Baxter

URGENT FIELD SAFETY NOTICE

25th May 2016

Dear Customer,

Affected Product

Product Name: Vivia System

Product Codes: 5H51101

Serial numbers: All

Problem Description

Following the call we had earlier this week, Baxter is sending you this official communication.

Upon routine scheduled testing, Baxter has observed elevated levels of formaldehyde and calcium in the 5 water samples collected from the Vivia water sampling port in Ireland. Therefore an immediate investigation has been initiated.

As the root cause is unknown at this time, Baxter decided to put a hold on any use of the Vivia machine to mitigate any potential patient safety risk.

Hazard Involved

Please note that we have not received any adverse events involving these patients/sites, nor any safety signals. However, until we understand and evaluate the root cause, we insist that patients are switched to other dialysis options.

Action to be taken by the user

Baxter is kindly asking that you take the following actions:

1. Complete the enclosed customer reply form, and return it to Baxter by either faxing it to 01 206 5577 or scanning and e-mailing it to QA_Dublin@baxter.com or sending it by post to Baxter Healthcare Ltd, Unit 7 Deansgrange Business Park, Blackrock, Co. Dublin even if you don't have any inventory. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

2. Please forward a copy of this letter to other facilities or departments within your institutions to ensure that those locations are aware of this action.

3. If you are a dealer, wholesaler, or distributor/reseller that distributed any product to other facilities, please notify your customers of this communication in accordance with your customary procedures.

Further information and support

The root cause is unknown at this time. It could be from the source water, the sampling procedure or lab, the Vivia device or another source. We are diligently pursuing this answer to take appropriate corrective action.
Baxter is putting full effort towards understanding the root cause of this finding, and ensuring that a plan to full resolution is in place. The length of this effort is not known at this point in time.

For general questions regarding this communication, contact your local Baxter representative.

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

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

CUSTOMER REPLY FORM

(IMPORTANT PRODUCT INFORMATION LETTER DATED 25TH MAY 2016)

PRODUCT NAME: VIVIA SYSTEM

Product code: *5H51101*

Batch/Serial Number*: All*

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: *(Please Print)*	
Reply Confirmation Completed By: *(Please Print Name)*	
Title: *(Please Print)*	
Email and/or Telephone Number (Including Area Code):	

- ☐ We have received the above mentioned letter and have disseminated this information to our staff, other services and facilities.
- ☐ We have received the above mentioned letter and have disseminated this information to customers/Home Patients.
- ☐ We have received the above mentioned letter and we ask Baxter to disseminate this information to customers/Home Patients.

Signature/Date: REQUIRED FIELD	_____

Your signature above indicates understanding of the contents of the attached letter, that you performed the actions outlined and disseminated this information, if applicable.