

ASEPTIC FILLING SOLUTIONS



Flexicon... Filled with experience



For more than 30 years, Flexicon has been established as the preferred choice for aseptic liquid filling for GMP regulated industries, such as biotechnology and diagnostics.

Flexicon's products scale with your business, from stand-alone units for hand filling, through semi-automatic systems, to fully automatic filling, stoppering and capping machines. Systems are customised to fit a wide variety of vials and bottles.

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.

Flexicon is the only global manufacturer and supplier of peristaltic filling systems that has its own tubing manufacturing facility on campus.

Our Accusil tubing is optimised for filling accuracy, is fully validated, and is post-cured for high purity and laser-etched for traceability.

Accusil single-use tubing technology facilitates rapid process validation and changeover.

In addition, our aseptic single use fluid paths incorporate Accusil into a complete, bioburden validated, sterile assembly ready to fit and fill.

Introducing the new Flexicon PF7 tabletop filler

Flexicon's forward-looking product development policy continues to drive the expansion of a unique, high-quality range of products including the new PF7 tabletop filler.

The Flexicon PF7 is the result of 30 years of industry-focused experience. The PF7 is simple to operate, reduces risk of errors, is highly flexible and comes with Flexicon's trademark precision performance ensuring GMP and regulatory compliance. Learn more about PF7 on page 6.



Flexicon: Flexibility to expand as your needs grow

A truly scalable filling solution

Flexicon offers a range of products that can be built together to expand into larger systems as your needs grow. This scalable approach reduces

validation costs and limits extra investment as your demand for capacity increases.

Tabletop units

Fillers



Cappers



Semi-automatic systems

Filling



Filling and capping



Fully-automatic systems

Automation of filling, stoppering, capping and weight check



Modular filling and capping



Solutions for integration or retrofit

OEM fillers and controllers



Trolley solutions for piston pump replacement



Lab - R&D	Clinical I	Clinical II	Clinical III	Small Production	Full Production	High Speed
Sterile, single-use fluid path - aseptic (pages 22-23)						
Tabletop Dispensing Systems - PF7, 520Di, PF22 (pages 6-7)						
Tabletop Screw and Crimp Cappers - FS and FC (pages 8-9)						
	Vial/Bottle Handling - FlexFeed15 and FlexFeed20 (pages 10-11)					
			Filling/Screw Capping - FlexFeed30 (pages 12-13)			
		Filling and Stoppering - FP50 (pages 14-15)				
		Filling, Stoppering and Capping - FPC50 (pages 16-17)				
		FPC50 for integration into an isolator or a RABS - FPC50ISO (pages 16-17)				
			Fully Automatic Monobloc - FMB210 (pages 18-19)			
			Master Controllers, Trolleys and Pumps/Fillers - OEM Solutions (pages 20-21)			

PF7: Tabletop aseptic liquid filling

The PF7 is the latest addition to Flexicon's flexible, reliable and versatile range of peristaltic filling machines.

Flexicon products are the preferred choice for the biotechnology and diagnostic industries, and the enhanced features and application-specific design of PF7 continues that trend.

The PF7 has been developed for the filling of high-value sensitive fluids in GMP production and cleanroom environments.

- **Precision filling from as low as 0.2 ml**
- **Repeatable filling accuracies of better than $\pm 0.5\%$ to prevent costly over filling**
- **No foaming, splashing or dripping between fills**

- **User-programmable 'recipes' where users can define filling recipe parameters**
- **Connects to a range of balances and printers for error-free calibration and batch reporting to help compliance to GMP and regulatory demands**
- **Easy-to-clean surfaces with no entrapment areas, and an ergonomic design for operation on the bench or in isolators and LAF units**
- **Clear and intuitive colour display with large keypad for easy use when gowned up in cleanroom environments**



Faster fluid path changeover

Changing the fluid path can be achieved in less than a minute. The closed fluid path removes any risk of cross contamination, making the PF7 ideal for aseptic filling.

Designed for single-use fluid paths

Optimised for filling accuracy with Accusil tubing, the PF7 is designed to work with single-use fluid paths such as asepticus.

Reliable and secure

The PF7 comes with a five year warranty. IQ/OQ documentation available on request to assist with process validation.

Simple, powerful user interface

Large keys and a clear, colour display aids operation while working in gloves or behind glass within a RABS or LAF unit. The PF7 comes programmed with recommended filling parameters based on Flexicon's 30-years of experience. Users can also set custom filling parameters of their own for optimum accuracy.

Integration into automated filling solutions

The PF7 will connect to a variety of bottle handling systems such as the FlexFeed 15, 20, and 30, or third-party systems. A range of accessories are available including footswitches for remote operation.



Need higher capacity dispensing?

Flexicon's PF22 allows for fill amounts less than 5 ml up to more than 5000 ml.





A range of format parts is available to handle different types and sizes of caps, bottles and vials

Cappers ensure consistent quality crimps and torque

When there is need to increase productivity, while minimising operator fatigue and repetitive strain injury, our cappers can be added to your current process. Features offered by both crimp and screw cappers are:

- **Consistent quality closure**
- **Cap up to 1,000 units/hour**
- **Fast changeovers**

Deciding which capper is right for the process depends on the capping needs. Each capper has specific benefits.



Screw capper FC10

Crimp capper FS10

Crimp capper FS32

Screw cappers

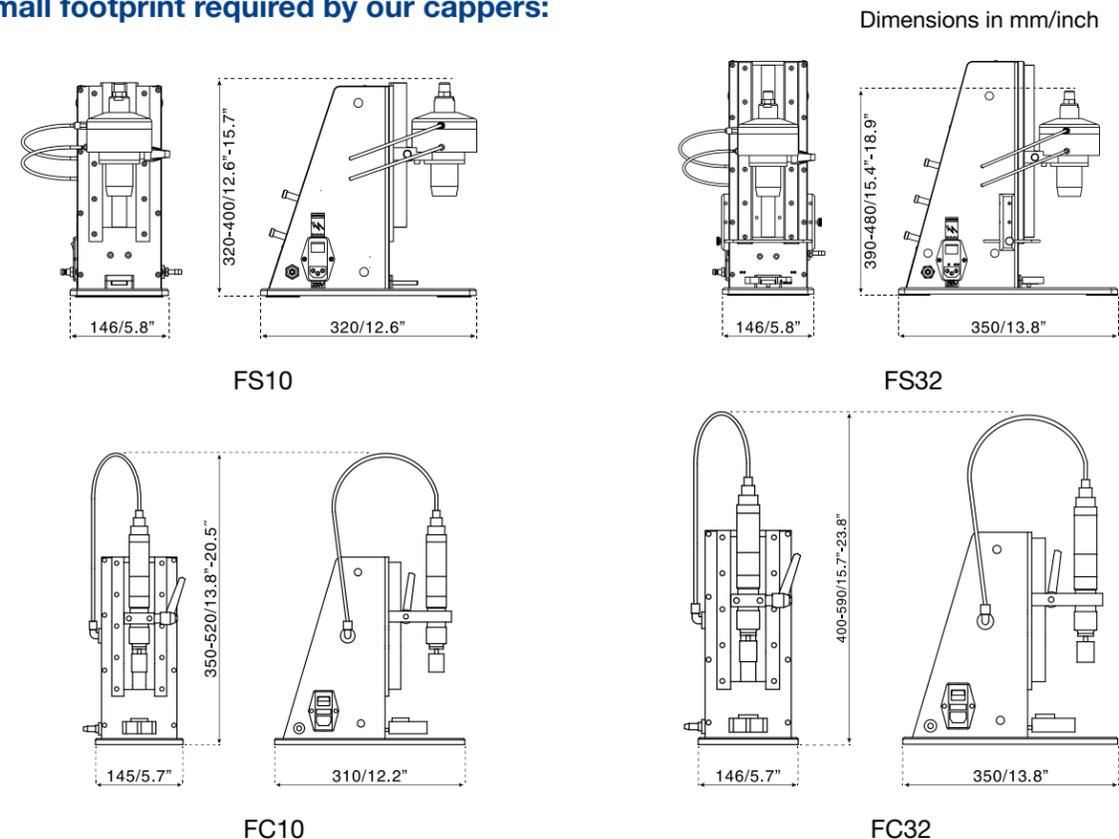
- **No tools needed for changeover**
- **Handles caps up to 65 mm and bottle sizes up to 100 mm in diameter**
- **Adjustable closing torque**

Crimp cappers

- **High quality aluminium overseal**
- **Low particle release**
- **Easy to mount crimp heads and bottle tools in standard or customised sizes are available**
- **Collection of used compressed air**

Capper Name	Maximum Cap Size		Maximum Bottle Size	
	Diameter	Height	Diameter	Height
FC10 Screw	50 mm	40 mm	55 mm	180 mm
FC32 Screw	65 mm	40 mm	100 mm	240 mm
FS10 Crimp	8–20 mm ISO 8362		73 mm	180 mm
FS32 Crimp	13–32 mm ISO 8362		95 mm	240 mm

If you don't have much room in your facility, consider the small footprint required by our cappers:



Automatic filling and tabletop vial and bottle handling system

As the need for more automation grows Flexicon's product line meets the needs of flexible production of small batches in contract filling and diagnostics operations where there are many different sizes of bottles.

The speed at which the vials/bottles are presented at the filling needle is fully adjustable, allowing light vials or bottles to be filled. Customised solutions can be designed to handle bottles with special shapes.

The FlexFeed15 and FlexFeed20, used in conjunction with one of our crimp or screw capping machines, provides a simple and very flexible means of production and customers can achieve a fast return on investment.

- **12 mm to 50 mm (FF15) / 78 mm (FF20) diameter bottles without any format parts**
- **Complete changeover in less than two minutes**
- **Prevents repetitive strain injuries**
- **Small foot print and designed for cleanroom environments**
- **Excellent return on investment**



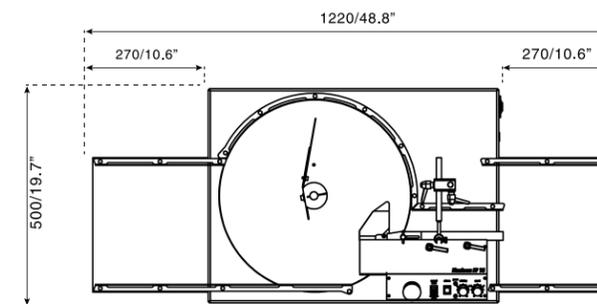
FlexFeed systems are ideal for contract filling where there are many different sized bottles or vials



Fast simple changover

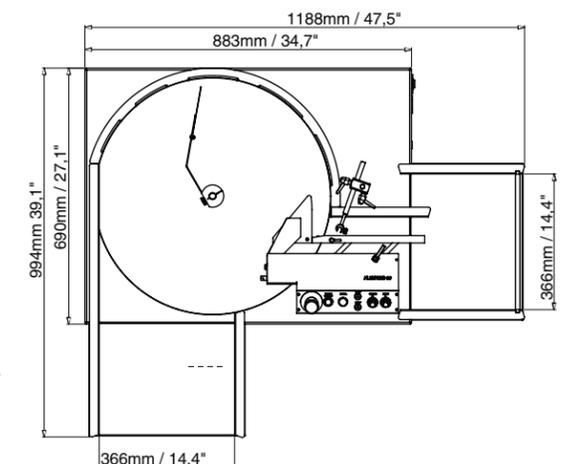
Changeover between different bottles or vials can be done in two minutes without format parts, tools or special operator skills.

FlexFeed15



Dimensions in mm/inch. On FlexFeed20 and FlexFeed15 the infeed tray can easily be mounted on the front or on the left side of the machine.

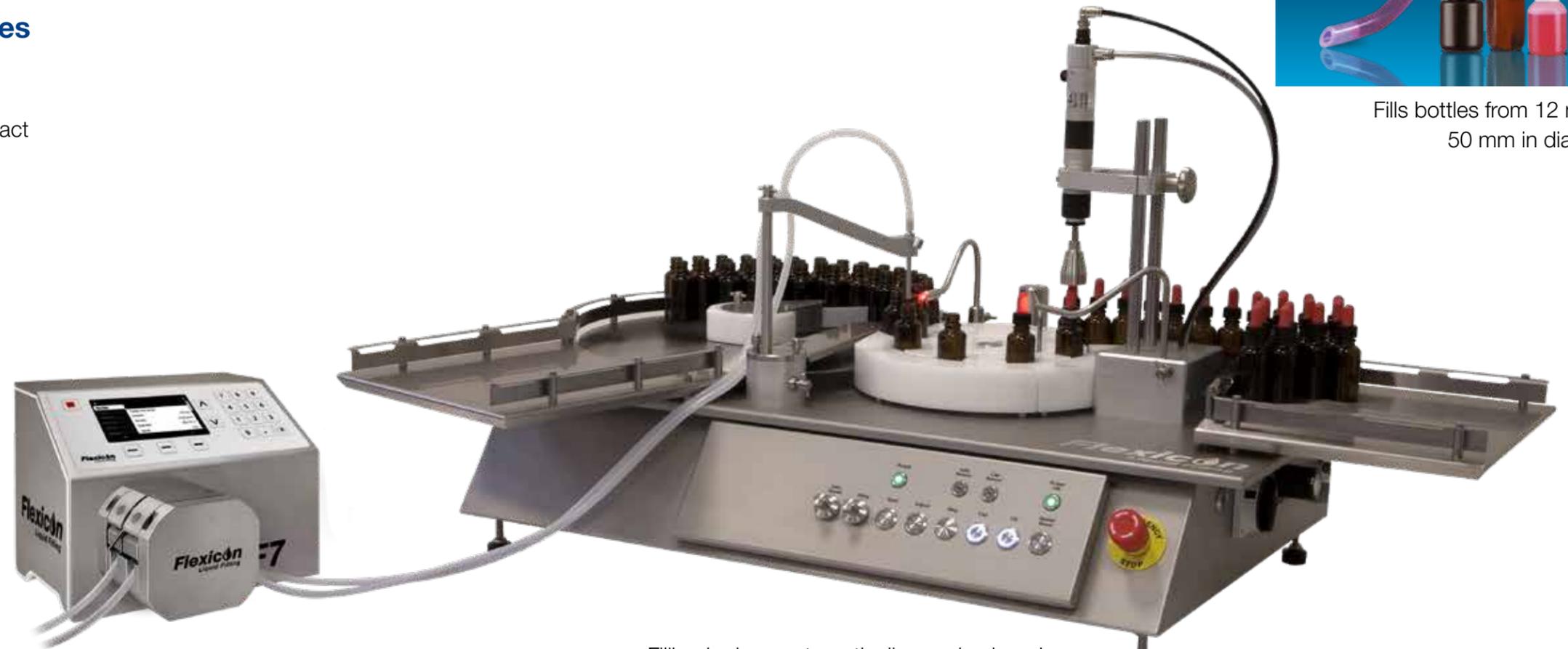
FlexFeed20



Semi-automatic filling and capping system for small batches

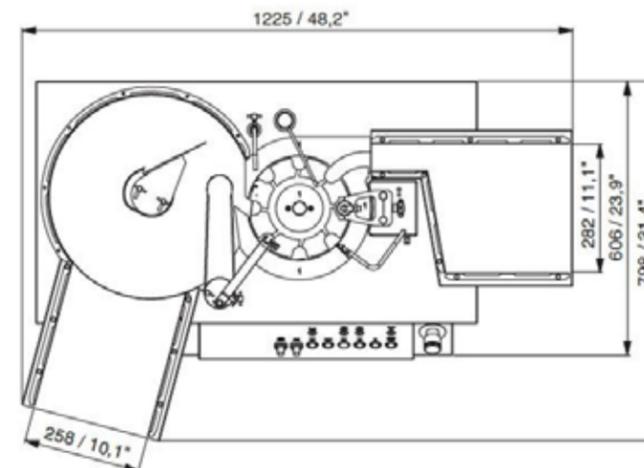
For a higher productivity, a more consistent screw capping and no more repetitive strain injuries, the FlexFeed30 is the answer for contract manufacturers and diagnostic companies.

- **Reduced production costs and increased productivity**
- **Consistent cap torque prevents leakage of liquid**
- **Up to 1200 units/hour**
- **Protects operators from repetitive strain injuries**
- **Complete cap and bottle change in less than five minutes**
- **Fills bottles from 12 mm to 50 mm in diameter**

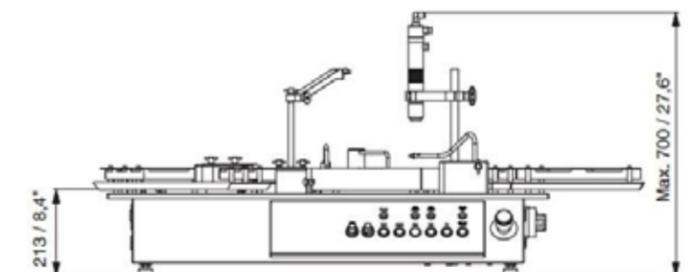


Fills bottles from 12 mm to 50 mm in diameter

Filling is done automatically, cap is placed manually and capping torque is applied automatically



Dimensions in mm/inch



Fully automatic filling and stoppering

Automating the key steps of aseptic filling cuts the risk of operator error and related contamination. The FP50 peristaltic filling system also eliminates the costs and risk issues of volumetric filling pumps.

The FP50 is a tabletop filling system used for biopharmaceutical research and development departments during clinical trial phases, or for contract manufacturing companies where it will increase flexibility and save costs.



- **Up to 25 units/minute**
- **Excellent filling accuracy prevents costly overfilling**
- **From less than 0.2 ml to 100 ml fills of 2R to 100H vials**
- **Full or partial stoppering**
- **Quick and simple format changes**
- **Universal format parts reduce costs**
- **Small footprint for UDF bench or RABS installations**
- **Increase your flexibility when filling smaller batches—just one machine will fill all your vials**

Stoppering with 13 mm and 20 mm stoppers requires no additional format parts

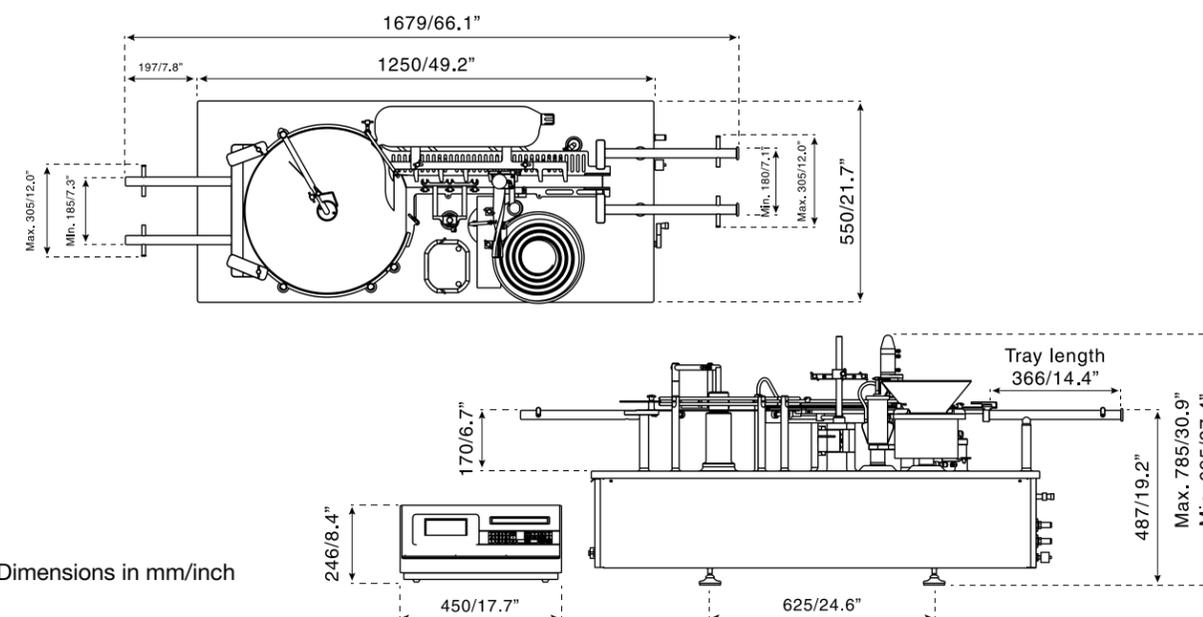


A customised FP50 is built into an isolator so that the fluid and the filled vials are completely contained.

Increase your flexibility when filling smaller batches—just one machine will fill all your vials



Fills from less than 0.2 ml up to 100 ml, maximum 25 vials per minute



Fully automatic filling, stoppering and capping with optional inline check weighing

The FPC50 provides a ready-to-use and easy-to-validate filling, stoppering and capping system for flexible small batch pharma production.

It is a modular system which offers options for in-line check-weighing and usage under a standard UDF hood or a RABS.

The FPC50 can also be customised for integration into an isolator with easy access to all areas of the machine through glove ports.

The universal format parts of the FPC50 allow for filling of a wide range of vials, stoppers and caps. The peristaltic filling system eliminates having product-dedicated or volume-dedicated pumps in stock.

We have an excellent record in providing short and reliable delivery times and performing seamless FAT, IQ and OQ tests, avoiding costly project delays.

- **High accuracy filling for less than 0.2 ml up to 100 ml with no splashing, dripping or foaming**
- **Fast and easy changeover between batches with very limited product waste at startup**
- **Universal format parts reduce costs and increase flexibility**
- **Up to 25 units/minute**
- **Batch report after each production run and full audit trail**
- **First class documentation and test protocols for FAT, SAT, IQ and OQ**
- **Software designed and qualified according to GAMP5**
- **Optional software to support 21 CFR Part 11**

A filling machine and single-use fluid path from one supplier makes validation easy and prevents costly overfilling

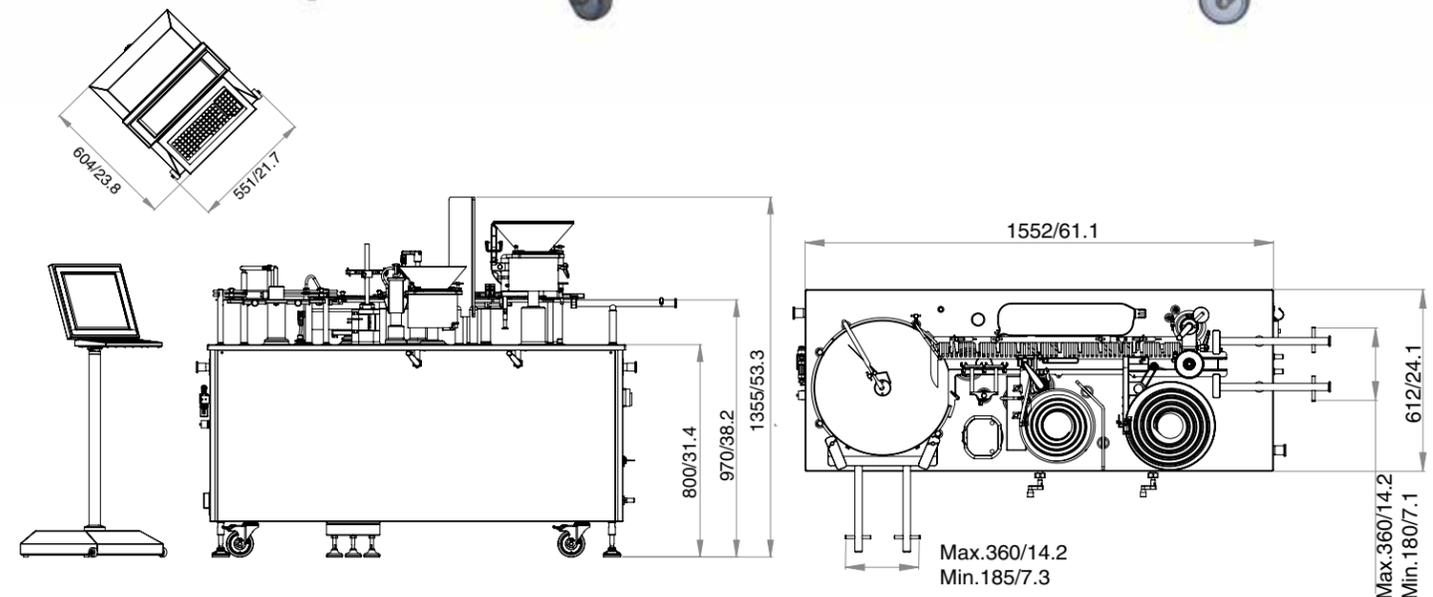
FPC50 crimping head for minimum air turbulence and fast changeover between caps



Universal format parts allow filling, stoppering and capping of a wide range of vials



Master controller can be situated outside an UDF hood or RABS unit



All dimensions in mm/inch. This drawing includes optional inline check weighing. The infeed tray can be mounted on the left side or on the front of the machine and the FPC50 can be customized for integration into RABS or isolators

Fully automatic filling, stoppering and capping for medium sized batches with easy setup and changover

The FMB210 is perfect for fully automated filling and capping for aseptic drug, ophthalmic and diagnostic applications. It can handle a wide range of container and closure types.

A unique tool platform allows simple, fast and accurate format changes where multiple products need to be processed on a single filler. It can be configured for a choice of infeed and outfeed options or other peripherals.



Above: An FMB210 installed within a laminar air flow cabinet.

Right: An FMB210 fed by a bottle unscrambler unit.

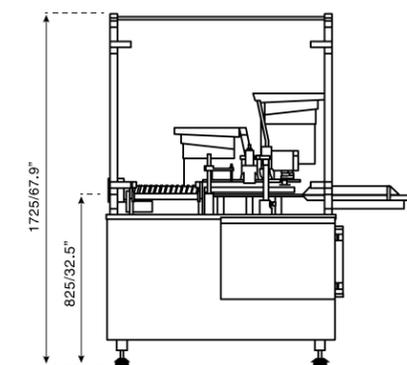
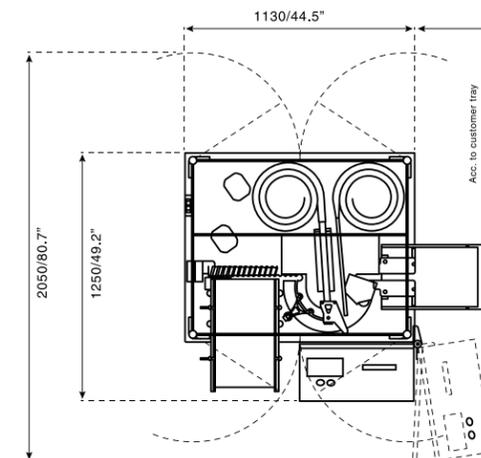
- **Ophthalmic and diagnostics: filling, dropper insert and precise electronic screw capping better than ± 10 Ncm (± 0.9 lbs/inch). Pneumatic screw capping is optional for higher throughput**
- **Aseptic filling of injectable drugs: filling, stoppering and roller closing of crimp caps**
- **Compact design means a small footprint that fits inside small cleanrooms**
- **Up to 75 units/minute: depending on type of cap, vial size and fill volume**
- **Completely closed peristaltic filling system ensuring no cross-contamination**

A filling machine and single-use fluid path from one supplier makes validation easy and prevents costly overfilling



Handles a wide range of containers and closure types

Modular design allows for customised infeed, outfeed and capping technology



Dimensions in mm/inch



Build custom production-scale filling systems of your own

Many filling machine manufacturers have already successfully incorporated Flexicon solutions into their filling lines, thereby adding value to their product and increased satisfaction from their clients.

- Full flexibility in fill volumes
- Prevent spillage between fills, foaming and splashing
- Fast changeover
- High filling accuracy reduces fluid costs
- Global support and high quality filling accessories

OEM applications include:

- Existing filling lines where piston pumps need to be replaced
- New high capacity filling lines for the biotechnology and pharmaceutical industries
- Filling lines for awkward shaped bottles for the diagnostics industry



Trolley solutions are supplied for integration into new or existing filling lines fitted with up to sixteen peristaltic fillers



Master controllers

Master controllers, such as the MC100 and the MC12, can control up to 16 pumps on a filling line. We supply stand-alone controllers, panel mounts and controllers for communication with filling line systems via PROFIBUS or DeviceNet. The MC100 receives filling data through an industrial fieldbus, calculates operating values for the fillers then transmits those through a FlexNet protocol to the fillers.



MC12 control unit with multiple PD12 fillers

The unit fulfils all the usual requirements and can be extended to include several filling stations, an electronic bottom-up fill system, a printer, a direct link to a balance for dynamic recalibration and more.

The MC12 master controller is capable of doing an automatic recalibration.

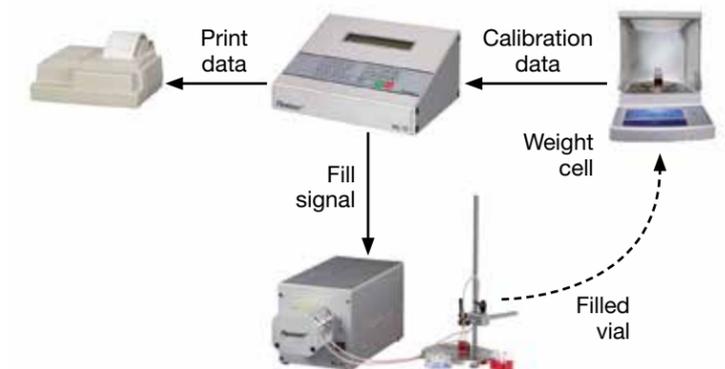
By connecting a load cell (balance) to the MC12, every data point is used to dynamically recalibrate without need for user input.

The PD12 filler is available in several versions as a stand-alone unit or for panel mounting. Panel mount versions can be ordered for vertical or horizontal integration and with a pump head in either anodized aluminium or in stainless steel.

Parallel Production Set-Up



Dynamic Recalibration Set-Up



asepticsu single-use fluid path technology

asepticsu™ is a sterile, single-use fluid path designed and developed by Flexicon. The combination of asepticsu and the gentle pumping action of Flexicon's peristaltic technology increases yield, lowers risk, and helps to reduce time to validation.

asepticsu simplifies your cleaning validation

asepticsu is a USP Class VI single-use fluid path that is fully traceable from end-to-end and is simple to validate. From the bag, to the tubing, through the pump, to the filling nozzle, asepticsu provides a fully assembled and lot traceable single-use wet end.

asepticsu is manufactured in our ISO Class 7 cleanrooms then pre-sterilised using a validated gamma irradiation process and double-bagged ready for use.



asepticsu enhances a complete filling system, such as the FPC50W (see page 16)

asepticsu



asepticsu single-use fluid paths matched with Flexicon fillers guarantee:

- Lower cost and time to validation
- Elimination of risk of contamination
- Prevention of costly over-filling
- Efficient production of small batches of product



Accusil precision tubing prevents costly overfilling

Accurate and consistent dispensing requires having the right tubing inside the right pump. Accusil™ is manufactured in our state-of-the-art extrusion facility to the highest quality, with a consistent wall thickness and a specific hardness for optimal tubing restitution.

Accusil fulfills biopharmaceutical requirements and is ideal for single-use filling

- Full biopharmaceutical compliance with USP Class VI, Ph. Eur. 6.8 Chapter 3.1.9, ISO 10993 and FDA CFR 177.2600.
- Industry leading validation pack available
- 100% traceability with laser-etched lot number, product specification and use-by-date
- Manufactured in an ISO 14644-1 Class 7 environment at state-of-the-art tubing production facility
- Double-bagged for protection against contamination



Accusil is manufactured and packaged in an ISO Class 7 cleanroom and is laser etched for 100% traceability

ACCUSIL



- Post-cured after extrusion for superior purity
- Fully sterilisable by gamma radiation, autoclave or ethylene oxide
- Animal Derived Content Free

Reduce your costs and increase your productivity with Accusil

- Excellent filling accuracy on PF7 and PD12 peristaltic pumps
- Tubing sizes for fill volumes from less than 0.2 ml up to more than 250 ml
- Short and reliable delivery time. Even for larger quantities

