

Baxter

Urgent Product Recall

July 20, 2005

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

Dear Director of Nursing:

Baxter Healthcare Corporation is sending this communication to provide you with important information concerning COLLEAGUE Infusion pumps. We have detected a design issue with the COLLEAGUE Infusion pumps, which may have been associated with a patient death. This design issue involves a clocking circuit contained in the pump that can disrupt internal communications in some devices.

We recommend that any pump that displays any of the following failure codes: 402, 403, 532, 533, 534, 535, 599, 702, 703, 704, 720, 804:21, 804:22, 804:24, 804:29, 804:34, 804:52, 804:54, 804:58 and 12:303:xxx:0006 be taken out of service. Failure codes 402, 403, 533, 535 and 599 were previously mentioned in our Urgent Device Correction letter dated March 15, 2005. You should also review the event history of your pumps and any pumps with a previous history of the aforementioned failure codes should be taken out of service. If you have any questions on how to access the event history, please refer to the enclosed page from the Service Manual or call Baxter Medication Delivery Services at 1-800-THE-PUMP.

COLLEAGUE pumps are designed to alarm, stop infusing, and display a failure code if it detects an abnormal situation. **Because this situation can occur during an infusion, it is imperative that institutions have a contingency plan to mitigate any disruptions during infusion therapy (e.g. have a back-up pump available). Additionally, you should consider not using these pumps in situations where a replacement pump is not available or where a delay in therapy may be life threatening,**

All pumps currently being processed through Baxter's service operations will be checked by reviewing the event history, before return to the customer, for any of the failure codes listed above. If a pump is found to have any of these failure codes, it will not be returned to you until a corrective action has been implemented. The company will voluntarily hold shipments of new COLLEAGUE pumps until the issue is resolved.

Baxter is currently developing an aggressive action plan to address this issue and we will immediately notify you once it is finalized.



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. It is imperative that all end users of COLLEAGUE pumps be notified.

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

Enclosure

Accessing the Configuration/Service Menu

To access the Configuration/Service Menu:

1. Power the pump on.
2. When the self-test completes, press the *Main Display* key.
3. Press the **Options** soft key.

The Options Menu is displayed.

4. Use the \updownarrow keys to highlight Configuration/Service and press the **Select** soft key.

The Passcode Entry screen is displayed.

Note: If you enter the wrong passcode and want to try again, press the **Cancel** soft key.

5. Enter the passcode:
6. Press the **Enter Passcode** soft key.

The Configuration/Service Menu (Figure 5-1) is displayed.

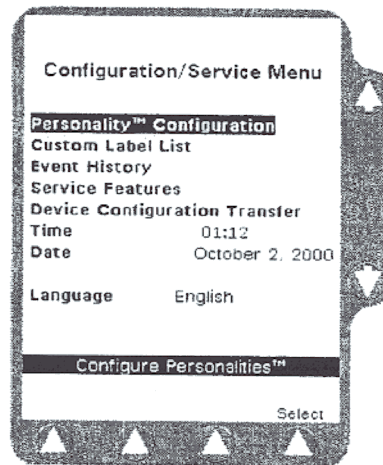


Figure 5-1 Configuration/Service Menu

Viewing the Event History

Note: To avoid disruption from a low battery situation or a Manual Tube Release pop-up when viewing event history, plug the pump in, and do not manually open the pump mechanism when viewing event history.

The **Event History** option on the **Configuration/Service Menu** lets you view up to 1,000 pump events that have occurred, including key presses.

Soft key presses are indicated in the event history by a number (1 through 4) corresponding to the soft keys as shown in Figure 5-14. The function of the soft keys varies depending on the Main Display screen displayed at the time.

To view the history:

Enter the Configuration/Service Menu.

- Use the $\uparrow\downarrow$ keys to highlight Event History.

Note: To maximize the number of events that can be shown, do not press the **Main Display** key when the pump is first powered on. Allow the display to appear automatically.

- Press the **Select** soft key. The **Event History** screen (Figure 5-14) is displayed.
- Use the **Page Up**, **Page Down**, or **Most Recent** soft keys or the $\uparrow\downarrow$ keys to scroll through the event history.
- Press the **Done** soft key to return to the Configuration/Service Menu.

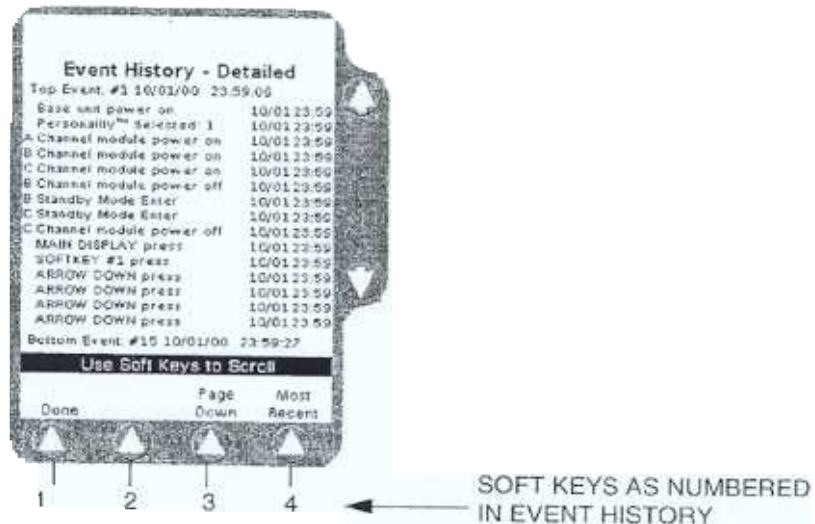


Figure 5-14 Example of Event History Display

**URGENT
DEVICE
CORRECTION**



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