

# 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

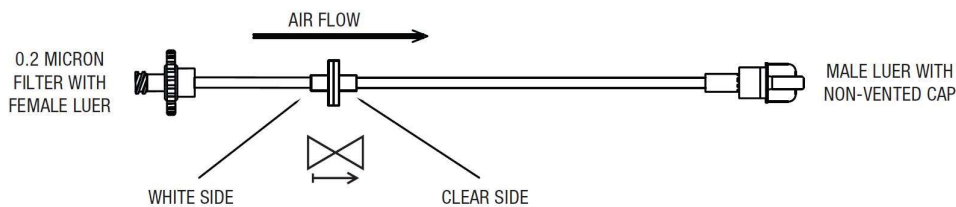
*Male Luer/Cap:*    Cracked    Leaking    Discolored    Blocked/Occluded    Poor Fit

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
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](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: \_\_\_\_\_