

Equivalency Statement

PF6 and PF7

Background

Flexicon Liquid Filling launched the PF7 peristaltic filler as a replacement to the PF6 peristaltic filler on 11 December 2017.

The PF6 peristaltic filler will still be available until 30 March 2018, when it will be discontinued. Flexicon will continue to support the PF6 for seven years after the discontinuation date above.

The PF7 peristaltic filler presents a range of improvements, including an HMI with a large intuitive colour display, USB connectivity to balances for error free calibration input, and user login with PIN protection.

The following statement is to demonstrate equivalence of the PF7 peristaltic filler and PF6 peristaltic filler in terms of performance, functionality and connectivity. The statement also communicates the additional functionalities and the change in communication structure of the PF7 peristaltic filler in comparison to the PF6 peristaltic filler.

Equivalence

Peristaltic performance

The PF7 continues to use the same pumphead as used on the PF6. The pumphead has received a few minor updates to improve usability and operation in conjunction with the PF7 as follows

- The mounting of the pumphead has been updated to enable removal and replacement from the drive without the need for opening the case work
- The Tube Bridge used on the pumphead now incorporates 3 reed switches, these enable the PF7 drive to detect the tube bridge and prevent operation without it being correctly installed
- The pumphead surface treatment has been updated to align with the PF7 drive, this results in a slight colour variance from the previous pumphead

None of these minor changes has an effect on the functionality of the pumphead, hence these changes do not influence the performance.

The equivalence of performance of the PF7 peristaltic filler and the PF6 peristaltic filler is only influenced by the use of an updated motor control in the PF7 peristaltic filler.

The graph below shows the PF7 motor speed through a typical dose compared to a PF6. The graph shows equivalence.

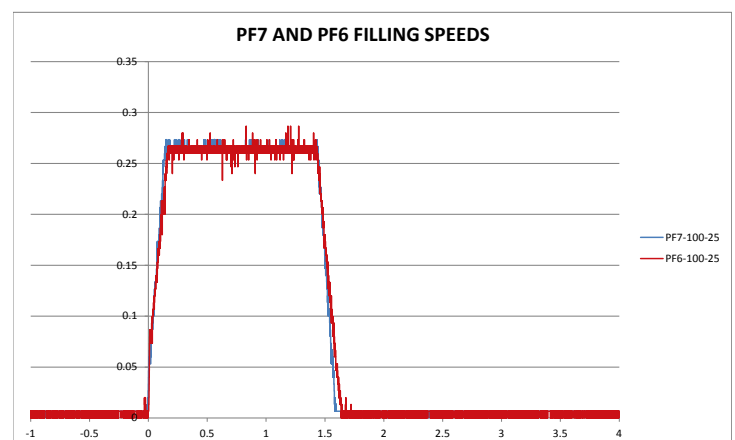


Figure 1: The PF7 peristaltic filler and the PF6 peristaltic filler have been proven to provide comparable acceleration, deceleration and running speed response times

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Filling experiments, filling 30 consecutive samples, with PF7 peristaltic filler in comparison to the PF6 peristaltic filler has shown full equivalence in filling accuracy.

24 ml			0.5 ml			250 ml		
	PF7	PF6		PF7	PF6		PF7	PF6
Ave	23.940	24.018	Ave	0.501	0.500	Ave	250.443	249.820
Std Dev	0.052	0.057	Std Dev	0.001	0.002	Std Dev	0.528	0.695
CV %	0.22%	0.24%	CV %	0.29%	0.38%	CV %	0.21%	0.28%
T-Test	1.1252E-06		T-Test	1.1966E-04		T-Test	2.5703E-04	

Tables showing the average weight, standard deviation, coefficient of variance of 30 consecutive filling on PF7 peristaltic filler and PF6 peristaltic filler filling 0.5ml, 24ml and 250ml. All comparative fillings have been tested for comparison using the T-test resulting in a $P < 0.5$

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Functionality

All existing PF6 functionalities have been retained in the new PF7 peristaltic liquid filler, with additional functionalities added

PF6 Function Number	Function Description	PF7 Function
Existing Functions		
Function 1	Volume	Selectable in Recipe menu
Function 2	Tube diameter	Selectable in Recipe menu
Function 3	Velocity	Selectable in Recipe menu
Function 4	Acceleration/Deceleration	Selectable as separate items in Recipe menu
Function 5	Reversing	Selectable in Recipe menu
Function 6	Batch Size	Selectable in Dispense menu
Function 7	Delay	Selectable in Recipe menu
Function 8	Completed fills	Displayed in the Dispense screen
Function 9	Specific gravity	Selectable in Recipe menu
Function 10	Fills per minute	Displayed in the Dispense screen
Function 15	Input mode	Wiring allows replication
Function 20	Operator	Selectable in Settings menu
Function 21	Batch no	Selectable in Dispense menu
Function 24	Print status	Icon indicates status
Function 29	Print parameters	Selectable in Reports menu
Function 31	Save program	Selectable in Recipe menu
Function 32	Load program	Selectable in Recipe menu
Function 33	Delete program	Selectable in Recipe menu
Function 34	Print program	Selectable in Reports menu (shows if printer attached)
Function 46	Language	Selectable in Settings menu
Function 47	Printer set up	Automatic as USB
Function 72	Volume format	Selectable in Settings menu
Function 80	Reset memory	Selectable in Settings menu
Prime	Button on front	Selectable in Prime menu
Continuous Pump	Pump key	Selectable in Prime menu
Calibrate	Calibrate key	Selectable in Calibrate menu

Table listing the existing PF6 peristaltic filler functionalities with description and similar functionalities in the PF7 peristaltic filler

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Function Description	PF7 Function
New Functions not available on the PF6	
Start delay	Selectable in Recipe menu
End delay	Selectable in Recipe menu
Recalibration reminder	Selectable in Recipe menu
Recalibration pause	Selectable in Recipe menu
Protected recipe	Selectable in Recipe menu
Prime slow	Selectable in Prime menu
Prime fast	Selectable in Prime menu
Multi fill calibration	Selectable in Calibrate menu
Test fill	Selectable in Dispense menu
Filling method	Selectable in Settings menu
Basic mode setup	Selectable in Settings menu
Log in/Log Out	Selectable in Settings menu
Default recipe	Selectable in Settings menu
Prime speeds	Selectable in Settings menu
First calibration value	Selectable in Settings menu
Auto delete	Selectable in Settings menu
Time & Date	Selectable in Settings menu
Sound level	Selectable in Settings menu
Pump info - run hours	Selectable in Settings menu
Pump info - software version	Selectable in Settings menu
Back up and reset	Selectable in Settings menu

Table listing the additional functions on the PF7 peristaltic filler

Connectivity

The connectivity towards the power source and external equipment such as printers, foot switch's and FlexFeed semi-automated filling systems have been updated. The functionality provided when connecting to external equipment has been retained.

Connectivity with a balance has been added to minimise the risk of human typing error when calibrating the fillings.

	PF6	PF7
Printer connection	RS232	USB
Balance connection	n/a	USB
Voltage change	Internal	External
Connection type	5 Pin DIN	(2x) 8 Pin M12

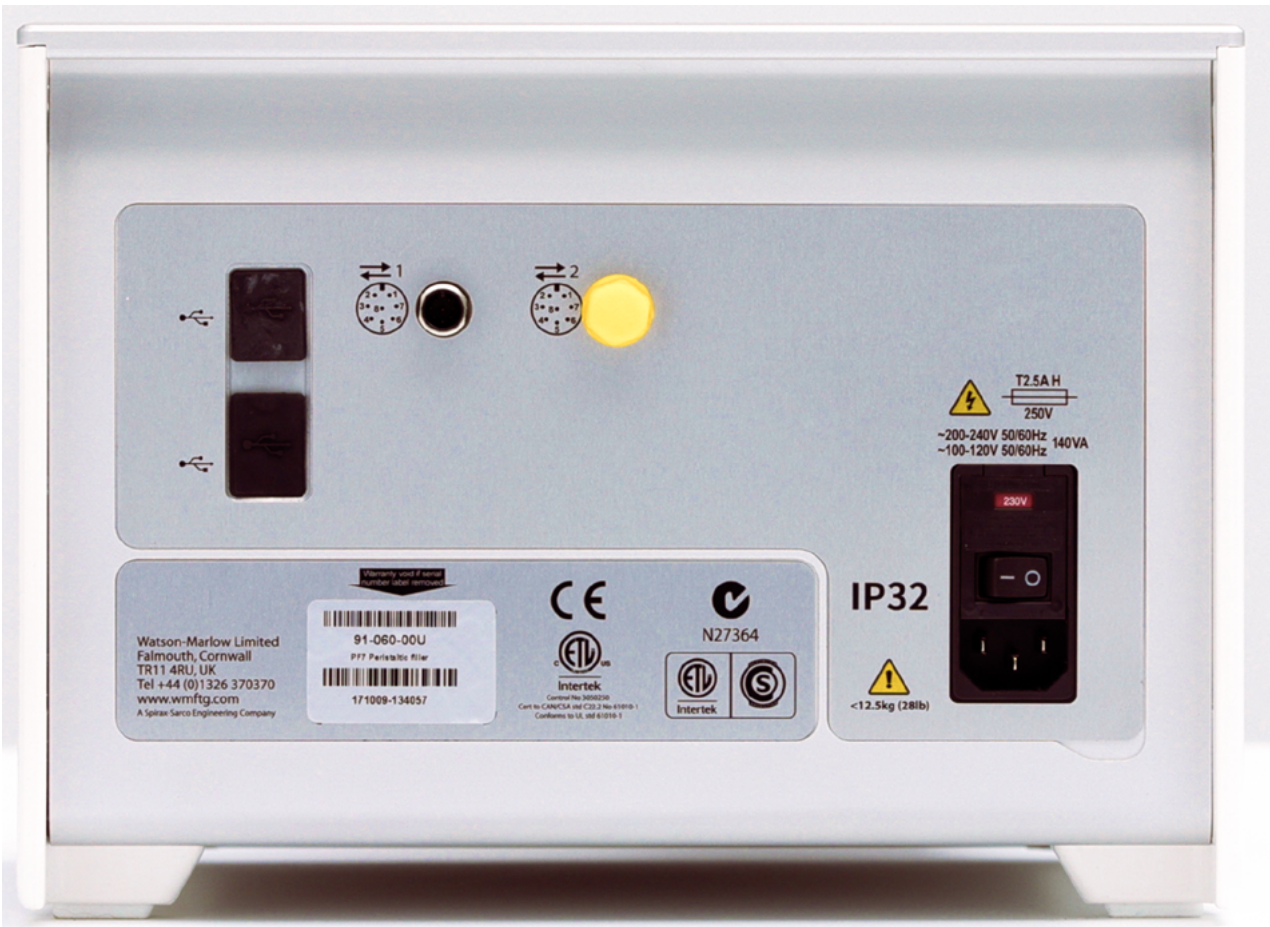
Changes in connectors

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	PF6	PF7	
		Connector 1	Connector 2
Pin 1	Input for start signal (+5 –50 VDC, min 100 mS positive edge triggered)	Discrete output (open drain) [Active when filling (start delay + filling + end delay)]	Discrete output (open drain) [Inactive when filling]
Pin 2	Output +24vDC max 250mA	Voltage output (Active)	Voltage output (Active)
Pin 3	Ground	Input pull-up	Input pull-up
Pin 4	Status Output, Max +24vDC, 100mA	Input [Start (5–24V)]	Input [Prime (5–24V)]
Pin 5	Status Output, Max +24vDC, 100mA	Relay Output [General error]	Relay Output [Paused]
Pin 6	n/a	Relay Output [General error]	Relay Output [Paused]
Pin 7	n/a	Relay Output [General error]	Relay Output [Paused]
Pin 8	n/a	Ground	Ground

Changes in Pin set-up of the connectors for external equipment, excluding printer and balance.



Layout of connectors on the rear of the PF7 peristaltic filler