

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

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.

Baxter

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 $\uparrow \downarrow$ 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.

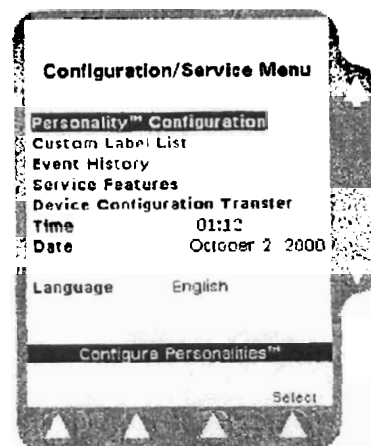


Figure 5-1 Configuration/Service Menu

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.

2. 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.

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



1 2 3 4 ← SOFT KEYS AS NUMBERED IN EVENT HISTORY

Figure 5-14 Example of Event History Display