

# Cue X6R5005 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    Discolored    Missing or Illegible Label    Missing or Separated Component

**Tubing:**  Flattened    Kinked    Hole    Cut/Sliced    Blocked/Occluded    Discolored    Incorrect Length  
 Separated (e.g. from Luer/Pouch)

**Female Luer:**  Cracked    Leaking    Discolored    Blocked/Occluded    Poor Fit    Disconnected

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

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

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

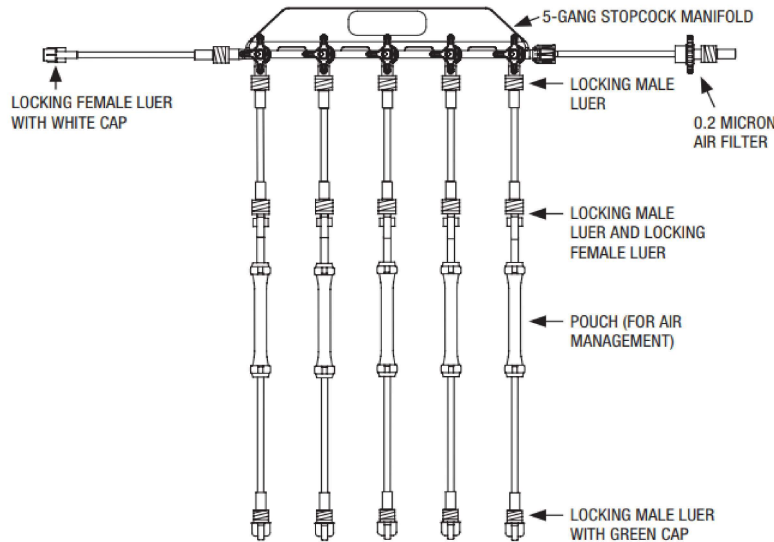
**Stopcock:**  Cracked    Leaking    Discolored    Blocked/Occluded    Valve Issue (explain below)

Other: \_\_\_\_\_ Associated Alert Name/Code (if applicable): \_\_\_\_\_

### Additional Problem Description / Explanation

Please circle specific components on the diagram where incident occurred

Cue X6R5005 Manifold Set – 5-lead



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)

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**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 [mdpmpqa.usa@fresenius-kabi.com](mailto:mdpmpqa.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: \_\_\_\_\_