

# LOVO X6R4902 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    Kit Installation    Disposable Kit Check    Disposable Kit Prime    During Procedure    After Procedure

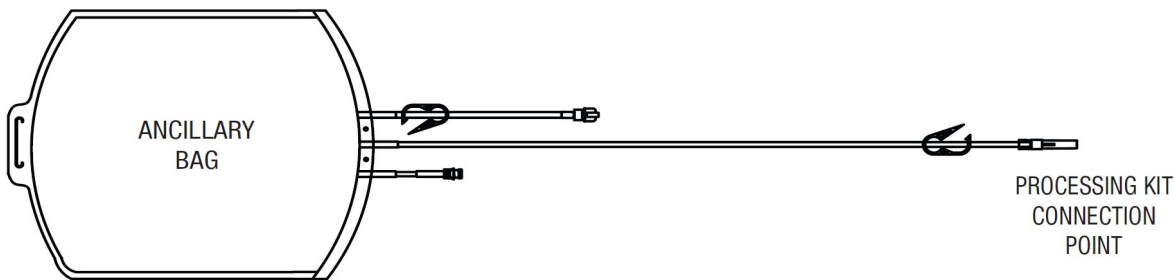
**Problem Type (Mark all applicable)**

**Packaging:**    Packaging Open    Mispacked    Illegible Label    Discolored    Missing or Separated Component (e.g. keeper)  
**Tubing:**    Flattened    Kinked    Hole    Cut/Sliced    Blocked/Occluded    Discolored  
**Container:**    Leaking Fluid    Improper Seal around Container Port    Discolored  
 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)

<p><b>Kit Return to Fresenius Kabi</b></p> <p>1. Sample available for evaluation?   Yes <input type="checkbox"/>   No <input type="checkbox"/></p> <p>2. Return label needed?   Yes <input type="checkbox"/>   No <input type="checkbox"/></p> <p>3. Sample return box needed?   Yes <input type="checkbox"/>   No <input type="checkbox"/></p> <hr/> <p><b>Center Authorized Signature/Date:</b></p> <div style="border: 1px solid black; height: 40px; width: 100%;"></div>	<p><b>Customer Information (please print)</b></p> <p><i>The following information is required to receive a credit</i></p> <p>Facility Name: _____</p> <p>Contact Name: _____</p> <p>Account Number (if known): _____</p> <p>Operator Name: _____</p> <p>Street Address: _____</p> <p>City/State/Zip: _____</p> <p>Phone Number: _____</p> <p>Contact Person's E-mail: _____</p>
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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.