined with aseptic single-use technology reduces risk with no cross-contamination, no line cleaning, rapid product change-over and simplified validation.

One-handed open/close pump design for easy tube loading in RABS and isolators

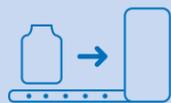


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- Automatically adjusting walking beam transports vials from the infeed to the different work stations
- No format parts are required for the entire vial range

GUARDING/ ENVIRONMENT CONTROL

- Standard guarding to protect both operator and product included
- Solutions for extended guarding to an existing LAF unit in ceiling
- Open RABS with complete integrated LAF solution from Flexicon
- Machine cabinet modified for integration into closed RABS or isolator from preferred partners
- Viable and non-viable particle monitor solutions available
- Interlocks on guarding to prevent accidental opening during production
- Optional glove ports with light curtain safety barrier
- Risk of contamination reduced through internal guarding partitions with 'mouse-hole' transfer prevents particulate from entering the filling area



INFEED

- Loading of vials into the machine from a removable or nest tray
- Customized solutions to meet most customer needs available upon request
- Buffering turntable to ensure continuous operation with minimal operator intervention



FILLING

- Peristaltic pump solutions with easy operation and high accuracy
- Bottom up filling available to prevent splashing and foaming, improving filling accuracy and ensuring gentle handling of valuable products
- Vial position sensors, prevents miss filling and contamination of the filling environment
- 100% in-line check weigh with dynamic prime, hands-free initial calibration and in-batch dynamic calibration
- Vial gas purging before and after liquid filling



STOPPER

- Format parts: vibrator bowl, chutes, jaws and pistons
- The vibrator bowl accommodates both 13mm and 20mm injection and lyophilization stoppers
- Optional chutes in guarding for easy refilling of stoppers



CAPPING

- Optional crimp force sensors with data capture ensures correct and reliable capping
- Format parts: vibrator bowl, chutes and crimping heads. For the crimp caps the same vibrator bowl can normally be applied for both 13mm and 20mm caps
- Chutes in guarding for easy refilling of stoppers and caps



REJECT

- Automatic reject station transfers out of tolerance vials from the vial track down to the reject tray, based upon information relayed from any of the modules



OUTFEED

- Vials collect on removable tray
- Removal of filled vials can be done without stopping production
- Customizable options for extended trays and conveyors available upon request



When supplied with in-line check weighing, the FPC60 offers unique dynamic prime, no intervention initial calibration and dynamic recalibration, meaning no waste in the batch start up process and confirmation every vial, from first to last, is filled within specification.

The all-new interface uses intuitive design with quick reference icons to identify key operations; guiding users to what they need.



Advanced user interface via remote access web tools

- Real-time supervisory oversight
- Batch data retrieval
- Recipe creation

Full regulatory compliant and designed for future regulation

- 21 CFR part 11*
- EudraLex Vol 4
- Serialization ready

FPC60 Technical specifications

Vials, stoppers and caps:

- Fill volume: less than 0.2 – 100ml
- Vials: ISO 2R – 100H
 - Diameter: 14mm – 52mm
 - Height: 30mm – 120mm
- Stoppers: 13mm and 20mm injection and lyophilization
- Caps: 13mm and 20mm flip-off or plain aluminium

Infeed/outfeed trays for vials:

- Width infeed tray: 185mm – 360mm
- Width outfeed tray: 180mm – 360mm
- Infeed for pre-sterilized, nested vials is optional

Production capacity:

- Up to 45 vials per minute*

**Individual results may vary. Accuracy and capacity depend on fill volume, inline check weighing, vial size and viscosity*

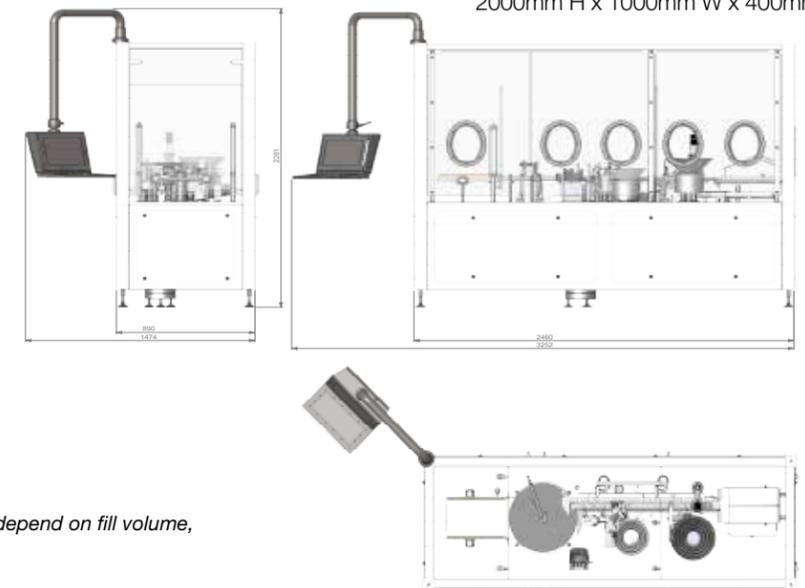
All dimensions in mm/inch

Filling accuracy:

- Peristaltic pump with better than $\pm 1\%$ accuracy*

Power:

- 200–240VAC 50/60Hz + PE max 20 AMP. (consumption max. 3200W)
- External electrical cabinet – 2000mm H x 1000mm W x 400mm D



BIOTECHNOLOGY AND PHARMACEUTICAL SOLUTIONS



Watson-Marlow Fluid Technology Solutions

Watson-Marlow Fluid Technology Solutions supports its customers locally through an extensive global network of direct sales operations and distributors

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