

End-User Alert

B. Braun Infusomat® Space® Pump Admin Sets

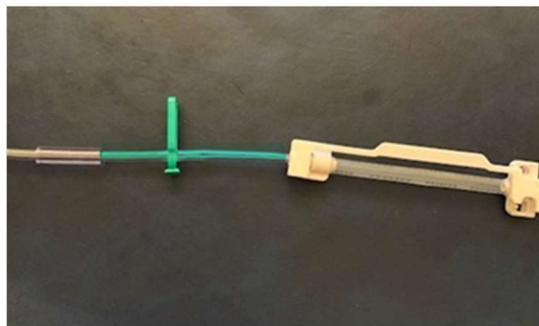
This information is provided in line with the recommendations from B. Braun Urgent Medical Device Correction Notice dated Oct. 23, 2023. The purpose is intended to support end-users until such time that replacement products are available.

Product affected: All Infusomat Space Pump Administrative Sets manufactured between January 1, 2022 and August 17, 2023. (Lot numbers equal to or higher than 0061902124 are NOT affected)

Reason for Correction Notice: Sets within the lot number range, **MAY** have tubing with varying outer diameters and/or length too short resulting in a need to stretch the tubing to properly fit with the Pump. This may result in possible false air-in-line alarm.

To mitigate any patient risk, End-Users should adhere to the following:

1. **If an alarm is ringing on the pump, always respond to the alarm by checking your patient first, then the pump and if it does not clear after following all the steps you were trained on. (See #5 reference list below).**
2. **Inspect tubing before use.** Do not use tubing with a noticeably smaller outer diameter or which needs to be stretched to fit within the Infusomat® Space® Pump.



- a. Inspect outer diameter of the tubing segment just to the left of the silastic tubing segment (highlighted in green) prior to use, looking & feeling for variation in the tube diameter (i.e.: tubing will be wider/narrower in some sections, inconsistent).
 - b. Pay attention to the length of the same segment, if you have to stretch the tubing to load it, then it is too short, do not use it.
3. When infusing high risk medications (e.g. vasopressors) or infusion with acute clinical effects (e.g. electrolytes):
 - a. If possible, have a second pump with an administration set available for exchange in the event of a false alarm and:
 - Swap out pump with another from your site's/program's supply;
 - Send alarming pump to your site Biomed/Clinical Engineering Department; and

- Submit Occurrence Report (e.g. RL6) following your site's patient safety occurrence reporting procedure.
 - b. If a second pump with an administration set is not available have a second administration set available for exchange in the event of a false alarm
 - c. Additional patient monitoring is required
4. If there is a false alarm and changing the administration set is not an option, wipe the administration set with 70% isopropyl alcohol as direction in Appendix A of the Alert. This may improve coupling between the administration set and air sensor allowing the infusion to continue.
5. In addition to above measures:
- Tips to Prevent Air-in-line: [<link to tip sheet>](#)
 - B. Braun Tips Sheet: Air-in-Line: [<link to tip sheet>](#)
 - Managing Air-in-Line Video: [<link to video>](#)
 - B. Braun Tips for Nurses, includes information on all alarms: [<link to tip sheet>](#)

Appendix A

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Isopropyl Alcohol Application to Administration Set

Instructions on wiping Infusomat® Space Administration sets with 70% Isopropyl Alcohol (IPA) to improve coupling with the air sensor in the event of a false alarm (if air-in-line alarm is encountered with no visible air in the infusion line).

Step 1



Using aseptic technique, open IPA wipe

Step 2



Close the roller clamp and remove the administration set from the infusion pump following the product instructions for use.

Step 3



Using the IPA pad, wipe the segment of the pump tubing between the silicone pump segment and the green, set-based anti-freeflow protection clamp

Step 4



Reinstall administration set into pump from right-to-left following product instructions for use.

Step 5



Close pump door and resume infusion following the product IFU and on-screen prompts.