

# LOVO X6R4917 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.: \_\_\_\_\_

### When Was the Problem Detected?

Before Use  During Use  After Use

### Problem Type (Mark all applicable)

**Packaging:**  Packaging Open  Mispacked  Illegible Label  Discolored  Missing or Separated Component (e.g. cap)

**Tubing:**  Flattened  Kinked  Hole  Cut/Sliced  Blocked/Occluded  Discolored

**Air Filter:**  Cracked  Leaking  Discolored  Blocked/Occluded

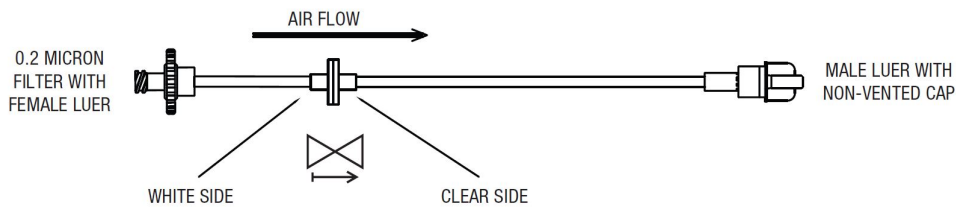
**Male Luer/Cap:**  Cracked  Leaking  Discolored  Blocked/Occluded  Poor Fit

Other: \_\_\_\_\_

### 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: \_\_\_\_\_