

Baxter

Urgent Product Recall

November 14, 2005

Re: Market Removal of Baxter/Sabratek 6060 Infusion Pumps

Dear Director of Nursing:

Baxter Healthcare Corporation is sending this communication to provide you with important safety information concerning the 6060 Infusion Pump. Baxter has received reports of failures within the PCA profile as well as reports of incidents that result in interruptions of therapy in various profiles. Details are outlined in the Reported Problems sections below. Due to the technological limitations of this product and the obsolescence of certain critical components, Baxter will be working with customers to conduct a controlled removal of all 6060 Infusion Pumps from the market. As the timing of this removal will depend upon your ability to evaluate and implement a substitute device, Baxter will coordinate with customers individually to ensure a smooth transition. We will continue to produce sets and provide service during the transition period.

During this period of product removal Baxter is advising you to:

- **Discontinue the use of the PCA profile to avoid a potential overinfusion or non-delivery condition. While the probability of occurrence of the PCA profile delivery failures is rare, patients should be converted to another delivery profile or device.**
- **Immediately discontinue the use of the pump for therapies where interruption of the infusion could cause immediate patient harm.**

Failure to follow the above instructions could result in an unsafe situation for the patient.

To help explain all of the current instructions relative to this and previous field corrective actions, a chart of the pump's profiles and the associated instructions is included with this notification as Attachment 1. This attachment should be distributed to all users of the pump.

Reported Problems

PCA Profile Delivery: The PCA mode should not be used, and should be disabled on all 6060 Infusion Pumps.

Event Log Discrepancies

Baxter has received one death and two serious injuries reports which may be associated with potential overinfusions within the PCA profile. In each case, the event histories indicated that the device failed to return to the basal rate following a bolus request, but also indicated that the bolus volume was not delivered. Despite exhaustive internal and external investigations, Baxter has been unable to replicate these types of failures.



Unrequested Bolus Dose

Baxter has identified that a frayed PCA cord or fluid ingress into the device may create an intermittent short of the PCA circuit and simulate the repeated pressing of the PCA button. As a result, bolus doses may be delivered (within the programmed prescription limits) without the patient initiating the request.

Undelivered PCA Bolus Requests

Baxter has received reports where the pump will not deliver requested PCA boluses while in the TOTAL MEDS ALLOWED mode.

Interruption of Therapy

Non-Delivery Without Indication

Baxter has received reports where the infusion unexpectedly stops without an alarm or malfunction code. This has been observed in the Auto-Ramp and 25-Period profiles.

Unwarranted Alarms

Baxter's investigation into the occurrence of some malfunction alarms has identified that the pump may incorrectly generate an alarm condition even if an error is not present. The most commonly seen malfunction alarms include Malfunction 7, 9, 20, 25, and 26 codes.

Product Removal

Baxter will be working with customers to conduct a controlled removal of all 6060 Infusion Pumps from the market. However, due to the quantity of pumps in the field, we recognize it may take customers time to safely replace their existing 6060 pumps with alternatives. During this transition period, Baxter will continue to provide service and sets for the 6060 pump.

Your Baxter Sales Representative will contact your facility within the next week to discuss alternatives and help coordinate the return of the 6060 pumps to 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 6060 pumps to other services or facilities, please forward this information. It is imperative that all end users of the 6060 pumps be notified.**



We apologize for any inconvenience this may cause you and your staff. We are committed to helping you work safely through this difficult situation. 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,

A handwritten signature in blue ink, appearing to read "Robert Smith".

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

Enclosures: 06/13/2005 Urgent Device Correction
02/19/2001 Urgent Product Recall

cc: Director of Pharmacy
Materials Management
Director of Biomedical Engineering
Director of Risk Manager



Attachment 1

IMPORTANT SAFETY INSTRUCTIONS - 6060 MULTI-THERAPY PUMP

It is important that you incorporate the following safety instructions for use of the 6060 device.
Failure to follow these instructions could result in an unsafe situation for the patient.

PROFILE	ACTIONS
Continuous	No restrictions
Intermittent	Utilize the Lockout Mode or make the pump profile-specific to the Intermittent profile to prevent the specific key sequence described in the 06/13/2005 Urgent Device Correction notification. Failure to do this may result in an overinfusion.
Auto-Ramp	Disable the Auto-Ramp profile in all pumps with SW versions 3.00 or higher per the 02/19/2001 Urgent Product Recall notification. Failure to do this may result in an overinfusion. Monitor the pump display to ensure the volume is updating during infusion. If the Volume Infused does not appear to be updating, an interruption of therapy may have occurred without alarm. Press the RUN / HOLD key twice to recover. If therapy does not resume, cycle power to the device and restart the therapy.
PCA	Disable the PCA profile. Refer to your Operator's Manual under "Making the Pump Profile Specific" in the section on "Delivery Options" for instructions on how to disable to the PCA profile.
25-Period	Monitor the pump display to ensure the volume is updating during infusion. If the Volume Infused does not appear to be updating, an interruption of therapy may have occurred without alarm. Press the RUN / HOLD key twice to recover. If therapy does not resume, cycle power to the device and restart the therapy.

For All Delivery Profiles:

- **Do not use for therapies where interruption of the infusion could cause immediate patient harm.**
- If a malfunction alarm occurs, turn the power OFF and back ON. Restart the infusion. If alarm persists, return the pump for service. **(Malfunction 26 is unrecoverable and must be immediately returned for service.)**
- Programming of the pump must be performed only by trained clinicians or healthcare providers trained and deemed competent by trained clinicians or under the direct supervision of trained clinicians.
- The Lockout Mode feature of the pump should be used to prevent unauthorized changes to the pump programming. Refer to your Operator's Manual under "Programmable Mode/Lockout Mode" in the section on "Delivery Options and Advanced Functions" for instructions on how to utilize the Lockout mode.
- The pump security codes, which disable the Lockout mode, must not be released to anyone other than trained healthcare professionals.
- Do not use the pump if fluid enters the cassette chamber.



Baxter 6060 Multi-Therapy Infusion Pump, Product Codes 2M9832, 2M9832P and 2M9832R

Sabratek 6060 Homerun® Infusion Pumps, Product Codes 606000, 606000-40, 606000-40L, and 606000-40I

**Customer Reply Form
(Urgent Product Recall Letter dated November 14, 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**

URGENT
DEVICE
CORRECTION

Baxter

June 13, 2005

Re: Baxter 6060™ and 6060E™ Multi-Therapy Infusion Pumps

Dear Director of Nursing / Director of Pharmacy:

Baxter Healthcare Corporation is providing this communication to inform you that we will be taking the following actions regarding the 6060™ and 6060E™ Multi-Therapy Infusion Pumps.

Partial Reprogramming in Intermittent Mode

Baxter has identified an overinfusion condition in the Intermittent mode of the 6060™ infusion pump where the pump may continue to deliver at the higher Dose rate instead of switching to the lower Keep Open (KO) rate once the first dose is completed. We have confirmed this condition is due to a software anomaly that occurs only when the clinician follows a specific sequence in reprogramming the pump during an infusion.

For this anomaly to happen, a specific sequence of events must occur: The infusion is running in the Intermittent mode; the pump is delivering at the Keep Open (KO) rate; the pump is then powered off and on; the clinician initiates reprogramming of the pump by selecting NO at the "Resume KO Dose 1?" prompt and selecting YES at the "Yes to Program" prompt; the clinician powers the pump off and on again; and the clinician selects YES at the "Resume KO Dose 1?" prompt.

Baxter is currently investigating long-term corrective actions to address this issue. Until such time that the corrective actions may be implemented, Baxter recommends that you perform the following:

1. Notify healthcare providers of the potential for an overinfusion condition in Intermittent mode if the above sequence is performed during an infusion.
2. In order to prevent this sequence from occurring, utilize the Lockout mode after programming the pump. Refer to your Operator's Manual under "Programmable Mode / Lockout Mode" in the section on "Delivery Options and Advanced Functions" for instructions on how to utilize the Lockout mode. If you need assistance in this process, please call the Baxter Medication Delivery Services at 1-800-THE-PUMP (1-800-843-7867).

Improper/Unauthorized Programming of Pump

Baxter has received reports of two patient deaths due to medication delivery errors resulting from improper programming of the infusion parameters into the 6060™ and 6060E™ Multi-Therapy Infusion Pumps. Baxter has also received reports where the infusion parameters programmed in the pump were modified by untrained individuals. This issue could occur in all models of 6060™ and 6060E™ infusion pumps. This may result in overinfusion or underinfusion conditions, depending upon the nature of the program modifications.

Baxter would like to reinforce the following:

Programming of the pump must be performed only by trained clinicians, or healthcare providers trained and deemed competent by trained clinicians or under the direct supervision of trained clinicians.

Baxter

The Lockout mode feature of the pump should be used to prevent unauthorized changes to the pump programming. Refer to your Operator's Manual under "Programmable Mode / Lockout Mode" in the section on "Delivery Options and Advanced Functions" for instructions on how to utilize the Lockout mode.

The pump security codes, which disable the Lockout mode, must not be released to anyone other than trained healthcare professionals. A copy of the warning from the Operator's Manual has been attached to this letter.

Baxter will provide updated training materials to further address this issue as they become available

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 distribute this product to other services or facilities, please forward this information as appropriate.

Should you provide infusion 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,



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

Chapter 1

Introduction

1

Overview

This manual provides operating instructions for the 6060™ Multi-Therapy Pump. The following information is provided in this chapter:

- “Features,” 1-2
- “Safety Summary,” 1-4

The 6060™ Multi-Therapy Pump (referred to in this manual as “the pump”) provides accurate, safe, and reliable volumetric delivery and may be used for subcutaneous, arterial, intravenous, and epidural delivery routes.

The pump is intended for infusion therapy. Pump users should be under the supervision of a clinician and should be instructed in using and troubleshooting the pump.

! WARNING !

This manual is intended for clinicians only. Do not permit patients to have access to this manual. Do not disclose the pump’s security codes to patients.

Baxter**Urgent:
Product Recall**

February 19, 2001

**Re: Baxter 6060™ Multi-Therapy Ambulatory Infusion Pump, product code 2M9832
Sabratek 6060 Homerun® Infusion Pump, product codes 606000-40, 606000-40L, 606000-40I**

Dear Customer,

This letter is to inform you that we received a report of an overinfusion condition in the model 6060™ infusion pumps listed above. We have confirmed this report is due to a software anomaly. This anomaly is a result of an error in programming logic and is only present in software versions AMBF or AMB 3.00 and higher (examples: 3.00.2, 3.01.0). Pumps with software versions lower than 3.0 (for example, 2.06.6) are not of concern. Relatively few pumps with software versions 3.0 and higher have been distributed.

This software anomaly is only clinically significant in the Auto-Ramp® mode of operation and only occurs under certain circumstances.

Please check the software version of the pumps in your inventory to determine if you have an affected version of software. To check the software version, turn on the pump, then press and hold the "No" key. When the word "password" appears, release the "No" key, type "100" and press the "Yes" key. The serial number (S/N) and date of manufacture appear first, then the software version.

If you do have version 3.00 or higher, you must disable the Auto-Ramp® mode immediately (unless it is already disabled). Refer to your Operator's Manual under "Making the Pump Profile Specific" in the section on "Delivery Options" for instructions on how to disable Auto-Ramp® mode. If you need assistance in this process, call the Baxter Product Information Center at 1 (800) 933-0303, and press "2" for clinical support.

If your pumps are software version 3.0 and higher and your therapy needs require the use of Auto-Ramp®, contact your Baxter Sales Representative to discuss options.

Please complete the attached reply sheet and return it to Baxter via fax using one of the indicated fax numbers. Returning the form promptly will prevent you from receiving a repeat notice.

Should you provide infusion pumps to other services, facilities, or home patients, please forward this information as appropriate.

As indicated, your Sales Representative is available to discuss this issue with you should you have any questions. Alternatively, you may call the Baxter Product Information Center at 1 (800) 933-0303.

The Food and Drug Administration has been advised of this communication.

We sincerely apologize for the inconvenience this may cause. Thank you for your assistance.

Sincerely,



Cathy Buhner
Manager, Quality Management
Baxter Healthcare Corporation