

# LOVO X6R4906A 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

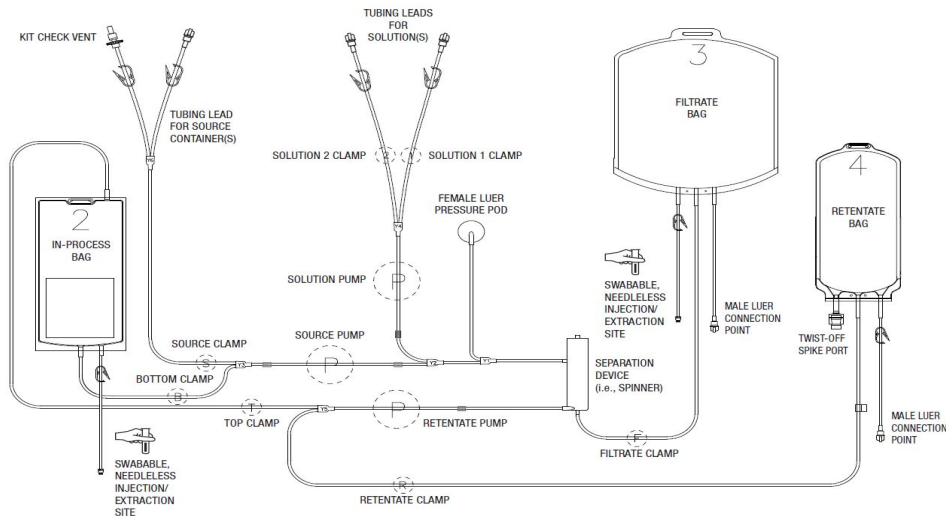
Container:  Leaking Fluid    Improper Seal around Container Port    Discolored

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](mailto: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
- 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](mailto: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: \_\_\_\_\_