

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

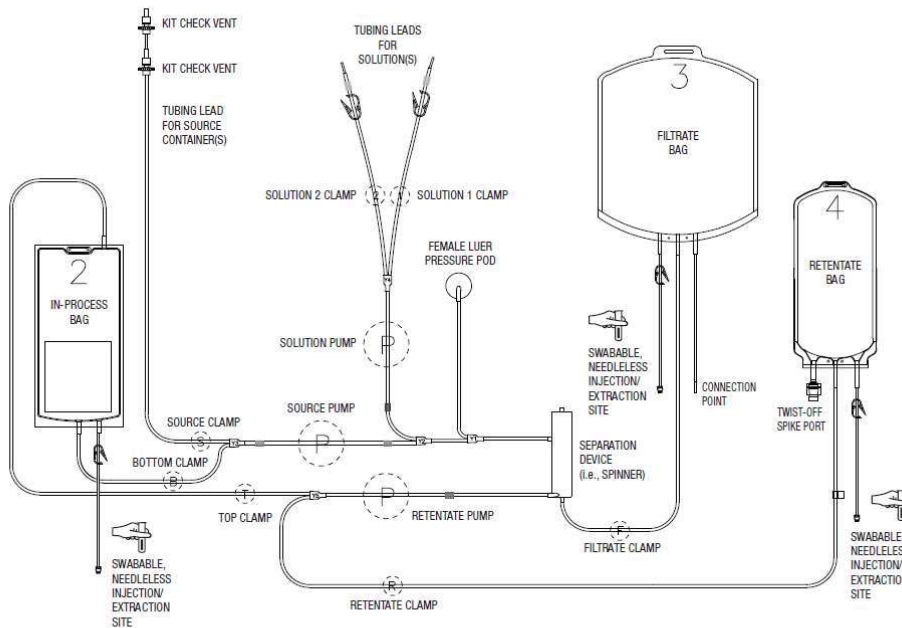
Other: _____ Associated Alert Name/Code (if applicable): _____

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 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: _____