

LOVO X6R4909A 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

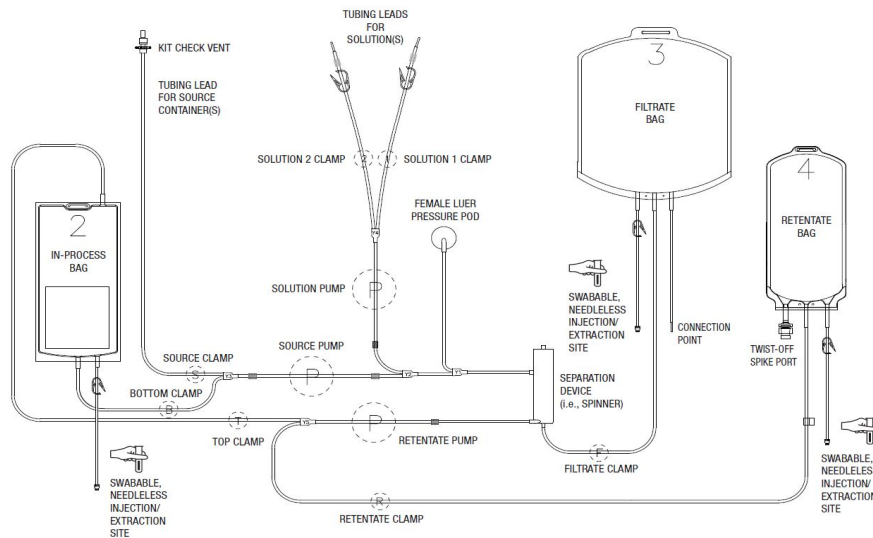
Pressure Pod: Cracked Leaking Fluid Poor Fit on Pressure Sensor Port

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



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

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: _____