Baxter

September 2015

PRODUCT RECALL

Dear Aseptic Production Manager,

Affected Product

Product Code	Description	Lot Number(s)
2C1079K	CE INFUSOR Patient Control Module Watch (PCM), 0.5 mL	15A056 and 15B047

Problem Description

Baxter Healthcare Ltd. is issuing a recall for the above affected lot numbers of the INFUSOR Patient Control Module Watch (PCM) 0.5ml due to complaints for partially detached back-plates on the underside of the device. A partial detachment of the PCM back-plate may cause an incomplete shut-off of the PCM watch tubing resulting in continuous flow of medication from the PCM to the patient.

Baxter has identified the root cause of this issue and corrective actions have been implemented. The above lots were produced prior to implementation of corrective actions.

Hazard Involved

Continuous flow of pain medication to the patient may result in sedation, respiratory depression, or respiratory failure resulting in the need for medical intervention. These conditions could lead to serious injury or death.

Actions to be taken by customer/user

1. Locate and quarantine all products with code numbers and batch numbers as listed in this communication from their facility. If you distribute these products to other facilities or departments within your institution, please forward a copy of this communication to them to ensure that they also locate and remove the affected products (the product codes can be found on the individual product package and shipping carton).
2. If you are a dealer, wholesaler, or distributor/reseller that distributed any of these products to other facilities, please notify your customers of this action so that they can locate and remove all affected products.
3. Acknowledge your receipt of this recall notification by completing the attached Customer Reply Form and return to Baxter by either faxing it to 01635 206034 or scanning and emailing it to UK_SHS_FCA@baxter.com. Returning the Customer Reply Form promptly will prevent you from receiving repeat notifications. Once your reply form is received you will be contacted by Baxter to

organize return and credit of the recalled products.

We apologise for any inconvenience this may cause you and your staff.

Should you have any clinical questions related to this please contact Baxter Medical Information on 01635 206345 or email MedInfo_UKI@baxter.com. For general queries, please contact the CQA department on 01604 704603 or email uk_shs_fca@baxter.com.

Any adverse reactions or quality problems experienced with the use of these products may be reported using one of the following options:

Reporting product quality complaints:

- Call: 01604 704 603
- Fax: 01604 704688
- Email: uk_shs_qad@baxter.com

Reporting adverse events with drugs:

- Call: 01635 206 360,
- Fax: 01635 206 281,
- Email: vigilanceuk@baxter.com

The MHRA has been notified.

Joanna Lorimer

Senior Product Manager
Elastomeric Devices
Integrated Pharmacy Solutions
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Attachment 1: Customer Reply form

Baxter

CUSTOMER REPLY FORM

Product Recall letter dated Sept 2015

CE INFUSOR Patient Control Module Watch (PCM), 0.5 mL

Product code: **2C1079K**

Batch Number: **15A056 and 15B047**

Please complete and return one copy of this form per facility either by fax (**Fax: 01635 206034**) or by **e-mail (UK_SHS_FCA@baxter.com)** as confirmation that you have received this notification. A fax cover sheet is not required.

Facility Name and Address:	
Reply Confirmation Completed By *(Please Print)*:	
Title *(Please print)*:	
Email and Telephone Number:	

Please check boxes as appropriate:

☐ We do not have any of the affected lots in our inventory.

☐ We do have the affected lots in our inventory and products have been quarantined.

Please list the quantity of the specific lot(s) to be returned below*:

Product Code	Lot number	Quantity in units to be returned
2C1079K	15A056	
2C1079K	15B047	

Your signature below indicates that you have received the attached letter; performed the actions as outlined in the letter as needed; and disseminated this information to staff and other services or facilities as applicable.

Signature/Date: REQUIRED FIELD	_____