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.

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

URGENT
DEVICE
CORRECTION

Baxter

December 13, 2005

Re: COLLEAGUE VOLUMETRIC INFUSION PUMP, PRODUCT CODES 2M8151 & 2M8151R;
COLLEAGUE 3 VOLUMETRIC INFUSION PUMP, PRODUCT CODES 2M8153 & 2M8153R;
COLLEAGUE CX VOLUMETRIC INFUSION PUMP, PRODUCT CODES 2M8161 & 2M8161R;
COLLEAGUE 3 CX VOLUMETRIC INFUSION PUMP, PRODUCT CODES 2M8163 & 2M8163R

Dear Director of Nursing:

Baxter Healthcare Corporation is sending this communication to notify you of an Urgent Device Correction related to the COLLEAGUE Volumetric Infusion Pump. During the investigation into resolution of issues previously communicated to customers, Baxter has identified additional issues that we want to bring to your attention. These issues fall into the following categories:

Battery Undercharging
Generation of False Air Detected Alarm due to IV Administration Set Tugging
Gearbox Wear
Underinfusion
Non-Detection of Upstream Occlusion

Additional information to help users avoid conditions that may interrupt therapy, along with other guidance on the usage of your COLLEAGUE pump, is described in the "Battery Usage Guide" (Attachment 1) and "Infusion Management Guide" (Attachment 2). These attachments should be provided to all users of the COLLEAGUE pump.

Battery Undercharging

Baxter has received one report of a patient death that may be associated with an undercharged battery.

Users of COLLEAGUE pumps should be aware that if the pump's batteries are not charged continuously for 12 hours after a Battery Low alert or Battery Depleted alarm occurs, the remaining operating time after a subsequent **Battery Low alert can be less than 30 minutes.** This will be followed by a Battery Depleted alarm with both an audible and visual notification and the infusion(s) will stop. In order to restart the infusion(s), users must plug the pump into a power outlet immediately.

In order to avoid the possibility of interruption or cessation of therapy, loss of configuration memory, and/or device failure, it is important that you follow the charging instructions listed in the Operator's Manual prior to using the pump under battery operation. **Please also refer to the "Battery Usage Guide" (Attachment 1) for additional information on proper battery usage and maintenance.**

Baxter

Generation of False Air Detected Alarm due to IV Administration Set Tugging

Baxter has received one report of a patient death that may be associated with an interruption of therapy due to a false Air Detected alarm.

Pulling or tugging on the IV administration set, between the pump channel and the patient, may cause a false Air Detected alarm, which will cause the pump to stop infusing and issue an audible and visual notification. In order to reduce the potential for this situation to occur, first select an appropriate length administration set. Before loading the set into the pump, position the keyed slide clamp at an appropriate location along the administration set to ensure that there is adequate length of tubing between the patient and the pump to reduce tugging on the set during activities such as moving the patient from one bed to another, or transportation of the patient from one facility location to another.

Gearbox Wear

Baxter has identified that worn gearbox components can result in Failure Codes 812:02 and 812:05, which will result in an audible and visual alarm and the interruption of therapy. As this is associated with age and wear on the pump, older pumps are more prone to exhibit these failures. As stated in the Operator and Service Manuals, if you experience these failure codes immediately remove the pump from service and have the pump evaluated by Baxter-trained service personnel. Baxter is in the process of developing actions to address this issue and will notify you once they are finalized.

Underinfusion

Baxter has received reports of underinfusion on the COLLEAGUE Volumetric Infusion Pump. Our investigation has shown that in the presence of an obstruction during IV Administration set loading, certain pump head components can be moved out of alignment, resulting in underinfusion. The amount of underinfusion is typically 5% to 9%, but may be up to 19% below the programmed infusion rate.

To avoid an obstruction during IV administration set loading:

- Ensure that when loading the IV administration set, the tubing is loaded along the entire length of the tubing channel to avoid a misload or incomplete load situation.
- Never insert tools or other objects into the tubing channel when attempting to load or unload the administration set.
- Never use the Manual Tube Release to load or unload the administration set during normal operation.

If you suspect the accuracy of your pump may be affected, perform the Annual Operational Checkout process (which includes an accuracy test) as described in the Service Manual. If the pump fails the accuracy test, remove the pump from service and have the pump inspected by authorized service personnel following the instructions outlined in the COLLEAGUE Volumetric Infusion Pump Service Manual.

Baxter is in the process of verifying changes to the pumping mechanism to better secure these components to reduce the potential for component movement and resulting underinfusion. Baxter will notify you when these changes are available.

Baxter

Non-Detection of Upstream Occlusion

As previously communicated in the attached March 17, 2005 Urgent Device Correction Buretrol letter, there is a potential for non-detection of upstream occlusion when Buretrol tubing sets are used with the Colleague Volumetric Infusion pump.

In addition to the condition described above, the following conditions should be avoided as they may result in the pump not detecting an upstream occlusion:

- Use of a source container which has had all air removed.
- Incomplete insertion of the spike into the source container.
- Improper venting of a rigid (glass bottle) or semi-rigid (plastic) container, including Buretrols. If using rigid non-vented containers, refer to the appropriate administration set instructions to determine the correct venting procedure.
- Unopened air vent above the burette chamber during infusion.

To help ensure upstream occlusions are detected by the pump when using a Buretrol set, do not invert the set and squeeze fluid back into the primary container. Doing this may wet out the vent filter, and obstruct airflow.

Baxter will notify you when the new release of the COLLEAGUE Volumetric Infusion Pump Operator's Manual is available. In the meantime, please immediately disseminate the attachments to all users. If you have any questions about this or any other issues regarding COLLEAGUE pumps, please contact Baxter Medication Delivery Services at 1-800-THE-PUMP (1-800-843-7867).

Please complete the attached reply form confirming your receipt and understanding 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 the COLLEAGUE Volumetric Infusion Pump to other services or facilities, please forward this information, as it is imperative that all end users are notified and confirm receipt of this notification. Additionally, if your pump is serviced by a third party, please forward this information to the service provider.

The Food and Drug Administration has been notified of this communication

Sincerely,

[Signature]

Robert Smith
Senior Director, Quality
Medication Delivery
Baxter Healthcare Corporation

Attachments: Attachment 1- Battery Usage Guide
Attachment 2 -Infusion Management Guide
Attachment 3 -March 17, 2005 Urgent Device Correction Buretrol Letter

cc: Director of Biomedical Engineering

Baxter

COLLEAGUE VOLUMETRIC INFUSION PUMP, PRODUCT CODES 2M8151 & 2M8151R;
COLLEAGUE 3 VOLUMETRIC INFUSION PUMP, PRODUCT CODES 2M8153 & 2M8153R;
COLLEAGUE CX VOLUMETRIC INFUSION PUMP, PRODUCT CODES 2M8161 & 2M8161R;
COLLEAGUE 3 CX VOLUMETRIC INFUSION PUMP, PRODUCT CODES 2M8163 & 2M8163R

Customer Reply Form
(Urgent Device Correction letter dated December 13, 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 other services, facilities, customers as applicable.

Signature/Date:
REQUIRED FIELD

_____

Baxter

Colleague
Product Information

Battery Usage Guide

It is imperative that institutions have a contingency plan to mitigate any disruptions of infusions of life sustaining drugs. The interruption or delay of life sustaining therapy may result in potential injury or death. You should consider not using these pumps in situations where a replacement pump is not available or where an interruption in therapy may be life threatening.

Before initially powering on the pump, charge the battery for at least 12 uninterrupted hours. A complete charge may take longer than 12 hours.

The Battery Charge Level Indicator will overstate the remaining battery charge level, and operating time after a "Battery Low" alert can be significantly less than expected, if the pump's batteries are subjected to any of the following conditions:

- Failure to recharge the batteries for at least 12 uninterrupted hours after occurrence of a "Battery Low" alert or a "Battery Depleted" Alarm.
- A pump stored with its power cord unplugged, especially with low or depleted batteries.
- More than one deep battery discharge, as indicated on the pump's "Battery and Pump History" screen.
- Batteries discharged/recharged more than 68 times as indicated on the pump's "Battery and Pump History" screen.
- Failure of the "Battery Discharge Test" included in the Colleague Pump Global Service Manual.

Continued pump operation using batteries that have been subjected to any of the above conditions may result in cessation of therapy and/or device failure and loss of configuration memory.

Always do the following to properly maintain the pump batteries:

Keep pumps plugged into an AC power outlet at all times except in the event of AC power loss or short-term portable operation.

Always store pumps plugged into AC power to maintain the battery charge whenever possible.

When a "Battery Depleted" Alarm occurs, immediately plug the pump into a source of AC power. Do not use the pump on battery power again until the batteries have been fully recharged.

Charge the battery for a minimum of 12 uninterrupted hours after a "Battery Depleted" Alarm occurs.

Never store the pump unplugged and powered on. The batteries may discharge completely, permanently damaging them.

Notify Central Supply or other appropriate departments as soon as a pump is removed from patient use so that it can be cleaned and the batteries can be recharged.

Pump batteries should be evaluated yearly by Baxter-trained, qualified personnel according to the procedures in the Service Manual, and whenever it is suspected that any of the conditions listed above may have occurred.

Baxter-trained, qualified personnel can view the pump's "Battery and Pump History" screen using the instructions provided in the Service Manual.

Infusion Management Guide

It is imperative that institutions have a contingency plan to mitigate any disruptions of infusions of life sustaining drugs. The interruption or delay of life sustaining therapy may result in potential injury or death. You should consider not using these pumps in situations where a replacement pump is not available or where an interruption in therapy may be life threatening.

Generation of Air-Detected Alarm Due to IV Administration Set Tugging

Pulling or tugging on the administration set tubing between the pump channel and the patient may cause a false Air Detected alarm, which will cause the pump to stop infusing. In order to reduce the potential for this situation to occur:

1. First, select an appropriate length administration set.
2. Before loading the set into the pump, position the keyed slide clamp at an appropriate location along the tube segment to ensure that there is adequate length of tubing between the patient and the pump to reduce tugging on the set.
3. Lastly, ensure there is sufficient slack in the tubing between the distal end of the pumping channel and the patient to prevent tube tugging during activities such as moving the patient from one bed to another, or transportation of the patient from one facility location to another.

Conditions That May Affect Pump Delivery Accuracy

Note that flow fluctuations can be caused by unusual conditions or combinations of conditions that may involve, but are not limited to the following:

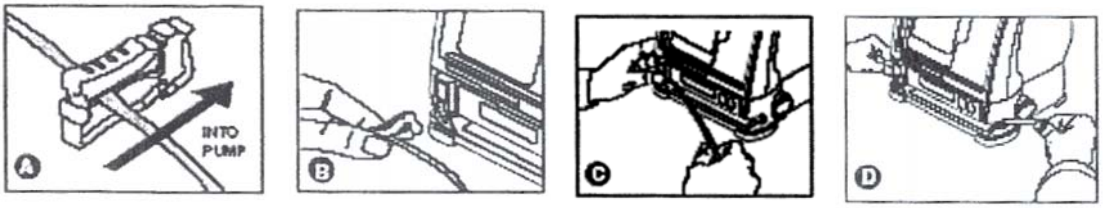
- Position of the infusion container
- Fluid density
- Positive and negative pressure
- The environment

Flow fluctuations are most likely to occur when the conditions mentioned above are exacerbated or when the pump is operated in conditions outside of its normal limits.

While the Colleague pump automatically closes the keyed slide clamp, always manually close the regulating clamp on the administration set before removing the set from the pump.

Loading the IV Administration Set

See the following instructions for proper loading of the IV Administration set:



When loading the IV set, pull the administration set taut and slide it all the way into and along the tubing channel (Figure C and D). The pump pulls in the keyed slide clamp, then loads the administration set into the pumping mechanism. The pump module displays LOADING and then STOPPED.

- Never insert tools or other objects into the tubing channel when attempting to load or unload the administration set.
- Never use the Manual Tube Release to load or unload the administration set during normal operation.

If the above instructions are not followed, there is a potential for misaligning the pump chamber components, which may result in an under-delivery condition.

Upstream Occlusion Detection

The pump may not detect an upstream occlusion if one or more of the following conditions exist:

- Use of a source container which has had all air removed.
- Incomplete insertion of the spike into the source container.
- Improper venting of a rigid (glass bottle) or semi-rigid (plastic) container, including Buretrols. If using rigid non-vented containers, refer to the appropriate administration set instructions to determine the correct venting procedure.
- The air vent above the burette chamber is not open.

To help ensure upstream occlusions are detected by the pump, do not invert the set and squeeze fluid back into the primary container. Doing this may wet out the vent filter, and obstruct airflow.

Fluid Getting into the Pumping Channel

Do not allow fluid to enter the tubing channel. Contact your Baxter Service Center for assistance immediately if fluid enters the tubing channel. The tubing channel should be cleaned as soon as possible by Baxter-trained, qualified personnel to minimize potential difficulties caused by fluid pooling and drying on the mechanism.

Avoidance of the Panel Lockout Button

During storage or patient transport, do not wrap the pump's power cord around the pump tightly enough to accidentally press the PANEL LOCKOUT button on the back. Baxter recommends securing the power cord with the strap provided with the pump instead of wrapping the power cord around the pump.

Verification of Infusion Site and Route

Clinicians are advised to verify the proper route of delivery and that the infusion site is patent

When using this pump, periodic patient monitoring must be performed to ensure that the infusion is proceeding as expected. The pump is capable of developing positive fluid pressures to overcome widely varying resistances to flow such as resistance imposed by small-gauge catheters, filters, or intra-arterial infusions. Although the pump is designed to stop fluid flow when an alarm occurs, it is neither designed nor intended to detect infiltrations and will not alarm under infiltration conditions.

Piggyback Infusion Feature

When using the piggyback infusion feature ensure:

- The medication/solution in the secondary source container is compatible with the medication/solution in the primary source container.
- The secondary administration set is connected to the appropriate injection site on the Continu-Flo administration set.
- The interruption of the primary infusion is clinically appropriate for the duration of the piggyback infusion.

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

URGENT
DEVICE
CORRECTION

Baxter

March 17, 2005

RE: BURETROL(R) SOLUTION SET 150ML BURETTE BALL VALVE, Product Code 2C7546(S) and INTERLINK BURETROL SOLUTION SET 150ML BURETTE BALL VALVE, Product Code 2C7566(S)

Dear Director of Nursing:

Baxter Healthcare Corporation is providing you with important information concerning the Buretrol sets listed above. These specific BURETROL Sets are currently labeled as acceptable for use with the COLLEAGUE Volumetric Infusion Pump (refer to "S" suffix following product code). When these sets are used with the COLLEAGUE pump, there is a potential for a non-detection of an upstream occlusion under certain conditions.

As a result of this information, we do not recommend product codes 2C7546(S) and 2C7566(S) for use with the COLLEAGUE Volumetric Infusion pumps.

Alternative product codes 2C7519(S) and 2C7564(S) are compatible sets that can be used with the COLLEAGUE Volumetric Infusion pump. If you have any questions concerning the compatibility of other BURETROL Sets with the COLLEAGUE Volumetric Infusion Pump, please contact Baxter Medication Delivery Product Information Center at 1-800-933-0303.

Please complete the attached reply form confirming your receipt of this letter, and fax it to Baxter using either fax number provided on the form. Returning the form promptly will prevent you from receiving a repeat notice. If you provide the affected BURETROL Sets to other services or facilities, please forward this communication as appropriate.

Since these products are no longer recommended for COLLEAGUE pump use, you may wish to return the products for credit and order an alternative by calling Baxter Healthcare Center for Service at 1-888-229-0001.

We apologize for any inconvenience this will 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 Division
Baxter Healthcare Corporation