

B. Braun Backcheck Valve Malfunction-June 11, 2024

Reason for urgent medical device correction: Issues with secondary infusions when connecting to the upper y-site of primary set (piggyback infusions) caused by **improper function of the backcheck valve** (valve stuck fully open or fully closed). This is causing:

- Secondary medication backing up into the primary bag
- Inability to prime sets during setup

Tubing affected:

- Primary (3 port) tubing, product # 363430
- TPN (1.2 Micron filter) tubing, product # 363424

BACKCHECK VALVE MALFUNCTION RESOLVED

December 10, 2024

Effective immediately, only the new/unaffected IV tubing with corrected backcheck valve, BB490100 (SH-SS SKU 00084), will be distributed for orders in SH-SS and the interim solution corrective action will not be routinely required by clinicians.

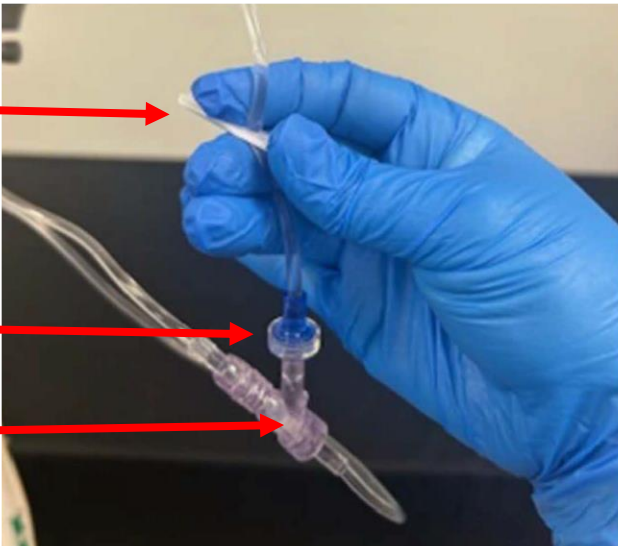
***Note:** Clinical units may still have affected stock (any lot number below 0061939336). Unaffected stock lot numbers are equal to or above this (0061939336), or containing the letters “VL” in the third and fourth digit (i.e. 00VL123456). Be aware that affected stock is still being used in Manitoba and patient’s that are transferred may have affected IV tubing.

Interim solution: When administering secondary medications via piggyback, clamp the primary line above the upper Y-site using the available slide clamp on the primary set (see diagram on page 2). This will require unclamping of the primary line after delivery of the secondary infusion. Set pump for manual “call back” so that it alarms when secondary medication infusion complete (see instructions on page 2). Reminder to flush the line at secondary medication infusion rate prior to resuming primary infusion.

Slide clamp requiring closing on primary set

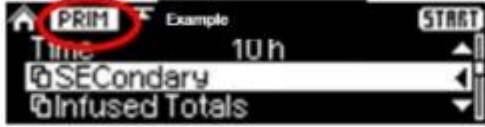
Faulty backcheck valve

Primary line upper y-site




To set pump to manual “call back”:

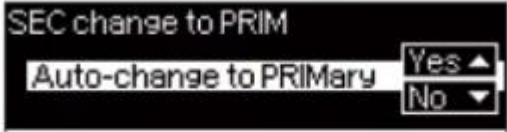
1. Program the PRIMary infusion
2. From the Home Screen, scroll down to locate and select “SECondary”




3. Select “Back to PRIM -- automatic”



4. Answer “No” to prompt “Auto-Change to PRIMary?”



5. You have now activated the Back to Prim manual function



Note: The Back to Prim – manual function will remain active until changed by the end-user.

References:

B. Braun Medical Inc., [Urgent Medical Device Correction, Electric Infusion Pump Administration Set, Single Use Infusomat and Outlook IV Administration Set, Backcheck Valve Malfunction](#), June 11, 2024.

Cancer Care Manitoba [How to activate B. Braun Infusomat Pump Back to Prime – Manual “Call Back”](#), June, 2024.

Concordia General Hospital [BBraun backcheck valve malfunction notice](#), June 21, 2024.