

Flexicon FPC60

Uniquely configurable fill/finish system



Flexicon...Filled with experience

Flexicon FPC60 — Uniquely configurable fill/finish system

Flexicon specialises 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.



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 asepticsu 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

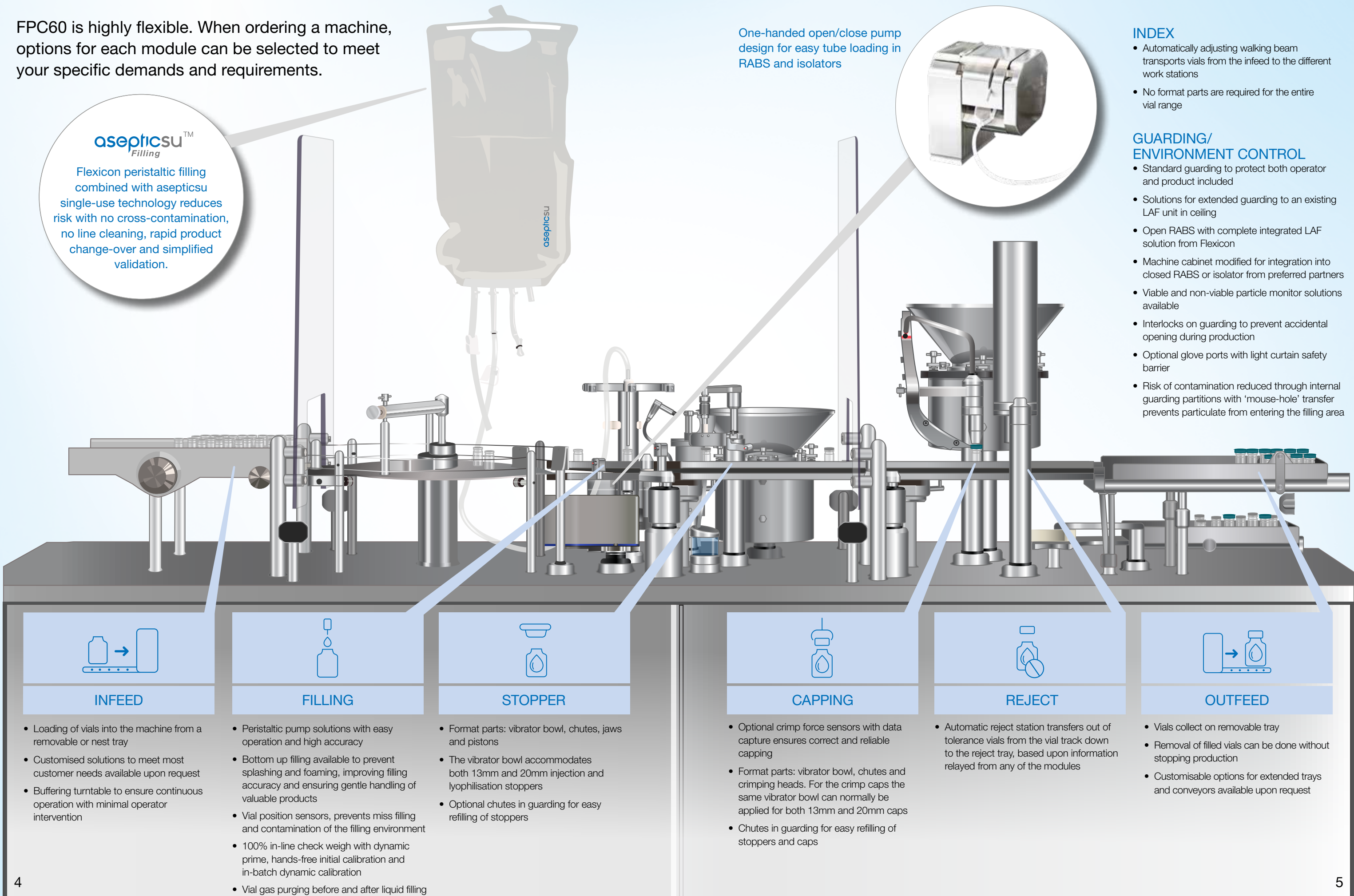


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- Automatically adjusting walking beam transports vials from the infeed to the different work stations
- No format parts are required for the entire vial range

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





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*
- GAMP5
- EudraLex Vol 4
- Serialisation 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 lyophilisation
- 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-sterilised, nested vials is optional

Production capacity:

- Up to 45 vials per minute*

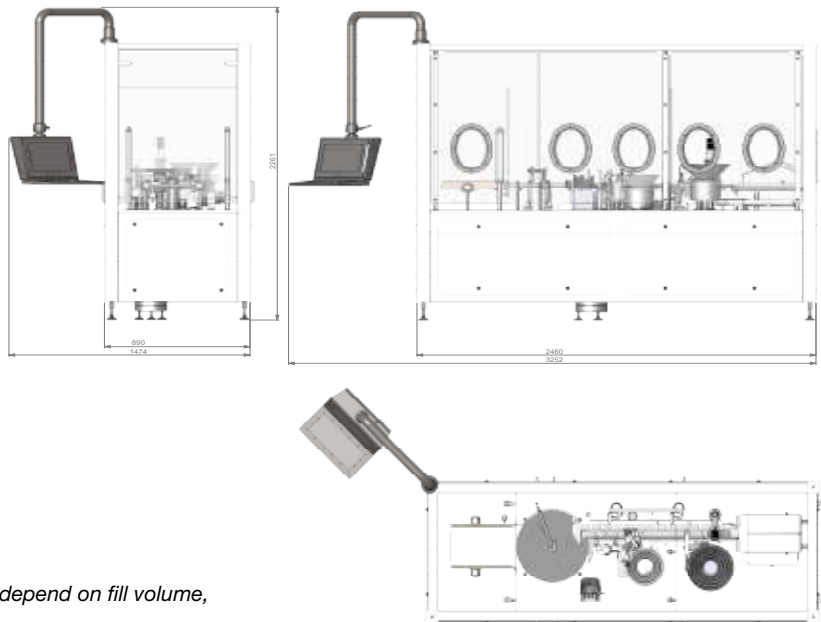
**Individual results may vary. Accuracy and capacity depend on fill volume, inline check weighing, vial size and viscosity*

Filling accuracy:

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

Power:

- 200–240VAC 50/60Hz + PE max 20 AMP. (consumption max. 3200W)





Fluid Technology Group

BIOTECHNOLOGY AND PHARMACEUTICAL



Watson-Marlow Fluid Technology Group

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

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