Shared health Soins communs Manitoba

B.Braun Product Complaint Form:

Infusomat Space Large Volume Pump

Please complete form and forward to your site Material Management Dept. and retain any defective products.

SECTION 1: End-user/department to complete with all available information

Section 1A

Supplier: B. Braun Medical
Contact: Donna Bird
Phone # 519-404-8125
Email Address: donna.bird@bbraun.ca

Section 1B ***Information will be kept confidential****

Individual Reporting Problem: _____

Facility: _____ **Dept:** _____

Phone #: _____ **Ext:** _____

Email Address: _____

Date Complaint Form Completed: _____

PROBLEM: Packaging Labeling X Defective Product Other, specify: _____

Product / Service : B. Braun Infusomat Space Large Volume pump, wireless

SupplierProduct# 8713051U

KN# or Serial #: _____

Date Problem Occurred: _____

Has pump and tubing (if available) been removed from circulation and sent to Biomed Dept? ☐ No ☐ Yes

If yes, provide date if available: _____

IMPACT OF PROBLEM: ☐ Minor (economic inconvenience) ☐ Serious (potential for harm) ☐ Severe (potential for critical incident)

Was RL6 (safety event) submitted? ☐ No ☐ Yes **If yes, provide incident# if available** _____

Details of Problem and Actions Taken to Date:

Please use checklist on following page for "**AIR IN LINE**" or "**DOWNSTREAM OCCLUSION** " alarm complaints. Other problems, please describe:

SECTION 2: ***Material Management***

Section3A

Material Manager _____ **Phone #** _____

Email _____

Reviewed and completed by Mat. Man. prior to submission to SCMSS ☐

Comments:

Material Management / Purchasing Dept. to send completed form via email to SCMSS@sharedhealthmb.ca

To view progress status and resolutions for complaints, please visit the SCMSS Complaint Resolution log:
SCM Product Complaints

***Please note** that additional information may be required to resolve the problem and will be gathered by SCMSS following receipt of the complaint form. Please email SCMSS@sharedhealthmb.ca should you have any questions.*

COMPLAINT #

Use for: "Air in line" alarm.

- ☐ Fluid is at room temperature
- ☐ Drip chamber is ½ to 2/3 filled
- ☐ Tubing is properly loaded
- ☐ IV line primed through pump and injection port sites inverted while primed
- ☐ ASV in place
- ☐ Used prime function to remove the air in the line and infusion restarted (IMPORTANT: DO NOT SELECT "NO" when it asks to prime the air in line. There needs to be an action on the alarm to deactivate it)
- ☐ Alarm reoccurs, use prime function again to remove the air in the line and restart infusion
- ☐ Open door, remove and visualize tubing, tap the tubing section and observe for bubbles
- ☐ No visible bubbles, use Alcohol pad and wipe segment of the tubing between the silicone pump segment and green clamp, reload the tubing and restart infusion
- ☐ Alarm re-occurs, fill out Product Vendor Complaint form. Please note the following info:

Medication: _____

Rate: _____

Date and Time: _____ Lot# of tubing (if possible): _____

KN# or Serial #: _____

Any other details about event not already mentioned:

_____

_____

_____

- ☐ Change the tubing. If possible send tubing to Biomed (HIPPO to Maintenance).
- ☐ Change the pump. HIPPO to Maintenance to send pump to Biomed

Use for: "Downstream Occlusion" Alarm

- ☐ IV site patent
- ☐ Tubing clamps are open, no kinks in tubing
- ☐ ASV in place (no more than 1 ASV in use)
- ☐ Pressure adjusted by recommended 1 increment at a time and infusion restarted
- ☐ alarm reoccurs, steps repeated, door of pump opened and tubing properly loaded
- ☐ alarm reoccurs, change the pump
- ☐ alarm reoccurs, change the tubing
- ☐ if the problem resolves with changing the pump, fill out Product Vendor Complaint Form. Please note the following info:

Medication: _____

Rate: _____

Date and Time: _____ Lot# of tubing (if possible): _____

KN# or Serial #: _____

Any other details about event not already mentioned:

_____

_____

_____

- ☐ Send pump and tubing (if possible) to Biomed (HIPPO to Maintenance)
- ☐ If alarm reoccurs, the resistance is most likely caused by IV site or positional IV.