Patient Safety Advisory

Veterans Health Administration Warning System
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AD06-03 **January 10, 2006**

Item: Ipump Pain Management System, APII Infusion Pump and PCAII Infusion Pump, manufactured by Baxter Healthcare Corporation.

Specific Incident: Baxter reports incidents of unrequested patient doses delivered due to the following:

Damaged PCA patient cord/button;
Partial button sticking; and
Fluid in the pump or PCA button.

The unrequested bolus doses do not exceed the programmed total prescription limits.
Although Baxter has identified approximately 50 VAMCs affected by this notice, none of the reported incidents are in VHA.

Recommendations:

1. Reinforce the need for user inspection for damage, including cords and switches before operating portable medical equipment. Damaged equipment should be removed immediately and reported to Biomedical Engineering.

2. Review and apply proper cleaning techniques for the identified pumps according to manufacturer recommendations.

3. Refer to Baxter's notice (attached) and user manuals for instructions to resolve identified failures.

4. If you have not received Baxter's notice, or have not replied yet, review Baxter's recommendations, document your actions on the attached reply form and fax it to Baxter at 1-800-270-5457.

Addl information: While this Advisory applies specifically to Baxter PCA pumps, the guidelines can apply to all PCA pumps.

Source: CEOSH and Manufacturer

Contact: Baxter Customer Support at (800) 422-9837.
Paul Sherman, VA Center for Engineering & Occupational Safety and Health (CEOSH) at (314) 543-6700.

Baxter Healthcare Corporation
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490
847.546.6311

URGENT
DEVICE
CORRECTION

Baxter

December 21, 2005

RE: Delivery of Unrequested PCA Doses due to Damaged PCA Cords or Fluid Ingress

Ipump Pain Management System (Product Code 2L3107, 2L3107R, and 2L3107K)
APII Infusion Pump (Product Code 2L3105, 2L3105K, 2L3105R, and 2L3105T, 2L3105W)
PCA II Infusion Pump (Product Code 2L3104 and 2L3104R)

Dear Director of Nursing:

Baxter Healthcare Corporation is sending this communication to provide you with important information regarding the Ipump Pain Management System, the APII Infusion Pump, and the PCA II Infusion Pump. Baxter has received reports of the Ipump delivering unrequested PCA doses due to an electrical short in the PCA circuit simulating repeated pressing of the PCA button. These unrequested bolus doses, however, will not exceed the programmed prescription limits.

Three specific conditions Baxter has identified that can produce an electrical short in the PCA circuit and simulate repeated pressing of the PCA button, are the following:

Damaged PCA Cord or Button
Partial Sticking of PCA Button
Fluid Ingress into Pump or PCA Button

To reduce the potential for any of these conditions from occurring during the operation of the Ipump, APII and PCA II devices, please review the information provided below:

Damaged PCA Cord or Button
Prior to or after each use ensure that the PCA cord is intact and has no cuts or missing insulation, and that the PCA connector and the button are securely attached to the cord

- Ipump – Please refer to Section 7 - Preventative Maintenance of the Ipump Operator's Manual.
- APII – Please refer to Section 4 - Visual Inspection of the APII Pump Functional Test Procedure
- PCA II – An addendum to the Operator's Manual is forthcoming.

Partial Sticking of PCA Button
If the pump displays "RELEASE THE PCA BUTTON" and the PCA button is not being intentionally pressed, there may be a mechanical or electronic fault in the PCA button. Immediately take the pump and PCA cord out of service for repair.

- Ipump – Please refer to Table 6-1 - Alert Messages and Responses of the Ipump Operator's Manual.
- APII and PCA II – An addendum to the Operator's Manual is forthcoming.

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Fluid Ingress into Pump or PCA Button

Avoid getting liquids inside the pump or permanent damage may result. This is especially important while cleaning the device, as cleaners must not be sprayed directly onto the pump or PCA cord and button.

- Ipump – Please refer to Section 7 - Preventative Maintenance of the Ipump Operator's Manual.
- APII – Please refer to Section 9 - Routine Maintenance of the APII Operator's Manual.
- PCA II – Please refer to section 4-3 of the PCA II Operator's Manual.

Baxter also recommends that institutions implement a regular preventative maintenance program and periodic replacement of PCA cords based on their own specific usage patterns.

Please complete the attached reply form, confirming receipt of this letter, and fax it to Baxter using the number provided. Returning the form promptly will prevent you from receiving a repeat notice. If you provide Ipump Pain Management System, APII Infusion Pump, or PCA II devices to other services, facilities or home patients, please forward this information as appropriate.

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

The Food and Drug Administration has been notified of this communication

Sincerely,

Robert Smith
Sr. Director, Quality
Medication Delivery
Baxter Healthcare Corporation

cc: Director of Biomedical Engineering

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(Product Code 2L3104 and 2L3104R)

Customer Reply Form
(Urgent Device Correction letter dated December 21, 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

Facility Name and Address:	
Reply Confirmation Completed By: *(Please print name)*	
Title: *(Please print)*	
Telephone Number (including Area Code):	

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.

Signature/Date:
REQUIRED FIELD _____

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