COMPLAINT REPORT (PN 100300/100301)

INSTRUCTIONS: (1) Describe the incident or event in *Section A*. **(2)** Add the administration methods information onto *Section B*. **(3)** For leaking, gastrointestinal, or flow rate related issues please also complete *Sections C-E*, as applicable. **(4)** Add in the complainant (source of complaint) information, onto *Section F*. **(5)** If patient related, add the patient or user's information onto *Section G*. **(6)** Add the patient's healthcare provider/caregiver info 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 (PN 100300/100301)	**A4. Lot Number:**

SECTION B – ADMINISTRATION METHODS INFORMATION

B1. Formula (please provide brand, name, caloric density, flavor) Example: *Peptamen Jr. 1.0 with Fiber, Vanilla*	**B2. Amount of Formula:**	**B3. Pump Model/Name:**	**B4. Pump Speed/Rate:**	**B5. IFU adequate?** ☐ Yes ☐ No	**B6. Formula Lot Number:**
_____	_____	_____	_____		_____

B7. Are you using a y-connector attached to the outlet of the cartridge? ☐ No ☐ Yes (*If 'Yes', add what is added through the y-connector in B7a)* **B7a. Comment:** _____	**B8. Configuration:** ☐ Single ☐ Tandem	**B9. Bolus Feeding Method:** ☐ Push Syringe ☐ Gravity ☐ By Pump **B9a. Duration of feeding**: _____ **B9b. How is flow rate controlled?** _____

B10. If using powdered formula, describe mixing methods. Include supplies used and caloric density (Typically kcal/oz)**:**
_____

SECTION C - LEAKING RELATED ISSUE (LK - Leakage)

Is this a leaking related issue? ☐ Yes ☐ No (*If 'Yes', please answer C1 – C10)*

C1. Is the leak coming from the feeding tube or extension set connected to the RELiZORB?	☐ Yes ☐ No ☐ N/A
C2. Is there visible damage or cracking on the cartridge?	☐ Yes ☐ No ☐ N/A
C3. Is the RELiZORB cartridge leaking?	☐ Yes ☐ No ☐ N/A
C4. Is the leaking visible at the initial connection?	☐ Yes ☐ No ☐ N/A
C5. Is the user waking up and finding that it was leaking?	☐ Yes ☐ No ☐ N/A
C6. Is an ENFit transition connector used?	☐ Yes ☐ No ☐ N/A
C7. Has there been any leaking when using the feeding tube or extension set without the RELiZORB?	☐ Yes ☐ No ☐ N/A
C8. Are connections clean and dry prior to setting up?	☐ Yes ☐ No ☐ N/A
C9. Is anything added to the formula or are non-enteral formula liquids put through the cartridge? (If 'Yes', specify what was added in C10)	☐ Yes ☐ No ☐ N/A

C10. Comments: _____

SECTION D – GASTROINTESTINAL ISSUE (GI – Gastro Issue)

Is this a gastrointestinal related issue? ☐ Yes ☐ No (*If 'Yes', please answer D1 – D3)*

D1. Are these new symptoms? (If 'Yes', add details in D3)	☐ Yes ☐ No ☐ N/A
D2. Have symptoms increased with use of RELiZORB? (If 'Yes', add details in D3)	☐ Yes ☐ No ☐ N/A

D3. Comments: _____

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SECTION E – FLOW RATE ISSUE (FR – Flow Rate)

Is this a flow rate related issue? ☐ Yes ☐ No (*If Yes, please answer E1 – E5)*

E1. Additives to formula? (If 'Yes', specify what was added and the amount in E1a-E1b)	☐ Yes ☐ No ☐ N/A
E1a. Name of additive(s): _____ **E1b.** Amount added: _____	
E2. Two (2) RELiZORB used in tandem configuration? (If 'Yes', answer E2a)	☐ Yes ☐ No ☐ N/A
E2a. Priming through both cartridges?	☐ Yes ☐ No ☐ N/A
E3. One (1) RELiZORB used with more than 500 mL of formula? (If 'Yes', answer E3a)	☐ Yes ☐ No ☐ N/A
E3a. Primed through the second cartridge when replacing after the first 500 mL?	☐ Yes ☐ No ☐ N/A

E4. Identify feeding type(s) or configuration and add comments, as applicable:
☐ Continuous ☐ Bolus (with pump) ☐ Bolus (manual)

E5. Comments: _____

SECTION F - COMPLAINANT INFORMATION (Fill in who originated, or the source of the complaint)

F1. Name: _____	**F2. Title:** _____	**F3. Email:** _____
F4. Telephone: _____	**F5. Address:** _____	

SECTION G – PATIENT/USER AND IMPACT INFORMATION (Complete this section if the issue is patient-related)

G1. Patient Name or Patient ID #: _____	**G2. Disease State:** _____	**G3. Age:** _____

G4. Alleged Device Failure and/or Impact to Patient/User:
_____

G5. Extent of Patient/User Harm: ☐ N/A – No Patient / User Harm Reported
_____

G6. Extent of Medical Intervention Required: ☐ N/A – No Patient / User Harm Reported
_____

SECTION H – PHYSICIAN/HEALTHCARE FACILITY CONTACT INFORMATION (Add the patient's provider info)

H1. Name: _____	**H2. Title:** _____	**H3. Address:** _____
H4. Telephone: _____	**H5. Email:** _____	

SECTION I – FEEDBACK REQUEST INFORMATION

I1. Is feedback/response requested for this incident/event? (select one)
☐ ***Yes*** (please answer I2 and I3. Alcresta QA will provide feedback/response) ☐ ***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? ☐ **Yes** ☐ **No**
J2. Is a photo of the defective product available? ☐ **Yes** ☐ **No** ☐ **N/A**
J3. If defective product is available for return to Alcresta, has the product been used? ☐ **Yes** ☐ **No** ☐ **N/A**

J4. Is replacement product requested and the patient/user is enrolled in the RELiZORB Support program?
☐ ***Yes (****NOTE - you must contact RELiZORB Support Services at 1-844-632-9271 to fulfill this request****)***
☐ ***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.