

# Pressure Infuser Disposable (Single Patient Use) – Lot 1 Nationally Contracted Products (NCP) Customer Report

NHS Supply Chain: Tower 1 Ward Based Consumables



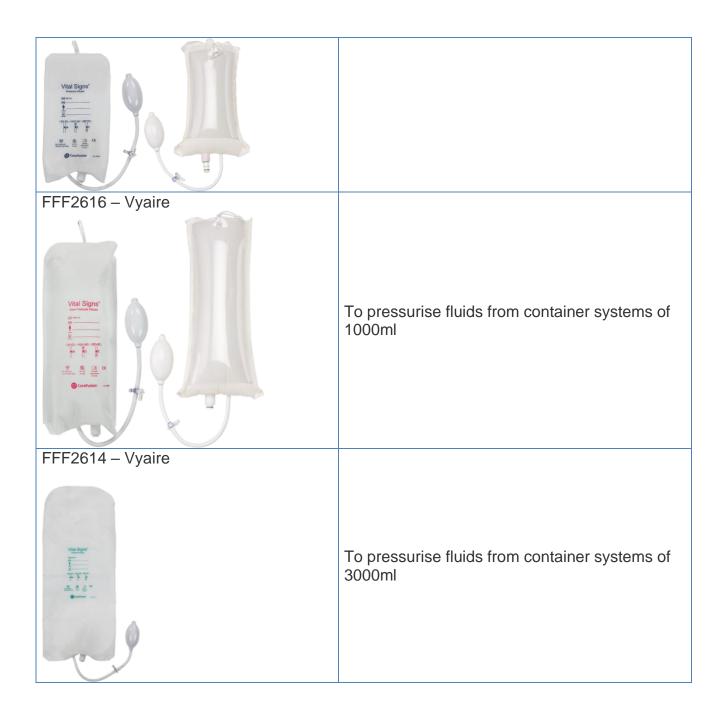


# Pressure Infuser Disposable (single patient use) – Lot 1 FFF939, FFF940, FFF941 and 5 new codes

Product Image (also attach in email*)	Description
FFF393 – Bluebox Medical	To pressurise fluids from container systems of 500ml - Length 16cm +/-20%, Width 13cm +/- 20%, Diameter 25.5cm +/-20% and 1 pint blood bags
FFF940 – Bluebox Medical	To pressurise fluids from container systems of 500ml - Length 27cm +/-20%, Width 11.5cm +/- 20%, Diameter 23cm +/-20%



FFF941 – Bluebox Medical	
	To pressurise fluids from container systems of 3000ml
FFF2613 – Fannin	
	To pressurise fluids from container systems of 500ml - Length 27cm +/-20%, Width 11.5cm +/- 20%, Diameter 23cm +/-20%
FFF2612 – Proact	
	To pressurise fluids from container systems of 1000ml
FFF2615 – Vyaire	To pressurise fluids from container systems of 500ml - Length 16cm +/-20%, Width 13cm +/-20%, Diameter 25.5cm +/-20% and 1 pint blood bags





NCP Code(s)	MPC Code(s)	Size(s)
FFF939	ZIT-500	500ml - Length 16cm +/-20%, Width 13cm +/-20%, Diameter 25.5cm +/-20% and 1 pint blood bags
FFF940	ZIT-1000	500ml - Length 27cm +/-20%, Width 11.5cm +/-20%, Diameter 23cm +/-20%
FFF941	ZIT-3000	3000ml
FFF2613	4010H	500ml - Length 27cm +/-20%, Width 11.5cm +/-20%, Diameter 23cm +/-20%
FFF2612	APPI01000	1000ml
FFF2615	IN800020	500ml - Length 16cm +/-20%, Width 13cm +/-20%, Diameter 25.5cm +/-20% and 1 pint blood bags
FFF2616	IN900020	1000ml
FFF2614	IN950006	3000ml

Indication(s) for use:	Designed to be used with 500ml, 1000ml and 3000ml fluid bags
User instructions:	Instructions for use will be provided with the products or made available on request
Supplier(s):	Bluebox Medical Limited Fannin UK Limited Merit Medical UK Ltd Proact Medical Ltd Vyaire Medical Products Limited
Sustainability:	NHSSC is committed to plan to ensure all NHS Suppliers are carbon neutral by 2045.



#### **Features and Clinical Benefits**

- Front panel allows users to view pressurised fluids and text.
- Durable construction, will not rip or tear.
- Sturdy loop hanger makes it easier to locate onto IV poles regardless of height
- IV fluid bag hook is designed to fit all standard bags and also accommodate the new generation of wider solution bags
- Smooth cuff material offers wipe clean surface
- Durable, easy to read, fully enclosed pressure gauge enables 360 degree viewing from any angle
- Latex-free no allergic reactions

Throughout the NCP programme on-going customer feedback supported by extensive clinical collaboration work led to the evolution of the product specification. A new outputbased performance specification was developed for the two key sizes, 500ml and 1000ml pressure infusers, to ensure the products selected in future are suitable for use in all clinical environments and applications. The specification was supported by defined clinical criteria identified through the engagement process. Submitted products undertook rigorous internal and external clinical product evaluation to ensure that they complied with the specification and would perform consistently in situ in all clinical environments and applications.

This work has resulted in clinically acceptable products. There are significantly different sized fluid bags in the market which impact on the performance of the pressure infuser when in use. In order to address this, the output-based performance specification and testing methodology was developed. Four products were included within the specification. Three of these products concentrated on the delivery of fluids for the sizes 500ml and 1000ml. The awarded products will identify the sizes of fluid bag most suitable for use with each pressure infuser.



## Compatibility

Designed to be used with all 500ml, 1000ml and 3000ml fluid bags.

- 500ml disposable pressure infuser with stopcock valve to pressurise fluids from container systems of 500ml. Length 18cm +/- 20% width 13cm +/- 20% diameter 25.5cm +/- 20%- and 1-pint blood bag
- 1000ml disposable pressure infuser with stopcock valve to pressurise fluids from container systems of 1000ml – AND to pressurise fluids from container systems of 500ml length 27cm +/- 20% width 11.5cm +/- 20% diameter 23cm +/- 20%
- 3000ml disposable pressure infuser with stopcock valve to pressurise fluids from container systems of 3000ml

### Evaluation

- The specification has been built using a strong user input with numerous stakeholders from varying clinical backgrounds.
- The specification has been built using
  - Key product information
  - Technical information
  - o Functional features
  - Product attributes
  - o Human factors
  - o National and International standards for example BSI ISO's
  - o National Guidelines / professional guidance
  - Best practice
  - Clinical Councils
- All available products have undergone evaluations to ensure they meet each of the specification points.
- All products were evaluated against the following criteria.



CE marking evident on individual product packaging

Lot number, expiry date and MPC must be stated on the individual product packaging

The words single use/single patient use/ symbol must be depicted on the product and/or individual product packaging

Products or packaging containing latex or does not contain latex must be labelled on the product line or packaging

Palm fitting pump capable of being used in one hand, for inflation, is present

Air control via thumbwheel or stopcock is present

Colour coded pressure gauge using green and red to show safe pressure range and over inflation respectively

Where IFUs are provided they must be written in English or pictograms

Able to be hung on equipment, for example an IV pole

Ability to see substance contents and fluid levels in fluid bags and containers

Infusers to house 500ml products - Inflation pump must allow inflation into safe pressure range (green band) within 2 minutes

Air control via thumbwheel or stopcock that can be used / reached with users' digit when holding the inflation pump

Individual packaging must be of durable construction preventing tampering and will not tear or rip apart during transportation and storage to avoid damage.

External Laboratory tested against the following criteria:

Criteria applicable to pressure infusers for pressurising 500ml fluid containers only:

Pressure Infusers for pressurising 500ml fluid containers must meet all the requirements in sections 1, 2 and 3 of this Specification and, when inflated to the top of the green band, the pressure infuser must maintain an end of line pressure of at least 200mmHg for:

- 1. 30 minutes on a 500ml fluid container containing 500ml fluid.
- 2. 30 minutes on a 500ml fluid container containing 350ml fluid.
- 3. 30 minutes on a 500ml fluid container containing 150ml fluid.



### Availability

Date available:	1 September 2022
Unit(s) of issue:	Various
Regional/national availability:	Nationally available products
Product example availability:	Suppliers can provide samples upon request with a 3-5 day lead time
Associated delists:	N/A – no delists

All NHS Supply Chain Nationally Contracted Products undergo a rigorous programme of stakeholder evaluation using <u>https://www.supplychain.nhs.uk/capa-framework/</u>, ensuring that products are safe, fit for purpose, value for money, and where possible, innovative.

#### **Further Questions?**

If you have any questions regarding the **Clinical and Product Assurance (CaPA) Framework**, please contact <u>capa@supplychain.nhs.uk.</u>

If you have any questions regarding the **NCP product(s)** or this **NCP Customer Report**, please contact <u>carol.wray@supplychain.nhs.uk</u>.

