



**IMPORTANT
PRODUCT
INFORMATION**

October 7, 2008

Re: FLO-GARD 6201 Volumetric Infusion Pump (Product Code 2M8063)

Dear Director of Biomedical Engineering/Materials Manager:

Baxter Healthcare Corporation is providing this communication to inform you of Important Product Information concerning the FLO-GARD 6201 Volumetric Infusion Pump, product code 2M8063.

We have identified that during the normal course of use or transport, a cable connecting the internal circuit board to the keypad may become dislodged, affecting keypad operability.

A review of complaint data over the past five years shows no reports of injuries related to this issue. Baxter has determined that this is not a safety concern, and has developed a solution that can be applied as part of routine service or preventative maintenance as follows:

- 1) If you are Baxter-trained to self-service the FLO-GARD 6201 infusion pumps, we have issued a Service Bulletin (07-27-58-498) which provides instructions for applying the solution to this issue. This Service Bulletin, which is an addendum to the FLO-GARD 6201 Operator's Manual (07-19-B1-688), can be accessed through the following Web address:

<https://gts.baxter.com/gts/displayLogin.do>

- 2) If Baxter services your FLO-GARD 6201 infusion pumps:

- This solution will be applied to all FLO-GARD 6201 pumps sent to Baxter for servicing or preventative maintenance.
- If you would like to have Baxter apply this solution prior to any scheduled servicing or preventative maintenance that you have planned, please contact Baxter Global Technical Services (GTS) at 1-800-THE PUMP (1-800-843-7867, prompt 1) to make arrangements.
- Please note that if you return your pumps to Baxter, we will perform this repair at no charge. However, if during this repair, we find other service items are required to bring the pump up to operational standards, you will be notified about any additional associated costs prior to Baxter servicing the device.

Baxter

If you are a dealer, wholesaler, or distributor/reseller of the product outlined above, please forward this communication as appropriate.

We apologize for any inconvenience this may cause you and your staff. If you have any questions concerning this communication, please do not hesitate to call your local sales representative or The Center for One Baxter at 1-800-422-9837.

Sincerely,

A handwritten signature in black ink, appearing to read "Ted Leggett". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Ted Leggett
Vice President, Quality
Medication Delivery
Baxter Healthcare Corporation



**FLO-GARD 6201 Volumetric Infusion Pump
IMPORTANT PRODUCT INFORMATION
CUSTOMER REPLY FORM
October 7, 2008**

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.

FAX#: 1 (847) 270 5457

Facility Name and Address:	
----------------------------	--

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

Required Fields:

Reply Completed By: (Signature/Date)	
Name <i>(Please Print)</i> :	
Title <i>(Please Print)</i> :	
Telephone Number (Inc. Area Code) :	

PLEASE PROVIDE YOUR SIGNATURE AND DATE IN THE INDICATED FIELD ABOVE. BAXTER CANNOT ACCEPT REPLY FORMS WITHOUT SIGNATURE AND DATE. THIS WILL PREVENT UNECESSARY REPEAT NOTIFICATIONS CONCERNING THIS ISSUE.