

MEMO

Date: September 12, 2023

To: Provincial Recall Notification Network

From: Audrey Mulla, Interim Executive Director, Provincial Supply Chain

Re: **Notice of Recall – B. Braun Infusomat® Space® Large Volume Pumps**

We are aware of a large number of product complaints related to the **B. Braun Infusomat® Space® Large Volume Pumps**. B. Braun has now issued an “Urgent Medical Device Correction” notice for this equipment related to false downstream and upstream occlusion alarms. The B. Braun notice is available [here](#).

Manitoba has a significant number of these pumps in operation at sites and programs across the province. We are working on a provincial response to this recall and will share specific details on the remediation plan (replacement of pump or of faulty sensor) in the coming days, site by site and program by program.

Affected Sites and Programs include:

Health Region/SDO	Site/Program
WRHA	All sites, including Churchill
NRHA	Thompson General Hospital (Spruce House) and Lynn Lake General
CCMB	All locations
SHSS	All sites
HSC	Dialysis Unit only

*Prairie Mountain Health, Interlake-Eastern Regional Health Authority, and HSC Winnipeg (with exception of dialysis) are NOT affected.

We anticipate that the majority of the pumps will need to be replaced, with others requiring replacement of the faulty sensors. Supply Chain Management Shared Service has secured a supply of replacement **B. Braun Infusomat® Space® Large Volume Pumps** with serial numbers that are NOT affected by faulty sensors. These pumps will be distributed over the coming weeks.

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 the remediation plan is being executed. Key messages for managers are forthcoming.

ACTIONS

Clinical End-Users - when responding to air-in-line, downstream occlusion, and/or high-pressure alarms, use the following educational materials:

- 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, including information on Downstream Occlusion: <[link to tip sheet](#)>

If, after taking these actions and the alarm persists, complete the following steps:

- 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.

Attention Clinical Engineering, this is a provincially coordinated response with Paul Prowse pprowse@sharedhealthmb.ca and Chris Rouire CRouire@pmh-mb.ca are coordinating the remediation efforts.

- Health Canada link for more information: [Space Infusion System - Infusomat Space Volumetric Infusion Pump - Canada.ca](#)
- SCMSS Recall and Alert Listing available at: [Recalls & Alerts - All Documents \(manitoba-ehealth.ca\)](#)

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