

**IMPORTANT  
PRODUCT  
INFORMATION**

**Baxter**

July 6, 2005

RE: SYNDEO PCA Syringe Pump (Product Codes 2L3113 and 2L3113R)

Dear Director of Nursing:

Baxter Healthcare Corporation is sending this communication to inform you of reports we have received from customers regarding the SYNDEO PCA Syringe Pump for the items listed below. There have been no Medical Device Reportable (MDR) events reported to Baxter for these items.

- **Service Code 919 or Service Code 920:** During an infusion in the 'Basal + PCA' or 'PCA only' modes, the SYNDEO pump may generate Service Code 919 or Service Code 920. Upon Service Code generation, the pump will stop the infusion, display the service code number on the screen, and emit an audible alarm. Service Code 919 and Service Code 920 do not occur in the "Continuous" mode.

If you experience Service Code 919 or Service Code 920, turn off the pump to silence the alarm, then turn on the pump and **reprogram the infusion**. If the service code occurs again, take the pump out of service and contact the Baxter Medication Delivery Services at 1-800-THE-PUMP (1-800-843-7867).

- **Pump Does Not Power ON:** While attempting to turn on the device by pressing the ON/OFF key, the pump may not power up properly. As a result, an infusion cannot be started on this pump. If you are unable to power on the unit, contact Baxter Medication Delivery Services at 1-800-THE-PUMP (1-800-843-7867) to arrange return of the pump for service.

Baxter is currently investigating long-term corrective actions to address these issues. When the revised software and hardware are available, SYNDEO PCA Syringe Pumps will be modified at no additional charge to you. We will notify you when these corrections are available.

# **Baxter**

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 SYNDEO PCA Syringe Pumps to other services, facilities, or home patients, please forward this information as appropriate.

We apologize for any inconvenience this may cause you and your staff. If you have questions regarding this communication, please call The Center for One Baxter at 1-800-422-9837.

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

Sincerely,

[Signature]

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

cc: Director of Biomedical Engineering



**Baxter SYNDEO PCA Syringe Pump (Product Code 2L3113 and 2L3113R)**

**Customer Reply Form  
(Important Product Information letter dated July 6, 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: <i>(Please print name)</i>	
Title: <i>(Please print)</i>	
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**

---