

Urgent field safety notice

On HF440, when fifth pump is activated: on syringe pump

Concerned products: All HF440 devices with fifth pump option

Action: Safety Information for syringe pump when using fifth pump

Date: 26 August 2015

Please read this information carefully

Due to a recent incident, we draw your attention about the use of syringe pump, when the fifth pump is activated on a HF440 blood purification machine.

It appears that the differentiation between constant and relative flow to the fifth pump may not be seen on the HF440 device.

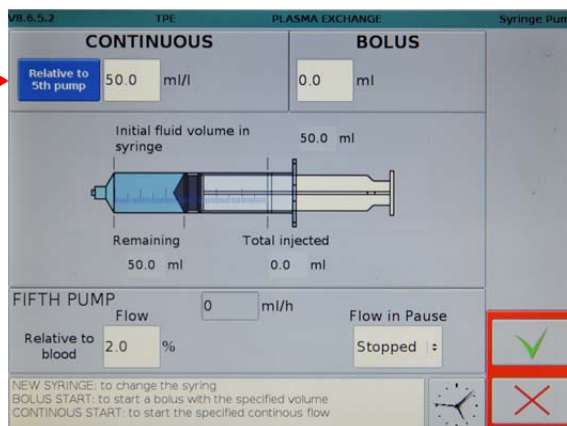
According to the fluid used, in the worst case, this can be lethal for the patient.

1. If you activate the relative flow of the syringe pump to the fifth pump, the screen is as below:

Relative to syringe pump:

50.0 ml/l

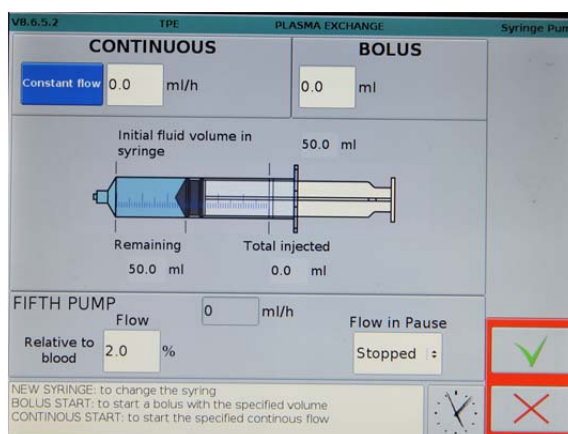
Fifth pump, relative to blood: 2.0%



2. If you press on the **blue button**, the constant flow of the syringe pump is activated and the screen is as below:

The value must be entered again in ml/h

The differentiation is low, **only button text and measurement unit has changed on the screen.**



Double validation is requested

When passing from constant to relative mode, the system is symmetrical.

We thank you to be very careful when using these modes.

A field safety corrective action is planned, to allow Infomed team to improve the user interface in the best delay.