COMPLAINT REPORT

Global Quality Complaint No.: (Fresenius Kabi Canada use only)

If the complaint is related to product, complete Sections 1.0, 2.0 and applicable Sections in 3.0.

If the complaint is related to Medical Device complete Sections 1.0 and 4.0 where applicable

If the complaint is regarding both product and device from Fresenius Kabi Canada, fill two forms: one for product and other for device.

If the filled-in form is a PDF fillable form, save the form to image (jpeg) format and send the jpeg file to canada_product_complaints@fresenius-kabi.com.

☐ **Product** ☐ **Device**

1.0 REPORTER INFORMATION					
Report received via	☐ Email	☐ Fax	☐ Mail	☐ Phone	☐ Verbal
	☐ Social Media	☐ Other (specify):			
Date of Occurrence: (mm/dd/yyyy)					
Reported by	☐ Institution Name:				
	☐ Patient Name:				
Department, if applicable					
Address:					
Phone Number					
Fax Number					
Email					
Wholesalers or Point of Sale that supply the product, if applicable					
Reporter's Account Number, if applicable					
Report completed by:	Name:			Date: (mm/dd/yyyy)	

2.0 PRODUCT INFORMATION (for Product Complaint only)			
Product Name:		Product Code:	
Lot Number:		Expiry Date:	
Sample/picture available?	☐ Yes ☐ No	Number of vials/bags:	
Is sample being returned?	☐ Yes ☐ No	Complaint sample pick-up location and time	
Was product being used by patient/ consumer?	☐ Yes ☐ No If Yes, how many patients and were they treated due to the defect?		
Description of Issue			

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3.0 COMPLAINT DETAILS (for Product Complaint only)
Check all boxes and provide information that apply to your product complaint.
3.1 Coring/Floating Particles
1. When did you notice the particles? ☐ Receiving ☐ Picking ☐ Before accessing bag/vial ☐ During compounding/reconstituting ☐ During storage after compounding/reconstituting ☐ Other (describe): 2. Device used to compound/ reconstitute? Gauge size: Manufacturer Name: Model: 3. Procedure/techniques used to compound/reconstitute (e.g. is the vial punctured in the designated piercing holes on the stopper?)
Are you able to provide sample spike set for our evaluation? ☐ Yes ☐ No (if Yes, send set with the complaint sample)
3.2. Precipitation/Crystallization Complaints
1. What is the warming procedure you used on precipitated vials (regarding temperature, did you do it in bath etc. and how long)?
2. Storage condition of the complaint samples:
3. When did you notice precipitation/crystallization on the vials:
4. Did you notice any cracks or damages to vials?
5. Have you opened or used the vials?

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3.3 Leaking/Broken/Cracked (Note: Refer to gWI-PH-OT-004 for free*flex*® complaints)
1. When was the leak/break/crack discovered (e.g. when received, during reconstitution, etc.)?
2. Is it leaking ☐ inside the overwrap ☐ in the packaging?
3. Where is it leaking and was the bag or vial accessed?
4. If it is a bag and it is used, provide the parameters of the spike set/needle:
5. If it is a vial, do you notice any crack/damage, etc.?
3.4 Vial/Bag Missing Lot Number/Expiry Date, Name, etc.
1. When did you notice the information missing?
2. Was the vial/bag in a package with others? ☐ Yes ☐ No
3. Is the product ☐ opened ☐ used?
3.5 Discoloration of Product
1. When did you notice the discoloration?
2. Describe the color and storage conditions:
3. Is the product ☐ reconstituted or ☐ compounded or ☐ used? If so, provide the composition and volume of reconstitute or solvent:
3.6 Black Oxalert or Missing Oxalert
1. When did you notice the black or missing oxalert (e.g. when receiving the box, during use, etc.)?
2. Are the bags still in outer cover? ☐ Yes ☐ No
3. Did you notice any damages to the side of the bag? ☐ Yes ☐ No If Yes, describe:

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4.0 DEVICE INFORMATION (for Device Complaint only)			
Device Name:	Device Code:		Lot/Serial No.:
Sample/picture available ☐ Yes ☐ No		Number of samples:	Expiry Date:
Is sample being returned? ☐ Yes ☐ No			
Is sample blood, cytotoxic or contaminated? ☐ Yes ☐ No If Yes, provide Serology Certificate:			

4.1 The device contributed to the incident by

- ☐ Agilia Partner software anomalies
- ☐ Device failure (complete Section 4.3 below)
- ☐ Deterioration in its effectiveness (complete Section 4.3 below)
- ☐ Error code/Alarm message
- ☐ Inadequacy in its labeling or instructions for use
- ☐ Pump software anomalies
- ☐ Vigilant MasterMed software anomalies

Description of Issue

4.2 Please check all applicable boxes

- ☐ Deficiency of device found before patient use
- ☐ Error code/Alarm message detected before infusion
- ☐ Error code/Alarm message detected during infusion
- ☐ Error code/Alarm message detected after infusion
- ☐ Incident caused by patient's condition (complete Section 4.4)
- ☐ Incident did not lead to harm because malfunction protection operated correctly
- ☐ Incident occurred because device was not used as intended as described in instructions for use (complete Section 4.3)
- ☐ Software anomalies detected at programming stage
- ☐ Software anomalies detected during infusion
- ☐ Issue not resolved

4.3 Defective Device Information

Frequency of occurrence:	Duration of occurrence:
Experience of the device user:	

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Age of the device:	How often is the device used?
Determination if product used according to directions:	
Previous problem with device:	
Environmental conditions if applicable:	
Parameters of control settings at the time of the reported problem:	
4.4 Defective Device Information	
Number of individuals directly involved in this incident:	
Patient's medical conditions and history if relevant to the issue:	
Injuries, reactions, severity of problem, treatment required:	
4.5 Software Anomaly Information	
Incident encountered:	
Number of individuals directly involved in this incident:	
Did the software incident lead to the pump malfunctioning? ☐ Yes ☐ No	
Injuries, reactions, severity of problem, treatment required:	

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5.0 ADDITIONAL COMMENTS