

# COM.TEC Kit Performance Report

**Important: If reaction or injury has occurred call Fresenius Kabi Product Complaint and Support at 1-800-933-6925.**

Incident Date: \_\_\_\_\_ Instrument S/N.: \_\_\_\_\_ Software Version: \_\_\_\_\_  
 UDI No.: \_\_\_\_\_ Product Code: \_\_\_\_\_ Lot No.: \_\_\_\_\_

**When Was the Problem Detected?**

Set Up     Prime \_\_\_\_\_%     Exchange     Reinfusion     After Procedure/QC

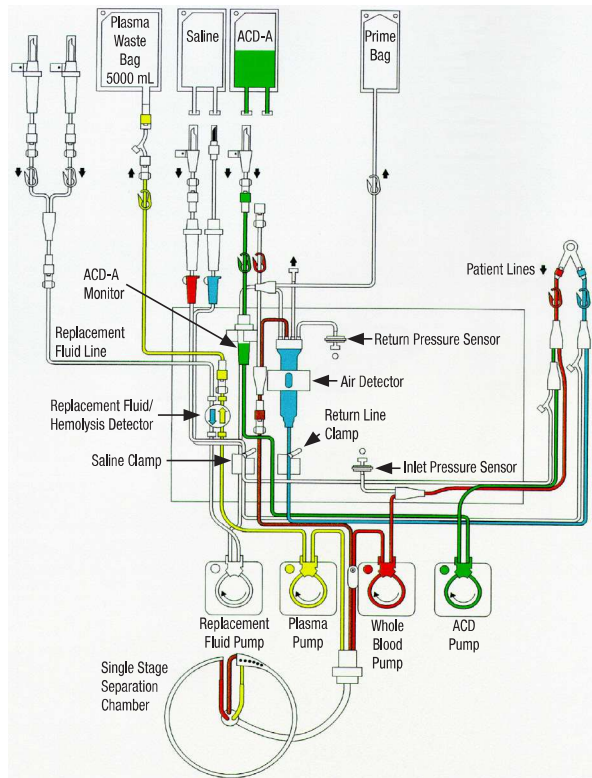
**Problem Type** (Mark all applicable)     Cut/Slice     Kink     Particulate Matter     Restriction/No Flow  
 Alarms (Specify) \_\_\_\_\_     Leak     Separated     Blood Leak  
 Cracked     Excess Air     Missing     RBC Contamination     Other (Specify Below)

**Please answer following questions:**

1. Was there any adverse event or injury, or any therapy interrupted? Yes  No
  2. If applicable, list name of any drug administered: \_\_\_\_\_
  3. Was the procedure successfully completed? Yes  No  N/A
  4. If no, was the procedure stopped due to a soft goods incident? Yes  No  N/A
  5. Was product lost? Yes  No  N/A
- Check box if you do **NOT** wish to receive response letters.

\_\_\_\_\_ E-mail address for letter recipient (if applicable)

**Please circle specific components on the diagram where incident occurred**



**Additional Problem Description / Explanation**

**Kit Return To Fresenius Kabi**

1. Sample available for evaluation? Yes  No
  2. Sample return box needed? Yes  No  Return label only
  3. Picture available for evaluation? Yes  No
- Please e-mail a clear picture **along with this report** to  
**MDComplaintSupport@Fresenius-kabi.com**

**Center Authorized Signature/Date:** \_\_\_\_\_

**Fax this report to 1-888-858-2983 or E-mail to MDComplaintSupport@Fresenius-kabi.com and include a copy of this form when returning a kit.**

**Customer Information (please print)**

**The following information is required to receive a credit**

Facility Name: \_\_\_\_\_  
 Contact Person: \_\_\_\_\_  
 Account Number (if known): \_\_\_\_\_  
 Operator Name: \_\_\_\_\_  
 Street Address: \_\_\_\_\_  
 City/State/Zip: \_\_\_\_\_  
 Phone Number: \_\_\_\_\_  
 Contact Person's E-mail: \_\_\_\_\_