

MEMO

Date: November 1, 2023

To: Provincial Recall/Alert Notification Network

From: Supply Chain Management Shared Services (SCMSS)

Re: **Notice of Urgent Medical Device Correction – B. Braun Infusomat® Space® Pump Administration Sets Air-in-Line Alarms**

B. Braun Medical Inc. issued a critical notice dated October 23, 2023, concerning the **B. Braun Infusomat® Space® Pump Administration Sets Air-in-Line Alarms**. This notification was distributed to all Service Delivery Organizations (SDOs) that have placed orders for this product. If you did not receive this notice click [here](#)

SCMSS is currently working with B. Braun to determine timelines as to the length of time end users will be required to carry out the interim measures detailed in the notice. All efforts are being made to secure unaffected lot numbers (i.e. product manufactured with the revised specifications). We are unable to confirm the date for when we would receive unaffected lot numbers, however they are not expected until after December 1, 2023 at the earliest with an allocation plan to be determined.

SCMSS will establish direct communication with SDO/Site Material Managers to inform them about the availability of unaffected lots. This enables internal SDO/Site communications, facilitating the implementation of B. Braun's recommendations to redirect products with lot numbers equal to or higher than 0061902124 (unaffected lots) to areas where high-risk medications (such as vasopressors) or other infusions with acute clinical effects (e.g., electrolytes) are administered.

The Notice identifies all “Article Numbers” affected, however not all have been purchased by the SDOs. A cross reference will be provided to the SDO/Site Material Managers so efforts are focused on only the product purchased by the SDOs.

Affected SDOs include:

Health Region/SDO	Site/Program
WRHA	All sites, including Churchill
NRHA	All sites
CCMB	All locations
SHSS	All sites
Shared Health-HSC	All locations
PMH	All sites
IERHA	All sites

In the meantime, please note the following actions and ensure this information is shared amongst your teams as we work together to mitigate any risk while we work through the inventory management cycle.

ACTIONS

Clinical End-Users - When responding to air-in-line:

1. 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. SCMSS has requested a visual tool to assist in this assessment by the end-users.
2. 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
3. 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 Attachment 02 of the Notice. This may improve coupling between the administration set and air sensor allowing the infusion to continue.
4. In addition to above measures, additional resources can be found here:
 - 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](#)>

For update to date information and resources please visit our website at [B. Braun Infusomat® Space® Large Volume Pumps - Shared Health - Health Providers \(sharedhealthmb.ca\)](#)

This includes an End-User Alert Poster to assist in communications at the department level.

If you have any questions, please contact scmss@sharedhealthmb.ca.