# 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: ____
Lot No.: _____ Video Jet No.: _____

**When Was the Problem Detected?**
☐ Before Use ☐ Kit Installation ☐ Disposable Kit Check ☐ Disposable Kit Prime ☐ During Procedure ☐ After Procedure

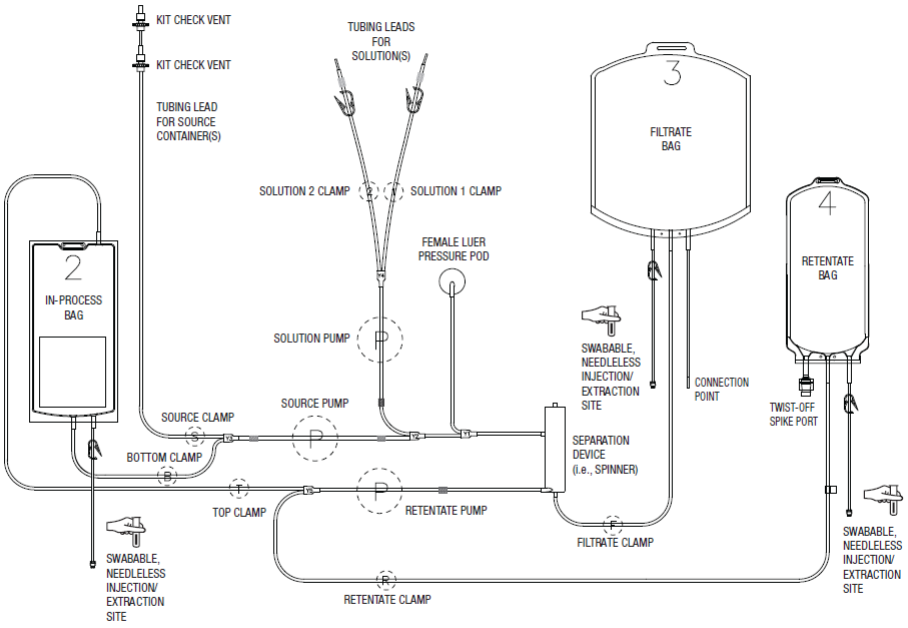
**Problem Type** (*Mark all applicable*)
*Packaging:* ☐ Packaging Open ☐ Mispacked ☐ Illegible Label ☐ Discolored ☐ Missing or Separated Component (e.g. keeper)
*Tubing:* ☐ Flattened ☐ Kinked ☐ Hole ☐ Cut/Sliced ☐ Blocked/Occluded ☐ Discolored
*Separation Device:* ☐ Cracked ☐ Leaking Fluid ☐ Noise
*Pressure 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 MDComplaintSupport@fresenius-kabi.com

# LOVO X6R4940A Product Performance Report

**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 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 Name: _____

Account Number (if known): _____

Operator Name: _____

Street Address: _____

City/State/Zip: _____

Phone Number: _____

Contact Person's E-mail: _____