Baxter

Urgent Field Safety Notice RECALL

30th April 2015

Dear Customer,

Affected Product

Product Code	Description	Lot #	Expiration Date
2C1079K	CE INFUSOR Patient Control Module Watch (PCM), 0.5 mL	13M061	30 November 2016

Problem Description

Baxter Healthcare Ltd is issuing a voluntary recall for the above affected lot number of the CE INFUSOR Patient Control Module Watch (PCM), 0.5mL due to complaints reported for leak in the reservoir. This issue is being investigated and only affects the 0.5 mL PCM Watch.

Hazard Involved

Leaks may allow for medication contamination, which could result in infection or other serious adverse health consequences. At this time, there have been no reports of adverse events.

Action to be taken by the user

Baxter is kindly asking that you take the following actions:

- Locate and remove 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).

- 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.

- Acknowledge your receipt of this recall notification by completing the attached Customer Reply Form and return to Baxter by either faxing it to 01 206 5577 or scanning and emailing it to qa_dublin@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 replacement of the recalled products.

We apologize for any inconvenience this may cause you and your staff. Any adverse reactions or quality problems experienced with the use of this product must be reported through your local Baxter Sales Representative.

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The Health Products Regulatory Authority has been notified.

Yours Sincerely,

_____
Ian Gavigan
Head of CQA UK/Ireland
Baxter Healthcare Ltd.
Deansgrange Business Park
Blackrock
Co. Dublin
Ph: 01 2065500

Attachment 1: Customer Reply form

 Baxter is a registered trademark of Baxter International, Inc.

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CUSTOMER REPLY FORM related to Product Recall letter dated 30th April 2015

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

Product code: **2C1079K**
Batch Number: 13M061

Please complete and return one copy of this form per facility either by fax (Fax : 01 206 5577) or by e-mail (qa_dublin@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/or Telephone Number (including Area Code):	

Please quarantine all affected product and prevent from use until it is collected by Baxter

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	13M061	

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	_____

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