

**URGENT
DEVICE
CORRECTION**



February 7, 2006

RE: Auto Infusion AS50 Syringe Pump
Product Code 1M8550

Dear Director of Nursing:

Baxter Healthcare Corporation is conducting a voluntary recall of Auto Infusion AS50 Syringe Pumps for the specific serial numbers listed below. Baxter has discovered that a non-conforming gasket was used in the manufacturing of these specific pumps. These affected pumps may be more susceptible to Electro-Static Discharge (ESD), which could increase the potential to fail during use, causing the pump to stop infusing, and issue an audible and visual alarm. There are no known reports of adverse events or injuries associated with this issue.

Baxter records indicate that you have one or more affected pumps with the following serial number(s):

(Note: This will be a mail merge, customer serial numbers will appear here)

_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

To address this issue, please take the following immediate actions:

1. Locate the pump(s) listed above and remove them from service.
2. Contact Baxter at 1-800-THE-PUMP (1-800-843-7867) to arrange for the return of the pump(s) in order to replace the non-conforming gasket(s).
 - a. If you are a Baxter-trained, self-service customer, you can call the number above to obtain replacement gaskets. Refer to Chapter 7 of your Auto Syringe AS50 Service Manual to access and replace the gaskets in your AS50 pump. Appendix C also references the appropriate part number, BAS40-01-486.
3. Please complete the attached reply form confirming receipt of this letter and fax it to Baxter at the number provided on the form. If you no longer have one or more of the pumps with the affected serial numbers, please indicate this in the appropriate section of the reply form. Returning the reply form promptly will prevent you from receiving a repeat notice.



If you distribute Auto Infusion AS50 Syringe Pumps to other facilities, or if you are a dealer, wholesaler or distributor/reseller of any of the affected products, please forward this communication 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,

A handwritten signature in cursive script that reads "rsmith".

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

cc: Biomedical Engineers

Baxter

Auto Syringe AS50 Infusion Pump – Product Code 1M8550 Non-Conforming Gasket

Customer Reply Form (Urgent Device Correction letter dated February 7, 2006)

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):	

Check any that apply:

- We have identified the following affected serial numbers and have contacted 1-800-THE-PUMP to arrange for replacement of gaskets:

- The following affected AS50 pumps by serial number have been scrapped:

- We no longer have the following affected Auto Syringe AS50 Infusion Pumps:

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 FIELD

Signature/Date:
