

SAFER PRACTICE NOTICE

Issue: B Braun has issued a voluntary Urgent Medical Device Correction for IV administration sets due to the potential for the backcheck valve to malfunction causing backflow of medication from a secondary infusion (piggyback) into a primary IV line. It may also cause an inability to prime the tubing. The backcheck valve above the upper Y-site used to infuse medication is the affected component. The backcheck valve may malfunction when its valve remains:

- Stuck in the open position resulting in the backflow of medication from the secondary set into primary bag
- Stuck in the fully closed position resulting in inability to prime the IV set

Risks to patients are dependent on many factors such as clinical status, medication, dose and duration or rate of infusion. Although there have been no reports of serious injury or death, **serious injury or death may occur.**

Corrective actions are being implemented by B Braun with the manufacturing of new administration sets, however it is unknown when new unaffected sets will be available. Thus, an interim solution to address this issue has been recommended.

Key Messages:

- Backflow of secondary medication into primary bag results in the intended dose of medication not being delivered (underdosing) or is delivered in a potential rapid or prolonged period of time (overdosing). These risks are dependent on the primary rate of infusion if the clinician is not aware that backflow has occurred.
- If backflow is detected or observed, clinicians will have difficulty quantifying how much of the original infusion has been delivered to patient and what remains in the primary fluid bag.
- If backflow is undetected, medication will be in the line resulting in compatibility risks with any other med administrations and this may affect drug trough levels and decision making on therapeutic drug therapy.
- Inability to prime the IV set can create delays in initiation of therapy while replacement IV tubing set is obtained.
- Discussions have identified variations in IV medication flushing practices can create similar risks to patient health (please see Impact of Antibiotic Underdosing below)
- Risk to patient safety noted with all of the above scenarios

Summary of Facts

- Backcheck valves below the level of the pump have not been identified in this urgent correction notice
- Critical medication infusions should not be infused via secondary methods
- Best practices include giving meds via direct route or “push” based on drug monographs
- B Braun’s “**Back to PRIM**” function, similar to Baxter’s callback feature, currently is programmed to automatic. Therefore, when a secondary infusion is completed, the pump will automatically go back to the primary rate with NO ALARM.
- Changing the **Back to PRIM** function to manual will cause the pump to stop infusing and generate an alarm to alert clinicians once secondary medication programming is completed.

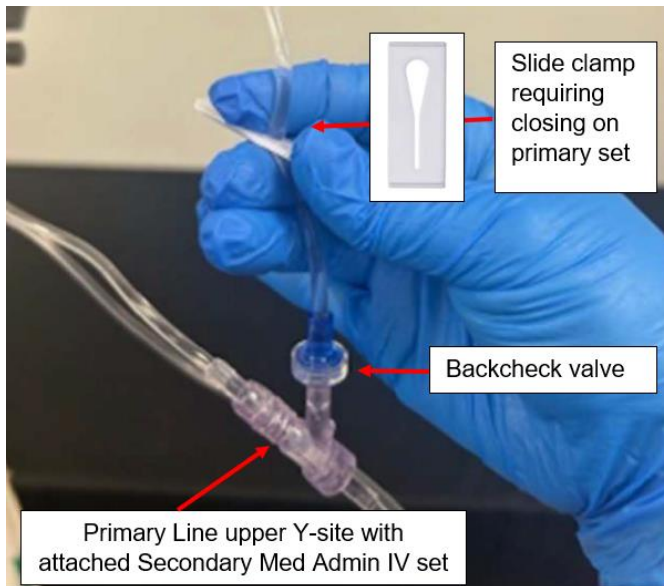
IV Med Flushing Practices and Urgent Correction

Notice for B Braun backcheck Valve

- Changing the **Manual** pump mode will generate an alarm to alert clinicians once secondary medication programming is completed.
- Up to 1/3rd (one-third) of medication will be in the primary IV tubing at the end of the secondary infusion, necessitating a flush be programmed to ensure patients are receiving the full dose of medication.

Immediate Interim Recommended Actions:

- **Clinicians need to close the primary IV tubing slide clamp when Y-site is used for secondary medication administration via pump.**
- Consider priming with normal saline prior to hanging expensive medication that may be discarded/lost if the backcheck valve is closed and you cannot prime tubing set. Please note, Cytosets and straight sets (which do not have ports) are not affected by this current correction notice.
- Review steps for programming a flush for intermittent medications



Immediate Interim Measures for Patient Safety

1. Clamp primary line using slide clamp when delivering meds by secondary infusion sets via pump
2. Change pump programming mode to Manual (see instruction below) for an audible alarm when secondary med total VTBI is completed
3. Program a med flush, up to 1/3rd (one-third) of the dose remains in the primary IV line
4. Unclamp the primary IV tubing and Press **Start** to infuse the **PRIMary** line

Note – secondary med infusions programmed at a rate 300ml/hr or more already required the clamping of the primary infusion line to prevent concurrent flow.

How to change the pump setting to “Manual”

- 1.) Enter the **Secondary** menu
- 2.) Arrow down to the setting **Back to PRIM**
- 3.) Press left arrow key to change setting to **Manual**
 - When the left arrow key is pressed the pump asks “Auto-change to **PRIMary**?” Up arrow for Yes or down arrow for No. Select “**No**” for Manual.

Note – The pump will remain in manual mode until changed by a clinician or at any scheduled maintenance (such as pump upgrades or visits to clinical engineering)

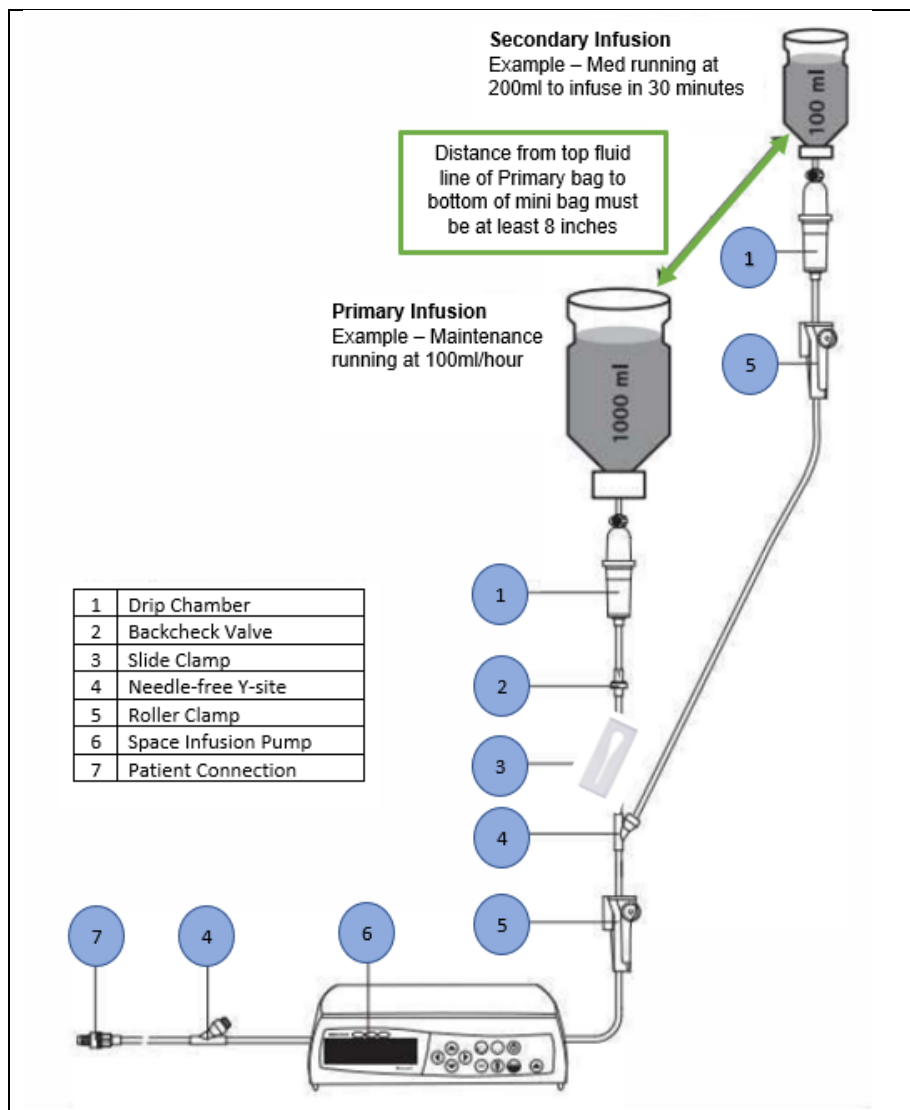
- 4.) Program **SEC**ondary infusion using drug library and ensure primary IV tubing is clamped
- 5.) Infuse medications and when **VTBI** reaches 0 the pump will stop infusing and alarm to notify clinician that the **SEC**ondary is complete.
- 6.) Program a medication flush
- 7.) Arrow up on **SEC**ondary home page and use the left arrow to resume **PRIMary** infusion
- 8.) Unclamp the primary IV tubing and Press **Start** to infuse the **PRIMary** line

About the Impact of Antibiotic Underdosing

Did you know that up to 1/3rd (one-third) of the total prescribed IV dose of medication remains in the line once the mini bag is emptied? When infusion practices do not include standards for flushing medications, underdosing may occur (incomplete administration of a drug to a patient). Underdosing can result in not achieving therapeutic levels required to treat infections and contributes to drug-resistant infections or superbugs and can result in serious harm or death to patients.

Line flushing is described as the act of pushing an appropriate solution through the IV tubing connected to patients to deliver the full dose of medication. Flushing at the same rate as the medication was being infused is important to avoid rapid infusions (risks for adverse reactions to drug therapy) or delayed delivery with a slower IV rate (subtherapeutic effect, may impact trough levels, risk of drug incompatibilities if additional drugs infused in IV line).

<https://www.pslhub.org/learn/patient-safety-in-health-and-care/medication/medication-administration/antibiotic-underdosing-and-disposal-in-nhs-organisations-across-great-britain-20-november-2023-r10473/>



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For more information on this Safer Practice Notice please contact your clinical leadership.

Safer Practice Notices are issued by the Provincial Patient Safety Team in collaboration with Regional Clinical Practice Leads. The purpose of the notice is to communicate recommended changes as a result of events that have been reported and investigated.

