

**SECTION 1: END-USER INFORMATION**

Name:		Phone no.:		Email:	
Facility:		Dept.:			

**SECTION 2: DETAILS ABOUT THE PATIENT IMPACT**

Date problem occurred:		Product complaint(s) being reported:	<input type="checkbox"/> Pump <input type="checkbox"/> IV Tubing
Seriousness of incident	<input type="checkbox"/> Death	<input type="checkbox"/> Permanent damage or impairment of a body function or structure	<input type="checkbox"/> Potential for death or serious deterioration in state of health
	<input type="checkbox"/> Life-threatening (actual)		
	<input type="checkbox"/> Unexpected medical or surgical intervention		<input type="checkbox"/> Other (specify)
Was a safety event/incident report submitted? (e.g. RL)	<input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, please provide incident #:	
Impact to patient:	<input type="checkbox"/> Delay in treatment	<input type="checkbox"/> Risk for drug reactions/side effects with too rapid of an infusion	<input type="checkbox"/> Interruptions to clinical care due to time required to resolve alarms (e.g. patient assessments, patient turns, dressing changes, support with activities of daily living)
	<input type="checkbox"/> Vital signs compromised		
	<input type="checkbox"/> Risk for infection/introduction of contaminants		
	<input type="checkbox"/> Under dosing of ordered medication/fluids		
	<input type="checkbox"/> Emotional distress		
	<input type="checkbox"/> Other (please explain)		
	<input type="text"/>		
Action(s) taken:	<input type="checkbox"/> Repeated priming to clear air	<input type="checkbox"/> Tubing replaced (triple bag and send to material management)	<input type="checkbox"/> Changed out pump (isolate and send to bioengineering department)
	<input type="checkbox"/> Followed B Braun tips to resolve alarms (Air-in-Line and Occlusion)		
	<input type="checkbox"/> Other (please specify)		
	<input type="text"/>		
Additional details:	Medication/Fluid:	<input type="text"/>	
	IV rate:	<input type="text"/>	
	Other:	<input type="text"/>	

**SECTION 3: PRODUCT COMPLAINT DETAILS**

Pump model information:	B Braun Infusomat, model 8713051U		
What is the pump serial number or asset tag number (e.g.KN #):	<input type="text"/>		
What is the lot number of the product found on packaging? (if known)	<input type="text"/>		
Product expiry date:		Tubing sent to Materials Management	<input type="checkbox"/> Yes <input type="checkbox"/> No

<p><b>Problem with pump being reported:</b></p>	<p>Alarm (please complete IV tubing section for alarm events)</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Air in line – not visible and unresolved</li> <li><input type="checkbox"/> Downstream Occlusion – unresolved</li> <li><input type="checkbox"/> Upstream Occlusion – unresolved</li> <li><input type="checkbox"/> Alarm High Pressure</li> <li><input type="checkbox"/> Accuracy of fluid/medication delivery</li> <li><input type="checkbox"/> Other (please explain)</li> </ul> <div style="border: 1px solid black; height: 100px; width: 100%; margin-top: 10px;"></div>	<p>Battery</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Failure</li> <li><input type="checkbox"/> Did not charge</li> <li><input type="checkbox"/> Other (please explain)</li> </ul> <div style="border: 1px solid black; height: 80px; width: 100%; margin-top: 10px;"></div> <p>Space Station</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Other (please explain)</li> </ul> <div style="border: 1px solid black; height: 50px; width: 100%; margin-top: 10px;"></div>
<p><b>Problem with IV tubing being reported:</b></p>	<p>Select product</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> 3 port set (BB490100)</li> <li><input type="checkbox"/> 2 port set (BB490102)</li> <li><input type="checkbox"/> Non-ported set (BB362035)</li> <li><input type="checkbox"/> TPN Basic 0.2-micron filter set (BB490103)</li> <li><input type="checkbox"/> TPN Lipids 1.2-micron filter set (BB470103)</li> <li><input type="checkbox"/> UV-resistant 0.2-micron filter set (BB470119)</li> <li><input type="checkbox"/> Blood tubing Y-set (BB490105)</li> <li><input type="checkbox"/> Straight blood set (BB8270066)</li> <li><input type="checkbox"/> 0.2 Filtered Cyto-Set (BB35414)</li> <li><input type="checkbox"/> Cyto-Set (BB835817)</li> <li><input type="checkbox"/> Other:</li> </ul> <div style="border: 1px solid black; height: 30px; width: 100%; margin-top: 10px;"></div>	<p>Select problem</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Missing part</li> <li><input type="checkbox"/> Broken port</li> <li><input type="checkbox"/> Leaking</li> <li><input type="checkbox"/> Severed</li> <li><input type="checkbox"/> Crimping</li> <li><input type="checkbox"/> Backcheck valve malfunction</li> <li><input type="checkbox"/> Difficulty spiking blood bag</li> <li><input type="checkbox"/> Other (please specify)</li> </ul> <div style="border: 1px solid black; height: 30px; width: 100%; margin-top: 10px;"></div>

**SECTION 4: MATERIALS MANAGEMENT DEPARTMENT ONLY**

Name:	Phone no.:	Email:
<input type="checkbox"/> Reviewed prior to submission to Shared Health - Supply Chain Management <a href="mailto:SCMSS@sharedhealthmb.ca">SCMSS@sharedhealthmb.ca</a>		
Comments:		

To view progress status and resolutions for complaints, please visit the SCMSS Complaint Resolution tracker: [SCM Product Complaints](#)

COMPLAINT #:	
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