



Baxa Ltd (Head Office) • Radius Court • Eastern Road • Bracknell • RG12 2UP • UK • Tel (+44) (0)1344 392902 • Fax (+44) (0)1344 392903
web: www.baxa.com • e-mail: info@baxa.co.uk

URGENT FIELD SAFETY NOTICE

Baxa Corporation Exacta-Mix™ 2400 Compounder Valve Actuator

Date: 3rd June 2008

Attention: CEO, Pharmacists and all users of the above product.

Details of affected devices: Baxa Corporation EM2400 Compounder

Description of the problem

We have identified a remote possibility for an unintended ingredient delivery as a result of a damaged valve actuator on the EM2400 Compounder.

The valve actuators are the part of the main module onto which the valve sets are placed. The valve actuators open and close each valve for fluid delivery.

Under certain conditions, using an EM2400 Compounder with a damaged valve actuator may result in the valve remaining open. The valve actuator will rotate to the closed position. However, if the valve actuator is damaged, the valve itself may not close as there is not sufficient engagement to close the valve and the user will not receive a notification. This would result in the delivery of an unintended ingredient.

Advice on action to be taken by the user

Immediately alert all compounder users of this issue to ensure that when the device is used, the valve actuators are always inspected for damage.

Inspect all valve actuators before setup and after tear-down to ensure they are not damaged or bent. Do not use the compounder if the valve actuators are damaged or bent.

When cleaning the compounder or prior to installing the valve set, inspect the valve actuators and ensure that they are completely intact. **Do not use the main module if any of the 24 valve actuators are damaged.** Contact Technical Support to have the main module replaced.

If a damaged valve actuator is noticed *after* using the EM2400, immediately hold all pumped bags and contact Baxa Technical Support. Unintended ingredients could be in the bags. **Do not infuse any bags if damage is noticed after they have been pumped.**

Do not try to repair or adjust a damaged or bent valve actuator.



Baxa Ltd (Head Office) • Radius Court • Eastern Road • Bracknell • RG12 2UP • UK • Tel (+44) (0)1344 392902 • Fax (+44) (0)1344 392903
web: www.baxa.com • e-mail: info@baxa.co.uk

Transmission of this Field Safety Notice

This notice should be passed to all those who need to be aware within your organisation.
Please keep a copy of the Safety Alert with your Operating Procedures.

Contact Reference

Please contact:

Baxa Ltd, Radius Court, Eastern Road, Bracknell RG12 2UP, UK

Tel +44(0)1344 392902 Fax +44(0)1344 392903 • e-mail: techsupport@baxa.co.uk

In order that Baxa can ensure that all necessary facilities are aware of this Field Safety Notice, please complete, sign and return the attached Fax Confirmation to Baxa Ltd at +44 (0)1344 392903.

MHRA are aware of this action.

Sincerely,



Director of Quality
+44 (0) 1344 392935
c.price@baxa.co.uk



Baxa Ltd (Head Office) • Radius Court • Eastern Road • Bracknell • RG12 2UP • UK • Tel (+44) (0)1344 392902 • Fax (+44) (0)1344 392903
web: www.baxa.com • e-mail: info@baxa.co.uk

URGENT FIELD SAFETY NOTICE

**Baxa Corporation EM2400 Compounder
Valve Actuator**

Fax Confirmation

Facility:

Address:

I confirm that this Field Safety Notice has been received and understood:

Signed:

Date:

Please sign and return this form by fax to Baxa Ltd at
+44 (0)1344 392903 or email to quality@baxa.co.uk