

This Baxter notice is referred by a FDA's Preliminary Public Health Notification, which can be accessed at:

<http://www.fda.gov/cdrh/safety/042806-baxter.html>

The FDA is neither endorsing nor validating the information in this notice by making it available.



**IMPORTANT
PRODUCT
INFORMATION**

February 25, 2005

Re: COLLEAGUE VOLUMETRIC INFUSION PUMP, PRODUCT CODES
2M8151, 2M8151R, 2M8161, 2M8161R, 2M8153, 2M8153R, 2M8163, 2M8163R

Dear Biomedical Engineer:

Baxter Healthcare Corporation is sending you this letter to provide you with important supplemental information to the letter dated January 21, 2003, regarding sealed lead-acid batteries used in the COLLEAGUE family of infusion pumps. Key points from this information are provided below. An Operator's Manual Addendum is enclosed and should be distributed within your facility, as appropriate.

Battery Service Life, Replacement and Pump Storage

- A lead-acid battery has 68 or more full discharge/recharge cycles during its service life. In the Operator's Manual Addendum are recommendations for optimizing the battery service life.
- The more often a battery is cycled, the sooner it will require replacement.
- Always replace both batteries at the same time, with two new batteries.
- Never store the pump unplugged and powered on. The batteries may discharge completely, resulting in permanent damage. For pump and battery storage recommendations, please see the enclosed Operator's Manual Addendum.

Swollen Battery

- At the end of a battery's life, swelling can occur. While we have not received any reports of adverse events related to the swelling of batteries, the pump case can become hot to the touch and internal pump damage can occur.
- Swelling can be prevented if both batteries are replaced before the end of their useful lives and can be postponed by good battery charging and pump usage patterns.
- COLLEAGUE pumps listed on the table below have been manufactured with an overcurrent protection circuit in the battery harness. This overcurrent protection circuit provides integral fuses and diodes to help protect the batteries from overcurrent damage and swelling during charging.

Product Codes	Serial numbers listed and higher serial numbers are not affected
2M8151	13120001CS
2M8161	13110181CC
2M8153	13120001CT
2M8163	13110338TC

Baxter

- In February 2005, we implemented replacing the battery harness in our Repair Service Depot operations. Any pumps that require battery replacement will receive the battery harness with overcurrent protection circuit as they are processed through our service centers.
- We encourage your institution to install the battery harness during routine battery replacement or as part of the device's recommended annual preventative cycle. The battery harness with the overcurrent protection circuit will be provided at no additional charge. Please follow the instructions on the reply form to place an order for the harness. Initially, we will have a limited number of battery harnesses with overcurrent protection circuit, and circumstances may require us to partially fill your order.

Excessive Discharge

- Damaging discharges may occur when the pump is left on battery power for an extended period of time after the 'Battery Depleted' alarm occurs.
- When batteries become damaged due to excessive discharge, the battery indicator will overstate the amount of charge remaining.
- As a reminder, you must connect the pump to AC power when the Battery Low Alert occurs. While in Battery Alert, a properly maintained battery will provide approximately 30 minutes of infusion time left.
- Damaged batteries do not impact the pump's ability to function properly while on AC power, provided that no other failures or alarm conditions are present.
- During preventive maintenance, it is important to look in the Battery and Pump History service screen to identify the number of discharges below the alarm threshold. If more than one excessive discharge is listed in the battery history log, we recommend testing or replacing both batteries. Specifics concerning preventative maintenance and battery test /installation instructions are listed in the product Service Manual.
- Future software updates will address the issue of battery damage due to excessive discharge. You will be notified when the software is available.

Please complete the attached reply form, confirming your receipt of this letter, and fax it back to Baxter using the number provided. To order battery harnesses with protection circuit, please complete the additional information requested on the reply form.

If you have questions concerning this communication, please contact Baxter Medication Delivery Services at 1-800-THE-PUMP (1-800-843-7867). If you have provided COLLEAGUE devices to other services, facilities, or home patients, please forward this information as appropriate. The Food and Drug Administration has been advised of this communication.

We appreciate your time and attention to this communication.

Sincerely,

[Signature]

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

Enclosure: COLLEAGUE Operator's Manual Addendum



**COLLEAGUE VOLUMETRIC INFUSION PUMP (Battery)
Customer Reply Form
(Important Product Information Letter Dated February 25, 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

All Customers Please Complete This Portion. Please Print Clearly.

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

We understand the contents of the letter and have disseminated this information to our staff and to other services, facilities, or home patients, as applicable.

Signature/Date:
(REQUIRED FIELD) _____

To order the battery harnesses with protection circuit: Please complete additional information below

Please send battery harnesses with protection circuit (part number BHRNSKIT) for the number of infusion pumps listed below:

_____ 2M8151 COLLEAGUE Single Channel Infusion Pump

_____ 2M8153 COLLEAGUE 3 Channel Infusion Pump

_____ 2M8161 COLLEAGUE CX Single Channel Infusion Pump

_____ 2M8163 COLLEAGUE CX 3 Channel Infusion Pump

Ship to address (if different than address listed above)	
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