FRESENIUS KABI

# 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) | | |

| | | | |
|---|---|---|---|
| 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 | | | |

**Global Quality Complaint No.**:

| 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<br>☐ During compounding/reconstituting<br>☐ During storage after compounding/reconstituting<br>☐ Other (describe):<br><br>2. Device used to compound/ reconstitute? Gauge size:<br>Manufacturer Name:<br>Model:<br><br>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<br>(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? |

**Global Quality Complaint No.**:

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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?<br>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<br>If Yes, describe: |

**Global Quality Complaint No.**:

| 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<br>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:

**Global Quality Complaint No.**:

| | |
|---|---|
| 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: | |

**Global Quality Complaint No.**:

## 5.0 ADDITIONAL COMMENTS