May 3, 2005

Re: Flo-Gard 6201 and 6301 Volumetric Infusion Pumps – Pole Clamps; Product Codes 2M8063, 2M8064, 2M8063R, 2M8064R

Dear BioMedical Engineer:

Baxter Healthcare Corporation is sending this communication to provide you with important information concerning the pole clamps used with Baxter's Flo-Gard 6201 and 6301 Volumetric Infusion Pumps. As part of an ongoing review of past service activities, Baxter has reviewed reports regarding the pole clamp mounting screws coming loose.

During your routine maintenance or as part of the recommended annual preventive cycle, please inspect the Flo-Gard pole clamp. If the pole clamp appears to be loose, the following steps should be followed to ensure that the pole clamp is properly secured:

1. The recessed area in the housing for the clamp body must be clean.
2. The three mounting screw holes in the housing must not show signs of cracking.
3. The ground wire must be attached to the center screw.
4. The screws must be M4X10 with captive washer.
5. Loctite 425 threadlocker must be applied to each of the three screws.
6. Torque the screws to 7.8 in-lb.

Attached is the Service Bulletin issued in April 2002 with additional information about servicing the Flo-Gard pole clamps.

Please complete the attached reply form confirming your receipt of this letter and fax it back to Baxter at the number provided on the form. Returning the form promptly will prevent you from receiving a repeat notice. If you provide Flo-Gard Volumetric Infusion pumps to other services or facilities, please forward this information as appropriate.

We apologize for any inconvenience this will cause you and your staff. If you have questions regarding this communication, please call Baxter Medication Delivery Services at 1-800-THE-PUMP.

The Food and Drug Administration has been notified of this action.

Sincerely,

Dirk E. Stevens
Vice President, Quality
Medication Delivery Division
Baxter Healthcare Corporation

Enclosure

Flo-Gard and Baxter are registered trademarks of Baxter International, Inc.
Loctite is a Registered trademark of Loctite Corporation. 2005-029-MD
Flo-Gard 6201 and 6301 Volumetric Infusion Pumps – Pole Clamps; Product Codes 2M8063, 2M8064, 2M8063R, 2M8064R

Customer Reply Form
(Urgent Device Correction letter dated May 3, 2005)

Please complete and return this form to the FAX number listed below as confirmation that you have received this notification. A fax cover sheet is not required.

1-847-270-5457

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We understand the contents of the letter and have disseminated this information to our staff and to other services or facilities, as applicable.

Signature/Date: REQUIRED FIELD

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Service Bulletin

Product Code(s) Affected: 2M8063, 2M8064
Product Name(s):
FLO-GARD 6201 Volumetric Infusion Pump
FLO-GARD 6301 Volumetric Infusion Pump
Usage: (X) Internal / (X) External

Title: Replacement of Pole Clamp Body Assembly

Purpose
To provide specifications for servicing the IV pole clamp assembly used on the FG-6X01 infusion pump family.

Documents and Materials
07-27-01-652 Pump Service Upgrade Label Usage
07-26-01-047 Pump Service Upgrade Label, Basic
Loctite 425 * Thread locker

Scope
This document must be referenced during any service involving the IV pole clamp assembly. In addition, all pumps being serviced in shop must meet the requirements listed below. A pump service upgrade label with box 2 marked indicates these requirements have already been met.

Specifications
Refer to the service manual Figure 8-4 Rear Housing Assembly, External. Attachment of the pole clamp body to the rear housing.

When servicing the pump ensure the pole clamp body is properly secured to the rear housing.

- The recessed area in the housing for the clamp body must be clean
- The three mounting screw holes in the housing must not show signs of cracking.
- The ground wire must be attached to the center screw.
- The screws must be M4X10 with captive washer.
- Loctite 425 threadlocker must be applied to the each of the three screws.
- Torque the screws to 7.8 in-lb.

Attach and/or mark box 2 of the Pump Service Upgrade Label.

* Loctite is a registered trademark of Loctite Corporation.