

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.

**URGENT
DEVICE
CORRECTION**

Baxter

March 15, 2005

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

Dear Biomedical Engineer:

Baxter Healthcare Corporation is sending this communication to provide you with important information concerning the COLLEAGUE infusion pump.

Inadvertent Power Off

It has come to Baxter's attention that COLLEAGUE pump users may inadvertently press the ON/OFF key, instead of the Start key when attempting to start an infusion. Always verify that the pump is infusing after pressing the Start key.

Baxter is in the process of modifying the product design to reduce the likelihood of users inadvertently powering off the device. When the design modifications are available, we will notify you.

External Communications Port Failures

COLLEAGUE pumps include a serial communications port on the back of the pump that can be used while the pump is running for connection to nurse call systems or hospital information systems for remote pump monitoring. This port is designed for one-way data transfer from the pump to the hospital system only. If your hospital uses the external monitoring capabilities of the COLLEAGUE pump for a nurse call system or for remote pump monitoring, please ensure that the external computer or monitoring system does not send data to the pump. Also ensure that the pump is powered off when connecting and disconnecting the cable to the DB9 port. Failure to do so may result in a 16:336 failure condition. If this 16:336 failure condition occurs during an active infusion, the pump must be powered off and powered on and the infusions restarted. Always follow the 'Colleague Volumetric Pump Service Manual' for proper cable configuration and connections.

Baxter is in the process of modifying the product software to make it more fault-tolerant of this situation. When the revised software is available, we will notify you.



Information Regarding Pump Failure Codes

When the pump detects an anomalous situation, it is designed to alarm, stop infusing, and display a failure code. Because this situation can occur during the infusion of any therapy, it is imperative that institutions have a contingency plan to mitigate any disruptions of infusions of life sustaining drugs.

Failure codes beginning with 402, 403, 533, 535, and 599, related to electronics failures, have occurred at an infrequent rate during pump operation. If you experience one of these failures, the pump should be taken out of service and inspected by authorized service personnel who should follow the instructions outlined in the 'Colleague Volumetric Infusion Pump Service Manual'.

810:04 and 810:11 Failure Codes – These failure codes are generated when the baseline reading of the air-in-line sensor is too high or when the air-in-line sensor no longer has measurable signal noise, indicating that the sensor is saturated. Two potential causes for the 810:04 and 810:11 alarms are miscalibration and fluid in the air-in-line sensor assembly. Avoid getting fluid on the tubing set or in the pump channel. If you experience one of these failures, the pump should be taken out of service and inspected by authorized service personnel who should follow the instructions outlined in the 'Colleague Volumetric Infusion Pump Service Manual'.

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 COLLEAGUE infusion pumps to other services or facilities, please forward this information as appropriate.

We apologize for any inconvenience this will cause you and your staff. If you have questions regarding this communication, please call Baxter Medication Delivery Services at 1-800-THE-PUMP.

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

cc: Director of Nursing