

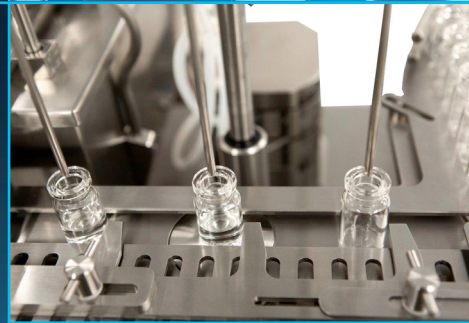
FPC50

FILLING, STOPPERING AND CAPPING MACHINE

- Filling machine and single-use fluid path from one supplier
- High accuracy from less than 0.2ml up to 100ml
- Optimum protection of liquid and operator
- Fast and easy changeover between batches
- First class documentation



WORLD LEADERS IN ASEPTIC PERISTALTIC FILLING



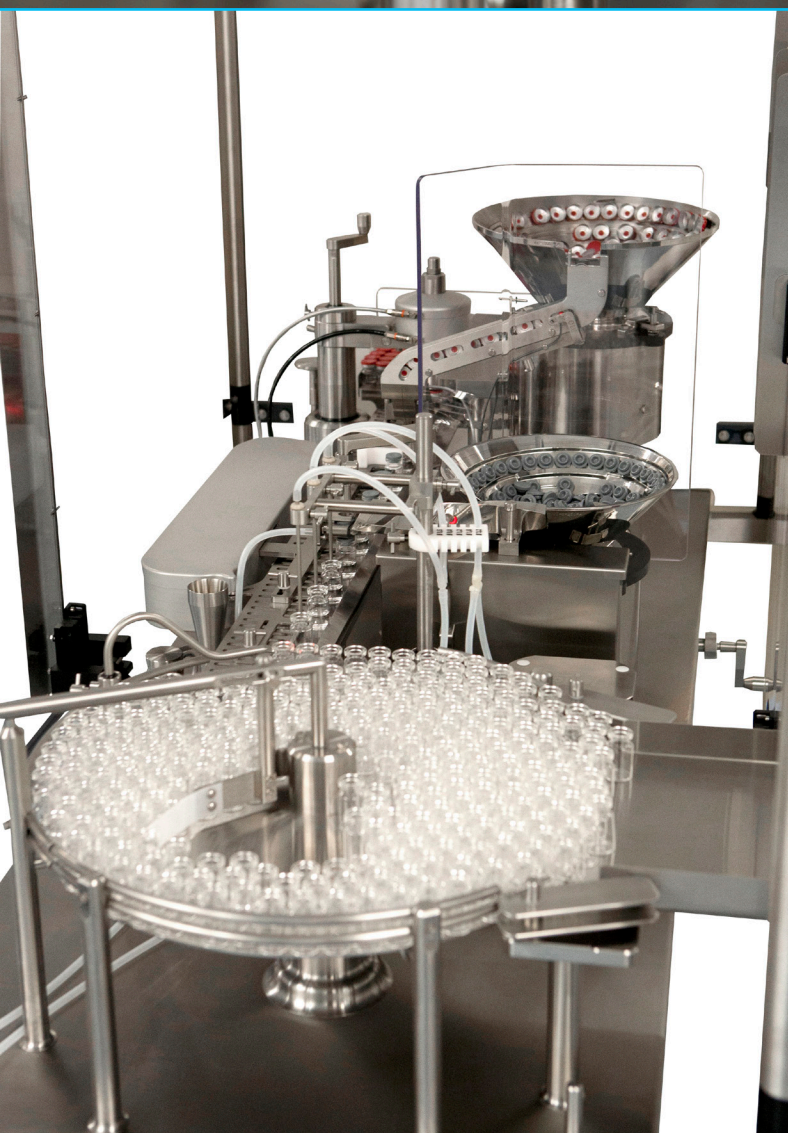
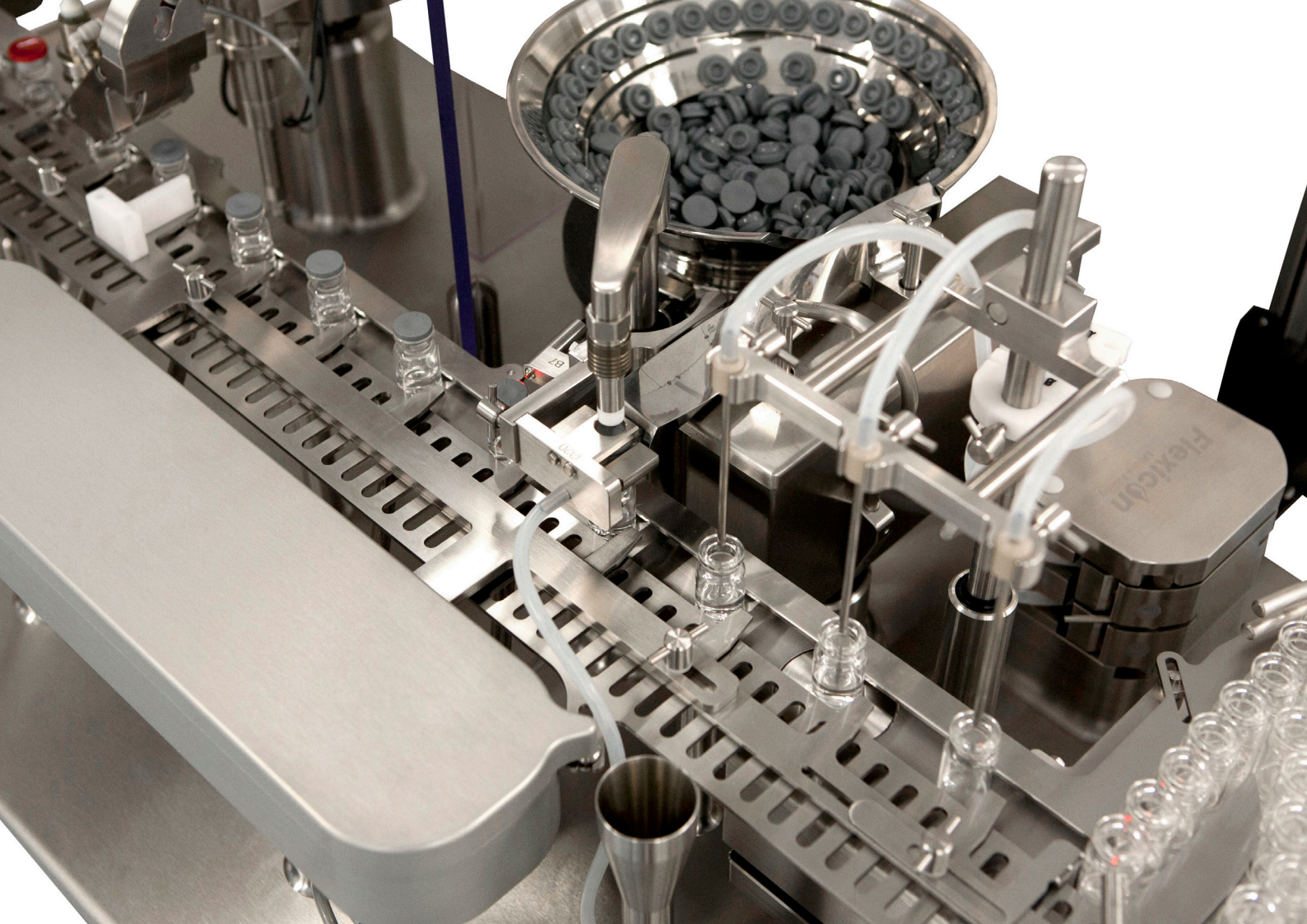


Photo supplied courtesy of the National Institute for Bioprocessing Research and Training (NIBRT), showing their world class facility in Dublin.



FPC50 offers superior filling technology with optional in-line 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 inline 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.

Excellent filling accuracy can be obtained on fill volumes from less than 0.2ml to 100ml

The entire fluid path is designed for single-use, making cleaning validation extremely simple and permits fast changeover between the various liquids to be filled.

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.

Changeover 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.

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

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.

The FPC50 is a modular system and can be customised according to customer requirements. A wide range of modules for infeed, outfeed, guarding, gas purging, particle counting, UDF hoods and solutions for integration into a RABS or an isolator are available. Please contact your local product specialist for further information. Modules illustrated in this brochure might not be included in all quotations/projects.

- High accuracy filling from less than 0.2ml up to 100ml with no splashing, dripping or foaming
- Fast and easy changeover between batches
- Universal format parts reduce costs and increase flexibility
- Small footprint and easy access to all areas of the machine
- Optional in-line check-weighing
- Modular system with very reliable delivery times
- Disposable aseptic fluid path ensures simple cleaning validation
- Fluid path and filling machine from one supplier provide optimum performance
- 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
- Customisable for integration into a UDF hood, a RABS or an isolator

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 2R and 100H.

Format parts for stoppers consist only of a vibrator bowl, chutes, jaws and pistons. The vibrator bowl for the stoppers can be applied for both 13mm and 20mm injection and lyophilisation stoppers.

In a similar manner format parts for crimp caps consist of a vibrator bowl, chutes and crimping heads. For the crimp caps the same vibrator bowl can normally be applied for both 13mm and 20mm caps.

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.

Vials can be loaded into the machine from a removable infeed tray on the front or on the left side of the machine. Collection of filled vials takes place on a removable tray.

Operator interface is an easy-to-use touch screen and a keypad.

FPC50 has integrated support of nozzles for gas purging before and after filling of liquid. Also, a stand for holding a single-use fluid path with a 1, 5 or 10 litre bag is an integrated part of the machine.

In-line check weighing is optional and the balance is fully protected against transfer of vibrations from the machine cabinet.

A standard FPC50 is designed for use under a UDF hood or inside an open RABS. However, a wide range of modules are available for maximum protection of product and operators. That is, modules allowing for a customised integration into a closed RABS or an isolator.

Optional:

- Infeed suitable for nested vials
- Balance for in-line check weighing
- Probe for particle counter near open vials
- Valve for gas purging of vials before and after liquid filling
- Gas purging below stopper prior to insertion into a vial
- Guarding extended to an existing UDF unit in ceiling
- Chutes in guarding for easy refilling of stoppers and caps
- Interlocks on guarding
- Guarding between capping, stoppering and filling stations with "mouse holes" for vial transfer
- Open RABS with integrated UDF
- Machine cabinet modified for integration into closed RABS or isolator from preferred partners
- C-lock software for protection of batch reports, data on SQL database or recipes from being changed or deleted
- Extended outfeed for removable trays or connection to a conveyor belt
- IQ/OQ protocols and test
- Fluid path assemblies or components suitable for accurate filling of a wide range of fill volumes

Applications:

- Filling, full stoppering of injection stoppers and crimp capping.
- Filling and partial stoppering of lyophilisation stoppers
- Crimp capping

Vials, stoppers and caps :

- 2R-100H vials with diameter from 16mm to 52mm
 - 13mm and 20mm injection and lyophilisation stoppers
 - 13mm and 20mm flip-off aluminium caps and/or plain aluminium caps
- Dimensions according to ISO8362 1-7. Samples to be sent to Flexicon prior to final quotation.

Filling volume:

From less than 0.2ml to 100ml

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 25 vials per minute for 1ml fill in a 6R vial (without in-line check weighing)
 - Up to 14 vials per minute for 1ml fill in a 6R vial (100% in-line check weighing)
- Capacity with or without check weighing will depend on fill volume and vial size

Filling accuracy:

Better than $\pm 1\%$ at constant suction level and a viscosity like water is the acceptance criteria during factory acceptance test.

Mains:

110/230VAC – 50/60Hz. The power supply must have an automatic power switch and permanent protective earth (PE) suitable for equipment containing frequency inverters in accordance with the applicable national safety regulations.

Power consumption:

Max. 1200W

Air supply / pneumatic connection:

Clean and dry air according to ISO 8573-1:2010 (1.4.2). Min. 0.5 - 0.77MPa. An air filter and drain must be mounted close to the equipment (Not included)

Air consumption:

Max. 100 litres per minute

Materials:

AISI304, AISI316L, anodised aluminium, polycarbonate and PTFE. Stopper contact parts in AISI316L and PTFE.

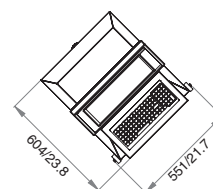
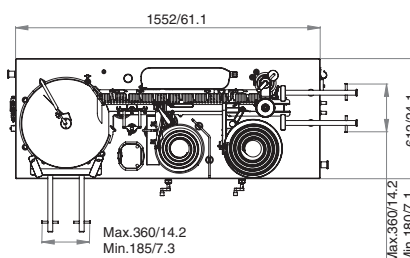
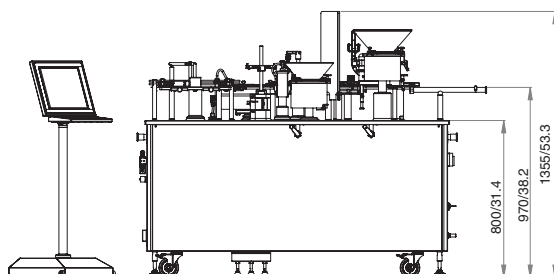
Interface:

- USB for printer, mouse, external hard disc, USB memory stick or similar
- Ethernet connection is available to connect the FPC50 to a local network or as Internet connection for remote support
- 2 x external connections for ready/error signals from for example a particle counter, a UDF unit or a RABS

Weight:

- 400kg - 600kg

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



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