

# LOVO X6R4940A Product Performance Report



**Important: If reaction or injury has occurred call Fresenius Kabi Post-Market Quality Assurance at 1-800-933-6925.**

Incident Date: \_\_\_\_\_ Instrument S/N.: \_\_\_\_\_ Software Version: \_\_\_\_\_ UDI No.: \_\_\_\_\_  
Lot No.: \_\_\_\_\_ Video Jet No.: \_\_\_\_\_

### When Was the Problem Detected?

Before Use    Kit Installation    Disposable Kit Check    Disposable Kit Prime    During Procedure    After Procedure

### Problem Type (Mark all applicable)

**Packaging:**    Packaging Open    Mispacked    Illegible Label    Discolored    Missing or Separated Component (e.g. keeper)

**Tubing:**    Flattened    Kinked    Hole    Cut/Sliced    Blocked/Occluded    Discolored

**Separation Device:**    Cracked    Leaking Fluid    Noise

**Pressure Pod:**    Cracked    Leaking Fluid    Poor Fit on Pressure Sensor Port

**Container:**    Leaking Fluid    Improper Seal around Container Port    Discolored

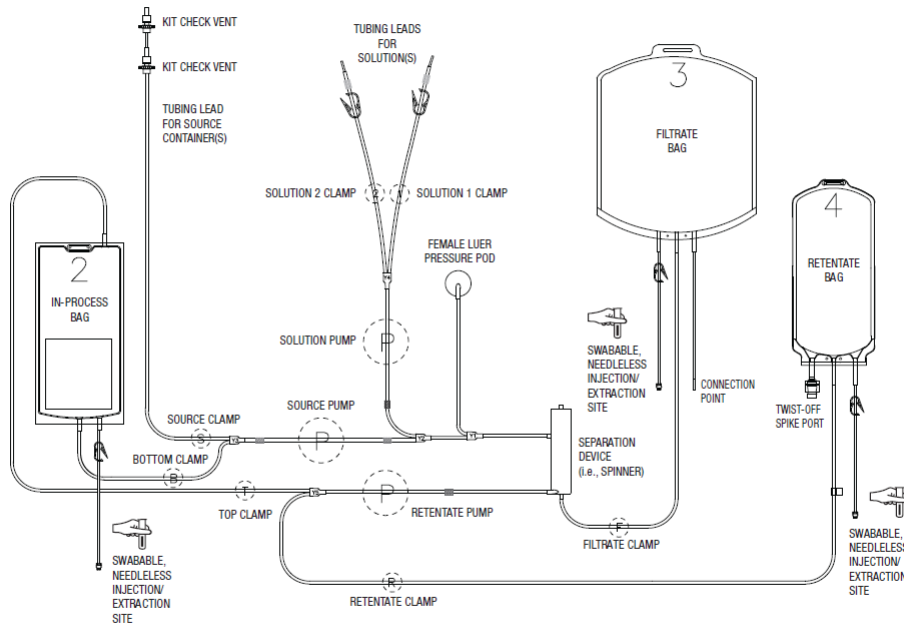
Other: \_\_\_\_\_ Associated Alert Name/Code (if applicable): \_\_\_\_\_

### Additional Problem Description / Explanation

Please circle specific components on the diagram where incident occurred

### X6R4940A LOVO Disposable Kit

#### LOVO Cell Processing Disposable Kit with Dual Kit Check Vents (A)



**Note:**  
Kit layout subject to minor deviations from actual kits.

Picture available for evaluation?   Yes    No

If a picture is available, please e-mail a clear picture along with this report to [mdpmqa.usa@fresenius-kabi.com](mailto:mdpmqa.usa@fresenius-kabi.com)

Continued on Next Page

---

**Please answer the following questions:**

1. Was there any adverse event or injury? Yes  No   
2. Was the procedure successfully completed? Yes  No  N/A   
3. If no, was the procedure stopped due to a soft goods incident? Yes  No  N/A   
4. Was product lost? Yes  No  N/A   
5. Did the procedure involve clinical or patient material? Yes  No  N/A   
Check box if you do **NOT** wish to receive response letters.

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

---

**Kit Return to Fresenius Kabi**

1. Sample available for evaluation? Yes  No   
2. Return label needed? Yes  No   
3. Sample return box needed? Yes  No

**Center Authorized Signature/Date:**

Fax this report to 1-888-858-2983 or E-mail this report to [mdpmqa.usa@fresenius-kabi.com](mailto:mdpmqa.usa@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 Name: \_\_\_\_\_  
Account Number (if known): \_\_\_\_\_  
Operator Name: \_\_\_\_\_  
Street Address: \_\_\_\_\_  
City/State/Zip: \_\_\_\_\_  
Phone Number: \_\_\_\_\_  
Contact Person's E-mail: \_\_\_\_\_