

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

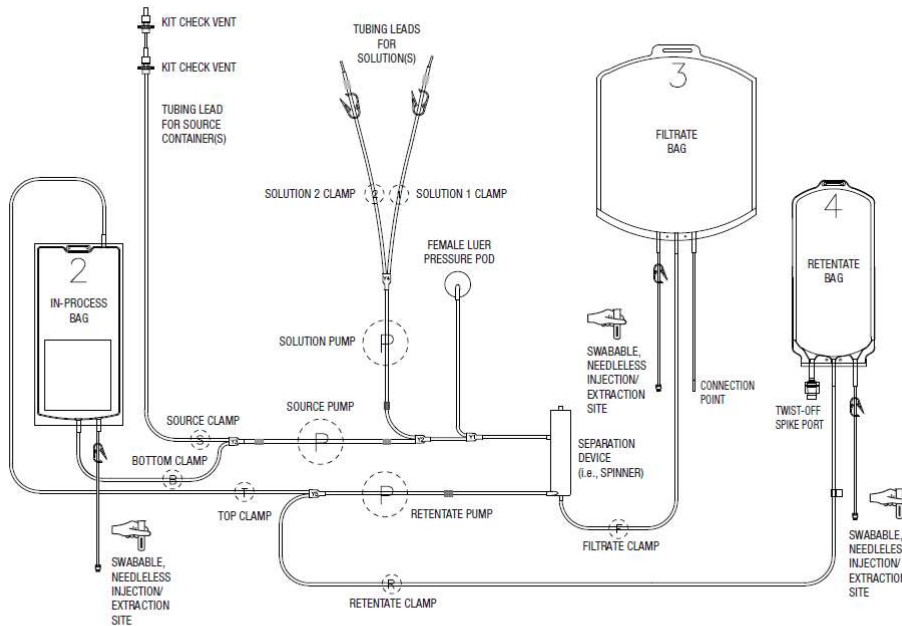
Other: _____ Associated Alert Name/Code (if applicable): _____

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

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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 mdpmga.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: _____