

COMPLAINT REPORT

INSTRUCTIONS: (1) Describe the incident or event in *Section A*. (2) For leaking, gastrointestinal, or clogging related issues please also complete *Sections B-D*, as applicable. (3) Add in the complainant (source of complaint) information, onto *Section E*. (4) If patient related, add the patient or user's information onto *Section F*. (5) Add the patient's healthcare provider/caregiver info onto *Section G*. (6) Add the patient's formula and pump information onto *Section H*. (7) Add who to contact if Alcresta feedback is needed onto *Section I*. (8) If available, please indicate if defective samples may be returned to Alcresta and if replacement product is needed onto *Section J*. (9) If you are filling out this form, please enter your contact information onto *Section K*.

Once completed, return this form to Alcresta Quality Assurance < QForms@alcresta.com >

SECTION A - COMPLAINT AND PRODUCT INFORMATION

A1. Complaint Description: *Describe the incident/event which lead up to the complaint in detail*

A2. Event Date: *(On what date did the incident occur?)* Month _____ Day _____ Year _____

A3. Product Name: RELiZORB | **A4. Lot Number:**

SECTION B - LEAKING RELATED ISSUE (LK - Leakage)

Is this a leaking related issue? Yes No *(If 'Yes', please answer B1 – B7)*

- | | |
|--|---|
| B1. Is the leak coming from the feeding tube or extension set connected to the RELiZORB? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| B2. Is the RELiZORB cartridge leaking? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| B3. Is the leaking visible at the initial connection? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| B4. Is the user waking up and finding that it was leaking? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| B5. Is an ENFit transition connector used? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| B6. Has there been any leaking when using the feeding tube or extension set without the RELiZORB? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

B7. Comments:

SECTION C – GASTROINTESTINAL ISSUE (GI – Gastro Issue)

Is this a gastrointestinal related issue? Yes No *(If 'Yes', please answer C1 – C3)*

- | | |
|---|---|
| C1. Are these new symptoms? <i>(If 'Yes', add details in C3)</i> | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| C2. Have symptoms increased with use of RELiZORB? <i>(If 'Yes', add details in C3)</i> | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

C3. Comments:

SECTION D – FLOW RATE/CLOGGING ISSUE (FR – Flow Rate)

Is this a flow rate or clogging related issue? Yes No *(If Yes, please answer D1 – D4)*

- | | |
|--|---|
| D1. Additives to formula? <i>(If 'Yes', specify what was added and the amount in D1a-D1b)</i> | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| D1a. Name of additive(s): _____ D1b. Amount added: _____ | |
| D2. Two (2) RELiZORB used in tandem configuration? <i>(If 'Yes', answer D2a)</i> | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| D2a. Priming through both cartridges? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| D3. One (1) RELiZORB used with more than 500 mL of formula? <i>(If 'Yes', answer D3a)</i> | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| D3a. Primed through the second cartridge when replacing after the first 500 mL? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

D4. Comments:

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SECTION E - COMPLAINANT INFORMATION (Fill in who originated, or the source of the complaint)					
E1. Name:		E2. Title:		E3. Email:	
E4. Telephone:		E5. Address:			
SECTION F – PATIENT/USER AND IMPACT INFORMATION (Complete this section if the issue is patient-related)					
F1. Patient Name:		F2. Age:			
F3. Alleged Device Failure and/or Impact to Patient/User:					
F4. Extent of Patient/User Harm: <input type="checkbox"/> N/A – No Patient / User Harm Reported					
F5. Extent of Medical Intervention Required: <input type="checkbox"/> N/A – No Patient / User Harm Reported					
SECTION G – PHYSICIAN/HEALTHCARE FACILITY CONTACT INFORMATION (Add the patient’s provider info)					
G1. Name:		G2. Title:		G3. Address:	
G4. Telephone:		G5. Email:			
SECTION H – FORMULA and PUMP INFORMATION (Add the patient’s formula and pump info)					
H1. Formula Brand Name / Manufacturer:		H3. Amount of Formula Used:	H4. Pump Model:	H5. Pump Speed / Rate:	H6. IFU was adequate? <input type="checkbox"/> Yes <input type="checkbox"/> No
H2. Formula Lot Number:					
SECTION I – FEEDBACK REQUEST INFORMATION					
I1. Is feedback/response requested for this incident/event? (select one)					
<input type="checkbox"/> Yes (please answer I2 and I3. Alcresta QA will provide feedback/response) <input type="checkbox"/> No					
I2. Respond by Date:		I3. Send Response to (name, phone/email, and best time to contact):			
SECTION J – DEFECTIVE PRODUCT RETURN AND REPLACEMENT INFORMATION					
J1. Is the defective product available for return to Alcresta upon request? <input type="checkbox"/> Yes <input type="checkbox"/> No					
J2. Is a photo of the defective product available? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A					
J3. If defective product is available for return to Alcresta, has the product been used? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A					
J4. Is replacement product requested and the patient/user is enrolled in the RELiZORB Support program? <input type="checkbox"/> Yes (note - you must contact RELiZORB Support Services at 1-844-632-9271 to fulfill this request) <input type="checkbox"/> No					
SECTION K – REPORTER INFORMATION (Enter your information, the preparer of this form)					
K1. Your Name:		K2. Your Title:		K3. Your Email:	
K4. Your Address:			K5. Your Telephone:		
K6. Alert Date: (On what date were you aware of the incident?) Month _____ Day _____ Year _____					

***Thank you for completing this report. Please send to <QForms@alcresta.com>
Alcresta Quality Assurance representative will contact you if additional information or follow-up is required.***