LOVO X6R4906 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

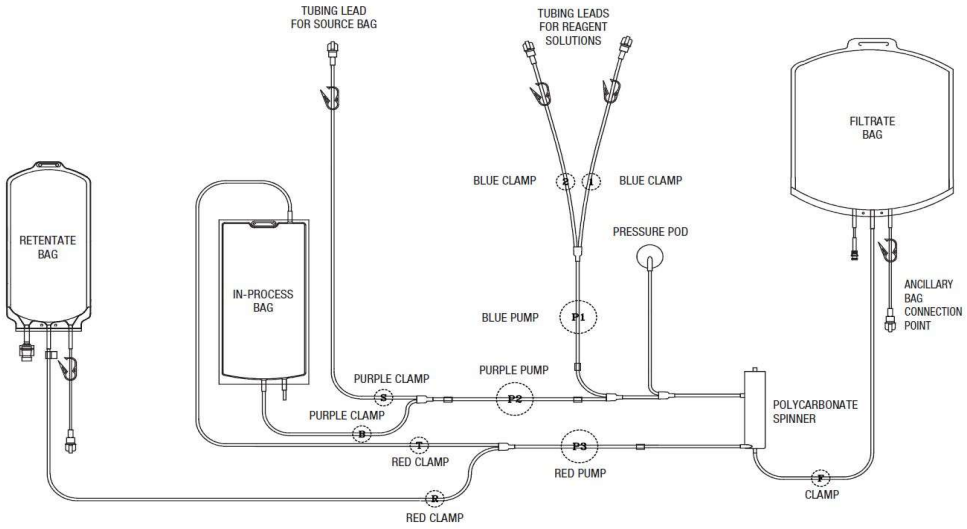
Problem Type (*Mark all applicable*)
Packaging: ☐ Packaging Open ☐ Mispacked ☐ Illegible Label ☐ Discolored ☐ Missing or Separated Component (e.g. keeper)
Tubing: ☐ Flattened ☐ Kinked ☐ Hole ☐ Cut/Sliced ☐ Blocked/Occluded ☐ Discolored
Separation Device: ☐ Cracked ☐ Leaking Fluid ☐ Noise
Pressure Pod: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

X6R4906 LOVO Disposable Kit



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: _____