

23 March 2009



Baxa Corporation
14445 Grasslands Drive
Englewood, CO 80112-7062
www.baxa.com

Exacta-Mix™2400 Compounder Safety Alert

This Safety Alert applies to the Exacta-Mix™ 2400 (EM2400) Compounder Operating Software, all released versions, manufactured by Baxa Corporation.

Dear EM2400 Compounder User:

As a medical device manufacturer, Baxa is committed to continuous improvement of our products. We test and re-test our products on a routine basis. As part of our testing, we have learned about a potential product safety issue that we want you to know about.

Summary:

Interacting with the EM2400 touch-screen while the pump door is open may cause an inaccurate ingredient delivery.

Detailed Description:

1. If the user lifts the Pump Door in either of the two states noted below:
 - a) During pumping (e.g., using the pump door as an emergency stop). In this state, the EM2400 gives the user a warning that the "Pump Door Was Opened."
 - b) The user encounters a bubble or occlusion alarm. In this state, the Pump Door is opened to investigate the alarm.
2. If the user presses the "RESUME" button at any time while the pump door is open, the compounder will reset the ordered ingredient to the full amount. In addition, the user will receive the following message "Unable to start because pump door is open."
3. This will result in an over delivery of an individual ingredient. The amount of over delivery can be from 0% - 100%, depending on the amount of ingredient delivered before the pump door was opened.

Recommended Actions:

- A. Communicate this Alert to all pharmacy personnel who use the EM2400.
- B. Instruct pharmacy personnel who use the EM2400 to **Close Pump Door before pressing "RESUME."**
- C. If "RESUME" is pressed while the pump door is open, follow these steps:
 - a. Immediately place an "X" on the bag label
 - b. Clear the bubble or occlusion
 - c. Discard the bag
- D. Instruct all Pharmacy personnel who check bags after production to inspect the MixCheck™ Report for any bubble or occlusion alarms. If a bubble or occlusion is noted in the MixCheck Report, review the procedures used by the operator to ensure the steps noted above were followed.

E. Contact Baxa Technical Support (800-678-2292) if you need any assistance. Technical Support for the EM2400 is available 24 hours a day, 7 days a week.

We will be providing you with a warning label for the EM2400 as soon as possible.

Additionally, we are working on a product upgrade to address this issue.

The US Food and Drug Administration (FDA) has been notified about this Safety Alert.

Sincerely,

A handwritten signature in black ink that reads "Pat Hynes". The signature is written in a cursive style with a large initial "P".

Pat Hynes
Vice President, Global Quality
(303) 617-2121 Office
(303) 598-0679 Cell
pat.hynes@baxa.com